

# CORPORATE RESPONSIBILITY

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2014 REPORT



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# OUR APPROACH



**We are committed to improving health and well-being around the world. From developing new therapies that treat and prevent disease to helping people in need, we are guided by a rich legacy and inspired by a shared vision.**

Our company's [core values](#) are driven by a desire to improve life, achieve scientific excellence, operate with the highest standards of integrity, expand access to our products and employ a diverse workforce that values collaboration.

Our corporate responsibility approach is aligned with the company's [mission and values](#) and articulates how we see our responsibilities in the areas of access to health, ethical and transparent business practices, environmentally sustainable operations, scientific advancement, employee wellness, and value creation for our shareholders.

Since successfully managing social, ethical and environmental issues involves all employees, we have established a companywide corporate responsibility framework, as well as a list of [key performance indicators](#) to measure our company's performance and progress in our areas of strategic focus.

Integrated into our approach to corporate responsibility is also a commitment to constructive engagement with stakeholders. We recognize that issues that matter to key stakeholders can very quickly become material issues for our shareholders. So we seek to balance our responsibilities in ways that support our fiduciary duty to generate long-term shareholder value, while also considering the needs of other stakeholders. [Learn more about our stakeholder engagement process.](#)

Corporate responsibility is at the heart of our company's mission to discover, develop and provide innovative products and services that save and improve lives, and it underscores our commitment to developing and rewarding our employees, protecting the environment, and operating with the highest standards of ethics and transparency.

These commitments help us to deliver long-term returns by pursuing opportunities where the need is great and where we have unique capabilities to make a real difference in people's lives. Through innovative research, groundbreaking partnerships and smarter processes, we are focusing on four priority areas: Access to Health, Environmental Sustainability, Employees, and Ethics & Transparency.

## ACCESS TO HEALTH

We are committed to discovering smart, sustainable ways to expand global access to healthcare.

## ENVIRONMENTAL SUSTAINABILITY

We are committed to discovering environmentally sustainable ways to meet the world's health needs, now and in the future.

## EMPLOYEES

We are committed to discovering more ways to create a workplace where our employees and business can thrive.

## ETHICS & TRANSPARENCY

We are committed to discovering better ways to build and strengthen trusted relationships by demonstrating the highest ethical standards and communicating with greater transparency.

## ABOUT THIS REPORT

As part of our commitment to being transparent about our corporate responsibility initiatives, including our business activities and operations, we publish an annual corporate responsibility report.

### GRI G4-18

This report covers our company's corporate responsibility activities and progress as of December 31, 2014, with some additional information relating to 2015, and updates the 2013 report published in August 2014.

We have sought to provide a comprehensive view of how our company works, and have focused on what is most important. As much as possible, we have guided readers to where they can go for more information, including our corporate headquarters' website and our annual financial reports.

We use several external guidelines and measurement frameworks to inform the scope of our reporting. These include the

Global Reporting Initiative (GRI), the Access to Medicine Index, the Millennium Development Goals and the 10 principles of the UN Global Compact.

In 2014, we completed a formal corporate responsibility (CR) materiality assessment to understand our economic, environmental and social impacts to identify stakeholder expectations regarding our performance and to help further refine a corporate responsibility strategy that aligns with our company's business strategy. We plan to engage stakeholders on an ongoing basis to support this journey and help us deliver greater value to society and to our business. Going forward, our reporting will be more closely aligned with the GRI G4 guidelines on the basis of the top issues identified during the CR materiality process.

We have also published an [executive summary](#) that is available to view or download as a PDF.

In this report, we define where we do not report metrics as follows: NA = not available; N/D = no data; N/R = not reported. Data in this report relate to worldwide operations for the calendar year 2014, except where stated. We plan to publish our next comprehensive corporate responsibility report in 2016.

#### GRI G4-23

On October 1, 2014, the company divested its Consumer Care segment (MCC), which developed, manufactured and marketed over-the-counter foot care and sun care products.

There have been no other significant changes from previous reporting periods in the scope, boundary or measurement methods applied in this report. Acquisitions and divestitures are thoroughly discussed in the company's 2014 10-K.

# CEO LETTER



**At Merck & Co., Inc., Kenilworth, NJ, USA, corporate responsibility is reflected in every part of our company and through the work of every employee.**

## GRI G4-1

Our company leaders worldwide incorporate, practice and reinforce the principles of corporate responsibility in all of their daily activities. Corporate responsibility is both a beacon and a mindset, grounding our operating principles and guiding our commitment to expanding access, operating ethically, engaging our employees and protecting the environment.

As a biopharmaceutical company, we firmly believe that the best way to create intrinsic, long-term value for both society and our shareholders is through the discovery and development of transformational medicines and vaccines. Our success—and our future—is predicated on what has long defined our company: innovating at the intersection of scientific opportunity and unmet medical need. We intend to stay at the forefront of biopharmaceutical science and remain steadfastly committed to making meaningful impact on the lives of patients while delivering value for our customers and shareholders.

Through our pipeline and commercial portfolio, we are focused on many of the world's most vexing and urgent health challenges, and are poised to play a leading role in addressing them. Accordingly, our commercial and research priorities are highly aligned with the current and projected global burden of disease as defined by the World Health Organization (WHO). This includes the increasing need for new therapies targeted to historically difficult-to-treat diseases such as hepatitis C and antibiotic-resistant infections.

In 2014, we received approval for seven products, including GARDASIL<sup>®</sup>9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and BELSOMRA<sup>®</sup> (suvorexant). We now have more than 10 Phase 3 programs that target many of the world's most urgent public health issues, and our scientists are engaged in the most innovative areas in biomedical research today, including:

- **Immuno-oncology**—the science of using the body's own immune system to fight cancer. KEYTRUDA<sup>®</sup> (pembrolizumab), the first anti-PD-1 treatment approved in the U.S. for advanced melanoma, is now being studied in over 30 cancers in more than 20 combination settings.
- **Chronic hepatitis C infection**—a disease epidemic that the WHO estimates is now affecting as many as 130 to 150 million people globally. Our investigational, combination HCV therapy has shown high virologic cure rates across a broad range of patient types, including many with harder-to-treat disease and various complicating co-morbid conditions.
- **Cardio-metabolic disease**—the number one cause of death globally. Our investigational medicine called anacetrapib is being studied to determine if it can further reduce certain cardiovascular risks.
- **Alzheimer's disease**—a condition that afflicts more than 36 million people globally. This number is projected to

double almost every 20 years, skyrocketing to more than 115 million people by 2050 and costing the U.S. in excess of \$1 trillion dollars.

- **Antibiotic resistance**—the growing worldwide challenge of so-called “superbugs” that are developing resistance to common antibacterial and antifungal treatments. These infections are increasingly causing serious illness and even death. Some estimates place the growing worldwide cost of these superbugs at more than \$100 trillion dollars by the year 2050. Earlier this year we completed our acquisition of Cubist, a biotechnology company with a history of developing and commercializing products for use in the hospital setting, particularly in the areas of infectious diseases and antibiotic resistance. The combined portfolios of our organizations are complementary, with each bringing important expertise and capabilities.
- **Emerging global pandemics**—including the fight against Ebola. Our investigational Ebola vaccine with our partner NewLink Genetics is in three large-scale clinical trials in some of the hardest hit countries in West Africa, including Guinea, Liberia and Sierra Leone.

Through our scientific innovation in these and other areas, we intend to play a major role in transforming global healthcare. Yet we also believe that to truly make a difference, we need to bring the best of our company—including our scientific, business and creative expertise—to bear to enable those innovations to reach patients who need them.

For example, *MSD for Mothers*, known as *Merck for Mothers* in the U.S. and Canada, our company's 10-year, \$500 million initiative, is fostering the next generation of solutions to reduce maternal deaths worldwide. Through partnerships with local, on-the-ground organizations all around the world, our programs have helped develop quality maternal healthcare and family planning services for an estimated 3.5 million women in 30 countries in just 3½ years. And with our partners in Uganda and Zambia, we've seen maternal mortality ratios in targeted areas fall by 30 and 35 percent, respectively. There remains much more work to do, but we remain committed to our vision of a world where no woman dies giving life.

We are also making progress in supporting our employees, protecting the environment, and building our relationships with the communities in which we work and live. And we continue to build the trust and confidence of our stakeholders by embodying ethics and transparency in everything we do.

Our company has a long history of environmental stewardship, and we realize that our strategy and efforts need to evolve in order for us to operate in an increasingly resource-constrained world. To advance in that effort, we have identified the issues that are important to our business and our stakeholders so that we can prioritize them for action. We have focused our environmental sustainability strategy on improving the efficiency of our operations, designing for the environment, and reducing the impacts and risks in our value chain. For example, during 2014, we used 7.2 billion gallons of water versus 9.0 billion gallons used in 2009, a 19 percent reduction.

We are proud of the progress being made in developing a 21st century workforce that includes the world's top, diverse talent and is driven by the desire to apply cutting-edge science to develop effective medicines and vaccines that save and improve lives around the world. Our nine Employee Business Resource Groups (EBRGs), with about 8,000 members, are a testament to our commitment and proof that inclusion drives success. In 2014, we received the Special National Award from DiversityInc for the important role these EBRGs play in impacting our business. This national award recognizes the company's innovation in driving business performance through the EBRGs by cultivating the diversity of our talent, enhancing our corporate responsibility and creating new, innovative business insights linked to our company's business agenda.

We believe in the dignity of every human being and in respecting individual rights. The company has established global policies and processes to demonstrate this respect, including our global *Public Policy on Human Rights* and *Our Values and Standards* (Code of Conduct), which reaffirms our commitment to scientific excellence, ethics and integrity. We are committed to reporting on our progress and through this report and our ongoing activities, we confirm our commitment to support the 10 universally accepted principles of the UN Global Compact.

We will continue to listen and engage with our stakeholders globally to benefit from broader perspectives and to share our own. And we will continue to respond in ways that help bring our new products to more people and sustain our business.

We are proud of our achievements, and are motivated by the vision and energy of the partners we work with to make these advances possible. But we recognize, in view of the growing needs of people around the world, that we can never be content with the status quo.

The challenges the world faces continue to be more complex to address, but more costly to ignore. In light of these challenges, we are poised to be bold, flexible and innovative in our efforts to address them. I firmly believe that our company is, and will continue to be, a positive force for change in the world.

A handwritten signature in black ink, appearing to read "Ken Frazier", with a long horizontal flourish extending to the right.

Kenneth C. Frazier

Chairman and Chief Executive Officer

Merck & Co., Inc., Kenilworth, NJ, USA



Our Approach

# REPORTING INDICES

**Since the release of our first corporate responsibility report in 2005, our company has been committed to using the Global Reporting Initiative (GRI) guidelines to report our performance on environmental, social and governance (ESG) issues.**

Except in 2009, due to the harmonization processes following the merger with Schering-Plough, we have utilized the GRI as well as the Access to Medicine Index (ATMI), the United Nations Global Compact (UNGC), and the UN Millennium Development Goals as our overall framework for corporate responsibility reporting. Our 2014 corporate responsibility report once again reflects our commitment to the GRI as well as to the other indices in our report.

[ACCESS TO MEDICINE INDEX ›](#)

[GRI INDEX ›](#)

[UN MILLENNIUM DEVELOPMENT GOALS ›](#)

[UN GLOBAL COMPACT ›](#)

# ACCESS TO MEDICINE INDEX

## In preparing our disclosures relating to access to medicine performance, we have referred to the **Access to Medicine Index (ATMI)**.

This index is a first step toward a useful framework for transparent reporting about access to medicine performance, which will help inform our stakeholders and also enable us to compare our performance with that of peers on relevant metrics. We believe that this will help us focus on continuously improving the things that matter most. The table below summarizes where our disclosures can be found on the website in relation to the ATMI criteria.

Index #	Description	Report Location/Direct Answer
<b>General Access to Medicine Management</b>		
ATM Governance		Access to Health Our Approach to Access CR Governance
ATM Management System		Our Approach to Access
Stakeholder Engagement		Stakeholder Engagement
<b>Public Policy and Market Influence</b>		
Advocacy and Lobbying		Public Policy and Advocacy
Competitive Behavior		Sales & Marketing
Market Behavior		Sales & Marketing

### Research and Development

Innovative R&D

Research & Development  
Infectious Diseases  
Global Burden of Disease  
Access to Health Guiding Principles

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Adaptive R&D

Research & Development  
HIV/AIDS  
Vaccines  
MSD for Mothers  
Access to Health Guiding Principles

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Intellectual Property  
Sharing

Public Policy  
HIV/AIDS  
Neglected Tropical Diseases  
Public Policy Statements  
Clinical Research

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### Equitable Pricing, Manufacturing and Distribution

Marketing Approval

Product Registration  
Access to Health Statement of Guiding  
Principles

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Equitable Pricing

Commercialization  
Our Approach to Access  
Pricing  
Access to Health Statement of Guiding  
Principles  
Public Policy Statements

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Manufacturing and  
Distribution

Manufacturing & Supply Chain  
Access to Health  
HIV/AIDS  
Vaccines  
Women's Health  
Access to Health Statement of Guiding  
Principles

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### Patents and Licensing

Patents

Our Approach to Access  
Research & Development  
HIV/AIDS  
Merck Product Patents  
Women's Health  
Vaccines  
Public Policy Statements

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Non-Exclusive  
Voluntary Licensing

HIV/AIDS  
Manufacturing & Supply Chain  
Women's Health  
Neglected Tropical Diseases  
Public Policy Statements  
Access to Health Statement of Guiding  
Principles

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### Capability Advancement in Product Development and Distribution

Capacity Building in R&D

Infectious Diseases  
Our Approach to Access  
Health  
Research & Development  
Key Initiatives  
Access to Health Statement of Guiding Principles

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Capacity Building in  
Quality Management  
and Distribution

**Key Initiatives**  
**Access to Health Statement of Guiding  
Principles**

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**Product Donations and Philanthropic Activities**

Product Donations

**Product Donations**  
**Medical Outreach Program**  
**Key Initiatives**  
**Public Policy Statements**

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Philanthropy

**Our Giving**  
**Community**  
**Key Initiatives**

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# GRI INDEX

## We are reporting on our corporate responsibility efforts in alignment with the Global Reporting Initiative's (GRI) G4 Guidelines.

### GRI G4-32

This framework offers a useful method for transparent reporting about environmental, social and governance performance. Greater transparency on such matters is beneficial to our business because it helps to inform our stakeholders and also enables us to compare performance with that of peers on relevant metrics. We believe that this will help us focus on continuously improving the things that matter most.

Throughout this report, flags denote which GRI indicators are relevant to the text, where applicable. Roll over a flag to see a brief description of that GRI indicator.

The table below summarizes where the disclosures can be found.

### Assurance

WSP conducted an independent third party review of our 2014 greenhouse gas and water inventories, and provided limited assurance for the data that we submit to CDP and for the Corporate Responsibility report. Our environmental data can be found [here](#). Please see WSP's limited assurance of our environmental data [here](#).

Index #	Description	Report Location/Direct Answer
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## GENERAL STANDARD DISCLOSURES

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### Strategy & Analysis (G4-1)

GRI G4-1	CEO Letter	CEO Letter
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### Organizational Profile (G4-3 to G4-16)

GRI G4-3	Organization name	Merck & Co., Inc., Kenilworth, NJ, USA
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GRI G4-4	Primary brands, products and services	<b>Our Business</b> <b>2014 Form 10-K</b>
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GRI G4-5	Headquarters location	Kenilworth, NJ, USA
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GRI G4-6	Where the organization operates	<b>Company Fact Sheet</b>
GRI G4-7	Nature of ownership and legal form	<b>2014 Form 10-K</b>
GRI G4-8	Markets served	<b>Our Business 2014 Form 10-K</b>
GRI G4-9	Scale of the organization	<b>Economic Impact 2014 Form 10-K</b>
GRI G4-10	Total number of employees by type	<b>Positive Work Environment: Performance</b>
GRI G4-11	Collective bargaining agreements	<b>Human Rights</b>
GRI G4-12	Supply chain description	<b>Manufacturing &amp; Supply Product Supply</b>
GRI G4-13	Organizational changes during the reporting period	<b>Restructuring 2014 Form 10-K</b>
GRI G4-15	External charters, principles, or other initiatives	<b>Millennium Development Goals UN Global Compact Our Approach to Access Water Use: Partnerships Human Rights</b>
GRI G4-16	Membership associations	<b>Public Policy: Industry Associations</b>

#### Identified Material Aspects and Boundaries (G4-17 to G4-23)

GRI G4-17	Entities included in financial statements	<b>2014 10-K</b>
GRI G4-18	Process for defining report boundaries and content	<b>Our Approach</b>
GRI G4-19	Material aspects included in the report	<b>Materiality</b>
GRI G4-22	Restatements	Restatements of information are included on the specific performance data pages and tabs.
GRI G4-23	Changes from previous reports in terms of scope and/or boundaries	<b>Our Approach</b>

#### Stakeholder Engagement (G4-24 to G4-27)

GRI G4-24	Stakeholder groups	<b>Stakeholder Groups</b>
GRI G4-25	How stakeholders were identified	<b>Engagement mechanisms</b>
GRI G4-26	Approach to stakeholder engagement	<b>Stakeholder Engagement Stakeholder Groups</b>
GRI G4-27	Topics raised during stakeholder engagements	<b>Stakeholder Groups</b>

#### Report Profile (G4-28 to G4-33)

GRI G4-28	Reporting period	January 1, 2014–December 31, 2014
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GRI G4-29	Date of most recent report	2013
GRI G4-30	Reporting cycle	Annual
GRI G4-31	Report contact	<b>Contact Us</b>
GRI G4-32	"In accordance" option, GRI Index and report assurance	GRI Index <b>FAQ</b>
GRI G4-33	Policy regarding report assurance	<b>FAQ</b>

### **Governance (G4-34 to G4-53)**

GRI G4-34	Governance structure of the organization	<b>Corporate Governance 2014 Form 10-K</b>
GRI G4-38	Composition of the board and its committees	<b>Corporate Governance</b>
GRI G4-39	Whether the chair of the board is also an executive officer	<b>Corporate Governance</b>
GRI G4-40	Nomination and selection processes for the board and its committees.	<b>2015 Proxy Statement</b>
GRI G4-41	Board conflicts of interest.	<b>2015 Proxy Statement</b>
GRI G4-42	Board and executives' roles in the organization's mission statements, strategies, policies, and goals related to sustainability impacts	<b>CR Governance 2015 Proxy Statement</b>
GRI G4-43	Board knowledge of sustainability topics	<b>CR Governance</b>
GRI G4-45	Board role in the identification and management of sustainability impacts, risks, and opportunities	<b>CR Governance</b>
GRI G4-46	Board role in reviewing risk management processes for sustainability topics	<b>CR Governance Board Committee Charter</b>
GRI G4-47	Frequency of the board's review of sustainability impacts, risks and opportunities.	<b>Board Committee Charter</b>
GRI G4-48	Highest committee or position that formally reviews and approves the organization's sustainability report	<b>CR Governance</b>
GRI G4-49	Process for communicating critical concerns to the board	<b>CR Governance 2015 Proxy Statement</b>
GRI G4-51	Remuneration policies for the board and senior executives	<b>Corporate Governance</b>
GRI G4-52	Process for determining remuneration.	<b>2015 Proxy Statement</b>
GRI G4-53	Stakeholders' views on remuneration.	<b>2015 Proxy Statement</b>

### **Ethics and Integrity (G4-56 to G4-58)**

GRI G4-56	Code of conduct	<b>Ethics &amp; Transparency</b> <b>Merck Code of Conduct</b>
GRI G4-57	Helplines or advice lines for employees	<b>Office of Ethics</b>
GRI G4-58	Mechanisms for reporting concerns about unethical or unlawful behavior	<b>Office of Ethics</b>

## SPECIFIC STANDARD DISCLOSURES

### Economic (EC1 to EC8)

GRI G4-EC1	Economic value	<b>2014 Form 10-K</b>
GRI G4-EC2	Climate change risks	<b>Energy Use &amp; Climate Change</b> <b>2014 Form 10-K</b> <b>CDP Climate Change</b>
GRI G4-EC3	Benefit plan coverage	<b>Compensation Benefits</b> <b>2014 Form 10-K</b> <b>2015 Proxy Statement</b>
GRI G4-EC4	Financial assistance from the government	Not applicable
GRI G4-EC7	Infrastructure investments	<b>Employee Giving: Performance</b> <b>Supporting Our Communities</b> <b>Our Giving</b> <b>Fellowship for Global Health</b>
GRI G4-EC8	Indirect economic impacts	<b>Access to Health</b>

### Environmental (EN1 to EN33)

GRI G4-EN1	Materials by weight or volume	<b>Emissions, Effluents &amp; Waste: Performance</b>
GRI G4-EN2	Recycled input materials	<b>Emissions, Effluents &amp; Waste: Performance</b>
GRI G4-EN3	Energy consumption (Scope 1 & 2)	<b>Energy Use &amp; Climate Change: Performance</b>
GRI G4-EN4	Energy consumption (Scope 3)	<b>Energy Use &amp; Climate Change: Performance</b>
GRI G4-EN6	Energy reductions	<b>Energy Use &amp; Climate Change: Performance</b> <b>CDP Climate Change</b>
GRI G4-EN8	Water withdrawals by source	<b>Water Use: Performance</b> <b>CDP Water Disclosure</b>
GRI G4-EN10	Water recycled and reused	<b>Water Use: Initiatives</b> <b>CDP Water Disclosure</b>
GRI G4-EN15	GHG emissions (Scope 1)	<b>CDP Climate Change</b> <b>Energy Use &amp; Climate Change: Performance</b>
GRI G4-EN16	GHG emissions (Scope 2)	<b>Energy Use &amp; Climate Change: Performance</b> <b>CDP Climate Change</b>
GRI G4-EN17	GHG emissions (Scope 3)	<b>Energy Use &amp; Climate Change: Performance</b> <b>CDP Climate Change</b>

GRI G4-EN18	GHG emissions intensity	<b>CDP Climate Change</b>
GRI G4-EN19	Reduction of GHG emissions	<b>Energy Use &amp; Climate Change: Performance CDP Climate Change</b>
GRI G4-EN20	Ozone-depleting substances (ODS)	<b>Emissions, Effluents &amp; Waste: Performance CDP Climate Change</b>
GRI G4-EN21	NOx, SOx and other emissions	<b>Emissions, Effluents &amp; Waste: Performance CDP Climate Change</b>
GRI G4-EN22	Water discharge	<b>Emission, Effluents &amp; Waste: Performance CDP Water Disclosure</b>
GRI G4-EN23	Waste by type and disposal method	<b>Waste Prevention &amp; Management: Performance</b>
GRI G4-EN24	Significant spills	<b>EHS Management &amp; Compliance: Performance</b>
GRI G4-EN25	Hazardous waste	<b>Emissions, Effluents &amp; Waste: Performance</b>
GRI G4-EN27	Mitigation of environmental impacts of products and services	<b>Product Stewardship Emissions, Effluents &amp; Waste</b>
GRI G4-EN28	Products and packaging materials reclaimed	<b>Packaging</b>
GRI G4-EN29	Environmental fines and sanctions	<b>EHS Management &amp; Compliance: Performance</b>
GRI G4-EN30	Environmental impacts from product distribution and employee travel	<b>Energy Use &amp; Climate Change: Performance</b>
GRI G4-EN31	Environmental investments	Merck reports on some of our environmental protection expenditures in the <b>2014 Form 10-K</b> . These expenditures are integrated into our sites' operating budgets. We do not currently have a system to tag expenditures as related to environmental protection and report them separately.
GRI G4-EN32	New suppliers screened using environmental criteria	<b>Procurement &amp; Supplier Relations</b>
GRI G4-EN33	Supply chain environmental impacts	<b>Procurement &amp; Supplier Relations</b>

#### **Labor Practices & Decent Work (LA1 to LA15)**

GRI G4-LA1	Number and rate of new employee hires and turnover	<b>Positive Work Environment: Performance</b>
GRI G4-LA2	Benefits provided to full-time employees	<b>Compensation &amp; Benefits</b>
GRI G4-LA4	Notice periods regarding operational changes	Merck does not have the same minimum notice period in all countries. Local legislation and collective bargaining agreement specifications vary, with notice periods ranging from four weeks to six months.

GRI G4-LA6	Rates of injury, occupational disease, lost days, absenteeism, and work-related fatalities	<b>Employee Safety: Performance</b>
GRI G4-LA7	Workers with high incidence risk for diseases	<b>Employee Health</b>
GRI G4-LA8	Health and safety topics covered in agreements with trade unions	While we do have a “Health and Safety” section in our U.S. trade union agreements, the specific language varies from agreement to agreement. They address medical services and surveillance, the company’s commitment to make a responsible provision for employee health and safety, and in some cases address protective equipment training.
GRI G4-LA9	Average hours of training for employees	We conduct extensive training programs worldwide, however, we do not currently track the average number of hours of training per employee.
GRI G4-LA11	Employees receiving performance and career development reviews	<b>Positive Work Environment: Performance</b>
GRI G4-LA12	Composition of governance bodies and employees	<b>Global Diversity &amp; Inclusion: Performance</b>
GRI G4-LA14	New suppliers that were screened using labor practices criteria	<b>Procurement &amp; Supplier Relations</b>
GRI G4-LA15	Negative impacts for labor practices in the supply chain	<b>Procurement &amp; Supplier Relations</b>

### Human Rights (HR1 to HR12)

GRI G4-HR1	Investment agreements and contracts that include human rights clauses or underwent screening	<b>Human Rights Procurement &amp; Supplier Relations Business Partner Code of Conduct</b>
GRI G4-HR2	Employee training on human rights	<b>Office of Ethics: Performance Code of Conduct</b>
GRI G4-HR4	Significant risk of freedom of association in operations and suppliers	<b>Human Rights Procurement &amp; Supplier Relations Business Partner Code of Conduct</b>
GRI G4-HR5	Significant risk of child labor in operations and suppliers	<b>Human Rights Business Partner Code of Conduct</b>
GRI G4-HR6	Significant risk of forced or compulsory labor in operations and suppliers	<b>Human Rights Procurement &amp; Supplier Relations Business Partner Code of Conduct</b>
GRI G4-HR7	Security personnel trained in the organization’s human rights policies	The nature of our business does not require extensive security personnel in our global operations.
GRI G4-HR8	Incidents of violations involving rights of indigenous peoples	Our operations do not significantly impact indigenous communities.
GRI G4-HR9	Operations that have been subject to human rights assessments	<b>Procurement &amp; Supplier Relations</b>

GRI G4-HR10	New suppliers screened for human rights	<b>Procurement &amp; Supplier Relations</b>
GRI G4-HR11	Human rights impacts in the supply chain	<b>Procurement &amp; Supplier Relations</b>
GRI G4-HR12	Grievances about human rights impacts	<b>Office of Ethics</b>
<b>Society (SO1 to SO10)</b>		
GRI G4-SO1	Local community engagement, impact assessments and development programs	<b>Manufacturing &amp; Supply Chain Product Stewardship Product &amp; Patient Safety</b>
GRI G4-PR2	Non-compliance concerning the health and safety impacts of products and services	<b>Quality &amp; Safety Standards: Performance</b>
GRI G4-PR3	Product and service information required for labeling	<b>Product and Patient Safety</b>
GRI G4-PR4	Non-compliance with regulations concerning product and service labeling	<b>Sales &amp; Marketing</b>
GRI G4-PR5	Surveys measuring customer satisfaction	We do not report on this indicator as it is unlawful due to privacy laws to have a global, companywide harmonized customer database that contains identifying information about our customers that could be accessed on an inter-country level.
GRI G4-PR6	Sale of banned or disputed products	Not applicable
GRI G4-PR7	Non-compliance with regulations concerning marketing communications	<b>Sales &amp; Marketing</b>
GRI G4-PR8	Complaints regarding breaches of customer privacy and losses of customer data	<b>Global Privacy Program: Performance</b>

# MILLENNIUM DEVELOPMENT GOALS

**The private sector, including the research-based pharmaceutical industry, has an important role to play in contributing to the achievement of the United Nations Millennium Development Goals (MDGs).**

At the 2008 Annual Meeting of the World Economic Forum, in Davos, Switzerland, our company joined UN Secretary General Dr. Ban Ki-moon, U.K. Prime Minister Gordon Brown and leaders from other private and public sector organizations to endorse a “Call to Action on the Millennium Development Goals,” pledging to work together to accelerate progress toward the MDGs. The table below summarizes where information can be found on our website in relation to how we are contributing to the MDGs.

Index #	Description	Report Location/Direct Answer
<b>MDG 1</b>	Eradicate extreme poverty and hunger	<b>Health</b>
<b>MDG 2</b>	Achieve universal primary education	<b>Education</b>
<b>MDG 3</b>	Promote gender equality and empower women	<b>Global Diversity &amp; Inclusion</b>
<b>MDG 4</b>	Reduce child mortality	<b>Vaccines Health Key Initiatives</b>

**MDG 5**

Improve maternal health

**Women's Health  
MSD for Mothers**

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**MDG 6**

Combat HIV/AIDS, malaria and other diseases

**HIV/AIDS  
Infectious Diseases  
Vaccines  
Global Burden of Disease**

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**MDG 7**

Ensure environmental sustainability

**Environmental Sustainability**

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**MDG 8**

Develop a global partnership for development

**Our Approach to Access  
Women's Health  
Key Initiatives**

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# UN GLOBAL COMPACT

In January 2009, our company signed on to the United Nations Global Compact, the world’s largest and most widely embraced corporate citizenship initiative.

**GRI G4-15**

By signing on, we confirm our commitment to support the UN Global Compact’s 10 universally accepted principles in the areas of human rights, labor, environment and anti-corruption. Signatories to the compact are required to annually report their activities in support of their commitment to instill accountability, drive continuous improvement, safeguard the integrity of the UN Global Compact as a whole, and contribute to the development of a repository of corporate practices.

The table below summarizes where these disclosures can be found on our website, and the letter from our CEO serves as our statement of continued support for the initiative.

Index #	Description	Report Location/Direct Answer
<b>2014 COMMUNICATION ON PROGRESS</b>		
<b>Human Rights</b>		
UNGC-2	Businesses should make sure that they are not complicit in human rights abuses	<b>Human Rights Procurement &amp; Supplier Relations</b>
UNGC-1	Businesses should support and respect the protection of internationally proclaimed human rights	<b>Human Rights</b>
<b>Environment</b>		
UNGC-7	Businesses should support a precautionary approach to environmental challenges	<b>Product Stewardship Environmental Sustainability Procurement &amp; Supplier Relations EHS Management &amp; Compliance</b>
UNGC-8	Businesses should undertake initiatives to promote greater environmental responsibility	<b>Product Stewardship EHS Management &amp; Compliance</b>

UNGC-9	Businesses should encourage the development and diffusion of environmentally friendly technologies	<b>Product Stewardship Green Chemistry</b>
<b>Anti-Corruption</b>		
UNGC-10	Businesses should work against corruption in all its forms, including extortion and bribery	<b>Code of Conduct Office of Ethics Procurement &amp; Supplier Relations</b>
<b>Labour</b>		
UNGC-6	Businesses should support the elimination of discrimination in respect of employment and occupation	<b>Global Diversity &amp; Inclusion Office of Ethics Human Rights Human Rights of Our Employees</b>
UNGC-3	Businesses should uphold the freedom of association and the effective recognition of the rights to collective bargaining	<b>Human Rights</b>
UNGC-4	Businesses should support the elimination of all forms of forced and compulsory labor	<b>Human Rights</b>
UNGC-5	Businesses should support the effective abolition of child labour	<b>Human Rights</b>



Our Approach

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# MATERIALITY

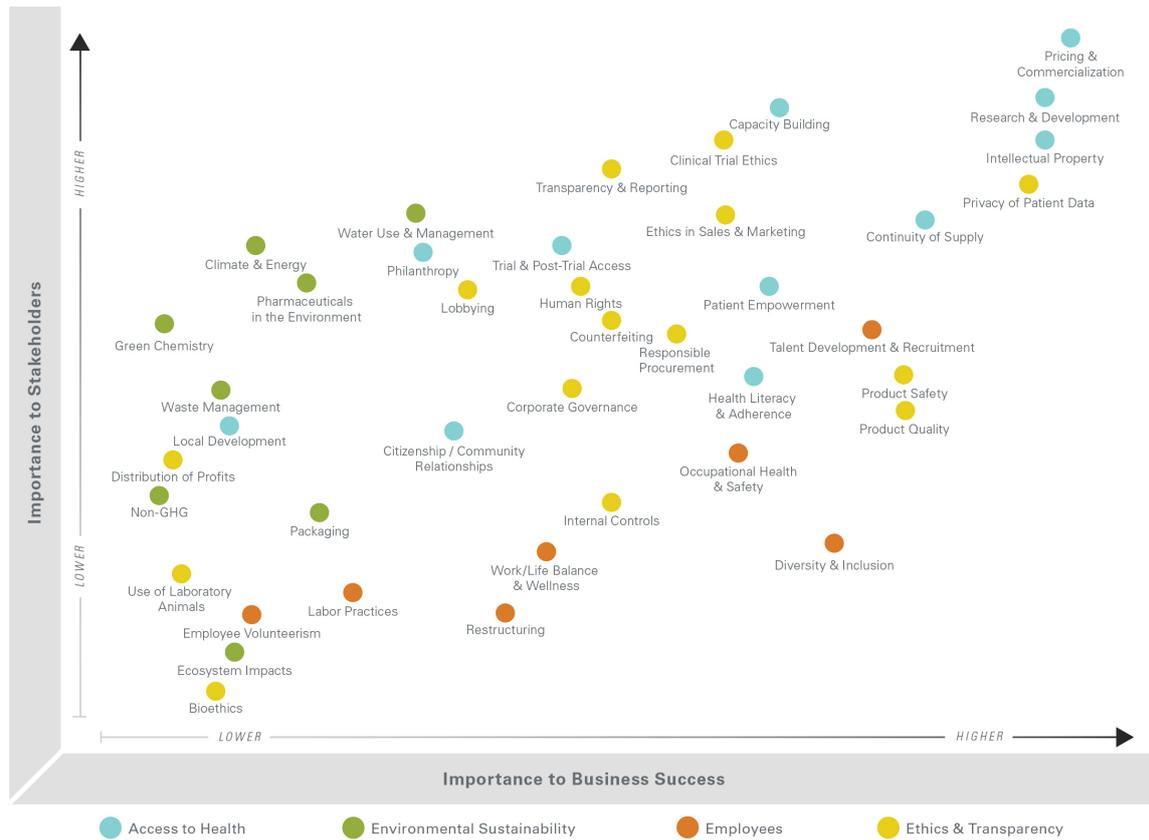
## MAIN

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**In 2014, we completed a formal corporate responsibility (CR) materiality assessment with support from Business for Social Responsibility (BSR).**

We did this to better understand our economic, environmental and social impacts to identify stakeholder expectations regarding our performance and to help further refine a corporate responsibility strategy that aligns with the company's business strategy. We use the Global Reporting Initiative (GRI) reporting framework to inform our definition of CR materiality and our selection of CR material issues.

## CR MATERIALITY ASSESSMENT RESULTS



### Access to Health

### CAPACITY BUILDING

Training and educational programs, local infrastructure improvements, skills and technology transfer to emerging countries

### INTELLECTUAL PROPERTY

Patent protections and flexibility, licensing agreements, and generics policies

### PHILANTHROPY

Foundation giving/cash and product donations

## **PRICING AND COMMERCIALIZATION**

Pricing strategy including differential pricing, affordability, pricing transparency, reimbursement strategy, commercialization strategy/availability/registration

## **R&D**

Research in unmet medical needs and driving innovations that create value for society (understanding that this will vary by country), i.e. not "me too" drugs

## **CONTINUITY OF SUPPLY**

Ensuring continuity of supply (including assurance of manufacturing, inventory tracking, pandemic readiness)

## **TRIAL AND POST-TRIAL ACCESS**

Gender balance, enrolling diverse patient populations, development of trial sites ex-USA, and post-trial access (including compassionate use)

## **DISEASE FOCUS**

Focus on development of medications/treatments based on health needs rather than lifestyle

## **HEALTH ADHERENCE**

Engaging with patients and HCPs to ensure adherence to medication/treatment regimens

## **HEALTH LITERACY**

Engaging with patients and HCPs to promote understanding of medical conditions or diseases and the reasons they are being treated

## **CITIZENSHIP/COMMUNITY RELATIONS**

Engagement and dialogue with external stakeholders including local communities, NGOs, foundations, local governments, universities, etc.

## **LOCAL DEVELOPMENT**

Contribution to local economic development

## **Environment**

### **NON-GHG**

Non-Greenhouse gases (with local impact): VOCs, SOx, NOx, etc.

### **CLIMATE AND ENERGY**

Energy management, which includes reducing carbon footprint through energy conservation/efficiency, use of renewable energy that reduce greenhouse gas emissions (includes Scopes 1,2, and 3 GHGs)

### **WASTE MANAGEMENT**

Handling, management, and disposal of hazardous and non-hazardous waste

## **WATER USE AND MANAGEMENT**

Influent and effluent parameters includes source, scarcity, recharge rates, quality, treatment, and impact on local community

## **ECOSYSTEM IMPACTS/ USE OF NATURAL SUBSTANCES**

Use of natural substances (e.g. plants & animals) and materials including preservation of biodiversity, etc.

## **GREEN CHEMISTRY**

Use of substances and processes that are environmentally beneficial, avoidance of chemicals of concern

## **PACKAGING**

Impact of packaging including design, materials, processing and life cycle

## **PHARMACEUTICALS IN THE ENVIRONMENT**

Pharmaceuticals in the environment attributed to biological waste from patients/animals or unused/expired medicines

## **Employees**

### **DIVERSITY & INCLUSION**

Employee diversity and inclusion, prevention of discrimination, and equal opportunity

### **LABOR PRACTICES**

Management-worker relationships, freedom of expression and association, right to collective bargaining

### **RESTRUCTURING**

Change management through restructuring, reorganization

### **EMPLOYEE VOLUNTEERISM**

Employee volunteerism through humanitarian programs

### **TALENT DEVELOPMENT AND RECRUITMENT**

Recruiting, training and development, leadership development, retention, career management and promotion, compensation and benefits.

### **WORK LIFE BALANCE AND WELLNESS**

Employee wellness programs, rewards, incentives, quality and burnout monitoring

## **Ethics & Transparency**

### **DISTRIBUTION OF PROFITS**

Distribution of our revenue including socially responsible investment, value sharing, ratio of executive compensation to other employees, tax strategy, investments in local markets

## **LOBBYING**

Lobbying and political contributions, relationship with public authorities, public policy and market influence

## **HUMAN RIGHTS**

Human rights of employees, supply chain, and patient populations

## **BIOETHICS**

Use of genetic resources, stem cells, GMOs, nanotechnologies, etc.

## **CORPORATE GOVERNANCE**

Board structure and independence, executive compensation, and accountability

## **ETHICS IN SALES AND MARKETING**

Brand management and promotion, ethical marketing, competitive behavior, prevention of anti-competitive practices, compliance with regulatory authorities, anti-corruption/anti-bribery

## **PRIVACY OF PATIENT DATA**

Policies, standards, procedures and trainings that cover privacy of patient data/ loss of personal data

## **INTERNAL CONTROLS**

Policies, standards, codes of conduct and audits applicable to internal operations and employees

## **TRANSPARENCY & REPORTING**

Transparency and reporting including tax transparency and sustainability reporting, e.g. GRI, CDP, etc.

## **CLINICAL TRIAL ETHICS**

Management of clinical trial data including transparency, following of global standards to ensure ethics in R&D, and the sharing of clinical data within the scientific community

## **USE OF LABORATORY ANIMALS**

Internal standards and transparent reporting on the use of laboratory animals, consideration of alternatives to animal testing and training, and animal health issues

## **PRODUCT SAFETY**

Management of product quality, i.e. ensuring that products are compliant and highly trusted

## **COUNTERFEITING**

Monitoring, evaluation, and reception of counterfeit drug supply

## **RESPONSIBLE PROCUREMENT**

Integration of sustainability measurements and performance indicators through supply chain policies, sourcing guidelines, supplier scorecarding, supplier preferential sourcing programs, sustainable materials guidelines, and design for the environment practices. This may include the addition of social/environmental criteria to tender requests, including alternative methodologies or inputs to reduce the environmental impact

## OCCUPATIONAL HEALTH & SAFETY

Precautions that minimize hazards and promote employee health, safety, and well-being. This includes conducting assessments, providing personal protective equipment, and preparing emergency response plans

# PROCESS

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## OUR OBJECTIVE

The materiality analysis completed in 2014 helped refresh our corporate responsibility framework and link our CR strategy to our core business. Based on feedback from stakeholders and the company's own analysis, we validated our four fundamental focus areas:

- Access to Health
- Environmental Sustainability
- Employees
- Ethics & Transparency

For each of these focus areas, our report details the challenges and opportunities we face as a company; our strategy; and our performance.

Our CR strategy, based on the recent CR materiality analysis, confirmed that our approach to CR continues to serve as a value driver for the business as a whole and for society.

## OUR PROCESS

The 2013–2014 assessment followed a tailored process that included desktop research; a review of corporate objectives and strategies; analysis of media coverage; stakeholder feedback on prior reporting; industry benchmarking; consultative interviews with stakeholders both inside and outside the company; and intensive internal workshops and socialization sessions across the business. We leveraged our survey submissions to CDP (formerly the Carbon Disclosure Project), the Dow Jones Sustainability Indexes (DJSI) and the Access to Medicine Index (ATMI), in addition to referencing the most current sustainability and corporate responsibility research reports, to select and refine a list of environmental, social and governance (ESG) issues for further analysis.

From a list of hundreds of potentially material issues, we identified 42 to test with internal and external stakeholders. Internally we engaged with senior executives from key functional areas and business units including Ethics & Compliance, Global Clinical Development, Scientific Affairs, Global Health Innovation, Global Medical Affairs, Global Public Policy, Human Resources, Manufacturing, Market Access, Philanthropy, Safety and Environment, Vaccines and others. Our goal was to understand which of the 42 material issues were most linked to our company's business strategy and to our business success. We asked our business leaders to select the issues of highest importance in terms of their impact on:

- Financial value and revenue
- Operational excellence
- Compliance with regulations
- Corporate reputation
- Shareholders
- Employees and their level of engagement

Externally, we engaged more than 30 stakeholder groups that represented a cross section of advocacy interests, including on-the-ground implementation partners, socially responsible investors, environmental NGOs, public health advocates and health providers. Through in-person interviews, we asked our stakeholders to indicate which issues were important to their groups or communities; where action from the private sector, and from our company in particular, is critical; and how we can drive excellence through our corporate responsibility efforts.

Stakeholders were asked to rank the list of 42 material issues and impacts; assess our company's performance on these

priority issues; and share their expectations related to strategy, reporting and stakeholder engagement. This process is less of an accounting exercise and more of a strategic one, designed to both understand our impacts and articulate our priorities.

We asked stakeholders to evaluate our 42 priority issues based on criteria heavily influenced by the International Integrated Reporting Council (IIRC), including impacts on and contributions to the six “capitals”: Financial, Manufactured, Intellectual, Social and Relationship, Human, and Natural. We augmented these criteria with considerations such as critical risk factors, unique opportunities for the private sector and for our company, and contributions to the global sustainability agenda set by the United Nations.

Once all of the internal and external interviews were complete, BSR quantified the ranked issues using a scale tailored to the specific inputs of our materiality assessment. The results were aggregated into BSR’s materiality tool and the issues were mapped onto a materiality map, showing the relative importance of each issue. Internal input was plotted on the x-axis, corresponding to “Influence on Business Success” and external input was plotted on the y-axis, corresponding to “Importance to Stakeholders.” Together with BSR, we analyzed the results along with the information we had received during the interview process to finalize the materiality map.

The 42 issues were then matched up with our company’s four key CR focus areas, and the final results were endorsed by our Public Policy & Responsibility Council, comprising senior executives from key company functions and divisions.

The resulting map of issues is shown on the previous tab. We will continue to use this materiality process to refine and inform our approach to reporting and to help us prioritize our efforts around issues of greatest significance to multiple stakeholders and to our company’s future success.

## ASSESSING THE MATERIAL IMPORTANCE OF AN ISSUE

While Access to Health and Ethics & Transparency issues continue to play a leading role in shaping our stakeholders’ views about our corporate reputation and ability to generate long-term value, we recognize that many other ESG issues are also of interest to stakeholders. For this reason we will continue to report and communicate on additional ESG issues on our website and through dialogue with individual stakeholders.

- Each issue is evaluated based on its importance to the business (x-axis) and to stakeholders (y-axis). Company interviews inform importance to business success, and external sources determine importance to stakeholders.
- Issues of great importance to our business *and* stakeholders are highlighted as priorities in the top-right quadrant

## TAKING CR MATERIALITY FORWARD

Having concluded our 2013-2014 materiality assessment, we are well positioned to further refine our CR framework and increase our commitment level to sustainable development through ambitious goals, metrics and programs. We plan to engage stakeholders on an ongoing basis to support this journey and help us deliver greater value to society and to our business. Going forward, our reporting will be more closely aligned with the GRI G4 guidelines on the basis of the top issues identified during the CR materiality process.

This report covers our company’s global operations, including subsidiaries, unless stated otherwise. It includes activities at all of our facilities, owned and leased, over which we have operational control unless otherwise noted. The basis for reporting on other matters specific to the operations of our business—including joint ventures, subsidiaries, leased facilities, outsourced operations and other entities that can affect comparability from period to period—can be found in our 2014 Annual Report and Form 10-K, which is filed with the United States Securities and Exchange Commission and is also available in the Financial Reports section of our [corporate headquarters’ website](#).



Our Approach

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# CR GOVERNANCE

**Our company aspires to being open and transparent about how we operate, in order to earn and retain the trust and confidence of our customers, employees, shareholders and other important stakeholders. Our reporting and governance structure is an integral part of this commitment.**

## THE OFFICE OF CORPORATE RESPONSIBILITY

Our corporate responsibility performance is dependent on all of our employees—from our chairman and CEO, to staff in each business unit, subsidiary, manufacturing plant and research laboratory. All employees are aware of our corporate responsibilities through our company's Code of Conduct, but we also recognize that a central coordinating function is necessary in order to ensure a comprehensive approach to corporate responsibility.

The Office of Corporate Responsibility coordinates the development, implementation and communication of our global corporate responsibility approach and, with the strategic guidance of the Public Policy and Responsibility Council, is responsible for reporting on our company's corporate responsibility performance. The Office of Corporate Responsibility works with business units and functional areas to integrate our corporate responsibility principles into business policies, strategies and practices, and brings the voice of external stakeholders into decision-making processes.

In December 2014, our company announced the appointment of Dr. Julie Gerberding as executive vice president for strategic communications, global public policy and population health. In this newly created Executive Committee position, Dr. Gerberding, who most recently served as president of our Vaccine division, is responsible for the company's global public policy, corporate responsibility and communications functions, as well as the company's Foundation and *MSD for Mothers* (known as *Merck for Mothers* in the U.S. and Canada). Dr. Gerberding also leads new partnership initiatives that will accelerate our company's ability to contribute to improved population health, a measure of impact that is increasingly valued by governments and other global health organizations.

### GRI G4-49

The Office of Corporate Responsibility, which supports the company's business strategy, is accountable for producing an annual corporate responsibility report. To contact members of the Office of Corporate Responsibility, please [click here](#).

## THE PUBLIC POLICY AND RESPONSIBILITY COUNCIL

GRI G4-43

The Public Policy and Responsibility Council is a senior-level decision-making governance body responsible for developing and monitoring our corporate responsibility approach, commitments and progress against key performance indicators. Membership includes senior leaders across all divisions and major functions of the company. The Council's responsibilities include reviewing external issues that may affect our business and reputation; providing high-level guidance on our overall approach to corporate responsibility, such as deciding on priority issues; developing policies and position statements; identifying key external stakeholders and engaging in outreach; providing input into our company's annual corporate responsibility report; and providing ongoing counsel and guidance to the Office of Corporate Responsibility.

## THE CORPORATE RESPONSIBILITY REPORT WORKING GROUP

Each member of the Corporate Responsibility Report Working Group works directly with a member of the Public Policy and Responsibility Council to promote further integration of corporate responsibility into the business. Individual members have been chosen to be active advocates for corporate responsibility within their respective areas. In addition, the members of the working group, a diverse selection of employees from all divisions of the company, serve as content experts in their respective areas and work closely with the Office of Corporate Responsibility to help set goals and develop metrics that support and measure our overall corporate responsibility strategy and objectives.

## BOARD COMMITTEE ON GOVERNANCE, PUBLIC POLICY & CORPORATE RESPONSIBILITY

GRI G4-48

GRI G4-46

GRI G4-45

GRI G4-42

Six independent directors constitute our company's Board Committee on Governance, Public Policy & Corporate Responsibility. Chaired by William B. Harrison, Jr., the committee is responsible for advising the company's Board of Directors and management on company policies and practices that pertain to the company's responsibilities as a global corporate citizen; its special obligations as a healthcare company whose products and services affect health and quality of life around the world; and its commitment to the highest standards of ethics and integrity in all its dealings.

Additionally, the committee is responsible for taking a leadership role in shaping the corporate governance of the company, including the development of a set of corporate governance guidelines for Board approval.

In addition to the Board Committee on Governance, Public Policy & Corporate Responsibility, other Board committees oversee issues related to corporate responsibility, such as audit and compliance, executive compensation and research.



Our Approach

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# STAKEHOLDER ENGAGEMENT

## **Our company understands that we must rise to the challenge of greater stakeholder expectations.**

We also recognize that we can't solve major health, environmental and economic challenges alone, but must collaborate with others who share our commitment and who bring their own unique expertise to the table. This understanding forms the core of our company's approach and commitment to stakeholder engagement.

We conduct stakeholder engagement at both the corporate and the local level, depending on the issue. We engage with industry, governments, policy makers, nongovernmental organizations (NGOs), opinion leaders, patient groups, academic organizations, our employees and others to inform our policies, our practices and the development of our products. Our intention is to build lasting relationships with our stakeholders from the outset, to understand their objectives, their expectations of our company and the potential for collaboration, and to enhance their understanding of—and trust in—us.

We strive to exchange information, views and recommendations; share activities and progress against key goals; and work in partnership toward common objectives. Engagement may take the form of one-on-one meetings, expert input forums or roundtable discussions, industry coalitions or formal partnerships.

## **STAKEHOLDER REVIEW OF OUR REPORTING**

In March 2015, a facilitation team convened 10 experts in corporate sustainability and reporting in a secure virtual ThinkTank on [Convetit](#), an online engagement platform. Our goal during these discussions was to listen to our stakeholders' perspectives and recommendations and to use the insights gained through these and ongoing discussions to inform future reporting.

Over a period of eight days, participants weighed in at their convenience, creating a shared conversation leading to an array of key takeaways in the three primary aspects of our reporting:

1. Communications
2. Materiality
3. Metrics

Participants commended many aspects of our reporting, while also identifying specific areas for improvement. We were pleased with the substantive exchange and candid feedback.



Stakeholder Engagement

# STAKEHOLDER GROUPS

**We engage with a diverse group of stakeholders with varying perspectives and opinions to understand their needs and expectations, and to gain insights that can inform our efforts to improve access to healthcare and foster progress towards solutions that benefit society.**

GRI G4-24

GRI G4-26

GRI G4-27

## PATIENTS AND CAREGIVERS

We embrace the opportunity to engage patient organizations and to actively listen to patients to better understand their healthcare journeys, expected outcomes and decision-making considerations, particularly as it relates to how they take medication, and the challenges they may encounter when taking several medications or treating multiple conditions. We feel that listening to patients is critical to further inspire effective and relevant medical and scientific innovation. For more information on our work with patient groups, please [click here](#).

## HEALTHCARE PROFESSIONALS

Doctors and patients look to us to provide accurate and balanced information about our products. We are therefore committed to providing appropriate and balanced information to physicians and other healthcare providers about our medicines, vaccines and ongoing research. We interact continually with physicians, healthcare professionals and researchers to conduct research and clinical trials, to share information and to gain new perspectives on needs and opportunities. For more information on our interactions with these stakeholders, please [click here](#).

## PAYERS

We are aware of payers' concerns over healthcare costs and limited budgets, and of the debates on how to make medicines and vaccines more affordable and accessible. We work with payers worldwide to inform their understanding of the relationship between the prices of our products and the true value they deliver to patients and healthcare systems. We also develop programs with payers to make sure our products can reach the people who need them most. [Learn more](#) about our access initiatives.

## GOVERNMENTS, MULTILATERAL ORGANIZATIONS AND REGULATORS

We are committed to conducting our business according to the letter and spirit of the law and regulations, as well as the various standards of business practice that we endorse.

We work with policy makers, legislators, multilateral organizations and governments worldwide to ensure that policy and regulatory environments globally, nationally and locally foster patient access to medicines and vaccines, and that they are conducive to ethical business practices, science and innovation. [Learn more](#) about our public policy and advocacy positions.

## SHAREHOLDERS

We strive to create shareholder value by identifying opportunities to meet customer needs and by managing our business responsibly to achieve superior financial results over the long term. To this end, we measure and report our performance on financial and other parameters and we work hard to protect and retain our assets, including our intellectual property rights, our resources, our employees and our reputation.

We also report on environmental, social and governance indicators that are relevant to our business and long-term performance through the publication of our annual corporate responsibility report.

## INTERNATIONAL AND LOCAL ORGANIZATIONS

We work hard to identify the best organizations and individuals to work with in order to address societal challenges and to inform debates on pressing issues. We have decades of experience in developing partnerships, especially those focused on improving global health. Such partnerships are driving the evolution of private-sector involvement in meeting societal challenges.

Our partnerships include a variety of ventures, with a range of participants and priorities—from small collaborations focused on distributing one type of medicine to larger entities fighting a disease. Our objectives for health partnerships might include developing a medicine or vaccine, distributing a donated or subsidized product, or strengthening health services. For more information on our public-private partnerships, please [click here](#).

## LOCAL COMMUNITIES

We strive to make a positive contribution to local communities through responsible and safe operations and through our philanthropy and employee volunteer efforts. Our objective is to develop culturally appropriate mechanisms to engage and build relationships with our local community stakeholders. For more information on our contributions to communities, please [click here](#).

## ENVIRONMENTAL STAKEHOLDERS

We work to reduce the environmental effects of our operations and products and to promote sustainable environmental practices within the company, among our partners and throughout our supply chain. For more information on our environmental performance, please [click here](#).

## EMPLOYEES

Because the talent, diversity and integrity of our people drive our success, we are committed to discovering more ways to create a workplace where our employees—and our business—can thrive.

We recognize the challenge of balancing professional achievement and personal well-being. To this end, we work hard every day to foster a positive working environment for our employees by providing resources to improve their health and that of their families, opportunities for professional development and more opportunities to get involved in the communities where they live. For more information on our employee relations, please [click here](#).

## SUPPLIERS AND BUSINESS PARTNERS

We seek out the best suppliers and partners with whom to research, develop, produce and distribute our medicines, vaccines and consumer products and to perform commercial services. We strive to engage a diverse supplier base and foster responsible approaches on the part of suppliers regarding labor, employment, human rights, health and safety, ethics, diversity, and protection of the environment. For more information on our approach to procurement and supplier relations, please [click here](#).

## TRADE AND INDUSTRY ASSOCIATIONS

We engage with stakeholders through membership in numerous organizations. Within these groups, we aim to inform relevant debates in ways that are constructive and that ultimately foster improved patient access to medicines and vaccines globally. For more information, please [click here](#).

We welcome your comments, questions and feedback to help guide the development of our programs, our reporting efforts and our corporate responsibility website. [Contact us](#).



Stakeholder Engagement

# ENGAGEMENT MECHANISMS

**Throughout 2014, we applied various mechanisms to engage stakeholders, ranging from one-on-one discussions and expert input forums to informal discussions during conferences and meetings.**

GRI G4-25

The engagement helped to inform our strategy and actions on a number of issues as well as those of others within the broader health community. The following examples illustrate the types of engagements in which we participate.

## ACCESS TO HEALTH

In 2013, we continued our engagement with key external stakeholders, including international funding organizations (IFOs), nongovernmental organizations (NGOs) and government aid agencies, which in many cases play an active role in expanding access to medicines for patients through direct operational activities or through advocacy on issues related to access. Our objective is to enhance our engagement in a way that is consistent with our company's sustainable access objectives. This approach provides opportunity to gain a better understanding of our stakeholders, their objectives and their needs, and can work toward developing mutually beneficial solutions.

Throughout 2014, we continued our involvement in the Gates/CEO Global Health Roundtable, a joint initiative by the Bill & Melinda Gates Foundation and the biopharmaceutical industry that seeks new ways to collaborate to improve global health, specifically by combating infectious diseases in developing countries. Since the inception of the Roundtable in 2009, our company has been an active participant in a number of Roundtable projects, including efforts to help reduce the global burden of neglected tropical diseases (NTDs) in line with the World Health Organization's 2020 goals to discover and develop new combination drugs for tuberculosis, and to strengthen immunization systems and vaccine delivery, as well as other initiatives to improve access to medicines and vaccines. In April 2014, our chief executive officer, Kenneth C. Frazier, assumed the position of co-chair, along with Bill Gates, of the Gates/CEO Roundtable.

### MSD for Mothers

Throughout 2014, *MSD for Mothers* (known as *Merck for Mothers* in the U.S. and Canada) collaborated with a broad range of stakeholders from government, multilateral organizations and the business community to advance our joint goal of improving maternal health worldwide.

- In the U.S. and India, we built on our work with leading professional organizations—namely the American College of Obstetricians and Gynecologists (ACOG) and the Federation of Obstetric and Gynaecological Societies of India

(FOGSI)—by developing, implementing and advocating for standardized measures to improve the quality of care women receive at health facilities.

- We joined with the World Bank to elevate the important role of local private providers in reducing maternal mortality, hosting a high-level side event during the 2014 U.N. General Assembly. Leaders from the U.S. Agency for International Development, the U.N. and our partners at Population Services International also participated, and we were joined by more than 400 in-person and online stakeholders from government, foundations, companies, media, NGOs and U.N. agencies. The event was an important milestone in *MSD for Mothers'* broader advocacy efforts to raise awareness that private doctors, midwives and drug shops are delivering a substantial proportion of maternal healthcare throughout the world.
- We expanded our engagement with the World Health Organization (WHO) to advance heat stable carbetocin to treat postpartum hemorrhage, the leading cause of maternal death. WHO is initiating clinical trials of the drug in 2015 in 11 countries, involving nearly 30,000 women.
- We convened the *MSD for Mothers* Advisory Board for a meeting in Uganda, where we engaged this prominent group of maternal health leaders for site visits to our Ugandan project and technical meetings about *MSD for Mothers'* priorities and activities moving forward.

## OUR VACCINES

Our company collaborates with a broad set of global stakeholders to improve access to vaccines. We help inform the vaccine policy environment through stakeholder engagement with important international organizations such as the WHO, the GAVI Alliance Board and UNICEF. Additionally, we engage stakeholders from regional and national organizations, contributing to the development and implementation of regional and national vaccination programs.

- Our partnership with GAVI and other Alliance partners is helping to ensure that infants and girls in the poorest countries have access to rotavirus and Human papillomavirus (HPV) vaccines.
- Through active engagement of the GAVI Alliance, we helped to foster an environment that led to mobilization of funding and partner technical support for the introduction of new vaccines in the world's poorest countries. Focusing on the anticipated need for our HPV and rotavirus vaccines, GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] and ROTATEQ® (rotavirus vaccine), we collaborated with GAVI and other members of the Alliance, including UNICEF, to understand estimated country demand for the vaccines over time, and to determine the lowest possible access prices that could be sustainably offered to GAVI and UNICEF for the vaccine volumes to be delivered to these poorest countries. To date, 16 of the 23 countries approved by GAVI for HPV have selected GARDASIL and five GAVI-eligible countries are using ROTATEQ. This resulted in greater than 10 million doses of GARDASIL and ROTATEQ being shipped to GAVI-eligible countries through 2014.
- Given the uncontrolled spread and devastating impact of the current Ebola epidemic, together with Newlink Genetics and a global network of partners we are collaborating in unprecedented ways with the singular focus of speeding the research, development, manufacturing, regulatory approval and deployment of a well-tolerated and effective Ebola vaccine. In less than four months, the development program advanced from first in humans to initiation of Phase II/III trials. The scope of the collaboration extends well beyond our company, Newlink and Genetics to many international partners leading clinical evaluation in the U.S., Canada, Europe and Africa (e.g., government agencies in Liberia, Sierra Leone and Guinea, the WHO, NIH, Public Health Agency of Canada, local academic and research centers), government agencies and funders providing critical programmatic and funding support (e.g., U.S. Department of Defense, BARDA, CDC, BMGF, the European Commission), and international organizations preparing for procurement and distribution (e.g., WHO, GAVI, UNICEF) should the vaccine candidate be demonstrated to be efficacious and well-tolerated and approved by regulatory authorities. Together with Newlink, we continue to engage stakeholders through this strong alliance network to advance the vaccine development program but also to establish a precedent for industry and the global health community's response to public health emergencies and foster a new, inclusive model for communications and collaboration.

## WOMEN'S HEALTH

We engage with key global donors and funding organizations, including the Bill & Melinda Gates Foundation, the U.S. Agency for International Development (USAID), John Snow, Inc. (JSI), the Department for International Development (DFID), the Swedish International Development Cooperation Agency (Sida), the Norwegian Agency for Development Cooperation (Norad), the Clinton Health Access Initiative (CHAI), the Children's Investment Fund Foundation (CIFF) and the United

Nations Population Fund (UNFPA) through a joint oversight board with the Bill & Melinda Gates Foundation, which serves to ensure the success of the IMPLANON® Access Program.

The board meets formally three times per year to discuss issues related to product production and capacity-building activities. During 2014, we engaged closely with stakeholders and customers at the global and national levels in emerging markets to develop effective strategies to ensure a seamless transition from IMPLANON® (etonogestrel implant), our long-acting reversible contraceptive implant, to our next-generation implant, IMPLANON NXT® (etonogestrel implant). Input from and coordination with stakeholders including ministries of health, USAID, UNFPA, JSI, CHAI and the Bill & Melinda Gates Foundation were critical to ensure plans were and continue to be in place to train local healthcare professionals, avoid stockouts at local delivery points and support overall coordinated supply planning. In addition, these stakeholders shared with us that the cost of our placebo trainers used in the clinical training for IMPLANON NXT was becoming a barrier to the introduction of the product. This led to our decision in early 2015 to make the placebo trainers available at no cost in donor-funded countries.

As a supporter of Family Planning 2020 (FP2020),<sup>1</sup> representatives from our company are active members in two of the four FP2020 working groups:

- The Country Engagement Working Group, which provides support to countries as they develop, implement and monitor progress against their transformational family-planning plans
- The Market Dynamics Working Group, which is addressing tensions and information gaps in the market that can unlock new and important opportunities to ensure that access to contraceptive supplies and services is expanded to new users

Representatives from our Women's Health team participate in the Bellagio Group, a group of international experts on family planning and reproductive health that strives to find innovative solutions that expand contraceptive choice and accelerate universal access to reproductive health services by increasing the availability of long-acting reversible contraceptives (LARCs).

The group convened in October 2014 in Mexico City to discuss ongoing efforts to expand access.

In January 2014, during the Seventh Asia Pacific Conference on Sexual and Reproductive Health Rights in Manila, our company held a forum with key public, private and civil society partners to discuss ways to work together to accelerate the rollout of contraceptive supplies and methods following the passage of the Philippines' historic reproductive health law.

## **INFECTIOUS DISEASE—HIV AND VIRAL HEPATITIS**

We engage in multiple ways with community representatives and other external stakeholders working in infectious disease, with an emphasis on HIV and viral hepatitis, to address issues related to care and treatment both in the developed and the developing world. We meet regularly with national, regional and global community advisory boards to discuss issues of treatment and treatment access with community representatives. Over the past year, we have met with the European AIDS Treatment Group's European Community Advisory Board to discuss both HIV and HIV-HCV coinfection, with the European Liver Patients Association community advisory board, with HIV and HCV treatment advocates in the United States through multiple venues, with the Eastern European and Central Asian Community Advisory Board, and with the World Community Advisory Board meeting on the hepatitis C virus (HCV), and the World Hepatitis Alliance Advisory Committee, among others.

We are also actively engaged in multi-stakeholder-based organizations to address treatment issues in HIV and viral hepatitis. These engagements include engagement with international and national coalitions such as the National Viral Hepatitis Roundtable, National Hepatitis Corrections Network, the Viral Hepatitis Action Coalition, a public-private partnership developed by the CDC Foundation to help make meaningful advances in the prevention, screening and treatment of viral hepatitis, and with the International AIDS Society's (IAS) Industry Liaison Forum, a mechanism to inform and support collaboration and partnership between the pharmaceutical industry and the IAS.

Our company is also a long-standing member of the Private Sector Delegation to the Global Fund for HIV, TB and Malaria, the largest multilateral funder of HIV, TB and malaria prevention, care and treatment in the developing world. The Private Sector Delegation represents the private sector in the multi-stakeholder governance structure of the Global Fund, alongside donor and implementer government, civil society, community and private foundation delegations.

<sup>1</sup> An outcome of the London Summit was the formation of FP2020 to track progress and report on the financial and policy commitments made at the Summit, identify obstacles and barriers to their achievement and recommend solutions.

# WORKING WITH PATIENT GROUPS

**Our company's mission is to continue to improve the health of people through the discovery, development and marketing of innovative products that contribute to the quality of life.**

## OUR COMMITMENT TO PATIENT ENGAGEMENT AND PATIENT ORGANIZATIONS

We embrace the opportunity to engage patient organizations and to actively listen to patients to better understand their healthcare journeys, expected outcomes and decision-making, particularly as it relates to how they take medication, and challenges they may encounter when taking several medications or treating multiple conditions. We feel that listening to patients is critical to further inspire effective and relevant medical and scientific innovation.

We are committed to learning from the patient perspective and empowering patients, caregivers and healthcare professionals by making public the results of clinical trials in a timely manner, whether or not the outcomes are positive or negative. [Learn more.](#)

We have a strong commitment to health literacy, and we believe that clear, simple information about clinical trials, diseases and medicine should be available and accessible to people across a range of health-literacy levels. [Learn more.](#)

We believe that our contributions to organizations such as patient groups, health-related charities and nongovernmental organizations (NGOs) are fundamental to our goals and corporate responsibility. Because of the gaps in patient care and changes to health policy in such areas as vaccination, oncology, heart disease, HIV, hepatitis C infection and other chronic conditions, there is a compelling need for the pharmaceutical industry to work more closely with patient organizations and key stakeholders to understand outcomes from the patients' point of view, improve access to therapies, validate measurement tools and increase awareness of diseases.

## PRACTICES

We have a long history of collaboration with patient groups and health-related charities, including work related to improving knowledge and understanding of diseases and treatment options, as well as information and decision-making among consumers in healthcare.

Because we recognize the legal and reputational risks of inappropriate donations or sponsorships, we have guidance documents, policies and management systems in place to ensure the integrity of our practices. We also comply with all applicable laws and regulations.

## PRINCIPLES

Because patients are at the core of health systems, it is especially important to support patient societies and associations. Working with patient groups, we develop appropriate programs and projects to support their important efforts. We believe in collaborating with healthcare stakeholders—including government and other payers, healthcare providers and patient organizations—to engage in programs that aim to improve patient education and patient care in therapeutic areas where we have expertise.

That's why we support and participate in programs that help patient organizations increase disease awareness and improve access to medicines and better healthcare. We work with patient organizations to disseminate and share quality medical, scientific and pharmacoeconomic information, consistent with legal and regulatory obligations, and with respect for their independence.

Decisions to contribute funding to patient societies are dependent on:

- A written proposal on the project, including the ways in which the funding will advance educational and disease-awareness objectives
- An internal review by relevant company groups
- The consistent application of company policies and procedures, including those related to contributions; advertising and promotion; sales and marketing; and to our ethical business practices as outlined in our company's Code of Conduct

## DECISIONS

We adhere to all guidelines and regulations that are relevant to relationships with patient organizations and to the provision of information about diseases and available therapies in individual countries. We will continue to explore ways to expand our stakeholder engagement processes, build trust with stakeholders, and identify opportunities to gain and share insights with key stakeholders on relevant corporate responsibility issues. We welcome stakeholder feedback.



Our Approach

# PUBLIC POLICY

## MAIN

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**We believe it is our responsibility to work with policy makers and other stakeholders to explain our views ethically and transparently.**

We are committed to participating constructively and responsibly in the political process, and to providing clarifying analysis and information on the issues that affect our business and patient care.

A major element of our corporate responsibility approach is our public policy advocacy work and our outreach to stakeholders. In this section, we describe how we inform and advocate for public policies that foster research into innovative medicines and that improve access to medicines, vaccines and healthcare.

We also describe our approach to engaging with stakeholders. We believe this engagement is fundamental to our understanding of—and response to—society’s expectations of our company. From drug discovery and development to distribution, our engagement with stakeholders guides our business strategy and decisions, and strengthens stakeholders’ understanding of—and trust in—our business.

We recognize that our outreach activities can help highlight and address important issues, leveraging the expertise of all our stakeholders to develop sustainable solutions to such challenges as disease, lack of education, environmental challenges and corruption. The company has pioneered far-reaching programs and partnerships, the results of which demonstrate that more can be achieved by working together than by individual stakeholders working alone—and can make a sustainable difference.

## ENGAGING RESPONSIBLY

Government proposals to regulate the healthcare system may directly affect the company’s business and incentives for pharmaceutical innovation. Important policy initiatives can also increase patient access to medicines and vaccines and to healthcare insurance coverage—particularly for patients in disadvantaged communities and regions.

That is why it is appropriate for the company to help inform the debate on these issues in the U.S. and other countries. Our participation in the political process is guided by the following principles:

- Improving patient access to healthcare, including to medicines and vaccines
- Encouraging innovation by protecting intellectual property rights, advocating for government support of basic research, and supporting efficient and effective regulatory systems, among other issues

Our Executive Committee has overall governing responsibility for the company’s public policy strategy, as guided by the Governance, Public Policy and Corporate Responsibility Committee of the Board of Directors. Our Global Public Policy Leadership Team, headed by Julie Gerberding, Executive Vice President of Strategic Communications, Global Public Policy and Population Health, leads the development and communication of policy positions on major issues. Statements summarizing our position on key public policy issues are posted on the [public policy page](#) of our corporate headquarters website.

## HOW WE ENGAGE

We engage in public policy debates primarily by communicating information to government officials and policy makers.

Our Federal Policy and Government Relations office in Washington, DC, is responsible for advocacy activities with the U.S. Congress and other bodies of the federal government. Advocacy at the state level is managed by our State Government Affairs & Policy organization. Outside the U.S., advocacy activities are managed at the regional, country or local level, with support from regional and corporate policy staff.

To assist with our advocacy and policy analysis work, our company and our affiliates contract with a range of private firms specializing in government affairs advocacy. These firms employ government affairs consultants with particular expertise on issues important to our company. Our U.S. Action Network also informs our U.S.-based employees and retirees about important legislative issues, and serves as a vehicle through which they can communicate with their representatives in Congress.

All of our employees and external business partners must abide by our global corporate Code of Conduct, *Our Values and Standards*, which applies to our interactions with government officials and to advocacy activities on public policy issues. This code is intended to ensure that all information provided to governmental entities is complete and accurate to the best of an employee's knowledge and belief. In the U.S., there are also important federal and state lobbying-registration and disclosure laws with which we comply.

Our corporate policy on ethical business practices includes guidelines on the U.S. anti-kickback laws and Foreign Corrupt Practices Act, making clear that no illegal payments of any kind (monetary or otherwise) are to be offered or made to an individual or entity—including a local, state or federal government or political party official or candidate in the U.S.; a government or political party official or candidate of any other nation; or officials of public international organizations—at any time or under any circumstances.

To improve access to information about our advocacy activities, we disclose costs associated with lobbying in the EU and the U.S. [Click here](#) for our 2014 reporting to the EU Transparency Register. Costs are based on the pro rata salary costs of MSD staff and on the proportion of employee time and outsourcing spent on initiatives involving interest-representation to European institutions.

In the U.S., in compliance with the [Lobbying Disclosure Act](#), we file quarterly reports with the U.S. Congress describing the issues we are lobbying about and the amount of money we spend each quarter. These reports incorporate the expenses associated with lobbying the federal government, including those incurred by our Office of U.S. Policy and Government Relations, and the portion of our trade association dues associated with federal lobbying.

## OUR TOP LOBBYING ISSUES

In the U.S. in 2014, the top five issues at the federal level for which our company lobbied were:

- Defense of Medicare Part D
- The 340B drug pricing program
- Combatting antimicrobial resistance
- Comprehensive tax reform
- Implementation of the Affordable Care Act

In the U.S. in 2014, the top issues at the state level for which our company lobbied were:

- State implementation of the health benefit exchange component of the federal Affordable Care Act
- Support for patient access to medicines in Medicaid, AIDS Drug Assistance and other state programs
- Protection and improved access to immunizations
- Initiatives to address pharmaceuticals in the environment and responsible disposal

In Europe in 2014, our advocacy focused on:

- Fostering a framework for a sound pricing regime in and across diverse EU member state economies
- Support for government vaccination, hepatitis and diabetes programs
- Standards for health technology assessment and health literacy
- Science-based policies for biological medicines
- Implementation of the Clinical Trial Directive, of the Cross-Border Healthcare Directive and the Pharmacovigilance

Directive

Our senior vice president of Global Public Policy and Corporate Responsibility presents the company's advocacy priorities to members of our Executive Committee and the Governance, Public Policy and Corporate Responsibility Committee of the Board of Directors annually, and provides periodic updates throughout the year.

# POLITICAL CONTRIBUTIONS

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**Where permitted by law in the U.S., Canada and Australia, our company provides corporate political contributions, primarily to the electoral campaigns of individual candidates.**

GRI G4-SO6

Our employees can also participate in the political process by joining a nonpartisan political action committee (PAC), through which they can pool their financial resources to support federal and state candidates. Except for administrative expenses, the our company's Employees Political Action Committee (PAC) is completely funded by voluntary contributions from eligible employees. The PAC supports legislators from both major parties who understand and appreciate the work we do to discover and develop medicines and to make them available to the patients who need them.

Our corporate policy governing its corporate and PAC contributions can be found [here](#). In addition, we have developed [Principles Governing Corporate and Political Action Committee Spending](#). These principles are modeled on provisions in the [Model Code for Political Spending](#), established by the [Center for Political Accountability](#), and are intended to promote corporate accountability.

We maintained a Top 5 ranking on the [Center for Political Accountability \(CPA\)-Zicklin Index of Corporate Political Accountability and Disclosure](#), released by the CPA in conjunction with the [Carol and Lawrence Zicklin Center for Business Ethics Research](#) at the Wharton School of the University of Pennsylvania.

We have a formal [PAC Contributions Committee](#) that makes decisions on spending for the PAC. This committee also makes decisions on our company's corporate political contributions. The committee is chaired by our executive vice president and general counsel and includes senior managers representing different divisions and corporate functions. The general counsel approves contribution recommendations, following review and approval by the committee.

To ensure compliance with our company policy and federal and state law, outside legal experts provide periodic guidance to our company on required disclosure of its political activities. We also perform periodic audits to assess and enforce compliance with our policy governing our corporate and PAC contributions, and we require those individuals who recommend corporate political contributions in the U.S. to certify their knowledge of and adherence to our corporate [Policy and Principles Governing Corporate Political and Political Action Committee Contributions](#).

As required by our company policy and procedures, our executive vice president and general counsel send an annual report on the company's corporate political contributions for the previous year to [our company's Board of Directors](#). The report discloses contributions in the U.S, Australia and Canada, including the name of each candidate, committee or event and the amount disbursed. It also reports on trade association dues spent on lobbying and political activity in the U.S. for dues greater than \$25,000. Our senior vice president of public policy and corporate responsibility also submits a midyear report on corporate political contributions to the Board for its review. In addition, our contributions, policies and practices are reviewed and overseen by the [Governance, Public Policy and Corporate Responsibility Board Committee](#). For both reports, which also describe any changes in our policies, we invite comments and questions.

To improve access to information about our corporate political and PAC contributions in the U.S., our company semiannually posts its contributions, categorized by state, candidate and amount.

## OUR CORPORATE POLITICAL CONTRIBUTIONS

In 2014, we spent a total of \$822,600 in U.S. corporate political contributions. These contributions supported the campaigns of candidates for state-level offices in 25 states plus the District of Columbia. They also were used to support state legislative leadership committees of both parties, industry-affiliated PACs, and a number of national organizations representing elected state officials. The latter groups meet periodically to discuss policy issues. Examples are the Republican Governors Association and the Democratic Governors Association. Information on all contributions can be accessed through the above link. Our representatives involved in state-government-affairs activities made the recommendations for specific contributions. These recommendations were reviewed and approved by the Corporate Political Contributions Committee, which mirrors the our company's PAC Contributions Committee in membership and oversight procedures. Outside legal counsel conducted a thorough review of all proposed contributions to ensure that they were permitted under state law. Final approval was provided by the general counsel of our company.

To view a listing of our corporate and PAC contributions made within the U.S. during 2015, please [click here](#).

We also provide grants to organizations that represent elected officials to support public policy advocacy. State Government Affairs reviews its grants and corporate memberships on an annual basis to decide which may be considered for the upcoming calendar year based on budget constraints and policy priorities. Groups that received our support in 2014 included, but were not limited to, the National Governors Association, the Council of State Governments and the National Black Caucus of State Legislators. We disclose all [public policy grants](#) as part of our general grants disclosure.

The only other countries in which we provide corporate contributions to candidates or political parties are Canada and Australia. These contributions are subject to the same policies and governance procedures discussed above. To view our company's contributions made in Canada during 2015, please [click here](#). To view our company's contributions made in Australia during 2015, please [click here](#).

Archived corporate political contribution reports are available [here](#).

Our vice president of State Government Affairs was co-chair of the Conference Board Committee on Corporate Political Spending in 2014, which is dedicated to accountability, disclosure, education and engagement on issues of corporate political activity. In 2012, the committee released a report, "Corporate Political Spending: Policies and Practices, Accountability and Disclosure." We have also previously supported the development of the *Handbook on Corporate Political Activity: Emerging Corporate Governance Issues*, which grew out of discussions held at two roundtables organized by The Conference Board Governance Center in 2010.

## INDUSTRY ASSOCIATIONS

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### **Our company is a member of numerous industry and trade groups.**

We work with these groups because they represent the pharmaceutical industry and business community in debates led by governments and other stakeholders, and because they help the industry reach consensus on policy issues.

When our trade associations actively lobby on our core business issues, outlined above, we seek to align their positions with our own. There are times, however, when we may not share the views of our peers or associations—both on issues that are central to our business and those that, while important, are not directly material to our mission. With representatives on the boards and committees of industry groups and trade associations, we can voice questions or concerns we may have about policy or related activities. We may even recuse ourselves from related trade association or industry group activities when appropriate.

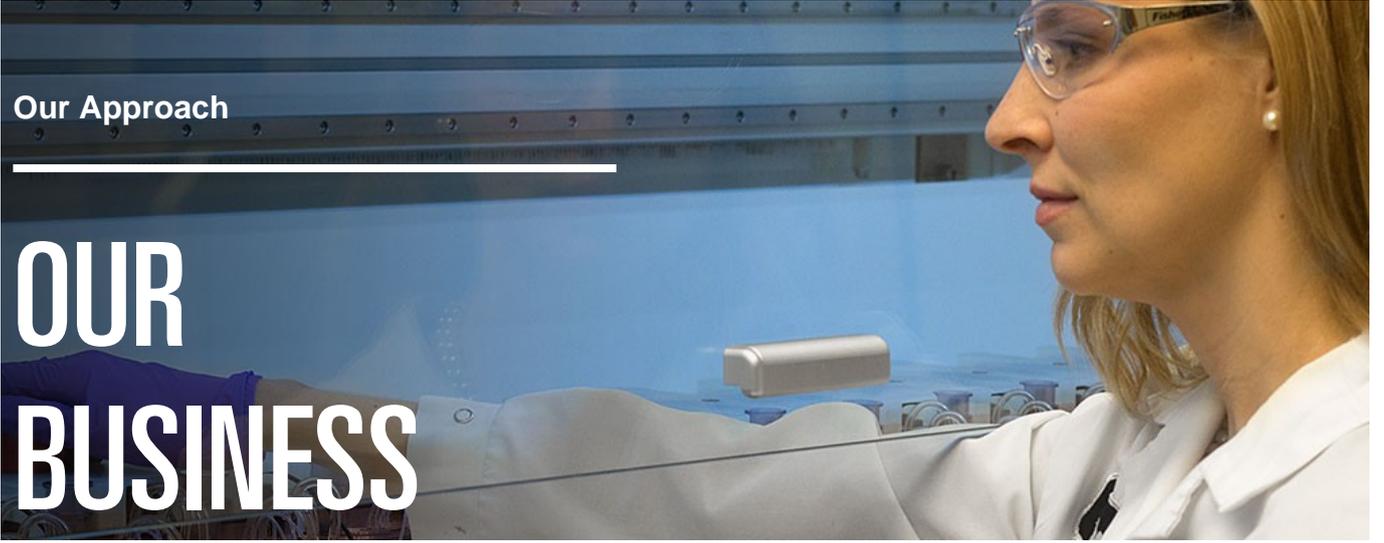
#### GRI G4-16

Our executive vice president and general counsel sends an annual report to our company's Board of Directors on trade association dues spent the previous year on lobbying and political activity in the U.S. for dues greater than \$25,000. The Governance, Public Policy and Corporate Responsibility Committee of the Board of Directors has ongoing oversight of the company's membership in trade associations and grassroots lobbying activities.

For a list of industry and trade groups of which we are members and our dues (dues that are greater than \$25,000) to trade associations that are used for political purposes, please [click here](#).

Through our top-three trade associations (listed below), we engaged on the following policy issues in 2014:

- **Pharmaceutical Research and Manufacturers of America (PhRMA):** Federal deficit reduction; defense of Medicare Part D; and implementation of the Affordable Care Act
- **U.S. Chamber of Commerce:** Federal deficit reduction; the reauthorization of the Prescription Drug User Fee Act; defense of Medicare Part D; corporate tax reform; and the Trans-Pacific Partnership
- **Biotechnology Industry Organization (BIO):** Federal deficit reduction; protecting incentives for innovation; and defense of Medicare Part D



Our Approach

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# OUR BUSINESS

**From developing new therapies that treat and prevent disease to helping people in need, we're committed to improving health and well-being around the world.**

Our vision is to make a difference in the lives of people globally through our innovative medicines, vaccines, biologic therapies and animal products. We aspire to being the best healthcare company in the world, and are dedicated to providing leading innovations and solutions for tomorrow.

We have made it our mission to provide innovative, distinctive products and services that save and improve lives and satisfy customer needs; to achieve recognition as a great place to work; and to provide investors with a superior rate of return.

We continue to focus our research on conditions that affect millions of people around the world—such as Alzheimer's and cancer—while expanding our strengths in such areas as vaccines and biologics.

We also devote extensive time and energy to increasing access to medicines and vaccines, through far-reaching programs that donate and deliver our products to the people who need them.

We're applying our global reach, financial strength and scientific excellence to doing more of what we're passionate about: improving health and improving lives.

GRI G4-4

GRI G4-8

## PRESCRIPTION PRODUCTS AND PRESCRIBING INFORMATION

Our core business is the discovery and development of prescription medicines for diseases and conditions that impact millions of people.

We invest billions of research dollars to find medicines that can help improve lives. Today, our company has more than 50 prescription products in key therapeutic areas such as cardiovascular disease, respiratory disease, oncology, neuroscience, infectious disease, immunology and women's health.

To learn more, [click here](#).

## NAME

The company, Merck & Co., Inc., Kenilworth, NJ, USA, is known as MSD outside the United States and Canada and is listed on the New York Stock Exchange under the symbol "MRK."

## VACCINES

Vaccines are one of the greatest public health success stories in history, and our company has played its part in that story.

We are dedicated to the complex business of researching and producing vaccines. Our unique vaccines have helped prevent a number of diseases, including ones never thought preventable. To learn more, [click here](#).

## ANIMAL HEALTH

Through our company's animal health business, we are a global leader in the research, development, manufacturing and sale of veterinary medicines.

We offer a broad choice of vaccines, anti-infective and antiparasitic drugs, a complete range of fertility management products, pharmaceutical specialty products, innovative delivery solutions, performance technologies, and value-added programs, such as pet recovery services and livestock data management tools. [Learn more about our Animal Health business.](#)\*

## CONSUMER PRODUCTS

Effective October 1, 2014, Bayer AG purchased our company's consumer care business. [Read the press release](#).

## PRODUCTS

We are a global healthcare company that delivers innovative health solutions through our prescription medicines, vaccines, biologic therapies and animal health products.

[View a list of products](#) marketed in the U.S.

## PIPELINE

Our company has a robust pipeline, with a wide range of product candidates across each phase of development. [View our pipeline](#).

## SENIOR LEADERSHIP

Kenneth C. Frazier, chairman of the board, president and chief executive officer

Robert M. Davis, executive vice president and chief financial officer

[View the list of Executive Committee members](#).

\* Note: The website listed above may refer to products that either are not available in your country or are marketed under a different trade name. In addition, the safety and efficacy data and the withholding periods for a specific product may be different depending on local regulations. Please consult your veterinarian for more information.



Our Business

# ECONOMIC IMPACT

**Sustainable business success depends on making quality products that people value through sound financial stewardship and responsible governance that ensures we are meeting customers' needs ethically and transparently.**

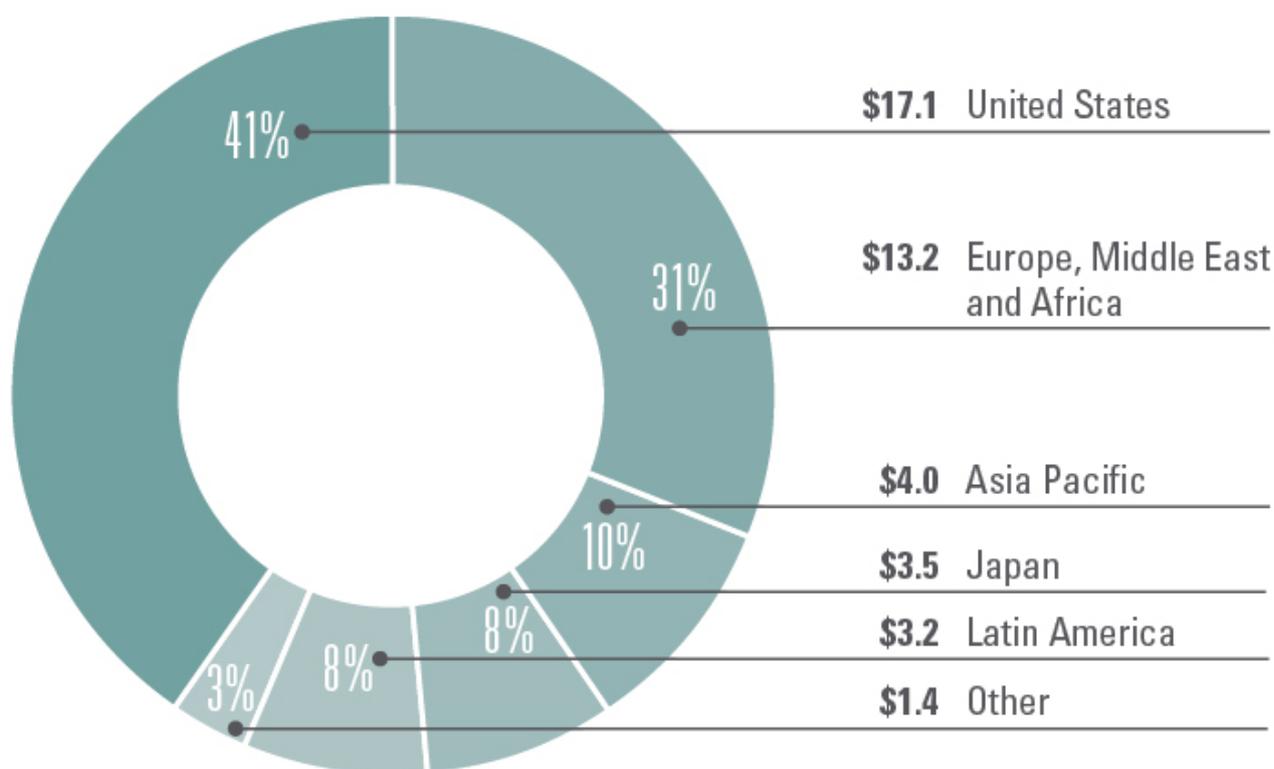
Globalization and the expanding reach of firms during the past decade have escalated expectations for multinational enterprises to create more social value, beyond compliance with regulations and philanthropy. Corporate responsibility has emerged as an important element of the private sector's response to these expectations and demands.

While it can be seen as a way to improve one's reputation, or simply as a response to a moral imperative to do good, we believe that corporate responsibility is critical to our business success and can provide us with new opportunities to create shared value. Our principal economic contribution to society is made through the discovery, development, manufacturing and marketing of our products, which directly improve and maintain the health of individuals and communities around the world, helping them to lead more productive lives.

For additional information about our business and economic impact, please see our **Form 10-K** for the year ended December 31, 2014.

GRI G4-9

## 2014 REVENUES BY GEOGRAPHIC REGION (IN BILLIONS)



Note: May not add to 100 percent due to rounding.

U.S.	\$17.1 Billion
Europe, Middle East and Africa	\$13.2 Billion
Asia Pacific	\$4.0 Billion
Japan	\$3.5 Billion
Latin America	\$3.2 Billion
Other	\$1.4 Billion
	Product Sales (\$ in millions)

Pharmaceutical	36,042
Animal Health	3,454
Consumer Care <sup>1</sup>	1,547
Other Revenues	1,194

<sup>1</sup> On October 1, 2014, the company divested its Consumer Care segment that developed, manufactured and marketed over-the-counter, foot care and sun care products. <sup>2</sup> Other revenues are primarily composed of alliance revenue, miscellaneous corporate revenues and third-party manufacturing sales. On October 1, 2013, the company divested a substantial portion of its third-party manufacturing sales.

Financial Information	2010	2011	2012	2013	2014
Sales (\$USM) <sup>1</sup>	45,987	48,047	47,267	44,033	42,237
Research and development expenses (\$USM)	11,111	8,467	8,168	7,503	7,180
Number of employees	94,000	86,000	83,000	77,000	70,000
Number of stockholders of record	171,000	166,100	157,400	149,400	142,000
Annual cash dividend paid per share (\$US)	1.52	1.56	1.69	1.73	1.77
Global tax expense as reported on income statement (\$USM)	671	942	2,440	1,028	5,349

<sup>1</sup> Reflects the divestiture of our Consumer Care (MCC) business on October 1, 2014, including a gain on the sale, as well as a gain recognized on an option exercise by AstraZeneca, gains on the dispositions of other business assets and a loss on extinguishment of debt.





# SUPPORTING OUR COMMUNITIES

## **Our company contributes substantial economic and social value to the countries and local communities in which we operate.**

As of December 31, 2014, Merck & Co. Inc, Kenilworth, NJ, USA (including its Banyu subsidiary in Japan) had a physical presence in 76 countries, with 424 active (occupied) research, manufacturing, sales and administrative sites. In all of these locations, we recognize that our success depends in large part on our relationships and interactions with local communities, including elected officials, business and community leaders, charitable organizations, neighbors, educators, local media and our own employees.

We aspire to have a positive effect on the communities in which we operate worldwide, and we recognize our responsibility toward those affected directly or indirectly by our operations and activities. We rely on local communities not only for our workforce, but also for some of our suppliers and for our ability to do business. Through ongoing engagement and dialogue, we work to understand the concerns and needs of our communities, and we seek to respond by addressing local challenges in ways that build stronger communities and support the sustainability of our business.

### **GRI G4-EC7**

We contribute to our communities in three key ways:

- Making direct and indirect economic contributions, such as employment, training, support of local suppliers and local R&D, and paying taxes
- Managing our community impact—for example, by ensuring confidence in environmental and safety performance and by respecting human rights
- Addressing community needs through philanthropy and community involvement

Underlying our community approach is our commitment to respecting human rights. As a signatory to the [United Nations Global Compact](#), we are committed to protecting and promoting fundamental human rights not only within our immediate workforce but also within our broader sphere of influence, including within our local communities. [Learn more about our commitment to protecting and promoting fundamental human rights.](#)

## **WORKING WITH LOCAL COMMUNITIES**

Our signature [Neighbor of Choice \(NOC\)](#) community program supports the work of local nonprofit organizations that strive to improve the quality of life of the residents in communities where we have a presence.

Established in the 1990s, our NOC program helps to build relationships of trust and support with these local organizations and residents by responding to needs identified by the communities themselves. We take seriously the shared responsibility of helping to improve the quality of life of neighbors in need. [Learn more.](#)



Our Approach

# AWARDS & RECOGNITION

**Over the years, we have received numerous awards and recognition for our comprehensive approach to corporate responsibility. The following is a selection of awards and recognition received throughout 2014 and 2015.**

## GLOBAL RECOGNITION

### **FTSE4Good Index**

Our company is a FTSE4Good constituent member. The FTSE4Good Index Series measures the performance of companies that meet globally recognized corporate responsibility standards. (October 2014)

### **Access to Medicine Index**

Our company ranked #7 on the 2014 Access to Medicine Index. This index evaluates the top 20 research-based pharmaceutical companies' access-to-medicine activities in developing countries. (November 2014)

### **Calvert Investments**

Calvert Investments continues to assess the diversity practices of the largely multinational companies that make up the Standard & Poor's 100 Index (S&P 100). Using an in-depth methodology, Calvert examines companies' diversity policies, programs and performance; identifies the leaders and laggards; and provides recommendations to help companies identify and remedy operational gaps. Based on the 10 diversity criteria in Calvert's report, our company tied for first place among 10 other companies in the 2014 survey.

### **Global Leaders Council for Reproductive Health**

*MSD for Mothers*, known as *Merck for Mothers* in the U.S. and Canada, collaboration with the Bill & Melinda Gates Foundation and IntraHealth received the Resolve Award for Service Delivery from the Global Leaders Council for Reproductive Health. The award was given in recognition of innovative and scalable healthcare service-delivery methods implemented in Senegal, West Africa. (March 2015)

### **U.S. News and World Report**

The HMR Diet, developed by HMR Weight Management Services (HMR), a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, earned the #2 spot as a Best Weight-Loss Diet, according to *U.S. News & World Report's* Best Diets of 2015. This annual list ranks the best diets in the U.S. based on reviews from nutritionists, physicians and dietitians. (January 2015)

### **CECP (Committee Encouraging Corporate Philanthropy)**

Our Chairman and CEO Kenneth C. Frazier was recognized as a CEO who is a "Force for Good" by CECP, a global nonprofit

organization and coalition of CEOs who believe societal improvement is an essential measure of business performance. Mr. Frazier was honored for his “focus on a long-term commitment to innovative research and development as well as business and humanitarian initiatives to improve global health.”

#### **Japan’s Ministry of Economy, Trade and Industry (METI)**

MSD in Japan received the “Best Career Education Award” in the Large Corporation category from Japan’s Ministry of Economy, Trade and Industry (METI) for its Science School program. Started in 2011 in partnership with UNESCO, Science School offers basic science lessons at Japanese elementary schools. The goal is to help revive interest in science among Japanese school children. Science School was also recognized as an excellent model for other educational- support programs. (February 2015)

#### **Golden Peacock Global Award for Sustainability**

We received the Golden Peacock Global Award for Sustainability at the 14th London Global Convention on Corporate Governance and Sustainability for our comprehensive approach to corporate responsibility. The Golden Peacock Awards were founded in 1991 by the Institute of Directors (IOD) and are now recognized worldwide for their independence, integrity, transparency and thorough evaluation of applications. (November 2014)

#### **Manufacturing Leadership Council**

Our Virtual Technical Network (VTN)—which created a new way of working and collaborating by combining social computing and inclusion—received a 2014 Manufacturing Leadership Council Award. VTN was recognized in the Workplace Leadership category as a breakthrough project helping to shape the future of connectivity and global collaboration. (March 2014)

#### **Pet’s & Vet’s Packaging Forum**

MSD Animal Health in France was awarded the Packaging Innovation Award in the Veterinary products category by the Pet’s & Vet’s Packaging Forum for our anti-inflammatory for cattle, FINADYNE<sup>®</sup> Transdermal (flunixin meglumine). The award was established in 2014 to encourage innovative achievements in packaging, veterinary drugs and devices. Our company was recognized for the innovative capacity of our research and for our commitment to support treatment adherence by providing veterinarians the most suitable and possible practical delivery devices. (February 2015)

#### **InformationWeek Elite 100**

We ranked #49 on *InformationWeek* magazine’s Elite 100: Winning Digital Strategies list for using new data-collection and analysis models to improve the reliability of our vaccine manufacturing process. This list is InformationWeek’s selective annual ranking of business technology innovators, that use technology to positively impact business by providing a better product to customers or cutting the cost of delivering a product. (May 2014)

#### **The Chronicle of Philanthropy**

We ranked #3 in corporate donations of cash and products in *The Chronicle of Philanthropy*’s annual survey of philanthropic giving by U.S. corporations. (July 2014)

#### **Fortune**

We were ranked #5 in *Fortune* magazine’s 2015 list of the World’s Most Admired Companies within the Pharmaceutical Industry. (February 2015)

#### **Corporate Responsibility Magazine**

We placed #27 in *Corporate Responsibility Magazine*’s annual ranking of the 100 Best Corporate Citizens among leading public companies in the U.S. The 2015 list is based on 298 disclosure and performance measures, which are gathered from publicly available information in seven categories: environment, climate change, human rights, employee relations, governance, philanthropy and finance. (March 2015)

The magazine also ranked our company #2 on its 2014 Industry Sector Best Corporate Citizens list in the Healthcare sector. The ranking was based on 324 data elements across seven categories: climate change, employee relations, environment, financial performance, governance, human rights and philanthropy. Only publicly disclosed data on companies’ websites was taken into account for the ranking. (October 2014)

#### **Corporate Register**

Our company’s 2012 Corporate Responsibility report took third place in the Innovation in Reporting category in the Corporate Register Reporting Awards (CRRRA) in 2014.

#### **STOXX<sup>®</sup> Global ESG Leaders**

We are a component of the STOXX<sup>®</sup> Global ESG Leaders indices—an innovative series of environmental, social and governance (ESG) equity indices that are based on a completely transparent selection process. (October 2014)

#### **MSCI Global Sustainability Index Series**

We are a constituent of MSCI Inc., a leading provider of global benchmark indexes, has over 500 equity and fixed income environmental, social, and governance (ESG) indexes. The family of MSCI Global Sustainability Indexes includes the MSCI World ESG Index, MSCI EM ESG Index, and the MSCI ACWI ESG Index. (July 2015)

### **Dividend Channel**

Our company was named as a Top Socially Responsible Dividend Stock by Dividend Channel, signifying a stock with above-average "DividendRank" statistics including a strong 2.9% yield, as well as being recognized by prominent asset managers as being a socially responsible investment, through analysis of social and environmental criteria. Environmental criteria include considerations like the environmental impact of the company's products and services, as well as the company's efficiency in terms of its use of energy and resources. Social criteria include elements such as human rights, child labor, corporate diversity, and the company's impact on society.

## **ACCESS TO HEALTH**

### **Maternity Care Coalition**

We were honored with the Spirit of Motherhood Award by the Maternity Care Coalition for *MSD for Mothers'* U.S. and international efforts to bring together community organizations, the scientific and medical community, and others who contribute their expertise and raise awareness to reduce maternal mortality and morbidity. (February 2015)

### **United Nations Foundation**

We were recognized by the United Nations Foundation for our continued commitment to global health. The United Nations Foundation highlights the achievements of leaders from multiple sectors who have helped tackle the world's most pressing challenges. The UN Foundation noted the groundbreaking *MSD for Mothers* program, as well as our company's participation in the Foundation's Measles and Rubella Initiative and other programs and partnerships focused on improving health outcomes. (November 2014)

## **ENVIRONMENTAL SUSTAINABILITY**

### **U.S. Environmental Protection Agency (EPA) ENERGY STAR**

We received an ENERGY STAR 2015 Partner of Year—Sustained Excellence Award from the U.S. EPA for our continued improvement in energy performance and leadership in energy management in both the pharmaceutical and industrial sectors.

The EPA also awarded our West Point, New York, USA, site's CoGen3 CHP unit its 2014 ENERGYSTAR CHP (Combined Heat and Power) merit award. CHP systems can qualify for this award if they demonstrate considerable fuel and emissions savings over comparable, state-of-the-art heat and power generation systems.

