

**CORPORATE  
RESPONSIBILITY  
REPORT  
2012**



# CORPORATE RESPONSIBILITY



**At Merck, corporate responsibility is our daily commitment to discovering innovative solutions to the world's biggest health challenges.**

It is this simple promise that informs all of our actions as we apply our global resources, our talents and our scientific and operational expertise to some of the most significant health, social, environmental and economic challenges in the world today. Ultimately, it helps us to discover better ways to deliver greater value to both shareholders and society.

Through innovative research, groundbreaking partnerships and smarter processes, we are focusing on **four areas of priority**: Access to Health, Environmental Sustainability, Employees, and Ethics & Transparency. With a focus on these priority areas across our entire organization, we are committed to leading the future of healthcare.



**KENNETH C. FRAZIER, CHAIRMAN  
AND CHIEF EXECUTIVE OFFICER**

## LETTER FROM THE CEO

**At Merck, corporate responsibility underscores our steadfast commitment to help the world be well.**

Merck people share an unwavering commitment to our mission to save and improve lives around the world, and to uphold the highest standards of ethics and integrity.

We believe that innovative and productive research and development is the only sustainable way to create true and enduring value for all of our stakeholders, and we are focused on tackling some of healthcare's most daunting challenges. By continuing to invest in the discovery and development of medicines and

vaccines, we believe Merck can have a profound impact on people's lives for years to come.

In addition, we are resolute in our promise to develop and reward our employees, protect the environment and support the communities in which we work and live. Furthermore, we are operating ethically and transparently in order to earn and retain the trust and confidence of our stakeholders. This report, which also serves as our annual Communication on Progress Report to the UN Global Compact, is one of the ways in which we increase our transparency.

We continue 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.

But the challenges, too, are great. Of the seven billion people alive today, six billion live in emerging and developing markets. We believe we have an obligation, as well as an opportunity, to help meet their unmet health needs by advancing effective and safe medicines at affordable and sustainable prices.

In the developed world, the costs to treat chronic diseases are large and increasing. Today these costs represent approximately three-quarters of all healthcare expenses, and two-thirds of the increase in healthcare spending is due to the increased prevalence of treated chronic disease.

The global economy continues to be uncertain, an ongoing challenge to pharmaceutical companies that can invest a billion dollars or more over the 10 to 20 years it takes to bring a new drug to market.

But we are determined to advance our mission, and, in 2012, we made progress through a number of important initiatives:

- Expanding our product portfolio, as well as our local development and distribution capacity, through important joint ventures
- Developing new partnerships to reduce maternal mortality through Merck for Mothers, our 10-year, \$500 million initiative that is applying the company's scientific and business expertise—as well as its financial and human resources—to address this issue around the world
- Celebrating the 25th anniversary of Merck's MECTIZAN® (ivermectin) Donation Program and its success in contributing to the goals of eliminating river blindness and lymphatic filariasis
- Strengthening the impact that Merck employees have on communities throughout the world, by recently increasing paid time off, from 20 to 40 hours per year, for employee volunteerism; throughout 2012, Merck employees volunteered through a variety of programs, resulting in more than 221,000 total volunteer hours
- Emphasizing the importance of raising ethical and compliance-related concerns through an updated mandatory training program, which

provides additional guidance on the Merck Code of Conduct

- Identifying and implementing major projects to cut water use, protect water quality and reduce operating costs through improvements to water and wastewater infrastructure

We are proud of our progress, but remain focused on the work ahead. We have made progress in meeting the objectives identified in Merck's Access to Health Guiding Principles, but we must address the ongoing challenge of creating a companywide strategy to expand access to our discoveries in both developed and developing markets while continuing to build a sustainable business.

To do this, I believe that healthcare companies, regulators, payers, governments, and other stakeholders must work collaboratively to bring safe, effective, affordable medicines and vaccines to the world's people.

It is critical, therefore, that Merck continues to take a leadership role in the pharmaceutical industry, building partnerships with a wide range of stakeholders to advance R&D, enable access to medicines and vaccines, and help improve quality of life across the globe.

The world is changing, but Merck's focus on pursuing the best science and building a sustainable business is steadfast, and even more important, our people remain deeply committed to our mission and our company.

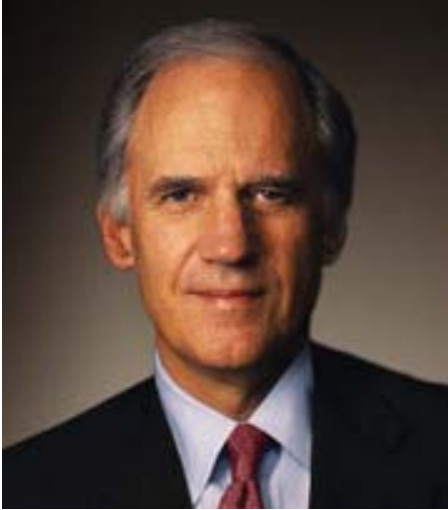
Know that we take very seriously our special responsibility to provide genuine and enduring value to customers, patients, employees, communities and shareholders for generations to come.

Be well,



**Kenneth C. Frazier**

Chairman and  
Chief Executive Officer  
July 2013



**WILLIAM B. HARRISON, JR.**

## BOARD LETTER

Dear Stakeholders,

Merck has a long history of bringing innovative medicines to market to address some of the world's most profound unmet medical needs. We do this while delivering long-term returns on our company's investment in R&D and, critically, within a robust governance structure and in a manner that is ethical and transparent.

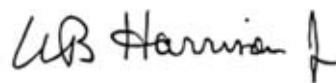
In May 2012, the Board merged the Governance Committee and the Public Policy and Social Responsibility Committee in recognition of the value of incorporating policy review and corporate responsibility within the company's governance framework.

Among its responsibilities, the Committee takes a leadership role in shaping the corporate governance of the company. The Committee also advises the Board and management on policies and practices that pertain to the company's responsibilities as a global corporate citizen, including our special obligations as a healthcare company with products and services that affect health and quality of life around the world, and our commitment to uphold the highest standards of ethical behavior in all of our dealings. The Committee's combined responsibilities reflect the strong alignment in our approach to corporate governance, policy and responsibility.

As Lead Director of the Board and Chair of the Governance, Public Policy and Corporate Responsibility Committee, I am proud of Merck's legacy of achievement in helping the world be well. I also understand the challenges we face as we continue to deliver on Merck's mission to develop and provide innovative products and services that save and improve lives around the world.

We are confident in the innovation and integrity that drive and direct our future course. We care deeply about both the results we achieve and how we achieve them.

Sincerely,



**William B. Harrison, Jr.**

Lead Director and Chair, Committee on Governance, Public Policy and Corporate Responsibility

## OUR APPROACH

**We aspire to be the best healthcare company in the world and are committed to improving health and well-being around the world by providing leading innovations and solutions for tomorrow.**

At Merck, our vision is to make a difference in the lives of people globally through our innovative medicines, vaccines, biologic therapies, consumer health and animal health products. We have made it our mission to provide innovative, distinctive products and services that save and improve lives and satisfy customer needs; to be recognized as a great place to work; and to provide investors with a superior rate of return.

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.

In short, corporate responsibility at Merck is a daily commitment and a simple promise that is embedded in our business and informs all of our individual actions. It extends to how we achieve our business goals by discovering and demonstrating:

- Smart, sustainable ways to expand global access to effective healthcare

- Environmentally sustainable ways to meet the world's health needs now and in the future
- Better ways to strengthen a workplace where our employees—and our business—can thrive
- Better ways to build and strengthen trusted relationships
- The highest ethical standards and communicating with greater transparency

Since successfully managing social, ethical and environmental issues involves everyone at Merck, we established a companywide corporate responsibility framework, as well as a list of **key performance indicators** to measure the 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.

## MATERIALITY

**A materiality assessment is an important means to ensure that annual corporate responsibility reports reflect the organization's significant economic, environmental, and social impacts or fundamentally influence the assessments and decisions of stakeholders.<sup>1</sup>**

In 2010, Merck conducted a materiality assessment to guide us in the development of our corporate responsibility framework and to ensure that our strategic approach was linked directly to our core business drivers. Our approach includes precise criteria in certain areas including: business relevance; satisfying stakeholder demands; opportunities for improvement; and areas of potential leadership.

Key issues were identified through a consideration of numerous sources, including:

- Merck corporate plans, objectives and strategies
- Company policies and initiatives related to company policies
- Employee surveys and other input from employees
- Customer feedback obtained through focus groups and other methods
- Shareholder resolutions and other feedback received through ongoing dialogue with shareholders

- Input from investors and investor groups committed to sustainable investing
- Partners, nongovernmental organizations, suppliers and other stakeholders
- Media coverage
- Stakeholder feedback on prior corporate responsibility reporting
- Industry benchmarking
- The Global Reporting Initiative (GRI), Access to Medicine Index, the UN Global Compact principles and other external guidelines

Based on this analysis, an overall set of issues were identified as those most significant to the company. The key issues in this report have been approved by Merck’s Public Policy and Responsibility Council based on the three parameters used to define and determine materiality for the purpose of our corporate responsibility reporting:

1. Impact on Merck’s ability to achieve its business strategy
2. Level of concern to external stakeholders
3. Degree to which Merck can control and influence the topic or issue

As part of our ongoing **stakeholder engagement** process, we review the suggestions and expectations of our stakeholders to ensure that we are reporting on issues that are of most relevance to them, as compared with those identified through our own evaluations. In this way, we can

determine the areas of our corporate responsibility approach that require further review and identify issues that we might clarify in the future.

Merck recognizes the importance of issues that may not be within the company’s immediate or total control, such as climate change, global poverty and access to medicines, particularly in the developing world. We believe that we can, however, influence progress in these areas by addressing these issues, particularly through public policy and advocacy or through partnerships with others.

We will continue to seek additional feedback in order to further refine our key corporate responsibility issues in future reports. While we had anticipated including a materiality index in this report, a new materiality assessment is being conducted in 2013 to ensure that we capture those issues that are most important to our stakeholders as well as new and evolving areas of interest.

<sup>1</sup><https://www.globalreporting.org/resource/library/Materiality.pdf>

## CR GOVERNANCE

**Merck 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. Our reporting and governance structure is an integral part of this commitment.**

### The Office of Corporate Responsibility

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

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

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

In addition to the Office of Corporate Responsibility, Merck established the Public Policy and Responsibility Council, a senior-level decision-making governance body responsible for developing and monitoring Merck's corporate responsibility approach, targets and progress against key performance indicators. Membership includes senior Merck leaders across all divisions and major functions. The council's responsibilities include reviewing external issues that may affect Merck's business and reputation; providing high-level guidance on Merck's 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 Merck'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 with the Office of Corporate Responsibility to help set goals and develop metrics that support and measure Merck's overall corporate responsibility strategy and objectives.

### Executive Committee

Our Executive Committee manages the business of Merck, and is headed by Merck's Chairman and Chief Executive Officer, Kenneth C. Frazier. The committee's members, representing the many areas of the company, are responsible for reviewing the nonfinancial corporate responsibility indicators annually and the company's progress against our corporate responsibility commitments, and reviewing and approving the annual corporate responsibility report. [Learn more](#).

### Board Committee on Governance, Public Policy & Corporate Responsibility

Six independent directors comprise Merck's Board Committee on Governance, Public Policy & Corporate Responsibility, which is responsible for advising the 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.

# STAKEHOLDER ENGAGEMENT

**At Merck, we understand 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 Merck's approach and commitment to stakeholder engagement.

Merck conducts stakeholder engagement at both the corporate and the local level, depending on the issue. We engage with industry, governments, policy makers, non-governmental 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 Merck 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.

For more information on our stakeholder engagement efforts, you may also visit

our pages on specific **stakeholder groups** that we work with, **feedback** that we've received, and how we **work with patient groups**.

## STAKEHOLDER GROUPS

**Engagement may take the form of one-on-one meetings, expert input forums or roundtable discussions, industry coalitions, or formal partnerships.**

### Patients and Their Families

Everything we do is ultimately for patients, for whom we have an important responsibility to ensure that our innovative products meet their health needs. For more information on our work with patient groups, please [click here](#).

### Doctors, Healthcare Professionals and Scientists

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 and vaccines, and about our ongoing research. And 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 rising healthcare costs and limited budgets, and we listen to the debates on how to make medicines and vaccines more affordable and accessible. We work with payers worldwide to make sure they understand that the prices of our products reflect their true value. We also develop programs with payers to make sure our products can reach the people who need them most. To learn more about our access initiatives, [click here](#).

### Governments, Multilateral Organizations and Regulators

We are committed to conducting our business according to the letter and spirit of laws and regulations, as well as the various standards of business practice that we endorse. Where laws or regulations do not exist or are inadequate, we have created our own standards and use them to guide our practices.

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. To learn more about our public policy and advocacy positions, [click here](#).

### 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—using financial and other parameters—honestly and accurately, and we work hard to protect and retain our assets, including our intellectual property rights, our resources, our top employees and our reputation.

Merck also reports on environmental, social and governance indicators that are relevant to our business and long-term performance—and we support efforts to standardize nonfinancial reporting. For information related to investing in Merck, please [click here](#).

**Issue Experts**

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. Merck has 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 particular 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](#).

## STAKEHOLDER FEEDBACK

**We strive to make a positive contribution to local communities through responsible and safe operations and through our philanthropy and employee volunteer efforts.**

**Communities Where We Operate**

Our objective is to develop culturally appropriate mechanisms to engage and build relationships with our local community stakeholders.

Some Merck sites have created community review boards, which meet regularly; others host neighborhood or town hall meetings to seek input from community members. In the case of a new facility, site expansion or major capital project, we meet with community stakeholders to consider the potential impact of our plans—whether direct or indirect—and to factor community opinions and concerns into the planning process from an early stage. 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 Merck’s 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, health and safety, ethics, diversity, and protection of the environment. For more information on Merck’s approach to supply chain management, please [click here](#).

## Industry Associations

Merck engages 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 a list of our memberships, please [click here](#).

## Engagement Mechanisms

In 2012, Merck used various mechanisms to engage stakeholders, ranging from one-on-one discussions, surveys and expert input forums, to informal discussions during conferences and meetings. 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

Merck participated in the London Summit on Family Planning in July 2012, which launched the Family Planning 2020 initiative, designed to meet the need for modern family planning in developing countries. Together, we are continuing to work closely with the governments of the 70 target countries and other key stakeholders to mobilize the political will to prioritize family planning methods and the required infrastructure, capabilities and resources to secure access to modern family planning for 120 million more women by 2020. Engagement with members of the reproductive health and family planning community has also

helped to inform Merck's access strategy for its contraceptive implant, including a tiered-pricing approach, support for capacity building among healthcare providers, and a new public-private partnership announced in **May 2013**.

Merck Chairman and Chief Executive Officer, Ken Frazier, serves as a commissioner of the UN Commission on Life-Saving Commodities for Women and Children, which aims to build consensus around priority actions for increasing the availability, affordability, accessibility and rational use of essential commodities for women's and children's health. In September 2012, Merck leaders attended the launch of the Commission's report outlining an initial list of 13 essential, overlooked commodities in four categories (reproductive health, maternal health, newborn health, and child health) that will be considered by the Commission in order to further its understanding of the main barriers that prevent access to many medicines and health products.

In 2012, Merck continued its 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 2009, Merck has been an active participant in a number of Roundtable projects including efforts to help reduce the global burden of 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.

During the formation and implementation of the women's health preventive services provisions of the Affordable Care Act in the U.S., Merck worked collaboratively with a number of U.S. women's health groups, including Planned Parenthood of America, the National Family Planning & Reproductive Health Association, and the National Campaign to Prevent Teen and Unplanned Pregnancy, to ensure that the provisions included access for women to products and services at first-dollar coverage.

In Europe, Merck senior leaders engaged with members of the European Parliament, the World Health Organization-EURO, the European Centers for Disease Control (ECDC), and other EU institutions, national policy makers, key opinion leaders, patient associations and women's leagues on health inequalities affecting Eastern European women in accessing cervical cancer prevention. As a result of this collaboration, a call to action was issued that contributed to the release of updated ECDC guidelines in September 2012 with a focus on access.

In January 2012, Ken Frazier participated in the launch of the London Declaration on Neglected Tropical Diseases (NTDs) along with other private-sector leaders, donors, endemic country governments and multilateral organizations. These leaders committed to working together to control or eliminate 10 NTDs by 2020, in alignment with World Health Organization targets. In November 2012, Merck

participated in the “Uniting to Combat NTDs: Turning the London Declaration into Action” meeting, which was convened to develop the concrete actions needed to make the 2020 goals a reality.

In 2012, Merck participated in a workshop sponsored by the Center for Biologics Evaluation and Research (CBER), the branch of the U.S. FDA that regulates vaccines and biologics, and other agency partners, including the National Institutes of Health, the Centers for Disease Control and Prevention, and the National Vaccine Program Office, focused on the development of cytomegalovirus vaccines (CMV). CMV, also known as human herpes virus 5, infects approximately half of the U.S. population by adulthood. Congenital CMV infection causes mental retardation, learning disabilities, hearing loss, vision loss, and other disabilities. Discussion at the workshop focused on the importance of CMV as a pathogen, the significant potential public health value of a CMV vaccine, clinically relevant endpoints for Phase 3 vaccine trials to address CMV indications, and priorities for further vaccine-related research on CMV. Engagement between Merck participants and diverse sets of stakeholders from academia, professional organizations, patient advocacy groups, and the U.S. government in discussions such as these help inform our research and development strategies.

## Animal Health

In 2012, Merck Animal Health supported efforts of the International Federation for Animal Health (IFAH) to join with national governments, nongovernmental organizations and the private sector in a

new collaborative partnership led by the Food and Agriculture Organization (FAO) on the environmental benchmarking of livestock supply chains. The partnership is expected to pave the way to an agreed methodology to measure the environmental impact of the livestock supply chain and help assess mitigating measures, as well as ways to improve production performance to ensure the sustainability of future food supplies.

## WORKING WITH PATIENT GROUPS

**Merck’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.**

Despite significant medical advances in many therapeutic areas, many countries have made limited progress in their level of patient treatment and in providing broad-based access to available therapies. This situation arises in part from the tension between the best clinical practices (as defined by evidence-based medicine) and the pressures of cost containment in publicly financed health systems.

In this context, 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,

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 to improve access to therapies and increase awareness of the disease.

### Practices

Merck has a long history of collaboration with patient groups and health-related charities in areas that are relevant to our business, including knowledge and understanding of diseases and treatment options, and information and decision-making among consumers in healthcare.

Because we recognize the legal and reputational risks of inappropriate donations or sponsorships, we have 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, or to develop appropriate programs and projects with, patient societies and associations. 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 fund and participate in programs that help patient organizations increase disease awareness and

improve access to medicines and better healthcare. And we work with patient organizations to disseminate and share quality medical, scientific and pharmaco-economic 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 Merck groups
- The consistent application of Merck policies and procedures, including those related to contributions; advertising and promotion; sales and marketing; and to our ethical business practices as outlined in *Our Values and Standards* guide

## Decisions

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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.

In response to stakeholder feedback, 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.

## ABOUT THIS REPORT

**As part of our commitment to be transparent about our corporate responsibility initiatives, including our business activities and operations, we report on our performance annually on this website.**

This report covers Merck's corporate responsibility activities and progress as of December 31, 2012, with some additional information relating to 2013.

Where possible, we link readers to further information on [Merck.com](http://Merck.com) and in our [annual financial reports](#).

We have used several external guidelines and measurement frameworks to inform the scope of our reporting. These include the [Global Reporting Initiative \(GRI\) G3.1 Guidelines](#), the [Access to Medicine Index](#), the [Millennium Development Goals](#), and the 10 principles of the [UN Global Compact](#).

This report has been prepared consistent with the GRI's Sustainability Reporting Guidelines and we are self-declaring to Level A. While this report has not been reviewed externally prior to publication, we are currently having this application level checked by GRI.

Data in this report relate to worldwide operations for the calendar year 2012, except where stated. We plan to publish our next comprehensive corporate responsibility report in 2014.

There have been no significant changes from previous reporting periods in the scope, boundary or measurement methods applied in this report.

Acquisitions and divestitures are discussed in the company's [2012 Merck Form 10-K](#).

We also have published a brochure of 2012 highlights. Please visit [MerckCR.com](#) for an interactive version, or visit the [downloads & media section](#) of this website to view or print a copy of the brochure.

## 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, consumer health and animal products. We aspire to be 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 be recognized as a great place to work; and to provide investors with a superior rate of return.

The categories in which we have products include heart and respiratory health, diabetes, infectious diseases, suncare, animal health and women's health. 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.

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

### Prescription Products & 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, Merck 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](#).

### Vaccines

Vaccines are one of the greatest public health success stories of the 20th century, and Merck has played its part in that story.

We are one of only a few companies that remain dedicated to the complex business of researching and producing vaccines. Our unique contributions include the development of vaccines that help prevent now-rare diseases, such as measles and mumps, as well as diseases such as shingles and cervical cancer. To learn more, [click here](#).

### Animal Health

Through Merck'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 and pharmaceutical specialty products; innovative delivery systems; and performance technologies and value-added programs, such as pet-recovery services and livestock-data-management tools. To learn more, [click here](#).

### Consumer Care

Through our consumer health products, we strive to enhance the quality of life for people and their families around the world.

Each day, millions count on one or more of our industry-leading brands to help prevent or treat various common conditions. These brands include such household names as CLARITIN® for allergies, COPPERTONE® for sun care and DR. SCHOLL'S® for foot care. To learn more, [click here](#).

### Pipeline

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



## ECONOMIC IMPACT

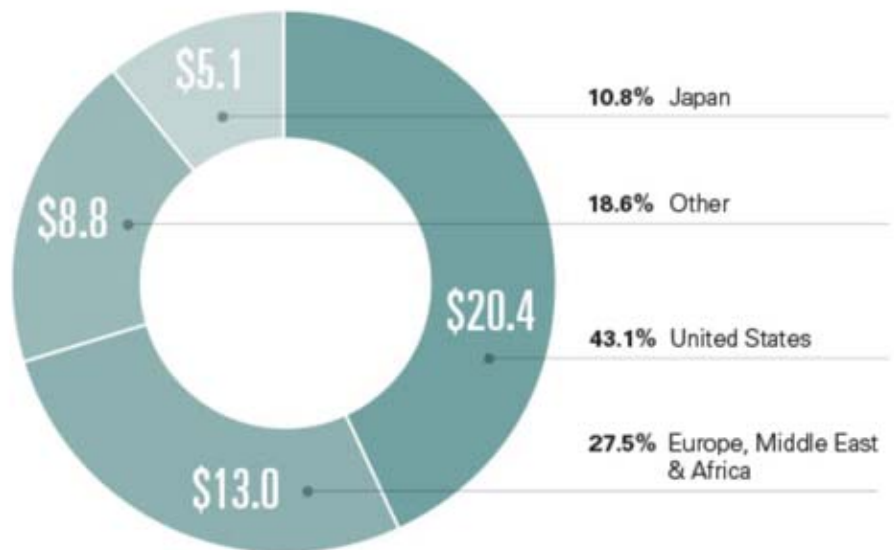
**Sustainable business success depends on making quality products that people value through sound financial stewardship and responsible governance that ensures we are meeting customers' needs ethically and transparently.**

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, at Merck 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.

During 2012, we delivered strong performance across all areas of our company. In addition, we demonstrated that our growth strategy is creating shareholder value while enabling us to continue investing for profitable global growth.

### 2012 REVENUES (IN BILLIONS)



One example of strong performance is the JANUVIA® (sitagliptin) family of oral medications for treating type 2 diabetes. With 2012 sales of \$5.7 billion, JANUVIA achieved the distinction of being the highest-selling product family on an annual basis in Merck's history. In addition, we continued to launch VICTRELIS® (boceprevir), a major advance for the treatment of chronic hepatitis C, in markets around the world.

Also in 2012, Merck's vaccine sales reached \$5.1 billion. In fact, considering the sales we make to customers and the contribution from our joint venture with Sanofi-Pasteur in Europe, we are now one of the leading vaccine companies in the world. Both GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], a vaccine that helps prevent cervical cancer and other diseases caused by human papillomavirus (HPV); and

ZOSTAVAX® (zoster vaccine live), for the prevention of herpes zoster, commonly known as shingles, experienced double-digit growth.

For more information on our sales in 2012, [click here](#).

Importantly, we continued to advance our pipeline, successfully completing four new drug applications. At the same time, the disappointing outcome of a key late-stage cardiovascular research and development (R&D) program at the end of the year led us to decide not to file for U.S. approval of our Phase III drug, TREDAPTIVE, and remove it from markets around the world. An update on Research and Development can be found in the company's **Form 10-K**.

To help address healthcare needs around the world, Merck continues to grow globally. We expect to see continued

Financial Information	2010	2011	2012
Sales (\$USM)	45,987	48,047	47,267
Research and Development (\$USM)	11,111	8,467	8,168
Number of employees	94,000	86,000	83,000
Number of stockholders of record	171,000	166,100	157,400
Annual cash dividend paid per share (\$US)	1.52	1.52	1.68
Global tax expense as reported on income statement (\$USM)	671	942	2,440

growth in key emerging markets and Japan from both the expansion of our product portfolio as well as future contributions from joint ventures such as Supera Farma in Brazil, which we announced in 2012, and Simcere in China, announced earlier.

Our **Merck Animal Health** and **Merck Consumer Care** businesses complement our Human Health business and are also important contributors to our growth strategy. We are a leader in many categories in both areas and intend to leverage that leadership to enhance Merck's overall performance.

By driving growth in our broad product portfolio and reducing costs, in 2012 we were able to absorb the impacts of a challenging year, reinvest for future growth and increase shareholder value.

For additional information about our business and economic impact, please see our **Form 10-K** for the year ended December 31, 2012.

## SUPPORTING OUR COMMUNITIES

**Merck contributes substantial economic and social value to the countries and communities in which we operate.**

Through our local research, manufacturing and sales operations; by purchasing products and services from numerous and diverse suppliers; and by investing in community infrastructure, we generate skilled-employment opportunities and market activity that directly and indirectly drive income and economic growth. Through our research activities, Merck contributes to local research and development (R&D) capacity in the life sciences sector, which is critical to building national competitiveness in the 21st century. By granting licenses for our products and our technical know-how to small and

medium-size companies, we contribute to their growth and to the local scientific knowledge base. Through our national and local tax payments, we help support government-financed pensions, health systems and local infrastructure.

As of December 31, 2012, Merck (including its Banyu subsidiary in Japan) had a physical presence in 81 countries, with 485 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 employees.

At Merck, we aspire to having 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.

We contribute to our communities in three key ways:

- Direct and indirect economic contributions, such as employment, training, support of local suppliers and local R&D, and paying taxes

- Managing our community impacts— for example, by ensuring confidence in environmental and safety performance and respecting human rights
- Addressing community needs through philanthropy and community involvement

Underlying our community approach is our commitment to respect 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**.

## AWARDS & RECOGNITION

The following are highlights of recent awards for and recognition of Merck's\* comprehensive approach to corporate responsibility.

### Global Recognition

#### Dow Jones Sustainability Index

For the fourth year in a row, Merck has placed on the Dow Jones Sustainability North America Index, which is based on a thorough analysis of corporate economic, environmental and social performance. The North America Index captures the leading 20 percent of firms (in terms of sustainability) out of the largest 600 North American companies.

#### FTSE4Good Index

Merck is a FTSE4Good constituent member. The FTSE4Good Index Series measures the performance of companies that meet globally recognized corporate responsibility standards.

#### STOXX® Global ESG Leaders Indices

For the second consecutive year, Merck has placed on the STOXX® Global ESG Leaders Indices—an innovative series of environmental, social and governance (ESG) equity indices that are based on a transparent selection process.

#### Access to Medicine Index

Merck ranked No. 4 on the 2012 Access to Medicine Index, which assesses and ranks pharmaceutical companies on various criteria related to global access to medicines.

#### *Business Review Weekly (BRW), Australia*

*Business Review Weekly*, one of Australia's leading financial publications, placed MSD in Australia amongst the Top 50 Most Innovative Companies in 2012. This list acknowledges organizations that have embedded innovation within their operations to bring to market compelling new ideas, products and ways of doing business.

#### Korean Management Association Consulting

MSD in Korea was named Corporate Social Responsibility Leader of the Year in the category of Innovation, at the 2012 Korea Management Awards organized by the Korean Management Association Consulting. MSD won the award in recognition of its long-standing commitment to corporate responsibility in Korea through several strategic and sustained corporate responsibility programs targeted at key stakeholders.

#### *The Chronicle of Philanthropy*

In its annual survey of philanthropic giving by U.S. corporations, *The Chronicle of Philanthropy* ranked Merck No. 2 in Corporate Donations of Cash and Products among some of the country's largest corporations.

#### Pro Bono Institute (PBI)

The PBI presented the members of Merck's legal department with its Laurie D. Zelon Pro Bono Award. This award recognizes individuals and organizations that have provided exemplary pro bono service. Justice Zelon is an associate justice of the California Court of Appeal known for her pro bono leadership and contributions to enhancing justice for all.

#### *Fortune*

*Fortune* magazine ranked Merck the fourth Most Admired Company within the Pharmaceutical Industry on its annual list of the World's Most Admired Companies in 2012. Within the industry, Merck retained its second-place ranking in "Social Responsibility."

#### Shared Interest

Merck was recognized for its commitment to building healthy communities in southern Africa by Shared Interest, a New York-based social investment fund that works to mobilize resources for southern Africa's economically disenfranchised communities.

#### Access to Health

#### Prix Galien Award

Merck/MSD was awarded the Belgian Prix Galien 2011 for VICTRELIS® (boceprevir). The award was created in Belgium in 1982 to recognize exceptional medical and scientific research and innovation, and is considered one of the highest distinctions in the pharmaceutical

and biochemical industries. MSD was one of two recipients of the Prix Galien 2011 for the most innovative new drug, along with Janssen Pharmaceuticals for telaprevir. VICTRELIS and telaprevir are the first of a new class of drugs, known as HCV protease inhibitors. The award recognizes the first major advances in the treatment of chronic hepatitis C in the last 10 years.

### American Library Association

The *Merck Manuals* website was selected as one of the Best of Free Reference Web Sites of 2012 by a unit of the American Library Association known as Emerging Technologies and Reference, or MARS. Voted for by member librarians from around the United States, the Merck Manuals site was one of 26 websites to be recognized as an outstanding site for reference information.

### Environmental Sustainability

#### Maplecroft Climate Innovation Index

The Maplecroft Climate Innovation Index identifies global companies that demonstrate superior management, mitigation and adaptation in climate innovation. Merck ranked 45th out of the top 100 global companies (and 17th among the top 100 U.S. companies) out of a total universe of more than 300 reviewed companies. Merck placed third out of the 10 pharmaceutical companies that made the global ranking.

### Newsweek Green Ranking

Merck has appeared on *Newsweek's* Green Rankings list ever since it was first published, in 2009. The Green Rankings assess companies' environmental footprint (including greenhouse gas emissions and water use); environmental management (including environmental policies, programs and initiatives); and disclosure (including company reporting and involvement in transparency initiatives). Merck moved up 107 places on the Global 500 list in 2012.

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

Merck was recognized with the 2012 ENERGY STAR Sustained Excellence Award from the U.S. EPA for its continued improvement of energy performance and its leadership in energy management in both the pharmaceutical and industrial sectors. Merck has been an ENERGY STAR partner since 1996 and has been recognized by the EPA for seven consecutive years—twice as the Partner of the Year and now, for the fifth time, for Sustained Excellence.

### Employees

#### DiversityInc

Merck ranked No. 16 on *DiversityInc's* annual list of the "Top 50 Companies for Diversity" in 2012, making it the company's tenth consecutive appearance on the list. This list is the leading assessment of diversity management in corporate America as well as globally.

### Working Mother Magazine

In 2012, Merck received the new *Working Mother* Quarter Century Award for being one of three employers who has made the 100 Best Companies list for 25 years. This list recognizes companies dedicated to providing employees with benefits, including career advancement, childcare, flexible work arrangements and leave for new parents.

### U.S. Hispanic Advocacy Association

The U.S. Hispanic Advocacy Association honored Merck with one of only four Bravo awards presented for Vision, Leadership and Commitment to Diversity and Inclusion Best Practices.

### G.I. Jobs Magazine

Merck was recognized as one of the Top 100 Military-Friendly Employees by *G. I. Jobs* magazine in its seventh annual survey. This is the fourth consecutive year that Merck has received this honor.

### National Association for Female Executives (NAFE)

Merck was listed among NAFE's Top 50 Companies for Executive Women in 2011 and 2012. The NAFE list recognizes American corporations that have promoted women into top executive positions and created a culture that identifies, promotes and nurtures successful women.

## **PhRMA Research and Hope Award**

A team of Merck scientists who led the discovery and development of VICTRELIS, a first-in-class treatment for hepatitis C, were honored with the American Chemical Society's 2012 "Heroes of Chemistry" award.

## **NAACP Legal Defense and Educational Fund (LDF)**

Merck's dedication to improving human life while fostering a diverse, inclusive and collaborative work environment was honored by the NAACP Legal Defense and Educational Fund (LDF) in 2012. The LDF presented Merck Chairman and Chief Executive Officer, Ken Frazier, with its National Equal Justice Award, which recognizes individuals whose leadership and actions in business, government, law, culture and other fields have led to tangible advancements in human equality and justice.

## **Ethics & Transparency**

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

For the second consecutive year, Merck ranked No. 1 in the CPA-Zicklin Index of Corporate Political Disclosure and Accountability, with a score of 97 out of 100.

## **Corporate Responsibility Magazine**

*Corporate Responsibility* magazine listed Merck No. 6 in its 2012 ranking of the Best Corporate Citizens in Government Contracting.

## **AC Nielsen Survey**

MSD in the Persian Gulf region was named the Most Trusted and Valued Company in the Gulf region in a market research survey conducted by AC Nielsen in 2012. MSD also came out on top in terms of reputation among pharmacists and government officials across the region.

\*Merck is known as MSD outside of the United States and Canada.

# FOCUS AREAS



While our overall focus on access to health remains unchanged, we have identified four focus areas to ensure that we are well positioned to discover better ways to manage the many challenges that lie ahead.

# ACCESS TO HEALTH



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](#).

## KEY PERFORMANCE INDICATORS

ACCESS TO HEALTH	2011	2012
<b>Research &amp; Development</b>		
Top 20 global burdens of illness addressed by our products and pipeline <sup>1</sup>	53%	55%
GCP/PV audits by regulatory agencies of Merck or clinical trial investigators that led to significant fines, penalties, warning letters or product seizures	0	0
Initiated (new) licenses for new technologies	52	61
Narrative of compounds provided to Product Development Partnerships <sup>2</sup>	Online	Online



## KEY PERFORMANCE INDICATORS

ACCESS TO HEALTH	2011	2012
<b>Manufacturing &amp; Supply</b>		
Product recalls in the United States	0	4
Countries we currently supply with our products	140	140
Local and regional manufacturing partnerships <sup>3</sup>	130	84
Products available via local and regional manufacturing partnerships	NA	34
<b>Registration</b>		
New product and device registrations <sup>4,5</sup>	334	437
Local regulatory agency GCP/PV training requests fulfilled that will help strengthen agency capabilities with their GCP/PV compliance oversight role <sup>6</sup>	Online	Online
Products submitted that have achieved WHO prequalification (cumulative)	10	10
<b>Commercialization</b>		
Products for which we have access pricing <sup>7</sup>	19	19
Countries where at least one product has intra-country pricing of public and private sectors <sup>8</sup>	49	49
Investment in patient- and provider-education programs	\$93.9M	\$91.1M

## KEY PERFORMANCE INDICATORS

ACCESS TO HEALTH	2011	2012
<b>Community Investment</b>		
Healthcare workers trained through major programs and partnerships <sup>9</sup>	51,600	38,166
Investment in partnerships for activities to address underlying barriers to health, such as health system strengthening and capacity building <sup>10</sup>	\$34.7M	\$23.8M
People reached through our major programs & partnerships <sup>9,11</sup>	255M	269M

<sup>1</sup> As defined by the WHO and excluding accidents, premature births and self-inflicted injuries.

<sup>2</sup> For information on product development partnerships, visit the "Partnerships" tab [here](#).

<sup>3</sup> The number of partnerships decreased in 2012 following the evaluation of the manufacturing capabilities needed to support and sustain our Access goals.

<sup>4</sup> Data includes new products and new indications.

<sup>5</sup> For information on new registrations by region, click [here](#).

<sup>6</sup> For information on local regulatory agency GCP/PV training requests, click [here](#).

<sup>7</sup> Differential pricing intended to facilitate access for the at-need population.

<sup>8</sup> Countries with an MSD trading equity.

<sup>9</sup> "Major" is defined as an investment by Merck's Office of Corporate Philanthropy and/or The Merck Foundation of more than \$300,000 per year and/or an engagement with a national government.

<sup>10</sup> Includes investments by Merck's Office of Corporate Philanthropy and/or The Merck Foundation; also includes funding for nutrition and access to clean water.

<sup>11</sup> Includes treatments approved for river blindness and lymphatic filariasis through the Merck MECTIZAN<sup>®</sup> Donation Program.

## OUR APPROACH TO ACCESS

**It is unacceptable that the vast majority of people around the world are unable to benefit from advances in medicines and healthcare.**

As a global healthcare company, Merck believes it has an important role and responsibility in improving access to medicines, vaccines and quality healthcare worldwide. To help address this challenge, we are committed to discovering smart, sustainable ways to expand access to healthcare, which is also necessary to sustain our business in the longer term.

The enormity of this challenge, however, is far greater than our ability alone to address it. Barriers to quality care and medical treatment—such as a lack of trained healthcare professionals, weak infrastructure, civil strife and a shortage of safe drinking water in many parts of the world—make even basic healthcare delivery difficult at best.

We believe our role is to work in partnership with others—governments, donors, patient organizations, healthcare professionals, nongovernmental organizations (NGOs), multilateral organizations and others in the private sector—to lend them 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.](#)

In addition, we are implementing a multipronged strategy to improve access to medicines and vaccines by examining our approach to research and development, manufacturing and supply, registration, commercialization and community investment.

To guide our efforts in these key areas of activity, we follow our companywide [Access to Health Statement of Guiding Principles](#) to ensure that we are striving to expand access in innovative ways on an ongoing basis:

### Research and Development

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

### Manufacturing and 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

Merck 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 Merck'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.](#)

During 2012, we engaged in a number of practices, programs and partnerships to help drive progress in achieving the objectives outlined in our Access to Health Guiding Principles. Examples include:

Merck 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, Merck entered into an agreement with researchers at the University of California, San Francisco (UCSF), and provided to UCSF scientists a series of compounds for screening, which have the potential to lead to better and safer treatments for patients suffering from Schistosomiasis, a blood-borne parasitic disease that affects millions of people living in the developing world.

Merck is committed to ensuring we have the internal and external supply capability to make our medicines and vaccines available, accessible and affordable to a minimum of 80 percent of the world's population by the end of 2015. To realize this goal, we have executed manufacturing and supply

agreements with local manufacturers to broaden access to our products in local markets. For more information, visit

**Manufacturing & Supply Chain.**

In 2012, we also implemented the Richard T. Clark Fellowships for World Health. The objectives of the program are to improve health literacy, increase access to health services and products, enhance access to health education and improve health outcomes, while also providing unique career development opportunities that help expand employees' understanding of critical needs in different parts of the world. This program helps to put Merck's mission into action and makes a unique difference in people's lives and the lives of the employees who become **Fellows**.

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 Statement of Guiding Principles.

As we strive for continuous improvement, 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 approach, brainstorm more innovative mechanisms and models, and reevaluate our targets and metrics. Our goal is to develop a more consistent and cohesive approach to our access strategies that helps to make our medicines and vaccines available to more people in more places, while at the same time building a sustainable business in developing countries. Two additional workshops are planned in 2013.

However, we recognize that we do not have all the answers to the access challenge, so, in addition to our ongoing internal discussions, we also spend significant time with external stakeholders who have other perspectives and experience. By listening to and working with groups such as the GAVI Alliance, UNICEF, UNAIDS, Project HOPE, Médecins Sans Frontières (MSF) and Oxfam, we learn a great deal about how we can do more and move closer to our common goal of facilitating greater access and, ultimately, helping to save lives.

There is also a need for relevant industry-specific indicators that will allow comparisons across the industry. Such indicators are beginning to be developed. One example is the Access to Medicine

Index (ATMI), which ranked Merck No. 4 in its 2012 Index. Merck believes that the ATMI represents an important first step in this process, but more work is needed to ensure that all indicators are relevant and provide true measures of corporate responsibility. Toward that end, we remain committed to working with the ATMI and other organizations, including the Global Reporting Initiative (GRI), to develop meaningful measurements for Merck and our industry.

# RESEARCH & DEVELOPMENT

## Medicines discovered and developed by Merck scientists save and improve countless lives around the globe.

In the past 60 years, innovative medicines and vaccines have helped to dramatically improve public health and the economic well-being of societies and individuals in many countries.

As a result of such biomedical advances and increasing economic prosperity, diseases that were prevalent 100 years ago, such as smallpox and polio, have all but disappeared. The global burden of illness looks very different today, and the World Health Organization (WHO) projects that it will look different again in 20 years.

Merck is committed to addressing medical needs through scientific excellence: R&D expenses were \$8.2 billion in 2012. The talent of our scientists, combined with the dramatic scientific and technological advances of the past decade, has led to an exciting period of Merck research, as we seek new and more-effective ways to treat diseases.

Merck’s research philosophy is based on satisfying unmet medical needs globally. In assessing our research priorities, we also explore the scientific and commercial feasibility of conducting research with the potential to develop a product that is useful, considering available knowledge, theories, technologies and skills. Our R&D is focused on the following therapeutic areas:

- Cardiovascular Disease
- Diabetes and Endocrinology
- Neuroscience and Ophthalmology
- Oncology
- Infectious Diseases

*“Innovation is the centerpiece of our growth strategy at Merck. We continue to make significant progress on our strategy to drive growth from our existing portfolio and to bring forward breakthrough medicines and vaccines that address unmet medical needs and return significant value to our shareholders.”*

**Kenneth C. Frazier**  
Merck Chairman and  
Chief Executive Officer

- Respiratory and Immunology
- Vaccines

We pursue therapies in a variety of modalities, from small molecules and vaccines to biologics (including peptides, small proteins and antibodies) and RNAi (RNA Interference—a method of selectively silencing genes).

Merck Research Laboratories (MRL) commits resources to the discovery and development of innovative products that help improve and save lives around the world and to delivering the most value to our customers. Our products and research priorities are aligned with the current and projected global burden of disease as defined by the WHO, as well as with the increasing need for new therapies targeted to treatment-resistant diseases, such as hepatitis C.

Merck’s R&D model is designed to increase productivity and improve the

## 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.

**PIPELINE**

**Merck’s research pipeline** illustrates the progress of our R&D discovery efforts.

The company currently has a number of candidates under regulatory review in the United States and internationally. An update on our Research & Development can be found in the company’s **10-K Report**.

probability of success by prioritizing resources on disease areas of unmet medical need, scientific opportunity and commercial opportunity. We are committed to research in specific therapeutic areas and to clinical development in support of new products. **Learn more.**

Faced with the complex challenges of bringing important new drugs to patients while simultaneously controlling the rising costs of innovation, Merck is also using important new preclinical, clinical and quantitative tools to help us rapidly differentiate between drugs that will clearly meet patient needs and those that will not. A focus on translational medicine is also critical to these efforts, 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 (Phase

I, if possible) to provide preliminary evidence of their potential benefit before proceeding with further development.

In addition, Merck is 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 the trial thousands of times, exploring the impact of different factors that influence a disease, a patient population, and efficacy and safety 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 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 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 preclinical and clinical compounds and technology platforms that have the potential to drive both near- and long-term growth. In this regard, MRL establishes significant external alliances to accelerate drug discovery and development, improve R&D productivity, and successfully commercialize novel therapeutics and vaccines. **Learn more.**

**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. Merck utilizes 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 Merck to consult on pediatric development issues and key pediatric policy questions. For a listing of all of our pediatric clinical trials, **click here.**

## PARTNERSHIPS

**Merck supports academic and community-based physicians and researchers in expanding clinical and scientific knowledge and improving the understanding of the appropriate use of Merck products.**

### **The Merck 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 will be generated and properly disseminated in peer-reviewed publications.

We believe in broader disclosure of financial relationships between physicians and the pharmaceutical industry. In 2008, Merck endorsed the Physician Payment Sunshine Act, mandating disclosure of certain financial relationships. Even in the absence of a legislative requirement, in October 2009, we began voluntarily disclosing all payments to U.S.-based healthcare professionals who speak on behalf of Merck about our products and other healthcare issues. [Click here](#) for more information and a list of disclosures.

Merck 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, Merck sponsors research conferences—such as selected Gordon Research Conferences, an international forum where researchers discuss advances in biologic, chemical and physical science—that cover areas in which Merck is conducting research.

Merck also collaborates 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**

**BioPontis Alliance** and Merck are working to bridge the gap between early academic discovery science and the development of medicines and technologies that impact human health. BioPontis, a first-of-its-kind hybrid investment fund and scientific development company, selects promising scientific inventions from academic laboratories, and invests in and directly develops a portfolio of technologies that address unmet medical needs in cancer and infectious and neurological diseases. BioPontis partners include New York University, Columbia University, Memorial Sloan-Kettering Cancer Center, the University of Pennsylvania, the University of North Carolina at Chapel Hill and the University of Florida.

The **California Institute for Biomedical Research (Calibr)** and Merck have established a collaboration to accelerate the translation of basic biomedical research into innovative new medicines to treat disease. Calibr will offer academic scientists around the world a streamlined, efficient and flexible path for translating their biomedical research into novel medicines. Calibr investigators will work collaboratively with academic scientists to advance new discoveries in preclinical proof-of-concept efforts, at which stage commercial partnerships will be sought for further development.

Calibr has been designed to provide expertise and resources to academic scientists so that they can maximize the therapeutic potential of their discoveries.

**PatientsLikeMe (PLM)** and Merck have established a health information collaboration focused on patient-based research into psoriasis and aimed at producing new insights into this common autoimmune disease in the U.S. (estimated by the National Psoriasis Foundation to affect over 7.5 million Americans). Under the agreement, PLM will work directly with Merck's clinical researchers and epidemiologists to analyze and interpret data reported by patients with psoriasis. This effort will focus on evaluating the impact of psoriasis on affected patients and informing a novel approach to improving outcomes.

PLM is the world's leading online health data sharing platform. PLM creates new knowledge by charting the real-world

course of disease through the shared experiences of patients. While patients share information to help improve their outcomes, the data they provide allows researchers to learn how these diseases act in the real world and helps accelerate the discovery of new, more effective treatments.

The Regenstrief Institute (RI) and Merck have signed a five-year agreement to collaborate on a range of projects that will use clinical data to inform personalized delivery of healthcare. The work will explore novel methods for studying diseases and interventions for chronic conditions such as diabetes, cardiovascular disease and osteoporosis.

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

Merck launched the Merck Lumira Biosciences Fund (Fund). The Fund will provide investment capital to support early-stage biotechnology companies with operations in Québec. The Fund represents a novel collaboration between a pharmaceutical company and a specialized venture capital firm.

Merck is 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 Merck. 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

The Biomarkers Consortium, in which Merck also participates, 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. Merck contributes to a number of FNIH projects and is actively discussing participating in future projects.

Merck has continued its 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.

Within Europe, Merck participates in the **Innovative Medicines Initiative (IMI)** project RAPP-ID (Development of Rapid Point-of-Care Platforms for Infectious Diseases). This consortium of 19 partners from across the pharmaceutical, diagnostics and academic worlds aims



to address the increasingly urgent need to diagnose and treat suspected infections more accurately and rapidly, and will work to develop new diagnostics. The development of rapid, point-of-care diagnostic tests for specific infections would not only facilitate enrollment in clinical trials but also lead to more appropriate use of agents in clinical practice.

Merck, together with 26 partners, is also involved in another IMI consortium, OrBITO, whose primary aim is to investigate and develop novel predictive biopharmaceutical tools for oral drug delivery.

Overall, Merck continues to review further opportunities to participate in IMI projects aligned with its areas of interest.

## GOVERNANCE

At Merck, 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, headed by the president of Merck Research Laboratories (MRL), develops the divisional strategy, allocates resources, and manages the R&D portfolio. The team comprises the heads of functional areas within 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 Merck employees must abide by our **Code of Conduct**, which applies to the way we work with external researchers, doctors and academics. According to Merck's 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 Merck, 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 MRL policy, Merck does not tolerate fraud or misconduct in our research activities—whether by an employee or an external business partner. Merck deals promptly, directly and appropriately with all reported cases. MRL policy is aligned with Merck's policy on **Reporting and Responding to Potential Company Violations**.

### MRL Compliance

To help ensure compliance, Merck has 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.

Merck's Compliance Program is based on Chapter 8 of the U.S. Federal Sentencing Guidelines, Sentencing of Organizations, as amended, which set 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 Merck'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 has a core cross-functional team representing the key functional areas within MRL. 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 Merck standards and corporate policies, as well as necessary education related to specific requirements applicable to the research community.

## PERFORMANCE

R&D Summary <sup>1</sup>	2009	2010	2011	2012
Research & Development Expenses (US\$B) <sup>2</sup>	5.8	11	8.5	8.2
Employees involved in research activities	17,200	15,500	14,100	13,600
New products approved	1	3	3	2
Products in the pipeline and under regulatory review	47	43	34	41
Top global burdens of illness addressed by our products and pipeline <sup>3</sup>	53%	53%	53%	55%
Established significant external licenses	51	46	52	61
Filed U.S. patent applications	308	220	223	192

<sup>1</sup> Amounts for 2009 include the impact of the merger with Schering-Plough Corporation on November 3, 2009.

<sup>2</sup> Excludes restructuring and acquisition-related expenses.

<sup>3</sup> As defined by WHO and excluding accidents, premature birth and self-inflicted injuries.

## PRODUCT SAFETY

### Safety is our highest priority.

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 this far.

If the compound makes it through this stage of testing, 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 through 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.

## PATIENT SAFETY

**We recognize that when people take our medicines and vaccines, they must have confidence in their efficacy and safety. Ensuring this confidence is crucial to us.**

Medicines and vaccines are widely tested before they are approved for marketing. This testing is governed by a comprehensive regulatory scheme and our research policies. We assess the safety of our products in rigorous clinical trials before our products are approved. Merck is committed to the timely registration of clinical trial information and disclosure of trial results—regardless of their outcome. **Learn more** about our clinical trials.

### Monitoring & Compliance

The Global Clinical and Pharmacovigilance Compliance (GC&PVC) function at Merck is part of the Merck Research Laboratories (MRL) Compliance organization, which resides in 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 Merck Human Health, Merck Animal Health and Consumer Care divisions within Merck. MRL has a comprehensive, risk-based audit and compliance oversight program that encompasses a broad range of GCP&PV audits and assessments of the following:

- **Clinical investigator sites:** Audits to assess compliance with the protocol and with Good Clinical Practice and Good Pharmacovigilance Practice 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 guidances
- **Country operations audits:** Periodic and systematic assessments of Merck's clinical trial and Animal Health operations and activities carried out by our subsidiaries worldwide
- **Business partner audits:** Audits of companies external to Merck where 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 Merck senior management that the operations, processes and computerized systems and technology supporting Merck Human Health, Animal Health and Consumer Care development activities comply with applicable global regulations and guidelines as well as internal company policies and procedures.

## Risk Management

Merck Global Safety leads the development of Risk Management & Safety teams for all products, from the beginning of Phase IIb throughout the product life cycle. Global Safety 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, 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 contributes 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

In late 2007, Merck senior leadership launched the SafetyMatters initiative to investigate potential enhancements to our

## REPORTING AN ADVERSE EXPERIENCE IN THE U.S.

To speak with a Merck healthcare professional about Merck products, or to report an adverse experience with a specific Merck product, please call the Merck 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.

Merck Global Safety manages a global system for the collection, management and reporting of adverse experience (AE) reports received by Merck worldwide. [Learn more.](#)

already robust approach to identifying and evaluating health outcomes of interest (HOIs) in connection with our marketed products. The goal of SafetyMatters is to explore and implement the appropriate use of emerging technologies and methods for HOI identification and evaluation, and thereby 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 Merck. As of March 15, 2013, the Merck Pharmacoeconomics and Database Research Unit has successfully created and utilized 27 SafetyMatters Disease Cohorts in 16 product-specific areas.

**Product Label Reviews**

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.

**Observational Medical Outcomes Pilot (OMOP)**

The **Observational Medical Outcomes Pilot (OMOP)** initiative is a partnership between PhRMA and the FDA to comprehensively assess the validity of methods of observational analysis to evaluate the safety of marketed drugs in large patient-level claims and electronic-health-record-databases. In March 2009, Merck, in collaboration

with United BioSource Corporation (UBC), was recognized by OMOP as a leader in the development of coding algorithms for HOIs used in observational research, and was selected to pursue this work on behalf of the entire OMOP research community. The UBC-Merck collaboration, continuing its efforts to help construct the OMOP clinical coding library. OMOP is complementary to our internal SafetyMatters initiative. Merck continues to support OMOP’s activities in 2013 and conduct internal tests of distributed database systems and methods, both internally and with external partners. We are continuing to explore synergies and linkages between OMOP and SafetyMatters to establish standards for the use of modern epidemiology data sources and analytic techniques to evaluate product safety in observational claims and electronic-health-record databases.

**Communicating About Product Risks**

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 United States. Outside the United States, 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**

**Merck Global Safety manages a global system for the collection, evaluation and reporting of adverse experience (AE) reports received by Merck 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, Merck has 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 the timely and accurate monitoring of the safety profile of Merck’s investigational and marketed products globally.

To report an adverse experience to regulatory authorities, we need at least minimal information: the name of the Merck product involved, an 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 Merck Research Laboratories employees—including all contract personnel—working in areas related to clinical research and global safety undergo training on Merck's AE policies and procedures when they join the company. All other employees are trained on AE reporting procedures as part of *Our Values and Standards* training.

## CHIEF MEDICAL OFFICER

**The Office of the Chief Medical Officer (CMO) collaborates with colleagues throughout the company to ensure that we remain firm in our commitment to patient safety and well-being and that we demonstrate this commitment in all of our decisions and actions.**

Dr. Michael Rosenblatt, executive vice president and chief medical officer, leads this effort, representing the independent voice of patients and medicine within Merck at the highest levels and serving as the primary voice of Merck to the global scientific and medical community. He advises senior leadership and the Merck Board of Directors on key medical matters and also serves as the company's medical spokesperson, communicating with global health stakeholders, including the media and policy makers, about our products, our policy positions and other matters affecting patients.

Our CMO and his team collaborate with external scientists, academics and governments, sharing ideas and exchanging fresh insights so that Merck can better address global health challenges. Inside Merck, they provide medical and scientific perspective to inform R&D and commercial and corporate strategies, including our social responsibilities. The team also plays a direct role in fostering scientific transparency; establishing publication guidelines; providing medical reference information and education for physicians, other health professionals and consumers; and enhancing employee wellness. Most recently, the team has expanded its focus to include the use of health information technology and partnerships to help advance the understanding of Merck products and create new opportunities for clinical trial optimization, disease modeling, and personalized patient care.

In short, the CMO and his team play a unique role in helping Merck and our employees keep a sharp focus on patients in everything we do, building on our long-standing commitment to helping the world be well.

## CLINICAL RESEARCH

**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.

Merck conducts 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 Merck'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 Practices (ICH/GCP). However, individual country regulations and guidelines should remain the primary source 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 United States, in more than 70 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.

### Regulatory Agency Training

In 2012, Merck Research Laboratories (MRL) Compliance supported two Good Clinical Practice (GCP) educational training requests. These efforts aim to enhance regulatory agency knowledge and capabilities in their GCP-compliance inspection and oversight role. The venues supported in 2012 were as follows:

- **August 2012:** MRL Compliance was invited to present on the topic of "Inspection of Electronic Source Data" at the Electronic Medical Records Clinical Trial Workshop in Taiwan. Conference attendees included Taiwanese regulators.
- **September 2012:** MRL Compliance was invited to chair a session facilitating a discussion on the topic of "Source Documents" at the Clinical Research Coordinator & Clinical Trial Conference in Japan. Conference attendees included Japanese regulators.

## CLINICAL TRIAL DESIGN

**Merck's clinical trials are designed, conducted and monitored in accordance with the same Merck global standards, whether they take place in the United States 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 a trial begins to determine the number of patients needed to participate. It is also necessary to assess the feasibility of successfully conducting the trials.
- **Acceptability of the trial design by regulatory agencies:** When necessary, Merck Research Laboratories (MRL) consults with regulatory agencies on design issues.
- **Ethical perspectives**

All Merck 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 and Monitoring

Our clinical trials are designed, conducted and monitored in accordance with the same set of Merck global standards, whether the trials take place in the United States or elsewhere around the world. In addition to following Merck global standards, the conduct of our clinical trials adheres to the ICH GCP standards and to the principles that have their origin in the Declaration of Helsinki. [Learn more](#) about our new 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 monitor and study team; when appropriate, a standing, internal data-monitoring committee of Merck Research Laboratories senior managers reviews unblinded data from ongoing trials in a prespecified, scientifically acceptable manner. The goals of the committee are to protect the safety of trial participants and assess whether the risk-benefit profile is favorable. The committee'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 monitor 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 data-monitoring committee (DMC) composed of external experts independent of Merck is assembled to provide review and make recommendations to Merck about the further conduct of the study. In addition, it is Merck's policy to establish scientific advisory committees composed of external scientific leaders and Merck scientists. With these committees, Merck 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. Merck also has 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).

Merck requires assurance that patients involved in trials, and/or their legal representatives understand the procedures, use and disclosure of personal health information, use of biological samples, and the risks/benefits involved in a clinical study, and that a patient's participation is voluntary. In circumstances where patients receive payment or reimbursement for trial participation, this compensation is appropriate for the cost and inconvenience incurred and clearly outlined in the consent form for full transparency.

Informed consent is obtained prior to initiation of any clinical study procedures, including those performed solely to determine eligibility for participation in the trial. A consent form, approved by both Merck and the IRB/ERC and translated into a language familiar to the study subject, must be carefully reviewed and approved by all participants to ensure that their the subjects' participation in the study is voluntary and informed. The consent procedures conform to all legal statutes and government regulations concerning research in human subjects and the privacy and security of the medical information. If a prospective study participant cannot read the form, a patient advocate may read the consent form, with consent documented and witnessed.

## Compassionate Use Program

Merck has 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 to new treatments under development for certain patients. Merck may also decide to conduct an expanded access program for a limited number of qualified patients according to a clinical protocol. Merck may conduct these compassionate-use programs under the following circumstances: 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; and a marketing authorization application is planned in the future.

## Protecting Personal Health Information

Merck is 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. Merck has been actively involved in the IPPC since 2006 to engage in a constructive dialogue with European data-protection authorities and other regulators on privacy standards for biomedical research.

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 a mandatory course for all Merck clinical research associates (CRAs) who monitor clinical trials, as well as for all contract research organizations (CROs) that monitor clinical trials on behalf of Merck.

CRAs monitoring on behalf of Merck 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 as per protocol
- Regulatory file documents are accurate and maintained as per ICH guidelines and sponsors DPs
- Source documentation, including drug accountability logs, are maintained as 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 as per sponsor requirements

## Contract Research Organizations

Approximately 50 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, Merck performs rigorous assessments and due diligence audits to ensure that the CRO complies with Good Clinical Practice (GCP) standards and is aligned with Merck's own Code of Conduct. Merck clinical trial teams 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, Merck works 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, Merck will limit and possibly cease future award opportunities with a CRO until the issues have been fully remediated.



## POST-MARKETING ACTIVITIES

### Merck continues to research regularly 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 non-interventional 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. Merck works closely with

regulatory authorities to design a study that will fulfill the specific requirement.

- **Epidemiological studies:** Merck has 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, Merck has systems of active data collections 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

Merck monitors the use and safety of its products. 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, United Healthcare, Pennsylvania and New Jersey Medicare, Harvard Pilgrim Health Care, Nordic Country Registries, Clinical Practice Research Database, and Mayo Clinic Olmsted County, Minnesota.

Select Post-Marketing Safety Studies			
Product	Study Type	Population	Status
ARCOXIATM (etoricoxib)	Safety	ARCOXIA-prescribing patterns and safety in 6,000 patients in the United Kingdom	Ongoing
ARCOXIA	Safety	Study of 6,439 patients prescribed ARCOXIA in United Kingdom, France, Germany	Ongoing
ARCOXIA	Safety	22,283 patients in Sweden with ankylosing spondylitis	Ongoing
FOSAMAX® (alendronate)	Safety	General practice research database in the United Kingdom	Completed 2012
GARDASIL®	Safety	189,629 female adolescents and women in the U.S.	Completed 2010
GARDASIL (human papillomavirus quadrivalent [types 6, 11, 16, 18] vaccine recombinant)	Safety and effectiveness	56,000 in Nordic countries	Ongoing
GARDASIL	Safety	Up to 135,000 males in the U.S.	Ongoing
ISENTRESS® (raltegravir potassium)	Safety in HIV population	U.S. cohort of 1,000	Ongoing
ISENTRESS	Safety	HAART Consortium for Safety Studies (HIV antivirals)	Ongoing
ISENTRESS®	Safety	EU cohort	Ongoing
NEXPLANON® (contraceptive device)	Safety	7,100 women in the United States with insertions and removals of NEXPLANON	Ongoing
NOMAC/E2 (contraceptive)	Safety	Long-term safety study in 61,500 women prescribed NOMAC/E2	Ongoing
NUVARING® (contraceptive device)	Safety	~35,000 women worldwide	Completed 2012
PROSCAR®/PROPECIA® (finasteride)	Safety	Registry study based in four Nordic countries	Ongoing
ROTATEQ® (rotavirus vaccine, live, oral, pentavalent)	Safety and effectiveness	85,150 infants in the U.S. vaccinated with ROTATEQ	Completed 2010
SAPHRIS/SYCREST (asenapine)	Safety	3,000 patients in the United Kingdom prescribed SAPHRIS/SyCREST	Ongoing
SAPHRIS/SYCREST	Safety	Four safety utilization studies in the United Kingdom	Ongoing
SAPHRIS/SYCREST	Safety	1,000 patients in the United Kingdom prescribed SAPHRIS/SYCREST	Ongoing
SAPHRIS/SYCREST	Safety	3,000 patients in the United Kingdom with bipolar disorder	Ongoing

VARIVAX®	Effectiveness over 15 years	~43,000 children and adolescents, location TBD	Completed 2010
vermakalant hydrochloride	Safety	Registry study to characterize use, dosing and safety following administration of vermakalant IV in 2,000 patients	Ongoing
VICTRELIS® (boceprevir)	Safety	Drug utilization of boceprevir and clinical management of health outcomes of interest in 1,000 chronic hepatitis C patients in Europe	Ongoing
VYTORIN® (ezetimibe + simvastatin)	Safety	Follow up of SEAS patients using Nordic and United Kingdom cancer registries	Ongoing
ZOSTAVAX® (zoster vaccine live)	Safety	~29,000 people 60 years of age or older in U.S.	Completed 2010
ZOSTAVAX	Effectiveness	At least 30,000 subjects 50 years or older in the U.S.	Ongoing

## PERFORMANCE

Number of New Product and Device Registrations	2009	2010	2011	2012
Asia Pacific	85	77	41	66
Central & Eastern Europe, Middle East & Africa	155	129	101	196
European Economic Area	82	95	95	31
The Americas	95	90	93	139
United States	2	2	4	5
Phase II-V Clinical Trials (percentage of patients)	2009	2010	2011	2012
Asia Pacific	30%	10%	8%	16%
Central & Eastern Europe, Middle East & Africa	4%	9%	5%	5%
European Economic Area	35%	30%	19%	26%
The Americas	17%	3%	16%	6%
United States	15%	49%	51%	46%
Summary of Trial Disclosure Activities	2009	2010	2011	2012
Manuscripts of clinical trial results and related papers submitted to peer-reviewed journals	176	277	245	238
Number of GCP/PV inspections conducted by regulatory agencies worldwide <sup>1</sup>	87	87	104	44

<sup>1</sup> Of the GCP/PV inspections conducted by regulatory agencies worldwide during 2009-2012, none resulted in critical observations that led to significant fines, penalties, warning letters or product seizures.

## CLINICAL TRIALS

**Merck is committed to the timely registration of clinical trial information and the disclosure of trial results—regardless of their outcome.**

In response to physician and patient requests for improved information, Merck registers clinical trials at [ClinicalTrials.gov](http://ClinicalTrials.gov) and has been posting results of clinical trials at the site since October 2008. Prior to October 2008, Merck posted results of clinical trials at [ClinTrialResults.org](http://ClinTrialResults.org). As of December 2011, the study results maintained in PhRMA's ClinicalStudyResults.org database were transferred to [Merck.com](http://Merck.com) because PhRMA announced that the database would be discontinued by the end of 2011. Registration and posting of results provides patients and physicians with information about clinical trials that are open and recruiting patients. Registration and posting of results enables researchers who analyze, report or publish the results of clinical trials to have timely information about our medicines and vaccines.

### Clinical Trial Registration

Merck has long been committed to publishing the results of our clinical trials, regardless of their outcome, in a timely manner. We believe that clinical trial registries serve an important function for patients and their healthcare providers. They learn about and gain access to relevant clinical trials of experimental treatments or preventive agents. We continually assess changing global requirements 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. Beginning in 2005, Merck registered clinical trials that began or were completed in 2002 or later and posted results for marketed products. Since February 2007, Merck's policy has been to register at initiation clinical trials (Phases I–V in patients of investigational and marketed products in which treatment is assigned) that it sponsors and conducts worldwide on [ClinicalTrials.gov](http://ClinicalTrials.gov).

In keeping with our publication guidelines, Merck discloses balanced and accurate information regarding our registered clinical trials of marketed products, regardless of their outcome. In addition, in the United States, we disclose clinical trial results of marketed products on websites designed for this purpose. Until January 2009, we posted study results on ClinicalStudyResults.org. Since then we have posted results at ClinicalTrials.gov. A synopsis of the studies is posted 30 days after the product is first marketed in the United States or within 12 months after the last patient's final visit for the primary outcome occurs, whichever is later.

### **Disclosure of Clinical Trial Results**

For many years, Merck has been committed to publishing results of hypothesis-testing trials, predating recent questions about the publication of such

data. We expanded our commitment in 2007 by disclosing results from registered trials of marketed products, as noted above in the introduction to this section. Merck's **Guidelines for Publication of Clinical Trials and Related Works** are posted online. These guidelines contain additional information about how Merck works 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 three 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

We adhere 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. Merck staff or contract writers that 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.

We adhere to ICMJE or journal-specific guidelines for disclosure of potential conflicts of interest for the full author team. Reported potential conflicts

of interest include both financial and nonfinancial ones.

In July 2011, Merck introduced its latest transparency policy for its clinical trials. Called the Protocol Transparency Initiative, this voluntary practice involves providing the clinical study protocol to biomedical journals upon submission of a manuscript on a clinical trial, allowing journal editors and peer reviewers to use this protocol in their evaluation of the manuscript for publication. Furthermore, if the journal accepts the manuscript, Merck allows the journal—at its sole discretion—to post key sections of the protocol on its website when the manuscript is published.

Merck complies with all applicable laws and regulations associated with registration of clinical trials and posting results. 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 our position on clinical trial registries, [click here](#).

### Access to Merck Clinical Trial Databases

In addition to disclosing results of clinical trials, we respond to requests from external researchers to share Merck 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.

## ANIMAL RESEARCH

**Laboratory animal research is indispensable to the discovery, development, manufacture and marketing of innovative medicines that treat and prevent disease.**

Merck is dedicated to the ethical and responsible treatment of all animals used in the development of medicines and vaccines. Merck does 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. At Merck, 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; as Merck's Institutional Official (IO) on animal welfare, this individual provides independent monitoring of animal research globally. The IO regularly communicates with senior management and the internal compliance committees on animal welfare. The IO also assists in the development of global policies and guidelines for animal research. All Merck sites hosting animal-based research have active and engaged Institutional Animal Care and Use Committees (IACUCs) or Ethical Review Committees (ERCs) that 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 all proposed animal studies, husbandry, and veterinary care facilities and investigate any research concerns. The IACUCs/ERCs regularly communicate with and send status reports to the IO regarding animal welfare.

Our 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 [http://www.aphis.usda.gov/animal\\_welfare](http://www.aphis.usda.gov/animal_welfare). As further evidence of our commitment to the highest level of animal care, Merck Research Laboratories (MRL) research sites voluntarily seek and 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 (AAALACi)**, an external, independent

organization. In fact, 100 percent of MRL facilities are accredited by AAALACi.

All Merck scientists involved with 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 of misconduct. Qualified veterinarians work with the scientific staff to consult and assist on all animal related research projects. Merck places high value on its animal-welfare stewardship responsibility; violation of these policies is grounds for employee disciplinary action, up to and including dismissal.

### Laboratory Animals

Merck is 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 proposed study that may involve discomfort or distress, even if it is relieved, must perform a literature search to assure that there is no other viable alternative methodology. It is important to note that, as in most R&D programs, a large variety of in vitro (test tube) studies are performed at Merck prior to or instead of animal studies. Laboratory animals are only used to answer important scientific questions or fulfill a regulatory requirement. Laboratory animals involved in research within MRL are all specifically bred for research purposes.

In Merck Research Laboratories, greater than 97 percent of the laboratory 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 government inspections and voluntary AAALAC site visits. The animal facilities are staffed with veterinarians and professional animal care technicians.

### Contract Research

Merck holds similar expectations for standards of animal care and use at our contract laboratories and animal vendors. Merck performs due diligence on and monitors external laboratories that perform in vivo studies on our behalf, and holds them accountable to 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 Group. All agreements with contract laboratories include terms regarding Merck's expectations for animal care and use as well as regulatory compliance. Additionally, in vivo research conducted at third-party laboratories is subject to protocol review by a Merck IACUC or an equivalent committee. Noncompliance with regulations or standards can lead to termination of the relationship.

### Support for Animal Science and Laboratory-Animal Well-Being

Merck also advocates for the development of best practices and dissemination of information by supporting and participating with

nongovernmental organizations such as the Scientist Center for Animal Welfare, the Institute for Laboratory-Animal Research at the National Academy of Sciences, and the American College of Laboratory-Animal Medicine Foundation.

### Replacement, Reduction and Refinement

Merck is 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 "3Rs"—Replacement, Reduction and Refinement—for laboratory-animal-based research.

- **Replacement**—using nonanimal systems or less-sentient species (for example, cell cultures, computer modeling, bacterial assays and fish models). At Merck, there is an entire department dedicated to in vitro biology 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, Merck has statisticians on staff who advise on study design and analysis in order to minimize the number of animals included in a study.
- **Refinement**—minimizing any distress or discomfort during a study (extensive literature reviews contribute to the

use of the best scientific models, and analgesics or tranquilizers are used whenever possible). Merck scientists have access to specialized software that search 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.

Merck's Animal Welfare group collects, promotes and disseminates information on the principles and practice of the 3Rs. Training on the 3Rs is part of staff orientation for animal research. It is our responsibility to use the most appropriate methodology and to aggressively seek scientifically valid 3R approaches to animal research. Merck also has 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. We also provide funding to support 3Rs research at external organizations such as the Johns Hopkins Center for Alternatives to Animal Testing (CAAT) and the European Partnership for Alternative Approaches to Animal Testing (EPAA).

As an example of the third R, Refinement, we have created 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.

### Internal Merck Animal-Alternative Award

To support the 3Rs philosophy, since 1994, Merck has presented an Animal-Alternative Award annually to the team or teams of Merck scientists that develop new techniques to support the alternative principle, and has published their work to share innovations with the greater scientific community. The 2011 Animal-Alternative Award recognized process refinement in bladder catheterization. The 2010 award was given for validation of an electrocardiogram-parameters model in a guinea pig model that replaced a canine model.

## REGENERATIVE MEDICINE

**Many of the most advanced scientific technologies in regenerative medicine involve animal or human embryonic stem cells.**

Merck believes that such research has the potential to help identify important new medicines and therapies for important unmet needs, and 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 adult stem cells.

We have a Regenerative Medicine Oversight Committee comprising both internal and external experts. This committee helps oversee our

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.

Merck, along with the scientific community, believes 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. Such conditions may include Parkinson's disease, cancer, cardiovascular disease, diabetes, osteoarthritis and trauma.

The company conducts research using stem cells in full accordance with all applicable laws and regulations and our own research policies. Merck research policy involving stem cells is guided by USA National Academy of Sciences and the International Society of Stem Cell Research guidelines.

## GENETIC RESEARCH

**Genetic research examines how variations in DNA affect the system of human biomolecules—such as RNA and proteins—thereby affecting disease and an individual patient's response to drugs.**

The advent of DNA-sequencing methodology used to sequence the human genome—combined with advances in microarray technology, powerful computing hardware and software, and high-throughput analysis

of biomolecules—has made it practical to initiate studies that may help us understand which genetic determinants cause or contribute to a disease or drug response.

Merck scientists have a strong commitment to understanding how genes work and how they are linked to diseases and drug treatments. For example, our scientists identified two genes in mice that could someday be targets for obesity-prevention drugs.<sup>1</sup> Finding genetic signatures that can be influenced with drugs is very complex because, in addition to environmental and behavioral factors, many genes may contribute to each individual's condition.

We collect genetic samples in Merck clinical trials and analyze data from such trials so that we can apply new technologies to improve the development of new medicines and vaccines. The collection of samples represents the critical foundation of all clinical genetic research strategies. 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 Harmonization (ICH) E6 Good Clinical Practices guidelines, and the 1997 UNESCO Declaration on the Human Genome and Human Rights.

<sup>1</sup> Xia Yang. Validation of candidate causal genes for obesity that affect shared metabolic pathways and networks. *Nature Genetics* 2009 (41): 415-23.

## R&D FOR LOW- AND MIDDLE-INCOME COUNTRIES

**Merck has a long history of both in-house research and engagement with external research partners on diseases that are prevalent in low- and middle-income countries.**

We continue to seek ways in which we can contribute expertise and resources to these disease areas.

We apply our R&D expertise and technology to identify potential products that would address unmet needs in resource-poor settings, particularly treatments for infectious diseases, such as HIV and hepatitis, and for vaccine-preventable disease. We are also involved in a number of product-development partnerships and research collaborations to further develop treatments to address the burden of disease in low- and middle-income countries.

Merck recognizes 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 neglected diseases, 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 in order to understand key research priorities and opportunities,

and to provide relevant expertise and resources.

We also recognize that our access strategy and research capabilities 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.

### INFECTIOUS DISEASES

**About one in four deaths worldwide is caused by infectious and/or parasitic diseases—totaling nearly 15 million fatalities each year.**

Merck aims to develop new anti-infectives for the treatment of HIV and the hepatitis C virus (HCV) as well as other infectious diseases. Merck also has a broad range of resources to address neglected tropical diseases (NTDs), malaria and tuberculosis (TB). For decades, we have been directly engaged in activities directed toward prevention and treatment of NTDs, malaria and TB through program implementation, R&D, and policy and advocacy efforts. We aim to build on our leadership position in the coming years, through a variety of in-house activities and strategic external partnerships.

We are also committed to developing medications that provide benefits to patients in the greatest need, and thus increasing access to medicines among patients worldwide.

### HIV/AIDS

Merck has sought to make a difference in the fight against HIV, including in the developing world. Since 1985, we've been engaged in R&D efforts for both HIV prevention and treatment. After decades of working 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 that's been made.

In December 2011, the Merck Global Health Innovation (GHI) fund invested \$5 million in Daktari Diagnostics Inc., a developer of point-of-care diagnostic systems for global health applications. Merck GHI led the \$10 million round, joined by the company's current investor group. Funds will be used to complete development and bring to market Daktari's initial products, intended for use in monitoring HIV patients worldwide, and to expand the point-of-care product-development pipeline. Daktari's product-development pipeline is focused on diagnostic tests for conditions prevalent in low- and middle-income countries, including HIV, tuberculosis, hepatitis, typhoid and conditions related to maternal health. Products are designed for use by minimally trained health workers who support care at district hospitals, health centers and other local health facilities in the developing world.

Merck is committed to working with governments, donors, innovator and generic manufacturers, multilateral organizations, and civil society to address the full range of factors affecting access to care.



Read more about our [global HIV-treatment-access strategy](#).

### Hepatitis Therapy

Merck is committed to building on its strong legacy in the field of viral hepatitis by continuing to discover, develop and deliver vaccines and medicines to help prevent and treat viral hepatitis. The WHO reports that every year, 3 to 4 million people are infected with the hepatitis C virus (HCV). About 150 million people are chronically infected and at risk of developing liver cirrhosis and/or liver cancer. More than 350,000 people die from hepatitis C-related liver diseases every year. To address the medical need, company researchers developed the first approved therapy for chronic HCV in 1991 and the first combination therapy in 1998. Extensive research efforts are under way to develop oral therapies that bring innovation to viral hepatitis treatment.

In May 2011, Merck announced that it entered into agreements with Roche, through its respective subsidiaries, to improve treatment, diagnosis and awareness of chronic hepatitis C infection in developed and emerging markets. Researchers affiliated with both companies collaborate to examine novel combinations of marketed and investigational medicines from both organizations to expedite the availability of potential new treatment regimens for patients with HCV. Several studies are ongoing under the clinical collaboration.

### THE CONTINUING LEGACY OF OUR LANDMARK HEPATITIS B PROGRAM

In the 1980s, there were more than 100 million people living with hepatitis B in China. An estimated 10 percent of China's 20 million newborns were infected every year. In September 1989, MSD signed an agreement with China to transfer the company's recombinant hepatitis B vaccine manufacturing technology. During the technology transfer, MSD trained Chinese engineers and technicians from two vaccine manufacturing plants in Beijing and Shenzhen. According to the Chinese Disease Control and Prevention Center, the program has prevented more than 30 million infections in the past two decades. The vaccine is administered to 92 to 93 percent of infants annually, reducing the proportion of infections amongst infants under 5 from 10.1 percent in 1987 to 0.96 percent in 2006.

*"MSD did a great deed. It is truly an invaluable gift for Chinese people."*

**Xiaofeng Liang**, Director of the Immunization Programs Center, Centers for Disease Control and Prevention (CDC), Chinese Ministry of Health

### Neglected Tropical Diseases

Efforts to address neglected tropical diseases (NTDs) have gathered significant momentum over recent years.

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.

#### The London Declaration

In January 2012, Merck announced that it had joined 12 other global pharmaceutical companies, as well as governments and other leading organizations, including the World Health Organization (WHO), the Bill & Melinda Gates Foundation

and the UK Department for International Development (DFID), in signing the London Declaration, a collaborative effort to accelerate progress toward eliminating or controlling 10 NTDs by the end of the decade. This initiative includes a research component that identifies gaps that need to be addressed in order to achieve the stated goals. To guide the effort against NTDs, the WHO unveiled a new publication and strategy, **"Accelerating Work to Overcome the Global Impact of Neglected Tropical Diseases— A Roadmap for Implementation."**

For more information on Merck's contributions to this initiative, please refer to the **Mectizan® (ivermectin) Donation Program**.

## Chagas Disease

In alignment with our commitment to discovering a treatment for Chagas disease, in June 2010 we announced plans to initiate 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. In planning the study, Merck 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. The study is ongoing.

## Other R&D Initiatives for Infectious Diseases

In June 2009, Merck and the nonprofit organization **Drugs for Neglected Diseases Initiative (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, Merck is 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. Merck

and DNDi will share joint intellectual property rights on drug candidates generated through early development, and Merck will retain the option to undertake late clinical development and registration of these drug candidates. In addition, Merck continues to collaborate with DNDi through the **Richard T. Clark Fellowship for World Health**.

In 2011, Merck joined a newly established R&D consortium called **WIPO Re:Search**, with a mission to accelerate the discovery and development of medicines, vaccines and diagnostics for NTDs, malaria and tuberculosis by making intellectual property (IP) and know-how available to the global health research community. Merck is contributing financial support and IP in partnership with the World Intellectual Property Organization (WIPO), BIO Venture for Global Health (BVGH) and other partners, as well as facilitating specific R&D activities via strategic partnerships with consortium members. Through the consortium, Merck signed a collaborative agreement with researchers at the University of California, San Francisco, who will screen Merck compound libraries.

In January 2012, Merck joined six other pharmaceutical companies, four research institutions and the Bill and 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 each other and with academic research

institutes, in order to develop the best drug prospects, regardless of where they originate.

In 2012, Merck continued its partnership with the NYU Langone Medical Center and the PATH Malaria Vaccine Initiative (MVI) by generating vaccine candidates whose functional activity is to block an essential early stage of malaria infection: the invasion of the human liver by the malaria parasite. The partnership leverages Merck's own technological know-how along with the NYU Langone Medical Center's extensive research into malaria and MVI's critical program oversight and funding resources.

In March 2009, Merck and Medicines for Malaria Venture (MMV), a nonprofit virtual R&D organization dedicated to reducing the burden of malaria, announced an exclusive, royalty-free license to pursue development of a licensing agreement for an investigational drug candidate (MK-4815) for the treatment of malaria in the developing world. In June 2012, MMV terminated its license, and all rights to MK-4815 were returned to Merck. We are in the process of identifying a new out-licensing partner.

MSD Spain is a founding supporter of **Fundación Medina**, a nonprofit public-private partnership between MSD, the Junta de Andalucía and the University of Granada that focuses on the discovery of new compounds and innovative therapies for infectious diseases, including malaria.

## VACCINE-PREVENTABLE DISEASES

**Vaccines are one of the greatest public health success stories of the last two centuries.**

Merck has been at the forefront of vaccine advances for decades and remains committed to discovering and developing vaccines that address vital unmet and emerging global health needs.

### **MSD-Wellcome Trust Hilleman Laboratories**

Merck looks to establish new business models and partnerships for research and development. A case in point is the **MSD-Wellcome Trust Hilleman Laboratories**. Established in 2009, the research entity is the first-of-its-kind R&D joint venture with a nonprofit mission to focus on developing affordable vaccines to prevent diseases that commonly affect low-income countries. In 2011, Hilleman Laboratories announced that its first project would be a feasibility study into how new thermostabilizing technologies might be used to develop a rotavirus vaccine designed specifically with the needs of developing countries in mind. The laboratories, located in New Delhi, India, are now fully staffed and operational.

## MERCK BIOSIMILARS

**Merck is focused on delivering high-quality biosimilar products to the patients who need them and capitalizing on the patent expirations of a number of currently marketed recombinant biologic medicines.**

### **Recombinant Biologic Medicines**

Recombinant biologic medicines are large, complex molecules that may be as much as a thousand times larger than their small-molecule drug counterparts. Predominantly due to their size, biologics are typically injected into the body, whereas many small molecules can be taken orally. The manufacturing processes for biologics also differ significantly from those of small-molecule drugs.

Biologics are generally produced in complex, genetically engineered living systems such as bacteria or cultured mammalian cells. This differs substantially from the chemical reactions used to produce small molecules. For this reason, the properties of the biologic are dependent on the engineered organisms and the manufacturing process.

A pathway for approving small-molecule generic drugs was established in 1984. This original legislation, however, was not designed to encompass biologic molecules which, at that time, were in their relative infancy. With the pending expiration of patents covering some important biologic products, the laws and policies governing development of biosimilars are still emerging around the world.

### **Merck's Position in the Biologics Industry**

Merck has a long legacy of biologic product development, including ongoing work in vaccines for prevention of disease, novel biologic therapies for disease treatment, and the development of biosimilars to enhance access to biologic treatment options. We advocate for consistent, high-quality standards and the use of state-of-the-art scientific techniques and knowledge, with the aim of ensuring that the benefits of biosimilars reach a broad patient population.

We are confident that we have established the capabilities, resources and expertise necessary to become a leader in delivering biosimilars.

### **Establishing the Scientific Standard for Biosimilars**

We support developing an efficient approach to bringing biosimilars to market and recognize the primary importance of patient safety in this effort. The complexity of developing and manufacturing biosimilars results in a product that is similar, but not identical to, the original product—therefore adequate characterization of biosimilars is essential. We believe that all biosimilar applicants should be required to conduct clinical trials that demonstrate safety and efficacy for biosimilar products. The impact of interchanging products on safety, efficacy or immunogenicity cannot be adequately predicted by analytical characterization, structure-function relationships or animal studies. As such, Merck supports a policy where drug selection is limited to prescribers.

The regulatory landscape for biosimilars development and approval is evolving rapidly. The FDA issued draft guidance on biosimilar product development in February 2012, the first step in implementing a shortened U.S. regulatory pathway for biosimilars. The draft guidance refers to the “totality-of-evidence,” which bases biosimilar development on a strong scientific foundation and will require companies to provide extensive analytical, preclinical and clinical data to demonstrate biosimilarity.

The FDA has introduced the opportunity for extrapolation with scientific justification, which would allow companies to market biosimilars for multiple indications. The draft guidance also distinguishes between biosimilarity and interchangeability. Establishing interchangeability between a biosimilar and an innovator biologic would allow for substitution, although the FDA is determining specific criteria.

While still in draft form, the guidance lays out rigorous scientific and clinical requirements to establish biosimilarity in alignment with Merck’s biosimilar development strategy. We will, of course, adapt our approach as the guidance is refined and finalized and new regulatory requirements are implemented.

### Portfolio and Partnerships

Merck is developing a well-diversified portfolio of candidates targeting several important clinical indications. We have disclosed a rituximab biosimilar candidate and have a portfolio of other undisclosed candidates.

In January 2011, we announced a strategic alliance with PAREXEL International Corporation to provide a broad range of regulatory and clinical services to Merck, including exclusivity for certain developmental biosimilar candidates. This agreement positions Merck for success with an industry-leading partner that has the expertise and resources to conduct clinical development of the company’s portfolio of candidates, which will allow timely delivery of products to the marketplace.

In June 2011, Merck announced a global strategic collaboration with Hanwha Chemical Corporation to develop and commercialize a candidate biosimilar form of ENBREL® (etanercept). Following our most recent pipeline review, a decision was made to deprioritize Merck’s biosimilar etanercept program and discontinue the development collaboration with Hanwha. This does not impact the local co-distribution agreement between Hanwha and MSD Korea for biosimilar etanercept in the local marketplace.

In September 2011, Merck entered into a multiyear capacity-sharing agreement with MedImmune. The agreement provides Merck with flexible access to state-of-the-art biologics manufacturing operations and allows for rapid scale-up of programs.

In February 2013, Merck and Samsung Bioepis Co., Ltd., entered into a biosimilar agreement to develop and commercialize multiple pre-specified and undisclosed biosimilar candidates. Samsung Bioepis Co., Ltd., will be responsible for preclinical and clinical development, process development and manufacturing, clinical trials and registration, and Merck will be responsible for commercialization. This agreement allows Merck to efficiently advance a portfolio of biosimilar candidates with Samsung Bioepis while continuing to progress an internal pipeline that includes novel, biobetter and biosimilar programs.

# GLOBAL BURDEN OF DISEASE

Through a systematic and critical evaluation of our capabilities and an analysis of unmet medical needs, Merck has focused its research efforts on several priority disease areas.

Focusing our research in this direct manner ensures Merck continues to develop drugs and vaccines to address unmet medical needs. Merck’s current pipeline and list of marketed products are aligned with major global burdens of illness, as defined by the **World Health Organization (WHO) Global Burden of Disease Project**.

The diseases that Merck is addressing rank high on the WHO list of disease burdens of developed countries and are also projected to become prevalent in the developing world and middle-income markets by 2030. Our research into vaccines and infectious diseases addresses major burdens of illness 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.

Considering **Merck’s pipeline** and the list of products we currently market, we estimate that Merck addresses 55 percent of the top global burdens of illness as defined by the WHO.<sup>1</sup>

Leading Causes of Disease, Condition or Injury by Rank	2008 Mortality <sup>1</sup>	2030 Projected Mortality <sup>2</sup>	2008 Projected Disease-Adjusted Life Years <sup>3</sup>	2030 Projected Disease-Adjusted Life Years <sup>4</sup>
Ischemic heart disease	1	1	4	2
Cerebrovascular disease	2	2	6	4
Lower respiratory infections	3	4	1	6
Chronic obstructive pulmonary disease	4	3	12	5
HIV and AIDS	5	10	3	10
Diarrheal diseases	6	20	5	19
Trachea, bronchus, lung cancers	7	5	NR	20
Road traffic accidents	8	7	8	3
Diabetes mellitus	9	6	17	11
Tuberculosis	10	22	15	25
Unintentional injuries	11	11	7	9
Prematurity and low birth weight	12	23	9	13
Neonatal infections	13	21	11	12
Hypertensive heart disease	14	8	NR	NR
Stomach cancer	15	9	NR	NR
Self-inflicted injuries	16	13	19	23
Malaria	17	NR	13	NR
Birth asphyxia and birth trauma	18	NR	10	16
Nephritis/nephrosis	19	12	NR	NR
Cirrhosis of the liver	20	18	NR	NR
Colorectal cancer	21	15	NR	NR
Liver cancer	22	14	NR	NR
Unipolar depressive disorders	NR	NR	2	1

<sup>1</sup> Projections of Mortality and Burden of Disease 2004–2030: Mortality Baseline Scenario, 2008, WHO Regions, GBD 2004 Summary Tables.

<sup>2</sup> Projections of Mortality and Burden of Disease 2004–2030: Mortality Baseline Scenario, 2030, WHO Regions, GBD 2004 Summary Tables.

<sup>3</sup> Projections of Mortality and Burden of Disease 2004–2030: Standard DALYs (3% discounting, age weights), Scenario, 2008, WHO Regions, GBD 2004 Summary Tables.

<sup>4</sup> Projections of Mortality and Burden of Disease 2004–2030: Standard DALYs (3% discounting, age weights), Scenario, 2030, WHO Regions, GBD 2004 Summary Tables.

Note: NR = not reported because less than 1.0% of total burden.

## MANUFACTURING & SUPPLY CHAIN

**Merck is committed to providing patients and customers with high-quality products and a reliable supply of safe and effective medicines and vaccines.**

Merck manufactures medicines and vaccines that are sold in more than 140 countries.

We maintain strict product-quality standards and multiple supply-chain safeguards to ensure the safety and supply of our products—no matter where our medicines and vaccines are manufactured.

We verify incoming materials, and manufacture, store, handle and distribute our products according to current Good Manufacturing Practices (cGMP) as well as other regulatory requirements (e.g., those of the European Medicines Agency

and U.S. Food and Drug Administration), as applicable.

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). These commitments are unequivocal in our role as a global healthcare leader.

The Company is committed to ensuring we have the internal and external supply capability to make our medicines and vaccines available, accessible and affordable to a minimum of 80 percent of the world's population by the end of 2015. To realize this goal, we have executed manufacturing and supply agreements with local manufacturers to broaden access to our products in local markets, including Russia, China, Saudi Arabia and Latin American countries. In addition, the company is investing in its manufacturing capabilities to

meet the local market needs. In 2012, we expanded our solid-dose product packaging facility in Pandaan, Indonesia, which will help support the introduction of new products in South East Asia. We also built and opened a new packaging facility in Hangzhou, China, to support the China market and, eventually, other markets in Asia Pacific.

## QUALITY & SAFETY STANDARDS

**From research and development to the manufacturing and distribution of our medicines, vaccines and other products, safety and quality are our first considerations.**

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 (cGMP)**.

All manufacturing facilities that Merck owns and operates, and any company from which we purchase formulated pharmaceuticals, active ingredients and sterile products, must comply with cGMP standards. These standards include requirements for verifying the sources of incoming materials, and for the manufacturing, storage, handling and distribution of products.

### OUR COMMITMENTS

- We will maintain strict quality standards and effective supply-chain management to ensure the 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 expand our low-cost manufacturing network for pharmaceuticals, biologics and vaccines through local and regional partnerships
- We will invest in critical manufacturing capabilities to meet local market needs

Counterfeit products are a growing global problem and a serious threat to public health. We at Merck believe that maintaining the integrity of our supply chain is of paramount importance. Merck's 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 Merck's anti-counterfeit program, [click here](#).

## Supplier Selection

Merck maintains strict quality standards no matter where in the world our products are manufactured. Once we have made a decision to engage an external manufacturer, that manufacturer is required to comply with Merck's business requirements set forth in the contract, regardless of geography.

We conduct due diligence and pre-contract audits of every potential new supplier of active pharmaceutical ingredients or formulated products and sterile products to determine its acceptability and compliance with cGMP. Merck reviews 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 Merck. Only if the supplier meets Merck's 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 the supplier continues to meet cGMP. 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 of the product produced (e.g., whether it is a formulated pharmaceutical, active ingredient or sterile product) and how it is used by Merck
- Whether the formulated pharmaceutical, active ingredient or sterile product is produced using dedicated equipment and/or in a dedicated facility
- The technical complexity of the manufacturing process and operations (i.e., manufacturing difficulty) involved in producing the formulated pharmaceutical, active ingredient or sterile product

Quality tests are performed on all active pharmaceutical ingredients that Merck purchases 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 drug 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). 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 United States. The standards are recognized and used in more than 130 countries.

## Education and Training

We provide appropriate and ongoing training on quality and cGMP for our employees, to ensure 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

Quality & Product Safety	2009	2010	2011	2012
Number of product recalls in the United States	NA	7	0	4
Annual percentage of units manufactured/sold and recalled during a given year (our recall rate globally)	NR	NR	NR	0.19%
NA: Not available				
NR: Not reported				

In 2012, Merck initiated a total of four product recalls in the United States. These were voluntary actions undertaken by the company as part of our commitment to ensuring product quality. These recalls specifically included (1) three prescription product Class II recalls and (2) one prescription product Class III recall. The recall classifications were determined by the FDA, after consultation with Merck.<sup>1</sup>

<sup>1</sup> Definition of Recall Classifications: (<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm#RecallClassifications>)

## PRODUCT SUPPLY

**Merck's 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 make sure that we are operating a lean and efficient network while ensuring compliance with rigorous quality, safety and environmental standards.

### Vaccine Supply

We have invested more than \$1 billion in new manufacturing resources to ensure that we have the long-term supply capabilities to meet demand for our vaccines around the world. We have modernized some of our processes and equipment at our facility in West Point, Pennsylvania; we are expanding our vaccine manufacturing facilities in Elkton, Virginia, and Mirabel, France; production has started at our new facility in Durham, North Carolina, and we are preparing to soon produce vaccines in our new facility in Carlow, Ireland. Our goal is to have sufficient manufacturing capacity for all our vaccines, including, as appropriate, redundancy in our supply chain for certain vaccines, so that we eliminate supply disruptions when temporary issues arise in manufacturing.

### Other Product Supply

In 2012, the company experienced manufacturing issues concerning certain women's health products.

As part of our efforts to continuously improve our manufacturing, we have identified and are implementing 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.

Merck remains 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

**Counterfeit pharmaceutical products are a growing global problem and a serious threat to public health.**

They can include wrong doses of 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 or falsely represent that the product was manufactured or distributed by the identified manufacturer or distributor.



As counterfeiters have become more sophisticated, counterfeit products have become so similar in appearance to authentic products that, without laboratory testing, it is difficult to tell the authentic from the counterfeit medicines.

For Merck, maintaining patient safety and protecting our reputation are paramount. We maintain a comprehensive worldwide anti-counterfeiting strategy and operational program that has three goals:

- Secure the supply chains
- Deter, rapidly detect and respond to counterfeit activity
- Raise public and stakeholder awareness of the risks posed by counterfeits, and advocate for increased enforcement to shape relevant regulatory requirements

## Management

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, 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 works with regulatory and law enforcement authorities to prosecute offenders; and Global Public Policy, which coordinates our advocacy activities to support stronger anti-counterfeiting laws.

## Maintaining a Secure Supply Chain

Merck has in place strict policies and procedures designed to keep our drug distribution system safe and secure, and to deter counterfeit products from entering the supply chain.

In the United States, for example, we require customers to purchase our products directly from Merck or Merck-authorized distributors. In addition, we publish the names of authorized distributors on Merck's [website](#), and we audit a majority of our distributors to ensure compliance with Merck policies and procedures.

Merck also partners with law enforcement agencies to detect and respond to threats from counterfeit products, including U.S. authorities on importing counterfeit pharmaceuticals and EU authorities on importing or transshipping counterfeit pharmaceuticals through the European Union. Working with customs authorities, we have helped identify high-risk ports, borders and postal depots, and have drafted a framework of action for use by customs authorities to detect and respond to counterfeit activities.

In a number of developing countries, moreover, we have provided training to customs officials, in conjunction with the [Pharmaceutical Security Institute](#),

on trademarks and industry import and export practices.

In the United States, the greatest identified threat to patients receiving counterfeit medicines is through the distribution of pharmaceutical products via illegitimate online drug sellers. In response to this threat, Merck maintains a proactive Internet monitoring program designed to identify threats to our patients from illegitimate online drug sellers and to mitigate those threats through civil and criminal enforcement actions.

Merck promptly reports all confirmed counterfeit activities to regulatory and/or law enforcement agencies. We work with regulators and distributors to remove counterfeit products from the market, and with law enforcement officials to trace counterfeit products back to an original source of supply.

## Product Security

Protecting authentic Merck product is an integral part of Merck's anti-counterfeit mission. Each new Merck drug is assessed using a standard methodology for risk prior to regulatory approval. Our key focus in this process is the patient-safety threat should a counterfeit or illegally diverted Merck product be introduced into the supply chain. The risk level assigned to a new Merck product is used to determine which product security features will be included on the product and packaging prior to the product's market release.

Serialization—or putting a unique identification number on each package

that goes to market—is one of the tools Merck is investing in to secure its supply chain and prevent counterfeiting. A serial number on individual packages makes it possible for anyone along the supply chain—from a distributor to a pharmacist or a patient—to scan the code and authenticate it as genuine Merck product. Serial numbers may take the form of a 2D barcode or scratch-off labels. A Radio Frequency Identification (RFID) tag is another way, but is currently not part of the company's serialization plans.

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 which, in turn, helps to detect counterfeit medicines.

Although still in its early stages, serialization is expected to be mandated in many markets by 2015, including the United States, Europe, Turkey, China, Brazil, Argentina and South Korea. As these requirements evolve, the challenge for Merck and other pharmaceutical companies will be how best to address them, given that each market may have its own (and, perhaps, conflicting) requirements. As a result, we continue to work with industry associations and regulatory agencies to develop a standardized system that will uniquely identify or code products to create a more secure global pharmaceutical-product supply chain.

### Forensic Laboratory

A key part of our ability to identify suspected counterfeits is our advanced forensic laboratory that analyzes suspected counterfeit products and, if possible, identifies where they came from. Lab findings are shared with regulatory and/or law enforcement agencies, and may be used to support subsequent enforcement actions and legal proceedings. Merck 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 increase their forensic-testing capabilities.

### Public Awareness

We 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 Partnership for Safe Medicines and the Rx360 Consortium are a few examples of industry collaborations in which we participate. These collaborative efforts support the production of reports,

whitepapers and data-circulation initiatives, as well as promote intelligence sharing necessary to combat threats from counterfeit medicines.

## PUBLIC POLICY

**Merck supports 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**, Merck supports the efforts of the White House's Intellectual Property Enforcement Coordinator to combat online pharmaceutical crime. 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 Pharmaceutical Distribution Security Alliance (PDSA), Merck supports the passage of U.S. legislation that would create a national system and uniform standards to track product across the pharmaceutical supply chain. PDSA includes over 20 partners in the domestic pharmaceutical distribution supply chain working to achieve a national solution towards product tracking

- Merck supports the Anti-Counterfeiting Trade Agreement, which would increase protection against a wide range of intellectual property infringements
- In 1997, Merck 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. Merck continues to be an active participant in this organization, and is pushing for increased levels of intelligence sharing among the members.
- Merck supports the SAFE DOSES Act legislation 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 in order to deter this criminal behavior and take down the organizations that are perpetrating it.

## Commitments

- Continue in the execution of a proactive, worldwide corporate anti-counterfeit 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 greatest benefit
- Continue advocacy efforts to support the development of a standardized system to identify and code medical products

## EXTERNAL SUPPLIER NETWORK

**Merck purchases goods and services from thousands of suppliers around the world. We also work with numerous licensees worldwide to market and distribute our products.**

About 1,000 suppliers make up approximately 85 percent of the company's annual spending on goods and services worldwide. Some of these are external manufacturing companies that make key ingredients or components for our products, manufacture finished products for us, package our products, or transport our medicines. Others are suppliers that provide general business goods and services such as marketing and research support, business travel, building management, or office equipment and supplies.

At Merck, we use a defined sourcing process to qualify and select our suppliers. We set high standards for conducting business ethically and strive

## PERFORMANCE

Summary	2010	2011	2012
Investigations of suspected counterfeit Merck product	179	164	116
Substantiated cases of counterfeit Merck product <sup>1</sup>	122	106	47

<sup>1</sup> For 2012, 15 cases are still pending a conclusion.

to conduct business with organizations that share our commitment. All suppliers and service providers are expected to comply with basic principles and standards in a number of key areas, including quality, labor and human rights; health, safety & environment; and ethical business practices, as described in the Merck Business Partner Code of Conduct. These expectations are communicated to suppliers during our supplier selection process.

Our **Business Partner Code of Conduct**, developed in 2011, and the **Supplier Performance Expectations** document were published and disseminated in 2012. The Code is based on our own code of conduct, **Our Values and Standards**, as well as The Pharmaceutical Supply Chain Initiative's (PSCI) **Pharmaceutical Industry Principles** and the **10 Principles of the United Nations Global Compact**.

Reference to the Business Partner Code of Conduct is now included in strategic sourcing requests for information, quotes and proposals, and is a standard requirement in all global procurement issued contracts and purchase order terms and conditions.

We also audit select suppliers based on risk. Where audits identify opportunities for enhancement or deficiencies, we collaborate closely to ensure that concerns are addressed in a responsible and compliant manner.

## **Managing External Manufacturers**

Merck 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 Merck's business requirements set forth in the contract, regardless of geography.

Prospective external manufacturers of active pharmaceutical ingredients and finished products are screened for safety, environmental and human rights issues, in addition to quality, supply and technical competence requirements and other compliance issues. The environmental, health and safety screening includes a survey covering such topics as compliance, fatalities, major incidents and labor practices.

Based upon the screening results and the activities being undertaken by the supplier, certain external manufacturers are subject to a more detailed on-site assessment conducted by a multidisciplinary team, which may include quality, safety, environmental, technical and procurement representatives. External manufacturers contracted by Merck are re-assessed using a risk-based approach; higher-risk external manufacturers are subject to more frequent on-site assessments.

Merck continues to support the **Pharmaceutical Industry Principles for Responsible Supply Chain Management Initiative (PSCI)**.

The PSCI 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 Merck contracts are expected to understand and align with these principles.

## **Ensuring Privacy of Personal Information**

Many Merck suppliers, such as contract research organizations, market research agencies, systems developers and other service providers, process personal information in connection with their performance of services for Merck. We require these suppliers to provide appropriate privacy protection for personal information that they handle for, or on behalf of, or otherwise in connection with the performance of services for Merck, in accordance with our privacy policies and applicable privacy laws, regulations and guidelines.

## PERFORMANCE

### External Manufacturing – Environmental Health & Safety Assessment Summary

External Manufacturing: Environmental, Health & Safety Assessment Summary	2009	2010	2011	2012
<b>Assessment Type<sup>1</sup></b>				
Prospective external manufacturers <sup>2</sup>	45	39	44	42
Current external manufacturers <sup>2</sup>	70	26	27	39
<b>Total assessments</b>	<b>115</b>	<b>65</b>	<b>71</b>	<b>81</b>

<sup>1</sup> Data prior to 2010 was based on aggregating the information from our respective individual legacy companies (pre-merger).

<sup>2</sup> Counts of current external manufacturers' assessments and follow-up visits have been aggregated and restated for 2009 and 2010.

Throughout 2012, we successfully executed a detailed communications plan to implement the **Merck Business Partner Code of Conduct**. Specific actions included the following:

- All Supplier Management (global procurement, external manufacturing and supplier development, and performance management) employees completed the Business Partner Code of Conduct training; this training is mandatory for all new employees in Supplier Management as part of our ongoing training and development program
- Letters were issued to 10,000 suppliers to introduce the Business Partner Code of Conduct
- Global procurement supplier relationship leads conducted in-person meetings with our top 300+ suppliers

- Reference to the Business Partner Code of Conduct is included in all strategic sourcing requests for information, quotes and proposals, and is a standard requirement in all global procurement-issued contracts and all purchase order terms and conditions

## SUPPLIER DIVERSITY

**Our suppliers should reflect the people we are in business to serve—our customers.**

At Merck, we believe that having a diverse supplier base helps us to better understand and anticipate the needs of the people we serve. That is why we cast a wide net in search of talent, seeking qualified suppliers from all segments of the global community.

Our Supplier Diversity program includes large and small HUB Zone, minority-, women-, veteran-, service disabled-, people with a disability- and lesbian and gay-owned (LGBT) business enterprises. We believe that working with qualified suppliers from diverse segments of the business community supports our business objectives and economic development in all the communities we serve.

### OUR POLICY

It is Merck policy to provide maximum practical opportunity to diverse suppliers to provide goods and services to the company as a part of our global procurement process. The use of diverse suppliers is an integral part of our purchasing procedures, just as equal opportunity employment is central to our personnel policies and procedures. We recognize that supplier diversity creates a competitive advantage for our company and positively impacts the global community. We believe that the success of the company and society depends on enabling diverse businesses to share and grow in the global market.

Merck has had a Supplier Diversity program in the United States for many years, which is managed by our Global Procurement Group.

The program includes the following major areas of focus: strategic external outreach and globalization, supplier development and mentoring, compliance,

customer-focus, and internal awareness. Minority-, women-, LGBT-, and veteran-owned business entities must be at least 51 percent owned, operated and controlled by minorities (Black, Hispanic, Asian and Native American), women, veterans, or LGBT individuals who are U.S. citizens, and the business must be headquartered in the United States or Puerto Rico.

Merck hosts Supplier Diversity Procurement and Education Forums to increase qualified, diverse suppliers' understanding of Merck's business needs, to introduce these suppliers to the Merck business professionals who are involved in supplier selection, and to increase Merck's knowledge about current and potential diverse suppliers. Merck's most recent forum was focused on women-owned businesses across various products and services in partnership with the Women Presidents' Educational Organization. More than 90 businesses learned best practices for developing strong value proposition statements to attract and engage new clients.

In addition, our Supplier Diversity program offers coaching and feedback on performance, as well as a Supplier Diversity Mentor/Champion Program to help develop qualified, diverse suppliers. Through the program, we conduct supplier assessments and create joint development plans with qualified, diverse suppliers that focus on increasing supplier growth, competitiveness and sustainability. Merck senior executives champion each mentored supplier, and create targeted growth and development

plans that include Merck-sponsored training and guidance.

We also participate in more than 30 external supplier conferences and networking events focused on minority-, women-, veteran-, and LGBT-owned businesses, and are active in external organizations, including the National Minority Supplier Development Council, the U.S. Pan Asian American Chamber of Commerce, Women's Business Enterprise National Council, National Gay and Lesbian Chamber of Commerce and the U.S. Hispanic Chamber of Commerce.

### **Our Supplier Diversity Program is Going Global**

We are proud to be recognized as a leader in the area of supplier diversity and look continuously for ways to expand and improve our program. In 2008, we began to expand our program globally. Our approach may be different, depending on local laws and regulations, but we look forward to continuing to build a supplier base that reflects our diverse customers.

We are active members of the following organizations:

- **Canadian Aboriginal and Minority Supplier Council (CAMSC)**
- **Minority Supplier Development U.K. (MSDUK)**
- **Minority Supplier Development China (MSD China)**
- **WEConnect Canada**

## PERFORMANCE

### SUPPLIER DIVERSITY SUMMARY FOR U.S. AND PUERTO RICO

#### Spending on diverse suppliers

2012	14.45%
2011	16.4%
2010	15%

#### Number of external supplier events supported

2012	32
2011	32
2010	32

Every Merck employee and contingent worker is responsible for understanding and appropriately applying the global purchasing policy, which includes supplier diversity objectives.

Merck has more than quadrupled its purchases from minority-, women-, and veteran-owned suppliers in the United States and Puerto Rico over the past seven years. In 2005,

Merck spent \$215 million of our total U.S. and Puerto Rico procurement dollars with minority-, women-, and veteran-owned firms. In 2012, we spent \$1.058 billion with diverse suppliers and have plans for continued growth.

We intend to continue to grow the Supplier Diversity program by expanding relationships with existing suppliers and introducing new suppliers whose products, services and strategies support our business objectives.

Our goal is to achieve world-class status by 2017 and maintain performance of close to, or greater than, \$1 billion in diverse spending year after year.

# PRODUCT REGISTRATION

**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 would 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)

### 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)
- Pedvax HIB (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)

In 2013 we anticipate receiving prequalification of IMPLANON NXT® (etonogestrel) and plan to submit applications to the WHO for adult and pediatric formulations of ISENTRESS® (raltegravir).

In order to make our products available to the people who need them throughout the world, we registered 437 products and devices in 2012. 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 are disclosing registration information for ROTATEQ, GARDASIL and our four antiretrovirals (ARVs), and updating this information every six months. Click below for details:

- [\*\*ROTATEQ\*\*](#)
- [\*\*GARDASIL\*\*](#)
- [\*\*ATRIPLA\*\*](#)
- [\*\*CRIXIVAN\*\*](#)
- [\*\*ISENTRESS\*\*](#)
- [\*\*STOCRIN\*\*](#)



Registration	2011	2012
New product and device registrations <sup>1,2</sup>	334	437
Local regulatory agency GCP/PV training requests fulfilled that will help strengthen agency capabilities with their GCP/PV compliance oversight role <sup>3</sup>	Online	Online
Products submitted that have achieved WHO prequalifications	10	10

<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> For information on local regulatory agency GCP/PV training requests, visit our **Clinical Research** section.

Learn more about our commitment to register our:

- [HIV/AIDS medicines](#)
- [Women's health products](#)
- [Vaccines](#)

## COMMERCIALIZATION

Merck strives 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
- Within countries, we will seek to identify innovative strategies for differential pricing or other 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 United States who do not have prescription drug or health insurance coverage and who, without our assistance, could not afford their Merck medicine or vaccines, the **Merck Patient Assistance Program** provides medicines and adult vaccines for free.

In developing-world markets, we recognize that access and funding for healthcare can be limited. Therefore, we develop and support various sustainable strategies to improve access, including directing differential pricing to needy patient sub-segments. We currently have differential pricing for 19 of our products, and 49 countries have implemented intra-country pricing for at least one of our products.

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 patients must be at the center of their healthcare. Merck is also committed to improving **health literacy**, which empowers people to make informed health decisions in the context of everyday life that range from individual health choices to healthcare policy. Health literacy varies greatly among countries, as shown in the recent **European Health Literacy Survey** of the University of Maastrich, which was completed with the support of the European Commission. Merck/MSD was not only a collaborating partner in the survey, but we also support several important country-specific initiatives aimed at clear communications that empower patients to make better healthcare decisions. In Germany, for example, Merck/MSD is collaborating with representatives of patient organizations and groups that support the elderly to revise the wording and layout of patient materials that provide information about our medicines in a more consumer-friendly way.

Additionally, we invest in activities aimed at increasing knowledge among patients and physicians, because we believe that providing support to third-party medical, scientific and patient organizations is an important way to improve health and advance patient care. **Learn more.**

Commercialization Summary	2011	2012
Products for which we have access pricing <sup>1,2</sup>	19	19
Countries where at least one product has intra-country pricing of public and private sectors <sup>3</sup>	49	49
Investment in patient- and provider-education programs	\$93.9M	\$91.1M

<sup>1</sup> Differential pricing intended to facilitate access for the at-need population.

<sup>2</sup> The number of products for which we have access pricing for 2011 has been revised to correct an error in our reporting.

<sup>3</sup> Countries with an MSD trading entity.

## PRICING

**Throughout the world, healthcare costs are rising for a variety of reasons; chief among them are greater utilization and complexity of services and technologies that convert once-fatal diseases into chronic conditions.**

As populations continue to age in the developed world, and better health technologies and pharmaceuticals improve health and prolong life, payers are increasingly focusing on pharmaceutical spending in their overall healthcare budgets.

The pharmaceutical industry is faced with a variety of healthcare systems and government policies in developed countries, where it must balance patient access to the best treatments with 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.

Despite differences in national approaches, we price our products in all OECD (Organisation for Economic Co-operation and Development) countries to foster access while ensuring a reasonable return on our investment (ROI). A sustainable ROI supports Merck's future funding of innovative drugs and vaccines that can help address unmet medical needs that currently exist throughout the world and benefit patients.

Our prices around the world are determined by several factors, including the value of our products to patients, payers and physicians relative to competitor products; the ability and willingness of various customers—including national, regional or local institutional payers, physicians, employers and patients—to pay for our products; and the cost and value of other treatment options, such as hospitalization. The prices of our medicines and vaccines

also reflect government regulation and currency fluctuation effects.

While striving to maintain a consistent global approach, Merck also considers the national, competitive and regulatory conditions in 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, making the challenge of ensuring access to new treatments extend beyond national price or reimbursement setting alone.

In the private sector, particularly in developed countries like the United States, 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.

In developing-world markets, Merck recognizes that access and funding for health care, 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. Merck actively works 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 needy 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 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, women’s health and vaccine franchise areas. For example, in May 2013 Merck and a group of partners announced an agreement in which we will reduce the cost of IMPLANON® (etonogestrel implant) for millions of women in some of the world’s poorest countries to improve their access to contraceptives. [Click here](#) for more information. Merck is committed to continuing its 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.

Pricing	2011	2012
Products for which we have access pricing <sup>1,2</sup>	19	19
Countries where at least one product has intra-country pricing of public and private sectors <sup>3</sup>	49	49

<sup>1</sup> Differential pricing intended to facilitate access for the at-need population  
<sup>2</sup> The number of products for which we have access pricing for 2011 has been revised to correct an error in our reporting  
<sup>3</sup> Countries with an MSD trading entity

To learn more about our product pricing, click on one of the links below:

- [HIV medicines](#)
- [Vaccines](#)
- [Women’s health products](#)

## HEALTH LITERACY & HEALTHCARE DISPARITIES

**Low health literacy is a \$200-billion global problem.<sup>1</sup>**

As a research-based healthcare company, Merck’s mission is to improve the well-being of people around the world. 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 their disease through a better understanding of the treatment 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.