Our company has been an ENERGY STAR Partner since 1995 and recognized by the EPA for 10 consecutive years—twice as Partner of the Year and, now, for an eighth time, for Sustained Excellence. (April 2015)

### **Newsweek Green Rankings**

We ranked #142 on *Newsweek's* 2015 Global 500 Green Rankings list and #86 on the 2015 U.S. 500 list, compared to #351 and #261, respectively, in 2014. We have appeared on *Newsweek's* Green Rankings list ever since it was first published in 2009. The 2015 *Newsweek* rankings measure the environmental performance of large public companies using eight key performance indicators, including energy use, greenhouse gas emissions, water use and waste generation. (June 2015)

### **CDP**

CDP is an international not-for-profit organization that provides a global system with which companies and cities can measure, disclose, manage and share vital environmental information. Companies voluntarily submit annual reports, and CDP scores the reports based on transparency in disclosure and performance. Our company's CDP scores have improved every year since 2009. Our 2014 disclosure score was 88 out of 100, and our performance score was "B." (2014)

### **Whitehouse Council on Environmental Quality**

We were recognized for both disclosing emissions and for implementing greenhouse gas (GHG) targets on the White House's Federal Supplier Greenhouse Gas Management Scorecard. The scorecard was developed to encourage major federal suppliers to adopt similar standards in line with the new aggressive efficiency standards for federal agencies. (March 2015)

# EMPLOYEES

## **DiversityInc**

We were recognized for the 13th consecutive year as one of the Top 50 Companies for Diversity by DiversityInc, ranking #16 in 2015. Our company also ranked #1 for Employee Resource Groups and #6 for People with Disabilities. (April 2015)

## **Minority Engineer Magazine**

We ranked #28 on *Minority Engineer* 2015 magazine's Readers' Choice Top 50 Employers list. The Readers were asked to name employers with whom they would most like to work or that they believe would provide a positive working environment for members of minority groups. (March 2015)

## **Physicians for Peace**

We received the Charles E. Horton Humanitarian Award from the international nonprofit Physicians for Peace for our employee Fellowship program and the assistance our company provides through this program to humanitarian organizations working to save and improve lives worldwide. (October 2014)

## **Top Employers Institute, Italy**

For the second consecutive year, MSD in Italy ranked among the top 10 companies in Italy for the excellent working conditions offered to employees among the companies certified by Top Employers Institute. The indicators of excellence examined were training and development, career paths, salary, benefits and non-monetary compensation, employee health programs, attention to the rights of individuals, and the general conditions of the work environment. (February 2015)

## **Business Insider Magazine**

We ranked #50 on *Business Insider* magazine's list of the best companies to work for in America. (April 2015)

## **Black Enterprise Magazine**

We were named to *Black Enterprise* magazine's 40 Best Companies for Diversity list. Our company was singled out for our commitment to diversity in senior management and on our Board of Directors. We were the only pharmaceutical company to make the list. (January 2015)

## **Másfamilia Foundation**

MSD in Spain was re-awarded its Work-Life Balance (EFR) Certificate, promoted by the Másfamilia Foundation and supported by the Ministry of Health and Social Policy. The certificate recognizes organizations that are involved in creating a new work culture by adding an all-inclusive management system, which brings balance to the work, family and personal spheres through commitment, respect and flexibility. (June 2014)

## **Ministry of Economy, Trade and Industry (METI) of Japan**

MSD in Japan was recognized by the Ministry of Economy, Trade and Industry (METI) of Japan for the company's commitment to diversity and inclusion as part of its strategic business plan, the creation of a dedicated Diversity and Inclusion team within Human Resources, and the establishment of the MSD Japan Female Leaders Network. (May 2014)

## **CAREERS & the disABLED Magazine**

We were ranked #18 on the readers' choice 2015 Top 50 Employers list by *CAREERS & the disABLED* magazine, the nation's first and only career-guidance and recruitment magazine for people with disabilities. The list honors corporations for creating a progressive environment for people with disabilities, as reported by readers of the magazine. (March 2015)

## **Equal Opportunity Magazine**

Our company ranked #6 on the 21st annual Top 50 Employers in *Equal Opportunity Magazine*. The readers of *Equal Opportunity Magazine* selected the top companies in the country for which they would most prefer to work or that they believe would provide a positive working environment for members of minority groups. This list is the result of an annual reader survey mailed to randomly selected readers of the magazine. (March 2015)

## **Working Mother Magazine**

In 2014, our company was named to *Working Mother's* list of the 100 Best Companies for Working Moms for the 28th straight year. This list recognizes companies dedicated to providing employees with benefits, including career advancement, childcare, flexible work arrangements and leave for new parents. (September 2014)

## **Professional Woman's Magazine**

*Professional Woman's Magazine* named our company to its 2014 Best of the Best list of Top STEM Employers for Women and its 2015 Best of the Best Top Healthcare Employers list. (March 2015)

## **The Human Rights Campaign**

We received a score of 100 percent in the Human Rights Campaign's 2015 Corporate Equality Index and placed on its Best

Places to Work list in recognition of our company's commitment to global diversity and inclusion for lesbian, gay, bisexual and transgender employees. (March 2015)

#### **U.S. Veterans Magazine**

We were recognized as a Top Veteran-Friendly Company for our outreach and accessibility to veterans, African Americans, Hispanics, Latinos and women in a special Best of the Best issue of *U.S. Veterans Magazine*. (August 2014)

#### **Navy Reserve**

We received a 2014 award from the Navy Reserve in appreciation for being an employer that supports Navy Reserve sailors. (July 2014)

#### **PRWeek**

Our company's "The Facts About Fasting During Ramadan" patient-education initiative won the Global PR Breakthrough Award at the 2015 PRWeek Global Awards ceremony. The award recognizes "transformative work that crosses national borders and brings a company to a new level of engagement or understanding among key stakeholders." "The Facts About Fasting During Ramadan" helps people with type 2 diabetes who choose to fast during the holy month of Ramadan. The innovative patient-education initiative is the first global campaign launched by a pharmaceutical company to help the more than 50 million Muslims with diabetes who fast during Ramadan. (May 2015)

## **ETHICS & TRANSPARENCY**

#### **CPA-Zicklin Index of Corporate Political Accountability and Disclosure**

We ranked #5 on the CPA-Zicklin Index of Corporate Political Accountability and Disclosure, which benchmarks the top 300 companies in the S&P 500 on their political-spending disclosure and oversight. 2014 marks our company's fourth consecutive year in the top five since the index was first published in 2011. (September 2014)

#### **International Data Group (IDG)**

To enhance enterprise collaboration, our company envisioned and implemented EngageZone—a cloud-based solution that enables the life sciences industry to share information and applications with hundreds of companies without compromising intellectual property or network security. EngageZone was jointly developed with Exostar. In 2015, EngageZone was named an honoree of a 2015 CSO50 Award from IDG's chief sustainability officer. Launched in 2013, the prestigious CSO50 Awards recognize 50 organizations for security projects and initiatives that have created outstanding business value and thought leadership for their companies.



**Millions of people in both developed and developing countries are living longer, more productive lives due, in part, to better healthcare and easier access to innovative medicines and vaccines.**

Better healthcare, in combination with a myriad of technological advances, is also helping to improve the economic circumstances of many individuals and countries. Some people are still excluded as a result of poverty, lack of education, discrimination and other complex factors.

For more information on our approach to access, [click here](#).

**GRI G4-EC8**

**KEY PERFORMANCE INDICATORS<sup>1</sup>**

	2011	2012	2013	2014
<b>Research &amp; Development</b>				
Top 20 global burdens of illness addressed by our products and pipeline <sup>2</sup>	53%	55%	88%	88%
GCP/PV audits by regulatory agencies or clinical trial investigators that led to significant fines, penalties, warning letters or product seizures	0	0	0	0
Established significant external licenses and collaborations <sup>3</sup>	52	61	40	35
Narrative of compounds provided to product development partnerships <sup>4</sup>	Online	Online	Online	Online
<b>Manufacturing &amp; Supply</b>				
Annual percentage of units manufactured/sold and recalled during a given year (recall rate globally) <sup>5</sup>	NR	0.19%	0.11%	0.22%
Number of local and regional manufacturing partnerships to enable access <sup>6</sup>	130	84	68	104
Number of products available by local and regional partnerships <sup>6</sup>	NA	34	354	499
<b>Registration</b>				
New product and devices registrations <sup>7,8,9</sup>	179	204	179	176
Local regulatory agency GCP/PV training requests fulfilled that will help strengthen agency capabilities in agencies' GCP/PV-compliance-in-oversight role <sup>10</sup>	Online	Online	Online	Online
Products submitted that have achieved WHO prequalification	10	10	11	11
<b>Commercialization</b>				
Number of our products that are supported with differential pricing <sup>11,12,13</sup>	NA	NA	24	35
Number of low- and lower-middle-income countries where inter- and/or intra-country pricing has been implemented <sup>11,14</sup>	NA	NA	70	114

Investment in patient- and provider-education programs <sup>15</sup>	\$97.8M	\$71.4M	\$61.3M	\$52.3M
Community Investment	2011	2012	2013	2014
Healthcare workers trained through major programs and partnerships <sup>16</sup>	52,000	38,000	22,000	137,000
Investment in partnerships for activities to address underlying barriers to health, such as health-system strengthening and capacity-building <sup>17</sup>	\$35M	\$24M	\$24M	\$32M
People reached through our major programs and partnerships <sup>18</sup>	273M	269M	302M	267M

NA: Not available. NR: Not reported.

<sup>1</sup> Data for Access to Health are reflective of our Human Health business only; information on our Animal Health business is reported separately.

<sup>2</sup> As defined by the Institute for Health Metrics and Evaluation (IHME), which replaces for 2013 the previously used WHO chart of leading causes of disease, condition or injury.

<sup>3</sup> Candidates in our company's research pipeline or under regulatory review are as of February 20, 2015, as reported in the U.S. Securities and Exchange Commission for 10-K, page 16, filed on February 27, 2015. This includes candidates in Phase II, Phase III, or under regulatory review as of February 20, 2015. As candidates attain regulatory approval, they are removed from this pipeline view.

<sup>4</sup> For information on product-development partnerships, visit the "Partnerships" tab at

<http://www.merckresponsibility.com/access-to-health/research-development/#tab-5591a965c9e82>

<sup>5</sup> Beginning in 2014, this figure includes recalls within our Animal Health business.

<sup>6</sup> Previously, we reported products available through specific agreements, but we have now expanded our reporting to all of our products, including the various strengths and presentations that are sold or distributed through a partnership in local markets, to more accurately reflect our efforts to address local needs.

<sup>7</sup> Data include new products and new indications.

<sup>8</sup> Data for all years have been updated based on a tracking-system upgrade that corrected miscounts in prior years.

<sup>9</sup> For information on new registrations by region, visit

<http://www.merckresponsibility.com/access-to-health/research-development/clinical-research/#tab-5591b7745c6c4>

<sup>10</sup> For information on local regulatory agency GCP/PV training requests, visit

<http://www.merckresponsibility.com/access-to-health/research-development/clinical-research/>

<sup>11</sup> In 2013, we modified our Key Performance Indicators for differential pricing so that we can more broadly capture and accurately reflect our support.

<sup>12</sup> Differential pricing intended to facilitate access for the at-need population.

<sup>13</sup> Our products include HIV treatments, vaccines and other patented products.

<sup>14</sup> Countries as defined by the World Bank 2013 GNI Classification, including UN-defined Least Developed Countries.

<sup>15</sup> In 2013, we refined our support to prioritize and align resources to complement our core business strategy, which resulted in an overall decrease in funding.

<sup>16</sup> 2014 figure includes healthcare workers trained through the African Programme for Onchocerciasis Control, of which we are a major funder.

<sup>17</sup> Includes investments by the Office of Corporate Responsibility, MSD for Mothers and/or our company's Foundation, a U.S.-based, private foundation.

<sup>18</sup> 2013 figures have been reconciled to reflect revised field data for the MECTIZAN Donation Program.



Access to Health

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# OUR APPROACH TO ACCESS

**Millions of people worldwide are living longer, healthier, more productive lives today thanks, in part, to better healthcare and access to innovative medicines and vaccines. At the same time, it is unacceptable that the vast majority of people around the world are unable to benefit from these advances in medicines and healthcare.**

As a global healthcare company, our company believes it has an important role and responsibility in improving access to medicines, vaccines and quality healthcare worldwide, thereby helping to reduce the burden of disease around the world. We also believe that expanding access is a business imperative for optimizing and sustaining our business over the long term.

Barriers to quality care and medical treatment—such as a lack of trained healthcare professionals, weak infrastructure, civil strife and a shortage of safe water in many parts of the world—make even basic healthcare delivery difficult at best, and these challenges go well beyond what we can directly address alone.

We believe our role is to work in partnership with others—local communities, governments, donors, patient organizations, healthcare professionals, nongovernmental organizations (NGOs), multilateral organizations and others in the private sector—to contribute our expertise and knowledge.

We also have an important role to play through our public policy and outreach efforts, to advocate for changes that will improve access. [Learn more.](#)

Our access to health strategy supports the company's overall mission to discover, develop and produce innovative products and services that save and improve lives around the world. Our mission to improve the health and wellness of people around the world by expanding access to medicines and vaccines is one of our company's [five core values](#) and part of our [corporate strategy](#).

To guide our efforts, we follow our companywide [Access to Health Statement of Guiding Principles](#), which articulate and guide our approach.

## RESEARCH & DEVELOPMENT

We will engage in R&D to provide medicines and vaccines that address vital global health needs. [Learn more.](#)

## MANUFACTURING & SUPPLY

We are committed to providing patients and customers with high-quality products and a reliable supply of safe and effective medicines and vaccines. [Learn more.](#)

## REGISTRATION

We will register our products in a timely fashion in markets where they are needed. [Learn more.](#)

## COMMERCIALIZATION

We will commercialize our products in a way that develops our company's business and meets local needs in a responsible and efficient manner. [Learn more.](#)

## COMMUNITY INVESTMENT

We recognize that we cannot address complex public health challenges on our own; therefore, we will engage in community investment to address the barriers to access where we believe we can make the strongest contribution. [Learn more.](#)

### GRI G4-15

These Guiding Principles help us to embed policies and practices into our operations and business strategies that expand access in innovative ways and on an ongoing basis. Our Principles contributed significantly to an industry-wide effort through the Business for Social Responsibility (BSR) Healthcare Working Group to develop the [Guiding Principles on Access to Healthcare \(GPAH\)](#). In 2013, we were one of 13 pharmaceutical companies to sign on to the GPAH, which provides a common framework to shape global health goals through multisector partnerships. In 2014, we contributed to an analysis of the Guiding Principles in action through the [2014 Status Report](#), and we continue to participate as a member of the BSR Healthcare Working Group to identify collaborative ways to use the Guiding Principles as a framework for measurable ways to improve access to healthcare.

In addition, because of our leadership in this area, our Principles and key performance indicators informed the global health work of the Interfaith Center on Corporate Responsibility (ICCR) and the recent development of its [Statement of Principles and Recommended Corporate Practices to Promote Global Health](#).

As we strive for continuous improvement in our access approach, we reevaluate our policies, practices and programs, as well as the metrics we employ to measure our progress, on an ongoing basis. Toward this end, in December 2012 and May 2013, we held internal access workshops to review our current access programs and strategies, share best practices, identify gaps and opportunities in our capabilities and our approach, brainstorm more innovative mechanisms and models, and reevaluate our targets and metrics. Discussions at the workshops helped to embed our Access to Health Guiding Principles more fully into the business, through identifying and pursuing new opportunities to reach more patients and grow our business with nontraditional customers and in countries in the middle to lower range of the economic pyramid.

We also have a group dedicated to ensuring access to essential medicines in Africa called the Institutional Business Africa (IBA) unit. IBA consists of a dedicated team of public health and medical specialists based across sub-Saharan Africa that fosters strategic partnerships and provides policy and technical guidance to countries focused on the areas of family planning and vaccines to achieve sustainable benefits for lives and communities across the African continent. IBA is guided by four important principles, represented by the abbreviation PASS:

- **P**: Public health outcomes, guided by leading global alliances focused on reproductive health (RHSC, FP2020) and immunizations (GAVI), aligned with country public health goals
- **A**: Affordability, focusing on economic levels and optimization of available funding
- **S**: Sustainability for countries, ensuring a long-term perspective is in place for country programs using our products
- **S**: Sustainability for our business, ensuring we can maintain our commitment to long-term partnerships that leverage our innovative products and services

Illustrating the impact of this approach, we embarked on a five-year partnership with the Bill & Melinda Gates Foundation (the Implant Access Program) that makes available Implanon<sup>®</sup> (etonogestrel implant), our one-rod contraceptive implant, at an affordable access price over a six-year period (2013-2018). Additionally, through our in-country partnerships with governments focused on preventing HPV-related cervical cancer and genital warts, we provide access to our vaccine GARDASIL<sup>®</sup> [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] through Gavi, the Vaccine Alliance.

In addition to these internal mechanisms, we also recognized the need to engage more effectively with external stakeholders to better understand their needs in order to expand access to our products and sustain our business over the long term. Throughout 2014, we continued to develop our approach to engaging with key external stakeholders, including international funding organizations, nongovernmental organizations (NGOs), and government aid agencies that in many cases play active roles in expanding access to medicines for patients through direct operational activities, or through advocacy on issues related to access. Our objective is to enhance our engagement in a way that is consistent with our sustainable access objectives. Our goal is to develop a more consistent and cohesive approach utilizing effective internal mechanisms and innovative partnerships that help to make our medicines and vaccines available to more people in more places, while at the same time building a sustainable business.

Measuring how we're doing is a challenging but important component of our access strategy, as it enables us, through relevant quantitative indicators, to demonstrate our progress in implementing our Principles and to measure the effectiveness of our efforts.

Various stakeholders are also calling on the global pharmaceutical industry to provide greater transparency about the impact of access strategies and initiatives, as well as evidence of how access strategies are integrated into an overall business strategy. In response, we developed and report annually on *key performance indicators* and articulate the business case for our overall approach, as reflected in our Access to Health Guiding Principles.

There is also a need for relevant industry-specific indicators that will allow comparisons across the industry. One example is the *Access to Medicine Index (ATMI)*, which is issued every two years and which ranked our company No. 7 in the 2014 Index, scoring above the mean in five of the seven technical components of the Index—General Access to Medicine Management, Pricing, Manufacturing & Distribution, Research & Development, Capability Advancement, and Product Donations and Philanthropic Activities. We believe that the ATMI is one mechanism for measuring our efforts to facilitate access to health, but more work is needed to ensure that all indicators are relevant and provide true measures of corporate responsibility access efforts. Toward that end, we remain committed to working with the ATMI and other organizations to develop meaningful measurements for our company and our industry.



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# FEATURE STORY

## We are discovering new ways to help people living with cancer.

Cancer is a complex disease—and the unmet medical need for new approaches remains high. Cancer incidence is expected to rise by almost 70 percent over the next two decades, and by 2030 it's expected that more than 20 million new cases of cancer will be diagnosed each year across the globe. We are investing significant resources to develop innovative oncology medicines to help people living with cancer worldwide.

Melanoma accounts for approximately 5% of all new cancers in the U.S. It can spread to lymph nodes and distant organs and is the leading cause of death from skin disease.

For many cancers there have been significant breakthroughs, but 2014 was a breakthrough year for oncology at our company. We advanced our broad and fast-growing immuno-oncology clinical development program across more than 30 different types of cancer, with outstanding results.

Lung cancer is the leading cause of cancer death in men in 87 countries and in women in 26 countries.

Our commitment to scientific innovation and our passion to help people fight cancer helped drive KEYTRUDA® (pembrolizumab) from clinical program initiation to FDA approval in fewer than four years.

In September 2014, KEYTRUDA, our anti-PD-1 therapy, was approved by the U.S. FDA for certain patients with advanced melanoma. Its FDA Breakthrough Therapy designation for patients with certain advanced non-small-cell lung cancer (NSCLC) followed in October.

KEYTRUDA is driving our research efforts to understand the role of the immune system and the PD-1 pathway in cancer treatment. We have more than 100 clinical trials, and today we are seeing robust anti-tumor activity with KEYTRUDA across 13 different cancers. We are moving at an unprecedented pace because we believe we need to do everything possible to help outpace cancer.

The rapid advances we are making with KEYTRUDA reflect our unwavering commitment to pursue breakthrough science to help people with these most challenging diseases.

## PROVIDING ACCESS TO KEYTRUDA

We are dedicated to working with health authorities, governments, payors, policy makers and physicians to help enable access to KEYTRUDA.

Even before KEYTRUDA was approved, we provided approximately 4,000 eligible patients around the world with access to the medicine through our Expanded Access Program (EAP) for advanced melanoma. The U.S. EAP for the drug concluded in September 2014 with KEYTRUDA's U.S. FDA approval.

To provide transition assistance for enrolled EAP patients in the U.S., we established a new access program for oncology. As KEYTRUDA receives approval in other countries, EAP patients will be similarly transitioned.

## UNDERSTANDING THE ROLE OF THE IMMUNE SYSTEM IN CANCER

Over the past few years, dramatic progress has been made in understanding the role of the immune system in cancer. Science has identified ways that cancer tumors can evade the immune system via specific pathways, especially the PD-1 pathway. We now know that we can stimulate a patient's immune system to attack a tumor. KEYTRUDA does this by blocking the PD-1 pathway. By deepening our understanding of the science of the PD-1 pathway, we have the potential to unlock the power of the immune system to fight cancer. Through the KEYTRUDA development program, we are committed to improving long-term disease control and survival of people with a wide range of cancers.

"Our company's efforts to provide access to KEYTRUDA have brought new hope to thousands of patients with advanced melanoma around the world who were in desperate need."

— Dr. Michael Rosenblatt, Chief Medical Officer, Merck & Co., Inc., Kenilworth, NJ, USA

# KEY INITIATIVES



**As a global healthcare company, we believe we have an important role and responsibility in improving access to medicines, vaccines and quality health care worldwide, thereby helping to reduce the burden of disease in the parts of the world that need it most.**

We believe our role is to work in partnership with others—local communities, governments, donors, patient organizations, healthcare professionals, nongovernmental organizations (NGOs), multilateral organizations and others in the private sector—to contribute our expertise and knowledge.

The programs highlighted here are examples of our ongoing efforts.

## **African Comprehensive HIV/AIDS Partnerships**

Together with our company's foundation and the Bill & Melinda Gates Foundation, we established the African Comprehensive HIV/AIDS Partnerships (ACHAP) in 2002 to support Botswana, a country disproportionately affected by HIV/AIDS.

## **Alliance to Reduce Disparities in Diabetes**

Diabetes represents a significant economic burden in the U.S. To address the growing problem of healthcare disparities related to type 2 diabetes in the U.S. among low-income and underserved adult populations, our company's foundation in 2009 launched the Alliance to Reduce Disparities in Diabetes, with a commitment of \$15 million.

## **China-MSD HIV/AIDS Partnership**

Our company's foundation has committed \$36 million to establish the China-MSD HIV/AIDS Partnership (C-MAP). C-MAP was the first large-scale public-private partnership between the Chinese government and a multinational company to focus on HIV/AIDS prevention and control.

## **GARDASIL® Access Program**

Through the GARDASIL® Access Program, we pledged to donate at least 3 million doses of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant] for use in smaller-scale human papillomavirus (HPV) vaccination projects in eligible lowest-income countries around the world, to enable participating organizations and institutions in those countries to gain operational experience in designing and implementing HPV vaccination projects.

## **HIV Care Collaborative**

To help address remaining barriers to HIV care, especially among underserved populations, our company's foundation launched a three-year initiative—the HIV Care Collaborative for Underserved Populations in the United States—to connect more people living with HIV to the care they need to stay healthy.

## **MCAN**

The Merck Childhood Asthma Network, Inc. (MCAN), a U.S.-based organization, is the only private foundation focused solely on addressing the complex and growing problem of childhood asthma within the United States. MCAN's mission is to enhance the quality of life for children with asthma and their families, and to reduce the burden of the disease on them and on society.

## **MECTIZAN® Donation Program**

The MECTIZAN® (ivermectin) Donation Program is the longest-running disease-specific drug donation program and public-private partnership of its kind, and is widely regarded as one of the most successful public-private health collaborations in the world.

## **Medical Outreach Program**

Our company's Medical Outreach Program (MMOP) was established in 1958. It is the primary mechanism through which our company donates its pharmaceuticals and vaccines for humanitarian assistance in the developing world and in support of disaster relief and emergency situations worldwide.

## **MSD for Mothers**

*MSD for Mothers* is a 10-year, \$500 million initiative focused on creating a world where no woman dies giving life. Working together with committed partners, we believe we can help make pregnancy and childbirth a safe, healthy, and joyful experience for women.

## **U.S. Patient Assistance Programs**

We believe that no one should go without the medicines or vaccines they need. More than 55 years ago, our company created our first U.S. Patient Assistance Program, Inc. (PAP) to keep affordable medicines within patients' reach. Today, our patient assistance offerings include several programs.

# ACHAP

## MAIN

Together with our company's foundation, a U.S.-based, private foundation, and the Bill & Melinda Gates Foundation, we established the African Comprehensive HIV/AIDS Partnerships (ACHAP) in 2000 to support Botswana, a country disproportionately affected by HIV/AIDS.

The partners selected Botswana because of its HIV/AIDS disease burden—Botswana had one of the highest adult prevalence rates in the world—its viable existing healthcare infrastructure, and its strong political will and commitment to address the challenges of HIV/AIDS.

In July 2000, our company's foundation and the Gates Foundation established ACHAP with a commitment of \$106.5 million. In addition, our company agreed to donate our antiretroviral (ARV) medicines STOCRIN® (efavirenz) and CRIXIVAN® (indinavir sulfate) to Botswana's national ARV treatment program for the duration of the partnership. In November 2008, we expanded our donations to include ATRIPLA® (efavirenz 600mg/emtricitabine 200mg, tenofovir disoproxil fumarate 300mg) and ISENTRESS® (raltegravir).

Initially, ACHAP's comprehensive approach included the prevention and treatment of HIV/AIDS, care and support for those infected, and mitigation of the disease's effect on the community. In 2010, our company's foundation committed an additional \$30 million to support Phase II of ACHAP. Funding through our company's foundation concluded in 2014; however, we provided an extension of the grant period through May 2015.

At the outset, we sought to create a program that would leverage private-sector management expertise to help resolve social and public health issues. We hoped to create a model of care, which, if successful, could inform and encourage others in government, international organizations, foundations and the private sector who are working to address HIV/AIDS in other countries or regions.

## LESSONS LEARNED IN BOTSWANA

- A successful national response to HIV/AIDS requires a sound policy designed to enable stakeholders to drive and guide the right course of action
- Local, national and international partners must integrate and align all efforts with the national blueprint
- Success depends on building local capacity and gaining agreement on a common strategy at all levels
- It is possible to implement effective ARV therapy in the public health sector, even in a resource-limited setting
- A sustainable solution must address both treatment and prevention
- ACHAP is considered an important model for addressing the African HIV epidemic, and the lessons learned can help to inform positive action in other countries in the region
- Working collaboratively and in a complementary fashion with other development partners enables the expansion and

strengthening of key programs

## BEYOND HIV TREATMENT

While much progress had been made in Botswana during the first 10 years of ACHAP, particularly in the areas of HIV treatment and the expansion of HIV counseling and testing services, it was recognized that much more needed to be done as part of a comprehensive, sustainable and successful response to the AIDS pandemic in the country. It was widely recognized that if Botswana was to get ahead of this epidemic, the focus must be on prevention. In addition, ACHAP recognized the need to build greater capacity among local organizations, increasing the capacity of communities to provide and utilize HIV/AIDS services.

Therefore, priorities for ACHAP during Phase II evolved to include the scaling-up of prevention efforts, addressing the needs of HIV patients co-infected with tuberculosis (TB), improving the cost-effectiveness of the *Masa* antiretroviral treatment program and strengthening the capacity of local organizations to carry out a sustainable national response. The ultimate goal is for the efforts and programs ACHAP supports to become either self-sustaining or integrated into the efforts led by the government of Botswana.

## EVALUATING ACHAP'S IMPACT

In late 2013, our company's foundation engaged FSG—a nonprofit strategy and evaluation consulting firm—to conduct a strategic review and assessment of ACHAP and its 15 years of support for HIV treatment, prevention and care in Botswana. The key objectives of this assessment were to (1) understand ACHAP's impact on strengthening health systems and reducing the burden of HIV/AIDS in Botswana, (2) inform the future vision and transition planning for ACHAP and (3) distill lessons learned from the partnership to share with the broader global health field. The ACHAP assessment culminated in a public report, prepared by FSG, that was published in October 2014.

## ACHIEVEMENTS

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**The African Comprehensive HIV/AIDS Partnerships (ACHAP) demonstrates how public-private partnerships can make a meaningful and lasting contribution to a major public health challenge, helping to restore hope and transform the morale and prospects of an entire nation.**

ACHAP has made a significant contribution to Botswana's response to the HIV/AIDS epidemic and has served as a catalyst for providing urgently needed infrastructure, equipment, human resources, training and program support for the Botswana Antiretroviral (ARV) program.

Major contributions and achievements of the program include:

- Halved the mortality rate in adults, saving more than 50,000 lives between 2002 and 2007
- Dramatically reduced mother-to-child transmission and reduced new infections among children by at least 80 percent (from around 40 percent sero-conversion to less than 5 percent)
- Contributed to significant improvements in the safety of the blood supply
- Developed sustainable treatment by supporting the recruitment of more than 200 positions, on civil service terms, to help staff the treatment program and its rollout to the clinics over the project period. Through successful absorption of these staff positions into the government establishment and with ongoing training of new staff, patient access to treatment is now available in 34 central sites and more than 560 satellite clinics countrywide. The satellite clinics are able to prescribe and dispense ARVs.
- Supported the development of the First National Strategic Framework for HIV/AIDS (2003–2009) and the Second National Strategic Framework (2010–2016)

- Increased laboratory capacity so that more than 200,000 patients could be supported in their treatment in the public sector through a decentralized diagnostic and monitoring capacity that increased from an initial two referral centers to 14 district and primary hospitals. This enabled the laboratory network system to cope with up to 20,000 new patients per year nationally.
- Supported the introduction of provider-initiated routine HIV counseling and testing as part of routine medical care provision in addition to supporting voluntary HIV counseling and testing that is requested by clients
- Provided training, in collaboration with Harvard University and the Botswana Ministry of Health (MOH), for more than 10,000 of Botswana's healthcare workers in eight core modules on HIV/AIDS clinical care and medication adherence, largely with in-country faculty. This effort expanded on an earlier effort in which about 3,200 physicians, nurses and other healthcare professionals received hands-on, clinic-based training from international HIV/AIDS experts through the partnership's preceptorship program between 2002 and 2006.
- Successfully transitioned its treatment program technical support to the government of Botswana, a milestone reflecting just how much this program has matured over the past 15 years
- Piloted a treatment optimization program that aimed to reduce delays to antiretroviral therapy (ART) initiation by providing point-of-care CD4 testing services and enhanced community-based HIV testing. During the implementation of the project between August 2013 and August 2014, approximately 28,000 persons received HIV testing and counseling. Additionally, about 8,000 CD4 T cell counts were performed, with 14 percent of them among persons newly diagnosed with HIV infection and 17 percent among HIV-infected persons under CD4 T cell monitoring. The median time to initiation of ART among those eligible for treatment was reduced from 27 days to 22 days.
- The MOH reported that by the end of October 2014, the total number of patients on highly active antiretroviral therapy (HAART) in the country was 245,340 – 237,211 (97 percent) of them were adults and 8,129 (3 percent) were children. The public sector accounts for 92 percent of the coverage (226,767 patients) and the private sector for 8 percent (18,573 patients). Among the patients treated in the public sector, 63 percent were females. Based on the projected population in need of ART, close to 94 percent of the eligible adults and 88 percent of the eligible children are receiving treatment.
- Between 2009 and August 2014, ACHAP supported the circumcision of 101,680 Botswana males. ACHAP achieved 80 percent of the target established at the beginning of Phase II (127, 000) and contributed approximately 75 percent of the procedures performed in the country during the corresponding period.
- In 2010, ACHAP supported the development of a National Tuberculosis (TB) Strategy and TB/HIV policy guidelines. In 2011, ACHAP supported the review of the TB Strategy with technical assistance from the World Health Organization (WHO).
  - ACHAP provided technical and financial support to the Botswana National TB Program (BNTP) Monitoring and Evaluation unit for routine data management, and for the evaluation of the Community TB Care (CTBC) service models for efficiency, effectiveness and sustainability.
  - ACHAP also provided financial support for a study to evaluate the use of an instrument for rapid TB diagnosis (Gene Xpert) to facilitate early treatment initiation to improve TB/HIV treatment outcomes.
- ACHAP also supported the MOH to conduct the TB/HIV Knowledge, Attitude and Practice (KAP) Study (2011), the findings of which informed the development of the BNTP Advocacy, Communications and Social Mobilization (ACSM) strategy and its subsequent implementation.
  - The national TB case notification rate has decreased from 623 per 100,000 persons in 2002 to 337 per 100,000 persons in 2013. The proportion of tuberculosis patients being tested for HIV has steadily increased from 68 percent in 2008 to 95 percent in 2013. Of these patients with TB, about 63 percent are co-infected with HIV, representing a slight decline from 64 percent in 2012. The coverage of co-trimoxazole prophylactic therapy increased from 32 percent in 2008 to 92 percent in 2013, and the coverage of ART increased from 20 percent to 75 percent during the same period of time.

## PERFORMANCE

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The following indicators—HIV-infected population, new infections and annual deaths (adult and children), and orphans—have been substantially revised. The figures provided previously for the years 2009–2012 were based on the modeling exercise conducted by the government of Botswana (GOB) in the year 2008 and presented in the report *HIV/AIDS in Botswana: Estimated Trends and Implications Based on Surveillance and Modeling*. NACA, MOH, ACHAP; 2008. These estimates and projections were based on the entire history of HIV surveillance among women attending antenatal clinics (to establish the trends) and the results of the national survey, Botswana AIDS Impact Survey (BAIS) II (to set the level in 2004). The modeling used two programs, EPP and Spectrum.

The GOB revised the estimates and projections in developing its investment case for the HIV program and in providing current data to UNAIDS for the Global AIDS Response Progress Reporting. The current projections are based on surveillance and program data and results of the Botswana AIDS Impact Survey (BAIS) III, which was conducted in 2008, and the results from the survey conducted in 2013 (BAIS IV). The modeling uses the program “Spectrum.”

The estimates for the period 2009–2014 differ considerably from the 2008 projections used previously for this report. Consequently, we are presenting definitive estimates/projections from the most recent modeling exercise, which constitute the official figures that Botswana reports to UNAIDS.

ACHAP Summary	2010	2011	2012	2013	2014
	ACHAP				
Estimated HIV+ population (total population) <sup>1</sup>	309,590	313,370	317,070	319,750	321,390
New HIV infections (adults only, ages 15+) <sup>1</sup>	10,530	10,370	9,840	8,850	8,050
Annual AIDS deaths (adults only, ages 15+) <sup>1</sup>	6,390	5,900	5,520	5,550	5,760
New HIV infections (children only, ages 0 to 14) <sup>1</sup>	560	390	390	320	340
Annual AIDS deaths (children only, ages 0 to 14) <sup>1</sup>	660	510	370	230	170
Total orphans <sup>1</sup>	154,214	147,285	139,934	132,540	125,962
Investment by our company's Foundation (US\$M)	6	6	3.5	6	5
Total value of product donations (US\$M) <sup>2,3</sup>	24.3	23.8	29	15.2	9.1
	Testing & Treatment				
Botswana (adults and children) receiving antiretroviral therapy (ART) by year-end <sup>4</sup>	161,219	178,684	201,822	229,055	245,340
ART coverage of eligible population (adults and children) <sup>4,5</sup>	>95%	>95%	>95%	90%	~94%
HIV+ pregnant women who received ART to reduce the risk of mother-to-child transmission <sup>6</sup>	92%	92%	94%	94.5%	94.6%
	Prevention				
HIV prevalence rate (ages 15 to 49) <sup>7</sup>	26.0%	26.0%	25.6%	24.3%	ND
Adjusted HIV prevalence rate among pregnant women <sup>8</sup>	ND*	30%	ND	ND	ND
HIV prevalence rate among pregnant women ages 15 to 19 <sup>8</sup>	ND	10%	ND	ND	ND
Blood supply that was HIV+ <sup>9</sup>	1.0%	1.8%	1.7%	1.0%	1.0%
	Infrastructure Development & Capacity-Building				
Healthcare workers trained through the ACHAP program (cumulative) <sup>10</sup>	7,645	8,068	16,674	17,214	17,218
Infectious-disease-care clinics and satellite facilities constructed to screen and treat patients with HIV/AIDS (cumulative)	35	35	35	35**	35

<sup>1</sup> Estimates from HIV/AIDS in Botswana Estimated Trends and Implications Based on Surveillance and Modeling. NACA, MOH, ACHAP; 2008

<sup>2</sup> Value of our company-branded product donations is based on the company's access pricing for our antiretroviral medicines.

<sup>3</sup> The 2012 and 2013 figures include the value of our company-branded donations and value of purchased generic ATRIPLA.

<sup>4</sup> ART program data for 2014 have been officially released only through October. The 2012 figure was updated with additional data through November (data for December are not available). Figure for 2009 was changed based on data correction released on March 2010.

<sup>5</sup> Eligibility criteria changed in 2012 with the threshold for treatment increasing from 200 to 350 CD4 T cell/  $\mu$ l.

<sup>6</sup> Figures based on PMTCT Program Data (They differ considerably from SPECTRUM –calculated coverage). Figure for 2013 also corrected based on the latest information shared by the program.

<sup>7</sup> Prevalence reported for 2009–2012 based on 2008 projections (1). Prevalence reported for 2013 is based on estimated prevalence in BAIS IV.

Source: Botswana AIDS Impact Survey (BAIS IV), 2013 Summary Results. Statistics Botswana, NACA, MOH.

<sup>8</sup> Assessment originally conducted every two years, most recent government decision is to conduct it every four years. Thus, no data are available for 2012–2014.

<sup>9</sup> Figures have been updated based on the 2014 data from the National Blood Transfusion Service.

<sup>10</sup> The values for 2009 and 2010 are for the KITSO program only. The values for 2011 and 2012 have been revised to include training through the KITSO programs as well as other programs (e.g., SMC, TB).

\* ND (No data available for the particular year).

\*\* No additional facilities were constructed during the year. However, ACHAP supported the renovation of 24 targeted IDCCs with the objective of improving TB infection control. The facilities were equipped with extractor and directional (propeller) fans to improve ventilation.

It is important to note that the estimated population infected with HIV is increasing because of increased access to highly active antiretroviral therapy (HAART) for those eligible for treatment. This means that persons who are infected with HIV and who would have otherwise died are being treated and are surviving for longer periods of time. At the same time, new HIV infections are still occurring, adding to the number of people living with HIV. People on treatment increased from around 93,000 in 2007 to 245,340 by the end of October 2014. The proportion of those infected who will die from AIDS will, however, decline based on treatment availability.

# ALLIANCE TO REDUCE DISPARITIES IN DIABETES

## MAIN

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**Healthcare disparities refer to differences or inequities in access to, and outcomes of, health services.**

In the United States, disparities for many chronic health conditions, including diabetes, are a growing national concern. The U.S. Centers for Disease Control and Prevention estimates that nearly 29.1 million people—9.3 percent of the U.S. population—have diabetes. In adults, type 2 diabetes accounts for 90 percent to 95 percent of all diagnosed cases.

Diabetes represents a significant economic burden in the United States. The American Diabetes Association estimates that the total cost of diagnosed diabetes was approximately \$245 billion in 2012.

To address the growing problem of healthcare disparities related to type 2 diabetes in the United States among low-income and underserved adult populations, in 2009, our company's foundation, a U.S.-based, private foundation, launched the Alliance to Reduce Disparities in Diabetes (Alliance), with a commitment of \$15 million. The Alliance concluded operations in 2014.

“Patients enrolled across the Alliance sites really responded when care and support were delivered outside the box. Building community partnerships and fostering the spirit of empowerment among patients were just a few of the keys to the Alliance’s success. We were reminded of something fundamental—that most of the work in managing chronic disease occurs outside of the healthcare system.”

—Jeffrey Brenner, M.D., executive director, Camden Coalition of Healthcare Providers, the Alliance’s Camden, New Jersey, site.

## ALLIANCE GOALS

The Alliance worked to minimize disparities in diabetes outcomes and enhance the quality of diabetes care by improving prevention and management services. The Alliance collaborated with national, regional and community partners to develop and implement comprehensive, evidence-based diabetes programs that:

- Applied proven, community-based and collaborative approaches to addressing healthcare disparities related to type 2 diabetes among low-income and underserved adult populations
- Enhanced patient and healthcare provider communication, mobilized community partners, and assisted healthcare organizations in reducing disparities in diabetes care and outcomes

- Disseminated important findings to foster the development of comprehensive prevention and management programs designed to improve the quality of healthcare for adults who have or are at risk for diabetes
- Increased awareness among federal, state and local policymakers of health system and policy changes that can reduce healthcare disparities in diabetes
- Promoted collaboration and information exchanges to strengthen the efforts of interested stakeholders around the country that share the vision and goals of the Alliance

Results from an evaluation of the Alliance to Reduce Disparities in Diabetes were published in a series of 10 articles in the November 2014 supplemental issue of the peer-reviewed journal *Health Promotion Practice*. The Alliance's findings reveal that a new model of chronic disease management for vulnerable populations with diabetes shows significant promise in strengthening coordination of care, reducing diabetes health disparities and improving health outcomes.

## ALLIANCE PROGRAMS

Through grants to five organizations, our company's foundation supported multifaceted, community-based programs that addressed the key factors that can improve health outcomes for people living with diabetes. The five grantee communities were Camden, New Jersey; Chicago, Illinois; Dallas, Texas; Memphis, Tennessee; and Wind River Reservation, Wyoming. The University of Michigan's Center for Managing Chronic Disease served as the Alliance's National Program Office.

## PROGRAM APPROACH

Alliance programs focused on integrating three areas of intervention:

**Patients:** Patients who are better educated about diabetes and empowered in terms of disease management become more engaged in their healthcare overall; they become better at managing their conditions themselves by adopting behaviors that help prevent health problems and by communicating more effectively with physicians and other clinicians.

**Clinicians:** Clinicians who are more skilled in communicating with diverse patient groups—and are aware of diverse cultural beliefs—are more effective in providing care and educating their patients.

**Health Systems:** Healthcare organizations that implement and support clinical systems, policies or practices addressing effective disease management and quality improvement can help to reduce disparities in diabetes care.

## ALLIANCE PROGRAM SITES

Camden Coalition of Healthcare Providers (Camden, New Jersey): The Camden Citywide Diabetes Collaborative aimed to better coordinate and improve the quality of comprehensive primary care services for city residents with diabetes.

University of Chicago (Chicago, Illinois): The University of Chicago program focused on redesigning and improving the quality of diabetes management and care provided at community health centers on Chicago's South Side.

Baylor Scott & White Quality Alliance (Dallas, Texas): The Diabetes Equity Project focused on helping physicians develop strategies that promote effective care and management for low-income, uninsured and underserved people with diabetes in Dallas.

Healthy Memphis Common Table (Memphis, Tennessee): The Diabetes for Life program promoted community outreach and diabetes self-management through local churches in Memphis.

Wind River Reservation (Fort Washakie, Wyoming): An effort led by the Eastern Shoshone Tribe and its collaborating partners sought to improve access to diabetes care and management among the Eastern Shoshone and Northern Arapaho tribes of the Wind River Reservation.

## PUBLIC POLICY

Alliance program sites continued to make progress in addressing diabetes disparities in their communities. Yet they also reported facing systemic and structural barriers in the healthcare system that challenged their ability to deliver and sustain effective diabetes care for those most in need. To help overcome these barriers, program sites initiated organizational and health system changes. [Learn more.](#)

Additionally, the Alliance programs emphasized the need to connect their “on the ground” experience with the national policy dialogue about improving the quality of healthcare and reducing diabetes disparities in the United States. To advance the national conversation about ways to overcome systemic barriers to providing effective diabetes care, the Alliance published a set of policy considerations titled “Policy Considerations That Make the Link: Connecting Community Experience and National Policy to Reduce Disparities in Diabetes.”

## PERFORMANCE

### CROSS-SITE ALLIANCE PROGRAM EVALUATION

Our company’s foundation, a U.S.-based, private foundation, engaged RTI International to conduct a five-year (2009–2013), independent cross-site evaluation of the Alliance and its programs. The final results of the evaluation were published in the November 2014 special supplement of *Health Promotion Practice*. Final results from the evaluation are provided below.

Overall, 48 clinics or practices participated in at least two of the three areas of intervention (i.e., patients, providers and systems). Cumulatively, from 2009 to 2013, 141 individual physicians were actively engaged in program implementation (e.g., recruiting patients with type 2 diabetes, and identifying and implementing systems changes in the practice setting). In addition, Alliance sites served a diverse patient population through their programs. From 2009 to 2013, across the sites, 40 percent of patients were Hispanic or Latino, 40 percent were African-American, 8 percent were Native American, 7 percent were white, 1 percent were Asian, and 4 percent were of another racial or ethnic background or of unknown ethnicity.

The Alliance program sites enrolled participants on a rolling basis since the program was first implemented in 2009. Enrollment was ongoing through December 2013. Data collection has been completed, and the values reported are the final baseline and follow-up measures. The data presented below were aggregated across the five sites in an independent evaluation.

Patient & Provider Participation (cumulative over time)	2010	2011	2012	2013
Number of adults with type 2 diabetes enrolled in DSME <sup>1</sup>	804	1,570	2,151	2,361
Number of providers who received cultural awareness training <sup>2</sup>	39	72	138	172

<sup>1</sup> DSME: Diabetes self-management education. DSME commonly addresses enhancing self-care behaviors (such as nutrition, exercise and blood-glucose monitoring) and informed decision-making in order to improve clinical outcomes and quality of life.

<sup>2</sup> Cultural awareness training is part of a process by which better patient care is delivered. It helps clinicians become better communicators and makes them more aware of cultural differences.

Patient Self-Reported Outcomes	Baseline	Follow-up as of 12/2013
Diabetes competence <sup>1</sup>	4.9	6.2
		Diabetes Self-Care Behaviors <sup>2</sup>
General diet	3.7	4.7
Diabetes-specific diet	4.0	4.6
Exercise	2.6	2.9
Blood-glucose testing	4.1	5.0
Foot care	4.1	5.5
		Quality-of-Life Measures
Physical functioning <sup>3</sup>	42.1	42.9
Mental functioning <sup>4</sup>	43.3	47.8
		Objectively Measured Patient Clinical Outcomes

Hemoglobin A1c <sup>5</sup>	8.4	7.7
Low density lipid (LDL) cholesterol <sup>6</sup>	101	99
Blood pressure <sup>7</sup>	129/79	128/78

<sup>1</sup> Weighted averages for the cohort of participants with baseline and follow-up measures for four competence questions rated on a scale from 1 to 7, where higher ratings reflect better feelings of competence about engaging in diabetes self-management. The baseline score here demonstrates slightly above-average competence and shows improvement at follow-up.

<sup>2</sup> Weighted averages for each behavior for the cohort of participants with baseline and follow-up measures. Self-care behaviors are scored on a scale from 0 to 7, indicating how many of the prior seven days a behavior was performed. Higher numbers reflect more days on which the behavior was performed. The scores here demonstrate that participants, on average, engaged in these behaviors between three to four days a week at baseline and that there was improvement at follow-up.

<sup>3</sup> Weighted averages shown for baseline and follow-up measures for the cohort of participants for self-reported physical functioning (e.g., physical ability or limitations, bodily pain); higher scores reflect better physical functioning. Population norm: 50. Scores are below population norm at baseline and follow-up.

<sup>4</sup> Weighted averages shown for baseline and follow-up measures for the cohort of participants for self-reported mental functioning (e.g., feelings of depression, anxiety, calm); higher scores reflect better mental functioning. Population norm: 50. Scores are below population norm, but mental functioning shows improvement over time.

<sup>5</sup> Weighted averages for the cohort of participants with baseline and follow-up measures for the hemoglobin A1c blood test. Lower numbers indicate better values. Changes in hemoglobin A1c show improvement over time.

<sup>6</sup> Weighted averages for the cohort of participants with baseline and follow-up blood LDL cholesterol tests. Lower numbers indicate better values. Changes in LDL cholesterol show slight improvement over time.

<sup>7</sup> Weighted averages for the cohort of participants with baseline and follow-up measures for blood pressure measurements. Lower numbers indicate better values. Changes in blood pressure show no improvement over time.



# CHINA-MSD HIV/AIDS PARTNERSHIP

## MAIN

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To help support the National HIV/AIDS Prevention and Control Action Plan, developed by the Ministry of Health, in China and address the growing burden of HIV/AIDS, our company's foundation, a U.S.-based, private foundation, committed \$30 million over eight years (2005–2012) to establish the China-MSD HIV/AIDS Partnership (C-MAP).

The first phase of C-MAP officially launched in 2007 in Sichuan Province as an innovative public-private partnership to advance improvements in HIV awareness and prevention, counseling and testing uptake, and treatment coverage.

During Phase I, C-MAP developed an integrated disease management model and achieved significant progress in raising HIV awareness among the general public, improving HIV testing rates and expanding antiretroviral treatment (ART) coverage.

Building on C-MAP's achievements during Phase I, our company's foundation committed an additional \$6 million over three years (2014–2016) to support a second phase of C-MAP to strengthen integrated HIV treatment capacity and coverage, promote cooperation between the township and county health systems of Sichuan Province's Liangshan Prefecture and expand the program to new sites in Chongqing Municipality and Fujian Province. This next phase focuses on improving HIV/AIDS management and treatment services by strengthening the capacity of healthcare workers to support effective patient referrals and by promoting quality HIV care through health worker training in effective HIV diagnosis, treatment and disease management.

C-MAP focuses on the following key program objectives:

1. Promoting HIV counseling and testing to improve early diagnosis of HIV-positive patients and timely entry into care and treatment
2. Improving effective referral of newly diagnosed HIV-positive patients to ART services
3. Enhancing the capacity and capability of primary healthcare workers to support effective patient referral and promote high-quality HIV treatment services
4. Expanding ART coverage for eligible HIV-positive patients
5. Increasing patient adherence on antiretroviral therapy

# PERFORMANCE

## C-MAP was the first large-scale public-private partnership between the Chinese government and a multinational company to focus on HIV/AIDS prevention and control.

Since 2007, the partnership successfully established an overall HIV prevention and treatment network in Liangshan. This, coupled with training, helped improve the capacity of local healthcare providers, expanded antiretroviral treatment (ART) coverage, and created a replicable model for HIV prevention and control in other ethnic-minority areas.

Phase II of C-MAP launched in 2014 and is already showing signs of progress in treatment coverage, patient referrals and adherence, and physician training. Performance indicators below reflect aggregate data from across the Sichuan Province, Liangshan Prefecture; Chongqing Municipality; and Fujian Province.

	C-MAP Summary Phase II (2014–2016)	2014
Investment by our company's Foundation (US\$M)		3.0
	HIV Testing, and Patient Referrals and Treatment	
Number of people who have received HIV testing and counseling		236,625
HIV test and detection efficiency ratio (ratio of new HIV+ detected among number of HIV tests)		0.07%
Number and rate of successful patient referrals for treatment services <sup>1</sup>		90.2% (5595/6200)
	ART	
Number of newly diagnosed adults who are receiving ART		3,764
Number of HIV+ adults who are receiving ART		9,200
Number of newly diagnosed children who are receiving ART		31
Number of children with HIV who are receiving ART		81
Proportion of eligible patients receiving ART		80.9%
Proportion of patients who are adherent to ARV treatment for 12 months		94.1%
Rate of viral load suppression (viral load less than 400 copies) among patients who are adherent to ARV treatment for 12 months		74.6%
	Healthcare Capacity-Building	
Number of physicians who received training		1,856

<sup>1</sup> Successful referral is defined as those patients who are referred from a testing site to an ART center and remain on treatment for at least one month.



## Key Initiatives

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# GARDASIL ACCESS PROGRAM

## MAIN

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**In 2007, our company made a major commitment to helping improve access to GARDASIL<sup>®</sup> [human papillomavirus quadrivalent (Types 6, 11, 16, 18) vaccine, recombinant] in developing countries.**

Through the GARDASIL Access Program, we pledged to donate at least 3 million doses of GARDASIL for use in smaller-scale human papillomavirus (HPV) vaccination projects in eligible lowest-income countries around the world, to enable participating organizations and institutions in those countries to gain operational experience in designing and implementing HPV vaccination projects. The program received proposals from applicants to conduct smaller-scale HPV vaccination projects rather than nationwide programs. All applicants were required to secure formal endorsement from their respective ministries of health, and were encouraged to follow World Health Organization (WHO) recommendations and guidelines for HPV vaccination.

In 2012, Gavi, the Vaccine Alliance, a public-private partnership focused on increasing access to immunization in developing countries, opened the funding window for HPV vaccines—giving countries the opportunity to introduce the vaccine sustainably through a demonstration or national program.

In this context, and following consultation with a wide array of stakeholders, including WHO, Gavi, PATH (an international nonprofit organization), other public health organizations, select ministries of health and some GARDASIL Access Program participants, and Axios Healthcare Development (AHD), a U.S. nonprofit organization, we decided that the GARDASIL Access Program would no longer be awarding doses of GARDASIL to new projects. However, options for use of the remaining doses of GARDASIL are currently being explored. Importantly, commitments to already-awarded projects will continue to be honored.

2014 included the conclusion of eight projects in seven countries, including a two-year GARDASIL Access Program demonstration project in Zambia.

As of February 2015, seven countries (Cameroon, Ghana, Kenya, Mali, Tanzania, Uganda and Uzbekistan) that participated in the GARDASIL Access Program were among the first approved by Gavi for HPV programs using GARDASIL. In addition, Lesotho, which completed two HPV vaccination projects with the support of the GARDASIL Access Program, continues to conduct a national HPV vaccination program without support from Gavi.

By actively disseminating information from the operational experiences and the lessons learned by participants, the program is contributing to the public knowledge base on HPV vaccine access and child and adolescent immunization models in developing countries.

The program is managed by AHD with strategic guidance provided by the independent GARDASIL Access Program Advisory Board, made up of international public health experts. AHD administers the program in consultation with Advisory Board recommendations and coordinates delivery of donated vaccine to participants. Technical assistance is provided by Axios

International, a public health consultancy specializing in developing and emerging countries.

# PERFORMANCE

## GARDASIL® Access Program Summary

Doses of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant] donated to participating organizations/institutions	2014	96,800
	2013	191,470
	2012	182,360
	2011	390,400
	2010	275,200
Market value of GARDASIL donated to participating organizations/institutions (US\$M)	2014	13.0
	2013	25.7
	2012	23.6
	2011	50.6
	2010	35.6
Lowest-income countries reached by the GARDASIL Access Program (cumulative)	2014	21
	2013	21
	2012	20
	2011	17
	2010	12

As of December 31, 2014:

- More than 1,330,000 doses of GARDASIL have been shipped to 26 grantees in support of their proposed HPV vaccination projects in 21 countries: Bhutan, Bolivia, Cambodia, Cameroon, Georgia, Ghana, Guyana, Haiti, Honduras, Kenya, Kiribati, Lesotho, Mali, Moldova, Mongolia, Nepal, Tanzania, Papua New Guinea, Uganda, Uzbekistan and Zambia
- 28 HPV-vaccination projects have been completed in 18 countries: Bhutan, Bolivia (four projects), Cambodia (two projects), Cameroon, Ghana, Guyana, Haiti, Honduras (four projects), Kenya, Kiribati, Lesotho (three projects), Mali, Moldova, Nepal (three projects), Tanzania, Uganda, Uzbekistan, and Zambia
- There are two ongoing HPV-vaccination projects in two countries: Georgia and Mongolia
- Axios routinely interviews all GARDASIL Access Program participants and analyzes their formal progress reports to synthesize lessons learned from the program
- Axios publishes newsletters periodically to update stakeholders on program progress
- A second manuscript, "Evaluation of 21 HPV Vaccination Programs Implemented in 14 Lowest-Income Countries, 2009–2013," was published in June 2014.

# HIV CARE COLLABORATIVE

## MAIN

In the U.S. alone, there are about 50,000 new HIV infections each year, and nearly a third or more of people living with HIV are not in care.<sup>1</sup>

To help address remaining barriers to HIV care, especially among underserved populations, our company's foundation, a U.S.-based, private foundation, launched a three-year initiative—the HIV Care Collaborative for Underserved Populations in the U.S. (the Collaborative)—to connect more people living with HIV to the care they need to stay healthy. The Foundation has committed \$3 million to supporting local health departments in Atlanta, Georgia; Houston, Texas; and Philadelphia, Pennsylvania. These are among the 10 cities with the highest HIV burden in the U.S.<sup>2</sup> Research shows that when you are able to connect those who are HIV-positive with ongoing care, it not only reduces HIV risk behaviors but also reduces viral load from antiretroviral therapy (ART), all of which contributes to overall decreases in HIV transmission.<sup>3</sup> This is why the U.S. National HIV/AIDS Strategy (NHAS) calls for the establishment of “a seamless system to immediately link people to continuous and coordinated quality care when they are diagnosed with HIV.”<sup>4</sup> In alignment with this overall NHAS goal, the Collaborative is tackling this challenge head on, working to improve access to available healthcare for HIV-positive people by:

- Integrating innovative, community-based approaches with local public health systems to improve timely access to quality HIV care for underserved adult populations
- Helping to reduce new HIV infections among populations at greatest risk
- Sharing important findings and lessons learned to further the development of innovative programs that connect people living with HIV/AIDS to needed care and treatment

The Collaborative builds on efforts already underway at the three program sites:

- **Atlanta/Fulton County Department of Health and Wellness:** Bridging the Gap is implementing a community-based care linkage coordinator and referral program for HIV-positive clients referred to, and enrolled in, the county's HIV primary care clinic
- **Houston Department of Health and Human Services:** The Expanded Linkage to Care Initiative brings together healthcare providers, community groups and researchers to implement community-wide system-navigator and data-matching programs to help identify and reengage all those living with HIV who have fallen out of care
- **The City of Philadelphia Department of Public Health:** The Engaging HIV+ Patients in Care Initiative uses system navigators to help guide HIV patients through the local healthcare system to improve access to regular care and management of HIV-related comorbidities

The George Washington University (GWU) Milken Institute School of Public Health serves as the National Program Office for the HIV Care Collaborative. GWU provides overall technical assistance to each of the program sites and helps foster a “peer-learning” network among the health departments and local partners through regular meetings, site visits and forums for sharing best practices, lessons learned and key challenges. GWU also is evaluating the progress and results of the Collaborative programs.

<sup>1</sup> Centers for Disease Control and Prevention, "Estimated HIV Incidence in the United States," 2007–2010. *HIV Surveillance Supplement Report*. 2012;17(No.4). December 2012.

<sup>2</sup> Centers for Disease Control and Prevention. *HIV Surveillance Report*, 2013; vol.25. [www.cdc.gov/hiv/library/reports/surveillance](http://www.cdc.gov/hiv/library/reports/surveillance). Published February 2015. Accessed April 24, 2015.

<sup>3</sup> Mugavero MJ, Amico KR, Horn T, Thompson MA. "The State of Engagement in HIV Care in the United States: From Cascade Continuum to Control." *Clinical Infectious Diseases*. 2013 Oct;57(8): 1164-71.

<sup>4</sup> The White House Office of National AIDS Policy, "National HIV/AIDS Strategy for the United States," July 2010. [www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf](http://www.whitehouse.gov/sites/default/files/uploads/NHAS.pdf).

# PERFORMANCE

## Our company's foundation—a U.S.-based, private foundation—is working with George Washington University to conduct a three-year (2013–2015) cross-site evaluation of the HIV Care Collaborative (the Collaborative) programs.

A cohort of newly identified and previously lost-to-care HIV-positive adults is enrolled in a medical care linkage and engagement intervention that deploys community health workers in public health settings. The cohort's medical care utilization is followed over time to assess clinical outcomes and process measures associated with the Collaborative.

Previously designed client-level data systems are used to track patient characteristics, service utilization, quality of care and clinical outcomes. Client-level data systems include electronic health records and administrative databases designed to document federally funded health and support services utilization, processes and clinical outcomes. Qualitative techniques will be used to assess the impact of implementation of the Patient Protection and Affordable Care Act (ACA), shifts in HIV public health funding, changes in state health laws that promote HIV screening and engagement in care, and other policy changes.

The interim results from the evaluation provide an overview of enrollment and outcome measures for clients who are enrolled in the Collaborative intervention across the three program sites. From January 2013 through June 2014, 1,369 HIV-positive adults were referred to Collaborative program sites for screening and enrollment. Among this group, 388 clients (28 percent) enrolled in the Collaborative for linkage to HIV medical care and patient navigation services provided by community health workers for an average of three months. Among enrolled Collaborative clients, 42 percent were newly identified HIV-positive adults and 58 percent were HIV-positive adults who had previously dropped out of medical care.

The Collaborative sites have enrolled participants on a rolling basis since the program was first implemented in January 2013. Enrollment will be ongoing through September 2015. Note that the data below are not site-specific, but rather were aggregated across the three program sites (Fulton County, city of Houston, city of Philadelphia).

Among the clients enrolled by the Collaborative between January 1, 2013, and June 30, 2014, a mean of 89 percent were successfully linked to medical care through the Collaborative intervention. Newly identified HIV-positive adults had a significantly lower mean rate of successful linkage to medical care than HIV-positive adults who had previously dropped out of care (89 percent versus 91 percent, respectively).

Among the 388 clients enrolled from January 1, 2013, through June 30, 2014, and then followed for six months: 59 percent were retained in medical care for at least six months; 57 percent were prescribed antiretroviral (ARV) therapy; 48 percent had at least two CD4 cell counts or percentages at least three months apart; and 53 percent had HIV viral suppression.

Collaborative Client Enrollment	Enrolled Clients Linked to Care <sup>1</sup>	Mean Linkage Rates (Low-High Ranges)
Newly identified HIV+ adults who were linked to care through the Collaborative <sup>2</sup>	146	89% (77%–93%)
HIV+ adults who were out of care and relinked to care through the Collaborative <sup>3</sup>	203	91% (82%–96%)

<sup>1</sup> Clients who were enrolled on a rolling basis in the Collaborative intervention from January 1, 2013, through June 30, 2014, and followed for six months after enrollment to calculate process and outcome measures

<sup>2</sup> Adults who were 18 years of age or older and newly identified as HIV+ at the Collaborative sites, or another HIV-counseling and -testing site that referred the individual to the Collaborative site for linkage to care and patient navigation services. These individuals were not previously in HIV care.

<sup>3</sup> Adults who were 18 years of age or older, had been previously identified as HIV+ and had previously received HIV care. These individuals were out of HIV care for at least six months before enrollment in the Collaborative intervention.

Objectively Measured Patient Process and Quality of Care Measures <sup>1,2</sup>	Mean Rates (Low-High Ranges)
Six-month retention rate of HIV+ adults in the observation period <sup>3</sup>	59% (20%–86%)
Six-month rate of HIV+ adults prescribed HIV antiretroviral (ARV) therapy in the observation period <sup>4</sup>	57% (55%–58%)
Six-month rate of HIV+ adults with at least two CD4 counts or percentages in the observation period, at least three months apart <sup>5</sup>	48% (34%–66%)

<sup>1</sup> Objectively measured patient process and clinical outcomes data were gathered from the health records of clients enrolled in the Collaborative between January 1, 2013, and June 30, 2014, and followed in health records for at least six months. Quality measures adopted by the Collaborative are based on measures established by the federal Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB), which can be found at: <http://hab.hrsa.gov/deliverhivaidscare/coremeasures.pdf>.

<sup>2</sup> Information from Collaborative clients' health records were reported for the six-month period following completion of the Collaborative intervention. The denominator used to calculate the rates excluded clients who did not complete or were lost to follow-up during the Collaborative intervention, deceased, incarcerated or moved out of the area served by the participating sites.

<sup>3</sup> The numerator is defined as clients who had at least one medical visit in the six months following completion of the Collaborative intervention.

<sup>4</sup> The numerator is defined as the number of clients who were prescribed HIV antiretroviral medication in the six months following completion of the Collaborative intervention. HIV antiretroviral therapy consists of any combination of HIV medications, other than the regimens or components identified as not recommended at any time by the Panel on ARV Guidelines for Adults and Adolescents. Guidelines for the use of ARV agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at: <http://aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>.

<sup>5</sup> The numerator is defined as the number of clients with at least two CD4 cell counts or percentages performed in the observation period at least three months apart.

<sup>6</sup> The numerator is defined as the number of clients with an HIV viral load less than 200 copies/mL at least once in the observation period.

Objectively Measured Patient Outcome <sup>1,2</sup>	Mean Rate (Low-High Ranges)
Six-month rate of HIV+ adults with HIV viral suppression in the observation period. <sup>3</sup>	53% (38%–64%)

<sup>1</sup> Objectively measured patient process and clinical outcomes data were gathered from the health records of clients enrolled in the Collaborative between January 1, 2013, and June 30, 2014, and followed in health records for at least six months. Quality measures adopted by the Collaborative are based on measures established by the federal Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB), which can be found at: <http://hab.hrsa.gov/deliverhivaidscare/coremeasures.pdf>.

<sup>2</sup> Information from Collaborative clients' health records were reported for the six-month period following completion of the Collaborative intervention. The denominator used to calculate the rates excluded clients who did not complete or were lost to follow-up during the Collaborative intervention, deceased, incarcerated or moved out of the area served by the participating sites.

<sup>3</sup> The numerator is defined as the number of clients with an HIV viral load less than 200 copies/mL at least once in the observation period.

## Key Initiatives

# MCAN

## MAIN

**The Merck Childhood Asthma Network, Inc. (MCAN), a U.S.-based, nonprofit 501(c)(3) organization established in 2005, is the only private foundation focused solely on addressing the complex and growing problem of childhood asthma in the United States.**

Funded by our company's foundation, a U.S.-based, private foundation, MCAN's mission is to enhance the quality of life for children with asthma and their families, and to reduce the burden of the disease on them and society.

Led by Floyd Malveaux, M.D., Ph.D., a nationally recognized expert in asthma and allergic diseases, dean emeritus of the College of Medicine, and professor of microbiology and medicine at Howard University, MCAN is a respected authority, effective catalyst and influential advocate for children with asthma. Through research, community programs and partnerships, MCAN is working to:

- Improve access to and quality of asthma healthcare for children, especially the vulnerable and medically underserved
- Advocate for policies that expedite implementation, dissemination and sustainability of evidence-based asthma care
- Increase awareness and knowledge of asthma and quality asthma care

MCAN funds evidence-based programs that involve tailored asthma case management and the reduction of environmental risk factors and triggers in the home. These programs are implemented in several settings: community health centers, school systems, community-based organizations, public housing and primary care centers.

MCAN advocates for policies that support science-based asthma care by working with partners such as the Milken Institute School of Public Health at George Washington University, the U.S. Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH).

Our company's foundation committed \$41.1 million to support MCAN over 11 years (2005–2015). The investment in MCAN was \$4.4 million in 2013 and \$2.8 million in 2014. MCAN will conclude operations in 2015, and will share program outcomes and impacts in a final report that will be released in late 2015 and available on [www.mcanonline.org](http://www.mcanonline.org).

## PROGRAMS

### MCAN CARE COORDINATION PROGRAM SITES (2010–2014)

Through the **Care Coordination grant portfolio**, MCAN studied the feasibility and effectiveness of implementing and sustaining care-coordination models developed during MCAN Phase I in communities with significant childhood-asthma

morbidity and/or disparities in outcomes. Care Coordination program sites participated in a cross-site evaluation to assess outcome and process measures focused on care coordination and clinical outcomes. Preliminary findings from the evaluation indicate that the percent of participants with “not well controlled” asthma decreased from 49 percent at baseline to 18 percent at 12-month follow-up. Final results were presented at the 2015 American Thoracic Society International Conference on Tuesday, May 19, 2015.

## CARE COORDINATION PROGRAM SITES

### **Los Angeles Unified School District, “YES WE CAN Children’s Asthma Program”**

This program used a care-coordination and education model that extends beyond the immediate school clinic to foster systemic changes among health, educational and community settings. The program triaged students and families into appropriate levels of intervention, aimed to improve the coordination of care among schools, clinics and community providers, and focused on measuring symptom reductions and school days missed. The program was successful in reducing days of school missed due to asthma from approximately 13 days to five days a year.

### **University of Illinois at Chicago School of Public Health, “Addressing Asthma in Englewood”**

This program centered on a community-educator model, linking children with asthma to appropriate services, community groups and local agencies. A home-visit case-management program was also provided to enhance asthma education and to identify and mitigate asthma triggers. Among the participants who completed the case-management program, emergency room visits for asthma decreased from 40 percent to 27 percent over 12 months.

### **RAND Corporation and University of Puerto Rico, “La Red de Asma Infantil de MSD de Puerto Rico”**

This program carried out evidence-based interventions as part of an asthma care coordination program across home, healthcare and community settings. Implemented in a federally qualified health center (FQHC) in San Juan, Puerto Rico, “La Red” aimed to promote asthma-friendly communities throughout the island of Puerto Rico and improve access to quality asthma healthcare for this highly vulnerable and underserved community. After participating in La Red, the percentage of families who reported an asthma-related emergency department visit in the past 12 months decreased from 67.1 percent to 39.1 percent.

### **Children’s Hospital of Philadelphia, “Asthma Healthcare Navigator Program”**

This program deployed asthma healthcare navigators in four primary care centers operated by the hospital to work with primary care providers as integral members of the families’ asthma care teams. They helped families identify and reduce asthma triggers in the home, as well as provided self-management education and other resources for families of high-risk children with asthma. Over 12 months, caregivers reported a significant reduction in the number of days their child with asthma used rescue medications over a two-week period (from 5.87 days at baseline to 2.74 days at follow-up).

## COMMUNITY HEALTHCARE FOR ASTHMA MANAGEMENT AND THE PREVENTION OF SYMPTOMS (CHAMPS)

**CHAMPS** is an innovative translational research- and community-based clinical partnership funded by MCAN and led by the Milken Institute School of Public Health at the George Washington University. Additional partners include Rho, Inc., and the RCHN Community Health Foundation. The project is designed to demonstrate how tailored, evidence-based asthma management programs that have been proven efficacious in randomized, controlled trials can be implemented in FQHCs, where many low-income children and families receive care. Community health centers participating in the CHAMPS program include: El Rio Community Health Center (Tucson, Arizona), Cherry Street Health Services (Grand Rapids, Michigan), and Costa Salud Community Health Center (Rincón, Puerto Rico).

CHAMPS is concluding its final data collection and will continue to analyze results throughout 2015. Other activities in its final year include disseminating key findings and developing a training tool for other health centers that are interested in adopting the intervention.

## HEAD-OFF ENVIRONMENTAL ASTHMA IN LOUISIANA (HEAL), PHASE II

With support from MCAN, **HEAL, Phase II** built upon the lessons learned from the Head-off Environmental Asthma in Louisiana (HEAL) project, a post-Katrina research initiative that studied the effects of mold and other indoor allergens on

children with moderate-to-severe asthma. HEAL identified the challenges and effectiveness of implementing a multifaceted intervention in asthma case management and of environmental mitigation designed to help improve the health outcomes of children with asthma.

In HEAL, Phase II, the Xavier University of Louisiana Center for Minority Health & Health Disparities Research and Education, the Daughters of Charity Services of New Orleans, and the Children's Health Fund worked together to disseminate and implement a multifaceted intervention in existing healthcare systems. They provided individualized counseling by certified asthma educators and community health workers who made home visits to families of children with poorly controlled asthma. The asthma educators provided tailored counseling for children with asthma ages 2–18 and their families to improve asthma management, avoid exposure to asthma triggers and reduce the occurrence of symptoms. Preliminary results from HEAL, Phase II indicate that children with uncontrolled asthma decreased from 71 percent at baseline to 38 percent at the 12-month follow-up.

## NATIONAL AMBULATORY MEDICAL CARE SURVEY (NAMCS)

The National Ambulatory Medical Care Survey (NAMCS) is a national survey of physicians designed to increase understanding of how care is being delivered in providers' offices. MCAN, the National Institutes of Health (NHLBI, NICHD, NIEHS, NIAID), the Centers for Disease Control and Prevention (NCEH, NIOSH, NCHS), the U.S. Environmental Protection Agency (EPA) and the Agency for Healthcare Research and Quality provided support and expertise to help develop specific questions for the 2012 NAMCS, which focused on the NAEPP asthma guidelines and their use.

The 2012 survey will evaluate the implementation of the NAEPP guidelines from the healthcare provider's perspective and help in identifying barriers to the uptake of critical elements of guideline-based management of asthma. These findings, which are still being analyzed, can inform ongoing strategies to increase effective implementation of the NIH guidelines.

## PUBLIC POLICY

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**MCAN partnered with the Milken Institute School of Public Health at the George Washington University and First Focus to establish the Childhood Asthma Leadership Coalition (CALC), the only national multisector coalition dedicated to improving policymaking that addresses childhood asthma.**

Since its inception in June 2012, CALC has grown to over 20 leading organizations representing a range of expertise in childhood asthma, public health, environmental health, poverty, housing, healthcare, and healthcare economics.

With the guidance of its members, CALC has focused on advancing Medicaid policies that directly impact access to care for low-income children with asthma; educating stakeholders on the Patient Protection and Affordable Care Act (ACA) opportunities; protecting federal funding for childhood-asthma-related programs; and examining current gaps in asthma research and opportunities to foster translational research that brings effective interventions from the research bench to the bedside to the community.

CALC also has had considerable success in fostering working relationships with congressional leaders; federal leaders at the U.S. Department of Housing and Urban Development, the U.S. EPA the CDC, the NIH and Centers for Medicare and Medicaid Services; and other national and state coalitions.

## PERFORMANCE

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**Demographic Characteristics of Enrolled Participants in MCAN's Translational Research Projects**

Characteristic/Variable	Care Coordination	HEAL Phase II	CHAMPS
Patients enrolled through 2014 (N)	805	222	314
Age (Mean)	7.05	9	7.8

Sex (%)	Care Coordination	HEAL Phase II	CHAMPS
Male	59.7	55	61

Race/Ethnicity (%)	Care Coordination	HEAL Phase II	CHAMPS
White	1.8	9	6
Black	50.6	84	9
Other (Asian, Native Am., Mixed, Hisp.)	5.4	7	2
Hispanic <sup>1</sup>	42.3	10	83

<sup>1</sup>Hispanics: not a mutually exclusive category

#### Preliminary Clinical Characteristics of MCAN Project Participants at Baseline and 12 months

Characteristic/Variable	Care Coordination: Baseline <sup>^</sup> [N=805]	Care Coordination: 12-Month Follow-Up <sup>^</sup> [N=805]	HEAL, Phase II: Baseline [N=222]	HEAL, Phase II: 12-Month Follow-Up [N=187]	CHAMPS: Baseline [N=314]	CHAMPS: 12-Month Follow-Up [N=301]
Missed school days, past year (Mean) <sup>1,2</sup>	11.3	4.06	1.4	0.5	1.5	0.6
Limited activities, past month (Mean)	6.27	1.92	-	-	4.7	1.6
Nighttime awakenings, past month (Mean)	6.55	2.02	-	-	4.7	1.1
Emergency room visits, past year <sup>3,4</sup>	2.86	1.09	41%	22%	5.9	0.6
Hospitalizations, past year <sup>5,6</sup>	1.11	0.36	10%	5%	0.3	0.03
Daytime symptoms within the past 2 weeks	7.38	3.13	7.9	5.0	8.7	2.7
Use of rescue medication within the past 2 weeks <sup>7,8</sup>	5.73	2.01	55%	45%	8.2	2.0

<sup>^</sup> Care Coordination data are for individuals who had baseline and follow-up outcomes.

<sup>1</sup> The HEAL, Phase II figure is for the past three months.

<sup>2</sup> The CHAMPS figure is for the past month.

<sup>3</sup> The Care Coordination and CHAMPS figures are mean amounts of visits.

<sup>4</sup> The HEAL, Phase II figure is the percentage of participants who reported that they had an ER visit within past year.

<sup>5</sup> The Care Coordination and CHAMPS figures are mean amounts of hospitalizations.

<sup>6</sup> The HEAL, Phase II figure is the percentage of participants who reported that they had a hospitalization within the past year.

<sup>7</sup> The Care Coordination and CHAMPS figures are mean days using rescue medication within the past two weeks.

<sup>8</sup> The HEAL, Phase II figure is the percentage of participants who reported that they used their rescue medication within past two weeks.



## Key Initiatives

# MECTIZAN DONATION PROGRAM

## MAIN

One of the most significant initiatives undertaken by our company to help improve access to medicines in developing countries is the **MECTIZAN<sup>®</sup> (ivermectin) Donation Program.**

In 1987, we announced that we would donate MECTIZAN, our medicine for the treatment of onchocerciasis, to all who needed it, for as long as needed. In 1998, this donation was expanded to include mass treatment for the elimination of lymphatic filariasis (LF) in African countries where onchocerciasis and lymphatic filariasis are co-endemic. The MECTIZAN Donation Program is the longest-running disease-specific drug donation program and public-private partnership of its kind.

To facilitate the donation and delivery of MECTIZAN, we established a multisectoral partnership involving the World Health Organization (WHO), the World Bank, ministries of health, nongovernmental development organizations (NGDOs) and local communities. In 1988, we also established the MECTIZAN Donation Program at the *Task Force for Global Health*, as well as the MECTIZAN Expert Committee to provide technical and scientific advice on the implementation of the program. This balanced governance and organizational structure continues to support and facilitate the donation of MECTIZAN.

For more information on the MECTIZAN Donation Program, review the [MDP Annual Highlights](#).

## ONCHOCERCIASIS

More commonly known as “river blindness,” onchocerciasis is transmitted through the bite of black flies and can cause intense itching, disfiguring dermatitis, eye lesions and, eventually, blindness. At the inception of the program, the disease was one of the leading causes of preventable blindness worldwide, and approximately 130 million people were at risk for the disease.

MECTIZAN relieves the agonizing itching that accompanies the disease and halts progression toward blindness—two characteristics of the disease that dramatically affect the quality of life. MECTIZAN is well-suited for distribution in remote areas by community health workers through mass distribution programs. It is the only well-tolerated drug known to halt the development of river blindness.

In Africa, while the original goal of the program was to control onchocerciasis, recent evidence from the WHO indicates that elimination is now feasible in Africa. As a result, the program’s strategy shifted from disease control to disease elimination, and the partners in this program are now working toward the goals established by the WHO to eliminate both LF and onchocerciasis by 2020 and 2025, respectively.

In Latin America, where the initial goal was to eliminate onchocerciasis through regular mass treatment with MECTIZAN—so far, four out of the six originally endemic countries have stopped treatment as a result of the interruption of transmission. Colombia and Ecuador were certified free of onchocerciasis by the WHO in 2013 and 2014, respectively; Guatemala and

Mexico have submitted their requests to the WHO for certification. The remaining two countries, Brazil and Venezuela, are continuing treatment in an area in the Amazon jungle.

## LYMPHATIC FILARIASIS (LF)

LF is a devastating parasitic infection spread by mosquitoes. It is caused by threadlike parasitic worms that damage the human lymphatic system. The disease is endemic in 72 countries and is currently estimated to have infected more than 120 million people, with more than 40 million incapacitated or disfigured with swelling of the limbs, breasts (lymphedema) and genitals (hydrocele). Swollen limbs also often develop dramatically thickened, hard, rough and fissured skin (elephantiasis). An annual single dose of MECTIZAN, administered with a second drug, albendazole (donated by GlaxoSmithKline), is the recommended treatment in areas where onchocerciasis coexists with LF.

In addition to providing MECTIZAN free of charge, in December 2007 we announced a donation of \$25 million over eight years (2008–2015) as part of an initiative with the World Bank to fund the African Programme for Onchocerciasis Control (APOC). APOC was originally established to support the control of the disease in African countries affected by river blindness through the development of self-sustaining MECTIZAN distribution programs named CDTI (community-directed treatment with ivermectin) programs. Many of these programs have implemented at least one other health intervention in addition to MECTIZAN delivery, thereby helping countries and their partners to improve healthcare by expanding health services in these hard-to-reach communities.

“Through the donation of MECTIZAN, Merck & Co., Inc., Kenilworth, New Jersey, USA, has been a valued partner in the effort to eliminate river blindness and lymphatic filariasis. We look forward to building on our achievements to date, and to expand as needed the delivery of the donated medicine to achieve the elimination targets.”

—Dr. Ariel Pablo Mendez, Assistant Administrator for Global Health, USAID

## THE LONDON DECLARATION

Our company is an original signatory of the London Declaration, a collaborative effort to accelerate progress toward eliminating or controlling 10 neglected tropical diseases (NTDs) by the end of the decade. We joined 12 other global pharmaceutical companies, and many other stakeholders including endemic country governments, the WHO, the Bill & Melinda Gates Foundation, USAID, the UK Department for International Development (DFID), NGOs and other organizations in this effort. Our company joined several other pharmaceutical companies committed to continuing or increasing their donations of medicines to treat or prevent these diseases; donors committed financial resources; and NGOs agreed to support implementation needs. The partners came together under the banner of Uniting to Combat NTDs to track progress and identify gaps (e.g., NTD research, additional funding, etc.) that need to be addressed in order to reach the goals of the London Declaration. [Learn more](#) about the London Declaration. For more information on our NTD research, visit [Infectious Diseases](#).

## ADVERSE-EXPERIENCE REPORTING

While side effects following treatment with MECTIZAN are rare, we have developed a rigorous program for monitoring and reporting any adverse experiences (AEs) in the field. With the help of local NGOs, all field-based community distributors are trained in AE reporting; all AEs must be reported to the company, which then reports them to drug safety and regulatory agencies in the U.S. and internationally.

The MECTIZAN Expert Committee, ministries of health and the WHO also play key roles in making sure best practices are applied for surveillance of AEs at the community level. The AE reporting form itself has been revised several times throughout the program’s history. Currently we are working with the WHO, endemic countries and the other drug-donation programs to

develop a common AE reporting form to standardize reporting requirements.

# PERFORMANCE

## COMMITMENTS

While much has been achieved in the treatment and progress toward elimination of onchocerciasis (river blindness), there remain a number of additional challenges that we and our partners are actively addressing.

To ensure a continued supply of MECTIZAN® (ivermectin) to support the activities of other program partners, we remain committed to continuing to donate as much MECTIZAN as is necessary to eliminate river blindness globally and to eliminate lymphatic filariasis (LF) in African countries where the diseases coexist.

Beyond addressing river blindness and LF, the MECTIZAN Donation Program is a key component of the growing trend toward integrated programs to address Neglected Tropical Diseases (NTDs). In fact, the integration of onchocerciasis and LF efforts via the MECTIZAN Donation Program, which began in 1998, set the foundation for many of these efforts, and we will remain engaged with key stakeholders to help with integration of the programs where feasible.

As a result of our activities and of the collaboration and contributions of a wide range of committed partners, we expect to achieve the following milestones in the years ahead:

- Although we expected the transmission of river blindness in all areas of the Americas to be halted by 2013\*, mass treatment is still ongoing in remote areas of Brazil and Venezuela. We continue to work toward the goal of stopping treatment in those areas in collaboration with the local program partners.
- In accordance with the goals outlined in the WHO Roadmap for Neglected Tropical Diseases, we expect the elimination of LF and river blindness by 2020 and 2025, respectively

River Blindness and Lymphatic Filariasis (LF) Summary 2010 2011 2012 2013* 2014					
Direct investment in the MECTIZAN Donation Program (US\$M)	5.5	5.5	5.5	5.5	5.5
Treatments approved (in millions)	220.0	270.0	266.0	302.0	267.0
Market value of MECTIZAN donations (US\$M)	651	747	906	1,092	861
Countries with LF elimination programs supported by the MECTIZAN Donation Program (cumulative target: 29)	17	17	22	22	25
Latin American countries where treatment with MECTIZAN has been stopped to allow for post-treatment surveillance and certification that the disease has been eliminated (cumulative target: 6)	2	4	4	4	4
Treatments with MECTIZAN approved for river blindness (in millions)	100.0	140.0	116.0	168.0	109.6
Treatments with MECTIZAN approved for LF (in millions)	120.0	130.0	150.0	127.0	147.0

\*2013 figures have been reconciled to reflect revised field data for the MECTIZAN Donation Program.

In 2014, 109.6 million treatments were approved for river blindness (with 71.1 million of those being for both river blindness and LF) and 147 million treatments were approved for LF. To date, our company invested approximately \$66 million in direct financial support for the MECTIZAN Donation Program, in addition to donating over 1.32 billion and 983 million treatments of MECTIZAN for river blindness and LF, respectively.

The donation of MECTIZAN also has led to the development of CDTI (community-directed treatment with ivermectin) programs, through which trained community volunteers distribute medicines, a critical element to effective mass-treatment programs in remote areas that often lack trained healthcare workers. CDTI strategy has been and continues to be used to distribute MECTIZAN to more than 146,000 communities in 29 countries in Africa where river blindness is a public health problem. The CDTI strategy has enabled other health and social services—such as vitamin A distribution, cataract identification, immunization campaigns, training programs for community health workers and census taking—to be introduced in often-remote communities.

## IMPACT

- An estimated 40,000 cases of river blindness are prevented by the MECTIZAN Donation Program annually
- The African Program for Onchocerciasis Control (APOC) estimates that 1 million disability-adjusted life years (DALYs) per year are averted
- The impact of the MECTIZAN Donation Program extends beyond the immediate health benefits; estimates show that investments in river blindness control programs (e.g., MECTIZAN treatment and aerial spraying to control black fly populations) are helping people live not only healthier but also more productive lives
- In 2013, Colombia received verification from the World Health Organization that river blindness was eliminated, becoming the first country to achieve that milestone. Ecuador followed in 2014, and Guatemala and Mexico expect to receive verification by 2016.
- In Africa, the distribution of MECTIZAN has stopped in 16 districts in Uganda, two districts in Mali and one district in Sudan where it is believed that onchocerciasis transmission has been interrupted
- For LF in African countries coendemic with onchocerciasis, in 2014, treatment was stopped in 23 implementation units (IUs) in Benin, 33 IUs in Burkina Faso, 70 IUs in Ghana, 26 IUs in Malawi, two IUs in Niger, 30 IUs in Nigeria, six IUs in Tanzania and 16 IUs in Uganda. Post-treatment surveillance is ongoing in Togo and Yemen.

APOC believes that interrupting the transmission of river blindness in the Central African Republic, the Democratic Republic of the Congo and South Sudan will be the most problematic and will require the longest time frame. Civil unrest and poor infrastructure contribute to the slow progress in these countries.

# MEDICAL OUTREACH PROGRAM

## MAIN

**Established in 1958, our company's Medical Outreach Program (MMOP) is the primary mechanism through which our company donates its pharmaceuticals and vaccines for humanitarian assistance in the developing world and in support of disaster relief and emergency situations worldwide.**

The MMOP, managed by our Office of Corporate Responsibility, is one mechanism through which we help to expand access to our products, particularly in the developing world. The program enables us to donate critical pharmaceuticals and vaccines to a limited number of qualified, U.S.-based nongovernmental organizations (NGOs). The scope of the MMOP varies from year to year and is influenced by changing medical needs in developing countries, the quantity of our medicines available for donation, and the random nature of natural and man-made disasters.

Donations of our medicines are made primarily through six qualified NGOs:

- AmeriCares
- Catholic Medical Mission Board (CMMB)
- Direct Relief
- IMA World Health
- MAP International
- Project HOPE

Each of these organizations has a long-standing relationship with the company; demonstrates integrity of purpose; provides assurance that our products will be securely warehoused and not diverted, mishandled or misappropriated; and has well-established programs for the ill and needy in developing countries. The company, through the MMOP, monitors the NGOs and maintains the controls necessary for the proper distribution and handling of our medicines. We do not provide donations of expired products or of products with inadequate dating. We donate products with sufficient dating to ensure the proper administration prior to expiry. The MMOP comprises three components:

### **Annual Product Allotment Program**

Through this program, the six NGOs with which we work can request medicines of their choice from our company's current product line at specified times, up to an annually authorized amount. Through this innovative approach to donations, our partners can receive a sustained and predictable supply of needed medicines, as is crucial to the effective planning of ongoing humanitarian programs. The first program of its kind in the industry, it has served as a model for other pharmaceutical companies' donation programs.

### **Ongoing Donations of Pharmaceuticals & Vaccines**

Donations of our pharmaceuticals and vaccines are also made in response to proposals from our partners to address some of

the specific shorter-term needs of their programs around the world. We also offer products to our partners proactively, based on supply, for use in their ongoing humanitarian programs.

### Disaster & Emergency Relief

Our disaster relief program is designed to provide assistance in response to major disasters and to support efforts in preparedness and recovery. The Office of Corporate Responsibility serves as the central clearinghouse for information regarding our companywide response to major disasters, and makes decisions related to our donations of cash, as well as medicines and vaccines, through the MMOP. For more information, please [click here](#).

In conducting the MMOP, we observe the World Health Organization (WHO) Guidelines for Drug Donations. We are also a member of the Partnership for Quality Medical Donations (PQMD), an alliance of NGOs and medical product manufacturers dedicated to raising the standards of medical donations to meet the needs of underserved populations and disaster victims around the world.

## PERFORMANCE

In 2014, donations of medicines, vaccines and consumer healthcare products supported vaccination programs in the Dominican Republic and Haiti; provided disaster assistance in the U.S., the Philippines, Paraguay, El Salvador, St. Vincent and the Grenadines, Liberia and Sierra Leone; supported partner medical mission programs; and reached many thousands more worldwide through the ongoing medical programs of the NGOs with which we work.

We also work with our MMOP partners to add value beyond our donated medicines. For example, in 2013 we initiated a supply chain and facility review process with our NGO partners, and as of March 2015 we have completed evaluations of three of our partners. Collaborative evaluations of domestic medicine warehouse facilities allow us to jointly identify improvements in medicine storage and handling to optimize supply chain effectiveness. Recommendations have included such items as regular storage-rack inspection and maintenance, strengthening of delivery receipt procedures, and improvements in material-handling procedures.

In addition to the MMOP, our local subsidiaries and our other divisions have donated products with a U.S. market value of more than \$2.8 million for humanitarian aid.

MMOP Summary	2010	2011	2012	2013	2014
Countries and territories reached by the MMOP	97	82	92	86	91
People reached by the MMOP <sup>1</sup>	NA	NA	NA	NA	433,624
Value of donations of medicines, vaccines and consumer care products (US\$M) <sup>2,3,4</sup>	75.2	89.8	86.3	69.4	110.2
Disaster relief contributions (product) (US\$M) <sup>2</sup>	10.90	10.40	0.78	2.40	8.5

<sup>1</sup> Based on converting volume of medicines and vaccines donated in 2014. Conversion factors for this estimate were developed by IMS Health® using our US Product Information found on our company's product webpage; evidence-based factors using the IMS LifeLink® Dx, Patient Medical Claims Data, January 1, 2014 through December 31, 2014, were also developed and used for validation purposes.

<sup>2</sup> We set the value of our product donations based on the U.S. wholesale acquisition cost.

<sup>3</sup> Figure includes the value of product donations through the MMOP program only. Product donations to ACHAP are included in the ACHAP section.

<sup>4</sup> The 2014 figure does not include donations of our company's consumer care items. All our consumer care donations made in 2014 are captured in the subsidiary and divisional figure (\$2.8M in 2014). Effective October 1, 2014, Bayer AG purchased our company's consumer Care business.

# MSD FOR MOTHERS



## MAIN

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### OUR COMMITMENT

The preventable death of a woman from complications of pregnancy and childbirth is a tragedy with devastating effects on families, communities and nations. Although there has been impressive progress in reducing these deaths in recent decades, the world is not on track to meet the Millennium Development Goal target of a 75 percent reduction in the maternal mortality rate by the December 2015 deadline.

Applying our scientific and business expertise to the challenge, *MSD for Mothers*, our company's 10-year, \$500 million initiative, is bringing the next generation of solutions to reduce maternal deaths worldwide. We are investing in programs that have a high potential for lasting impact. Focusing on regions and communities where the problem is particularly severe, *MSD for Mothers* operates like a living laboratory: designing and testing health solutions for women that can achieve broad scale. We're working in close collaboration with more than 75 implementing partners, and to date we've initiated more than 50 projects in 30 countries—all contributing to our vision of a world where no woman dies giving life.

In 2014, our third year, *MSD for Mothers* improved access to quality maternal healthcare and family planning services for an estimated 3.5 million women around the world. Below is an update on our progress.

### OUR APPROACH

*MSD for Mothers* is providing transformational solutions to improve the quality of care, from admission to discharge, and access to family planning for women giving birth at healthcare facilities. *MSD for Mothers*, now in its fourth year, has so far contributed to improved access to quality maternal healthcare and family planning services for an estimated 3.5 million women in 30 countries around the world.

*MSD for Mothers* is data-driven and committed to contributing learnings from our projects and partnerships to the maternal health field because we believe our efforts are and will continue to yield important lessons that could help advance the global effort to end preventable maternal mortality.

### 2014 HIGHLIGHTS

Our major achievements in 2014 include the following:

- Established a collaboration with Ferring Pharmaceuticals and the World Health Organization (WHO) to develop a new, proprietary formulation of carbetocin, used to prevent excessive bleeding (postpartum hemorrhage) in women after childbirth, that is designed to be heat-stable—stable even in hot and tropical climates (ICH climatic zones IV A and B)

- Raised awareness of the importance of the local private sector as a key stakeholder in the provision of care to pregnant women while strengthening 680 health facilities, training over 4,370 health workers and improving access to quality care for an estimated 141,000 women
- Supported the scale-up of an innovative supply chain model to increase access to family planning methods for 2.6 million women in Senegal as part of our \$50 million family planning partnership with the Bill & Melinda Gates Foundation

## IMPROVING ACCESS

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***MSD for Mothers* has projects in more than 30 countries around the world, with intensive focus in India, Senegal, Uganda, the U.S. and Zambia.**

Our goal is to test innovative models that expand women's access to affordable, quality care and have the potential to be expanded and sustained. We're striving to find solutions that will have a lasting impact on ending preventable maternal mortality, today and for years to come.

### STRENGTHENING LOCAL PRIVATE HEALTHCARE

One way we're working to increase access to affordable, quality maternal health services is by improving the care delivered by local private providers, such as independent doctors, midwives and drug shop owners. While in the developing world, maternal health is typically thought to be a responsibility of the public sector, women often turn to private providers as their first source of care. Women seek care from private providers for a range of reasons, including proximity to their home, flexible hours, a sense of personalized care and sensitivity to local needs and customs. However, this care can be unregulated, expensive and of variable quality.

We believe that strengthening the ability of private providers to meet the health needs of pregnant women and complementing care being given in the public sector could have an impact on reducing maternal mortality. In 2014, we expanded our work with private providers in India and Uganda, where our partners are helping set, maintain and deliver standards for affordable, quality care in the local private health sector.

In **Uganda**, we've partnered with Population Services International (PSI) and its local affiliate, PACE, on a project called *MSD for Ugandan Mothers* (MUM). We're working with PACE to ensure that pregnant women—particularly those in remote and low-income communities—have access to affordable, quality maternal health products and services through the ProFam network of privately owned franchise clinics. This comprehensive project is also working beyond the clinic setting, helping women overcome common barriers to care, such as cost, transportation and limited supplies. In 2014, MUM expanded the ProFam social franchise to include 140 health facilities in more than 40 districts nationally (covering over a third of the country) and improved access to quality care for an estimated 75,000 women.

The following are some of the highlights of the MUM project through 2014:

- More than 200 providers trained and mentored in delivering quality maternal healthcare
- More than 260 drug shop owners trained to offer vital health information, referrals to care and clean delivery kits
- Nearly 190 private motorcycle taxi drivers trained to safely transport pregnant women to care
- Established nearly 45 "mothers' clubs" to encourage women to save for childbirth costs
- Established community health insurance programs with nearly 3,800 members
- Recruited and trained more than 350 community health workers to conduct community outreach and education

In **India**, we've partnered with leading health organizations to strengthen private maternal healthcare in Jharkhand, Rajasthan and Uttar Pradesh—three states with some of the highest rates of maternal mortality in the country.

- **Pathfinder International** and **World Health Partners** are expanding access to maternal healthcare by linking the public and private sectors, adding maternal health services to an existing health franchise, connecting remote providers to higher-level care through referral and telemedicine, and ensuring that quality supplies reach the last mile

- **Jhpiego** and the **Federation of Obstetric and Gynaecological Societies of India (FOGSI)** are developing standards of quality care and helping providers meet those standards through training, continuous quality improvement and accreditation
- **Hindustan Latex Family Planning Promotion Trust (HLPPT)** is adapting a sustainable franchise network of private hospitals and health workers to a new context so women in rural and peri-urban areas have better access to care throughout their pregnancy

Now at their halfway point, these projects have already strengthened 540 health facilities, trained 2,500 health workers and improved access to quality care for an estimated 66,000 women.

In addition to our programs and evaluation efforts that are identifying and testing solutions to help ensure that private providers are affordable and delivering quality maternal health services, we have undertaken related advocacy efforts. Our goal is to ensure that women have access to affordable, quality maternal health services *wherever* they seek care (through public or private sources). That's why we are raising awareness among policymakers, donors and other global health stakeholders about the complementary role of private providers and the importance of working with them to help end preventable maternal deaths.

To support our programmatic and advocacy efforts, we are working with the [London School of Hygiene and Tropical Medicine](#) to help us better understand where women are receiving maternal healthcare.

In 2014, the London School analyzed data from Demographic and Health Surveys (DHS) in 57 low- and middle-income countries—the largest study of its kind—and will publish a series of articles on their research in 2015. The early findings show that the local private sector is delivering a considerable proportion of maternal health services and is a much greater source of care than previously measured for poor and rich women alike. The findings suggest that the local private sector—an often overlooked part of the healthcare system—needs more attention as a potential sector that could help decrease maternal mortality globally.

*MSD for Mothers* co-hosted a panel discussion with PSI and the World Bank during the United Nations General Assembly to share the School's initial findings and discuss the role of private health providers in reducing maternal mortality (see [highlights video](#)).

In 2015, we will continue working with our research partners at the London School, our NGO partners on the ground, and other influential groups like the World Bank and USAID to better understand and advocate for a more global focus on leveraging local private providers as a tool to help save women's lives.

## ADDRESSING THE DISTANCE PROBLEM

In **Zambia**, many women live in remote communities, making it difficult for them to reach a health facility that can provide treatment in the event of a childbirth complication. *MSD for Mothers* is supporting the design of new entrepreneurial models of maternity homes, residences near health facilities where pregnant women can stay until they go into labor. The goal is twofold: 1) make it easier for pregnant women to reach care at the time of childbirth; and 2) ensure the sustainability of these homes through community ownership and income-generating activities. In 2014, we completed a planning phase to design the homes and selected two sets of partners—Boston University/Zambia Center for Applied Health Research and Development and Africare/University of Michigan—to implement the program beginning in mid-2015.

## EXPANDING ACCESS TO FAMILY PLANNING

Family planning is recognized as one of the most cost-effective ways to lower maternal mortality rates—potentially averting a third of maternal deaths by reducing the overall number of pregnancies and helping women adequately space their pregnancies. In **Senegal**, as part of our collaboration with the Bill & Melinda Gates Foundation, we are supporting the scale-up of an innovative supply chain model to eliminate stock-outs of contraceptives at health facilities—a serious barrier to family planning.

In 2014, our partner IntraHealth International increased the availability of contraceptive products in nearly two-thirds of the country by reducing total stock-outs to less than 10 percent from 80% in approximately 1,000 health facilities. In total, we've reached more than 2.6 million women. Additionally, we've enlisted our employees with expertise in supply chain management to conduct a costing evaluation of this model, which will inform the Senegalese government's plans for national expansion.

We also ensured that in all of our maternal health programs in India and Uganda, postpartum family planning was an integrated service offered to all pregnant women.

## NOT JUST A DEVELOPING WORLD PROBLEM: BOLSTERING MATERNAL HEALTH IN THE U.S.

While most countries have seen a sharp decline in maternal mortality, surprisingly, it is on the rise in the U.S. In fact, the rate of women dying during pregnancy and childbirth in the U.S. more than doubled in the past 25 years.

*MSD for Mothers* is now supporting work in 16 states across the country to respond to five major challenges that contribute to maternal mortality in this country: 1) inconsistent management of obstetric emergencies; 2) lack of good data on why women are dying during pregnancy and childbirth; 3) rise in chronic conditions among pregnant women (e.g., obesity, diabetes, hypertension); 4) inadequate attention to the postpartum period when many deaths occur; and 5) lack of awareness of maternal mortality and morbidity.

The following are key accomplishments of our U.S. projects in 2014:

- The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN), the California Maternal Quality Care Collaborative, and the American Congress of Obstetricians and Gynecologists—District II put in place new treatment guidelines at more than 225 hospitals in five target states. There are now “safety bundles,” toolkits that include processes and checklists designed to help address three of the leading causes of maternal death (embolism, obstetric hemorrhage and preeclampsia/eclampsia), enabling health providers to deliver consistent, evidence-based care.
- The Association of Maternal and Child Health Programs helped 12 states strengthen their ability to review maternal deaths and understand why they are occurring. Early results have identified a need for state departments of health to focus more intently on chronic conditions like hypertension, cardiovascular disease, substance abuse, and mental health problems among pregnant women.
- *MSD for Mothers* supported community-based projects in Camden, New Jersey; New York City; and Philadelphia to improve care for low-income and high-risk pregnant women. These projects are testing new models of care for pregnant women with chronic conditions—a pioneering area that hopefully will reveal learnings around reimbursement for services provided by community health workers.
- To address the often neglected six weeks following childbirth—known as the postpartum period—*MSD for Mothers* initiated a collaboration with AWHONN to develop discharge guidelines for use with every woman leaving the hospital after giving birth. The goal is to help new mothers identify health problems as early as possible and ensure that they remain in close contact with their health provider.
- To increase awareness of leading pregnancy complications in the U.S., we launched a campaign to encourage expecting families to have a PEP Talk—a conversation with a healthcare professional about the three leading potential complications (preeclampsia/eclampsia, embolism and postpartum hemorrhage). Our Chief Medical Officer, Dr. Michael Rosenblatt, supported the launch of this campaign (see video) and “near-miss” survivor Jennifer Albert shared her personal story about the importance of raising awareness (see video).

## JOINING THE U.S. GOVERNMENT TO DRAMATICALLY REDUCE MATERNAL DEATHS

*Saving Mothers, Giving Life* is a five-year public-private partnership led by the U.S. government to reduce maternal mortality in sub-Saharan Africa, beginning in Uganda and Zambia. *MSD for Mothers* is a founding partner of the initiative, and our programs in both countries contribute to its work to put in place lifesaving maternal and newborn health interventions. In its first year, *Saving Mothers, Giving Life* produced impressive results: Maternal mortality ratios fell by 30 percent in target districts of Uganda and by 35% in target facilities in Zambia.

For a complete list of our partners, please visit [here](#).

## TECHNOLOGY

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## ADVANCING LIFE-SAVING PRODUCTS

As a research-based healthcare company, innovations in lifesaving products is one of the most important and distinct contributions we can make to improve maternal health. Our scientists and others are deeply involved in identifying, developing and advancing new and/or improved products to address unmet maternal health needs in the developing world. Our focus continues to be on preventing and treating the two leading causes of maternal death worldwide: obstetric hemorrhage and preeclampsia/eclampsia.

In 2014, *MSD for Mothers*, Ferring Pharmaceuticals and the WHO established a collaboration to develop a new, proprietary formulation of carbetocin, used to prevent excessive bleeding (postpartum hemorrhage) in women after childbirth, that is designed to be heat-stable—stable even in hot and tropical climates (ICH climatic zones IV A and B).

Postpartum hemorrhage is the leading cause of maternal deaths around the world.

The development of a medicine that can be stored at elevated temperatures has the potential to significantly improve management of bleeding following childbirth in many countries where cold temperatures during storage and distribution of the medicine are difficult to achieve and maintain. The availability of a heat-stable carbetocin product could help reduce maternal deaths in these countries. The WHO will conduct a multi-country clinical study to evaluate the effectiveness of heat-stable carbetocin in vaginal deliveries, as compared to the current standard of treatment, oxytocin. If the results of the study are positive, the aim is to make the medicine available in the public sector of developing countries that have a high burden of maternal mortality, at an affordable and sustainable price.

*MSD for Mothers* is also interested in devising an easier-to-administer dosing regimen for magnesium sulfate, the current gold standard for managing seizures in pregnant women suffering from preeclampsia/eclampsia. The first step toward this goal, identifying a dose range using our internal modeling and simulation expertise and data from collaborating universities and hospitals from around the world, is to be completed by the end of 2015.

## DIGITAL INNOVATIONS

Digital innovations—especially mobile technology solutions—are playing an increasingly important role in advancing global health and development efforts, empowering people to learn and make decisions about their health and access much-needed health services in new and interactive ways. *MSD for Mothers* is exploring the potential of digital innovations to improve the quality of care for pregnant and postpartum women.

In India, we partnered with White Ribbon Alliance and Gram Vaani to pilot a new, interactive voice response service that enables women to learn about the care they deserve and rate the quality of care they receive. Built to reach low-income women, particularly those with limited literacy, this project aims to hold health providers accountable for their services and ensure that women become active participants in their care. Our pilot test in 20 districts in Jharkhand has already reached nearly 11,000 women, and found early success among both women and health providers.