A person’s level of health literacy may cut across age, gender, education, or income level. 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 screening for disease, increased rates of disease and mortality and poor adherence to treatment. Poor health literacy is also a contributing factor to healthcare disparities.<sup>2</sup>

**KEY DEFINITIONS**

**Healthcare Disparities:**

Differences or gaps in care experienced by one population compared with another population, due in part to:

- Lack of access to care
- Provider biases and other issues
- Poor provider communication
- Poor health literacy

**Health Literacy (U.S.):** The degree to which individuals have the capacity to obtain, process and understand basic health information and services needed to make appropriate health decisions.

Poor health literacy is a serious challenge to improving health outcomes around the world, and Merck’s commitment to

advancing health literacy is fundamental to how we do business. We recognize the potential Merck has to help improve millions of lives<sup>3</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.<sup>4</sup> 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 their 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.

**Health Literacy and Health Equity: Key Priorities across the Globe**

The office of the CMO 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. Merck proudly participates 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. In the EU, Merck is building on the promotion of health literacy programs—one of the action points of the EU’s strategic approach for 2008–2013. We highlight some of our U.S. and EU initiatives below.

**Reducing Healthcare Disparities and Improving Health Literacy: Initiatives in the U.S.**

Many payers, integrated health systems, and large medical groups share a common interest in reducing healthcare disparities and addressing poor health literacy. Merck has created and shared resources used by these organizations, including:

- Case studies, cultural pointers, and cultural competence brochures designed to help healthcare providers better understand their patients from diverse cultures

**A PERSPECTIVE FROM MERCK’S CHIEF MEDICAL OFFICER: HEALTH LITERACY AND HEALTH EQUITY ARE FUNDAMENTAL TO MERCK’S 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, Merck’s 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 must partner with patients to promote their understanding of their medical condition or disease, the reasons they are being treated, and the appropriate use of medications and other treatments. This will result in maximizing the benefit and minimizing safety issues when using our medicines. Merck is committed to improving health literacy as part of our mission to improve health.”<sup>5</sup>

and effectively manage cross-cultural communications

- An online video that provides tips on implementing universal health literacy precautions in a practice session, and a workbook modeling the “teach back technique.” “Teach back” is a model designed to confirm that a patient understands medical concepts communicated to them by having them explain them back to the physician or clinician.
- Live presentations including Delivering Quality Care to Diverse Populations; Implementing Universal Precautions (Ensuring Clear Communication and Patient Understanding); and Relationship-Centered Care

Merck is actively integrating health literacy principles into our patient education materials. A training program is being developed that will provide clear instructions to the creators of these materials on how to implement health literacy best practices. These best practices are driven by recent research in the field of health literacy, as well as feedback Merck has already received from healthcare providers and patients themselves. Merck is also working to increase the diversity of images and languages in patient materials.

Internally, nearly 1,000 Merck employees participated in optional health literacy awareness sessions offered in partnership with the Business Insight Roundtables (including African Ancestry, Asia Pacific, Differently Able, Hispanic/Latino, Interfaith, LGBT, Native American/Indigenous, Veteran and Women). For more information on the Business Insight Roundtables, please visit the Initiatives

In 2013, Merck launched a Merck Investigator Studies Program (MISP) focused on health literacy, diversity and adherence. This program welcomes proposals from all therapeutic areas, and includes studies that evaluate the following:

- Effectiveness of novel, scalable approaches, such as new technologies, systems approaches and social media to help patients manage and improve sustained-medication adherence employing principles of health literacy
- Effectiveness of community-based interventions aimed at improving health literacy among patients and/or providers, with the goal of enhancing quality of care and improving sustained-medication adherence and/or patient health outcomes
- Application of health literacy principles to increase enrollment and retention of diverse populations, including African Americans, Latinos and Asians, in U.S. clinical trials

tab on our [Diversity & Inclusion](#) page. Following these sessions, multiple groups conducted follow-up activities promoting health literacy within their culture.

### **Reducing Disparities in Diabetes Care in the United States**

In the U.S., disparities related to diabetes and other chronic conditions are a growing national concern. More than 25 million people—nearly 8.3 percent of the U.S. population—are affected by diabetes, the majority with type 2. The cost of treating the condition reached approximately \$245 billion in 2012.

In 2009, the Merck Foundation launched the [Alliance to Reduce Disparities in Diabetes](#) with a commitment of \$15 million over five years to address healthcare disparities related to type 2 diabetes among low-income and underserved adult populations in the U.S. The Alliance collaborates 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. At the end of 2012, the outcomes of the approximately 2,100 adults with type 2 diabetes who are enrolled in Alliance programs had improved in almost every measurement category, including such self-care behaviors as diet, exercise and blood-glucose testing, as well as in clinical measures including hemoglobin A1C and low-density lipid cholesterol.

Also in 2012, the Alliance released a report entitled [Policy Considerations That Make the Link: Connecting Community Experience and National Policy to Reduce Disparities in Diabetes](#), which focuses on ways to overcome systemic barriers to effective diabetes care and advance the national dialogue on healthcare disparities.

## Healthcare Disparities and Health Literacy: Initiatives in the European Union (EU)

Health literacy is among the many important activities included in the EU health strategy. To further raise the profile of the issue, and to discuss the role of health literacy in public health and health systems, in 2012, Merck/MSD initiated a broad stakeholder dialogue with the European Patients' Forum, the European Public Health Alliance, the Standing Committee of European Doctors and the University of Maastricht. In addition, several members of the European parliament recently tabled amendments in legislative proposals such as "Health and Growth" and "Horizon 2020," proposals that will frame future EU funding for health literacy projects. The European Commission has integrated its approach to health literacy in several initiatives. The expectation is that a health strategy focusing on health literacy will result in more citizen- and patient-centered healthcare in the future.

This focus aligns with Merck's health literacy programs underway in a number of EU countries, including Austria, Belgium, Bulgaria, Germany, Romania, Spain, Switzerland and the UK:

- With the support of MSD Spain, a report entitled *Health Literacy and Adherence Consensus: A key tool to achieve better health results and contribute to healthcare systems' sustainability* was released in Madrid, Barcelona and Seville in 2012. Developed by different Institutions of the Sanitary System in Spain, including sanitary agents and the

Spanish Patients Forum, the report was developed to raise awareness among policy makers and the public about the importance of health literacy to adherence. It received large national media coverage.

- In 2012, MSD Austria developed a new application for smartphones and computers to improve the patient-doctor relationship and help HIV patients monitor their symptoms throughout their treatment. Many physicians report that their patients have difficulty explaining their symptoms during a short and often stressful doctor's visit. The App, My Positive Diary, augments the clinic visit by incorporating health literacy in the daily treatment practice of HIV patients.

Throughout 2012, several Merck/MSD subsidiaries across Europe initiated projects in the area of health literacy:

### Austria

At the European Health Forum Gastein, the Bulgarian Member of the European Parliament, Antonia Parvanova, announced that the European Health Literacy Survey (HLS.EU) won the European Health Award. The European Health Award is issued every year at this high-level EU health conference. MSD had supported the survey in Ireland, Austria and at the European level with the launch conference in Brussels in 2011. For more information, [click here](#).

Health literacy has become the top-ranking health target in Austria for the next two decades. In the context of a comprehensive healthcare reform

agenda, Austria has defined ten compulsory healthcare objectives. This is one of the results of MSD Austria's active support of the Austrian health literacy survey and related advocacy for health literacy. Showcasing the fruitful collaboration between political decision-makers, scientific leaders and MSD, these objectives and the results of the Austrian Health Literacy Survey have been presented at a high-level press conference organized by health authorities, supported by MSD. Health literacy was also a key topic of workshops and discussions at the European Forum Alpbach, the most important policy meeting in Austria.

### Bulgaria

- With the support of MSD Bulgaria, the results of the European Health Literacy Survey have been presented in a press conference in Bulgaria. The focus was on health inequalities with regard to health literacy, comparing data for Bulgaria with other EU countries that participated in the survey. Speakers were leading academics from the Faculty of Public Health at the Medical University of Sofia who had participated in the survey.

### Germany

Enabling patients to play a more active role in the management of their HIV disease was the objective of a program supported by MSD Germany. In countries with comprehensive HIV management programs, patients can feel overwhelmed by the medical specificities of their therapy, and left alone in trying to develop communication and coping strategies. A

German nongovernmental organization (NGO), Gesundheitstraining e.V., offers interdisciplinary training to people living with HIV/AIDS (PLWHA), which covers medical knowledge (treatment literacy), patient/doctor relationships, communication, law, lifestyle choices (nutrition, physical activity), life planning, psycho-social aspects, and coping strategies.

In addition, MSD Germany undertook further initiatives in the area of health literacy. Through the German Working Group, "Patient-Friendly Patient Information Leaflets," the following projects in the area of patient information have been launched:

1. Improving patient information leaflets for MSD products
2. Increasing access to audio versions of patient leaflets for visually impaired people.

## United Kingdom

MSD UK funded the research and publicity of London South Bank University's (LSBU) 'Evaluating Health Literacy Levels in England' study. The study was written by a team of international experts led by Professor Gillian Rowlands of LSBU. This is a groundbreaking study that mapped levels of health literacy in England for the first time, and was presented to key national stakeholders at a Parliamentary launch in December 2012. The study and launch event gained widespread national media coverage and was followed by a policy roundtable involving the research team and representatives from MSD, UK government departments, think tanks

and patient groups. The complete findings of the research will be published in 2013.

<sup>1</sup> Advancing Health Literacy to Improved Quality, Adherence, and Outcomes, Ruth M. Parker, MD, slide 21

<sup>2</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>3</sup> Implementing Health Literacy in a Large Company, An example from Pharma, May 10, 2012

<sup>4</sup> Health Literacy in Europe (Dec 13, 12)

<sup>5</sup> Health Literacy Overview, Business Insight Roundtable, 4 June, 2012

## THE MERCK MANUALS

**In 1899, we published the first edition of *The Merck Manual*, a 192-page resource book designed to aid physicians and pharmacists.**

By the 1980s, *The Merck Manual* was the world's best-selling medical text and had been translated into 16 languages. The 19th edition, published in July 2011, now comes with a free app for pocket mobile devices. This updated edition reflects progress in both medicine and technology, as it keeps pace with the many electronic platforms used to deliver information to healthcare professionals.

In 1955, we published the first edition

of *The Merck Veterinary Manual* for veterinarians, which has now sold over 1 million copies and has been translated into 6 languages. The latest edition, published in 2010, is available in its 10th edition.

In 1997, we published *The Merck Manual—Home Edition* to provide the benefits of the Manual to the general public. Now in its third edition, the renamed *The Merck Manual—Home Health Handbook* has sold more than 3 million copies and has been translated into 12 languages. As part of our commitment to provide medical information as widely as possible, we offer the content of these *Merck Manuals* on the Web free of charge. Registration is not required, and use is unlimited.

**The Merck Manual** site is updated to ensure that its information is as current as possible. In addition, since 2011, we donated more than 40,000 copies of *The Merck Manual* to nongovernmental organizations (NGOs) for distribution to physicians, nurses and community health workers throughout developing countries.

In December 2012, Merck transitioned ownership of *The Merck Index* to the Royal Society of Chemistry (RSC).

### THE MERCK MANUAL NAMED ONE OF BEST FREE REFERENCE WEBSITES OF 2012

In 2012, ***The Merck Manual*** website was elected as one of the Best Free Reference Web Sites of 2012 by a unit of the American Library Association known as the Emerging Technologies and Reference section, or MARS.

Voted for by member librarians from around the United States, ***the Merck Manual*** site is one of 26 websites to be recognized by MARS this year as an outstanding site for reference information and is included in the list of **MARS Best of Free Reference Web Sites of 2012**.



Merck began publishing *The Merck Index* in 1889, when our core focus was chemicals. Since then, the book has become a comprehensive reference on chemicals, drugs, and biological, and has been widely used by generations of students and scientists from academia and industry around the world. RSC launched the 15th edition of the reference in April and will retain The Merck Index title for the duration of this edition's publishing cycle.

Other books we publish include as *The Merck Manual of Health & Aging*, which provides professionals and consumers with useful healthcare information for older adults; *The Merck/Merial Manual for Pet Health*, which covers the full spectrum of today's pets—from dogs, cats and horses to birds, reptiles, fish and other exotic pets; and *The Merck Manual of Patient Symptoms*, a guide for medical students, residents, nurse practitioners and physician assistants.

## RESOURCES

**With research showing that three out of four Americans fail to take their prescribed medicines as directed, the following resources are designed to help consumers stay on course with their treatment and have better conversations with their healthcare professionals about the medicines they have been prescribed.**

### MerckEngage

**MerckEngage.com**, a free online tool available in the U.S., offers resources that reinforce healthy lifestyle choices,

provide disease-specific education, support adherence to therapy, and help U.S. healthcare consumers have more productive interactions with their 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. The program is designed to support the healthcare professional/healthcare consumer relationship by providing tools and tips, online, in print, through a call center and through mobile devices, for healthier living between office visits. MerckEngage.com is also available in Spanish.

### The Adherence Estimator

Patients often fail to reach clinical goals because they don't take medications when they are supposed to. At Merck, we remain committed to identifying the reasons why patients do not always take prescribed medicine and support the development of improved evidence-based interventions that can lead to improved adherence.

The Adherence Estimator, a patient-centered tool designed to help identify patients who may be at risk of medication nonadherence and provide information regarding reasons for risk of discontinuing therapy. The Adherence Estimator was designed to be administered shortly after the initiation of a new medicine for certain asymptomatic chronic conditions and to be completed for each new medication

prescribed. It asks questions about three key areas that affect adherence: patients' concerns about prescription medication, their perception of the need for prescription medication, and their perceived financial burden due to the cost of 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.

### NATIONAL COMMUNITY PHARMACISTS ASSOCIATION HIGHLIGHTS ADHERENCE ESTIMATOR

Merck is collaborating with the National Community Pharmacists Association (NCPA) on a number of efforts to improve medication adherence. Adherence is a high priority for NCPA, which represents the owners of more than 23,000 community pharmacies across the country. One of the collaborative efforts involves building awareness of the Adherence Estimator® as a resource that pharmacists can use to help improve adherence and patient health outcomes.

A column in the June, 2012 issue of *America's Pharmacist*, NCPA's journal, highlights the Adherence Estimator as a resource pharmacists may use when educating patients on the importance of taking medications as prescribed.

For more information, **read the column in *America's Pharmacist*.**

## SPARSH

SPARSH is a support initiative for diabetes patients who are taking certain Merck medicines. The program was created in India in partnership with physicians who voiced the need for more robust patient support. Enrolled patients receive counseling, through telephone calls, on diabetes care, the complications of diabetes, and diet and exercise.

## Resources for Healthcare Professionals

**Merck Medicus**—Relaunched in the United States on June 1, 2012, this site is an online and mobile medical resource providing high-quality, relevant and trusted medical information. Created by Merck, the platform offers medical professionals a wide variety of easy-to-use medical applications and an innovative design that allows users to quickly and easily access the latest medical news, clinical research, visual tools and patient education resources in over 60 specialties.

Merck Medicus collaborates with an advisory board of healthcare professionals who represent a wide range of practices and specialties. These experts work together to identify the types of content Merck Medicus users will find most helpful. All 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. With no subscription or registration fees, the site provides access to:

- The latest medical news and clinical developments in 60+ specialist areas
- Selected full-text articles from *The Lancet*
- Weekly research summaries from major peer-reviewed publications
- Conference coverage from medical congresses
- Full online access to trusted medical references
- A library of 60,000 medical images to enrich presentations and research
- A wide range of resources to enhance interactions with patients at the point of care, including interactive 2D and 3D anatomy tools and 5,000+ patient handouts

The platform's concept, first introduced in 2001, has undergone a redesign to meet the needs expressed by HCPs and reflecting the evolution of healthcare professionals' usage of digital information and mobile technologies.

**Univadis**®—A comprehensive online medical-information resource from Merck/MSD 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 Univadis site features breaking medical news, accredited education courses and cutting-edge tools tailored to each medical specialty and clinician need.

One of the most trusted sources of medical knowledge worldwide, Univadis provides content that is independently developed by top scientific leaders and is provided in local languages, free of charge, to medical professionals.

Since its launch in 2001, Univadis has been helping physicians seeking online medical information and services, which enable them to better manage the care of their patients. This comprehensive resource, covering 24 therapy areas, provides healthcare professionals with the latest news, views, insights,

## THE JAMA NETWORK AND MERCK ANNOUNCE STRATEGIC COLLABORATION

In December 2012, the JAMA Network announced a new collaboration to enhance the medical information available on Merck Medicus™ and Univadis®, Merck's medical information and education websites, and to expand The JAMA Network's global reach.

Through this collaboration, selected abstracts, articles and author videos from JAMA and the nine specialty journals available on The JAMA Network will also be available through Merck Medicus™ and Univadis®. These materials are now available in English, Mandarin, French, Italian and Spanish. Brazilian, German, Portuguese and Japanese language translations will be added in 2013.

**[Read the full press release.](#)**

research and education to help them stay informed and up to date.

Univadis covers most disease areas as well as a range of useful services, including breaking medical news, over 400 peer-reviewed education courses, award-winning 3D Anatomy, 3,000 medical images and tools specifically tailored to the needs of healthcare professionals' medical specialty.

Information and services are provided by independent third parties such as Elsevier, Springer Healthcare, The Lancet, BMJ Learning, McGraw-Hill, Trip Database and Primal Pictures.

# COMMUNITY INVESTMENT

**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 healthcare 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 Merck’s efforts to develop and implement effective philanthropic and business strategies to help remove barriers to access, challenges remain due to the complex and multifaceted nature of the problem.

While Merck does 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 and cannot wait for better solutions that would make them more widely available. For that reason, Merck remains committed to donating our medicines, vaccines and consumer health products through organized programs as appropriate. Our primary programs involving a donation of Merck products include: the **Merck Medical Outreach Program**, the **Mectizan Donation Program**, the **African Comprehensive HIV/AIDS Partnerships** and the U.S.-based **Patient Assistance Program**. In 2012, we provided over \$1.63B in market value of donated Merck products.

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, 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.

For example, in 2011, the company launched the Richard T. Clark Fellowship for World Health. This global program is designed to leverage the skills and talents of Merck employees to build and support humanitarian organizations that meet the health needs of the underserved. While providing unique career-development

Community Investment	2011	2012
Healthcare workers trained through our major programs and partnerships <sup>1</sup>	51,600	38,166
Investment in partnerships for activities that address underlying barriers to health, such as health system strengthening and capacity building <sup>2</sup>	\$34.7M	\$23.8M
People reached through our major programs and partnerships <sup>1,3</sup>	273M	269M

<sup>1</sup> "Major" is defined as an investment by Merck's Office of Corporate Philanthropy and/or The Merck Foundation of more than \$300,000 per year and/or an engagement with a national government.

<sup>2</sup> Includes investments by Merck's Office of Corporate Philanthropy and/or The Merck Foundation; also includes funding for nutrition and access to clean water.

<sup>3</sup> Includes treatments approved for river blindness and lymphatic filariasis through the Merck MECTIZAN® Donation Program

opportunities that help employees understand critical needs in different parts of the world, the program aims to strengthen the capacity and reach of charitable organizations by providing technical and hands-on volunteer support, rather than funding alone. [Learn more.](#)

Merck recognizes that building the capacity of healthcare professionals is a major factor in addressing global health challenges.

## PROGRAMS

### Earth Institute's Millennium Villages Community Health Worker Training Program

Since 2009, with support from the Merck Foundation, the Earth Institute at Columbia University has been conducting 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 aims to advance 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 helps ensure that participating community health workers are skilled, well-trained, properly remunerated, regularly supervised and fully integrated into their countries' healthcare systems. To date, MVP has trained approximately 932 CHWs who are overseeing approximately 500,000 people across 14 Millennium Villages. The MVP also expanded the CHW supervisor program in 2012, training

26 new Senior CHWs and retraining an existing 20 Senior CHWs with new tools for conducting observational and shadow visits to strengthen the performance of CHWs.

### BroadReach Institute for Training and Education's Management and Leadership Academy

With support from the Merck Foundation, the **BroadReach Institute for Training and Education (BRITE)** is implementing 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 aims to 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 is also working with Abt Associates in implementing this MLA program and is receiving additional support under the USAID-funded Zambia Integrated Systems Strengthening Program (ZISSP). BRITE and ZISSP are working in close partnership with the Ministry of Health 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 aim to conduct training for healthcare professionals in all nine

provinces, across 27 target districts, of Zambia. The MLA team completed 18 sessions of the first three workshops in the MLA training series. By the end of 2012, approximately 1,200 healthcare workers from various levels of the health system had been trained through these workshops in Zambia.

### Merck Vaccine Network–Africa

As part of our commitment to the GAVI Alliance, Merck initiated the **Merck Vaccine Network–Africa (MVN–A)**, a 10-year philanthropic initiative supported by the Merck Foundation to help strengthen the capacity of Expanded Program on Immunization (EPI) health workers in sub-Saharan Africa. Formally endorsed by the GAVI Alliance in 2003, the MVN–A supported collaborative partnerships in the development and implementation of sustainable EPI management-training programs in Kenya, Mali, Uganda and Zambia. Through these MVN–A training programs, more than 1,700 EPI health workers were trained across all four countries. The Merck Foundation concluded funding support for the MVN–A in 2012.

### Pneumococcal Disease Prevention and Capacity-Building

Over the course of three-year, phased programs in Nicaragua and Honduras, Merck committed to donate 1.7 million doses of PNEUMOVAX® 23 (Pneumococcal Vaccine Polyvalent) and provide charitable grants amounting to \$1 million to Project HOPE to support efforts to vaccinate vulnerable populations against pneumococcal infections, a major cause of pneumonia.

In partnership with the Nicaraguan and Honduran ministries of health, and utilizing grant funding from Merck, Project HOPE is improving the capacity of each national immunization program by training health workers to plan and implement successful vaccination campaigns. Project HOPE is also providing vital equipment and supplies to each ministry of health, including refrigerators required for the proper storage of vaccines and computers to help monitor and evaluate immunization activities as the initiatives progress in both countries.

As of 2012, the program has trained 5,046 health workers in Nicaragua and 1,298 in Honduras. As of the end of 2012, 100 percent of the donated doses of PNEUMOVAX® 23 have been distributed and more than 80 percent of doses have been administered to patients in both countries. The remaining vaccines will be administered in 2013, with major national vaccination campaigns scheduled in April in both countries. The project has also fostered cross-border sharing of best practices and lessons learned between the National Immunization Program counterparts in each country.

### **Catholic Medical Mission Board—Global Health-System Strengthening Program**

In late 2011, Merck provided \$100,000 in funding to the Catholic Medical Mission Board (CMMB) for their Global Health Systems Strengthening (GHSS) program. The goal of the five-year (2012–2016) program is to increase the demonstrated organizational capacity of 25 of CMMB’s developing country partners to manage their pharmaceuticals and supplies in a

cost-effective and sustainable manner. The program will contribute directly to the WHO’s stated health-system strengthening (HSS) goal of improving norms, standards, procurement, policies and quality standards for medical products.

In November 2012, Merck funding supported GHSS training activities in Haiti. This training was targeted, but not limited to, small hospitals, health centers and/or clinics that do not have a pharmacist on staff. These facilities are often staffed by personnel with little formal training in the safe handling and management of medicines. Thirty-one participants from 20 different consignees attended the training. In addition, personnel from the Ministry of Health participated and conducted a session of the program. In 2013, the remaining Merck funding will be utilized to conduct a second training in Haiti, provide assistance to the consignees for locally-led action plan development and facility upgrades, and reporting and compliance activities.

### **United Nations Foundation—Measles Initiative**

Since 2001, the **Measles Initiative** has contributed to saving lives by supporting 80 countries in delivering more than 1 billion doses of measles vaccine and helping to raise measles vaccination coverage to 85 percent globally. In 2008, Merck provided a \$2 million grant to the United Nations Foundation to support the Measles Initiative and advance disease surveillance efforts in Africa.

In 2010, we continued our support with an additional \$250,000 to support measles immunization and disease surveillance activities in Nigeria during early 2011. More than 28 million children were vaccinated during the measles campaigns in Nigeria, achieving a national coverage level of 99 percent of the target population. Merck’s support enabled the timely notification and investigation of suspected measles cases and outbreaks in the country. Following the immunization campaigns and investigation of outbreaks, the scale of measles outbreaks decreased significantly—by 75 percent.

In 2011, Merck provided \$300,000 to strengthen measles surveillance and routine immunization efforts in India. In 2011 and 2012, more than 81 million children were vaccinated through multiple measles “catch-up” campaigns in India.

In addition, many of our partnerships focused on HIV/AIDS are also involved in healthcare capacity-building.

**[Learn more.](#)**

## **PUBLIC-PRIVATE PARTNERSHIPS**

**A key element of Merck’s access strategy is promoting and participating in public-private partnerships (PPPs).**

We work with local communities, governments, nongovernmental organizations (NGOs), multilateral organizations, academic institutions,

corporations and others to address specific health and development challenges that go well beyond what Merck can directly accomplish alone.

Merck has decades of experience in developing PPPs in various areas. In 1987, with many partners, we launched the **Merck MECTIZAN® (ivermectin) Donation Program (MDP)**, the first large-scale, comprehensive global health initiative of its kind. Today, the MDP is recognized as one of the world's most successful global healthcare collaborations, and one that continues to have significant positive impact on tens of millions of people.

Merck has applied our experience in global health partnerships to programs around the world that are helping to prevent and treat HIV/AIDS, other chronic conditions, and vaccine-preventable illnesses. While many involve financial or in-kind support, Merck also seeks to leverage the expertise and skills of our employees in order to contribute in additional meaningful ways.

We work closely with our partners on the ground to formulate specific goals and metrics for the partnerships in which we are involved. For example, the **African Comprehensive HIV/AIDS Partnerships (ACHAP)** sets targets that are reviewed annually by the ACHAP Board, on which two Merck representatives sit.

We also have rigorous governance and oversight mechanisms in place for all of our programs and partnerships. And we require all of our grantees to submit regular (usually annual) reports outlining how Merck funds or medicines were

used and what was accomplished. For some of our larger initiatives, including the MDP and ACHAP, we have commissioned third-party evaluations on program effectiveness.

Learn more about our public-private partnerships in this section and in [HIV/AIDS](#) and [Women's Health](#).

## MERCK CHILDHOOD ASTHMA NETWORK

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

Funded by The Merck 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., PhD, a nationally recognized expert in asthma and allergic diseases and emeritus dean 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 programs that involve tailored asthma case management and the reduction of environmental risk factors/triggers in the home. These programs are implemented in several different 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 George Washington University School of Public Health and Health Services, the U.S. Environmental Protection Agency, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health (NIH).

The Merck Foundation has committed \$41 million to support MCAN over 9 years (2005–2014). The investment in MCAN was \$5.4 million in 2011 and \$5.14 million in 2012.

## PROGRAMS

### MCAN Care Coordination Program Sites (2010–2014)

Through the Care Coordination grant portfolio, MCAN is seeking to demonstrate 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 are participating in a cross-site evaluation to assess outcome and process measures focused on care coordination and clinical outcomes.

**Current Care Coordination program sites:**

**Los Angeles Unified School District, “Yes We Can Children’s Asthma Program”**

This program uses a care-coordination and education model that extends beyond the immediate school clinic to include systemic changes among health, educational and community settings. The program triages students and families into the appropriate level of intervention, improves the coordination of care among schools, clinics and community providers, and focuses on measuring symptom reductions and school days missed.

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

This program centers on a community educator model, linking children with asthma to appropriate services, community groups and local agencies. A home-visit case-management program is also provided to enhance asthma education and to identify and mitigate asthma triggers.

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

This program carries out evidence-based interventions as part of an asthma care

coordination program across home, healthcare and community settings. Implemented in the Nemesio Canales Housing Project in San Juan, Puerto Rico, La Red promotes asthma-friendly communities throughout the island of Puerto Rico and improves access to quality asthma healthcare for this highly vulnerable and underserved community.

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

In this program, asthma healthcare navigators located within four primary care centers operated by the hospital, work with primary care providers as an integral member of the families’ asthma care teams. They assist families in identifying and reducing asthma triggers in the home, and provide self-management education and other support and resources for families of high-risk children with asthma.

**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 George Washington University (GWU) School of Public Health and Health Services. 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 controlled trials can be implemented in Federally Qualified Community Health Centers, where many low-income children and families receive health 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 Rincon Health Center (Rincon, Puerto Rico).

**Head-Off Environmental Asthma in Louisiana (HEAL), Phase II**

With support from MCAN, HEAL, Phase II, builds 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 of asthma case management and 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, Daughters of Charity Services of New Orleans, and the Children’s Health Fund are the “on the ground” partners working to disseminate and implement the multifaceted intervention in existing healthcare systems. They provide individualized counseling through certified asthma educators who make home visits to children with poorly controlled asthma. The asthma educators provide tailored counseling for children with asthma, ages 2–18, and their families, to improve asthma management, avoid exposure to asthma triggers, and reduce the exacerbation of symptoms.



**Comprehensive Asthma Project (CAP)**

The Comprehensive Asthma Project (CAP) was a collaboration between MCAN and the American Academy of Pediatrics (AAP) aimed at improving the quality of asthma care for children by pediatricians throughout the United States. CAP provided support to AAP chapters and member practices to disseminate and facilitate implementation of the asthma guidelines that were established by the National Asthma Education and Prevention Program (NAEPP) of the National Heart, Lung, and Blood Institute (NHLBI). This effort also aimed to reduce disparities in asthma outcomes among practices that serve low-income and medically underserved patients/caregivers.

**National Ambulatory Medical Care Survey (NAMCS)**

The National Ambulatory Medical Care Survey (NAMCS) is a national survey of physicians, whose goal is 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 Environmental Protection Agency and the Agency for Healthcare Research and Quality provided support and expertise to develop specific questions for the 2012 NAMCS, which focused on the NAEPP asthma guidelines and their use.

This survey will allow evaluation of guideline implementation 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 can inform ongoing strategies to increase effective implementation of the NIH guidelines.

**PUBLIC POLICY**

**The Merck Childhood Asthma Network (MCAN) has collaborated with the Department of Health Policy at the George Washington University (GWU) and First Focus to establish the Childhood Asthma Leadership Coalition (CALC), a national multisector coalition to improving policy making around childhood asthma.**

The CALC is made up of individuals and organizations who are leading advocates and experts in childhood asthma, public health, environmental health, poverty, housing, healthcare and healthcare economics.

Coalition members are working together toward the shared goal of improving the prevention, diagnosis, treatment and long-term management of childhood asthma through federal policy change and targeted state efforts. Collaboration and leadership on childhood asthma is especially important at this critical time in Washington when policy makers are making important decisions about the future of federal investments in

our nation's public health and health coverage systems. By establishing a unified and informed voice using credible experts, CALC sets a clear vision for policy solutions and develops a practical pathway for achieving desired outcomes.

Relying on a strong foundation of evidence-based policy analysis to inform its work, the CALC's leading policy goals include:

- Ensuring the availability of stable and continuous health insurance for children with asthma;
- Developing high-quality clinical care, case management, and asthma education for all children;
- Reducing asthma triggers in homes and communities;
- Creating a nationwide strategic plan for asthma research to develop new and effective treatments; and
- Identifying new opportunities to improve asthma care that arise from the implementation of the Patient Protection and Affordable Care Act (ACA).

## PERFORMANCE

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

Characteristic/Variable	Care Coordination	HEAL Phase II	CHAMPS
Patients Enrolled in 2012 (N)	729	186	200
Age (Mean)	7.7	9.0	8.9
<b>Sex (%)</b>			
Male	61	54	60
<b>Race/Ethnicity (%)</b>			
White	1	82	6
Black	45	11	4
Other	54	6	90
Hispanic (%)	48	11	90
Missed School Days, Past Year (Mean)	10.92	1.5 <sup>1</sup>	1.06 <sup>2</sup>
Limited Activities, Past Month (Mean)	5.76	-	4.01
Nighttime Awakenings, Past Month (Mean)	5.82	-	4.09
Emergency Room Visits, Past Year (Mean)	2.89	-	7.56
Hospitalizations, Past Year (Mean)	0.73	-	0.47

<sup>1</sup> Past 3 months  
<sup>2</sup> Past month

# ALLIANCE TO REDUCE DISPARITIES IN DIABETES

**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 25.8 million people—8.3 percent of the U.S. population—are affected by diabetes. Type 2 diabetes accounts for 90 to 95 percent of all diagnosed cases.

Diabetes represents a significant economic burden in the United States. New study findings from the [American](#)

[Diabetes Association](#) estimate that the total costs of diagnosed diabetes were 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, the Merck Foundation in 2009 launched [The Alliance to Reduce Disparities in Diabetes \(Alliance\)](#), with a commitment of \$15 million through 2013.

### Alliance Goals

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

- Apply proven, community-based and collaborative approaches to address healthcare disparities related to type 2 diabetes among low-income and underserved adult populations
- Enhance patient and healthcare provider communication, mobilize community partners, and assist healthcare organizations in decreasing disparities in diabetes care and outcomes
- Disseminate important findings to aid in the development of comprehensive prevention and management programs to help improve the quality of healthcare for adults who have or are at risk for diabetes

- Increase awareness among policy makers at all levels of changes that can help to reduce healthcare disparities in diabetes
- Promote collaboration and information exchanges to strengthen the efforts of interested stakeholders around the country that share the vision and goals of the Alliance

## Alliance Programs

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

## Program Approach

Alliance programs focus on integrating three core components:

- **Patients:** Patients who are better educated and empowered may become more engaged in their healthcare overall; they may 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
- **System:** Healthcare organizations that implement and support clinical systems, policies or practices related to 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 aims 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 focuses on redesigning and improving the quality of diabetes management and care provided at community health centers on Chicago's South Side.

### Baylor Health Care System, Institute of Chronic Disease and Care Redesign

**(Dallas, Texas):** The Diabetes Equity Project focuses 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 promotes 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 seeks to improve access to diabetes care and management among the Eastern Shoshone and Northern Arapaho Tribes of the Wind River Reservation.

## Public Policy

While Alliance program sites continue to make progress in addressing diabetes disparities in their communities, they also report facing systemic and structural barriers in the health care system that have challenged their ability to deliver and sustain effective diabetes care for those most in need. The Alliance programs emphasize the need to connect their "on the ground" experience with the national policy dialogue on healthcare disparities in the United States. To advance the national conversation on ways to overcome systemic barriers to effective diabetes care, the Alliance released a report in November 2012 entitled, **"Policy Considerations That Make the Link: Connecting Community Experience and National Policy to Reduce Disparities in Diabetes."**

## PERFORMANCE

### Cross-Site Alliance Program Evaluation

The Foundation is working with **RTI International** to conduct a five-year (2009–2013), cross-site evaluation of the Alliance and its programs. The initial results from the evaluation provided an overview of provider enrollment and participation as well as baseline patient self-reported outcome measures.

In 2012, 47 clinics or practices participated in at least two of the three areas of intervention (i.e., patients, providers, and systems). Cumulatively, from 2009 to 2012, 171 individual physicians have been actively engaged in program implementation (e.g., recruiting patients with type 2 diabetes; identifying and implementing systems change in the practice setting). In addition, Alliance sites have served a diverse patient population through their programs. From 2009 to 2012, across the sites, 39 percent of patients were Hispanic or Latino, 39 percent were African American, 7 percent were Native American, 7 percent were white, 1 percent was Asian, and 7 percent were of another racial or ethnic background or their ethnicity was unknown.

The Alliance program sites have been enrolling participants on a rolling basis since the program was first implemented in 2009. Enrollment will be ongoing through 2013. Because not all program participants started at the same time, the numbers and values for participant baseline and follow-up measures will change over time until program

implementation is completed. For ease of interpretation, we present the most recent overall baseline and follow-up data on all participants who had these measures as of December 2012. Note that the data below are not site-specific, but rather were aggregated across the five sites in an independent evaluation.

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

<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. Note: The number of adult enrollees reported in 2010 and 2011 has been adjusted to reflect a change in enrollment criteria for one of the program sites. The more conservative enrollment criteria resulted in an overall decrease in their participant numbers.

<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 12/2012
Diabetes competence <sup>1</sup>	5.2	6
<b>Diabetes Self-Care Behaviors<sup>2</sup></b>		
General diet	3.8	4.6
Diabetes-specific diet	4.1	4.3
Exercise	2.9	3.4
Blood-glucose testing	4.1	5.1
Foot care	4.2	5.4

Patient Self-Reported Outcomes	Baseline	Follow-Up as of 12/2012
<b>Quality-of-Life Measures</b>		
Physical functioning <sup>3</sup>	40.3	<b>40.4</b>
Mental functioning <sup>4</sup>	44.3	<b>46</b>
<b>Objectively Measured Patient Clinical Outcomes</b>		
Hemoglobin A1c <sup>5</sup>	8.5	<b>7.9</b>
Low-density lipid (LDL) Cholesterol <sup>6</sup>	100	<b>99</b>
Blood pressure <sup>7</sup>	131/80	<b>130/78</b>

<sup>1</sup> Weighted averages for the cohort of participants with baseline and follow-up measures to 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 reflecting how many of the past 7 days a behavior was performed. Higher numbers reflect more days on which the behavior is performed. The scores here demonstrate participants, on average, engaged in these behaviors between 3 or 4 days a week at baseline, and there is 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), where 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), where 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 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 slight improvement over time.

## C-MAP

**Today, an estimated 780,000 Chinese citizens are living with HIV.**

This figure is according to the *Joint Assessment of HIV/AIDS Prevention, Treatment and Care in China*, published by China's State Council AIDS Working Committee Office and the UN Theme Group on HIV/AIDS in China.

In 2005, the Merck Foundation committed \$30 million over seven years to establish the China-MSD HIV/AIDS Partnership (C-MAP). This comprehensive HIV/AIDS initiative has project offices in three places: in Beijing; in Chengdu, the capital of Sichuan province; and in Sichuan Province's Liangshan Prefecture.

C-MAP focuses on six goals:

- Raising awareness and reducing discrimination among target populations through training and education
- Deploying comprehensive, integrated risk-reduction approaches to reduce HIV transmission among at-risk populations
- Establishing a service network to provide continuous treatment, care and support for people living with HIV/AIDS
- Providing support to orphans and families affected by HIV to alleviate negative social and economic consequences of the disease

- Building capacity of healthcare workers and organizations
- Strengthening HIV surveillance, monitoring and evaluation systems, as well as data management and analysis, to track program implementation, assess program outcomes, and identify and apply best practices

C-MAP collaborates with approximately 11,500 people working in 1,600 implementing organizations, including departments within the government of China, medical and health institutions, civil society, international organizations, grassroots healthcare workers, and beneficiary groups. The government of China, through its Ministry of Health, is providing staff, facilities and equipment.

## PERFORMANCE

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

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

<b>C-MAP Summary</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
Investment by The Merck Foundation (US\$ millions) <sup>1</sup>	4.5	7	7	0.37
<b>Education</b>				
Middle school students who have received HIV education	1,066,328	1,802,100	871,736	0
Teachers trained to provide HIV/AIDS education to middle school students	173	353	1,442	0
Government leaders and policy makers who have received HIV information and education	5,604	40	300	0
Yi ethnic community members who have received HIV information and education	60,747	57,353	262,000	25,614
Migrant workers who have received HIV information and education	2,831,548	152,050	1,541,681	288,552
<b>Intervention</b>				
At-risk individuals who have received HIV interventions	89,215	89,389	111,006	208,530
<b>Treatment and Testing</b>				
People who have received HIV testing and counseling (PITC Initiative) <sup>2</sup>	131,489	283,036	202,234	35,288

C-MAP Summary	2009	2010	2011	2012
Newly identified HIV/AIDS patients for whom personal epidemic profiles were completed	3,804	4,508	4,545	2,443
Newly identified HIV-positive patients who have received CD4 testing	3,169	10,640	3,996	2,272
Pregnant women tested for HIV (PMTCT Initiative) <sup>3</sup>	16,864	47,043	51,230	0
Diagnosed AIDS patients who are receiving ART	290	1,447	3,526	4,149
<b>Care and Support</b>				
Care activities held at the county level	89	1,034	4,181	3,241
<b>Capacity-Building Initiatives</b>				
Healthcare workers/physicians trained (includes lab workers)	13,024	10,909	650	65
Staff at implementing organizations that have received project management training	394	975	837	240
<b>Monitoring and Evaluation</b>				
Target population that were included in baseline survey & comprehensive surveillance	6,655	28,023	77,695	0
People that received HIV mass screening in target counties	46,454	0	0	0

## ACHAP

**In 2000, the Merck Foundation/ Merck and the Bill & Melinda Gates Foundation established the African Comprehensive HIV/AIDS Partnerships (ACHAP) to support Botswana, a country disproportionately affected by HIV/AIDS.**

The partners selected Botswana because of its HIV/AIDS disease burden— Botswana has 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, The Merck Foundation and the Gates Foundation established ACHAP with a commitment of \$106.5 million, and Merck agreed to donate its 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, Merck expanded its 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, The Merck Foundation committed an additional \$30 million over five years (2010–2014) to support Phase II of ACHAP. This additional funding is enabling ACHAP to build on its progress by:

<sup>1</sup> Note: Some indicators for 2012 are listed as zero, because C-MAP did not support those activities.

<sup>2</sup> The Program for Infant/Toddler Care (PITC Initiative).

<sup>3</sup> Preventing Mother-to-Child Transmission (PMTCT Initiative).

- Positioning ACHAP as a successful country-led, public-private partnership model, now and in the future, through focused and sustained stakeholder relations and engagement
- Systematically transitioning the support of the antiretroviral (ARV) treatment program to the government of Botswana
- Supporting the scale up of safe male circumcision among HIV-negative males aged 15–29 years
- Strengthening the National Tuberculosis (TB) Programme in order to improve access to and utilization of integrated TB and HIV services by 2014
- Improving the generation, utilization and sharing of strategic information and knowledge from HIV/AIDS and TB programs in Botswana in order to inform and improve programs in Botswana and the region by 2014
- 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

From the beginning, Merck and the Gates Foundation have sought to create a program that would leverage private-sector management expertise to resolve social and public health issues. They also hoped to create a model of care, which, if successful, could inform and encourage others in government, international organizations, foundations and the private sector 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

## Looking Ahead

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

Therefore, priorities for ACHAP now include the scaling-up of prevention efforts, addressing the needs of HIV patients co-infected with 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.

## PARTNERSHIPS

**The main partners in the African Comprehensive HIV/AIDS Partnerships (ACHAP) are Merck/ The Merck Foundation, the Bill and Melinda Gates Foundation and the Government of Botswana, but ACHAP works with many different partners from the private sector and civil society.**

### Government

Within the government, ACHAP works closely with the National AIDS Coordinating Agency within the Office of the President; the Ministry of Health, particularly the Departments of HIV/AIDS Prevention and Care, and Public Health; and various other ministries. The Madikwe Forum, created to bring together ACHAP and senior officials from the Ministries of Health, Finance and Development Planning, Education and Skills Development, Labour and Home Affairs, Local Government, Youth Sport and Culture, the National AIDS Coordinating Agency and Defense, Justice and Security for regular



consultation, helps to monitor progress of ACHAP programs, provide strategic and policy guidance and address issues that arise.

## Local Communities

ACHAP works with local institutions, including district administrations, district health management teams and facilities, healthcare workers and other cadres, supporting the national HIV response at the district and community levels. Local community leaders and civil society organizations are also critical to implementation.

## Other Development Partners

From a multilateral perspective, ACHAP has worked with the United Nations Development Programme (UNDP), the United Nations Children's Fund (UNICEF), the United Nations Joint Programme on HIV/AIDS (UNAIDS), the World Health Organization (WHO), the United Nations Population Fund (UNFPA), the World Bank, the European Commission and the Global Fund for HIV/AIDS, TB and Malaria (GFATM). ACHAP also collaborates with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), the U.S. Centers for Disease Control (CDC), and the U.S. Agency for International Development (USAID).

## Academia

Academic institutions also play an important role in building the capacity for healthcare, most notably in developing critical ARV training and preceptorship programs for healthcare workers. Key among ACHAP's academic partners are

the University of Botswana, Harvard University, the University of California Los Angeles (UCLA) and the University of Pennsylvania.

## Nongovernmental Organizations (NGO)

The local NGO community is very involved in the ACHAP partnership, including NGOs focused on youth prevention, and/or support for people living with HIV and AIDS as well as HIV/AIDS service organizations.

## STRATEGY

### ACHAP launched in 2000 with four objectives:

- To improve accessibility of comprehensive HIV prevention, care and support
- To improve access to highly active antiretroviral therapy (HAART) in the public sector for all people living with HIV/AIDS
- To strengthen sustainable improvement in healthcare systems and mitigate the impact of the HIV/AIDS epidemic
- To support the National AIDS Coordinating Agency (NACA) in performing a thorough needs assessment in HIV/AIDS prevention and care in all districts in Botswana

In the first four years, the program was delivered through national initiatives, in line with the above objectives, and through an invitation for proposals from a variety of organizations, including

tertiary institutions and research and civil society organizations, in line with the program goals. In 2005, a strategic plan was developed with the following six strategic objectives:

- To scale up the quality of—and access to—comprehensive HIV prevention services
- To expand HIV counseling and testing capacity
- To increase coverage of quality HIV/AIDS treatment services to all eligible people
- To increase the capacity of communities to utilize and provide HIV/AIDS services
- To improve ACHAP's institutional capacity to deliver effectively on its strategic objectives
- To strengthen partnerships and build capacity to support the sustainability of the national response

In 2007, ACHAP expanded its support to target co-infection of HIV and tuberculosis (TB). HIV infection has fueled an explosive increase in TB cases in Botswana since the early 1990s. In fact, it was estimated that 60–80 percent of TB patients were HIV-positive (MOH, CTBC Assessment, 2010), and HIV-related TB was the leading cause of death among adult AIDS patients. In response, ACHAP's support was intended to strengthen TB/HIV integration to reduce mortality due to TB/HIV co-infection by supporting the National TB Programme, thereby improving access to and utilization of integrated HIV and TB services on a national scale by 2014.

One of the strengths of ACHAP has been its alignment with government strategy, as well as its ability to harness private-sector expertise in support of national efforts to address HIV/AIDS. All ACHAP programs are developed through extensive consultation with all relevant government ministries. Partnership programs must build local capacity, demonstrate a measurable impact on the epidemic, be cost-effective, be appropriate to the setting in which they are delivered, and be sustainable beyond the life of the partnership. All programs were required to fit within the strategic goals of the Government of Botswana's National Strategic Frameworks for HIV/AIDS.

## ACHIEVEMENTS

**The African Comprehensive HIV/AIDS Partnership (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 ARV program.

Major achievements of the program:

- Halved the mortality rate in adults, saving over 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 zero-conversion to less than 5 percent)
- Contributed to significant improvements in blood-supply safety. As of October 2012, 169,515 patients were on treatment in the public sector, of which 62 percent were females. Children under 13 years of age accounted for 4.5 percent (8,357) of the public sector patients. A further 15,802 patients were treated by the private sector under the government's Outsourcing Program.
- Another 15,194 patients were being treated in the private sector of the country by the Medical Aid Schemes and Workplace Programs. This gives a total of 200,511 patients currently receiving highly active antiretroviral therapy (HAART) in Botswana, which amounts to 98.4% of the projected 203,751 adults and children in need of antiretroviral therapy (ART) at the end of October 2012. There were 2,685 new clients started on HAART in the public sector in October 2012, of which 79 percent were treated in clinics. A cumulative total of 20,784 patients have died while on HAART since the inception of the antiretroviral (ARV) program in 2002.
- Developed sustainable treatment by supporting the recruitment of over 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 over 200 clinics countrywide.

- 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 130,000 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 system to cope with up to 20,000 new patients per year.
- Supported the introduction of routine HIV counseling and testing as part of routine medical care provision
- Provided training, in collaboration with Harvard University and the Botswana Ministry of Health, for more than 8,000 of Botswana's healthcare workers in eight core modules on HIV/AIDS clinical care, 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.
- ACHAP has 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 decade

- As of December 2012, ACHAP has supported the circumcision of 46,025 Batswana males
- In 2010, ACHAP supported the development of a National Tuberculosis (TB) Strategy and the TB/HIV policy guidelines. These were launched in 2011. Thereafter, with technical assistance provided through the World Health Organization (WHO), four priority areas for implementation were identified. In 2012, ACHAP-supported districts were aided to disseminate these policies and align their TB plans to the new policies. ACHAP also supported the Ministry of Health (MOH) to conduct the TB/HIV knowledge, attitude and practice (KAP) study, which was to inform the development of the Botswana National TB Program (BNTP) Advocacy, Communications and Social Mobilization (ACSM) strategy. National TB Case Notification rate fell from 536 in 2009 to 333 per 100,000 in 2011. The percentage of TB patients enrolled under community TB Care increased from 9 percent in 2009 to 61.3 percent in 2012.

ACHAP has made significant contributions in the area of HIV prevention, including the development of a national plan for scaling up prevention, as well as improving condom availability and safe blood transfusions. Prevention initiatives during the first phase of the program did not have the same impact or effectiveness as the treatment program. With the achievement of virtually all treatment objectives in the first phase, efforts are now continuing in the second phase to slow the spread of HIV infection and meet the ambitious national goal of “zero new infections by 2016.”

## PERFORMANCE

ACHAP Summary	2008	2009	2010	2011	2012
<b>ACHAP</b>					
Estimated HIV+ population (total population) <sup>1</sup>	341,613	350,557	357,847	363,105	366,861
New HIV infections (adults only, ages 15+) <sup>1</sup>	18,271	18,129	17,965	17,791	17,560
Annual AIDS deaths (adults only, ages 15+) <sup>1</sup>	6,539	8,732	10,584	12,659	14,126
New HIV infections (children only, ages 0 to 14) <sup>1</sup>	874	870	860	843	819
Annual AIDS deaths (children only, ages 0 to 14) <sup>1</sup>	575	482	501	550	597
Total orphans <sup>1</sup>	123,637	122,181	134,381	123,427	125,662
The Merck Foundation Investment (US\$M)	0	6.5	6	6	3.5
Total value of product donations (US\$M) <sup>2,3</sup>	8.4	21.4	24.3	23.8	29

<b>ACHAP Summary</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
<b>Testing &amp; Treatment</b>					
Batswana (adults and children) receiving ART by year-end <sup>4</sup>	117,045	140,167	161,219	178,684	<b>200,511</b>
Batswana (adults and children) with advanced HIV infection receiving antiretroviral therapy (ART) <sup>1</sup>	81%	87%	92%	95%	<b>98%</b>
HIV-positive pregnant women who received ART to reduce the risk of mother-to-child transmission	89%	94%	92%	92%	<b>94%</b>
<b>Prevention</b>					
HIV prevalence rate (ages 15 to 49)	25.0%	26.0%	25.9%	25.8%	<b>25.6%</b>
Adjusted HIV prevalence rate among pregnant women <sup>5</sup>	NA	32%	NA	30%	<b>NA</b>
HIV prevalence rate among pregnant women ages 15 to 19 <sup>5</sup>	NA	13%	NA	10%	<b>NA</b>
Blood supply that was HIV positive <sup>6</sup>	4%	4%	NA	NA	<b>1.70%</b>

The Estimated HIV+ Population is increasing because the highly antiretroviral therapy (HAART) coverage is above 95 percent, which means that people who are HIV+ and who would have otherwise died, are kept alive for longer periods of time. At the same time, new HIV infections are still occurring, adding to the number of people living with HIV. In addition, annual AIDS deaths are also increasing as a result of the increase in the number of people getting infected. So despite the fact that people on treatment increased from around 93,000 in 2007 to over 200,000 by the end of 2012, the proportion of deaths have always been estimated to be around 9 percent, which means that the actual number of deaths will increase. The proportions of those that will have died based on treatment availability, will, however, decline.

ACHAP Summary	2008	2009	2010	2011	2012
<b>Infrastructure Development &amp; Capacity Building</b>					
Healthcare workers trained through the ACHAP program (cumulative)	6,300	7,078	7,645	7,645	>8,000
Infectious disease care clinics and satellite facilities constructed to screen and treat patients with HIV/AIDS	35	35	35	35	34
NA: Data not available.					
<sup>1</sup> Estimates from "HIV/AIDS in Botswana Estimated Trends and Implications based on Surveillance and Modeling."					
<sup>2</sup> Value of Merck branded product donations based on Merck's Access pricing for our anti-retroviral medicines.					
<sup>3</sup> The 2012 figure includes the value of Merck branded product donations and value of purchased generic ATRIPLA.					
<sup>4</sup> The 2012 figure is as of October 2012.					
<sup>5</sup> Measurement taken every two years.					
<sup>6</sup> In 2011, prevalence was not calculated by the national laboratory as there was no confirmatory test done.					

## HIV CARE COLLABORATIVE

**In the United States alone, there are still 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, the Merck Foundation

launched a three-year initiative—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. The Foundation has committed \$3 million to support local health departments in Atlanta, Georgia; Houston, Texas; and Philadelphia, Pennsylvania. These are among the top 10 cities with the highest HIV burden in the United States.<sup>2,3</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. 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:

- Introducing innovative, community-based approaches with local 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:** *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 re-engage 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) School of Public Health and Health Services 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, Vital Signs: HIV Prevention Through Care and Treatment—United States, *CDC Morbidity and Mortality Weekly Report*, December 2, 2011.

<sup>2</sup> Mugavero, M.J., Lin, H.Y., Allison, J.J., et al., (2007) “Failure to Establish HIV Care: Characterizing the “No Show” Phenomenon,” *Clinical Infectious Disease*, 45, 127–30.

<sup>3</sup> Centers for Disease Control and Prevention, Estimates of New HIV Infections in the United States. August 2008. [www.cdc.gov/hiv/topics/surveillance/resources/factsheets/pdf/incidence.pdf](http://www.cdc.gov/hiv/topics/surveillance/resources/factsheets/pdf/incidence.pdf).

<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

### Cross-Site HIV Care Collaborative Program Evaluation

The Merck Foundation is working with George Washington University (GWU) to conduct a three-year (2013–2015), cross-site evaluation of the HIV Care Collaborative programs. A cohort of newly identified and previously lost-to-care HIV-positive adults will be enrolled in care linkage, engagement and retention interventions, using linkage workers and patient navigators. The cohort’s care will be tracked longitudinally to assess: clinical and other outcomes associated with these interventions. Previously designed client-level data systems will be used to track patient characteristics, service utilization, quality of care, 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. Best practices in linkage, engagement, and retention in HIV care will be documented and disseminated to inform similar efforts in other communities.

In 2013, we anticipate that a baseline process and outcome measures will be available for the three participating program sites and their service partners. The following measures will be captured across the programs:

### Patient Participation Measures

- Number of newly identified HIV-positive adults enrolled in the HIV Care Collaborative
- Number of HIV-positive adults who were lost to HIV medical care but have now been re-engaged in care

### Patient Process Measures

- Number of newly diagnosed HIV-positive adults who are identified through HIV screening
- Number of newly identified HIV-positive adults linked to HIV medical care by HIV Care Collaborative service linkage workers and patient navigators
- The number of months from first HIV-positive test to linkage to care for newly diagnosed HIV-positive adults
- The three- and six-month retention rates of HIV-positive adults at baseline and after HIV Care Collaborative service linkage or patient navigation intervention

### Quality of Care Measures

- The baseline and annual rate of HIV-positive adults who had two or more medical visits
- The baseline and annual rates of HIV-positive adults prescribed highly active antiretroviral therapy (HAART)

### Patient Outcome Measures

- Baseline and trends in HAART treatment outcomes, as measured by longitudinal changes in CD4 count and viral suppression

## MERCK MECTIZAN DONATION PROGRAM

**One of the most significant initiatives undertaken by Merck to help improve access to medicines in developing countries is the Merck MECTIZAN® (ivermectin) Donation Program.**

In 2012, we celebrated the 25th anniversary of the MECTIZAN Donation Program, the longest-running disease-specific drug donation program and public-private partnership of its kind. At events held throughout the year, we celebrated the accomplishments of the program, acknowledged the contributions and commitments of our many partners and developed plans to change from a control- to an elimination-strategy going forward. For more information, see [MDP Annual Highlights](#).

In 1987, Merck announced that it would donate MECTIZAN, our breakthrough medicine for the treatment of onchocerciasis, to all who needed it, for as long as needed. 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. The disease is one of the leading causes of preventable blindness worldwide.

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.

To facilitate the donation and delivery of MECTIZAN, and to eliminate river blindness, Merck established a multisectoral partnership involving the World Health Organization (WHO), the World Bank and UNICEF, as well as ministries of health, nongovernmental development organizations and local communities. At the program’s inception in 1988, Merck also established the MECTIZAN Donation Program Secretariat, housed at the **Task Force for Global Health**. The Secretariat works with the independent MECTIZAN Expert Committee which provides technical support and strategic oversight for the program. In 1991, Merck, the Secretariat and the WHO established the **Non-Governmental Development Organization (NGDO) Coordination Group** for Onchocerciasis Elimination; NGOs play a critical role in MECTIZAN distribution through their work with ministries of health, their expertise in program management and their financial support. They have also played an important role in developing communication strategies that are helping to achieve high coverage and compliance with treatment. This balanced governance and organizational structure continues to support and facilitate the donation of MECTIZAN.