## PROGRAMS

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**In India and Uganda, we are working to improve the ability of local health businesses to deliver affordable, quality maternal healthcare.**

### UGANDA



Midwives like Lorna (above) are seasoned healthcare workers offering a wide range of services including family planning, antenatal care, labor and delivery, routine immunizations, and basic newborn care. (Photo credit: PACE-Uganda [KK Big Sky])



Donata (left) owns Central Clinic, a local drug shop in Mubende. Drug shops sell subsidized Maama kits that include childbirth supplies women are often required to bring to a health facility when they are ready to give birth. (Photo credit: PACE-Uganda [KK Big Sky])



A group of children and their mothers looks on as the MUM program checks in on one of the MUM clubs. (Photo credit: PACE-Uganda [KK Big Sky])



Community insurance treasurers like Sarah (left) educate expecting families about the benefits of investing in health coverage ahead of time so women can receive medical care whenever they need it. Here, Sarah distributes membership cards to members of her community insurance group. (Photo credit: PACE-Uganda [KK Big Sky])



Dr. Wagodoma (right) receives a pregnant woman at the Ibulanku Health Centre III in Iganga. While midwives are the primary maternal caregivers in Uganda, Dr. Wagodoma helps to provide specialist care and delivery services when needed. (Photo credit: PACE-Uganda [KK Big Sky])

## INDIA



A private midwife and ASHA (community health worker) on their way to a home visit with a pregnant woman. Through the MATRIKA Project, community health workers and midwives work together to educate women about safe motherhood and refer them to public and private facilities for maternal health services. (Photo credit: Pathfinder International with World Health Partners [Simon de Trey-White])



A private provider gathers her hospital's community health workers to discuss their work educating women about family planning and safe motherhood. HLFPT is expanding a franchise network of private hospitals, clinics and health workers so women in rural and peri-urban communities have better access to care throughout their pregnancies. (Photo credit: HLFPT and the Merrygold Network [Rakesh Kumar])



Private community health workers help women plan for childbirth. HLFPT is expanding a franchise network of private hospitals, clinics and health workers so women in rural and peri-urban communities have better access to care throughout their pregnancies. (Photo credit: HLFPT and the Merrygold Network [Rakesh Kumar])



An OB/GYN conducts an antenatal care visit and answers questions about pregnancy and childbirth. The MATRIKA Project is working to improve access to affordable, high-quality maternal health services and family planning among low-income women. (Photo credit: Pathfinder International with World Health Partners [Simon de Trey-White])



Dr. Sameer Sachan, a rural private provider, consults with an urban doctor via telemedicine about a pregnant woman's care. The MATRIKA Project is working to connect women in remote areas to high-quality maternal healthcare through telemedicine and by strengthening the link between public and private health sectors. (Photo credit: Pathfinder International with World Health Partners [Simon de Trey-White])

## U.S.

In the U.S., our programs are working to improve maternal health across the U.S., with a focus on regions where rates of maternal deaths and severe complications are disproportionately high.



It is important for pregnant women to receive care and support for a healthy and safe pregnancy and childbirth. MSD for Mothers is helping to fund community programs that support women throughout their pregnancy. (Photo credit: Mark Tuschman; Erika Lansner)



Pregnant women meet to discuss issues relating to their pregnancy and receive prenatal care at the Camden Coalition of Healthcare Providers' (CCHP) centering pregnancy session in Camden, N.J. (Photo credit: Mark Tuschman; Erika Lansner)



A mother holds her newborn at her local health center. She is part of the Camden Coalition of Healthcare Providers' centering pregnancy program, a new model of maternal and postpartum care for women. (Photo credit: Mark Tuschman; Erika Lansner)



A community health worker emerges from her MOMobile in Philadelphia. MSD for Mothers is helping to support the Maternity Care Coalition's home-visiting program for high-risk pregnant women. (Photo credit: Mark Tuschman; Erika Lansner)



Many of the community programs that MSD for Mothers is helping to fund support fitness and nutrition classes to help pregnant women manage chronic health conditions. (Photo credit: Mark Tuschman; Erika Lansner)

## AROUND THE WORLD

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Through the **Global Giving Program**, we are collaborating with MSD offices around the world to support nearly 30 projects in 24 countries that are responsive to local maternal health needs. Working in countries as diverse as Colombia, Lebanon, Malawi and the Philippines, these grants-based programs are training health providers in maternal care services, linking pregnant women to care and raising awareness of safe motherhood.

**Our Fellowship for Global Health** program grew to 20 employees who participated in 12-week assignments with our partners on the ground in India, Uganda, the U.S. and Zambia, providing assistance in business training, business planning, data management, quality assurance, feasibility studies and recommendations for income generating activities.

In addition, more than 50 employees across the company are heavily engaged in *MSD for Mothers*, providing technical expertise to support our product innovation efforts and strengthen our programs. They include experts in areas as diverse as pharmacokinetics, cost-effectiveness, marketing, data analysis and information technology.

A new **Executive Ambassadors** program enrolled 13 senior female leaders from across the company to gain a deeper understanding of *MSD for Mothers* and identify how to both strengthen the initiative with our resources and leverage it for the company.

We also continued to raise awareness among our employees about *MSD for Mothers* and provide opportunities for them to become involved. There are now more than 200 employee “ambassadors” in 19 countries who helped support the second annual “May Is for Mothers” event, expanding its reach to 14 sites and more than 1,500 employees globally. Employees learned about *MSD for Mothers* programs, participated in the “Tribute to Mothers” walk, wrapped baby bundles for new

mothers in India and registered as volunteers with local non-profit organizations related to maternal health.

## PERFORMANCE

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	<i>MSD for Mothers Performance Metrics</i>	2014
Number of providers/community health workers trained (in target countries)		4,370
Number of districts/regions reached (in target countries)		143
Number of women with improved access to quality care (in target countries)		3,534,889
Number of women with improved access to modern contraception (in Senegal)		2,619,805
Number of facilities upgraded or maintained to BEmONC or CEmONC states or high-quality care facilities (in target countries)		1,682
Number of women delivering in facilities providing high-quality care (in target countries)		69,260

# U.S. PATIENT ASSISTANCE PROGRAMS

## MAIN

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**Our company believes that no one should go without the medicines or vaccines they need.**

That is why our company provides our medicines and adult vaccines for free to people who do not have prescription drug or health insurance coverage and who, without our assistance, could not afford these medicines and vaccines. This is consistent with our company's long-held values and tradition of putting patients first.

More than 55 years ago, our company created our first U.S. patient assistance program (PAP) to keep affordable medicines within patients' reach. Today, our patient assistance offerings include several programs. Through these programs, we have provided more than 34 million free prescriptions and vaccines, representing a total value (wholesale acquisition cost) of more than \$3.6 billion in the past 12 years alone.

Learn more about our U.S. patient assistance programs, including eligibility requirements.

## COMMUNICATING OUR PROGRAMS TO DOCTORS & CONSUMERS

We are working to raise awareness of our patient assistance programs among doctors and eligible patients via brochures and applications distributed by our sales representatives to physicians' offices and clinics nationwide. All toll-free phone lines for our medicines include an option for patients to learn about our patient assistance programs. In addition, information about these programs is being added to all of our new direct-to-consumer advertisements, including a phone number for more information.

## PARTNERSHIP FOR PRESCRIPTION ASSISTANCE

We also participate in the pharmaceutical industry initiative Partnership for Prescription Assistance (PPA). The Partnership brings together America's pharmaceutical companies, as well as doctors, patient advocacy organizations and civic groups, to help low-income, uninsured patients get free or nearly free brand-name medicines. PPA does this through a single website that provides information for and access to more than 475 public and private patient-assistance programs, including more than 200 programs offered by pharmaceutical companies like ours. To date, PPA has helped millions of Americans get free or reduced-cost prescription medicines.

Our participation in PPA underscores the company's commitment to helping the uninsured gain access to our medicines. To learn more about the Partnership for Prescription Assistance, visit [www.pparx.org](http://www.pparx.org).

<sup>1</sup> You do not have to be a U.S. citizen. If you do not meet the prescription drug coverage criteria, but your income meets the program criteria and there are special circumstances of financial and medical hardship that apply to your situation, you can request that an exception be made for you.

<sup>2</sup> For income limits in Alaska, Hawaii, Puerto Rico, the U.S. Virgin Islands and Guam, please call 1-800-727-5400.

\* Offered through Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, U.S.A.

\*\* Offered through our company's Patient Assistance Program, Inc.

## PERFORMANCE

Patient Assistance Programs Performance	2010	2011	2012	2013	2014
Patients utilizing our U.S. Patient Assistance Programs (PAPs) <sup>1</sup>	343,382	379,500	444,178	400,000	301,713
30-day prescriptions filled under our company's Patient Assistance Programs (millions) <sup>2</sup>	2.1	2.5	2.2	1.2	1.6
Total value of our company's medicines dispensed under our Patient Assistance Programs (US\$M) <sup>3</sup>	322.8	301.2	559.0	566.4	432.9

<sup>1</sup> Totals represent 2011 to 2014 volumes of our Patient Assistance Program, our company's Vaccine Assistance Program, the Patient Bulk Replacement Patient Assistance Program, the SUPPORT Program, the ACT Program and the our company's Hotline. Totals for 2009 and 2010 include our Patient Assistance Program, the Vaccine Patient Assistance Program, the Schering-Plough Patient Assistance Program and the Schering-Plough Pharmaceutical Patient Assistance Program.

<sup>2</sup> Totals are based on the U.S. wholesale acquisition cost (WAC) and cover all programs.

The main driver of the decrease in patient and prescription volumes for 2013–2014 is the periodic changes in the products covered by the various patient assistance programs. These changes are due, in part, to company divestitures, the introduction of competing products and the availability of generic alternatives.

# RESEARCH & DEVELOPMENT

## MAIN

**Our passion is improving health. That is what keeps us at the forefront of scientific discovery and innovation. Applying breakthrough science to develop meaningful new medicines and vaccines is our legacy.**

## OUR COMMITMENTS

- We will evaluate and reflect, where appropriate, the needs of emerging markets in the R&D of our products
- We will conduct our clinical trials, including trials in Low Income and Middle Income countries, in accordance with the global standards of Good Clinical Practices, applicable local regulatory requirements and following the ethical principles that have their origin in the Declaration of Helsinki
- We will collaborate with diverse partners to expand our R&D capacity to address unmet needs, including those in emerging markets and least-developed countries
- We will pursue opportunities to provide access to compound libraries and molecules to spur development of new products

We are committed to addressing unmet medical needs through innovative research and development: R&D expenses were \$7.2 billion in 2014. The talent of our scientists, combined with recent scientific and technological advances, is leading to an exciting period for research as we seek new and more effective ways to treat diseases.

## PIPELINE

Our company prioritizes its research and development efforts on advancing candidates that we believe represent the next areas of breakthrough science that will make a difference and deliver value for patients, physicians and payers. This focus includes candidates that target many of the world's most urgent global health challenges, such as our immuno-oncology program, including KEYTRUDA® (pembrolizumab), which is being studied in multiple oncology indications; a BACE inhibitor for Alzheimer's disease (MK-8931); our next-generation HCV candidate (grazoprevir/elbasvir); and an investigational HIV medicine (doravirine). We also strengthened our portfolio through numerous acquisitions, including Cubist (antimicrobials); Idenix Pharmaceuticals (HCV); and OncoEthix (oncology). In addition, our company initiated several late-stage clinical research collaborations, including working with NewLink Genetics on the development of an investigational Ebola vaccine and a cardiovascular-focused collaboration with Bayer. We pursue therapies in a variety of modalities, including small molecules, vaccines and biologics.

Our company is prominently positioned at the intersection of invention and the burden of disease. Our products and research

priorities are aligned with the current and projected global burden of disease as defined by the World Health Organization (WHO), as well as with the increasing need for new therapies targeted to treatment-resistant diseases such as hepatitis C and antibiotic-resistant infections.

Our research pipeline illustrates the progress of our R&D efforts. We currently have a number of candidates under regulatory review in the U.S. and internationally. An update on our R&D activities can be found in the company's 10-K Report.

## PEDIATRIC R&D

We are including pediatric clinical trials in the company's new drug and vaccine development strategies worldwide, where relevant, in response to unmet clinical needs.

Further, where appropriate, we will seek approval for pediatric indications and develop age-specific formulations. We utilize an internal Pediatric Development Advisory Committee to review and provide input into all pediatric development strategies across various therapeutic areas. The committee serves as a Center of Excellence within our company to consult on pediatric development issues and key pediatric policy questions. For a listing of all of our pediatric clinical trials, [click here](#).

### GRI G4-PR1

Our R&D model is designed to increase productivity and improve the probability of success by prioritizing resources based on scientific opportunity, medical need, and commercial potential. We are committed to advancing our most promising research and clinical development to bring forward new medicines and vaccines that will make a meaningful difference in patients' lives. [Learn more](#).

Faced with the complex challenges of bringing important new therapies to patients while simultaneously controlling the rising costs of innovation, we are using important new preclinical, clinical and quantitative tools to help us rapidly differentiate between developmental candidates that will clearly meet patient needs and those that will not. A focus on genetics, genomics and translational medicine is also critical to these efforts, for instance, enabling us to develop biomarkers—those characteristics that can be objectively measured and evaluated as indicators (or markers) of normal biologic processes, disease or responses to therapy. Since biomarkers provide critical information in the drug discovery and development processes, our intent is to apply them very early in the development of novel therapeutic candidates to provide preliminary evidence of their potential benefit before proceeding with further development.

In addition, we are using novel quantitative approaches to analyzing preclinical experiments to inform our clinical trials and to develop models based on published literature. By integrating our knowledge from these sources, we can develop mathematical models that allow us to explore possible clinical trial scenarios. We now have the capability to first simulate a trial thousands of times, exploring the impact of different factors that influence a specific disease and/or patient population, and the related efficacy and safety of responses.

With this integrated approach we can optimize the next phase of clinical trials and, importantly, make pivotal decisions earlier and more confidently, increasing productivity and improving the probability of success. By eliminating likely failures sooner and focusing on those mechanisms that appear more promising, we believe we can bring innovative products to patients faster, while still maintaining a rigorous focus on scientific excellence and safety.

We recognize that real-world data have a significant impact on how medicines and vaccines are developed and evaluated. Through the contributions of epidemiologists, health economists, outcome researchers, data specialists and other health policy researchers across our company, we strive to comprehensively assess the best available information on the value of our medicines and vaccines.

We also recognize that individuals or companies cannot successfully develop drugs single-handedly. Most cases of true innovation come from robust and honest collaboration among individuals and organizations with diverse backgrounds and capabilities, brought together by the idea of changing the course of human health. As part of our R&D strategy, therefore, we pursue opportunities to establish external alliances to complement our substantial internal research capabilities, including research collaborations, as well as license agreements for preclinical and clinical compounds that have the potential to drive both near- and long-term growth. In this regard, our research laboratories established significant external alliances to advance drug discovery and development, improve R&D productivity, and successfully commercialize novel therapeutics and vaccines. [Learn more](#).

# PARTNERSHIPS

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## We support academic and community-based physicians and researchers in expanding clinical and scientific knowledge and improving understanding of the appropriate use of our products.

Our company's Investigator Studies Program is an example of our effort to advance science and improve patient care by supporting, through the provision of drugs and vaccines and/or total or partial funding, high-quality research that is initiated, designed, implemented and sponsored by external investigators. Results are documented and properly disseminated in peer-reviewed publications.

As an early supporter of the Physician Payments Sunshine Act (PPSA), we believe in broad disclosure of financial relationships between physicians and the pharmaceutical industry. In October 2009, we began voluntarily disclosing all payments to U.S.-based healthcare professionals who speak on behalf of our company, about our products and other healthcare issues.

We now comply with the PPSA provisions of the U.S. Affordable Care Act, which requires pharmaceutical manufacturers to annually disclose information on certain additional payments and other transfer of value furnished to U.S. licensed physicians and U.S. teaching hospitals to the Department of Health and Human Services (HHS). In addition to submitting such information to HHS's Center for Medicare & Medicaid Services each year, we post the information annually on this website.

Visit the [transparency disclosures](#) section of the report for more information and a full list of disclosures.

Our company is a member of and supports numerous professional associations, including the American Association for the Advancement of Science (AAAS), the U.S. National Institutes of Health (NIH), the U.S. National Science Foundation (NSF), the World Medical Association (WMA) and the Institute of Medicine (IOM). In addition to promoting dialogue and the exchange of ideas in research, we sponsor research conferences—such as selected Gordon Research Conferences, an international forum in which researchers discuss advances in biologic, chemical and physical science—that cover areas in which our company is conducting research.

We also collaborate with external researchers and other members of the pharmaceutical industry by participating in selected scientific consortia. Consortia are an important mechanism by which researchers can work together in a precompetitive manner to address complex scientific challenges common to all parties. These consortia are typically in the form of public-private partnerships.

## PUBLIC-PRIVATE RESEARCH PARTNERSHIPS

### **Regenstrief Institute (RI)—Personalized Delivery of Healthcare**

In 2012, we signed a five-year agreement with the Regenstrief Institute to collaborate on a range of projects that will use clinical data to inform personalized delivery of healthcare. The ongoing work explores novel methods for studying diseases and interventions for chronic conditions such as diabetes, cardiovascular disease and osteoporosis.

Regenstrief is an internationally respected informatics and healthcare research organization, recognized for its role in improving quality of care, increasing the efficiency of healthcare delivery, preventing medical errors and enhancing patient safety. Ultimately, the collaboration seeks to improve the health of patients through data analytics, healthcare innovation, education and research that supports evidence-based healthcare.

### **Bayer's soluble guanylate cyclase (sGC) modulators.**

In May 2014, we partnered with Bayer in a new endeavor to develop and commercialize a portfolio of launched and pipeline assets representing a new class of potentially promising cardiovascular compounds called soluble guanylate cyclase (sGC) modulators.

The initial compounds in the collaboration include ADEMPAS® (riociguat)—the first drug approved for both the treatment of patients with pulmonary arterial hypertension (PAH) and inoperable/residual chronic thromboembolic pulmonary hypertension (CTEPH) and marketed for these indications by Bayer in many countries, including the U.S., Germany and Japan—and

vericiguat, currently in Phase 2 development for patients with worsening heart failure. Our company's scientists have years of experience with sGC modulators and are working to advance compounds for future inclusion into the collaboration. In principle, the collaboration is set up to include future sGC assets into joint development whenever they reach Phase 2 readiness.

### **GE Healthcare & Luminex—Alzheimer's Disease**

We are aggressively advancing research on Alzheimer's disease through projects with imaging and diagnostic companies to help determine which patients may benefit most from novel treatments in development.

We have a clinical study collaboration, license and supply agreement with GE Healthcare for the use of Flutemetamol, an investigational positron emission tomography (PET) imaging agent, to support our company's development of MK-8931, a novel oral beta amyloid precursor protein site cleaving enzyme (BACE) inhibitor and our lead investigational candidate for Alzheimer's disease.

Accumulation of beta amyloid in the brain is a pathological characteristic related to Alzheimer's disease. Currently, Alzheimer's disease is diagnosed by clinical examination (i.e., medical history, physical, neurological, psychiatric and neuropsychological exams; laboratory tests; and magnetic resonance imaging [MRI] or computed tomography [CT] scans). A diagnosis of Alzheimer's can only be confirmed through histopathological identification of characteristic features, including beta amyloid plaques, in post-mortem brain samples. There is a serious unmet need for a reliable method for measuring beta amyloid deposits to help physicians diagnose Alzheimer's disease.

We are also collaborating with Luminex Corporation to develop a companion diagnostic device that will be evaluated to help screen patients for recruitment into our clinical development program for MK-8931.

Luminex technology is being used to measure concentrations of two candidate biomarkers (A $\beta$ 42 and t-tau) in cerebrospinal fluid (CSF) samples from patients with mild cognitive impairment (MCI). The candidate device will be evaluated as a means to identify subjects with MCI who have a higher risk of developing AD to support patient selection for our therapeutic BACE inhibitor clinical program.

### **Pfizer, Abide Therapeutics & Samsung Bioepis—Diabetes**

In 2013, we announced early-stage diabetes and metabolic research partnerships as well as clinical collaborations that we hope will bring forward the next wave of oral therapies.

We entered into a worldwide (except Japan) collaboration agreement with Pfizer for the development and commercialization of Pfizer's ertugliflozin (PF-04971729). This compound is an investigational oral sodium glucose cotransporter (SGLT-2) inhibitor being evaluated for the treatment of type 2 diabetes. A Phase IIb study has been completed on ertugliflozin. Under the terms of the agreement, we will collaborate with Pfizer on the clinical development and commercialization of ertugliflozin and ertugliflozin-containing fixed-dose combinations with metformin and JANUVIA<sup>®</sup> (sitagliptin) tablets.

Abide Therapeutics, a biopharmaceutical company pioneering innovative approaches to selectively target a group of enzymes known as serine hydrolases, has entered into a collaborative agreement with our company to discover, develop and commercialize small-molecule therapies directed against three novel targets to treat metabolic diseases, with a focus on type 2 diabetes.

We have also entered into an agreement with Samsung Bioepis to develop, manufacture and commercialize MK-1293, an insulin glargine candidate for the treatment of patients with type 1 and type 2 diabetes. Under the terms of the agreement, the companies will collaborate on clinical development, regulatory filings and manufacturing.

### **Adimab—Biologics**

We continue to expand our biologics footprint through discovery, development and commercialization partnerships.

Adimab, a technology leader in the discovery of fully human antibodies, expanded its existing research collaborations with our company in January 2013. The latest agreement provides our company expanded access to Adimab's technology to discover and optimize fully human antibody candidates, including potentially bispecific antibody candidates, across all disease areas. Adimab scientists will discover therapeutic antibody candidates to multiple targets nominated by our company over a three-year period.

### **Predictive Safety Testing Consortium—Safety-Testing Methods**

We are a member of the Predictive Safety Testing Consortium (PSTC), a unique public-private partnership led by the nonprofit Critical Path Institute (C-Path). The PSTC brings together pharmaceutical companies to share and validate their safety-testing methods under the advisement of the U.S. Food and Drug Administration (FDA) and the European Medicines

Agency (EMA).

The 18 corporate members of the consortium share internal experiences with preclinical and clinical safety biomarkers in kidney, liver, skeletal muscle, testicular toxicity, vascular injury and cardiac hypertrophy. All biomarker research programs have a strong translational focus to select new safety tools that are applicable across the drug-development spectrum. Advancing the science and use of biomarkers in drug development is a critical area of focus for our company. The following are notable PSTC achievements:

- The FDA and EMA qualified seven new urine tests that signal kidney injury
- The PSTC opened a biomarker-qualification process with the FDA for new biomarkers of drug-induced liver and skeletal muscle injury
- The Japanese Pharmaceuticals and Medical Devices Agency (PMDA) qualified new biomarker laboratory tests that signal kidney injury

### **Biomarkers Consortium—Biomarker-Based Technologies**

The Biomarkers Consortium, in which we participate, is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH). Its goal is to combine the forces of the public and private sectors to accelerate development of biomarker-based technologies, medicines and therapies for the prevention, early detection, diagnosis and treatment of disease. Working together, the members of the Biomarkers Consortium are building uniquely powerful collaborations that are accelerating the development of biomarker-based technologies, medicines and therapies.

To date, the Biomarkers Consortium has launched 10 projects in areas as diverse as Alzheimer's disease, cardiovascular disease and breast cancer; a number of other promising projects are also moving toward implementation. Our company contributes to a number of FNIH projects within this consortium.

### **National Institutes of Health Alzheimer's Disease Neuroimaging Initiative (ADNI)**

We continued our participation in the National Institutes of Health Alzheimer's Disease Neuroimaging Initiative (ADNI), the largest public-private partnership in Alzheimer's disease research. This study, which is designed to gain new insights into the onset and progression of Alzheimer's disease, has now expanded to ADNI2, with the goal of improving clinical trial design and aiding drug development. ADNI2 will seek to identify and track early changes in the brain before the onset of Alzheimer's symptoms by using imaging techniques and biomarker measures in blood and cerebrospinal fluid.

### **Accelerating Medicines Partnership (AMP)—New Diagnostics & Therapies**

We are also a member of the Accelerating Medicines Partnership (AMP), a venture between the National Institutes of Health (NIH), 10 biopharmaceutical companies and several nonprofit organizations to transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets of disease. The ultimate goal is to increase the number of new diagnostics and therapies for patients and reduce the time and cost of developing them.

AMP will begin with three-to-five-year pilot projects in the three disease areas of Alzheimer's disease, type 2 diabetes, and autoimmune disorders of rheumatoid arthritis and systemic lupus erythematosus (lupus). Our company is contributing to the type 2 diabetes and rheumatoid arthritis/lupus projects.

### **Innovative Medicines Initiative (IMI)—Accelerating Research**

Within Europe, we participate in a number of Innovative Medicines Initiative (IMI) projects. Europe's largest public-private initiative aiming to speed drug development and improve safety, IMI supports collaborative research projects and builds networks of industrial and academic experts to boost pharmaceutical innovation.

An ongoing IMI project centers on collaboration with the European Patients' Academy on Therapeutic Innovation (EUPATI) by developing standards and trainings for patient advocacy group leaders.

Each of these consortia builds on expertise from partners in academia, the pharmaceutical and biotechnology sectors as well as certain public bodies, to ensure a cohesive approach to these challenging areas of research.

### **Harvard Multi-Regional Clinical Trials (MRCT) Center**

We are a participating member in the Harvard Multi-Regional Clinical Trials (MRCT) Center working group, and have partnered with MRCT to develop a template for return of results for our company's clinical trials based, in part, on EMA requirements.

The Harvard MRCT Center's mission is to improve the design, conduct and oversight of multiregional clinical trials, focusing on trials sited in or involving the developing world; simplifying research through the use of best practices; and fostering

respect for research participants, efficacy, safety and fairness in transnational, transcultural human subject research.

### **Clinical Trials Transformation Initiative (CTTI)/Duke University**

We continue to focus efforts on improving the way in which clinical trials are recruited and conducted.

To further those efforts, we are an active member of the Clinical Trials Transformation Initiative (CTTI), in association with Duke University. CTTI works with industry and academic partners to identify and promote practices that will increase the quality and efficiency of clinical trials, and will foster a high-quality clinical trial system that is patient-centered and efficient, enabling reliable and timely access to evidence-based prevention and treatment options. Current working groups are focused on patient-informed consent processes and standards.

### **Institutes of Medicine (IOM)**

We have partnered with the Institutes of Medicine (IOM), an independent, nonprofit organization that works outside of government to provide unbiased and authoritative advice to decision makers and the public. As a member of the IOM's Health Literacy and Health Care Disparities Roundtable members, we are actively seeking opportunities to improve the representation of racial and ethnic minorities in clinical trials.

In addition, our company worked closely with the IOM and a range of other global organizations in the development of the document *Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk* (Released: January 14, 2015), which articulated a forward-thinking set of standards for the sharing of clinical trial data information.

## **GOVERNANCE**

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### **Our governance structure is as vital to our success as the life-changing products we bring to market.**

Governance defines who makes investment and portfolio decisions, what we invest in and how we'll stay on track to deliver on our goals.

The Research Leadership Team develops the divisional strategy, allocates resources and manages the R&D portfolio. The team comprises the heads of functional areas within our company's research laboratories (MRL), and each area provides expert, efficient support of our drug candidates—ushering them from drug discovery through product-life-cycle management.

## **CODE OF CONDUCT**

All of our employees must abide by our *Code of Conduct*, which applies to the way we work with external researchers, doctors and academics. According to our *Guiding Principles for Business Practices Involving the Medical and Scientific Community*, all activities involving the medical and scientific community that are sponsored or supported by our company, including our subsidiaries, are to have a legitimate, well-articulated business purpose. In addition, all activities are to be implemented in accordance with the highest standards of ethics and integrity, having the utmost regard for patient health and safety.

## **RESEARCH MISCONDUCT**

In accordance with our company's policy, we do not tolerate fraud or misconduct in our research activities—whether by an employee or an external business partner. We deal promptly, directly and appropriately with all reported cases. MRL policy is aligned with our company's *Corporate Policy on Reporting and Responding to Misconduct*.

## **COMPLIANCE**

To help ensure compliance, we have clear policies in place to provide guidance to employees on ethical and lawful conduct. It

is each employee's responsibility to conduct himself or herself ethically and lawfully.

Our company's compliance program is based on Chapter 8 of the U.S. Federal Sentencing Guidelines, Sentencing of Organizations, as amended, which sets forth the elements of an effective compliance program, as well as more specific guidance for the pharmaceutical industry issued by the Office of the Inspector General in 2001. [Learn more](#) about our company's compliance programs.

The company's Compliance Charter has allocated responsibility and accountability for compliance to the divisional level. Therefore, each division has established its own compliance committee to tackle specific divisional issues and requirements.

The stated objective of the MRL Compliance Committee Charter is to ensure ongoing compliance with applicable laws and requirements in all MRL business areas through appropriate management structure, processes and training. To manage compliance in MRL, the committee is composed of the Research Leadership Team. In this way, compliance efforts encompass the entire division and go beyond simply addressing the conduct of clinical trials.

The MRL Compliance Committee also promotes ethical science and provides guidance to MRL employees on our company's standards and corporate policies, as well as necessary education related to specific requirements applicable to the research community.

## PERFORMANCE

R&D Summary	2010	2011	2012	2013	2014
Research and Development expenses (US\$B) <sup>1</sup>	11.10	8.50	8.20	7.50	7.20
Employees involved in research activities	15,500	14,100	13,600	12,300	11,400
New products approved <sup>3</sup>	3	3	3	0	7
Products in the pipeline and under regulatory review <sup>4</sup>	43	34	41	35	33
Top 20 global burdens of illness addressed by our products and pipeline <sup>2</sup>	53%	53%	55%	88%	88%
Established significant external licenses and collaborations. <sup>5</sup>	46	52	61	40	35
Filed U.S. patent applications	220	223	192	159	125

<sup>1</sup> Excludes restructuring and acquisition-related expenses.

<sup>2</sup> As defined by the Institute for Health Metrics and Evaluation (IHME), which replaces the previously used WHO chart of leading causes of disease condition or injury.

<sup>3</sup> Form 10-K

<sup>4</sup> Candidates in our company's research pipeline or under regulatory review are as of February 20, 2015, as reported in the United States Securities and Exchange Commission Form 10-K, page 16, filed on February 27, 2015. This includes candidates in phase II, phase III, or under regulatory review as of February 20, 2015. As candidates attain regulatory approval, they are removed from this pipeline view.

<sup>5</sup> Starting in 2014, this metric no longer includes select early licenses and research collaborations that were included in the metric for previous years.



Research & Development

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# PRODUCT & PATIENT SAFETY

## MAIN

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**We recognize that when people take our medicines and vaccines, they must have confidence in their efficacy and safety.**

### GRI G4-PR1

Our company's medicines and vaccines are widely tested before they are approved for marketing. This testing is governed by a comprehensive regulatory scheme and by our research policies. We assess the safety of our products in rigorous clinical trials before they are approved. We are committed to the timely registration of clinical trial information and disclosure of trial results—regardless of the outcome.

[Learn more about our clinical trials.](#)

#### **Reporting an Adverse Experience in the U.S.**

To speak with one of our healthcare professionals about our company's products, or to report an adverse experience with a specific product, please call our company's National Service Center at 800-444-2080. The center can assist you Monday through Friday from 8 a.m. to 7 p.m. Eastern time. Adverse experiences and product-related emergencies can be reported at any time by dialing 800-444-2080.

Our company's Global Safety function manages a global system for the collection, management and reporting of adverse experience (AE) reports received by our company worldwide. [Learn more.](#)

## MONITORING & COMPLIANCE

The Global Clinical and Pharmacovigilance Compliance (GC&PVC) function at our company is part of our company's Research Laboratories (MRL) Compliance organization, which in turn is part of the Global Compliance Organization (GCO). This group is responsible for conducting independent, periodic audits of the processes, computerized systems, technology and collaborative partners supporting the Human Health and Animal Health divisions within our company. Our company's research laboratories have a comprehensive, risk-based audit and compliance oversight program that encompasses a broad range of GC&PVC audits and assessments of the following:

- Clinical investigator sites: Audits to assess compliance with the protocol and with GC&PVC regulations and guidelines

- Collaborative partners: Pre-contractual assessments and selected post-contractual audits of contracted research organizations (CROs), central laboratories and other third-party business partners and vendors
- Computerized systems and technology: Audits and assessments of the computerized systems and technology supporting clinical development
- Internal process/systems audits: Systematic evaluations of compliance of clinical and animal health development processes with standard operating procedures, Global Development Procedures (ICH-GCP) and other applicable regulations and guidance
- Country operations audits: Periodic and systematic assessments of our company's clinical trial and animal health operations and activities carried out by our subsidiaries worldwide
- Business partner audits: Audits of external companies with which a licensing or development agreement exists in which compliance with contractual and regulatory requirements is assessed
- Verification audits: Audits to verify that the corrective actions that have been implemented are effective at remediating the noncompliance

Through the oversight and implementation of this comprehensive audit program, GC&PVC provides independent assurance to our company's senior management that the operations, processes and computerized systems and technology supporting our Human Health and Animal Health development activities comply with applicable global regulations and guidelines as well as internal company policies and procedures.

## RISK MANAGEMENT

Clinical Safety and Risk Management (CSR) leads the Risk Management & Safety teams for all products, from the beginning of Phase IIb through the end of the product life cycle. CSR is responsible for the formation of a proactive clinical safety risk-management strategy, including the Risk Management Plan, which is a regulatory requirement in many countries for marketed drugs and vaccines.

Development of the overall risk-management strategy incorporates all available internal information (e.g., basic research data and animal and human studies with the product and/or related products) and external information (e.g., literature and public data related to the class of drugs and/or therapeutic target) that contribute to the overall risk-benefit assessment of the product. The strategy focuses on activities needed to identify, evaluate and manage potential patient-safety risks. The Risk Management & Safety teams assess patient safety using product labeling, physician and patient educational programs, and other risk-minimization strategies, as appropriate. The Risk Management & Safety teams also implement strategies to determine the effectiveness of these interventions, as appropriate.

**SafetyMatters Initiative**—The goal of SafetyMatters is to explore and implement the appropriate use of emerging technologies and methods for health outcomes of interest (HOIs) identification and evaluation, and to further improve post-licensure monitoring and evaluation of our marketed products. A cornerstone of SafetyMatters is the proactive development and utilization, as needed, of Disease Cohorts based on data contained in large medical claims and electronic health-record databases licensed by our company. As of March 15, 2015, our company's Pharmacoepidemiology and Database Research Unit has successfully created and utilized 30 SafetyMatters Disease Cohorts in 18 product-specific areas.

**Product Label Reviews**—The ongoing oversight and monitoring of our product labels are a major focus of our safety efforts. Our label review teams monitor information on our products and work with our product safety teams to develop or update product labeling. We communicate relevant information regularly to regulatory agencies worldwide.

**Innovative Medical Evidence Development and Surveillance (IMEDS)**—The Innovative Medical Evidence Development and Surveillance (IMEDS) program is a partnership between the Pharmaceutical Research and Manufacturers of America (PhRMA), academia and the FDA. The IMEDS program is a public-private partnership created to build upon the significant progress made on research methodology by the FDA's Sentinel Initiative, including its Mini-Sentinel pilot. IMEDS's primary objective is to advance the science and tools necessary to support post-marketing evidence generation on regulated products, including safety surveillance and evaluations, and to facilitate utilization of a robust electronic healthcare data platform for generating better evidence on regulated products in post-marketing settings.

Our company supports IMEDS through participation in the Observational Health Data Sciences and Informatics (OHDSI) program, dedicated to advancing pharmacoepidemiology methods development for distributed database systems, and through representation on the Scientific Advisory Committee of IMEDS by our CMO. We continue to explore synergies and linkages between IMEDS and our own SafetyMatters initiative to establish standards for the use of modern epidemiology data sources and analytic techniques for evaluating product safety in observational claims and electronic health-record databases.

## PRODUCT SAFETY

We rigorously study our products, and work with regulators and healthcare professionals over many years to characterize their safety profiles. Initially, test compounds are evaluated in the laboratory. If they pass stringent laboratory tests, the compounds move into next-stage testing in animals. Only a few compounds ever make it that far. If the compound makes it through the animal-testing stage, we then begin clinical development, during which multiple studies are conducted over several years.

Clinical testing begins in Phase I in a small number of people and progresses through Phase III, in which the safety and efficacy of a medicine is rigorously evaluated. If the clinical studies are successful, we submit extensive documentation and data to regulators in a product-licensing application. Before approving a medicine or vaccine for use, regulators scrutinize these extensive data and analyses. Even after a product is approved, we continue to actively monitor the safety of our medicines and vaccines in various ways, including post-marketing studies. If we identify safety issues following a product's approval, we work closely with the regulatory authorities to communicate promptly and appropriately with healthcare professionals and patients.

## COMMUNICATING ABOUT PRODUCT RISKS

### GRI G4-PR3

Our information leaflets in our product packaging contain information on possible side effects and, if appropriate, how to avoid some potential problems. We include contact details on our corporate website for patients, caregivers and health professionals to report adverse experiences in the U.S. Outside the U.S., adverse events are reported according to local laws and practices.

Depending on label changes and their context, we may determine, in consultation with regulatory agencies, that more extensive communications may be appropriate. In such cases, we work with regulatory authorities to contact healthcare professionals in a timely manner, so that they can communicate these findings to patients through appropriate mechanisms. Contacting healthcare professionals might include "Dear Doctor" letters and media releases.

## ADVERSE EVENT REPORTING

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**Global Safety manages a global system for the collection, evaluation and reporting of adverse experience (AE) reports received by our company worldwide.**

Although regulations vary by country, most countries require drug manufacturers to promptly review AE information they receive from any source, both domestic and foreign, relating to the use of their products. Manufacturers are also required to have written procedures in place for evaluating and reporting adverse experiences.

In accordance with global regulatory reporting requirements, we have developed a written procedure to provide personnel worldwide—including all contractors—with a consistent and thorough process for identifying, evaluating and reporting AEs occurring in association with the use of our products. These procedures cover the reporting of AEs originating in clinical studies and those associated with the use of marketed products. Adherence to these procedures ensures timely and accurate monitoring of the safety profile of our investigational and marketed products globally.

To report an adverse experience to regulatory authorities, we need at least minimal information: the name of the our product involved, the adverse experience, an identifiable patient and an identifiable reporter. In addition to submission of individual AE reports to regulatory authorities, either within 15 calendar days or periodically, we also file aggregate reports either quarterly, twice a year or annually for as long as we market a product.

Our Risk Management & Safety teams review adverse experience information received from all sources (foreign, domestic, clinical trials, published literature, post-marketing) for our products and determine what actions may need to be taken with reference to the evolving safety profile of our products. These teams include physicians and epidemiologists who are trained

to review this type of data.

It can be difficult to determine the exact cause of an adverse experience because many patients have more than one condition and may be taking multiple products. Our Global Safety staff takes great care to make sure that AE reporting is as accurate as possible. We review the data to determine if there are any patterns or emerging trends that need additional surveillance.

Another major safety focus is the ongoing oversight and monitoring of our product labels. Our Label Review teams monitor information on our products and work with our Product Safety teams to develop or update product labeling. Information is then communicated to regulatory agencies worldwide.

Employees responsible for monitoring and reporting adverse experiences undergo rigorous training every other year. New employees within our research laboratories—including all contract personnel—working in areas related to clinical research and global safety undergo training on our AE policies and procedures when they join the company. All other employees are trained in AE reporting procedures as part of our Code of Conduct training.

Research & Development

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# CHIEF MEDICAL OFFICER



**The Office of the Chief Medical Officer (CMO) collaborates with external groups and stakeholders, along with colleagues throughout the company, to ensure that the patient remains the focal point of the healthcare ecosystem, as is consistent with our commitment to patient safety and well-being.**

Dr. Michael Rosenblatt, Executive Vice President and Chief Medical Officer, leads this effort, representing the independent voice of patients and medicine within the company at the highest levels and serving as the primary voice of the company to the global scientific and medical community. He advises senior leadership and our company's Board of Directors on key medical and patient safety matters, and also serves as the company's medical spokesperson, communicating with the media and health policy makers about our medicines and vaccines, and our positions on matters affecting patients.

The Office of the CMO collaborates with external physicians and scientists, professional and patient organizations, academic leaders and governments in order to enhance interactions and understanding between the company and the global medical and patient communities, and to foster bi-directional exchange with patient organizations globally. Bi-directional exchange requires that we continually demonstrate our ability to listen to patients to inform our planning while also delivering information that is understandable and meaningful to patients.

Inside the company, Dr. Rosenblatt and his team provide medical, scientific and patient perspective to inform Research and Development, commercial and manufacturing strategies while at the same time providing input on the company's corporate social responsibilities. The team also plays a direct role in fostering health literacy and healthcare equities standards, establishing clinical trial data-sharing guidelines.

We are working with the National Health Council and European Patient Forum to learn from them and to engage in a dialogue to understand the capabilities of their patient organization members. In addition to regulators, health authorities and industry trade organizations, the Office of the CMO is working with leading organizations in the fields of patient engagement and healthcare disparities including the Multi-Regional Clinical Trials Center (MRCT) at Harvard University, Clinical Trials Transformation Initiative (CITI) at Duke University, Institutes of Medicine (IOM), Brookings Institute, National Minority Quality Forum (NMQF) and the Association of Black Cardiologists (ABC). In November 2014, the Office of the CMO was awarded leadership of an Innovative Medicines Initiative 2 (IMI 2) proposal to develop a patient engagement repository that will aggregate learnings from a variety of stakeholders globally.

The CMO and his team play a unique role in helping our company and our employees incorporate the voice of the patient in everything we do, building on our long-standing commitment to helping the world be well.

# CLINICAL RESEARCH

## MAIN

**Clinical testing begins with Phase I studies, which are designed to assess the safety, tolerability, pharmacokinetics and preliminary pharmacodynamic activity of the compound in humans.**

Pharmacokinetics refers to what the body does to the drug, while pharmacodynamics refers to what the drug does to the body. If these initial tests are favorable, additional, larger Phase II studies are initiated to determine the effectiveness of the compound in the affected population, to define appropriate dosing for the compound and to identify any adverse effects that could limit the compound's usefulness.

If data from the Phase II trials are satisfactory, companies will invest in large-scale Phase III trials to rigorously evaluate the compound's safety and efficacy. Upon satisfactory completion of those trials, companies submit regulatory filings for marketing approval with the appropriate regulatory agencies around the world to have the product candidate approved for marketing.

We conduct clinical trials worldwide to evaluate the safety and efficacy of our products. These trials are fundamental to the development of innovative medicines and vaccines that treat and prevent illness in humans. It is our company's policy that all investigational studies in human subjects must be conducted in a manner consistent with laws, regulations and guidelines for the protection of human subjects, including those issued by The International Conference on Harmonisation Good Clinical Practice (ICH GCP). However, individual country regulations and guidelines should remain the primary determinant of specific requirements for the conduct of medical research.

Consistent with the trend in the pharmaceutical industry, significantly more than half of the patients participating in our clinical trials are enrolled outside the U.S., in more than 50 countries. We have a commitment to the study of diverse patient populations, including minorities, women and children in our clinical trials in all regions of the world. As a result, we strive to obtain information among diverse populations, ensuring a thorough evaluation of the safety and efficacy of our medicines and vaccines. These efforts allow us to seek regulatory approvals throughout the world and thereby offer our medicines globally to patients who need them.

### Clinical Research Key Performance Indicator 2011 2012 2013\* 2014

GCP/PV audits by regulatory agencies of the company or clinical trial investigators that led to significant fines, penalties, warning letters or product seizures.	0	0	0	0
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\* Complete Response Letter Received for Sugammadex (MK-8616)

On September 20, 2013, our company received a Complete Response Letter from the Food and Drug Administration (FDA) for the resubmission of the New Drug Application (NDA) for Sugammadex. The letter cited Good Clinical Practice (GCP) inspection deficiencies with respect to a clinical study conducted to assess hypersensitivity. Following discussions with the FDA, we committed to conducting a confirmatory hypersensitivity study, which was completed and submitted to the FDA in

October 2014. While not resulting in significant fines, penalties, warning letters or product seizures, this information is provided for full disclosure.

# CLINICAL TRIALS

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## **Our company is committed to the timely registration of clinical trial information and the disclosure of trial results—regardless of their outcome.**

We comply with all applicable laws and regulations associated with registration of clinical trials in publicly accessible registries and subsequent posting of the results from these trials. We have put into place the processes necessary for compliance with The Food and Drug Administration Amendments Act of 2007 and the European Medicines Agency (EMA) clinical trial Directive 2001/20/EC, including those related to clinical trial registration and posting results. Registration provides patients and physicians with information about clinical trials that are open and recruiting patients. Registration of trials and posting of results after trials are completed enable medical researchers to have timely information about our medicines and vaccines.

### CLINICAL TRIAL REGISTRATION

We believe that clinical trial registries serve an important function for patients and their healthcare providers by enabling them to learn about and gain access to relevant clinical trials of experimental treatments or preventive agents. We continually assess changing global requirements for clinical trial registration and update our clinical processes and practices to make sure the company is compliant with them.

For those who analyze, report or publish the results of clinical trials, a clinical trial registry also provides information on trials in progress and the ability to track such trials over the course of development. We register clinical trials in patients of investigational and marketed products in which treatment is assigned that we sponsor and conduct on [www.clinicaltrials.gov](http://www.clinicaltrials.gov), [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu) or [www.encepp.eu/](http://www.encepp.eu/) at trial initiation.

For our position on clinical trial registries, [click here](#).

### DISCLOSURE OF CLINICAL TRIAL RESULTS

Our company has long been committed to sharing the results of our clinical trials, regardless of their outcome, in a timely manner. Clinical trial results will be disclosed by posting a results synopsis on the following publicly accessible websites: [www.clinicaltrials.gov](http://www.clinicaltrials.gov), [www.clinicaltrialsregister.eu](http://www.clinicaltrialsregister.eu) or [www.encepp.eu](http://www.encepp.eu). We also post trial results synopses on our corporate headquarters website.

If a clinical trial of a marketed product is terminated early for safety reasons, we will promptly disclose medically important information to regulatory authorities and the public, update the status on ClinicalTrials.gov within 30 days, and submit a manuscript to a journal (or post a summary online) within 12 months after the last patient's last visit occurs. If the trial was terminated for efficacy reasons, the results will be disclosed within 12 months after the last patient's last visit occurs. Summaries of terminated trials will provide information about patient disposition, safety and adverse experiences, as well as an explanation as to why the trial was terminated early.

For many years, our company has been committed to publishing results of hypothesis-testing trials in peer-reviewed medical literature. Our [Guidelines for Publication of Clinical Trials in the Scientific Literature](#) are posted online and have been in place, with periodic updates to incorporate any changes in good publication practices for industry-sponsored clinical trials, since 2003. In keeping with our publication guidelines, we disclose balanced and accurate information about our registered clinical trials in the peer-reviewed medical literature. These guidelines contain information about how we work with external authors and contributing writers. We also adhere to the [International Committee of Medical Journal Editors \(ICMJE\)](#) guidelines for authorship, requiring that authors meet all four of the following criteria:

- Make substantial contributions to study conception and design, or acquisition of data, or analysis and interpretation of data
- Draft the article or revise it critically for important intellectual content
- Give final approval of the version to be published
- Be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Our company adheres to the authorship criteria of respected biomedical journals if their criteria differ from those of the ICMJE. In addition, individuals who do not meet the criteria for authorship but who provide support are recognized in acknowledgments when the manuscript is published. Our staff or contract writers whom we hire may facilitate the development of a manuscript when the lead author provides oversight and direction; the efforts of the writers will then be acknowledged in the publication.

Our company also adheres to ICMJE or journal-specific guidelines for disclosure of potential conflicts of interest, including both financial and nonfinancial conflicts, for the full author team.

Our Protocol Transparency Initiative, a voluntary practice of providing the clinical study protocol to biomedical journals upon submission of a manuscript reporting clinical trial results, allows journal editors and peer reviewers to use this protocol in their evaluation of the manuscript for publication. Further, if the journal accepts the manuscript, we allow the journal—at its sole discretion—to post key sections of the protocol on its website when the manuscript is published.

## ACCESS TO OUR CLINICAL TRIAL DATABASES

In addition to disclosing results of clinical trials, we respond to requests from external researchers to share our clinical trial data. We have multiple clinical trial databases that are of high value to the external clinical research community. We evaluate each request based on criteria that balance the need to advance science with the need to protect intellectual property and confidential information. Our evaluations comply with applicable privacy and data-protection laws, rules and regulations.

## CLINICAL TRIAL DATA SHARING

We are committed to the PhRMA/EFPIA Principles for Responsible Clinical Trial Data Sharing.

Learn more about our policies and perspectives:

- Procedure on Access to Clinical Trial Data
- Procedure on CSR Synopsis Posting
- External Scientific Review Board (ESRB) Charter

Scientific and medical researchers who wish to submit a proposal for access to our data may send an inquiry by clicking [here](#).

## CLINICAL TRIAL DESIGN

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**All of our clinical trials are designed, conducted and monitored in accordance with the same global standards, whether they take place in the U.S. or elsewhere around the world.**

We consider many factors when we design a clinical trial:

- **Our questions and objectives:** Clinical study designs vary according to the specific objectives of the study. For example, the design of a study to assess the efficacy of a medicine in treating a particular condition is different from that of one seeking to determine the optimal dose of a medicine in a particular group of people.
- **Statistical appropriateness and feasibility of conducting the study:** To make sure trial results are statistically meaningful, it is necessary before the trial begins to determine the number of patients needed to participate. It is also

necessary to assess the feasibility of successfully conducting the trial.

- **Acceptability of the trial design by regulatory agencies:** When necessary, our Research Laboratories consult with regulatory agencies on design issues.
- **Ethical perspectives**

All of our company studies, regardless of the study design, use a standard format:

- The study objectives and endpoints (i.e., measurements) must be clearly stated before the study begins
- The hypothesis or scientific question being asked by the study must be clearly defined
- A plan for the analysis of the data must be developed before the trial begins and is finalized before the trial is completed

The benefits of this format include strengthening the scientific credibility and regulatory acceptability of the results and ensuring timely data analysis and publication of results.

## DESIGN, CONDUCT, OVERSIGHT & MONITORING

All of our clinical trials are designed, conducted and monitored in accordance with the same set of global standards, whether the trials take place in the U.S. or elsewhere around the world. In addition to following our company's global standards, the conduct of our clinical trials adheres to the International Conference on Harmonisation Good Clinical Practice (ICH GCP) standards and to the principles that have their origin in the Declaration of Helsinki. [Learn more](#) about our policy on clinical trial ethics.

We seek input from local clinical investigators and external consultants with specific, relevant experience when designing our clinical trials. For early clinical trials in Phase II, studies are monitored on an ongoing basis by the clinical director and study team; when appropriate, an internal standing data-monitoring committee (DMC) of MRL senior managers reviews unblinded data from ongoing trials in a prespecified, scientifically acceptable manner. The goals of the DMC are to protect the safety of trial participants and assess whether the risk-benefit profile is favorable. The DMC's recommendations are communicated internally to relevant scientists and can be distributed externally to clinical investigators, review boards or regulatory agencies, as appropriate.

For all Phase III and other clinical trials intended to support registration, studies are monitored by the clinical director and study team. In addition, if unblinded data will need to be monitored to ensure patient safety or to make decisions about continuing a study, a DMC composed of external experts independent of our company is assembled to provide review and make recommendations to us about the further conduct of the study. In addition, it is our policy to establish scientific advisory committees composed of external scientific leaders and our scientists. With the participation of these committees, we can obtain expert advice on the design of the trial, provide for transparent review and discussion of the data, and foster a collaborative approach to the publication and presentation of findings. We also have established a companywide, global approach for assessing clinical safety by implementing internal organ-specific safety boards to support the evaluation and management of organ-specific safety issues.

All protocols and related documents are reviewed and approved by external and independent Institutional Review Boards (IRBs) or Ethical Review Committees (ERCs).

We require assurance that patients involved in trials, and/or their legal representatives, understand the procedures and the use and disclosure of personal health information, the use of biological samples, and the risks/benefits involved in a clinical study. A consent form, approved by both our company and the IRB/ERC and translated into a language familiar to the study subject, must be carefully reviewed and signed by all participants to document that their participation in the study is voluntary and informed. Informed consent is obtained prior to initiation of any clinical study procedures, including those performed solely to determine eligibility for participation in the trial. In circumstances where patients receive payment or reimbursement for trial participation, this compensation is appropriate for the cost and inconvenience incurred and is clearly outlined in the consent form for full transparency. The consent procedures conform to applicable legal statutes and government regulations concerning research in human subjects and the privacy and security of medical information. If a prospective study participant cannot read the form, a patient advocate may read the consent form, with consent documented and witnessed.

## PROTECTING PERSONAL HEALTH INFORMATION

We are a member of the International Pharmaceutical Privacy Consortium (IPPC), an association of research-based pharmaceutical companies formed in 2002 that has worldwide responsibility for the protection of personal health information and other types of personal data. We have been actively involved in the IPPC since 2006 in order to engage in a constructive dialogue with European data-protection authorities and other regulators on privacy standards for biomedical research.

## MONITORING

In accordance with ICH GCP guidelines, trial sponsors should appoint clinical trial monitors who are trained to monitor the trial adequately. Accordingly, ICH GCP training is mandatory for all of our clinical research associates (CRAs) who monitor clinical trials, as well as for all contract research organizations (CROs) that monitor clinical trials on behalf of our company.

CRAs monitoring on behalf of our company will visit sites throughout the study to ensure that:

- The principal investigator and site staff are qualified and have adequate facilities and equipment to conduct clinical research throughout the duration of the study
- Site staff are adequately trained on the protocol, procedures and equipment
- Site staff adhere to protocol requirements, sponsor's development procedures (DPs) and ICH guidelines
- Clinical supplies are stored and dispensed per protocol
- Regulatory file documents are accurate and maintained per ICH guidelines and sponsor's DPs
- Source documentation, including drug accountability logs, is maintained per ALCOA (attributable, legible, contemporaneous, original and accurate) guidelines
- Subject safety is maintained through review of source documentation, including drug accountability logs
- Data reported to the sponsor are accurate and reported per sponsor requirements

## CONTRACT RESEARCH ORGANIZATIONS

Approximately 30 percent of our late-stage development trials are currently outsourced to contract research organizations (CROs) for the execution of studies. Before agreeing to work with each CRO, we perform rigorous capability assessments to ensure that the CRO has adequate procedures, infrastructure and expertise to ensure compliance with Good Clinical Practice (GCP) standards and is aligned with our own Code of Conduct. Clinical trial teams within our company oversee the studies being run by CROs, and periodic audits are performed on CROs with which we do business. If and when we identify violations of the contract or GCP standards, we work with the CRO on a corrective action plan. If improvements are not made within a defined period of time, or if repeat violations are noted and unsatisfactorily remediated, we will limit and possibly cease future award opportunities with a CRO until the issues have been fully remediated.

We have a procedure for early access to non-registered products for named patient programs and country-specific authorizations. This procedure recognizes the importance of providing access for certain patients to new treatments under development.

We may also decide to conduct an expanded access program for a limited number of qualified patients according to a clinical protocol. We may conduct these compassionate-use programs if all of the following circumstances apply:

- The disease is life-threatening or severely debilitating
- No effective alternative treatments are available for patients, or a patient has failed to respond to available treatments
- A patient is not eligible for a clinical trial
- A marketing authorization application is planned in the future

[Learn more](#) about expanding patient access to our company's investigational medicines.

## POST-MARKETING

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## We regularly research the effectiveness and safety profiles of our products.

We conduct several types of studies after approval, as appropriate:

- **Post-approval studies on new indications:** Some drugs may be effective for more than one indication. For example, an oncology product can be developed to treat several types of cancer. In such cases, a clinical trial generally must be conducted to evaluate the safety and efficacy of the drug in each new patient population.
- **Commitments to regulatory authorities:** For some products, regulatory authorities require companies to conduct additional interventional or noninterventional studies after the product is approved. A study could be required for multiple reasons, such as obtaining further information on the safety of the product. We work closely with regulatory authorities to design a study that will fulfill the specific requirement.
- **Epidemiological studies:** We have a long history of working closely with external experts in pharmacoepidemiology to understand the types of patients utilizing our products, as well as to examine the effectiveness and safety profiles of many of our marketed products as they are used in clinical practice in healthcare systems based in several different populations.
- **Pregnancy registries:** For some products, we have systems of active data collection that can facilitate the early detection of teratogenicity, substances or agents that can interfere with normal embryonic development, and other serious adverse experiences in patients who, inadvertently or purposefully, use a particular drug during pregnancy. Useful information about the effects of exposure in pregnancy can best be obtained by the careful collection and analysis of post-marketing surveillance data. Reports of the aggregate data in each registry are updated annually and shared with regulatory authorities.

### Post-Marketing Safety Studies

We monitor the use and safety of our products and we have a long history of conducting post-marketing safety studies to examine our products as they are used in clinical practice. Learn more about our post-marketing activities below. We also work closely with external experts in pharmacoepidemiology and drug utilization to examine the utilization and safety of our marketed products as they are used in healthcare systems based in several populations. These include Kaiser-Permanente (KP) Southern California, KP Northern California, UnitedHealthcare, Pennsylvania and New Jersey Medicare, Harvard Pilgrim Health Care, Nordic Country Registries, the Clinical Practice Research Database and Mayo Clinic Olmsted County, Minnesota.

### Regulatory Agency Training

In 2014, our company supported three venues organized to advance both industry and regulatory agency knowledge and capabilities in their Pharmacovigilance (PV) compliance inspection and oversight roles.

**May 2014:** Annual Drug Information Association (DIA) European Union (EU) Qualified Person for Pharmacovigilance (EU QPPV) Forum: Our company's EU QPPV participated in the annual DIA EU QPPV Forum, co-chairing and facilitating several discussions with regulators and inspectorates on "Practical Challenges with Implementation of the New EU Legislation and Guidance for Pharmacovigilance."

**June & September, 2014:** European Medicines Agency (EMA) Workshops: At the invitation of the EMA, our EU QPPV and deputy each attended two workshops on behalf of both EFPIA and EuropaBio providing input to discussions on next steps for implementation of new/updated EU legislation and guidance for PV. Meeting attendees included European agency regulators and inspectorates.

**July 2014:** MRL Clinical Quality Management was invited to present on the topic of "Quality Management" to the Ministry of Food and Drug Safety (MFDS), South Korea. Meeting attendees included South Korean regulators.

#### Select Post-Marketing Safety Studies

Product	Brief Description	Countries	# of Patients	End Date
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ARCOXIA® (etoricoxib)	To describe dispensed etoricoxib prescribed by dentists including the associated dental procedures, patient demographics, dosing, year and country; to describe any dispensed etoricoxib prescribed by dentists that was not associated with dental procedures; to describe off-label use of etoricoxib among patients aged less than 16 years and with doses >90 mg/day including the associated dental procedures, patient demographics, dosing, year and country; and to describe the duration of use of etoricoxib and the number of tablets dispensed.	Denmark, Norway, Sweden, Finland	500 15-Aug-15
ARCOXIA (etoricoxib)	Analysis of prescribing patterns of etoricoxib by GPs, characteristics of patients prescribed etoricoxib and incidence rates of adverse events (AEs) among patients prescribed etoricoxib in the U.K. using CPRD data.	U.K.	61,184 30-Jun-17
ARCOXIA (etoricoxib)	Analysis of use of etoricoxib in EU patients with Ankylosing Spondylitis (AS), patient characteristics and health outcomes of interest (e.g., upper GI, CV and renal events) for etoricoxib and other NSAIDs using CPRD, THIN and IMS data.	U.K., Germany, France	15,366 31-Jan-18
ARCOXIA (etoricoxib)	To describe characteristics of Swedish patients with AS or Spondylarthropathy (SpA) and analysis of health outcomes of interest (e.g., CV, GI, renal) in AS/SpA patients taking etoricoxib, other coxibs, non-selective NSAIDs and/or not exposed to NSAIDs.	Sweden	22,283 15-Jun-15
GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine Recombinant]	A Post-Authorization Safety Study to assess many aspects of the impact of GARDASIL® vaccine on and related behavioral characteristics of the female population of several Nordic countries.	Denmark, Iceland, Norway Sweden	56,000 19-Dec-14
GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine Recombinant]	To describe the general safety of GARDASIL among males within 60 days following the administration of each dose of the vaccine by estimating: a) the incidence of health outcomes resulting in emergency room (ER) visits or hospitalizations occurring in the combined 60-day risk periods after each dose of GARDASIL; and b) the rates of such health outcomes as compared to rates in a post-vaccination self-comparison reference period (relative rate). As per a commitment to the FDA, the study will end upon accruing 135,000 males or 6 years after study start (2017).	U.S.	135,000 1-Dec-18
ISENTRESS® (raltegravir potassium)	To assess the incidence of predefined HOIs for patients utilizing ISENTRESS and comparative cohorts. HOIs as main outcome include malignancy, hepatic events, lipodystrophy, mortality.	Greece, Italy, Portugal, Spain, Israel, Belgium, France, Germany, Luxembourg, Switzerland, Austria, Denmark, U.K., Finland, Ireland, The Netherlands, Sweden, Norway, Hungary, Serbia, Czech Republic, Slovakia, Bulgaria, Poland, Romania, Croatia, Belarus, Russia, Estonia, Latvia, Lithuania, Ukraine, Argentina	7,742 6-Mar-14
ISENTRESS (raltegravir potassium)	To assess the incidence of prespecified health outcomes of interest (e.g., malignancy, hepatic events, skin events, muscle events, lipodystrophy) among HIV-infected patients treated with ISENTRESS.	U.S.	7,956 9-Dec-14

NEXPLANON® (etonogestrel implant)	To characterize the frequency of specific insertion-, localization- and removal-related events and clinically significant consequences among NEXPLANON users in the U.S. during standard clinical practice.	U.S.	7,100	30-Mar-18
NOMAC/E2® (nomegestrol acetate (+) estradiol)	A prospective observational cohort study to monitor the safety of NOMAC/E2 in women in the EU and Australia.	Australia, Austria, France, Germany, Hungary, Italy, Poland, Russia, Spain, Sweden	101,000	29-Dec-17
PROSCAR®/PROPECIA® (finasteride)	To further investigate the association between finasteride exposure and the development of breast cancer in men residing in Denmark, Sweden, Finland and Norway via registries available in the four countries.	Denmark, Sweden, Finland and Norway	428,000	1-Mar-16
RIBAVIRIN®	Retrospective drug utilization study, which collects data on the prescribing behavior of physicians treating pediatric patients for hepatitis C with RIBAVIRIN.	Italy, Spain, U.K., France, Germany	10 physician sites	31-Mar-15
ROTATEQ®	Noninterventional study to monitor the effectiveness and safety of a new enhanced thermostable Vaccine Vial Monitor-Compatible (VVMC) formulation of Rotavirus Vaccine, Live, Oral (ROTATEQ) in children aged <5 years in routine conditions of use in public health practice in Mali, Africa.	Mali	5,000	31-Jan-19
SYCREST®(asenapine)	To monitor clinically important identified and potential risks within a cohort of patients diagnosed with bipolar disorder and treated with asenapine.	U.K.	3,000	1-Oct-18
SYCREST (asenapine)	To describe on- and off-label use of asenapine.	U.K.	3,000	1-Oct-17
SYCREST (asenapine)	To study the utilization and safety of asenapine in (asenapine naïve) new-user patients and patients initiated in secondary care with shared-care GP prescribing arrangements under normal conditions of use in primary care.	U.K.	5,000	15-Oct-18
SYCREST (asenapine)	To describe the incidence of selected identified risks of asenapine in the mental healthcare setting.	U.K.	1,000	15-Oct-17
TEMODAR® (temozolomide)	Retrospective case-control study within a cohort of patients with malignant brain cancer using a database, augmented with information obtained from medical records, to assess the relation, if any, between temozolomide exposure and severe acute liver injury (SALI).	U.S.	720	16-Dec-15
VICTRELIS®(boceprevir)	To describe drug utilization patterns of VICTRELIS; to describe baseline characteristics of patients initiating treatment and to describe the clinical management of prespecified protocol-defined HOI: anemia, neutropenia, thrombocytopenia and rash.	France, Germany, U.K., Spain	1,000	31-May-16
ZOSTAVAX®	Post-authorization long-term effectiveness study of ZOSTAVAX given to individuals 50 years old and over, enrolled in Kaiser Permanente Northern California healthcare maintenance organization.	U.S.	30,000	30-Oct-23

## PERFORMANCE

	Number of New Product & Device Registrations <sup>1</sup>	2010	2011	2012	2013	2014
Asia Pacific		51	39	64	39	31
Central & Eastern Europe, Middle East & Africa		55	55	61	60	63
European Economic Area		32	28	29	28	22
The Americas		62	55	47	50	52
U.S.		3	2	3	2	8

<sup>1</sup> Data for all years have been updated based on a tracking system upgrade that corrected miscounts in prior years.

Phase II-V Clinical Trials (percentage of patients)	2010	2011	2012	2013	2014
Asia Pacific	10%	8%	16%	35%	49%
Central & Eastern Europe, Middle East & Africa	9%	5%	5%	8%	7%
European Economic Area	30%	19%	26%	33%	21%
The Americas	3%	16%	6%	10%	7%
U.S.	49%	51%	46%	14%	16%

	Summary of Trial Disclosure Activities						
	2010	2011	2012	2013	2014		
Manuscripts of clinical trial results and related papers submitted to peer-reviewed journals			277	245	238	137	146
Number of GCP/PV inspections conducted by regulatory agencies worldwide			87	104	44	149	99



Research & Development

# ANIMAL RESEARCH

**Laboratory animal research is indispensable to the discovery, development, manufacture and marketing of innovative medicines that treat and prevent disease.**

Our company is dedicated to the ethical and responsible treatment of all animals used in the development of medicines and vaccines. We do not perform animal testing for its cosmetic products. Decisions regarding animal care, use and welfare are made by balancing scientific knowledge and regulatory requirements with consideration of ethical and societal values.

## ANIMAL RESEARCH OVERSIGHT

Animal research is highly regulated and monitored by the government and it is also internally monitored by an animal welfare oversight group. A veterinarian with expertise in animal welfare and laboratory animal medicine manages the oversight group and works closely with our company's Institutional Official (IO) for our company's research laboratories (MRL), and our Manufacturing Division (MMD), as well as the IO for Animal Health, to provide independent monitoring of animal research globally. The IO regularly communicates with senior management and our internal compliance committees, as required, to address animal welfare issues. Additionally, all of our company sites hosting animal-based research have active and engaged Institutional Animal Care and Use Committees (IACUCs) or Ethical Review Committees (ERCs) that review, approve and monitor research studies. The committee membership includes veterinarians and scientists knowledgeable in animal-based research and often includes nonscientists and community members. Committees review proposed animal studies and animal care facilities and investigate, as appropriate, any research-animal welfare concerns. The IACUCs/ERCs regularly communicate with and provide status reports to the IO regarding animal welfare compliance.

Global policies and guidelines governing appropriate animal research practices are in place and kept up to date. These standards for the care and use of animals in studies meet or exceed applicable local, national and international laws and regulations. U.S. regulations and annual inspection results can be found at [www.aphis.usda.gov/animal/welfare/index.shtml](http://www.aphis.usda.gov/animal/welfare/index.shtml). As further evidence of our commitment to the highest level of animal care, MRL research sites voluntarily secure a third-party review and accreditation of our animal research programs and facilities by the **Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC)**, an external, independent organization. As of the end of 2014, all MRL facilities are accredited by AAALAC.

Our scientists whose work involves research animals must be trained to perform the duties required. Training includes review of regulations and policies, instruction on how to search for animal research alternatives, explanation of the role of the IACUCs/ERCs and training on how to raise concerns about misconduct. Qualified veterinarians work with the scientific staff to consult on and assist with all animal-related research projects. Our company places high value on its animal welfare stewardship responsibility; violation of these policies is grounds for employee disciplinary action, up to and including dismissal.

## RESEARCH ANIMALS

We are dedicated to the ethical and responsible treatment of all animals involved in the development of medicines and vaccines. Decisions regarding animal use and welfare are made by balancing scientific and regulatory requirements with consideration of ethical, welfare and societal values. Additionally, any investigator proposing a study that may involve discomfort or distress, even if it is relieved by analgesics or anesthetics, must perform a literature search to assure that there is no other viable alternative methodology. It is important to note that a large variety of nonanimal (in vitro, or test tube) studies are performed at our company prior to or instead of animal studies. Research animals are used only to answer important scientific questions or fulfill a regulatory requirement. Animals involved in research within MRL are all specifically bred for research purposes.

In MRL, more than 97 percent of the research animals are rodents. The care and use of laboratory animals in biomedical research is highly regulated. In general, the regulations govern housing, feeding, veterinary care and research project review by the IACUC/ERC as well as unannounced government inspections. Our animal facilities are staffed with veterinarians and professional animal care technicians trained and certified as research-animal experts.

## CONTRACT RESEARCH

We hold similar expectations for standards of animal care and use at our contract laboratories and animal vendors. We perform due diligence on and monitor external laboratories that perform animal studies on our behalf, and hold them accountable for the same regulations and standards that govern our internal animal research. Animal studies may not begin until a site has been approved by the Animal Welfare Compliance Assurance Group. All agreements with contract laboratories include terms regarding our company's expectations for animal care and use as well as regulatory compliance. Additionally, animal research conducted at third-party laboratories is subject to protocol review by a company IACUC/ERC or an equivalent committee. Noncompliance with regulations or standards can lead to termination of the relationship.

## SUPPORT FOR ANIMAL SCIENCE AND RESEARCH-ANIMAL WELL-BEING

We also advocate for the development of best practices and dissemination of information by supporting and participating with nongovernmental organizations to foster a greater understanding of biomedical research, advancements in research-animal science and development of alternatives to animal use.

## REPLACEMENT, REDUCTION AND REFINEMENT

We are committed to the philosophy of using the best scientific methodologies and animal alternatives whenever possible or permissible by law. To promote this commitment, we subscribe to the "3 Rs"—replacement, reduction and refinement—for animal-based research.

**Replacement**—using nonanimal systems or less-sentient species (for example, cell cultures, computer modeling, bacterial assays, and fly or worm models). Our scientists have access to specialized software that searches the scientific literature for viable alternatives to animal research. In addition, the company employs information specialists in our research library, trained by the Animal Welfare Information Center of the U.S. National Agricultural Library, to assist our scientists in identifying potential animal alternatives. We also have extensive in vitro expertise and investments, including an in vitro department that develops and utilizes nonanimal research methods (cell cultures) in the discovery and development of new medicines and therapies, and experts in computer modeling and simulation.

**Reduction**—using the minimum number of research animals necessary to obtain valid scientific data. Sophisticated animal models that yield precise data, such as telemetric monitoring models that monitor ECG and blood pressure, reduce the number of animals needed. In addition to state-of-the-art data collection and sharing systems, we have statisticians on staff who advise on study design and analysis in order to minimize the number of animals included in a study.

**Refinement**—minimizing distress or discomfort. Our scientists conduct extensive literature reviews to choose the best scientific models and design the most effective studies. When animals are required for a study, anesthetics, analgesics and tranquilizers are used whenever possible to minimize or eliminate potential pain or distress.

Our company's Animal Welfare group collects, promotes and internally disseminates information on the principles and practice of the 3 Rs. Training on the 3 Rs is part of staff orientation for animal research. It is our responsibility to use the most appropriate methodology and to aggressively seek scientifically valid 3-R approaches to animal research. As an example of the third R, Refinement, we have created a world-class imaging department that allows scientists to view cancers and other pathologic diseases in animals and monitor the long-term effectiveness of new treatments in a noninvasive manner. In addition, we have voluntarily made the decision not to use chimpanzees (or to fund their use directly or indirectly in studies by external research partners) in biomedical research in the foreseeable future. Recent scientific advances now allow researchers to use alternative methodologies that in many circumstances replace the need for chimpanzees in biomedical research.

## INTERNAL ANIMAL ALTERNATIVE AWARD

To support the 3-R philosophy, since 1994 we have presented an Animal Alternative Award annually to the team or teams of our company's scientists that develop new techniques to support the alternative principle and publish their work to share innovations with the greater scientific community. Awards have been given for reducing the number of animals used by utilizing sophisticated telemetric monitoring, replacing a canine model with a guinea pig model, and applying imaging techniques such as MRI to reduce the number of animals needed for tumor studies.



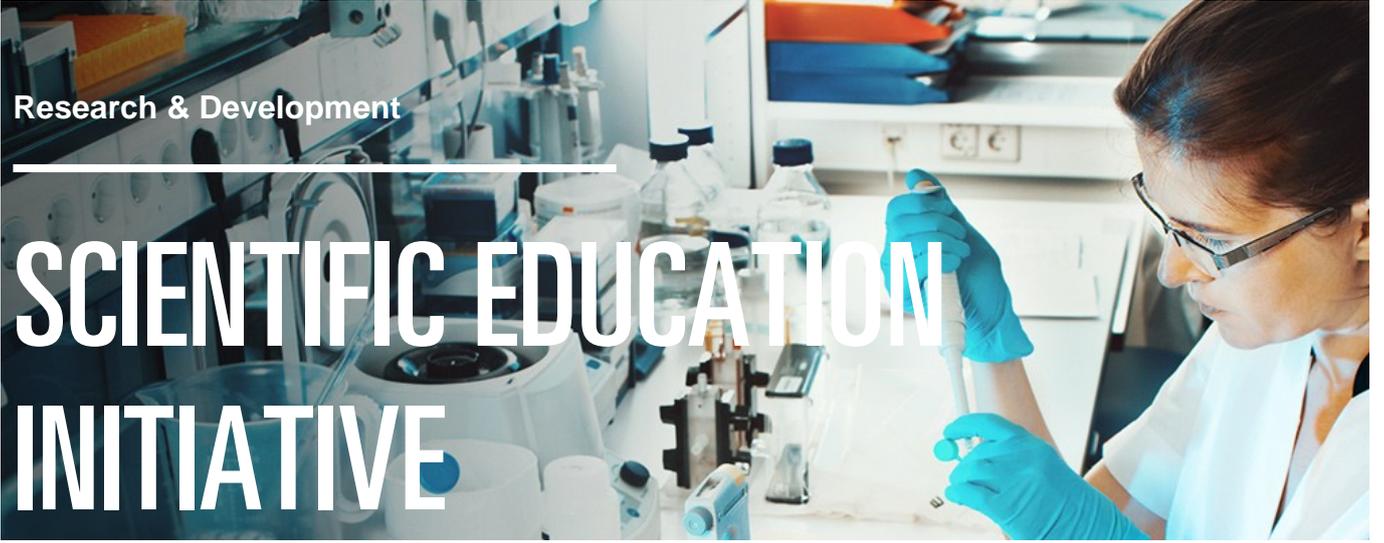
Research & Development

# REGENERATIVE MEDICINE

## Many of the most advanced scientific technologies in regenerative medicine involve animal or human embryonic stem cells.

Together with the scientific community, we believe that research using stem cells has the potential to help identify medicines, therapies and vaccines that will treat, cure or prevent diseases and alleviate the suffering of patients with significant unmet medical needs. Such conditions may include Parkinson's disease, cancer, cardiovascular disease, diabetes, osteoarthritis and trauma. We have been conducting research into the biology of stem cells for more than a decade. This research has involved the use of animal and human stem cells as well as induced pluripotent stem cells.

The company conducts research using stem cells in full accordance with all applicable laws and regulations and our own research policies. Our research policy involving stem cells is guided by the U.S. National Academy of Sciences as well as the International Society of Stem Cell Research guidelines. The Regenerative Medicine Oversight Committee, which comprises both internal and external experts, oversees company-sponsored research involving stem cells, including highly targeted research using human embryonic stem cells, stem cells developed through somatic cell nuclear transfer, and induced pluripotent stem cells. The committee is responsible for ensuring that all projects involving stem cells adhere to our policies.



Research & Development

# SCIENTIFIC EDUCATION INITIATIVE

## We're collaborating with academia to educate tomorrow's doctors about biopharmaceutical development.

The rigorous curriculum of medical school is designed to give future physicians the information and skills they need to begin clinical practice. For most, clinical practice will inevitably mean prescribing a medicine or vaccine to a patient. Yet few medical students are trained to understand the drug development process or how pharmaceutical research can be applied to patient care. In 2010, our company and the Yale School of Medicine collaborated to bridge this knowledge gap.

Our Drug Development Program, in partnership with Yale University is a comprehensive, five-module, six-hour Web-based course on drug development, established for second-year medical students and graduate students in health sciences. Authored by our scientists and medical professionals and approved by Yale faculty, the program has been utilized by more than 45 academic institutions. The program consists of an interactive course that takes students through the development process from target identification and validation through the clinical trial, the regulatory review process and post-approval monitoring.

A second course on the Principles of Clinical Research and Design (PCRD) was developed in 2011 in response to a call for action from the NIH Clinical and Translational Science Awards (CTSA) program to foster new collaborations between academia and industry. Additionally, many universities outside of the U.S. requested information to better understand how clinical studies are designed and implemented. The course includes topics on both interventional and noninterventional studies and addresses the concepts of bias and confounding, randomization and blinding, etc.

Today the programs are part of the Scientific Education Initiative in our Global Center of Scientific Affairs within our company's research laboratories. The e-initiative is a program focused on working with academia to develop and share high-quality, balanced, unbranded education on translational science topics.

"When industry and academia share knowledge and expertise with one another, we all learn—and we all benefit. Collaborations enable a win for patients, academic institutions and businesses. By sharing our expertise about drug discovery and clinical research, we're helping future physicians to fill a knowledge gap and we're helping to deepen the respect for and understanding of the roles the drug researcher and the physician play in promoting health."

*Michael Rosenblatt, M.D.*

*Executive Vice President and Chief Medical Officer*

Since the program was first introduced, the courses have been translated into five additional languages (Spanish, Mandarin Chinese, Japanese, Turkish and Russian). Case studies and other resources are being developed with collaboration from The Ohio State University's Center for Clinical and Translational Science (CCTS).

"We are very excited to participate in this collaboration with Merck & Co., Inc. Kenilworth, NJ, USA. By providing a comprehensive introduction to the primary methodologies used in clinical research with both real-life and hypothetical illustrative case studies, we believe we can better inform our trainees about the processes that translate discovery to the bedside, and ultimately into clinical practice to influence our ability to improve health."

*Rebecca Jackson, M.D.*

*Associate Dean for Research*

*The Ohio State University, College of Medicine and Director of the CTSC*

Since the end of 2014, the courses have been used by more than 45 schools in 13 countries.



Research & Development

# GENETIC RESEARCH

**Genetic research examines how variability in DNA affects the system of human biomolecules (such as RNA and proteins) as well as the consequent phenotypes to affect human disease or patient response to drugs.**

The rapid development of new technologies that interrogate variability in human DNA, combined with powerful computing hardware and software, has made it practical to investigate genetic determinants for risk of human disease or predictors of human response to drugs.

Our scientists have a strong commitment to understanding how genetic variation is associated with disease and response to drug treatments. This commitment includes understanding variation in human genes to identify new drug targets, as well as investigating human genetic variation that might predict which patients are most likely to respond efficaciously or with adverse reactions to a specific drug.

We conduct genetic research using approaches that include:

- Collaboration with external organizations that have collected human genetic samples and health data
- Our own clinical trials

Collecting genetic samples is a critical foundation for clinical genetic research strategies. We collect genetic samples in our clinical trials primarily to understand how variable genetics impact patient response to the drugs. This enables us to communicate information to regulatory authorities and prescribers that will improve the use of our medicines.

During clinical trials, we obtain appropriate subject consent for use of the genetic samples in accordance with the ethical principles that have their origin in the Declaration of Helsinki, U.S. FDA requirements (21 CFR 50.20, 50.25 and 50.27), the International Conference on Harmonisation (ICH) E6 Good Clinical Practices guidelines, and the 1997 UNESCO Declaration on the Human Genome and Human Rights. When collaborating with external organizations, we ensure that consent has been obtained by individuals who have contributed DNA and/or health-related data to the organization via these same standards.



Research & Development

# BIOLOGICS AND BIOSIMILARS

**Our company is focused on building its biologics capabilities to enhance its growing pipeline of biologics-based therapeutic candidates. We also remain committed to delivering high-quality biosimilar products to help meet the growing needs of patients and healthcare systems worldwide.**

## BIOLOGICS AND BIOSIMILARS

Biologics have revolutionized the treatment of patients suffering from some of the most debilitating and life-threatening diseases, and the potential for discovering novel biological therapies remains high. Biologics are complex proteins derived from living sources and are generally more complex than small-molecule drugs, which are usually produced through a chemical process.

In addition to our robust and expanding pipeline of originator biological products to address unmet medical needs, we believe high-quality biosimilars can improve patient accessibility to these lifesaving biological medicines across the globe, while respecting the intellectual property rights of the originator.

## PORTFOLIO AND PARTNERSHIPS

We are developing a diversified portfolio of innovative biologic candidates targeting several important clinical indications, including immuno-oncology and recurrence of *C.difficile* infection. In September 2014, we entered into an exclusive worldwide licensing agreement (through respective subsidiaries) with Sun Pharmaceuticals Industries, Ltd., for tildakizumab, our investigational therapeutic antibody candidate currently in late-stage clinical trials for the treatment of chronic plaque psoriasis.

In February 2015, we entered into a broad strategic collaboration with NGM Biopharmaceuticals, Inc. to discover, develop and commercialize novel biologic therapies across a wide range of therapeutic areas. The collaboration includes multiple therapeutic candidates currently in preclinical development at NGM, including one being evaluated for the treatment of diabetes, obesity and nonalcoholic steatohepatitis (NASH).

In 2013, we entered into an agreement with Samsung Bioepis Co., Ltd. to develop and commercialize multiple biosimilar candidates. Since 2013, this partnership has made significant progress on a portfolio that includes biosimilar candidates in

immunology, oncology and diabetes. Five biosimilar candidates are in Phase III development and are expected to be filed with regulatory authorities around the world between 2015 and 2016.

Under the agreement, Samsung Bioepis is responsible for clinical development, process development and manufacturing, clinical trials and registration for four of the five drug candidates. Our company is responsible for those activities for the remaining drug candidate and has full responsibility to commercialize all approved products. This agreement allows our company to efficiently advance a portfolio of biosimilar candidates with Samsung Bioepis while continuing to progress an internal pipeline of innovative therapeutics.

## PUBLIC POLICY

Our advocacy position on biologics and biosimilars is built upon a foundational objective of seeking to improve health outcomes while maintaining patient safety. All of our policies associated with biologics, biosimilars or any other drug regulation are motivated first and foremost by our focus on the patient.

Our advocacy recognizes the complexity of all biologic products, both innovator biologics and biosimilars, and seeks to establish sound policy parameters for development and use of biologics that ensure patients have access to high-quality, safe and effective medicines. Our policies regarding biologics and biosimilars are based on science and reflect a balanced approach consistent with our status as a developer of both biosimilars and originator biologics.

For more information, please refer to our public policy statement on [Biosimilars and Originator Biologics](#).



Research & Development

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# GLOBAL BURDEN OF DISEASE

**Through a systematic and critical evaluation of our capabilities and an analysis of unmet medical needs, we focus our research efforts on several priority disease areas.**

Focusing our research in this direct manner ensures that we will continue to develop drugs and vaccines to address unmet medical needs. Our current pipeline and list of marketed products are aligned with major global burdens of disease, based on the Global Burden of Disease 2010 (GBD2010) study.

Using the GBD2010 Visualization tools developed by the Institute for Health Metrics and Evaluation (IHME), the diseases that we are addressing rank high on the list of worldwide causes of death. Our research into vaccines and infectious diseases addresses major burdens of disease that are prevalent in all countries, and our preventative treatments could have the greatest immediate impact in the developing world, where healthcare infrastructure is weak or nonexistent.



## 2010 Mean Rank (95% UI)\*

1	Ischemic heart disease
2	Stroke
3	COPD
4	Lower respiratory infections
5	Lung cancer
6	HIV/AIDS
7	Diarrhea diseases
8	Road injury
9	Diabetes
10	Tuberculosis
11	Malaria
12	Cirrhosis
13	Self-harm
14	Hypertensive heart disease
15	Preterm birth complications
16	Liver cancer
17	Stomach cancer
18	Chronic kidney disease
19	Colorectal cancer
20	Other cardio & circulatory

 Communicable, maternal, neonatal, and nutritional disorders

 Injuries

 Non-communicable diseases

\* Source of table: GBD2010 Visualization tool, Institute for Health Metrics and Evaluation (IHME)

Considering **our pipeline** and the list of products we currently market, we estimate that our company addresses 88 percent of the top 20 causes of death as defined by the IHME, excluding road injury, self-harm and preterm birth.



## MAIN

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**Our company is committed to providing patients and customers with a reliable supply of high-quality, safe and effective medicines and vaccines.**

### OUR COMMITMENTS

- We will maintain strict quality standards and effective supply-chain management to ensure the efficacy, safety and supply of our products no matter where they are manufactured
- We will sustain an interdependent, flexible supply chain to take into account global and local market supply needs
- We will engage and invest in local and regional partnerships to enable market access

We manufacture medicines and vaccines that are sold in more than 140 countries.

#### GRI G4-PR1

Our product quality and safety processes and procedures are broad in scope and include stringent standards, compliance education and training. We also support industry and regulatory efforts to develop and optimize quality and manufacturing standards worldwide, including alignment with those of the International Conference on Harmonization (ICH). Our commitments in this area are unequivocal in our role as a global healthcare leader.

#### GRI G4-12

We seek to develop the capacity and capability to serve a significant proportion of the world's population. Our manufacturing division has undertaken an ambitious program to reduce the cost of production by reducing underutilized capacity, increasing efficiency through Lean and Six Sigma projects at manufacturing sites, reducing procurement spending and improving supply performance, including on-time deliveries and reduction of supply shortages.

Furthermore, we have entered into manufacturing and supply agreements with local manufacturing partners to broaden access to our products in local markets, including in Russia, China and Saudi Arabia and in Latin American countries.

We remain committed to providing our patients and customers with a reliable supply of high-quality, safe and effective medicines and vaccines. Since 2013, we have increased the number of products available through these partnerships by 41 percent through our business development efforts. We strive to have relationships with partners that meet our standards for quality manufacturing and distribution and today have 104 relationships that we are engaged with to provide access to our products.

# PERFORMANCE

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	Manufacturing & Supply Summary	2012	2013	2014
Number of local and regional manufacturing partnerships to enable access		84	68	104
Number of products available by local and regional partnerships		34	354	499

# QUALITY & SAFETY STANDARDS

## MAIN

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**From research and development to the manufacturing and distribution of our medicines, vaccines and other products—safety, quality and efficacy are our primary considerations.**

### GRI G4-PR1

We apply and adhere to a strict set of quality standards, and we have policies and procedures in place to identify, measure, control and sustain product-quality excellence. We continuously strive to improve these standards in order to enhance procedures and ensure ongoing compliance with Current Good Manufacturing Practices (CGMPs).

All manufacturing facilities that we own and operate, and any company from which we purchase formulated pharmaceuticals, active ingredients and sterile products, must comply with Current Good Manufacturing Practices (CGMPs). These standards include requirements for incoming materials, manufacturing, storage, handling and distribution of products.

Counterfeit products are a growing global problem and a serious threat to public health. We believe that maintaining the integrity of our supply chain is of paramount importance. Our corporate global anti-counterfeiting program has three primary goals: securing the supply chain; deterring, rapidly detecting and responding to counterfeit activity; and raising public awareness about the risks posed by counterfeits. To learn more about our anti-counterfeiting program, [click here](#).

## SUPPLIER SELECTION

Our company maintain strict quality standards no matter where our products are manufactured. Once we have made a decision to engage an external manufacturer, that manufacturer is required to comply with our business requirements set forth in the contract, regardless of geography.

We conduct audits of every potential new supplier of active pharmaceutical ingredients or formulated products and sterile products to determine its acceptability and compliance with CGMPs. We review the systems that the potential supplier uses to purchase materials in order to ensure the quality of the products the supplier hopes to provide to us. Only if a supplier meets our stringent criteria, which include a review of the company's regulatory inspection and outcome history, will we then negotiate a commercial agreement. These agreements include detailed provisions relating to the quality standards we require suppliers to uphold in order for them to manufacture a product for our use. To learn more about how we work with external suppliers, [click here](#).

## AUDITS AND INSPECTIONS

We conduct periodic audits to further ensure that suppliers continue to meet CGMPs. Through such audits, we evaluate the continued acceptability of the facility from a quality assurance and regulatory compliance perspective.

The frequency of quality auditing depends on a number of factors, including:

- The nature and complexity of the product produced (e.g., whether it is a formulated pharmaceutical, active ingredient or sterile product) and how it is used by our company.
- Reliance on supplier test results and previous audit results

Quality tests are performed on all active pharmaceutical ingredients that we purchase as part of our overall supplier-qualification process, and further tests are performed during subsequent stages of manufacturing. Quality tests are performed on all formulated products before we release them to the marketplace.

Testing of chemicals used in the manufacturing of our products is conducted in accordance with our specifications, which in many cases include the applicable Pharmacopeia standards (i.e., the United States Pharmacopeia (USP), the European Pharmacopeia (EUP) and the Japanese Pharmacopeia (JP)). The USP is the official standard for all prescription and over-the-counter medicines, dietary supplements and other healthcare products manufactured and sold in the U.S. These standards are also recognized and used in more than 130 countries.

## EDUCATION AND TRAINING

We provide appropriate and ongoing training on quality and CGMPs for our employees, to ensure that they are prepared to perform their duties effectively. These systems not only ensure that all applicable employees are trained, but they also monitor the effectiveness of training.

## PERFORMANCE

### GRI G4-PR2

Quality & Product Safety	2010	2011	2012	2013	2014
Number of product recalls in the United States <sup>1,2</sup>	7	0	4	2	3
Annual percentage of units manufactured/sold and recalled during a given year (our recall rate globally) <sup>1,2</sup>	NR	NR	0.19%	0.11%	0.22%

<sup>1</sup> Definition of Recall Classifications: <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm#RecallClassifications>. <sup>2</sup> Beginning in 2014, product recalls now include data from our Animal Health business.

In 2014, we initiated a total of three product recalls in the U.S. These were voluntary actions undertaken by the company as part of our commitment to ensuring product quality. These recalls specifically included two human health product Class III FDA recalls and one animal health product USDA recall. The recall classifications were determined by the FDA, after consultation with Merck & Co., Inc., Kenilworth, NJ, USA.

# PRODUCT SUPPLY

**Our global supply strategy leverages both our internal manufacturing capabilities and those of external manufacturers that provide specialized skills, expertise and various types of manufacturing services.**

This strategy is designed to ensure that we are operating a lean and efficient network while ensuring compliance with rigorous quality, safety and environmental standards.

In 2013, we received U.S. Food and Drug Administration (FDA) and EU approval to manufacture bulk varicella at our company's site in Durham, North Carolina for use in our vaccines to protect against chickenpox and shingles. The approval has enabled the site to produce bulk varicella supply for the U.S. and helped to boost our overall global supply capabilities. The Durham facility has been part of our more than \$1 billion investment in our vaccine manufacturing capabilities over the past nine years. Our company has also modernized and expanded vaccine operations at its facilities in West Point, Pennsylvania and Elkton, Virginia, and built a new facility in Carlow, Ireland. In April 2015, the new facility in Carlow received approval to supply PNEUMAOVAX<sup>®</sup>23, with plans to obtain approval to fill GARDASIL<sup>®</sup>9 (Human Papillomavirus 9-valent Vaccine, Recombinant), our 9-valent HPV vaccine, in early 2017.

We have made progress in creating adequate manufacturing capacity for most vaccines, including, as appropriate, redundancy in our supply chain for certain vaccines, so that we eliminate supply disruptions when temporary issues arise in manufacturing.

Antivenin (*Latrodectus mactans*) (Equine), commonly referred to as Black Widow Spider Antivenin (BWSA), is on allocation (high demand) and is listed on CBER's (Center for Biologics Evaluation and Research) website for products under allocation. The allocation protocol limits customers' purchases to two doses.

Our BCG vaccine, used to treat tuberculosis and bladder cancer, is on backorder. We are committed to resuming supply and being out of backorders by 1Q2016.

As part of our efforts to continuously improve our manufacturing, we have implemented enhancements to our manufacturing processes. Our goal is to ensure consistent manufacturing and quality standards at all facilities, to drive sustainable compliance excellence and long-term performance at the sites, and to minimize manufacturing issues in the future.

We remain committed to the development and commercialization of our products and to ensuring that we are a reliable global supplier of quality vaccines and medicines.

# ANTI-COUNTERFEITING

## MAIN

Producing, distributing, marketing and/or selling counterfeit medical products are serious criminal offenses, and the threat of these actions has become a significant global public health risk and reality. Counterfeit pharmaceuticals can include the wrong doses of an active ingredient, no active ingredient or, in some cases, harmful or poisonous ingredients.

We define a counterfeit medicine as a product that contains an unauthorized use of trademark, trade name, other identifying mark, imprint or device, or any likeness thereof to adulterate, falsely purport or falsely represent a product or material's identity, source, or history. As counterfeiters have become more sophisticated, counterfeit products have become so similar in appearance to authentic products that, without laboratory testing, it is often difficult to tell the authentic from the counterfeit medicines.

## ANTI-COUNTERFEITING STRATEGY

Maintaining product efficacy and patient safety, and protecting our reputation, are paramount. We maintain a comprehensive, worldwide anti-counterfeiting strategy and operational program that has three primary strategic deliverables:

- **Product & Supply Chain Security:** Enable product protection through use of sophisticated product-security features and supply chain security measures
- **Investigations & Enforcement:** Deter, detect and respond to counterfeit activity in ways that mitigate risks to patient safety
- **Advocacy, Engagement & Awareness:** Raise public and stakeholder awareness of the risks posed by counterfeits, and advocate for increased enforcement to shape relevant regulatory requirements

To focus our work in this area, our Anti-Counterfeiting Steering Committee oversees our global anti-counterfeiting strategy to ensure that our goals are reached.

The cross-functional team is led by senior leaders from Global Human Health, Quality, Manufacturing, and Global Security. These areas are responsible for the worldwide marketing and sale of our products, investigating suspected counterfeit events, testing suspected counterfeit products and preparing investigative reports.

Other functional areas involved in our anti-counterfeiting efforts include: Packaging Technology, which incorporates security features into our products; Legal, which manages trademarks and other forms of intellectual property, and provides Global Security with information necessary to assist law enforcement and regulators in enforcement efforts; Global Public Policy, which coordinates our advocacy activities to support stronger anti-counterfeiting laws; and Compliance, which liaises with

federal regulators in relation to the management of controlled substances.

## ANTI-COUNTERFEITING OPERATIONS

Consistent with our long-standing commitment to provide high-quality, safe and effective medicines and vaccines to patients who need them, we executed a comprehensive Anti-Counterfeiting Operations program that delivers on our three primary strategic deliverables.

### Product & Supply Chain Security

We carefully manage our supply chain through strict policies and procedures designed to keep the legitimate drug distribution system safe and secure. In the U.S., for example, we require customers to purchase our products directly from our company or distributors authorized by our company. In addition, we publish the names of authorized distributors on our corporate headquarters' [website](#). We conduct risk-based audits of our distributors to ensure compliance with our policies and procedures. Proactive threat assessments are also completed on facilities and supply routes identified to be at risk for cargo thefts and other illicit activity.

Product security features deployed on our products are a key measure taken to protect our patients. Our pharmaceutical products are protected with best-in-class product-security features, uniquely applied on the basis of a global, risk-based assessment methodology. Our key focus in this assessment is the patient-safety threat should a counterfeit or illegally diverted product of our company be introduced into the supply chain.

Each of our new drugs is assessed using this methodology for risk prior to regulatory approval. The risk level assigned to a new product is used to determine which product security features will be included on the product and packaging prior to the product's market release. A complementary threat assessment is also performed on marketed products for which a credible counterfeit threat has been identified and for which updates to packaging security features may be required.

These product security features, along with our advanced forensic detection capabilities, enable us to accurately authenticate all finished products in our portfolio.

Serialization—or putting a unique identification number on each package that goes to market—is one of the tools we are investing in to secure our supply chain and prevent counterfeiting. A serial number on individual packages enables anyone along the supply chain—from a distributor to a pharmacist to a patient—to scan the code and authenticate it as a genuine product of Merck & Co., Inc., Kenilworth, N.J., USA.

Serialization is an important part of the company's efforts to combat the threat of counterfeit drugs, as it adds a robust layer to the company's product-security platform. It provides the ability to uniquely identify and rapidly authenticate individual packs.

Many countries around the world are requiring serialization on pharmaceutical packages, or are considering such mandates. Serialization is required today in China, Turkey, Argentina, South Korea, Nigeria and India, and will soon be required in Saudi Arabia, Brazil, the U.S. and Europe. Unfortunately, each country's regulations are different, making it very challenging for our packaging sites and distribution networks to meet these diverse and complex requirements. We responded by launching the Global Product Serialization Initiative in 2012, with the goal of meeting these varying requirements in a robust, standardized and effective way. We are working with industry associations and regulatory authorities to help shape these new requirements, and advocate for simple, standardized and common-sense regulations that are truly effective at protecting against counterfeit products.

### Investigations & Enforcement

Our company's Anti-Counterfeiting operations are driven by intelligence-led decisions to identify, prioritize and aggressively pursue criminal enterprises responsible for the manufacture and distribution of counterfeit and other illicit medications, and to identify and enable meaningful enforcement actions against those offenders.

We respond to every notification of suspected counterfeit or illicit medicine, responding in alignment with local regulatory requirements and in support of our global patient-safety mission. We also proactively conduct threat assessments and other risk-based operations to identify offenses that threaten the health and safety of patients. These proactive activities are intended to identify, assess and develop effective enforcement actions for high-value targets engaged in illegal activities involving our products that have the potential for negative patient-safety impact.

Another key aspect of investigations is the forensic analysis of suspect products. This forensic testing is aimed at concluding if a suspect product is counterfeit, diverted, or otherwise illicit. Counterfeit products are characterized to gain further intelligence

and understanding of the counterfeiters and the threats to public health. Our company also has forensic detection devices in the field to analyze and detect counterfeits in different regions around the world. As counterfeiters improve their skills and techniques, our forensic scientists have pioneered the use of several analytical tools for pharmaceutical-counterfeits detection, and continue to explore new analytical tools that would increase their forensic-testing capabilities. Lab findings are shared with regulatory and/or law enforcement agencies, and may be used to support subsequent enforcement actions and legal proceedings.

To support and enable enforcement actions, we partner with law enforcement agencies to detect and respond to threats from counterfeit products. This includes working with U.S. authorities on the importation of counterfeit pharmaceuticals and with EU authorities on the importation and/or transshipment of counterfeit pharmaceuticals through the EU. Working with customs authorities, we have helped identify high-risk ports, borders and postal depots, and have provided a framework of action for use by customs authorities to detect and respond to counterfeit activities. This training enables customs agents to identify suspicious pharmaceutical shipments and take appropriate actions to detain suspicious shipments and/or have suspect products analyzed.

### **Advocacy, Engagement & Awareness**

We are committed to cooperating with relevant government agencies, other pharmaceutical manufacturers, wholesalers, distributors, health professionals, consumer groups and key related organizations in fighting the problem of counterfeit pharmaceutical products and in educating the public about the risks of counterfeit products and how to protect against them. This effort includes a multi-pronged approach to communicate the threat that counterfeit medicines pose and to mitigate this threat as effectively as possible, recognizing that it cannot be entirely eliminated.

Collaboration and information-sharing in order to raise public and stakeholder awareness of the issue and risks is a crucial focus of our Anti-Counterfeiting program. Through active partnerships with other pharmaceutical companies, and associations focused on security, patient safety and public health, we provide effective advocacy on high-priority anti-counterfeiting policy initiatives. Our Global Security staff provides law enforcement and customs training worldwide. In 2014, our Global Security trained more than 3,400 law enforcement and customs officials worldwide.

Additionally, we actively collaborate with international law enforcement agencies that prioritize the investigation, prosecution and disruption of counterfeit medicines and associated criminal enterprises. One example of our public-private collaborations for anti-counterfeiting is our participation in the Pharmaceutical Industry Initiative to Combat Crime (PIICC), a program initiated by the international police agency, INTERPOL. PIICC is aimed at providing investigative support and capacity-building for pharmaceutical crimes through the organization and coordination of regional and global operations to expose, disrupt and take down transnational criminal networks engaged in pharmaceutical crime. PIICC programs include trainings, information dissemination and investigative analytical support.

We further support efforts to educate the public about the risks of counterfeit drugs and how to protect against them, as well as efforts to develop industry collaborations to support a unified response to the threat of counterfeit medicines. Our partnerships with the Pharmaceutical Security Institute (PSI), the Association of Safe Online Pharmacies (ASOP), the International Anti-Counterfeiting Coalition (IACC), the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) the Partnership for Safe Medicines, Quality Brands Protection Committee of China Association of Enterprises with Foreign Investment (QBPC) and the Rx360 Consortium are a few of the industry collaborations in which we participate. These collaborative efforts support the production of reports, white papers and data-circulation initiatives, as well as promote the intelligence-sharing necessary to combat threats from counterfeit medicines.

## **PUBLIC POLICY**

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**We support increased enforcement of existing anti-counterfeiting laws and the adoption of new public policies to strengthen existing laws and enforcement programs, including increased criminal and civil penalties for counterfeiters.**

We advocate for such change in a number of ways:

- As a member of the Alliance for Safe Online Pharmacies, we support initiatives to raise awareness of the dangers of

purchasing from rogue sites and of the options to access legitimate online pharmacies

- As a member of the Global Intellectual Property Center, we support the White House's Intellectual Property Enforcement Coordinator
- As a member of the Pharmaceutical Distribution Security Alliance (PDSA), our company supported the passage of the Drug Quality and Security Act (DQSA), U.S. legislation that creates a national system and uniform standards to track products across the pharmaceutical supply chain. PDSA includes over 20 partners in the domestic pharmaceutical distribution supply chain working to achieve a national solution toward product tracking.
- We support the Anti-Counterfeiting Trade Agreement, which increases protection against a wide range of intellectual property infringements
- In 1997, our company and other pharmaceutical companies created the Pharmaceutical Security Institute (PSI) to develop global security strategies focused on both prevention and enforcement to ensure public safety and product integrity. We continue to be an active participant in this organization, and are pushing for increased levels of intelligence-sharing among the members.
- Our company supported the SAFE DOSES Act, which was signed into law in the U.S. in October 2012. The bipartisan legislation modernizes the U.S. Criminal Code to increase criminal penalties for medical-product cargo theft and provides law enforcement tools to deter this criminal behavior and take down the organizations that are perpetrating it.

## PERFORMANCE

	Summary	2010	2011	2012	2013	2014
Investigations of suspected counterfeit product <sup>1</sup>		179	164	116	222	434
Substantiated cases of counterfeit product <sup>1</sup>		122	106	48	40	107

<sup>1</sup> In 2014, this number has increased as a result of a change to internal reporting guidelines for suspected counterfeit events.

## COMMITMENTS

- Continue in the execution of a proactive, worldwide corporate anti-counterfeiting strategy focused on securing the supply chain, detecting and responding to counterfeit events, and raising awareness of the risks of counterfeit pharmaceutical products
- Take proactive measures to identify, assess and mitigate threats to our patients associated with counterfeit and other fraudulent products
- Take actions to raise public awareness of the risks posed by counterfeits and advocate for increased enforcement to shape relevant regulatory requirements
- Train key stakeholders and business partners in the identification of suspicious activities and/or suspected counterfeit products
- Continue to partner with industry groups to provide advocacy on high-priority anti-counterfeiting policy initiatives, and explore new partnership opportunities with patients and other external stakeholders
- Develop metrics to gauge the impact of specific actions to ensure that resources remain focused on the areas that can have the greatest benefit
- Following on the passage of the Drug Quality and Security Act (DQSA) in the U.S., continue advocacy efforts to support the development of a standardized system to identify and code medical products
- Develop data analytics and intelligence management capabilities to enhance threat detection and mitigation activities associated with counterfeit and other illicit events, including increased levels of intelligence-sharing within the Pharmaceutical Security Institute (PSI) and other public and private partnerships
- Comply with all DQSA reporting requirements and associated actions for suspect and illegitimate products impacting the U.S. patient population, as set forth in the regulation



Access to Health

# PRODUCT REGISTRATION

## MAIN

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**We are committed to registering our products in a timely fashion in markets where they are needed.**

### OUR COMMITMENTS

- We will work to initiate registration of our products in all countries where there is a public health need in a timely manner in conjunction with local regulatory authorities
- We will work to strengthen the regulatory science capabilities of local regulatory authorities to expedite product registrations
- We will work with the World Health Organization to prequalify our products, where appropriate, to expedite access in low-income countries

In addition, an important goal is to reduce the historic gap in product introduction between developed and developing countries. One way we strive to reach this goal is by prequalifying medicines and vaccines through the World Health Organization (WHO). WHO prequalification is required by UN agencies, which often procure healthcare products throughout developing countries in the absence of reliable national medicines authorities that could certify products for meeting required quality, safety and efficacy standards. As such, WHO prequalification is an important step toward fostering global access.

We have secured WHO prequalification for the following products:

#### Family Planning Products

- EXLUTON® (lynestrenol oral contraceptive)
- IMPLANON® (etonogestrel implant)
- MARVELON® (desogestrel – ethinyl estradiol)
- IMPLANON NXT® (etonogestrel)

#### Vaccines

- GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant]
- ROTATEQ® (Rotavirus Vaccine, Live, Oral, Pentavalent)
- MMR-II® (Measles, Mumps, Rubella Virus Vaccine Live)
- PedvaxHIB [Haemophilus b Conjugate Vaccine (Meningococcal Protein Conjugate)]

## HIV/AIDS Treatments

- STOCRIN® (efavirenz)
- CRIXIVAN® (indinavir sulfate)
- ATRIPLA® (efavirenz 600 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg)

All of our formulations of ISENTRESS® (raltegravir), including the 400mg tablet, the 100mg and 25mg chewable tablets, and the granules for suspension have been approved by the U.S. Food and Drug Association (FDA) and the European Medical Agency, making these formulations eligible for purchase by both the U.S. Presidents Emergency Plan for AIDS Relief (PEPFAR) program and the Global Fund for HIV, TB, and Malaria. We are evaluating the potential to submit these products for WHO prequalification.

In order to make our products available to the people who need them throughout the world, we registered 176 products and devices in 2014. The majority of these products were registered in low- and middle-income countries in the Asia-Pacific, Central and Eastern Europe, Middle East and Africa, and Americas regions.

To increase the transparency of the company's product registration status, we continue to disclose registration information for ROTATEQ, GARDASIL and our four antiretrovirals (ARVs), and update this information every six months. Click below for details:

- ROTATEQ
- GARDASIL
- ATRIPLA
- CRIXIVAN
- ISENTRESS
- STOCRIN

Learn more about our commitment to register our:

- HIV/AIDS medicines
- Women's health products
- Vaccines

## PERFORMANCE

	Registration	2011	2012	2013	2014
New product and device registrations <sup>1,2,3</sup>		179	204	179	176
Local regulatory agency GCP/PV training requests fulfilled that will help strengthen agencies' capabilities with their GCP/PV compliance oversight role <sup>4</sup>		Online	Online	Online	Online
Products submitted that have achieved WHO prequalification (cumulative)		10	10	11	11

<sup>1</sup> Data includes new products and new indications.

<sup>2</sup> For information on new registrations by region, visit our [Clinical Research](#) section.

<sup>3</sup> Data for all years have been updated based on a tracking system upgrade that corrected miscounts in prior years.

<sup>4</sup> For information on local regulatory agency GCP/PV training requests, visit our [Clinical Research](#) section.



Access to Health

# COMMERCIALIZATION

## MAIN

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**We strive to commercialize our products in a way that both develops our business and meets local needs in a responsible and efficient manner.**

### OUR COMMITMENTS

- We will price our products through differential pricing frameworks, taking into consideration the level of economic development, the distribution channel and the public health need
- Across and within countries, we will seek to identify innovative and sustainable strategies for differential pricing or other commercial approaches that allow for greater flexibility to better reach at-need segments, pursuing partnerships with private, government or nonprofit resources and distribution channels
- We will evaluate and address public health needs by working with our local healthcare providers globally to increase knowledge of product need and use; we will invest in activities to improve patient awareness and education

We recognize that we have an important role to play in helping to make our medicines and vaccines as accessible and affordable as possible for the people who need them.

In many countries, private health insurance plans are able to negotiate significant rebates and discounts with pharmaceutical manufacturers that enable patients to obtain healthcare and medicines at competitive prices.

For people in the U.S. who do not have prescription drug or health insurance coverage and who, without assistance, could not afford our company's medicines or vaccines, our Patient Assistance Programs provide medicines and adult vaccines for free.

We recognize that in developing-world markets, access and funding for healthcare can be limited. Therefore, we develop and support various sustainable strategies to improve access, including directing differential pricing to patient sub-segments. Key performance indicators for differential pricing (see performance tab) have been slightly modified so that we can more broadly capture and accurately reflect our support for access through differential pricing. Currently, we have differential pricing for 35 of our products, and 114 countries have implemented inter- or intra-country pricing for at least one of our products. Our increased efforts to expand overall access to our medicines have allowed us to surpass in 2014 our 2016 target of at least 30 products supported by differential pricing. More specifically, initiatives expanding innovative concession program offers for our hepatitis C virus and women's health product portfolios in low and middle-income markets, and renewal of our PAHO agreement supported by additional price concessions covering several of our vaccine products, have contributed significantly to this notable increase of our differentiated prices in both the scope of our products and eligible countries. We remain committed to continued growth in identifying and implementing opportunities to support access through differential pricing.

In addition, we know that doctors and patients look to us to provide accurate and balanced information about our products.

We adhere to strict ethical sales and marketing practices in each of our businesses, be it pharmaceuticals, vaccines, consumer health or animal health.

We believe that providing support through grants to third-party medical, scientific and patient organizations is an important way to advance our mutual objectives to improve health and advance patient care. We have robust standards and policies in place to ensure that our grants support a full range of topics and activities important to healthcare improvement.

Optimizing our focus for grant support in key therapeutic areas like diabetes, acute hospital care, vaccines and oncology meets unmet medical educational needs and provides the best opportunities to improve and advance health and patient care. [Learn more.](#)

## PERFORMANCE

	Commercialization Summary	2011	2012	2013	2014
Number of products that are supported with differential pricing <sup>1,2</sup>		NA	NA	24	35
Number of low- and lower-middle-income countries where inter- and/or intra-country pricing has been implemented <sup>3</sup>		NA	NA	70	114
Investment in patient- and provider-education programs <sup>4</sup>		\$97.8M	\$71.4M	\$61.3M	\$52.3M

NA: Not Available

<sup>1</sup> Differential pricing intended to facilitate access for the at-need population.

<sup>2</sup> Products include HIV treatments, vaccines and other patented products.

<sup>3</sup> Countries as defined by World Bank 2013 GNI Classification and includes UN-defined Least Developed Countries.

<sup>4</sup> In 2014, we adjusted the calculation basis for certain grants to ensure alignment with geographic and programmatic focus areas, resulting in refined figures for 2011-2013.



Commercialization

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# PRICING

## MAIN

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**Throughout the world, healthcare costs are rising for a variety of reasons. Chief among them are the greater utilization and greater complexity of services and technologies that have converted once-fatal diseases into chronic conditions.**

As populations continue to age in the developed world and the developing world, and better health technologies and pharmaceuticals improve health and prolong life, payers are increasingly focusing on the affordability of medicines in the short term.

The pharmaceutical industry is faced with a variety of healthcare systems and government policies in developed countries, where patient access to the best treatments is often balanced against the constraint of limited budgets. For example, in most European countries and in Canada, the government both regulates healthcare and provides it to its citizens. We understand these management and budgetary pressures. We also recognize that innovative medicines are a relatively small part of total healthcare spending, especially when compared with other treatment options such as hospital care. We believe the value society places on innovative therapies should reflect their contribution to health and to savings for the overall health system over time, including their benefits after generics are introduced.

Despite differences in national approaches, we price our products in all OECD (Organisation for Economic Co-operation and Development) countries based on the value that they bring to patients and the healthcare system to enable access for patients who need them, and to support our continued investment in discovering and developing innovative medicines and vaccines that can help address unmet medical needs that currently exist throughout the world.

Our prices around the world are determined by several factors, including the value our products bring to patients, payers and physicians relative to competitor products and interventions, such as hospitalization; and the ability and willingness of various customers—including national, regional or local institutional payers, physicians, employers and patients—to pay for our products. The prices of our medicines and vaccines also reflect government regulation and currency fluctuation effects.

While striving to maintain a consistent global approach, we also consider the national, competitive and regulatory conditions within each market individually. It is important to recognize that the price a consumer pays is also affected by duties and tariffs imposed on imported medicines and vaccines, as well as price markups by intermediaries, including wholesalers and pharmacies.

Given the choices available within a class of drugs today, powerful and sometimes monopolistic buyers in the pharmaceutical

marketplace—particularly governments and national health systems—have intensified pricing pressure throughout the developed world. In price-controlled environments (particularly prevalent in Europe), most governments use international price comparisons and therapeutic-reference pricing as levers to set their own purchasing price. In addition, in a growing number of markets worldwide, decisions about medicines are increasingly being relegated to regional payers, extending the challenge of ensuring access to new treatments beyond national price- or reimbursement-setting alone.

In the private sector, particularly in developed countries like the U.S., price competition has been spurred by private health insurance plans. These payers are able to negotiate significant rebates and discounts with pharmaceutical manufacturers, based on their ability to direct utilization. Where competition exists among health insurance plans, patients are able not only to obtain healthcare and their medicines at competitive prices but also to take advantage of innovative pharmacy services that have improved the quality of pharmacy care.

We recognize that in developing-world markets, access and funding for healthcare, particularly for pharmaceuticals, can often be limited. In many of these markets, most or all of the cost of treatment is borne by the patient. We actively work to develop and support various sustainable strategies to improve access, particularly for economically at-risk patient segments. In terms of pricing, these strategies can include directing differential pricing to patient sub-segments, either directly through national or local programs or indirectly through third-party healthcare funding sources that demonstrate reasonable and secure product distribution to intended patient segments. Our key performance indicators for differential pricing have been slightly modified so that we can more broadly capture and accurately reflect our support for access through differential pricing.

Our willingness to provide differential pricing strategies is evident for many of our products, including some of our best-in-class innovative brands in our HIV, hepatitis C virus (HCV), women's health and vaccine franchise areas. In 2014, several of our initiatives to expand access supported with differential pricing have contributed to improvements in access and availability:

- Our previous partnership agreement entered in 2013 reducing cost for IMPLANON® (etonogestrel implant) has resulted in notable access growth for this contraceptive. For example, in Egypt, our commercial-access efforts supported with our lower access differentiated price has realized a sixfold increase in 2014 IMPLANON contraceptive units for women. Furthermore, we supported an NGO-led initiative in Mexico to include IMPLANON contraception in their mobile family-planning clinics targeting low-income-population areas.
- Our Vaccine Division announced an agreement with the Instituto Butantan, a Brazilian biomedical research center and a state-supported producer of vaccines. The agreement was initiated to help advance the prevention of cervical cancer in Brazil via the distribution of GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant].
- Introduced RECOMBIVAX HB®, indicated for the prevention of infection caused by all known subtypes of hepatitis B virus, at a competitive price through the National Immunization Program
- We supported the Ministry of Health (MOH) in Egypt with a lower differentiated price for REMERON® (mirtazapine) tablets, an antidepressant, allowing the government to offer 15,000 units of the product to eligible patients for free; we anticipate further growth in 2015
- We expanded the scope of lower- and middle-income markets supported with differential pricing for our HCV treatment product portfolio. HCV treatment programs at access price levels were implemented in various markets, such as Nigeria, Ghana and all of French West Africa. We expanded innovative treatment cost-concession programs in India to areas that have higher HCV disease prevalence rates, including the states of Haryana and Jammu & Kashmir. In Vietnam, we recently implemented a program that offers lower differential pricing and patient cost microfinancing for HCV treatment. In Ukraine, we introduced a second pegylated interferon 2a brand, Unitron, at an intra-market lower differential price for at-need patients.
- In South Africa, we supported expanded access with differential pricing to several additional products, including ISENTRESS® (raltegravir) for pediatric formulation, SINGULAIR® (montelukast sodium) and COZAAR® (losartan potassium) tablets

We are committed to continuing our efforts to develop commercial-access-program solutions, including flexible pricing programs, targeted as appropriate to address cost burden for patients at need throughout the world.

## PERFORMANCE

Pricing2011201220132014

Number of products that are supported with differential pricing<sup>1,2</sup>

NA NA 24 35

Number of low- and lower-middle-income countries where inter- and/or intra-country pricing has been implemented<sup>3</sup>

NA NA 70 114

<sup>1</sup> Differential pricing intended to facilitate access for the at-need population.

<sup>2</sup> Products include HIV treatments, vaccines and other patented products.

<sup>3</sup> Countries as defined by World Bank 2013 GNI Classification, and includes UN-defined Least Developed Countries.

NOTE: We have realized a notable increase in both products (+46%) and geographic scope (+63%) supported with differentiated pricing intended for the at-need populations.<sup>4</sup>

To learn more about our product pricing, click on one of the links below:

- [HIV Medicines](#)
- [Vaccines](#)
- [Women's Health Products](#)

<sup>4</sup> It should be noted that year-over-year differential pricing performance metrics can be impacted based on timing of local market or third-party contract renewals and/or product life-cycle introductions or deletions. Therefore, increases or decreases in these pricing metrics should not be interpreted to anticipate level of trend growth in future years.

# MAIN

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## As a research-based healthcare company, our mission is to improve the well-being of people around the world.

Low health literacy is a major source of economic inefficiency; the current burden is estimated at \$106 billion to \$238 billion annually, or 7–17 percent of all personal healthcare expenditures. “When one accounts for the future costs of low health literacy that result from current actions (or lack of action), the real present-day cost of low health literacy is closer in range to \$1.6 trillion to \$3.6 trillion.”<sup>1</sup> Achieving our mission is about more than discovering the molecules or the mixtures that can help make people well. It’s also about improving people’s capabilities to make healthy choices, manage their therapies and navigate health systems.

Patients should be empowered to manage disease through a better understanding of the treatments and the medicines prescribed. Health literacy is a critical factor in this understanding. Without it, the chances that a patient will correctly use and fully benefit from our discoveries are slim.

Health literacy is also an important factor in disease prevention. Low health literacy has been linked to poor health outcomes such as higher rates of hospitalization and less frequent use of preventive services.<sup>2</sup> “When people receive accurate, easy-to-use information about a health issue, they are better able to take action to protect and promote their health and wellness.”<sup>3</sup>

Low levels of health literacy may span all age, gender, education and/or income groups. It can be compounded by the emotional state of patients who are trying to grasp the implications of a new diagnosis. It is linked to increased hospitalization rates, less frequent screenings for disease, increased rates of disease and mortality, and poor adherence to treatment. “Health literacy is a stronger predictor of a person’s health status than age, income, employment status and race.”<sup>4</sup> Poor health literacy is also a contributing factor to healthcare disparities.<sup>5</sup> Some population groups, including the elderly, recent immigrants who do not speak English, minorities and those with low income, are particularly vulnerable to poor health literacy.<sup>4</sup>

## Key Definitions

**Health Disparity:** A higher burden of illness, injury, disability or mortality experienced by one population group relative to another group

**Healthcare Disparity:** Differences between groups in health insurance coverage, access to and use of care, and quality of care<sup>6</sup>

**Health Literacy (U.S.):** The degree to which individuals have the capacity to obtain, communicate, process and understand basic health information and services to make appropriate health decisions

**Health Literacy (Europe):** Health literacy refers to the capacity to make sound health decisions in the context of everyday life—at home, in the community, at the workplace, in the healthcare system, in the marketplace and in the political arena (Consensus Paper (2013), Making health literacy a priority in EU policy).

Poor health literacy is a serious challenge to improving health outcomes around the world, and our commitment to advancing health literacy is fundamental to how we do business. We recognize the potential we have to help improve millions of lives<sup>7</sup> by improving how we communicate as we shepherd discoveries from the lab to the marketplace. We also know it will take a multifaceted effort focused on public policy, engaging diverse stakeholders and new ways of communicating in order to translate confusing terminology into clear and meaningful information that can improve lives. That's why we are calling for collaboration among government agencies, healthcare providers, patient advocacy groups and healthcare companies to do more, together, to increase patient understanding about healthcare and treatment plans.

At a time when patients and family members are increasingly involved in their own care, clear communication at every point along the patient journey, from researching symptoms to seeking diagnosis to managing disease, is a crucial adjunct to the medicines we discover.

## A PERSPECTIVE FROM OUR CHIEF MEDICAL OFFICER

### Health Literacy and Equity Are Fundamental to Our Mission to Improve Health

Because of their direct impact on patient health, both health literacy and health equity are key priorities for the Office of the Chief Medical Officer (CMO). In the words of Dr. Michael Rosenblatt, our chief medical officer:

"Health literacy is vital to achieving the best possible results from medical care, medicines and vaccines. The mission of the Office of the Chief Medical Officer is to serve the best interests of patients and the field of medicine. We are committed to leading the pharmaceutical industry in redefining how to apply health literacy principles to our direct and indirect communications with patients, including clinical trials, medication labeling for patients and patient education. Each year, we continue to identify additional opportunities, in all divisions of our company, where it is appropriate to apply health literacy principles. We have begun to share these best practices externally, to provide a model for effective patient engagement.

For example, currently at the point of dispensing medication, there are barriers and practices that can compromise a patient's proper understanding and sustained adherence to drug regimens. We believe that clear information about medicines should be provided to people across a range of health literacy levels. We have partnered with leaders in the field of health literacy to develop and test new approaches to patient labeling. Several rounds of market research indicate that these approaches result in strong comprehension of medication information by patients across a range of health literacy levels. We believe that this approach may be viewed as a model that could be adapted by the FDA, other pharmaceutical companies, other industries in healthcare (e.g., health insurers, medical device makers), and health systems that generate patient-facing communications.

"We will continue to partner with patients and their caregivers to promote their understanding of their medical conditions or diseases, the reasons they are being treated, and the appropriate use of medications and other treatments. The result will be maximizing the benefit and minimizing safety issues when patients use our medicines. We are committed to improving health literacy as part of our mission to improve health."

## HEALTH LITERACY AND HEALTH EQUITY: KEY PRIORITIES ACROSS THE GLOBE

Our company is committed to ensuring diversity in clinical trials, championing health literacy across countries and divisions, and proposing new solutions to improve healthcare equity across the globe. In the U.S., our vision is to be recognized by healthcare stakeholders as a leader in the areas of reducing healthcare disparities and improving health literacy through innovative programs and resources, and through a demonstrated commitment to improving patient health outcomes. We proudly participate on both the Institute of Medicine Health Literacy Roundtable as well as the Roundtable on the Promotion of Health Equity and the Elimination of Health Disparities. Our participants are active in the IOM; for instance, a 2013 [publication](#) highlighted the importance of the definition of Health Care Equity.

Our vision in Europe is to ensure citizen- and patient-centered health systems. Health literacy is a key enabler to ensure that citizens and patients can take an active role with regard to their health. In addition, health literacy activities lead to “better readable” health systems where patients can easily navigate and receive the care needed.<sup>8</sup> Empowered citizens and “readable” health systems contribute to better health and more efficient healthcare.

We have been engaging in Europe with various stakeholders such as the European Commission and patient, physician, pharmacy and nurse associations toward those goals. In parallel, the European Commission launched a tender for study on the impact of health literacy in health outcomes and healthcare expenditure in 2014. In addition, the European Commission undertook a Europe-wide survey on “European citizens’ digital health literacy” among more than 26,000 citizens.<sup>9</sup> Finally, many affiliates of our company have translated health literacy into programs to improve the health of citizens and patients in high-priority areas such as diabetes or HIV/AIDS. We highlight some of our U.S. and global health-literacy initiatives in the next two tabs.

Because of collaboration across countries, in Australia we became active in health literacy for the first time. This work is also detailed in the global tab.

<sup>1</sup> Vernon, et al. Low Health Literacy: Implications for National Health Policy. The National Patient Safety Foundation. October 2007.

<sup>2</sup> U.S. Department of Health and Human Services (HHS). Quick Guide to Health Literacy. Fact Sheet. Available at [health.gov/communication/literacy/quickguide/](http://health.gov/communication/literacy/quickguide/). Accessed June 1, 2013.

<sup>3</sup> U.S. Department of Health and Human Services (HHS). Office of Disease Prevention and Health Promotion. *National Action Plan to Improve Health Literacy*. Washington, DC: Author. 2010.

<sup>4</sup> Weiss BD. Health Literacy: Health literacy and patient safety: Help patients understand. The American Medical Association (AMA) Foundation and the AMA. May 2007.

<sup>5</sup> AHRQ 2012 Health Disparities Report (page 5). [http://www.ahrq.gov/research/findings/nhqrdr/nhqr12/nhqr12\\_prov.pdf](http://www.ahrq.gov/research/findings/nhqrdr/nhqr12/nhqr12_prov.pdf)

<sup>6</sup> Henry J. Kaiser Family Foundation. Disparities in Health and Health Care: Five Key Questions and Answers. December 2012.

<sup>7</sup> Implementing Health Literacy in a Large Company. An example from Pharma. May 10, 2012.

<sup>8</sup> See Kickbusch, Ilona; Maag, Daniela: Health Literacy. In: Heggenhougen, Kris; Quah, Stella (Hrsg.): International Encyclopedia of Public Health, San Diego: Academic Press, Vol. 3, 2008, S. 204-211, p. 209f.

<sup>9</sup> European Commission: European Patients’ Digital Health Literacy. Flash Eurobarometer 404. 2014; [http://ec.europa.eu/public\\_opinion/flash/fl\\_404\\_en.pdf](http://ec.europa.eu/public_opinion/flash/fl_404_en.pdf) (accessed: 3/16/2015)

## U.S. INITIATIVES

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### SHAPING THE EXTERNAL ENVIRONMENT—HEALTHCARE PROVIDERS

While the skills of individual patients and caregivers are an important part of health literacy, there is also a need to reduce the complexity of the healthcare system. Poor health literacy and healthcare disparities may negatively impact quality, adherence and patient safety. Many payers, integrated health systems and large medical groups share a common interest in reducing healthcare disparities and addressing poor health literacy. Individuals with limited health literacy have a lower quality of communication with health professionals.<sup>1</sup> Patient-centeredness, cultural competency and health literacy may all play a role in reducing health disparities. By taking a systematic approach to promote health literacy, medical practices and other healthcare organizations may help to improve the quality of patient care. We have created and shared resources used by these organizations, including:

- In-depth overviews of health literacy and healthcare disparities. These decks were updated in 2014 to reflect input from payers, integrated delivery systems and large medical groups.

- Case studies, cultural pointers and cultural-competence brochures designed to help healthcare providers better understand patients from diverse cultures and effectively manage cross-cultural communications.
- A new online video by Dr. Ruth Parker teaching and modeling the use of “teach back:” “Teach back” is a model designed to confirm that patients understand medical concepts communicated to them by having the patients explain the concepts back to the physician or clinician. Also available are a workbook modeling the “teach back technique” and an accompanying slide set providing additional details.
- An online video by Dr. Darren DeWalt that provides tips on implementing universal health-literacy precautions. A universal precautions approach assumes that everyone may have difficulty understanding health information and creates an environment where patients of all literacy levels can comprehend and participate appropriately in their health and healthcare.<sup>2</sup> Excerpts from the video describing implementation of universal health-literacy precautions using the toolkit are included on the Agency for Healthcare Research and Quality (AHRQ) website. This video has already been viewed more than 5,000 times on our company’s site.
- Live presentations, including Delivering Quality Care to Diverse Populations; Implementing Universal Precautions (Ensuring Clear Communication and Patient Understanding); and Relationship-Centered Care.

## SHAPING THE EXTERNAL ENVIRONMENT—PATIENTS/HEALTHCARE CONSUMERS

Patients require health literacy skills to understand and navigate the healthcare system; talk to providers; engage in self-management; perform basic numeracy skills; adopt healthy behaviors; and act on news and information.<sup>3</sup> Our consumer-engagement platform, available in the U.S., provides unbranded health-literate content in support of our pharma and vaccine brands. This multi channel health and wellness program is designed to improve engagement and adherence, help U.S. consumers strive to meet their goals for a healthy lifestyle and provide a platform to educate patients on real-time health-related issues. The following is an example of health insurance content available on our consumer-engagement platform.

As the Patient Protection and Affordable Care Act (ACA) extends health insurance coverage to millions of healthcare consumers, many of whom exhibit lower health literacy, more focus is needed to ensure that this growing universe of patients have the information needed to make informed health decisions.

In 2013, in anticipation of the implementation of the ACA, the Institute of Medicine Health Literacy Roundtable published the discussion paper “Let’s Ask 4: Questions for Consumers and Providers About Health Insurance.” A consumer version focused on answering four questions: What are my choices? How do I get it? How do I use it? How much will it cost me? We worked directly with authors of the discussion paper to develop an online, interactive version of the guide, called “Know Your Health Insurance.” The interactive guide launched during the first quarter of 2014, in time to support consumers when they were making important decisions about how to purchase and use health insurance. Know Your Health Insurance uses responsive design technology so consumers can view the site on a PC, smart phone or tablet, and it is available in Spanish. Our team also developed a short presentation of the market trends and market research used to develop this site, which the team shares with customers or organizations interested in helping consumers purchase insurance that is appropriately aligned with their families’ financial and health-care needs.

We have had a leadership role (since 2014) on the Harvard Multi-Regional Clinical Trials Return of Results working group. This multi-stakeholder group, including representatives from patient advocacy, industry, and academia, worked collaboratively to develop a health-literate template and supporting guidance document for returning results to clinical trial participants.

## SHAPING THE EXTERNAL ENVIRONMENT—BEST PRACTICES FOR INDUSTRY

We have partnered with academia to create a new approach to the development and testing of patient product labeling for new molecules. The purpose of the collaboration is to demonstrate patient understanding and use by optimizing the development and testing processes. The collaboration is between leaders in the field of health literacy at Northwestern University and Emory University, and a cross-divisional team at our company, including labeling, legal and regulatory policy. Best practices from the field of health literacy and patient feedback are incorporated throughout the development of patient labeling for new molecules. Patient input is provided several times: in focus groups during the initial development, and later to confirm comprehension of the final draft label for FDA submission.

Notably, our past approach included conducting market research across a broad range of education levels; however, few respondents presented with limited health literacy. They are harder to locate, less likely to participate and are not represented adequately in the databases of market research agencies serving the pharmaceutical industry. Northwestern University and Emory University helped us apply best practices from the field of health literacy to secure these respondents. This process

has consistently achieved strong comprehension in respondents with both limited and adequate health literacy (85 percent or better in both groups). This process and results were first presented in 2014, with additional conference presentations planned in 2015. Our commitment to health literacy in patient labeling is highlighted on the IOM Health Literacy Roundtable website in a member spotlight [here](#).

In 2014, we shared an overview of health literacy and market research best practices during a keynote session at the PMRG Marketing Research Conference, “Addressing the Health Literacy Challenge Through 360 Degree Collaboration.” Panelists included Kara Jacobson from Emory University, who provided her insights on industry-academia collaboration. Because of the positive response to the panel, PMRG decided to make health literacy an advocacy issue for their organization. This is one example of how we are working to share innovative best practices, applied from the field of health literacy and implemented in pharmaceuticals, across the industry. Looking ahead, in 2015, we will draft a publication for submission to a market research journal, designed to share health literacy and market research best practices with others in the pharmaceutical industry.

## SHAPING OUR INTERNAL ENVIRONMENT

Health literacy is about the ability to deliver patient communications in an understandable and actionable way. We work to integrate health literacy principles into our patient-education materials. A training program was developed for us by an organization specializing in health literacy, and the program was launched in late 2014. The training provides clear instructions to the creators of materials on how to implement health-literacy best practices. These best practices are derived from recent research in the field of health literacy, as well as feedback we have already received from healthcare providers and patients themselves. Although this training was designed for creators of patient education in the U.S., employees in other divisions and countries have found this training very helpful in applying health literacy principles to their own communications, either direct communications to patients or those given to patients by healthcare providers.

Because clear communication is valued by everyone, we continued to work on simplifying our own employee communications. In 2013, we applied health literacy principles to our employee enrollment materials for health insurance.

We also have improved the diversity of images and languages used in patient-education materials. Over the last several years, hundreds of new photographs, reflective of diverse populations, were taken. In 2013, many of these images were made available on an internal global site at no cost across all divisions of the company, and they continue to be used across the company in many internal and external communications.

We are unique in the industry in our dedication of resources to health literacy. A full-time health literacy and healthcare disparities strategy role has been in place since 2011. This person engages both internally and externally in the U.S. and globally. Although many pharmaceutical companies recognize the importance of health literacy, and have professionals who focus on health literacy as part of their responsibilities, we are one of two companies in the pharmaceutical industry with a person fully dedicated to health literacy strategy. In 2013, a market research position was created to ensure creation and consistent application of best practices for health literacy in screening and testing across the business. We continue to work with market research vendors to improve their ability to recruit and engage patients with limited health literacy.

## DEMONSTRATING SCIENTIFIC EXCELLENCE

In 2013, we launched our company’s Investigator Studies Program focused on health literacy, diversity and adherence. This was the first investigator studies program at our company that was not specific to a therapeutic area. Four U.S. studies are ongoing, with results anticipated in 2015–2016. Because of our strong and continued commitment, these areas of interest will be reopened in 2015 to fund several additional studies.

This program welcomes proposals from all therapeutic areas, and includes studies that evaluate the following:

- Studies that evaluate the effectiveness of novel, scalable approaches (e.g., new technologies, systems approaches, social media) to help patients manage and improve implementation of evidence-based guideline recommendations for sustained medication adherence employing principles of health literacy.
- Studies that evaluate the effectiveness of community-based interventions that focus on patients and/or providers, aimed at improving health literacy; these interventions should enhance quality of care and improve implementation of evidence-based guideline recommendations for sustained medication adherence and/or patient health outcomes.
- Studies to evaluate the application of health literacy principles to increase enrollment and retention of diverse populations (e.g., African American, Latino, Asian) in U.S. clinical trials.

Health literacy may include oral, written and/or numeracy.

In 2013, we partnered with Northwestern Medicine, Walgreens and Alliance of Chicago community health centers to collaborate on a study with a deceptively simple goal: provide clear instructions on prescription medicine labels so patients don't make mistakes and overcomplicate taking their daily medications. This new study will test whether prescribing medications to be taken at four standard intervals—in the morning, noon, evening and bedtime—improves patients' understanding and proper use of medications over time, and if this leads to better management of chronic disease. This standard is referred to as a Universal Medication Schedule (UMS). This study will include 600 patients, English or Spanish speaking, living with diabetes and/or hypertension, followed for one year. Community health centers affiliated with the Alliance of Chicago will be the sites for the study. In 2014, the EHR and pharmacy systems were designed to support the study, and pharmacists and prescribers were trained. The first patient enrollment begins in January 2015. It is a three arm, physician-randomized "pragmatic trial" usual care (control); UMS with Electronic Health Record (EHR) tools; and UMS, EHR tools and SMS text reminders for the first seven days following a new or changed prescription. The primary outcomes include self-management knowledge, prescription adherence, and measures of blood sugar control and blood pressure.

## REDUCING DISPARITIES IN DIABETES CARE IN THE U.S.

In the U.S., disparities in many chronic health conditions, including diabetes, are a growing national concern. The U.S. Centers for Disease Control and Prevention estimates that nearly 29.1 million people—9.3 percent of the U.S. population—are affected by diabetes. Type 2 diabetes accounts for 90 percent to 95 percent of all diagnosed cases. The American Diabetes Association estimates that the total cost of diagnosed diabetes was approximately \$245 billion in 2012. In 2009, to address the growing problem of healthcare disparities related to type 2 diabetes in the U.S. among low-income and underserved populations, our company's foundation, a private, U.S.-based foundation, launched the *Alliance to Reduce Disparities in Diabetes* with a commitment of \$15 million. The Alliance collaborated with national, regional and community partners to develop and implement comprehensive, evidence-based diabetes programs, with the goal of minimizing disparities in diabetes outcomes and enhancing the quality of diabetes care through improved prevention and management services. The Alliance concluded its operations in 2014.

<sup>1</sup> Koh HK, et al. New Federal Policy Initiatives to Boost Health Literacy Can Help the Nation Move Beyond the Cycle of Costly 'Crisis Care.' *Health Affairs*. 2012;31(2):434-443.

<sup>2</sup> Agency for Healthcare Research and Quality. *Health Literacy Universal Precautions Toolkit*. AHRQ Pub No. 10-0046-EF. April 2010. U.S. Department of Health and Human Services (HHS). Available at [ahrq.gov](http://ahrq.gov). Accessed June 25, 2013.

<sup>3</sup> U.S. Department of Health and Human Services (HHS). Quick Guide to Health Literacy. Fact Sheet. Basics. Available at [health.gov/communication/literacy/quickguide/factsbasic.htm](http://health.gov/communication/literacy/quickguide/factsbasic.htm). Accessed June 1, 2013.

## GLOBAL INITIATIVES

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### **We collaborate with various stakeholders in policy development for health literacy and support programs that improve health literacy levels of citizens and patients.**

In the EU, we do this together with European associations of physicians, pharmacists, nurses, patients and policy makers from the European Parliament and other EU institutions.<sup>1</sup> This work resulted in a 2014 breakfast on health literacy in the European Parliament in Brussels, Belgium, and a lunch session at the European Health Forum in Bad Hofgastein, Austria.

In spring, the European Commission launched a tender for study on the impact of health literacy in health outcomes and healthcare expenditure. This was the result of various meetings between the health literacy network and the European Commission. In parallel, the European Commission undertook a Europe-wide survey on "European citizens' digital health literacy" among more than 26,000 citizens.<sup>2</sup> The survey showed that more than nine out of 10 respondents agree that their research on the Internet helps them improve their knowledge of health-related topics; however, almost four out of 10 people do not trust information from the Internet to make health-related decisions.

Health literacy can help people to find, understand and use information about health to make healthy decisions.<sup>3</sup> Our

engagement in health literacy aims for a multi-stakeholder approach that improves health literacy of citizens and patients.

## AUSTRALIA

### Health Literacy Integration in Australia | “Healthcare in Practice”

Health literacy is a significant issue for Australia. Health information and systems have become increasingly complex and harder to understand. Like many other developed countries, almost 60 percent of adult Australians have low individual health literacy, which means they may not be able to effectively exercise their choice or voice when making healthcare decisions.<sup>1</sup>

MSD Customer Centricity in Australia has identified that a coordinated and collaborative approach to address health literacy based on embedding health literacy into systems, ensuring effective communication and integrating health literacy into education. Australia has been working closely with our U.S. colleagues to incorporate “health literacy in action” skills and “teach-back” training within its program Healthcare in Practice.

Healthcare in Practice is a unique program for delivering chronic disease management in general practice. It combines MSD’s long experience in developing user-friendly CDM software with our deep insights into practice-level process optimization, skills development and behavior change. It aims to deliver high-quality care plans, rigorous implementation and outcomes tracking for patients with chronic conditions.

Healthcare in Practice:

- Uses clinically validated search algorithms to identify chronic disease patients that are not to target from within existing practice databases
- Helps practices to develop the processes and skills needed to implement and review effective care plans for chronic disease patients
- Gives healthcare providers the training and materials they need to communicate effectively with patients, improve patient health literacy and improve plan concordance
- Tracks outcomes at a patient and a practice level

MSD Customer Centricity recognizes that engagement with consumers is essential for both individual health and healthcare and for the development of better healthcare systems. Improving health literacy ensures that consumers can fully participate in these programs and offer better health outcomes for patients in Australia.

<sup>1</sup> Australian Commission on Safety and Quality in Health Care. Health Literacy: Taking action to improve safety and quality. Sydney: QCSQHC. 2014. p2.

## AUSTRIA

**It’s Crucial to Care | Diabetes Nurse Service in Austria:** To support patients in their self-management, MSD Austria has implemented a diabetes nurse service in collaboration with physicians. Newly diagnosed diabetes patients who show an increased need for educational training can subscribe to the MSD patient program. The individual training with a diabetes nurse also involves the patient’s partner and family to secure the most efficient outcome. Information on diabetes, lifestyle management, medication and glucose monitoring enhances the health literacy of patients and their families. By defining individualized, measurable and achievable self-management goals, adherence and health outcomes are to be improved. The program covers a free educational basis training and follow-up calls after three, six and nine months. After 12 months the quarterly collected data is to be discussed with the family doctor. In 2015, the patient program will be combined with a screening program in collaboration with the Austrian Pharmacists Association.

## BELGIUM

**Well Done—MSD Health Literacy Awards:** The Well Done – MSD Health Literacy Awards rewards projects that make a significant contribution to the health literacy of citizens in Belgium and/or Luxembourg. The 2014 edition resulted in 37 health literacy projects from which three were selected for the First Line, Specialty Care and Community Award. The award is a joint effort between MSD and key stakeholders, including sick funds, patients and HCP associations, members of parliament and the National Institute for Health and Disability Insurance. It provides a platform for exchange on health literacy where MSD’s leadership in health literacy plays an important role. More about the initiative on [www.welldoneawards.be](http://www.welldoneawards.be)

## GERMANY

**MiMi (With Migrants for Migrants) Initiative for Maternal Health in Germany:** Approximately 18.9 percent of the German population has a migration background—around half of them are women. These women are disadvantaged due to several factors, such as lack of language skills or cultural differences concerning the role of women. Therefore, in 2014, MSD Germany rolled out the successful MiMi initiative to pregnant migrant women, thus, linking it to the global campaign MSD for Mothers. The Ethno-Medical Center in Hannover, which is supported by MSD, will train German-speaking migrants to teach other migrants in their mother tongue about family planning and pregnancy.

**MSD Medicine Cabinet App** In 2014, the MSD Medicine Cabinet App was launched. It helps people to receive an overview of their medicine cabinet at home. After comfortably scanning the drugs' barcodes, the various functions can be used. The App reminds the user to buy a new package in time, it highlights the expiration date and personal information can easily be added. Furthermore, all information can be shared with family members. With this tool, the company helps patients to organize their medicine cabinet and empowers them to use their medicines safely.

**Update: Patient-Friendly Package Inserts** Since 2009, MSD Germany has been cooperating with patient and eldercare organizations to adjust its package inserts regarding comprehensibility, readability and patient-friendliness. In doing so, MSD wants to enhance patients' adherence to and support the success of a treatment. Recently, a major accomplishment of this working group was reported: Atozet® was launched with a patient-friendly and understandable package insert. It was developed based on the former adjustments that the working group had undertaken for the Inegy® package insert.

## HUNGARY

**Industry Supporting Health Literacy Research:** While some countries in Europe, such as Austria, Bulgaria or Spain, have a clear understanding of health literacy levels in their respective populations due to their participation in the European Health Literacy Survey (HLS.EU), little is known in Hungary. In addition, health literacy appears not to be on the public health agenda, and no term for health literacy exists in Hungarian. To close this gap, the industry association of pharmaceutical companies (AIPM) in Hungary created a separate working group on health literacy under the leadership of MSD with the purpose to replicate the European Health Literacy Survey (HLS.EU) in Hungary. In addition, a reference group has been initiated that consists of representatives from all relevant stakeholders to help guide future activities and initiatives.

## IRELAND

**Health Literacy Friendly Healthcare Settings:** In 2014 MSD Ireland focused all its efforts on the development of the Crystal Clear Mark, the first independent accreditation for "health literacy friendly" healthcare settings, which is to be started in 2015. MSD, the National Adult Literacy Agency (NALA) and the Irish Department of Health partnered to launch the Crystal Clear Pharmacy and GP Programme, which allows pharmacies and general practices to apply for a quality mark which recognizes their healthcare setting as health literacy friendly. Other partners to the Programme include the Irish Pharmacy Union and the Irish College of General Practitioners. The programme includes online education for healthcare professionals and an online self-completion audit. Following successful completion of the audit, the healthcare setting can apply for the Crystal Clear Mark. MSD's pharmacy and GP sales force are receiving very positive feedback from customers on this programme which puts patient needs at the very centre of how their service is delivered. The programme also encourages continuing education and helps pharmacies differentiate their business. NALA plans to extend this programme to other setting such as hospitals, social welfare offices and citizen advice bureaus.

## ITALY

**Long-Term Project for Patient Association Volere Non Basta (Asking for Something Is Not Enough):** The Fondazione MSD, in partnership with Rome Sapienza University and Milan Engineering School, has designed and has sponsored a long-term educational plan to train patients to communicate in an effective/sharp way and to be able to use the empowerment tools appropriately. It is an articulated program that meets patient associations' emerging needs to be more and more vocal through media and act as protagonists in the policy decision-making process.

**Biological Medicines Literacy:** MSD Italy initiated a multi-stakeholder platform with experts from economics, pharmacology, medicine and legal, and 20 patients associations to discuss the specificities of biological medicines. An output of the meeting was the e-book "Biosimilar, an open debate" (<http://bio-similari.it>), which includes contributions from experts and patients.

**"Pronti" ("Be Ready") and "Con Te" ("With You"):** The two initiatives "Pronti" ("Be ready") and "Con te" ("With you") promoted a meaningful dialogue between patients and physicians. The former supported HIV patients in the context of ageing

and co-morbidities; the latter focused on hepatitis C patients to provide better understanding of the disease and how to improve quality of life, and it gave physicians tools to support their patients. In addition, education through information was also the objective of “LOVE IT,” a 360-degree cross-media campaign with Italian Society of Gynecology and Obstetrics (SIGO), leveraging on Italian “The Pill Without a Pill” campaign actions and aimed at creating a cultural movement on contraception.

## ROMANIA

**StayWell–Health Literacy for Healthcare Professionals:** According to the Foreign Investors Council in Romania, one of the biggest issues physicians see is related to their low salaries, a real barrier for their health literacy, i.e., medical education. The low wages compared to the rest of the EU also represents one of the causes for “doctors’ migration” from Romania to other countries—with important impact on the number of physicians locally. With StayWell, MSD Romania has developed a platform dedicated to physicians, pharmacists and patients, with disease information, Continuous Medical Education, webcasts, apps and news to help the medical community stay informed. The prelaunch in November 2014 received positive feedback, and the full launch is foreseen for 2015.

## SWITZERLAND

**Publication on Health Literacy in Switzerland:** In 2014, the Alliance Health Literacy and the Swiss Academy of Medical Sciences (SAMS) have been developing a handbook on health literacy in Switzerland. The publication describes the role and responsibilities of healthcare stakeholders to foster health literacy in Switzerland and presents some best practices. As a founding member of the Alliance Health Literacy, MSD has been involved as member of the editorial team. The book, to be published in 2015, not only shows the Alliance’s commitment to health literacy but also helps to bring the topic to the attention of healthcare policy.

**Health Literacy Award:** For the second time, the Alliance Health Literacy issued the Health Literacy Award in Switzerland. The first prize (13k CHF) went to a Streetdance health promotion project for girls and young women; the second and third prizes (3k CHF each) went to a patient-education program for stroke patients provided by the University hospital of Canton Vaud (CHUV) and to a project that organizes discussion rounds about health topics for migrant women, respectively. The Health Literacy Award has been initiated by the Alliance Health Literacy, which consists of Public Health Switzerland, Health Promotion Switzerland, the Swiss Medical Association (FMH), Careum and MSD. The award fosters programs and organizations concerned with improving health literacy.

<sup>1</sup> See, e.g., European Health Forum Gastein: EHFG 2013: New Consensus Paper calls for EU action on health literacy; Bad Hofgastein 2013; <http://www.ehfg.org/health-literacy.html> (accessed: 3/16/2015)

<sup>2</sup> European Commission: European Patients’ Digital Health Literacy. Flash Eurobarometer 404. 2014; [http://ec.europa.eu/public\\_opinion/flash/fl\\_404\\_en.pdf](http://ec.europa.eu/public_opinion/flash/fl_404_en.pdf) (accessed: 3/16/2015)

<sup>3</sup> See Kickbusch, Ilona; Maag, Daniela: Health Literacy. In: Heggenhougen, Kris; Quah, Stella (Hrsg.): International Encyclopedia of Public Health, San Diego: Academic Press, Vol. 3, 2008, S. 204-211, p. 209f.



Health Literacy

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# THE MANUALS

## The MSD Manuals are one of the most widely used medical information resources.

First published in 1899 as a small reference book for physicians and pharmacists, the Manual has grown in size and scope to become one of the world's most widely used comprehensive medical resources. Over the years, the Manual has been translated into 17 languages, and a consumer version has been published since 1997. In 1999, digital versions were made available online and as handheld apps to take advantage of advances in technology and to better meet the information needs of readers.

As the Manual evolved, it continually expanded the reach and depth of its offerings to reflect the mission of providing the best medical knowledge of the day to a wide cross-section of users, including medical professionals and students, veterinarians and veterinary students, and consumers.

## MISSION STATEMENT

We believe that health information is a universal right and that every person is entitled to accurate, accessible and usable medical information. And we believe that we have a responsibility to protect, preserve and share the best current medical information to enable more informed decisions, enhance relationships between patients and professionals, and improve healthcare outcomes around the world.

## FULFILLING THE MISSION

As a sign of our deepened commitment to worldwide medical information access, we are making the manuals available for free in digital form in multiple languages to professionals and patients around the world.

In 2015, we embarked on our most aggressive and far-reaching medical knowledge initiative to date, "Global Medical Knowledge 2020." Through this worldwide project, we aim to make the best current medical information accessible, understandable and usable for more than 3 billion professionals and patients around the world by 2020. As part of this project, all manuals will be made available for free online and through mobile apps in multiple languages. The translations will be kept current with the English version.

Through "Global Medical Knowledge 2020," we strive to enable more informed decisions, enhance relationships between patients and professionals, and improve healthcare outcomes around the world. The initiative is a direct reflection of our company's broad corporate commitment to addressing unmet medical needs and improving global health.



Health Literacy

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# RESOURCES FOR HEALTHCARE PROFESSIONALS

**Univadis® is a comprehensive online medical-information resource from Physicians Interactive—a subsidiary of Global Health Innovation—for healthcare professionals worldwide.**

This online resource provides high-quality, relevant and trusted medical information essential for healthcare practice. With an easy-to-use interface, the site features breaking medical news, accredited education courses and cutting-edge tools tailored to each medical specialty and clinician need.

The medical and scientific content comes from independent third parties, such as scientific leaders, educational institutions and medical societies, as well as through partnerships with a range of world-leading medical publishers. Sponsor organizations provide educational funding to expand and augment the site's core content in adherence with the strict editorial principles of independence, relevance and quality.

With no subscription or registration fees, Univadis provides access to:

- The latest medical news and clinical developments in 60+ specialist areas
- Selected full-text articles from *The Lancet* and *JAMA*
- Weekly research summaries from major peer-reviewed publications
- Conference coverage from medical congresses
- Full online access to trusted medical references
- A library of thousands of medical images to enrich presentations and research
- A wide range of resources to enhance interactions with patients at the point of care, including interactive 3-D anatomy tools and patient handouts

Univadis creates unique opportunities for long-term and meaningful partnerships with scientific and healthcare organizations in addition to the world-class publishers that our company already works with. Univadis aims to be a valuable partner to build lasting relationships with our 2.9 million individual healthcare users globally.

# HEALTH RESOURCES FOR PATIENTS

**According to a study published by the *New England Journal of Medicine*, an estimated one-third to half of all patients in the U.S. reportedly do not take their medications as prescribed.**

The following resources are designed to help patients stay on course with their treatments and to have better conversations with their healthcare providers about the medicines they have been prescribed.

Our [consumer-engagement program](#), a free health-support program available only in the U.S., offers resources that help U.S. consumers achieve their health goals by reinforcing healthy lifestyle choices, providing disease-specific education, supporting adherence to therapy, and facilitating more productive interactions with healthcare professionals. The site also provides support and encouragement for caregivers, who are often engaged in the day-to-day care and treatment decisions of family members and friends.

The program also provides healthcare professionals with health-support materials and tools for their patients. It is designed to support the relationship between healthcare professionals and healthcare consumers by providing tools and tips—online, through a call center and through mobile devices—for healthier living between office visits.

## THE ADHERENCE ESTIMATOR

Patients often fail to reach clinical goals because they don't take medications as directed. We remain committed to identifying the reasons why patients do not always correctly take prescribed medicine, and we support the development of improved evidence-based interventions that can lead to improved adherence.

The **Adherence Estimator**<sup>®</sup> is a validated, patient-based resource that gauges the likelihood of a patient adhering to a newly prescribed oral medication for certain chronic conditions. The Adherence Estimator asks questions about three key areas that affect adherence: patients' perceived concerns about prescription medication; their perception of the need for or their commitment to a prescription medication; and their perceived financial burden from the cost of a prescription medication. After respondents answer the questions, the resource provides information to enable the patient and healthcare provider to discuss any concerns that the patient may have. We recently developed [ConversationStarters](#), a guided and interactive video, based on the Adherence Estimator. This new resource enables patients to send their responses to their prescriber online.

## SPARTA

SPARTA is a proven adherence platform that supports patients on any of our company's therapies, to improve adherence to these medications while also providing access to various tools and resources to assist in the management of conditions.

SPARTA was created in Australia in 2009, in partnership with physicians and pharmacists who voiced the need for more-robust patient support. In addressing this unmet need, modules were created to support enrolled patients with managing their chronic conditions. The modules consisted of various patient touch points (e.g., telephone support, disease education and SMS/email reminders) to help patients understand their condition better, realize the importance diet and exercise in managing their condition and ultimately improve medication adherence. SPARTA grew from 60,000 patients in Asia-Pacific in 2013 to more than 150,000 patients across the globe in 2015.

Based on a recent analysis of 40,000 patients across seven countries, 85 percent of patients taking part in the SPARTA program took their medications for more than 10 months and took it correctly 95 percent of the time. In subset of 2,000 patients, 70 percent of participants increased or started an exercise routine and 80 percent made positive changes to their diets.

SPARTA has been launched in Australia, India, the Philippines, Indonesia, Vietnam, Brunei, China, Malaysia and Singapore. Additional 2015 launches are planned in Venezuela, Mexico, Colombia, Saudi Arabia, UAE, Chile, Hong Kong and Sweden, with several other regions including EUCan, planning launches in 2016.

## PROJECT SAMBHAV

(Hindi for "making it possible") is a first-of-its-kind, multi-stakeholder initiative led by MSD in India to collectively address key barriers to hepatitis C treatment. Launched in 2012, the program has two components—a financing component to reduce cost as a barrier, and a disease management program to increase disease awareness and facilitate adherence to prescribed treatments.

Throughout 2014, the program expanded to 11 cities across four Indian states. More than 200 treatment centers have participated in the program, and nearly 1,000 patients, representing 30 percent to 40 percent of patients treated in these states, took part in the finance program.



Access to Health

# COMMUNITY INVESTMENT

## MAIN

**We recognize that we cannot address complex public health challenges on our own; therefore, we engage in community investment to address the barriers to access where we believe we can make the strongest contributions.**

## OUR COMMITMENTS

Through innovative approaches and partnerships, we will invest our expertise, human resources, financial resources, products and market-based solutions to:

- Support capacity-building, including healthcare professional training, to deliver healthcare solutions
- Address underlying barriers to health, such as health-system strengthening
- When market-based solutions are inadequate or unavailable, we will pursue programs to provide direct access to our medicines and vaccines.

Despite efforts to develop and implement effective business and philanthropic strategies to help remove barriers to access, challenges remain due to the complex and multifaceted nature of the problem. To truly address—and, ultimately, solve—the issues of access in developing and middle-income markets, the international community must pool its resources and expertise to strengthen healthcare infrastructure, to ensure adequate financing for health, and to help build local healthcare capacity through training and support. Even in developed countries, challenges remain to reach groups of underserved populations.

Examples of our community investment follow:

*MSD for Mothers* is a 10-year \$500 million initiative focused on improving the health and well-being of mothers during pregnancy and childbirth. Our company created *MSD for Mothers* to address this critically important issue. We are committed to using our business and scientific expertise to improve maternal health and are already working in more than 30 countries around the world. [Learn more.](#)

The MSD Fellowship for Global Health is a three-month, field-based corporate pro bono program that is designed to leverage the skills and talents of our employees worldwide. It pairs the best minds from within our company with nonprofit partner organizations around the world to provide meaningful and systematic improvements in health service delivery for people in the greatest need. While strengthening the capacity and reach of nonprofit organizations, the program also provides rich professional development experiences for our employees. [Learn more.](#)

For additional examples of our support for healthcare capacity-building and health-system strengthening activities, please visit the [Key Initiatives](#), [Giving – Health](#), [Women’s Health](#) and [Vaccines](#) pages.

We also recognize that adequate solutions are not always available when patients need them. And while we do not believe that donating medicines alone is a sustainable, long-term solution to the global challenge of access to medicines, we recognize that millions of patients need medicines now. For that reason, we remain committed to donating our medicines and vaccines through organized programs, as appropriate.

Our primary programs involving donations of our products are: the Medical Outreach Program (MMOP), the MECTIZAN<sup>®</sup> Donation Program (MDP), the African Comprehensive HIV/AIDS Partnerships (ACHAP) and our U.S.-based Patient Assistance Programs (PAP).

In 2014, the number of people reached through our programs decreased. The decrease was mainly driven by the timing of treatment cycles within countries through the MECTIZAN Donation Program.

## PERFORMANCE

	Community Investment	2011	2012	2013*	2014
Healthcare workers trained through our major programs and partnerships <sup>1</sup>		52,000	38,000	22,000	137,000
Investment in partnerships for activities that address underlying barriers to health, such as health-system strengthening and capacity-building (\$M) <sup>2</sup>		35	24	24	32
People reached through our major programs and partnerships (M)		273	269	302	267

\* 2013 figures have been reconciled to reflect revised field data for the MECTIZAN Donation Program.

<sup>1</sup> 2014 figure includes healthcare workers trained through the African Program for Onchocerciasis Control, of which we are a major funder.

<sup>2</sup> Includes investments by the Office of Corporate Philanthropy, MSD for Mothers and our company's Foundation.

Access to Health

# INFECTIOUS DISEASES

**We have a long-standing commitment to discovering, developing and delivering novel medicines in the global fight against infectious disease. About one in four deaths worldwide is caused by infectious and/or parasitic diseases—totaling nearly 15 million fatalities each year.**

Our company has a long history of both in-house research and engagement with external partners to address infectious diseases and we continue to seek new ways in which we can contribute expertise and resources to these disease areas.

We apply our R&D resources, expertise and technology to identify potential products that would address unmet needs in the treatment of infectious diseases, such as HIV, hepatitis C virus (HCV) and drug-resistant bacteria. We are also involved in a number of product-development partnerships and research collaborations to further develop treatments to address these diseases, as well as neglected tropical diseases (NTDs) and tuberculosis (TB).

We recognize that new methods and a broader scope of partnering—with both public and private entities—are critical to continuing innovation. This is true for all diseases, and especially true for diseases prevalent in low- and middle-income countries, for which the relevant expertise spans academia, local public health authorities, industry and international agencies. We plan to continue to expand our interactions with these groups to provide relevant expertise and resources.

We also recognize that our research capabilities and our access strategies play an important role in recruiting outstanding scientists as well as potential external research collaborators seeking to make the products developed from their discoveries available to patients worldwide.

## **Reaffirming Our Commitment to Developing Innovative Medicines for the Treatment of Infectious Diseases**

In April 2015, during the 25th European Congress of Clinical Microbiology and Infectious Diseases (ECCMID), our company reaffirmed its long-standing commitment to discovering and developing novel medicines in the global fight against infectious diseases, including infections caused by resistant bacteria and other pathogens. [Read the full press release.](#)

As a leader in infectious diseases, we are committed to:

- Maintaining active R&D programs to address unmet medical needs in the prevention and treatment of infectious diseases
- Monitoring antibacterial resistance emergence in collaboration with external partners, as exemplified by our long-standing commitment to surveillance studies
- Supporting responsible use of antimicrobials to help slow development of resistance and preserve current therapeutic options
- Advocating for improvements in regulatory guidance and financial incentives to support and accelerate innovation in the development of new antimicrobials, vaccines, services and solutions

Learn more:

- Antimicrobials/Antibiotics
- Hepatitis C
- HIV
- Neglected Tropical Diseases
- Tuberculosis

# ANTIMICROBIAL/ ANTIBIOTICS

**Overuse and improper use of antimicrobials, such as antibiotics, help accelerate the rate of development of drug-resistant germs and increase the need for new medicines.**

The rise in antimicrobial resistance over the past 10 years has become one of the world's most pressing public health problems. An estimated 2 million illnesses and 23,000 deaths are thought to be caused by antibiotic resistance in the U.S. each year. Our company's long-standing commitment to the global fight against infectious disease goes hand-in-hand with a commitment to help slow the rate of emergence of potentially deadly resistant organisms.

Since 2002, we have sponsored the Study for Monitoring Antimicrobial Resistance Trends (SMART). The SMART program is one of the world's largest programs for tracking trends in antimicrobial resistance. Clinical samples have been collected from patients with complicated intra-abdominal infections since 2002 and from patients with complicated urinary tract infections since 2010, and analyzed for their *in vitro* susceptibility to 12 commonly used antibiotics in different regions of the world to monitor changing trends in antibiotic susceptibility. The information collected and shared is designed to help local and global health agencies improve surveillance so they can better understand trends in antimicrobial resistance and select appropriate antibiotics for their patients.

## A DEARTH OF ANTIBIOTIC RESEARCH AND DEVELOPMENT

An added complication to the ongoing battle against resistant infections is the fact that while resistance is increasing, the number of new antimicrobial medicines being developed has decreased over the past several years. Discovering novel medicines to combat resistant bacteria requires more effort, and the perceived commercial value of such medicines is low compared with other disease treatments. To address this issue in part, the U.S. Food and Drug Administration (FDA) and the European health authorities are actively working on updating regulatory guidance and reforming the regulatory environment to help provide incentives for innovation in key areas of unmet need, including antibiotics. We are one of only a handful of pharmaceutical companies that continue to have active antibacterial discovery and development programs.

- The FDA granted Fast Track status to MK-3415A, an investigational agent that works by neutralizing the key toxins associated with *Clostridium difficile* infections that can be directly related to antibiotic use and resistance. Fast Track is a process designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need.
- MK-7655, a beta lactamase inhibitor, is also being developed as a fixed-dose combination with imipenem. The antibiotic is designed to treat resistant gram-negative bacteria.
- MK-8228 is being developed to prevent human cytomegalovirus (CMV)–related infection in high-risk recipients of certain stem cell transplants. Currently, no therapy is approved to prevent CMV infections in these stem-cell-transplant

patients.

Hospital Acute Care is a priority therapeutic area for our company. Continued innovation toward developing new medicines is critical to address the growing resistance to current therapies. We are committed to working with partners to help address this growing area of unmet need and improve patient outcomes. In total, we have more than 16 ongoing clinical trials evaluating antimicrobial agents that are projected to enroll approximately 18,000 patients.

## ACQUISITION OF CUBIST PHARMACEUTICALS

Our company's commitment to expand its antibiotic capabilities was further reinforced in January 2015, when we finalized the acquisition of Cubist. Cubist's portfolio complements our own broad portfolio of antibiotics, antifungals and anesthetics. The combination of the two companies will establish an even stronger presence in the Hospital Acute Care segment while advancing a pipeline of candidates that hold the potential for making a meaningful difference in the lives of patients around the world.

## COLLABORATING TO DISCOVER NEW ANTI-INFECTIVE AGENTS

In addition to our own in-house anti-infective research efforts, we seek to augment our expertise and resources through collaboration with scientists around the world. We have multiple ongoing collaborations focused on the discovery of novel anti-infective agents:

- **Bristol-Myers Squibb and MassBiologics, U.S.** — Licensing agreement to develop [actoxumab/bezlotoxumab \(MK-3415A\)](#), an investigational combination of therapeutic antibodies targeting two *Clostridium difficile* pathogenic toxins (A and B)
- **Medina Discovery, Spain** — Collaboration in the areas of microbiology and natural product chemistry, with a focus on screening and validation of drug targets for infectious disease
- **Orchid Pharma, India** — A collaborative research agreement focused on the discovery, development and commercialization of novel agents for the treatment of bacterial and fungal infections
- **Center of Excellence for Translational Medicine, U.S.** — National Institutes of Health grant to Rutgers University supporting multiple academic and industry groups in collaboration to advance the discovery of novel antimicrobial agents.

In addition, our company actively collaborates with leading antimicrobial scientists to investigate and validate novel therapeutic targets, evaluate new pathways for drug targeting, and develop novel tools and technologies to aid research. We have a number of ongoing collaborations with scientists at universities including Harvard, Princeton and Yale. [Learn more.](#)

## NEGLECTED DISEASE RESEARCH

- **Drugs for Neglected Diseases Initiative (DNDi)** – A collaboration to support discovery and development of improved treatments for neglected tropical diseases
- **WIPO Re:Search** – Our company is a founding member of WIPO Re:Search, a consortium of public and private organizations that facilitate research on neglected tropical diseases, malaria and tuberculosis
- **London Declaration** – Our company is an original signatory to the London Declaration, a collaborative effort launched in 2012 to accelerate progress toward eliminating or controlling 10 neglected tropical diseases by advancing drug treatment and R&D activities.

## FACILITATING ANTIMICROBIAL RESEARCH

By providing the broad scientific community access to research tools and information, we recognize that we can fuel basic research and potentially expedite scientific progress toward the development of new anti-infective agents. In the last five years, our researchers have published over 30 peer-reviewed research articles. Our company also provides access for researchers to published small molecule chemical probes and genetic tools, as well as recent clinical isolates and genetically engineered libraries of disease-relevant bacterial and fungal strains developed in our laboratories.

# HEPATITIS C

**For nearly three decades, our company has been at the forefront of the response to the hepatitis C virus (HCV) epidemic. We have helped to make a difference through our commitment to scientific innovation, multisector collaborations and efforts to expand access to HCV treatment.**

We are dedicated to applying our scientific expertise, resources and global reach to deliver healthcare solutions that support people living with HCV worldwide.

The World Health Organization (WHO) estimates that 3 percent of the world's population may be infected with HCV and that as many as 170 million people may be chronically infected and at risk of developing liver cirrhosis and/or liver cancer. Our scientists have been engaged in research to address HCV infection since the discovery of the virus in the late 1980s.

- Company researchers developed the first approved therapy for chronic HCV, interferon  $\alpha$ 2b, in 1991
- In 1998, the first combination therapy developed by our scientists for chronic HCV, interferon  $\alpha$ -2b+ribavirin, was approved. We also launched boceprevir, one of the first direct-acting antiviral medicines against HCV, in 2011.

Currently, we have extensive research efforts underway to develop new oral therapies to bring continued innovation to viral hepatitis treatment.

- Our HCV clinical development program includes Phase 2 and 3 studies dedicated to multiple genotypes and broad patient populations, including those who are the most difficult to treat —patients with chronic kidney disease (including those on hemodialysis), patients with cirrhosis, patients with HIV/HCV coinfection, patients on opiate substitution therapy and patients with inherited blood disorders.
- The company's most advanced pipeline therapy, grazoprevir/elbasvir, is an investigational oral, once-daily, fixed-dose combination for chronic HCV treatment, consisting of grazoprevir, an investigational oral, once-daily HCV NS3/4A protease inhibitor, and elbasvir, an investigational oral, once-daily HCV NS5A replication complex inhibitor.

## ACCESS TO MEDICINES IN EMERGING MARKETS

As a global healthcare company, our role is first and foremost to discover and develop innovative medicines to address unmet medical needs. We also recognize that we have an important role to play, in partnership with other stakeholders, in working to improve access to quality healthcare, including access to our medicines, as reflected in our [Access to Health Statement of Guiding Principles](#).

In many developing countries, the spread of HCV is facilitated by unsafe medical practices,

such as the reuse of needles and syringes by medical practitioners.<sup>1</sup> The use and misuse of intravenous drugs is also a major route for HCV transmission.<sup>1</sup> Health systems in many countries most impacted by HCV are poorly equipped to widely diagnose HCV and deliver care and treatment for those with HCV.<sup>2</sup>

Together, these factors are contributing to the heightened HCV disease burden in these regions.

We are committed to developing sustainable solutions to improve awareness, diagnosis, and access to care and treatment in areas where HCV disease burden is the greatest.

## WE SEEK TO ELEVATE AWARENESS OF HCV THROUGH:

- Educational programming for patients and providers to better identify and address unmet needs
- Academic research initiatives addressing the burden of HCV in areas most impacted by the disease

## WE WORK TO ENHANCE ACCESS TO OUR HCV MEDICINES THROUGH:

- Access pricing for low-income countries to help facilitate the initiation of treatment programs
- Differential pricing frameworks based on disease burden and country income in middle-income countries

## WE ENGAGE IN LOCAL PARTNERSHIPS WITH COMMUNITY, GOVERNMENTS AND OTHER KEY STAKEHOLDERS THROUGH:

- Collaborations with governments to initiate awareness and screening programs
- Supporting international programming through civil society groups, including regional HCV research initiatives

## COLLABORATIONS

Our company recognizes that global elimination of HCV will require the combined efforts of all stakeholders—governments, donor organizations, policymakers, advocacy groups, nongovernmental organizations (NGOs) and the private sector—to build a framework for promoting awareness, prevention and treatment of viral hepatitis, especially among populations most at risk for chronic HCV. We remain committed to strengthening new and existing partnerships to achieve greater access to healthcare. Several of the collaborations that we have undertaken are highlighted below:

### India

Recognizing the high prevalence, high cost burden and challenges of treatment adherence of HCV, MSD India initiated *Project Sambhav (Making It Possible)*, a program aimed to educate patients and their families about HCV and help manage the cost of treatment. Through *Project Sambhav*, MSD India provides subsidies for financing for treatment to eligible patients and counseling to help educate about treatment, adherence and transmission prevention.

### Vietnam

Our company's foundation awarded a multiyear grant to Population Services International (PSI), a leading global health organization, to conduct educational outreach targeting at-risk populations and healthcare providers. Additionally, service providers from high-prevalence areas were trained to promote an understanding of HCV and facilitate referrals for diagnosis and prevention counseling.

### Ukraine

During the past five years, we have collaborated with the local government, advocacy groups and scientific leaders to raise awareness and understanding of chronic HCV among both patients and healthcare providers. MSD supported the development of a National Treatment Program, a public awareness program that has greatly increased the level of discussion and awareness of HCV in Ukraine. MSD continues to collaborate with these partners on ways to improve HCV treatment.

### Thailand

Our company initiated several programs, including the Liver Evaluation and Disease Awareness (LEAD) program, to help address low diagnosis and awareness of HCV in Thailand. As part of the LEAD program, healthcare providers are trained to be aware of and recognize at-risk populations to help ensure interventions prior to disease manifestations/complications.

## **Egypt**

Recognizing the urgent need for action in Egypt, we collaborated with the Ministry of Health (MOH), advocacy and industry partners to develop targeted programming to fight HCV. The initiation of communications campaigns, screening programs and treatment subsidies across the country has helped increase awareness and understanding of chronic HCV in Egypt. In 2013, our company launched the first Middle East School of Hepatology (MESH), which provided numerous medical professionals from across the region with advanced medical education targeting hepatic disease in the Middle East.

<sup>1</sup> European Association for the Study of the Liver. Therapy of Hepatitis C: Clinical Application and Drug Development. <http://virtualpressoffice.easl.eu/download/hcvspecialconferencehighlights-easlaasld.pdf>.

<sup>2</sup> Ewen Callaway. "Hepatitis C Drugs Not Reaching Poor." *Nature* 508:295-296. 17 April 2014.



Infectious Diseases

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# HIV/AIDS

## MAIN

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### For more than 25 years, our company has been committed to addressing the global challenge of the HIV epidemic.

With over 30 million people infected and 2 million new infections each year globally, the challenge of HIV is vast, impacting both developed and developing countries. These challenges include scientific, behavioral and programmatic aspects that continue to evolve as the epidemic evolves.

Since 1985, we've been engaged primarily in research and development efforts in both HIV prevention and treatment. These efforts continue today. But research is just one part of our comprehensive strategy to address unmet needs in HIV.

Our company has also sought to make a difference in the fight against HIV through efforts to enhance access to our HIV medicines, particularly in the developing world, and through partnerships that seek to strengthen health systems to better deliver prevention and treatment services. Clearly, the need is greater than the results that any one stakeholder can deliver, requiring coordinated efforts among many.

### IT TAKES A MULTIFACETED APPROACH TO IMPROVE ACCESS

We are committed to working with governments, donors, innovative and generic manufacturers, multilateral organizations and civil society to address the full range of factors affecting access. After a decade of specific efforts to increase access to HIV treatment in the developing world, it is clear that access to care is about more than the price of medicines and that collaboration has been essential to the progress made against HIV.

We have seen that increasing access requires a broad, comprehensive approach. Consequently, we are committed to improving patient access through expanded availability, enhanced access strategies and multi-sectoral partnerships.

To make this possible, we have employed multiple strategies to address the needs of particular regions and countries, including: seeking rapid and broad registration of our antiretroviral medicines (ARVs); providing support for clinical studies in resource-limited settings; implementing differential-pricing strategies; signing voluntary licenses with generic manufacturers; developing pediatric formulations; and establishing strong collaborations with governments, manufacturers and other stakeholders.

### FOCUSING ON UNMET NEED IN PEDIATRIC TREATMENT

Most recently, we have worked to increase access to the pediatric formulations of our integrase inhibitor, raltegravir, in the areas of greatest need. We have developed several pediatric formulations of raltegravir, which, following clinical studies conducted in collaboration with the IMPAACT Network, have been approved by the U.S. FDA for children as young as 4

weeks of age. Studies in infants below 4 weeks of age are ongoing.

Pediatric HIV treatment is an area where multi-sector efforts are needed to facilitate development of appropriate formulations and to promote manufacturing and supply of these pediatric formulations.

The burden of pediatric HIV falls primarily in sub-Saharan Africa and in lower-income countries. The lack of demand for pediatric HIV medicines in high-income countries provides little commercial incentive for the development of optimized pediatric combinations, such as those seen in adults. Given this, public-private partnerships are key mechanisms to facilitate availability of new pediatric formulations and to develop optimized formulations and combinations of pediatric ARVs.

Recognizing the particular challenges of addressing the needs of children with HIV, we recently entered into an agreement with the Medicines Patent Pool (MPP). The agreement is designed to improve access to raltegravir for pediatric populations in 92 low- and middle-income countries where 98 percent of the children infected by HIV live.

### **Announcement of Collaboration with the Medicines Patent Pool to Expand Access to Pediatric Formulations of Raltegravir in Developing Countries**

In February 2015, we announced an agreement with the Medicines Patent Pool (MPP) to license our pediatric formulations of raltegravir for use in treating HIV-1 infection in infants and children from 4 weeks to under 12 years of age in developing countries. This is the MPP's first agreement to provide access to an HIV integrase inhibitor for use in combination HIV therapy for infants and children in this age range.

The agreement also allows for development of novel pediatric formulations of raltegravir and novel combinations—in support of the “Global Pediatric Antiretroviral Commitment-to-Action” announced by the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR); the Pediatric HIV Treatment Initiative (PHTI); and the Global Fund to Fight AIDS, Tuberculosis and Malaria; to accelerate the development of new, high-priority pediatric ARV co-formulations.

## **ENHANCING ACCESS IN THE DEVELOPING WORLD**

To facilitate access to raltegravir in sub-Saharan Africa, and in low-income countries, the areas of greatest need and the least ability to finance healthcare, we instituted a multi-strategy model that includes developing a low-cost supply chain with manufacturing partners that has enabled us to reduce our Access price in sub-Saharan Africa, Low-Income and Least Developed Countries, and to grant nonexclusive voluntary licenses to multiple generic manufacturers to supply generic raltegravir in these regions.

Given the varying levels of economic development and national strategies, in other middle-income countries we have implemented differential strategies to make meaningful improvements in patient access. We are focused on working with governments and with other country stakeholders to develop strategies tailored to each country’s HIV-access needs. As part of this effort, we have implemented a differential pricing policy based on country income level, disease burden, treatment-guideline position, patient access through national AIDS treatment programs, and market conditions. As conditions evolve, we continue to refine these country-specific models.

## **ADDRESSING ACCESS ISSUES IN THE DEVELOPED WORLD**

In developed countries, our commitment to addressing patient access needs has not wavered. In the U.S., for example, many state AIDS Drug Assistance Programs (ADAPs) have struggled to meet growing need. Over the last two decades, our company has lowered or frozen the price of its ARVs four times. We also continue to offer support to eligible patients through our comprehensive Patient Assistance Programs and Co-Pay Assistance Program. Since 2010, we have worked with Welvista and with HarborPath to offer immediate access to no-cost HIV medicines to patients on ADAP waiting lists and to support a common portal for patients accessing company-sponsored Patient Assistance Programs.

## INNOVATION AND COLLABORATION LEAD TO RESULTS

We constantly strive to discover new ways to apply our expertise, human and financial resources, and market-based solutions to address the complex challenge of patient access. Our strategies are designed to enable us to facilitate access while continuing to develop new medicines. They also help us move beyond the limits of what we can achieve if we work alone.

This desire to redraw the boundaries of possibility enabled us to pave the way for two successful private-public partnerships that were created in the last two decades in some of the countries hit hardest by HIV. Since 2000, we have been donating our ARVs to the African Comprehensive HIV/AIDS Partnerships (ACHAP) to support treatment scale-up in Botswana, and through our company's foundation, we have committed more than \$122 million to both this partnership and the MSD-China HIV/AIDS Partnership (C-MAP). The number of people in Botswana on HIV treatment increased from around 93,000 in 2007 to over 245,000 in 2014. In the areas served by the partnership in China's Sichuan Province, Chongqing Municipality and Fujian Province, the number of adult HIV-positive patients on treatment was 9,200 in 2014.

We remain committed to fulfilling our shared responsibility to improve access and to helping the world win the long-term battle against HIV. Continued dedication and strengthened investment from all stakeholders are needed to fully address the evolving challenges of the epidemic, including the multifaceted barriers to access. We look forward to building new partnerships and collaborations to move toward our common goal of achieving greater access to healthcare and continuing the fight against HIV.

## INITIATIVES

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### **Multi-stakeholder efforts, including those of governments, civil society, donors and the private sector, are needed to address the challenges of delivering comprehensive HIV prevention, care and treatment.**

Improving access to HIV medicines requires more than simply making our medicines and vaccines available at reasonable prices. We believe that to truly address the issue of access in low- and middle-income markets, the international community must pool its resources and expertise to strengthen healthcare infrastructure, to ensure adequate financing for health, and to help to build local healthcare capacity through training and support. Pharmaceutical companies alone cannot solve these immense public-health problems. Sustainable solutions will come from comprehensive approaches that draw on the expertise of all stakeholders.

For this reason, a key element of our approach to increasing access to HIV medicines is promoting and participating in public-private partnerships with governments, multilateral organizations, community-based organizations, other corporations and nongovernmental organizations (NGOs) to address specific health and development challenges beyond those over which we have immediate and direct control. While many partnerships involve our providing financial or in-kind support, we also seek to leverage our expertise and the skills of our employees to contribute in additional meaningful ways.

## ENSURING ACCESS TO OUR HIV MEDICINES FOR U.S. AIDS DRUG ASSISTANCE PROGRAMS

We have a long history of working closely with leaders from the HIV community to ensure that our approach to pricing our medications is fair and reasonable, balancing our interest in conducting extensive HIV research with efforts to support broad access to our medicines.

We were the first company to provide a price freeze for the unique U.S. state AIDS Drug Assistance Programs (state ADAPs) when, in the late 1990s, they began to suffer a funding challenge. In 2008, we announced a price freeze on ISENTRESS® (raltegravir) for state ADAPs, and in 2010, we extended the ISENTRESS price freeze and that of CRIXIVAN® (indinavir sulfate), which was first established in 2003 for eligible state ADAPs, through December 31, 2013. We also provide expanded financial relief to state ADAPs through increased discounts.

In November 2013, together with the ADAP Crisis Task Force (ACTF), we announced that we would extend our commitment

to support state ADAPs, which had struggled to meet growing need in recent years due to funding shortfalls. Through the new agreement, which was extended through December 31, 2014, we have:

- Provided continued support for initiatives that provide low-income individuals living with HIV with access to medicines
- Provided access for eligible ADAPs to obtain ISENTRESS film-coated tablets at the same “frozen” low price in effect since January 2012. We first “froze” the price of ISENTRESS for eligible ADAPs in 2008.
- Added a “frozen” low price to eligible ADAPs for ISENTRESS chewable tablets for the treatment of HIV-1 infection in children and adolescents 2 years of age and older and weighing at least 10 kg. ISENTRESS is the only integrase inhibitor approved for use in a regimen in HIV-1–infected pediatric patients.

ADAPs reach approximately one-third of people with HIV estimated to be receiving care nationally. The renewal of the existing special pricing program through 2014 was our fourth major ADAP response in five years.

## SUPPORT™ PROGRAM IN THE U.S.

Our commitment to patients’ access to our products is reflected in our **SUPPORT™ Program** which helps answer questions related to insurance coverage and provides free reimbursement-support services for patients who have been prescribed ISENTRESS or CRIXIVAN. A Program Specialist can also help patients apply for the Patient Assistance Program, which provides ISENTRESS and CRIXIVAN free of charge to eligible patients. Our company’s Patient Assistance Program was designed primarily to help those who do not have insurance coverage; however, individuals who have insurance, including Medicare Part D, but still have trouble paying for their medicines may request that an exception be made, provided that their income is not above a set limit. More information about the SUPPORT Program can be obtained by calling 1-800-850-3430. [Learn more.](#)

## OTHER ACCESS AVENUES: HARBORPATH, CPAPA

We were one of the first companies to provide our HIV medicines to uninsured patients on waiting lists for drugs under the AIDS Drug Assistance Program (ADAP). We continue to provide our HIV medicines to patients on ADAP waiting lists through HarborPath, a nonprofit organization dedicated to helping the uninsured living with HIV and/or hepatitis C gain access to free medications offered through a single portal.

We also participate in the national Common Patient Assistance Program Application (CPAPA) for HIV medications. The form was developed by the Department of Health and Human Services (DHHS), participating pharmaceutical companies, the National Alliance of State and Territorial AIDS Directors (NASTAD) and community stakeholders. The form can be used both by people living with HIV and by their providers, and reduces the need to complete several different and individual PAP application forms for HIV medications.

## CO-PAY ASSISTANCE PROGRAM IN THE U.S.

In addition to the SUPPORT Program, we have a program in the U.S. for eligible patients on ISENTRESS. If patients have private insurance and an out-of-pocket cost for ISENTRESS, they may be eligible to receive a savings coupon. The coupon provides savings toward their out-of-pocket costs, up to a maximum of US\$400 per prescription of ISENTRESS (regardless of the number of tablets supplied by the prescription). The coupon can be used up to 12 times prior to its expiration date. Restrictions, terms and conditions, apply. [Learn more.](#)

# PUBLIC POLICY

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**We actively engage with stakeholders involved in HIV/AIDS outreach**

## and public policy through a number of mechanisms.

In the U.S., we have established ethnically diverse HIV Community Advisory Boards that include HIV community leaders from across the nation. We meet with these boards regularly to discuss new data, clinical trial design, and marketing and access strategies. We also meet regularly with the European Community Advisory Board of the European AIDS Treatment Group to discuss similar issues, and we engage with stakeholders in public policy discussions through numerous scientific and policy events and initiatives.

# PARTNERSHIPS

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## Improving access to care requires more than simply making our medicines available and affordable. Collaboration is essential to enhancing access in HIV.

The most important factors for long-term sustainability are strengthening healthcare infrastructure, ensuring adequate financing for health, and helping to build local healthcare capacity through training and support. Public-private partnerships have a critical role to play in this process, drawing on the complementary expertise of all stakeholders—governments, international agencies, community organizations, donors, the private sector, nongovernmental organizations (NGOs), patients and others—to identify the most promising and efficient ways to address the impact of HIV in a variety of resource-limited settings.

To learn more about our partnerships to address the challenge of HIV, visit:

- African Comprehensive HIV/AIDS Partnerships (ACHAP)
- MSD-China HIV/AIDS Partnership
- HIV Care Collaborative

# RESEARCH

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## Our company has had an intensive, broad-based HIV clinical research program in place since 1985 that has sought to address both treatment and prevention.

In addition to our own research efforts, we also have entered into collaborations with other researchers and scientific organizations to help accelerate the search for new treatments and possible cures. Our work has been pioneering, and was pivotal in the development of new antiretroviral (ARV) treatments including protease inhibitors (PIs), non-nucleoside reverse transcriptase inhibitors (NNRTIs) and an integrase inhibitor. We have also played an important role in collaboration with others to define the principles for combination ARV treatment that are the standard for today's treatment paradigm.

## HISTORIC TIMELINE OF OUR HIV RESEARCH EFFORTS

- In 1989, our scientists established the role of protease in the HIV life cycle and were the first to publish the crystal structure of HIV protease shortly thereafter; they were also among the first to discover and develop medicines for the treatment of HIV
- In 1992, our scientists helped to discover efavirenz, a non-nucleoside reverse transcriptase inhibitor
- In 1996, we introduced CRIXIVAN® (indinavir), a protease inhibitor
- Beginning in 1999, we sought registration for efavirenz as STOCRIN® in many countries around the world. Efavirenz remains a key component in treatment regimens around the world, including in the WHO HIV Treatment Guidelines.

- In 2005, together with our partners, we began a large trial to test the efficacy of a developmental cellular-immune-based vaccine. The study, known as the STEP trial and cosponsored with the National Institutes of Health (NIH) and the HIV Vaccine Trials Network (HVTN), was designed to evaluate whether the vaccine prevented HIV infection and whether it reduced virus levels in those who developed infection. In an interim analysis, the vaccine did not reduce the incidence of infection nor did it reduce virus levels, and the study was discontinued.
- In 2006, a partnership between Merck & Co., Inc., Kenilworth, NJ, U.S.A., Bristol-Myers Squibb and Gilead was established to develop a once-daily, single-tablet-regimen HIV treatment. It resulted in the approval of ATRIPLA<sup>®</sup> (efavirenz, emtricitabine, tenofovir disoproxil fumarate), which was marketed by Bristol-Myers Squibb and Gilead in the U.S., Canada and Europe and by our company in many low- and middle-income countries around the world. The combination of the drugs included in ATRIPLA has become the standard first-line HIV regimen in the WHO guidelines.
- In 2007, we introduced ISENTRESS<sup>®</sup> (raltegravir), the first integrase inhibitor and the first ARV treatment to target the integrase enzyme, one of the components the HIV virus needs for replication. Integrase inhibitors are now the backbone in three of the four preferred first-line regimens in the United States Department of Health & Human Services treatment guidelines.

We continue to focus on comprehensive research and development that targets HIV, recognizing the need for new methods to address the epidemic. Our current R&D work in HIV includes programs to develop novel HIV-prevention technologies, new HIV antiretroviral medicines, and approaches to addressing HIV latency and eradication.

We have an active HIV R&D program to develop new HIV antiretroviral medicines that address unmet needs in HIV treatment. Among the clinical development programs currently underway are the development of a once-daily formulation of raltegravir, currently in Phase III trials, a novel second-generation non-nucleoside reverse transcriptase inhibitor in Phase III, and several earlier-stage clinical development programs, demonstrating our ongoing commitment to HIV therapeutic R&D.

## BIOMEDICAL PREVENTION RESEARCH

We began research into an HIV vaccine shortly after the virus was identified in the mid-1980s and have been actively involved in HIV biomedical prevention R&D since that time. In addition to testing CTL-based vaccine approaches, our scientists have also tested antibody-based approaches and have studied novel immunogen designs based on essential and conserved regions of the HIV envelope glycoprotein.

Our current R&D efforts in prevention focus on developing a novel HIV prevention option for women utilizing our company's proprietary vaginal contraceptive ring technology and HIV antiretrovirals. This development program is being conducted in partnership with the National Institutes of Health.

*“Building on our long-standing commitment to the HIV community, we continue to evaluate new drug candidates we believe have the potential to make a meaningful difference in the lives of HIV patients.”*

Daria Hazuda, Ph.D., vice president, Infectious Diseases, MRL

## ONGOING RESEARCH EFFORTS TO ERADICATE HIV

In July 2011, we announced that we would be participating in two collaborative efforts led by two prominent academic institutions, the University of North Carolina (UNC) Chapel Hill and the University of California San Francisco (UCSF), to develop new approaches toward eradicating HIV. UNC, researchers from nine additional U.S. universities, and our scientists continue to study HIV latency and ways to purge persistent infection of the virus from the body. Separately, researchers at UCSF are working with an international team of academics, government staff and our scientists on a five-year research effort to define HIV's reservoirs, better understand the reservoirs and test potential treatments. The National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, is the primary funding organization for both of these research efforts. We do not receive any funding for participation in either effort.

# PEDIATRICS

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**As part of the company's commitment to fight HIV/AIDS, we have conducted extensive research and development (R&D) efforts to bring forth pediatric formulations for our HIV antiretrovirals (ARVs).**

## R&D EFFORTS FOR PEDIATRIC FORMULATIONS FOR OUR ARVS

In 2007, we began collaborating with the National Institute of Allergy and Infectious Diseases (NIAID), the National Institute of Child Health and Human Development (NICHD) and the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Network, to conduct a Phase I/II, multicenter, open-label, noncomparative study to evaluate the safety, tolerability, pharmacokinetics and antiretroviral activity of ISENTRESS® (raltegravir) in children and adolescents: IMPAACT P1066. This study of three formulations—a film-coated tablet, a chewable tablet and granules for oral suspension—included more than 150 HIV-infected children ranging from 4 weeks to 18 years of age in the U.S., Latin America and Africa.

On the basis of results from this study, all three formulations of ISENTRESS have now been approved by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency for use in infants (as young as 4 weeks of age and weighing at least 3 kg), toddlers, children or adolescents. Both the chewable tablets and the granules for suspension are dosed based on weight.

Efforts to register these three formulations of raltegravir broadly in the countries with the greatest pediatric HIV burden are ongoing. And as of October 2014, the pediatric formulations are registered in more than 45 countries.

Also in collaboration with IMPAACT, we are conducting one study in neonates, IMPAACT P1097, examining raltegravir levels in term infants born to mothers who have taken raltegravir in pregnancy (these infants were not given raltegravir directly), which has completed enrollment. A new component of this study (P1097A) is ongoing, and will similarly examine raltegravir levels, but this time in low-birth-weight (including preterm) infants whose mothers have taken raltegravir in pregnancy. Another study, IMPAACT P1110, of active raltegravir dosing to neonates at high risk for acquiring HIV infection, is now open. This study, which uses the granules-for-suspension formulation, aims to define the safety and appropriate dose of raltegravir for neonates from birth to 6 weeks of age.

The burden of pediatric HIV falls primarily on sub-Saharan Africa and on low- and low-middle income countries. The lack of demand for pediatric HIV medicines in high-income developed countries provides little commercial incentive for the development of pediatric optimized combination formulations, such as the optimized combination formulations for adults. In May 2014, UNITAID—in cooperation with the Medicines Patent Pool (MPP) and the Drugs for Neglected Diseases Initiative (DNDi)—announced an integrated partnership intended to increase access to pediatric HIV treatment by developing improved or new pediatric formulations of HIV medicines. In support of this initiative, we announced that we had entered into negotiations with the MPP for licenses for the pediatric formulations (chewable tablets and granules for suspension) of raltegravir. In February 2015, we announced an agreement with the MPP allowing for generic supply of pediatric raltegravir formulations in 92 low- and middle-income countries, where 98 percent of children infected by HIV live. [Read the full press release.](#)

## AVAILABILITY

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**We continually look for ways to reduce the cost of our antiretrovirals**

## (ARVs) for people living in the world's poorest countries and those hit hardest by the epidemic.

One way is to work with external manufacturers and suppliers to achieve incremental efficiencies. For ISENTRESS<sup>®</sup> (raltegravir), we have established a low-cost supply chain with external partners for commercialization in all low-income countries and all countries in sub-Saharan Africa.

With the implementation of this supply chain, we have been able to reduce the price of ISENTRESS to US\$1.85 per day (ex-MSD) in these countries. We have also granted multiple nonexclusive licenses to several Indian generic manufacturers for the manufacture and commercialization of the 400 mg tablet formulation of raltegravir in 60 low-income and sub-Saharan African countries. In addition, in February 2014, together with Cipla, we announced a strategic partnership to co-market raltegravir (400 mg tablet) in the Indian market. In February 2015, together with the Medicines Patent Pool (MPP), we announced a licensing agreement for pediatric formulations of raltegravir for children less than 12 years of age covering 92 low- and low-middle-income countries.

To date, we have also granted royalty-free licenses for efavirenz to six South African generic manufacturers.

### Compulsory Licensing

We understand that access to medicines is a particularly complex issue in many developing countries, and we respect that international trade agreements—especially the World Trade Organization's TRIPs agreement (trade-related aspects of intellectual property rights) and subsequent Declaration on TRIPs and Public Health agreements—provide countries with the authority, in limited circumstances, to use compulsory licensing. In the case of medicines, we further respect that compulsory licenses may be issued, under limited and specified circumstances, to meet a health crisis or emergency.

However, both the letter and the spirit of international trade rules suggest that such authority should be used only in the most extraordinary and limited circumstances in order to support all forms of innovation around the world. We will work vigorously with governments and other stakeholders in the developing world to meet the health needs of patients and increase access to medicines. For more information on our public policy position on compulsory licensing, [click here](#).

## ANTIRETROVIRAL REGISTRATION

We are committed to pursuing rapid registration of our antiretrovirals (ARVs), including registration in those countries most affected by HIV/AIDS. Currently, our ARVs are registered or available through import waiver in many countries. Since the first approval in 2007, ISENTRESS has received regulatory approval in more than 100 countries. Details of registration and availability of our four ARVs are available through the links below:

- ATRIPLA<sup>®</sup> (efavirenz, emtricitabine, tenofovir disoproxil fumarate)
- CRIXIVAN<sup>®</sup> (indinavir sulfate)
- ISENTRESS<sup>®</sup> (raltegravir)
- STOCRIN<sup>®</sup> (efavirenz)

### World Health Organization Prequalification

STOCRIN, CRIXIVAN and ATRIPLA have received World Health Organization (WHO) prequalification. WHO prequalification verifies that medicines meet the quality, safety and efficacy requirements of UN agencies, including UNICEF and the Pan American Health Organization. All of our company's formulations of ISENTRESS, including the 400 mg tablet, the 100 mg and 25 mg chewable tablets, and the granules for suspension, have been approved by the U.S. FDA and the European Medical Agency, making these formulations eligible for purchase by both the U.S. PEPFAR program and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. We are evaluating the potential to submit these products for WHO prequalification.

## HIV PRICING POLICIES

Our differential-pricing policy is part of our commitment to addressing HIV through a multi-pronged strategy, with the goal of ensuring that our HIV antiretroviral (ARV) medicines reach as many of those in need as possible.

### Pricing Policy for HIV Medicines in the Developing World

Our differential-pricing program not only facilitates access, but also helps us sustain our investment in clinical and medical education programs in developing countries with the greatest disease burden and least ability to finance healthcare, while maintaining an incentive to sustain innovation and provide our medicines in countries with a lower HIV disease burden and a greater ability to finance healthcare.

**ISENTRESS<sup>®</sup>, STOCRIN<sup>®</sup>, CRIXIVAN<sup>®</sup>**

We offer our lowest Access price for our HIV medicines to countries based on a combination of highest disease burden and lower country income (gross national income [GNI] per capita), as defined by the World Bank. A list of eligible Access countries is provided [here](#). As of July 1, 2014, the Access prices for our HIV medicines for eligible customers<sup>1</sup> are:

			<b>HIV Pricing</b>
Drug Name	Daily Dose	Pricing US\$ ppy (unit)	
			STOCRIN <sup>®</sup>
50mg tablet	4 (200mg)	169 (0.12)	
200mg tablet	3	394 (0.36)	
600mg tablet	1	237 (0.65)	
30mg/ml suspension (bottle)	9 ml	310 (0.094)	
30mg/ml suspension (bottle)	12 ml	413 (0.094)	
			CRIXIVAN <sup>®</sup> (indinavir)
400mg cap	4	394 (0.27)	
			ISENTRESS <sup>®</sup> (raltegravir)
400mg tablet	2	675 (0.925)	
100mg chewable tablet	based on weight	(.60)	
25mg chewable tablet	based on weight	(.30)	

Countries classified as lower-middle income and upper-middle income<sup>2</sup> by the World Bank are eligible for prices that are discounted from those in high-income countries. These prices will vary based on, among other things, a combination of country income, disease burden, treatment guideline positioning, patient access through national AIDS treatment programs and market conditions, and will be negotiated with each government. For high-income countries, we will make ISENTRESS available at competitive prices that take into account the innovation and value that ISENTRESS represents.

**ATRIPLA**

We sell ATRIPLA at US\$1.68 per day, or US\$613 per year, in 98 Access countries, as defined by our agreement with Gilead.

1 Customers eligible for public-sector Access pricing in eligible Access countries will include: governments and programs fully funded by governments and/or by multi- and bilateral donors (e.g., the Global Fund, PEPFAR, UNITAID); UN System organizations; NGOs and other noncommercial providers of HIV treatment in sub-Saharan Africa; World Bank–defined low-income countries, UN-defined least developed countries and India. We offer these products on a Delivered Duty Unpaid (DDU), Carriage and Insurance Paid (CIP), or Carriage Paid To (CPT) airport-of-destination (Incoterm, 2000) basis. Additional costs may include freight, insurance, customs handling, taxes and duties.

2 Customers eligible for public-sector pricing in low-middle and upper-middle income countries will include: governments and programs fully funded by governments and/or by multi- and bilateral donors (e.g., the Global Fund, PEPFAR, UNITAID); UN System organizations; and NGOs. Low- and middle-income countries that are members of the European Union are not eligible for pricing under this Access program.

Infectious Diseases

# NEGLECTED TROPICAL DISEASES



**Our company initiated research on MECTIZAN<sup>®</sup> (ivermectin) for use in humans for river blindness, a neglected tropical disease (NTD), in 1978 and continues to conduct research to address the burden of neglected tropical diseases today.**

The World Health Organization (WHO) reports that the burden caused by many of the 17 diseases that affect more than 1 billion people worldwide can be effectively controlled and, in many cases, eliminated or even eradicated. In 2012, the WHO published a new strategy, *Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases—A Roadmap for Implementation*, to set targets for what can be achieved by the end of the decade.

## THE LONDON DECLARATION

We are an original signatory to the London Declaration, a collaborative effort launched in 2012 to accelerate progress toward eliminating or controlling 10 NTDs by the end of the decade. Our company joined 12 other global pharmaceutical companies and many other stakeholders, including endemic country governments, the WHO, the Bill & Melinda Gates Foundation, USAID, the UK Department for International Development (DFID), nongovernmental organizations (NGOs) and other organizations in this effort. Together with the other pharmaceutical companies, we committed to continuing or increasing donations of medicines to treat or prevent these diseases; donors committed financial resources; and NGOs agreed to support implementation needs. The partners came together under the banner of “Uniting to Combat NTDs” to track progress and identify gaps that need to be addressed in order to reach the goals of the London Declaration. Through our MECTIZAN Donation Program, we are helping achieve the disease control and elimination goals for two diseases, onchocerciasis (river blindness) and lymphatic filariasis, or LF.

Although existing tools are having a major impact, several NTDs require new or improved drugs and diagnostics to achieve the goals of the London Declaration. We are engaged in various efforts to advance progress toward developing new drugs and diagnostics. For example, our company, along with several other companies, is providing access to compound libraries with external researchers through the World Intellectual Property Organization’s Re:Search (WIPO Re:Search) Consortium and Drugs for Neglected Disease Initiative (DNDi). [Learn more](#) about our Social Licensing Approach for NTDs.

Taken together, through our drug donations for onchocerciasis and lymphatic filariasis and our research and development activities for schistosomiasis, visceral leishmaniasis and Chagas disease, we are supporting the London Declaration goals for five NTDs.

For more information on progress toward the London Declaration goals, please

see <http://unitingtocombatntds.org/report/delivering-promises-driving-progress-second-report-uniting-combat-ntds>.

For more information on our company's drug donations for onchocerciasis and lymphatic filariasis, please refer to the MECTIZAN® (ivermectin) Donation Program.

## RESEARCH & DEVELOPMENT

### WIPO Re:Search

Our company is one of the founding members of WIPO Re:Search, a consortium of public and private organizations that facilitate research on neglected tropical diseases, malaria and tuberculosis. Through this consortium, we entered into an agreement with researchers at the University of California, San Francisco (UCSF), providing UCSF scientists with a series of compounds for screening that have the potential to lead to better and safer treatments for patients suffering from schistosomiasis. Schistosomiasis is a blood-borne parasitic disease that affects millions of people living in the developing world. In addition, we have provided relevant expertise to other WIPO Re:Search members as requested and appropriate.

### G-FINDER Survey

To contribute to global awareness and advocacy on R&D for NTDs, we participate in the annual G-FINDER survey. Since 2008, G-FINDER has reported on global investments into neglected disease R&D from a range of public and private institutions, and is considered a unique source of current information and ongoing trends for stakeholders engaged in NTDs.

### DNDi Collaboration

In June 2009, our company and the nonprofit organization DNDi entered into a collaborative agreement to support the discovery and development of improved treatments for a range of NTDs. The partnership focuses on numerous NTDs, including visceral leishmaniasis and Chagas disease, both of which infect millions of people. Through a nonexclusive, royalty-free license to DNDi, we are contributing small-molecule assets and related intellectual property for DNDi to conduct early-development programs for drug candidates for treatment of NTDs, with the primary goal of manufacturing and distributing drugs at low cost to the public sector in resource-poor countries. We will share joint intellectual property rights on drug candidates generated through early development, and our company will retain the option to undertake late clinical development and registration of these drug candidates. In 2013, we continued to collaborate with DNDi by placing one of our scientists on rotation at DNDi through the MSD Fellowship for Global Health.

## CLINICAL RESEARCH

A Phase II investigational proof-of-concept clinical study to evaluate the oral antifungal agent posaconazole (marketed as NOXAFIL® oral suspension in the U.S. and the EU, and in several other countries) for the treatment of chronic Chagas disease is ongoing. In planning the study, we consulted with international agencies and research organizations to identify current medical needs and reach consensus on a study design for posaconazole in asymptomatic chronic Chagas disease. Study completion is anticipated in 2015. [Learn more.](#)

Infectious Diseases

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# TUBERCULOSIS



**In January 2012, we joined six other pharmaceutical companies, four research institutions and the Bill & Melinda Gates Foundation to launch the TB Drug Accelerator (TBDA) partnership, which aims to speed the discovery of essential new treatments for tuberculosis (TB).**

Through the partnership, companies will share targeted sections of their compound libraries and data with one another and with academic research institutes, in order to develop the best drug prospects, regardless of where they originate. As of the end of 2014, in collaboration with several TBDA members we had identified several promising classes of molecules that inhibit mycobacterium tuberculosis growth. Activities for 2015 will continue to focus on progressing these molecules toward identification of drug candidates, while also identifying additional novel hits by completing an internal screen of our company's compound collection.

# VACCINES

## MAIN

Vaccines are one of the most valuable health innovations in modern times, according to the World Health Organization (WHO), the U.S. Centers for Disease Control (CDC) and Prevention, and other leading health authorities.<sup>1,2,3,4,5</sup>

We aim to increase population vaccine coverage and achieve the broadest possible access to our vaccines within a sustainable framework—one that allows ongoing research, development and distribution of innovative vaccines that address important unmet health needs. Consistent with our overarching Access to Health Statement of Guiding Principles, we have a comprehensive strategy that includes the following commitments:

## OUR COMMITMENTS

- Support ongoing surveillance and assessments to understand infectious diseases trends and their impact on people
- Engage in innovative research and development (R&D) to provide vaccines that address vital global health needs
- Strive to maintain the highest standards of safety and product quality in all stages of vaccine development and manufacturing
- Invest in manufacturing improvements to help assure reliable product supply and lower production costs
- Use tiered (or differential) pricing—systematically pricing vaccines at differing levels appropriate to the value they create under economic conditions where they are used—to facilitate broad access
- Work with governments and nongovernmental organizations (NGOs) to build sustainable and effective vaccine delivery programs that reliably reach people

<sup>1</sup> WHO, UNICEF, World Bank. State of the world's vaccines and immunization, 3rd ed. Geneva, World Health Organization, 2009. [http://whqlibdoc.who.int/publications/2009/9789241563864\\_eng.pdf?ua=1](http://whqlibdoc.who.int/publications/2009/9789241563864_eng.pdf?ua=1). Accessed September 23, 2014.

<sup>2</sup> Centers for Disease Control and Prevention. Ten Great Public Health Achievements—United States, 2001–2010. *Morb Mortal Wkly Rep.* 2011;60(19):619–623.

<sup>3</sup> Centers for Disease Control and Prevention. Ten Great Public Health Achievements—Worldwide, 2001–2010. *Morb Mortal Wkly Rep.* 2011;60(24):814–818.

<sup>4</sup> Centers for Disease Control and Prevention. Achievements in Public Health, 1900–1999 Impact of Vaccines Universally Recommended for Children – United States, 1990–1998. *Morb Mortal Wkly Rep.* 1999;48(12):243–248.

<sup>5</sup> World Medical Association. Statement on the Prioritisation of Immunisation. World Medical Association 63 General Assembly, 2012; Bangkok, Thailand. <http://www.wma.net/en/30publications/10policies/v4/>. Accessed September 23, 2014.

## Our company conducts innovative research and development to provide vaccines that address vital unmet and emerging global health needs.

For more than 100 years, our scientists have been discovering vaccines that have been impacting lives. We remain one of the few companies dedicated to the complex business of researching and producing vaccines to address the public health burden of disease for people around the world.

We support the Millennium Development Goal of reducing childhood mortality (MDG 4) through our efforts to address two main causes of death in children under 5 years of age in the developing world from preventable or treatable disease: diarrheal and pneumococcal diseases.<sup>1</sup> In addition, some of the vaccines being researched by our scientists target diseases that are particularly prevalent in the developing world. This includes collaborations to address diseases of important global significance, such as HIV and malaria.

We are also working to develop a vaccine to prevent dengue. Each year, it is estimated that there are 390 million people infected with dengue viruses throughout the tropics and subtropics, resulting in up to 100 million cases of dengue fever, with at least 500,000 of those cases being classified as severe.<sup>2</sup> Furthermore, it is currently estimated that there are 3.97 billion people living in more than 140 countries where dengue transmission occurs, and there is no registered vaccine or specific therapy to protect these people at risk. We look to establish new business models and partnerships for research and development.

A case in point is the MSD-Wellcome Trust Hilleman Laboratories headquartered in India. Hilleman Laboratories, founded in 2009, is the first-of-its-kind nonprofit research and development joint venture with a mission to develop affordable vaccines for global health. Its expertise in medical research is targeted toward creating new vaccines in areas of unmet need as well as adapting existing vaccines for more effective delivery in low-income countries. Beginning in 2011, Hilleman Laboratories has been focused on a project to develop a heat-stable rotavirus vaccine including the development of a novel delivery device. The new thermostable rotavirus vaccine is anticipated to enter human clinical trials in 2015.

In addition, in 2014, Hilleman Laboratories initiated an international collaboration to develop a low-cost oral cholera vaccine. Working closely with academic institutions in Sweden as well as clinical and manufacturing organizations in Bangladesh, Hilleman Laboratories is bridging the gap between academia and biotech for advancement of affordable life-saving vaccines. Hilleman Laboratories continues to engage the external global health community through various forums, including ongoing dialog with its Strategic Advisory Group, which is composed of leading health experts who provide the laboratories with input on customer needs, strategic direction and disease-area needs.

<sup>1</sup> UNICEF: Progress for Children Report, 2011

<sup>2</sup> [www.denguevaccines.org](http://www.denguevaccines.org)

## MANUFACTURING & SUPPLY

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### We invest in manufacturing improvements to help assure reliable product supply and lower production costs.

We continue to make investments in manufacturing capacity as part of our long-term strategy to reach more people around the world with our vaccines. As evidence of our progress toward supplying more of the globe, in 2014 nearly 60 percent of vaccine doses provided went to ex-U.S. countries as compared to approximately 30 percent in 2010.

In 2013, we received approval from the U.S. Food and Drug Administration (FDA) to manufacture bulk varicella at the company's site in Durham, North Carolina, for use in our vaccines against chickenpox and shingles. This approval will enable the site to produce bulk varicella supply for the U.S. and help boost the company's overall global supply capabilities. The

Durham facility is part of our more than \$1 billion investment in our vaccine manufacturing capabilities over the past nine years.