In 1998, Merck expanded the Merck MECTIZAN Donation Program to include the prevention of lymphatic filariasis (LF) in African countries where the disease

coexists with river blindness. 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 currently estimated to infect more than 120 million people, with more than 40 million incapacitated or disfigured with swelling of the limbs, breasts (lymphoedema) and genitals (hydrocele). Swollen limbs often develop dramatically thickened, hard, rough and fissured skin (elephantiasis).

In lymphatic filariasis, parasitic filarial worms are transmitted by a mosquito and lodge in the lymphatic system. Those affected may develop kidney damage caused by blockage of the lymphatic system.

Merck has made a long-term commitment to donate as much MECTIZAN as necessary to treat river blindness and to prevent lymphatic filariasis. The goal is to eliminate both lymphatic filariasis and onchocerciasis by 2020 and 2025, respectively.

In December 2007, Merck announced a **donation of \$25 million over eight years** as part of an initiative with the World Bank to raise approximately \$50 million to help eliminate river blindness in Africa. The World Bank has raised the remaining \$25 million, providing all the funding necessary for 28 African countries affected by river blindness to develop self-sustaining MECTIZAN distribution programs by 2015. With this funding, many community-directed treatment with ivermectin (CDTI) programs will also be able to implement at least one

*“Twenty-five years after the donation of Mectizan through the Mectizan Donation Program, we are now close to eliminating river blindness from the Western Hemisphere. This remarkable achievement is also considered feasible in parts of Africa where we once hoped only to control the disease. Thanks to this donation and to the commitment of endemic countries, nongovernmental organizations (NGOs), UN agencies and the donor community, we can now envision a world free of this blinding and disfiguring skin disease.”*

**Dr. Margaret Chan**  
Director-General, World Health Organization

other health intervention in addition to MECTIZAN delivery, while helping countries and their partners to improve healthcare by expanding other health programs to hard-to-reach communities.

### Adverse Experience Reporting

While side effects following treatment with MECTIZAN are rare, Merck has 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 Merck, which then reports them to drug safety and regulatory agencies in the United States and internationally.

The MECTIZAN Expert Committee, ministries of health and the WHO also play a key role 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 during the more than 25-year history of the program, to incorporate feedback from clinicians and public health administrators in the field.

## PERFORMANCE

### Commitments

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

To ensure continued supply of MECTIZAN (ivermectin) to support the activities of other program partners, Merck remains 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 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 lymphatic filariasis efforts via the

MECTIZAN Donation Program, which began in 1998, set the foundation for many of these efforts, and Merck will remain engaged with key stakeholders to help with integration programs where feasible.

As a result of our activities and the collaboration and contributions of the 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 now anticipate treatment will be stopped in those foci by 2015
- By 2015, program partners plan to achieve 100 percent geographic coverage of treatment with MECTIZAN in all river blindness-affected areas in Africa

In accordance with the goals outlined in the WHO Roadmap for Neglected Tropical Diseases, we expect the elimination of lymphatic filariasis and river blindness by 2020 and 2025, respectively.

In 2011, 116 million treatments were approved for river blindness (with 34 million of those being for both river blindness and LF) and 150 million treatments were approved for LF. To date, Merck has invested approximately \$50 million in direct financial support for the MECTIZAN Donation Program, in addition to donating over 1.15 billion treatments of MECTIZAN.



The donation of MECTIZAN also has led to the development of community-directed treatment with ivermectin (CDTI) 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 28 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 Merck MECTIZAN Donation Program annually
- In the 19 countries of the African Program for Onchocerciasis Control (APOC), more than 8.2 million disability-adjusted life years have been saved between 1995 and 2010
- 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. By 2016, it is expected that all six formerly affected countries in the Western Hemisphere (Brazil, Colombia, Ecuador, Guatemala, Mexico, Venezuela) will have achieved verification that river blindness has been eliminated.

- In 2009, Togo became the first sub-Saharan African country to stop treatment for LF; continuing surveillance confirms that transmission of the **disease was successfully interrupted**. In addition, transmission has been interrupted in several endemic areas in Nigeria, Mali, Senegal, Sudan and Uganda.

<b>River Blindness and Lymphatic Filariasis (LF) Summary</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
Direct investment in the MECTIZAN® Donation Program (US\$M)	5.5	5.5	5.5	5.5	5.5
Treatments approved (in millions)	174.2	211	220	270	266 <sup>1</sup>
Market value of MECTIZAN donations (US\$M)	549	606	651	747	906
Countries with LF elimination programs supported by the MECTIZAN Donation Program (Target: 30)	15	17	17	17	22
Latin American countries where treatment with MECTIZAN has been stopped to allow for post-treatment surveillance and certification that the disease has been eliminated (Target: 6)	1	1	2	4	4
Treatments with MECTIZAN approved for river blindness (in millions)	86.7	100	100	140 <sup>1</sup>	116
Treatments with MECTIZAN approved for LF (in millions)	87.5	109	120	130	150

<sup>1</sup> In 2011, approximately 18 million of the 140 million treatments approved were pre-approved for distribution in 2012, which resulted in a reduction of treatments approved in 2012.

# GARDASIL ACCESS PROGRAM

**In 2007, Merck made a major commitment to help improve access to GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, 18) Vaccine, Recombinant] in developing countries.**

Through the GARDASIL Access Program, Merck 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, the GAVI 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 sustainably introduce the vaccine through a demonstration or national program.

In this context and following consultation with a wide array of stakeholders,

including WHO, GAVI, PATH, other public health organizations, select ministries of health and some GARDASIL Access Program participants, Merck and Axios Healthcare Development (AHD), a U.S. nonprofit organization, decided that the GARDASIL Access Program would no longer be awarding doses of GARDASIL to new projects. However, Merck’s full donation commitment of at least 3 million doses of GARDASIL will be honored, and options for how remaining doses of GARDASIL could be used are currently being explored. Importantly, commitments to already-awarded projects will continue to be honored.

In addition, the collection of information from past and current program participants by AHD will continue to be a key focus as a means of sharing the data and experience from the GARDASIL Access Program with the public health community.

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.

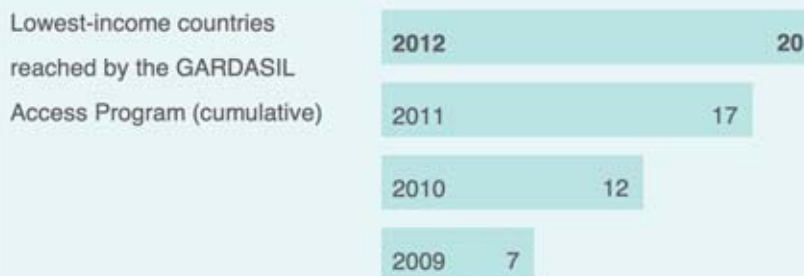
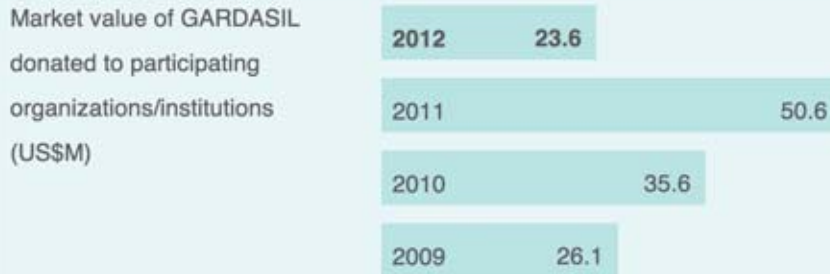
The program is managed by AHD with strategic guidance provided by the independent GARDASIL Access Program Advisory Board, made up of international public health experts. AHD administers the program in consultation with Advisory Board recommendations, and coordinates delivery of donated vaccine to participants. 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	2012	182,360
	2011	390,400
	2010	275,200
	2009	201,600

**GARDASIL® ACCESS PROGRAM SUMMARY**



As of December 31, 2012:

- More than 1,049,560 doses of GARDASIL have shipped to 23 participants in support of their proposed HPV-vaccination projects in 20 countries: Bhutan, Bolivia, Cambodia, Cameroon, Georgia, Ghana, Guyana, Haiti, Honduras, Kenya, Kiribati, Lesotho, Mali, Moldova, Mongolia, Nepal, Tanzania, Papua New Guinea, Uganda and Uzbekistan
- 17 HPV-vaccination projects have been completed in 12 countries: Bhutan, Bolivia, Cambodia, Cameroon, Haiti, Honduras, Lesotho, Moldova, Nepal, Tanzania, Uganda and Uzbekistan

- There are 11 ongoing HPV-vaccination projects in 10 countries: Georgia, Guyana, Honduras, Kenya, Kiribati, Lesotho, Mali, Mongolia, Nepal and Papua New Guinea
- Axios Healthcare Development routinely interviews all GARDASIL Access Program participants and analyzes their formal progress reports to synthesize lessons learned from the program
- The manuscript “Assessment of eight HPV vaccination programs implemented in lowest-income countries” was published in *BioMed Central Public Health* on May 23, 2012
- Axios publishes newsletters periodically to update stakeholders on program progress

## MERCK VACCINE NETWORK—AFRICA

**In Africa, approximately 8.3 million infants each year do not receive the most basic vaccines.**

According to the World Health Organization (WHO), one major reason for low immunization coverage in many developing countries is the lack of skilled healthcare workers.

As a founding partner in the **GAVI Alliance**, an historic public-private partnership committed to increasing access to immunization in lowest-income countries, Merck responded to this public health challenge by launching a multiyear philanthropic initiative designed to help strengthen the capacity of Expanded Program on Immunization (EPI) healthcare workers in sub-Saharan Africa.

Formally endorsed by the GAVI Alliance in 2003, the Merck Vaccine Network—Africa (MVN-A) supported collaborative partnerships in the development and implementation of sustainable EPI-management training programs in Kenya, Uganda, Mali and Zambia. MVN-A also helped support achievement of the UN Millennium Development Goals, including that of reducing by two-thirds the mortality rate among children under five by 2015.

With \$4.8 million in support from the **Merck Foundation**, MVN-A program partners established training programs in Kenya, Mali, Uganda and Zambia, which

provided mid- to high-level immunization program managers in these four countries with training in vaccine management and immunization services. Each MVN-A program was managed and administered by two primary institutions that forged a broader collaborative partnership with ministries of health and education, nongovernmental organizations, medical and nursing schools, and multilateral organizations such as WHO and UNICEF:

- **MVN-A Kenya:** Indiana University School of Medicine (Indianapolis, Indiana, USA) and Moi University School of Medicine (Eldoret, Kenya)
- **MVN-A Mali:** Center for Vaccine Development at the University of Maryland School of Medicine (Baltimore, Maryland, USA) and Centre pour le Développement des Vaccins, Mali (Bamako, Mali)
- **MVN-A Uganda:** Task Force for Global Health (Decatur, Georgia, USA) and Makerere University School of Public Health (Kampala, Uganda)
- **MVN-A Zambia:** Brighton and Sussex University Hospitals NHS Trust (Brighton, England, UK) and University Teaching Hospital of the University of Zambia School of Medicine (Lusaka, Zambia)

Each MVN-A program developed and adapted customized training curriculums and methodologies to improve the capacity of EPI healthcare workers and address evolving

national immunization management needs. These tools were based on the findings of baseline training needs assessments in all four countries,

which helped to identify specific gaps in the knowledge, skills and practice of EPI healthcare workers, as well as inadequacies in reference materials, cold chain equipment and logistical resources.

Health worker training initiatives in sub-Saharan Africa face numerous operational challenges, including maintaining, adapting and continuously improving training activities to address high staff turnover; internal health worker migration from low-population rural areas to high-population urban areas; and unforeseen events, such as natural disasters and political unrest that can lead to disease outbreaks.

For this reason, each MVN-A training program was fully integrated into existing national healthcare infrastructures, ensuring complete alignment with the immunization priorities identified by each country's ministry of health and also with strategic policies and initiatives endorsed by regional and international stakeholders, such as the WHO, UNICEF and the GAVI Alliance.

## PERFORMANCE

**From 2003 to 2012, MVN-A programs in Kenya, Mali, Uganda and Zambia trained more than 1,700 Expanded Program on Immunization (EPI) healthcare workers across all four countries.**

Trainees in each country have demonstrated significant improvement in perceived ability, competence, knowledge and skills in most targeted areas of EPI management. In addition, MVN-A graduates have returned to their home medical facilities to disseminate their expertise and knowledge to fellow healthcare workers.

As the Merck Foundation concluded its funding support in 2012, MVN-A collaborators advanced efforts to sustain their training programs in close partnership with key national stakeholders. For example, ministries of health have enlisted MVN-A graduates to conduct operational-level training (Kenya, Mali and Uganda), disease outbreak

MVN-A Performance Data Summary	2008	2009	2010	2011	2012
Merck investment in MVN-A (US\$)	800,000	600,000	600,000	200,000	200,000
Number of health workers trained through MVN-A <sup>1</sup>	142	313	205	233	100

<sup>1</sup> In 2010, the MVN-A programs in Kenya and Mali allocated significant time and resources toward program evaluation, sustainability planning and publication efforts, leading to fewer healthcare workers trained across all four countries when compared to 2009. As the program phased down in 2012, fewer healthcare workers were trained than in 2011.

responses (Kenya, Uganda), mass immunization campaigns in camps of internally displaced persons (Kenya), and new vaccine introductions (Kenya, Mali and Zambia).

In 2012, the Merck Foundation sponsored a new report, “Boosting the Immunization Workforce: Lessons from the Merck Vaccine Network–Africa,” to share the lessons learned from the MVN-A initiative.

The report, authored by **FSG**, includes seven key lessons that can help others in the immunization and broader global health field when designing or implementing similar vaccine-delivery training programs in the future.

## MERCK MEDICAL OUTREACH PROGRAM

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

The MMOP, managed by Merck’s 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 Merck to donate critical

pharmaceuticals, vaccines and consumer health products 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 Merck medicines available for donation, and the random nature of natural and man-made disasters.

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

- **AmeriCares**
- **Catholic Medical Mission Board (CMMB)**
- **Direct Relief International**
- **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 Merck 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 Merck medicines. Merck does not provide donations of expired products or of products with inadequate dating, ensuring proper administration prior to expiration.

The MMOP comprises three components:

### **The Merck Annual Product Allotment Program**

Through this program, the six NGOs with which we work can order fully dated medicines of their choice from the 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, 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 and Vaccines**

Donations of Merck’s pharmaceuticals and vaccines are also made in response to proposals from our partners to address specific shorter-term needs of their programs around the world. We also offer medicines and vaccines to our partners proactively, based on supply, as they become available, for use in their ongoing humanitarian programs.

### **Disaster and Emergency Relief**

Merck’s disaster relief program is designed to provide assistance during major disasters and to support efforts in preparedness and recovery. Merck’s Office of Corporate Philanthropy serves as the central clearinghouse for information regarding Merck’s companywide response to major disasters, and it works with the Office of Corporate Responsibility to make

decisions related to our donations of cash, as well as medicines, vaccines and/or consumer health products through the MMOP. For more information, please [click here](#).

In conducting the MMOP, Merck adheres to the [World Health Organization \(WHO\) Guidelines for Drug Donations](#).

Merck played an important role in the development of these guidelines through our involvement in 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

MMOP Summary	2009	2010	2011	2012
Countries and territories reached by the Merck Medical Outreach Program	99	97	82	92
Value of donations of medicines, vaccines and consumer care products (US\$M) <sup>1,2</sup>	80.2	75.2	89.8	86.3
Disaster relief contributions (product) (US\$M) <sup>1</sup>	0.4	10.9	10.4	0.78 <sup>3</sup>

<sup>1</sup> We value our product donations based on the U.S. wholesale acquisition cost.

<sup>2</sup> Figure includes the value of product donations through the MMOP program only. Product donations to the African Comprehensive HIV/AIDS Partnerships (ACHAP) are included in the ACHAP section.

<sup>3</sup> Includes products that were donated for disaster relief in 2012, but will be used for disaster relief in 2013

In 2012, donations of medicines, vaccines and consumer healthcare products supported vaccination programs in Honduras, Nicaragua, Haiti and Kyrgyzstan; provided disaster assistance in the United States; supported partner medical mission programs; and reached many thousands more worldwide through

the ongoing medical programs of the NGOs with which we work.

In addition to the MMOP, local Merck subsidiaries and other Merck divisions donated the equivalent U.S. market value of more than \$21.8 million in products for humanitarian aid.

## PATIENT ASSISTANCE PROGRAM

**Merck believes that donating medicines and vaccines, while not a sustainable solution to the challenge of patient access to healthcare in the United States, can provide needed assistance under certain circumstances.**

To address the complex issues involved in the challenges of access to healthcare, Merck is working with government and private sector partners to help find long-term policy approaches that make health coverage available to the people who need it. In the meantime, Merck has created several programs to help address this challenge.

More than 50 years ago, Merck created our first U.S. Patient Assistance Program to keep affordable medicines within patients' reach. Today, our patient assistance offerings include seven programs. Through these programs, Merck has provided more than 33 million free prescriptions and vaccines, representing a total value (wholesale acquisition cost) of more than \$2.67 billion in the past ten years alone.

### **Merck Patient Assistance Program:**

The Merck Patient Assistance Program has provided Merck medicines free of charge to millions of eligible individuals who, without our assistance, could not otherwise afford them. A single application may provide for up to one year of medicine free of charge, and

## ELIGIBILITY FOR MERCK PROGRAMS

If you have been prescribed a Merck medicine, you may be eligible for the program if all three of the following conditions apply:

1. You are a U.S. resident and have a prescription for a Merck medicine from a doctor licensed in the United States.<sup>1</sup>

AND

2. You do not have insurance or other coverage for your prescription medicine. Some examples of other insurance coverage include private insurance, HMOs, Medicaid, Medicare, state pharmacy-assistance programs, veteran's assistance, or any other social service agency support.

AND

3. You cannot afford to pay for your medicine. You may qualify for the program if you have a household income of \$45,960 or less for individuals, \$62,040 or less for couples, or \$94,200 or less for a family of four.<sup>2</sup>

More information is available at [MerckHelps.com](http://MerckHelps.com).

an individual may reapply as many times as needed. Under certain circumstances, individuals who don't meet the prescription drug coverage criteria may still qualify for the Merck Patient Assistance Program if they attest that they have special circumstances of financial and medical hardship, and their income meets the program criteria.

**SUPPORT™ Program:** To ease the healthcare reimbursement process, Merck has created the SUPPORT™ Program to help patients who have been prescribed ISENTRESS® (raltegravir) 400 mg Film-Coated and 25 mg and 100 mg Chewable Tablets, and CRIXIVAN® (indinavir sulfate) 100 mg, 200 mg and 400 mg Capsules. The SUPPORT Program provides both personalized reimbursement support that helps patients navigate what can be a complex insurance and reimbursement system and provides assistance with

prior authorization, identifying insurance options and reimbursement. The program also provides medicine free of charge to eligible patients lacking coverage for ISENTRESS and CRIXIVAN.

**ACT Program:** The ACT Program is specifically designed to assist patients with insurance reimbursement issues and questions, and to provide product free of charge for those eligible individuals lacking coverage for Merck's oncology and hepatitis C medicines.

**Merck Hotline for INVANZ®, PRIMAXIN® and CANCIDAS®:** The Merck Hotline for INVANZ (ertapenem sodium), PRIMAXIN (imipenem and cilastatin) and CANCIDAS (caspofungin acetate) program provides reimbursement support and patient assistance/product replacement to healthcare facilities.

## Merck Vaccine Patient Assistance

**Program:** Launched in 2006, the Merck Vaccine Patient Assistance Program offers a private and confidential program that provides Merck's adult vaccines free of charge to uninsured adults age 19 or older who cannot afford their medicines.

## Merck Bulk Replacement Patient

**Assistance Program:** The Merck Patient Assistance Program, Inc., may be able to provide medicines and adult vaccines free of charge through periodic bulk replenishments to eligible facilities that serve a large percentage of low-income, uninsured patients. Types of eligible facilities include outpatient pharmacies of disproportionate share hospitals and nonprofit healthcare clinics that have a licensed outpatient central-fill pharmacy that is owned and operated by the facility. The eligible facilities, under an Agreement with the Merck Patient Assistance Program, Inc., review the eligibility of patients for assistance under the program's criteria, with replenishment being limited to patients meeting specified income and insurance criteria.

Effective February 1, 2013, patients may qualify for the program if their household income is \$45,960 or less for individuals, \$62,040 or less for couples, or \$94,200 or less for a family of four.

Most of Merck's PAPs also continue to be available to Medicare beneficiaries who are not enrolled in a Medicare drug plan, as well as Medicare beneficiaries who enroll in a Medicare drug plan but still cannot afford their Merck medication. Such individuals have to attest that they have special circumstances of financial and medical hardship and that their income meets the program criteria.

For program details, including eligibility requirements, visit [MerckHelps.com](http://MerckHelps.com) or call 1-800-PAP-5400 (1-800-727-5400).

## Designed for Ease of Use

In recent years, we redesigned the Merck Patient Assistance Program with the goal of simplifying and streamlining the patient assistance process for both healthcare providers and patients. As a result:

- A simple one-page, two-sided form was created
- To request enrollment, only a completed application signed by both the patient and the prescriber is required
- Education materials and applications are available in Spanish
- Patients can receive a 90-day supply of Merck medicines with up to three refills—for a total of up to one year of medication
- Up to three scripts per application can be submitted
- We provide the option of mailing medicines directly to a patient's home or to a prescriber's office

- Under special circumstances, patients with insurance who have extenuating circumstances can request that an exception be made
- In an effort to simplify patient access further, the exceptions process no longer requires a prescriber's signature to the "exceptions request" authorization form, although a prescriber's signature is still required on the initial PAP application

## Communicating Our Programs to Doctors and Consumers

Merck is also working to raise awareness of our PAP to doctors and eligible patients via brochures about and applications for the Merck Patient Assistance Program distributed by our sales representatives to physician offices and clinics nationwide. All toll-free phone lines for Merck medicines include an option for patients to learn about the Merck PAP. Also, PAP information is added to all new Merck direct-to-consumer advertisements, including a phone number for more information.

## Partnership for Prescription Assistance

Merck also participates 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 by offering one place—a single website—that provides information and access to more than 475 public and private patient assistance programs, including more than 200 programs offered by pharmaceutical companies like Merck. To date, the PPA has helped more than 6.8 million patients.

Merck's participation in PPA underscores the company's commitment to helping the uninsured gain access to Merck medicines. To learn more about the Partnership for Prescription Access, 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, U.S. Virgin Islands and Guam, please call 1-800-727-5400.



PERFORMANCE

MERCK PATIENT ASSISTANCE PROGRAMS

Patients utilizing Merck's Patient Assistance Program (PAP) <sup>1</sup>	<b>2012</b>	<b>444,178</b>
	2011	379,500
	2010	343,382
	2009	331,890

30-day prescriptions filled under Merck's PAP (millions) <sup>2</sup>	<b>2012</b>	<b>2.2</b>
	2011	2.5
	2010	2.1
	2009	1.4

Total value of Merck medicines dispensed under Merck's patient assistance programs (US\$M) <sup>3</sup>	<b>2012</b>	<b>559</b>
	2011	301.2
	2010	322.8
	2009	302.1

<sup>1</sup> Totals represent 2011 and 2012 volumes of the Merck Patient Assistance Program, the Merck Vaccine Patient Assistance Program, the Merck Patient Bulk Replacement Patient Assistance Program, the SUPPORT Program, the ACT Program and the Merck Hotline. Totals for 2009 and 2010 include the Merck Patient Assistance Program (MPAP), the U.S. Merck Vaccine Patient Assistance Program (MVPAP), the Schering-Plough Patient Assistance Program and the Merck/Schering-Plough Pharmaceutical Patient Assistance Program. The 2009 total also includes legacy Schering-Plough PAP numbers for the first half of the year; legacy Schering-Plough and Merck/Schering-Plough products were integrated into the Merck patient assistance programs effective August 2010.

<sup>2</sup> Totals for 2011 and 2012 represent volumes of MPAP, MVPAP, SUPPORT Program, the ACT Program and the Merck Hotline. For 2009 and 2010, totals include legacy Merck data only; legacy Schering-Plough data is not available due to integration following the merger.

<sup>3</sup> Totals are based on the U.S. wholesale acquisition cost (WAC) and cover all Programs.

# COMMITTED TO IMPROVING ACCESS TO HIV CARE

**Our commitment to helping improve access in HIV is steadfast, to meet the evolving needs of the community.**

The challenge of HIV is vast. For more than 25 years, Merck has sought to make a difference in the fight against HIV, particularly in the developing world. But the need is greater than the results any one stakeholder can deliver, requiring coordinated efforts among many. 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.

## It Takes a Multifaceted Approach to Improve Access

Our commitment to working with governments, donors, innovative and generic manufacturers, multilateral organizations and civil society to address the full range of factors affecting access is strong. Since 1985, we've been engaged in **research and development** efforts in both HIV prevention and treatment. But research is just one part of our comprehensive strategy to strengthen access.

We have seen that ensuring access requires a broad, comprehensive approach. This is why we are committed

to improving patient access through expanded availability, enhanced access strategies and extensive local community support.

To make this possible, today we employ many strategies to meet the needs of a particular region or country, including seeking rapid **registration** of our antiretrovirals; developing **pediatric formulations**; generating support for clinical studies in resource-limited settings; creating differential-pricing policies; establishing strong collaborations with government, manufacturers and other stakeholders; and providing local investment through on-the-ground support for affected communities.

We believe it is critical to invest in HIV at the local level. This investment supports healthcare professionals and the communities they serve, and assists in providing much-needed education to help ensure appropriate HIV care and treatment in all regions of the world. In sub-Saharan Africa, for example, Merck has expanded resources to provide medical education to healthcare workers and to help ensure appropriate use of our antiretrovirals. We have invested at a local level in local representatives to provide training and services through an accessible, skilled workforce in regions where HIV infection is highly prevalent. In the U.S., we are working closely with numerous U.S. AIDS service organizations (ASOs) to help address healthcare disparities through educational programs and resources that align with the National HIV/AIDS Strategy (NHAS).

To facilitate access in sub-Saharan Africa, and in **Low-Income countries**, the

areas of greatest need and least ability to finance healthcare, we instituted an innovative model that utilizes a low-cost supply chain with manufacturing partners. This enabled us to reduce our lowest Access price in these specific countries. We have also granted non-exclusive voluntary licenses to two generic manufacturers to supply generic raltegravir in these regions. This is coupled with our commitment to provide local, on-the-ground support, including medical education in sub-Saharan Africa. This initiative was announced in June 2011.

Given the different levels of economic development and national strategies, we have implemented a different approach for Middle-Income countries 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, among other things, a combination of treatment-guideline position, patient access, market conditions, country income and disease burden. We continue to explore the best country-specific models in these regions.

In developed countries, our commitment to addressing patient access needs has not wavered. In the United States, for example, many state AIDS Drug Assistance Programs (ADAP) have struggled to meet growing need. Over the last two decades, Merck lowered or froze the price of its antiretrovirals four times. Since 2010, Merck has worked with Welvista to offer immediate access

to no-cost HIV medicines to patients on ADAP waiting lists. We also continue to offer support to eligible patients through Merck's comprehensive Patient Assistance Programs and Co-Pay Assistance Program.

## 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 bounds of possibility enabled Merck to pave the way for two successful private-public partnerships that were created in the last decade in some of the countries hardest hit by HIV. Merck has donated its antiretrovirals to the **African Comprehensive HIV/AIDS Partnerships**, and The Merck Company Foundation has committed more than \$115 million to both this partnership and the **China-MSD HIV/AIDS Partnership**. By 2010, over 90 percent of people in Botswana in need of HIV treatment were receiving it, compared with 5 percent when the program began in 2000. In the areas served by the partnership in China's Sichuan Province, the number of AIDS patients on treatment increased from zero to close to 1,500 in just three years.

Merck remains 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

### **Despite Merck's efforts to develop and implement effective philanthropic and business strategies to help remove barriers to access, challenges remain because of the complex and multifaceted nature of the problem.**

Improving access to HIV medicines requires more than simply making our medicines and vaccines available at reasonable prices. We believe that to truly address—and, ultimately, solve—the issue of access in low- and middle-income markets, the international community must pool its resources and expertise to strengthen healthcare infrastructure, ensure adequate financing for health, and 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 Merck's 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 Merck has immediate and direct control. While many include 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 to U.S. AIDS Drug Assistance Programs (ADAPs)**

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 Merck's interest in conducting extensive HIV research while supporting broad access to our medicines.

Merck was the first company to provide a price freeze to the unique state U.S. AIDS Drug Assistance Programs (state ADAPs) when, in the late 1990s, they began to suffer a funding challenge. In 2008, Merck announced a price freeze on ISENTRESS® (raltegravir) for state ADAPs, and in 2010 Merck extended that price freeze of ISENTRESS and that of CRIXIVAN® (indinavir), which was first established in 2003 to eligible state ADAPs, through December 31, 2013. Merck also is providing expanded financial relief to state ADAPs through increased discounts.

## Welvista

Through Welvista, Merck provides ISENTRESS and CRIXIVAN to patients on waiting lists for drugs under the ADAP program.

## Merck's Patient Assistance Programs (PAPs) in the United States

Merck's commitment to patients' access to its products is reflected in its **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 help patients apply for the patient assistance program, which provides ISENTRESS and CRIXIVAN free of charge to eligible patients who do not have insurance coverage. More information about the SUPPORT™ Program can be obtained by calling 1-800-850-3430 or visiting this site.

## Merck's Co-Pay Assistance Program in the United States

In addition to the SUPPORT Program, Merck has 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 (regardless of the number of tablets supplied on the prescription) of ISENTRESS. The coupon can be used up to 12 times prior to the expiration date. Restrictions and Terms and Conditions apply. [Learn more.](#)

## PUBLIC POLICY

### Merck actively engages with stakeholders involved in HIV/AIDS outreach and public policy through a number of mechanisms.

In the United States, Merck has established ethnically diverse HIV Community Advisory Boards that include HIV community leaders from across the nation. Merck meets 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

### 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.

In this section, we outline some of the many programs and partnerships Merck supports around the world to help address the challenge of HIV.

## Africa

### African Comprehensive HIV/AIDS Partnerships (ACHAP)

In 2000, the Merck Foundation/Merck and the Bill & Melinda Gates Foundation established the African Comprehensive HIV/AIDS Partnerships (ACHAP) to support Botswana, a country disproportionately affected by HIV/AIDS. The partners selected Botswana because of its HIV/AIDS disease burden—Botswana has 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. [Learn more](#) about ACHAP.

### Keeping HIV-Positive Mothers and Their Babies Healthy: mothers2mothers

Since 2008 Merck has supported mothers2mothers (m2m) to facilitate HIV-prevention programs for mothers at prenatal clinics in rural Lesotho. The program aims to reduce the number of babies born with HIV through the prevention of mother-to-child transmission (PMTCT). M2m also develops and implements HIV-skills training for women in HIV management, in order to better serve the community.

Since m2m initiated its program in Lesotho, the organization has opened 75 sites, hired 24 site coordinators, and trained 91 “Mentor Mothers.” In 2012 alone, m2m enrolled 11,148 new women who had 119,754 one-on-one interactions and fostered a total of 144,594 client interactions.

### **Integrating Clinic and Outreach Health Education Programming Among Pediatric HIV Patients in Mombasa, Kenya**

In 2012, Merck provided support to Project Sunshine’s initiative at Bomu Hospital in Mombasa, Kenya to address issues of access to medical care, stigma associated with HIV/AIDS and social support. Working in conjunction with Bomu Hospital, Project Sunshine Kenya provides locally-driven, sustainable programming for children and families living with HIV/AIDS and is the site for the piloting of innovative programs to foster adherence and to expand health education.

### **Community Engagement: An integral scale-up strategy towards zero HIV infections among children in Nairobi’s Mukuru slums, Kenya.**

In 2012, Merck provided support to Concern Worldwide for its initiative to enhance Prevention of Mother-to-Child Transmission (PMTCT) and mother-to-child protection services, serving 1,500 children affected by HIV and AIDS and new babies born to approximately 1,200 HIV+ pregnant women in 14 communities of Nairobi’s Mukuru slums. The Mukuru slums are disproportionately impacted by HIV with estimated prevalence of over

10-15 percent prevalence, compared to Nairobi’s prevalence of 7.8 percent, or the national average of 6.1 percent. Through community-based programs, Concern Worldwide’s program seeks to increase the number of women seeking PMTCT services and strengthen referral linkages for PMTCT and pediatric HIV treatment services, increasing the number of children identified as HIV-positive who enter treatment.

### **Eastern Europe/Middle East**

#### **Promoting Prevention and Raising Awareness in the Russian Federation**

Merck has supported the Social Partnership Development Fund (SPDF) in the Russian Federation to expand HIV prevention and community outreach projects. The strategic aim of this fund is to raise awareness of HIV treatment among people living with HIV/AIDS, medical specialists, service providers and healthcare officials. The SPDF has provided web-based updates on HIV treatment and care guidelines, has expanded HIV information on drug registration/availability, and has developed and disseminated materials on HIV treatment in.

### **Asia Pacific**

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

The China-MSD HIV/AIDS Partnership (C-MAP), a collaboration between Merck and China’s Ministry of Health, works toward the comprehensive prevention and treatment of HIV/AIDS in Sichuan Province, China. Established in 2005 with an initial seven-year, US \$30 million commitment from the Merck Foundation,

the program is the most extensive HIV/AIDS prevention and treatment initiative to be conducted to date through collaboration between the Chinese government and a foreign company in China. First introduced in three counties in Liangshan Prefecture, Sichuan Province, C-MAP has been extended to another 20 regions and prefectures in Sichuan, reaching a total of 62 project sites. In the areas served by the partnership in China’s Sichuan Province, the number of AIDS patients on treatment increased from 0 to more than 3,500 in just four years. [Learn more](#) about C-MAP and the progress being made through this collaborative effort.

### **United States**

Merck is committed to reducing healthcare disparities and improving access to HIV treatment and care in the United States. As part of this commitment, Merck engages in collaborations to reduce the impact of HIV on those most in need and most at risk. Merck works with leading AIDS service organizations (ASOs) to develop solutions that strengthen access to treatment, care and support for disproportionately affected communities.

#### **HIV Care Collaborative**

In the U.S. alone, there are still approximately 50,000 new HIV infections each year, and nearly a third or more people living with HIV are not in care. In 2012, the Merck Foundation launched a three-year initiative—HIV Care Collaborative for Underserved Populations in the United States—designed to help link more people

living with HIV to the care they need. The Foundation committed \$3 million to support the efforts of local health departments in Atlanta, Georgia; Houston, Texas; and Philadelphia, Pennsylvania. These cities are among the top 10 with the highest HIV burden in the United States. [Learn more](#)

### **The Black Treatment Advocates Network (BTAN)**

Black Americans face a severe burden of HIV in the U.S., accounting for almost half (46 percent) of all people living with HIV. Among individuals living with HIV/AIDS in the U.S., Black Americans are less likely to receive HIV treatment and often are the least likely to remain in care.

To address the critical disparity in HIV-treatment outcomes and strengthen the link to care, in 2010 Merck established collaboration with the Black AIDS Institute (BAI) to launch the Black Treatment Advocates Network (BTAN). BTAN trains, mobilizes and equips teams of treatment advocates to link HIV-positive Black Americans with care, raise science and treatment literacy, and strengthen local and national leadership. The initiative has trained 150+ high-potential advocates and supported access and linkage efforts in high-prevalence communities. BTAN has served more than 70,000 people living with HIV/AIDS and is active in nine high-burden U.S. regions. Through this initiative, Merck and the BAI work together to address disparities in HIV care in Black communities across the United States.

### **“Everyone Has a Story”**

In the United States, women account for more than one-quarter of all new HIV/AIDS diagnoses. Among Black Americans, one in 30 women will receive a positive HIV diagnosis at some point in her lifetime.

To address the disproportionate impact of HIV on Black American women, in 2009 Merck began collaborating with SisterLove, Inc., an Atlanta-based HIV/AIDS service organization, to develop a mini documentary that addresses the unique challenges HIV-positive women of color face. The result was “Everyone Has a Story” (EHAS)—an educational capacity- and skills-building initiative for healthcare professionals (HCPs) and HIV-positive women. EHAS uses video-based storytelling to empower individuals to address stigma, navigate disclosure, build strong relationships with providers and live healthier lives. It also improves cultural competency among HCPs.

### **“You Are Not Alone”**

With Merck’s support, Gay Men’s Health Crisis (GMHC), an internationally recognized Aids Service Organization (ASO), developed a social marketing campaign—“You Are Not Alone”—to raise awareness about the importance of medical care, treatment and adherence. The campaign targets the most affected groups in the U.S., including young men of color who have sex with men, women of color and Latinos. It provides critical information to help HIV-positive individuals access to treatment, health information and healthcare services.

### **Sharing Stories, Creating Hope (Compartiendo Historias, Construyendo Esperanza)**

Hispanics/Latinos make up 16 percent of the total U.S. population yet account for 20 percent of all new HIV cases. Hispanics/Latinos also experience disproportionately high rates of delayed testing, diagnosis and entry into care.

To address these disparities, in 2011 the Latino Commission on AIDS and Merck came together to develop Sharing Stories, Creating Hope, a groundbreaking multimedia educational initiative. The bilingual initiative, launched in 2012, supports capacity-building efforts across the U.S. to enhance interactions between Latinos/Hispanics living with HIV and their healthcare providers, and to support access and adherence.

### **The Quilt in the Capitol and the “Call My Name” National Tour**

In 2012, Merck began collaborating with the NAMES Project to bring the AIDS Memorial Quilt to the International AIDS Conference in Washington, D.C., and to support a four-month “Call My Name” national tour. The “Call My Name” tour uses quilting workshops to raise awareness of HIV in disproportionately impacted communities and to commemorate lives lost to the epidemic. Merck’s support of Call My Name and the Quilt in the Capitol effort are part of its long-standing commitment to reduce health disparities in HIV treatment and care.

## HIV RESEARCH

**Merck has had an intensive, broad-based HIV clinical research program 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.

### Timeline of Merck's HIV Research Efforts

- In 1989 Merck scientists established the role of protease in the HIV life cycle, were the first to publish the crystal structure of HIV protease shortly thereafter, and were among the first to discover and develop medicines for the treatment of HIV
- In 1996 Merck introduced CRIXIVAN® (indinavir), a protease inhibitor. Merck also developed efavirenz, a non-nucleoside reverse transcriptase inhibitor
- Beginning in 1999, Merck sought registration for efavirenz as STOCRIN® in many countries around the world
- Merck's work in the early phase of HIV research played an important role in collaboration with others in defining the principles for combination antiretroviral (ARV) treatment to suppress the virus to undetectable levels

- In 2006, a partnership between Merck, Bristol-Myers Squibb and Gilead to develop a once-daily, single-tablet regimen HIV treatment resulted in the approval in the U.S. of ATRIPLA® (tenofovir, emtricitabine, efavirenz). ATRIPLA is marketed by Bristol-Myers Squibb and Gilead in the United States, Canada and Europe. Merck is working to register and distribute ATRIPLA in many developing countries around the world.
- In 2007, Merck's efforts to address the growing problem of multidrug resistance led to the approval in the U.S. of ISENTRESS® (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. ISENTRESS offers patients a different way to target the HIV virus as part of a treatment regimen.
- Merck continues to focus on comprehensive research and development that targets HIV, recognizing the need for new methods to address the epidemic. Merck's current R&D work in HIV includes

basic research on HIV neutralizing antibodies, programs to develop novel HIV-prevention technologies, new HIV antiretroviral medicines and new drugs targeting HIV latency.

### Preventing HIV through Microbicides

To help find new ways to prevent and treat HIV/AIDS, in 2008 Merck granted the International Partnership for Microbicides (IPM) a non-royalty-bearing, nonexclusive license to develop, manufacture and distribute a novel ARV compound (L'644) for use as a vaginal microbicide to help protect women in developing countries. The compound, the fourth we have licensed to IPM, is a member of a class of ARV molecules known as fusion inhibitors, which inhibit HIV infection by preventing the virus from fusing with the surface of target cells—an early step in the HIV infection process—potentially representing a novel way to block infection. Merck is also collaborating with IPM to advance early-stage product development research efforts. This recent agreement follows a similar IPM-Merck agreement announced in 2005.

### STAKEHOLDER ENGAGEMENT TO ADVANCE MERCK'S R&D EFFORTS

*"Merck deserves recognition for its exemplary commitment to HIV-prevention research. This arrangement helps IPM pursue development of compounds that target HIV at many points in the virus life cycle. We're working toward the day when millions of women around the world will have access to safe and effective microbicides—and partnerships like this will help us get there."*

**Dr. Zeda Rosenberg**  
CEO of IPM

Merck regularly communicates, interacts and collaborates openly with scientific leaders in the HIV/AIDS field to advance science. In the United States, for more than a decade, Merck has had an established physician advisory board that includes international and national scientific leaders. This advisory board meets with Merck regularly to discuss and advise Merck on HIV research and development strategy, emerging scientific issues and clinical program design. At the international level, Merck has also established a similar advisory board with international scientific and clinical leaders worldwide to gain input on emerging challenges in HIV care in developing countries.

### New Research Efforts to Eradicate HIV

In July 2011, Merck announced that several company researchers will participate in two new collaborative efforts led by the prominent academic institutions of the University of North Carolina (UNC) Chapel Hill and the University of California San Francisco (UCSF) to develop new approaches towards eradicating HIV, the virus that causes AIDS. UNC, researchers from nine additional U.S. universities and Merck scientists are studying HIV latency and identifying ways to purge persistent infection of the virus from the body. Separately, researchers at UCSF are working with an international team of academic, government and Merck 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. Merck does not receive any funding for participation in either effort.

*“Collaboration has been the hallmark of much of the progress made against HIV since the virus was first identified 30 years ago. Continued collaboration is absolutely essential to better understand HIV reservoirs and identify potential approaches to the daunting challenge of eradicating HIV. Merck is honored and excited to participate in these important new undertakings.”*

**Daria Hazuda, PhD**  
 Vice President, Merck  
 Research Laboratories

## PEDIATRIC TREATMENTS FOR HIV

**As part of the company's commitment to fight HIV/AIDS, Merck has conducted extensive research and development efforts to bring forth pediatric formulations for its ARVs.**

Our commitment extends to ongoing collaborations to help improve access to ARV treatment for children living with HIV in resource-limited settings.

### Extensive R&D Efforts for Pediatric Formulations for Merck ARVs

In 2007, Merck began collaborating with NIAID, the National Institute of Child Health and Human Development (NICHD), and the International Maternal, Pediatric, Adolescent AIDS Clinical Trials (IMPAACT) Group, 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. The trial involves HIV-infected children ranging from 4 weeks to 18 years of age in the United States, Latin America and Africa.

This is a study of three formulations: the adult tablet, a chewable tablet and an investigational granule formulation for oral suspension. The study is designed to collect intensive pharmacokinetics and short-term safety data in order to make a dose selection, and also provide data on safety and efficacy at the selected dose with chronic use over 48 weeks. There is a protocol extension to five years. The study was initiated in older children and has sequentially enrolled younger patients.

On the basis of results from this ongoing study (IMPAACT P1066), in December 2011 Merck gained FDA approval of ISENTRESS for use in children 2 to 18 years of age. The chewable formulation is approved for children ages 2 to 11 years and weighing at least 10 kg (with dosage based on weight), and the film-coated tablet (at 400 mg po BID) is approved for children ages 6 to 18 years and weighing at least 25 kg). Through this study, a



second pediatric formulation (granules for suspension) in children less than 2 years of age is being evaluated.

Also in collaboration with IMPAACT, one study in neonates, IMPAACT P1097, examining raltegravir levels in infants born to mothers who have taken raltegravir in pregnancy (these infants were not given raltegravir directly), has completed enrollment. Another study, IMPAACT P1110, of active raltegravir dosing to neonates, is about to open; this study aims to define the safety and appropriate dose of raltegravir for neonates at risk for acquiring HIV infection. Merck is dedicated to continuing the work necessary to obtain regulatory approval for the granules for suspension pediatric formulation of ISENTRESS.

**STOCRIN® (efavirenz)** is indicated for the treatment of HIV-1 infection and has pediatric indications for patients ages 3 to 17 years in many countries, particularly in the developing world. For many of the countries, for which Merck has the right to distribute STOCRIN under our agreement with Bristol-Myers Squibb, we are currently marketing four formulations: STOCRIN oral solution, STOCRIN 50 mg, STOCRIN 200 mg and STOCRIN 600 mg tablets.

**CRIXIVAN® (indinavir)** is indicated for the treatment of HIV-1 infection and has pediatric indications in some countries. CRIXIVAN has not been evaluated in children under 3 years of age.

**Working to Improve Access in Resource-Limited Settings**

Merck is also working in partnership with the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) Partnership for Pediatric AIDS Treatment to identify scientific and technical solutions to improve access to ARV treatment for children living with HIV in resource-limited settings. Participating in this effort are the U.S. government, multilateral organizations such as the United Nations Children’s Fund (UNICEF) and the United Nations Joint Programme on HIV/AIDS (UNAIDS), research-based pharmaceutical companies and generic-drug companies. The partners have committed to work toward identifying scientific obstacles to treatment, share best practices and take concrete, practical steps to address barriers to access.

**HIV VACCINES**

**Merck began research into an HIV vaccine shortly after the virus was identified in the mid-1980s and has been actively involved in HIV vaccine R&D since that time.**

Merck’s research effort has targeted both antibody-based and cellular-immune-based vaccine approaches to preventing HIV infection. In 2005, Merck and its partners began a large trial to test the efficacy of a Merck developmental cellular-immune-based vaccine. The study, known as the STEP trial, was cosponsored with the National Institutes of Health (NIH) and the HIV Vaccine Trials Network (HVTN) and

designed to evaluate whether the vaccine prevented HIV infection; and whether the vaccine 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.

In September 2007, Merck announced that its vaccination in a Phase II clinical trial of the company’s investigational HIV vaccine (V520) was being discontinued because the vaccine was not effective.

Merck continues to work with the research community to understand the study results of the STEP trial and its implications for the field of AIDS-vaccine R&D. Merck scientists continue to research antibody-based approaches and have been studying novel immunogen designs based on essential and conserved regions of the HIV envelope glycoprotein. Merck has recently established collaborative research projects with academic investigators to advance promising antibody-based approaches for an HIV-1 vaccine.

**ANTIRETROVIRAL REGISTRATION**

**Merck is committed to pursuing rapid registration of our antiretrovirals (ARVs), including in those countries most affected by HIV/AIDS.**

Currently, Merck ARVs are registered or available through import waiver in many countries. Since the first approval

in 2007, ISENTRESS® (raltegravir) has received regulatory approval in more than 90 countries for use in treatment-experienced adult patients infected with HIV-1, and in 47 countries for use in treatment-naïve adult patients infected with HIV-1. Merck is in the process of filing ISENTRESS in additional countries around the world.

Details of registration and availability of our four ARVs are available through the links below:

- **ATRIPLA**® (tenofovir, emtricitabine, efavirenz)
- **CRIXIVAN**® (indinavir sulfate)
- **ISENTRESS**® (raltegravir)
- **STOCRIN**® (efavirenz)

**World Health Organization (WHO) Prequalification**

STOCRIN, CRIXIVAN and ATRIPLA have received World Health Organization (WHO) prequalification. Merck is committed to working with the WHO for the prequalification of ISENTRESS. WHO prequalification verifies that medicines meet the quality, safety and efficacy requirements of UN agencies, including UNICEF and the Pan American Health Organization—an important step toward providing global access.

**HIV SUPPLY CHAIN**

**Merck continually looks for ways to reduce the cost of its antiretrovirals (ARVs) for people living in the world’s poorest countries and those hardest hit by the epidemic.**

One way is to work with external manufacturers and suppliers to achieve incremental efficiencies. For ISENTRESS® (raltegravir), Merck has established a low-cost supply chain with generic partners for commercialization in all Low-Income countries and all countries in sub-Saharan Africa. This supply chain is being registered in these countries. 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) price in these countries. We are committed to reviewing this price regularly.

Merck has granted two non-exclusive licenses to two Indian generic manufacturers, Emcure Pharmaceuticals Ltd. and Matrix Laboratories Ltd., for the manufacture and commercialization of raltegravir in 60 Low-Income and sub-Saharan African countries. We have also granted royalty-free licenses for efavirenz to six South African generic manufacturers.

Manufacturers to whom Merck has granted a royalty-free voluntary license for efavirenz include:

- Emcure Pharmaceuticals S. Africa and Arrow Pharma S. Africa—joint license granted in 2011

- Sonke Pharmaceuticals—license granted in 2009
- Aspen Pharmacare—license granted in 2008
- Aurobindo Pharma—license granted in 2008
- Cipla Medpro—license granted in 2008
- Adcock Ingram Healthcare—license granted in 2007

**Patent Pool for HIV Medicines**

Merck, in principle, supports the objectives of the Medicines Patent Pool Foundation for expanding access to HIV medicines in the developing world. Merck has demonstrated its commitment to improved access to HIV medicines through long-standing efforts over many years, including differential pricing, voluntary licensing, public-private partnerships, philanthropic programs and continued research and development efforts in HIV.

Given the current low demand for raltegravir, its position in treatment guidelines in the developing world, the need for ongoing clinical research to better define how it is best used in the developing world, the need for medical education and adequate monitoring tools, such as routine viral load monitoring, to ensure its appropriate use, Merck does not think that the Medicines Patent Pool presents the most appropriate tool to increase access to raltegravir in the developing world at this point in time.

While we continue to monitor and assess the Medicines Patent Pool

proposal, Merck’s immediate focus is on implementing our access strategy for ISENTRESS in Low-Income countries and sub-Saharan Africa as part of our ongoing efforts to further enhance global access to our HIV medicines.

Merck remains willing to meet with the Medicines Patent Pool Foundation to continue to discuss developments with the patent pool.

**Compulsory Licensing**

Merck understands that access to medicines is a particularly complex issue in many developing countries and respects 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 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. Merck will work vigorously with governments and other stakeholders in the developing world to meet the health needs of patients and increase access to its medicines.

For more information on Merck’s public policy position on compulsory licensing, [click here](#).

**HIV PRICING POLICIES**

**Merck’s differential-pricing policy is part of its commitment to addressing HIV, with the goal of ensuring that its 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 it also helps us sustain our investment in clinical and medical education programs in developing-world 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® (raltegravir), STOCRIN® (efavirenz), CRIXIVAN® (indinavir)**

Merck offers its lowest Access price for its 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, 2011, the Access prices for Merck’s HIV medicines for eligible customers<sup>1</sup> are:

HIV Pricing		
Drug Name	Daily Dose	Pricing US\$ ppy (unit)
STOCRIN® (efavirenz)		
50mg tablet	4 (200 mg)	169 (0.12)
200mg tablet	3	394 (0.36)
600mg tablet	1	237 (0.65)
30mg/ml suspension (bottle)		
	9 ml	310 (0.094)
	12 ml	413 (0.094)
CRIXIVAN® (indinavir)		
400mg cap	4	394 (0.27)
ISENTRESS® (raltegravir)		
400mg tab	2	675 (0.925)

Countries classified as Low-Middle Income and Upper-Middle Income<sup>2</sup> by the World Bank are eligible for prices that are discounted from those in developed, high-income countries. These prices will vary based on, among other things, a combination of treatment guideline positioning, patient access, market conditions, country income and disease burden, and will be negotiated with each government.

For high-income countries, Merck will make ISENTRESS® (raltegravir) available at competitive prices that take into account the innovation and value that ISENTRESS represents.

## **ATRIPLA® (tenofovir, emtricitabine, efavirenz)**

Merck sells ATRIPLA at US \$1.68 per day, or US \$613 per year, in 98 Access countries, as defined by our agreement with Gilead.

## **Antiretroviral (ARV) Pricing**

Merck is committed to reviewing the prices of our ARVs based on efficiencies in manufacturing and supply, and/or reductions in the costs of active ingredients.

Since 2000, Merck has lowered the Access price of STOCRIN by more than 95 percent from an introductory price of US \$10/day in 1998, to US \$0.65/day. Since 1996, Merck has lowered the Access price of CRIXIVAN by 84 percent, from an introductory price of US \$12/day to US \$1.64/day.

<sup>1</sup> 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 bi-lateral donors (e.g., the Global Fund, PEPFAR or 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. Merck offers 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.

<sup>2</sup> 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 bi-lateral donors (e.g., the Global Fund, PEPFAR or 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.

# VACCINES

**Vaccines are one of the greatest public health success stories of the last two centuries.**

## OUR COMMITMENTS

- Engaging in innovative Research and Development (R&D) to provide vaccines that address vital global health needs
- Reducing the gap between vaccine availability in developed countries and the introduction of vaccines in the developing world through the timely registration and introduction of our vaccines
- Developing creative solutions and participating in partnerships that will help increase access to our vaccines, especially in resource-constrained markets. We also are focused on improving our products, increasing our manufacturing capacity, lowering our prices and addressing overall implementation challenges

Vaccines have resulted in the global eradication of smallpox and the elimination of polio from the Western Hemisphere and much of Asia. In addition, vaccines for diseases like measles, pertussis and diphtheria have dramatically reduced childhood mortality worldwide. However, because

of gaps in areas such as the healthcare infrastructure and available workforce in low and some middle income countries, preventive measures such as immunization programs can be difficult to deliver, yet they are particularly critical to the health and economies of these countries. Merck is committed to

working with partners to help prevent disease and save lives through a comprehensive approach of developing new and innovative vaccines, working to make them available and affordable to those who need them globally, and establishing programs to help address implementation challenges.



*A young girl is immunized during the September 2012 phased launch of a national vaccination program with GARDASIL in the Republic of Uganda.*

In September 2012, a new partnership was launched that will help address vaccine access challenges in sub-Saharan Africa. The Republic of Uganda, through the Ministry of Health (MoH) and supported by Merck, initiated a national vaccination program with GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant]. Cervical cancer is the most frequent cancer diagnosed among women in Uganda,<sup>1</sup> and incidence rates of the disease in the country are about three times the global average.<sup>2</sup> Through this agreement with Merck, the vaccination program is being implemented with 460,000 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 represents the first phase of Uganda's national roll-out plan for human papillomavirus (HPV) vaccination. Uganda is anticipated to scale up to a full national HPV vaccination program with support from the Global Alliance for Vaccines and Immunization (GAVI) alliance in 2014.

<sup>1</sup>WHO 2010 Summary Report p4A

<sup>2</sup>WHO 2010 Summary Report p6A

For additional details on Merck's partnerships and programs to expand access to GARDASIL and ROTATEQ® (Rotavirus Vaccine, Live, Oral, Pentavalent), see the **Cervical Cancer** and **Rotavirus** sections of this report.

In May 2013, Merck Vaccines President, Dr. Julie Gerberding, and Merck Vaccines Chief Public Health Officer, Dr. Mark Feinberg, joined scientists from around the world to sign a scientific declaration on polio eradication. The Eradication and Endgame Strategic Plan, by the Global Polio Eradication Initiative is a new strategy to reach and sustain eradication of polio by 2018. The plan was developed in consultation with a range of technical experts, governments, funding partners, and stakeholders, and received unanimous support from the World Health Organization Executive Board in January. More than 400 scientists, doctors, and technical experts from 75 countries have endorsed the declaration, and more than 25 universities and schools of public health have publicly shown their support for the declaration and all it represents.

Merck 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 World Health Organization (WHO), the GAVI Alliance Board and UNICEF. Additionally, Merck engages stakeholders from regional organizations, such as the Pan American Health Organization (PAHO), and from national organizations, contributing to the development and implementation of regional and national vaccination programs.

Through active engagement of the GAVI Alliance, Merck helped to foster an environment that led to mobilization of funding and partner technical support for new vaccines introduction in the world's poorest countries. This engagement included the sharing of best practices that had been gleaned from several of our vaccine access initiatives in GAVI-eligible countries. Focusing on the anticipated need for our HPV and rotavirus vaccines, GARDASIL and ROTATEQ, 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 what were 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. In 2013, Merck was awarded a significant portion of the first UNICEF HPV vaccines tender for GAVI countries. GAVI is expected to support the introduction of HPV vaccines in 28 countries by the end of 2017. Also, in addition to a 2012 GAVI/UNICEF award

to supply ROTATEQ to Rwanda, in 2013 Merck received a second award to supply ROTATEQ to an additional three African countries. Merck's 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.

## VACCINE RESEARCH & DEVELOPMENT

**Merck conducts innovative research and development to provide vaccines that address vital unmet and emerging global health needs.**

For more than 100 years, Merck scientists have been discovering vaccines that have been impacting lives. Vaccines discovered and developed by Merck have made unique contributions to public health, including helping to prevent diseases like measles, mumps, shingles and cervical cancer. Merck remains 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. Merck supports the Millennium Development Goal of reducing childhood mortality (MDG 4) through our efforts to address two main causes of death from preventable or treatable disease in children under five in the developing world: diarrheal and pneumococcal diseases.<sup>1</sup> In addition, some of the vaccines being researched by Merck scientists target diseases that

are particularly prevalent in the developing world. This includes research programs and collaborations for diseases such as HIV, malaria and dengue.