These investments demonstrate the company's continued commitment to providing high-quality vaccines to meet increasing global demand for these products. In addition, we continue to explore potential partnerships with low-cost manufacturers to bring down the cost of vaccines.

We have a long history of progress in this area. Our hepatitis B license of technology to manufacturers in China dates back to the 1990s, and has resulted in over 100 million doses of recombinant hepatitis B vaccine being produced by our collaborators each year to address the public health burden of hepatitis B in China.

In 2014, together with the Instituto Butantan, a Brazilian biomedical research center and vaccine producer, we signed an agreement outlining the terms of a productive development partnership (PDP) for the technology transfer of GARDASIL<sup>®</sup>, our company's quadrivalent human papillomavirus (HPV) vaccine. This agreement culminates several years of work and follows the inclusion of GARDASIL in Brazil's National Immunization Program. Through this important transfer of vaccine technology, the government of Brazil will be able to fully support its long-term national vaccination efforts against HPV-related diseases.

## PRICING

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**Our company works with governments, international health and development organizations, donor groups, nongovernmental organizations (NGOs), and others to support countries' population health aims and help improve sustainable access to our vaccines.**

We use tiered pricing for vaccines as an equitable way to achieve twin objectives: to expand access to people who need vaccination, and also to ensure sufficient return on investment over time to support the complex and costly research and development and other activities necessary to create new vaccines.

We consider a variety of factors in arriving at a price in a given country, including public health need, health and economic value of the vaccine, country's ability to support vaccine delivery and achieve population health coverage, the country's level of economic development, fiscal capacity for investments in health and actual health spending, country's mechanism and policies for procuring vaccines, and others.

In the developing world, we offer ROTATEQ<sup>®</sup> and GARDASIL<sup>®</sup> at an access price that is significantly less than the price of these vaccines in developed markets. The access price is exclusive to the public sectors of the Global Alliance for Vaccines and Immunization (GAVI)-eligible countries, meeting the needs of the developing world by facilitating access to these innovative vaccines in the poorest countries, while making sure they remain affordable and sustainable in the long term. We believe that our pricing approach contributes to wider access to our vaccines, while taking into account our need to continue investing in vaccine research, development and production.

For additional information regarding pricing, see [Public Policy Statement: Access to Our Vaccines](#).

## STAKEHOLDER ENGAGEMENT

**Our partnership with GAVI and other Alliance partners is helping to ensure that infants and girls in the poorest countries have access to rotavirus and HPV vaccines.**

Through active engagement of the GAVI Alliance, we have helped to foster an environment that led to mobilization of funding and partner technical support for the introduction of new vaccines in the world's poorest countries. Focusing on the anticipated need for our Human Papilloma Virus (HPV) and rotavirus vaccines, GARDASIL<sup>®</sup> and ROTATEQ<sup>®</sup>, our company collaborated with GAVI and other members of the Alliance, including UNICEF, to understand estimated country demand for the vaccines over time, and to determine the lowest possible access prices that could be sustainably offered to GAVI and UNICEF for the vaccine volumes to be delivered to these poorest countries. To date, 16 of the 23 countries approved by GAVI for HPV have selected GARDASIL, and five GAVI-eligible countries are using ROTATEQ. This has resulted in greater

than 10 million doses of GARDASIL and ROTATEQ being shipped to GAVI eligible countries through 2014.<sup>8</sup> For additional information regarding our HPV program, please visit: [GARDASIL Access Program](#).

<sup>1</sup> WHO, UNICEF, World Bank. State of the world's vaccines and immunization, 3rd ed. Geneva, World Health Organization, 2009. [http://whqlibdoc.who.int/publications/2009/9789241563864\\_eng.pdf?ua=1](http://whqlibdoc.who.int/publications/2009/9789241563864_eng.pdf?ua=1). Accessed September 23, 2014.

<sup>2</sup> Centers for Disease Control and Prevention. Ten Great Public Health Achievements—United States, 2001–2010. *Morb Mortal Wkly Rep*. 2011;60(19):619–623.

<sup>3</sup> Centers for Disease Control and Prevention. Ten Great Public Health Achievements—Worldwide, 2001–2010. *Morb Mortal Wkly Rep*. 2011;60(24):814–818.

<sup>4</sup> Centers for Disease Control and Prevention. Achievements in Public Health, 1900–1999 Impact of Vaccines Universally Recommended for Children – United States, 1990–1998. *Morb Mortal Wkly Rep*. 1999;48(12):243–248.

<sup>5</sup> World Medical Association. Statement on the Prioritisation of Immunisation. World Medical Association 63 General Assembly, 2012; Bangkok, Thailand. <http://www.wma.net/en/30publications/10policies/v4/>. Accessed September 23, 2014.

<sup>6</sup> November 2014 Press Release with NewLink Genetics

<sup>7</sup> GAVI Press Release

<sup>8</sup> Numbers provided by Brendan Cooley

## EBOLA

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### A NOVEL MODEL OF COLLABORATION AND AN UNPRECEDENTED RESPONSE TO A GLOBAL HEALTH CRISIS IN WEST AFRICA

The Ebola epidemic that was first reported in 2014 is the largest in history, and has taken a devastating toll on affected countries in West Africa. Though in some areas the outbreak is declining, the virus has the potential to spread to other parts of Africa and beyond, and eliminating the outbreak at its source in West Africa is a critical international health priority.



In November 2014, our company announced that we had entered into a collaboration with NewLink Genetics Corporation to research, develop, manufacture and distribute NewLink's investigational rVSV-EBOV (Ebola) vaccine candidate. The rVSV-EBOV vaccine was created by scientists at the Public Health Agency of Canada's (PHAC's) National Microbiology Laboratory.<sup>6</sup> In collaboration with Newlink Genetics, we are working with global partners including the WHO, CDC, GAVI, the U.S. Department of Health and Human Services, the U.S. Department of Defense, the Wellcome Trust, West African country governments and many others to advance research and development for this vaccine candidate as expeditiously as possible.

The two companies have also committed to provide the vaccine to GAVI-eligible countries at the lowest possible access price if the vaccine meets regulatory standards for safety and effectiveness in clinical trials and is appropriately licensed.<sup>7</sup> The vaccine candidate has been studied in Phase I studies, and sufficient safety and immune response data were generated to support moving the vaccine forward for Phase II/III testing. Phase II/III testing was initiated with studies starting in Liberia on February 2, 2015, in Guinea on March 7, 2015 and in Sierra Leone on April 9, 2015. Thus the vaccine candidate has been able to move quickly into three large-scale trials in affected countries in West Africa.

Through these efforts, we hope to apply our vaccine development expertise and commercial leadership to expedite the development of a vaccine for Ebola and, if demonstrated to be efficacious and well-tolerated, to make it available to individuals and communities at risk of Ebola virus infection around the world. This partnership represents a new model of collaboration to address a critical global disease threat. For additional information regarding our humanitarian response to the

Ebola crisis, please see our [Giving](#) section.

# ROTAVIRUS

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## We are pursuing multiple approaches to increase global access to ROTATEQ<sup>®</sup> (rotavirus vaccine, live, oral, pentavalent).

Rotavirus gastroenteritis is a leading cause of severe diarrhea in infants and young children. In 2008, an estimated 453,000 rotavirus gastroenteritis-associated child deaths occurred worldwide.<sup>1</sup> Since 2009, the World Health Organization's (WHO's) Strategic Advisory Group of Experts (SAGE) has recommended the inclusion of rotavirus vaccination in all national immunization programs, helping to ensure access to rotavirus vaccines in the world's poorest countries.<sup>2</sup>

We believe that we have an important role in contributing toward this goal. Since its launch in 2006, ROTATEQ has been registered and approved in more than 120 countries, and approximately 136 million doses have been distributed worldwide (numbers as of December 2014). Currently, Africa accounts for a large proportion of the global total of rotavirus deaths with nearly a quarter of a million African children dying from the dehydrating diarrhea caused by rotavirus infection every year.<sup>3</sup> Together with our partners, including country governments, the GAVI Alliance and other stakeholders, we are working to expand access to rotavirus vaccines to help address this problem. Currently, four African countries—Rwanda, Burkina Faso, Gambia and Mali—have launched national immunization programs using ROTATEQ.

A case study<sup>4</sup> conducted by AMP on the introduction in Burkina Faso concluded that the introduction was successful and the three-dose schedule integrated well into the current schedule of the National Immunization Programme. This case study enabled identification of challenges and solutions, providing useful information for countries planning to introduce the rotavirus vaccine in the future. We continue to evaluate and implement approaches aimed at improving product attributes to better meet the specific needs of low- and middle-income countries in the future. This includes work to develop a heat-stable rotavirus vaccine being conducted through the MSD-Wellcome Trust Hilleman Laboratories.

## Rotavirus Vaccine Impact in Rwanda<sup>5</sup>

Rwanda is a small country with approximately 10.5 million citizens. Infant mortality is 50/1,000 births, while under 5 mortality is 76/1,000 births. In 2011, 21 percent of under-5 deaths were due to diarrhea. In May 2012, Rwanda became the first African country to introduce the pentavalent rotavirus vaccine, ROTATEQ, into its national immunization program. In 2013, three-dose vaccine coverage was high at 96 percent. A study conducted in Rwanda found that after ROTATEQ introduction:



- Rotavirus hospital admissions decreased in all age groups post-vaccine introduction, with the greatest decrease occurring among children 3 to 17 months of age
- The proportion of total hospital admissions due to diarrhea decreased from ~20 percent pre-vaccine introduction to 13 percent post-vaccine introduction
- Annual peak in diarrheal hospitalizations, which corresponds to a peak in rotavirus disease, was substantially blunted in 2013 compared to the 2009 – 2011 baseline.

<sup>1</sup> Tate, J., et al., 2008 estimate of worldwide rotavirus-associated mortality in children younger than 5 years before the introduction of universal rotavirus vaccination programmes: a systematic review and meta-analysis, *Lancet*, February 2012, p. 136.

<sup>2</sup> [http://www.who.int/mediacentre/news/releases/2009/rotavirus\\_vaccines\\_20090605/en/index.html](http://www.who.int/mediacentre/news/releases/2009/rotavirus_vaccines_20090605/en/index.html), Accessed March 6, 2013.

<sup>3</sup> Preventing Rotavirus Disease in Gambia, RotaFlash.

<sup>4</sup> GIN August 2014: Burkina Faso AMP.

<sup>5</sup> Impact of Rotavirus Vaccine Introduction in Rwanda.

## CERVICAL CANCER

**Our company is committed to supporting public health initiatives that increase access to vaccines where they are most needed.**

In March 2014, more than 5,000 municipalities in Brazil kicked off the national campaign of human papillomavirus (HPV) immunization using GARDASIL<sup>®</sup> [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] to vaccinate appropriate girls in Brazil of age 9–13. In Brazil, cervical cancer is a leading cause of death in women, with more than 5,000 women dying of the disease each year.<sup>1</sup> GARDASIL is now being supplied to the National Immunization Plan (NIP) through a partnership between our company and Instituto Butantan, a Brazilian biomedical research center and vaccine producer.

This partnership highlights our commitment to working closely with governments and scientific institutions to ensure broad and sustained access to GARDASIL. We have a long-standing commitment to helping improve access to GARDASIL in developing countries, where more than 85 percent of the world's cervical cancer cases occur.<sup>2</sup> We have engaged in a number of multidisciplinary partnerships that help resource-poor countries gain access to HPV vaccination.

## HPV VACCINATION PARTNERSHIPS

In September 2012, the Republic of Uganda, through the Ministry of Health (MoH) and supported by our company, announced the launch of a vaccination program with GARDASIL. Cervical cancer is the most frequent cancer diagnosed among women in Uganda,<sup>3</sup> and incidence rates of the disease in the country are about three times the global average.<sup>4</sup> An estimated 3,500 women in Uganda are diagnosed with cervical cancer each year.<sup>5</sup> Through this agreement with our company, the vaccination program was implemented with just under a half million doses of GARDASIL donated to 12 districts in Uganda, enough to vaccinate approximately 140,000 eligible girls 9 to 13 years of age over a two-year period. The program represented the first phase of Uganda's national rollout plan for HPV vaccination. As a result of phase 1, Uganda is planning to launch its full national HPV vaccination program in 2015 with support from the Global Alliance for Vaccines and Immunization (GAVI).



A young girl is immunized during the September 2012 phased launch of a national vaccination program with GARDASIL in the Republic of Uganda.

In 2010, we also partnered with the Government of Bhutan and the Australian Cervical Cancer Foundation (ACCF) to initiate a six-year program aimed at reducing incidence of cervical cancer in Bhutan. Through this partnership, Bhutan became the first developing nation in the world to implement a national cervical cancer vaccination program. The first year of the program provided an opportunity for appropriate girls and young women from ages 12 to 18 to be vaccinated with GARDASIL, and achieved an approximately 90 percent vaccination rate for all three doses, according to the Bhutan MoH. In subsequent years, the program has continued to provide an opportunity for appropriate 12-year-old girls to be vaccinated with GARDASIL. These programs in Uganda and Bhutan are serving as models for other developing countries that aspire to implementing national cervical cancer vaccination programs.

## CERVICAL CANCER PREVENTION & TREATMENT PARTNERSHIPS

Our company is working to create novel partnerships that take a comprehensive approach to cervical cancer prevention and treatment. For instance, in September 2011, we announced plans to contribute \$3 million to Pink Ribbon Red

Ribbon™(PRRR) to address both cervical and breast cancer in sub-Saharan African nations. PRRR is a historic initiative that brings together public- and private-sector partners, including Susan G. Komen for the Cure®, the George W. Bush Institute, the President's Emergency Plan for AIDS Relief (PEPFAR), UNAIDS, the U.S. government and other corporate organizations. Through this commitment, we continue to work with Susan G. Komen for the Cure to support the initiative to raise awareness about the burden of breast and cervical cancer; work toward increased access to cervical cancer screening and treatment for women and HPV vaccination of eligible girls in sub-Saharan Africa; and serve as a catalyst for additional partners to garner support for increased capacity in cervical and breast cancer prevention and treatment.

In 2013 and 2014, Botswana, with support from our company and from PRRR, successfully completed a two-year HPV-vaccination demonstration project to gain experience for an anticipated national HPV-vaccination rollout. The project provided the Ministry of Health with valuable learning that will guide the rollout of the national program, which launched in 2015. Secondary cervical cancer prevention and treatment are being supported through PRRR partners providing community awareness, increased capacity through healthcare worker training, and screening and treatment equipment.

Also in 2013, following our donation of 180,000 doses of GARDASIL through the GARDASIL Access Program, the Zambian MoH, in collaboration with PRRR partners, initiated a two-year HPV vaccination demonstration program in three districts. Together with PRRR partners, we have provided technical support for the program, which concluded in the fall of 2014. Results to-date indicate that in 2014, 86 percent of the targeted population of girls received the first two vaccine doses. The Zambia MoH is leveraging the results of this program to make preparations for a transition to a GAVI-supported HPV-vaccination program. Additionally in 2013, the African Center of Excellence for Women's Cancer Control, in coordination with local nongovernmental organizations (NGOs) and the Zambian government and with our support through its partnership with Susan G. Komen for the Cure, began work on a strategic national cancer plan: initiated cervical and breast cancer advocacy activities to increase awareness and reduce stigma throughout Zambia: conducted technical training for more than 350 medical staffers: and supported cervical cancer screening activities.

In April 2011, we began providing GARDASIL to a first-of-its-kind cervical cancer program in Rwanda, including both HPV vaccination and HPV DNA testing. Over the three-year program, which concluded in 2013, we provided nearly 1.4 million doses of GARDASIL. This program was made possible by a collaboration established in 2009 between our company and QIAGEN, the leading global provider of sample and assay technologies, to increase access to HPV vaccination and testing. This initiative marked the first time a vaccine manufacturer and a molecular diagnostics company have collaborated to address the burden of cervical cancer in one comprehensive approach. As part of the program, on which we worked closely with the Government of Rwanda, more than 96 percent of eligible girls were vaccinated with the full three doses of GARDASIL in 2011 and 2012. In 2014, Rwanda transitioned to GAVI support, becoming the first nation to conduct a national HPV vaccination program with GAVI funding.

## COMMITMENT TO SUPPORT HPV VACCINE INTRODUCTION

Beginning in 2006, we partnered with the international nonprofit organization PATH to provide GARDASIL for the conducting of post-licensure HPV-vaccine demonstration projects in Peru, Vietnam and India. GARDASIL was provided to vaccinate approximately 30,000 appropriate girls participating in "HPV Vaccines: Evidence for Impact" demonstration projects. The overall initiative was designed to strengthen the capacity of developing countries to prevent cervical cancer by generating and providing necessary evidence for public-sector introductions of HPV vaccines, informing global advocacy efforts and providing analyses to help accelerate access to HPV vaccines. The projects suggest that high coverage with HPV vaccines can be achieved through various delivery strategies in the countries studied.

Additionally, through the charitable GARDASIL Access Program, we donated more than 1.3 million doses of GARDASIL for use in smaller-scale HPV-vaccination projects in eligible lowest-income countries around the world. The program has enabled organizations and institutions in 21 countries to gain operational experience in designing and implementing HPV-vaccination projects, with the goal of supporting the development of successful child and adolescent immunization models.

In light of changes in the global health funding landscape, and after consultation with various stakeholders, it was decided that, as of August 2012, the GARDASIL Access Program will no longer award doses to new projects. As of March 2015, seven countries (Cameroon, Ghana, Kenya, Mali, Tanzania, Uganda and Uzbekistan) that participated in the GARDASIL Access Program are among the first approved by the GAVI Alliance for HPV programs using GARDASIL, and five of the programs are already underway.

In addition, Lesotho, which completed two HPV-vaccination projects with the support of the GARDASIL Access Program, has now been able to scale up to a national program with its own resources. Information from past and current program participants will continue to be disseminated in the public health community by Axios Healthcare Development, a U.S.

nonprofit organization that manages the GARDASIL Access Program. Learn more about the GARDASIL Access Program and this development.

Learn additional information regarding our Patient Assistance Programs, including our company's Vaccine Patient Assistance Program.

<sup>1</sup> Globocan 2012 data (accessed March 20, 2014): [http://globocan.iarc.fr/old/bar\\_pop.asp?selection=24076&title=Brazil&sex=2&statistic=0&window=1&grid=1&color1=5&color1e=&color2=4&color2e=&orientation=1&submit=%C2%A0Execute](http://globocan.iarc.fr/old/bar_pop.asp?selection=24076&title=Brazil&sex=2&statistic=0&window=1&grid=1&color1=5&color1e=&color2=4&color2e=&orientation=1&submit=%C2%A0Execute)

<sup>2</sup> CDC Global Health p1A.

<sup>3</sup> WHO 2010 Summary Report p4A.

<sup>4</sup> WHO 2010 Summary Report p13A.

<sup>5</sup> WHO 2010 Summary Report p4A.

# WOMEN'S HEALTH

## MAIN

The private sector has an important role to play in contributing to the achievement of the United Nations Millennium Development Goals regarding women's health.

### OUR COMMITMENTS

- Facilitate sustained access for our family planning products and services, and engage in partnerships that address specific reproductive health and development challenges.

The fifth Millennium Development Goal, *Improve Maternal Health*, sets targets of reducing maternal mortality (Goal 5a) and achieving universal access to reproductive healthcare (Goal 5b) by 2015, both major contributors to the overall health of women, families and society.<sup>1</sup> While progress has been made, rates of maternal mortality remain high in many countries, and access to modern contraceptive methods remains limited, especially among the poorest and least-educated women and girls. As the deadline for achieving the Goals approaches, we continue to support country efforts to accelerate access and to help shape the future Sustainable Development Goals to ensure that reproductive health and rights are included.

Enabling couples to determine whether, when and how often to have children is vital to helping achieve safe motherhood, healthy families and healthy communities. Voluntary family planning and broadening the method mix of family planning options help protect the health of women by reducing high-risk pregnancies, and help protect the health of children, adolescents and mothers by allowing sufficient time between pregnancies. Research has shown that appropriately spacing pregnancies helps improve both mother and child survival rates<sup>2</sup> and reduces the risk of preterm birth.<sup>3</sup> The use of family planning methods can also reduce the number of unsafe abortions and associated complications.<sup>4</sup>

Access to modern contraceptives is an important aspect of family planning. Our multifaceted approach supports efforts to improve access to family planning services and contraceptives for the women most in need of them. We are actively engaged in areas where maternal mortality is high and the prevalence of contraceptive use is low.<sup>5</sup>

<sup>1</sup> [http://www.undp.org/content/undp/en/home/mdgoverview/mdg\\_goals/mdg5/](http://www.undp.org/content/undp/en/home/mdgoverview/mdg_goals/mdg5/).

<sup>2</sup> [http://www.rhcatalyst.org/site/DocServer/Birth\\_Spacing\\_Research\\_Update\\_USAID\\_12-30-02\\_Final.pdf?docID=162](http://www.rhcatalyst.org/site/DocServer/Birth_Spacing_Research_Update_USAID_12-30-02_Final.pdf?docID=162)

<sup>3</sup> [http://www.marchofdimes.com/news/jul19b\\_2011.html](http://www.marchofdimes.com/news/jul19b_2011.html), [www.guttmacher.org/pubs/AddingItUp2009.pdf](http://www.guttmacher.org/pubs/AddingItUp2009.pdf)

<sup>4</sup> Singh, S., et al., Guttmacher Institute and United Nations Population Fund; 2009.

<sup>5</sup> <http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities/about>

# PARTNERSHIPS

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**We participate in a number of coalitions that support women's reproductive health by increasing access to family planning, working to reduce maternal mortality and promoting collaboration between the public, private and not-for-profit sectors.**

Throughout the world, we have partnered with organizations and supported projects that work to increase women's access to health services, reduce maternal mortality, increase awareness of reproductive/sexual health among adolescents and vulnerable populations, prevent mother-to-child transmission of HIV/AIDS, and promote women's empowerment and access to economic opportunities.

## PARTNERING FOR IMPLEMENTATION

**Reproductive Health Supplies Coalition (RHSC):** The RHSC is a global partnership of public, private and nongovernmental organizations dedicated to helping all people in low- and middle-income countries gain access to and use affordable, high-quality supplies that ensure better reproductive health.

The Coalition brings together diverse agencies and groups with critical roles in providing contraceptives and other reproductive health supplies. These include multilateral and bilateral organizations, private foundations, governments, and civil society and private-sector representatives. We participate in various RHSC working groups, including the Market Development Approaches Working Group. In October 2014, we participated in the annual meeting of the Coalition, which also marked its 10th anniversary. During this five-day event, held in Mexico City and cohosted by the Mexican Ministry of Health, we were honored for our contribution through the Implanon Access Initiative in a video highlighting the RHSC's achievements. [Watch the video.](#)

**The C-Exchange:** Brought together under the auspices of the global advocacy organization Women Deliver, the C-Exchange is a private-sector forum that aims to inform, engage and support members in their efforts to improve the health and well-being of girls and women.

**Family Planning 2020 (FP2020):** In 2014, we participated in two FP2020 working groups: the Country Engagement working group, which works to facilitate access to funding, technical assistance and country-to-country support for transformational, country-owned family planning programs; and the Market Dynamics Working Group, which seeks to improve global and national markets to sustainably ensure choice and equitable access to a broad range of high-quality, affordable contraceptive methods in target countries. FP2020 works with governments, civil society, multilateral organizations, donors, the private sector, and the research and development community toward enabling 120 million more women and girls than have access to contraception today to use contraceptives by 2020. It is based on the principle that all women, no matter where they live, should have access to lifesaving contraceptives, and supports the UN Secretary-General's global effort for women and children's health. For an update on FP2020 progress since it was created in 2012, click [here: http://progress.familyplanning2020.org/](http://progress.familyplanning2020.org/).

**The Bellagio Group:** We are a member of the Bellagio Group, a group of international experts on family planning and reproductive health that strives to find innovative solutions that expand contraceptive choice and accelerate universal access to reproductive health services by increasing availability of long-acting reversible contraceptives (LARCs). The Group asserts that if all women, men and young people do not have a full and informed choice of contraceptive options, they do not have full access. Read the group's [statement and recommendations for action](#).

For more information on how we partner with customers and other stakeholders, please visit our [Access to Reproductive Health](#) section.

# PERFORMANCE

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## WOMEN'S HEALTH: ACCESS TO HEALTH COMMITMENTS

**Goal:** Facilitate sustained access for our family planning products and services that address specific reproductive health and development challenges.

The following metrics are for our family planning products intended for underserved segments of the world's poorest countries (defined as Family Planning 2020 Countries<sup>1</sup>) that are supplied through the public sector and social marketing organizations.

	IMPLANON <sup>®</sup> or IMPLANON NXT <sup>®</sup>	EXLUTON <sup>®</sup>	MARVELON <sup>®</sup>
Number of FP2020 countries where product is registered/# pending IMPLANON NXT <sup>1</sup>	41/19	25	24
Number of FP2020 countries in which we supplied product	28	7	6
Number of women reached in FP2020 countries <sup>2</sup>	3,790,000	116,165	668,455
% of orders supplied on time in full in FP2020 countries	100%	100%	100%

<sup>1</sup> There are additional unregulated markets where our products may be available that are not represented by these numbers.

<sup>2</sup> Number represents potential number of women who could be reached based on number of products provided.



# ACCESS TO REPRODUCTIVE HEALTH

**Our commitment to providing access to reproductive health starts with our research and development, which has resulted in a diverse portfolio of contraceptive products.**

Beyond our research, we continue to work hard to develop sustainable business models that will help improve access to our products for the people who need them most. Our partnerships with governments, international organizations and nongovernmental organizations (NGOs) help support and implement programs and policies that improve access and promote capacity-building by helping to train healthcare professionals and address other barriers to care.

## RESEARCH & DEVELOPMENT

We have a strong legacy of research and development of contraceptive products that have supported women's family planning efforts. Over the years, we have been responsible for the development of a wide range of contraceptive options, including a single-rod contraceptive implant, a once-monthly vaginal contraceptive ring, and progestin-only and combined oral contraceptives.

In 2014, our researchers continued to develop new formulations of our existing women's health products to better meet conditions in developing countries. Our research efforts include research and work on an investigational intrauterine system (IUS) containing a candidate progesterone agonist and a once-monthly vaginal contraceptive ring.

## SUSTAINABLE BUSINESS MODEL TO PROMOTE ACCESS

We are committed to making our contraceptive products available to women around the world. We take a comprehensive approach to access that includes high-quality manufacturing and supply chain management; extensive registration and World Health Organization (WHO) prequalification of our family planning products; responsible commercialization that incorporates training and capacity-building; policy advocacy; and community investment.

In developing countries that have high rates of maternal mortality and low rates of contraceptive prevalence, we have created a sustainable business model to promote access to contraceptive health programs. These activities are focused primarily on sub-Saharan Africa and countries in Asia and Latin America with high unmet need.

## HIGH-QUALITY MANUFACTURING & SUPPLY CHAIN MANAGEMENT

We work to ensure that we have sufficient manufacturing capacity to meet short-, medium- and long-term availability of our contraceptive products for reproductive health programs conducted by governmental organizations, NGOs and other customers.

We continuously examine our supply chain seeking to reduce inefficiencies, optimize yields and lower costs of production, and have passed these savings on to our customers in the form of lower prices, particularly in lower-income markets. We also invest in new technologies to increase the efficiency of our operations and to be able to produce more affordable products at the same high quality to meet increasing demand.

### Expanding Access Through Manufacturing Investments

In October 2014, global reproductive health stakeholders gathered alongside local government leaders and some 100 of our employees in Oss, the Netherlands, to celebrate the opening of a new \$88 million (€70 million) state-of-the-art manufacturing line for the company's long-acting reversible contraceptive implant, IMPLANON NXT® (etonogestrel implant). With the opening of the new facility, we can manufacture and package more than 10 million units of IMPLANON NXT per year in order to meet the growing demand for long-acting family planning options, particularly in low- and middle-income countries.



Attendees participated in a panel discussion about what more is needed to expand access before being the first to tour the new facility—the only manufacturing location in the world to produce IMPLANON NXT.

John Skibiak, director of the Reproductive Health Supplies Coalition (RHSC), pointed out that increasing access requires more than “doing more of the same.” “It requires strategic thinking by all parties involved,” John said. “We need to work together to provide choice, quality and affordable supplies. No institution or sector can hope to achieve these goals alone.”

To view a video from the event, [click here](#).

## REGISTRATION & PREQUALIFICATION

We seek to ensure global access to our contraceptive products by obtaining and maintaining up-to-date product registrations around the world. In addition to existing and in-process registrations, numerous registrations are planned for products in countries of various income levels.

### REGISTRATIONS

The following metrics are for our family planning products intended for underserved segments of the world's poorest countries (defined as Family Planning 2020 or FP2020 Countries ) that are supplied through the public sector and social-marketing organizations. In 2014, IMPLANON NXT was approved in several FP2020 countries including (but not limited to) Benin, Cambodia, Chad, Côte d'Ivoire, the Democratic Republic of Congo, Laos, Myanmar, Nicaragua, Nigeria, Zambia and

Zimbabwe.

Note: For World Bank country classifications, please [click here](#).

	IMPLANON® or IMPLANON NXT®	EXLUTON®	MARVELON®
Product is WHO Prequalified	Yes	Yes	Yes
Number of FP2020 countries where product is registered/# pending IMPLANON NXT <sup>1</sup>	41/19	25	24
Number of FP2020 countries in which we supplied product	28	7	6
Number of women reached in FP2020 countries <sup>2</sup>	3,790,000	116,165	668,455
% of orders supplied on time in full in FP2020 countries	100%	100%	100%

<sup>1</sup> There are additional unregulated markets where our products may be available that are not represented by these numbers.

<sup>2</sup> Number represents potential number of women who could be reached based on number of products provided.

## PREQUALIFICATION

In order to facilitate institutional purchases of family planning products and provide quality assurance, we have secured WHO prequalification for EXLUTON (lynestrenol), IMPLANON (etonogestrel implant), IMPLANON NXT (etonogestrel implant) and MARVELON (desogestrel-ethinyl estradiol).

Product	International Nonproprietary Name (IN)	Date of Prequalification
MARVELON®	Ethinylestradiol + Desogestrel	October 21, 2010
IMPLANON®	Etonogestrel	June 18, 2010
EXLUTON®	Lynestrenol	June 18, 2010
IMPLANON NXT®	Etonogestrel	May 23, 2013

## COMMERCIALIZATION

The success of reproductive health programs in the developing world relies upon the close cooperation and coordination of many partners. They include pharmaceutical companies like ours that discover, develop and manufacture contraceptive products; national governments that seek to support family planning through policies that increase the use of contraception and through investment in both procurement and capacity-building; international, bilateral and multilateral donors that finance the purchase of reproductive health commodities and invest in service delivery management and implementation; NGOs that support implementation of such programs; and healthcare professionals and health extension workers who counsel and provide care for women around the world.

As one of many partners, we take the following steps to support family planning programs and to help increase awareness of and access to a broad choice of contraceptive products.

In February 2014, the South African Ministry of Health announced it would make IMPLANON NXT available free of charge to all women, regardless of their socioeconomic status, as part of what the Health Minister called “the biggest family planning program South Africa has ever seen.” We made IMPLANON NXT available through the IMPLANON® Access Program at its lowest access price. Together with the South African government, we conducted training for more than 70 “master trainers” across all provinces and deployed four registered nurses to offer additional training through more than 40 training events that reached an estimated 400 healthcare providers.

## REQUESTS FOR QUOTATION

The company receives and responds to “Requests for Quotation” from developing countries’ governments seeking supplies for their own programs (financed by government funds, by multilateral organizations like the World Bank or through bilateral aid); from donor country aid agencies (e.g., the U.S. Agency for International Development [USAID]), the U.K. Department for International Development [DFID], and KfW, a German government-owned development bank) seeking to purchase reproductive health commodities that will be donated to programs in one or more countries; from multilateral agencies, such as the United Nations Population Fund (UNFPA), donating to one or more countries; or from nongovernmental agencies seeking supplies for programs that they manage in one or more countries.

In responding to these requests, we adhere to the specific guidelines of each proposal and acts in full compliance with local and international laws and requirements.

## PRICING

For contraceptive product pricing, we consider a nation’s level of economic development and other relevant factors, including the types of family planning programs implemented by the local government.

In upper-middle-income and high-income countries, we provide our products at prices that take into account the innovation and value they represent. With a commitment to making our contraceptive products available to the public sector, we also offer discounts to organizations that serve women of all income levels, like Planned Parenthood affiliates, so that the women who rely on their services have routine access to contraceptive options that include nondaily and long-acting reversible methods.

We believe that our pricing approach will help improve product availability while also allowing the company to continue to invest in research, development, production, and the training and education necessary to help ensure appropriate counseling on and use of our products.

In May 2013, our company and a group of public- and private-sector partners announced an agreement to expand contraceptive access and options for millions of women in some of the world’s poorest countries. Under the agreement, we reduced the cost of IMPLANON and our next-generation implant, IMPLANON NXT (etonogestrel), by approximately 50 percent for the next five years (through 2018) in the targeted poorest eligible countries of focus for the reproductive health community. [Learn more.](#)

In November 2015, we announced our decision to extend our access pricing to these same targeted countries through 2023, an additional five years beyond the expiration of the 2013 agreement. [Learn More.](#)

## Laos Widens Family Planning Options for Women



In October 2014, more than 3,000 units of IMPLANON NXT traveled from the company's manufacturing site in the Netherlands to the Vientiane International Airport in Laos. Representatives from the Lao Ministry of Health (MoH) and UNFPA were waiting to take them immediately to two hospitals in the capital where training with healthcare workers was being carried out jointly by our company, the Ministry of Health (MoH) and UNFPA.

Under its national Family Planning Program, the Lao MoH was able to procure the implant with funding from UNFPA, making it the first implant available in the country. As part of the launch and training sessions, our medical representatives trained master trainers, who then went on to train other healthcare workers throughout the country.

In total, we trained 58 healthcare providers—including doctors, nurses, midwives and midwife teachers—on insertion of the implant and counseling in its use.

Prior to the training sessions, Population Services International (PSI) had promoted the availability of the new implant program in local communities. As a result, during the training, an estimated 1,300 women lined up to receive the implant following counseling.

“The importance of an additional family planning method now introduced in Laos cannot be underestimated,” said Anna af Ugglas, Technical Specialist, UNFPA, Laos.

## PARTNERING FOR IMPLEMENTATION

For family planning programs in the developing world involving our contraceptive implants IMPLANON and IMPLANON NXT, the company requires the recipient governments and partnering NGOs to sign its Cooperation Agreement for the Receipt and Use of IMPLANON (CARUI). The cooperation agreement includes:

- Our commitment to a comprehensive service approach that provides and/or supports capacity-building in service delivery, including pre- and post-insertion counseling and insertion/removal training
- Distribution requirements that must be met by our company and local partners to ensure that all clinics/providers meet training and quality assurance requirements, provide sustained services over the duration of the product's life (three years) and can access referral centers in case more specialized care related to IMPLANON is required
- Our commitment to “training of trainers” and providing training materials, including audiovisual materials, training kits, artificial arm models and placebos; we may provide additional technical assistance for direct and cascaded training activities by healthcare providers with our local partners on a case-by-case basis
- Procedures to report product complaints and adverse events
- Provisions regarding compliance with the applicable laws of the U.S. and the recipient country, and our ethical and business compliance policies

In the countries where our products are included in family planning programs, we work closely with ministries of health and local implementing partners, who play a pivotal role in supporting training, counseling and other related activities. Our local implementing partners have included Jhpiego, EngenderHealth, Marie Stopes International (MSI), International Planned Parenthood Federation (IPPF), Population Services International, DKT and Pathfinder International. Such collaboration ensures that countries have the expertise and support they need to achieve their reproductive health objectives.

In 2014, we worked with more than 28 countries in sub-Saharan Africa, Asia and Central America to provide contraceptive products through numerous partnerships with governments, donors and NGOs. Some of the countries we engaged with included Madagascar, Ethiopia, Kenya, Uganda, Tanzania, Nigeria, South Africa, Yemen, Pakistan, the Philippines, Cambodia and Ecuador.

## PUBLIC ADVOCACY

We support the ambitious but, we believe, achievable goal set by the public health community in 2012 of ensuring that voluntary lifesaving family planning information, services and products reach an additional 120 million women and girls in the world's poorest countries by 2020.

In 2014, we continued to support this goal through public policy and advocacy efforts and stakeholder engagement. In December 2014, we were one of a dozen private-sector companies to offer public feedback on the proposal for a Global Financing Facility (GFF) in support of *Every Woman, Every Child*. In our feedback, we stated our belief that the GFF should support universal access to reproductive health and rights, including voluntary family planning and immunization for children and adolescents, as well as the development of comprehensive system approaches, health system strengthening (capacity-building, supply chain, sustainable financing), demand generation and measurement that holds systems and local and global actors accountable.

We will continue to engage in the evolving policy discussions to ensure that reproductive, maternal, neonatal, child and adolescent health continue to be prioritized in the post-2015 era.

<sup>1</sup> IMPLANON NXT is known as NEXPLANON in the U.S. and a number of other countries.

<sup>2</sup> Includes 70 countries identified by the external reproductive health community during the July 2012 London Family Planning Summit, plus South Africa. These countries are those with a 2010 per capita gross national income less than or equal to US\$2,500 per year, based on the World Bank classification using the Atlas Method. They are thought least likely to meet the Millennium Development Goals set by the UN General Assembly in 1990 to reduce the number of infant and young child deaths by two-thirds and to improve maternal health by 2015.

<sup>3</sup> There are additional unregulated markets where our products may be available that are not represented by these numbers.

<sup>4</sup> Number represents potential number of women who could be reached based on number of products provided.

# ANIMAL HEALTH



## MAIN

### Our mission is the science of healthier animals.

Animals work for us, feed us and give us comfort and support. People also have a responsibility to care for animals and ensure their well-being. Which is why our focus is all about making animals healthier. Healthier animals mean sustainable food supplies, protection against zoonotic diseases,<sup>1</sup> reduction of the burden of certain food-borne diseases, and longer, richer companionship for pet owners.

### 2014 PERFORMANCE HIGHLIGHTS

- European and U.S. registration for the veterinary medicinal product BRAVECTO<sup>®</sup> (fluralaner) chewable tablets for dogs. This new ectoparasiticide for dogs provides veterinarians and pet owners with a unique and prolonged active period against fleas and ticks for up to 12 weeks (eight weeks for *Rhipicephalus sanguineus* and *Amblyomma americanum* ticks).
- European registration for the veterinary medicinal product PORCILIS PCV M Hyo<sup>®</sup>, Europe's first single-shot vaccine to protect piglets from both porcine circovirus type 2 and *Mycoplasma hyopneumoniae* infections
- U.S. registration for the veterinary medicinal product Once PMH<sup>™</sup> IN, the only intranasal vaccine to control bacterial pneumonia in cattle, including calves as young as 1 week, providing an aid in the control of respiratory disease caused by *Mannheimia haemolytica* and in the prevention of disease caused by *Pasteurella multocida*—the leading causes of early-onset bovine respiratory disease (BRD)
- European registration for the veterinary medicinal product FINADYNE<sup>®</sup> Transdermal Pour-on, the first transdermal non-steroidal, anti-inflammatory drug for cattle, combining convenience with a novel delivery method that simplifies administration for veterinarians and farmers alike
- European registration for NOBILIS<sup>®</sup> IB Primo QX for chickens, the first vaccine to use SPHEREON<sup>™</sup> technology to protect chickens against viral infectious bronchitis caused by the QX-like variants of the infectious bronchitis virus
- Expansion of educational initiatives, like NOBIVAC<sup>®</sup> Global Vet Exchange Program for veterinarians; “Creating Connections” to improve cattle welfare for farmers; our new Dairy Care365<sup>™</sup> training module to help dairies create and maintain a low-stress animal-handling approach; and “Healthy Pet = A Happy Family” to raise awareness of dog and cat diabetes among pet owners

Our global Animal Health business is dedicated to preserving and improving the health, well-being and performance of animals by offering veterinarians, farmers, pet owners and governments one of the widest ranges of veterinary

pharmaceuticals, vaccines, and health management solutions and services in the world. Our animal health business employs more than 6,500 people worldwide and is present in more than 50 countries. Our company operates a global network of manufacturing sites and dedicated R&D facilities, and offers products for various species, including ruminants (cattle, sheep, goats), poultry, swine, aquatic animals and companion animals (dogs, cats, horses) in 150 countries. Our animal health business focuses our corporate responsibility efforts in the following areas:

- Protecting animal health
- Contributing to public health
- Supporting a sustainable, global food supply and managing our global footprint
- Ensuring ethical business practices

*Note: This section includes information about how Merck & Co., Inc., Kenilworth, NJ, USA contributes to societies through its Animal Health business. Information and data on the performance of our Animal Health business in the environment and in other areas is contained within the main sections of our global corporate responsibility report.*

<sup>1</sup> Zoonotic diseases are any disease or infection that is naturally transmissible from vertebrate animals to humans or vice versa (World Health Organization). Foodborne diseases in general encompass a wide spectrum of illnesses caused by microbial, parasitic or chemical contamination of food.

## PERFORMANCE

	Performance	2013	2014
Number of rabies vaccines donated annually to Afya projects		200,000 doses	200,000 doses
Value of equine vaccines donated annually to the Unwanted Horse Veterinary Relief Campaign		US\$125,000	US\$115,000
Number of annual rabies vaccinations carried out in collaboration with the Global Alliance for Rabies Control and the Bombay Veterinary College		50,000 doses	15,000 doses
Number of new products approved (annually)		5	8
Number of published research manuscripts submitted for publication in peer-reviewed veterinary journals with MAH authorship or support		16	53

# PROTECTING ANIMAL HEALTH

## Making adequate protection more convenient.

- Intranasal administration of Once PHM<sup>®</sup> IN is effective and convenient because the vaccine antigens are delivered directly to the mucosal surfaces in the nose, the major sites for immune response in cattle. While annual revaccination is recommended, the vaccine can be administered more frequently, depending on a farm's risk assessment or if a herd faces epidemic conditions. Because there is no injection site, carcass quality is not compromised.
- The ready-to-use single-injection of PORCILIS PCV M Hyo<sup>®</sup>, Europe's first single-shot vaccine to protect piglets from both porcine circovirus type 2 and *Mycoplasma hyopneumoniae* infections, reduces the number of vaccinations given to young piglets, provides adequate protection against both diseases, and requires no mixing.
- FINADYNE<sup>®</sup> Transdermal Pour-on combines convenience with a novel delivery method that simplifies administration for veterinarians and farmers alike. The availability of pre-calibrated packaging makes it easier to ensure that the correct dose is given each time, and the red-colored solution facilitates accurate and quick measurement of the dose volume for each animal. Additional benefits include needle-free administration with no injection-site lesions, a higher-value end product and better user-safety.
- BRAVECTO<sup>®</sup> chewable tablets are a breakthrough innovation, offering up to 12 weeks (8 weeks for *Rhipicephalus sanguineus* and *Amblyomma americanum* ticks) of protection against fleas and ticks, the longest-lasting oral flea and tick prevention currently available. The active substance, fluralaner, a new ectoparasiticide belonging to the isoxazoline group, is combined with a flavored chewable tablet that dogs accept readily.

## KEEPING PETS HEALTHY

Pets play an increasingly significant role in many families, and their health and quality of life are important. In 2014, the U.S. Food and Drug Administration (FDA) approved VetPen<sup>®</sup>, the first insulin pen for use in diabetic dogs and cats.

## INVESTING IN VETERINARY EDUCATION AND CONTINUED PROFESSIONAL VETERINARY DEVELOPMENT

With support from our company's Foundation, a U.S.-based, private foundation, our Animal Health business invests in the future of the veterinary profession by supporting research, education and specialized skills training so that veterinarians will have the resources they need to provide the best healthcare possible for the animals they treat. For example:

In 2014, our Animal Health business provided a total of \$300,000 in grants to veterinary students, allocated as follows:

- A \$100,000 grant to AABP for the 2014 AABP Bovine Veterinary Student Recognition Awards; a \$185,000 grant was

given to the American Veterinary Medical Foundation

- A \$15,000 grant was provided to the Food Systems Fellowship Program of Michigan State University College of Veterinary Medicine
- We also contributed €10,000 to the Gustav Rosenberger Memorial Fund. This fund provides annual grants to young and promising veterinarians who come from countries where bovine medicine needs further development and who intend to apply the knowledge obtained in those countries.

## PROFESSIONAL DEVELOPMENT

- We launched the Dairy Care365™ training series, a program to educate U.S. dairy farm workers in best practices for handling and managing dairy cattle
- We have been offering poultry and swine health training courses to veterinarians for more than 20 years. For the past four years, an extended-level course on poultry has been conducted in collaboration with the University of Georgia's Department of Poultry Science.
- NOBIVAC® Global Vet Exchange Program was launched, which will give 10 small-animal veterinarians the opportunity to visit clinics in other countries and to share their knowledge and experience in veterinary care
- We also sponsor fish-vaccination training to fish producers and veterinarians

	Performance	2013	2014
Scholarships provided to students through our Animal Health Grant Program		NR	38

NR: Not reported.



Animal Health

# CONTRIBUTING TO PUBLIC HEALTH

**Protecting animal health helps protect human health and contributes to a sustainable food supply.**

## CONTRIBUTIONS TO PUBLIC HEALTH

Global trade, global migration and climate change are increasing the spread of highly infectious diseases such as foot-and-mouth disease, swine fever and peste des petits ruminants, and zoonotic diseases—such as avian flu. Highly infectious diseases have a direct impact on food production and the livelihood of farming families, whose income is dependent on the productivity and survival of their animals. A fast, flexible approach to vaccination can help control such diseases in the animal reservoir and minimize the medical, social and economic impact that could occur if left unchecked.

## FULL RANGE OF VETERINARY SOLUTIONS FOR PUBLIC HEALTH

We provide a range of vaccines and treatments to keep livestock healthy to ensure a stable food supply and help control organisms that can ultimately affect the health of people.

### SALMONELLA

Foodborne microbial bacteria, such as Salmonella, are also a growing concern, particularly for poultry farmers. Human consumption of poultry or eggs infected with the bacteria can result in severe illness in humans, pushing governments and industry to implement adequate measures to reduce this risk. We have developed a Food Safety Platform for poultry farmers that includes a broad-spectrum Salmonella vaccine and services that ensure effective, timely intervention if an outbreak occurs among poultry. Through a unique Pin-Point Monitoring Program, poultry producers can identify critical food-safety hazard points and be prepared to respond quickly and effectively. This combination of vaccines, biosecurity and other measures has contributed significantly to the reduction in incidence of human salmonellosis.

### LEISHMANIASIS

Our Animal Health canine preventative product protects dogs against tick-borne leishmaniasis, helping to control one of the

world's most deadly parasitic diseases in the animal reservoir, which is linked to 60,000 human deaths annually.

## RABIES

Rabies, a fatal neurological disease, is widespread throughout Africa, with more than 25,000 people—mostly children—dying from the disease each year after being bitten by a domestic dog, the main carrier of the disease. Globally, the disease kills an estimated 55,000 people annually.

Our Animal Health business donates more than 200,000 doses of rabies vaccine annually to *Afya Serengeti Project* in Tanzania and Kenya. By tackling rabies in domestic dog populations, we've helped to dramatically reduce the number of rabies-infected dog bites, and also helped to protect the fragile wild dog population.

We collaborate with the Global Alliance for Rabies Control, and the Bombay Veterinary College in Mumbai, India, to support mass-vaccination of pets and improved educational awareness in 10 villages surrounding Bangalore and Pune. Based on this positive outcome, we continued our support for rabies control in India by donating rabies vaccines to Mission Rabies and World Veterinary Services.



Animal Health

# SUPPORTING A SUSTAINABLE FOOD SUPPLY

**By 2050, the United Nations estimates there will be an additional 2 billion people in the world. To feed them, we will need to help animal producers become more efficient and more sustainable.**

Animal diseases cost farmers a significant proportion of their meat, fish and dairy yield every year. In fact, the World Organization for Animal Health estimates that animal disease reduces global food production by 20 percent. Its impact on food output is greatest in developing countries, where two-thirds of the world's 1.5 billion poor are reliant on livestock as their main source of food and income.<sup>1</sup> Preventing disease-related costs will also be crucial if we are to meet the increasing demand for animal protein, created by rising standards of living and population growth. In addition, the land and water available for agriculture is decreasing. Not only will food-producing animals have to stay healthy, they will have to be reared more efficiently, too.

As economies continue to grow and lifestyles change around the globe, the global appetite for meat, milk and eggs increases. In fact, the UN Food and Agriculture Organization (FAO) expects the global demand for animal protein to double by 2050.

Our portfolio of animal health products is focused on helping farmers keep their livestock healthy and productive. Targeted intervention with vaccines, antiparasitics, anti-infectives and other veterinary medicines and services helps protect the health and well-being of animals, and helps producers to avoid and/or limit their production losses.

## PROTECTING POULTRY FLOCKS AND ENSURING THE LIVELIHOOD OF FARMERS

Through the introduction of a vaccine against a specific virus strain causing infectious bronchitis (IB) in chickens, farmers in Argentina recognized significant reduction of mortality in their chicken flocks and improved their productivity. Often a novel approach can bring important additional features to protect against devastating diseases such as infectious laryngotracheitis and New Castle disease in chickens, like our innovative vector-vaccine concept to protect against severe poultry diseases that were first introduced a few years ago in South America. Another innovation is the SPHEREON<sup>®</sup> technology. In 2014, NOBILIS<sup>®</sup> IB Primo QX, which protects chickens against viral infectious bronchitis caused by QX-like variants of the infectious

bronchitis virus, was the first vaccine developed using this technology in the EU.

Currently, half of all the fish consumed globally is farmed (proceedings of the National Academy of Sciences (PNAS)).

Demand for fish is also rising, and farmed fish are becoming more important—in order to meet this demand and protect wild fish. Our SLICE Sustainability Project, developed in partnership with fish farmers, continues to help control parasites and keep fish healthy. SLICE® (emamectin benzoate) controls sea lice, the naturally occurring parasites that live in the ocean and threaten the health and welfare of salmon. Our “Strep Control—Your Tilapia Health” program helps fish farmers to identify the strain and biotype of *Streptococcus agalactiae* present on their farm, implement a surveillance and vaccination program, and train staff on appropriate control strategies against the most prevalent disease affecting tilapia. In 2014, this program delivered a new fish vaccine to protect tilapia and other fish against the biotype 1 strain of *Streptococcus agalactiae*, the biotype specific to Thailand and other key tilapia-producing regions in Asia, including Malaysia.

## MANAGING OUR ENVIRONMENTAL FOOTPRINT

We are taking action to help preserve the resources of our planet. While supporting our customers to ensure a sustainable food chain, we also look to reduce the environmental footprint of producing our animal health products. [Learn more](#) about our environmental sustainability strategy.

<sup>1</sup> OIE, B. Vallat. Opening speech, European Veterinary Week, Brussels, Nov. 10, 2008.

# ENSURING ETHICAL BUSINESS PRACTICES

**We invest millions of dollars each year into the research and development of novel animal health products and the continued investigation of existing products.**

As with our human health pharmaceuticals and vaccines, we test our investigative animal health medicines and vaccines vigorously for safety, quality and efficacy before submitting them to regulatory agencies for additional review, research, testing and, ultimately, approval after thorough review by independent regulatory authorities.

The authorization standards for veterinary medicines are at the same level as those for human medicines. On average, it takes 5 to 12 years to bring a veterinary product to market. A science-based, predictable regulatory environment is one of the key conditions necessary for innovation and for providing our customers with high-quality products. We support global harmonization of the regulatory process for veterinary medicines through participation in and dialogue with the [International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products](#) and the [Codex Alimentarius](#).

The approval process for medicines and vaccines used in farm animals also establishes withdrawal periods, from the time the last dose of product is given until the animals or products enter the food chain. These withdrawal periods ensure the safety of human consumption of meat, milk and eggs from medicine- and vaccine-treated animals.

Our submissions to regulatory agencies also include an environmental assessment that appraises the effects of the use of our products on flora, fauna, soil and water. When necessary, restrictions are placed on the use of our products to protect the environment.

Once a product is on the market, we monitor all aspects that could affect product safety. Findings are assessed and reported, as appropriate, to regulatory authorities and addressed through appropriate measures.

## STRUCTURED HERD HEALTH MANAGEMENT

The most effective means of preventing development and spread of antimicrobial resistance is to reduce the need for antimicrobial treatment. The key is disease prevention, which can be aided by vaccination. In a number of countries, we support veterinarians with our ResCalf and ResPig programs to develop a structured approach to improving lung health and preventing bovine respiratory disease in calves and respiratory diseases in pigs. Respiratory disease can seriously affect the health of cattle and pigs and lead to economic losses. With monitoring and high-quality technical support and advice, combined with vaccination, early in 2014 we introduced Once PMH<sup>®</sup> IN in the U.S., the only intranasal vaccine to deliver dual bacterial pneumonia protection in healthy beef and dairy cattle, including calves as young as one week of age. We also

received approval for PORCILIS® PCV M Hyo vaccine, the first ready-to-use single-injection combination vaccine to protect piglets against porcine circovirus and *Mycoplasma hyopneumoniae* infections during the fattening period. By bringing vaccines like these to the market, we help to control these disease complexes and reduce the need to use antibiotics to treat sick animals.

## MAKING A DIFFERENCE IN WIDER SOCIETAL NEEDS

Our Animal Health business uses our experience, resources and science to help our partners keep animals healthy, ensure a sustainable food supply, protect public health, and help people and pets enjoy their lives together. We are committed to making a difference in the health and welfare of animals and in wider societal needs.

## ACCESS TO VETERINARY EXPERTISE

Access to veterinary expertise and medicines significantly impacts the livelihoods of small landholders and their families.

- **Milk for Malawi**—Through our partnership with Shire Highlands Milk Producers Association, our Animal Health business lends financial and in-kind support to Malawian dairy farmers to improve the quality and quantity of milk supplies. In 2014, we responded to a need to increase the genetic variation among the bulls used for artificial insemination by sending a shipment of semen of Jersey bulls from Zambia. At the end of 2014, a shipment of NILZAN® boluses was initiated, and these dewormers arrived early 2015.
- **Enhancing the poultry value chain in Ethiopia**—Our global poultry business joined the Dutch consortium Holland Africa Poultry Partners (HAPP) in 2012. The consortium envisions facilitating the important role the domestic poultry sector could play in Ethiopia and its growing economy. Our colleagues within the animal health business are involved in activities such as knowledge seminars about commercial and sustainable poultry farming, practical training sessions, incoming and outgoing trade missions, and participation in Ethiopian poultry trade fairs.
- **Joining forces for Bamboutos-Menoua Pig Holders**—The Bamboutos-Menoua Smallholder Integrated Pig Project in Cameroon, under the coordination of Heifer International, aims to improve the livelihood of 1,500 resource-poor project participants as well as their direct dependents, by helping them increase their income, improve gender relations, improve mobilization of group resources, and mitigate the effects of HIV/AIDS in sustainable ways. Our Swine business supports the animal health–related components, amongst others, with veterinary medicines. Toward the end of July 2014, almost 1,400 families had received pigs, either as “original placing” or as “passing on the gift”, e.g., from the first litter of a sow, a family is required to pass four piglets to another family.

# ENVIRONMENTAL SUSTAINABILITY

**Our company has a long history of environmental stewardship and compliance, but we realize that our strategy and efforts need to evolve in order for us to operate in an increasingly resource-constrained world.**

UNGC-7

UNGC-8

UNGC-9

- We have identified the issues that are important to our business and our stakeholders so that we can prioritize them for action
- We envision Sustainable Operations & Supply Chain, Innovative Products & Packaging, and Environmental Sustainability being fully integrated into business decisions
- We have focused our Environmental Sustainability Strategy on improving the efficiency of our operations, designing for the environment, and reducing the impacts and risks in our value chain
- We have defined environmental-footprint measures and established a set of goals to improve the sustainability of our operations

## KEY PERFORMANCE INDICATORS<sup>1,2</sup>

	2011	2012	2013	2014
Greenhouse gas emissions (metric tons of CO <sub>2</sub> e)	2,001,000	1,918,000	1,811,000	1,676,000
Water usage (thousand gallons)	8,900,000	8,700,000	7,500,000	7,200,000
Operational waste generated (metric tons)	119,000	116,000	100,000	87,000

<sup>1</sup> Includes facilities worldwide.

<sup>2</sup> In accordance with the Greenhouse Gas Protocol, prior-year data have been adjusted to add or remove facilities that have been acquired and sold. Adjustments also reflect changes in methodology to ensure consistency from year to year.



Environmental Sustainability

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# SUSTAINABILITY STRATEGY

**Our company demonstrates respect and care for the environment in everything we do, because we believe that a healthy planet is essential to human health and the sustainability of our business.**

We recognize that climate change could significantly impact global health and present long-term risks to our business. We also know that the world's resources are limited, and that over the next few decades the demand for energy, clean water and natural resources will increase substantially due to population growth and economic development. We understand that business has a responsibility to use resources wisely and drive innovations that will enable global development while protecting and preserving the planet.

Our Environmental Sustainability Strategy focuses on three main areas:

## EFFICIENT OPERATIONS

Reducing our environmental impacts through energy efficiency and water-use-reduction initiatives, as well as efficiently using raw materials and handling our wastes

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## DESIGN FOR ENVIRONMENT

Innovating to reduce the environmental impacts of our new products and packaging through the use of Green Chemistry, life cycle assessments and other sustainable design principles

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## REDUCE RISKS IN VALUE CHAIN

Understanding the environmental impacts and risks that are upstream and downstream of our own operations, and working to minimize those impacts through collaboration with our suppliers and customers to address our shared needs and interests in more efficient and environmentally beneficial ways

# ENVIRONMENTAL GOALS

**Our company has established three environmental sustainability goals that are fully aligned with our business and focus on key global environmental challenges.**

Last year, we announced a new, streamlined set of environmental goals that align with our business strategy by driving cost reduction, making efficiency improvements and lowering risk. These goals will help prepare us to meet the challenges of a world with limited natural resources and a changing climate.

Goal	Target <sup>1</sup>	2014 Progress
<b>WATER</b> 	Driving down our water use 15% by 2015 and 25% by 2020 versus a 2009 baseline	20% reduction since 2009
<b>CLIMATE</b> 	Reducing our emissions of greenhouse gases 15% by 2020 versus a 2012 baseline	12% reduction since 2012
<b>WASTE</b> 	Continuing to send less than 30% (by weight) of our operational waste to landfills and incinerators through 2017	23% of operational waste sent to landfills and incinerators without energy recovery

<sup>1</sup> The baseline year of 2009 for water use was originally set in 2010, and was retained when the environmental goals were updated in 2014. The baseline year of 2012 for greenhouse gas (GHG) emissions was established in 2014 after the previous GHG goal was achieved early.

The following charts demonstrate our continued progress toward these goals.

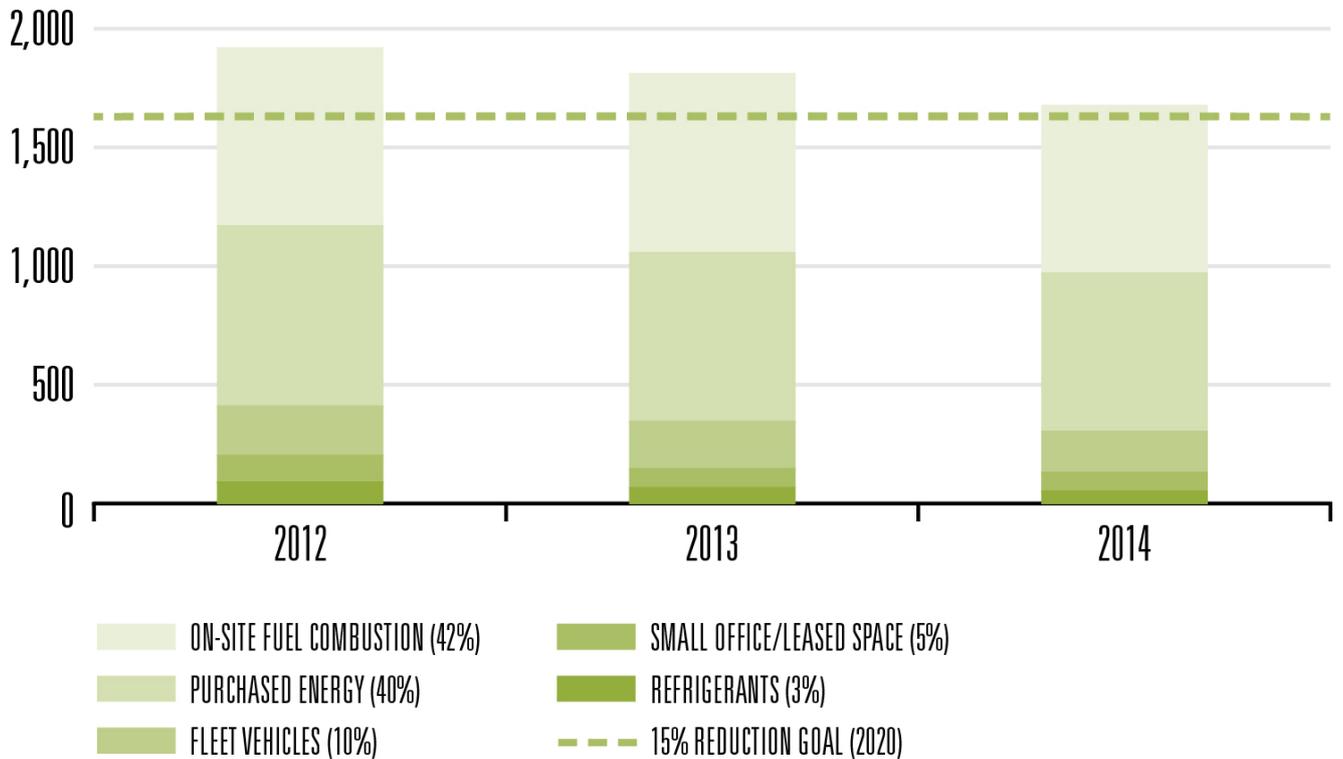
# GLOBAL WATER USE

(BILLIONS OF GALLONS)



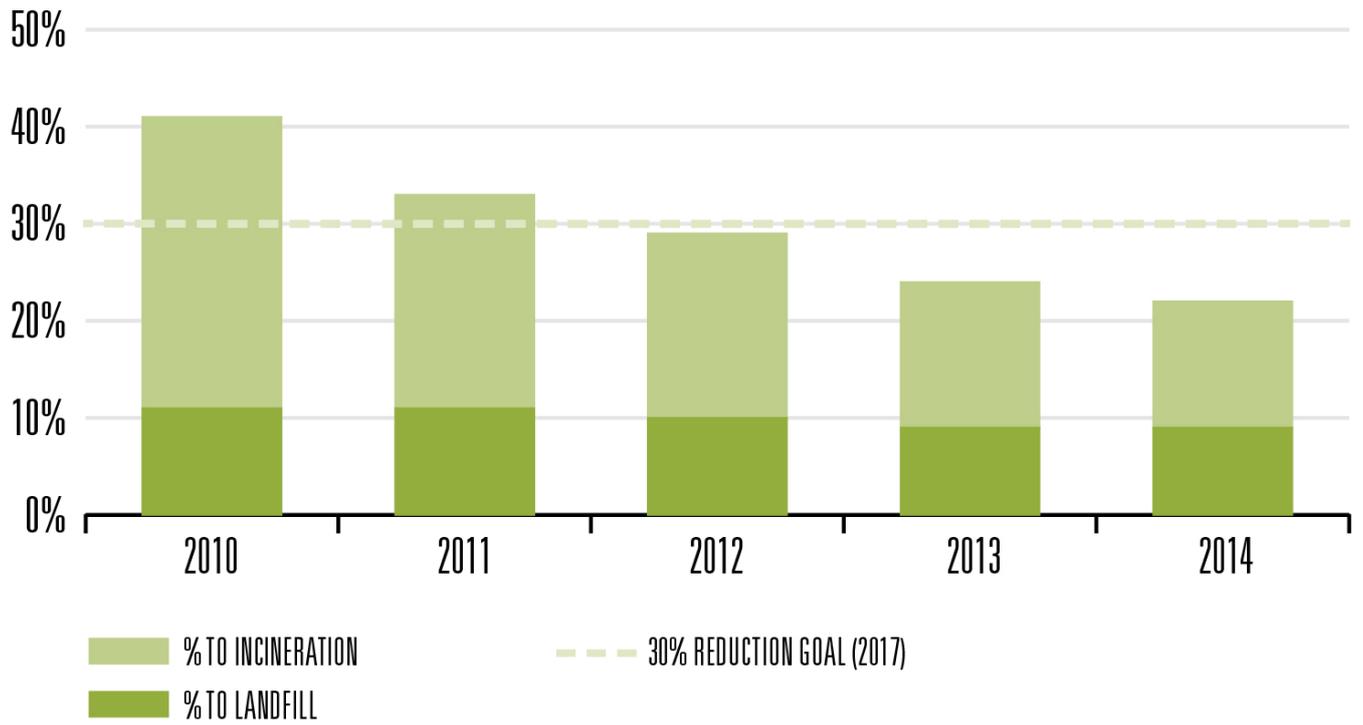
# GLOBAL GHG EMISSIONS

(THOUSANDS OF METRIC TONS CO<sub>2</sub>e)



# GLOBAL OPERATIONAL WASTE

(% TO LANDFILL & INCINERATION WITHOUT ENERGY RECOVERY)





Environmental Sustainability

# EHS MANAGEMENT & COMPLIANCE

## MAIN

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**Protecting our people, our communities and the environment, and being in full compliance with the law, are fundamentally important to the way our company operates.**

UNGC-7

UNGC-8

Our mission and values are articulated by our Code of Conduct, *Our Values and Standards*, which serves as a vehicle to communicate them to all employees. Our EHS values and commitments are further detailed in our corporate policy, *Respect for Environmental, Health and Safety (EHS)*. In addition to compliance with all applicable country, regional and local safety and environmental laws, we strive for EHS performance that is among the best in the pharmaceutical industry. As our EHS Policy states, we:

- Maintain a safe and healthy working environment for all employees, contractors and guests
- Foster a culture of EHS excellence that is built on integrity, accountability, collaboration and active employee participation, and seek to continuously improve our systems, processes and standards in further support of that culture
- Look to manage the resources we use as we design, develop and manufacture products and provide commercial services, so as to minimize the impact on the environment. We monitor our use of energy and water and the generation of waste to reduce our environmental impact.
- Understand the potential hazards associated with our products and take action to reduce any potential risk or adverse impact
- Promote EHS excellence in our supply chain and expect third parties doing work on our behalf to do the same. We enter into business relationships with partners that share our commitment to responsible EHS stewardship.

Our EHS Management System follows the classic “Plan, Do, Check, Act” model, which is implemented through a set of interwoven business processes that span the corporation.

- The planning process includes development of goals, objectives and metrics based on a review of company performance, EHS programs, applicable regulations and other external factors. [PLAN]
- Standards, Guidelines and Tools, which are integrated into the EHS Management System, detail the program-implementation expectations for sites and operating organizations. [DO]
- Governance committees, from the executive-level EHS Council through site-compliance committees, review performance and progress against objectives. Central audits and self-assessments raise issues. Monthly and annual performance metrics reflect progress. [CHECK]
- Corrective actions and continuous-improvement initiatives are established to resolve EHS concerns that are surfaced during performance reviews, assessments, audits or routine surveillance of the regulatory landscape [ACT]

Subtopics addressed in tabs at the top of this page:

- Training
- EHS Governance
- Internal Auditing
- Performance

## TRAINING

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**Training is critical to building worldwide competencies that will improve compliance, reduce risks and drive continuous improvement.**

We have a global standard that defines the EHS training expectations for all employees. Three categories of training programs exist:

- **Managers** – covers specific management responsibilities with regard to environmental and safety compliance and promoting a “safety first” culture
- **EHS professionals** – designed to drive more consistent technical expertise and improved EHS program and support capabilities around the world
- **Overall employee population** – covers the specific information our employees need to perform their jobs in a safe and environmentally compliant manner, focusing on hazards and control measures employees encounter on the job

These training programs are reviewed periodically to ensure they remain current. Our EHS training program materials are available in both instructor-led as well as e-learning formats. Recently, we developed an EHS course for senior company leadership that highlights the importance of EHS to the business, the critical role senior leaders play in EHS performance, and the specific actions leaders can take to drive their areas of accountability toward EHS excellence.

## EHS GOVERNANCE

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**Our commitment to the environment and employee health and safety begins with the company’s Executive Committee, which has established the corporate EHS Council.**

This council, composed of senior-level executives from the business units, is responsible for overall EHS governance as well as leading and driving enterprisewide excellence in EHS management and performance. Specifically the council:

- Establishes strategy, policy and Standards
- Provides enterprisewide oversight of environmental and employee safety issues, risk mitigation and control strategies

- Monitors performance, establishes continuous-improvement targets, and recognizes and promotes excellence
- Allocates resources and/or sponsors projects to address specific concerns

An EHS Standards Committee chartered by the Council provides stewardship over the Standards and enables business engagement in the development of new or revised Standards. Each area of the business is responsible for executing against the Standards, contributing to development of programs, supporting internal audits and communicating significant EHS events. Divisional compliance committees have been established to provide governance on implementation of the Standards and for other EHS matters. The vice president of Global Safety and the Environment (GSE) is responsible for communicating to the Executive Committee and EHS Council regarding progress on goals, objectives and metrics, as well as other material issues. The VP of GSE partners with business leaders to establish long- and short-term goals and performance measures.

Our corporate EHS organization is responsible for:

- Developing corporate policies, procedures, guidelines, standards, tools and programs to set expectations and to support EHS compliance
- Providing technical and regulatory support to site-safety and environmental staff and operating organizations
- Managing and implementing an internal audit program targeted at understanding the current state of compliance and identifying potential issues
- Tracking and communicating internal and external trends that should be addressed
- Anticipating, tracking and commenting on new regulations affecting our business and, where appropriate, developing plans to address them

Our site-safety and environmental professionals around the world support the EHS needs of their business areas, which include manufacturing, research operations, sales and administrative activities, by:

- Ensuring that line management fully understands EHS requirements
- Establishing, assessing and improving programs
- Providing regulatory and technical support to employees and the operating areas
- Routinely assessing performance against both regulatory and company requirements
- Acting as the primary liaison with local regulators and inspectors
- Investigating incidents and developing corrective action plans to address identified root causes

## INTERNAL AUDITING

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### **We have a detailed and rigorous internal corporate safety and environmental audit program.**

Our global corporate EHS audit program is one way in which we identify and resolve compliance and performance issues.

- Our audit leaders are full-time professional auditors with extensive experience in auditing procedures. Audit team members consist of EHS professionals with extensive site and subject-matter expertise. In many cases, particularly outside of the United States, our internal auditors work with independent consultants who have regulatory expertise in the laws of the host country.
- All audit findings are addressed through the development of corrective and preventative action plans, which are reviewed, approved by the audit leader and regional GSE leader, and tracked to completion
- Findings from our audit program are communicated to appropriate parts of our organization so that learnings may be shared and actions can be taken
- Audit performance and key program metrics are reviewed as part of our governance process

The audit frequency for a given facility is primarily risk-based. Manufacturing and research sites are generally audited every one to two years, depending on the type of facility, its size and other factors. Less complex facilities, such as sales and business offices and our warehouses, are typically audited every five years.

# PERFORMANCE

**Our centralized environmental, health and safety (EHS) information system allows us to collect, manage, learn from and share our safety and environmental performance data more efficiently.**

GRI G4-EN29

GRI G4-SO8

We collect and analyze data reflecting both leading and lagging metrics to look for potential trends and identify opportunities that could help us to drive performance improvement. We continuously explore new ways to learn from and report on our performance.

Global Environmental & Safety Compliance Performance Data Summary <sup>1</sup>	2010	2011	2012	2013	2014
	Notices of Violations (NOVs)/Citations				
Environmental	32	26	14	6	15
Safety	32	21	30	9	11
	Fines				
Environmental fines paid (US\$)	70,201	11,791,765	27,100	1,167	81,600
Number of environmental fines	9	15	2	1	4
Safety fines paid (US\$)	631	7,500	121,827	3,827	0
Number of safety fines	1	2	2	2	0

<sup>1</sup> Previously reported data have been restated for consistency with Global Reporting Initiative (GRI) guidelines.

## NOTICES OF VIOLATIONS, FINES & SETTLEMENTS

We report all forms of EHS compliance notices using the term Notices of Violations (NOVs), which includes citations, letters of warning, and notices of noncompliance from environmental and safety-focused regulatory agencies.

In 2014, we had 239 EHS-related inspections of our facilities around the world. We received 11 safety NOVs and no safety-related fines in 2014. We received 15 environmental NOVs and paid \$81,600 in fines associated with four environmental incidents in 2014. Over the last five years, the number of NOVs and fines received by our company has been trending downward.

## SIGNIFICANT ENVIRONMENTAL EVENTS

GRI G4-EN24

A "significant environmental event" is defined as an environmental release that results in environmental harm to humans, aquatic organisms or wildlife, or any environmental release that requires reporting to the U.S. Securities and Exchange Commission. We experienced no significant environmental events in 2014.

# ENERGY USE & CLIMATE CHANGE

## MAIN

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**Scientific data support that climate change is occurring, and we are taking action to reduce the future economic and public health risks associated with a changing climate.**

### GRI G4-EC2

We have made it a priority to reduce our demand for energy and have taken steps to establish responsible internal policies and practices focused on reducing energy usage at all sites and greenhouse gas (GHG) generation throughout the company. By taking these steps, we are not only minimizing GHG emissions but we are also reducing our operating costs and mitigating the business impacts expected to be associated with future climate change requirements. We report our GHG emissions as required by regulations in certain countries and annually through CDP, in whose system our score has improved each year. The disclosure we submitted to CDP in 2014, which reflected our 2013 performance data, received a score of 88B. The number (88) is a reflection of our disclosure, and the letter (B) is a reflection of our performance. We track the generation of five GHGs associated with operating our facilities and our fleet:

- Carbon dioxide (CO<sub>2</sub>)
- Methane
- Nitrous oxide
- Hydrofluorocarbons
- Sulfur hexafluoride

We have established and met several GHG-reduction goals over the last decade with the most recent one being realized in 2012. We now have a goal to achieve a 15 percent absolute reduction of our Scope 1 and 2 GHG emissions between 2012 and 2020. The primary avenue for achieving this goal will be lowering our energy demand through improved facility efficiencies.

We have an Energy Center of Excellence (CoE) that identifies, shares and standardizes best practices, and prioritizes the funding of energy projects to reduce energy usage across the company. While we have implemented some renewable energy projects, our program emphasizes energy efficiency and conservation, because using less energy provides a better balance of business needs and environmental impact reduction. Our manufacturing facilities, warehouses, laboratories, major offices and vehicle fleet are the priority targets of our energy-demand-reduction programs, as they represent the majority of our energy consumption.

## INITIATIVES

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## The company has launched initiatives around the world to improve energy use, reduce greenhouse gas (GHG) emissions from our operations and understand our supply chain–related impacts.

We have established an Energy Capital Fund of up to \$10 million per year to transition to more energy-efficient technology and to better position the company to respond to energy demands in the future. In 2014, we met the target spend of more than \$10 million, which resulted in \$3.8 million annual savings and a reduction of more than 9,500 metric tons of carbon dioxide from our facilities.

### FACILITIES

We strive to make our facilities as energy efficient as practical.

- When we purchase facilities, we evaluate them for energy efficiency and assess them against our best practices as part of their integration into our company
- We require all new facilities to comply with our Energy Design Guide and Energy Conservation Planner
- We build all new laboratories and offices following cost-effective energy-efficient practices. We have several facilities that are LEED-certified.
- In 2014, we conducted energy “treasure hunts” at two facilities in the U.S. At each facility, volunteers spent three days looking for opportunities to reduce demand for both energy and water. Since 2010, the company has conducted treasure hunts at 11 facilities across the world. This process has identified nearly 1,000 energy-efficient project opportunities, many of which have been successfully implemented. In 2014, we also began the “Treasure Hunt Online” to help generate energy-savings ideas that can be shared with all our sites.
- In 2014, our employees were granted access to a training curriculum that allows employees to learn more about energy management and energy systems. Through this program, employees can earn an energy manager certification.
- Three of our U.S. facilities were awarded the 2014 ENERGY STAR label by the U.S. EPA for superior energy efficiency and environmental performance among U.S. pharmaceutical manufacturing plants
- Four of our buildings were certified ENERGY STAR in the top quartile
- Three international sites met the ENERGY STAR challenge for Industry, achieving a 10 percent reduction in energy use over five years

### WORK PRACTICES

The company takes advantage of technology advances in order to save energy, time and money to reduce emissions.

- Site energy use is tracked monthly by our Energy Center of Excellence (CoE) through a centralized system
- Employees are encouraged to make use of e-meetings whenever possible as opposed to traveling for business
- A “Rail Travel” option is included in our online business-travel-booking tool to make it easier to travel by train when appropriate. Traveling by train has a smaller carbon footprint than traveling by either airplane or personal vehicles.
- The carriers who transport our products use alternatives to air freight whenever practical. Between 2013 and 2014, we increased ocean shipping by 10 percent, which reduced the amount of products shipped by air. This helps to reduce the GHG impacts within our value chain.

### RENEWABLE ENERGY

Photovoltaic (PV) arrays, wind turbines and other renewable energy installations help us to reduce energy-demand peaks and to postpone or avoid adding new power plants.

- One site in Pennsylvania has a combination green and solar-photovoltaic roof. The solar array, comprising 110 panels, generated almost 25 megawatt hours (MWh) of electricity in 2014. The roof’s 2,700 square feet of green plants provide insulation to the building and extend the roof’s life by protecting it from ultraviolet (UV) light. In addition to these benefits, the green roof reduces the impacts of storm-water runoff by capturing about 90 percent of rainwater, or approximately 60,000 gallons, based on annual rainfall estimates. In 2014, a project to expand the green roof to the

adjacent building was completed, adding an additional 6,300 square feet of “green space.”

- Several sites host solar arrays producing more than 5,400 MWh of energy annually
- One site in the U.K. hosts two 2MW wind turbines that generate more than 11,700 MWh of energy per year

## VEHICLE FLEET

Approximately 10 percent of our energy use is associated with our vehicle fleet. We calculate our fleet’s GHG emissions based on estimated fuel economy and actual total miles driven.

- Our global fleet-management principles include maximum limits for carbon dioxide emissions (g/km) in the selection of fleet vehicles
- We have reduced the number of sales fleet vehicles on the road by almost 2,000 vehicles since 2012
- Over the last few years, we have converted our U.S. Human Health sales fleet from cars with six-cylinder engines to cars with four-cylinder engines
- Our European fleet continues to convert to more efficient vehicles and is on track to meet the EU targets of a fleet average of 130g of CO<sub>2</sub>/km by 2015 and 95g CO<sub>2</sub>/km by 2021

## PARTNERSHIPS

**U.S. Environmental Protection Agency (EPA) ENERGY STAR:** This partnership provides a broad energy-management strategy that serves as a useful framework for measuring our current energy performance, setting goals, tracking savings and rewarding improvements. In 2015, the EPA has again recognized our company with the Sustained Excellence Award. This is the 10th consecutive year we have been recognized by ENERGY STAR for excellence in energy management. For more information on our awards, [click here](#).

## PERFORMANCE

GRI G4-EN6

GRI G4-EN15

GRI G4-EN16

GRI G4-EN17

GRI G4-EN19

Global Energy Use & GHG Summary <sup>1</sup>	2010	2011	2012	2013	2014
Total energy (gigajoules)	26,396,800	26,415,000	25,330,400	24,709,400	22,726,000
Total greenhouse gas (GHG) emissions (metric tons CO <sub>2</sub> e)	2,077,000	2,007,000	1,918,000	1,811,000	1,676,000

<sup>1</sup> In accordance with the Greenhouse Gas Protocol, prior-year data have been adjusted to add or remove facilities that have been acquired and sold. Adjustments also reflect changes in methodology to ensure consistency from year to year.

GRI G4-EN3

	Energy by Source Scope 1 & 2 (% of total) <sup>1</sup>					
Natural gas (Scope 1)		53%	57%	57%	58%	59%
Purchased electricity (Scope 2) <sup>2</sup>		27%	25%	26%	24%	24%
Fleet fuel (Scope 1)		14%	13%	12%	12%	11%

Purchased steam (Scope 2)	4%	2%	3%	4%	3%
Fuel oil (Scope 1)	2%	2%	1%	2%	2%
Spent solvents (Scope 1)	0.6%	0.7%	0.7%	0.5%	0.4%
Coal (Scope 1)	0.0%	0.0%	0.0%	0.0%	0.0%

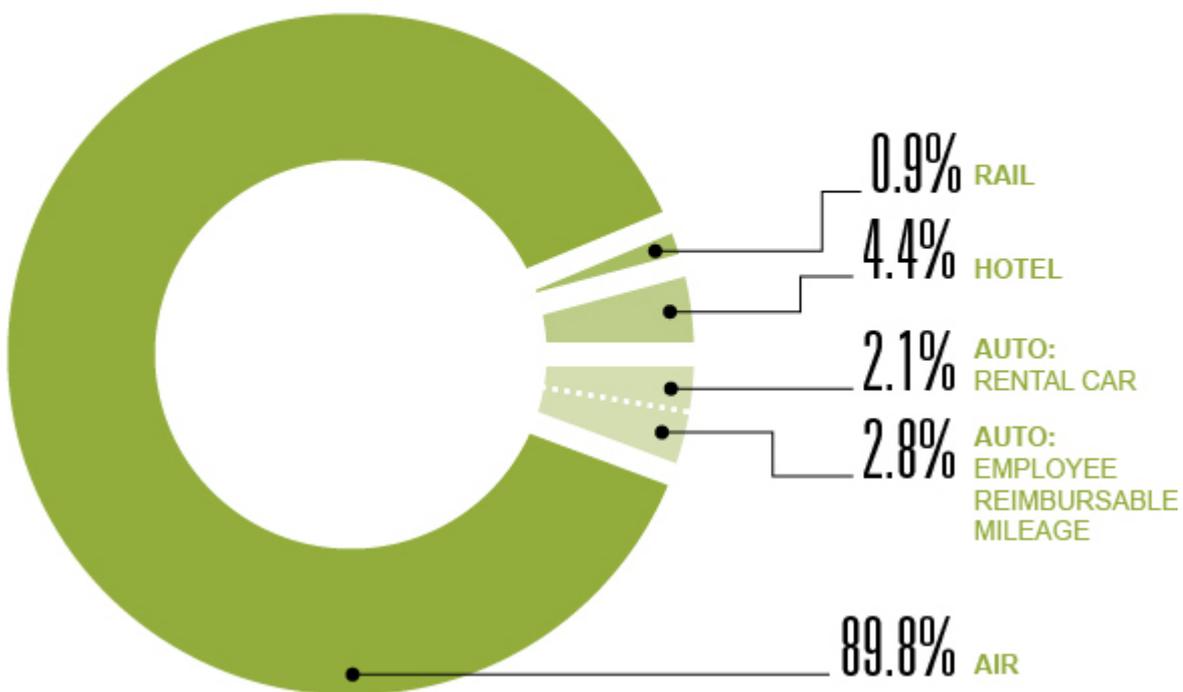
<sup>1</sup> May not add to 100 percent due to rounding.

<sup>2</sup> Includes solar, wind and other renewables generated on-site where renewable energy credits have been sold.

Energy-efficiency and demand-reduction projects at multiple sites contributed to lowering our energy consumption and reducing our direct greenhouse gas (GHG) emissions. The most significant contributors to decreasing our GHG emissions were demand reduction/conservation; consolidating our office, lab and manufacturing spaces; and shifting some power supplies from purchased electricity to on-site-generated electricity through combined heat and power systems.

GRI G4-EN4

## 2014 BUSINESS TRAVEL GHG EMISSIONS (SCOPE 3)



GRI G4-EN17

GRI G4-EN30

GHG Emissions Related to Employee Business Travel (metric tons CO <sub>2</sub> e), Scope 3	2010	2011	2012	2013	2014
Air <sup>1</sup>	113,962	115,149	112,659	111,146	112,750
Rail	607	90	280	195	1,082
Hotel	9,900	9,814	5,975	5,445	5,514
					Auto
Rental Car	2,973	3,011	3,149	2,479	2,625
Employee reimbursable mileage <sup>2</sup>	-	9,158	4,986	3,927	3,533
<b>Total</b>	<b>127,442</b>	<b>137,222</b>	<b>127,049</b>	<b>123,192</b>	<b>125,504</b>

<sup>1</sup> 2013 air travel calculation updated to U.K. Defra 2013 Factors.

<sup>2</sup> No data available for 2010.



# WATER USE

## MAIN

### **Our business, our suppliers, our communities and our customers depend on having access to clean water.**

Our global water strategy aims to achieve sustainable water management within our operations and our supply chain. As part of our “Be Well” commitment, we are also striving to reduce the impact of water-related illnesses. Water-use reduction is a priority for us and is one of our three environmental performance goals. To achieve these strategic objectives, we are focusing on five specific commitments:

1. Understanding and reducing our operational water footprint
2. Reporting publicly on our water use and goals
3. Advocating for effective water policy
4. Working with partners to address water needs in communities globally
5. Encouraging and empowering our employees to be water stewards at work, at home and in their local communities

Much of the water we use is for cooling utility systems in manufacturing plants that produce our medicines. Our efforts to reduce this use of water are a major part of our goal-realization strategy. As we strive to meet the health needs of most of the world, we are increasingly operating and engaging with people and partners in regions of the world where clean water and sanitation are under great strain. Even in established markets, our business faces serious water-related risks. The initiatives, partnerships and goals to help address our global water risks are identified in the following sections. Click on the links below for related information about:

- [Wastewater](#)
- [Pharmaceuticals in the environment](#)
- [Environmental goals](#)

## INITIATIVES

### **We are engaged in numerous initiatives worldwide to reduce our water use and to understand the water-related risks and impacts in our upstream supply chain.**

GRI G4-EN10

Our Water Standard includes assessing the impact of each facility's operations on its local watershed, assuring compliance,

and driving continuous improvement in how water is used and in the quality of water discharged. Our Energy Center of Excellence includes the total cost of water in energy-project evaluations and drives best practices that conserve both energy and water.

Our water-use-reduction initiatives include:

- Consideration of water use in process design
- Cooling-system optimization
- Prompt repairs and maintenance of steam-distribution systems and traps
- Recovery and reuse of steam condensate and water purification of “reject water”
- Process-water purification-system optimization
- Avoiding the use of water in mechanical seals, such as in pumps

Many of our sites employ a variety of technologies and techniques aimed at reducing our water footprint and improving operational performance.

- Closed-loop cooling systems are employed at more than half our facilities worldwide and reduce our freshwater use by more than 5 billion gallons a year
- Reverse osmosis (RO) reject water is reused for nonpotable and nonprocess applications such as cooling-tower feed water, fire water and irrigation, and saves an estimated 50 million gallons of freshwater every year

We have committed approximately \$88 million from a \$100 million capital reserve fund for improvements in infrastructure to help achieve the company’s water commitments at our operating facilities around the world. Facility-specific projects:

- In 2013, our facility in Elkton, Virginia, completed a water-reduction project that has saved more than 450 million gallons per year, generated 40 kWh of energy and reduced operating costs by approximately \$500,000 annually. The project included optimization of the site’s groundwater-pumping network and the installation of heat-recovery equipment.
- Our Cherokee manufacturing facility in Pennsylvania is scheduled to complete a project in 2015 that is expected to reduce water use by 600 million gallons per year and save \$430,000 annually in operating expenses. The project will move existing once-through cooling water users to an upgraded closed-loop cooling system. In addition, the cooling-water distribution pumps will be fitted with variable frequency drives, which will reduce overall energy use.
- The Heist, Belgium, facility is nearing completion of a water-reduction project that will reuse wastewater streams in the site’s scrubber and cooling tower and replace three liquid-ring vacuum pumps with a single dry-pump system. The project will reduce water use by 11 million gallons per year and lower annual operating costs by approximately \$125,000.
- Our West Point, Pennsylvania, facility implemented a project to optimize the sequencing of the Water for Injection (WFI) stills, reuse water from the reverse osmosis units and reduce the number of water softener regenerations. The project has reduced water use by 7.8 million gallons per year, and generated annual cost savings of \$190,000.

[Click here](#) to learn more about our water-use-reduction initiatives.

## PARTNERSHIPS

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**We have endorsed the UN CEO Water Mandate, a public commitment to adopt and implement a comprehensive approach to water management, and we have aligned our water program with its principles.**

GRI G4-15

The CEO Water Mandate endorsers have a responsibility to make water-resources management a priority and to work with governments, UN agencies, nongovernmental organizations (NGOs), local communities and other interested parties to address global water challenges. The company has partnered with the Safe Water Network, through which we are supporting

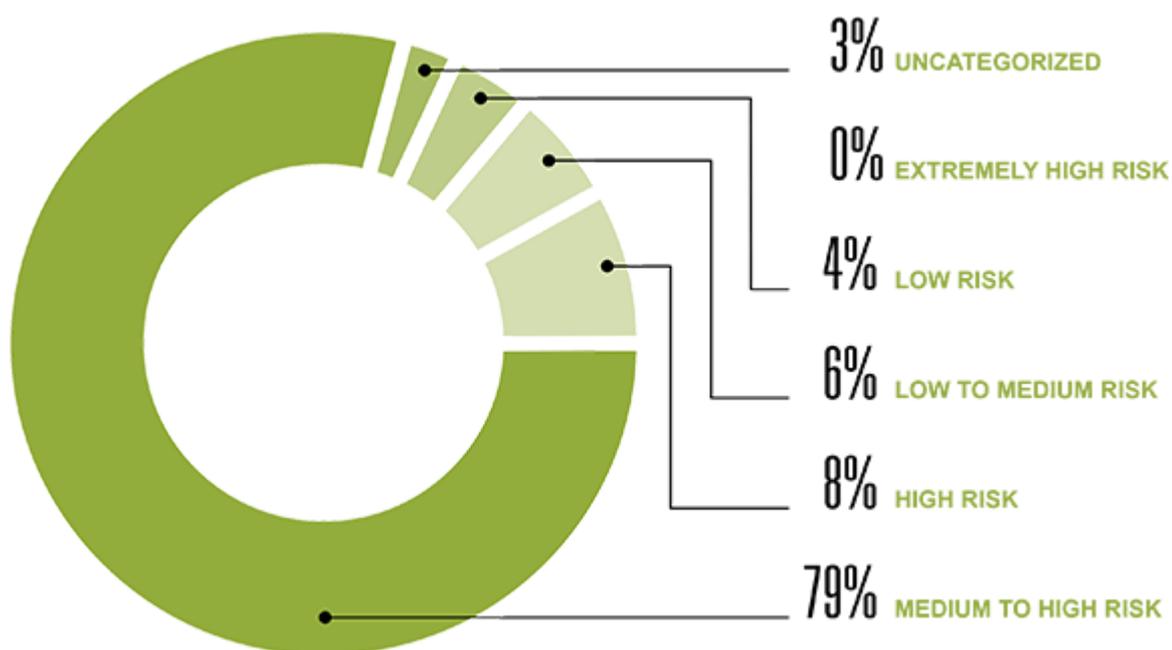
efforts to bring sustainable water solutions to the rural poor in India. The initiative is providing safe water to more than 80,000 people by creating 18 new sites in Safe Water Network's existing field projects in the state of Andhra Pradesh. Through the company's support, Safe Water Network recently launched the improved "iJal" brand ("my water" in Hindi) to increase demand and strengthen the quality, safety and reliability of the water stations.

## PERFORMANCE

Water Use (billion gallons) <sup>1</sup>	2009	2010	2011	2012	2013	2014
Total water usage by risk <sup>2</sup>	9.0	9.0	8.7	8.7	7.5	7.2
Extremely high risk <sup>3</sup>	0	0	0	0	0	0
High risk	1.1	1.1	1.0	1.0	0.9	0.6
Medium to high risk	6.8	6.9	6.6	6.7	5.7	5.7
Low to medium risk	0.6	0.6	0.6	0.5	0.5	0.4
Low risk	0.3	0.2	0.3	0.3	0.3	0.3
Uncategorized	0.2	0.2	0.2	0.2	0.2	0.2
Total water usage by source	9.0	9.0	8.7	8.7	7.5	7.2
Pumped water (surface water and groundwater)	6.5	6.4	6.1	6.4	5.3	5.1
Purchased water	2.5	2.7	2.6	2.3	2.2	2.1

<sup>1</sup> In accordance with the Greenhouse Gas Protocol, prior-year data have been adjusted to add or remove facilities that have been acquired and sold. Adjustments also reflect changes in methodology to ensure consistency from year to year.

<sup>2</sup> World Resources Institute, Aqueduct Water Risk Atlas Overall Water Risk. <sup>3</sup> Our manufacturing facility in Indonesia used 12 million gallons in 2014.



### GRI G4-EN8

During 2014, we used 7.2 billion gallons of water versus 9.0 billion gallons used in 2009. This reflects a 20 percent reduction in water use over this period. The realization of several water-savings initiatives combined with reduced demand across our manufacturing network contributed to a water-use reduction of 0.3 billion gallons from 2013.

Approximately 71 percent of the total water we used in 2014 was supplied from nearby surface water and groundwater resources, with the balance sourced from municipal water supplies. Many of our facilities employ water reuse and recovery strategies, including recirculation of water in cooling towers and condensate recovery.

We use the WRI water-risk-assessment tool called "Aqueduct" to measure and map our water risks. The overall risk score relies on 12 different measures grouped into three categories: physical risk quantity (seven measures), physical risk quality

(two measures) and regulatory & reputational risk (three measures), which are combined to generate an overall water-risk score.

In 2014, we operated 16 manufacturing and/or research facilities in areas of high overall water risk and one facility in extremely high overall water risk. These facilities are in the U.S., Mexico, China, South Africa and Indonesia. The two manufacturing facilities that use the most water are located in areas of medium to high overall water risk in the U.S.

# EMISSIONS, EFFLUENTS & WASTE



## MAIN

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**Our Environmental Sustainability Strategy emphasizes improving the efficiency of our operations.**

### GRI G4-EN27

The management of emissions, effluents and waste from our facilities is important to the communities where we operate and is the focus of our environmental permits and other regulatory requirements. To minimize our environmental footprint, we look for opportunities to avoid the use of hazardous materials, reuse or recycle materials, and prevent the generation of waste. When prevention, reuse and recycling are not practical, we apply controls and treatment technologies to prevent human health impacts and minimize environmental impacts.

Reducing emissions and waste begins with the design of our manufacturing processes. Through our [Green Chemistry](#) program, we design new processes that use fewer and safer chemicals; consume less energy, water and other resources; and generate less waste. Our process-development chemists and engineers have the expertise and the partners to support the development of more sustainable ways to synthesize our products.

By tracking our emissions, effluents and waste worldwide, we are able to identify the best opportunities to reduce our direct environmental footprint, evaluate the overall impact of new projects and ensure that we maintain reductions achieved through past initiatives.

More information is available on how we manage our solvent use, air emissions, wastewater effluents, and on our waste prevention & management and remediation programs. Data about our performance in these areas can be accessed through the [Performance](#) tab above.

## PERFORMANCE

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Please visit the [Air](#), [Wastewater](#) and [Solvent](#) sections for discussion of performance trends.

### GRI G4-EN1

### GRI G4-EN2

### GRI G4-EN20

### GRI G4-EN21

## GRI G4-EN22

## GRI G4-EN25

Emissions, Effluents & Waste<sup>1,2</sup>

Manufacturing Solvent Use (metric tons)	2010	2011	2012	2013	2014
Fresh solvents	37,000	38,000	34,000	32,000	25,000
Recovered solvents	25,000	19,000	16,000	15,000	13,000
Recovered-solvent usage rate	40%	33%	32%	32%	34%
Air Pollutant Emissions (metric tons) <sup>3</sup>					
Ozone-depleting substances (ODS)	1.2	0.6	2.6	1.6	1.5
Nitrogen oxides (NOx)	628	620	616	581	544
Sulfur oxides (SOx)	87	86	66	56	54
Volatile organic compounds (VOCs)	853	651	645	553	530
Wastewater Characteristics (metric tons)					
Total chemical oxygen demand (COD) discharged	5,052	2,950	2,284	2,099	1,767
COD discharged to surface water <sup>4</sup>	556	600	278	288	242
COD discharged to municipal treatment plants <sup>4</sup>	4,496	2,350	2,006	1,811	1,525
Total nutrients discharged <sup>5</sup>	365	286	249	191	177
Nutrients discharged to surface water	71	54	58	25	32
Nutrients discharged to municipal treatment plants	294	232	191	166	145
Operational Waste Generation (metric tons) <sup>1</sup>					
Total operational waste generation	120,500	119,000	116,000	100,500	87,000
Hazardous waste <sup>6</sup>	68,500	65,000	63,000	54,000	46,000
Nonhazardous waste <sup>3</sup>	52,000	54,000	53,000	46,500	41,000

<sup>1</sup> Includes facilities worldwide.<sup>2</sup> Previously reported data have been restated per our methodology, which includes adding facilities that have been acquired, and removing facilities that have been sold.<sup>3</sup> Data is not measured or weighed, it is estimated based on volume and conservative assumptions and factors.<sup>4</sup> COD: Chemical oxygen demand.<sup>5</sup> Nutrients = Sum of total Kjeldahl nitrogen + nitrate-nitrogen + phosphorus.<sup>6</sup> Hazardous waste includes all waste that requires special handling, as defined by a national, state/provincial or local regulatory agency (e.g., RCRA, special waste, chemical waste, dangerous waste). It also includes petroleum products, pharmaceutical actives/intermediates, medical/biological/infectious materials, or any other materials or compounds that are specially regulated due to the hazard they pose to human health and/or the environment.

# AIR EMISSIONS

## We are committed to controlling air emissions from our facilities to reduce local, regional and global impacts.

The largest component of air emissions at our sites is carbon dioxide (CO<sub>2</sub>) generated from boilers and power-generation turbines (for heat and energy), and from other combustion processes, such as thermal oxidizers (for treating air emissions) and incinerators (for destroying waste). These combustion processes also result in emissions of nitrogen oxides (NO<sub>x</sub>) and sometimes sulfur oxides (SO<sub>x</sub>), depending on the fuels used. We strive to make our facilities more energy efficient through our energy-management programs. By making these improvements, we also reduce emissions of NO<sub>x</sub> and SO<sub>x</sub> from our operations. For more information on our greenhouse gas (GHG) emissions and energy use, [click here](#).

Solvents are one of the largest sources of air emissions in our manufacturing processes and emissions from solvent use are the primary component of volatile organic compound (VOC) emissions. In an effort to reduce these emissions, we use pollution-control technologies such as conservation vents, carbon filters, thermal oxidizers, condensers and scrubbers. A key element of our Green Chemistry program is to design processes and cleaning operations that use fewer solvents, resulting in reduced VOC emissions.

Air Pollutant Emissions by Type (Metric Tons) <sup>1</sup>	2010	2011	2012	2013	2014
Ozone-depleting substances (ODS)	1.2	0.6	2.6	1.6	1.5
Nitrogen oxides (NO <sub>x</sub> )	628	620	616	581	544
Sulfur oxides (SO <sub>x</sub> )	87	86	66	56	54
Volatile organic compounds (VOCs)	853	651	645	553	530

Previously reported data have been restated per our methodology, which includes adding facilities that have been acquired and removing facilities that have been sold.

<sup>1</sup> Data are estimated using conservative assumptions and factors, not measured or weighed.

Our emissions data reflect the facilities we own and operate, our leased facilities, and our vehicle and aircraft fleet-related emissions. The decrease in VOC, SO<sub>x</sub> and NO<sub>x</sub> emissions between 2013 and 2014 is attributed to more accurate emission-tracking methods and to a reduction in the use of solvent in our manufacturing operations. Emissions of ozone-depleting substances (ODS) are the result of nonroutine releases from temperature-control and fire-suppression systems, and can vary significantly from year to year. We expect our emissions of ODS to be lower following the phase-out of these substances by the European Union on January 1, 2015.

# WASTEWATER EFFLUENTS

**Throughout 2014, we have committed \$88 million of the allocated \$100 million for water and wastewater infrastructure improvements, the remainder of which is estimated to be committed by 2018.**

We operate wastewater-treatment plants at many of our production and research facilities. Approximately 48 percent of the wastewater from our manufacturing plants is treated on-site before being discharged to rivers or other surface-water bodies, with the balance going to local municipal wastewater-treatment facilities that have the technology and capacity to treat our wastewater.

Chemical oxygen demand (COD) and nutrients like nitrogen and phosphorus are indicators of the quality of the wastewater discharged from our operations. COD is a measure of the overall pollutant load of our discharges. Nutrient enrichment is a water-quality concern globally and in many watersheds where our facilities are located.

To assure that our factory discharges do not contain residual pharmaceutical products that present a risk to human health or the environment, we have established compound-specific discharge criteria, as well as procedures for managing and controlling active pharmaceutical ingredients (APIs). In addition, our production facilities have, or are being provided with, API-treatment technology to ensure that our wastewater meets these internal standards. Over the past three years, we have committed \$10 million of our \$100 million water-infrastructure-improvement initiative to install API-treatment technology at seven facilities.

Learn more:

- Pharmaceuticals in the environment, see the [Product Stewardship](#) section
- Our water use and conservation program, see the [Water](#) section

Wastewater Characteristics (metric tons) <sup>1</sup>	2010	2011	2012	2013	2014
Total chemical oxygen demand (COD) discharged	5,052	2,950	2,284	2,099	1,767
COD discharged to surface water <sup>2</sup>	556	600	278	288	242
COD discharged to municipal treatment plants <sup>2</sup>	4,496	2,350	2,006	1,811	1,525
Total nutrients discharged <sup>3</sup>	365	286	249	191	177
Nutrients discharged to surface water	71	54	58	25	32
Nutrients discharged to municipal treatment plants	294	232	191	166	145

<sup>1</sup> Previously reported data have been restated per our methodology, which includes adding facilities that have been acquired, and removing facilities that have been sold.

<sup>2</sup> COD: Chemical oxygen demand.

<sup>3</sup> Nutrients = sum of total Kjeldahl nitrogen + nitrate-nitrogen + phosphorus.

We report both what we discharge to surface water as well as what is discharged to municipal treatment plants where additional treatment is provided. Our 2014 COD discharge of 1,767 metric tons was 16 percent lower than our 2013 discharge. Our nutrient load has also improved by 7 percent, with 2014 discharges totaling 177 metric tons. The reductions in both COD and nutrient load were associated with project-based improvements and lower production volumes than those of the prior year.

# WASTE PREVENTION & MANAGEMENT

## MAIN

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**We strive to minimize the amount of waste we generate, and to send less waste to disposal outlets and more of our used materials to recycling, composting and energy-recovery facilities.**

The amount of waste we generate reflects the efficiency of our processes and our business. Our facilities track and report the amount of operational waste they generate and how it is managed.

Different types of waste are given different names in various parts of the world. For this report, we have divided our operational waste into two categories:

1. **Hazardous waste**, which includes the heavily regulated or high-risk waste streams that need to be either recovered, neutralized, treated or destroyed to address a particular hazard such as toxicity, flammability, corrosivity, radioactivity, pharmaceutically active or infectious
2. **Nonhazardous waste**, which includes all other operational wastes

*Note that operational waste does not include construction or demolition project waste because the amounts of project-related waste can vary dramatically from year to year based on the number and size of projects.*

We continuously strive to decrease the total amount of operational waste we generate and utilize environmentally beneficial disposal methods like recycling, composting and waste-to-energy as much as possible. This lowers our manufacturing costs as well as shrinks our environmental footprint. Our [Green Chemistry](#) program supports the design of efficient new manufacturing processes that use less solvent and generate less hazardous waste.

To make sure that our hazardous and nonhazardous waste is managed in an environmentally responsible manner, we maintain a list of approved waste facilities. Approved facilities demonstrate that they have the systems, technologies and practices to manage our waste streams responsibly and in compliance with all applicable requirements.

For more about [Green Chemistry](#), [click here](#).

For more about [solvent use](#), [click here](#).

## INITIATIVES

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## We launched initiatives around the world to reduce the amount of waste that is generated and sent to landfills and incinerators without any energy recovery. Below are just a few examples.

**Green Chemistry–Based Reductions:** Applying advances in biocatalysis technology is allowing us to reduce the amount of solvent used to make our pharmaceutical compounds. For more details, please read the JANUVIA®(sitagliptin) innovative manufacturing case study.

**Container Reuse:** Prior to the year 2000, the containers we used for storing and transporting our bulk tablets were used just once and then discarded. Since establishing a process for returning, washing and reusing these bins, we have avoided the purchase of more than 330,000 containers. In addition to reducing waste and greenhouse gas (GHG) emissions, this initiative has saved the company more than \$7 million.

**Waste Recycling & Energy Recovery:** One of our largest research and vaccine manufacturing facilities, located in West Point, Pennsylvania, increased its recycling rate and was able to divert 84 percent of its operational waste and construction and demolition debris from landfills. This diversion performance has been certified by GreenCircle, an independent performance data-verification firm.

**Waste Partnerships:** Fifteen of our facilities in the U.S. have partnered with a regional service company to drive cost and recycling rate improvements, saving more than \$100K annually.

## PERFORMANCE

Operational Waste Generated (Metric Tons) <sup>1</sup>	2010	2011	2012	2013	2014
Total operational waste generation	120,500	119,000	116,000	100,500	87,000
Hazardous waste <sup>2</sup>	68,500	65,000	63,000	54,000	46,000
Nonhazardous waste <sup>3</sup>	52,000	54,000	53,000	46,500	41,000

Previously reported data have been restated per our methodology, which includes adding facilities that have been acquired and removing facilities that have been sold.

<sup>1</sup> Operational waste does not include construction and demolition debris.

<sup>2</sup> Hazardous waste includes all wastes that require special handling, as defined by a national, state/provincial or local regulatory agency (e.g., RCRA, special waste, chemical waste, dangerous waste). It also includes petroleum products, pharmaceutical actives/intermediates, medical/biological/infectious materials, or any other materials or compounds that are specially regulated due to the hazard they pose to human health and/or the environment.

<sup>3</sup> Nonhazardous waste is not typically weighed. Weights are estimated based on volume using conservative assumptions and factors.

### GRI G4-EN23

In 2014, we managed a total of 87,000 metric tons of waste from our operations, a 13 percent decrease from 2013. Of this, 46,000 metric tons were hazardous waste, a 15 percent reduction versus the prior year. The reduction is in large part a result of certain manufacturing processes being discontinued or transferred to external partners.

Of the hazardous waste we generated in 2014, 68 percent was beneficially reused in some way. More than 26 percent of our hazardous waste was sent off-site for recycling and was either returned to us for reuse or sold to other industries. Another 36 percent was burned to generate power or as a fossil fuel substitute in industrial furnaces, such as cement kilns. Of the hazardous waste that couldn't be recycled or beneficially reused, 23 percent was incinerated. Also, approximately 4 percent was sent to hazardous-waste landfills.

We recycled, reused or composted 55 percent of the 41,000 metric tons of nonhazardous waste we generated in 2014. Recycling and composting rates are increasing as more large-scale composting and broader recycling infrastructure is becoming available in the regions where we operate. We are evaluating and refining the programs in place at our facilities to reduce waste generation and increase recycling.

# SOLVENT USE

## Solvents are a significant part of our operational and supply chain environmental footprint.

Solvents play a key role in the manufacture of our active pharmaceutical ingredients and certain other products, as well as in equipment cleaning. Because of their significance to our business and the life cycle impact they represent, we focus on designing our processes to use solvents efficiently and to minimize or avoid their use where practical. Where we use solvents, we manage and control them in our emissions, effluents and waste.

We have an active Green Chemistry program to design our new processes using fewer solvents and other hazardous materials and to reuse and recycle more of the solvents we do use. For cleaning our manufacturing equipment, we use water-based methods when they are equally effective as solvents. At each of our manufacturing sites, we have engineers who are responsible for identifying and driving process-improvement projects. When it isn't practical to reuse regenerated solvents in our own production processes, we either work with suppliers who recover the spent solvents for resale to other industries or burn them as a source of energy. In some cases, we operate special boilers at our facilities that are approved to burn solvents, which reduces our energy costs and other emissions.

Emissions from solvent use are the primary component of volatile organic compound (VOC) emissions to air. To control emissions of solvents into the environment, we employ treatment technologies and controls such as conservation vents, carbon filters, thermal oxidizers, condensers and scrubbers. Any spent solvents that leave our site as hazardous waste are managed at off-site facilities that are on our approved list of waste management sites.

Click on the links below for more information about:

- [Green Chemistry](#)
- [Emissions, Effluents & Waste](#)
- [Procurement & Supplier Relations](#)

Solvent Use (Metric Tons) <sup>1</sup>	2010	2011	2012	2013	2014
Fresh solvents	37,000	38,000	34,000	32,000	25,000
Recovered solvents	25,000	19,000	16,000	15,000	13,000

<sup>1</sup> In accordance with the Greenhouse Gas Protocol, prior-year data have been adjusted to add or remove facilities that have been acquired and sold.

In 2014, we used 25,000 metric tons of new solvents and 13,000 metric tons of recovered solvent in our production processes and cleaning activities. The decrease in total solvent use is the result of lower production volumes of active pharmaceutical ingredients at our facilities combined with newer, more material-efficient processes. In 2014, we used recovered solvents for 34 percent of our manufacturing and cleaning needs.



Emissions, Effluents & Waste

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# ENVIRONMENTAL REMEDiation

## **Management practices for emissions, effluents and wastes have evolved significantly in the past 30 years.**

With research and manufacturing operations dating back more than 100 years, some of our facilities operated at a time when there were few regulations and little understanding of good environmental practices. Because the company has responsibility for remediation of those sites, we have launched investigations and aggressive and appropriate cleanup projects to protect the health and safety of our neighbors and broader communities, our employees and the environment, and to comply with all applicable requirements.

For example, our facility in Elkton, Virginia, near Shenandoah National Park has been operating as a pharmaceutical manufacturing facility since 1941. Over its history, leakage from underground storage tanks and an on-site landfill has resulted in groundwater contamination. The site now pumps the groundwater to control the migration of the contaminant plume, and the water is subsequently used as cooling water for the site's pharmaceutical operations. Recently, a project was completed to improve the efficiency of the system—pumping less groundwater while maintaining or improving containment of the contamination. The project has reduced operational costs and contributed significantly to our water-use-reduction goal, while continuing to achieve the remediation strategy approved by the Virginia Department of Environmental Quality.

For remediation and environmental liabilities, including at formerly owned and operated sites, we spent \$20 million in 2013 and \$12 million in 2014. In addition, the company is a potentially responsible party at 18 multiparty Superfund sites in the U.S.

# PRODUCT STEWARDSHIP

**We are committed to understanding, managing and reducing the impacts of our products and the materials associated with discovering, producing and delivering them to our customers.**

UNGC-7

UNGC-8

UNGC-9

GRI G4-EN27

Ensuring that our products are designed, made and used in a safe and environmentally sound manner is one of our highest priorities. We deliver on this commitment by actively pursuing improvement initiatives, maintaining a highly trained and capable internal scientific community, and collaborating with experts in academia and consortia with active programs in this field.

GRI G4-PR1

Our product stewardship programs focus on identifying and either preventing or controlling potential safety and environmental hazards throughout the product life cycle. We conduct extensive testing of our products to identify and understand potential safety, health and environmental hazards. We manage and communicate information about hazardous materials to keep our employees, contractors, transporters and other partners safe. Our chemists and engineers are trained on the green chemistry principles and are provided tools and resources to help them design manufacturing processes that use fewer resources and safer materials. We use innovations like nanotechnology to make our products more effective while recognizing that extra care is required when dealing with these new materials.

Our program extends downstream to our customers and consumers through the design of effective product packaging. We also provide for product returns and guidance on the disposal of unused medicines.



Product Stewardship

# PHARMACEUTICALS IN THE ENVIRONMENT

**We are committed to understanding and managing the environmental impacts of our products throughout their life cycles—from discovery through manufacturing, use and disposal.**

Environmental risk assessments are conducted on products during the development phase through product launch to understand and manage product impacts. We assess products in a manner consistent with the most stringent applicable global regulations. Product environmental safety profiles are reassessed during periodic renewals of product filings. We use that information to establish or revise compound-specific criteria and procedures to assure that wastewaters discharged from our facilities do not contain residual products that present a risk to human health or the environment.

We carefully monitor scientific research on the issue of pharmaceuticals in the environment (PIE) and, in particular, studies that evaluate the potential effects pharmaceutical products may have on the aquatic environment and human health. We support the use of science-based environmental risk assessments, and we will continue to collaborate with regulatory, academic, healthcare and research organizations to identify additional data needs on the transport, fate and effects of pharmaceuticals in the environment.

For more information about how we reduce the impacts of our products in the process design stage, read about our [Green Chemistry](#) program.



Product Stewardship

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# NANOTECHNOLOGY

**We support the use of nanotechnology to develop innovative drugs and vaccines that address the unmet medical needs of people and animals.**

Nanotechnology broadly describes the use of very small materials—ranging from the extreme size reductions of normal materials to unique, minute substances such as carbon nanotubes and other exotic materials. We have a [public policy statement](#) that explains our approach for using nanotechnology responsibly.

The testing required for all drugs ensures that nano-based pharmaceuticals are safe and effective for patient use. Our safety and health professionals closely monitor the developments in this area. Based on current knowledge of nanoparticles, our existing methods for assessing risks and applying controls are well-suited to minimize exposure to employees and the environment.

Here are a few examples of how we use nanotechnology to improve health:

- **Human Health:** EMEND® (aprepitant) uses a nanoscale milling approach to make its granules very small so that they are more easily absorbed by the digestive tract
- **Animal Health (Intervet):** Nanoscale milling is used for the active ingredient in PANACUR® (fenbendazole) to produce a stable and more easily re-suspendable formulation, which makes the product easier to administer and provides for improved dosing



Product Stewardship

# PACKAGING

## **Our intention is to optimize our product packaging—to use as little packaging as possible.**

The packaging we use for our finished products and for our in-process materials serves a range of purposes. The foremost purpose is to protect the purity, efficacy and physical integrity of the product. Packaging also provides the customer with information and convenience, the pharmacist or provider with easy and accurate dispensing at the point of purchase, and our business with marketing value. For some products, the packaging also serves safety functions, such as child-resistance and tamper evidence.

In recent years, we have systematically reduced the number of unique pharmaceutical product images worldwide and have implemented strategies to reduce the amount of packaging line scrap we generate. We have also developed guidelines that will help our packaging engineers design new product packages that are better for the environment. As we continue to expand our packaging-improvement efforts, we are making sure that our changes do not increase product loss rates, since that would offset the environmental benefits of packaging improvements.

To help us evaluate the environmental differences between packaging options, we use COMPASS<sup>®</sup> (Comparative Packaging Assessment), a simplified life-cycle-assessment software tool developed by GreenBlue. The COMPASS tool has been thoroughly vetted by independent verifiers and member companies within the Sustainable Packaging Coalition (SPC), and is supported by the U.S. Environmental Protection Agency (EPA).

For more information about waste-reduction efforts at our facilities, [click here](#).

# GREEN CHEMISTRY

**Finding safer and more efficient ways to make lifesaving, innovative medicines is good for business and contributes to our “Be Well” mission.**

## UNGC-9

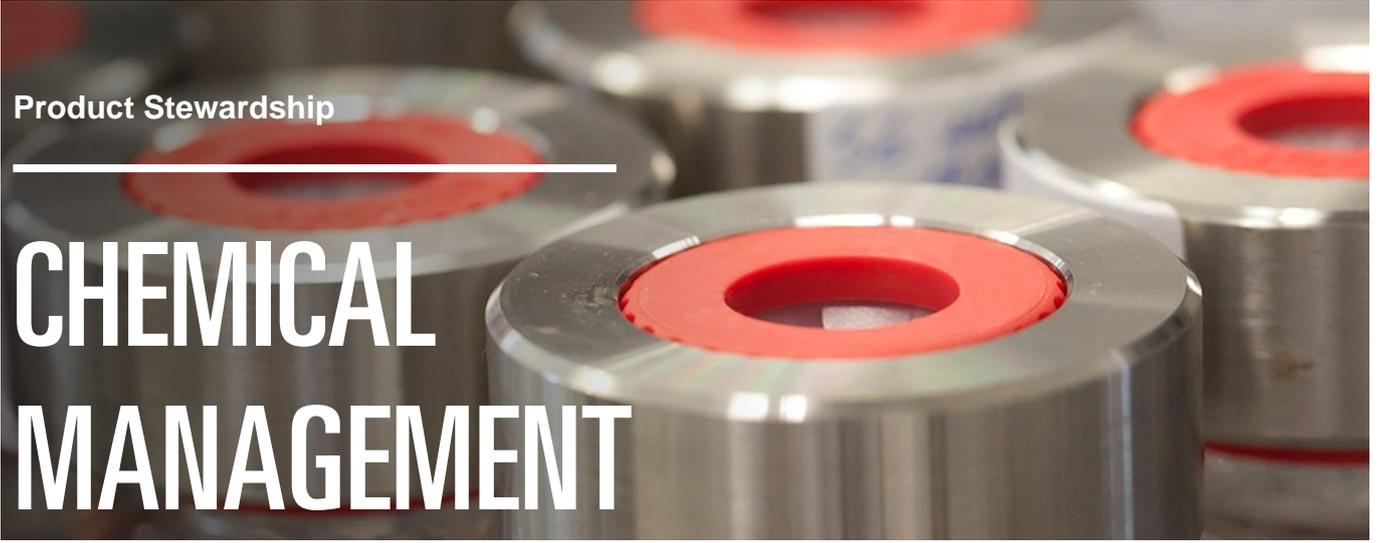
One of the key components of our Environmental Sustainability Strategy involves designing our products with the environment in mind. Green chemistry is one of the primary ways in which we are reducing the use of hazardous substances in the manufacturing of our products. Our scientists and engineers are trained in the use of the 12 principles of green chemistry and engineering to give them the skills to design more environmentally benign manufacturing processes. Recently, we have increased our focus on innovations such as biocatalysis, which provides a more sustainable means for manufacturing complex pharmaceutical compounds than traditional chemical synthesis methods. Bioprocesses typically have superb selectivity and minimal by-product-formation characteristics, thereby decreasing waste.

As part of our Green Chemistry program, we calculate the process mass intensity (PMI) of our new high-production-volume pharmaceutically active products for human use. PMI reflects the number of kilograms of raw materials used to produce one kilogram of an active pharmaceutical ingredient (API), and is one indicator of process efficiency. The PMI metric is a useful way of comparing different processes and tracking improvements over time.

Since the establishment of the annual Presidential Green Chemistry Award by the U.S. Environmental Protection Agency in 1996, we have been the only pharmaceutical company to be recognized with three Green Chemistry Awards for innovative process improvements.

We are a founding member of the American Chemical Society's Green Chemistry Institute® (ACS GCI) Pharmaceutical Roundtable, a partnership between the ACS GCI and member pharmaceutical companies. Roundtable members work together to create green chemistry tools and to advance research on new ways to apply green chemistry and green engineering principles to pharmaceutical discovery and production processes. We are currently collaborating with other ACS GCI member companies to develop new green chemistry tools and publish information about sustainable production practices that are specifically relevant to bioprocessing.

For more information about our efforts to increase use of recovered solvents and prevent waste, [click here](#).



Product Stewardship

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# CHEMICAL MANAGEMENT

**A comprehensive and effective chemical-management program is critical to ensuring the safety and protection of our employees, the communities in which we operate and the environment.**

We have procedures, systems and processes in place to manage the approval, procurement, inventory, receipt, transfer, storage, use and disposal of chemicals at all of our sites. We provide our employees and others with information about the identities and potential hazards of the chemicals in our operations and final products through proper labeling of chemicals and creation of safety data sheets.

Complying with chemical substance and product requirements is a top priority for us. We track numerous existing and emerging chemical control regulations that require notification and registration of specific types of chemicals. To fulfill these requirements, our scientists complete assessments of the environmental and human health risks of our substances and submit the required regulatory notifications. Additionally, we provide details on product use and risk-based control measures as necessary and in accordance with applicable regulations.

For information about how we manage the environmental fate and effects of our own compounds and products, [click here](#).

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# EMPLOYEES

**The superior talent, competitive skill set and collaborative approach to problem-solving characteristic of our company’s global employee population make them our greatest strength and most powerful resource for business growth. They are *the fundamental link* to our vision of solving the greatest healthcare challenges and helping the world “be well.”**

We recognize that harnessing the knowledge and insight of a best-in-class workforce—one that is gender-balanced and diverse—requires leadership, a corporate culture of respect and engagement, as well as a thoughtful and strategic approach to employee development, workplace inclusion, and work/life flexibility. Through the Office of Global Diversity and Inclusion and through Employee Business Resource Groups (EBRGs) we support programs that actively welcome the different and diverse perspectives of all employees—across race, gender, ethnicity, culture, age, disability, religion, gender identity, gender expression and veteran status. At our company, we have ten EBRGs (Women, Latino/Hispanic, African-Ancestry/Black, Asia Pacific, Native American/Indigenous, Millennials, LGBT, Interfaith, Differently Able and Veterans).

We encourage and support continuous learning and ensure that employees have ample opportunities to network, build important stakeholder relationships, learn new skills, and hear the perspectives of senior leaders to further their knowledge and ability to contribute to the business. Leveraging a new program called “DRIVEN” (Delivering Real Insights Via Employee Networks) employees are able to make meaningful contributions to the business in a private, market research on-line community. This enables efficient and compliant engagement of our EBRGs to provide business, customer, brand and research development insights via market research methods.

Balancing professional objectives with personal goals can be challenging at times. Therefore, we offer well-managed flexible work arrangements—flextime, job-sharing, part-time, compressed work week, telecommuting and remote work—to support the demands of many employees while enabling them to fully contribute to their professional goals.

We value the health and safety of employees and provide ample resources to support and nurture healthier habits at work and at home.

We strive to create an environment that encourages employees to “bring their whole selves to work.” We offer a wide variety of tools, programs and resources to enable us to tap into the unique perspectives and innovative ideas of our employees to meet the healthcare needs of an increasingly diverse customer base.

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## KEY PERFORMANCE INDICATORS

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Diversity & Inclusion	2011	2012	2013	2014
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Executive roles held by women <sup>1,2</sup>	35%	31%	31%	31%
Women on the Board	17%	17%	17%	17%
Underrepresented ethnic groups on the Board	11%	25%	25%	25%
Underrepresented ethnic groups in the workforce (U.S.)	29%	24%	24%	24%
Well-Being				
Response rate to the Voice Survey	63%	77%	77%	78%
Employees who completed a health assessment (U.S.)	58%	58%	62%	57%
Overall turnover rate <sup>3</sup>	14.0%	11.0%	15.5%	15.0%
Lost-time incident rate (LTIR) <sup>4</sup>	0.30	0.27	0.28	0.20
Recordable injury rate (RIR) <sup>4</sup>	0.74	0.62	0.61	0.57
Volunteerism				
Employees who took release time according to the global policy on employee volunteerism <sup>5</sup>	11.0%	15.0%	NA	12.5%
Volunteer hours <sup>5</sup>	213,000	221,000	NA	186,400

NA: Not available.

<sup>1</sup> Beginning with 2012, data reported for women are global; previously, these data were limited to the U.S.

<sup>2</sup> "Executive" is defined as the chief executive officer and two structural levels below.

<sup>3</sup> Overall turnover incorporates all types of turnover, including restructuring.

<sup>4</sup> Workplace injury rates for 2012 have been restated for accuracy as well as associated percentage change vs. prior year.

<sup>5</sup> As a result of the transition to a new website and vendor for our employee giving programs, our company's total volunteer hours are not available for 2013.



Employees

# POSITIVE WORK ENVIRONMENT

## MAIN

**A positive, inclusive and high-performing work environment is essential for employees to feel welcomed and valued, and to be able to fully contribute to the business objectives of their teams.**

To achieve our company's mission of being the best healthcare company in the world, we must ensure that we provide an inclusive and welcoming environment with supporting leadership behaviors to encourage high levels of employee engagement. We provide numerous opportunities for employee development and professional growth, competitive compensation and benefits, and a focus on health and safety. We leverage global diversity and inclusion to create a 21st century workforce that is gender-balanced and inclusive of top, diverse talent.

Our efforts to build a positive, inclusive and high-performing working environment are based upon the following principles:

- We operate as a unified company with all employees sharing in the mission of being the best healthcare company in the world
- We share a strong core of ethics and integrity
- We put patients and customers first
- We value diversity and inclusion as essential, integrated elements of our culture and leadership
- We demonstrate scientific, business and operational excellence
- We are results-driven and highly competitive
- We are empowered to make decisions, and we hold ourselves accountable for the outcomes
- We innovate and take appropriate risks
- We value feedback and learn from our successes and our mistakes
- We encourage debate and communicate candidly and respectfully
- We are efficient, agile and responsive to change

## LEADERSHIP BEHAVIORS, EMPLOYEE DEVELOPMENT AND PROFESSIONAL GROWTH

Our company's employee behavior standards are closely aligned with the company's business strategy and Code of Conduct. Our seven leadership behaviors apply to every employee, and support us in our efforts to consistently perform at a level of excellence, achieve our strategic goals, and create and sustain our high-performance culture.

Our leadership behaviors:

- Focus on Customers & Patients
- Make Rapid, Disciplined Decisions
- Act with Courage & Candor

- Build Talent
- Demonstrate Ethics & Transparency
- Drive Results
- Foster Collaboration

We conduct rigorous and transparent annual performance reviews of employees at all levels to guide company decisions relating to compensation and rewards. Employee performance is measured, in part, by how well employees demonstrate our leadership behaviors. In this way, we seek to emphasize not just what an employee achieves, but also how he or she achieves it. It is critical to our company that the annual incentive bonus of management-level employees is determined, in part, by demonstrated leadership that is consistent with the behaviors.

In addition, we conduct an annual employee-development planning process in which managers discuss with each of their employees his or her strengths and development needs. The manager and employee then jointly create an action plan to strengthen areas in need of development and build new leadership skills.

## GLOBAL DIVERSITY & INCLUSION

We are proud of our long-standing commitment to leveraging diversity and inclusion as key pillars in our growth strategy. For more than 30 years, our company has distinguished itself as a leader in Global Diversity & Inclusion (GD&I) and has received numerous accolades and recognition as a best-practice company in this area. We work collaboratively to leverage the innovation that results from a dynamic, inclusive organization led by a diverse team of leaders to achieve business results. Through GD&I we are able to reinforce our vision of being the best healthcare company in the world.

GD&I contributes in meaningful and sustainable ways to superior business performance. Through strategic oversight and governance of Employee Business Resource Groups (EBRGs), we are able to harness employee business insights, support talent management goals and drive corporate reputation and community responsibility. Our company is committed to GD&I through enterprisewide, senior-level commitment to diversity, recruitment, retention and talent-management strategies; inclusive and flexible work-life and workplace strategies; and external marketplace and strategic alliance engagement.

For more information, [click here](#).

## WORK-LIFE INTEGRATION

Our company takes a comprehensive and holistic view toward work-life integration. We focus on a broad array of programs to appeal to employees at all stages of life. Employees who manage multiple responsibilities in the home and in the workplace, employees who are caregivers to elderly parents, employees who are single-head-of-household parents, employees with apparent or nonapparent disabilities, and employees who have religious obligations—indeed, all employees—benefit from the greater work-life integration.

In addition, we understand that employees with disabilities—apparent and non-apparent disabilities—may require workplace accommodations to enable them to contribute to their fullest potential. To support these employees, we have developed a comprehensive strategic platform to address full disability inclusion. Our *Workplace EnABLEment* program is the first enterprisewide, customized disability inclusion strategy that addresses the entire spectrum of the employee experience with a strategic road map that includes recruiting, retention and advancement, the Just-in-Time manager training toolbox and employee education program, communications support, community outreach, supply-chain engagement, strategic alliance support and a measurement system to track results.

For more information, [click here](#).

# WORK-LIFE

HOME	BENEFITS	DISCOUNTS
<ul style="list-style-type: none"><li>• Child care, including Backup Care Connection®</li><li>• Financial Planning</li><li>• Pregnancy</li><li>• Emotional Health</li><li>• Becoming a parent</li></ul>	<ul style="list-style-type: none"><li>• Academics and Education, including Merck's College Coach and Tuition Assistance Programs</li><li>• Childcare and Aging, including Merck on-site Child Learning Centers</li><li>• Backup care and national discount programs</li><li>• Adoption Assistance</li></ul>	<ul style="list-style-type: none"><li>• Shopping</li><li>• Entertainment</li><li>• Travel</li><li>• Family</li><li>• Home &amp; Auto</li></ul>

## WELLNESS

A healthy and safe workforce is a more productive workforce. Our company provides employees with a wide variety of health programs, in alignment with the highest standards of local medical care and regulatory requirements, to enhance their health and well-being. Through our various wellness programs, we offer a range of confidential personal tools, programs and activities to support an individual's health choices and to build a work culture that reinforces healthy, safe behaviors.

In the U.S., employees can access our Employee Assistance Program, which provides free short-term counseling on health matters as well as legal consultations and financial counseling.

For more information, [click here](#).

## EMPLOYEE GIVING

Our employees around the world are actively engaged in their communities. The opportunity to engage benefits employees, their communities and our company. We offer a number of programs through which employees can contribute to the communities in which they work and live. For more information, [click here](#).

**Partnership for Giving:** In 2014, our company's Foundation matched U.S. (including Puerto Rico) employee and retiree contributions, up to \$30,000 per donor, to eligible U.S. nonprofit organizations. The \$30,000 per year will remain the same for active employees; retiree contributions will be matched up to \$10,000 annually beginning in 2015. Our support for employee contributions to worthy causes not only assists thousands of organizations, but also expresses our engagement in and support of our communities.

**Employee Volunteering:** Our Global Employee Volunteerism Policy is designed to expand our culture of volunteerism and to encourage employees worldwide to volunteer. We consider active employee volunteering as a way to engage with individuals and groups in our communities, and are expanding opportunities for employee involvement in local communities around the world. [Learn more](#).

**Company Blood Drives:** For employees who wish to donate blood, we run regular blood drives at many of our sites around the world.

For more information on these and other programs, [click here](#).

## EMPLOYEE COMMUNICATION & ENGAGEMENT

We offer many ways for employees to comment on our company's mission, goals, business strategy, performance and work environment. For example, an employee opinion survey provides global feedback that management rigorously analyzes and uses to inform decisions.

We also conduct quarterly internal business briefings via live webcasts, which are then archived. In addition, our company's CEO and Executive Committee members meet regularly with smaller groups of employees for informal breakfast and town hall discussions.

For access to company news and videos, the company has a global enterprise portal, known as "Sync," including divisional and functional news channels where organizational communities are able to share interests, messages and ideas online. In addition to the Sync portal, employee communications vehicles include quarterly employee business briefings, town halls and email communications from senior management, as necessary, to communicate more broadly with employees worldwide.

If our employees have any concerns or wish to report behaviors that seem at odds with our company's Code of Conduct, they can contact the company ombudsman and/or our AdviceLine.

For more information on how we communicate and engage with our employees, [click here](#).

## PERFORMANCE

GRI G4-10

GRI G4-LA1

GRI G4-LA11

Positive Work Environment Summary						
	2009	2010	2011	2012	2013	2014
Number of employees (approximate)	100,000	94,000	86,000	83,000	76,000	70,000
Total compensation paid to employees/payroll, excluding benefits (US\$B)	NA	9	8.8	8.3	7.7	7.4
Employee Categories Covered by a Standardized Performance Appraisal Process						
Executives <sup>1</sup>	100%	100%	100%	100%	100%	100%
Middle management	100%	100%	100%	100%	100%	100%
Line supervisors	100%	100%	100%	100%	100%	100%
Non-managers <sup>2</sup>	100%	90%	93%	93%	93%	94%
Turnover						
Overall turnover rate <sup>3</sup>	5%	11%	14%	11%	15.50%	17.3%
Voluntary turnover rate	NA	6%	6%	5%	5.80%	8.10%
Avoidable voluntary turnover rate	NA	1%	1%	1%	2.40%	5.55%
Involuntary termination rate	NA	5%	7%	5%	7.20%	9.03%

NA: Data not available.

<sup>1</sup> "Executives" refers to the first two levels below the Chief Executive Officer.

<sup>2</sup> Includes all "non-managers" (previously "individual contributors") who are not subject to a collective bargaining agreement (unions).

<sup>3</sup> Includes all types of turnover, including restructuring.

Total Number and Rates of New Employee Hires by Region	Number of Hires	Hire Rate
EM—Asia Pacific	1,882	15.92%
EM—EEMEA (Eastern Europe, Middle East and Africa)	414	11.08%
EM—Latin America	395	6.60%
EUCAN (Europe and Canada)	63	0.31%
Japan	63	1.65%
U.S.	1,077	4.50%



Positive Work Environment

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# TRAINING & EDUCATION

The Global Learning & Development team, under the leadership of the Chief Learning Officer (CLO), has a unified approach that maximizes the value of Learning & Development investments by leveraging resources, learning platforms and other synergies across the enterprise.

Our Learning & Development philosophy serves as the foundation for employee development, confirms our commitment to our people, aligns with our business strategy and is committed to transforming our company into a learning culture.

Each of our three main divisions—Research and Development, Sales and Marketing and Manufacturing—as well as major support functions, such as our enabling areas, have consolidated their training organizations under the direction of the CLO to build the required leadership, professional, functional and technical skills.

To support our global employee base, we sponsor curriculum and access to communities—portals that build leadership and management skills for all levels of employees across the globe.

## KEY TALENT PROGRAMS

In partnership with the HR Talent Management team, the Leadership Learning & Development COE is reaching deeper, wider and earlier into the organization to develop talent. We are striving to develop a cross-functional general management mindset, knowledge of the business and end-to-end thinking in leaders earlier in their careers.

Key investments and programs to support the development of key talent are the Executive Development Program, Emerging Leaders Program, Women's Leadership Program and Business Leadership Program.

## MANAGEMENT FOUNDATIONS

This is a comprehensive program that focuses on building the core, common and critical knowledge and skills for new managers. Using a variety of learning methods, new managers focus on what they will need to know and do to be effective in their role and to gain the knowledge and skills to manage others.

## TEAM DEVELOPMENT

There is a suite of programs for team development and team building, ranging from formal learning experiences to “action learning”—based activities that help teams develop skills and competencies as they pursue real business goals.

## L&D FOR LEARNING & DEVELOPMENT

Our L&D employees will make a lasting impact on our contribution to human health, customer and shareholder satisfaction. Our focus on talent management for the learning organization will be our key enabler.

## MYCAREER

myCareer is a tool intended to be used by employees, managers and Human Resources as the source for professional development, performance management, talent management and learning within the company. The primary business purpose of myCareer is to facilitate more effective, consistent and efficient companywide performance management, talent review, succession planning, and associated employee performance and development processes through a single, integrated and automated global system of record for critical talent data about our employees.

## CAREER & LEARNING PORTAL

The Career & Learning Portal provides employees at all levels with thousands of resources to support their career development and learning needs. Resources are aligned to our Leadership Behaviors, Professional Competencies, Career Accelerators and Functional Competencies, and are available in the following formats: "On-Demand" Web-based modules, classroom programs, articles, books (including audio books), webcasts and suggestions for "on-the-job" development activities. The Career & Learning Portal also provides a community in which employees can connect with and learn from others.

Positive Work Environment

# COMPENSATION & BENEFITS

**In 2014, we paid a total of \$7.4 billion in payroll expenses, excluding benefits.**

## GRI G4-EC3

Our company's compensation programs are designed to recognize and reward employees for their accomplishments and the value they bring to the company. We are committed to providing competitive pay programs designed to help attract, retain and motivate the key talent we need to succeed in all aspects of our business. We monitor all elements of our total compensation program to ensure that they are competitive with those of other companies—and appropriate to the markets in which we compete for talent.

"Total Rewards" is the comprehensive package of compensation and benefit plans, programs and resources offered to employees that enhances the value of working at our company. These plans, programs and resources include compensation and financial rewards, health and insurance benefits, opportunities for employees to develop their skills and grow their careers, and programs that help support the demands of managing an employee's professional and personal well-being. Our philosophy behind these programs is rooted in maintaining our competitive position in the market while providing a comprehensive and valuable package of rewards that supports our business, recognizes individuals and aligns employees with the future needs of our company. Information on our Total Rewards package is available to all employees on the company's portal.

## BENEFITS

### GRI G4-LA2

In the U.S., we generally offer health, life, disability and business travel insurance, and retirement income benefits to all employees, including part-time employees. Employees also can opt to contribute to tax-free Flexible Spending Accounts for reimbursement for certain health spending and/or dependent-care costs.

Outside the U.S., while benefits may vary by region and country, we offer health insurance, life and injury insurance, disability insurance, retirement income benefits and insurance for business travel. In addition, in many countries where legally permitted, including the U.S., we extend healthcare and various insurance benefits to employees' same-sex domestic partners and their partners' eligible dependent children.

Worldwide, our company offers retirement benefits that are competitive with those of our peers and general industry. In the U.S., for example, we offer a defined benefit pension plan, as well as a 401(k) plan with company-matching contributions. To assist in personal investment decision-making, we offer all U.S. employees the Ernst & Young Financial Planning Program at

no cost. And U.S.-based employees who are at least age 55 and have at least 10 years of service as of age 40 (for certain employees, service before age 40 also counts) are eligible for subsidized medical benefits at retirement. Outside the U.S., we have more than 80 pension plans (including defined benefit, cash balance or defined contribution plans) in over 40 countries. They supplement the government-sponsored Social Security pension benefits to improve employees' financial security for retirement income.

For employees that are traveling between sites or otherwise traveling on company business, we offer business travel accident insurance, a global medical benefits abroad policy and emergency travel assistance.

## **OTHER BENEFITS AND SERVICES**

At certain company sites, including the company headquarters in Kenilworth, N.J., USA, employees can see a healthcare professional on-site—and usually on the day they need to—for such services as immunizations, biometric screenings and treatment for minor aches and pains. At many of our sites, we also offer services such as cafeterias, child care, dry cleaning, gyms and fitness classes, and oil changes for automobiles. In the U.S., our employees can bank through our company's Employees Federal Credit Union, which offers competitive interest rates on savings accounts and lending.

In the U.S., where there are collective bargaining obligations, there is no set period of time between notice and action. We make reasonable efforts to ensure that employees are aware of information, and we comply with any and all contractual and legal requirements. Outside the U.S., the number of weeks' notice required for major operational changes is set out by statute rather than collective bargaining agreements.



Positive Work Environment

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# WORK-LIFE BALANCE

**Today's professionals are interested not only in intellectually challenging work and the opportunity to contribute to company goals, but also in finding work environments that are flexible to personal life needs and interests. In short, they desire work-life integration.**

With this in mind, we have developed work-life integration programs that are innovative and that meet the needs of today's talent and employee pools, while enhancing our reputation as an employer of choice.

We take a comprehensive and holistic view of work-life integration. We have instituted a broad array of programs to appeal to employees at all stages of life. Employees who manage multiple responsibilities in the home and in the workplace, employees who are caregivers to young children and/or elderly parents, employees with visible or nonapparent disabilities, and employees who have religious obligations—indeed all employees—benefit from the greater work-life integration offered at our company.

We recognize the following benefits that a holistic work-life effort provides:

- A work environment that attracts talented applicants
- Improved employee performance and reduced absenteeism
- Increased employee engagement
- Greater employee and customer loyalty
- Decreases in sick leave
- An enhanced reputation in the marketplace
- Lowered staff attrition rates
- Higher levels of teamwork and collegiality
- A perception of the organization as genuinely innovative

## GLOBAL FLEXIBLE WORK ARRANGEMENTS

We believe flexible work arrangements offer a different and smarter way of working that enhances employees' commitment to the company, increases productivity and makes employee teams more competitive. The company has had a flexible work arrangement policy globally since 2008.

In developing our global Flexible Work Arrangement Policy, we've challenged traditional assumptions about where and how work can and must be done. Flexibility reflects our belief that job effectiveness is determined by employee performance and results, not by the number of hours one is seen in the office. What is produced or accomplished is more important than when

or where the work is done.

Employees and managers work together to assess the opportunities and challenges of a proposed arrangement. While the overall process should be collaborative, managers are accountable for making the final decision in light of business requirements, recognizing that some positions may not lend themselves to a flexible work arrangement. All regular full- or part-time employees are eligible to apply for a flexible work arrangement, which includes:

**Part-Time Work:** Employees' workloads and hours are decreased to less than the standard workweek requirements along with commensurate reduction in benefits and compensation.

**Job Sharing:** Two employees on reduced schedules and workloads share the overlapping responsibilities of one full-time position; benefits and compensation are reduced accordingly.

**Flextime:** Employees with full-time job responsibilities modify the start time and quit time of a standard day while being present for departmentally established "core hours" (hours of mandatory attendance, such as 10:00 a.m. to 3:00 p.m.), if any.

**Compressed Work Weeks:** Employees compress full-time job responsibilities into fewer than five days per week or 10 days per two weeks.

**Telework:** Employees fulfill full-time job responsibilities up to several days a week at sites other than their primary location—usually their home or a satellite office.

**Remote Work:** Employees fulfill full-time job responsibilities working primarily as home-based or mobile employees, with limited presence in a regular company facility.

**Summer Hours:** The Summer Hours program offers U.S. employees an additional resource in our flexible work schedule portfolio. Specifically, eligible employees are able to work nine-hour days Monday through Thursday, and the final four hours on Friday (departing no earlier than noon).

**Other:** Other options, including hybrid arrangements, seasonal work, project-based approaches, etc., may also make business sense. Employees and managers are encouraged to consider and pilot other alternatives.

## THOUGHTFUL COMMUNICATION WITH EMPLOYEES AND MANAGERS

To ensure deep and broad-scale awareness of all our programs, the company uses a thoughtful, integrated communications approach to help all employees manage work-life integration. We provide training to managers in helping employees find new ways of working to achieve business goals, while supporting employees' work-life effectiveness, and we use internal communications, employee networking events, mentoring and leadership-development forums to maintain high levels of employee morale, enthusiasm and productivity.

We recently launched our employee portal, About Me, featuring Work-Life programs and resources as one of the four key components of our Total Rewards. The site is one where U.S.-based employees can build awareness and take advantage of the wide variety of U.S.-based programs that we offer.

In addition, for U.S.-based employees not subject to a collective bargaining agreement, the company offers paid time off and leaves of absence and other benefits to help employees manage work-life issues. They include:

**Vacation, Holiday and Year-End Shutdown:** We provide employees with fixed holidays, year-end shutdown days and a set number of paid vacation days to use throughout the year based on years of service or work experience for new hires.

**Parental Leave:** Employees get one week of paid parental leave for the birth or adoption of a child.

**Childcare Leave:** Employees receive unpaid, job-protected leave to care for a newborn child, adopted child or child placed in foster care within the first six months (182 days) following the child's birth, adoption or foster care placement.

**Transportation Services:** Free commuter/shuttle services from specific locations near our headquarters in Kenilworth, New Jersey, and other locations enable employees to save on transportation costs and commute time while reducing their carbon footprint. Transit and parking reimbursements are also available at certain locations.

**Backup Dependent Care:** Temporary backup dependent-care services for employees are provided by LifeCare, for children and adults, when employees are scheduled to work and their regular care arrangements are unavailable. Employees are eligible for 10 days' usage per dependent per year for a nominal out-of-pocket fee. Employees can also take advantage of significant online resources.

**National Care Discount Programs:** We have made arrangements with three childcare providers to offer discounts to employees on their regular tuition.

**College Coach:** College Coach is an educational counseling service for dependent children ranging from kindergarten to grade 12 that offers a comprehensive menu of education topics and helps employees manage their professional and family responsibilities through live webinars, online support and personalized counseling. The program helps employees and their families reach their academic goals—reducing stress and keeping employees happy and productive, both at home and at work.

**Special Needs:** The Autism Spectrum Disorder (ASD) Program is for employees and their children as they plan for and navigate school and college options for students with diagnosed ASD and related conditions. Once qualified, employees can receive personalized counseling and participation in one live webinar.

**Website for Exceptional Caregivers:** This website provides online caregiver support and online elder care support programs on a range of topics and resources relating to children with special needs.

**Adoption Assistance:** This program provides employees with reimbursement of up to \$10,000 for eligible adoption-related expenses.

**Employee Assistance Program:** This program offers employees access to confidential, professional assessment, referral, counseling and educational services.

**Ernst & Young Financial Planning:** Ernst & Young (EY) is the provider of our company's financial planning benefit. This benefit is available anytime employees need personal financial planning assistance. EY planners are available to help reduce financial stress by assisting with topics ranging from cash flow, credit card and debt management, retirement savings and investing, education funding and more.

For U.S.-based employees who are subject to a collective bargaining agreement, work-life benefits may be offered in accordance with the agreement. For employees based outside the U.S., work-life benefits offered differ by location and may be subject to a collective bargaining agreement or local legal requirements.



Positive Work Environment

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# ENGAGING OUR EMPLOYEES

## MAIN

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**Historically, employee engagement at our company is quite high, and this trend continued throughout 2014.**

We strive to foster this engagement in many ways: by promoting a positive work environment, by requiring ethical business practices and by communicating proactively with our employees.

Also critical to our success is employee feedback. As we do with our external stakeholders, we work to understand our employees' concerns, needs and thoughts pertaining to the company's strengths and weaknesses, and we incorporate these findings into our strategies, processes and programs to help us achieve our business goals.

And because our employees are our most prominent and valuable ambassadors to most of our external stakeholders, we make sure that we communicate important news about the company to employees as quickly as possible and through the most appropriate channels. Employees generally are notified within minutes of most major external announcements concerning the company.

For example, through our global enterprise portal, known internally as "Sync," employees can gain access to company news and videos, divisional and functional news channels, and organizational communities that allow them to share interests, messages and ideas online. Other employee communications vehicles include quarterly Employee Business Briefings, periodic town hall meetings and email communications from senior management, as necessary.

## PROFESSIONAL NETWORKING AND COLLABORATION

We also enable employees to give their feedback through our online news site and via brief, three-to-five-question surveys and open-comment forms attached to key communications. Soliciting employee feedback on the subject of the communication in real time gives us the information we need to close knowledge gaps and address employee concerns. Such direct employee feedback has resulted in "meet and greet" sessions hosted by our CEO and our Executive Committee that give employees yet another opportunity to share information with senior leaders in a more personal setting.

We conduct global employee briefings every quarter. Our CEO and members of the Executive Committee speak to employees about how we are fulfilling our company mission and goals. These sessions cover topics such as the quarterly performance update, pipeline progress, customer stories and anticipated product developments.

## EMPLOYEE SURVEYS

As part of our mission to maintain a satisfying and productive work environment, we routinely survey all employees to learn

their perspectives on the business and on how we are responding to the needs of our workforce. We also conduct an annual employee opinion survey, the Voice Survey, with content based on our business needs.

Offered in 20 languages, the Voice Survey helps our company leaders and managers understand employees' perspectives on our culture and its effect on the company's ability to meet our business objectives, as well as what drives employee engagement. We communicate highlights of the survey results through meetings with our employees, in our employee publications, on our intranet and through emailed summaries.

Our 2014 results showed that employee confidence in our mission and future as a healthcare leader remains strong. Employee favorability ratings improved on nearly every culture and engagement dimension relative to 2013. However, employees noted concerns about being compensated fairly for their work.

Executive Committee members and leaders of the company's strategic change initiatives use the results of our annual surveys as part of their ongoing strategic planning.

## OTHER RESOURCES FOR EMPLOYEE FEEDBACK

In addition to the employee surveys, our "ombudsmen" within our Office of Ethics provide an avenue for employees to raise concerns in confidence and, where necessary, recommend appropriate action. Our anonymous helpline, which operates in accordance with applicable legal standards for employee-based hotlines, is available 24/7 to listen and provide advice to employees worldwide. [Learn more.](#)

## PERFORMANCE

Employee Engagement	2010	2011	2012	2013	2014
Response rate to MSD Voice Survey	64%	63%	77%	77%	78%
Percentage of employees "fully engaged" or "engaged" <sup>1</sup>	51%	49%	NA	NA	NA
Engagement Index (favorable response rate)	NR	NR	78%	78%	79%

NA: Not Available.

NR: Not Reported.

<sup>1</sup> In 2012, our company changed survey vendors and methodology, which allowed us to streamline our process as well as to focus on those elements of culture and engagement that are most important to our ability to execute our unique strategy.

In September 2014, 78 percent of our employees worldwide (more than 50,000 respondents) completed the Voice Survey. This participation rate is considered high by the independent organization that administered the survey on our behalf. As an incentive for completing the Voice Survey, we donated \$1,000 to Every Mother Counts, a nonprofit organization dedicated to making pregnancy and childbirth safe for every mother, for each division/function that achieved a 60 to 70 percent response rate on the survey. The donation doubled for each 10 percentage points above that range. Response rates across the divisions and functions resulted in a donation of \$71,000.

## HIGHLIGHTS FROM SEPTEMBER 2014 RESPONSES

Responses indicate that employees are engaged (79 percent) and empowered (69 percent) despite many company challenges in 2014. Moreover, the company's focus on innovation has had an impact, as 68 percent of employees feel business challenges are creatively addressed, 58 percent believe that ideas are implemented quickly and 56 percent feel that they can effectively take risks in their work. Innovation was an opportunity area for us last year and now represents a definitive strength for the organization.

We continue to see high marks for reputation and trust—83 percent favorable. This high level of favorability shows that employees continue to believe in our mission of saving and improving lives, and continue to believe that our company acts with the highest levels of ethics and integrity. Another area of strength is our company's ability to achieve our goal of becoming the best healthcare company in the world. In fact, 82 percent of employees answered this item favorably, and 79 percent of employees understand how transforming the company will enable achievement of our long-term growth strategy.

As in previous years, employees gave high ratings to their immediate managers (81 percent favorable) especially in terms of supporting diversity and inclusion and in valuing how work gets done. Furthermore, 69 percent of employees have confidence in senior leadership and their direction.

The 2014 Voice Survey results also highlight a few opportunity areas for the company. Thirty percent of employees feel that customer focus can improve, specifically when it comes to understanding what customers think is important. Only 53 percent of employees feel appropriately rewarded for hard work, though scores on this dimension are still on par with other pharmaceutical companies. Finally, 38 percent of employees believe collaboration between work groups remains an issue.

Overall results are encouraging and suggest positive momentum for the organization. Employees feel the strategy is moving us in the right direction.



Employees

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# WELLNESS

**In keeping with our company's business mission to save and improve lives we are committed to providing a safe and healthy workplace for our employees around the world.**

We want to ensure that our employees return home from work every day healthy and safe. As part of this commitment, we expect every employee to perform his or her job without compromising personal safety and health, or the safety and health of other members of our workforce and the communities in which we operate.

We provide employees with access to a wide variety of health services, programs, resources and tools to support their health and well-being. We also take preventive actions and closely track workplace accidents, injuries and illnesses so we can address problems promptly and work toward eliminating occupational injuries and illnesses.

We believe there are many benefits to this approach. First, the health and well-being of our workforce has a direct link to optimal workforce performance. Whether work is done at the office or at home, sickness or injury often can affect a person's ability to perform and contribute effectively. Because our business is promoting optimal health, we believe we must lead by example. We also believe that a constructive approach to our employees' health and overall well-being helps to recruit and retain top talent.

Finally, knowing which health issues most affect our workforce can help us make the right investments to improve the health of our people. We strive to understand our employees' needs, as well as the needs of their families, and develop programs to support them each and every day.

Since environmental, health and safety (EHS) matters are closely connected, we manage them collaboratively across numerous functions. A key element of our EHS management system is the monitoring of health and safety risks and performance.



Wellness

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# EMPLOYEE HEALTH

**As a global healthcare company, we are committed to supporting our employees to help them manage and improve their overall health and well-being.**

Our Global Employee Health department works closely with the Global Benefits department to provide a wide range of health and wellness services and worklife programs to our employees, retirees and their covered dependents.

These offerings cover the continuum of care for those who are well, those at risk, those with acute or chronic illnesses, and those requiring complex or catastrophic care. Many of these services and programs are provided at on-site employee health clinics or through programs managed by our vendor partners. These all work in conjunction with our comprehensive coverage through our health benefits offerings. Health services and programs available to our employees include:

## *LIVE IT*

Our culture of health for our employees is branded as “*LIVE IT: Be Well at MSD.*” *LIVE IT* is an initiative that brings together all of our U.S. health and wellness offerings under one integrated platform and provides most U.S.-based employees and eligible family members with access to a broad suite of innovative health and wellness tools, programs and information. “*LIVE IT*” continues to expand globally (and is branded *LIVE IT: Be Well at MSD*) to certain regions outside the U.S. to improve the health and well-being of our employees worldwide.

We partner with Health Advocate in the U.S. to help employees and their families navigate the complicated healthcare and health insurance system. Health Advocate is designed to make employees’ lives easier by saving hours of effort, with activities such as:

- Helping resolve complicated medical and dental insurance claims
- Finding doctors, providers or facilities
- Scheduling appointments for physicians, treatments and tests
- Securing second opinions
- Assisting with eldercare and Medicare issues
- Getting cost estimates for medical procedures
- Assisting in the transfer of medical records
- Researching and locating the latest treatments
- Locating work-life resources

The program is available to most U.S.-based employees and their dependents at no cost, and is also available to employees’

parents and parents-in-law for any healthcare or eldercare issues they may be facing.

## OUR WEBSITE

Our company offers a health and wellness website to U.S.-based employees and their dependents that features a personal health assessment, online interactive health tools and information, health-coaching programs and more. The website is designed to raise awareness about an individual's health status and to motivate employees to manage and improve their health and well-being. It includes topical health summaries based on scientific evidence and links to reliable healthcare information. Mobile technology solutions continue to be added to help employees manage their health while not at their desks during the workday.

Immediately after completing the online Personal Health Assessment (PHA), an employee receives a customized report that summarizes his or her health status and offers suggestions for personal goal setting. Anyone who takes the assessment and wants to work on an identified health risk has access to an online lifestyle coach who provides advice and encouragement and regularly monitors progress. A special tobacco-cessation coaching program, branded *LIVE IT: Tobacco-Free*, is also offered to those who wish to quit using tobacco products. Participation in the health assessment and in other programs is voluntary and confidential.

During the annual benefit enrollment period each fall, employees and their covered spouses/same-sex domestic partners are encouraged to take the PHA as part of our *LIVE IT* initiative.

Results from the PHA are used to help develop programs such as the Weight Watchers Reimbursement Program. In the fall of 2014, our company introduced its own clinically proven weight-loss program through our subsidiary, HMR Weight Management Services Corp., called "Healthy Solutions<sup>®</sup> at Home." The resource is available to help employees, their family members and friends who may struggle with maintaining a healthy weight.

## ON-SITE CLINICS

Many of our on-site clinics offer employees the opportunity for lipid, blood glucose and other laboratory services, including blood collection ordered by a personal physician. Each year during the annual enrollment period, employees can make an appointment to have their biometric screening done in preparation for their annual PHA. To support new mothers returning to work, our clinics also offer worksite lactation programs. "Lunch and learn" programs and site-based wellness activities, including walking and weight-reduction programs, are also available at some sites.

## CAFETERIA COLLABORATION

What we eat and drink affects our daily physical and mental well-being and our longer-term health and resilience. To contribute to a healthy work culture, we work with our on-site food vendor at most of our U.S. facilities to increase the availability and visibility of healthy food choices and to raise awareness of proper nutrition. Employees also receive discounts for healthy food purchases. In addition, many of our sites around the globe have cafeterias that offer healthy food options and nutrition education. Our food vendor is an integral partner of our *LIVE IT* team, and we jointly sponsor healthy eating events that correspond with the National Health Calendar.

## FITNESS CENTERS

We offer access to on-site fitness centers at several large U.S. facilities, as well as at other company facilities around the world. In the U.S., professional fitness managers organize programs and events to encourage employees to eat well, manage their weight, exercise and participate in various fitness challenges and other special events. We also offer on-site massage therapy services at these centers at a reasonable cost to employees. Often, nonmembers can participate in the fitness center's special programs for a nominal fee.

## OCCUPATIONAL HEALTH

### GRI G4-LA7

As a global organization, our company has numerous operating divisions and work assignments—each with its own range of requirements. Particular work assignments may involve potential exposure to one or more occupational hazards, such as noise, mixtures of chemicals or hazardous biological compounds. Our company maintains a continuing and concerted effort to assess and control workplace hazards (chemical, biological and physical) and to make sure that each employee's work assignment is safe and consistent with his or her evaluated capabilities. Beginning in 2012, major progress was made in standardizing our occupational health procedures that now span the globe.

Occupational health programs are developed and implemented in accordance with identified health risks and applicable regulatory requirements. In the event that an employee becomes injured or ill while performing his or her job, we have programs in place for treatment and rehabilitation.

## WORK-RELATED INJURY AND ILLNESS MANAGEMENT

Our company's Global Employee Health professionals are clinically trained and dedicated to supporting efficient and effective quality healthcare for employees who become injured or ill as a result of their work. They advise on and coordinate healthcare with providers or agencies to ensure a smooth treatment-and-recovery process, while complying with both company and applicable regulatory record-keeping requirements.

## ACUTE EPISODIC HEALTHCARE

Most Global Employee Health clinics provide nonwork-related acute episodic healthcare, including the diagnosis and treatment of minor non-occupational illnesses or injuries; health maintenance counseling; and appropriate referral to specialty services.

## TREATMENT DECISION SUPPORT

We have partnered with our health plan providers (Aetna and Horizon BCBS) to enhance the care management our members receive through an innovative Single Nurse Model approach. Through this voluntary and confidential program, one clinical nurse manages both the acute care needs for the member and their family, as well as helping to develop customized care plans for chronic condition needs.

Through Health Advocate, our company offers a resource for newly diagnosed U.S.-based employees to obtain information specific to their diagnoses. Health Advocate can also help U.S.-based employees and their dependents access expert second opinions for complex or critical illnesses, or explore options regarding the need for surgical or nonsurgical treatments and procedures. A personal Health Advocate will help set up the appointment and transfer any required medical records. The goal is to provide a full range of options so employees can make the most informed decisions about their course of therapy.

## DISABILITY MANAGEMENT/DISABILITY ACCOMMODATIONS

The Disability Leave team and our Global Employee Health group work with external vendors in the U.S. to develop and implement short- and long-term disability management and return-to-work policies and programs. Optimizing the health and productivity of our employees is a key goal of these efforts. Our centralized Workplace EnABLEment program in the U.S. ensures that employees with apparent and nonapparent disabilities are able to be accommodated, where feasible, to enable them to work to their full potential.

## BUSINESS TRAVEL PROGRAM

We are concerned about the health and safety of our employees who travel on business, especially to international locations. Our Global Employee Health group maintains up-to-date information about infectious diseases that are prevalent in all countries and their required immunizations. Business travelers are given any required immunizations, information on health conditions in the country of their destination, a traveler's guide, a travel kit containing over-the-counter medications they may need, and an international emergency travel-assistance card. Employees may also consult with a Global Employee Health–licensed healthcare provider for specific travel-related prescription medications that may be needed during travel, possible preventive medical care prior to departure, information regarding the availability of medical care in the country of destination and the possibility of medical care after return, as needed.

## ANNUAL FLU SHOTS AND PANDEMIC FLU PLANNING

Most of our sites around the world offer employees annual flu shots. In the U.S., our Global Employee Health group provides annual flu shots at no cost to employees at site-based employee health clinics. With guidance from Global Employee Health, most of our sites have also developed site-specific pandemic flu preparedness plans, employing a variety of countermeasures that focus on heightened awareness and tactical procedures.

## SMOKING POLICIES

The majority of our sites around the world have either a no-smoking policy or a smoke/tobacco-free policy in place. These policies send a strong message that the company is committed to promoting healthy lifestyles and to protecting its employees and visitors from the harmful effects of tobacco. In addition, the majority of U.S.-based employees have access to *LIVE IT: Tobacco-Free*, a telephonic personal health-coaching program that helps participants quit the tobacco habit. Our new corporate headquarters in Kenilworth, N.J., USA, is a tobacco-free campus.

## AUTOMATIC EXTERNAL DEFIBRILLATOR PROGRAM AND EMERGENCY RESPONSE

At many of our sites, on-site health clinic staff respond to medical emergencies while also working with volunteers who help as emergency responders. Our Global Employee Health group provides direct oversight for automatic external defibrillators and associated training, provided at many of our sites in the U.S.

## VACCINATIONS

Our on-site clinics in the U.S., as well as many around the world, offer employees both occupational vaccinations (including travel-related vaccinations) and non-occupational vaccinations for such diseases as pneumonia, shingles and cervical cancer. Through the Express Scripts Retail Vaccination Program available through our Medical Plan, applicable to most U.S.-based employees, participants may also receive certain vaccinations at participating retail pharmacies without member coinsurance/copay.





Employees

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# GLOBAL DIVERSITY & INCLUSION

## MAIN

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**We are proud of the progress being made in developing a 21st-century workforce that is inclusive of the world's top, diverse talent and is driven by the desire to apply cutting-edge science to develop effective medicines and vaccines that save and improve lives around the world.**

### UNGC-6

We have a long history of working collaboratively to leverage the innovation that results from a dynamic organization led by a diverse team of leaders; this enables us to achieve business results and to reinforce our vision of being the number one trusted and valued healthcare partner to patients, healthcare providers and payers worldwide. We seek the best, the brightest and those with a passion for scientific excellence.

We actively promote opportunities for people of all backgrounds across race, gender, ethnicity, culture, age, disability, religion, gender identity, gender expression and veteran status. We recognize that a workforce that is representative of the global markets offers distinct competitive advantages, such as diversity of thought, greater consumer insights, faster speed to market, higher levels of productivity and business innovation. Global Diversity & Inclusion (GD&I) contributes in meaningful and sustainable ways to superior business performance. We have senior-level commitment to GD&I, we leverage best-practice recruitment, retention and talent management strategies to achieve workplace goals, and we partner with strategic advocacy groups to support transformative business results.

## CEO COMMITMENT TO GD&I

Our company's commitment to diversity and inclusion begins with our Chairman and President, Kenneth C. Frazier. His leadership, support, and ability to drive accountability are indispensable to our ability to create a workforce that represents the global marketplace. Mr. Frazier chairs the company's executive diversity governance structure, which includes nine Employee Business Resource Groups (EBRGs) supporting women, African ancestry/black, Hispanic/Latino, Asian/Pacific Islander, Native American/Native Indigenous, interfaith, LGBT, differently able and veteran employees. He meets periodically with the GD&I Center of Excellence, and personally communicates his commitment to GD&I in external and internal communication channels.

Members of the Executive Committee and the Office of Diversity & Inclusion collaborate to drive business results through D&I. Each member is involved in external philanthropic organizations that support diverse communities at large.

- **Willie Deese, president, Manufacturing Division**, serves as board member of North Carolina A&T State University.

Willie also serves as the executive sponsor for our company's Veteran's Employee Business Resource Group.

- **Adam Schechter, president, Global Human Health**, is an executive board member for the National Alliance for Hispanic Health, an organization focused on improving the health of Hispanic communities in the U.S. and working with others to secure health for all. Adam also serves as the executive sponsor for our Women's Employee Business Resource Group.

Additionally, other Executive Committee members within our company act as executive sponsors as follows:

- **Richard DeLuca, president, of our Animal Health business**, executive sponsor for our Hispanic/Latino Employee Business Resource Group
- **Clark Golestani, chief information officer**, executive sponsor for our Native American/Native Indigenous Employee Business Resource Group
- **Michael Holston, executive vice president and general counsel**, executive sponsor for our LGBT Employee Business Resource Group
- **Roger Perlmutter, executive vice president and president of MRL**, executive sponsor for our Differently Able Employee Business Resource Group
- **Michael Rosenblatt, chief medical officer**, executive sponsor for our Interfaith Employee Business Resource Group

## GLOBAL DIVERSITY & INCLUSION GOVERNANCE

The Global Diversity & Inclusion Center of Excellence (COE) oversees our company's integrated efforts to include diversity and drive inclusion in all business practices. The COE is led by Celeste Warren, vice president, Human Resources, MMD. The Global Diversity & Inclusion COE consults with the Office of Ethics and Human Resources to resolve workplace issues involving diversity and oversees compliance with local, state and federal regulations.

## EMPLOYEE BUSINESS RESOURCE GROUPS

The Employee Business Resource Group (EBRG) is composed of senior business leaders from across our company who provide guidance to nine employee groups to leverage diversity and inclusion for positive business outcomes. Executive sponsors work directly with the EBRG leaders to identify opportunities to leverage business insights, maximize and cultivate the diversity of our talent, and enhance our corporate reputation and community responsibility.

There are three priority areas for the EBRGs:

- Business Insights
- Talent and Inclusion
- Corporate Reputation and Responsibility

Under this structure, all employees globally are able to get involved by joining an Employee Business Resource Group or a local chapter of an ERG and to contribute by providing perspective and ideas on how to address the opportunities and challenges facing our company today and in the future.

EBRGs are one of the ways that we intentionally drive inclusion best practices for our employees. For employees who share similar affiliation, the EBRGs represent excellent opportunities to support and contribute to our company's business goals, to network, to engage in community outreach, to participate in leadership development opportunities and to share business insights with our company leaders.

The leaders of each EBRG are nominated for a two-year period to serve as leaders for their demographic groups at an enterprise level, act as educational and cultural resources for other employees and business groups, and serve as contact points for and build key strategic relationships with our company's external community. These EBRG leaders provide guidance to local-chapter ERGs that operate at numerous office, laboratory, manufacturing and field locations around the world. ERG membership is open to employees at all levels, and participation in ERG-hosted events is also open to all full- and part-time employees.

The EBRG structure provides strategic oversight to and is aligned with the company's ERGs: the Women's EBRG is aligned with the our company's Women's Network (MWN); the African Ancestry EBRG is aligned with the League of Employees of African Descent (LEAD); the Hispanic/Latino EBRG is aligned with our company's Hispanos Organization (MHO); the Veteran EBRG is aligned with the Veterans Leadership Network (VLN); the lesbian, gay, bisexual and transgender (LGBT) EBRG is

aligned with our company's Rainbow Alliance (MRA); the Asia Pacific EBRG is aligned with the Asia Pacific Association (APA); the Differently Able EBRG is aligned with our company's Allies for Disabilities (AFD); and the Interfaith EBRG is aligned with our company's Interfaith Organization (MIO).

Over 8,000 of our employees are members of an EBRG today.

## **THE WORKFORCE: BECOMING A "TALENT MAGNET" FOR BEST-IN-CLASS GLOBAL, DIVERSE EMPLOYEES**

We understand that by consistently harnessing the knowledge and insights of a diverse workforce—one with unique backgrounds and affiliations—we are able to deliver more innovative solutions to patients around the world. A clear expectation is set for all leaders within the company to achieve GD&I goals. These goals guide rewards and incentives set at the individual manager, divisional and corporate level, and reflect functional affirmative action plan targets developed in accordance with legal requirements and diversity objectives. Through GD&I best practices, policies and programs, we ensure that candidate pools are broad and representative of top, best-in-class talent from diverse backgrounds; that all applicants are treated fairly and equally in the selection process; and that our company is regarded as a "talent magnet" for the most qualified and best-trained employees around the world.

## **THE WORKPLACE: CREATING AN INCLUSIVE ENVIRONMENT AND SUPPORTIVE LEADERSHIP BEHAVIORS**

By actively promoting diversity and inclusion best practices, we work to create a positive and flexible work environment that enhances our employees' commitment to the company, increases employee engagement, drives higher levels of productivity and sharpens our ability to excel in the competitive global landscape.

With this in mind, the company takes a comprehensive approach to ensuring that employees have personal and career development opportunities, build important stakeholder relationships throughout their careers, learn new skills and hear the perspectives of the senior-most leaders in order to network and broaden their insights and knowledge.

Our employees also have the opportunity, through the nine EBRGs, to contribute to the company, whether it be suggestions regarding how to more fully leverage a product launch, how to enhance communications to a diverse segment of the market, or how to leverage national advocacy and local organizations to strengthen strategic alliances in the communities we serve. The EBRGs also play a critical role in providing networking opportunities, offering leadership development sessions and building awareness of their specific constituencies' interests and heritage for greater understanding and appreciation.

## **THE MARKETPLACE: ACHIEVING A COMPETITIVE ADVANTAGE IN THE GLOBAL MARKETPLACE**

We recognize that customers in the U.S., as well as worldwide, are becoming increasingly diverse, and that true competitive advantage lies in mirroring the markets we serve. As an example, women account for more than half of the world's population and patients. They make 90 percent of all the healthcare decisions for themselves, their children and families, and those in their care, representing an estimated \$2.3 trillion in healthcare purchases within the U.S. and approximately \$5 trillion globally.

Women of color (African ancestry/black, Hispanic/Latino, Asian/Pacific Islander and Native American/Native Indigenous) also represent a core customer and patient group for our company within the U.S. While they represent an emerging "minority" in the U.S. (35 percent of the U.S. female population, with \$1.3 trillion in consumer spending), they represent half of all mothers aged 15–44 in the U.S. with children under their care, and are the dominant global majority with specific healthcare needs. They are disproportionately impacted by chronic illness and conditions, such as diabetes, hypertension, HIV and osteoporosis.

As the global emerging markets will continue to be important to our pharmaceutical and vaccine businesses, increasing the representation of diverse talent within our company will help drive competitive business results. To operate successfully in this global marketplace, and to achieve our vision of being the number one trusted and valued healthcare partner to patients, healthcare providers and payers globally, we are focusing on further aligning our internal workforce and executive population to better reflect and understand those we serve. We believe that having a diverse, inclusive workforce and organization makes us a more innovative and agile company, better attuned to the needs of our customers and able to respond to these

opportunities in a seamless, integrated fashion.

## CORPORATE PHILANTHROPY & VOLUNTEERISM

### Corporate Philanthropy

Providing support for the communities in which we live and work is an important value at our company and a central tenet of being a globally responsible corporate citizen. In alignment with this value, our company provides support for a number of educational programs and nonprofit organizations that promote diversity and inclusion. We have maintained a relationship with these organizations because we understand that supporting them helps to build stronger and more robust relationships in the community and enables us to reinforce our role as employer of choice.

Our strategic alliances include:

- Purdue University and the Kilimanjaro School of Pharmacy
- United Negro College Fund (UNCF)
- National Alliance for Hispanic Health

### Employee Volunteerism: “Colleagues That Care”

“Colleagues That Care” is a global, companywide employee volunteer event led by the EBRGs in partnership with our company’s Foundation, a U.S.-based, private foundation, and the Office of Corporate Responsibility.

The objectives of “Colleagues That Care” are:

- To raise awareness about the importance of diversity and inclusion at our company, and demonstrate how much we can accomplish together when we act with a diverse, inclusive and global mindset.
- To make a positive contribution to our ongoing commitment to corporate responsibility and support employees’ efforts to give back to their communities.
- To generate 100,000 hours of employee volunteer time to support a nonprofit charity of their choice or visit our company’s internal volunteering website to look for company-sponsored volunteering opportunities.

In addition to “Colleagues That Care”, our employees participated in and recorded volunteer hours for a number of events that focus on individuals with disabilities: National Veterans Wheelchair Games, Buddy Walk for CHOP, Ronald McDonald House volunteer events and Cookies for Hospice, to name a few. The Differently Able EBRG also facilitated a Disability Awareness night with the Phillies with the Arc Alliance, a local chapter of the Arc of the U.S., and helped establish a mothers’/grandmothers’ support group at the Arc Alliance for moms/grandmothers involved in the care of individuals with disabilities.

### Strategic Partnerships

We value the opinions and thought leadership of key influencers and national advocacy groups within the diverse communities we serve. Among the external partnerships and strategic alliances we support are the following organizations:

- Ascend
- Catalyst
- Careers on Students with Disabilities (COSD)
- DiversityInc.
- Executive Leadership Council
- Gay, Lesbian & Straight Education Network (GLSEN)
- Hispanic Association on Corporate Responsibility (HACR)
- Healthcare Businesswomen’s Association
- Hiring Our Heroes
- Human Rights Campaign
- National Council of La Raza (NCLR)
- National Reservation Economic Summit (National RES)
- Office of Disability Employment Policy (ODEP)
- Out & Equal
- Simmons College
- Society of Women Engineers

- Tanenbaum Center
- U.S. Business Leadership Network (USBLN)
- Work and Family Institute

## OUR GD&I EMPLOYEE AWARDS

We recognize that our success depends upon the harmonious collaboration of our employees in achieving clearly stated business goals. That's one reason the company sponsors the Chairman's GD&I Awards in recognition of the outstanding commitment of employees to achieving diversity excellence. The objective of the GD&I Awards is to recognize employees at all levels around the world who demonstrate an extraordinary commitment to integrating diversity and inclusion throughout our company, at both the individual and the team level.

The six categories of GD&I excellence are:

### Individual Categories

- Integrates and Collaborates
- Enhances Our External Image
- Demonstrates Personal Leadership
- Demonstrates Management Excellence

### Team Categories

- Enhances Our Image Through External Outreach
- Supports Business Through Inclusion

# INITIATIVES

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## WORKFORCE INITIATIVES

We utilize targeted recruiting firms, attend career fairs and leverage strategic alliances with organizations such as the Society of Women Engineers; the National Society of Hispanic MBAs (NSHMBA); the National Black MBA Association (NBMBA); Ascend; Simmons College; Catalyst; the Gay, Lesbian & Straight Education Network (GLSEN); Career Opportunities for Students with Disabilities (COSD); 100,000 Jobs Mission; and more, to net the company a broad representation of talent with important functional skills and training.

Other examples of our company's diversity recruitment strategy include:

### Women

- We utilize targeted recruiting firms, attend career fairs, and leverage strategic alliances with organizations such as the Society of Women Engineers, Catalyst and Simmons College to achieve a broad representation of female talent
- We have a presence in targeted media that reaches prospective female candidates. Examples include:
  - *Woman Engineer* magazine—The most widely read recruitment magazine for female engineers
  - *Working Mother* magazine—Provides important information to readers on top companies for working moms, including companies dedicated to providing employees with benefits, such as career advancement. Our company has been recognized on this list for 26 consecutive years.
  - National Association for Female Executives—Represents an important source of information for female executives
  - *Professional Woman's Magazine*—a highly regarded media publication for working women. We were acknowledged as a "2014 Best of the Best List of Top STEM Companies."

### Underrepresented Ethnic Groups (UEGs)

- The National Society of Hispanic MBAs (NSHMBA), the National Black MBA Association (NBMBA), Ascend and others, to net the company a broad representation of talent with important functional skills and experience.
- We partner with several diversity-focused professional organizations in order to find diverse talent for entry-level through professional-level positions within the company, targeting women, African Americans, and Hispanics. We are

able to target diverse constituencies through our relationships with such organizations as Simmons College, the NBMBMA, the NSHMBA, and The National Council of La Raza.

- Working with the National Alliance for Hispanic Health, we launched a program to promote science education—the Ciencia (Science) Hispanic Scholars Program. Similar to African Americans, the number of Hispanics who currently hold Ph.D.s in biology and chemistry is very low. The Ciencia program is designed to help Hispanic students achieve access in the pursuit of undergraduate degrees in science, technology, engineering and mathematics (STEM) related fields.
- Despite statistics suggesting that more than 50 percent of new entrants into tomorrow’s workforce will be people of color, African-Americans currently hold less than 3 percent of PhDs in biology and chemistry. To help address this imbalance, we joined with UNCF to help expand the pool of world-class African-American biomedical scientists and, in so doing, achieve the complementary goals of enhancing economic competitiveness and social diversity in the U.S. The Science Initiative with UNCF, a U.S.-based initiative, was launched in 1995 with a 10-year, \$20 million grant from our company’s Foundation. In 2005, the Foundation renewed its commitment to the UNCF with a five-year, \$13 million grant, and in 2011, the Foundation pledged another \$14 million to the UNCF over five years.
- The company and employee association members partner with several diversity engineering associations, such as the National Society of Black Engineers (NSBE) and the Society of Hispanic Professional Engineers (SHPE) in an effort to source qualified engineering talent and those individuals with STEM training for positions throughout the company and in specific regional locations. Moreover, we collaborate with several minority research science organizations—such as the National Organization for the Professional Advancement of Black Chemists and Chemical Engineers (NOBCCChE) and the American Indian Science and Engineering Society (AISES)—in an effort to create a 21st century workforce that is inclusive of top, diverse talent in the STEM disciplines.
- We have been recognized with a notable award in 2014: Diversity Inc Top 10 Companies for Recruitment (Rank No. 6), given to companies who “demonstrate significant racial/ethnic and gender diversity in their workforce and new hires, as well as in the talent pipeline into management, within management, at the top three levels of the organization and for the top 10 percent highest-paid employees.”

#### **Veterans, LGBT and People with Disabilities (PwD) Talent Sourcing**

- We joined the 100,000 Jobs Mission, a growing coalition of employers who aim to hire at least 100,000 veterans by 2020. Our company was the first pharmaceutical member company to join, and we encouraged our industry colleagues to join the effort as well.
- Our company also integrates its veterans outreach strategy with the PwD strategy by visiting the Walter Reed Military hospital in Washington, D.C. and having a presence at military bases as soldiers transition to civilian life.
- We utilize targeted recruiting firms, attend career fairs, leverage strategic alliances with organizations such as Out & Equal, GLSEN and others to identify and recruit LGBT talent.
- To address the lack of disability sourcing organizations and to build relationships with potential disability talent sources, we have developed two distinct approaches—our Volunteer Days and Career Day Models. Each model acts as a means for our company to enter into new relationships and strengthen current relationships with disability talent sources, creating a customized talent pipeline specific to the needs of our growing workforce.
- There are a variety of resources that can currently be classified as targeted postings to people with disabilities. By posting on relevant job boards and advertising our careers website on a variety of print and electronic media, passive outreach can be maximized. We currently post jobs online to a large diversity job board presence. Seven job boards that we currently post to are directly related to disability. The plan is to identify strategic partnerships that can be expanded for greater visibility.
- The company collaborates with Career Opportunities for Students with Disabilities (COSD) to help more effectively prepare students with disabilities for recruitment opportunities in the industry.
- We recognize that almost 50 percent of veteran employees in the workforce have a disability that requires support in the form of workplace accommodations and inclusion. The company supports Cornell University’s Beyond the Yellow Ribbon initiative as a means to recruit veterans and build awareness of its full inclusion strategies.
- Our company held Disability Mentoring Day at multiple sites to provide college-bound high school students, college students, the Office of Vocational Rehabilitation and students at schools for those with developmental delays, the opportunity to:
  - Interact with company mentors for one-on-one coaching and counseling
  - Learn from Human Resources how to approach resume writing, job interviews, and self-identification as a person with a disability
  - Explore positions at our company such as marketing, research and finance
  - Experience hands-on sessions allowing participants to use laboratory equipment, to “gown up” for sterile-area jobs, and learn from employees how to be the best employee you can be in any position you accept
- In partnership with Drexel University, we implemented our inaugural Disability Career Day. The day consisted of

having recruiters, members of the Differently Abled EBRG and other relevant company colleagues on the Drexel campus to provide professional and career skill development for people with disabilities. Recruiters provided attendees with general career skills and personal resume review sessions. Disability-specific information was also provided including ADA Overviews, Disclosure Dialogue, etc. The overall environment and atmosphere of this gathering was extremely informal and low key. The program was enthusiastically supported by Drexel and company stakeholders and is something we plan to implement at additional core schools in the future.

- The Career Link Mentoring Program is a collaborative project between the USBLN and Cornell University's Employment and Disability Institute. Our company is among the member companies that support the USBLN Career Link Mentoring Program by providing a six-month career mentoring opportunity to 40–50 college students and recent graduates with disabilities.
- Branding plays an important role in developing meaningful relationships with sites for “Careers Days” and events we will attend. In order to create a customized talent pipeline for people with disabilities, a long-term commitment to stakeholders has been made. Once the stakeholders (students, veterans, vocational rehabilitation clients) realize that we are fully committed to disability-inclusive diversity, then we will become sought-after and have brand recognition within the disability community.

## WORKPLACE INITIATIVES

### Mentoring Programs

We ensure that employees have ample opportunities to network, build important stakeholder relationships and learn new skills. One hundred percent of Executive Committee members are mentors, helping and enabling other employees to achieve their full potential. In addition, our EBRGs have developed targeted mentoring for their constituents, recognizing that culture plays a role in how careers are furthered.

### Work-Life Integration

Work-life integration is also key. We focus on a broad array of programs to appeal to employees at all stages of the life cycle. Employees who manage multiple responsibilities in the home and in the workplace, who are caregivers to elderly parents, single-head-of-household parents, employees with apparent or nonapparent disabilities, and those who have religious obligations—indeed, all employees—benefit from the greater work-life integration offered at our company. Some examples of our work-life integration programs are: onsite child care, domestic partner benefits to LGBT employees, ability to work from home or telecommute, paternity leave, adoption services, onsite prayer rooms and much more.

### Health, Safety & Well-Being

Through a partnership with eSSENTIALS.com, our company offers a desktop app that empowers people with physical disabilities to access company websites. People who cannot browse the Web using conventional methods due to conditions such as arthritis, paralysis or amputation can use this app to browse completely hands-free using tools like motion technology and voice-activated navigation. The eSSENTIAL Accessibility app™ provides a suite of keyboard and mouse replacement solutions, among other tools, designed to help people with physical, reading and age-related disabilities get online.

U.S.-based employees can also access our Employee Assistance Program, which provides free short-term counseling on health matters as well as legal consultations and financial counseling.

### Full Inclusion & Workplace EnABLEment

We have a long-standing commitment to full disability inclusion. This history is reflected in the following industry “firsts” and record of accomplishment.

- In 1983, our company received its 1st Office of Federal Contract Compliance Programs (OFCCP) Exemplary Voluntary Efforts Award. We continue to achieve compliance with the OFCCP guidelines.
- Our company was the first U.S. pharmaceutical company to earn NFB-NVA certification for our corporate U.W. website, which signifies that a website is as accessible to blind people as to the sighted
- We had the honor of addressing the Senate Health, Education, Labor and Pensions (HELP) Committee in July 2011 on the subject of disability employment
- Our company participated in the first-ever CEO Summit on the Benefits of Disability Employment in June 2012
- *HR Magazine* (“Opening Doors—Spotlight on Anne Marie Geiger, Merck [ & Co., Inc., Kenilworth, NJ, USA]”), *Thinking Beyond the Label* (“A Chemist’s Formula for Success at Merck [ & Co., Inc., Kenilworth, NJ, USA]—James Schiller”), and Mercer’s “A...Social Approach to Disability Inclusion” article recognized our company for its commitment to full

inclusion

- We were selected by Cornell University to videotape best practices for the “Beyond the Yellow Ribbon: Employer Preparedness to Include Veterans with Disabilities in the Workplace” program
- We ranked among the “Top 50 Employers” in *CAREERS & the disABLED* magazine
- Our company was one of two companies profiled as “Leading Veteran/Disability Employers” in *The P.E.R.C.E.V.D. Principles* book by Ed Crenshaw
- In 2014, we were recognized with the Dr. Robert Greenberg Award for Innovation for demonstrating innovation in the preparation and recruitment of college students with disabilities for employment

We recognize that full inclusion of employees with disabilities—both apparent and non-apparent disabilities—has the potential for positive business impact. The business case for people with disabilities is strong and compelling. Globally, approximately 10 percent of the world population is believed to live with a disability—that represents nearly 700 million persons. If these individuals were a country, they would be twice as large as the total U.S. in size. These are the patients and customers we serve at our company. Within the U.S. alone, there are an estimated 54 million persons who are affected by either an apparent or nonapparent/hidden disability. For perspective, the 54 million people in the U.S. with an apparent or nonapparent disability comprise a group that is comparable in size to the U.S. Hispanic market.

Given our company's mission and the business case for people with disabilities, we have developed a comprehensive strategic platform to address full disability-inclusion. The strategy is broken down into four facets that, when combined and utilized appropriately, will develop a customized pipeline talent for PwD. These core facets are:

- Disability Inclusive Culture
- Building Meaningful Relationships
- Targeted Posting
- Branding

It is important to note that while these facets are separated by name, the success of one facet will have an impact on the success of another. In a sense, they are connected to each other.

Workplace EnABLEment is a comprehensive strategic platform to address full disability inclusion. This program is the first enterprise-wide disability inclusion strategy that addresses the entire spectrum of the employee experience. But it does not stop there; it also supports the evolution of a social culture within our company by providing tools for sharing insights and targeted resources that support inclusive leadership.



<sup>1</sup> [http://www.who.int/disabilities/world\\_report/2011/report/en/](http://www.who.int/disabilities/world_report/2011/report/en/)

## LEADERSHIP DEVELOPMENT & TRAINING

Our company offers employees a variety of training programs and development opportunities that reinforce our commitment to diversity and inclusion.

- Our **Women’s Sponsorship Program** represents a powerful example of how—through collaboration with the Women’s EBRG—we are proactively helping the advancement of women as leaders. It reflects a true understanding of the significant value women play in enhancing and driving business results and supports this understanding with a structured, measurable and focused initiative to forge business relationships with key stakeholders.
- **Unconscious Bias Education**—Using thought leadership related to unconscious bias in the workplace, all Vice Presidents within our company and above were introduced to Unconscious Bias Education (UBE) as an enabler to identify the hidden biases we all possess and to mitigate their impact on the employment life cycle. UBE has been proven as a key enabler to help organizations:
  - Raise awareness of leaders and enable them to understand their own inherent biases
  - Positively impact leaders’ abilities to more fairly assess, retain, develop, promote and retain diverse talent
  - Develop leaders’ “cultural competence” for working with others who are different from themselves
  - Improve leaders’ capability in operating and competing effectively in the global arena, which translates

into success with customers and within the marketplace

- **Executive Leadership Council**—Our company supports the ELC, an organization that provides recognition, executive seminars, peer coaching and leadership opportunities to help African American mid-career and senior-level executives with their personal and professional development
- **Simmons Leadership Forum**—Our company partners with Simmons to inspire, enrich and empower their women executives. We recognize that developing the leadership potential of women executives and positioning them for success delivers a tangible competitive advantage for their organizations. In so doing, we send a strong signal to our employees that we regard developing, promoting and retaining female executives very seriously.

As a result of collaboration with Simmons College, we have experienced:

- Greater retention and promotion of high-performing women employees
- Increased job satisfaction among participants
- Increased productivity among participants and their departments
- Shared learning and better communication across the organization
- Improved interpersonal dynamics that enhance group effectiveness
- Stronger peer and mentoring networks for women

Beyond these programs, we offer our employees other training options to reinforce our commitment to diversity and inclusion. One in particular—Microinequities Training—helps create a more fully inclusive work environment by providing employees with an opportunity to learn about and avoid noninclusive behaviors.

## SELF-IDENTIFICATION PROGRAM

Our company has been engaged in launching a new Self-Identification program for employees. This program not only supports government and OFCCP Compliance requirements, but also furthers the company's full inclusion goals. A comprehensive program was launched in 2014 to assist employees with voluntarily identifying their status as a person with a disability, or someone from the LGBT, veteran or other diverse communities. Mirian Graddick-Weir, executive vice president, Human Resources, kicked off the program with an invitation to employees to participate. A special video highlighting the personal testimonials of employees was also used to encourage others to participate in the program.

The major dimensions of this Self-Identification program include:

- Leveraging senior executives, including EBRG Leaders, as champions to build trust, teamwork and direct communication
- Crafting employee messages that support our company's inclusion goals of helping individuals—regardless of differences—recognize their full potential and treating all with respect and dignity
- Creating a safe haven for company employees to share and exchange information and personal “stories” using a personalized video series, communications technology and social media to inform and engage
- Creating a clear, concise, “step-by-step/how-to” guide to help employees complete the self-identification process
- Engaging in strategic partnerships and alliances with external stakeholders that are 51 percent or more owned, operated, controlled and managed by individuals with disabilities
- Driving momentum via a year-round communications calendar, beginning with a launch in October—Disability Awareness Month
- Measuring and tracking program participation rates

### Marketplace Initiatives

**GARDASIL**<sup>®</sup> [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] — Our company supports diverse employees who bring their specific cultural, ethnic, religious, gender and other demographic knowledge and understanding to bear on business challenges and opportunities. One example is the obtaining of Halal certification for GARDASIL, our human papillomavirus (HPV) vaccine. Through this certification, we expanded access to GARDASIL for the Muslim community, helping to improve and save lives around the world. [Learn more](#) about our vaccines.

**Emerging Global Markets**—The emerging markets now account for approximately 22 percent of our company's pharmaceutical sales, with China continuing as a key growth driver. Over the past two decades, we have successfully introduced more than 40 innovative medicines and vaccines in China. In October 2013, our company's Foundation committed

an additional \$6 million over three years (2014–2016) to support a second phase of the China-MSD HIV/AIDS Partnership (C-MAP).

**MSD for Mothers**—Our global 10-year, \$500 million initiative was launched in 2011 to help create a world where no woman dies giving life. *MSD for Mothers* and its partners in India—Hindustan Latex Family Planning Promotion Trust, Pathfinder International with World Health Partners, and the White Ribbon Alliance for Safe Motherhood with Gram Vaani—are working to accelerate India's progress toward the United Nations' Millennium Development Goal 5: reducing the global maternal mortality rate by 75 percent by 2015.

**Brazil's Science without Borders Initiative**—Kenneth C. Frazier, our chairman and chief executive officer, is one of 24 CEOs of Brazilian and U.S. companies appointed by both governments to provide policy advice to President Barack Obama and President Dilma Rousseff under the U.S.-Brazil CEO Forum. The Forum's recommendations focus on incremental improvements in the bilateral economic framework, seeking to maximize commercial and investment exchanges between both countries. In a meeting with presidents Obama and Rousseff in April 2012, the CEOs committed to supporting Brazil's Science Without Borders initiative, whereby nearly 100,000 students will join top international universities for part of their education between 2012 and 2016. The Forum's member companies are contributing with internships for graduation students and research opportunities for more advanced degrees, to which our company has contributed with 15 internships. Mr. Frazier is currently serving his second term (2013–2016) as a Forum member.

**HIV Awareness & Education**—To commemorate World AIDS Day 2013, we encouraged people impacted by HIV to take action with the educational HIV campaign, *I Design*. Visitors to [www.ProjectIDesign.com](http://www.ProjectIDesign.com) were able to mark the day by making a pledge to learn more about HIV, educate someone else about the condition or help themselves or a loved one manage their HIV care.

## Employee Business Resource Groups & Marketplace Initiatives

In addition to these major initiatives, our EBRGs have had a direct impact throughout 2014 in driving business results for our company:

- EBRGs collectively developed a “horizontal” leadership initiative tied directly to business performance by providing key insights to our company's business agenda through the use of leading-edge technology coupled with consumer insights uniquely leveraging the EBRG membership. Traditionally, consumer research has been conducted through focus groups and surveys with customers and consumers external to a company participating in the research. We have found unique and innovative ways to simultaneously achieve critical business insights by better leveraging their employee resource groups with Delivering Real Insights Via Employee Networks (DRIVEN), launched in the fall of 2014—all in a more cost-effective and timely manner. The initiative provides for a private market research online community (MROC) that engages members of our company's employee resource group to provide both business and strategic consumer insights. DRIVEN uniquely taps into the organization's intellectual capital, scientific expertise and market knowledge—in this case, members of the employee resource groups, who are eager to help achieve the company's business goals. With DRIVEN, we use cutting-edge technology to gather consumer research insights while also safeguarding the privacy of the employees who participate. Brand, customer and business teams within the organization are all able to obtain feedback from targeted market segments more efficiently and cost effectively than they would through traditional external research.
- Our Hispanic/Latino EBRG continued to partner with *LATINA Style* magazine to raise the visibility of our company's customer-engagement program in the Hispanic market. Its website provides valuable information in an easy-to-navigate and accessible way for consumers to have access to vital healthcare information on topics such as fitness, healthy living, caregiving and specific health issues, including diabetes, asthma, cholesterol and more. The site is one of the few consumer healthcare information sites available in both Spanish and English. The availability of this rich source of health information can help to close a gap that exists in the Hispanic community for culturally and linguistically relevant health information and health-related educational resources.
- The African Ancestry/Black EBRG focused on the issue of healthcare disparities within the African-American communities by developing a strategic partnership with the HBCU (Historically Black Colleges and Universities) Network to provide critical information and resources that will promote a healthy lifestyle, manage health conditions prevalent in the community and connect this audience with the resources offered on our customer engagement platform. This resulted in the development of a Health & Wellness Microsite on HBCUConnect.com, featured cover stories in HBCU CONNECT and social media activation accessing over 700,000 African Americans on Facebook and Twitter.
- The Native American/Native Indigenous EBRG continued to develop Sacred Dream, a revenue-generating business that will provide employment opportunities for tribal residents. Sacred Dream addresses growing healthcare disparities

among Native American and indigenous populations. Its business strategy includes the development of a healthcare expansion model in partnership with tribal and government organizations.

## PERFORMANCE

### GRI G4-LA12

Diversity & Inclusion Performance	2010	2011	2012	2013	2014
Women in the workforce <sup>1</sup>	50%	51%	47%	47%	48%
Women on the Board	17%	17%	17%	17%	17%
Women in executive roles <sup>1,2</sup>	32%	35%	31%	31%	32%
Women on the senior management team <sup>3</sup>	39%	42%	35%	35%	31%
Women in management roles <sup>4</sup>	47%	43%	38%	37%	37%
Underrepresented members of ethnic groups on the Board	11%	11%	25%	25%	25%
Underrepresented members of ethnic groups in executive roles (U.S.)	15%	17%	16%	17%	21%
Underrepresented members of ethnic groups on the senior management team (U.S.)	20%	15%	23%	23%	15%
Underrepresented members of ethnic groups in the workforce (U.S.)	24%	29%	24%	24%	24%
Underrepresented members of ethnic groups in management roles (U.S.)	25%	19%	18%	18%	20%
New hires that were female <sup>1</sup>	51%	50%	45%	46%	49%
New hires that were members of underrepresented ethnic groups (U.S.)	25%	25%	27%	25%	22%

<sup>1</sup> Beginning with 2012, data reported for women is global. Previously, it was limited to the U.S.

<sup>2</sup> "Executive" is defined as the chief executive officer and two structural levels below.

<sup>3</sup> "Senior management team" is defined as the fourth structural level below the CEO.

<sup>4</sup> "Management role" is defined as all other managers with direct reports not reflected in notes 2 or 3.

Note: Our company has publicly disclosed EEO-1 information since 1999. Our 2013 data is available at

<http://www.merckresponsibility.com/wp-content/uploads/2015/08/2013EEO-1-diversity-brochure.pdf>.

NA: Data not available.

Total Workforce by Region and Gender	Female 2013	Male 2013	Unknown 2013	Total 2013	Female 2014	Male 2014	Unknown 2014	Total 2014
Asia Pacific	5,977	6,984	0	12,961	4,585	5,124	0	9,709
EEMEA	2,281	2,024	96	4,401	1,708	1,393	10	3,111
Latin America	3,160	3,683	196	7,039	2,347	2,498	170	5,015
EUCAN	11,389	10,478	162	22,029	9,263	7,784	84	17,131
Japan	925	3,214	0	4,139	815	2,489	0	3,304
U.S.	12,933	13,785	0	26,718	10,247	9,878	0	20,125
Total	36,665	40,168	454	77,287	28,965	29,166	264	58,395

Total Workforce by Region and Gender (%)	Female 2013	Male 2013	Unknown 2013	Total 2013	Female 2014	Male 2014	Unknown 2014	Total 2014
Asia Pacific	7.73%	9.04%	0%	16.77%	7.85%	8.77%	0%	16.63%
EEMEA	2.95%	2.62%	0.12%	5.69%	2.92%	2.39%	0.02%	5.33%
EUCAN	14.74%	13.56%	0.21%	28.50%	15.86%	13.33%	0.14%	29.34%
Japan	1.20%	4.16%	0%	5.36%	1.40%	4.26%	0%	5.66%
U.S.	16.73%	17.84%	0%	34.57%	17.55%	16.92%	0%	34.46%
Total	47.44%	51.9%	0.59%	100%	49.60%	49.95%	0.45%	100.00%

Employees

# RESTRUCTURING

**In October 2013, the company announced a global restructuring program (the “2013 Restructuring Program”) as part of a global initiative to sharpen its commercial and research & development focus.**

## GRI G4-13

As part of the 2013 Restructuring Program, the company expects to reduce its global workforce by approximately 8,500 positions. These workforce reductions will come primarily from the elimination of positions in sales, administrative and headquarters organizations, as well as research & development. The company will also reduce its global real estate footprint and continue to improve the efficiency of its manufacturing & supply network. Since inception of the 2013 Restructuring Program through December 31, 2014, we have eliminated approximately 6,095 positions comprising employee separations, as well as the elimination of contractors and vacant positions. The remaining actions under the 2013 Restructuring Program are expected to be substantially completed by the end of 2015. In 2014, approximately 4,555 positions were eliminated under this plan.

In July 2011, in the midst of a challenging business environment, the company announced the latest phase of its global restructuring program (the “Merger Restructuring Program”), which was initiated in conjunction with the merger of our legacy business and the legacy Schering-Plough businesses.

The Merger Restructuring Program was intended to support our strategic direction as a customer-focused, innovative and diversified global healthcare company, and to enable the company to invest in key areas for future growth, including emerging markets, biologics, vaccines and consumer care.

As part of the Merger Restructuring Program, the company expected to reduce its workforce, as measured at the time of the merger, by an additional 12 to 13 percent across the company worldwide. A majority of the workforce reductions in this phase of the Merger Restructuring Program related to manufacturing (including Animal Health), administrative and headquarters organizations.

Previously announced workforce reductions of approximately 17 percent in earlier phases of the program primarily reflected the elimination of positions in sales, administrative and headquarters organizations, as well as eliminations resulting from the sale or closure of certain manufacturing and research & development sites, and from the consolidation of office facilities.

From the inception of the Merger Restructuring Program through December 31, 2013, we eliminated approximately 26,880 positions through employee separations, as well as the elimination of contractors and vacant positions. Through December 31, 2014, 28,410 positions have been eliminated under the Merger Restructuring Program.

In October 2008, we announced a global restructuring program (the “2008 Restructuring Program”) to reduce our cost

structure, increase our efficiency and enhance our competitiveness. From its inception in 2008 through June 30, 2013, we eliminated approximately 6,460 positions as part of the 2008 Restructuring Program. These position eliminations consisted of employee separations and the elimination of contractors and vacant positions. The 2008 Restructuring Program was substantially completed in 2011, with the exception of certain manufacturing-related actions, that are expected to be completed by 2015. As of July 1, 2013, the remaining future separations under the 2008 Restructuring Program were transferred to the Merger Restructuring Program, and any remaining activities under the 2008 Restructuring Program are now being accounted for as part of the Merger Restructuring Program.

The company will continue to hire employees as necessary in strategic growth areas of the business, and will continue to pursue productivity and operational efficiencies and to regularly evaluate its manufacturing supply-chain capabilities.

While we believe these actions are necessary to support our competitive advantage, they have been and continue to be difficult decisions that impact some of our colleagues, their families and local communities. We have been and are committed to making these decisions in a responsible way, with respect, transparency and open, ongoing communication. Eligible employees affected by restructuring actions are eligible to receive benefits and other services that may include severance pay, continuance of healthcare benefits and outplacement services.

For updated information on our restructuring program, please see our most recently filed quarterly and annual reports.

# ETHICS & TRANSPARENCY



**The foundation of our strategy is our unwavering commitment to values and integrity.**

## GRI G4-56

All employees are expected to behave ethically and in compliance with our Code of Conduct and policies. The Code of Conduct, called *Our Values and Standards*, is the foundation of our company's ethics and compliance program.

We believe ethics and compliance training is an important part of creating a strong culture. The Global Compliance Training Series (GCTS) portfolio of required fundamental courses helps build awareness of the company's Code of Conduct, policies and legal and regulatory requirements applicable to our business. The GCTS courses are mandatory for targeted employees.

We aspire to be the most trusted healthcare company in the world. Our values and standards are an essential part of how we build trust and confidence with customers, partners, employees, the general public and other stakeholders. We're working every day to earn trust by engaging audiences on all sides of the issues that matter, and by going beyond mandatory disclosure to proactively communicate key information in greater detail.

We disclose information through a variety of mechanisms, including our financial and corporate responsibility reporting, participation in voluntary efforts such as CDP, through the media, and through one-on-one stakeholder discussions.

## GRI G4-SO5

### KEY PERFORMANCE INDICATORS

	2011	2012	2013	2014
Employees trained on our Code of Conduct	90%	92%	99%	99%
Substantiated allegations to concerns/issues raised	65%	60%	58%	60%
Reported concerns regarding privacy practices, breaches of privacy, and losses of personal data and devices that were substantiated <sup>1</sup>	68%	23%	26%	18%

<sup>1</sup> Privacy concerns include all concerns escalated to our Privacy Office about the company's privacy practices. Substantiated concerns are those that are determined to be inconsistent with our privacy standards or that involve the loss of, theft of or unauthorized access to personal data.



Ethics & Transparency

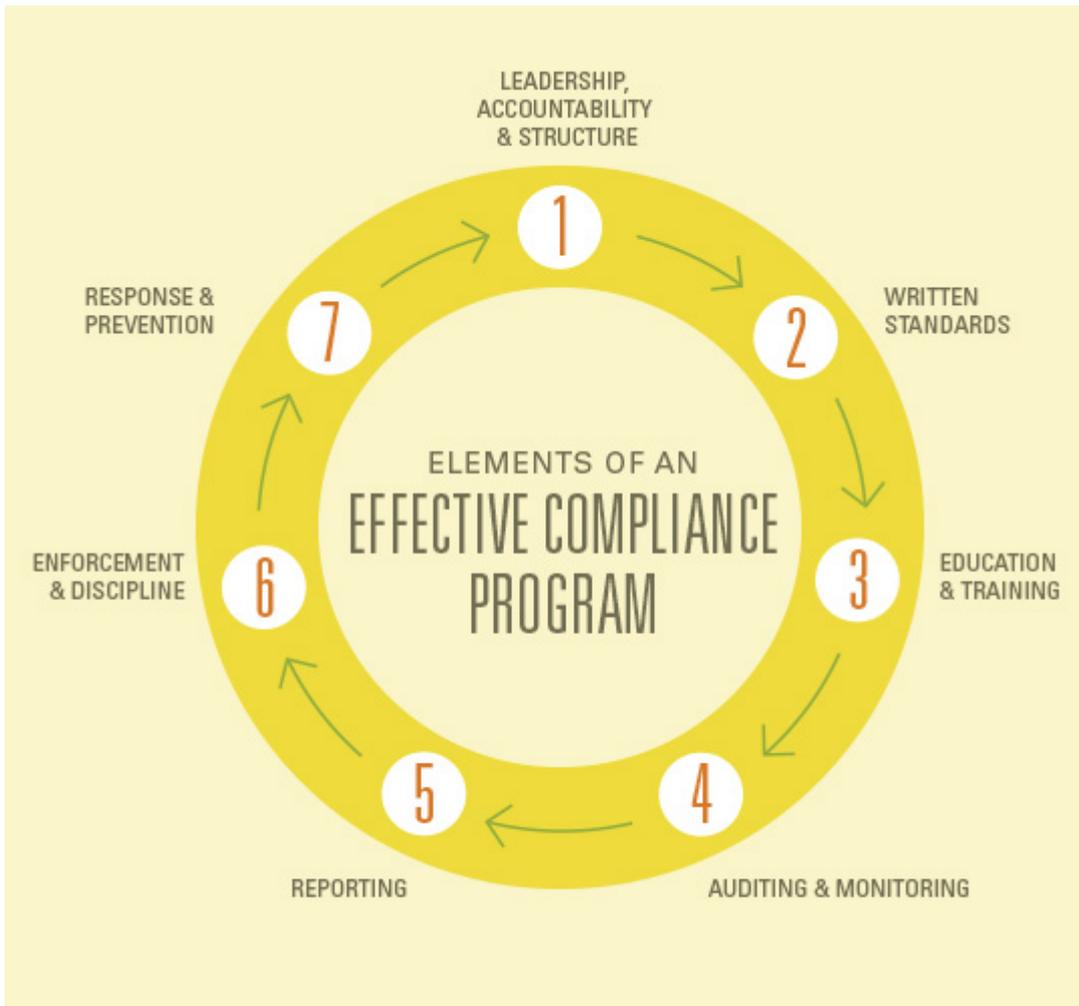
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# COMPLIANCE

**Being an ethical company is about much more than simply adhering to the letter of the law—but that's an important step.**

As part of our long-standing commitment to ethics and good corporate citizenship, our first step is always to comply with the laws and regulations that govern the way we market and sell our medicines, vaccines and other products. We have a well-established global compliance program that is consistent with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Practice requirements, as well as other applicable regional or country industry codes of conduct, including those issued by the Pharmaceutical Research and Manufacturers of America (PhRMA) and European Federation of Pharmaceutical Industry Associations (EFPIA).

The global compliance program is built around the core elements of an effective compliance program:



Our company's Board of Directors and senior management, including the chief ethics and compliance officer and members of the Corporate Compliance Committee, provide the foundational elements of leadership, accountability and structure to oversee the company's global compliance program. Written standards, including a corporate *Code of Conduct*, compliance-related policies and procedures, education, training and communications, reinforce the importance of ethical and compliant business practices.

The Corporate Compliance Committee meets at least four times per year to review the compliance status across the company's business divisions worldwide as part of the committee's effort to assess the effectiveness of the company's compliance program.

# OFFICE OF ETHICS

## MAIN

**How we operate is as important as what we do.**

UNGC-6

UNGC-10

It is critically important to our patients, consumers, purchasers, healthcare professionals, employees and investors, and to the sustainability of our business success, that we adhere to all applicable laws and regulations, follow ethical business practices, maintain good corporate governance, practice transparency and treat people with respect.

We have strong management oversight, comprehensive corporate policies and procedures and a long history of abiding by legal and regulatory requirements and of promoting high ethical standards. Every employee worldwide is responsible for adhering to business practices that are in accordance with the letter and spirit of the law and with ethical principles that reflect the highest standards of corporate and individual behavior.

Our company's Office of Ethics was established in 1995 with the goal of further supporting our company's commitment to the highest standard of corporate conduct, responsibility and accountability. The Office of Ethics is led by the vice president, Office of Ethics, who reports to the company's chief ethics and compliance officer. The mission of the Office of Ethics is to actively support the company's commitment to the highest standards of ethics and compliance by facilitating behavior consistent with *Our Values and Standards*, the Code of Conduct, and by fostering a culture that promotes the prevention, detection and resolution of potential misconduct. The Office of Ethics helps to protect and promote the company's high ethical standards on a worldwide basis by developing and overseeing global initiatives designed to deter illegal, unethical and improper behavior related to the company's business.

The Office of Ethics is responsible for updating the Code of Conduct and for ensuring that employees are aware of and trained on the Code of Conduct. One key responsibility of the office is to serve as a channel for the receipt and investigation of employee concerns about potential ethics or compliance violations. A second key area of responsibility is the mandatory global compliance training program that all employees must complete. A third key area is corporate policies to ensure that employees have standards that provide guidance on expected behaviors and responsibilities.