Merck looks to establish new business models and partnerships for research and development. A case in point is the **MSD-Wellcome Trust Hilleman Laboratories**. Established in 2009, it is the first-of-its-kind research and development joint venture with a not-for-profit mission to focus on developing affordable vaccines to prevent diseases that commonly affect low-income countries. In 2011, Hilleman Laboratories announced that its first project would be a feasibility study of how new thermostabilizing technologies might be used to develop a rotavirus vaccine designed specifically with the needs of developing countries in mind. In 2012, the laboratories, now fully staffed and operational in New Delhi, India, worked with collaborators to advance R&D on this important project. In addition, Hilleman Laboratories continued to engage the external global health community through various forums, including ongoing dialogue 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

## AVAILABILITY & AFFORDABILITY

**Merck is committed to registering our vaccines worldwide in a timely manner, developing creative solutions, and participating in partnerships that will help increase access, especially in resource-constrained markets.**

We also are focused on improving our products, increasing our manufacturing capacity, lowering our prices and addressing overall implementation challenges.

### Registration & Prequalification

Merck seeks to reduce the gap between vaccine availability in developed countries and the introduction of vaccines in low and middle income countries through the timely registration and introduction of our vaccines.

GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18)] is currently registered in more than 125 countries, and ROTATEQ® (rotavirus vaccine, live, oral, pentavalent) is registered in more than 100 countries. In addition to registration, World Health Organization (WHO) prequalification is an important step in Merck's access efforts, signifying that vaccines meet the quality, safety and efficacy requirements of UN agencies, including those of UNICEF and the Pan American Health Organization (PAHO). Merck received WHO prequalification for ROTATEQ in October

2008, MMR®II (Measles, Mumps and Rubella Virus Vaccine Live) in December 2008 and GARDASIL in May 2009.

### Pricing

In the developing world, Merck offers ROTATEQ and GARDASIL 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 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 more developed, middle-income countries, Merck provides our vaccines at differential prices in relation to a country's ability to pay.

In April 2012, GAVI announced that eligible countries would be able to apply for funding to allow for broader access to HPV vaccines. Merck supports continued efforts to increase access to HPV vaccines, and continues to work with the GAVI Alliance and other partners to evaluate what can be done to increase long-term sustainable access in GAVI-eligible countries.

In addition, we continue to look for novel ways to further reduce the price of our vaccines in developing countries. An important approach is to pursue manufacturing efficiencies and explore

potential partnerships with low-cost manufacturers to bring down the cost of vaccines. Merck has 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. Merck is also working with the Serum Institute of India Limited, an Indian company, to develop and commercialize a pneumococcal conjugate vaccine (PCV) for use in emerging and developing countries.

### Partnerships to Address Implementation Challenges

Merck continues to pursue a systematic approach to overcoming access barriers, and has pursued a number of public-private partnerships to study the public health impact of our vaccination programs and to facilitate the introduction of vaccines in resource-poor settings. The faster we improve access to vaccines like these, the more lives we can impact. For more details on the initiatives, please see the **Rotavirus** and **Cervical Cancer** sections.

## ROTAVIRUS

**Merck is pursuing multiple approaches to increase global access to ROTATEQ® (rotavirus vaccine, live, oral, pentavalent).**

Rotavirus gastroenteritis is a leading cause of severe diarrhea in infants and young children worldwide.<sup>1</sup> In 2008, an estimated 453,000 rotavirus gastroenteritis associated child deaths occurred worldwide.<sup>2</sup> Since 2009, the WHO's Strategic Advisory Group of Experts (SAGE) has recommended the inclusion of rotavirus vaccination in all national immunization programs, helping ensure access to rotavirus vaccines in the world's poorest countries.<sup>3</sup> Merck believes that we have an important role in contributing towards this goal.

Since its launch in 2006, ROTATEQ has been registered and approved in more than 100 countries. In the same year in which it was registered and launched in the U.S., ROTATEQ was also launched in Nicaragua through a joint program that was established between Merck and the Nicaraguan Health Ministry—marking the first time there was access to a vaccine in the public sector of a developing country in the same year that it was first licensed in a developed country. This program, which was completed in 2009 and transitioned to GAVI funding in 2010, achieved an estimated 94 percent vaccine coverage (percent receiving third dose of ROTATEQ) among Nicaraguan infants.

The successful public-private partnership (PPP) was recognized as a model for the rapid adoption of a vaccine in a developing world setting and is described in a **case study**. **Learn more**<sup>4</sup> about the joint program in Nicaragua.

<sup>1</sup> Lancet Infect. Dis. 2012\_Tate p1A

<sup>2</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>3</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>4</sup> Khawaja and et. al, Evaluating the health impact of a public private partnership to reduce rotavirus disease in Nicaragua, Human Vaccines and Immunotherapeutics, p. 777.





*The first dose of RotaTeq administered to an infant in Rwanda by the Permanent Secretary.*

In 2012, Rwanda became the first African country to introduce ROTATEQ through a national immunization program. In Rwanda, diarrheal infections rank third among causes of death in children less than 5 years of age, representing a critically important public health issue. Merck is pleased to be working in partnership to make ROTATEQ available in Rwanda and other GAVI-eligible countries.

In addition, Merck continues to evaluate and implement approaches that will improve product attributes to better meet the specific needs of low and middle-income countries in the future.

## CERVICAL CANCER

**Merck has a long-standing commitment to help improve access to GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] in developing countries, where more than 85 percent of the world's cervical cancer cases occur.<sup>1</sup>**

Merck is committed to supporting public health initiatives that increase access to vaccines where they are most needed. We have engaged in a number of multi-disciplinary partnerships that help resource-poor countries gain access to human papillomavirus (HPV) vaccination.

### Public-Private Partnerships

In September 2012, the Republic of Uganda, through the Ministry of Health (MoH) and supported by Merck, announced the launch of a national vaccination program with GARDASIL. Cervical cancer is the most frequent cancer diagnosed among women in Uganda,<sup>2</sup> and incidence rates of the disease in the country are about three times the global average.<sup>3</sup> An estimated 3,500 women in Uganda are diagnosed with cervical cancer each year.<sup>4</sup> Through this agreement with Merck, the vaccination program is being implemented with 460,000 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 represents the first phase of Uganda's national roll-out plan for human papillomavirus (HPV) vaccination.

In 2010, Merck 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 between the ages of 12 and 18 to be vaccinated with GARDASIL, and achieved an approximately 90 percent vaccination rate for all three doses, according to the Bhutan Ministry of Health. In subsequent years, the program continues 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 implement national cervical cancer vaccination programs.

### Partnerships for Cervical Cancer Prevention and Treatment

Merck is also working to create novel partnerships that take a comprehensive approach to cervical cancer prevention and treatment.

For instance, in September 2011, Merck announced its plans to contribute \$3 million over three years to Pink Ribbon-Red Ribbon™, to address both cervical and breast cancer in sub-Saharan African nations. Pink Ribbon-Red Ribbon 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 three-year commitment, Merck will work with Susan G. Komen for the Cure to support the initiative to raise awareness about the burden of breast and cervical cancer, mobilize additional partners and work towards increased access to cervical cancer screening, treatment for women and HPV vaccination of appropriate girls in sub-Saharan Africa.

In July 2012, Merck announced, through its partnership with Susan G. Komen for the Cure, that it will support the African Center of Excellence for Women's Cancer Control. Activities supported, in coordination with local NGOs, the Zambian government, the US government and PRRR partners, include the scale up of breast and cervical cancer education to increase knowledge and awareness and reduce stigma throughout Zambia. Merck will also support the Zambian Ministry of Health's plans to conduct an HPV vaccine demonstration project across the province of Lusaka by donating 180,000 doses of GARDASIL to vaccinate 25,000 eligible girls over two years, and will provide technical support for the program.

In April 2011, Merck began providing GARDASIL to a first-of-its-kind cervical cancer program in Rwanda, including both HPV vaccination and HPV DNA testing. Merck has committed to provide over 1.4 million doses of GARDASIL over the three-year program. This program

was made possible by a collaboration established in 2009 between Merck 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, which Merck worked on closely with the Government of Rwanda, more than 96% of targeted girls were vaccinated with the full three doses of GARDASIL in 2011 and 2012.

### **Commitment to Support HPV Vaccine Introduction**

Beginning in 2006, Merck partnered with the international nonprofit organization, PATH, to provide GARDASIL for the conduct 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.<sup>5</sup>

Additionally, through the charitable GARDASIL Access Program, Merck has donated more than one 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 to gain operational experience 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. However, Merck's full donation commitment of at least three million doses of GARDASIL will be honored, and options for how remaining doses of GARDASIL could be used are currently being explored. Experiences and lessons learned from past and current Program participants will continue to be disseminated to the public health community by Axios Healthcare Development, a U.S. non-profit organization, which manages the GARDASIL Access Program. [Learn more](#) about the GARDASIL Access Program and this development.

<sup>1</sup> CDC Global Health

<sup>2</sup> WHO 2010 Summary Report

<sup>3</sup> WHO 2010 Summary Report

<sup>4</sup> WHO 2010 Summary Report

<sup>5</sup> LaMontagne et al, Bull World Health Org 2011.

# MERCK FOR MOTHERS

**Although maternal mortality has declined substantially over the past two decades, the world is off track to meet the UN Millennium Development Goal 5 (MDG5) to reduce the rate of maternal mortality by 75 percent by 2015.**

*Merck for Mothers* is our company’s 10-year, \$500 million initiative to address one of the world’s oldest and most preventable health tragedies—the death of a woman from complications during pregnancy and childbirth. We are working closely with governments, international organizations, health experts and those on the front lines to apply Merck’s business and scientific expertise to accelerate progress toward reducing maternal mortality.

*Merck for Mothers* is addressing the two leading causes of maternal mortality: postpartum hemorrhage (bleeding after childbirth) and preeclampsia (hypertensive disorders). We are also focusing on family planning, which is known to play an important role in reducing maternal mortality.

Since launching *Merck for Mothers* in 2011, we have pledged US\$105 million to initiate over 30 projects in more than 20 countries and collaborated with more than 75 implementing partners and advocacy organizations. Our work focuses on three key areas—product innovation, access to affordable care, and advocacy and awareness. More information on each of these areas is available in the tabs above.

## Engaging Merck Employees

Throughout the year, events at 18 Merck sites raised awareness about *Merck for Mothers* and provided information through internal channels, including our online newsletter and employee associations. The 2012 “May is for Mothers” employee events, which were designed to increase awareness and understanding about the program, were conducted by volunteer employee ambassadors in nearly two dozen Merck locations around the world. Across the participating sites, more than 2,300 employees heard about Merck’s commitment and how to volunteer their time and talent with maternal health organizations. Along with the event, employees around the world showed their support for *Merck for Mothers* by sending nearly 13,000 e-cards throughout the month of May.

## Evaluating the Program

*Merck for Mothers* has engaged a team of evaluators from The London School of Hygiene and Tropical Medicine, with expertise in measurement of maternal mortality, to conduct a robust evaluation of *Merck for Mothers* as well as provide ongoing support and guidance. We have identified a set of metrics that represents the priorities and objectives of the program. We will begin reporting next year on a subset of those metrics, as noted below. We will also continue to analyze the program and review and refine the metrics, as necessary.

In support of *Saving Mothers, Giving Life*, we have enlisted Columbia University to assess the progress of the program and identify the elements that are most effective in reducing maternal mortality. The evaluations are also designed to inform program adaptations as the initiatives move forward and advance the maternal health field. Results of the evaluations will be made public.

### Merck For Mothers

Merck for Mothers Performance Metrics	Report
Number of facilities upgraded or maintained to BeONC <sup>1</sup> /CEmONC <sup>2</sup> states or high-quality care facilities	2014
Number of women delivering in facilities providing high-quality care	2014
Number of providers/community health workers trained	2013
Maternal deaths averted	2016
Number of unplanned pregnancies averted	2015
Number of partnerships/initiatives/committees that MFM participates in and their impact in leveraging others	2013

<sup>1</sup> BeONC—Basic Emergency Obstetric and Newborn Care

<sup>2</sup> CEmONC—Comprehensive Emergency Obstetric and Newborn Care

**The Year Ahead**

In 2013, we plan to embark on programs in India, the country with the highest number of maternal deaths, and Zambia. *Merck for Mothers* will also begin efforts in Brazil and the U.S., two countries with pockets of high maternal mortality and morbidity. In the U.S., Merck will be supporting several projects to address gaps in data on maternal deaths, improve clinical practice in emergency obstetric care, and strengthen community-based efforts to link pregnant women with pre-existing conditions to care.

**2012 Commitments and Progress**

**PRODUCT INNOVATION**

Developing and improving user-friendly technologies to diagnose, prevent and treat postpartum hemorrhage and preeclampsia

**Merck’s Partnership with PATH—**

Researchers from Merck and PATH, a leading technology nonprofit organization, have rigorously evaluated 40 maternal health innovations and identified those with the greatest potential to save women’s lives in low-resource settings. As a result of the evaluation, the global health community has an in-depth, comparative assessment tool, available at <http://sites.path.org/mnhtech/assessment/>, to help inform decisions about where to invest its scarce resources in technologies to reduce maternal mortality.

**ACCESS TO AFFORDABLE CARE**

Improving the quality, accessibility and affordability of maternal health services, so more women can have healthy pregnancies and births

**Saving Mothers, Giving Life (SMGL)—**

Merck is a founding member of *Saving Mothers, Giving Life*, a five-year public-private partnership to reduce maternal mortality in sub-Saharan Africa. Other partners are the U.S. Government, the Government of Norway, the American College of Obstetricians and Gynecologists, Every Mother Counts (an advocacy organization) and Project C.U.R.E. (a nonprofit distributor of donated medical supplies and equipment). Early results show:

- The number of pregnant women delivering in healthcare facilities has increased by nearly 50 percent in the targeted districts in both Uganda and Zambia
- The percentage of pregnant women who had their fourth antenatal care visit has doubled in Ugandan target districts since SMGL’s launch, allowing enough time for women to get needed checks in line with WHO recommendations
- In Uganda, eight labor/delivery rooms, seven operating theatres and seven maternity blocks serving approximately 100,000 people are now fully functional
- All of the facilities in the targeted districts in Uganda which provide Caesarean sections are now able to provide safe blood for women who are hemorrhaging

- More than 300 new doctors, nurses, midwives and technical officers have been added to the health workforce in both Uganda and Zambia, providing both basic and comprehensive emergency obstetric as well as HIV care

**Partnering with the Bill & Melinda Gates Foundation on Family Planning—**

*Merck for Mothers* and the Bill & Melinda Gates Foundation have established a \$50 million partnership to increase access to family planning. The new collaboration will focus on three key areas:

- Increasing awareness of and education about family planning services among women and girls in resource-limited settings
- Improving the supply chain for quality family planning resources and services to advance maternal health
- Working with governments, the private sector, civil society and local health providers to increase support and access to family planning services

**Exploring Ways to Improve the Provision of Maternal Care—***Merck for Mothers*

is committed to helping governments reach their Millennium Development Goal (MDG) targets and focusing its efforts on understanding and strengthening the often neglected—but growing—role that private healthcare providers and businesses play in healthcare delivery in the developing world. *Merck for Mothers* programs in countries with a high burden of maternal mortality are aligned with this strategy and focus on improving access to affordable, high-quality care.

## Merck for Ugandan Mothers (MUM)

**Program**—We launched the Merck for Ugandan Mothers (MUM) Program, a partnership with Population Services International and its local affiliate, the Program for Accessible Health, Communication and Education, to explore how best to expand and improve the private delivery of maternal healthcare in up to 30 districts over three years. The MUM program is valued at \$9 million and complements the work of SMGL, which is designed to strengthen the public maternal health system. The program has accomplished the following:

- Conducted a small field-based acceptability study to inform the contents of Mama Kits, which are all-in-one kits that contain everything needed to help provide a clean and safe delivery
- Recruited 36 clinics in 7 districts to join the ProFam franchise network of private clinics offering quality maternal health services
- Adapted a 5-day training curriculum on labor and delivery care for private healthcare providers, and developed a supportive supervision system for ongoing quality assurance and training

## Merck for Mothers Global Giving

**Program**—During its first year, the *Merck for Mothers Global Giving Program* awarded \$9 million in grants to support 22 projects designed to improve maternal health in 18 countries around the world. The programs are funded by the *Merck for Mothers* initiative. Through the *Global Giving Program*, Merck's country offices support initiatives globally. Examples include:

- In partnership with the Zuellig Family Foundation in the Philippines, grants are supporting a three-year project

that provides community leadership training to more than 2,000 frontline practitioners, including midwives and barangay health workers, on a range of maternal health issues, from antenatal care to obstetric emergencies.

- Merck is partnering with the World Lung Foundation to roll-out new mHealth (mobile health) technologies to support health workers in managing obstetric emergencies in remote areas of Tanzania. The funding also helps improve information sharing from clinical audits and creates a distance-learning platform to boost access to expertise in other parts of the country.
- In Peru, grants are supporting Pathfinder International's three-year project to advance the Peruvian Ministry of Health's strategy to improve maternal and newborn health in the La Libertad region by updating and distributing obstetrics and neonatal emergency training manuals and by working with community leaders to inform the public about maternal health issues.

## ADVOCACY AND AWARENESS

**Advocacy**—Merck has represented the private sector in several global initiatives, including:

- U.N. Commodities Commission on Life-Saving Commodities for Women and Children: Merck Chairman and Chief Executive Officer, Ken Frazier, served as a commissioner on the U.N. Commodities Commission on Life-Saving Commodities for Women and Children, which is charged with developing a roadmap to increase access to essential medicines, medical devices, and other

reproductive, maternal and child health commodities in low resource settings. The Commission's report (released in September 2012) identified major barriers to access—such as weak supply chains and lack of affordable products—and recommended concrete steps to overcome them to save and improve the lives of women and children. Merck is continuing to collaborate with the Commission.

- Innovation Working Group (IWG): Merck served as a co-chair of the IWG's Task Force on Sustainable Business Models with the Norwegian Government. The task force led the research and development of *Fostering Healthy Businesses: Delivering Innovations in Maternal and Child Health*, a report published by the UN Secretary-General's Every Woman, Every Child initiative, which has informed *Merck for Mothers'* programming concerning the private provision of healthcare.

## Awareness

—*Merck for Mothers* launched a U.S. consumer awareness campaign. "Once Upon a Birth" was designed to celebrate the universal experience of telling "birth day" stories in a way that resonates with people as a means of educating them about maternal mortality and introducing them to *Merck for Mothers*. The 2012 campaign activities included extensive social and traditional media outreach, including a satellite media tour and a **Facebook page** where individuals can share a story and trigger a donation to *Join My Village*, an initiative that empowers women and girls in developing countries. In 2012, the Facebook content was viewed by more than 4.6 million people, received more than 9,400 likes, and 81 stories were shared.

## WOMEN'S HEALTH

**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.**

The fifth Millennium Development Goal, Improve Maternal Health, sets a target 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, the 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.

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 helps protect the health of women by reducing high-risk pregnancies and helps protect the health of children and mothers by allowing sufficient time between pregnancies. Research has shown that appropriately spacing pregnancies helps improve 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. At Merck, 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)

<sup>4</sup> Singh S., et al., Guttmacher Institute and United Nations Population Fund; 2009. [www.guttmacher.org/pubs/AddingItUp2009.pdf](http://www.guttmacher.org/pubs/AddingItUp2009.pdf)

<sup>5</sup> <http://www.everywomaneverychild.org/resources/un-commission-on-life-saving-commodities/about>

## PARTNERSHIPS

**Merck participates 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, Merck has partnered with organizations and supported projects that work to increase women's access to health services, to reduce maternal mortality, to increase awareness of reproductive/sexual health among adolescents and vulnerable populations, to prevent mother-to-child transmission of HIV/AIDS, and to promote women's empowerment and access to economic opportunities.

Improving access to information is essential to ensuring that girls and women can manage their health, reduce unintended pregnancies, and understand

and obtain essential health services. Merck supports various programs and partnerships that provide health education and increase awareness around the world.

### 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. Merck participates in various RHSC working groups, including the Market Development Approaches Working Group and the Resource Mobilization and Awareness Working Group. We also signed on to the RHSC's Hand to Hand campaign to reach the goal of 100 million new users of modern contraception by 2015.

**The C-Exchange**—The overall goal of the C-Exchange is to convene a group of corporate partners that will work together to bring women's health products and services to market and scale them up in developing countries. The C-Exchange will focus on technological solutions that, if accessible, will help improve the health of girls and women. Access to

four of the solutions—contraception, mobile communications, HPV testing and vaccination, and misoprostol—is available today, but scaling up can be complex and challenging. Merck is a member of the C-Exchange’s leadership group of 10 to 12 private-sector corporations committed to helping **Women Deliver**—a global advocacy organization working to improve the health and well-being of girls and women—shape, create and lead the C-Exchange.

**Family Planning 2020 (FP2020)**—Merck participates in the FP2020 Country Engagement Working Group, which is working to facilitate access to funding, technical assistance, and country-to-country support for transformational, country-owned family planning programs. FP2020 works with governments, civil society, multilateral organizations, donors, the private sector, and the research and development community to enable 120 million more women and girls 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 more information on how we partner with customers and other stakeholders, please visit our **[Access to Reproductive Health](#)** section.

## ACCESS TO REPRODUCTIVE HEALTH

**At Merck, 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 development organizations help support and implement programs that improve access and promote capacity-building by helping to train healthcare professionals and address other barriers to care.

### Research & Development

Merck has 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 2012, Merck researchers continued to develop new formulations of our existing women’s health products to better meet conditions in developing countries, including heat-stable formulations, and to develop innovative long-acting reversible contraceptive solutions relevant to the needs of women in low- and middle-income markets.

### Sustainable Business Model to Promote Access

Merck is committed to making its 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; and community investment.

**Merck supports the ambitious, but we believe achievable, goal set out by the global reproductive health community in 2012 of ensuring that voluntary life-saving family planning information, services and products reach an additional 120 million women and girls in the world’s poorest countries by 2020. We also support the UN Commission on Life-saving Commodities for Women and Children’s call to improve equitable access to 13 overlooked commodities, including contraceptive implants.**

In developing countries that have high rates of maternal mortality and low rates of contraceptive prevalence, our Institutional Family Planning Services division has created a sustainable business model to promote access to contraceptive health programs. These activities are focused primarily on sub-Saharan Africa and markets 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 and nongovernmental organizations and other customers.

In 2012, we dedicated resources to examining our supply chain to reduce inefficiencies, optimize yields and lower costs of production. We have passed these savings on to our customers in the form of lower prices, particularly in lower-income markets. We also invested in new technologies to increase the efficiency of our operations and to be able to produce more affordable product at the same high quality to meet increasing demand.

## 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 (registered/registration submitted as of December 2012)						
Product	Low income countries (36)	Low-middle income countries (54)	Upper-middle income countries (54)	High income countries (non OECD) (39)	High income countries (OECD) (31)	Total current registrations
IMPLANON® (etonogestrel implant)	17/4	18/4	17/3	8/0	0/0	60/11
IMPLANON NXT® (etonogestrel)	0/0	1/2	10/5	3/1	24/3	38/11
MULTILOAD® intra-uterine (contraceptive) device	2/1	4/0	16/1	6/0	28/0	56/2
NOMAC® (nomegestrol acetate)	0/0	1/6	9/8	4/0	26/3	40/17
NUVARING® (etonogestrel/ethinyl estradiol vaginal ring)	1/0	14/1	29/7	12/0	31/2	87/10
CERAZETTE® (esogestrel)	1/0	15/0	25/1	9/1	26/0	76/2
MARVELON 28® (ethinylloestradiol and desogestrel)	5/0	11/0	9/0	0/0	9/0	34/0
MARVELON 21® (ethinylloestradiol and desogestrel)	3/1	14/0	25/1	13/0	26/0	81/2
EXLUTON® (lynestrenol)	3/0	4/1	14/0	2/0	2/0	25/1
EXLUTON FP® (lynestrenol)	4/3	11/0	2/0	0/0	0/0	17/3

Note: For World Bank country classifications, please [click here](#).



**WHO Prequalification**

In order to facilitate institutional purchases of family planning products and provide quality assurance, Merck has secured WHO prequalification for EXLUTON® (lynestrenol), IMPLANON® (etonogestrel implant), IMPLANON NXT® (etonogestrel implant) and MARVELON® (desogestrel-ethinyl estradiol).

Prequalifications		
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 Merck that discover, develop and manufacture contraceptive products; national governments that seek to support family planning by increasing the use of contraception; international, bilateral and multilateral donors that finance the purchase of reproductive health commodities and invest in service delivery management and implementation; nongovernmental organizations 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, Merck takes the following steps to support family planning programs and to help increase awareness and access to a broad choice of contraceptive products.

**Requests for Quotation**

Merck 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., USAID, DfID, KfW) 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, Merck adheres 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 type 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.

In order to facilitate the purchase of our products for use in institutional family planning programs in low-income and lower-middle-income countries, we price our reproductive health commodities at their lowest access prices when selling them to qualified buyers.

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 and use of our products.

In July 2011, Merck and the Reproductive Health Supplies Coalition (RHSC) announced a partnership to enhance access and appropriate and effective use

of IMPLANON® (etonogestrel implant) for qualified buyers in developing countries. Under the initiative, IMPLANON is available at Merck's lowest access price to donor agencies and family planning members of RHSC in sub-Saharan Africa, and in all other Low Income countries as defined by the World Bank<sup>1</sup> and Lower Middle Income countries<sup>1</sup> with maternal mortality ratios of >200 according to UN data.<sup>2</sup>

Less than one year later, in November 2012, RHSC announced that the initiative had met its initial target of supplying 4.5 million units of the product, triggering a further credit rebate for the eligible recipient countries.

In May 2013, building on the company's previous price announcement, Merck and a group of public- and private-sector partners announced an agreement to further expand contraceptive access and options for millions of women in some of the world's poorest countries. The increased volume generated from the success of the initial initiative with RHSC and the guarantee of continued volume has allowed Merck to achieve improved economies of scale making the further price reduction possible. Under the agreement MSD will reduce the cost of IMPLANON and its next-generation implant, IMPLANON NXT® (etonogestrel), by approximately 50 percent for the next six years in the targeted poorest eligible countries of focus for the reproductive health community. [Learn more.](#)

### Partnering for Implementation

For family planning programs in the developing world involving Merck's contraceptive implant IMPLANON, the company requires the recipient governments and partnering NGOs to sign a Cooperation Agreement for the Receipt and Use of IMPLANON (CARUI). The cooperation agreement includes:

- Merck's 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 Merck 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
- Merck's commitment to "training of trainers" and providing training materials, including audiovisual materials, training kits, artificial arm models and placebos; Merck may provide additional technical assistance for direct and cascaded training activities of 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 Merck's ethical and business compliance policies

In the countries where Merck 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**, **International Planned Parenthood Federation**, **Population Services International**, **Pathfinder International** and **DKT**. Such collaboration ensures that countries have the expertise and support they need to achieve their reproductive health objectives.

In 2012, we worked with more than 30 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 where our Institutional Family Planning Services engaged in partnerships in 2012 include Madagascar, Ethiopia, Kenya, Uganda, Tanzania, Nigeria, Bangladesh, Vietnam and Cambodia.

As part of our capacity-building and training commitment, Merck provided support and educational grants for governments and/or local implementing partners to train more than 15,000 healthcare providers in sub-Saharan Africa, Asia and Central America in 2012. Merck also trained and/or provided medical education to many healthcare providers around the world.

## Public Advocacy

Merck supports the ambitious, but we believe achievable, goal set out 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.

We were pleased to have been asked to participate in the London Summit on Family Planning in July 2012, at which we affirmed our partnership with RHSC to make IMPLANON available at our access pricing.

We also participated in the September 2012 launch of a report by the UN Commission on Life-Saving Commodities for Women and Children that recognized the importance of contraceptive implants and of women's choice in deciding which method and product is right for them. Merck Chariman and Chief Executive Officer, Ken Frazier, was one of the Commission's 19 commissioners. And we continued to engage with partners and donors to ensure that multiple options are available to countries as they seek to address the unmet contraceptive needs of women.

<sup>1</sup>World Bank Classification of countries as of 18 July 2011, Atlas Method

<sup>2</sup>WHO/UNICEF/UNFPA/The World Bank, Estimates of Maternal Mortality 2008

# MERCK ANIMAL HEALTH

Our mission is the science of healthier animals.

## 2012 PERFORMANCE HIGHLIGHTS

- Launch of a new vaccine against Peste des Petits Ruminants (PPR), a severe, fast-spreading and devastating viral livestock disease for sheep and goats which is highly prevalent in Africa, Middle East and Asia
- Approval from Indonesian authorities to market AQUAVAC® Strep Sa, an inactivated vaccine that aids in the protection against Streptococcus agalactiae infections in tilapia and other susceptible fish
- Introduction of CANINSULIN VetPen, the first insulin pen specifically designed for diabetic dogs and cats
- Launch of new educational tools and reference materials to support SLICE® Sustainability Project, a comprehensive, six-step integrated strategy to help the world's salmon producers develop lasting, sustainable control programs for managing sea lice, a costly parasite The HomeAgain® Pet Recovery Service reunited more than 1 million lost pets with their families
- Merck Animal Health entered public-private partnership to develop innovative strategies against bacterial udder infections (mastitis) in dairy cattle

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 science within Merck Animal Health is all about making animals healthier. Healthier animals mean sustainable food supplies, protection of human health against zoonotic diseases, support to reduce the burden of certain food-borne diseases,<sup>1</sup> and longer, richer companionship for pet owners.

Merck's 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.

Merck Animal Health employs more than 6,400 people worldwide, and is present in more than 50 countries. The 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.

At Merck Animal Health, we focus our corporate responsibility efforts on the following areas:

- **Protecting animal health**
- **Contributing to public health**
- **Supporting a sustainable, global food supply**
- **Ensuring ethical business practices**

**Note:** This section includes information about how Merck contributes to societies through its animal health business. Information and data on Merck Animal Health's performance in the environment and in other areas is contained within the main sections of Merck's global corporate responsibility report.

<sup>1</sup> Zoonotic diseases are any disease or infection that is naturally transmissible from vertebrate animals to humans and vice versa (WHO). Foodborne diseases in general encompass a wide spectrum of illnesses caused by microbial, parasitic or chemical contamination of food.

## PROTECTING ANIMAL HEALTH

**Merck Animal Health tackles the world's biggest animal health challenges, and collaborates with our customers to answer their specific needs.**

### Keeping Pets Healthy

Pets play an increasingly significant role in many families, and their health and quality of life are important. Merck Animal Health provides veterinary medicines that help to keep pets healthy.

Effective vaccines help prevent many bacterial and viral infections in dogs, cats, horses and other companion animals. For example, thanks to effective immunization, rabies is controlled in many regions of the world. In addition, dogs can be protected against severe diseases such as parvo virus, distemper and hepatitis.

In 2009, in response to a call from the American Veterinary Medical Association, we made available, in the United States, the first vaccine against the canine influenza virus to protect dogs against the highly contagious respiratory infection that can harm them when they are housed in shelters, kennels and other communal facilities. Today, this product remains the market leader. In addition,

regular deworming and tick and flea control with our anti-parasitic products can keep our pets healthy and reduce the risk of transmitting zoonotic diseases to people.<sup>1</sup>

Merck Animal Health vaccines also help protect cats against feline panleukopenia virus, feline herpes virus and feline calicivirus; and rabbits from hemorrhagic disease. As the market leader in equine vaccines, Merck also helps protect horses against both established and newly emerging diseases, including equine influenza, the most common viral respiratory disease found in horses; and the West Nile virus, which can also affect people.

We also continuously strive to make our treatments as gentle on pets as possible. Our newest anti-flea products, for example, minimize pet exposure to chemicals by limiting their activation to within the flea.

While the range of preventative products available to veterinarians and owners continues to grow, animals still get sick. Our broad range of products spans antibiotics and other anti-infectives, anti-parasitics, as well as treatments for chronic conditions such as osteoarthritis, cardiovascular disease and diabetes.

### Investing in Veterinary Education

Merck Animal Health invests in the future of the veterinary profession by supporting research, education and specialized skills training so veterinarians have the resources they need to provide the best healthcare possible for the animals they treat. For example:

## REUNITING PETS WITH THEIR OWNERS

Through 2012, nearly 11 million pets in the United States have been enrolled in Merck's HOMEAGAIN® microchip-based pet recovery program, which has resulted in more than 1 million successful recoveries so far. Merck Animal Health first launched the service in 1996.



Among these reunions is Chewie, a Peekapoo who was lost from his family for two years, when his four-legged canine companion, Jack, opened the front door of their Arizona home and let Chewie out. As his owners, the Baumgardners were a military family who moved frequently, the parents were devastated over the loss, because pets were the one constant in their children's lives. Their daughter, who received Chewie seven years earlier as a present for her eleventh birthday, remained hopeful, knowing he had a microchip. After the family relocated to California, they received a call from an animal

clinic in Arizona. A good Samaritan found Chewie along the highway and took him to be scanned for a microchip. Because the family had kept their contact information current in the HOMEAGAIN microchip registry database, Chewie was reunited with his family.

Another memorable reunion is the story of Scrub, a courageous cat from Mississippi who lost his way during the aftermath of Hurricane Katrina. Scrub was lost for five years, but found just 15 miles from his home and scanned for a microchip at a shelter. His owner, Jennifer Noble, had kept her contact information current in the HOMEAGAIN database, which enabled the shelter staff to get in touch with her. Directors at the Humane Society of South Mississippi said it was unlikely Scrub would have returned home without the help of the HOMEAGAIN Pet Recovery Service.

- We provide scholarships to veterinary students pursuing careers in large animal medicines in the United States, and support award programs for outstanding veterinary students in the Philippines.
- We also support the Gustav Rosenberger Memorial Fund, which supports the training of young veterinarians from South America, Eastern Europe, Asia and Africa. The fund provides annual grants to young and promising veterinarians who come from a country where bovine medicine needs further development and intend to apply the knowledge obtained in that country.

<sup>1</sup>Zoonotic diseases are any disease or infection that is naturally transmissible from vertebrate animals to humans and vice-versa (WHO).

## 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, and zoonotic diseases, such as avian flu, in the world today. Experts estimate that 60 percent of all human diseases can move from human to animal and vice-versa. In fact, during the past three decades, approximately 75 percent of new emerging human

infectious diseases have been zoonotic. A fast, flexible approach to vaccination can help control such diseases and minimize the medical, social and economic impact that could occur if left unchecked.

### Foot-and-Mouth Disease

To control a recent outbreak of foot-and-mouth disease among cows in South Korea, we provided half of the country's vaccines (12 million doses). In India and Germany, we produce our foot-and-mouth disease vaccine to meet the need for specific-strain combinations of the virus. Merck Animal Health is also working with governments by holding antigen banks for a fast response to outbreaks of this devastating livestock disease. The antigens held in these banks are the active ingredients of vaccines. Should an outbreak occur, companies such as Merck can quickly turn the antigens into vaccines for rapid use.

### Salmonella

Food-borne microbial diseases, such as Salmonella, are also a growing concern, particularly for poultry farmers. Human consumption of poultry 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 the broadest spectrum Salmonella vaccine available; 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 respond quickly and

effectively. This combination of vaccines, biosecurity and other measures has contributed significantly to the reduction in incidence of human salmonellosis. For more information, [click here](#).

### Swine Influenza

To help control the swine influenza virus, we developed the first pentavalent inactivated vaccine to control the most common strains in pigs.

### Leishmaniasis

Merck Animal Health's canine preventative product protects dogs against leishmaniasis, helping to the control one of the world's most deadly parasitic diseases, 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 domestic dogs, who are the main carriers of the disease. Globally, the disease kills an estimated 55,000 people.

Merck Animal Health donates more than 200,000 doses of rabies vaccine annually to the **Afya Serengeti Project** in Tanzania and Kenya. By tackling rabies in these East African nations' domestic dog populations, we've helped to dramatically reduce the number of rabies-infected dog bites, and also helped to protect the countries' fragile wild dog population.

In India, we also sponsor two similar projects, in collaboration with the Global Alliance for Rabies Control and Bombay Veterinary College in Mumbai, to support mass vaccination of pets and improved educational awareness in 10 villages surrounding Bangalore and Pune. Through the program, education about rabies prevention and treatment is provided to the community—from small children to adults and village leaders. The program involves medical and veterinary professors, experts in the field of rabies and medical students from area universities. Special accommodations are made to educate people in their own dialects, with sensitivity to local customs.

## SUPPORTING A SUSTAINABLE FOOD SUPPLY

**By 2050, it is estimated there will be an extra 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, so does the appetite for meat, milk and eggs. In fact, The United Nations Food and Agriculture Organization expects the global demand for animal protein to double by 2050.**

Our portfolio of products is focused on helping farmers keep their livestock productive. Targeted intervention with vaccines, anti-parasitics, anti-infectives, and other veterinary medicines helps protect the health and well-being of animals, and helps producers limit their production losses. For example, we help control parasites through our Lung Health platform, which allows customers to tackle complex problems like bovine respiratory disease. We also help farmers protect cattle from bovine viral diarrhea through vaccination. In addition, we provide products that help farmers raise beef more efficiently and sustainably, which means meeting the food demands of a growing population while conserving precious natural resources.

**Currently half of all fish consumed globally is farmed.**

Demand for fish is also rising, and farmed fish are becoming more important—in order to meet this demand and protect wild fish.

Protecting fish from disease, and controlling bacteria and parasites, is vital to ensure consistent, sustainable harvests. Our vaccines aid stock replenishment by allowing fish to better convert feed, grow efficiently and stay healthy. Our vaccines have been developed to fight a large range of infectious diseases in cold- and warm-water species such as salmon, trout, sea bass, bream, tilapia and many others.

Our SLICE Sustainability Project, developed in partnership with fish farmers, helps control parasites and keeps 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. In turn, it improves the efficiency and long-term value of fish production.

### Improving Animal Husbandry Practices

Providing access to veterinary expertise and medicines makes a significant impact on the livelihoods of small land holders and their families.

In Malawi, Merck Animal Health is helping dairy farmers increase milk production, improve the health of their

animals and improve milk quality. In Cameroon, we are supporting a project with Heifer International to train farmers on veterinary medicines. And in Ethiopia, we are providing financial and educational support to expand knowledge on poultry health and access to veterinary medicines within the domestic poultry industry. Other examples include:

- Developing the Dairy Care365 Training Series, a program to educate U.S. dairy farm workers in best practices for handling and managing dairy cattle
- Offering poultry and swine health training courses to veterinarians for more than 20 years. Through these courses, which are held in the Netherlands, hundreds of veterinarians from important poultry- and swine-production countries and companies around the world have received training. The courses are conducted in collaboration with the Dutch Animal Health Service. For the past three years, an extended level course on poultry has been conducted in collaboration with the University of Georgia's Department of Poultry Science in the United States.
- Sponsoring fish-vaccination training to fish producers and veterinarians

<sup>1</sup> OIE, B.Vallat; Opening speech European Veterinary Week, Brussels, Nov 10, 2008

## ENSURING ETHICAL BUSINESS PRACTICES

### Product Safety

We invest millions of dollars each year into the research and development of novel animal health products and the continued investigation of

existing products. Like 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, such as the U.S. Food and Drug Administration or the European Medicines Agency.

**The standards for authorization of veterinary medicines are at the same level as for human medicines. On average, it takes 5–12 years to bring a veterinary product to the 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. Merck Animal Health supports global harmonization of the regulatory process for veterinary medicines through its 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 for human consumption of the 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 the product on flora, fauna, soil and water. When necessary, restrictions are placed on the use of these products to protect the environment.

Once a product is on the market, we— together with other stakeholders such as veterinarians, authorities and animal owners—monitor all aspects that could affect product safety. Findings are assessed and, if need be, reported to regulatory authorities and addressed through appropriate measures.

### Antimicrobial Stewardship

In animal health, antibiotics are used both to treat infections and to prevent disease in companion animals and farm animal populations. Antibiotics are used to treat individual diseased animals, to treat herds that have high morbidity and mortality rates, and to prevent disease



in herds that are at high risk of illness. In some regions of the world, antibiotics are also used in feed for farm animals to improve the stability and balance of an animal's intestinal bacteria, improve its digestion, and, therefore, its efficient use of nutrients.

In recent years, there have been widespread efforts to manage antibiotic use in animals to reduce the potential for antibiotic resistance and keep these products effective. Merck supports these efforts. In addition, Merck does not market antibiotics that are listed by the World Health Organization as important for human health, for productivity enhancement in food animals.

Merck engages in research to increase our knowledge of the proper use of antibiotics in animals for the benefit of both human and animal health. Merck operates and participates in public and industry surveillance programs that would detect the emergence of bacterial resistance of animal pathogens, or bacteria of human health concerns, to antibiotics we market. Merck is active in research programs to develop alternative approaches to the use of antibiotics in animals.

Merck also promotes, with its customers, adherence to guidelines on responsible use of antimicrobials developed by international and national organizations such as the World Health Organization, the World Organization for Animal Health, the World Veterinary Association, the American Veterinary Medical Association, and the European Platform

for Responsible Use of Medicines in Animals. Merck provides continuing education opportunities on responsible use of antibiotics at international, national and local veterinary meetings. Merck also sponsors and delivers educational programs and materials on practices to ensure sustainable use of antibiotics to veterinarians, farmers and feed companies. Finally, Merck supplies guidelines for resistance management, and provides educational materials on appropriate dosage and length of use of its antibiotics.

For more information, please see Merck's [\*\*Public Policy Position Paper on Antimicrobial Stewardship\*\*](#).

## Partnering with External Experts

In research and development, as well as in post-marketing surveillance, we partner with external researchers, veterinarians and academics where it requires external expertise to advance animal health and welfare. We also consult with external experts to engage in scientific communications regarding our products.

The experts and consultants whom we hire may conduct research, engage in authorship, and/or speak on our behalf regarding research results or scientific product profiles. In exchange for these services, we pay a fair market value. In order to be transparent, we require that

## RESPONSIBLE USE OF ANTIBIOTICS

Merck Animal Health is a member of and supports the [\*\*European Platform for the Responsible Use of Medicine in Animals \(EPRUMA\)\*\*](#), a multi-stakeholder platform that aims to ensure best practices through responsible use of medicines—including antimicrobials—in the prevention and control of animal diseases.

## PREVENTION AND CONTROL OF INFECTIOUS DISEASES IN AQUACULTURE

The most effective means to prevent 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. Data from a report in Norway<sup>1</sup> shows that vaccination using Merck Animal Health vaccines against cold water vibriosis and furunculosis in salmon substantially reduced the need for antimicrobials. The annual usage of antimicrobial agents in farmed fish in Norway declined by 98 percent from 1987 to 1996, and has remained at that low level, despite a tripling in production.

such experts and consultants disclose our sponsorship when they publish or speak with our support. The final decision on whether to publish the results of their research is made by external experts.

## Sales & Marketing

Veterinarians rely on animal health companies to provide accurate and balanced information about their medicines and vaccines. Merck believes the best way to provide this information is to maintain informative, ethical and professional relationships with veterinarians, as well as with other customers.

Our interactions with customers are governed by laws, regulations, corporate and divisional policies, as well as Merck's global code of conduct, **Our Values and Standards**. We enforce these through our global business practices and compliance program. We also adhere to Merck's Guiding Principles for Ethical Business Practices with the medical and scientific community, and follow voluntary industry codes including:

- The **International Federation for Animal Health Statement of Principles**
- The U.S.-based **Animal Health Institute Advertising Guidelines**
- The U.K.-based **National Office of Animal Health Code of Practice for the Promotion of Animal Medicine**

<sup>1</sup>NORM/NORM-VET 2010. Usage of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Norway. Tromsø / Oslo 2011. ISSN:1502-2307 (print) / 1890-9965 (electronic).

## CONSUMER CARE

**Through our consumer health products, we help people take back their lives to live more fully and more joyfully every day.**

Merck Consumer Care (MCC) comprises approximately 1,500 team members in more than 50 countries. We specialize in helping to give people comfort and relief from the physical strains of the day, the damaging effects of the environment and the natural transitions of life. Each day, millions count on one or more of our industry-leading brands that help prevent or treat various common conditions. These include household names such as CLARITIN® for allergies, COPPERTONE® for sun care, DR. SCHOLL'S® for foot care and many more.

At MCC, we focus our corporate responsibility efforts on the following areas:

- Developing meaningful and highly trusted products that help prevent or treat common conditions
- Reducing the impact of our products on the environment
- Engaging with stakeholders to ensure appropriate access and use of our products
- Investing in the communities in which we operate

### Developing Meaningful and Highly Trusted Products

At MCC, we are committed to producing the next generation of breakthroughs in consumer health and wellness so that people around the world can live their lives more fully. In order to develop these products, we place consumers at the center of our decisions, invest in research and development (R&D) to develop science-based solutions and work tirelessly to bring these innovations to those consumers who need or value them.

Merck is dedicated to increasing access to products to help people better manage their health conditions and improve the quality of their lives. Rx to over-the-counter (OTC) switch is an important part of this strategy. As part of this strategy, in January 2013, MCC received FDA approval for OXYTROL FOR WOMEN (oxybutynin transdermal system, 3.9 mg/day), the first and only OTC treatment for overactive bladder in women. OXYTROL FOR WOMEN addresses an important unmet need for overactive bladder, or OAB, a condition that affects more than 20 million American women. Despite the fact that OAB is a treatable medical condition, more than 80 percent of women with OAB do not seek treatment. By achieving FDA approval of OXYTROL FOR WOMEN as an over-the-counter product, we hope to provide a treatment option that can help women with OAB recognize and treat their symptoms.

In developing these types of breakthroughs, we place consumers at the center of our decisions. And we never forget that product safety and

quality are integral to the trust we have with consumers. We adhere to the highest standards of ethical behavior in everything we do—it is what our consumers expect of us and what we expect of ourselves.

### The Impact of Our Products on the Environment

MCC is committed to playing a role in protecting the planet for future generations and we realize that doing so is important for our business.

For consumer products, packaging plays an important role in protecting our products, providing information and clarifying competitive differences. With the wide reach of our consumer products, ensuring continued improvement to the environmental impact of our products is important to our customers and stakeholders. Two particular areas of focus for MCC in this effort are materials reduction and packaging efficiency.

As part of this focus, in 2012, MCC successfully moved the packaging of Afrin® and Coricidin® products to 100 percent recycled paperboard. Through this initiative, MCC is delivering value to our retailers and consumers through our environmental sustainability efforts. This effort is resulting in less waste in the environment and a cost-savings on the production line.

In addition to internal initiatives, we continue to look for creative ways to partner locally to support recycling programs in the communities in which we operate. In 2012, the Coppertone team, in partnership with **TerraCycle**, a company

that develops eco-friendly products from recycled material, launched a program in Brazil encouraging consumers to recycle Coppertone packaging. Through this program, the MCC team is creating greater value for our consumers while supporting our environmental sustainability goals.

For more information regarding MCC and Merck's overall environmental sustainability goals, please [click here](#).

### Ensuring Appropriate Access to and Use of Our Products

As a developer and manufacturer of consumer products, we have a critical role to play in ensuring appropriate use of and access to those innovations.

We actively participate in and play leadership roles across many important organizations, including Consumer Healthcare Product Association (CHPA), Consumer Health Products Canada, Personal Care Products Council (PCPC), and others.

Through our involvement with these organizations, we work to address relevant and timely issues of concern for our consumers. For instance, in 2012, we continued to work through CHPA and with other leading makers of OTC cough syrup to build awareness among parents, care givers and healthcare professionals about the issue of cough syrup abuse in teenagers. Through the development of an array of educational campaigns and tools, CHPA and industry partners, including MCC, are working to curb abuse among teenagers while allowing for

appropriate access and use of medicines that enable self-care for our consumers.

### Community Investment

MCC is committed to supporting the communities in which we operate through the development of new and innovative consumer-awareness programs, as well as through product donations and employee volunteerism.

As part of this commitment, MCC recently announced the launch of a new health and wellness initiative in the U.S., the Active Family Project. The Active Family Project helps inspire families to live life more fully by spotlighting healthy habits, providing tips and information and sharing fun family activities, while building a national community of moms dedicated to adopting and promoting an active and healthy lifestyle, for the people they care about most. For additional information on the Active Family Project, please see [www.activefamilyproject.com](http://www.activefamilyproject.com).

MCC also has a continued commitment to enable the public to make informed sun care choices. For example, in 2013, MCC launched a new sun care awareness campaign, *Making the Sunscreen Grade*. This campaign is intended to equip parents with information to help ensure their children are protected from the sun during the school day. This campaign is centered on driving parents' education and awareness of sun protection, most importantly, beyond traditional beach and pool occasions. For additional information regarding this program and tools, [click here](#).

In addition, MCC actively supports our communities through product donations and employee volunteer programs. For additional information on product donations, [click here](#), or for information on employee volunteerism, please visit the Volunteering tab on our [Employee Engagement](#) page.

# ENVIRONMENTAL SUSTAINABILITY



## ENVIRONMENTAL SUSTAINABILITY

Merck has a long history of environmental responsibility and compliance, but we realize that the world's current approach to resource use is not sustainable and that more needs to be done.

Our Environmental Sustainability strategy:

- **Materiality Assessment**—We have identified the issues that are important to our business and our stakeholders so that we can prioritize them for action.
- **Vision**—We envision sustainable operations and supply chain, innovative products & packaging, and environmental sustainability being fully integrated into business decisions.
- **Road Map**—In the near term, our focus is on becoming leaner and smarter. Our medium-term focus is on transformation. Our long-term focus is on realizing our sustainability vision.
- **Goals**—We have defined environmental footprint measures and have established goals to improve the sustainability of our operations.

## KEY PERFORMANCE INDICATORS

ENVIRONMENTAL SUSTAINABILITY	2011	2012
Greenhouse gas emissions (million metric tons of CO <sub>2</sub> e)	2.10	1.98
Emissions of volatile organic compounds (metric tons)	931	807
Water usage (billion gallons)	9.1	9.1
Waste generated (metric tons)	186,500	179,000
Waste recycling rate	54%	52%

For more details on our environmental data, please download the Excel spreadsheet on the [Downloads & Media](#) page.

## ENVIRONMENTAL MATERIALITY

**An environmental materiality assessment identifies the issues that are important to the business, the community and the environment so the company can prioritize them for action.**

Our materiality assessment involved conducting interviews with senior management in key business areas of Merck and gathering input from both internal and external stakeholders. We considered regulatory, reputational and supply risks as well as cost impacts.

The key areas identified by our environmental materiality assessment included:

- Protecting water resources
- Conserving energy and reducing GHG emissions
- Reducing and reusing materials

The outcomes of this assessment led directly to the selection of our corporate **environmental goals**.

Our global operations include research laboratories and farms; manufacturing and packaging facilities; warehouse and distribution centers; a field sales force; and business offices. Most of our direct environmental footprint is associated with the resources and materials we use to discover and manufacture our products,

as well as the wastes that are generated, treated and disposed of as the result of those activities.

Our products include prescription medicines, vaccines, biologic therapies, and a diverse portfolio of consumer and animal health products. To ensure high levels of product safety for our customers, we use very pure ingredients in our manufacturing processes, which makes it more difficult to reuse and recycle key chemicals. We also use rigorous cleaning regimens. The discovery and production of vaccines and biologic therapies generally involve living microorganisms that require strict, sterile growth conditions and the use of highly purified water.

While we focus our environmental programs, goals and external reporting on the impacts of our own operations, we also recognize that the issues that are material to us are mirrored in our supply chain by partners who make products, chemicals, packaging components, and other materials and services that we consume to run our business. For more information on our supply chain, **[click here](#)**.

# ENVIRONMENTAL SUSTAINABILITY VISION

**At Merck, we strive to respect and care for the health and well-being of people and the environment in everything we do, while delivering lifesaving, innovative medicines to the world.**

Our environmental sustainability efforts center on three areas:

## Innovative Products & Packaging

- Challenging our scientists, colleagues and partners to imagine, discover and develop products that address global health needs in ways that protect and preserve the environment
- Working to minimize the life-cycle footprint of the packaging used to protect the integrity of our products

## Sustainable Operations

- Promoting ways to drive manufacturing efficiency and minimize the environmental footprint of our operations to preserve and protect the Earth's natural resources
- Striving to integrate sustainability into our business decision-making processes throughout the company, to make sure our activities support Merck's "Be Well" mission not only for human and animal health but also for the environment

## ENVIRONMENTAL SUSTAINABILITY ROADMAP

### Our Vision

We respect and care for the environment in everything we do. A healthy planet is essential to healthy people and the health of our business.

Innovative products and packaging	Sustainable operations and supply chain	Systems and lifecycle thinking
<b>2010-20 NEAR-TERM LEANER AND SMARTER</b>		2015-30 / MEDIUM-TERM TRANSFORMATION
		2025-50 / LONG-TERM ENVIRONMENTAL SUSTAINABILITY
<b>1. Set near-term targets and communicate long-term vision</b>	<ul style="list-style-type: none"> <li>• Create 2015 and 2020 environmental goals</li> <li>• Establish and communicate environmental sustainability vision</li> </ul>	DONE DONE
<b>2. Drive business process change</b>	<ul style="list-style-type: none"> <li>• Identify and implement business processes toward environmental sustainability</li> </ul>	ONGOING
<b>3. Report on progress</b>	<ul style="list-style-type: none"> <li>• Provide transparency on progress and engage with stakeholders</li> </ul>	ONGOING
<b>4. Focus on water</b>	<ul style="list-style-type: none"> <li>• Work toward more sustainable water management in our operations and supply chain</li> </ul>	ONGOING

## Sustainable Supply Chain

- Partnering with suppliers throughout our value chain who share our vision and who are also striving for sustainable operations
- Collaborating with suppliers to meet the shared needs of each of our businesses in more efficient ways with less environmental impact



## ENVIRONMENTAL GOALS

OUR ENVIRONMENTAL GOALS		STATUS	GOALS	
		2012	2015	2020
AIR & CLIMATE CHANGE	Reduce greenhouse gas emissions (GHG)	GOAL MET -10%	-10%	
	Reduce volatile organic compound emissions (VOC) <sup>1</sup>	-26%		-20%
WATER	Reduce total water use	-4%	-15%	-25%
	Reduce chemical oxygen demand (COD) in discharges <sup>1</sup>	-57%	-15%	-20%
	Reduce nitrogen and phosphorous in discharges <sup>1</sup>	-13%	-10%	-15%
PACKAGING	Eliminate PVC from non-primary packaging	~240 PRODUCTS	100%	
	Use more sustainable paper products <sup>2</sup>	40%	50%	
	Sell more products with sustainable packaging <sup>3</sup>	IN PROGRESS		50%
WASTE	Use recovered solvents in manufacturing <sup>4</sup>	35%		40%
	Reduce nonhazardous waste generation	+2%		-30%
	Recycle more nonhazardous waste <sup>5</sup>	54%	60%	
	Improve process mass intensity (PMI) <sup>6</sup>	IN PROGRESS		-20%

All Goals have a 2009 baseline unless otherwise stated.

<sup>1</sup> Changes to our operations could impact the goal baseline and improvement. Performance against these targets will be tracked until the goal year.

<sup>2</sup> Sustainable paper products include paper and packaging made from at least 30% post-consumer recycled content or from certified fiber.

<sup>3</sup> Measured as percent of revenue from products with at least one sustainable packaging attribute.

<sup>4</sup> Measured as percent of total solvent use that is recovered material.

<sup>5</sup> Measured as percent of total nonhazardous waste generated that gets recycled.

<sup>6</sup> Process mass intensity is a measure of how efficiently materials are used in the synthesis of an active pharmaceutical ingredient (API) for human health products.

# EHS MANAGEMENT & COMPLIANCE

**Protecting our people, our communities and the environment, and being in full compliance with the law are fundamentally important to the way we operate.**

Our mission and values are articulated by our corporate **Environmental, Health and Safety (EHS) Policy**. Merck's **Code of Conduct**, Our Values and Standards, serves as a vehicle to communicate EHS expectations and the EHS mission to all employees. 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.

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]
- EHS 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 EHS Council through site compliance committees, review performance and progress against objectives. Central audits and self-assessments surface issues. Monthly and annual performance metrics reflect progress [CHECK]
- The EHS Management System includes programs and processes that surface potential EHS concerns, establish corrective actions and drive continuous improvement [ACT]

Subtopics addressed in tabs:

- Governance, Roles & Responsibilities
- Internal Auditing Program
- Training
- Performance

## EHS GOVERNANCE

**Merck's commitment to environmental, 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 enterprise-wide excellence in EHS management and performance.

Specific Council duties include:

- Establishing EHS strategy, policy and standards
- Providing enterprise-wide oversight of EHS issues, risk mitigation and control strategies

- Monitoring EHS performance, establishing continuous-improvement targets and recognizing and promoting EHS excellence
- Allocating resources and/or sponsoring projects to address specific EHS concerns

An EHS Standards Committee chartered by the EHS Council provides stewardship over the EHS Standards and enables business engagement in the development of new or revised EHS Standards.

Our internal business partners are responsible for executing against the EHS Standards, contributing to development of the EHS programs and supporting internal audits and communicating significant EHS events. Each of these business partners has Compliance Committees to provide governance on implementation of EHS 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 EHS 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

Our site and operating area EHS professionals support the EHS needs of their business partners, which include manufacturing, research operations, sales and/or administrative activities, by:

- Ensuring that line management fully understands EHS requirements
- Establishing, assessing and improving EHS programs
- Providing regulatory and technical support to employees and the operating areas
- Routinely assessing performance against both regulatory and Merck 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

### **Merck has a global internal corporate safety and environmental audit program.**

The audit frequency for a given facility is risk-based. Manufacturing and research sites are typically audited every one to three years, depending on their size and other factors. Less complex facilities, such as sales and business offices and our warehouses, are typically audited every five or more years. 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.

Our corporate EHS audit practices are detailed and rigorous in order to effectively identify and address compliance and performance issues.

- Our audit leaders are full-time professional EHS auditors with extensive experience in auditing procedures, regulatory requirements and potential facility hazards
- Our pool of auditors consists of staff members with extensive subject-matter expertise who receive biannual training in the audit process
- We place significant emphasis on rapid and sustainable resolution of all identified compliance and internal control issues

- Findings from our audit program are used to alert other Merck site EHS managers to potential compliance concerns, both through routine summaries and as focused, proactive alerts
- Audits are also used to identify proven practices to be shared with other sites

## TRAINING

### **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.

Training materials are available in both instructor-led as well as e-learning formats and in versions that are specific to our managers, our EHS Professionals and our overall employee population. Manager training covers specific management responsibilities with regard to environmental and safety compliance and promoting a “safety first” culture. EHS Professional training is designed to drive more consistent technical expertise and improved EHS program and support capabilities around the world.

General employee EHS topics focus on hazards and control measures for our overall employee population. Last year a total of 14 core content modules were developed and translated into seven languages to drive global alignment and to support site training needs.

## PERFORMANCE

**Merck's 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.**

We collect and analyze both leading and lagging metrics to look for potential trends and identify opportunities that could help us to drive EHS performance improvement. We continuously explore ways to expand the scope and use of EHS information systems to enhance our ability to collect, maintain, analyze, learn from and report EHS data.

### Regulatory Inspections

In 2012, Merck was inspected 249 times by EHS regulatory agencies around the world. This represents a 25 percent increase in the number of regulatory (primarily safety) inspections over the prior year. Regulatory inspections helped to confirm the improved compliance status of our facilities. Where compliance issues were identified, they did not represent significant risks to human health or the environment and are not expected to result in significant enforcement actions. Corrective actions to address identified issues were implemented in a timely manner.

### Notices of Violation, Fines & Settlements

The term Notices of Violation (NOVs) used in this report includes all EHS compliance notices, sometimes referred to as citations, letters of warning, and notices of non-compliance from primarily environmental and safety-focused regulatory agencies.

Merck received 30 safety NOVs in 2012, a 43 percent increase over the prior year. This increase is related to a 71 percent increase in the number of fire-safety and life-safety inspections in 2012. Merck paid two safety-related fines totaling \$121,827 in 2012.

Merck received 14 environmental NOVs in 2012, a 46 percent reduction from the prior year. Merck paid \$27,100 in fines associated with environmental enforcement actions in 2012.

### Environmental Events

Merck experienced 62 water permit exceedances in 2012, versus 81 in 2011; and 10 air permit exceedances in 2012, versus 7 in 2011. Overall, there were 18 percent fewer environmental permit exceedances in 2012. These events were generally minor and temporary.

This report reflects the number of spills and releases at our facilities that are either greater than 55 gallons or that require reporting to a regulatory authority. Merck experienced 102 such spills and releases in 2012. This is 20 fewer spills, or a 16 percent reduction, from 2011. Spills and releases that are outside of secondary containment are rigorously assessed to understand potential impact and drive appropriate mitigation strategies when needed.

<b>Global Environmental &amp; Safety Compliance Performance Data Summary<sup>1</sup></b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
<b>Regulatory Inspections<sup>2</sup></b>				
Safety	117	69	58	<b>100</b>
Dangerous goods	6	3	7	<b>5</b>
Environmental	164	152	134	<b>144</b>
Product-related	0	4	1	<b>0</b>
<b>Environmental Events</b>				
Reportable spills and releases	92	127	122	<b>102</b>
Water permit exceedances	130	94	81	<b>62</b>
Air permit exceedances	13	12	7	<b>9</b>
Other permit exceedances	NR	3	1	<b>2</b>
<b>Notices of Violations (NOVs)/Citations</b>				
Environmental	30	32	26	<b>14</b>
Safety	5	32	21	<b>30</b>
<b>Fines</b>				
Environmental fines paid (US\$)	8,000	70,201	1,791,765	<b>27,100</b>
Number of environmental fines	1	9	15	<b>2</b>
Safety fines paid (US\$)	1,350	631	7,500	<b>121,827</b>
Number of safety fines	11	1	2	<b>2</b>
<sup>1</sup> Previously reported data have been restated. Safety violations were corrected to reflect fire-safety violations not previously reported for one site.				
<sup>2</sup> Regulatory Inspections has been revised to exclude noncore inspections (e.g., elevator and cafeteria).				
NR: Not reported.				

## Commitments

As our EHS Policy states, we:

- Comply with the letter and spirit of all applicable laws, regulations and other requirements designed to protect safety, health and the environment
- Create and maintain a safe and healthy working environment for all employees, contractors and guests
- Protect our environment and the communities in which we operate; conserve resources, promote recycling, reduce hazardous-material use and prevent pollution
- Promote a global standard of care that minimizes EHS impacts from our operations, products and partnerships
- Foster a culture of EHS excellence built upon integrity, accountability, collaboration and the active participation of all
- Continuously improve our systems, processes and performance and integrate EHS throughout our global operations
- Engage stakeholders and communicate our progress and performance
- Provide appropriate resources and build individuals' knowledge and capabilities to achieve these commitments

# ENERGY USE & CLIMATE CHANGE

**Scientific data supports that a gradual warming of our climate, commonly referred to as climate change, is under way and is very likely due to human activities.**

Merck has made it a priority to reduce our demand for energy and has taken steps to establish responsible internal policies and practices focused on reducing energy usage and greenhouse gas (GHG) generation. By taking these steps, we are not only minimizing GHG emissions but we are also reducing our operating costs and mitigating the business impacts associated with future climate change requirements.

We report our GHG emissions as required by regulations in certain countries and annually through the **Carbon Disclosure Project**. We track the generation of five greenhouse gases:

- Carbon dioxide (CO<sub>2</sub>)
- Methane
- Nitrous oxide
- Hydrofluorocarbons
- Sulfur hexafluoride

Merck has established a goal to reduce our GHG emissions by 10 percent between 2009 and 2015. The primary avenue for achieving this goal is reducing our energy demand. 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 conservation because using less energy provides a better balance of business needs and environmental impact reduction. Our manufacturing facilities, warehouses, laboratories, major offices, and our vehicle fleet are the priority of our energy-demand-reduction programs because they represent the majority of our energy consumption.

## INITIATIVES

**Merck has launched initiatives around the world to improve energy use and reduce greenhouse gas (GHG) emissions from our operations.**

Management has committed up to 50 million USD from 2009 to 2015 to help drive these reductions and to better position the company to respond to energy demands in the future.

### Facilities

We strive to make our facilities as energy-efficient as practical.

- When we purchase new facilities, we evaluate them for energy efficiency and assess them against our best practices as part of their integration into Merck
- We require all new facilities to comply with our Energy Design Guide and Energy Conservation Planner, and we factor the potential for future emissions into capital expenditure planning

- Two of our Puerto Rico manufacturing plants have partnered to reduce fossil fuel consumption. As part of the U.S. EPA comparable fuels program, our plant in Barceloneta managed over 900,000 gallons of spent solvents as comparable fuels in 2012. This program reduces the Arecibo plant's fuel oil costs and avoids the shipment of these spent solvents to the U.S. mainland for disposal, saving over \$1.5 million dollars in direct disposal costs.
- We build all new laboratories and offices following cost-effective practices. Most recently, we achieved LEED® certification for our new Hangzhou, China, multidivisional facility and for a laboratory in Durham, North Carolina.
- We have conducted "treasure hunts" at multiple research and manufacturing facilities. At each facility, volunteers spent three days looking for opportunities to reduce demand for both energy and water. This has identified many project opportunities that have been successfully implemented.

### 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 has a combination green and solar-photovoltaic roof. The solar array comprising of 110 panels has generated almost 24 megawatt hours (MWh) of electricity. The

2,700 square feet of green plants provide insulation to the building and extend the roofs life by protecting it from ultraviolet (UV) light. In addition to these other 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.

- Several sites host solar arrays producing more than 5,400 MWh of energy annually
- One site hosts two 2 MW wind turbines that generate more than 11,700 MWh of energy annually

## Vehicle Fleet

More than 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 and the total number of miles driven annually
- Over the last few years, we have converted our U.S. Human Health sales fleet, which represents 28 percent of the global corporate fleet miles, from cars with 6-cylinder engines to cars with 4-cylinder engines

## 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 2013, the EPA has again recognized Merck with the Sustained Excellence Award. This is the eighth consecutive year we have been recognized by ENERGY STAR for excellence in energy management. For more information on our awards [click here](#).

## PERFORMANCE

<b>Global Energy Use and GHG Summary<sup>1</sup></b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
Total energy (trillion BTU)	26.6	26.6	26.1	<b>25.0</b>
Total greenhouse gas (GHG) emissions (million metric tons CO <sub>2</sub> e)	2.21	2.18	2.10	<b>1.98</b>
<b>Energy by Source, Scope 1 &amp; 2 (% of total)<sup>2</sup></b>				
Natural gas [Scope 1]	52%	54%	57%	<b>57%</b>
Fleet fuel [Scope 1]	14%	12%	12%	<b>12%</b>
Fuel oil [Scope 1]	2%	2%	2%	<b>2%</b>
Spent solvents [Scope 1]	0.1%	0.6%	0.7%	<b>0.6%</b>
Coal [Scope 1]	0.0%	0.0%	0.0%	<b>0.0%</b>
Purchased electricity <sup>3</sup> [Scope 2]	28%	28%	26%	<b>26%</b>
Purchased steam [Scope 2]	4%	4%	2%	<b>3%</b>

<sup>1</sup> In accordance with the Greenhouse Gas Protocol, prior-year data have been adjusted to add facilities that have been acquired and remove those that have been sold. Adjustments also reflect changes in methodology to ensure consistency from year to year.

<sup>2</sup> May not add to 100% due to rounding.

<sup>3</sup> Includes solar, wind and other renewables generated on-site where renewable energy credits have been sold.



<b>GHG Emissions Related to Employee Business Travel (metric tons CO<sub>2</sub>e), Scope 3</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
Air	105,498	113,962	115,149	<b>112,659</b>
Rail	631	607	90	<b>280</b>
Hotel	9,403	9,900	9,814	<b>5,975</b>
<b>Auto</b>				
Rental car	3,036	2,973	3,011	<b>3,149</b>
Employee reimbursable mileage <sup>1</sup>	-	-	9,158	<b>4,986</b>
<b>Total</b>	<b>118,568</b>	<b>127,442</b>	<b>137,222</b>	<b>127,049</b>

<sup>1</sup> No data available for 2009 and 2010.

Various projects discussed in the “Initiatives” subsection have allowed us to consume less energy and reduce our direct greenhouse gas emissions. The two most significant contributors to decreasing our GHG emissions are significantly lower fleet miles driven, moving to higher-fuel-economy vehicles, and shifting some power supplies from purchased electricity to on-site generated electricity.

We have reduced our direct GHG emissions, which include those from our facilities, our fleet, and those associated with the electricity we purchase by 10.4 percent since 2009, which meets our 10 percent reduction goal three years ahead of schedule. We are committed to continuously seeking energy reductions and are evaluating options for setting a new GHG reduction goal.

# WATER

**Our business, our suppliers, our communities and our customers depend on access to clean water.**

Merck’s global water strategy aims to achieve sustainable water management within our operations and our supply chain and, as part of our “Be Well” commitment, to reduce the impact of water-related illness. We do this through our partnerships, advocacy efforts and employee volunteerism.

To achieve these strategic objectives, we are focusing on five specific commitments:

- Understanding and reducing our operational water footprint
- Reporting publicly on our water use and goals
- Advocating for effective water policy
- Working with partners to address water needs in communities globally
- Encouraging and empowering our employees to be water stewards at work, at home and in their local communities

As we expand to meet the needs of emerging markets, 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 water risks are addressed in the following sections.

For information about **wastewater** and **pharmaceuticals in the environment**.

## INITIATIVES

**Merck is engaged in numerous initiatives worldwide to reduce our water use.**

- We have reserved approximately \$100 million for improvements in infrastructure to help achieve Merck’s water commitments at our operating facilities around the world
- By the end of 2016, all of our facilities will operate in alignment with the principles and objectives established in the Merck Water Standard. This includes assessing the impact of each facility’s operation on its local watershed, assuring compliance, and driving continuous improvement in how water is used and the quality of water discharged.
- Our Energy Center of Excellence considers the total cost of water in energy-project evaluations and drives best practices that conserve both energy and water. Examples include:
  - 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

- We have conducted energy and water “treasure hunts” at four of our research and manufacturing facilities. At each facility, volunteers spent three days looking for opportunities to reduce demand for both energy and water, resulting in the implementation of projects that have reduced costs, while conserving water and resources as well as reducing GHG and other emissions and water discharges.
- Our West Point, Pennsylvania facility is expected to save 600,000 gallons of fresh water by reusing wastewater streams. That site’s incinerator-emission control system is being upgraded with a wet scrubber to reduce acid gas emissions. The wastewater will be used to cool the combustion gases.
- New laboratories and offices follow LEED® criteria and performance. Where possible, this also applies to build-to-suit leased office facilities. We have achieved LEED certification for our new Hangzhou, China, multidivisional facility, and for our new laboratory in Durham, North Carolina.

## PARTNERSHIPS

**Merck 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 the UN CEO Water Mandate principles.**

The CEO Water Mandate endorses 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.

Merck is in the second year of a three-year partnership with the Safe Water Network, through which we are supporting efforts to bring sustainable water solutions to the rural poor in India. The initiative will provide safe water to 20,000–30,000 people by adding a dozen new sites to Safe Water Network’s existing field projects in the state of Andhra Pradesh. Through Merck’s support, Safe Water Network recently implemented an innovative education campaign in rural Indian communities that uses technology to communicate the importance of clean drinking water to their health.

We are also partnering with UN-Habitat and Coca-Cola on the innovative “Support My School” campaign, which aspires to increase access to clean water and sanitation facilities for school children across India.

## PERFORMANCE

### WATER USE (BILLION GALLONS)

Pumped water (surface and groundwater)	<b>2012</b>	<b>6.6</b>
	2011	6.3
	2010	6.6
	2009	6.7
Purchased water	<b>2012</b>	<b>2.5</b>
	2011	2.8
	2010	3.0
	2009	2.8
Total water usage	<b>2012</b>	<b>9.1</b>
	2011	9.1
	2010	9.6
	2009	9.5

Note: Previously reported data have been restated.

Merck has established public **goals** to reduce our use of water by 15 percent and 25 percent by 2015 and 2020, respectively. To facilitate achieving these goals, Merck has committed funding for improvements in reducing water demand and enhancing wastewater treatment.

At Merck, much of the water we use is for cooling utility systems in manufacturing plants that produce active pharmaceutical ingredients; these systems require large volumes of cooling water. Approximately 42 percent of the water we used globally in 2012 was for once-through non-contact

cooling, a process by which water is pumped into a plant, circulated through heat-exchange piping to cool processes, and then discharged. Our efforts to reduce this use of water are a major part of our goal realization strategy.

During 2012, Merck used 9.1 billion gallons of water versus 9.5 billion gallons in 2009. This reflects a 4 percent reduction in water use over this period. Approximately 73 percent of the total water we used was supplied from nearby surface water and groundwater resources, with the balance sourced from municipal water supplies. Many Merck facilities employ water reuse and recovery strategies including recirculation of water in cooling towers and condensate recovery. During 2012, we recycled or reused 3.3 billion gallons of water, which means we used 26 percent less freshwater than would have been used without these water recycling and reuse strategies.

## EMISSIONS, EFFLUENTS & WASTE

**Merck is committed to designing, operating and maintaining our facilities and manufacturing processes in a manner that protects people and the environment.**

The management of emissions, effluents and wastes from our facilities is important to the communities where we operate and it's the focus of most of our environmental permits and regulatory requirements. To minimize our environmental footprint, we design processes that avoid or reduce demand for 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 reduce environmental and human health impacts.

By tracking our emissions, effluents and wastes worldwide, we are able to identify the greatest opportunities to reduce our direct environmental footprint, evaluate the overall impact of new projects and ensure that we maintain reductions achieved through past initiatives.

Reducing emissions and wastes of all types begins with the original design of our pharmaceutical manufacturing processes and continues through their installation and operation. Through our **green chemistry** program we design new processes that use more benign chemicals and reduce generation of waste and consumption of energy, water and other resources. Our process development chemists have the green chemistry expertise and partners to support the development of more sustainable ways to synthesize our products. Our engineers look for projects to make our production more efficient.

More information is available on how we manage our **solvent use**, our **air emissions**, our **wastewater effluents**, our **waste prevention and management** and our **remediation program**, as well as data about our performance in these areas on the tab above.

## PERFORMANCE

Emissions, Effluents and Waste	2009	2010	2011	2012
<b>Manufacturing Solvent Use (metric tons)</b>				
Fresh solvents <sup>1</sup>	51,000	49,000	48,800	<b>46,000</b>
Recovered solvents	31,900	34,400	27,800	<b>24,400</b>
Recovered solvent use	39%	41%	36%	<b>35%</b>
<b>TRI Emissions (metric tons)<sup>2</sup></b>				
TRI emissions to air	341	287	217	<b>195</b>
TRI emissions to water	607	248	141	<b>149</b>
Total TRI emissions	948	535	358	<b>344</b>
<b>Air Pollutant Emissions by Type (metric tons)</b>				
Ozone-depleting substances (ODS) <sup>3</sup>	13.2	1.3	0.6	<b>2.9</b>
Nitrogen oxides (NOx) <sup>4</sup>	583	647	649	<b>640</b>
Sulfur oxides (SOx) <sup>4</sup>	114	77	78	<b>59</b>
Volatile organic compounds (VOCs) <sup>5</sup>	1,094	1,075	931	<b>807</b>
<b>Wastewater Characteristics (metric tons)</b>				
Chemical oxygen demand (COD) discharged to surface water	432	561	606	<b>280</b>
COD discharged to municipal treatment plants	6,113	5,000	2,761	<b>2,529</b>
Total COD discharged	6,545	5,561	3,367	<b>2,809</b>
Nutrients discharged to surface water	46	72	56	<b>58</b>

Please visit the [Air](#), [Wastewater](#) and [Solvent](#) sections for discussion of performance trends.

Emissions, Effluents and Waste	2009	2010	2011	2012
Nutrients discharged to municipal treatment plants	331	321	258	270
Total nutrients discharged <sup>6</sup>	377	393	314	328
<b>Waste Generated</b>				
Hazardous waste generated (metric tons) <sup>7</sup>	71,800	78,200	78,600	71,600
Hazardous waste recycled	27%	22%	30%	27%
Hazardous waste for energy & other recovery	24%	29%	27%	31%
Industrial waste generated (metric tons) <sup>8</sup>	36,900	41,900	55,000	53,600
Nonhazardous waste generated (metric tons) <sup>5</sup>	52,700	54,000	52,900	53,800
Nonhazardous waste recycled	47%	49%	54%	55%

TRI: Toxic release inventory

COD: Chemical oxygen demand

Previously reported data has been restated per our methodology, which includes adding facilities that have been acquired, and removing facilities that have been sold.

<sup>1</sup> Data includes purchases of solvents in bulk (tank trucks, railcars) and large containers (>100 liters).

<sup>2</sup> Includes worldwide facilities.

<sup>3</sup> Seven tons of emissions were associated with a single halon-based, fire-suppression-system event in Pennsylvania in 2009.

<sup>4</sup> Numbers have been adjusted to incorporate emissions from leased facilities and fleet vehicles.

<sup>5</sup> Data is estimated using conservative assumptions and factors, not measured or weighed.

<sup>6</sup> Nutrients = sum of total Kjeldahl Nitrogen + Nitrate-Nitrogen + Phosphorus.

<sup>7</sup> 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>8</sup> Industrial waste includes a variety of nonhazardous streams related to manufacturing that are either wastewaters that cannot go to the sewer or are sludges.

## AIR EMISSIONS

**We are committed to controlling air emissions from our facilities to reduce local, regional and global impacts.**

The largest source of air emissions at our sites is carbon dioxide (CO<sub>2</sub>) from the production and use of 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 (NOx) and sometimes sulfur oxides (SOx), depending on the fuels used. As we reduce the need for energy production through our efficiency projects, we will also be reducing the emissions of NOx and, in some cases, the emissions of SOx. For more information on our greenhouse gas emissions and energy use, [click here](#).

The largest source of air emissions from our manufacturing processes is due to the use of solvents. Emissions from solvent use are the primary component of both volatile organic compounds (VOCs) and Toxic Release Inventory (TRI) compound emissions to air. Merck uses various pollution control technologies to reduce these emissions, including conservation vents, carbon filters, thermal oxidizers, condensers and scrubbers.

Air Pollutant Emissions by Type (metric tons)	2009	2010	2011	2012
Ozone-depleting substances (ODS) <sup>1</sup>	13.2	1.3	0.6	2.9
Nitrogen oxides (NOx) <sup>2</sup>	583	647	649	640
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Previously reported data has been restated per our methodology, which includes adding facilities that have been acquired, and removing facilities that have been sold.

<sup>1</sup> Seven tons of emissions were associated with a single halon-based, fire-suppression-system event in Pennsylvania in 2009.

<sup>2</sup> Numbers have been adjusted to incorporate emissions from leased facilities and fleet vehicles.

<sup>3</sup> Data is 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. In addition to our greenhouse gas goal, which is the focus of the **Energy & Climate Change** section of this report, our green chemistry Process Mass Intensity (PMI) goal and our VOC reduction goal target reducing air pollutants.

VOC emissions decreased over 26 percent from the 2009 baseline year, in large part because of certain processes being either discontinued or moved to external manufacturers. Some of the reductions reflect more accurate emission-tracking methods. We will continue monitoring our progress toward the VOC goal until the end of 2015, because our performance could be impacted by the acquisition and sale of facilities.

Reductions in the use of distillate fuels and in the number of fleet vehicles have contributed to decreases in sulfur oxide (SOx) emissions, while nitrogen oxide (NOx) emissions have remained relatively constant, in part due to more extensive use of emergency generators during Hurricane Sandy-related power outages. Emissions of ozone-depleting substances (ODS) are the result of non-routine releases from temperature-control and fire-suppression systems, and can vary significantly from year to year. Emissions of ozone-depleting substances will be lower after the phase out of these substances by the European Union on January 1, 2015.

## WASTEWATER EFFLUENTS

**We are committed to providing effective wastewater treatment at our facilities to protect water quality in the regions where we operate.**

Merck has compound-specific criteria and procedures to assure that our factory discharges do not contain residual product that presents a risk to human health or the environment. In addition, our production facilities have, or are being provided with, technology to assure that active pharmaceutical ingredients are effectively treated to meet these standards. For more on pharmaceuticals in the environment, see the **Product Stewardship** section. We operate wastewater-treatment plants at many production and research facilities. Approximately 71 percent of the total wastewater from our manufacturing plants is treated on-site and then discharged directly to surface water. Where they have the ability to treat our production wastewater, we discharge to a local municipal wastewater treatment facility.

Chemical Oxygen Demand (COD) and nutrients like nitrogen and phosphorus are relevant 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. Merck has established public **goals** to improve



Wastewater Characteristics (metric tons)	2009	2010	2011	2012
Chemical oxygen demand (COD) discharged to surface water	432	561	606	280
COD discharged to municipal treatment plants	6,113	5,000	2,761	2,529
Total COD discharged	6,545	5,561	3,367	2,809
Nutrients discharged to surface water	46	72	56	58
Nutrients discharged to municipal treatment plants	331	321	258	270
Total nutrients discharged <sup>1</sup>	377	393	314	328

Nutrients = sum of total Kjeldahl Nitrogen + Nitrate-Nitrogen + Phosphorus.

<sup>1</sup> Previously reported data has been restated per our methodology, which includes adding facilities that have been acquired, and removing facilities that have been sold.

the quality of our operational wastewater discharges. The water quality goals focus on the discharge of COD, total nitrogen and total phosphorous.

For information about our water use and conservation program, see the **Water** section.

Because access to water in certain regions of the world is limited due to poor water quality, we have a goal of reducing our total discharge of water pollutants, measured as COD, by 15 percent and 20 percent by 2015 and 2020, respectively. Nutrients such as nitrogen and phosphorus, trigger water quality problems in many parts of the world. Our goal is to reduce discharge of these pollutants by 10 percent and 15 percent by 2015 and 2020, respectively.

To facilitate achieving these goals, Merck has committed funding for improvements in reducing water demand and enhancing wastewater treatment. We are in the process of executing approximately 56 water-focused capital projects globally and expect the projects to extend over the next four years. These projects will directly support our goals to improve water-use efficiency and reduce discharges of chemical oxygen demand (COD) and nutrients (nitrogen and phosphorus).

We report both on what we discharge to surface water, as well as what is discharged to municipal treatment plants, where additional treatment is provided. Our 2012 COD discharge of 2,809 metric tons was 57 percent lower than our 2009 discharge. The COD improvement is largely associated with

installation of wastewater treatment systems at a production facility in Latin America. Our nutrient load has also improved by 13 percent, with 2012 discharges totaling 329 metric tons. We will continue to monitor progress against these goals to the target year, because changes related to the acquisition and sale of our facilities could impact our performance improvement.

## WASTE PREVENTION & MANAGEMENT

**We prioritize our improvement efforts based on the internationally recognized waste hierarchy, which characterizes practices from most favorable to least favorable: prevention, reduction, reuse, recycling, energy recovery and disposal.**

We globally track and report our waste in three categories:

1. Hazardous: high risk or heavily-regulated waste streams that need to be either recovered, neutralized, treated or destroyed to address a particular hazard (e.g., toxic, pharmaceutically active, flammable, corrosive, radioactive, infectious)
2. Industrial: wastewater streams that cannot be sewerred and sludge-type wastes
3. Nonhazardous: all other wastes, excluding construction- and demolition-debris from large capital projects.

To make sure that our hazardous and industrial wastes are managed in an environmentally responsible manner, we have an approved list of waste facilities. Approved facilities must demonstrate that they have the systems, technology and practices to manage our waste streams responsibly and in compliance with all applicable requirements.

The primary component of our hazardous wastes is solvent from our manufacturing operations. The remaining hazardous waste is comprised primarily of research-related wastes and discarded product that needs to be incinerated or autoclaved, or otherwise treated to address exposure risks. At a number of our facilities, we are able to recover spent solvents and reuse them on-site in our processes. This reuse lowers our manufacturing costs because it reduces the amount of new solvent we need to purchase, and it decreases the amount of waste solvents we need to transport off-site for treatment as hazardous waste.

To reduce the amount of hazardous waste we generate, we have established a **green chemistry program and goal and a solvent use goal**. For more about green chemistry, [click here](#). For more about solvent use, [click here](#).

Waste reflects the efficiency of our business, so we track all wastes and look for ways to consume less and recycle more. This year, we have split our nonhazardous waste category into industrial waste and nonhazardous waste. The driver for this is to help ensure that our industrial waste streams are managed responsibly while we focus on improving our nonhazardous waste recycling rate. Construction and demolition debris

associated with large capital projects is excluded from our global tracking and reporting because it skews the data and increases year-to-year variability.

In 2012, Merck managed a total of 179,000 metric tons of waste from our operations, a 4 percent decrease from 2011. Of this, 71,600 metric tons were hazardous waste, a 7 percent reduction versus the prior year. The reduction is in large part a result of certain processes being discontinued or moved to external partners.

Of the hazardous waste we generated in 2012, 58 percent was beneficially reused in some way. Over 27 percent were spent solvents that were recovered

off-site and reused, either by Merck or by other industries. Another 31 percent was burned to generate power or as a source of energy in industrial furnaces, such as cement kilns. Of the hazardous waste that couldn't be recycled or beneficially reused, 36 percent was incinerated and approximately 3 percent (all non-liquids) was sent to hazardous waste landfills.

We have made public commitments to increase our non-hazardous waste recycling in the short term (2015) and to reduce our generation in the longer term (2020). We recycled 55 percent of the 53,800 metric tons of nonhazardous wastes we generated in 2012. We are evaluating and refining the programs at our facilities to drive waste reductions.

Waste Generated (metric tons)	2009	2010	2011	2012
Hazardous waste generated <sup>1</sup>	71,800	78,200	78,600	71,600
Hazardous waste recycled	27%	22%	30%	27%
Hazardous waste for energy & other recovery	24%	29%	27%	31%
Industrial waste generated <sup>2</sup>	36,900	41,900	55,000	53,600
Nonhazardous waste generated <sup>3</sup>	52,700	54,000	52,900	53,800
Nonhazardous waste recycled	47%	49%	54%	55%

Previously reported data has been restated per our methodology, which includes adding facilities that have been acquired, and removing facilities that have been sold.

<sup>1</sup> 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>2</sup> Industrial waste includes a variety of nonhazardous streams related to manufacturing that are either wastewaters that cannot go to the sewer or are sludges.

<sup>3</sup> Data is estimated using conservative assumptions and factors, not measured or weighed.

## SOLVENT USE

**The life cycle of solvents is a significant part of our operational and supply chain environmental footprint.**

Solvents play a key role in how we manufacture many of our products and how we clean some of our equipment. As a result, they are the primary component that we must manage and control in our emissions, effluents and wastes. Because of their significance in our business, we focus on designing our processes to use solvents efficiently and to minimize or avoid their use where practical.

We have an active **green chemistry** program to design our processes to use fewer solvents and other hazardous materials and to reuse and recycle the solvents we do use. For cleaning our manufacturing equipment, we seek to use water-based methods when they are equally effective. 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 generally work with external partners who either 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 to recover their energy value which reduces our energy costs and other emissions.

Solvents are the single largest source of air emissions from our manufacturing processes. Emissions from solvent use are the primary component of both

volatile organic compounds (VOCs) and Toxic Release Inventory (TRI) compound 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 permitted 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\*\*](#)
- [\*\*External Manufacturers\*\*](#)

The decrease in total solvent use is the result of lower production volumes of active pharmaceutical ingredients at Merck facilities and newer more material efficient processes. In 2012, we used recovered solvents for 35 percent of our manufacturing and cleaning needs.

We have a public solvent goal to reduce our consumption of new solvents by sustaining a high rate of recovered solvent use. Our goal is to use recovered solvents to meet 40 percent of our solvent demand in manufacturing by 2020. In 2012, Merck used 46,000 metric tons of new solvent and 24,400 metric tons of recovered solvent in our production processes and cleaning activities. By focusing on solvent consumption instead

of hazardous waste generation, we are placing the emphasis on process improvements, where initiatives have the best potential for cost savings.

## 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 were operating at a time when there were few regulations and little understanding of good environmental practices. As a result, Merck 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 remediation and environmental liabilities, including at formerly owned and operated sites, Merck spent \$17 million in 2009, \$16 million in 2010, \$25 million in 2011 and \$14 million in 2012. In addition, Merck is a potentially responsible party at 18 multiparty Superfund sites in the United States.

Solvent Use	2009	2010	2011	2012
Fresh solvents	51,000	49,000	48,800	46,000
Recovered solvents	31,900	34,400	27,800	24,400

## PRODUCT STEWARDSHIP

**Merck is committed to understanding the safety and environmental profile of the processes, chemicals and components we use to produce our products and to ensuring that potential hazards and risks are communicated and responsibly managed throughout the product life cycle.**

Ensuring that our products are designed, used and managed safely and in an environmentally sound manner is one of Merck's highest priorities. Our Product Stewardship program focuses on identifying and controlling potential safety and environmental hazards during the research, manufacturing, use and disposal of our products and the chemicals we use. We deliver on this commitment through actively pursuing initiatives to improve product stewardship, maintaining a highly trained and capable internal scientific community, and collaborating with other companies.

Our product stewardship efforts begin early in the development process and continue throughout the product life cycle. Merck scientists use green chemistry principles to reduce the environmental footprint of our products and our manufacturing processes. Extensive testing of our products is completed to identify and understand potential safety, health and environmental hazards. Safety and environmental risk assessments are completed throughout

the product lifecycle, which drives adjustments to processes, facilities and management systems to maintain a high level of protection. Sound engineering principles are employed in the design of production facilities to ensure manufacturing operations are controlled.

The program extends to the consumer through the design of packaging that protects the product during transport and strives to minimize its own environmental footprint. Programs are in place to ensure compliance with chemical regulations as products and chemicals are transported, imported and exported. We also provide support to customers concerning product returns, and guidance on the disposal of unused medicines.

## 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.**

To date, scientists have found no evidence of adverse human health effects from the trace levels of pharmaceuticals detected in the environment. Merck uses a risk-based approach to evaluate the environmental impacts of pharmaceuticals potentially entering the environment during their use, manufacturing or disposal. In most countries, an environmental risk assessment (ERA) must be conducted

and submitted to regulatory authorities before a product can be placed on the market. Each product's environmental safety profile must also be reassessed during periodic notification renewals. Because Merck markets products around the world, our products are assessed in a manner consistent with the most stringent applicable global regulations.

Merck supports the recommendations of the **SMARxT Disposal Program**, designed to educate consumers about how to dispose of medicines in a safe and environmentally responsible manner. SMARxT Disposal provides practical guidance on how to safeguard children and pets, and if necessary one's identity, when disposing of medicines.

## NANOTECHNOLOGY

**Merck supports the use of nanotechnology to develop innovative drugs, vaccines and consumer products that address the unmet medical and wellness 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.

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 to

workers and the environment are valid, and our existing controls are well suited to minimize exposure to employees and the environment.

Examples of how Merck is using nanotechnology:

- 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
- Merck Animal Health (Intervet): Nanoscale milling is used for the active ingredient in PANACUR® (fenbendazole) to produce a stable and more easily re-suspendable formulation
- Merck Consumer Health: Some Coppertone® products contain micronized zinc oxide, which provides improved broad-spectrum UVA/UVB protection from the sun's damaging rays, reducing the risk of sunburn, early skin aging and skin cancer. Nanoparticles of titanium dioxide (TiO<sub>2</sub>) and zinc oxide (ZnO) have been extensively studied, and current scientific data, including our own studies, demonstrate that skin contact with these particles does not represent a health concern.

## PACKAGING

**The packaging we use for our finished products and for our in-process materials must preserve the sterility, purity and efficacy of our products and prevent breakage. Our finished products must meet customer needs and, for some products, our packaging must be child-safe and tamper-evident.**

Without compromising these attributes, we have worked to eliminate packaging waste by reducing the number of unique pharmaceutical product images worldwide and by reducing packaging line scrap. As we continue to expand our packaging-improvement efforts, we are making sure that changes to our product packaging do not increase product discards, which would offset the environmental benefits of packaging improvements.

We have joined the **Sustainable Packaging Coalition (SPC)**, which is a project of **GreenBlue**, a nonprofit that equips business with the science and the resources to make products more sustainable. The SPC is an industry working group dedicated to a more robust environmental vision for packaging. GreenBlue has developed a simplified life-cycle assessment tool, the COMPASS Comparative Packaging Assessment, which helps us evaluate the environmental differences between packaging options.

For more information about waste reduction efforts at our facilities, [click here](#).

### Packaging Goals

Our near-term (2015) packaging goals are aligned with two priorities—reducing our use of polyvinyl chloride (PVC) and increasing our use of sustainable forest fiber. We have identified over 240 products with non-product contact PVC packaging components and are exploring options for eliminating or replacing them. Our fiber goal is to source sustainable fiber to meet at least 50 percent by weight of our office paper and finished-product fiber packaging needs. The fiber materials that qualify toward our sustainable fiber goal are either 3rd party certified (e.g., by FSC, PEFC or SFI) or made of 30 percent or higher recycled-content fiber. As of 2012, approximately 40 percent by weight of our office paper and finished-products fiber packaging qualify toward our sustainable fiber goal.

Our longer-term (2020) packaging goal has a broader scope that addresses the full range of ways in which packaging can be more environmentally responsible. This will include size reductions, use of renewable materials, recycled content, recyclability, reusability and take-back programs. Our Sustainable Packaging Community of Practice is working closely with internal business partners to define how we can make our packaging better for the environment, for customers and for the business.

## GREEN CHEMISTRY

**Finding safer and more efficient ways to make our lifesaving, innovative medicines is good for business and contributes to our “Be Well” mission.**

Our scientists and engineers are provided with training and tools that support and inspire greener process designs. Recently, we have increased our focus on biocatalysis innovations, which could potentially provide a more sustainable means of synthesis than more traditional chemistry approaches for manufacturing complex pharmaceutical compounds. Bioprocesses benefit from often superb selectivity and minimal by-product formation, thereby decreasing waste. Most importantly, biocatalysis processes typically run in one of the greenest of reaction solvents—water.

As part of our Green Chemistry program, we calculate the process mass intensity (PMI) of all new and high-production-volume pharmaceutically active products for human use. PMI reflects the number of kilograms of raw materials used to produce one kilogram of API (active pharmaceutical ingredient) as an indicator of process efficiency. Measuring PMI is a standard approach used by the American Chemical Society Green Chemistry Institute’s Pharmaceutical Roundtable to measure and benchmark process efficiency among member companies. This year Merck is establishing a public goal to reduce the PMI (weighted by mass) of our twelve highest-volume pharmaceutical products by 20 percent between 2009 and 2020.

Merck is also 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 support research on applying green chemistry and green engineering principles to pharmaceutical discovery and production processes. Since the establishment in 1996 of the annual Presidential Green Chemistry Award by the U.S. Environmental Protection Agency, Merck is the only pharmaceutical company to have been recognized with three awards.

For more information about our efforts to increase use of recovered solvents and prevent waste, [click here](#).

## CHEMICAL MANAGEMENT

**A comprehensive and effective chemical management program is critical to ensuring the safety of our employees, neighbors and facilities, as well as protecting the environment.**

We have procedures in place to manage the approval, procurement, inventory, receipt, transfer, storage and labeling 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 requirements applicable to our chemical substances and products is a top priority for Merck. We are tracking and fulfilling obligations associated with numerous existing and emerging chemical control regulations that require notification and registration of specific types of chemicals. In support of these regulations, our scientists complete assessments of the environmental and human health risks of our substances. We provide details on product use as well as risk-control measures that may be necessary in accordance with the requirements of applicable regulations.

For information about how we manage the environmental fate and effects of our own compounds and products, [click here](#).

# EMPLOYEES



**Because the talent, diversity and integrity of our people drive our success, Merck is 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. And we understand that the more that's asked of us as a business, the more we rely on our employees to advance our vision. We work hard every day to help employees succeed, by providing resources to improve their health and that of their families, and by providing more opportunities to get involved in the communities where they live.

Whether through a culture that values inclusion and encourages engagement, or through new programs and tools that advance our physical and emotional well-being, we are always working to make Merck an exciting place that the world's best people are proud to be a part of.

## KEY PERFORMANCE INDICATORS

EMPLOYEES	2011	2012
<b>Diversity &amp; Inclusion</b>		
Executive roles held by women <sup>1,2</sup>	35%	31%
Women on the Board	17%	17%
Underrepresented ethnic groups on the Board	11%	25%
Underrepresented ethnic groups in the workforce (U.S.)	29%	24%
<b>Well-Being</b>		
Response rate to Merck and MSD Voice Survey	63%	77%
Employees who completed the health assessment (U.S.)	58%	58%
Overall turnover rate <sup>3</sup>	14%	11%
Lost-Time Injury Rate (LTIR) <sup>4</sup>	0.30	0.24
Recordable Injury Rate (RIR) <sup>4</sup>	0.74	0.59

## Volunteerism

Employees who took release time according to the global policy on employee volunteerism <sup>5</sup>	11%	15%
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Volunteer hours <sup>5</sup>	213,000	221,000
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<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 incorporate all types of turnover, including restructuring.

<sup>4</sup> LTIR/RIR: Calculated per OSHA methodology.

<sup>5</sup> Figures are based on data collected, reported and estimated worldwide.



# POSITIVE WORK ENVIRONMENT

**A positive working environment is essential for employees to achieve their potential. It helps attract new employees to Merck and motivates them to stay.**

To be a leading healthcare company and a high-performing organization, we must make sure that our workforce operates at the best of its abilities. That's why we provide numerous opportunities for employee development and professional growth; competitive compensation and benefits; a focus on health and safety; and a vibrant approach to diversity and inclusion. Our efforts to build a positive and high-performing working environment are based upon the following principles:

- We are a unified company, with all employees sharing in the mission of improving global health
- 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

Merck's employee behavior standards are closely aligned with the company's business strategy and **Code of Conduct**. These seven Leadership Behaviors apply to every Merck colleague and support us in our efforts to consistently perform at a level of excellence, achieve our strategic goals and help us create and sustain our high-performance culture.

### Merck 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. This is so critical to the

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.

## Diversity and Inclusion

We believe that our human and organizational differences, when managed successfully, will make us a more innovative, agile and profitable company. By leveraging our differences, we can build and sustain a workforce and culture in which people are engaged and motivated to work at the highest level of their individual and team capabilities. For more information, [click here](#).

## Work-life Integration

Merck takes a comprehensive and holistic view towards 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 with visible or nonapparent disabilities, or employees who have religious obligations—indeed, all employees—benefit from greater work-life integration

offered at Merck. For more information, [click here](#).

### Wellness

A healthy and safe workforce is a more productive workforce. Merck 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. U.S.-based employees can also access our Employee Assistance Program, which provides free short-term counseling on health matters, legal consultations and financial counseling.

Worldwide, where feasible, we provide timely accommodations for colleagues with a disability by engaging in an interactive assessment process to determine an appropriate accommodation to meet their individual needs. We also engage in preventative measures as well as closely tracking accidents, injuries and illnesses, so that we can address problems promptly and work toward eliminating occupational injuries and illness.

For more information, [click here](#).

### Employee Giving

Merck employees around the world are actively engaged in their communities. The opportunity to do so benefits

employees, their communities and Merck. For this reason, Merck offers 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 2012, the Merck Foundation matched U.S., (including Puerto Rico) employee and retiree contributions, up to \$30,000 per donor, to eligible U.S. nonprofit organizations. (Starting in 2014, the match for retirees will be \$20,000 per year and in 2015 and beyond, \$10,000 per year.) The \$30,000 per year will remain the same for employees). Our support for employee contributions to worthy causes not only assists thousands of organizations, but also expresses our engagement 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. Merck considers active employee volunteering as a way to engage with individuals and groups in our communities and is expanding opportunities for employee involvement in local communities around the world.

[Learn more](#).

**Merck Blood Drives:** For employees who wish to give blood, Merck runs regular blood drives at many of its 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 Merck'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, Merck'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, other 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 **Merck's Code of Conduct**, they can contact the Merck Ombudsman and/or the Merck AdviceLine.

For more information on how we communicate and engage with our employees, [click here](#).

## PERFORMANCE

Positive Work Environment Summary	2009	2010	2011	2012
Number of employees (approximate)	100,000	94,000	86,000	<b>83,000</b>
Total compensation paid to employees/payroll, excluding benefits (US\$B)	NA	9	8.8	<b>8.3</b>
<b>Employee Categories Covered by a Standardized Performance Appraisal Process</b>				
Executives <sup>1</sup>	100%	100%	100%	<b>100%</b>
Middle management	100%	100%	100%	<b>100%</b>
Line supervisors	100%	100%	100%	<b>100%</b>
Non-managers <sup>2</sup>	100%	90%	93%	<b>93%</b>
<b>Turnover</b>				
Overall turnover rate <sup>3</sup>	5%	11%	14%	<b>11%</b>
Voluntary turnover rate	NA	6%	6%	<b>5%</b>
Avoidable voluntary turnover rate	NA	1%	1%	<b>1%</b>
Involuntary termination rate	NA	5%	7%	<b>5%</b>

<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.

NA: Data not available.

## TRAINING & EDUCATION

To create a high-performance organization and stimulate individuals to achieve their full potential, we offer a wide range of training and educational programs and resources.

The Merck Talent Philosophy serves as the foundation for employee development, confirms our commitment to our people and aligns to our business strategy.

Each of Merck's three main divisions—research and development, sales and marketing and manufacturing—as well as major support functions, such as finance—have established training organizations to build the required functional and technical skills.

To support these organizations, we sponsor a curriculum that builds leadership and management skills for all levels of employees globally. This curriculum includes:

### **iLead and the Leadership Development Curriculum—Where leaders come to learn**

The iLead website, and associated Leadership Development Curriculum, houses approximately 7,000 learning resources that employees at all levels can use to develop their leadership skills. Resources are available in the following formats: "On-Demand" web-based

modules, classroom programs, on-the-job development suggestions, articles, tools and video podcasts.

## Career Maps

With the launch of Career Maps in 2012, employees have increased visibility into the key competencies and skills for roles across the company. The competencies within Career Maps are linked to learning resources, allowing employees to focus their professional development on building and enhancing critical skills.

## 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.

## You & Your Success

This course aims to help employees early in their careers align personal and professional objectives with practical strategies for achieving both.

## Merck Sigma

Based on the Six-Sigma approach, this course is designed to simplify processes, maximize efficiency, reduce errors and minimize risks. Merck conducts regular Lean Six-Sigma and change-management training courses for employees, which lead to “Yellow Belt,” “Green Belt,” “Black Belt,” “Executive Belt” and “Change Execution” certification in Merck Sigma tools and methods.

## Advancing Employee Education

Merck’s U.S. Educational Assistance program encourages employees to learn more for their current assignments and/or to help them prepare for new assignments. The program includes financial assistance for relevant undergraduate and graduate education.

other companies—and appropriate to the markets in which we compete for talent.

At Merck, “Total Rewards” are the compensation and benefits programs we offer to employees. Our philosophy behind these programs is rooted in maintaining our competitive position in the market while providing a comprehensive package of compensation and benefits that supports our business, rewards individuals and aligns employees with the future needs of our business. Compensation plans are designed to compensate employees for appropriate efforts performed in compliance with Merck’s policies and procedures. Information on Merck’s global compensation and rewards program is available to all employees on the company’s portal.

## Benefits

In many countries, we offer health insurance, life and injury insurance, disability insurance, retirement income benefits and insurance for business travel. In the United States, employees also can opt for tax-free Flexible Spending Accounts for health spending and/or dependent care costs. In addition, in many countries where legally permitted, we extend healthcare and various insurance benefits to employees’ same-sex domestic partners and their partners’ eligible dependent children.

Worldwide, Merck offers retirement benefits that are competitive with our peers and general industry. In the United States, for example, we offer a defined benefit pension plan, as well as a 401(k) plan with company-matching

# COMPENSATION & BENEFITS

**In 2012, Merck paid a total of \$8.3 billion in payroll expenses, excluding benefits.**

Merck’s compensation programs are designed to recognize and reward employees for their accomplishments and the value they bring to the company. Merck is 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 they are competitive with those of

contributions. To assist in personal investment decision-making, all employees are offered 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 from age 40 (for certain employees, service before age 40 also counts) are eligible for subsidized medical benefits at retirement.

**Other Benefits and Services**

At certain Merck sites, including company headquarters in Whitehouse Station, New Jersey, employees can see a healthcare professional on-site—and usually on the day they need to—for such services as immunizations and treatment for minor aches and pains. At many of our sites, we also offer services such as cafeterias, oil change for automobiles, child care, dry cleaning, gyms and fitness classes. In the United States, our employees can bank through the Merck Employees Federal Credit Union, which offers competitive interest rates on savings accounts and lending. Merck established the Credit Union in 1936 to help U.S. employees during the Depression.

**WORK-LIFE BENEFITS**

**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, Merck has developed work-life integration programs that are innovative and that meet the needs of today’s talent and employee pool, while enhancing our reputation as an employer of choice.

**FLEX WORK ARRANGEMENT**

HOME	BENEFITS	DISCOUNTS
Child care and parenting, including Backup Care Connection®	Academics and Education, including Merck’s College Coach and Tuition Assistance Programs	Shopping
Finances		Entertainment
Pregnancy	Childcare and Aging, including Merck onsite Child Learning Centers	Travel
Emotional Health		Family
Being a mother	Daily Life for information on community resources and pet care	Home & Auto
Safety		Health & Wellness
		Financial Services

Merck takes 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 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 Merck.

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
- Higher 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**

Merck believes 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 arrangements policy and tools for several years in the United States, and 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 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' workload 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 workload 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 2 weeks.
- **Telework:** Employees perform 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 perform full-time job responsibilities working primarily as a home-based or mobile employee, with limited presence in a regular company facility.
- **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 Merck 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 the use of internal communications, employee networking

events, mentoring and leadership-development forums to maintain high levels of employee morale, enthusiasm and productivity.

Merck also has a vibrant website supporting work-life effectiveness, where U.S.-based employees can build awareness and take advantage of the wide variety of U.S.-based programs that Merck offers.

In addition, Merck offers enhancements to existing work-life integration programs to help employees manage work-life issues. They include:

- **Parental Leave:** One week of paid parental leave for the birth or adoption of a child for U.S.-based employees not subject to a collective bargaining agreement.
- **Free Commuter Transportation Service:** A free commuter/shuttle service from specific locations near Merck headquarters in Whitehouse Station, New Jersey, enabling employees to save on transportation costs and commute time while reducing their carbon footprint.
- **Summer Hours:** Providing greater flexibility, Merck offers most U.S. employees the opportunity to have reduced week hours during the summer. 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).

**Dependent Care:** Dependent-care services for U.S.-based employees at Merck are provided by LifeCare, through

which specialists provide subsidized care for children and adults as a backup. Employees are eligible for 15 days' usage per dependent per year for a nominal out-of-pocket fee. Employees can also take advantage of significant online resources.

**College Coach:** College Coach is an educational counseling service that offers a comprehensive menu of education topics and helps U.S.-based employees manage their professional and family responsibilities through workshops, expert counseling and Web-based assistance. 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:** Autism Spectrum Disorder (ASD) Program is for U.S.-based 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 five hours of personalized counseling and participation in one live webinar.

**Website for Exceptional Caregivers:** This U.S. website provides online caregiver support and online elder-care support programs on a range of topics and resources relating to children with special needs.

**Program for Elder Caregivers:** This program for elder caregivers includes free online educational courses that Merck sponsors for U.S.-based employees who have the responsibility of caring for an older relative. The program includes: Empower Online (an eight-week online

elder-care support program that offers tools for self-care and self-assessment as a caregiver) and Making Sense of Memory Loss (an online class for those who care for someone in the early, middle or late-to-final stages of memory loss due to Alzheimer's disease or related dementia).

**Adoption Assistance:** This program provides U.S.-based employees with reimbursement of up to \$10,000 for eligible adoption-related expenses.

**Employee Assistance Program:** This program offers U.S.-based employees access to confidential, professional assessment, referral, counseling and educational services.

## ENGAGING OUR EMPLOYEES

**Historically, employee engagement at Merck is much higher than the average at most U.S. companies.**

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 about 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 with 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 are generally 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, Town Halls and email communications from senior management, as necessary.

### Professional Networking and Collaboration

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.

We also enable employees to give their feedback to 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, which 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 Merck mission and goals. These encouraging and educational sessions cover topics such as the quarterly performance update, pipeline progress, customer stories and anticipated product developments.

As part of our company’s efforts to fully engage employees, drive a culture of innovation and execute on our growth strategy, in November, we launched a 72-hour Transformation Jam to leverage the wealth of ideas throughout our company to help us remove obstacles and foster greater speed, integration, innovation and empowerment. The Transformation Jam brought thousands of employees from over 80 countries together to post more than 16,000 ideas. In 2013, the company is rolling out a number of initiatives aimed at addressing the feedback and ideas employees shared in the Jam.

## Employee Surveys

As part of our mission to maintain a satisfying and productive work environment, Merck routinely surveys all

employees to learn their perspectives on the business and how we are responding to the needs of our workforce. We also conduct an annual employee opinion survey, the Merck/MSD Voice, with content based on Merck’s business needs.

Offered in 20 languages, the survey helps Merck 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 2012 results showed that employee confidence in Merck’s mission and future as a healthcare leader remains strong. Results indicate that employees are most engaged by supporting Merck’s reputation. However, employees indicate that engagement can be increased by

greater empowerment as well as clearly defined career paths.

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. Based on 2011 results, for instance, we ensure that the harmonization of our compensation program includes a corresponding career framework and a set of tools to help employees better plan their career at Merck.

## Other Resources for Employee Feedback

In addition to the employee surveys, our ombudsmen within Merck’s Office of Ethics provides an avenue for employees to raise concerns in confidence and, when necessary, take 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	2009	2010	2011	2012
Response rate to Merck and MSD Voice Survey	NA	64%	63%	77%
Percentage of employees 'fully engaged' or 'engaged'	NA	51%	49%	NA <sup>1</sup>
Engagement Index (favorable response rate)	NR	NR	NR	78%

<sup>1</sup> In 2012, Merck 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 Merck’s unique strategy.



In September 2012, 77 percent of Merck employees (more than 60,000 respondents) worldwide completed the Merck and MSD Voice survey. This participation rate is considered high by the independent organization that administered the survey on Merck's behalf, and is significantly higher than the prior year. As an incentive to complete the Voice survey, Merck donated \$1,000 to Join My Village, an innovative, online social change initiative to empower women and girls in the developing world, 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 \$83,000—more than 5 times the 2011 contribution.

In 2012, Merck 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 Merck's unique strategy. Although we used a different instrument, many of the findings were consistent with our past survey:

- High levels of confidence in Merck's strategy
- Strong core values and reputation

### Highlights from September 2012 Responses

Responses indicate that employees are engaged (78 percent) and highly energized (85 percent). What's more, employees are strongly committed to Merck's success—91 percent say they are willing to put in a great deal more effort than would normally be expected to help the company succeed.

Employees showed continued confidence in the Merck strategy, with 80 percent saying they understand how transforming the company will help us achieve our long-term strategy. In addition, 84 percent agree that Merck has the ability to become the best healthcare company in the world.

One of the highest scoring areas in this year's survey was in the Reputation & Trust dimension. Overall, employees believe Merck/MSD operates with integrity (84 percent), that everyone is held to the same standards of ethical behavior (79 percent), and that management's decisions are consistent with the company's core values (76 percent). An overwhelming majority of employees (94 percent) believe strongly in the products and services Merck provides.

However, when it comes to two key drivers of Merck strategy—Innovation and Customer Focus—employees pinpointed a number of opportunities

for improvement, ranging from empowerment and cross-company collaboration to speed of decision-making. On Customer Focus, only 67 percent of employees believe we do a good job anticipating new products, while 71 percent believe Merck/MSD is truly customer-focused.

Employees gave high ratings to their immediate managers on a number of aspects ranging from diversity and inclusion to being responsive to suggestions for change. Employees also say that more needs to be done when it comes to career development. While 71 percent agree there are sufficient opportunities for training to improve their skills, only 60 percent say they have a reasonably good idea of their possible career paths.

For more information on Merck's strategy and approach to ethics, [click here](#).

## WELLNESS

**Just as our company's business mission is to protect and promote health, Merck is committed to providing a safe and healthy workplace for its 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, Merck expects 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 programs**. 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.

Merck believes there are many benefits to this approach. First, health is a key ingredient of optimal workforce performance. Whether at work or at home, sickness or injury often can affect a person's ability to perform and contribute effectively. Because our business is health, we believe we must lead by example. We also believe that a constructive approach to employee health helps to recruit and retain top talent.

Finally, knowing which health issues most affect Merck's workforce can help us make the right investments to improve the health of our people.

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. Health and safety performance is an important consideration in our annual assessment of scorecard performance, which is tied to compensation.

In this section, we provide data on **Employee Health** and **Employee Safety**.

## EMPLOYEE HEALTH

**As a global healthcare company, Merck is committed to helping employees manage and improve their health and well-being.**

Merck's Global Employee Health department works closely with the Global Benefits department to provide a wide range of health and wellness services and programs.

These offerings cover the continuum of care, for those who are well, those at risk, those with acute or chronic illness, and those requiring complex or catastrophic care. Many of these services and programs are provided at on-site employee health clinics or through programs offered by vendors in conjunction with our benefits coverage. Health services and programs available to Merck employees include:

### LIVE IT

In 2011, Merck launched LIVE IT, an initiative that brings together all of Merck's U.S. health and wellness offerings under one integrated program and provides most U.S.-based employees and eligible family members with access to a broad suite of helpful health and wellness tools, programs and information.

In June 2012, the company introduced a new healthcare resource through LIVE IT called Health Advocate. Health Advocate is a program designed to help U.S.-based 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 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

Merck offers a health and wellness website to U.S.-based employees and their dependents, which features a health assessment, online interactive health tools and information, health coaching programs, and more. The website is designed to raise awareness about health issues 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.