## RESOURCES FOR EMPLOYEES

GRI G4-57

GRI G4-58

GRI G4-HR12

The Office of Ethics serves as an employee resource for raising concerns about ethical and compliance-related concerns. There are multiple channels through which employees can contact the Office of Ethics. Employees can contact the Office of

Ethics directly, by toll-free telephone or email, to speak to an ethics officer or ombudsperson. Our company also provides a confidential toll-free intake service, called AdviceLine, through a third party that offers the option for the reporting person to remain anonymous.

The Office of Ethics is also responsible for managing our Ombuds Program, which offers an additional safe haven for U.S.-based employees to discuss work-related issues without fear of retaliation. This program confidentially addresses employees' concerns mainly relating to manager or coworker relations or fair treatment. In 2014, 43 percent of the calls that the Office of Ethics received were classified as part of the ombuds process.

## ADDRESSING MISCONDUCT

It is our policy to maintain a work environment where all employees are expected to report potential ethical and compliance concerns that are inconsistent with the company's Code of Conduct and policies. The company is committed to maintaining a process that ensures timely escalation and investigation of potential compliance concerns. Retaliation against employees who report such concerns is a violation of corporate policy and will not be tolerated. The Office of Ethics is responsible for oversight of the global processes for managing investigations into potential ethics and compliance concerns to ensure consistent and timely resolution of potential concerns and implementation of remediation actions. When we substantiate allegations of ethical misconduct, we take appropriate disciplinary actions in order to ensure that those who were responsible are held accountable. Disciplinary actions can include dismissal from the company, issuance of final written warning letters or financial penalties. We also take appropriate steps to address any needed improvements in organizational and process controls.

In 2014, we adopted a new policy that will give the company the discretion to recoup incentive payments made to employees in certain instances. This policy will apply when a senior leader engages in misconduct or fails to reasonably supervise an employee who engages in misconduct that results in a material policy violation relating to the research, development, manufacturing, sales or marketing of company products where the policy violation causes significant financial or reputational harm to the company.

## ANNUAL ETHICS & POLICY CERTIFICATION

An important component of our corporate compliance program is our annual ethics and policy certification. The annual review process requires all directors, officers, managers and other selected company employees to certify compliance with the Code of Conduct and corporate policies on ethical business practices, antitrust law compliance and insider trading. These employees are also expected to regulate their outside activities to avoid any conflicts of interest and certify, in writing, whether actual or potential conflicts of interest exist. Where potential conflicts are identified, the Office of Ethics will work with management to take actions to mitigate the potential conflict. In addition, all U.S.-based employees must certify compliance with our corporate policy on the effects of exclusions, debarments, suspensions and healthcare-related criminal convictions, reporting and screening.

The certification process also includes a question soliciting employees to report any concern they may have about the company's business not being conducted in full compliance with laws, regulations and company policies. Although the number of responses submitted represented less than 1 percent of all employees, the company investigated each issue to ensure full compliance with laws, regulations and company policy.

## PERFORMANCE

GRI G4-HR2

	Ethical Business Practices				
	2010	2011	2012	2013	2014
Employees trained on the Code of Conduct	71%	90%	92%	99%	99%
Employees trained on the Code of Conduct: 2014 annual refresher	NA	NA	NA	99%	99%
Employees who responded to disclosure statement on Conflicts of Interest form	100%	98%	99%	NA	100%

Concerns brought to the company's attention, such as employees seeking ombudsman services (most often relating to manager and employee relations) and guidance on conflict of interest or Code of Conduct issues	725	873	713	624	517
Allegations involving noncompliance with company policy investigated	NA	1,080	1,012	968	1,069
Substantiated allegations to concerns/issues raised	11%	65%	60%	58%	60%
Employees separated related to substantiated corporate policy violations <sup>1</sup>	NA	NA	166	313	365
Employees who received written warnings as disciplinary actions resulting from a substantiated concern <sup>2</sup>	NA	NA	232	269	323

Note: Commencing with the 2012 Report, the above chart reflects a new baseline as of 2011.

<sup>1</sup> This data represents investigations conducted on a companywide basis.

<sup>2</sup> Prior to 2012, this data was not tracked on a global basis.

NA: Not available.

# CODE OF CONDUCT

**Our Code of Conduct, *Our Values and Standards*, is considered to be the foundation of our company's success. These values and standards apply worldwide, wherever our company does business.**

UNGC-10

GRI G4-56

Ethics and integrity make up one of our company's five core values. These values are underscored in our company's Code of Conduct, *Our Values and Standards*, which was first developed and distributed to employees in 1999, and has been updated three times since then. The current edition includes antibribery and anticorruption guidance.

Our Code of Conduct, available in 26 languages, applies one standard of conduct to all employees worldwide.

The values and standards embodied in our Code of Conduct are designed to promote ethical business practices as our employees conduct activities in a continuously evolving business environment and to deter employee misconduct. These core values included in the Code of Conduct are intended to foster:

- Compliance with company policies and applicable governmental laws, rules and regulatory requirements
- Safeguards to protect the privacy of personal information, as well as honesty and transparency in communications about our products
- Measures to mitigate potential conflicts of interest
- Prompt internal reporting of potential violations of the Code of Conduct and policies
- Employee accountability for adherence to the values and standards set forth in the Code of Conduct

To download a copy of our Code of Conduct or locate company resources to raise a question or concern, [click here](#).

## ETHICS TRAINING & DEVELOPMENT

GRI G4-SO4

GRI G4-HR2

We provide training to all employees worldwide on our Code of Conduct to ensure awareness of our values and standards as well as a variety of associated topics such as privacy and preventing discrimination, human rights, harassment, corruption and bribery. Efforts continued throughout 2014 to integrate ethics and compliance content into business and leadership development courses for managers and senior leaders. Ethics and integrity are key leadership competencies that are assessed as part of annual performance reviews, and play an integral role in our decisions about employee advancement in

the company.

## EXTERNAL SUPPLIERS' ETHICAL STANDARDS

We abide by strict ethical standards in our own operations—and we insist on equivalent standards from our suppliers. We have a Business Partner Code of Conduct that is based on our own Code of Conduct, as well as the Pharmaceutical Supply Chain Initiative's (PSCI's) Pharmaceutical Industry Principles and The Ten Principles of the UN Global Compact.

To download a copy of the Business Partner Code of Conduct, [click here](#).

For more information on how we work with our suppliers to uphold ethical standards, please [click here](#).

A photograph of an office environment. In the foreground, a man in a blue and white checkered shirt is looking down at a document. To his right, a woman with short brown hair and large hoop earrings is also looking at the document. In the background, there is a desk with a printer, a telephone, and various papers. The text 'Ethics & Transparency' is overlaid in the top left corner of the image.

Ethics & Transparency

# GLOBAL PRIVACY PROGRAM

## MAIN

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**We have implemented a comprehensive global privacy program that promotes accountable privacy and data protection practices across our business and with our collaborative partners and suppliers.**

In 4Q 2013, our program was certified under the Asia-Pacific Economic Cooperation (APEC) Cross-Border Privacy Rules (CBPR) System. Our company was the first healthcare company in the world to achieve this certification. Our program is designed to assure that four core privacy values are embedded into the way we conduct our business, without regard to how our business, technology or other external factors may change. In 4Q 2014, we filed an application with the Belgian Privacy Commission for approval of its global privacy program under the European Union (EU) Binding Corporate Rules (BCR) cooperation procedure. Our company is the first company in the world to file an application for EU BCR approval based on an existing APEC CBPR certification. The aim of our dual certification strategy is to promote globally interoperable privacy standards across the more than 50 countries and economies combined in APEC and the European Economic Area.

# OUR PRIVACY VALUES

RESPECT	TRUST	PREVENTION	COMPLIANCE
We recognize that privacy concerns often relate to the essence of who we are, how we view the world and how we define ourselves, so we strive to respect the perspectives and interests of individuals and communities and to be fair and transparent in how we use and share information about them.	We know that trust is vital to our success, so we strive to build and preserve the trust of our customers, employees, patients and other stakeholders in how we respect privacy and protect information about people.	We understand that misuse of information about people can create both tangible and intangible harms for individuals, so we seek to prevent physical, financial, reputational and other types of privacy harms to individuals.	We have learned that laws and regulations cannot always keep pace with the rapid change in technologies, data flows, and associated shifts in privacy risks and expectations, so we strive to comply with both the spirit and letter of privacy and data protection laws and regulations in a manner that drives consistency and operating efficiency for our global business operations.

Our global privacy program is structured around a system of five core elements consistent with recognized standards for implementing an accountable privacy program. While the principle of accountability was first recognized in the *Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data* (the “*Guidelines*”), issued in 1980 by the Organisation for Economic Co-operation and Development (OECD), the essential elements for an accountable privacy program were first expressed in 2009 by the Accountability Project, an initiative originated by the Centre for Information Policy Leadership, with participation from privacy regulators, data protection authorities, business and academia. Our company established its system of five core elements in 2010, joined the Accountability Project in 2011, and has been an ongoing participant in its development, which is now led by the Information Accountability Foundation.

In 2013, the OECD published its first revision to the *Guidelines* since 1980. The revised *Guidelines* set forth a new standard for implementing accountability through privacy management programs. Our global privacy program is consistent with the standards of the revised *Guidelines*. Our program is modeled for continuous improvement, based on changes within our business and in the external environment that affect inherent privacy risks and the effectiveness of our privacy controls. The five core elements are:

## Awareness

- Promote and maintain a corporate culture that respects privacy and protects information about people
- Communicate timely information about updates to privacy laws, regulations, rules, guidelines and policy issues

## Policies & Standards

- Implement privacy and data-protection policies and standards that set forth operational principles and procedures, governance, accountability, incident handling and individual redress

## Training

- Implement a privacy-training curriculum designed to support the core elements of “Awareness” and “Policies & Standards,” and to provide functional knowledge aligned to roles and responsibilities

## Accountability

- Demonstrate the effectiveness of our program by:
  - Prospectively building and documenting appropriate privacy and data-protection requirements into our company’s processes and systems that will be maintained throughout process and system life cycles
  - Periodically verifying privacy and data protection compliance through audits, assessments and investigations
  - Reporting to government authorities as required by law
  - Management acknowledgement and responsibility for ensuring that requirements are addressed

## Metrics

- Define baseline and target metrics to determine the effectiveness, maturity and risks associated with the privacy program
- Collect and analyze data for each metric and evaluate program effectiveness, maturity and risks, as well as areas for enhancement, improvement and risk mitigation

In keeping with our privacy values, we continue to believe that trust is at the core of our privacy mission. We define Privacy TRUST as supporting each of the operational privacy and data protection principles to which we adhere:

**T**—Transparency: Being clear about how personal information is collected, used and disclosed (supports our privacy principle of Notice)

**R**—Respecting Choices: Such as whether or not people want to participate in our programs (supports our privacy principle of Choice)

**U**—Understanding Perspectives: Including that people have different levels of concern about their privacy based on cultural perspectives and personal experiences (supports our privacy principle of Necessity)

**S**—Security: Protecting personal information from loss, misuse, unauthorized access, disclosure, alteration or destruction (supports our privacy principles of Data Integrity, Security and Data Transfer)

**T**—Treating our stakeholders in a manner consistent with the company’s values (supports our privacy principles of Access, Correction, Enforcement and Dispute Resolution)

## Global Cross-Border Data Flows

As a U.S.-based corporation, we have relied on the Safe Harbor Framework for transfers of personal data from the European Economic Area (“EEA”) to the United States (the “Safe Harbor”) as a primary mechanism for facilitating cross-border data flow originating from European countries. We also have utilized the Safe Harbor principles to support the development of our comprehensive privacy program, including incorporation of Safe Harbor standards for movement of personal data to and from other countries.

Our company was one of the first pharmaceutical companies to certify its adherence to the Safe Harbor Framework. We first certified in November 2001. U.S. organizations that certify to the U.S.-EU Safe Harbor are recognized as providing adequate protection for personal data transferred from the EEA, and organizations that certify to the U.S.-Swiss Safe Harbor are recognized as providing adequate protection for personal data transferred from Switzerland. Our Safe Harbor certification applies to transfers of personal information about a broad range of stakeholders from the EEA and, since 2009, from Switzerland, including employees, customers, patients, clinical investigators, healthcare professionals and others. We have reaffirmed our adherence to the Safe Harbor Framework annually since 2001.

One key component of our approach to facilitating efficient cross-border data flows is annual management privacy certification. Each year, senior company organizational leaders, including the leaders of operating entities in countries around the world, certify their accountability for the implementation of privacy standards and requirements in the organizations and activities they lead.

In 2013, we became the first healthcare company in the world, and the second multinational company, to be certified under the new Asia-Pacific Economic Cooperation (APEC) Cross-Border Privacy Rules (CBPR) System. The APEC CBPR System provides a framework for organizations to ensure protection of personal information transferred among participating APEC economies. Achievement of APEC certification demonstrates to our customers, patients and other stakeholders our strong commitment to accountable, values-based privacy and data protection practices in every region of the world in which we operate. At the end of 2014, we filed an application for approval of our global privacy program under the European Union (EU)

Binding Corporate Rules (BCR) co-operation procedure. BCR serves as an externally enforceable code of conduct for ensuring protection of personal information transferred among entities and across country borders within a corporate group. In March 2014, EU and APEC officials announced a referential for facilitating approval under both systems. Our company launched its APEC CBPR to EU BCR dual certification project in the summer of 2014 in an effort to drive interoperability in practice between the two systems by seeking to demonstrate how an accountable global privacy program can serve as the basis for approval and ongoing compliance with the requirements of both systems.

### **Privacy Risk & Effectiveness**

In keeping with our commitments to accountability and continuous improvement of our program, in 2011 we developed a quantitative approach to consistently evaluating privacy risk and determining the impact of control effectiveness on privacy risks across our operations. We continue to apply this approach to new activities and initiatives to provide consistent guidance on required privacy standards and controls. In connection with our annual privacy compliance review, we also evaluated global and country operations, and we continue to pursue this quantitative approach to determine opportunities for improvement in specific areas and across our program.

### **Transparency & Privacy**

We aspire to being a leader in privacy transparency practices. We aim to achieve this by explaining our privacy practices in ways that enable our stakeholders to make meaningful choices about how we collect, use and disclose personal information about them.

Since 2007, we have been developing and publishing standardized comprehensive privacy notices for major categories of stakeholders about whom we collect, use and disclose personal information across our business. We adopted a format first proposed in 2007 for the U.S. financial services industry.<sup>1</sup> This standard format uses a tabular approach to categorize the information provided in the notices in order to make them easier to understand, and easier for people who interact with us in multiple ways to compare our practices. All of our standardized comprehensive notices, available in multiple languages, are published [online](#).

We recognize that health innovations continue at a rapid pace, and we strive to enhance our transparency practices to address these changes. In 2009, we updated our [Internet Privacy Policy](#) to include explanations of new ways in which we planned to collect personal information online using social media and mobile computing; the transparency standards we apply to these types of online technologies; and additional disclosures regarding collection of information from personal computers and other electronic devices. We also began implementing contextual privacy notices in our apps for mobile devices in 2009. Most of our privacy notices can be found in the description at the app store, as well as in the information, settings, email and reporting features of our mobile apps. In 2011, we began implementing notices in reference to our company's privacy practices on social media platforms through which we engage stakeholders, such as Facebook and Twitter. In 2012, we began implementing our first privacy notices for apps hosted on social media platforms, such as Facebook. In recognition of growing regulatory concerns regarding mobile app privacy, in 2013 we published a new stand-alone overview regarding our mobile app privacy practices. In 2014, we completed the development of global mobile privacy standards and integrated these requirements into our annual management certification.

<sup>1</sup>The proposed Model Privacy Notice was included in the Interagency Proposal for Model Privacy Form under the Gramm-Leach-Bliley Act, 72 FR 14940 (March 29, 2007).

## **ADVOCACY**

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**Our company is actively engaged in policy and advocacy efforts to further privacy standards and next-generation policy frameworks that promote the responsible collection, use and collaborative sharing of data in support of healthcare, biomedical research and other**

## innovations.

We are a member of the International Pharmaceutical Privacy Consortium (IPPC), an association of research-based pharmaceutical companies that supports worldwide responsibility for the protection of personal health information and other types of personal data. We are a corporate member of the International Association of Privacy Professionals, members of our company's Privacy Office serve on its Board of Directors and Certification Advisory Board, and we encourage development of privacy program management competencies among our privacy, compliance and IT employees through privacy training and professional certification. We also participate in other privacy and information policy organizations, such as the Centre for Information Policy Leadership (CIPL) and the Future of Privacy Forum, which encourage responsible information governance and the development of leading privacy practices.

In 2013, we became a founding supporter of the Information Accountability Foundation, a charitable organization created to build upon the work of the Accountability Project to further accountability-based information governance that facilitates information-driven innovation while protecting individuals' rights to privacy and autonomy.

## PERFORMANCE

### GRI G4-PR8

	Privacy Data	2010	2011	2012	2013	2014
Number of countries in which we conducted privacy compliance verification and risk assessment		87	137	137	137	137
Change in program control effectiveness (over 2010 baseline)		NA	32%	37%	39%	41%
Number of substantiated concerns regarding privacy practices, breaches of privacy and losses of personal data <sup>1</sup>		92	229	68	212	151
Percentage of reported concerns regarding privacy practices, breaches of privacy and losses of personal data that were substantiated		78%	68%	23%	26%	18%
Number of privacy breaches requiring notification by Merck & Co., Inc., Kenilworth, NJ, USA to individuals or government authorities		0	2	0	0	1
Number of privacy breaches requiring notification by third parties working for Merck & Co., Inc., Kenilworth, NJ, USA to individuals or government authorities		2	3	2	1	1

<sup>1</sup> Privacy concerns include all concerns escalated to our company's Privacy Office about our privacy practices. Substantiated concerns are those that are determined to be inconsistent with our own privacy standards or that involve loss of, theft of or unauthorized access to personal data.

# HUMAN RIGHTS

**Human rights are an important element of our company's commitment to conducting our business in a responsible manner.**

## UNGC-1

We respect human rights as recognized by the principles of the United Nations Global Compact and as defined in the United Nations Universal Declaration of Human Rights; the International Covenant on Economic, Social and Cultural Rights; the International Covenant on Civil and Political Rights; the Organisation for Economic Co-operation and Development (OECD) Guidelines for Multinational Enterprises; and the core labor standards set out in the International Labour Organization's (ILO's) Declaration on Fundamental Principles and Rights at Work.

## OUR BELIEF

We believe in the dignity of every human being and in respecting individual rights. Our company has established global policies and processes to demonstrate this respect, including our global Public Policy on Human Rights and *Our Values and Standards* (Code of Conduct), which reaffirms our commitment to scientific excellence, ethics and integrity.

*Our Values and Standards* outlines our responsibilities to our customers, our fellow employees, our suppliers, our communities and societies around the world, as well as to our shareholders. These responsibilities are not only the foundation of our company and what we stand for, but the basis of our success.

## OUR AIM

We seek to prevent or mitigate adverse human rights practices that are directly linked to our operations, products or services.

## OUR COMMITMENT

GRI G4-HR1

GRI G4-HR4

GRI G4-HR5

GRI G4-HR6

UNGC-2

UNGC-3

UNGC-4

UNGC-5

UNGC-6

Our commitment is formalized and manifested through various policies, including *Our Values and Standards* (Code of Conduct), our Global Labor Relations Guiding Principles, and our environmental governance and management systems. Specifically:

- **Labor Standards:** We maintain labor standards, including hours, conditions, wages and overtime pay practices, that are in compliance with the laws of the jurisdictions in which we operate
- **Health & Safety:** We provide a safe and healthy work environment in all of our operations, regardless of their size or function
- **Freedom of Association:** We respect our employees' right to freedom of association
- **Forced & Child Labor:** We condemn the use of forced labor and exploitative child labor as defined by the International Labor Organization's 1998 Declaration on Fundamental Principles and Rights at Work
- **Wages & Benefits:** We compensate our employees in accordance with market practice in a manner that supports their ability to meet their basic needs. We also offer our employees the opportunity to improve their skills and capabilities
- **Diversity & Equal Opportunities:** We value diversity and strive to provide equal opportunities for all individuals
- **Privacy:** We respect individual privacy expectations and protect personal information that we collect, use and disclose in connection with our business
- **Access to Healthcare:** We respect the right to health for all people and work toward expanding access to care
- **Customers:** We take into consideration the economic, social, geographic and cultural diversity of our customers as we develop and market our products
- **Business Partners:** We expect appropriate standards of conduct and respect for human rights, consistent with our own, from our suppliers, contractors, vendors and partners
- **Communities:** We respect the human rights of our neighbors in those areas where we have operations or facilities
- **International Standards:** We respect international standards on human rights and, where possible, contribute by working with partners
- **Nondiscrimination:** We do not discriminate in employment, contracting, wages, promotion, working conditions or in any other opportunity based on race, color, gender, gender identity, gender expression, genetic information, age, religion, ethnicity, national origin, ancestry, sexual orientation, marital status, disability or any other legally protected characteristic subject to compliance with applicable law
- **Compliance:** We adhere to local laws. When local protection is insufficient or nonexistent, we observe even more demanding standards consistent with our human rights policy to the extent that these standards do not violate local laws and regulations.

## OUR APPROACH

GRI G4-57

Our company has a number of global policies that address how we protect human rights. Our company's Executive Committee is also responsible for ensuring that governance processes are in place to provide oversight of the implementation and execution of these corporate policies. When we engage with third parties, we require specific contractual obligations and conduct a risk-based approach to due diligence and compliance monitoring. If a potential concern is raised regarding a human right, the concern is investigated and remediation action is taken for any substantiated concerns.

## RESOURCES FOR EMPLOYEES

Our Office of Ethics serves as an employee resource for raising concerns about ethical issues, including noncompliance with corporate policies. Employees globally can contact (via toll-free telephone or intranet) the AdviceLine, which is run by an outside vendor. Employees also can contact the Office of Ethics directly and speak with an ethics specialist. Noncompliance

with our policies including human rights are subject to escalation, investigation and remediation in accordance with our established global processes.

## ENGAGEMENT WITH SUPPLIERS

We expect our suppliers and service providers to comply with human rights and environmental standards that are compatible with our own, and to conduct their business in accordance with the highest ethical standards throughout their entire supply chain. The Business Partner Code of Conduct further communicates our expectations. The code is based on our own Code of Conduct, *Our Values and Standards*, as well as the Pharmaceutical Supply Chain Initiative's (PSCI's) *Pharmaceutical Industry Principles for Responsible Supply Chain Management* and *The Ten Principles of the United Nations Global Compact*. We have implemented procedures to provide business partners with our Business Partner Code of Conduct so that our values and standards, including protection of human rights, are clearly communicated at the outset. We have translated the Business Partner Code of Conduct into 26 different languages to help ensure that the content is widely understood.

[Learn more about environmental, labor and human rights in the supply chain.](#)

# HUMAN RIGHTS OF OUR EMPLOYEES

**Respect for human rights is embedded in our company’s Code of Conduct, *Our Values and Standards*.**

**UNGC-6**

In addition to *Our Values and Standards* and our Code of Conduct training programs, we established the Global Labor Relations Guiding Principles to support our Global Labor Relations Strategy and to ensure consistency worldwide. These principles support our commitment to respect employees’ lawful freedom of association globally.

**GRI G4-11**

Human Rights of Our Employees 2010 2011 2012 2013 2014

Worldwide employees represented by an independent trade union or covered by a collective bargaining agreement 30% 31% 31% 32% 31%

**GRI G4-58**

## MECHANISMS TO REPORT CONCERNS

Our Code of Conduct promotes the importance of maintaining a safe-to-speak-up environment, and employees are required to report policy violations to ensure these violations can be investigated and addressed. There are several ways in which employees can report suspected human rights violations:

- As a first step, employees can seek out an immediate supervisor or manager to discuss suspected violations
- If the matter is not successfully resolved, or if concerns remain, employees are encouraged to pursue the issue with their next level of management or Human Resources
- Employees can also contact the Office of Ethics for assistance. The Office of Ethics maintains an “AdviceLine” that is available to employees, either by telephone or the intranet, 24 hours a day, seven days a week. Staffed by an independent organization, the AdviceLine allows employees to remain anonymous, in accordance with applicable legal standards for operation of whistle-blowing hotlines.
- Another option is our company’s Ombuds Program, which offers a safe haven for U.S. employees to discuss work-related issues.

- We have a policy that prohibits retaliation against employees who raise concerns through any of the available mechanisms. Retaliation is not tolerated and is subject to disciplinary actions up to and including termination of employment.

# HEALTH AS A HUMAN RIGHT

**Although government has the primary responsibility for managing a health system that ensures the health of its citizens, pharmaceutical companies have a substantial role to play in realizing this right.**

Health as a universal human right is recognized by the United Nations Universal Declaration of Human Rights and the International Covenant on Economic Social and Cultural Rights (ICESCR).

The role of the pharmaceutical industry in respecting and promoting health as a human right is complex. We believe that our most basic role is our core activity of discovering, developing and delivering medicines and vaccines to address unmet medical needs.

We also recognize our ethical duty to support governments in their efforts to protect the right to health by “doing no harm.” We do this in a number of ways, including by:

- Monitoring and reporting on the safety of our products
- Providing healthcare workers and consumers with important information on the benefits and side effects of our products
- Safeguarding the health, safety and privacy of patients involved in our clinical trials

## SUPPORTING THE RIGHT TO HEALTH

Beyond these efforts, we also have the ability—and, we believe, the responsibility—to support the right to health and to effect positive change. We do this by promoting timely product registration; by helping to improve access to new medicines and vaccines; and through partnerships and public policy advocacy that seek to strengthen healthcare capacity and address deep-rooted and multifaceted barriers to access in ways that are aligned with our business mission and core capabilities.

Others have roles and responsibilities, too. Industrialized countries—where most research in life sciences takes place—must continue to foster innovation by funding basic research and supporting related institutions, and by recognizing the value of innovative medicines and vaccines.

Developing countries also must continue to make healthcare a budget priority; remove taxes and import duties on medicines that unnecessarily raise the price of medications; and limit product diversion to richer countries by price arbitragers. Emerging or middle-income countries should do the same, and should also recognize that they can and should pay more than the poorest countries for medicines, rather than take actions that remove incentives for innovation.

# TRANSPARENCY DISCLOSURES



**Our company aspires to be open and transparent about how we operate in order to earn and retain the trust and confidence of our customers, employees, shareholders and other important stakeholders.**

## GRI G4-SO6

We do this by proactively providing nonproprietary information to stakeholders about our business and how we operate which will help stakeholders make informed decisions about their interactions with the company and our products.

We disclose information through a variety of mechanisms, including our financial disclosures, the publication of our annual corporate responsibility report, and participation in voluntary efforts such as the CDP (formerly the Carbon Disclosure Project), through the media and through one-on-one stakeholder discussions. As part of this commitment to increasing transparency, we also disclose information in this corporate responsibility report in the following areas:

## CLINICAL TRIALS

Our company is committed to the timely registration of clinical trial information and the disclosure of clinical trials—regardless of their outcomes.

[Learn More about clinical trials.](#)

### **Clinical Trials Disclosures**

Since 2007, we have registered at trial initiation all clinical trials in patients in which treatment is assigned that our company sponsors and conducts worldwide on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). We also disclose results from registered clinical trials of marketed products—regardless of outcomes.

### **Clinical Trial Results**

The clinical study results of our company and Schering-Plough, previously posted on the Pharmaceutical Research and Manufacturers of America (PhRMA) Clinical Study Results Database, have been available as of December 2011 on our corporate headquarters website.

### **Clinical Trial Data Sharing**

We are committed to the PhRMA/EFPIA Principles for Responsible Clinical Trial Data Sharing.

Learn more about our policies and perspectives:

- Procedure on Access to Clinical Trial Data
- Procedure on CSR Synopsis Posting
- External Scientific Review Board (ESRB) Charter

Scientific and medical researchers who wish to submit a proposal for access to our company's data may send an inquiry by clicking [here](#).

### **Clinical Research Protocols**

Effective July 1, 2011, when we submit a manuscript on a study of an investigational or an approved medicine or vaccine to a biomedical journal, we will voluntarily include the protocol and statistical analysis plan. We previously supplied this material only upon request. Upon a journal's acceptance of the manuscript for publication, we will provide the journal, at its own discretion, with the opportunity to post on its website the key sections of the protocol, including the objectives and hypotheses, patient inclusion and exclusion criteria, study design and procedures, efficacy and safety measures, the statistical analysis plan, and any amendments relating to those sections.

## **CDP**

CDP is an independent not-for-profit organization working to drive greenhouse gas (GHG) emissions reduction and sustainable water use by businesses and cities.

CDP works with investors globally to advance the investment opportunities and reduce the risks posed by climate change by asking almost 6,000 of the world's largest companies to report on their climate strategies, GHG emissions and energy use in the standardized Investor CDP format. We have been disclosing climate information via the CDP for a number of years and more recently have participated in both its Water and Supply Chain disclosures.

- CDP Water Disclosure (2015)
- CDP Climate Change (2014)
- CDP Water Disclosure (2014)

## **EMPLOYEE DIVERSITY**

We were one of the first companies in the United States to annually disclose our Equal Employment Opportunity data and continue to do so annually.

We consider diversity and inclusion integral parts of the culture we seek to build. [Learn more.](#)

## **GRANTS TO MEDICAL, SCIENTIFIC AND PATIENT ORGANIZATIONS**

Our company has a leadership role as a global corporate citizen in our respective industries. We believe that providing support through grants or donations to third-party medical, scientific and patient organizations is an important way to advance our mutual objectives to improve health and advance patient care.

We have robust standards and policies in place to ensure that our grants are intended for and provided in support of improving patient care, and are not promotional or likely to be perceived as being promotional in nature, or provided to induce or reward prescription of our products. Further, any grant or donation must also be permitted by and aligned with local country laws and regulations.

To learn more about our disclosure of grants inside the United States, click [here](#).

To learn more about our disclosure of grants outside the United States, click [here](#).

## **PAYMENTS TO U.S.-BASED HEALTHCARE PROFESSIONALS**

As an early supporter of the Physician Payments Sunshine Act (PPSA), we believe in broad disclosure of financial relationships between physicians and the pharmaceutical industry.

In October 2009, our company began voluntarily disclosing all payments to U.S.-based healthcare professionals who speak on behalf of our company, about our products and other healthcare issues.

In April 2012, we expanded our payments report to include post-merger speaking activities related to legacy Schering Plough, our company's medical forums and Inspire Pharmaceutical products. [Learn more.](#)

## PAYMENTS TO EUROPEAN-BASED HEALTHCARE PROFESSIONALS

We will begin disclosing payments to European-based healthcare professionals and healthcare organizations in 2016.

We will begin disclosing payments to European-based healthcare professionals and healthcare organizations in 2016 in alignment with the disclosure code announced by The European Federation of Pharmaceutical Industries and Associations (EFPIA) in July 2013. Our company played a supportive role in the development and adoption of the code by the EFPIA board.

## PHILANTHROPIC GRANTS AND CONTRIBUTIONS

We report philanthropic grants and charitable contributions, including contributions made through the Office of Corporate Responsibility, our company's Foundation, US Global Human Health and the *MSD for Mothers* Program. (\*Reports were updated July 2015)

[Charitable Contributions Report 4Q2015](#)

[Charitable Contributions Report 3Q2015](#)

[Charitable Contributions Report 2Q2015](#)

[Charitable Contributions Report 1Q2015](#)

[Charitable Contributions Report 2014\\*](#)

[Charitable Contributions Report 2013\\*](#)

[Charitable Contributions Report 2012\\*](#)

[Charitable Contributions Report 2011\\*](#)

[Charitable Contributions Report 2010](#)

[Charitable Contributions Report 2009](#)

[Charitable Contributions Report 2008](#)

## CORPORATE POLITICAL ADVOCACY AND CONTRIBUTIONS

Our company is committed to participating constructively and responsibly in the political process. To improve access to information about our advocacy activities, we disclose our costs associated with lobbying in the European Union and the United States.

Where permitted by law in the United States, Canada and Australia, the company provides corporate political contributions, primarily to the electoral campaigns of individual candidates.

To improve access to information about our corporate political and PAC contributions in the United States, our company semiannually posts our contributions, categorized by state, candidate and amount. We post our contributions in Canada and Australia annually.

We also disclose a list of industry and trade groups of which we are members and our dues (dues that are greater than \$25,000) to U.S. trade associations that are used for political purposes. We encourage all trade associations to which we belong to publicly disclose their political activities as well. [Learn more.](#)

## POST-MARKETING REQUIREMENTS

We recognize the importance of providing transparent information about the status of our marketing and development

activities after a product has been approved by regulatory authorities. This information can help ensure healthcare providers and patients remain informed about our products.

To inform the public about post-marketing activities, we will, on a quarterly basis, post information concerning post-marketing requirements (PMRs) for U.S.-marketed products intended for human use on this website. Information will include the nature and status of the PMRs for the life cycle of a marketed product, in accordance with U.S. regulations. Information will include reference to clinical, non-clinical or pharmacovigilance studies/trials that have been identified as PMRs. Additional background on post-marketing requirements is available at the FDA website. Below are the column headings and explanations of terms found in the PDF files below of our company's PMRs. The PDF files are searchable.

#### **2016 U.S. Post-Marketing Requirements**

January

April

#### **2015 U.S. Post-Marketing Requirements**

January

April

July

October

#### **2014 U.S. Post-Marketing Requirements**

January

April

July

October

#### **2013 U.S. Post-Marketing Requirements**

January

April

July

October

#### **2012 U.S. Post-Marketing Requirements**

March

July

October

The following define the status used for each requirement. These definitions are consistent with those of the U.S. FDA. There may be differences in the status of the information posted to this website and that on the FDA Post-Marketing Commitments website due primarily to the differences in timing of the updates.

**Pending:** The study has not been initiated (i.e., no subjects have been enrolled or animals dosed) but does not meet the criterion for delayed (i.e., the original projected date for initiation of patient accrual or initiation of animal dosing has not passed).

**Ongoing:** The study is proceeding according to, or is ahead of, the original schedule. The FDA considers a study to be ongoing until a final study report is submitted to the FDA, as long as the activities are proceeding according to the original study schedule. If patient accrual or animal dosing has started but is not complete, and the projected date for completion of that milestone has passed, the study should be categorized as delayed.

**Delayed:** The progression of the study is behind the original study schedule. Delays can occur in any phase of the study, including patient enrollment, analysis of study results, or submission of the final study report to the FDA. While the original study schedule—not a revised schedule—serves as the basis for defining a study as delayed, each phase

of the study will be considered in its own right. If the applicant has one delayed phase, but gets back on schedule during the next phase, the delayed status will no longer apply.

**Terminated:** The applicant ended the study before completion and has not yet submitted a final study report to the FDA.

**Submitted:** The applicant has concluded or terminated the study and has submitted a final study report to the FDA, but the FDA has not yet notified the applicant in writing that the study commitment has been fulfilled or that the commitment has been released.

**Fulfilled:** The applicant has submitted the final study report for the commitment, and upon review of the final study report, the FDA is satisfied that the applicant has met the terms of the commitment.

**Released:** The FDA has informed the applicant that it has been released from its obligation to conduct the post-marketing study because the study is either no longer feasible or would no longer provide useful information.

Column Heading	Explanation
Product Name [TRADE NAME (generic name)]	Trade name used in the U.S. market (active ingredient[s] in the drug)
Due Date	The date by which our company has agreed to a final submission relating to the post-marketing requirement to the FDA
Status (Pending, Ongoing, Delayed, Terminated, Submitted, Fulfilled and Released)	The status of the requirement at the last quarterly update (see definitions below)
Explanation of Status	An explanation is provided where appropriate.
PMR Description	The description of the post-marketing requirement

# DISCLOSURE OF GRANTS INSIDE THE UNITED STATES

**We believe that providing support through grants or donations to third-party medical, scientific and patient organizations is an important way to advance our mutual objectives to improve health and advance patient care.**

We have robust standards and policies in place to ensure that our grants are intended for and provided in support of improving patient care, and are not promotional or likely to be perceived as promotional in nature, or provided to induce or reward prescribing our products. Further, any grant or donation must also be permitted by and aligned with local country laws and regulations.

We disclose grants of more than \$500 provided by the company's Global Human Health division to U.S. organizations in support of independent, accredited educational programs for healthcare professionals, as well as grants to patient organizations and other medical education or scientific societies/organizations in the United States, Europe, the Middle East, Africa and Canada.

We update grants to medical, scientific and patient organizations quarterly in the United States, and annually for ex-U.S. jurisdictions. We will continue to expand our disclosure into other regions as we work to build the infrastructure and systems necessary to allow us to report this information on a global basis. The following three principles guide our approach to providing financial support to medical, scientific and patient organizations:

## **Independence**

Our company respects the independence of medical, scientific and patient organizations and refrains from using our financial support to influence the policies of organizations or to promote specific medicines.

## **Transparency**

Our company supports transparency of financial support provided to medical, scientific and patient organizations. We believe this is an important step in building public trust with both our company and those to whom we provide support. Making our support public also enhances the visibility of our commitment to helping advance health and science.

## **Compliance with Local Laws**

In providing financial support to medical, scientific and patient organizations, we comply with all relevant local laws and regulations.

As part of our commitment to these principles, we regularly review and update our Code of Conduct to reaffirm our mission and commitment to scientific excellence, ethics and integrity. These principles are also reflected in the company's corporate policies, procedures and guidelines, which every one of our employees is responsible for understanding and appropriately applying.

## **DISCLOSURES IN THE UNITED STATES**

### **2015**

Grants made in the 4th Quarter 2015 in the U.S.

Grants made in the 3rd Quarter 2015 in the U.S.

Grants made in the 2nd Quarter 2015 in the U.S.

Grants made in the 1st Quarter 2015 in the U.S.

### **2014**

Grants made in the 4th Quarter 2014 in the U.S.

Grants made in the 3rd Quarter 2014 in the U.S.

Grants made in the 2nd Quarter 2014 in the U.S.

Grants made in the 1st Quarter 2014 in the U.S.

### **2013**

Grants made in the 4th Quarter 2013 in the U.S.

Grants made in the 3rd Quarter 2013 in the U.S.

Grants made in the 2nd Quarter 2013 in the U.S.

Grants made in the 1st Quarter 2013 in the U.S.

### **2012**

Grants made in the 4th Quarter 2012 in the U.S.

Grants made in the 3rd Quarter 2012 in the U.S.

Grants made in the 2nd Quarter 2012 in the U.S.

Grants made in the 1st Quarter 2012 in the U.S.

### **2011**

Grants made in the 4th Quarter 2011 in the U.S.

Grants made in the 3rd Quarter 2011 in the U.S.

Grants made in the 2nd Quarter 2011 in the U.S.

Grants made in the 1st Quarter 2011 in the U.S.

### **2010**

Grants made in the 4th Quarter 2010 in the U.S.

Grants made in the 3rd Quarter 2010 in the U.S.

Grants made in the 2nd Quarter 2010 in the U.S.

Grants made in the 1st Quarter 2010 in the U.S.

## 2009

Grants made in the 4th Quarter 2009 in the U.S.

Grants made in the 3rd Quarter 2009 in the U.S.

Grants made in the 2nd Quarter 2009 in the U.S.

Grants made in the 1st Quarter 2009 in the U.S.

## 2008

Grants made in the 4th Quarter 2008 in the U.S.

Grants made in the 3rd Quarter 2008 in the U.S.

# DISCLOSURE OF GRANTS OUTSIDE THE UNITED STATES

**Disclosure of grants to patient organizations has been mandatory in Europe since March 2009. However, in Europe, the Middle East and Africa, we voluntarily began disclosing financial support to patient organizations in 2008, and in Canada in 2009.**

In October 2009, our company in Europe, the Middle East, Africa and Canada, also began to disclose grants to other third-party organizations such as medical societies and scientific organizations. The information disclosed includes the organizations, the amounts received, the dates of payment and the projects for which the money was used. Disclosures include all donations and charitable contributions, grants and membership fees to professional societies or other medical or scientific organizations. We were a member of the working group to develop the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on Relationships between the Pharmaceutical Industry and Patient Organisations, which became effective on July 1, 2008.

We update grants to medical, scientific and patient organizations annually for ex-U.S. jurisdictions.

## DISCLOSURES OUTSIDE THE UNITED STATES

### 2014

Algeria

Austria

Belgium Luxembourg

Bulgaria

Canada

Côte d'Ivoire

Croatia

Cyprus

Czech Republic  
Finland  
France  
Germany  
Greece  
Gulf  
Hungry  
Ireland  
Israel  
Italy  
Lebanon  
Libya  
Morocco  
Netherlands  
OCP MFM  
Poland  
Portugal  
Romania  
Russia  
Serbia  
Slovakia  
Slovenia  
South Africa  
Spain>  
Turkey  
Ukraine  
United Kingdom

## 2013

Algeria  
Austria  
Belgium Luxembourg  
Bulgaria  
Canada  
Croatia  
Cyprus  
Czech Republic

Denmark

Egypt

EPA (English and Portuguese Africa)

Estonia

Ex-US HQ

Finland

France

FWA (French West Africa)

Germany

Greece

Gulf

Hungary

Ireland

Israel

Italy

Jordan

Latvia

Lebanon

Lithuania

*Merck for Mothers*

Morocco

Netherlands Haarlem Oss

Norway

OCP Foundation

Poland

Portugal

Public Policy

Romania

Russia

Serbia

Slovakia

Slovenia

South Africa

Spain

Sweden

Switzerland

Tunisia

Turkey

Ukraine

United Kingdom

Yemen

## 2012

Austria

Belgium Luxembourg

Bulgaria

Canada

Charitable Contributions

Croatia

Cyprus

Czech Republic

Denmark

Egypt

Estonia

Ex-US HQ

Finland

France

Germany

Greece

Gulf

Hungary

Ireland

Israel

Italy

Jordan

Kazakhstan

Latvia

Lebanon

Libya

Lithuania

Macedonia Montenegro

Morocco

MSD Europe

Netherlands Haarlem Europe

Netherlands Oss

Norway

Poland

Portugal

Romania

Russia

Serbia

Slovakia

Slovenia

South Africa

Spain

Sweden

Switzerland

Tunisia

Turkey

Ukraine

United Kingdom

## 2ND HALF OF 2011

Algeria

Austria

Belgium

Bosnia and Herzegovina

Bulgaria

Canada

Croatia

Cyprus

Czech Republic

Denmark

Egypt

Estonia

Finland

France

Germany

Greece

Gulf Market

Hungary

Ireland  
Israel  
Italy  
Jordan  
Latvia  
Lebanon  
Lithuania  
Morocco  
MSD Headquarters  
Netherlands  
Norway  
Poland  
Portugal  
Romania  
Russia  
Saudi Arabia  
Serbia and Montenegro  
Slovak Republic  
Slovenia  
Spain  
Sweden  
Switzerland  
Turkey  
Ukraine  
United Kingdom

## **1ST HALF OF 2011**

Algeria  
Austria  
Belgium  
Bosnia  
Bulgaria and Macedonia  
Canada  
Croatia  
Cyprus  
Czech Republic  
Denmark

Egypt  
Estonia  
Finland  
France  
Germany  
Greece  
Gulf Market  
Hungary  
Iraq  
Ireland  
Israel  
Italy  
Jordan  
Latvia  
Lebanon  
Lithuania  
Morocco  
MSD Europe  
Netherlands  
Norway  
Poland  
Portugal  
Romania  
Russia  
Saudi Arabia  
Serbia and Montenegro  
Slovakia  
Slovenia  
South Africa  
Spain  
Sweden  
Switzerland  
Syria  
Tunisia  
Turkey  
Ukraine  
United Kingdom

## 2010

Algeria

Austria

Belgium

Bosnia and Herzegovina

Bulgaria and Macedonia

Canada

Croatia

Cyprus

Czech Republic

Denmark

Egypt

Estonia

Finland

France

Germany

Greece

Gulf

Hungary

Iraq

Ireland

Israel

Italy

Jordan

Kazakhstan

Latvia

Lebanon

Lithuania

Morocco

Netherlands

Norway

Poland

Portugal

Romania

Russia

Saudi Arabia

Serbia and Montenegro

Slovak Republic

Slovenia

South Africa

Spain

Sweden

Switzerland

Syria

Turkey

Ukraine

United Kingdom

MSD Headquarters

## 2009

Algeria

Austria

Belgium

Bulgaria

Canada

Croatia

Cyprus

Denmark

EMEAC Headquarters

Estonia

Finland

France

Germany

Ireland

Israel

Italy

Jordan

Kazakhstan

Kuwait

Latvia

Lebanon

Lithuania

Morocco

Netherlands  
Norway  
Poland  
Portugal  
Romania  
Russia  
Saudi Arabia  
Serbia  
Slovenia  
South Africa  
Spain  
Sweden  
Switzerland  
Turkey  
United Kingdom

## 2008

Algeria  
Austria  
Belgium  
Bulgaria  
Croatia  
Cyprus  
Denmark  
EMEAC Headquarters  
Estonia  
Finland  
France  
Germany  
Ireland  
Israel  
Italy  
Jordan  
Latvia  
Lithuania  
MSD Europe  
Netherlands

Norway

Poland

Portugal

Romania

Schering-Plough

Serbia

Slovenia

South Africa

Spain

Sweden

Switzerland

United Kingdom

# PAYMENTS TO U.S.-BASED PHYSICIANS



## We believe in broad disclosure of financial relationships between physicians and the pharmaceutical industry.

As an early supporter of the Physician Payments Sunshine Act (PPSA), we believe in broad disclosure of financial relationships between physicians and the pharmaceutical industry. In October 2009, our company began voluntarily disclosing all payments to U.S.-based healthcare professionals who speak on behalf of our company, about our products and other healthcare issues.

Updated reports are posted annually reflecting payments and transfers of value to U.S.-based physicians, including those engaged in clinical research activities. We included both direct payments to individual physicians, as well as "indirect" payments to the research entity/institution with the name of the associated principal investigator(s). The latter does not imply a direct payment to the individuals but rather support for the work that they are doing in the context of the research on behalf of their entity/institution.

We comply with the PPSA provisions of the U.S. Affordable Care Act, which requires pharmaceutical manufacturers to annually disclose information on certain additional payments and other transfers of value furnished to U.S.-licensed physicians and U.S. teaching hospitals to the Department of Health and Human Services (HHS). In addition to submitting such information to HHS's Center for Medicare & Medicaid Services each year, we will post the information annually on this website.

### SEARCH 2015 PAYMENTS >

- Payments made in 2014
- Payments made in 2013

For information regarding payments made to U.S.-based health care professionals by Cubist Pharmaceuticals, now a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, please choose a link below.

- Payments made in 2014
- Payments made between August and December 2013

## THE IMPORTANCE OF ENGAGING WITH MEDICAL AND SCIENTIFIC LEADERS WITHIN THE UNITED STATES

We engage with healthcare professionals around the world to conduct company-sponsored clinical studies on the safety and

effectiveness of our products. We conduct these studies in accordance with strict regulatory requirements with “real world” physicians and their patients in order to learn more about our products and bring new medicines and vaccines to patients who need them. Once a product is approved for marketing, we continue to conduct studies in order to monitor ongoing safety and effectiveness.

We also engage with healthcare professionals through our Investigator Studies Program (MISP), whose mission is to advance the delivery of quality healthcare by supporting investigator-initiated original research that will enhance the understanding of disease entities and their treatment. This program is open to all academic and community-based physicians and researchers worldwide who are interested in conducting their own research. [Learn more.](#)

We are committed to the discovery and development of important new drugs and vaccines through collaboration with scientific leaders from academic and scientific organizations from around the world. Advice in the form of consulting engagements with external medical and scientific experts results in meaningful, scientific exchanges that bring real-world knowledge and perspectives to our company. These critical exchanges contribute to advancing science both at our company and in the broader scientific community, and ultimately help benefit human health. We also engage physicians as speakers in the U.S. through our company’s Medical Forums, which are designed to deliver balanced medical and scientific information to healthcare professionals so that patients can have access to the medicines and vaccines they need and use these products correctly. These programs are structured to be consistent with the PhRMA Code on Interactions with Healthcare Professionals and are conducted in compliance with FDA regulations to help ensure that our product information is presented in an appropriately balanced manner, with respect to potential benefits and risks.

# SALES & MARKETING



## MAIN

### We know that doctors and patients look to us to provide accurate and balanced information about our products.

We adhere to strict, ethical sales and marketing practices for all our businesses, whether pharmaceuticals, vaccines or animal health.

We believe the best way to provide this product information is for healthcare companies to maintain informative, ethical and professional relationships with healthcare providers. Our interactions with providers, other customers and consumers are governed by laws and regulations, and by our long-standing global Code of Conduct, *Our Values and Standards*. We enforce these external and internal standards through our Global Compliance Program. We recognize that both our reputation for integrity and the trust that our stakeholders place in us are dependent on our ethical practices. For this reason, we want to make certain that the ways in which we market and sell our products to our customers—healthcare professionals, health insurers and governments—provide accurate, balanced and useful information so that prescribers can make the best decisions for their patients. Our high ethical, sales and marketing standards require that scientific information is the predominant factor in prescribing decisions, which helps to reinforce our reputation for providing high-quality products and for contributing to improvements in public health.

Our professional sales representatives and other employees inform our customers about our medicines and vaccines and their appropriate use. In some countries, where permitted by law, we may also directly inform patients and other consumers about diseases and available treatments that they may wish to discuss with their doctors.

We also market our products directly to consumers at times. We believe direct-to-consumer (DTC) advertising contributes to greater awareness about conditions and diseases, which can benefit public health by increasing the number of patients appropriately diagnosed and treated.

GRI G4-PR4

GRI G4-PR7

Sales & Marketing Summary	2010	2011	2012	2013	2014
Number of warning letters or untitled letters from OPDP <sup>1</sup> or APLB <sup>2</sup> in the U.S. <sup>3</sup>	0	0	1	0	0

<sup>1</sup> OPDP: Since September 2011, the Division of Drug Marketing, Advertising and Communication (DDMAC) is now the Office of Prescription Drug Promotion (OPDP).

<sup>2</sup> APLB: Advertising and Promotional Labeling Branch (APLB) of the FDA Center for Biologics Evaluation and Research.

<sup>3</sup> Beginning in 2014, data now incorporates information from our Animal Health business.

NA: Data not available.

# HEALTHCARE PROFESSIONALS

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## Ethical relationships with healthcare professionals are critical to our mission of helping patients be well.

An important part of achieving this mission is ensuring that healthcare professionals have balanced and accurate information about our products. All of our sales and marketing activities are conducted in accordance with our Guiding Principles for Ethical Business Practices involving the Medical and Scientific Community. These principles are aligned with national regulations and worldwide industry codes, including the International Federation of Pharmaceutical Manufacturers & Associations Code of Practice and the World Health Organization's Ethical Criteria for Medicinal Drug Promotion.

These principles serve as a bridge between country laws and regulations, industry guidelines, and the company's *Values and Standards*, enabling us to interact with the medical and scientific communities, meet our ethical and legal obligations, and contribute to improvements in human health.

We provide promotional information in several ways, including:

- Product discussions between our professional representatives and healthcare professionals
- Promotional and/or educational meetings sponsored and organized by our company

We also provide non-promotional information through educational and scientific activities, including:

- Scientific presentations at medical conferences
- Support of independent continuing medical education (CME)
- Articles and related scientific studies published in peer-reviewed scientific journals
- Web-based tools such as Univadis®

Our interactions and informational materials must provide truthful, balanced and non-misleading information to healthcare professionals. All of our interactions with healthcare professionals are highly regulated by the government through laws such as the U.S. Anti-Kickback Statute; the Food, Drug & Cosmetic Act; the U.S. Foreign Corrupt Practices Act (FCPA); and anti-bribery laws in other countries.

### GRI G4-SO4

Our company's robust anti-bribery/anticorruption program and corporate policy ensure that all employees have the awareness and knowledge to comply with applicable laws and regulations, and understand that the company will not tolerate any act of impropriety. Our activities must comply not only with company policies but with applicable laws, including the laws of the U.S. and other countries in which we do business.

Our program prohibits the offer, promise or giving of any payment or benefit at any time to an individual or entity for the purpose of improperly influencing decisions or actions with respect to our business. This applies to direct engagements (e.g., those driven by our company) as well as indirect engagements (e.g., those managed through a third-party intermediary or partner).

We conduct anticorruption/anti-bribery training with relevant employees, which is supplemented with e-learning and/or face-to-face training with all employees that engage with non-U.S. government officials. In many countries, healthcare professionals are considered government officials because of their employment by a government hospital or are advisers or decision-makers for the government on matters that could affect our business.

## CONTINUING MEDICAL EDUCATION (CME) AND CONTINUING EDUCATION (CE) PROGRAMS

Our CME/CE Grant Program supports independent educational programs to maintain, develop or enhance the knowledge, skills and/or professional performance that a healthcare professional uses to provide services for patients, the public or the profession. We are committed to ensuring that our CME/CE programs are educational and not promotional. Through them, our goal is to increase physician knowledge about the latest scientific data and healthcare topics that result in improved patient care.

The environment in which we sponsor or support educational programs worldwide is complex, governed by a multitude of laws, regulations, and medical or industry association guidelines. We are committed to honoring them all in the countries in which we operate.

CME programs that we support or sponsor are governed by an internal policy and also must be aligned with appropriate standards such as the Accreditation Council for Continuing Medical Education (ACCME) standards for commercial support of CME in the U.S., the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Practice, and European Federation of Pharmaceutical Industry Associations (EFPIA). These standards specify independence, financial disclosure and other requirements applicable to CME programs sponsored by commercial entities, including pharmaceutical manufacturers. [Click here](#) for a list of grants of more than \$500 made to U.S. organizations by our company's Global Human Health division in support of independent, accredited educational programs for healthcare professionals.

## MEDICAL FORUMS

We deliver balanced medical and scientific information to healthcare professionals within the U.S. through our company's Medical Forums, which are conducted by external speakers. Speakers are selected based on their expertise in the relevant subject matter. By attending one of our Medical Forums, healthcare professionals participate in interactive learning on therapeutic and healthcare industry topics. The goal of these interactions is to help attendees achieve improved medical results for their patients.

With our strict standards for conducting our Medical Forums, we comply with the PhRMA Code on Interactions with Health Care Professionals as well as FDA regulations, which make sure that any product presentation is appropriately balanced with information regarding the product's potential benefits and risks and is consistent with approved product labeling.

We disclose certain payments to U.S. medical and scientific professionals who speak on behalf of the company. For a list of these disclosures, [click here](#).

## OBTAINING SERVICES FROM EXTERNAL HEALTHCARE PROFESSIONALS

We engage the service of external healthcare professionals only when we do not have the specialized talent or expertise internally, or when an external viewpoint is critical. Compensation provided to these healthcare professionals is based on fair market value of the service. We ensure that compensation provided to external healthcare professionals is fair and reasonable, and is aligned with fair market value of the service in the home country of the healthcare professional providing the service.

## PRESCRIPTION PRODUCT SAMPLES

Where sampling is permitted, our company has established country-specific guidance and policies on providing prescription product samples to healthcare professionals. This guidance specifies the appropriate distribution and use of samples to safeguard against the potential for misuse or abuse of our products, or the diversion of our products to inappropriate channels. In accordance with the law and ethical practices, we do not provide product samples to reduce or discount the price paid or reimbursed, or in exchange for prescribing, purchasing or contracting for our products or for recommending our products for formulary status.

## UNAPPROVED, OR "OFF-LABEL," USE OF OUR MEDICINES AND VACCINES

In accordance with laws, regulations, internal policies and ethical practices, our professional representatives and other members of our sales and marketing team are not permitted to promote product uses that are not consistent with the approved product label, sometimes referred to as "off-label" promotion. We have policies and training in place to address violations, and we ensure that physicians are aware that we do not encourage off-label use.

# PATIENTS

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**We believe that direct-to-consumer (DTC) advertising can be an important and helpful way to inform patients about diseases that may be relevant to them and about therapeutic options they may want to discuss with their physicians.**

We only conduct such advertising in countries where direct-to-consumer advertising is permitted. We try to help consumers achieve better health outcomes by delivering accurate, relevant and understandable information on disease prevention, identification and potential treatment. To remain true to this goal, we adhere to the letter and spirit of FDA regulations and guidelines governing DTC promotion, meet or exceed all Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines on DTC advertising, and follow a comprehensive set of internal policies and practices when engaging in DTC advertising within the U.S.

Our company has a long-standing policy of voluntarily submitting new U.S.-based DTC advertising campaigns to the FDA for its review and comment before running them. Under our DTC policies and practices, the information provided in our DTC advertising must:

- Contain appropriate product benefit and risk information
- Be appropriately balanced, consistent with FDA regulations, and use appropriate “taste and tone”
- If on television, run at appropriate times of the day or night and during appropriate programs
- Be approved by our company’s Promotion Review Team (PRT), a governing body consisting of a team of reviewers and approvers (including job owner, attorney, physician, Office of Promotion and Advertising Review (for U.S.), Regulatory, and a product scientific specialist), who ensure that promotional material is clinically and scientifically accurate, compliant with applicable laws and regulations, and compliant with company policy. In addition, we include information on our [Patient Assistance Programs](#) along with a toll-free phone number for more information, in all new U.S.-based DTC print and television advertisements.

We inform healthcare professionals about our products before we advertise them to consumers, and we do not launch DTC advertising in the U.S. until at least six months after a new product has been approved. We also implement comprehensive programs to educate physicians and other prescribers about a new product before starting product-specific DTC broadcast advertising in the U.S. These principles and our practices are reflected in the [PhRMA Guiding Principles on Direct-to-Consumer Advertisements about Prescription Medicines](#).

# ETHICAL PRACTICES

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**We believe that our marketing, sales and advertising activities make an important contribution to medicine by informing our customers of treatment options based on the most current scientific information and findings from rigorous clinical studies.**

We take our responsibilities related to our marketing, sales and advertising activities seriously and evaluate these activities on an ongoing basis to ensure they are consistent with laws and regulations as well as our own policies and values.

Our sales and marketing practices are governed by external laws, regulations and industry codes of conduct, and by our own global **Code of Conduct**, corporate policies and procedures, and our Global Compliance Program. Our Compliance Program seeks to prevent and address inappropriate practices, and we evaluate our policies and practices as appropriate. Our practices are monitored and compliance is enforced to ensure that our interactions with customers and consumers help inform their decisions accurately and in a balanced manner. We believe that compliance with all policies governing scientific, business and promotion-related activities, in letter and spirit, is a corporate and individual responsibility of the highest order.

Our ethical behavior strives to ensure that scientific information predominates in prescribing decisions.

## MECHANISMS FOR FOSTERING ETHICAL SALES & MARKETING PRACTICES

The key principles of our Guiding Principles for Ethical Business Practices Involving the Medical and Scientific Community are as follows:

- We provide current, accurate and balanced information about our products; we transmit sound scientific and educational information; and we support medical research and education.
- Our employees are prohibited from offering healthcare professionals items of personal benefit, such as tickets to sporting events, support for office social events, or gift certificates to stores or golf outings. Where permitted, we may occasionally provide healthcare professionals with approved educational items that are not of substantial monetary value and that are intended primarily for educational purposes. Such materials may include medical textbooks, medical journals or anatomical models.
- Our employees and others speaking on behalf of the company may provide presentations specifically designed to provide the type of information that practicing healthcare professionals have indicated is needed and most useful in the treatment of their patients, in accordance with U.S. FDA regulations and the regulations of other countries in which the presentations or discussions are taking place. In connection with such presentations or discussions, occasional modest meals may be offered to attendees and must occur in a venue and manner conducive to informational communication.
- A company representative may offer occasional modest meals to healthcare professionals in connection with an informational presentation; however, such meals must be in accordance with local codes and regulations.

Our sales representatives must provide truthful, non-misleading information in their interactions with the medical and scientific community. Our compliance program is consistent with applicable laws and regulations, and is aligned with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) Code of Pharmaceutical Marketing Practices, as well as with regional and country industry codes, such as the Pharmaceutical Research and Manufacturers of America (PhRMA) Code and the Compliance Program Guidance for Pharmaceutical Manufacturers, published by the Office of the Inspector General, U.S. Department of Health and Human Services. In addition to our global Code of Conduct and Guiding Principles for Interactions with Healthcare Professionals, we have several mechanisms in place to minimize noncompliance and foster ethical promotional practices:

**Hiring people with the right values and then reinforcing them:** We look for people who believe in a similar value system. In our interview process, we try to ascertain how candidates make decisions. We want people who will want to commercialize our medicines and vaccines based on the merits of our products and the science.

**Maintaining strict control over promotional materials:** Every promotional claim we make throughout the world has to be approved by our medical and legal experts for accuracy and balance, in accordance with legal requirements and ethical considerations. In the U.S., we also submit new promotional materials for new product approvals and new indications to the FDA prior to use.

**Ensuring strong medical, legal and compliance oversight:** Our medical and legal teams are active partners that help foster ethical promotional practices, helping to achieve business goals by reducing risk and increasing compliance with the laws and guidelines in a highly regulated environment. Our medical, legal and compliance teams are also involved in training the sales force to provide balanced information to physicians and healthcare decision-makers.

**Implementing a promotional approach that reflects customer input:** Our sales and marketing teams actively seek input from healthcare professionals, consumers and payers to understand their needs regarding our common goal of improving patient outcomes. We incorporate their feedback into training efforts and promotional activities in order to build trustworthy partnerships with our customers and to achieve our common goal.

**Enforcing a performance management system that rewards ethical behavior:** Our companywide annual performance management system considers not only what an employee has achieved but also how he or she has done so, with a specific focus on ethical behavior.

**Working to raise marketing standards industrywide:** We are active in numerous industry association committees that address marketing standards.

**Conducting continuous oversight, monitoring and risk assessment:** We conduct ongoing oversight and monitoring of our key risk areas and of any activities that have been identified through our annual risk assessment process.

## INTERNATIONAL MEDICAL MEDIA STANDARDS

The review and approval of global promotional and educational materials for healthcare practitioners follows a comprehensive and strict process as outlined in the International Medical Media Standards (IMMS) guidance document. The IMMS principles are followed by our employees on a worldwide basis and define the concept of fairness and balance in the communication of scientific/educational information. All such materials are reviewed and approved by medical and legal personnel, captured in a global database, and assigned a unique identifying number and expiration date. All regional and country medical personnel involved in the review and approval of promotional/educational material receive comprehensive training on corporate policies, IMMS, the medical-reviewer role, and the required database functionalities.

## TRAINING

As a condition of employment, all of our sales and marketing employees are required to be certified periodically on sales and marketing practices.

In the U.S., for example, employees who do not satisfactorily meet these training requirements may not conduct specific activities on their own and must complete the training again until they meet the requirements.

All new employees receive training and testing and must be certified on relevant policies and our company's ethical operating standards. And although many of our employees who market and sell our medicines and vaccines have advanced scientific or medical degrees and backgrounds, all of our sales representatives must complete general sales and product training. Training is specific to the country where an employee is based and covers the scope of the employee's responsibilities to ensure compliance with applicable laws and regulations.

Sales representatives in the U.S. are required to understand, among other things, their responsibilities under the Anti-Kickback Statute, the U.S. Prescription Drug Marketing Act and all applicable FDA promotional regulations. Sales representatives are trained on anti-bribery and anticorruption laws such as the U.S. Foreign Corrupt Practices Act (FCPA) and the U.K. Bribery Act.

After this initial training, we require periodic training aimed at recertifying employees on relevant policies and practices according to local and functional requirements. In addition to mandatory training on our Code of Conduct, employees receive training on other levels of business practices and compliance, according to their roles and responsibilities. We evaluate and update the content for all marketing and sales training periodically to ensure it remains relevant and current.

## INDUSTRY CODES OF CONDUCT

The pharmaceutical industry as a whole recognized that more needed to be done to address concerns raised by public officials and stakeholders in the healthcare community. Self-regulated industry codes of conduct such as the IFPMA, EFPIA and PhRMA codes set the standards that govern the industry's sales and marketing practices and ensure that companies have adequate policies and procedures in place to comply with the Codes.

## KEY COMPONENTS OF THE PhRMA CODE

Among the PhRMA Code's key components is an annual requirement for company CEOs and chief compliance officers to certify personally that they have processes in place that foster compliance with the Code. The Code also encourages companies to obtain third-party verification of their compliance policies and procedures. We have completed PhRMA Code certification in each of the last four years.

Other requirements of the Code have previously been incorporated into our already-strong ethical business practices. For example, the company follows the standards for commercial support of continuing medical education established by the Accreditation Council for Continuing Medical Education (ACCME), and our Compliance Program already required that

company representatives be periodically assessed to make sure they comply with relevant company policies and standards of conduct.

# PROCUREMENT & SUPPLIER RELATIONS

## MAIN

### PROCUREMENT PRACTICES

We have an extensive network of suppliers around the world. The Procurement and Supplier Management function is responsible for maintaining the standards by which third parties are identified, qualified and managed. Supplier selection and management follow a robust sourcing management process, in which Supplier Diversity principles are integrated throughout each stage.



### GLOBAL SUPPLIER DIVERSITY

We believe our diverse suppliers provide a source of innovation to help us better serve our customers. We continue to provide diverse suppliers with opportunities to innovate, grow and succeed. Small and diverse suppliers bring value to the company's supply chain and have a positive impact in our communities. Collaborating with diverse suppliers globally helps the world to be well.

We have had a Supplier Diversity program in the U.S. for many years, which is managed under the direction of our Global Supplier Management Group (GSMG). The Supplier Diversity program spans the following major areas of focus: inclusive procurement, strategic external outreach, globalization, supplier development and mentoring, compliance, customer focus, and internal awareness. For businesses headquartered in the U.S. and Puerto Rico, minority-, women-, LGBT-, disability- and veteran-owned business entities must be at least 51 percent owned, operated and controlled by the aforementioned respective individuals.

The inclusion of diverse suppliers is an integral part of our purchasing process and we continue to think of new ways to ensure that diverse suppliers are not only included but also truly considered when we source. In 2014, we added a supplier strategy component to the sourcing review process to ensure the inclusion of diverse suppliers in future purchasing

opportunities. In unique instances where no diverse supplier is included in the process or awarded the business, an explanation from the sourcing manager is required.

The company is continuing to grow its Supplier Diversity processes outside of the U.S. Conducting business with diverse suppliers globally, the company will bring business and economic value to our customers' and patients' communities while uplifting our company's brand. In Europe and South Africa, MSD has supplier diversity spend targets for small and medium enterprises (SMEs) and black-owned businesses, respectively. In Asia Pacific and Latin America, we are developing strategic plans for inclusive procurement that will result in economic impact.

We have advised, mentored and assisted small and diverse suppliers in building a strong foundation in their businesses for future success. Diverse suppliers are included in our Supplier Development & Performance Management (SD&PM) strategies for development and capacity-building. Through SD&PM, supplier assessments are performed and development plans are created to improve suppliers' performance in quality and operations and to develop their business as a whole.

In 2014, we established a Supplier Diversity Strategy Council (SDSC), which consists of category representatives in GSMG and Animal Health. The SDSC met and continues to meet monthly to review supplier diversity strategies, share best practices across all categories, and develop solutions that break down barriers to inclusive procurement.

Our performance in supplier diversity spend has nearly quadrupled in the U.S. and Puerto Rico since the inception of the program in 2005. In 2014, we spent \$805 million with diverse suppliers in the U.S. and Puerto Rico. Supplier Diversity and inclusive procurement have increasingly gained momentum in specialized areas of our business such as Manufacturing and Research & Development, where innovative solutions are consistently being realized. Our goal by the end of 2015 is to achieve and maintain performance of \$1 billion or greater with diverse suppliers.

For U.S. small-business performance in 2014, we spent \$529 million with small, small disadvantaged, small woman-owned, small veteran-owned, small service-disabled-veteran-owned and historically underutilized business zone (HUB) companies.

Meaningful external outreach is critical to finding qualified small and diverse suppliers. In 2014, the company participated in more than 30 supplier-diversity conferences and networking events globally, and is an active corporate member of the National Minority Supplier Development Council (NMSDC), the Women's Business Enterprise National Council (WBENC), the National Gay and Lesbian Chamber of Commerce (NGLCC), the U.S. Business Leadership Network (USBLN), the U.S. Pan Asian American Chamber of Commerce (USPAACC) and the U.S. Hispanic Chamber of Commerce (USHCC).

We recognize that supplier diversity creates a competitive advantage for our company and positively impacts and revitalizes the economy. There is a direct correlation between the support we provide to small and diverse businesses and the number of people these businesses hire from their local communities. We believe that the success of our company and society as a whole depends on enabling diverse businesses to share and grow in the global marketplace. This is why we are not only making a difference, but are also motivated to BE the difference.

## SUPPLIER AND THIRD-PARTY RISK MANAGEMENT

GRI G4-HR1

GRI G4-HR6

GRI G4-HR10

GRI G4-HR11

GRI G4-LA14

GRI G4-SO9

UNGC-2

UNGC-7

UNGC-8

UNGC-10

Third-party risk management is an enterprise-wide effort supported by Procurement, Supplier Management, the Office of the General Counsel, Compliance, and Environmental Health & Safety. Representatives from each function meet regularly to discuss, assess and manage issues that are risk drivers.

Our Business Partner Code of Conduct, along with our company's Supplier Performance Expectations, are communicated to all existing and potential third-party suppliers and are included in requests for information, proposals and quotes, supplier contracts, and purchase order terms and conditions. Our practice is to work with suppliers that share our commitment to ethics and integrity. In addition, we participate in the Pharmaceutical Supply Chain Initiative's (PSCI) Pharmaceutical Industry Principles and are a signatory to the 10 Principles of the United Nations Global Compact. We will endeavor to update our Business Partner Code of Conduct and contract language in 2015 to address new and emerging potential risks and increase our focus on Labor & Human Rights issues and environmental sustainability.

#### GRI G4-SO10

Using a risk-based approach, supplier assessments and audits are conducted based on multiple factors including engagement type, geography and potential impact of any issues to our finished products and our customers. The assessments and audits evaluate a supplier's ability to meet both industry and our standards for ethical business practices, including labor and human rights (enhanced program, intended to begin in 2015); anti-bribery and anti-corruption; privacy and data protection; environmental, health and safety issues; responsible sourcing of minerals (new and intended to begin in 2015); and animal welfare. Where assessments and audits identify opportunities for improvement or deficiencies, we collaborate closely to ensure that our concerns are addressed in a responsible and compliant manner.

## PROTECTING THE PRIVACY OF PERSONAL INFORMATION

Some of our suppliers and service providers, such as contract research organizations, market research agencies, information technology systems developers and other service providers, process personal information in connection with their performance of services for our company. We require these suppliers and service providers to provide appropriate privacy protection for personal information that they handle for, on behalf of or otherwise in connection with the performance of services for us, in accordance with our privacy policies and applicable privacy laws, regulations and guidelines.

## SUPPLIER ASSESSMENT FOR LABOR PRACTICES AND HUMAN RIGHTS

#### GRI G4-HR9

#### GRI G4-LA15

Our suppliers and service providers that meet certain criteria, such as all providers that directly impact our products, are required to complete a Supplier Self-Assessment questionnaire for Ethics & Compliance, which includes a Labor & Human Rights component. In an effort to strengthen the third-party Labor & Human Rights program and test the maturity of our suppliers' ethical business practices, Procurement, in conjunction with the Office of the General Counsel & Compliance, has identified enhancements, to include (i) developing a consistent definition across the enterprise for Labor & Human Rights Risk and (ii) implementing a process by which third parties and suppliers are assessed and managed. The target is to implement these enhancements in 2015.

## MANAGING EXTERNAL MANUFACTURERS OF OUR PRODUCTS

#### GRI G4-EN32

#### GRI G4-EN33

The company maintains strict quality standards—no matter where our products are manufactured in the world. Once we have made a decision to engage an external manufacturer, that manufacturer is required to comply with our business requirements set forth in the contract, regardless of geography.

Prospective external manufacturers of active pharmaceutical ingredients (APIs) and finished products are screened for environmental, health and safety (EHS) compliance, in addition to quality, and supply and technical competence requirements. The EHS screening includes a survey covering such topics as regulatory compliance, fatalities and major incidents.

Based on the screening results and activities undertaken by the supplier, certain external manufacturers are subject to a more

detailed on-site assessment conducted by a multidisciplinary team, which may include our company’s Quality, Safety, Environmental, Technical and Procurement representatives. External manufacturers we contract with are periodically reassessed using a risk-based approach; higher-risk external manufacturers are subject to more frequent on-site assessments.

**GRI G4-HR4**

We continue to support the Pharmaceutical Industry Principles for Responsible Supply Chain Management (the Principles). The Principles outline industry expectations for external manufacturers and licensees with regard to labor, health, safety, environment, ethics and management systems. The external manufacturers with which we contract are expected to understand and align with these Principles.

# PERFORMANCE

External Manufacturers Environmental, Health & Safety Assessment Summary					
	2010	2011	2012	2013	2014
Prospective external manufacturers	39	44	42	55	48
Current external manufacturers	26	27	39	45	68
Total assessments	65	71	81	100	116





# OUR GIVING

**To help improve the health and well-being of people around the world, our company supports qualified nonprofit organizations and innovative programs that are finding solutions to key global challenges.**

## GRI G4-EC7

Grants and Contributions Summary	2009	2010	2011	2012	2013	2014
Grants and contributions (total cash, in-kind and product, US\$M)	923	1,158	1,270	1,696	1,860	1,543
Cash grants and contributions (US\$M)	57	73	73	70	107	111
Product donations through U.S. Patient Assistance Program (US\$M)	188	323	301	559	566	433
Product donations for ex-U.S. programs and U.S. disaster relief (US\$M) <sup>2</sup>	678	762	893	1,067	1,185	997
Valuation of employee volunteer time (in-kind, US\$M) <sup>3</sup>	0	0	0	0	2.0	2.2

<sup>1</sup> Beginning in 2013, total giving includes "in-kind" contributions.

<sup>2</sup> Includes our Medical Outreach Program (including U.S. disaster relief), the African Comprehensive HIV/AIDS Partnerships, the MECTIZAN<sup>®</sup> Donation Program, the GARDASIL<sup>®</sup> Access Program and MSD division and subsidiary donations.

<sup>3</sup> Includes valuation of volunteer time for only those employees who participated in our Fellowship for Global Health program and our company's Legal Pro Bono program.

# PRIORITIES & GUIDELINES

## **Philanthropy is an important component of our company's commitment to corporate responsibility.**

Through our philanthropic programs, we have the ability to make a positive difference in addressing complex global health challenges and improving the quality of life in communities where we have a presence.

### **GUIDING PRINCIPLES**

Several key principles guide our philanthropic investments and program portfolio. We seek to:

- Address critical global health needs and social issues where we can have a meaningful impact and bring value to the company
- Collaborate successfully with key partners for optimal impact and effectiveness in advancing progress around these issues
- Leverage not only cash and product donations but also expertise and capabilities across our company

### **GIVING PRIORITIES**

Our giving priorities aim to strengthen the effectiveness and impact of our company's philanthropy while also aligning our programs with areas of global need in which we have substantial expertise and capability.

The following strategic priorities guide our philanthropic program investments:

- **Health:** Improve healthcare quality and health system capacity as well as increase access to care for underserved populations in selected disease areas of global need and relevance to our company—noncommunicable diseases (NCDs) or chronic conditions such as diabetes and cancer; hepatitis C; and HIV/AIDS. Through our program investments, we aim to support interventions with evidence of effectiveness to advance the quality of health services delivery, reduce healthcare disparities, strengthen training of healthcare workers and empower patients as active participants in managing their health.
- **Community:** Provide financial support and share the expertise of our employees through grant and volunteer programs that address critical health and social issues in communities where we have a presence

As of 2016, we have decided to phase out support of STEM education as a giving priority to more closely align our charitable

giving efforts with our Corporate Responsibility approach and our company's mission. As a result, we will not be making any new philanthropic investments in STEM education. This strategic alignment will enable us to focus our resources, including our philanthropic giving, on addressing the world's most pressing healthcare needs.



Our Giving

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# HEALTH

## MAIN

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**As a global healthcare company, we believe we have a responsibility to help increase access to medicines, vaccines and quality healthcare worldwide.**

In this effort, we are committed to discovering smart, sustainable ways to expand access, especially in parts of the world where there is limited or no healthcare infrastructure and resources. Given the immensity of this challenge, we believe we can make the strongest contribution by working in partnership with others—governments, donors, patient organizations, healthcare professionals, nongovernmental organizations, academic institutions, multilateral organizations and the private sector. Through these partnerships, we provide our expertise, human and financial resources, and products to improve the quality and capacity of global healthcare. Our support helps advance the quality of health services delivery, strengthen training for healthcare providers and foster efforts to empower patients as active participants in managing their health.

Our health philanthropy concentrates on select disease areas of global need: noncommunicable diseases (NCDs) or chronic conditions such as diabetes, cardiovascular disease and cancers; hepatitis C; and HIV/AIDS. Our program investments in these areas focus on innovative interventions with evidence of effectiveness in improving healthcare quality and reducing disparities in access and health outcomes among underserved populations who are particularly burdened by these diseases.

## NCDS

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### MERCK CHILDHOOD ASTHMA NETWORK (MCAN)

With funding from our company's Foundation, the Merck Childhood Asthma Network (MCAN), a U.S.-based initiative, supports programs that help increase access to and improve the quality of asthma healthcare for children. These programs also advocate for and recommend public policies that can expedite the implementation, dissemination and sustainability of science-based asthma care. [Learn more.](#)

### ALLIANCE TO REDUCE DISPARITIES IN DIABETES

With funding from our company's Foundation, Alliance program partners worked to decrease disparities in diabetes outcomes and improve the quality of healthcare for underserved adults living with or at risk for diabetes in five communities in the U.S.: Camden, New Jersey; Chicago, Illinois; Dallas, Texas; Memphis, Tennessee; and Wind River Reservation, Wyoming. [Learn more.](#)

# INFECTIOUS DISEASES

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## AFRICAN COMPREHENSIVE HIV/AIDS PARTNERSHIPS (ACHAP)

In 2000, together with our company's Foundation, The Bill & Melinda Gates Foundation established the African Comprehensive HIV/AIDS Partnerships to support Botswana's national HIV/AIDS strategy for preventing new HIV infections and reducing morbidity and mortality associated with HIV/AIDS. The comprehensive approach includes prevention, treatment, care and support.

## CHINA-MSD HIV/AIDS PARTNERSHIP (C-MAP)

This partnership between our company's Foundation and China's Ministry of Health is focused on strengthening integrated HIV treatment capacity in Sichuan Province's Liangshan Prefecture, Chongqing Municipality and Fujian Province. C-MAP aims to improve the quality of HIV/AIDS management and treatment services as well as expand overall treatment coverage.

## HIV CARE COLLABORATIVE

To help improve HIV care in the U.S., our company's Foundation established the initiative HIV Care Collaborative for Underserved Populations in the U.S. This initiative supports the efforts of local health departments in Atlanta, Georgia; Houston, Texas; and Philadelphia, Pennsylvania to connect more people living with HIV to the care and treatment they need to stay healthy.

## POPULATION SERVICES INTERNATIONAL (PSI)—HCV PREVENTION AND CAPACITY-BUILDING PROGRAM IN VIETNAM

With a three-year (2012–2014), \$650,000 grant from our company, PSI has been implementing a program in Vietnam to strengthen capacity in hepatitis C (HCV) prevention across multiple healthcare sectors. This program aims to improve access to HCV-prevention information and education among at-risk populations to help motivate the adoption of HCV-preventive behaviors. Through advocacy and capacity-building efforts, this program also aims to raise awareness and build support for the expansion and integration of HCV-prevention services into national public health programming. To date, PSI has reached more than 10,000 at-risk individuals with HCV-prevention education and information through a series of outreach events and face-to-face communications.

During 2014, PSI trained 112 outreach workers from Hanoi and Thai Nguyen provinces to integrate prevention messaging into outreach efforts, including development of a new HCV-prevention interpersonal communication tool to address common myths and misperceptions about HCV and HIV risks. Additionally, PSI trained 166 new HIV service providers to integrate HCV-prevention counseling, and referral for diagnosis and treatment, into routine HIV services delivery in three provinces (Thai Nguyen, HCMC & Nighe An).

PSI also implemented versions of community events designed to reach at-risk individuals. One such innovation was the very successful "haircut days." The haircut days were designed to attract and engage members of at-risk communities by offering free haircuts while delivering HCV-prevention counseling. Data collected before and after the haircut-day events revealed a substantial increase in the percentage of participants who perceive themselves to be at risk for HCV—a key factor identified as motivating HCV-prevention behaviors according to PSI's research conducted in 2013—from 14 percent prior to attending a haircut-day event to 100 percent post-participation in a haircut-day event. More than 1,200 individuals at risk for HCV were reached through the "haircut day" series.

# CAPACITY BUILDING

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## AFRICAN PROGRAMME FOR ONCHOCERCIASIS CONTROL (APOC)

APOC was established in 1995 by the World Health Organization (WHO) to carry out a sustainable strategy to control onchocerciasis (river blindness) in Africa using MECTIZAN® (ivermectin), our company's broad-spectrum antiparasitic medication that treats and prevents the spread of river blindness. In 2008, we committed \$25 million over eight years to the World Bank in support of APOC's continued development of country-led river-blindness efforts. In 2014, the APOC partnership supported treatment for an estimated 100 million people. In the coming years this number is expected to increase as the WHO and other partners pursue a strategy to eliminate onchocerciasis transmission using MECTIZAN, signaling a shift from a control strategy to an elimination strategy that will require broader treatment coverage.

While APOC developed the Community Directed Treatment with Ivermectin (CDTI) system to distribute and administer MECTIZAN, the delivery infrastructure established by this program is also being used to deliver other health interventions including vitamin A, cataract identification, bed nets, immunizations and more. The government of Nigeria was the first to announce national guidelines in February 2014 to integrate the distribution of bed nets and the distribution of MECTIZAN.

APOC is scheduled to close at the end of 2015, and our company and other stakeholders are working together to design a new program that will build on the foundation of APOC while recognizing new opportunities for disease control and elimination. Recent years have seen wider efforts to integrate Neglected Tropical Disease (NTD) programs, and resources such as the WHO NTD Roadmap and the London Declaration on NTDs—of which our company is a signatory—are helping to inform that process.

[Learn more about APOC.](#)

[Learn more about the MECTIZAN Donation Program.](#)

## THE MANAGEMENT AND LEADERSHIP ACADEMY OF THE BROADREACH INSTITUTE FOR TRAINING AND EDUCATION (BRITE)

With a \$4 million commitment from our company's Foundation, the BroadReach Institute for Training and Education (BRITE) implemented its Management and Leadership Academy (MLA) program in Zambia, which teaches critical management and leadership skills to healthcare professionals in order to build and strengthen the capacity of their local health systems. This program helped equip healthcare workers with the knowledge and skills to lead, own and, ultimately, transform the delivery of healthcare in their own countries. MLA teaches "results-based" management, focusing on solving current challenges by combining on-site workshops with case studies and extensive mentoring of program participants.

BRITE worked with Abt Associates in implementing this MLA program and received additional support under the USAID-funded Zambia Integrated Systems Strengthening Program (ZISSP). BRITE and ZISSP worked in close partnership with the Ministry of Health and the National Institute of Public Administration (NIPA)<sup>1</sup> in Zambia to support the ministry's ongoing efforts to develop management and leadership capacity at different levels of the health system.

Through the MLA program, BRITE and its partners conducted training for healthcare professionals in all 10 provinces across 27 target districts of Zambia. Since the launch of the program in 2011, the MLA has enrolled a total of 767 participants from all levels of the health system. As of December 2014, 669 have met USAID standards for management and leadership training, and 464 of these have met the requirements for a NIPA higher diploma in Management and Leadership, exceeding the USAID training target of 520 by 28.6 percent. The MLA certificate and, in particular, the NIPA Diploma, is an accredited health professional qualification that counts toward promotion within the civil service.

- During 2014, BRITE assessed the effectiveness and impact of MLA training on health workers' management and leadership knowledge, skills and practices. Below are several key findings from the program evaluation: MLA participants' management knowledge scores increased on average by almost 38 percent; management and leadership self-confidence rose by approximately 20 percent.
- Clinical data from two MLA case study sites (supported by stakeholder testimonials) registered significantly higher numbers of institutional deliveries—an important indicator of improved maternal and child health. Increased facility

births appeared to be correlated with MLA trainings.

BRITE has worked to integrate lessons learned through program experience and evaluation into specific MLA program improvements. For example, from 2011–2014, BRITE was able to increase MLA participant retention rates from 69 percent to 98 percent—largely by shortening course duration and achieving NIPA accreditation. In the coming year, BRITE will focus on helping ensure MLA programmatic sustainability by:

- Training approximately 80 “Master Trainers” from the ministries of health so that the government can provide MLA training to public health workers
- Working with NIPA to provide MLA in its general course offering in the fall of 2015

## ENGENDERHEALTH—MOBILE OUTREACH PROGRAM

With a three-year (2012-2014) grant from the Merck Foundation, a private, U.S.-based Foundation, **EngenderHealth** is working to build the capacity of health workers and implement mobile outreach services in order to increase the availability and accessibility of effective family planning and reproductive health services among underserved, rural populations in Ethiopia. This program helps improve maternal and child health outcomes in 15 remote districts in three regions of Ethiopia: Amhara; Oromia; and the Southern Nations, Nationalities and People’s Region (SNNP).

In each region, EngenderHealth works in close collaboration with Ministry of Health (MoH) partners to strengthen the capacity of health program managers and service providers. These capacity-building efforts facilitate the introduction and sustainability of high-quality family-planning services through regular outreach at decentralized health facilities that otherwise could not offer these services. EngenderHealth also works with selected community-based organizations in each of the three regions to conduct trainings for community-level health providers and volunteer “health agents.” The trainings help equip community health providers and volunteers to provide information and counseling on effective family planning through peer-group discussions.

In 2014, 52 service providers from mobile outreach facilities received training to strengthen their counseling skills as well as their provision of family planning services. An additional 78 health extension workers (community-level providers) received training on effective family planning methods, counseling skills, referrals and client follow-up. During 2014, the Mobile Outreach Program provided family planning services to more than 18,000 clients and disseminated information to approximately 195,000 married women of reproductive age and married men residing in some of the most remote districts in Ethiopia.

EngenderHealth is now focused on completing the end-of-project evaluation and facilitating a smooth transition of the program to the MoH. Efforts are underway to promote full government “ownership” of the mobile outreach program to ensure sustainability of the training and medical supplies. Final program results will be available later in the fall of 2015.

## THE COMMUNITY HEALTH WORKER TRAINING PROGRAM OF THE EARTH INSTITUTE’S MILLENNIUM VILLAGES PROJECT

From 2009 to 2013, with the support of almost \$2 million from our company’s Foundation, the Earth Institute at Columbia University conducted a community health worker (CHW) training program to strengthen community health services for more than 400,000 people in 10 African countries, as part of the *Millennium Villages Project (MVP)*. The initiative advanced the development of a professional cadre of CHWs to fill a critical gap in the delivery of primary healthcare for rural communities throughout Africa.

The program helped improve access to health services by developing a network of community health workers that are skilled, well-trained, properly remunerated, regularly supervised and fully integrated into their countries’ healthcare systems. Over the course of the five-year program, MVP trained approximately 1,500 CHWs, including more than 100 CHW supervisors, who are overseeing nearly 500,000 people across 14 Millennium Villages. Additionally, the MVP-designed mobile health platform, *CommCare*, is being used to monitor performance of the CHWs. Compiled in a monthly performance report, these “real-time” data allow managers and program advisors to identify areas for improvement, such as the tracking of vital statistics or quality improvement of case management, and to implement targeted CHW trainings. These data also facilitate the assessment of individual CHW performance, allowing managers to incentivize or promote the highest-performing CHWs and to target performance-improvement efforts for lower-performing CHWs. In 2014, the CHW program implemented a routine monthly distribution of “CHW Program Report Cards,” which are distributed to all management teams in the Millennium Villages.

The Millennium Villages team has been approached by a number of governments for assistance with the adaptation and scale-up of the CHW program. For example, in early 2014, the Nigerian government launched a National CHW Scale-Up initiative in Abuja, based on the MVP's advisory work for several years with the government of Nigeria. The MVP program also helped lay the foundation for a major campaign to expand CHWs and their efforts to help countries achieve the health-related MDGs. In 2013, the Earth Institute launched the *One Million Community Health Workers Campaign* to expand and accelerate CHW programs in sub-Saharan Africa.

## **SAVE THE CHILDREN FEDERATION, INC.—FRONTLINE HEALTH WORKERS PROGRAM**

With a \$5 million grant from our company's Foundation, *Save the Children* is implementing frontline health worker training programs in Pakistan and Nepal. When properly trained and supported, community health workers, midwives and health assistants can help reduce the rates of maternal and infant mortality caused by preventable and treatable diseases, such as pneumonia, malaria and diarrhea, and from complications of pregnancy and birth. Funding also provides support for *Save the Children's* Newborn and Child Campaign.

In Pakistan, this project is reaching seven remote and underserved districts (Shangla, Battagram, Haripur, Malakand, Swabi, Buner and Charsadda) of the Khyber Pakhtunkhwa (KPK) Province to increase access to quality, lifesaving maternal, newborn and child health services. This program also supports the National Maternal, Newborn and Child Health program of the Pakistan Ministry of Health. During 2014, 2,561 frontline health workers completed their training on Community Case Management (CCM) of pneumonia, diarrhea and malaria. Additionally, the project completed Trainings of Trainers sessions for 40 Master Trainers and 132 trainings of Lady Health Workers (LHWs). In the Battagram District, *Save the Children*, in collaboration with the Pakistan Department of Education, completed the planning and implementation of the Accelerated Education Program, which helps women reach the eighth-grade education level so that they can be eligible for training as Lady Health Workers. Sixteen (16) Accelerated Education Program centers (covering grades six to eight) were established. Additionally, 60 LHW candidates (who had already passed grade eight) began the 15-month training program, which was carried out in collaboration with the National Lady Health Worker program.

In Nepal, this program focuses on increasing the quality and coverage of maternal, newborn and child health services by training frontline health workers in two districts (Baitadi and Bajura) of the Far-Western Region. The project also focuses on strengthening national-level activities to improve the quality of pre-service frontline health worker training on maternal, newborn and child health at Nepal's health institutes. To date, 944 frontline health workers, traditional healers, Female Community Health Volunteers (FCHVs) and other stakeholders have been trained for the Community-Based Newborn Care (CBNC) Program in the Bajura District.

In partnership with the Ministry of Health and Population, the National Health Training Center and Bheri Zonal Hospital, the project provided 60-day Skilled Birth Attendant (SBA) trainings for nursing staff focused on safe delivery and newborn care. The purpose of the training is to ensure availability, access and utilization of skilled care for every birth. Following the training, the percentage of deliveries conducted by SBAs in Bajura increased from 39 percent in 2012–2013 to 47 percent in 2013–2014.

During 2014, *Save the Children* continued to advance its advocacy efforts through the Maternal, Newborn and Child Survival Campaign. To that end, *Save the Children* launched the *Save the Children Action Network (SCAN)*. SCAN is an organization dedicated to mobilizing Americans around ending preventable child death within a generation.

## **AMERICARES—HEALTH WORKFORCE SAFETY**

In 2014, we donated \$25,000 and 5,400 doses of RECOMBIVAX<sup>®</sup> HB to AmeriCares to help protect health workers and medical students in Tanzania's Lake Zone against hepatitis B infection. The goals of the program include: increasing hepatitis B coverage to 90 percent among health workers and students; collaboration with the Ministry of Health and Social Welfare in their objective to increase hepatitis B vaccination coverage among high-risk health workers nationally and documenting program outcomes including: workplace satisfaction; effective infection prevention and control protocols; effective reporting of needle stick injuries (and a decline in numbers); and best practices in waste segregation. Between 1,600 and 1,800 staff and medical students will be vaccinated (assuming a baseline will reveal an initial HBV rate of 10–20 percent), as well as a percentage of new hires throughout the program implementation, which is planned to run from January–June 2015. The program builds upon the successes of the Health Workforce Safety Program conducted from 2009–2012 by AmeriCares (also with support from our company) at the Bugando Medical Centre in Tanzania.

<sup>1</sup> NIPA is the national academic institution whose mandate is to build capacity in the Zambian civil service.

## OTHER GRANTS

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### CARE USA—BRIDGING HEALTH AND EDUCATION PROGRAMS FOR CHILDREN

In its fourth year of funding from our company, CARE USA is continuing its collaboration with Save the Children to serve young children and their families in resource-poor areas through the “5x5 Model” for early childhood development and care (ECDC), which addresses child development, health, nutrition, child protection and economic empowerment. As part of this initiative, CARE created *The Essential Package*, which provides a framework and specific tools to address the needs of vulnerable young children from conception through primary school. The ECDC project has adapted *Essential Package* materials and developed culturally relevant intervention packages that are being implemented in Chhattisgarh, India; El Salvador; and Honduras.

To date, these interventions have reached 12,000 children between the ages of 0–6 years and 16,000 caregivers (including pregnant and lactating mothers) in India. In El Salvador and Honduras, 1,058 children are participating in Early Childhood Care and Development community strategies (e.g., parenting circles) and 361,721 children are being evaluated with developmental screening measures as part of a more holistic approach to Integrated Management of Child Illness (IMCI).

Both CARE and Save the Children have worked closely with communities and governments to build capacity and strengthen their approach to integrated care. For example, in India, CARE has participated in discussions to formulate a policy framework at both the national and state levels for early childhood development and care. Last fall, a national ECDC policy was introduced, and CARE, along with other agencies, is working closely with the government of India to promote successful implementation of this policy. The government has identified preschool education as an important component, with an increased focus on early stimulation during home visits, as well as a focus on promoting optimal nutrition and health. As a result of Save the Children’s work in El Salvador, *The Essential Package* strategy has been included in the national plan to reduce neonatal morbidity and mortality, and the developmental screening tool for children under 5 has been implemented at a national level by the Ministry of Health.

### THE CHILDREN’S INN AT NIH

Our company has provided \$3.7 million through a public-private partnership for the initial construction of The Children’s Inn at the National Institutes of Health (NIH), the world’s premier biomedical research center, in Bethesda, Maryland. The Inn opened in 1990 and, since then, seriously ill children involved in treatment at the NIH have had a place to call home.

Most children who come to the NIH for treatment are facing life-threatening illnesses that resist conventional therapy. Since its opening, The Inn has hosted more than 11,500 children from all over the U.S. and from more than 80 other countries. Our company’s Foundation helps cover The Inn’s operating costs, and also provided a grant of \$3.7 million to build a 22-room addition, completed in 2004, increasing The Inn’s capacity to 59 rooms. Our employees also have generously supported The Inn through personal contributions as part of our company’s Partnership for Giving (P4G) program.

Our company’s Foundation pledged \$5 million over five years (2009–2013) to support the establishment of a transitional home adjacent to the NIH campus, called The Woodmont House. This home can accommodate up to five families at a time whose children are no longer in the acute phases of illness yet still require treatment at the NIH Clinical Center. Families stay free of charge and may participate in all of The Inn’s activities and programs. To date, The Woodmont House has served nearly 190 children and their families from 37 U.S. states and Puerto Rico, and nine other countries.

In 2014, our company’s Foundation pledged an additional \$5 million over five years (2014–2018) to help support the operations of The Woodmont House as well as a new pilot “isolation” project that is under way at The Woodmont House and The Inn. This pilot project was designed to accommodate families with children who must be isolated from the general pediatric population to avoid potential infections that would severely affect children with compromised immune systems. The “Isolate Inn” pilot program allowed The Woodmont House to accommodate four isolation patients and their families in 2014. Given the successful pilot, The Children’s Inn will continue the “Isolate Inn” program for patients on contact isolation.



# COMMUNITY

## MAIN

**We aspire to have a positive impact on the communities in which we operate around the world.**

Our community involvement programs reflect the priorities that our company shares with local stakeholders. We provide financial support and share the expertise of our employees through programs that focus on solving critical health and social issues in communities where we have a presence. In a variety of ways, these programs help address local community needs and enable our employees to contribute to the well-being of their communities.

Learn more about our economic impact on communities.

GRI G4-EC7

GRI G4-EC8

Community Giving Summary	2009	2010	2011	2012	2013	2014
	Contributions to Community Programs (US\$)					
Art	239,000	187,000	113,000	612,000	412,500	729,325
Civic	116,000	59,000	103,000	1,358,000	924,448	1,350,950
Education	293,000	462,000	614,000	404,000	630,644	923,465
Environment	228,000	52,000	158,000	125,000	157,977	148,665
Human Health Services	1,516,000	1,843,000	1,677,000	867,000	1,794,977	1,941,185

**As of 2016, we have decided to phase out support of STEM education as a giving priority to more closely align our charitable giving efforts with our Corporate Responsibility approach and our company’s mission. As a result, we will not be making any new philanthropic investments in STEM education. This strategic alignment will enable us to focus our resources, including our philanthropic giving, on addressing the world’s most pressing healthcare needs.**

## NEIGHBOR OF CHOICE

**Our signature Neighbor of Choice (NOC) community program supports the work of local nonprofit organizations that strive to improve the quality of life of the residents in communities where we have a presence.**

**GRI G4-SO1**

Established in the 1990s, the NOC program helps to build relationships of trust and support with local nonprofit organizations and residents of the communities in which we operate by responding to needs identified by the communities themselves. We take seriously the shared responsibility of helping to improve the quality of life of neighbors in need.

Giving Totals	2009	2010	2011	2012	2013	2014
Amount contributed (US\$M) <sup>1</sup>	3.2	3.5	2.7	2.8	2.3	2.2
Number of grants	345	282	112	170	181	126

<sup>1</sup> For 2011 to 2014, data include funding provided through the Office of Corporate Responsibility and our company's Foundation. Additional funding is provided through local U.S. sites and our company sites outside the United States that we do not track centrally.

In 2014, our company invited nonprofit organizations located in 19 communities in which we have a major presence to apply for support. In accordance with NOC program guidelines, a total of \$2.2 million in grants was awarded to 126 nonprofits in support of a wide range of educational, environmental and health services initiatives.

Below are examples of projects supported through the NOC grants program.

**UNITED STATES**

**Health**

In 2014, we partnered with the Cancer Support Community of Central New Jersey (CSC) to fund the *Cancer Transitions Program*, a six-week program designed to help patients achieve successful transition from active cancer treatment to post-treatment life. The program was implemented in six New Jersey counties: Somerset, Hunterdon, Union, Morris, Middlesex and Mercer, and included 15 to 18 cancer survivors participating in each session. CSC collected data to assess whether the six-week program had a positive impact on the physical and mental health of cancer survivors. Preliminary data have shown that program participants experienced positive changes following the six-week intervention to improve health-related quality of life and promote lifestyle change. These changes were still measurable at three to six months after participants completed the program. Survivors reported a significant decrease in stress as well as a significant increase in physical activity.

The *Fit for Life* program, funded by our company's site in Nebraska, enabled the Intercultural Senior Center to provide fitness equipment designed for a growing and diverse population of elderly residents. During 2014, enrollment in the program increased by 60 percent. Further, the Center has found that the *Fit for Life* exercise program helps keep the elderly actively engaged, both physically and mentally.



## Social Services

Our company's site in Carolina, Puerto Rico, partnered with the University of Puerto Rico to develop the Puerto Rico Agriculture Extension Service (PRAES) program to establish a *Local Strategic Prevention Plan* to prevent the use and abuse of alcohol, tobacco and other drugs among young people. In 2014, PRAES provided training and developed educational materials for use by educators and community advocates. Preliminary data suggest that the PRAES program has increased students' knowledge and contributed to the well-being of parents, teachers and students in the community.

Our partnership with Manna on Main in North Wales, Pennsylvania, continues to be one of the biggest success stories of the Neighbor of Choice (NOC) program and serves as an example of a partnership that includes both financial resources and employee support. In 2014, Manna served more than 22,200 meals to needy families in Montgomery County and started a child food security initiative, with more than 230 of our employees volunteering throughout the year. The Manna partnership was one of 30 NOC grants that the Pennsylvania site made in 2014, creating strong community relationships and building future collaborations.

A grant to the Boys & Girls Clubs of Harrisonburg and Rockingham County (BGCHR) in Virginia enabled the development of an after-school program for low-income children. The grant project—LEGO Robotics Program—enabled the purchase of the LEGO Education EV3 Robots, the software and the computers necessary to program the robots. BGCHR staff was equipped with lesson plans and training to effectively facilitate the club members' participation in the program.

## Education

Our partnership with Citizen Schools has been instrumental in scaling the Expanded Learning Time (ELT) initiative in Greater Boston. In 2014, our Research Laboratories (MRL) Volunteer Committee in Boston, MA, partnered with Citizen Schools to host an apprenticeship program at the site entitled "CSI: Boston," where our employees led middle-school students through the process of investigating a mock crime staged on the site through the use of science and deductive reasoning. Students analyzed footprints, fingerprints, animal hairs and even the DNA of the alleged perpetrator. They presented their findings (and exposed the criminal!) to an auditorium full of our company's employees. In the winter of 2015, employees will participate in the Citizen Schools "6 Degrees Networking Event," where 8th grade students in Citizen Schools will learn to navigate career pathways and learn important networking skills.

Our Animal Health Site in Nebraska has supported the Omaha Henry Doorly Zoo for many years. The 2014 grant to the Omaha Zoo Foundation in Nebraska enabled the zoo to expand and improve its comprehensive educational program by designing an innovative curriculum for preschool-aged children. The preschool curriculum aims to help close the achievement gap between children living at or below the poverty level and their middle-class peers. The partnership with the Omaha Zoo has yielded substantial benefits for the community and for our employees. In addition to offering numerous employee volunteer opportunities, the zoo ensured employees were aware of the progress of the preschool project and invited our company to the ribbon cutting. The zoo also is setting national standards for the integration of classroom-based learning, exploration and conservation.

Our partnership with the Kenan Fellows program is designed to advance leadership, curriculum design and inquiry-based instructional skills of teachers in North Carolina. A 2014 grant enabled the creation of a Fellows Partnership, which included support for five one-year professional development fellowship experiences for teachers working in Durham, North Carolina. Fellows interned for more than 200 hours in research labs. Through this experience, they participated in hands-on, innovative work that allowed them to actively engage in cutting-edge science as well as design activities that directly connect grade-specific learning standards to the work inside of the research labs. Additionally, the Fellows presented their work and curriculum at various conferences across the state. By the end of the 2014–2015 school year, Fellows will have shared their work with at least 200 educators statewide. Fellows have also reflected on their experiences with our employees. As one Fellow stated, “Your support has changed the way I teach ... and it is changing the way my students not only learn, but how they see themselves as creators of scientific research.”

**In 2014, we offered the Neighbor of Choice program at MSD sites in the following countries: France, Ireland, Italy, Mexico, the Netherlands, Singapore and the U.K. Below are examples of projects that were supported at various locations.**

## ENGLAND

MSD United Kingdom (U.K.) partnered with FareShare to tackle food insecurity in the region. This partnership aimed to increase the volume of donated food and to redirect any surplus to nonprofits that support vulnerable people. Since the 2014 grant award, two of the largest food companies in the U.K. have begun to donate their surplus food to FareShare. This action led to a substantial increase in the amount of food collected and enabled expansion of the service to additional nonprofits, including 20 new community projects. As a result, FareShare North East distributed more food and covered a larger geographic area, stretching from Northumberland in the North to Cleveland in the South.

Michael Shields, said “The support of Merck & Co., Inc., Kenilworth, N.J., USA has made a real difference to thousands of disadvantaged people. The NOC Award has enabled FareShare to reach more vulnerable individuals with our food and also enhance the variety and quality of food provided.”  
*Michael Shields, General Manager—Changing Lives, FareShare North East*

## IRELAND

The MSD team in Ballydine, Ireland, partnered with Newcastle National School to develop a sensory garden for children with developmental delays. Prior to the partnership, the school did not have a recreational space for the children, limiting their ability to participate in social and learning activities. The sensory garden was designed and developed to provide:

- An area to relieve stress, frustration and hyperactivity in children
- A space for open-air theatre, drama class performance, school assemblies/celebrations
- Educational space for science, math, language and horticultural learning

In addition to the grant support, the MSD team in Ballydine volunteered to help build the recreational space at the school. MSD employees created paths and paving to make the space more usable for children. MSD employees also created an extension to the vegetable garden where children can grow their own vegetables. Ms. Claire Moloney, school principal, commented on the impact that the MSD team in Ballydine has had on the school and the community.