Immediately after completing the online health assessment, 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 a lifestyle coach, who provides advice and encouragement and regularly monitors progress. Participation in the health assessment and other programs is voluntary and confidential.

In the fall of 2012, employees were encouraged to take the Personal Health Assessment (PHA) through LIVE IT. The PHA revealed that over 61 percent of employees would benefit from eating a healthier diet and better managing their weight. As a result, we looked for additional programs and resources that would offer employees a flexible, valuable and proven weight management program. As of May 2012, eligible U.S. employees can benefit from special savings

through Merck's Weight Watchers Reimbursement Program.

## On-Site

Many Merck clinics offer employees the opportunity for lipid, blood glucose and other laboratory services, including blood collection ordered by a personal physician. To support new mothers returning to work, clinics offer worksite lactation programs. "Lunch and learn" programs and site-based wellness activities, including walking and weight-reduction programs, are also available.

## 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 about proper nutrition. Employees also receive discounts for healthy food purchases. In addition, many Merck sites globally have cafeterias that offer healthy food options and nutrition education.

## Fitness Centers

Merck offers access to on-site fitness centers at several large U.S. facilities, as well as at other Merck/MSD 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.

## Occupational Health

As a global organization, Merck 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. The 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. In 2012, major progress was made in standardizing Merck occupational health procedures globally, including in Ireland, the United Kingdom, Mexico and China.

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

Merck'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 health care 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 non-work-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.

## Disease Management

Through its benefit offerings to U.S.-based employees, Merck offers a voluntary disease management program that offers confidential professional support for ongoing treatment and care for U.S. employees and their dependents with specific medical conditions. The goal is to help individuals achieve optimal health by providing evidence-based medical information and self-care guidance.

## Treatment Decision Support

Through Health Advocate, Merck also offers a resource for newly diagnosed U.S.-based employees to obtain information specific to their diagnosis. 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. In 2012, Merck introduced its Workplace EnABLEment program to ensure that employees with apparent and non-apparent disabilities are able to be accommodated, where feasible, to enable them to work to their full potential.

## Business Travel Program

Merck is 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 information on health conditions in the country of their destination, along with a traveler's guide, a travel kit containing over-the-counter medications they may need, any required immunizations, 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, 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 Merck sites around the world offer employees annual flu shots. In the United States, 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 Merck sites have also developed site-specific pandemic flu preparedness plans, employing a variety of countermeasures that focus on heightened awareness and tactical procedures.

## HIV/AIDS, Tuberculosis and Malaria Workplace Policy

Merck recognizes that infectious diseases present major healthcare burdens worldwide and pose an unprecedented challenge to people around the globe, including Merck employees, their families and the communities in which we operate. Three diseases alone—HIV/AIDS, tuberculosis (TB), and malaria—are pandemics that are responsible for approximately half of today's infectious disease mortality.

These diseases impose a significant and destabilizing social, economic and health burden on nations, communities and families, especially where there is inadequate access to treatment. The company believes that all of our employees should have access to prevention, care and treatment for HIV/AIDS, TB and malaria. Since 2005, we

have had in place a corporate policy provides benefits to our employees where local access to HIV TB and malaria prevention, care and treatment is inadequate.

**Smoking Policies**

The majority of Merck 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 to help participants quit the tobacco habit.

**Automatic External Defibrillator Program and Emergency Response**

At many Merck sites, on-site clinic staff respond to medical emergencies while also working with volunteers who help as 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**

Merck’s on-site clinics in the United States, 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

the Merck Medical Plan, applicable to most U.S.-based employees, participants may also receive their vaccinations at participating retail pharmacies without a copay.

**EMPLOYEE SAFETY**

**As a global healthcare company, Merck strives to provide a safe and healthy workplace.**

We are committed to providing a safe and healthy workplace for all of our employees around the world and to complying fully with all applicable country and local safety laws and regulations. We strive to eliminate work-related injuries, illnesses and unplanned events from our global operations through comprehensive safety programs that are part of an overall Environmental, Health & Safety (EHS) management system. The design of our facilities and processes, as well as our process controls, protection systems and emergency response capabilities, is a critical component of our overall effort to minimize the frequency and severity of safety and environmental incidents.

For consistency across the company, and to enable us to compare our performance with that of other multinational companies, we use the U.S.-based **Occupational Safety and Health Administration (OSHA)** injury and illness record-keeping criteria. Globally, we require that all recordable injuries, illnesses and incidents involving our employees be reported and investigated to determine their cause. We also require actions to be taken to prevent recurrence. We consolidate our injury and illness data

into a central system to analyze trends and determine appropriate responses. We also take steps—through internal safety alerts and bulletins—to communicate significant incidents, near-miss events, and conditions that could represent risks at other Merck operations and sites. To promote a strong safety culture, our manufacturing and research sites have active safety committees that implement awareness initiatives and address safety issues together with employees.

**Click here** for EHS governance, roles and responsibilities.

Select the Programs tab on this page for Employee Safety Programs.

Select the Performance tab on this page for our 2012 safety performance.

**PROGRAMS**

**Our employee safety programs and recent program initiatives are described in the following paragraphs.**

Our safety performance indicators, a discussion of performance trends, and our safety targets are available on the Performance tab above.

**Motor Vehicle Safety**

The goal of our Motor Vehicle Safety program is to reduce both the frequency and the severity of motor vehicle collisions globally, regardless of fault. As we do so, we anticipate a commensurate reduction in the injuries associated with those collisions, both for employees and for those members of the public with whom they share the road.

Implementation of global motor vehicle safety standards in all markets remains an area of focus for the company. In certain markets, Merck field-based sales employees operate two-wheeled vehicles that represent an increased risk of injury from vehicle collisions. In 2012, we introduced a comprehensive employee safety plan for the use of two-wheelers in select high-risk markets such as India, Vietnam and Thailand. The plan focuses on employee awareness and training, includes rules of operation, and mandates use of personal protective equipment.

See the Performance section for a discussion of our 2012 motor vehicle safety performance.

## Ergonomics

Ergonomics-related injuries and illnesses account for more than 20 percent of our global recordable injury rate. Our continued focus is on risk assessment and control, training, communication, and employee participation, to reduce the frequency and severity of ergonomics-related events. Our priority business areas are the manufacturing, research and sales environments where most ergonomic injuries and illnesses are related to manual material handling and repetitive motion. New staff resources will lead a global strategy to improve productivity while mitigating ergonomic risks and reducing injury rates.

See the Performance section for a discussion of our 2012 safety performance.

## Process Safety

Our process safety management (PSM) program identifies and addresses risks associated with our pharmaceutical, biological therapy, and vaccine production operations. This program applies not only to operations subject to process-safety regulations, but to all of our pilot plants and pharmaceutical, biological therapy and vaccine manufacturing operations worldwide. Early in product development, we begin testing our processes, products and intermediate materials to identify potential process-safety hazards. This testing effort continues throughout the product life cycle to assure that, at all stages, we keep safety at the forefront.

The PSM program drives the identification, evaluation and control of process-safety risks. Global PSM professionals work with operational and engineering personnel using structured techniques, such as hazard and operability studies, to review our operations. These reviews ensure that the facility, equipment, and operating controls and procedures effectively address the particular process hazards.

## Industrial Hygiene

Our industrial hygiene (IH) program protects the health of our employees throughout all stages of research and manufacturing by identifying chemical, physical and biological hazards, and assessing and properly controlling exposures.

To protect the health of our employees we apply a hierarchy of control measures that starts with seeking to eliminate or find a substitute for the

hazardous material or process. When this is not possible, we evaluate the feasibility of engineering controls such as containment controls or specific exhaust ventilation controls. Where engineering controls aren't feasible, we establish either work practice controls or the use personal protective equipment, including respirators. Existing processes and control strategies are formally evaluated to determine whether additional engineering and work practice controls are feasible. For new processes, appropriate engineering and operational controls are part of the design; those controls are then installed, verified, properly operated and maintained.

## Capital Projects Construction Safety

Merck has a strong construction safety program with a focus on educating and coaching our capital project construction contractors on safety fundamentals, and on driving continuous improvement in the safety culture of our construction partners. Our global engineering group has adopted Hearts and Minds™, a culture-based program that promotes safety as a personal value. The program has had a significant positive impact on our contractors' performance.

Merck uses the days-away, restricted and transferred (DART) rate for assessing our construction capital projects, instead of the lost-time incident rate (LTIR). DART includes restricted and transferred cases that are not included in LTIR and is deemed more appropriate for the construction safety program.

See the Performance section for a discussion of our 2012 performance.

## PERFORMANCE

### Our safety targets include:

- Achieve zero fatalities—our overarching safety goal
- Reduce companywide recordable and lost-time injury rates by 15 percent (2013 vs. 2012)

### Worker Safety

Global Safety	2009	2010	2011	2012
<b>Workplace Safety</b>				
Recordable Injury Rate (RIR)	0.92	0.79	0.74	<b>0.59</b>
RIR Percentage Change	NA	-14%	-6%	<b>-20%</b>
Lost-Time Incident Rate (LTIR)	0.41	0.32	0.3	<b>0.24</b>
LTIR Percentage Change	NA	-22%	-6%	<b>-20%</b>
Fatalities <sup>1</sup>	2	2	3	<b>1</b>
<b>Motor Vehicle Safety</b>				
Accidents Per Million Miles (APMM) <sup>2</sup>	10.97	10.4	9.9	<b>10.23</b>
<b>Capital Projects Construction Safety<sup>3,4</sup></b>				
RIR	NA	0.8	0.57	<b>0.78</b>
DART <sup>5</sup>	NA	0.48	0.16	<b>0.22</b>
Fatalities	NA	0	0	<b>0</b>

<sup>1</sup> All fatalities were transportation-related.

<sup>2</sup> APMM: Reflects both personal and business use of company-owned or -leased vehicles.

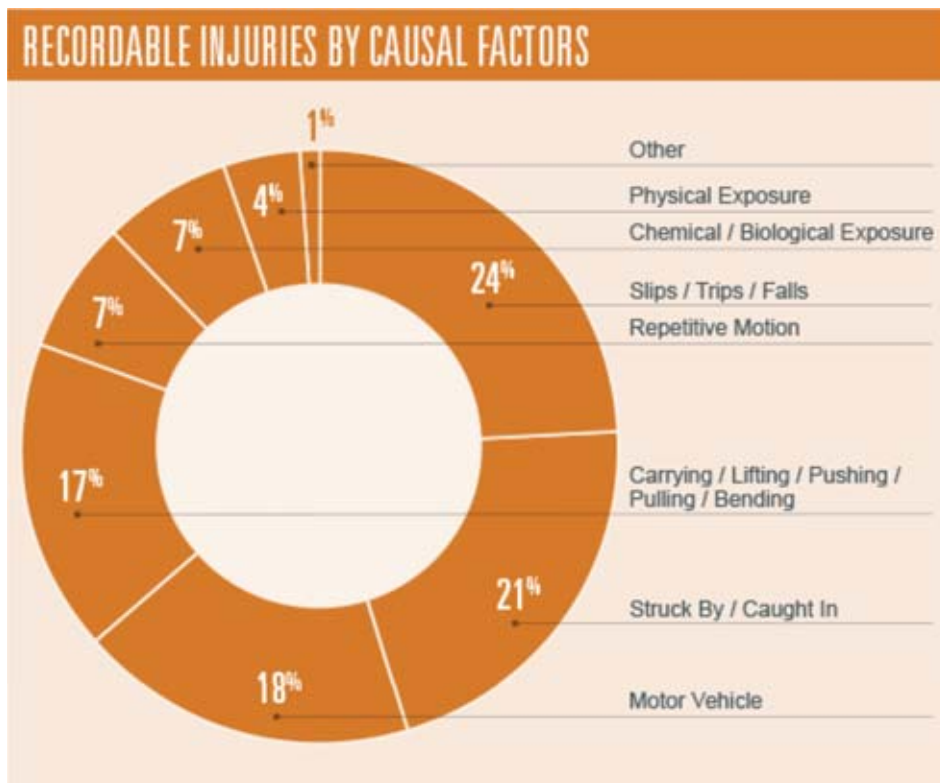
<sup>3</sup> LTIR/RIR: Calculated per OSHA methodology.

<sup>4</sup> Primarily reflects capital projects over \$100,000 managed by our global engineering group.

<sup>5</sup> DART: Days Away, Reassignment or Transferred calculated per OSHA 300 methodology.

NA: Data not available.

In recent years, more than 60 percent of our recordable employee injuries have been related to motor vehicle accidents, ergonomics issues, and slips, trips and falls.



### Workplace Safety Performance

Our workplace safety performance has improved in all areas. Specifically, our overall workplace injury and illness rate and our lost-time injury rate improved by 20 percent between 2011 and 2012. Also, the number of ergonomics-related injuries and illnesses has dropped by 22% from the prior year.

### Slip, Trip and Fall Performance

Although we reduced the number and severity of slip, trip and fall related injuries by 15 percent in 2012, they continue to

be a leading type of work-related injury, accounting for over 20 percent of all injuries. Slip, trip and fall prevention is a key component of Target Zero—our global injury reduction initiative. Additional efforts are being directed at reducing the number of slip and fall injuries among sales colleagues, which accounted for nearly half of the companywide slip, trip and fall injuries in 2012. We expect that the awareness programs and controls recently deployed in our manufacturing and research facilities will lead to further improvement.

### Motor Vehicle Safety Performance

While we saw a slight (3%) increase in the number of collisions normalized for miles traveled (accidents per million miles, or APMM) in 2012, the overall incidence of motor vehicle collisions normalized for the size of our fleet (% vehicles in accidents) improved slightly. Also, the number of employee injuries reported related to motor vehicle collisions in 2012 was lower than in 2011. The importance of motor vehicle safety was again demonstrated when, tragically, we lost one of our Merck colleagues in a motor vehicle accident in Thailand.

### Construction Project Safety Performance

Our 2012 construction safety recordable injury rate (RIR) of 0.78 and our DART rate of 0.22 are significantly better than the average recordable injury rates for private industry construction—an RIR of 3.9 and a DART rate of 2.1 based on U.S. Bureau of Labor Statistics.

We achieved zero recordable injuries on 95 percent of our 2012 projects. With over 6.4 million 2012 construction hours logged, only nine out of 166 projects experienced recordable injuries. In 2012, global engineering construction safety logged more than 43,000 safety observations (both corrective and positive). Observations logging is an important part of the safety program because it reflects worker engagement, emphasizes being observant, and identifies issues that could lead to injury events.



## DIVERSITY & INCLUSION

By focusing on people first, Merck has been and always will be inextricably linked to diversity.

We believe in the three pillars of global diversity and inclusion—talent, workplace and marketplace. Merck’s vision is to be the number one trusted and valued healthcare partner to the diverse patients of the world. That’s why our strategy promotes a consistent, focused, enterprise-wide approach, embracing global diversity and inclusion best practices that result in productivity and innovation.

We define diversity as a rich blend of organizational and human characteristics, backgrounds, experiences, capabilities and traditions. We define inclusion as providing a sense of belonging to all members of the organization so that they feel welcomed, respected and valued, and can contribute to the best of their abilities.

We believe that our wide variety of experiences, knowledge and skills, when managed effectively, make us a more innovative, agile and profitable company—able to quickly respond to the emerging global marketplace with critical business insights that reflect the needs of diverse patients and customers.

### Commitment from the Top

The single most significant driver of global diversity and inclusion at Merck resides at the very top—with Merck Chairman and Chief Executive Officer, Kenneth C. Frazier, who continues the company’s legacy and commitment, and views them as critical to innovation and our ongoing business success.

In August 2012, Merck joined with many other companies in filing an amicus brief with the Supreme Court in *Fisher v. University of Texas*. The plaintiff in this case challenged the role of affirmative action in university admissions processes. Merck’s amicus brief supports the continuing use of affirmative action because it is critical to the development of a diverse talent pool.

On page 12, the brief includes an example from Merck of the importance of a diverse employee population—obtaining Halal certification for GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant]—and it notes that “Merck has formed and supported many groups of employees who bring their specific cultural, ethnic, religious, gender and other demographic knowledge and understanding to bear on business challenges and opportunities.”

In November 2012, the NAACP Legal Defense and Educational Fund (LDF) presented Ken Frazier with its National Equal Justice Award, which recognizes individuals whose leadership and actions in business, government, law, culture and other fields have led to tangible advancements in human equality and justice.

In noting why Ken and Merck were selected for the award, the LDF said: “Merck is recognized as a global leader in medicine, scientific research and development. The company’s core values are driven by a desire to improve human life, achieve scientific excellence, expand access to their life-changing products and employ a diverse workforce that values collaboration.”

Merck also signed the AARP’s Work Reimagined Pledge in June, 2012. This demonstrated that Merck recognizes the value of experienced workers and represents a pledge to recruit across diverse age groups.

Other Merck Executive Committee members demonstrate their commitment to diversity and inclusion as well, including:

- Willie Deese, President, Merck Manufacturing Division, serves as board member of North Carolina A&T State University. He was recognized by Merck’s Lesbian, Gay, Bisexual and Transgender (LGBT) Community in 2012 for his advocacy for inclusion, diversity and LGBT rights at Merck. Willie also serves as the executive sponsor for Merck’s Veteran’s employee business-resource group.
- Bridgette Heller, President, Merck Consumer Care, serves on the board of directors for The ADT Corporation and has an extensive record of nonprofit service. She is currently a member of the national board of directors for Girl’s Incorporated, having previously served as board chair; a member of the executive leadership council; and a former member of the advisory board for the Center for

African American Studies at Princeton University. She has been recognized by several organizations, including Advertising Age, Essence and Black Enterprise, for her overall leadership and innovation in marketing. Bridgette was recognized by Merck's LGBT Community in 2012 for her openness and welcoming environment to hire a new VP and openly gay candidate. This was a big statement to the LGBT community at Merck. Bridgette is the executive sponsor for the company's Asian Pacific-Islander employee business-resource group.

- Cuong Do, Merck Chief Strategy Officer, serves as board member for Profectum Foundation, founded to help parents and practitioners become more adept and effective at working with individuals with special needs
- Adam Schechter, President, Global Human Health, serves as board member of Water.org. He serves on the board of directors for the European Federation of Pharmaceutical Industries and Associations, whose mission is to promote pharmaceutical research and development and the best conditions in Europe for companies to bring to patients new medicines that improve human health and the quality of life around the world. He is also 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 Merck's Women's employee business-resource group.

- Additionally, other Executive Committee members at Merck act as executive sponsors as follows;
  - Peter Kellog, Chief Financial Officer, executive sponsor for African Ancestry employee business-resource group
  - Richard DeLuca, President, Merck Animal Health, executive sponsor for Hispanic/Latino employee business-resource group
  - Michael Rosenblatt, Chief Medical Officer, executive sponsor for Interfaith employee business-resource group
  - Michael Holston, Chief Compliance Officer, executive sponsor for LGBT employee-resource group
  - Clark Golestani, Chief Information Officer, executive sponsor for Native/ Indigenous employee business-resource group

## Global, Diverse Talent

Through our diversity and inclusion strategy, we make sure that candidate pools are broad and diverse and that all applicants are treated fairly and equally. With a policy to promote equal opportunity globally, our management is responsible for enforcing it by making thoughtful and equitable efforts to correct imbalances in our global workforce.

We expect all Merck leaders to achieve key diversity and inclusion goals, and we use those goals to judge not only an individual manager's performance, but also division and corporate performance. To this end, we have developed

specific tools for defining, measuring and rewarding diversity performance, including functional affirmative action plans developed in accordance with legal requirements and diversity objectives.

## Inclusive Workplace & Leadership Behaviors

By actively promoting best practices, we work to create an inclusive work environment that enhances our employees' commitment to the company, increases employee engagement and productivity and helps to make us more competitive.

With this in mind, the company uses a comprehensive approach to make sure employees have personal and career development opportunities, build important stakeholder relationships throughout their career, learn new skills and hear the perspectives of the senior-most people in the company to broaden their insights and knowledge. Our employees also have the opportunity, through the nine employee business-resource groups, to offer their insights to make a positive impact on the company, whether it be suggestions regarding how to more fully leverage a product launch, enhance communications to a diverse segment of the market, or better understand customer needs.

We also maintain a strong emphasis on mentoring—both informal and formal—as a key to successful leadership development across the company. For example, in 2012 in the Asia Pacific Region, a mentoring framework was created to allow managing directors and

country leadership teams to mentor talent within the region. And we offer work-life integration programs throughout the organization to reflect the needs of today's talent and employee pool, to drive engagement and to enhance our reputation as an employer of choice.

## Global Marketplace

Merck recognizes that our customers worldwide are becoming increasingly diverse. To operate successfully as a global organization, and to reach our goal of achieving leadership among these customers, 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.

## Governance

The Global Diversity and Inclusion Center of Excellence (COE) oversees the company's integrated effort to include diversity in all business practices. This COE is led by the Chief Diversity Officer and Executive Talent Leader, who is responsible for creating the strategy for diversity and inclusion efforts at Merck and providing direction for the creation and management of tailored diversity initiatives that support our business priorities. The Diversity and Inclusion COE consults with our Office of Ethics and Human Resources to resolve workplace issues involving diversity, and

oversees compliance with local, state and federal regulations.

In 1983, Merck received its first Office of Federal Contract Compliance Programs (OFCCP) Exemplary Voluntary Efforts Award, which honors federal contractors that have demonstrated exemplary and innovative efforts to increase the employment opportunities of underrepresented ethnic groups, women, individuals with disabilities, and veterans. Since then, Merck continues to achieve compliance with the OFCCP guidelines under our functionally aligned affirmative action plans.

## One Merck Diversity & Inclusion Awards

Merck recognizes that our success depends upon the harmonious collaboration of our employees to achieve clearly stated business goals. That's one reason the company sponsors the Chairman's Global One Merck Diversity and Inclusion Awards in recognition of the outstanding commitment of employees to achieving diversity excellence.

The objective of the Diversity and Inclusion Awards is to recognize employees at all levels around the world who demonstrate an extraordinary commitment to integrate diversity and inclusion throughout our company, at both the individual and team level. In 2012, 28 finalists from Merck's global locations competed for honors in six categories. They were evaluated by a global judges' panel, which included 33 employees from multiple regions, divisions and levels in the company. The six categories of Global Diversity and Inclusion excellence were:

Individual Categories:

- Integrates and Collaborates
- Enhances Merck's External Image
- Demonstrates Personal Leadership
- Management Excellence

Team Categories:

- Enhances Merck's Image through External Outreach
- Supports Merck's Business through Inclusion

## Philanthropy

Providing support for the communities in which we live and work is an important value at Merck. In alignment with this value, the 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.

Our strategic alliances include:

- United Negro College Fund (UNCF)
- National Alliance for Hispanic Health
- NAACP Legal Defense and Educational Fund, Inc.
- The PhD Project
- Gay, Lesbian and Straight Education Network

## Partnerships

Whenever possible, Merck identifies and adopts best practices in the areas of diversity and inclusion. One avenue for achieving this has been through partnering with external organizations that promote thought leadership on diversity. Some additional external partnerships for Merck include:

- Asia Society
- Catalyst
- DiversityInc.
- Equal Employment Advisory Council
- Executive Leadership Council
- Healthcare Businesswomen's Association
- HISPA
- Human Rights Campaign
- Simmons College
- Tanenbaum Center
- USBLN
- Work and Family Institute

Since 2008, Merck and the faculty from The Center for Advanced Human Resource Studies (CAHRS) and the Employment and Disability Institute at the ILR School have participated in a series of research projects designed to identify leading employer practices/policies on the hiring, retention and advancement of people with disabilities and veterans.

## Employees with Disabilities

At Merck, we recognize that inclusion of people with disabilities can make lasting and significant contributions to our business goals.

We promote our commitment to colleagues who are differently able through our Workplace EnABLEment Program. This program assists with accommodations for employees. However, the program does not end there. Workplace EnABLEment also supports the evolution of a social culture at Merck by providing tools for sharing insights and targeted resources that support inclusive leadership.

Through these tools, where feasible, customized workplace accommodation and work-life support are provided to applicants and colleagues with apparent and non-apparent disabilities, including those actively employed at Merck, and those who desire to return to work from military or medical leave. Through the Workplace EnABLEment process, employees can directly initiate a request for an accommodation or ask questions about the process. The Workplace Accommodation Team will evaluate and, where feasible, facilitate employee requests and help with the employee's transition to work with a workplace accommodation.

Some examples of the types of accommodations afforded include:

- Structural considerations, including accommodations for ergonomic furniture, travel and hotels and widened office area access

- State-of-the-art adaptive technologies, such as voice recognition software and Braille readers and printers
- Flexible work arrangements and/or modified hours, if reasonable

## INITIATIVES

Merck has identified diversity and inclusion as a key growth strategy in recruiting, retention and leadership development programs.

Merck has had a substantial and sustained commitment to global diversity and inclusion as a strategic enabler of our vision to improve health outcomes for patients globally. By tapping into all employees' imagination and creativity, the company is unleashing a unique source of competitive advantage: its people.

### Business Insight Roundtable

Early in 2012, the company announced the launch of the Business Insight Roundtable (BIR). The Business Insight Roundtable is a powerful new resource in our commitment to saving and improving lives. In keeping with our focus on the needs of Merck patients, customers and colleagues around the world, this new diversity and inclusion governance structure will provide employees with better insights into our most pressing business priorities and better align our efforts to strategies that will help enhance our ability to outperform in the marketplace.

The Business Insight Roundtable is comprised of a group of nine senior business leaders from across Merck who

provide guidance to our nine Employee Business Resource Groups (EBRGs) to more fully integrate, leverage and align the multitude of local chapter Employee Resource Groups (ERGs) across the company. Ken Frazier, Chairman and Chief Executive Officer, along with our Executive Committee members, work directly with the BIR and EBRG leaders to identify opportunities to maximize and cultivate the diversity of our talent, enhance our corporate responsibility and glean business insights.

There are three priority areas for the Business Insight Roundtable and EBRGs:

- Talent and Inclusion
- Corporate Responsibility
- Business Insights

Under this new structure, all employees globally are able to get involved by joining an EBRG or local chapter ERG, and contribute by providing perspective and ideas on how to address the challenges facing the company today and for the future.

## Employee Business Resource Groups

Employee Business Resource Groups (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 the company's business goals, to network, engage in community outreach, participate in leadership development opportunities and provide business insights to Merck leaders.

The leaders of each EBRG are typically management-level employees who are nominated for a two-year period to serve as a leader for their demographic group at an enterprise level, act as an educational and cultural resource for other Merck employees and business groups and to serve as contact points for, and build key strategic relationships with Merck's external community. These EBRG leaders provide guidance to local chapter Employee Resource Groups (ERGs) that operate at Merck's 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 are also open to any full- or part-time employee.

Since the BIR and EBRG structure was launched in 2012 as the new governance and guidance mechanism over the ERGs which had previously been in existence, those previously existing ERGs have now each been aligned with an EBRG:

The Women's EBRG is aligned with the Merck 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 the Merck 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 the Merck Rainbow Alliance (MRA); the Asia Pacific EBRG is aligned with the Asia Pacific Association (APA); the Differently Able EBRG is aligned with the Merck Allies for Disabilities (AFD); and the Interfaith EBRG is aligned with the Merck Interfaith Organization (MIO).

During 2012, the Business Insight Roundtable and Women's EBRG, in particular, provided valuable insight to Merck's Marketing Team on [www.MerckEngage.com](http://www.MerckEngage.com), a free website designed to help healthcare professionals support their patients between office visits. Later in the year, the Business Insight Roundtable and African Ancestry EBRG provided insight to Merck's Consumer Care Marketing Team to enhance marketing sunscreen to those of African ancestry.

Collectively, the EBRGs educated their respective members in 2012 on health literacy and healthcare disparities. Over a dozen teleconferences were held, reaching close to 1,000 global employees across divisions. Participants were urged to increase their own health literacy, ensuring they are both providing details to medical providers and asking clarifying questions. [Learn more](#) about health literacy and healthcare disparities.

Merck's Hispanic/Latino EBRG and Merck Hispanos Organization maintain an active partnership with Hispanics Inspiring Students' Professional Achievement (HISPA). HISPA is an organization that brings role models (professionals) to grade-school children in order to support education in Science, Technology, Engineering and Mathematics (STEM) and Business.

## Recruiting

Merck has established several recruiting initiatives designed to seek and attract diverse job candidates:

### **United Negro College Fund (UNCF):**

Despite statistics suggesting that more than 50 percent of new entrants into tomorrow's workforce will be minorities, African Americans currently hold less than 3 percent of PhDs in biology and chemistry. To help address this imbalance, Merck 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 United States.

The UNCF/Merck Science Initiative (UMSI), was launched in 1995 with a ten-year, \$20 million grant from the Merck 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 has also provided \$3 million to support the summer intern stipends of the undergraduate Fellows since 1995.

### **National Alliance for Hispanic Health:**

In 2008, working with the National Alliance for Hispanic Health, Merck launched a program to promote science education, the Alliance/Merck Ciencia (Science) Hispanic Scholars Program. The program is designed to help Hispanic students achieve access in the pursuit of undergraduate degrees in science, technology, engineering and mathematics (STEM) related fields.

### **Veterans and People with Disabilities:**

In 2012, Merck created a dedicated staffing consultant role to focus on recruiting veterans and people with disabilities. This role focuses on the continued development of our external recruiting partnerships, such as Service Academy Career Conferences and the 100,000 Jobs Mission (see below). This consultant also partners with internal representatives from the respective Business Insight Roundtables to develop a recruiting strategy to attract and retain talent from these two constituencies.

In February 2012, Merck joined the 100,000 Jobs Mission ([100000jobsmission.com](http://100000jobsmission.com)), a growing coalition of employers who aim to hire at least 100,000 veterans by 2020. Merck was the first pharmaceutical member company to join and encouraged its industry colleagues to join the effort as well.

**American Association for the Advancement of Sciences (AAAS)** and the **National Technical Institute for the Deaf (NTID)**: Merck has partnered with the AAAS and the NTID since 2004 to recruit interns, with disabilities, in science, engineering, mathematics, computer sciences and other select fields of business. Merck also partners with the Emerging Leaders program managed by the National Business and Disability Council to hire interns and entry-level talent.

### **Career Opportunities for Students**

**with Disabilities:** The Company collaborates with Career Opportunities for Students with Disabilities (COSD) to help

more effectively prepare students with disabilities for recruitment in the industry.

Disability Mentoring Day is an effort to promote career development for students and job seekers with disabilities through job shadowing and hands-on career exploration. It provides an opportunity to emphasize connections between school and work, evaluate personal goals and explore possible career paths. Merck has participated in this event, hosted by the American Association of People with Disabilities (AAPD), for three years, and has provided more than 50 mentees with job-shadowing opportunities.

### **Diversity Conferences:**

Merck partners 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, Hispanics and the LGBT community. We are able to target diverse constituencies through our relationships with such organizations as the National Black MBA (NB MBA), the National Society of Hispanic MBAs (NSHMBA), Out for Work and The National Council of La Raza.

We also partner with several diversity engineering conferences, like National Society of Black Engineers (NSBE), Society of Hispanic Professional Engineers (SHPE) and Society of Women Engineers (SWE), in an effort to source qualified engineering talent. Moreover, we partner with several minority research science organizations—like The National Organization of Black Chemists and Chemical Engineers (NOBCChE) and the American Indian Science and Engineering

Society (AISES)—in an effort to increase the diverse talent in our Merck Research Laboratory division.

## Training & Leadership Development

Merck offers employees a variety of training programs and development opportunities that reinforce our commitment to diversity and inclusion. Courses such as Microinequities give employees an opportunity to learn about and avoid non-inclusive behaviors. To date, more than 22,000 employees have taken the Microinequities course.

In 2012, Merck’s “Inclusion as the How” web module was revamped and re-launched, and is available in 11 languages.

During 2012, numerous resources were introduced to improve Merck colleagues’ business acumen to help Merck achieve its objectives.

The EBRGs hosted multiple sessions and assisted in marketing both “Inclusion as the How” and business acumen sessions. These are just two examples of professional development for EBRG and ERG members, and Merck colleagues globally.

In 2011, Merck launched the Women’s Leadership Development Program, which is now part of our standard curriculum. The Program is designed to accelerate the development and readiness for more senior-level roles of director-level talent. A global initiative that Merck launched at Simmons College in Boston, Massachusetts, the program focuses on skills development, knowledge sharing and individual coaching to help position women as future Merck leaders.

The specific objectives of the program are to:

- Develop a talent pool to increase leadership diversity and improve business results
- Reflect the diverse nature of our customer base
- Increase retention of high-potential women leaders
- Have Merck be viewed as an employer of choice for senior women
- Create more opportunities for women’s career advancement

In 2012, approximately 100 women completed the Women’s Leadership Development program. Additionally, ten women attended the one-day Simmons Leadership Conference and just over 300 more employees benefitted from lunch-and-learn sessions around the world, using recorded sessions from that conference.

Additional 2012 investments reinforcing Merck’s commitment to Diversity & Inclusion include:

- Fifteen employees attended the Women’s Diversity Conference in National Harbor, MD
- Five employees attended the National Hispana Leadership Institute Conference
- Eight employees attended the Asia Society Conference
- Forty-nine employees attended the Leadership Excellence in Action Program
- Six employees attended the USBLN Conference
- Over twenty-five employees attended the Out & Equal Summit

PERFORMANCE

Diversity & Inclusion Performance	2009	2010	2011	2012
Women in the workforce <sup>1</sup>	50%	50%	51%	47%
Women on the Board	17%	17%	17%	17%
Women in executive roles <sup>2</sup>	25%	32%	35%	31%
Women on the senior management team <sup>3</sup>	32%	39%	42%	35%
Women in management roles <sup>4</sup>	41%	47%	43%	38%
Members of underrepresented ethnic groups on the Board	11%	11%	11%	25%
Members of underrepresented ethnic groups in executive roles (U.S.)	13%	15%	17%	16%
Members of underrepresented ethnic groups on the senior management team (U.S.)	16%	20%	15%	23%
Members of underrepresented ethnic groups in the workforce (U.S.)	24%	24%	29%	24%
Members of underrepresented ethnic groups in management roles (U.S.)	22%	25%	19%	18%
New hires that were female <sup>1</sup>	45%	51%	50%	45%
New hires that were members of underrepresented ethnic groups (U.S.)	30%	25%	25%	27%
Applications for diversity awards <sup>5</sup>	NA	380	NA	109
Countries represented in applications for diversity awards <sup>5</sup>	NA	34	NA	18

<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.

<sup>5</sup> Diversity & Inclusion Awards were not held in 2009 or 2011.

Note: Merck has publicly disclosed EEO-1 information since 1999. Our 2011 data is available at <http://www.merck.com/about/how-we-operate/diversity/2011EEO-1-diversity-brochure.pdf>.

NA: Data not available.



## RESTRUCTURING

**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 the legacy Merck and legacy Schering-Plough businesses.**

The Merger Restructuring Program was intended to support Merck’s strategic direction as a customer-focused, innovative and diversified global healthcare company, and enable the company to invest in key areas for future growth, including emerging markets, biologics, vaccines and consumer care.

As part of this latest phase, 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 and development sites and the consolidation of office facilities.

From the inception of the Merger Restructuring Program through December 31, 2012, Merck has eliminated approximately 22,400 positions through employee separations, as well as the elimination of contractors and vacant positions.

In October 2008, Merck announced a global restructuring program (the “2008 Restructuring Program”) to reduce its cost structure, increase efficiency, and enhance competitiveness. As part of the 2008 Restructuring Program, the company expects to eliminate approximately 7,200 positions—6,800 active employees and 400 vacancies—across the company worldwide. From the inception of the 2008 Restructuring Program through December 31, 2012, Merck has eliminated approximately 6,400 positions through employee separations and the elimination of contractors and vacant positions.

The company will continue to hire employees in strategic growth areas of the business as necessary, and will continue to pursue productivity and operational efficiencies and regularly evaluate its manufacturing supply chain capabilities.

While we believe these actions are necessary to support Merck’s competitive advantage, they are difficult decisions that will impact some of our colleagues, their families and local communities. We are committed to making these decisions in a responsible way, with respect, transparency and open, ongoing communication. Eligible employees affected by restructuring actions will be able to receive benefits and other services that may include severance pay, continuance of healthcare benefits and outplacement services.

For updated information on Merck’s restructuring program, please see our most recently filed quarterly and annual reports [here](#).

# ETHICS & TRANSPARENCY



## **AT MERCK, THE FOUNDATION OF OUR STRATEGY IS OUR UNWAVERING COMMITMENT TO VALUES AND INTEGRITY.**

All employees are expected to behave ethically and in compliance with the Merck 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 at Merck. The Global Compliance Training Series (GCTS) portfolio of required fundamental courses help build awareness of the Merck Code of Conduct. The GCTS includes Understanding the Merck Code of Conduct, Preventing Corruption and Bribery, Preventing Discrimination and Harassment, Protecting Trade Secrets, and several other courses that 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 the Carbon Disclosure Project, through the media, and through one-on-one stakeholder discussions.

## KEY PERFORMANCE INDICATORS

ETHICS & TRANSPARENCY	2011	2012
Employees trained on our Code of Conduct	90%	92%
Substantiated allegations to concerns/issues raised	65%	60%
Reported concerns regarding privacy practices, breaches of privacy, and losses of personal data and devices that were substantiated <sup>1</sup>	68%	23%

<sup>1</sup> Privacy concerns include all concerns escalated to the Merck Privacy Office about the company's privacy practices. Substantiated concerns are those that are determined to be inconsistent with Merck privacy standards or that involve loss of, theft of or unauthorized access to personal data.

# 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:

Merck’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 on a quarterly basis with each division to assess the effectiveness of its compliance program.



## OFFICE OF ETHICS

### **At Merck, how we operate is as important as what we do.**

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 law, 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 Merck employee 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.

Inappropriate behavior can never be rationalized as being in the company's interest. No act of impropriety advances the interest of the company; no act of impropriety will be tolerated.

The Merck 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. Now a part of the Global

Compliance Organization, the Office of Ethics is led by the Vice President, Office of Ethics and International Compliance, who reports to the company's Chief Ethics and Compliance Officer. The office is staffed by seven ethics officers who handle ethics concerns and ombuds matters. The office is supported by several ethics professionals who develop and manage ethics and compliance training, communication and reporting; and a number of administrative professionals support the work of the Office of Ethics staff. The 2012 budget for the Office of Ethics was \$2.5M.

The work of the Office of Ethics is further supported by a global team of professionals in the Global Compliance Organization who also carry out the global implementation of training, communications, reporting and investigations into potential compliance concerns at the divisional, regional and country levels.

### **Resources for Employees**

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. One is to contact (via toll-free telephone or intranet) the AdviceLine, which is run by an outside vendor. Employees can also contact the Office of Ethics directly, by telephone or email, to speak to an ethics officer.

The Office of Ethics is also responsible for managing the Merck 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 co-worker relations or fair treatment. About 40 percent of the calls that the Office of Ethics receives each year are classified as part of the ombuds process.

### **Addressing Misconduct**

It is Merck's 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 maintain 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 Merck substantiates allegations of ethical misconduct, it imposes any of a variety of disciplinary actions on those responsible, such as 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.

## PERFORMANCE

Ethical Business Practices	2009	2010	2011	2012
Employees trained in the Code of Conduct	NA	71%	90%	<b>92%</b>
Employees responded to disclosure statement on Conflicts of Interest form	NA	100%	98%	<b>99%</b>
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	652	725	873	<b>713</b>
Allegations involving noncompliance with company policy investigated	NA	NA	1,080	<b>1,012</b>
Substantiated allegations to concerns/issues raised	NA	11%	65%	<b>60%</b>
Employees separated related to substantiated corporate policy violations <sup>1</sup>	NA	NA	NA	<b>166</b>
Employees who received written warnings as disciplinary actions resulting from a substantiated concern <sup>2</sup>	NA	NA	NA	<b>232</b>

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.

## MERCK CODE OF CONDUCT

The Merck Code of Conduct, called *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.

Ethics and integrity make up one of our five core values, as outlined in our **mission statement**. These values are underscored in the company's Code of Conduct, *Our Values and Standards*, which was first developed and distributed to Merck employees in 1999, and was updated in 2002 and 2005. Edition III of the Code of Conduct was published in June 2011, and includes information on the Foreign Corrupt Practices Act (FCPA), which prohibits providing gifts and other benefits to gain business.

Our Code of Conduct, available in 26 languages, applies one standard of conduct to all employees worldwide, with ethical business practices serving as a key measure in all annual performance evaluations.

The values and standards embodied in Merck's Code of Conduct are designed to promote ethical business practices as our employees conduct activities in a continuously evolving business environment and 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 the Merck Code of Conduct or locate company resources to raise a question or concern, [click here](#).

## Ethics Training & Development

We provide training to all employees worldwide on our Code of Conduct to ensure awareness of our values and standards. In 2012, we introduced a new training program on the Code of Conduct that all employees were required to take. The purpose of this training is to provide guidance on the Code of Conduct, emphasizing the importance of raising concerns. This year, we are introducing an annual refresher training course on the Code of Conduct as an additional reminder to reinforce our values and standards. In addition to the Code

of Conduct training courses, we have other training programs that reinforce ethical business practices relating to specific topics, such as anticorruption, privacy, and preventing discrimination and harassment.

To assist in this effort, the Global Compliance Organization developed a training system that includes appropriate governance, clear procedures and documentation for training analysis, design, development, implementation and metrics on the number of trainings that are completed.

Ethics and integrity are key leadership competencies that are assessed as part of annual performance reviews. These core leadership competencies also play an integral role in our decisions about employee advancement in the company.

## Annual Ethics & Policy Certification

An important component of Merck's corporate compliance program is its 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, 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 Merck's 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 one percent of all employees, the company investigated each issue to ensure full compliance with laws, regulations and company policy.

## External Suppliers' Ethical Standards

We abide by strict ethical standards in our own operations—and we insist on equivalent standards from our suppliers. Merck has a Business Partner Code of Conduct that is based on Merck's Code of Conduct, *Our Values and Standards*, as well as the Pharmaceutical Supply Chain Initiative's (PSCI's) Pharmaceutical Industry Principles and the 10 principles of the United Nations Global Compact.

To download a copy of the Merck Business Partner Code of Conduct, [click here](#).

For more information on how we work with our suppliers to uphold ethical standards, please [click here](#).

# GLOBAL PRIVACY PROGRAM

**Merck has implemented a comprehensive global privacy program that promotes accountable privacy and data protection practices across our business and with our collaborative partners and suppliers.**

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.

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* 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 led by the Centre for Information Policy Leadership, with participation from privacy regulators, data protection authorities, business and academia. Merck established its system in 2010 and joined the Accountability Project in 2011.

Our system 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 implemented in sequence:

## 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 Merck 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

## MERCK PRIVACY VALUES

RESPECT	TRUST	PREVENTION	COMPLIANCE
We recognize that privacy concerns often relate to the essence of who we are and how we view the world, so our privacy program is rooted in the ethics of respect for people.	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 seek to prevent physical, financial, reputational and other types of privacy harm to individuals.	We aim to comply with both the letter and spirit of privacy and data protection laws that apply to our business and to how we process and transfer data globally.



- Collect and analyze data for each metric and evaluate program effectiveness, maturity and risks, and areas for enhancement, improvement and risk mitigation

Consistent with our privacy values, we continue to believe that trust is core to 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 concerns 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.

Merck 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 annually since 2001.

## Privacy Risk & Effectiveness

Consistent with our commitments to accountability and continuous improvement of our program, in 2011 we developed a quantitative approach to consistently evaluate privacy risk and determine the impact of control effectiveness on privacy risks across our operations. In 2012, we continued applying 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 utilized this quantitative approach to determine opportunities for improvement in specific areas and across our program.

## Transparency & Privacy

We aspire to be 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 developed and published 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 reference notices to Merck privacy practices on social media platforms through which Merck engages stakeholders such as Facebook and Twitter. In 2012, we began implementing our first privacy notices for Merck apps hosted on social media platforms, such as Facebook.

<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

**Merck is actively engaged in policy and advocacy efforts to further privacy standards and next-generation policy frameworks that promote responsible collection, use and collaborative sharing of data in support of healthcare, biomedical research and other innovation.**

Merck is 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. Merck is a corporate member of the International Association of Privacy Professionals, and we encourage development of privacy competencies through privacy training and professional certification of designated privacy leaders and stewards. Merck also participates 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 development of leading privacy practices. We also participate as a formal stakeholder in the [Center for Law, Ethics and Applied Research in Health Information \(CLEAR Health Information\)](#).

In 2012, we engaged in constructive discussions with U.S., European and Latin American regulators, scholars and business privacy leaders on Phase IV of the CIPL Accountability Project, including presentation of our approach to privacy risk assessment and piloting

of an organizational self-assessment tool for privacy accountability. The outcome of Phase IV was published in an [Accountability Self-Assessment Tool](#) released by CIPL in December 2012. In demonstration of our commitment to accountability as a key facet of our global privacy program, in 3Q 2012, Merck integrated the structure and standards of the *Accountability Self-Assessment Tool* into the management certification process that supports our annual privacy compliance verification.

## PERFORMANCE

Privacy Data	2010	2011	2012
Countries in which we conducted privacy compliance verification and risk assessment	87	137	137
Change in program control effectiveness (using 2010 as a baseline)	-	32%	37%
Substantiated concerns regarding privacy practices, breaches of privacy and losses of personal data <sup>1</sup>	92	229	68
Reported concerns regarding privacy practices, breaches of privacy and losses of personal data that were substantiated	78%	68%	23%
Privacy breaches requiring notification by Merck to individuals or government authorities	0	2	0
Privacy breaches requiring notification by third parties working for Merck to individuals or government authorities	2	3	2

<sup>1</sup> Privacy concerns include all concerns escalated to the Merck Privacy Office about the company's privacy practices. Substantiated concerns are those that are determined to be inconsistent with Merck privacy standards or that involve loss of, theft of, or unauthorized access to personal data.

## PUBLIC POLICY & ADVOCACY

**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.

In this section, 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. Merck 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 United States 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

Merck's 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. Merck's Global

Public Policy Leadership Team, headed by the senior vice president of Global Public Policy and Corporate Responsibility, 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 site.

### How Merck Engages

Merck engages in public policy debates primarily by communicating information to government officials and policy makers.

Our Federal Policy and Government Relations office in Washington, D.C., 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, Merck and its 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 the company. The Merck 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. In 2012, the Merck Action Network engaged Merck employees on three federal legislative issues:

- Urging Congress to protect the Medicare Part D program from the imposition of Medicaid-style rebates that would have had a stifling effect on pharmaceutical innovation
- Supporting swift passage of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA)
- Calling on Congress to repeal the Independent Payment Advisory Board (IPAB)

All Merck 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 United States, there are also important federal and state lobbying-registration and -disclosure laws with which Merck complies.

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 United States; 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 Merck's advocacy activities, we disclose costs associated with lobbying in the European Union and the United States. **Click here** for Merck's 2012 EU lobbying report. 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 United States, in compliance with the **Lobbying Disclosure Act**, Merck files 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 United States in 2012, the top five issues at the federal level for which Merck lobbied were:

- Federal deficit reduction
- Reauthorization of the Prescription Drug User Fee Act
- Defense of Medicare Part D
- Implementation of the Affordable Care Act
- Corporate tax reform.

In the United States in 2012, the top five issues at the state level for which Merck lobbied were:

- State implementation of the health benefit exchange component of the federal Affordable Care Act
- Budget support to help ensure patient access to medicines in state Medicaid and AIDS Drug Assistance Programs
- Continued funding for programs providing coverage for and access to immunizations
- Initiatives to address pharmaceuticals in the environment
- Proposals affecting patient access to specific over-the-counter medicines

In Europe in 2012, our advocacy focused on:

- Fostering a framework for a sound pricing regime across diverse EU economies
- Support for government vaccination and hepatitis C programs
- Standards for health technology assessment and health literacy
- Continuation of the Clinical Trial Directive, Transparency Directive and Water Framework Directive
- Implementation of the Cross-Border Healthcare Directive and the Pharmacovigilance Directive

Merck's senior vice president of Global Public Policy and Corporate Responsibility presents the company's advocacy priorities to members of Merck's 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

**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.**

Merck 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 Merck Employees Political Action Committee (Merck PAC) is completely funded by voluntarily contributions from eligible Merck employees. The PAC supports legislators from both major parties who understand and appreciate the work Merck does to discover and develop medicines and to make them available to the patients who need them.

Merck's corporate policy governing its corporate and PAC contributions can be found [here](#). In addition, we have developed the **Merck 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.

Merck has been ranked No. 1 for two consecutive years (2011 and 2012) 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.

Merck has a formal **PAC Contributions Committee** that makes decisions on spending for the Merck PAC. This committee also makes decisions on the 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 Merck policy and federal and state law, outside legal experts provide periodic guidance to the company on required disclosure of its political activities. We also perform periodic audits to assess and enforce compliance with Merck's policy governing its corporate and PAC contributions, and we require those individuals who recommend corporate political contributions in the United States to certify their knowledge of and adherence to our corporate Policy and Principles Governing Corporate Political and Political Action Committee Contributions.

As required by Merck policy and procedures, Merck's executive vice president and general counsel sends an annual report on the company's corporate political contributions for the previous year to the Merck Board of Directors. The report discloses contributions in the United States, 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 United States for dues greater than \$25,000. Merck's senior vice president of Public Policy and Corporate Responsibility submits a midyear report on corporate political contributions to the Governance, Public Policy and Corporate Responsibility Committee of the Board of Directors. For both reports, which also describe any changes in our policies, we invite comments and questions.

To improve access to information about Merck's corporate political and PAC contributions in the United States, the company semiannually posts its contributions, categorized by state, candidate and amount. We also disclose any contributions to committees known as "527 organizations."

### **Our Corporate Political Contributions**

In 2012, Merck spent a total of \$728,450 in U.S. corporate political contributions. These contributions supported the campaigns of candidates for state-level offices in 29 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. Merck 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 Merck 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 Merck.

To view a full listing of Merck's corporate and PAC contributions made within the United States in 2012, please [click here](#).

Merck also provides grants to organizations that represent elected officials to support public policy advocacy. Merck State Government Affairs reviews its grants and corporate memberships on an annual basis to decide which will be retained for the upcoming calendar year based on budget constraints and policy priorities. Groups that received Merck support in 2012 included, but are not limited to, the National Governors Association, the Council of State Governments, the National Association

of Latino Elected/Appointed Officials, the National Black Caucus of State Legislators, the National Conference of State Legislatures, and the National Hispanic 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 Merck's contributions made in Canada for 2012, please [click here](#). To view Merck's contributions made in Australia for 2012, please [click here](#).

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

Merck's vice president of State Government Affairs is co-chair of the **Conference Board Committee on Corporate Political Spending**, which is dedicated to accountability, disclosure, education and engagement on issues of corporate political activity. In 2012, the committee released a new report, **"Corporate Political Spending: Policies and Practices, Accountability and Disclosure."** Merck also has 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

**Merck 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—on both issues that are central to our business and those that, while important, are not directly material to our mission. With Merck 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.

Merck's executive vice president and general counsel sends an annual report to the Merck Board of Directors on trade association dues spent the previous year on lobbying and political activity in the United States 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 2012:

- **Pharmaceutical Research and Manufacturers of America (PhRMA):** Federal deficit reduction; the reauthorization of the Prescription Drug User Fee Act; 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 Korea-U.S. Free Trade Agreement
- **Biotechnology Industry Organization (BIO):** Federal deficit reduction; the reauthorization of the Prescription Drug User Fee Act; and defense of Medicare Part D



# HUMAN RIGHTS

**Human rights are an important element of Merck’s commitment to conducting our business in a responsible manner.**

Merck respects 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 Labor Organization’s (ILO’s) Declaration on Fundamental Principles and Rights at Work.

Human Rights of Our Employees	2009	2010	2011	2012
Worldwide employees represented by an independent trade union or covered by a collective bargaining agreement	NA	30%	31%	31%

NA: Data not available.

## Our Belief

Merck believes 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 Merck’s Global 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 to 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 Global Policy on Human Rights further strengthens our commitment in this area by defining specific roles and responsibilities to ensure that our policies are effectively implemented across Merck.

## Our Aim

We seek to prevent or mitigate adverse human rights practices that are directly linked to our operations, products or services.

## Our Commitment

Our commitment is formalized and manifested through various policies, including our Human Rights Policy, *Our Values and Standards* (Code of Conduct), our Global Labor Relations

Guiding Principles and our environmental governance and management systems. Specifically:

- 1. 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.
- 2. Health & Safety:** We provide a safe and healthy work environment in all of our operations, regardless of their size or function.
- 3. Freedom of Association:** We respect our employees’ right to freedom of association.
- 4. 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.
- 5. 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.
- 6. Diversity & Equal Opportunities:** We value diversity and strive to provide equal opportunities for all individuals.
- 7. Privacy:** We respect individual privacy expectations and protect personal information that we collect, use and disclose in connection with our business.
- 8. Access to Healthcare:** We respect the right to health for all people

and work toward expanding access to care.

9. **Customers:** We take into consideration the economic, social, geographic and cultural diversity of our customers as we develop and market our products.
10. **Business Partners:** We expect appropriate standards of conduct and respect for human rights, consistent with our own, from our suppliers, contractors, vendors and partners.
11. **Communities:** We respect the human rights of our neighbors in those areas where we have operations or facilities.
12. **International Standards:** We respect international standards on human rights and, where possible, contribute by working with partners.
13. **Non-Discrimination:** 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.
14. **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

Merck's Global Policy on Human Rights was developed with input from employees in key functional areas and from external stakeholders. It was approved by Merck's Executive Committee, which is also responsible for ensuring that governance processes are in place to provide oversight of the implementation and execution of the policy.

Merck's executive vice president/ chief ethics and compliance officer, who is a member of Merck's Executive Committee, advises the Executive Committee on human rights-related issues. Noncompliance with Merck's human rights policy is subject to escalation, investigation and remediation in accordance with internal corporate policies.

### Resources for Employees

Merck's 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 officer. Potential compliance violations 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. A new **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 **10 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 the company's Code of Conduct, *Our Values and Standards*.**

In addition to ***Our Values and Standards*** and our Code of Conduct training programs, Merck 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.

## **Mechanisms to Report Concerns**

Merck's Code of Conduct promotes the importance of maintaining a safe-to-speak-up environment and employees are required to report policy violations to ensure they 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 Merck Office of Ethics for assistance. In addition, 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 the Merck Ombuds Program, which offers a safe haven for U.S. employees to discuss work-related issues
- Merck has 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

**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).**

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.

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 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

**Merck aspires to be open and transparent about how it operates in order to earn and retain the trust and confidence of its customers, employees, shareholders and other important stakeholders.**

We will do this by proactively providing nonproprietary information to stakeholders about Merck’s business, how we operate, and decisions we take, which will help stakeholders make informed decisions about their interactions with the company and its products.

We will disclose information through a variety of mechanisms, including our financial disclosures, corporate responsibility reporting, participation in voluntary efforts such as the Carbon Disclosure Project, through the media, and through one-on-one stakeholder discussions. As part of our commitment to increase transparency, we also disclose information on our website about our business in the following areas:

## **Grants to Medical, Scientific and Patient Organizations**

Merck 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 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, we believe in broad disclosure of financial relationships between physicians and the pharmaceutical industry. In 2009, we began voluntarily disclosing all payments to U.S.-based healthcare professionals who speak on behalf of Merck or our products. As of June 2012, reports are posted quarterly reflecting payments and transfers of value to U.S.-based physicians including those engaged in clinical research activities. We include 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).

[Learn more.](#)

## **Payments to European-based Healthcare Professionals**

Merck will begin disclosing payments to European-based health care professionals and health care organizations in 2016 in alignment with the disclosure code announced by [The European Federation of Pharmaceutical Industries and Associations \(EFPIA\)](#) in July 2013. Merck played a supportive role in the development and adoption of the code by the EFPIA board.

## **Philanthropic Grants and Contributions**

Starting in March 2009, Merck began reporting all philanthropic grants made through the Office of Corporate Philanthropy and The Merck Foundation.

### **2013 Charitable Contributions**

[2Q 2013](#)

[1Q 2013](#)

### **2012 Charitable Contributions**

[4Q 2012](#)

[3Q 2012](#)

[2Q 2012](#)

[1Q 2012](#)

### **2011 Charitable Contributions**

[Charitable Contributions Report 2011](#)

### **2010 Charitable Contributions**

[Charitable Contributions Report 2010](#)

### **2009 Charitable Contributions**

[Charitable Contributions Report 2009](#)

**2008 Charitable Contributions**

[Charitable Contributions Report 2008](#)

**Corporate Political Advocacy and Contributions**

Merck is committed to participating constructively and responsibly in the political process. To improve access to information about Merck’s advocacy activities, Merck discloses its 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 makes corporate political contributions, primarily to the electoral campaigns of individual candidates.

To improve access to information about Merck’s corporate and political action committee contributions in the United States, Merck semiannually posts the company’s contributions categorized by state, candidate and amount. Merck also discloses any contributions to committees known as 527 organizations or organizations organized under the 501c(4) section of the U.S. tax code. Merck posts its contributions in Canada and Australia annually.