*“The garden continues to enhance the school and the village. A sense of pride now exists. In 2013 the school won the ‘Tidiest School in Tipperary’ and in December 2014 we were awarded the ‘Most Consistent Tidiest School in Tipperary’. We are extremely grateful to MSD for affording us the opportunity to do something so positive in both our school and local community.”*



Pictured: Niall Hassett, MSD; Mary Stafford (deputy principal/green school coordinator); Claire Moloney (principal); Greta Hayes (horticulturist); Joan O'Dwyer (chairperson, Board of Management); David O'Connell, general manager, MSD.

## MEXICO

In 2014, MSD Mexico partnered with Casa de la Amistad para Niños con Cáncer, A.C., an organization dedicated to supporting children with cancer. This partnership supported the implementation of a nutritional program to strengthen the health of children receiving cancer treatment. The project, “Healthy Eating and Psychomotor Stimulation through Physical Education for Poor Children and Young People with Cancer” has been supported by our company for two years. Program results have demonstrated improvements in the children’s health, with many maintaining their weight and reporting greater strength and energy.

MSD Mexico also partnered with The Xochimilco Ecological Park to create sustainable strategies for the maintenance of Lake Huetzalin at the Ecological Park of Xochimilco. The remediation of Lake Huetzalin’s water provided the following direct and indirect benefits:

- Removal of contaminating plants, such as the water lily (*Eichhornia crassipes*)

- Creation of floating wetlands-chinampas as a means to control the excess of water lily and its intensive reproduction, creating a natural ornamental element for the lake
- Conservation of native wildlife and migrant species
- Creation of feeding niches for the lake, which helped preserve habitats for endangered species such as the ajolote
- Enhancement of the circulation of water toward the channel system of the chinampa zone in Xochimilco

The Xochimilco project has raised MSD employees' awareness about the importance of the environment and helped demonstrate the company's commitment to being a responsible corporate citizen.

## SINGAPORE

MSD Singapore partnered with the Diabetic Society of Singapore (DSS) to provide diabetes awareness, education and counseling to people with diabetes, their family members and the public. DSS believes that through knowledge and discipline, people living with diabetes will be better equipped to achieve a healthy and productive life. MSD's support of this project enabled DSS to implement 10 diabetes treatment programs reaching 181 nursing staff. DSS also convened various public forums for people living with diabetes, including community health talks, cooking demonstrations and monthly national walks reaching more than 400 community residents.

# DISASTER RELIEF

## Our company provides disaster-relief assistance during major disasters and supports efforts in disaster preparedness and recovery.

Our global headquarters serve as the central clearinghouse for information regarding our companywide response to major disasters, and makes decisions related to the company's donations of cash and/or medicines and vaccines in a disaster situation.

We follow the long-standing recommendation by the Office of U.S. Foreign Disaster Assistance that a company's response is made on the basis of a firsthand assessment of need by local authorities and/or a designated relief agency. Where appropriate, and in consultation with local management, our company may donate pharmaceuticals and vaccines through the disaster and emergency relief component of our company's *Medical Outreach Program*. In major disaster situations, donations of our medicines may be made directly by our company's local subsidiary or manufacturing facility.

Our goals in providing disaster relief are to:

- Respond in a timely and appropriate manner
- Meet the needs of relief agencies and affected communities
- Provide consistent and coordinated companywide relief efforts
- Facilitate communication and dissemination of information among employees and key external groups, customers, neighbors and relief agencies
- Evaluate continued assistance through recovery stages
- Evaluate the need for, and feasibility of, providing support for important disaster preparedness efforts

	2009	2010	2011	2012	2013	2014
Disaster relief efforts assisted	7	6	13	6	10	10
Total giving value of disaster relief contributions (cash and products, US\$M) <sup>1</sup>	1.5	24.0	13.8	2.7	3.3	10.0

<sup>1</sup> 2012 figure includes products that were donated in 2012, but were used for disaster relief in 2013.

## RESPONSE TO THE EBOLA VIRUS DISEASE OUTBREAK

In addition to the agreement with NewLink Genetics to research, develop, manufacture and distribute NewLink's investigational Ebola vaccine candidate, our company has contributed both financial and product donations in support of Ebola relief efforts. We were among the first donors to provide a cash contribution to Direct Relief to support the transport of

medical supplies to the region, and the only company to provide funding to Project HOPE to conduct a Phase 1 assessment in Sierra Leone to determine a specific strategy for stopping the spread of the Ebola virus and preventing future outbreaks. In addition to the financial support, we sent two Infectious Disease employees who specialize in infection control to join the team of specialists with Project HOPE in conducting an eight-day rapid assessment and relief effort in Sierra Leone. Our company also partnered with the International Medical Corps to build, staff and provide training on effective Ebola isolation units and referral systems in the Bong County's Phebe and C.B. Dunbar Hospitals in Liberia. Finally, we have made product donations of PRIMAXIN® and PROVENTIL®, and included AVELOX® and SINGULAIR® in Medical Mission Packs that were distributed to the region by MAP International to support the overall health of the population in the affected regions. We continue to evaluate cash contributions and product donation opportunities to support Ebola relief and recovery efforts and are prepared to make additional commitments.

## CONTINUING SUPPORT FOR TYPHOON HAIYAN RELIEF EFFORTS (PHILIPPINES)

In collaboration with colleagues in MSD Philippines, our company responded quickly to the crisis, simultaneously confirming the safety of MSD employees in the Philippines and providing direct support (valued at more than \$2 million) to relief agencies working to address the immediate needs of the Filipino people.

In 2014, we continued to support recovery efforts by donating PNEUMOVAX® and MMRII® vaccine to Project HOPE to help protect those affected by the disaster from disease.

## CONTINUING SUPPORT FOR HURRICANE SANDY RECOVERY EFFORTS (U.S.)

To support the immediate relief efforts as a result of Hurricane Sandy, our company made cash and product donations that exceeded \$1.3 million to nonprofits and first responders. In the two years following Hurricane Sandy, affected communities continued to struggle in managing immediate relief and long-term rebuilding efforts. Many of these towns lacked the capacity to simultaneously manage recovery issues and take a long-term view regarding policies and investments that are needed to protect the community in the future. To address this critical need, our company's Foundation partnered with New Jersey Future to support a local recovery planning manager to focus on local-level planning and rebuilding. In 2014, with funding coming to an end in the communities of Sea Bright and the Highlands, the grant catalyzed funding in additional communities and institutionalized disaster preparations in both communities.

## AMERICAN RED CROSS

Our company is a long-standing member of the American Red Cross Annual Disaster Giving Program (ADGP). Our company's Foundation has pledged \$2.4 million over four years (2014–2018) to support the ADGP and to help ensure that the Red Cross can be on the scene of a disaster as soon as possible. When disasters occur, the Red Cross is there to provide essential relief services for those in need. Our support helps the Red Cross deliver assistance immediately across affected areas in the U.S. and globally, working in partnership with local agencies.

## OTHER GRANTS

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### NEW JERSEY PERFORMING ARTS CENTER (NJ PAC)

NJPAC is the home of one of the nation's largest and most comprehensive arts education programs. Each year it provides exposure and training to tens of thousands of young people throughout New Jersey who are interested in the performing arts through formal study, experiential learning and public performance. NJPAC has served more than 1 million children, families and educators since its inception in 1992.

We continued our support in 2014 with the renewal of a five-year \$1 million grant to help NJPAC offer a wide range of programs for young people: in-school and after-school performances, in-school residency programs, and arts training and

scholarships for children throughout the Garden State.

## **KIMMEL CENTER FOR THE PERFORMING ARTS**

We are also a supporter of the arts in Philadelphia. The Kimmel Center operates a world-class performing arts center that engages and serves a broad audience throughout Greater Philadelphia. The center, composed of three facilities with a total of 8,000 seats, attracts an annual audience of nearly 1 million with almost 200,000 coming from outside of Philadelphia.

With our support, the Kimmel Center works to “transform lives daily through the arts” across a broad spectrum of artistic disciplines and venues that appeal to a diverse Philadelphia community.

## **NEW JERSEY SYMPHONY ORCHESTRA (NJSO)**

Our company's Foundation continued its support of the New Jersey Symphony Orchestra in 2014 with a multiyear grant to nurture young minds, inspire creativity and promote lifelong learning through the experience of live music. Our company support fuels the *NJSO Broadcast Series*, which provides entertainment and expands access to the arts for a national audience. In total, the Broadcast Series has reached more than 572,000 listeners nationally. NJSO education and engagement initiatives through the Broadcast Series serve more than 40,000 young people and their families from largely underserved communities each season throughout New Jersey.

# EDUCATION

## MAIN

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### **Fostering the next generation of scientific leaders is a key part of our company's overall commitment to science education.**

We have a long history of promoting science education at the precollege, undergraduate, graduate and postdoctoral levels, and we have provided long-term support for programs that expand training capacity in the biomedical and health sciences. Our support continues through public-private partnerships with local, regional and national organizations that are committed to evidence-based approaches to learning.

Several years ago, our company's Foundation narrowed its focus in STEM (science, technology, engineering, mathematics) education to support efforts that enhance the quality of STEM education at the graduate and postgraduate levels, and that contribute to advancing women and minorities in the sciences. By the end of 2014, the Foundation concluded its K–12 science education programs, including the Merck Institute for Science Education (MISE), a U.S.-based initiative, having successfully completed all grant and partnership commitments.

**As of 2016, we have decided to phase out support of STEM education as a giving priority to more closely align our charitable giving efforts with our Corporate Responsibility approach and our company's mission. As a result, we will not be making any new philanthropic investments in STEM education. This strategic alignment will enable us to focus our resources, including our philanthropic giving, on addressing the world's most pressing healthcare needs.**

## K–12

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### **NATIONAL ACADEMY OF SCIENCES**

The Foundation awarded a three-year (2012–2014), \$1 million grant to the National Academy of Sciences to support a consensus study titled *Strengthening K–12 Science Education through a Teacher Learning Continuum*. This study brought together experts to review and synthesize available research on how to provide coherent support for elementary, middle- and high-school teachers across their careers. The expert committee will outline a coherent professional-growth continuum for

science teachers that is integrated with and supported by the school-, district- and state-level contexts in which teachers work. The final report will be published in June 2015.

# UNDERGRADUATE

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## **The *Ciencia* (Science) Hispanic Scholars Program, a U.S.-based partnership with the National Alliance for Hispanic Health (the Alliance) is dedicated to supporting a new generation of Hispanic scientists.**

Providing scholarships, summer research experiences and the support of an extraordinary network of mentors, the effort is expanding Hispanic student access to higher education and careers in science, technology, engineering and mathematics (STEM). Launched in 2008 with a \$4 million commitment from our company's Foundation, *Ciencia* is ensuring that Hispanic students with promise for study in the STEM fields are receiving the support they need to realize their dreams.

Between 2009 and 2013, 10 *Ciencia* Scholars were selected each year from high schools in Brownsville, Texas; Elizabeth, New Jersey; and Los Angeles, California. Selected Scholars receive support of up to \$20,000 in scholarships over their four years of college, up to \$22,500 to support summer research opportunities, and the services of the mentors from the Alliance *Ciencia* network. A total of 50 *Ciencia* Scholars have been supported since the inception of the program. During 2014, the second cohort of *Ciencia* Scholars graduated, bringing the number of *Ciencia* alumni to 18.

*Ciencia* Scholars are connected by online networks and attend an annual symposium conducted in partnership with the American Association for the Advancement of Science (AAAS), the Food and Drug Administration (FDA), the Howard Hughes Medical Institute (HHMI), the National Institutes of Health (NIH) and the National Aeronautics and Space Administration (NASA), among other partners. The symposium offers the Scholars the opportunity to learn new skills, share their research and support each other's personal and professional paths.

Our partnership with NAHH also awards 25 scholarships each year to Hispanic college students with a declared STEM major. The *Ciencia* National Award provided a one-time, \$2,000 scholarship to help students complete their education. To date, a total of 125 *Ciencia* National Awards have been supported. By preparing a new generation of scientists, *Ciencia* is helping secure a brighter future not only for these students, but for our nation and world.

The table below represents the demographic profile of the *Ciencia* Program award recipients:

Demographics	<i>Ciencia</i> Scholars	<i>Ciencia</i> National Scholarships
Female	52%	44%
Male	48%	56%
First generation in college	63%	76%

The Alliance is collaborating with Harvard University to conduct an external evaluation to assess the impact of the *Ciencia* Program. Data sources include surveys, focus groups and interviews with leaders of partner organizations, the *Ciencia* Scholars and the program manager. The results of the program evaluation will be published in the fall of 2015.

Of the two classes (or cohorts) of *Ciencia* Scholars that have graduated, 80 percent of participants were awarded a bachelor's degree in a STEM field. At a national level, only 16 percent of Hispanic students who begin college with the intention of majoring in a STEM field go on to graduate with a degree in a STEM field.<sup>1</sup> Among the Scholars who have graduated, about 56 percent have pursued professional careers in STEM fields. The remaining 44 percent of the Scholars who graduated are pursuing graduate and/or professional school programs, research fellowships and postbaccalaureate programs.

For more information on the National Alliance for Hispanic Health, [click here](#). For more information on the *Ciencia* Hispanic Scholars Program, [click here](#).

# GRADUATE/POSTGRADUATE

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## THE SCIENCE INITIATIVE WITH UNCF

African Americans currently hold fewer than 3.2 percent of all Ph.D.s in the U.S. in the biological sciences and chemistry.

To help address this disparity, we joined UNCF in 1995 to establish a groundbreaking program to support the Science Initiative with UNCF, a U.S.-based initiative. This groundbreaking program seeks to support the training and development of African American research scientists in the biological, chemical and engineering fields, and in so doing, to enhance economic competitiveness in the U.S.

Each year, the program provides scholarship and fellowship support to 37 outstanding African American students who are pursuing studies and careers in the biological and chemical sciences. Since its inception, our company's Foundation has committed a total of \$47 million to supporting the initiative.

The program's awards are made at the undergraduate, graduate and postdoctoral levels. The initiative is aimed at key transition points in education: undergraduate students entering their final academic year, graduate students who are midway through their dissertation research and postgraduate students entering their postdoctoral training. To date, our company has awarded more than 700 fellowships.

Awardees are selected through a national competition open to all eligible students at colleges and universities throughout the U.S. The awards provide financial support, hands-on training, mentoring relationships and institutional support to help the Fellows devote their attention to education. Undergraduate scholars also may receive paid summer internships at our company.

## MENTORING & NETWORKING WITH PAST FELLOWS

A key component of the program is the mentoring that Fellows receive from our scientists and from external scientists working in the life and physical sciences. Mentors share their expertise, and career advisers and colleagues help to ensure that the Fellows move seamlessly from one educational level to the next.

## IMPACT OF THE PROGRAM

Since its inception, the program supported the career development of African American students and postdoctoral fellows pursuing careers in the biomedical sciences. Through the program's support, Fellows are conducting research at some of the world's leading research institutions while developing peer-to-peer and professional networks.

Of the 60 undergraduate Fellows who have matriculated through the program, 72 percent have entered graduate school in Ph.D. or M.D. programs with a greater than 98 percent retention rate. In that same time period, 46 percent of graduate Fellows have completed their graduate studies. Within the same period, 11 of 30 postdoctoral Fellows have successfully transitioned into academic research positions in academia or industry.

	Our Investment in UNCF	1996–2014
Company and Foundation investment <sup>1</sup>		\$43.1M
	Degree Completion Rates of Fellows	
Undergraduate (B.A./B.S.)		100%
Ph.D.		99%
	Employment Outcomes of Graduate Fellows (Ph.D.s)	

Academic	75%
Business/industry	25%
Number of Fellows hired by our company (2002–2014)	18

<sup>1</sup> Represents total funding commitment (1996–2014).

## GRADUATE PROGRAM IN BIOTECHNOLOGY INNOVATION (PURDUE UNIVERSITY AND KILIMANJARO SCHOOL OF PHARMACY)

To help improve access to quality medicines in Africa, we partnered with the Kilimanjaro School of Pharmacy in Tanzania and Purdue University in Indiana to establish the first master’s degree program in Africa focused on building the knowledge and skills needed to develop and manufacture high-quality medicines.

Our company’s Foundation is supporting a partnership with Purdue University, the Kilimanjaro School of Pharmacy and the United Nations Industrial Development Organization (UNIDO) to fund a two-year pilot master of science degree program in biotechnology innovation and regulatory science. The program also includes our research scientists, who serve as faculty members to facilitate on-site instruction and virtual learning labs. The program has been identified by a number of regional African authorities as a key component of efforts to strengthen regional pharmaceutical manufacturing capabilities that are needed in the region.

In 2014, 41 graduate students, including 15 women, became the first cohort of master’s degree students admitted to the Biotechnology Innovation and Regulatory Science program at the Kilimanjaro School of Pharmacy and the Purdue University Graduate School. All 41 students were awarded scholarships from our company and attended a two-week live instructional session in September 2014. By the end of the fall semester, students submitted a proposal for their master’s degree projects, many of which have the potential for broader impacts, including installing a pharmacovigilance system in Kenya, installing a Quality Management System in the Ghana FDA and installing a quality system at the manufacturing facility at the Kilimanjaro School of Pharmacy. The 41 M.S. degree students are all on track to graduate with a master’s degree in the summer of 2016.

## PERFORMANCE

	MISE Summary	2009	2010	2011	2012	2013	2014
Our investment in MISE (US\$M) <sup>1</sup>		2.8	3.3	3.5	2.5	1.4	0.9
Student enrollment (NJ and PA MISE-supported school districts)		49,294	88,692	89,576	86,428	84,471	NA
Time spent teaching science at the elementary-school level (minutes/week)		121	149	159	179	179	NA
Teachers and principals attending workshops, including the Academy for Leadership in Science Instruction <sup>2</sup>		708	678	702	735	548	NA
Participants satisfied with the quality of professional development workshops		96%	95%	97%	94%	96%	NA
Principals reporting being prepared to support teachers implementing the NJ Core Curriculum Content Standards in Science (four NJ school districts; grades 6, 7 and 8) <sup>3</sup>		89%	86%	NR	86%	NR	NA
Grade 8 State Science Test Results: Percent proficient (NJ school districts) <sup>4</sup>		80%	80%	84%	88%	81%	NA
Grade 4 State Science Test results: Percent proficient (NJ school districts) <sup>4</sup>		61%	63%	73%	74%	64%	NA

<sup>1</sup> 2009 and 2010 data adjusted from previously reporting data for accuracy.

<sup>2</sup> Because MISE is winding down, graduating cohorts of the Academy are not being replaced.

<sup>3</sup> In 2012, the question asked whether “well-prepared.” In previous years, it asked whether “prepared.”

<sup>4</sup> In 2013, scores for both the 8th grade and 4th grade tests were lower across the state in 2013, with a more significant drop in scores for students with special needs.

NR: Data not reported. NA: Not applicable.

Our Giving

# FOUNDATION

**Our company’s Foundation (“the Foundation”)— established in 1957—is funded entirely by the company and is our company’s chief source of funding support for qualified nonprofit charitable organizations.**

Since its inception, the Foundation has contributed more than \$819 million to support initiatives that address important societal needs in a manner consistent with our company’s overall mission to help the world be well. The Foundation supports organizations and innovative programs that are aligned with our three focus areas: *health*, *education* and *community*. We also share the outcomes, lessons learned and best practices from our initiatives to contribute knowledge and help advance progress in these areas.

The Foundation’s strategic priorities aim to strengthen the impact of our giving while also aligning our programs with areas of global need in which we have substantial expertise and capability.

The following strategic priorities guide the Foundation’s program investments:

## HEALTH

We strive to improve healthcare quality and capacity as well as increase access to care for underserved populations in selected disease areas of global need and relevance to our company—noncommunicable or chronic conditions such as diabetes, cardiovascular disease and cancers; hepatitis C; and HIV/AIDS—through strategic collaborations and program investments. Key initiatives include:

- African Comprehensive HIV/AIDS Partnerships (ACHAP)
- Alliance to Reduce Disparities in Diabetes
- BroadReach Institute for Training and Education—Management and Leadership Academy
- China/MSD HIV/AIDS Partnership (C-MAP)
- Children’s Inn at NIH
- EngenderHealth—Mobile Outreach Program
- HIV Care Collaborative
- (MCAN) Merck Childhood Asthma Network
- Millennium Villages Community Health Worker Program
- Save the Children—Frontline Health Workers initiative

## EDUCATION

We seek to enhance the quality of STEM (science, technology, engineering, mathematics) education at the graduate and postgraduate levels and contribute to advancing women and minorities in the biomedical sciences. Key initiatives include:

- *Ciencia* (Science) Hispanic Scholars Program
- MISE National Academy of Sciences—Strengthening Science Education
- Purdue University—Kilimanjaro School of Pharmacy Master of Science Program
- United Negro College Fund Science Initiative

**As of 2016, we have decided to phase out support of STEM education as a giving priority to more closely align our charitable giving efforts with our Corporate Responsibility approach and our company's mission. As a result, we will not be making any new philanthropic investments in STEM education. This strategic alignment will enable us to focus our resources, including our philanthropic giving, on addressing the world's most pressing healthcare needs.**

## COMMUNITY

We provide financial support and share the expertise of our employees through grant and volunteer programs that address critical health and social issues in communities where we have a presence. Key initiatives include:

- Neighbor of Choice Program
- Partnership for Giving
- Join My Village

Our Giving

# PRODUCT DONATIONS

**We believe that it's not enough to discover and develop new medicines and vaccines. We believe that we also need to help get them to the people who need them.**

One important way to achieve this goal is through product donations that address specific health needs, whether in communities with a fundamental lack of access to healthcare and services or in acute or protracted humanitarian crises.

Our product donation programs and initiatives include:

- The MECTIZAN<sup>®</sup> Donation Program is one of the most significant initiatives undertaken by our company to help improve access to medicines in developing countries. Established more than 25 years ago, the MECTIZAN Donation Program is the longest-running disease-specific drug donation program and public-private partnership of its kind, and is widely regarded as one of the most successful public-private health collaborations in the world.
- Our Medical Outreach Program is the primary mechanism through which our company donate our pharmaceuticals and vaccines for humanitarian assistance in the developing world and in support of disaster relief and emergency response worldwide
- Our U.S. Patient Assistance Programs have provided our company's medicines and adult vaccines free of charge to people who do not have prescription drug or health insurance coverage and who, without our assistance, could not otherwise afford them

# GOVERNANCE

## **We recognize that our customers, communities, neighbors and investors have an interest in how we conduct ourselves and how we support our commitment to society.**

Our philanthropy must reflect efficient, responsible and ethical judgment and behavior. This is why our company's charitable contributions and our company's Foundation, a U.S.-based, private foundation, are periodically audited to ensure consistency in our giving criteria and grant-making as well as adherence to compliance and transparency requirements. Additionally, our company's Foundation's Board of Trustees provides oversight and strategic direction for the Foundation's program investments.

We use an online grants management system, which is global in reach. It allows qualified nonprofit organizations that are seeking cash contributions to electronically submit proposals and supporting documents. It also facilitates the submission of all required compliance documentation and helps ensure consistent review of grant requests.

We manage our philanthropic giving through two mechanisms:

- The Office of Corporate Responsibility supports charitable programs through cash and product donations and employee volunteerism. These programs contribute not only to the health and well-being of people around the world, but also to our employees, our neighbors and others within the communities where employees live and work and where the company conducts business. The Office of Corporate Responsibility also coordinates the company's disaster-relief assistance throughout the world.
- Established in 1957, our company's Foundation (the "Foundation") is a U.S.-based private foundation funded entirely by Merck & Co., Inc., Kenilworth, N.J., USA, and serves as the company's chief source of funding support to qualified nonprofit charitable and philanthropic organizations whose initiatives address important societal needs and whose goals are consistent with our giving priorities.

Our Medical Outreach Program (MMOP) is the primary mechanism through which we donate our pharmaceuticals and vaccines for humanitarian assistance in the developing world and in support of disaster relief and emergencies worldwide.

## **CHARITABLE GRANTS**

We report the company's charitable contributions and the Foundation's grants on this website. Information provided includes the names of recipient organizations, program names and descriptions, and amounts of the grants provided. We update this information quarterly. [Learn more.](#)

# EMPLOYEE GIVING



## MAIN

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**We believe that employee giving benefits our employees, their communities and our company.**

Around the world, our employees take an active role in giving back to their communities through a variety of programs offered by the company. We are proud of our employees' dedication to serving others. That is why our leading-edge Global Employee Volunteerism Policy provides each employee with the opportunity to take up to 40 hours of paid time off each year to engage in a variety of volunteer opportunities that support eligible nonprofit organizations. Additionally, our company offers a dollar-for-dollar matching gift program for active and retired U.S. and Puerto Rico employees, as well as our Dollars for Doers volunteer rewards program, which provides contributions to eligible organizations based on employee volunteer hours.

## VOLUNTEERING

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**Each year, thousands of our employees volunteer during work hours and on their personal time to give back to their communities.**

In 2013, we launched *MSD Gives Back*, a global volunteer program that supports the efforts of our employees by providing a single web-based portal through which employees can search for volunteer opportunities and log their volunteer hours. On the site, employees can also share their volunteer experiences through photos and stories and find tools and information related to all of our company's employee-giving programs.



Maite González of MSD in Spain spent four weeks volunteering with Amigos de Calcuta, a nonprofit organization dedicated to providing economic, educational and medical assistance to children in India.

## FELLOWSHIP FOR GLOBAL HEALTH

The MSD Fellowship for Global Health is a three-month, field-based corporate pro bono program designed to leverage the skills and talents of our employees. It pairs the best minds from the company with nonprofit partner organizations around the world to provide meaningful and systematic improvements in health service delivery for people in greatest need. While strengthening the capacity and reach of nonprofit organizations, the program also provides rich professional development experiences for employees. Between 2012 and 2014, 70 Fellows from 11 different countries worked with 24 nonprofit organizations.

The company's Fellowship program connects employees with nonprofit organizations and maximizes their business acumen to build organizational capacity, helping the institutions to provide increased access to health services, products and education to the communities they serve. The Fellows bring back experiences integral to our future success and our ability to deliver innovative health solutions to patients and customers around the world. [Learn more.](#)



These 2014 Fellows spent three months in India, helping nonprofit organizations build capacity and improve health service delivery for people in the greatest need.

## PRO BONO LEGAL PROGRAM

Our Pro Bono Legal Program has been nationally recognized for its leadership in providing legal services to the poor and disadvantaged. 2014 marked the 20-year anniversary of the program, which includes more than 150 attorneys, paralegals and administrative associates who provided approximately 3,200 hours of pro bono legal services to residents and nonprofit organizations that could not otherwise afford legal representation. Legal professionals within the company provide pro bono services in the U.S. and internationally in areas such as guardianship, domestic violence, family law, Social Security disability benefits, veteran affairs, bankruptcy and legal support for nonprofit organizations. Below are a few examples of recent projects supported through the company's Pro Bono Legal Program.

**Legal Services of Northwest Jersey, Inc. (LSNWJ)** provides legal assistance to low-income and vulnerable residents in meeting the basic needs essential to self-sufficiency. They provide a broad array of legal services, including representation, advice, advocacy, community education, and referrals to enable those residents to obtain and preserve employment, income supports, affordable housing and access to quality healthcare.

- Our company was instrumental in the creation and success of the LSNWJ Veterans Justice Initiative, a program that provides life-stabilizing, legal services to homeless veterans struggling to rebuild their lives
- Company attorneys provided representation as part of the LSNWJ Tenancy Project, serving low-income residents who are vulnerable to losing their housing. In 2014, the Tenancy Project completed 253 cases, providing client services and resolution such as additional time to secure alternate housing or preservation of current housing.
- **Pro Bono Partnership** offers business legal assistance to nonprofit organizations, thereby enhancing their ability to improve conditions in their communities, particularly for low-income and vulnerable populations. For many years, our company's legal professionals have provided support to the Pro Bono Partnership, which in 2014 provided business legal services for 596 nonprofit organizations.
- **Volunteer Lawyers for Justice (VLJ)** is a comprehensive pro bono program serving low-income clients with a variety of legal issues. Our support helps to maintain a core of dedicated attorneys trained to volunteer for the VLJ's "Bankruptcy in a Box" program, which was developed to meet the growing demand for consumer bankruptcy services and to help improve the lives of economically disadvantaged adults, children and families. In 2014, this program resolved 69 bankruptcy cases.

## SIGNATURE VOLUNTEER PROGRAMS

In 2015, we launched an innovative skills-based volunteer program in the United States. This initiative offers U.S. employees access to high-impact volunteer opportunities while providing nonprofit partners with much-needed skilled assistance to help build capacity for their organization.

**Making Positive Choices** is an initiative created in partnership with the Street Law organization to make a difference in the lives of young people from middle schools, high schools, juvenile justice settings and group homes. The program engages employees in New Jersey and Pennsylvania who are interested in using their unique professional knowledge to teach law, health, community safety, career planning and advocacy. In 2014, our employee volunteers contributed more than 1,540 volunteer hours, and 725 students benefitted from this program.

For years, employees of MSD in France have supported the **ARTZ Alzheimer's Program**, which is committed to improving the quality of life for people living with Alzheimer's disease or other forms of dementia by providing opportunities to experience art through visits to museums in Paris. In March 2014, we launched the U.S. pilot program. This program is managed and supervised by the organization Cultural Action Alzheimer's (CAA) in partnership with Arts & Minds at the Metropolitan Museum of Art ("the Met") in New York City. The U.S. program matched 14 company volunteers with 14 individuals living with Alzheimer's disease for focused visits to the Met where they viewed various art collections and engaged in conversations with an experienced educator. The program gives participants a chance to rediscover their former love of art, regain a social life and stimulate cognitive functions, and it offers a respite to families and caregivers.



A group of 14 employees volunteered their time through ARTZ Alzheimer's Program, a program that matches our volunteers with individuals living with Alzheimer's disease for focused visits to the Metropolitan Museum of Art in New York City.

**MSD Gives Back**, represents the numerous employee volunteer programs in places that address a variety of societal challenges. Through these programs, our employees around the world support important causes and programs in their own communities, donating their time to serve others.



Twenty employees from Global Compliance held a volunteer activity at the Community Food Bank of New Jersey to sort and package food for its various feeding programs.

Below are selected activities from 2014 that our employees participated in as individuals and teams around the world:

- MSD employees in Vietnam participated in an event to support poor patients at four local hospitals. Volunteers provided patients with gift bags that included food, clothing and cleaning products for adults, and snacks, toys and storybooks for children.
- Nine groups of company employees—222 individuals in total—planted and harvested fruits and vegetables for America's Grow-a-Row, a nonprofit organization that donates fresh produce to hunger relief agencies in New Jersey
- After receiving support from Bringing Hope Home—an organization in Wayne, Pennsylvania, dedicated to providing emotional and financial support to local cancer patients and their families—during her battle with cancer, employee Joanne O'Rourke returned the favor by using her volunteer time to help others through the program
- A total of 182 employees from our research laboratories volunteered 733 hours in 2014 with Manna on Main Street, a food pantry and soup kitchen in Lansdale, Pennsylvania. Volunteers stocked shelves, filled bags of food, unloaded deliveries, served customers, answered phones and cleaned.
- The goal of the "Colleagues That Care" volunteer initiative, led by our Employee Business Resource Groups (EBRGs), was to generate 100,000 hours of employee volunteer time in support of nonprofit organizations around the world. This initiative resulted in a companywide employee effort to give back to their communities by volunteering their time at organizations focused on individuals with disabilities, Ronald McDonald House locations globally or at other charities of their choice.
- In North Carolina, 50 charities received nearly 5,000 volunteer hours during an eight-week competition, as employees participated in a "Volunteer Throw Down" with another local organization
- Employees from the Rhode Island/Cape Primary Care Sales Teams participated in a "Save the Bay" beach cleanup. The teams picked up more than 146 pounds of trash and debris from Sabin Point in Rhode Island.



Employees Lisa Jakob and Graham Robb used their volunteer time to travel to Zambia for 10 days with Habitat for Humanity to build houses for two families in need.

**Overseas Volunteering**—Our company has an ever-growing commitment to overseas service and volunteerism, during which employees commit a few days or several weeks to serving others from regions other than their own.

- Alba Carbonell Mongay and Marina Flordelis Corral of MSD in Spain traveled to Cameroon for three weeks to volunteer with La Fundación Recover (The Recover Foundation). The pair worked on a project to create an advanced hospital equipment management model that the organization can apply to new and existing hospitals.
- After volunteering with Mercy Ships in 2013, Lorraine Schell returned to the *Africa Mercy*, which was docked in the Republic of the Congo, to join the ship's more than 400 crew members in delivering care to communities in need
- Employees Tamara Hayden and Kristin Baird traveled to Haiti for a weeklong mission trip. Kristin served on a medical/dental team that held clinics for the community, and Tamara worked with an education team that conducted lessons for 1,140 children across three schools.
- Michelle Vichnin from our vaccines business and Heather Sings in Global Scientific and Medical Publications traveled to the Andes Mountains of Peru to volunteer at CerviCusco, a nonprofit cervical cancer clinic. As part of a medical team on one of the clinic's "campaigns," traveling to remote parts of the country to perform cervical cancer screenings, Michelle spent time treating patients and instructing medical students, and Heather found her Spanish-speaking skills invaluable when helping to translate patients' requests.
- Colleagues Chris Tutino, Stephanie Olivier and Mike Dowling traveled to Guatemala to volunteer with From Houses to Homes, a New Jersey-based nonprofit that works to strengthen poor communities in rural Guatemala by building lasting, healthy homes and improving access to healthcare and education
- Our employee Elyse Bealer used her 40 hours of paid volunteer time to go on a service trip to Rwanda with HOPE International, a network of microfinance institutions and savings and credit associations that work to empower people to break the cycle of poverty through business training, savings services and small loans



Fifty volunteers from MSD in Serbia volunteered to help flood victims by reconstructing a kindergarten playground in Svilajnac that was damaged by heavy flooding.

## PARTNERSHIP FOR GIVING

### The Partnership for Giving (P4G) is our company's year-round matching gifts program.

It enhances the ability of active and retired company employees in the U.S. and Puerto Rico to support eligible health and human services agencies; accredited educational institutions; arts and culture; and animal welfare and environmental organizations of their choice by doubling their financial gifts. As volunteers, our employees in the U.S. and Puerto Rico are eligible to earn cash contributions for the organizations they support. Our Dollars for Doers program matches employee volunteer hours with up to two cash contributions per calendar year for employees who invest 40 hours or more of service with an eligible organization. To recognize and thank the organizations that have made a difference in our own lives and the lives of our families, employees in the U.S. and Puerto Rico are invited each year to nominate nonprofit agencies to receive a \$1,000 "thank you" grant through our "Touched by an Agency" program. Employees share their personal stories about these nonprofits, and each year the Merck Foundation, a U.S.-based, private foundation, awards these special contributions to up to 15 of the nominated organizations.

Partnership for Giving (P4G)	2010	2011	2012	2013	2014
Total Contribution (US\$M) <sup>1</sup>	21	27	27	28	26
Number of organizations that benefited	7,406	10,037	10,172	7,649	9,038
Number of company employees who gave	14,112	16,208	14,572	11,544	10,365
Touched by an Agency grants <sup>2</sup>	15	18	20	12	11

<sup>1</sup> Contributions through P4G include employee direct giving and donations made through payroll deductions, as well as Dollars for Doers and matching gifts from our company. <sup>2</sup> Total for 2014 reflects those organizations that provided the completed documentation required to claim the Touched by an Agency contribution.

## JOIN MY VILLAGE

## Join My Village is a partnership between the Merck Foundation, the General Mills Foundation and CARE.

In 2010, our company embarked on a partnership with General Mills and the humanitarian organization CARE International, to sponsor *Join My Village*, a unique social change initiative that empowers girls and women to overcome poverty. Since that time, we have contributed more than \$5 million in support, and our employees have joined the more than half a million online followers who engage with stories, videos, and other content that details the success of girls and women as they take part in educational, health and economic opportunities.

Our support of the *Join My Village* Maternal and Neonatal Health Programs in India, including a new adolescent health program, has provided essential care to 70,000 pregnant women in just two-and-a-half years.

The *Join My Village* educational programs have supported learning in two states in India, and directly reached more than 75,000 beneficiaries. The *Join My Village* program has made a significant impact on hundreds of thousands of women and girls in Africa and India, and as our role in this program comes to a close, we thank our employees for their participation around the globe.



Students at the Udaan School in India who are benefitting from the *Join My Village* program.

## PERFORMANCE

### GRI G4-EC7

Employee Engagement	Employee Giving					
	2009	2010	2011	2012	2013	2014
Employees who volunteered <sup>1</sup>	NA	NA	9,605	12,333	NA	8,667
Percent of total company population <sup>1</sup>	NA	NA	11.0%	15.0%	NA	12.5%
Employees who used PTO <sup>1</sup>	NA	NA	8,058	9,732	NA	6,240
Percent of total company population <sup>1</sup>	NA	NA	9.5%	12.0%	NA	9.0%
Total volunteer hours (TVH) <sup>1</sup>	NA	NA	213,000	221,050	NA	186,400
PTO hours <sup>1</sup>	NA	NA	130,900	142,082	NA	111,800

Ratio of PTO/TVH	NA	NA	61%	64%	NA	60%
Partnership for Giving (P4G)	2009	2010	2011	2012	2013	2014
Total contribution (US\$M) <sup>2</sup>	\$22	\$21	\$27	\$27	\$28	\$26
Number of organizations that benefited	6,777	7,406	10,037	10,172	7,649	9,038
Number of company employees who gave	11,222	14,112	16,208	14,572	11,544	10,365
Touched by an Agency grants <sup>3</sup>	15	15	18	20	12	11

<sup>1</sup> Figures are based on data collected, reported and estimated worldwide. Company population figures are based on an estimated workforce of approximately 69,000 in 2014.

<sup>2</sup> Contributions through P4G include employee direct giving and donations made through payroll deductions, as well as Dollars for Doers and matching gifts from our company.

<sup>3</sup> Total for 2014 reflects those organizations that provided the completed documentation required to claim the Touched by an Agency contribution.

NA: Not available. PTO: Paid time off. TVH: Total volunteer hours.

# MSD FELLOWSHIP FOR GLOBAL HEALTH



## MAIN

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**Our mission to improve and save lives underpins the idea behind the MSD Fellowship for Global Health (known as the Merck Fellowship for Global Health in the U.S. and Canada).**

### GRI G4-EC7

*The Richard T. Clark Fellowship for World Health is now the MSD Fellowship for Global Health. In the U.S. and Canada, the program is called the Merck Fellowship for Global Health. Fellows will still be referred to as Richard T. Clark (RTC) Fellows in recognition of retired Chairman and CEO Dick Clark.*

The MSD Fellowship for Global Health is a three-month, field-based corporate pro bono program designed to leverage the skills and talents of our employees worldwide. It pairs the best minds from our company with nonprofit partner organizations around the world to provide meaningful and systematic improvements in health service delivery for people in the greatest need.

The Fellowship program is one way that our company demonstrates its commitment to saving and improving lives, bringing together the passion, purpose and commitment of dedicated, talented people to achieve measurable outcomes.



The 2014 RTC Fellows gathered for a reintegration workshop and award ceremony after completing their three-month assignments working with global nonprofit organizations

**The program aims to:**

- Strengthen the capacity and reach of nonprofit organizations with technical and human capital support
- Provide rich professional development experiences for our employees
- Apply key learnings across our broader organization

The Fellowship program connects employees with nonprofit organizations and maximizes their business acumen to build organizational capacity, helping the institutions to provide increased access to health services, products and education to the communities they serve. The Fellows bring back experiences integral to our company's future success and our ability to deliver innovative health solutions to patients and customers around the world.

The Fellowship has grown dramatically since its inception, both in the number of Fellows engaged in assignments and in the way that Fellows contribute to the work of their nonprofit hosts. Between 2012 and 2014, 70 RTC Fellows from 11 different countries worked for 24 nonprofit organizations.

**Benefit to the Fellow**

- A unique, experiential learning opportunity for employees to build their leadership skills by applying their knowledge and skills within nonprofit organizations
- A firsthand customer and patient experience: Fellows can expect to have a greater understanding of the challenges and opportunities in global markets
- A renewed commitment to population health that supports our company's mission of helping the world be well

**Benefit to the Company**

- A leader, who is aware of and appreciates the challenges and opportunities of delivering medicines to the world's most vulnerable populations
- Demonstration of our commitment to saving and improving lives and to corporate responsibility

**Benefits to Global Health**

- Increase in the effectiveness of frontline global health enterprises through public-private partnerships collaborating to use the skills, experience and knowledge of high-achieving professionals
- A growing network of global health advocates within our company
- More effective nonprofit organizations operating in the global health space

## PROGRAM IMPACT

A survey of 2015 Fellows and nonprofit hosts demonstrates the program's excellence in operational performance, while generating significant gains in each of our targeted impact areas: processes, social impact, employee development and business benefit. [Click here](#) for more information.

- 100 percent of nonprofit partners reported extraordinary or substantial capacity gains
- 100 percent of Fellows reported leadership and professional capacity gains
- 96 percent of Fellows reported a better connection with the company mission

### Become a Fellowship Partner

Partner organizations are chosen based on opportunities for capacity-building and shared learning. If you are interested in applying, please submit a [project proposal](#). For more information about becoming a Fellowship partner, download the [NGO overview deck](#), the [Fellowship Guidelines for NGO Partners](#), and the [Project Proposal Template](#).

## MEET THE FELLOWS

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### Africare—Zambia

A *MSD for Mothers* Partner Organization



### ROBIN GELLER

Corporate Compliance—North Wales, Pennsylvania, U.S.A  
Business Training and Skills Transfer

"I am thrilled and humbled beyond belief to be able to participate in the Fellowship program. I am looking forward to making a small difference in a bigger mission, representing to the rest of the world the giving persona of our company and being an example for my children. I hope to gain new friendships, new knowledge, and the opportunity to broaden my impact on our company's business by having an even greater understanding of geopolitics and needs. I want to continue to contribute to 'repairing the world.'"



## MARINELLA GOVONI

Global Human Health—Cento (Fe), Italy  
Branding and Marketing Strategy for Maternity Homes

“I am truly honored for the opportunity to work with Africare in Zambia on a maternal and child health project. All mothers should enjoy pregnancy and the birth of their babies without worrying about health or safety issues. I am looking forward to offering my assistance to help advancing toward a world that allows this in all countries. I am very proud of our company, and grateful for the unique opportunity to dedicate time to improve access to healthcare worldwide in such a tangible way. I cannot wait to get to Zambia to start working with the Africare team!”



## MAUREEN HUGHES

Global Human Health—Toronto, Ontario, Canada  
Branding and Marketing Strategy for Maternity Homes

“By creating the Fellowship program, our company has demonstrated to me that it clearly understands that Corporate Responsibility isn’t simply a tool to impose our values and motivations on those who we feel are in need. Instead, it is a partnership of equals where both parties learn, thrive and succeed. There is incredible power in offering assistance to local governments, leaders and people so that we can ‘walk the walk’ together. The Fellowship program is a true example of a company that is intent on tackling worldwide health concerns beyond the pill.”



## **KARA SANDLER**

Corporate Finance—Kenilworth, New Jersey, USA  
Business Training and Skills Transfer

“It is an honor to be selected to work with Africare, a *MSD for Mothers* partner organization, to implement a Savings and Internal Lending Communities (SILC) model in Zambia. I look forward to bringing the skills I developed at our company to this important project designed to overcome poverty, which in turn presents an obstacle for pregnant women seeking early obstetric care and delivery services with a skilled provider. I am grateful for this extraordinary opportunity to step out of headquarters and serve on the front line in support of our company’s commitment to saving and improving lives.”

## **BIO Ventures for Global Health (BVGH)—USA**



## **ELLEN MINNIHAN**

MRL—Boston, Massachusetts, USA  
WIPO Research: Biopharmaceutical R&D Training

“Our company’s Fellowship program struck me as an opportunity to channel my passion for biomedical science and pharmaceutical research into a project with direct, measurable impact on urgent global medical needs. Through a partnership with BIO Ventures for Global Health, we will aim to collaborate with local experts at our host organizations in Africa to expand and enhance technical capabilities for infectious disease research and drug discovery. I am honored to be working in the company of other scientists and Fellows who share a similar commitment to improving global health, and I look forward to a challenging yet rewarding experience.”



**LIHU YANG**

MRL—Kenilworth, New Jersey, USA  
WIPO Research: Biopharmaceutical R&D Training

“I am thrilled to be part of the team working with BIO Ventures for Global Health supporting its Biopharmaceutical R&D Training program. Being able to directly participate in our company’s corporate responsibility efforts in Africa gives me personal satisfaction after working in this great company for over 25 years. I am looking forward to sharing the experiences I have accumulated with the African researchers to enrich their knowledge and capability in the biomedical and life sciences. I am looking forward to the adventure and am ready to face the challenges.”

## **Boston University Center for Global Health and Development—USA**

*A MSD for Mothers Partner Organization*



**KONSTANTIN REBROV**

Global Human Health—Tallinn, Estonia  
Governance Structures Development and Scaling Maternity Homes

“I am elated to have been selected as a 2015 Fellow! It is an honor to support our company’s partnership with Boston University’s Center for Global Health and Development, because of its commitment and attention to the medical needs of mothers around the globe. I will use this opportunity to help think through issues that impede access to maternal care—in turn, I hope to gain a deeper understanding of how various societal dynamics impact healthcare delivery. I am excited to be a part of a project that represents a sincere commitment to improving healthcare conditions for mothers and children.”

## STACEY HALES

Global Human Health—Upper Gwynedd, Pennsylvania, USA  
Creative Marketing and Demand Generation Strategy

“I am elated to have been selected as a 2015 Fellow! It is an honor to support Merck’s partnership with Boston University’s Center for Global Health and Development, because of its commitment and attention to the medical needs of mothers around the globe. I will use this opportunity to help think through issues that impede access to maternal care—in turn, I hope to gain a deeper understanding of how various societal dynamics impact healthcare delivery. I am excited to be a part of a project that represents a sincere commitment to improving healthcare conditions for mothers and children.”



## KINDRA HELDERLE

Global Human Health—North Wales, Pennsylvania, USA  
Creative Marketing and Demand Generation Strategy

“To experience firsthand the gift of changing people’s lives and the impact we can truly make globally is a big ‘WOW’ for me. The excitement of living in Zambia and experiencing a new culture, while being an ambassador for our company and working with Boston University to scale maternal homes is beyond words. My 19 years with the company has prepared me for this journey with the ability to listen and learn, yet act quickly and confidently to ensure we accomplish our goals. I look forward to sharing my experiences upon my return! Tukamonana limbi (See you later).”



## PATRICIA JOHNSON

Human Resources—West Point, Pennsylvania, USA  
Governance Structures Development and Scaling Maternity Homes

“The opportunity to collaborate with my colleagues, Boston University and the Zambia Centre for Applied Health Research and Development is both an exciting and humbling honor. We work every day at our company to improve the lives of millions of patients, and being able to work on a project that will have a meaningful impact on the public health and well-being of

Zambians is something I welcome and take very seriously. I am extremely appreciative for this extraordinary opportunity to help make a difference in an area of healthcare in a part of the world that needs and deserves attention.”

## **Centre for Catalyzing Change—India**

*A MSD for Mothers Partner Organization*



### **JAMES STACKHOUSE**

Global Human Health—Macquarie Park, Sydney, Australia  
Mobile Platform for Quality-of-Care-Feedback Procedures

“I applied to the Fellowship program so I could put into practice the core motive of our company, to ‘Be Well,’ in a truly meaningful way. The Fellowship is a unique opportunity to instigate change on a core project that impacts positively on the outcomes of less privileged communities. I know that the assignment will challenge me by placing me outside of my comfort zone and forcing me to adapt to ambiguous and ever-changing conditions. However, I’m confident that this will enable me to develop on both a professional level, in honing my project management skills (keeping it simple, doing more with less, listening to understand, beginning with the end in mind) and on a personal level by redefining my principles on what is truly important (the value of wealth beyond materialism, a greater understanding of others, respect for our privileged existence). Whilst I hold trepidation on the task ahead, I’m excited about launching myself into this life-altering experience, making a valuable contribution and along the way having a lot of fun!”

## **Hindustan Latex Family Planning Promotion Trust**

### ***(HLPPT)—India***

*A MSD for Mothers Partner Organization*



**NICHOLAS ALMEIDA**

MMD—West Point, Pennsylvania, USA  
Portfolio Analysis and Framework Design

“It is a privilege and honor to be selected as a member of the 2015 cohort of RTC Fellows, representing a company that fosters philanthropy and serves as a model for corporate responsibility, with a mission to discover, develop and provide innovative products and services that save and improve lives around the world. I look forward to leveraging my skills and experience to provide sustainable solutions that help HLPPT realize its vision of touching lives with quality care and compassion, bridging the gap of affordability and accessibility by delivering innovative, affordable and sustainable healthcare solutions in India.”



**ISABELLA BARTMANN**

Global Human Health—Vienna, Austria  
Business Plan

“24/7, high-standard health support is a luxury only a minority of the world’s population has access to. I was very lucky to grow up and live in a privileged country, and that’s why I’d like to give something back. Being selected to work with a global health partner in India is a unique opportunity to do just that. I can’t wait to dive into a totally different environment, face new challenges, meet new colleagues and make a contribution to a project with a real impact on people’s lives, in a country where, every year, more than 500,000 women die from childbirth or complications during pregnancy. I’m fortunate and humbled to participate in the Fellowship program. I feel that I will go there to give and yet will come back with even more.”

**Infectious Disease Research Institute—United States**



**SUSAN GALEA**

MRL—Upper Gwynedd, Pennsylvania, USA  
HIV Cure Initiative Investment Case

“It is an honor to have been accepted to the Fellowship program, and I am grateful to my management and colleagues for making it possible. I’m fortunate to work for a company that is willing to resource these Fellowships. The Infectious Disease Research Institute’s ultimate goal is the global eradication of HIV, partially by ‘addressing the barriers to collaboration that historically have impeded public-private collaboration.’ I hope to use my medical and regulatory experience to help address those barriers while also expanding my understanding of the challenges that exist in the delivery of equitable care globally.”



**TODD KENNEDY**

Global Human Health—Coto de Caza, California, USA  
HIV Cure Initiative Investment Case

“The ultimate goal of the HIV Cure Initiative is ‘nothing short of the global eradication of HIV.’ Can you imagine that? That is the kind of bold vision that inspires me and is part of our company’s culture! I am thrilled to work with IDRI and an international alliance of stakeholders to build an ‘investment case’ that will be a foundation for cross-sector collaboration. You, my colleagues and mentors, have taught me the value of trusted collaboration. I will put that collaborative spirit to use during and after the assignment so that together, one day, we can all celebrate a cure for HIV. What we do together matters!”

## **International AIDS Vaccine Initiative—United States**

### **Jhpiego—India**

*A MSD for Mothers Partner Organization*



## **SAMANTHA BRUNO**

MMD—West Point, Pennsylvania, USA  
Documentation of Lessons Learned

“It is rare that we get to step away from our day jobs for philanthropic work. I am so proud that our company sponsors this Fellowship program and has selected me to participate! I’m hoping I can utilize my skills to meaningfully help Jhpiego in its mission to prevent needless deaths of women and their families. Every bit of help we can provide will have far-reaching impact for our organizations, our customers and for ourselves. I expect I will come back from this experience changed in ways I cannot yet imagine!”



## **SCOTT WRIGHT**

Strategic Communications, Global Public Policy & Population Health—Upper Gwynedd, Pennsylvania, USA  
Branding Expansion Plan

“I feel incredibly privileged to have this once-in-a-lifetime opportunity to contribute towards and aid in ending maternal mortality. To be able to share my knowledge firsthand and collaborate with Jhpiego to further shape and deliver greater access to healthcare for women to have healthy pregnancies and births is an amazing honor. Put another way, imagine being able to say that work you were part of meant children didn’t have to grow up without mothers. The impact of what we’re collectively doing will be felt for generations. How often does anyone really get to say that? #endmaternalmortality.”

## **MSD Wellcome Trust Hilleman Labs Pvt., Ltd.—India**



## **KIMBERLY BISHOP**

Global Human Health—Tampa, Florida, USA

Create a Set of Organizational Guidelines to Present the Case for Vaccine Innovation

“The Fellowship program is a life-changing experience that goes beyond the scope of any individual assignment. This program allows a mutual opportunity to exist, sharing ideas between cultures and creating innovative product and business solutions for similar national health issues. It is an opportunity to serve others while establishing our presence as healthcare ambassadors. I believe that this is our moral responsibility.”



## **GARTH MEIHOFF**

Global Human Health—Lake Oswego, Oregon, USA

Conduct a Quantitative Assessment of the Health Impact of IP Vaccines

“Working with underserved populations has always been important to me. I am honored and excited to represent our company as an RTC Fellow and grateful for the opportunity to help protect some of the poorest populations against vaccine preventable diseases. In New Delhi, I look forward to working with Hilleman Labs to increase access to lifesaving vaccines. I am excited to apply my skills on a global level and gain a broader perspective toward a variety of populations. This life-changing experience will enhance my ability to better serve those in the U.S.”



**DAVID PEED**

Global Human Health—Charlotte, North Carolina, USA  
Business Model Review and Operational Strategy

“It is truly an honor to work for a company that provides an opportunity to participate in a program like the Fellowship program that will truly have an impact on the lives of thousands in developing countries. I am extremely excited to be part of a group that will be working with Hilleman Labs in New Delhi, India, as they continue their work to develop high-impact, affordable vaccines for people in developing countries in an innovative and sustainable manner. This program allows me to bridge my professional career with my personal desire to make a positive impact on those around me. I know the Fellowship will stretch me both personally and professionally, and I have no doubt that it will be life-changing.”



**MELISSA WOOTERS**

MRL—West Point, Pennsylvania, USA  
Conduct Experiments on an ETEC Vaccine

“I’m very excited to have been selected as an RTC Fellow. I look forward to my assignment at the Hilleman Labs in New Delhi, India. I feel privileged to work for a company whose impact is felt globally and for being selected for this unique opportunity. As a Fellow, I will get up each day with the opportunity to contribute to the greater good and common purpose, an expansion of the work I do every day. This program will help me to be more connected to the work I’m doing and understand how our work benefits people worldwide.”

## **Pathfinder International—India**

A MSD for Mothers Partner Organization



## AUDREY CHEN

MMD—West Point, Pennsylvania, USA  
Documentation and Communications Assistance

“I am thrilled and honored to have been selected as an RTC Fellow. The Fellowship represents an opportunity for me to leverage my skills in a meaningful and impactful manner. I look forward to traveling to and working in India to assist Pathfinder International and World Health Partners in their efforts to improve maternal healthcare and reduce maternal mortality.”



## REVA RAGHUPATHI

Global Human Health—North Wales, Pennsylvania, USA  
Sustainability Framework

“I am honored to have this opportunity to work with Pathfinder International and World Health Partners on a sustainability framework for Project Matrika in India. I look forward to an amazing learning journey and a chance to give back in any way I can. Many thanks to the Fellowship program and my management and colleagues for this opportunity to contribute on behalf of our company.”



## **NADIA VRANJAC**

Global Human Health—Sao Paulo, Brazil  
Documentation and Communications Assistance

“I truly believe being an RTC Fellow is a once-in-a-lifetime experience that allows us to learn how to work and live in a challenging and low-resource environment, while making a difference in other people’s lives. As a mom of two young kids, it’s amazing to have the opportunity to be part of a program where I can impact other mothers’ lives and to help fulfill MSD’s mission to prevent maternal mortality around the globe. It’ll definitely be a transformational journey for all of us as individuals and as employees.”

## **Possible – Nepal**



## **ANNE-MARIE ROVERS**

MMD—Oss, The Netherlands  
Financial Inventory Tracking

“The ability to meet and work with other cultures to help improve and resolve health issues in less-developed countries greatly inspires me. With the opportunity the Fellowship program is providing, I feel it enables me to actively support ‘Access to Medicine’ and stand side by the side with those who need it most! Being assigned to a project in Nepal after the disastrous earthquakes earlier this year makes it even more special. It has always been my aspiration to work abroad, and I am proud to be doing it on behalf of the company. It’s truly going to be a once-in-a-lifetime experience both personally and professionally.”



**TRAYCE SLUMSKY**

MMD—West Point, Pennsylvania, USA  
Financial Inventory Tracking

“Like millions of other people, I saw the events following the 2015 earthquakes in Nepal and thought, ‘I wish I could do something to help.’ I feel incredibly fortunate to work for a company that would not only allow that, but enable me to do so. I look forward to bringing back the feeling of accomplishment and satisfaction that I am sure I will find working with Possible Health. I want to bring that to all of my colleagues and apply it to our company’s mission. I only hope I can give as much value to the people of Nepal as I am sure I will receive.”

## **Programme for Accessible Health, Communication and Education (PACE)—Uganda**

A *MSD for Mothers* Partner Organization



**GINA HERNANDEZ**

Merck Manufacturing Division—Las Piedras, Puerto Rico Communication Strategies and Production of Communication Materials

“It is a privilege to be part of this great journey! Serving the *MSD for Mothers*–sponsored project for PACE in Uganda will enhance inspirational learnings that will contribute to the company’s mission of improving the lives of people around the world. It’s a challenge, sure it is; but, all I need is an open heart to give PACE all my knowledge and professional skills to lower the burden of maternal mortality. I look forward to being part of this transformational experience; Uganda, here I come with lots of energy and passion!”



## TANIA KUNDA

Global Human Health—Macquarie Park, New South Wales, Australia  
Conduct a Market Assessment to Inform Design Decisions for Social Franchise Networks

“The company’s value of improving lives is truly embodied in such a program as the Fellowship program. I am honored and privileged to be part of the cohort in 2015, and feel incredibly grateful for the experience that I am about to embark on. The collaboration with PACE and the *MSD for Mothers* program towards the fight against maternal mortality will allow me to experience the challenges faced by NGOs daily. I look forward to the journey, to learning and contributing to making a difference to the people of Uganda and the broader communities in need across the globe through this initiative.”



## BORISLOV TODOROV

Global Human Health—Sofia, Bulgaria  
Measurement and Assessment

“I am proud to work for a company that provides such unique opportunities to its employees. I realized that becoming an RTC Fellow will enable me to transform myself and my work into an integral part of this great project, which will allow me to expand the scope and outcomes of my work. Supporting PACE in Uganda will give me firsthand experience with our mission to help improve and save lives. I expect that working in direct contact with people benefiting from the solutions offered by our company will further teach me to think from their perspective and to think of patients first when making decisions.”

## ALUMNI

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## 2014—Cohort 5



**VIRGINIA BLANDON**

Associate Director, Medical Affairs  
Marie Stopes International (MSI)—Kenya

“I read an article from Tropical Medicine & International Health regarding adherence in chronic diseases. The study was done in Kenya at an urban informal settlement, called Kibera, in Nairobi. As a Fellow, I had the opportunity to walk through those muddy streets. I met wonderful people from around the world during my assignment at Marie Stopes International. Kenyans and Ghanaians touched my heart and will be part of me for the rest of my life. Plus I got to meet the wonderful people in my own organization from other countries that made me feel proud to be part of our company.”



**NICOLE BUIST**

Principal Scientist, Preclinical Development  
BIO Ventures for Global Health (BVGH)—USA

“The Fellowship experience was a beautiful gift that changed me both personally and professionally. Teaching and mentoring African researchers was incredibly inspiring, as I witnessed their ambition and drive despite the infrastructure challenges they faced. The three months went by very quickly, but I’m proud that we were able to make a difference in people’s lives while we were there. I came back with an overwhelming appreciation for everything in my life, including my family, friends, colleagues, home and workplace. I feel energized to take advantage of all the resources we have at our company to move molecules through the pipeline and better human health. Finally, I feel challenged to keep these African researchers and their mission in mind and look for ways to continue helping further their research remotely.”



## JILL CROUCHER

Senior Customer Representative, Sales  
Jacaranda Health—Kenya

“Memories continually come flooding back. From the day I got the e-mail saying that I was selected as a Richard T. Clark Fellow, to the somewhat daunting process of getting ready to spend three months in Nairobi, Kenya, and finally, trying to wrap my mind around exactly how I was going to make a difference to this maternal health clinic half way around the world. I had the chance to meet the most amazing people, both Fellows and all the support roles surrounding the Fellowship. The friendships that I formed with the other Fellows in Kenya will last a lifetime! From the first day on the job at Jacaranda Health, right up to the last, was some of the most rewarding work that I’ve ever been involved in. The learnings that I took away include the benefit of gaining shareholder feedback, the importance of sustainability and the value of ‘keeping it simple.’ They say some experiences change you forever. This is true of the Fellowship program. I am so grateful to have had this opportunity.”



## LEIGH ANNE GOOD

Associate Director, Sales  
Jacaranda Health—Kenya

“When I am asked about the Fellowship for Global Health, without hesitation I responded that it was the very best professional and personal experience of my life. Through living out our company’s mission in action, my Fellow colleague Jill and I were able to partner with Jacaranda Maternity and make a positive impact on maternal health for the women in Nairobi, Kenya. From my learnings at Jacaranda, I have been able to apply concepts, strategies and tactics to my regular role at our Company. I am filled with a renewed passion for making a difference in the lives of others. Personally, I grew in new ways. I had ‘once-in-a-lifetime experiences’ all while making lifelong friends. I am forever grateful to have served as an a Fellow, and it will be an experience I will carry into all future employment opportunitiesour company.”



## **ROSE HANLEY**

Director, Business Consulting  
Catholic Medical Mission Board (CMMB)—USA

“I look back on my Fellowship with pride and gratitude. I am proud that I was able to address CMMB’s strategic needs by applying the skills and experiences I have gained in my career. And, I am thankful for the relationships I have built outside and within our company. I remain in contact with CMMB—providing them additional input and hearing about their great progress implementing the strategies I helped to develop. I also value the continued community and connection to the diverse network of talented Fellows. The Fellowship has made the world feel smaller and more connected.”



## **TAMARA HAYDEN**

Associate Director, Marketing Communications/Channels  
Operation ASHA—India

“Not a week goes by where something doesn’t trigger a memory of my 2014 Fellowship experience in India. One of the most challenging assignments I have ever had was also the most rewarding in terms of development and personal growth. ‘You will become more resilient,’ I was told by someone beforehand. They were right. Another told me, ‘You will learn to be a better problem-solver and embrace challenges,’ and they were right. Above all, I came home with a desire to pay it forward and continue doing work to help others. To express my thanks to our company and to those who supported me in this opportunity, I want to keep spreading the word, internally and externally, about this incredible program.”



## JOANNA KELLER

Senior Specialist, Marketing Communications/Channels  
Jhpiego—India  
An *MSD for Mothers* Partner Organization



## PHILIP KUHL

Director, Business Consulting  
Possible (formerly Nyaya Health)—Nepal

“The Fellowship for Global Health helped the Nepali NGO, Possible, understand the market for medicines in Nepal, transform its operations and develop its staff. The collaboration between our team and Possible continues to pay dividends. Nearly a year after the completion of our work in Nepal, the team there continues to use the systems we implemented and has used its learnings to aid in the 2015 earthquake response. On a personal level, the Fellowship taught me how much my professional skills enhanced the operations of organizations on the front lines of global health delivery.”



## ADAM MARTIN

Senior Specialist, Marketing Communications/Channels

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)—USA  
An *MSD for Mothers* Partner Organization

"The most important lesson I learned from the Fellowship is that passion for one's work is infectious. Having enthusiasm for what you do makes the work seem easy, no matter the task. I saw how individual passion fostered enthusiasm and teamwork at AWHONN, and how important it was to the success of its programs. I am proud that I was able to contribute my knowledge and skills to help AWHONN get closer to its goal of reducing maternal mortality in the U.S. I have great satisfaction knowing that my impact continued beyond the end of my assignment."



**JAMES MATTEUCCI**

Associate Director, Account Management  
Jhpiego—India  
An *MSD for Mothers* Partner Organization



**GOWRI MURTHY**

Associate Principal Scientist, Clinical Research  
Operation ASHA—India

"Being selected for the Fellowship program was an honor, a once-in-a-career opportunity and a key to opening new avenues of growth within our company. During the three months we spent in India, we were fortunate to meet inspiring leaders in the community fighting against Tuberculosis as we assisted the NGO in India to further scale its unique treatment model. Upon my return to work, the growth and ability to take on 'stretch' objectives have given me the courage and voice to become more involved and push my contributions and development further. I am tremendously grateful to have had the opportunity to contribute to global health and improving lives, and to continue doing so as an alumna of this empowering program."



## SIVA MURTHY

Associate Director, Marketing

The Centre for Catalyzing Change (formerly the Centre for Development and Population Activities (CEDPA) India) and the White Ribbon Alliance for Safe Motherhood India (WRAI)—India An *MSD for Mothers* Partner Organization

“Working with the Centre for Catalyzing Change (C3) and my Fellowship partner from our company’s research laboratories, Agam Sheth, was truly a life-changing experience. It was very rewarding to have the opportunity to apply the business analytic skills and strategic thinking I have acquired in my 13 years at our company to scaling and sustaining an innovative mobile telephony–based platform aimed at lowering preventable maternal mortality in rural India. The Fellowship has uncovered latent skills in me, helped me appreciate organizational complexity and driven me to become a more effective change leader. I have learned to listen, to seek to understand and to collaborate effectively across functions and cultures. This experience was a gift, and it has been truly transformational!”



## NARDI ODIJK

Executive Director, Business Consulting

Possible (formerly Nyaya Health)—Nepal

“The year 2014 will always be connected to one of the most impactful experiences of my life. I was lucky enough to be part of the Fellowship program and lived in Nepal for three months. We worked for Possible Health, a U.S.-based NGO, to design a robust supply chain process and system for a hospital in the poorest part of Nepal that serves 300 to 500 patients per day. Together with my two buddies Philip and Bryan, we had a wonderful time and realized that people in our company, with some good years of professional experience, have a lot to share. What we were able to offer each day in the hospital made me enormously grateful.”



## HUGUES POULIN

Associate Director, Market Access  
Pathfinder International and World Health Partners (WHP)—India  
An *MSD for Mothers* Partner Organization

“The Fellowship for Global Health is a movement of thinkers and doers; entrepreneurial and change-minded organizational consultants with a professional background in business, communications or other skill areas. NGOs have the vision and passion, but there’s only so much they can do on their own. With the help of temporary extra expertise, they can grow to be bigger, better and stronger—multiplying their reach and impact. I acquired a huge amount of professional experience through my work with Pathfinder International and World Health Partners. For example, I learned how to effectively network and lobby for a social cause, how to conduct market research, and how to assess a communication campaign across a number of operational locations. Volunteering in India gave me the wonderful opportunity to do important and valuable work, empowering underprivileged women. The environment that I worked in was dedicated and encouraging. I was treated as a professional, a friend and a colleague working toward improving the health status of women and advocating for their rights. I was wholeheartedly welcomed to the team.”



## DAVE PROVEN

Associate Director, Financial Processes & Control  
Catholic Medical Mission Board (CMMB)—USA

“Children around the world are waiting to discover greatness, create wonders, amaze the world and love their parents. They shouldn’t have to worry about diseases that are preventable with vaccinations. As a employee of our company, I know that before the MMR vaccine, measles would infect about 4 million children, killing about 500. These numbers reinforce the importance of our company’s work, and my experience as a Fellow is a constant reminder of that. The children of today can’t wait.”



## **SALOME RILEY**

Associate Director, Sales  
Catholic Medical Mission Board (CMMB)—USA



## **AGAM SHETH**

Principal Scientist, Preclinical Development  
The Centre for Catalyzing Change (formerly the Centre for Development and Population Activities (CEDPA) India) and the  
White Ribbon Alliance for Safe Motherhood India (WRAI)—India An *MSD for Mothers* Partner Organization

Quote Needed



## NANCY SINGER

Executive Director, Learning & Development

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)—USA An *MSD for Mothers* Partner Organization

“One of the most remarkable experiences I had on my Fellowship was the opportunity to attend the initial meeting of Labor & Delivery personnel from three New Jersey–based hospital systems who all agreed to work as a collaborative, sharing best practices, innovative ideas and being honest about what’s worked and what hasn’t worked in their hospitals. This seems like a basic idea, but it was revolutionary, as this type of sharing does not typically occur. With the work being funded by *MSD for Mothers*, I found it inspiring to see so many people come together and work in a new way to help improve maternal health here in the U.S. I was very proud to be part of this work.”



## BARBARA WIESER

Senior Specialist, Marketing

Marie Stopes International (MSI)—Kenya

Quote Needed



## KATHERINE YOUNG

Principal Scientist, Biology-Discovery

BIO Ventures for Global Health (BVGH)—USA

“There are two concepts I embraced while on assignment that have stuck with me in my life and my job. The first is ‘meet someone where they are.’ In Africa, this meant understanding the current level of experience or infrastructure and helping them build from there, not assuming background that might not be there. I find myself thinking of this often when new people join projects I lead; not to assume, but to help them get up to speed from their current level of understanding. This concept has served me well in community work as well! The second concept is ‘stand on the shoulders of giants.’ While on

assignment, I reached out to colleagues and mentors to help frame presentations and demonstrations we did for our research institutes. I was keenly aware of being a conduit of information not just from myself but from other experts to the institutions we visited. In my job, I am embracing this as well by continuing a project to capture the historical anti-bacterial screening efforts from our company to help inform current and future colleagues.”

## —Cohort 4



**DARRELL PENN**

Senior Specialist, Market Research & Analytics  
Africare—Zambia

“The Fellowship afforded me a unique opportunity to step outside of my personal and professional commitments in order to give my full attention to the worthiest of endeavors. My work with Africare in Zambia on maternal waiting homes opened my eyes to the impact that healthcare providers and a global health leader, like Merck, can have on people’s lives by increasing access to lifesaving interventions. What’s more, I developed a true admiration for my new colleagues at the host organization, as well as a deep sense of empathy for those who live with very little material wealth. Although my work as a Fellow allowed me to impact the lives of others, what I did not realize is how much the experience would impact me”



**LISA MEEHAN**

Director, Shared Services Marketing  
Africare—Zambia

“The RTC Fellowship opened my eyes! My journey helped me to discover a part of the world and challenges that are far from my everyday experience. At the same time, it helped me to appreciate that I can play a role in developing solutions that can impact local, regional and global challenges. The program is empowering and inspiring.”



## **ADRIENNE ROBINSON**

Director, Business Affairs & Alliance Management  
CEDPA India and WRAI—Delhi, India

“Being an RTC Fellow has been the most enriching experience of my career because I was able to closely align with patients and their challenges. However, what I have learned extends beyond the assignment experience. Today, I feel surer than ever that there is more we each must do, and can do, to improve circumstances around us; it only requires a little extra effort to see this and act on it. We have many gifts to share, and you don’t have to be an RTC Fellow to do it. I hope to spread that type of energy to get others involved in making a difference in the things that are important to them.”



## **PAUL SCHAEFFER**

Associate Director, Project Management  
CEDPA India and WRAI—Delhi, India

“Working with CEDPA India and my Fellowship partner Adrienne Robinson was an unforgettable experience. It was extremely rewarding to apply the skills and knowledge that I have acquired in my 16 years at Merck to improving maternal health in rural India. The Fellowship was by far the most rewarding accomplishment of my career. I learned and grew in ways that I never expected. This experience was a gift, and it has changed my life forever!”



## **PAMELA POLINO**

Director, Scientific Affairs  
CGHD at Boston University—Zambia

“There are really no words to express the depth of my gratitude to Merck and the Richard T. Clark Fellowship program. Developing opportunities like this for employees is only accomplished when a company has a very deep sense of obligation for the health and well-being of the world. Merck is one of those companies. Merck marches on and makes a difference in so many lives every day, and it has never been clearer to me how much the world needs Merck. I have come back to the office renewed and revived to carry on with our mission. May the work that we started ensure the safe future for the mothers of Zambia.”



## **DAN BAIONI**

Specialist, Information & Analytics  
Hindustan Latex Family Planning Promotion Trust (HLFPPT)—Delhi, India

“I view the Fellowship as a pivotal moment in my lifetime. The team at the HLPPT does incredible things, and I feel honored to have been a part of those efforts. It was truly amazing to see the impact MSD for Mothers is making on women’s lives throughout India. Interacting with these women and seeing the gratitude in their eyes is something I will never forget. I am honored to have been chosen and I’m proud to be part of a company that is not only a donor of money, but also leverages the skills of its employees to improve the lives of patients around the world.”



## UMESH PATEL

Regional Marketing Leader, Acute Hospital Business Asia/Pacific Region  
International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)—Dhaka, Bangladesh

“I was fortunate enough to have the opportunity to work in Bangladesh for an amazing institution dedicated to improving the health of people living in poverty around the world. Since graduating college, I have only ever worked for Merck, so it was a great chance to challenge myself outside of my comfort zone. I must confess that with the delicate political situation in Bangladesh, I definitely got myself a challenging work environment! I feel much was accomplished in a short time, and Merck can be proud that we left a lasting legacy. None of this could have been achieved without the responsiveness of the staff at the icddr,b and their desire to partner with us. I feel privileged to have been selected for the RTC Fellowship, and I am confident that I have developed insights and skills that will benefit Merck moving forward.”



## JOIE GARFUNKLE

Associate Principal Scientist, Chemistry  
Medicines for Malaria Venture (MMV), Switzerland

“It has been an honor to be an RTC Fellow working with MMV for three months. My eyes have been opened to the world of neglected disease research and the effect an organization as small as MMV (approximately 60 employees) can have on the greater underserved healthcare communities. I return to Merck with a new zeal for my work and with inspiration that each and every one of us can make a difference.”



## ANDREAS VERRAS

Associate Principal Scientist, Chemistry  
MMV, Switzerland

“Working at a small non-profit organization on malaria drug discovery was an amazing experience, and I am truly grateful to Merck for allowing this opportunity through the RTC Fellowship. I was based in Geneva at MMV, which is a small company of 60 people. The work being done at MMV is really exceptional, but like many non-profit organizations, they work in a resource-constrained environment. This Fellowship allowed me to apply not only my skills and expertise, but also Merck’s significant computing power (software and IT support) to the projects. During the three months, I really felt embedded at MMV, but at the same time able to call upon the network of knowledge and considerable expertise at Merck. That, I think, is the beauty of this Fellowship.”



## MAGGIE KEANE

Director, Medical Affairs  
Pathfinder International and World Health Partners (WHP)—Delhi, India

“The RTC Fellowship experience was all that I imagined it would be and more. It was a privilege to help advance the MSD for Mothers initiative in India working alongside our amazing partner organizations, Pathfinder International and World Health Partners. There was no better way for me to learn more about the world, another country, global healthcare and myself than living and working in a different country and work environment for three months. And now, I have the distinct honor of being a member of an exclusive group of RTC alumni Fellows and kindred spirits. For all of those who are thinking about participating in an RTC Fellowship, I encourage you to dive in! You won’t regret it.”



## ROSE KESSLER

Senior Specialist, Medical Affairs  
PACE—Uganda

“Three months went by in the blink of an eye, but the Fellowship experience certainly endures. It was remarkable to be at the intersection of scientific and cultural exchange, to be inside the worlds of an NGO, Ugandan health clinics and rural villages. An enduring understanding, one of my core learnings was finding ways for tacit knowledge to become shared knowledge. PACE, Ugandans and I have very different backgrounds, but that was the beauty of our teamwork. It’s that exact diversity that drove our project. We expanded, built and fortified our ideas into sustainable action with a singular purpose, striving for the underserved. How vital and large it is to transfer your knowledge and individual and collective experiences with those who live on the front line day in and day out. My world is so much bigger. I thank the RTC Fellowship for being the perfect conduit for such powerful exchange. It’s unforgettable to be a part of our corporate social responsibility in Uganda.”



## JULIE HOLT

Associate Director, Learning & Development  
PACE—Uganda

“The RTC Fellowship offered my team the privilege of spending our three-month assignment in Uganda, where we partnered with PACE. We worked to see the healthcare limitations through Ugandan eyes, and then applied our diverse skill sets to our learnings. My role was to create standards and resources that are now an integral component of the credentialing process for healthcare clinic franchising in Uganda. As a result of the efforts of the PACE—Uganda Fellowship team, Ugandans may soon have increased access to quality care within their communities. My Fellowship experience continues to impress upon me the insurmountable value that can come from such an opportunity. I lived outside of my own culture and familiarity, learning more about myself in the process, which has affected me both professionally and personally. As a result, I have been able to improve how I tactically approach various projects, leading to a more impactful outcome. This was a life-changing experience for which I am immensely grateful, and I am proud to be a member of the Merck organization.”



## HANNE WESSEL LUND

Clinical Research Manager  
Physicians for Peace (PFP)—Norfolk, VA and Dominican Republic

“Participating in Merck’s RTC Fellowship has been a unique and challenging experience, both professionally and personally. I was thrilled to see the impact my host organization, Physicians for Peace, has by improving and restoring people’s lives in underserved countries. I have met with volunteers who dedicate their spare time to training and supporting colleagues in countries with limited access to healthcare, and I am truly impressed by these courageous professionals. During my 90 Fellowship days, I was involved with a mentoring program for pregnant teenagers and developed a toolkit for replication of the program. Improving maternal health and empowering adolescent girls is a challenge that needs more attention from the global community. I am delighted to see Merck’s commitment to improve maternal health, and I am thankful to Merck for giving me an opportunity that has enlightened my vision and desire to continue to strive for world health.”



## NICOLE WEIDNER

Senior Specialist, Financial Planning & Analysis  
PFP—Norfolk, VA and Dominican Republic

“I’m grateful to Merck for providing a once-in-a-lifetime development opportunity through the Richard T. Clark Fellowship program. Working with the passionate and dedicated staff and volunteers at PFP taught me invaluable lessons, both personally and professionally. I witnessed firsthand the unique synergy that results when private and public organizations unite to achieve the shared goal of improving health for people around the world. Even though it’s complete, this challenging experience continues to significantly impact my life. I’m proud of all that my colleagues at PFP and I were able to accomplish in just 90 days, and I am excited to see the operational plan implemented.”



## **DINESH PETHIYAGODA**

Senior Specialist, Marketing Communications/Channels  
Project HOPE—Windhoek, Namibia

“My initial understanding of the RTC Fellowship was that it would be a life-changing experience. In retrospect, it was all that and more; definitely something I will cherish for the rest of my life! I had a phenomenal experience working with Project HOPE to enhance the visibility of the organization’s work in the Africa region. We developed and implemented a comprehensive marketing and communications strategy in order to secure new donor funding. Working in four countries in sub-Saharan Africa, I saw firsthand how Project HOPE’s efforts were truly saving and improving lives in some of the most remote and needy areas by ‘helping people help themselves.’ This experience really engaged and motivated me to continue to focus on the patient and the impact we have on patients’ lives. I feel a deep sense of pride to work for a company that through the Merck Foundation is committed to doing so much good in the world, even during tough times.”

## **—Cohort 3**



## **JESSICA CARIDEO**

Associate Director, Global Marketing  
PSI

“Before I departed, I can’t tell you how many times I was told that the Fellowship experience would change my life. That’s a big expectation for a short-term experience, but I can honestly say that my time with PSI and in Cambodia was just that—life-changing. Working with the people at PSI who demonstrate such passion and enthusiasm for the work they do has given me a newfound energy and connection to Merck’s fundamental mission of serving patients. I am so proud of what my Merck colleagues and I learned at PSI, and, more importantly, what we were able to develop and contribute to support the organization’s efforts in such a short period of time. My perspective, both professionally and personally, has expanded, and I’ve made such strong bonds with the other Fellows. I’m so grateful for the experience. I feel lucky to call myself an RTC Fellow!”



## **DARWIN COX**

Director, Business Consulting  
PFP

"This Fellowship experience has opened my eyes to the personal aspect of healthcare. I can see how one person can truly make a difference in helping restore lives. It's a beautiful thing to witness a person's life being restored to normal activity after suffering a calamity. It is invigorating to step back and look beyond what it is we do each day and see what is being accomplished as a result of what we do. I'm astounded by the impact one small nonprofit can have in the world, in combination with its partners and volunteers. I am grateful to Merck, my manager and my wife for allowing me to participate in such a life-changing experience. I am charged and excited to see what lies ahead. Imagine the possibilities and excitement when tens of thousands of people realize the difference we are making and can still make in this world."



## **HILDE JAGERS**

Associate Director, Learning & Development  
PSI

"I am proud to have been part of the PSI family for three months during my Fellowship. This entire experience changed my perspective on so many things, as I worked with an organization that provides lifesaving products, clinical services and behavior-change communications to empower the world's most vulnerable populations to lead healthier lives. I was at the height of 'customer centricity' while working as part of a team that makes it all happen in the field. This experience forced me to get out of my comfort zone, and I brought back learnings that are invaluable to me in my daily responsibilities at MSD."



## **SKIPPER KOZELSKY**

Customer Manager, Sales  
PSI

“What a privilege it has been to work with PSI and help further its mission of improving the lives of the poor and vulnerable populations around the world. The passion, motivation and focus on doing what’s best for the patient are contagious, and I am still in awe over the extraordinary work that PSI does. The Fellowship has really been an experience of a lifetime. The memories made, perspectives gained and impact of helping others truly make this a unique opportunity. I’m grateful that the Richard T. Clark Fellowship allowed us another opportunity to further Merck’s mission to help others be well.”



## **MYLA MALONEY**

Associate Director, Learning & Development  
PSI

“Since joining Merck in 2001, I have often found myself ‘waiting’ to truly make a direct and positive impact on patients in need of healthcare. Not only did the RTC Fellowship afford a unique and significant way for me to do that, it also provided me with the important realization that, as employees of Merck, we help patients every single day. It felt unbelievably fulfilling to be able to contribute to the greater need of global healthcare by partnering with PSI to enhance its provider-engagement programs. The people I met and the experiences I had during the Fellowship taught me a tremendous amount that I will take with me in every future role that I have.”



## **NANCY PIETROSKI**

Senior Specialist, Medical Affairs  
MMV

“Living in a different country for a time opens up your global perspective beyond compare, and especially living in a city as multicultural as Geneva. Going into this with a very open mind, I asked many questions and quickly shed my ethnocentric perspective. I now know that taking a chance and moving to a new country and culture takes courage, but it also makes you far more knowledgeable and engaged. Working with the nonprofit Medicines for Malaria Venture, which operates under a Product Development Partnership (PDP), brought my experience full circle: first as a clinician participating in clinical research along with our patients; then in the pharmaceutical industry, then albeit for a short period, a bridge between industry and patients—the PDP. Through these channels, we endeavor to deliver better healthcare to all people, which should be a basic human right and not taken for granted.”



## **PAMELA RIZOS**

Specialist, Project Management  
PSI

“The Fellowship experience has touched my life in a unique, invaluable way. I was fortunate to work alongside PSI field staff and observe firsthand the power of communication skills in influencing healthcare in underserved areas. It was incredible to be part of a diverse team of Merck and PSI colleagues that worked together cohesively to create a comprehensive training toolkit for PSI field staff to further strengthen provider interactions and impact the lives of people around the world. Through our work, I was able to expand my own skill set as I learned more about communication techniques, developing marketing materials, conducting impactful training and developing staff. During our stay in Nepal, it was eye-opening to see how resources, despite being very limited, are being used flexibly and creatively to drive family planning and improve women's lives. I am thankful for everything I learned, for the amazing friendships that I made and for being a small part of changing the world.”



## **PHIENG SILIPHAIVANH**

Principal Scientist, Chemistry  
MMV

“I feel very fortunate to have been chosen as an RTC Fellow having been given the opportunity to work with colleagues at MMV who came from all over the world. During my three months at MMV, I found new ways to build collaborative relationships with external partners. I also learned that the resources and skills that I have acquired at Merck can be translated into a therapeutic area that was unknown to me before the start of the Fellowship.”



## **MARJORIE WATERS**

Director, Financial Planning & Analysis  
Save the Children

“The three months I spent with Save the Children were challenging and rewarding, both professionally and personally. It was eye-opening to work in an organization that is continually challenged for resources, and yet is working to solve some of the most difficult and important issues in the developing world. The Fellowship may end after three months, but the experience does not. My connection to Save the Children and the amazing people I met while there continues through e-mail. As we integrate back into our roles, I’ve realized how much I have changed. I have a new appreciation for what it means to do more with less and the need to focus efforts where they will deliver the most value. The Fellowship has strengthened my commitment to making sure that ‘what we do matters.’”

**—Cohort 2**



## ANDREAS BERG

Managing Director, MSD Norway  
CEDPA

"I believe all of us working for Merck/MSD feel motivated by the fact that at the end of the day, our business models are focused on "doing good" for people. Being a Fellow in the RTC Fellowship program took the dimension of "doing good" even further for me. It was very fulfilling to know we could add value for a nonprofit organization and by strengthening them, many less fortunate women in India would benefit. It is a huge privilege to be able to complete this type of assignment and still be an employee who can return to my daily job more highly motivated than before."



## NICOLE ROGGENDORF

Associate Director, Policy/Government Relations  
CEDPA

"The time I spent as an RTC Fellow in India was one of the most valuable in my life. I have learned a lot from the people at CEDPA, and from India, that I use daily in both business settings and my personal life. CEDPA's work to improve women's and girls' lives in India is of extreme importance. The RTC Fellowship program gave me the opportunity to be a part of this for a short time. I am proud to have been part of a team that helped CEDPA gain more visibility while continuing to expand their important work in India."



## MEHRDAD DOUSTDAR

Specialist, Marketing  
CEDPA

"The RTC fellowship experience has enriched my life in countless ways. I have broadened my horizons by getting to know a new and wonderful culture. I have also learned to look at business strategy not only from a for-profit view but also from a nonprofit perspective. However, my most important learning was to understand how important it is to have a value-based leadership and life. People working for nonprofit organizations like CEDPA India have tremendous enthusiasm and motivation for their work, because they realize that they are working for a greater cause. At Merck, we should always keep in mind that we are also working for a greater cause every day. We are helping patients and underserved men and women all over the world, and not only in developed countries. We are giving people a hand wherever support is needed! The RTC Fellowship program is the best example for demonstrating this. I truly believe that taking part in the RTC Fellowship program will be a life-changing experience for many, as it was for me! Thank you again for this great opportunity and experience!"



## SUGANDHA CHAUHAN

Associate Specialist, Policy & Communications  
Safe Water Network (SWN)

"I always fall short of words when I have to describe my experience as an RTC Fellow. The time I have spent working with SWN has truly been a rewarding experience, personally and professionally. The support and guidance we received from Merck, MSD India, SWN and our consultants has been outstanding and overwhelming. I truly believe that this opportunity makes you a better person for life and we learn to appreciate life more than ever. The most important thing I have learned in the three-month fellowship is to appreciate the opportunities we have and our ability to impact the lives of others. My best teachers have been the women I met in the villages who have taught me a great deal about life. I hope that with our continuous efforts, we will be able to improve the lives of these people."



**IRFAN TARAJIA**

Associate Director, Market Research & Analytics  
SWN

“My Fellowship assignment was undoubtedly unique and wonderful. It allowed me to be immersed in a nonprofit organization for three months, during which time I came to truly understand the challenges that millions of people face for their basic needs (like walking 10 km every day to fetch fresh water). Despite these difficult circumstances, the people I came into contact with stay energized and motivated because they have hope that things will get better. I am very proud of the Company’s commitment to philanthropy and appreciate the opportunity I had to dedicate my heart and mind to developing a sustainable, affordable model which guarantees safe water access for more than 35,000 people.”



**NAND KUMAR**

Specialist, Marketing Operations

“The Fellowship experience was an amazing journey—exciting, pulsating and inspiring. Perhaps the most invigorating part of the experience has been the opportunity to wear many hats while doing meaningful work to help the world’s poor... everything from global marketing to brand positioning and communications, stakeholder advocacy, international relations and media outreach.”

**—Cohort 1**



## **ALICIA M. BARTOLOZZI**

Specialty Account Executive, Managed Markets & Policy  
PSI

"I am struck how similar Merck is to a smaller nonprofit organization. At the end of the day, people, process, strategy, structure and culture rule the day!"



## **ROB DRIBBON**

U.S. Strategy & Planning Lead, Strategy & Commercial Model Innovation, U.S. Market  
PSI

"My Fellowship experience has enriched me in so many ways. Living and breathing the cultures of another organization, and of the countries we visited, has given me new perspectives that I can apply both personally and professionally at Merck. I am proud to have represented Merck along with my amazing Fellow colleagues, and to have contributed to PSI's mission of improving the health of people in the developing world."



## **MATT LUCAS**

Health Science Team Leader, Thrombosis  
PSI

"I'm very proud of our accomplishments with PSI this summer. The guidance that we developed will help PSI to optimize their Social Franchising Business Model, which is their mechanism toward expanding access to high quality, affordable health care to underserved populations. This will have clear impact on the healthcare system, the providers, and most importantly the consumers (or patients). Additionally, elements of our guidance centered around PSI putting processes in place to train and develop the skill sets of their sales representatives and managers (people native to the developing nations), helping them to become less dependent on foreign assistance. Working with PSI has been incredibly rewarding for me. It's a Win-Win for all."



## **JAN NISSEN**

Established Products Business Unit Leaders, U.S. Market  
PSI

"Not only was the Fellowship an unbelievable experience for me personally and professionally, but it also offered a great developmental opportunity for the individual who filled in for me during the three-month assignment. Upon my return, I appreciated the warm welcome from colleagues, and I feel energized to be back. I have kept in touch with our colleagues at PSI, and I am very encouraged and excited that the work we developed is heading into the implementation phase. It has been wonderful to talk with a few of the employees who will be in the next round of the Merck Fellowship program. It is apparent that their excitement matches our experience. It is so gratifying to see the company continue to invest in these programs that have such a dramatic impact on human life."



## JULIA SHOFF

US Regional Marketing Leader, Asthma and Chronic Obstructive Pulmonary Disease (COPD)  
PSI

“Our Fellowship experience was certainly ‘fair trade’—we learned as much as we shared! Drawing on our collective business experience, we were able to help PSI chart a course to meaningful improvements in its social franchising strategy and operations. In exchange, we made unique, firsthand contact with the healthcare ecosystem of the developing world and the governmental and nongovernmental organizations operating there.”

## PARTNERS

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Africare is the oldest and the largest African American–led organization in the development field, and is a leader in development assistance to Africa. Since its founding in 1970, Africare has delivered more than \$1 billion in assistance to millions of beneficiaries across the African continent. Africare’s staff has an unparalleled knowledge of the continent—its challenges and opportunities—and has nurtured valuable relationships with key figures ranging from community leaders and traditional authorities to presidents and prime ministers. Africare centers its development approach on active community participation and partners with local organizations to ensure institutional strengthening and capacity-building.



BIO Ventures for Global Health (BVGH) is a nonprofit organization whose mission is to engage private industry in global health initiatives. BVGH aims to accelerate the development of new drugs, vaccines and diagnostics that address the unmet medical needs of the developing world. It works at the crossroads of the biopharmaceutical industry and global health to find the common ground between the aspirations of the global health community and the strategic priorities of companies.

## Center for Global Health & Development

The Center for Global Health & Development (CGHD) at Boston University is a multidisciplinary research center that engages faculty from across the university to help solve the critical global health and social development challenges of our time. The mission of the center is not only to conduct high-quality applied research, but also to advocate for the use of this research to improve the health of underserved populations around the world. Through collaborative work with scientists worldwide, it also seeks to strengthen individual and institutional capacity to conduct and utilize research. Over 90 employees and field staff are engaged in center-based research activities in more than 20 countries.



The Centre for Catalyzing Change formerly the Centre for Development and Population Activities (CEDPA) India is an organization that envisions a future in India where women and girls are fully empowered and enabled to realize their rights, opportunities and achieve gender equality. It equips, mobilizes, educates and empowers women and girls to achieve gender equality. The focus areas for the Centre for Catalyzing Change include Gender Equity and Governance, Girls Education and Youth Development, and Reproductive Health and Rights.



Hindustan Latex Family Planning Promotion Trust (HLFPPT) is a not-for-profit organization founded to design and implement social interventions in the areas of reproductive health, encompassing maternal health, family planning, child health, HIV/AIDS and adolescent sexual health. HLFPPT works with a vision of increasing access to quality healthcare products and services. Over the last two decades, HLFPPT has reached out to more than 420 million people across rural and urban India to provide quality healthcare services at their doorsteps.



International AIDS Vaccine Initiative is a global not-for-profit organization whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. Founded in 1996, IAVI works with partners in 25 countries to research, design and develop AIDS vaccine candidates. The organization also conducts policy analysis and serves as an advocate for the AIDS vaccine field. It supports a comprehensive approach to addressing HIV and AIDS that

balances the expansion and strengthening of existing HIV-prevention and -treatment programs with targeted investments in the design and development of new tools to prevent HIV. IAVI is dedicated to ensuring that a future AIDS vaccine will be available and accessible to all who need it.



Infectious Disease Research Institute (IDRI) is a new breed of global health nonprofit, taking a comprehensive approach to address infectious diseases. It combines the high-quality science of a research organization with the product development capabilities of a biotech company to create new diagnostics, drugs and vaccines.

innovating to save lives



an affiliate of Johns Hopkins University

Jhpiego is an international nonprofit health organization affiliated with Johns Hopkins University. For 40 years, and in over 155 countries, Jhpiego has worked to prevent the needless deaths of women and their families. Jhpiego works with health experts, governments and community leaders to provide high-quality healthcare for constituents. Jhpiego develops strategies to help countries care for themselves by training competent healthcare workers, strengthening health systems and improving delivery of care. Jhpiego designs innovative, effective and low-cost healthcare solutions to ensure a level of care for women and their families. These practical, evidence-based interventions are breaking down barriers to high-quality healthcare for the world's most vulnerable populations.



MSD Wellcome Trust Hilleman Laboratories is a unique joint venture between the Wellcome Trust and Merck & Co., Inc., Kenilworth, NJ, USA, with a not-for-profit mission to focus on developing affordable vaccines for diseases that commonly affect low-income countries. Based in India, the MSD-Wellcome Trust Hilleman Laboratories will create a sustainable R&D business operating with a not-for-profit model. Launched in 2009, the pairing by two of the world's pre-eminent healthcare institutions provides an opportunity to integrate the best of both, to drive the investment and expertise needed to develop and deliver affordable vaccines. The venture is named in honor of the pioneering vaccine scientist Maurice Hilleman Ph.D. Dr. Hilleman is credited with the development of more than 30 vaccines, including vaccines for measles, mumps and hepatitis B, during a career that included nearly 30 years at our company.



Interventions for Health Impact

Programme for Accessible health, Communication and Education (PACE) is a non governmental organization in Uganda that implements programs aligned to the ministry of health in the areas of HIV/AIDS, malaria, child health and reproductive health. PACE, an affiliate of Population Services International (PSI), builds partnerships and works in collaboration with the Government of Uganda, district local governments, as well as with national and community-based organizations (CBOs) to implement its programs.



Pathfinder International's mission is to advance sexual and reproductive rights globally by catalyzing change locally. Pathfinder places reproductive health at the center of all it does—believing that health care is not only a fundamental human right, but is also critical for expanding opportunities for women, families, communities and nations, while paving the way for transformations in development. In more than 25 countries, Pathfinder provides women, men and adolescents with a range of quality health services—from contraception and maternal and neonatal health to HIV prevention and AIDS care and treatment.



Possible (formerly Nyaya Health) is a nonprofit healthcare company that delivers high-quality, low-cost healthcare to Nepal's rural poor by delivering transparent, data-driven healthcare. In addition to providing day-to-day care, Possible partners with government agencies to promote the creation of just systems and "infrastructure for equity," which creates the possibility for the right to health and sustainable change.



# PERFORMANCE DATA

**These are the Key Performance Indicators (KPIs). Please click here to download the full performance data spreadsheet.**

The following list of KPIs serve as baseline measurement for our corporate responsibility activities. These indicators are measured globally unless otherwise noted and cover all of our business units with the exception of joint ventures.

	<b>Access to Health<sup>1</sup></b>			
	2011	2012	2013	2014
<b>Research &amp; Development</b>				
Top 20 global burdens of illness addressed by our products and pipeline <sup>2</sup>	53%	55%	88%	88%
GCP/PV audits by regulatory agencies or clinical trial investigators that led to significant fines, penalties, warning letters or product seizures	0	0	0	0
Established significant external licenses and collaborations <sup>3</sup>	52	61	40	35
Narrative of compounds provided to product development partnerships <sup>4</sup>	Online	Online	Online	Online
<b>Manufacturing &amp; Supply</b>				
Annual percentage of units manufactured/sold and recalled during a given year (recall rate globally) <sup>5</sup>	NR	0.19%	0.11%	0.22%
Number of local and regional manufacturing partnerships to enable access <sup>6</sup>	NA	84	68	104
Number of products available by local and regional partnerships <sup>6</sup>	NA	34	354	499
<b>Registration</b>				
New product and device registrations <sup>7,8,9</sup>	179	204	179	176
Local regulatory agency GCP/PV training requests fulfilled that will help strengthen agency capabilities in agencies' GCP/PV-compliance-oversight role <sup>10</sup>	Online	Online	Online	Online
Products submitted that have achieved WHO pre-qualification	10	10	11	11
<b>Commercialization</b>				
Number of our products that are supported with differential pricing <sup>11,12,13</sup>	NA	NA	24	35
Number of low- and lower-middle-income countries where inter- and/or intra-country pricing has been implemented <sup>11,14</sup>	NA	NA	70	114
Investment in patient- and provider-education programs <sup>15</sup>	\$97.8M	\$71.4M	\$61.3M	\$52.3M
<b>Community Investment</b>				
Healthcare workers trained through major programs and partnerships <sup>16</sup>	52,000	38,000	22,000	137,000

Investment in partnerships for activities to address underlying barriers to health, such as health-system strengthening and capacity-building <sup>17</sup>	\$35M	\$24M	\$24M	\$32M
People reached through our major programs and partnerships <sup>18</sup>	273M	269M	302M	267M

NA: Not available. NR: Not reported.

<sup>1</sup> Unless otherwise stated, data for Access to Health are reflective of our Human Health business only; information on our company's Animal Health business is reported separately.

<sup>2</sup> As defined by the Institute for Health Metrics and Evaluation (IHME), which replaces the previously used WHO chart of leading causes of disease, condition or injury.

<sup>3</sup> Candidates in our company's research pipeline or under regulatory review are as of February 20, 2015, as reported in the U.S. Securities and Exchange Commission for 10-K, page 16, filed on February 27, 2015. This includes candidates in Phase II, Phase III, or under regulatory review as of February 20, 2015. As candidates attain regulatory approval, they are removed from this pipeline view.

<sup>4</sup> For information on product-development partnerships, visit the "Partnerships" tab at <http://merckresponsibility.com/access-to-health/research-development/#partnerships>

<sup>5</sup> Beginning in 2014, this figure includes recalls within our Animal Health business.

<sup>6</sup> Previously, we reported products available through specific agreements, but we have now expanded our reporting to all of our products, including the various strengths and presentations that are sold or distributed through a partnership in local markets, to more accurately reflect our efforts to address local needs.

<sup>7</sup> Data include new products and new indications.

<sup>8</sup> Data for all years have been updated based on a tracking-system upgrade that corrected miscounts in prior years.

<sup>9</sup> For information on new registrations by region, visit <http://merckresponsibility.com/access-to-health/research-development/clinical-research/#performance>

<sup>10</sup> For information on local regulatory agency GCP/PV training requests, visit <http://merckresponsibility.com/access-to-health/research-development/clinical-research/>

<sup>11</sup> In 2013, we modified our Key Performance Indicators for differential pricing so that we can more broadly capture and accurately reflect our support.

<sup>12</sup> Differential pricing intended to facilitate access for the at-need population.

<sup>13</sup> Our products include HIV treatments, vaccines and other patented products.

<sup>14</sup> Countries as defined by the World Bank 2013 GNI Classification, including UN-defined Least Developed Countries.

<sup>15</sup> In 2014, we adjusted the calculation basis for certain grants to ensure alignment with geographic and programmatic focus areas, resulting in refined figures for 2011-2013.

<sup>16</sup> 2014 figure includes healthcare workers trained through the African Programme for Onchocerciasis Control, of which we are a major funder.

<sup>17</sup> Includes investments by the Office of Corporate Responsibility, MSD for Mothers and/or our company's Foundation.

<sup>18</sup> 2013 figures have been reconciled to reflect revised field data for the MECTIZAN Donation Program.

## Environmental Sustainability<sup>1,2</sup>

	2011	2012	2013	2014
Greenhouse gas emissions (metric tons of CO <sub>2</sub> e)	2,001,000	1,918,000	1,811,000	1,676,000
Water usage (thousands of gallons)	8,900,000	8,700,000	7,500,000	7,200,000
Operational waste generated (metric tons)	119,000	116,000	100,500	87,000

<sup>1</sup> Includes facilities worldwide.

<sup>2</sup> In accordance with the Greenhouse Gas Protocol, prior-year data have been adjusted to add or remove facilities that have been acquired and sold. Adjustments also reflect changes in methodology to ensure consistency from year to year.

## Employees

	Diversity & Inclusion	2011	2012	2013	2014
Executive roles held by women <sup>1,2</sup>		35%	31%	31%	31%
Women on the Board		17%	17%	17%	17%
Underrepresented ethnic groups on the Board		11%	25%	25%	25%
Underrepresented ethnic groups in the workforce (U.S.)		29%	24%	24%	24%
	Well-Being	2011	2012	2013	2014
Response rate to the Voice Survey		63%	77%	77%	78%
Employees who completed a health assessment (U.S.)		58%	58%	62%	57%
Overall turnover rate <sup>3</sup>		14.0%	11.0%	15.5%	15.0%
Lost-time incident rate (LTIR) <sup>4</sup>		0.30	0.27	0.28	0.20
Recordable injury rate (RIR) <sup>4</sup>		0.74	0.62	0.61	0.57
	Volunteerism	2011	2012	2013	2014
Employees who took release time according to the global policy on employee volunteerism <sup>5</sup>		11.0%	15.0%	NA	12.5%
Volunteer hours <sup>5</sup>		213,000	221,000	NA	186,400

NA: Not available.

<sup>1</sup> Beginning with 2012, data reported for women are global; previously, these data were limited to the U.S.

<sup>2</sup> "Executive" is defined as the chief executive officer and two structural levels below.

<sup>3</sup> Overall turnover incorporates all types of turnover, including restructuring.

<sup>4</sup> Workplace injury rates for 2012 have been restated for accuracy as well as associated percentage change vs. prior year.

<sup>5</sup> As a result of the transition to a new website and vendor for our employee giving programs, our company's total volunteer hours are not available for 2013.

## Ethics & Transparency

	2011	2012	2013	2014
Employees trained on our Code of Conduct	90%	92%	99%	99%
Substantiated allegations to concerns/issues raised	65%	60%	58%	60%
Reported concerns regarding privacy practices, breaches of privacy, and losses of personal data and devices that were substantiated <sup>1</sup>	68%	23%	26%	18%

<sup>1</sup> Privacy concerns include all concerns escalated to our Privacy Office about the company's privacy practices. Substantiated concerns are those that are determined to be inconsistent with our privacy standards or that involve the loss of, theft of or unauthorized access to personal data.

# FORWARD-LOOKING STATEMENT

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This communication of Merck & Co., Inc., Kenilworth, NJ, USA (the "Company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include, but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; global trends toward healthcare cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the Company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the Company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The Company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the Company's 2014 Annual Report on Form 10-K and the Company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site ([www.sec.gov](http://www.sec.gov)).



The Office of Corporate Responsibility

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