Since 2008, we have also been disclosing the portion of dues that major U.S.-based trade associations report to us as being used for advocacy and/or political activities where dues are >\$25,000. We encourage all trade associations to which we belong to publicly disclose their political activities as well. [Learn more.](#)

**Post-Marketing Requirements**

Merck recognizes 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 health care providers and patients remain informed about our products.

To inform the public about post-marketing activities, Merck 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 Web Site](#).

Below are the column headings and explanations of terms found in the PDF files below of Merck PMRs. The PDF files are searchable.

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 when Merck 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 if the requirement is Delayed or Terminated.
PMR Description	The description of the post-marketing requirement

**US Post-Marketing Requirements – July 2013**

**US Post-Marketing Requirements – April 2013**

**US Post-Marketing Requirements – January 2013**

**US Post-Marketing Requirements – October 2012**

**US Post-Marketing Requirements – July 2012**

**US Post-Marketing Requirements – March 2012**

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 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.

**Clinical Trials Disclosures**

Since 2007, we have registered at trial initiation all clinical trials in patients

in which treatment is assigned that the company sponsors and conducts worldwide on [ClinicalTrials.gov](http://ClinicalTrials.gov). We also disclose results from registered clinical trials of marketed products—regardless of outcomes—on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov). [Learn more.](#)

**Policies and Perspectives**

**Clinical Trial Ethics**

**Clinical Trial Registries and the Publication of Clinical Trial Results**

**Merck Guidelines for Publication of Clinical Trials and Related Works**

**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, Merck will voluntarily include the protocol and statistical analysis plan. Merck 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.

**Carbon Disclosure Project**

The Carbon Disclosure Project (CDP) is an independent not-for-profit organization working to drive greenhouse gas emissions (GHG) reduction and sustainable water use by business 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. Merck has been disclosing climate information via the CDP for a number of years and more recently has participated in both their Water and Supply Chain disclosures.

### **CDP Climate Change (2013)**

### **CDP Water Disclosure (2013)**

### **CDP Supply Chain (2013)**

### **Employee Diversity**

We consider diversity and inclusion integral parts of the culture we seek to build. 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.

**Learn more.**

## DISCLOSURE OF GRANTS INSIDE THE UNITED STATES

**Merck 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 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.

Merck discloses 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.

Merck updates 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**

Merck 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**

Merck 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 Merck and those to whom we provide support. Making our support public also enhances the visibility of Merck's commitment to help advance health and science.

### **Compliance with Local Laws**

In providing financial support to medical, scientific and patient organizations, Merck will comply with all relevant local laws and regulations.

As part of our commitment to these principles, Merck regularly reviews and updates 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 Merck employee is responsible for understanding and appropriately applying.

### **Disclosures in the United States**

#### **2013**

[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, Merck voluntarily began disclosing financial support to patient organizations in 2008, and in Canada in 2009.**

In October 2009, Merck 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 organization, 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. Merck was also 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.

Merck updates grants to medical, scientific and patient organizations annually for ex-U.S. jurisdictions.

### Disclosures Outside the United States

**Grants made in 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 Inc](#)
- [Netherlands Haarlem Europe](#)
- [Netherlands Oss](#)
- [Norway](#)
- [Poland](#)
- [Portugal](#)
- [Romania](#)
- [Russia](#)
- [Serbia](#)
- [Slovak Republic](#)
- [Slovenia](#)
- [South Africa](#)

[Spain](#)  
[Sweden](#)  
[Switzerland](#)  
[Tunisia](#)  
[Turkey](#)  
[Ukraine](#)  
[United Kingdom](#)

**Grants and Donations—  
2nd half of 2011**

[Algeria](#)  
[Austria](#)  
[Belgium](#)  
[Bosnia and Herzegovina](#)  
[Bulgaria](#)  
[Canada](#)  
[Croatia](#)  
[Cyprus](#)  
[Czech Republic](#)  
[Denmark](#)  
[Egypt](#)  
[Estonia](#)  
[Finland](#)  
[France](#)  
[Germany](#)  
[Greece](#)  
[Gulf](#)  
[Hungary](#)  
[Ireland](#)  
[Israel](#)  
[Italy](#)  
[Jordan](#)  
[Latvia](#)  
[Lebanon](#)  
[Lithuania](#)  
[Morocco](#)  
[Netherlands](#)  
[Norway](#)  
[Poland](#)  
[Portugal](#)  
[Romania](#)  
[Russia](#)  
[Saudi Arabia](#)  
[Serbia and Montenegro](#)

[Slovak Republic](#)  
[Slovenia](#)  
[Spain](#)  
[Sweden](#)  
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[Turkey](#)  
[Ukraine](#)  
[United Kingdom](#)  
[MSD Headquarters](#)

**Grants and Donations—  
1st half of 2011**

[Algeria](#)  
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[Bosnia](#)  
[Bulgaria & Macedonia](#)  
[Canada](#)  
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[Czech Republic](#)  
[Denmark](#)  
[Egypt](#)  
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[Gulf Market](#)  
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[MSD Europe](#)  
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[Saudi Arabia](#)  
[Serbia & Montenegro](#)  
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[South Africa](#)  
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[Sweden](#)  
[Switzerland](#)  
[Syria](#)  
[Tunisia](#)  
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[United Kingdom](#)

**Grants made in 2010**

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[Saudi Arabia](#)  
[Serbia and Montenegro](#)  
[Slovak Republic](#)  
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[South Africa](#)  
[Spain](#)  
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[Switzerland](#)  
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[Ukraine](#)  
[United Kingdom](#)  
 MSD Headquarters

## **Grants made in 2009**

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[Serbia](#)  
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[United Kingdom](#)

## **Grants made in 2008**

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[Lithuania](#)  
[MSP Europe](#)  
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[Norway](#)  
[Poland](#)  
[Portugal](#)  
[Romania](#)  
[Schering-Plough](#)  
[Serbia](#)

[Slovenia](#)  
[South Africa](#)  
[Spain](#)  
[Sweden](#)  
[Switzerland](#)  
[United Kingdom](#)

## PAYMENTS TO U.S.- BASED HEALTHCARE PROFESSIONALS

**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, we began voluntarily disclosing all payments to U.S.-based healthcare professionals who speak on behalf of Merck about our products and other healthcare issues.

In April 2012, Merck expanded its payments report to include post-merger speaking activities related to legacy Schering Plough, Merck/Schering Plough and Inspire Pharmaceutical products.

As of June 2012, reports are posted quarterly reflecting payments and transfers of value to U.S.-based physicians including those engaged in clinical research activities. We include 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 individual but rather support for the work that they are doing in the context of the research on behalf of the entity/institution.

Later, Merck will be implementing the Physician Payments Sunshine Act 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.

- **Payments made in 2012 (A-M)**
- **Payments made in 2012 (N-Z)**
- **Payments made in 2011**
- **Payments made in 2010**
- **Payments made 3Q–4Q of 2009**

### **The Importance of Engaging with Medical and Scientific Leaders within the United States**

Merck engages with healthcare professionals around the world to conduct Merck-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.

Merck also engages with healthcare professionals through the Merck Investigator Studies Program (MISP) where the 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 at:

**[www.merckiisp.com](http://www.merckiisp.com)**

Merck is very 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 result in meaningful, scientific exchanges that bring to Merck real-world knowledge and perspectives. These critical exchanges contribute to advancing both science at Merck and in the broader scientific community, and ultimately help benefit human health. Merck also engages physicians as speakers in the U.S. through Merck Medical Forums which are designed to deliver balanced medical and scientific information to healthcare professionals so patients have access to the medicines and vaccines they need and use these products correctly. These programs are structured consistent with PhRMA Code on Interactions with HealthCare Professionals and are conducted in compliance with FDA regulations, to help ensure that any Merck product information is presented in an appropriately balanced manner, with respect to potential benefits and risks.

## SALES & MARKETING

**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, consumer health or animal health.

Merck believes the best way to provide this 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 through our global Business Practices and 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.

Sales & Marketing Summary	2009	2010	2011	2012
Number of warning letters or untitled letters from OPDP <sup>1</sup> or APLB <sup>2</sup> in the U.S.	NA	0	0	1

<sup>1</sup> 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.

NA: Data not available.

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 (DCT)** advertising contributes to greater awareness about conditions and diseases, which can benefit public health by increasing the number of patients appropriately diagnosed and treated.

We believe that our marketing, sales and advertising activities make an important contribution to medicine by informing our customers about treatment options that are based on the most current scientific information and findings from rigorous clinical studies. We take our marketing, sales and advertising responsibilities seriously and evaluate these activities regularly to ensure they are consistent with laws and regulations and with company policies and values.

## INTERACTING WITH HEALTHCARE PROFESSIONALS

**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 Merck sales and marketing activities are conducted in accordance with our Guiding Principles for Ethical Business Practices with the Medical and Scientific Community. These principles are aligned with national regulations and worldwide industry codes, including the [International Federation of Pharmaceutical Manufacturers & Associations \(IFPMA\) Code of Pharmaceutical Marketing Practices](#) and the [World Health Organization's Ethical Criteria for Medicinal Drug Promotion](#). To learn more about our ethical business practices, [click here](#).

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 improvement 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 Merck

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 [MerckMedicus.com](http://MerckMedicus.com)

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.

Merck's robust anti-bribery/anti-corruption 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 United States 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 Merck's business. This applies to direct engagements (e.g., those driven by Merck) as well as indirect engagements (e.g., those managed through a third-party intermediary or partner).

Merck conducts anti-corruption/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)

Merck sponsors educational programs designed to share medical and/or health economic information. Merck's CME/CE Grant Program supports independent educational programs that we believe are among the most likely to improve healthcare professional performance and patient outcomes. 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 United States. 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 the company's Global Human Health Division in support of independent, accredited educational programs for healthcare professionals.

## Merck Medical Forums

Merck delivers balanced medical and scientific information to healthcare professionals within the U.S. through its Merck Medical Forums, which are conducted by external speakers. Speakers are selected based on their expertise in the subject matter. By attending a Merck Medical Forum, healthcare professionals participate in interactive learning on relevant 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 Merck 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 the product's potential benefits and risks and is consistent with approved product labeling.

Merck discloses 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

Merck engages 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. Merck ensures 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, Merck 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 a Merck product or for recommending a Merck product 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.

# INTERACTING WITH PATIENTS

**Merck believes 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.**

Such advertising is only conducted by Merck in countries where direct-to-consumer advertising is permitted.

Credible data demonstrate that DTC advertising can have a positive effect on patient health in terms of diagnosis, treatment and adherence to prescribed therapies.<sup>1,2</sup> Ultimately, the decision of what treatment, if any, a patient receives rests with the physician, following consultation and discussion with the patient.

Merck tries 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, Merck adheres to the letter and spirit of FDA regulations and guidelines governing DTC promotion, meets or exceeds all **Pharmaceutical Research and Manufacturers of America (PhRMA) guidelines on DTC advertising**, and follows a comprehensive set of internal policies and practices when engaging in DTC advertising within the U.S.

Merck 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 Merck's 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 Merck's medical and legal departments to ensure that the medical community's views have been considered and that the content is consistent with approved labeling

In addition, we include information on **Merck's 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 United States 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.

## Disease Awareness

There are concerns that some diseases are underdiagnosed and undertreated. Merck is committed to ensuring that healthcare practitioners, patients and caregivers are informed about conditions and diseases such as high cholesterol, high blood pressure, osteoporosis and asthma in which we have extensive knowledge and expertise. To answer questions about symptoms, diagnosis and potential treatment options, we sometimes provide grants to organizations with specific expertise in disease areas of interest to us. For a list of grants to medical, scientific and patient organizations, [click here](#).

## ETHICAL SALES & MARKETING PRACTICES

**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 Merck 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 Business Practices and Compliance Program. Merck's compliance program seeks to prevent and address inappropriate practices, and we evaluate our policies and practices as appropriate. Our practices are monitored and **compliance** 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 activity, 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 "Merck's Guiding Principles for Business Practices Involving the Medical and Scientific Community" are as follows:

- We provide current, accurate and balanced information about Merck products; we transmit sound scientific and educational information; and we support medical research and education.
- Merck 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.

- Merck employees and others speaking on Merck’s behalf may provide presentations specifically designed to provide the type of information that practicing healthcare professionals have indicated to Merck 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 Merck 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, Merck has 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 United States, 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:** Merck’s 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 company-wide 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:** Merck is 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 Merck employees on a worldwide basis and define the concept of fairness and balance in the communication of scientific/educational information. At Merck, 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 United States, 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, testing and certification on relevant policies and Merck'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 United States 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.

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. Merck has completed PhRMA Code certification in each of the last three years.

Other requirements of the Code have previously been incorporated into Merck's 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.

# CORPORATE GOVERNANCE

**Corporate governance structures are established to make sure corporations are accountable to their owners—the shareholders.**

In exercising our fiduciary duty to our shareholders, the company takes a long-term perspective on shareholder value that takes into account both the company's relationship with society as a whole and the interests of our many diverse stakeholders.

## The Board

Our Board represents and protects the long-term interests of the company's shareholders. The Board meets a minimum of six times per year and as otherwise needed to provide strategic direction and review our progress on a wide variety of measures. In overseeing the affairs of the company, including our governance, the Board has four **committees** to help fulfill our obligations to Merck shareholders.

Kenneth C. Frazier, Merck's Chairman and Chief Executive Officer, is the only Merck executive serving on the Board. William B. Harrison, Jr., serves as the Board's lead director. As lead director, Mr. Harrison confers with management on matters involving the Board and serves as a liaison to shareholders on investor matters. Mr. Frazier is not a member of any of the Board's committees;

only independent directors serve on these committees.

The Board has a balanced membership, representing relevant areas of experience, types of expertise and backgrounds. While it is Merck's philosophy that the full Board should consider and act on matters of significance, the committees assist it in carrying out its responsibilities and provide greater focus in key areas.

## Board Independence & Performance

Some shareholders believe that the Board should be completely independent. Our policy is that the Merck Board should consist of a substantial majority of independent directors, in accordance with the standard for independence established in our **Policies of the Board**. As noted above, Mr. Frazier is the only member of the Board who is not independent.

For additional details on our Board's leadership structure, please see page 15 of **Merck's 2013 Proxy Statement**.

## Corporate Management

Merck's chairman, president and chief executive officer Kenneth C. Frazier is accountable to the Merck Board. Merck's **Executive Committee**, an internal management committee of Merck executives who report directly to Mr. Frazier, meets monthly and as needed to review the company's progress and to attend to other matters affecting the company.

## Compliance

Merck's Board of Directors and senior management, including the company's chief ethics and compliance officer and Corporate Compliance Committee, oversee the company's global compliance program. Merck's compliance program is designed to maintain a culture that promotes the prevention, detection and resolution of potential violations of law or company policies. The program is dynamic, involving regular assessments to ensure the program is responsive to the company's evolving business and associated compliance risks. The Global Compliance Organization (GCO) is led by the executive vice president and chief ethics and compliance officer, who reports directly to the CEO. The chief ethics and compliance officer presents a quarterly report on the state of ethics and compliance at Merck to the Audit Committee of the Board.

## Environment, Health and Safety Governance

We are committed to full compliance with all environmental and employee health and safety laws and regulations, to engaging with our stakeholders concerning these issues, and to actively identifying, understanding and addressing potential environmental, health and safety (EHS) risks.

Merck's Executive Committee has established an EHS Council to provide enterprise-wide leadership and governance of our EHS compliance and performance. In addition to a corporate EHS policy, we are continuing to implement and sustain a robust

compliance management program that effectively oversees and manages EHS issues affecting the company, in order to meet our responsibilities and commitments and to improve our performance.

### Risk Management

Merck's Corporate Audit and Assurance Services group is accountable to the Audit Committee of the Board for assessing the adequacy and effectiveness of the company's control environment related to financial reporting and operating processes. This includes the appropriate management and oversight of key company risks, in accordance with our corporate policy on audit, control and risk management.

### Disclosure

We are committed to a policy of full, accurate and timely disclosure of all material information in order to keep shareholders and the investing public informed about the corporation's business and operations. Accordingly, we have established a corporate disclosure policy that articulates the standards, processes and governance for the company's disclosure practices. Pursuant to the policy, Merck's Disclosure Committee oversees the company's disclosure practices and disclosure obligations.

### Executive Compensation

Each year, the Compensation and Benefits Committee of the Board of Directors considers the outcome of shareholder advisory votes on executive

compensation when making future decisions relating to the compensation of the Named Executive Officers; which includes the Chief Executive Officer, the Chief Financial Officer and the three other most highly paid executive officers; and our executive compensation program and policies.

In 2013, shareholders continued their strong support of our executive compensation programs, with over 88 percent of the votes cast for approval of the "say on pay" proposal at the 2013 Annual Meeting of Shareholders. The Compensation and Benefits Committee believes that the voting results conveyed our shareholders' strong support of the philosophy, strategy and objectives of our executive compensation programs. Furthermore, we continue to engage in constructive dialogue with our shareholders regarding our executive compensation programs and policies to ensure that investors understand the manner in which our policies support our long-term strategic objectives.

During 2012, Merck, along with several of our pharmaceutical peers, engaged in thoughtful discussions with a group of shareholders that led to the Compensation and Benefits Committee's adoption of a set of principles for a new incentive compensation recoupment policy. This new policy will provide the Compensation and Benefits Committee with full discretion to recoup certain incentive awards in instances of material violations of company policy that cause significant harm to Merck. This policy will apply to senior executives who engaged in the misconduct that led to the material violation or who failed in their supervisory

responsibility to manage or monitor conduct or risks appropriately. The formal policy will be finalized later in 2013 and will become effective January 1, 2014. It will supplement our existing recoupment policy which is triggered by a significant financial restatement caused by executive fraud or willful misconduct.

Additional information on executive compensation can be found in the company's [2013 Proxy Statement](#).

### Governance of Our Research Agenda

The Research Leadership Team, headed by the president of Merck Research Laboratories (MRL), develops the divisional strategy, allocates resources and manages the research and development portfolio. The Research Leadership Team is made up of the heads of functional areas within MRL. Each area provides expert, efficient support of our drug candidates—ushering them from drug discovery through product-life-cycle management.

### Safety Monitoring

Merck has an efficient global pharmacovigilance organization that collects, medically reviews and evaluates and reports adverse experiences to global health authorities in compliance with global regulatory reporting requirements. Our global product safety teams within MRL are responsible for monitoring the evolving safety profile of our medicines and vaccines. In parallel, at the country level, local pharmacovigilance teams at our subsidiaries worldwide are responsible for ensuring that adverse experience information is collected

and reported to our global product safety staff at headquarters and to local regulatory authorities.

## Corporate Responsibility Governance

Merck's Office of Corporate Responsibility identifies corporate responsibility issues that are important to our business success and our stakeholders, and formally manages targets and performance for those issues. To learn more, [click here](#).

## PERFORMANCE

Corporate Governance Summary	2009	2010	2011	2012
Independent directors on the Merck Board	17	16	16	11
Percent of board members who are independent	94%	94%	94%	92%
Separate chairman of the board and CEO	No	No	Yes <sup>1</sup>	No
Lead independent director	Yes	Yes	Yes	Yes
Independent Audit Committee	Yes	Yes	Yes	Yes
Independent Benefits and Compensation Committee	Yes	Yes	Yes	Yes
Independent Governance, Public Policy and Corporate Social Responsibility	Yes	Yes	Yes	Yes
Number of board meetings held or scheduled <sup>2</sup>	16	9	6	7
Shareholder support of the advisory vote on executive compensation	N/A	N/A	96.93%	97.18%

N/A: Not applicable

<sup>1</sup> The roles of chairman of the board and CEO were separate from January 1, 2011 to December 1, 2011.

<sup>2</sup> Meetings were held in person or via telephone.

# GIVING AT MERCK



**HEALTH**



**EDUCATION**



**COMMUNITY**



**EMPLOYEE ENGAGEMENT**

To help improve the health and well-being of people around the world, Merck supports qualified nonprofit organizations and innovative programs that are finding solutions to key global challenges.

<b>Contributions Summary</b>	<b>2008</b>	<b>2009</b>	<b>2010</b>	<b>2011</b>	<b>2012</b>
Merck's philanthropic contributions (total cash and product) (US\$M)	821	923	1,158	1,270	1,696
Cash contributions (US\$M)	55	57	73	73	70
Product donations through U.S. Patient Assistance Program (US\$M)	174	188	323	301	559
Product donations for ex-U.S. programs and U.S. disaster relief (US\$M) <sup>1</sup>	592	678	762	893	1,067

<sup>1</sup> Includes the Merck Medical Outreach Program (including U.S. disaster relief), the African Comprehensive HIV/AIDS Partnerships, the MECTIZAN Donation Program, the GARDASIL Access Program and MSD division and subsidiary donations.

# GIVING PRIORITIES & GUIDELINES

**Philanthropy is an important component of Merck's commitment to corporate responsibility.**

Through our philanthropic programs, we have the ability to make a positive difference in addressing complex global health challenges; advancing STEM (science, technology, engineering, mathematics) education; and improving the quality of life in communities where Merck has a presence.

## Guiding Principles

Several key principles guide Merck's philanthropic investments and program portfolio. We seek to:

- Address critical global health needs and social issues where Merck can have meaningful impact
- 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

In 2012, Merck conducted a strategic review of its giving history and program portfolio. This review resulted in a refined set of giving priorities designed to strengthen the effectiveness and impact of Merck's philanthropy while simultaneously more closely aligning our programs with areas of global need in which Merck has significant expertise and capability.

While Merck will maintain its focus on health, education and communities in which the company operates, our philanthropic programs will now support a more narrowly defined set of strategic priorities.

- **Health** Improve healthcare quality and capacity as well as increase access to care for underserved populations in selected disease areas of global need—HIV/AIDS, hepatitis C, and chronic conditions such as diabetes and cardiovascular disease
- **Education** Enhance the quality of STEM education at the graduate and post-graduate levels, and contribute to advancing women and minorities in the sciences
- **Community** Provide financial support and share the expertise of Merck employees through grant and volunteer programs that address critical health and social issues in communities where Merck has a presence



## FOUNDATION

**The Merck Foundation—a U.S.-based, private charitable foundation established in 1957—is funded entirely by the company and is Merck’s chief source of funding support for qualified nonprofit charitable organizations.**

Since its inception, the Merck Foundation has contributed more than \$740 million to support initiatives that address important societal needs in a manner consistent with Merck’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.

In 2012, the Foundation conducted a strategic review of its giving history and program portfolio. This review resulted in a refined set of giving priorities designed to strengthen the impact of the Foundation’s giving while more closely aligning our programs with areas of global need, where Merck has significant expertise and capability.

While the Foundation will maintain its focus on health, education and communities in which the company operates, its programs will support a more narrowly defined set of strategic priorities.

### Health

We strive to improve healthcare quality and capacity as well as increase access to care for underserved populations in select disease areas of global need—HIV/AIDS, hepatitis C, and chronic conditions such as diabetes and cardiovascular disease—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 (CMAP)**
- **Children’s Inn at NIH**
- **Drexel University School of Public Health—Center for Hunger-Free Communities)**
- **EngenderHealth—Mobile Outreach Program**
- **FXB Center, School of Nursing, University of Medicine and Dentistry of New Jersey—Health Worker Training Program**
- **HIV Care Collaborative**
- **Merck Childhood Asthma Network (MCAN)**
- **Merck Vaccine Network—Africa**
- **Millennium Villages Community Health Worker Program**

- **Save the Children—Frontline Health Workers initiative**
- **Sesame Workshop—Food for Thought**
- **University of Kentucky Center for Poverty Research**

### Education

We seek to enhance the quality of STEM (science, technology, engineering, mathematics) education at the graduate and post-graduate levels, and contribute to advancing women and minorities in the sciences. Key initiatives include:

- **Alliance/Merck Ciencia (Science) Hispanic Scholars Program**
- **Girls, Inc.—Eureka Expansion Program**
- **Merck Institute for Science Education**
- **National Academy of Sciences—Strengthening Science Education**
- **United Negro College Fund/Merck Science Initiative**
- **University of Colorado—XSci Extraordinary Educator Experiences**

## Community

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We provide financial support and share the expertise of Merck employees through grant and volunteer programs that address critical health and social issues in communities where Merck has a presence. Key initiatives include: the Neighbor of Choice program, the Richard T. Clark Fellowship for World Health, Partnership for Giving (P4G) and Join My Village.

- **Join My Village**
- **Neighbor of Choice Program**
- **Partnership for Giving**
- **RTC Fellowship for World Health**

## PRODUCT DONATIONS

**At Merck, 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 **Merck Medical Outreach Program** is the primary mechanism through which Merck donates our pharmaceuticals, vaccines and consumer health products for humanitarian assistance in the developing world and in support of disaster relief and emergency response worldwide.
- The **Merck Patient Assistance Program** have provided Merck medicines and adult vaccines free to people who do not have prescription drug or health insurance coverage and who, without our assistance, could not otherwise afford them.
- The **Merck MECTIZAN® (ivermectin) Donation Program** is one of the most significant initiatives undertaken by Merck to help improve access to medicines in developing countries. Established 25 years ago, the Merck 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.

## GIVING 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 the Office of Corporate Philanthropy and the Merck Foundation are periodically audited to ensure consistency in our giving criteria and grant-making as well as adherence to compliance and transparency requirements.

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 three mechanisms:

The **Merck Foundation** 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. Established in 1957, the Merck Foundation is a U.S.-based private foundation funded entirely by Merck.

The Office of Corporate Philanthropy supports charitable programs through cash donations and employee volunteerism. These programs contribute not only to the health and well-being of people around the world, but also to Merck employees, our neighbors and others in communities where employees live and work and where the company conducts business. The Office of Corporate Philanthropy also coordinates Merck's disaster-relief assistance throughout the world.

The **Merck Medical Outreach Program (MMOP)** is the primary mechanism through which Merck donates its pharmaceuticals, vaccines and consumer products for humanitarian assistance in the developing world and in support of disaster relief and emergencies worldwide. The Office of Corporate Responsibility manages the MMOP, the **Merck MECTIZAN® Donation Program** (Merck Mectizan Donation Program) and vaccine-access programs in the developing world.

### Charitable Grants

We report the charitable contributions made through the Office of Corporate Philanthropy and the Merck Foundation on our **website**. Information provided includes the names of recipient organizations, program names and descriptions, and amounts of the grants provided. Merck updates this information quarterly.

# HEALTH

**As a global healthcare company, Merck believes it has 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.

In 2012, Merck conducted a strategic review of its giving history and program portfolio to refine our focus areas and strengthen the impact of future philanthropic investments. As a result, we will be narrowing the scope of our health philanthropy to concentrate on select disease areas of global need: HIV/AIDS, hepatitis C, and chronic conditions such

as diabetes and cardiovascular disease. Our future programming in these areas will focus on innovative ways to improve healthcare quality, capacity and access for underserved populations who are particularly burdened by these diseases.

## ASTHMA

### **Merck Childhood Asthma Network (MCAN)**

With funding from the Merck Foundation, **MCAN** 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.](#)

## DIABETES

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

With funding from the Merck Foundation, **Alliance** program partners are working 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 United States: Camden, New Jersey; Chicago, Illinois; Dallas, Texas; Memphis, Tennessee; and Wind River Reservation, Wyoming. [Learn more.](#)

## HIV/AIDS

### **African Comprehensive HIV/AIDS Partnerships (ACHAP)**

In 2000, the Merck Foundation/Merck and The Bill and 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 (CMAP)**

This partnership between the Merck Foundation and China's Ministry of Health is implementing a comprehensive program to address HIV/AIDS in Sichuan Province, China. **CMAP** focuses on developing effective approaches for delivering prevention, care, treatment and support services.

### **HIV Care Collaborative**

To help improve HIV care in the United States, the Merck Foundation launched a three-year 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.

**University of Medicine and Dentistry of New Jersey (UMDNJ)—PMTCT Training Program**

The **François-Xavier Bagnoud (FXB) Center’s** School of Nursing, at UMDNJ, and the Botswana Ministry of Health, with support from the Merck Foundation, are working to build capacity and clinical knowledge among clinician trainers tasked with providing district-level training to healthcare workers in Botswana. These healthcare workers are responsible for scaling up services in the following areas: prevention of mother-to-child transmission (PMTCT) of HIV; infant and young child feeding (IYCF); and early infant diagnosis (EID) of HIV. These services support the health-related needs of an estimated 42,000 women who deliver each year in Botswana, with a focus on the approximately 14,000 pregnant or recently delivered women (per year) with HIV and their HIV-exposed infants. To date, approximately 110 healthcare workers have been trained through this program.

**HEPATITIS C**

**Population Services International (PSI)—HCV Prevention and Capacity Building Program in Vietnam**

With support from Merck, **PSI** is launching a multiyear program in Vietnam to strengthen capacity in hepatitis C (HCV) prevention programming across multiple healthcare sectors. This program is designed 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.

**CAPACITY BUILDING**

**African Programme for Onchocerciasis Control (APOC)**

**APOC** was established in 1995 by the World Health Organization (WHO) to control onchocerciasis (river blindness) in Africa using Merck’s MECTIZAN® (ivermectin), a broad-spectrum antiparasitic medication that treats and prevents the spread of river blindness. In 2008, Merck committed \$25 million over eight years to the World Bank in support of APOC’s continued development of country-led river blindness efforts. APOC will operate through 2015 and intends to treat more than 100 million people each year in 19 African countries, working to prevent more than 40,000 cases of river blindness each year and eliminating transmission of the disease, where feasible. [Learn more.](#)

**BroadReach Institute for Training and Education (BRITE)—Management and Leadership Academy**

The Merck Foundation is supporting implementation of the **BRITE Management and Leadership Academy (MLA)** in Zambia. The MLA program teaches critical management and leadership skills to healthcare professionals in order to build and strengthen the capacity of their local healthcare systems.

**EngenderHealth—Mobile Outreach Program**

With a three-year (2011–2013) grant from the Merck 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 (SNNP) Region. In each region, EngenderHealth works in close collaboration with Ministry of Health 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.

During 2012, 42 family planning service providers received training to strengthen their counseling skills as well as their provision of mobile outreach services. An additional 69 health workers received basic training on effective family planning

methods, counseling skills, and demand-generation strategies to help create a welcoming and productive services delivery environment at mobile outreach sites. District reproductive health experts also provided basic training on family planning counseling, client education and referral to more than 330 Health Extension Workers (community-level providers) from mobile outreach sites. To date, the Mobile Outreach Program has provided services to more than 2,150 underserved women residing in some of the most remote districts in Ethiopia.

**Millennium Villages Community Health Worker Program**

Merck Foundation funding supports implementation of Columbia University Earth Institute’s **Millennium Villages Community Health Worker Training Program**, which helps strengthen community health services through a professional cadre of health workers across 14 sites in East and West Africa.

**Merck Vaccine Network—Africa (MVN-A)**

With support from the Merck Foundation, **MVN-A** training programs have worked to improve childhood immunization coverage and strengthen the capacity of vaccination programs in Kenya, Mali, Uganda and Zambia. Through collaborative partnerships, the MVN-A programs provided mid- to high-level immunization-program managers with training in vaccine management and immunization services. Merck Foundation support for MVN-A concluded in 2012.

**Save the Children Federation, Inc.—Frontline Health Workers Program**

A five-year (2011–2015) funding commitment from the Merck Foundation to **Save the Children** is supporting frontline health worker programs in Pakistan and Nepal as well as advocacy efforts for Save the Children’s Newborn and Child Survival (NCS) Campaign. 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, diarrhea, and complications of pregnancy and birth.

In Pakistan, Save the Children has laid the groundwork for the training of frontline health workers in some of the neediest areas of the country. With project staff and a strategic implementation plan in place early in 2012, the program conducted its first Essential Newborn Care and Case Management “train-the-trainer” program in Islamabad for Lady Health Workers (doctors, Lady Health Visitors, medical technicians, and district health department staff). Similarly, in two districts of Nepal, Baitadi and Bajura, the project initiated the development of an implementation plan and the clinical training of health facility workers on the Community-Based Newborn Care (CBNC Program). In the Baitadi District, a total of 186 health workers participated. Additionally, training on the CBNC Program was conducted for 74 health workers at the Baitadi Public Health Office and for 831 female community health workers at the local level.

Importantly, advocacy efforts advanced through the Newborn and Child Survival (NCS) campaign. A part of this campaign included the launch of Every Beat Matters™, a public service campaign with the Ad Council in the United States, to give Americans a concrete way to help achieve the goal of ending preventable child deaths through the training of frontline health workers.

**United Nations Foundation—Measles Initiative**

The **Measles Initiative** has contributed to saving lives by supporting 80 countries in delivering more than 1 billion doses of measles vaccine. Since 2008, Merck has supported the Measles Initiative with \$2.5 million in grants to advance disease surveillance in Africa and India.

**OTHER HEALTH GRANTS**

**CARE USA—Bridging Health and Education Programs for Children**

With support from Merck, **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 care (ECDC), which addresses child development, health, nutrition, child protection and economic empowerment. As part of this three-year 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. CARE

developed and implemented the first version of *The Essential Package*, based on a home-based model of services delivery in Africa, in the initiative's first year.

In the second year, CARE completed a community-needs assessment in India and Central America, and adapted *The Essential Package* to address those needs. For example, formative research in Chhattisgarh, India, revealed obstacles to maternal and child health, such as limited access to hospitals caused by distance or lack of physical infrastructure (e.g., roads and bridges). These findings informed the expansion of *The Essential Package* to include new materials and additional modes of service delivery suited to India. The project also coordinated with existing maternal health and nutrition programs, as well as with the country's Ministry of Women and Child Development and other partners. More than 200 anganwadi workers, 1,000 Panchayati Raj Institution members and 600 women's self-help group (WSHG) members have been trained on the importance of early child development and techniques to ensure children's future development and academic success.

In El Salvador, *The Essential Package* was adapted to meet specific community needs, particularly in areas with high levels of poverty, and implemented at five levels: national, community, child care settings, households and individual children. During 2012, the team trained 809 people in the Helping Babies Breathe (HBB) strategy, 486 people implementing the Neonatal Resuscitation Program (NRP) and 292 people working in the

STABLE program for the stabilization and care of premature babies. Activities related to health, basic sanitation and nutrition have been implemented in 49 direct intervention communities. Additionally, Save the Children in Honduras and at the Salvadoran Institute for Children and Adolescents have delivered more than 18,000 neonatal kits in 14 hospitals throughout the country. They have also trained 794 health workers from 28 hospitals on issues related to neonatal mortality.

#### **The Children's Inn at NIH**

Merck provided \$3.7 million through a public-private partnership for the initial construction of **The Children's Inn** on the campus of 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 Children's Inn has hosted more than 11,500 children from all over the United States and more than 80 other countries. The Merck Foundation helps cover The Inn's operating costs, and also provided a grant of \$3.7 million to build a 22-room addition to The Inn, completed in 2004, increasing The Inn's capacity to 59 rooms. Merck employees have also generously supported The Inn through personal contributions as part of Merck's **Partnership for Giving (P4G)** program.

The Merck 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 51 families from 11 U.S. states and Puerto Rico, and eight other countries.

#### **Sesame Workshop—"Food for Thought: Eating Well on a Budget"**

Through this multiyear initiative, **Sesame Workshop** helped families learn how to nurture their children's development through good nutrition, even with limited household resources. The *Food for Thought* program was developed during recent challenging economic times to encourage children to eat healthy foods and be physically active, and to provide resources for helping children and adults make healthy food choices. *Food for Thought* outreach kits were launched in December 2010 and continue to be distributed by Sesame Street. With support from the Merck Foundation and UnitedHealthcare, Sesame Workshop developed and distributed more than one million Spanish and English Outreach Kits that included "Super Foods," an original video featuring the Sesame Street Muppets. Kits were distributed through the National WIC Association, Feeding America, the National Head Start Association and Witnesses to



Hunger (Drexel University), as well as through hundreds of local partners in rural, suburban and urban areas, including schools and local food banks.

The Field Research Corporation conducted an independent evaluation in 2011 of the impact of the *Food for Thought* Outreach Kits. The findings revealed that the kits had had a significant, positive effect on families' knowledge, behaviors and attitudes about how to cope with food insecurity and maintain healthy eating habits. For example, three out of four families reported that, as a result of using the kit, they were now serving meals with more fruits and vegetables and having their children participate in shopping and meal preparation. Further, nearly all participants in the program found the kits helpful and were motivated to seek information and support in stretching their food dollars, and in making healthier food choices. By supporting children who experience hunger, and by providing their families with strategies for healthier eating on a budget, *Food for Thought* has helped to contribute to important behavioral changes among children and their families.

### **Drexel University School of Public Health—Center for Hunger—Free Communities**

With a multiyear grant provided by the Merck Foundation, Drexel University School of Public Health supports the **Center for Hunger-Free Communities**, which uses innovative approaches to treat and prevent child hunger and improve low-income families' access to healthy food. The Center's model program, *Witnesses to Hunger*, has enabled mothers and caregivers of young children who have experienced hunger and poverty to be in the forefront of advocacy as witnesses. These efforts have helped shape future approaches to addressing hunger and poverty beyond policy change. The Center plans to expand the *Witnesses to Hunger* model beyond Philadelphia, Pennsylvania; Boston, Massachusetts; and Baltimore, Maryland; to other communities throughout the United States. Merck's support has helped the Center build its capacity, expand its reach and outreach, and establish a reputable presence and impact for its continued work in helping women and their children who are living in vulnerable communities.

### **University of Kentucky Center for Poverty Research**

In 2012, Merck concluded its final phase of funding to the **University of Kentucky's Center for Poverty Research** for the project "Grandparents, Grandchildren, and Hunger in the U.S.: Assessing Food Insecurity in Multi-generational Households." The Center's final report yielded useful data and conclusions on links between food insecurity and family structure, adult poverty, negative health outcomes and low nutrition intake—all data that can be useful to public policy makers, program administrators and health professionals. This research resulted in the publication of four reports:

1. *A Portrait of Food Insecurity in Multigenerational Households*
2. *Family Change and Transition in Food Insecurity Among Multigenerational Households*
3. *Food Insecurity and Health Outcomes Among Multigenerational Households*
4. *Health, Heat or Eat? The Effect of Food Insecurity on Consumption in Multigenerational Households*

The findings from this important work can help to support nutritional assistance efforts for those households facing increased food hardship, especially those in multi-generational settings.

## EDUCATION

**Fostering the next generation of scientific leaders is a key part of Merck's overall commitment to science.**

For our business to be sustainable, it's essential for us to have access to the best-trained scientific minds around the globe. The relationships we establish with scientific leaders help promote the development and well-being of the communities in which we operate.

Merck has 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, with a focus on evidence-based approaches to learning and rigorous evaluation.

In 2012, Merck completed a strategic review of its giving history and program portfolio, including its participation in the area of STEM (science, technology, engineering, mathematics) education. As a result of this review, the Merck Foundation will be considering other critical needs in the STEM education arena, particularly in the advancement of women and minorities at the graduate and postgraduate levels. Beginning in 2013, we will be phasing down support of K-12 science education programs.

### K-12

#### Merck Institute for Science Education (MISE)

The Merck Institute for Science Education (MISE) was established in 1993 as a nonprofit organization dedicated to improving K-12 science education through teacher and program development.

**MISE** collaborates with teachers, school administrators and parents to improve science education in the classroom and to build consensus around the urgency for reform. The Merck Foundation has provided more than \$50 million to support MISE since its inception. MISE has become a model for how corporations can support the nation's STEM (science, technology, engineering, mathematics) education objectives and make a lasting difference in education reform by focusing on the specific goals of:

- Developing and delivering research-based professional-development opportunities to enhance teachers' knowledge and skills
- Providing access to high-quality curriculum materials and resources
- Building communities of teachers and administrators that are committed to strengthening science teaching and learning within and across schools and school districts
- Promoting local, state and national policies that support effective science education

The work is guided by a vision of science education in which inquiry is an integral and regular part of the learning experience for all students. Inquiry-based teaching and learning imitate the thinking and methods of scientists and help students explore and understand the natural world. The MISE approach to instructional reform rests on the premise that when students are engaged in legitimate inquiry, they develop a greater interest in and deeper understanding of science than is possible through more conventional instructional approaches.

MISE also takes a long-term, systemic approach to science education reform, which focuses primarily on professional development to enhance the knowledge and skills of educators. MISE works in partnership with the New Jersey school districts of Elizabeth, Hillside, Linden, Newark (the state's largest school district), Rahway and Readington Township, and the Pennsylvania district of North Penn.

MISE programs receive support from an advisory board composed of leading experts in research, evaluation and systems reform in science education. This Board provides MISE with access to research and feedback that reflects a national perspective.

#### MISE Transition

The Merck Foundation is shifting its focus within STEM education to address pressing needs at the graduate and post-graduate levels. Because of this change in focus, the Foundation will be

phasing down its support of MISE in grades K–12 over the next two years. The Foundation, in collaboration with MISE, has developed a transition plan to ensure that the work of MISE will continue with its partner school districts during this two-year transition period. Through the summer of 2014, MISE will fulfill its commitments, including the completion of its signature professional-development program, the Academy for Leadership in Science Instruction, and the continuation of the Peer Teacher Workshop. In addition, MISE will develop a suite of tools that will draw on 20 years of professional-development experience. These tools will be disseminated to its partners, as well as to the K–12 science education field at large, to advance continuous improvement in the teaching of science.

## Key MISE Programs

**The Academy for Leadership in Science Instruction** is a three-year professional-development program through which teachers, principals and district administrators are able to work in school- and district-based teams to deepen their understanding of the fundamentals of leadership and strong science instruction in classrooms. The program was launched in August 2008, with 420 educators currently participating.

**The Peer Teacher Workshop** is a weeklong professional-development program focused on building teachers' capacity to engage in inquiry-based science instruction. During the past 17 years, MISE has offered more than 350 workshops attended by more than 5,000 educators.

The Peer Teacher Workshop program has served as a model for professional development in Thailand. Known there as UPGRADE, this program is in its third year of implementation. Although MISE is no longer directly involved, local agencies have taken the lead and expanded the program. UPGRADE is active in 531 schools in seven provinces, with 338 Thai educators qualified as teacher trainers. The legacy of the work of MISE is most apparent in the 23 master teachers from IN-STEP, who are now key to the development and implementation of UPGRADE, often serving as mentors to the teacher trainers. To date, approximately 40,600 students have received science instruction from an UPGRADE teacher.

For more information, visit [MISE](#).

## Evaluation of MISE Impact

MISE has had a significant impact on the teaching and learning of science in its partner school districts, according to research performed over a 20-year period by the Consortium for Policy Research in Education (CPRE); Horizon Research, Inc. (HRI); and Westat.

The most recent reports from Westat focused on the impact of MISE's work on science instructional practices and the ways in which schools and districts support science instruction. These 2011 findings suggest that an increased number of teachers and principals know and appreciate the practices shown by research to be effective. Teachers reported being prepared to use these practices and to collaborate with their

peers to do so. Teachers also reported that they had access to the materials and equipment they needed to teach science.

Additionally, principals reported an increased appreciation of various instructional approaches for building students' understanding of science as a process. Because principals are the instructional leaders of schools, their understanding is crucial to supporting an effective science program.

## Public Policy

While MISE has concentrated its efforts in local school districts in New Jersey and Pennsylvania, it has also sought to have a broader impact on state and national education reform through its public policy and stakeholder efforts.

MISE played a leadership role in the revision of the current N.J. Core Curriculum Content Standards in Science, which guide planning and instruction for K–12 teachers throughout the state.

MISE has played a significant role in the forthcoming Next Generation Science Standards, the new national standards in science instruction. MISE participated as a reviewer of the 2012 National Academy of Science publication *A Framework for K–12 Science Education*, which served as a foundation for the standards. MISE staff also provided feedback to the state of New Jersey as official reviewers of the standards, providing support for its status as the lead state in creating and implementing the new standards.

Currently, MISE is providing support to the National Research Council (NRC)

as it embarks on a study of effective professional development for teachers. Previous NRC studies have compiled and provided insight into research that has had a significant effect on schools and organizations nationwide, including MISE.

### Other K–12 Programs

#### Girls Inc. Eureka Expansion Program

In 2012, Merck awarded a two-year, \$365,000 grant to Girls, Incorporated, to implement the Eureka program in Memphis, Tennessee, which engages young women in hands-on STEM educational experiences on a college campus. The grant served as a catalyst for additional national and local investment, making it possible to expand Eureka from four to 10 communities in 2012. Results of the pre- and post-program surveys indicate that after one-year of participation: about two-thirds of Eureka participants are planning to attend a four-year college; over 80 percent of participants have a more favorable view of math; and 95 percent feel comfortable in science class.

#### Liberty Science Center's Young Learner Lab

National science leaders note that young children need opportunities to explore science by participating in enriching programs that help develop literacy skills. The Young Learner Lab sessions at the Liberty Science Center in Jersey City, New Jersey, designed for children between the ages of 3 and 8, provide developmentally appropriate learning sessions on such topics as elementary geology, simple machines, local flora

and fauna, engineering, and architecture. Through Young Learner Lab sessions, children can develop early theories about scientific concepts that may stimulate their imaginative talk and play. Over time, children are able to reflect on their theories by evaluating evidence and constructing new theories. In 2012, Liberty Science Center offered 94 Young Learner Lab workshops, reaching 1,183 students and 323 adults.

#### Rutgers University Future Scholars Program

The Merck Foundation committed \$750,000 over five years (2008–2012) to support the Rutgers University Future Scholars (RFS) program. This program is designed to address the critical educational needs of promising but underserved students in New Jersey, by identifying at-risk, low-income and first-generation students before they enter the eighth grade. Merck's investment in the RFS program served as a catalyst for the university's acquiring additional funding from corporate, private and family foundations, thus ensuring the sustainability of the program.

Every summer since 2008, the program has selected 200 rising 8th graders—50 each from New Brunswick, Piscataway, Newark and Camden public schools—based on their financial need, academic records, teacher recommendations, and personal statements. Selection jump-starts long-term support that includes five years of "pre-college" preparation advising and instruction, tutoring, mentoring, on-campus summer activities and winter seminars with Rutgers faculty. By the end of the five-year grant term,

1,000 students will have been supported by the RFS program.

Nearly 100 percent of RFS participants have been retained for each cohort, excluding those who have moved out of state. Scholars who have relocated within the State of New Jersey are currently still in the Program. In association with the Rutgers School of Social Work, a transfer coordinator has been charged with facilitating the participation of the out-of-district scholars in RFS program activities. In addition, 100 percent of the scholars currently enrolled in the program are "on target" for high school graduation and expected to enroll in a post-secondary-education degree program. Should the RFS students qualify and elect to attend Rutgers University, they receive a four-year, tuition-free education.

#### Sesame Workshop Education and Outreach Programs in China

Sesame Workshop, the nonprofit organization behind *Zhima Jie (Sesame Street)* in China, is responsible for a number of educational initiatives in that country.

In 2010 Merck awarded Sesame Workshop a two-year, \$2 million grant to create the TV series *Zhima Jie's Big Bird Looks at the World*, which aims to foster children's natural curiosity about their world and science and to promote "hands-on" exploration as a way of learning. By encouraging children to ask questions and explore those questions with age-appropriate experiments, this approach to science offers an alternative to China's traditional memorization-based instruction. As of the summer of 2012,

*Zhima Jie's Big Bird Looks at the World* ran nationally on CCTV Kids, reaching over 16 million preschoolers (aged 4–6) and almost 30 million mothers (women with children aged 4–9) nationwide. This innovative TV series was the fifth-highest-rated program overall among children aged 4–6 nationwide.

Sesame Workshop also launched a two-phase *Zhima Jie* educational community, a multimedia outreach project on emergency response and preparedness to help children and families cope in the aftermath of natural disasters as well as prepare for future potential emergencies. In total, 75,000 emergency preparedness kits have been distributed through Hope Schools to individual families in provinces that are either prone to or which have recently experienced a natural disaster, including Hebei, Sichuan, Gansu, Yunnan, Guangxi, Guizhou, Jiangxi, Henan, Shanxi, Shaanxi, Hainan, Ningxia and Inner Mongolia.

### National Academy of Sciences

In 2012, the Merck Foundation awarded a three-year, \$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*. The purpose of this study is to bring together experts who will review and synthesize available research on how to provide coherent support for elementary, middle and high school teachers' learning across their careers. An expert committee will consider existing programs for induction and professional development. The committee also 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 2014.

### University of Colorado Foundation

The Merck Foundation awarded a three-year (2011–2013), \$900,000 grant to the University of Colorado Foundation to support a transformative professional-development program for teachers—Xsci Extraordinary Educator Experiences—through experiential learning.

The Foundation's grant supports three primary activities: (1) The XSci Africa Science Learning Journey, in which two cohorts of urban, K–12 educators participate (one group from Colorado and the other from Michigan). On the journey, the teachers climb Mount Kilimanjaro (studying volcanology and ecosystem variation), experience the wilds of the Serengeti (studying biodiversity), and visit AIDS orphanages and guest-teach in local schools (studying health and culture in Tanzania). Additionally, the teachers each make personal documentary videos of their experiences, which serve as both a rich data source for the grant's research component and a powerful tool for making science exciting and relevant to their students; (2) Research that examines the effects of these experiences on teacher identity-construction and on their classroom STEM instruction; and (3) the XSTEM conference—a new national gathering that explores and promotes a higher level of collaboration and support around experiential STEM learning theory and practice in both formal and informal education.

The 2012 XSci Africa cohort successfully completed its journey to Tanzania. The educators also completed their **Teacher Documentaries** and showed them at a film festival that was open to the public. XSci researchers have begun to examine the effects of the experience on the teachers and their work in classrooms. The 2013 Michigan cohort has begun preparation for its trip to Africa in July, which, through a partnership with the Jane Goodall Institute, will also include work with the Gombe Stream chimpanzee research station. Both teacher cohorts are now interacting through the project's online community of practice, [www.xsciafrica.com](http://www.xsciafrica.com). It is on this website that teachers can share stories, resources, journals, videos, curricula and classroom ideas. Planning for the X2013 STEM conference is well under way, in collaboration with newly established partners, REI Education and the STEMx national network, ([www.stemx.us](http://www.stemx.us)). This collaboration now includes 17 U.S. states working to improve STEM education.

## UNDERGRADUATE

**The Alliance/Merck *Ciencia* (Science) Hispanic Scholars Program is a pioneering partnership with the National Alliance for Hispanic Health (the Alliance) dedicated to supporting a new generation of Hispanic scientists.**

Providing scholarship, 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 The Merck Company Foundation, *Ciencia* is ensuring that Hispanic students with promise for study in the STEM fields are receiving the support they deserve to realize their dreams.

Every year, high schools and Alliance member community organizations and scientists in Brownsville, Texas; Elizabeth, New Jersey; and Los Angeles, California, partner to select a class of 10 *Ciencia* Scholars drawn from among high school seniors who have demonstrated promise for STEM study. 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 mentorship and support of the Alliance *Ciencia* network of some of the nation's leading scientific minds. The community of Scholars now numbers forty, with 2013 seeing the first class of *Ciencia* Scholars graduate and become the first group of *Ciencia* alumni.

*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 one another's personal and professional paths.

The NAHH/Merck partnership also includes the awarding each year of the *Ciencia* National Scholarships, open to Hispanic college students with a declared STEM major from all 50 states, the District of Columbia, the U.S. territories and Puerto Rico. The program awards a \$2,000 onetime scholarship to help students with a demonstrated commitment and promise in their fields to complete their education. To date, 100 *Ciencia* National Scholarships have been awarded. By preparing a new generation of scientists, *Ciencia* is securing a brighter future not only for these students, but for our nation and world.

The Alliance has partnered with Harvard University to conduct an external evaluation to assess the impact of the *Ciencia* program. Data sources will include surveys, focus groups and interviews with leaders of partner organizations, the *Ciencia* Scholars, and the program manager.

For more information on the National Alliance for Hispanic Health, [click here](#).

For more information on the Alliance/Merck *Ciencia* Hispanic Scholars Program, [click here](#).

## GRADUATE/POSTGRADUATE

**African Americans currently hold fewer than 3.2 percent of all PhDs in the U.S. in the biological sciences and chemistry. To help address this disparity, Merck joined with UNCF in 1995 to establish the UNCF/Merck Science Initiative (UMSI).**

This groundbreaking program seeks to expand the pool of world-class

African-American biomedical scientists and, in so doing, to enhance economic competitiveness in the United States. Each year, the UMSI provides scholarship and fellowship support to 37 outstanding African-American students who are pursuing studies and careers in the biological and chemical sciences.

Awardees are selected through a national competition open to all eligible students at colleges and universities throughout the United States. The awards provide financial support, hands-on training, mentoring relationships and institutional support to help the UNCF/Merck Fellows devote their attention to education. Undergraduate scholars also may receive paid summer internships at Merck Research Laboratories.

**UMSI** was launched with a \$20 million grant from the Merck Foundation. In 2005, the Foundation renewed its commitment to UNCF with a five-year, \$13 million grant and in 2011 it pledged another \$14 million to UNCF over five years.

UNCF/Merck Science Initiative 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, Merck has awarded a total of 626 fellowships. Merck itself also has provided over \$3 million to support a summer internship program for undergraduate Fellows between 1995 and 2012.

## Mentoring and Networking with Past Fellows

A key component of the UMSI program is the mentoring that UMSI Fellows receive from Merck scientists and 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.

Each year, the program also invites all current awardees to participate in Fellows Day. This event brings together Merck scientists and Fellows to share their research through scientific symposiums and poster sessions.

<b>Merck investment in UNCF</b>	<b>1996-2012</b>
Merck Foundation UNCF/Merck investment in UNCF/Merck Science Initiative	<b>\$37.5M</b>
<b>Degree Completion Rates of Fellows</b>	
Undergraduate (B.A./B.S.)	<b>100%</b>
Ph.D.	<b>99%</b>
Former undergraduate Fellows who entered graduate school	<b>94%</b>
Former graduate Fellows who entered postdoctoral positions	<b>62%</b>
<b>Employment Outcomes of Graduate Fellows (PhDs)</b>	
Academic	<b>74%</b>
Business/industry	<b>22%</b>
Number of Fellows hired by Merck (2002 to 2012)	<b>14</b>

## PERFORMANCE

MISE Summary	2008	2009	2010	2011	2012
Merck investment in MISE (US\$M) <sup>1</sup>	3.9	2.8	3.3	3.5	2.5
Student enrollment (NJ and PA MISE-supported school districts)	35,210	49,294	88,692	89,576	86,428
Time spent teaching science at the elementary school level (minutes/week)	NR	121	149	159	179
Teachers and principals attending workshops, including the Academy for Leadership in Science Instruction	686	708	678	702	735
Participants satisfied with the quality of professional development workshops	97%	96%	95%	97%	94%
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>2</sup>	100%	89%	86%	NR	86%
Grade 8 State Science Test results: Percent proficient (NJ school districts)	55%	61%	63%	73%	74%
Grade 4 State Science Test Results: Percent proficient (NJ school districts)	NR	80%	80%	84%	88%

<sup>1</sup> 2009 and 2010 data adjusted from previously reporting data for accuracy.

<sup>2</sup> In 2012, the question asked whether "well prepared." In previous years, it asked whether "prepared."

NR: Data not reported.



# COMMUNITY

**At Merck, we aspire to have a positive impact on the communities in which we operate worldwide.**

Our community involvement programs reflect the priorities that Merck shares with local stakeholders. We provide financial support and share the expertise

of Merck employees through programs that focus on solving critical health and social issues in communities where Merck has 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.

Community Giving Summary (US\$)	2009	2010	2011	2012
<b>Contributions to community programs</b>				
Art	239,000	187,000	113,000	612,000
Civic	116,000	59,000	103,000	1,358,000
Education	293,000	462,000	614,000	404,000
Environment	228,000	52,000	158,000	125,000
Human Health Services	1,516,000	1,843,000	1,677,000	867,000

## NEIGHBOR OF CHOICE

**Our signature Neighbor of Choice community program supports the work of local nonprofit organizations that strive to improve the quality of life of the residents in communities where Merck has a presence.**

Established by Merck in the 1990s, the Neighbor of Choice (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. Merck takes seriously the shared responsibility of helping to improve the quality of life of neighbors in need.

Giving Totals	2008	2009	2010	2011	2012
Amount contributed (US\$M) <sup>1</sup>	2.1	3.2	3.5	2.7	2.8
Number of grants	358	345	282	112	170

<sup>1</sup> For 2011 and 2012, data includes funding contributed through Merck's Office of Corporate Philanthropy and The Merck Foundation. Additional funding is provided through local U.S. sites and Merck sites outside the United States that we do not track centrally.

In 2012, Merck invited nonprofit organizations located in 17 communities in which Merck has a major presence to apply for support. In accordance with NOC program guidelines, a total of \$2.8 million in grants was awarded to 170 nonprofits in support of a wide range of health, social service, educational, civic, arts/cultural and environmental initiatives.

Below are examples of projects supported through the Neighbor of Choice grants program.

### United States

#### Health

Neighbor of Choice support for the Hudson Perinatal Consortium in Jersey City, New Jersey, enabled expansion of its *Community Doulas* program, which

trains women in the local community to become doulas and to care for at-risk expecting women. The doulas' work has led to better birth outcomes, including a reduction in the incidence of preterm labor and an increase in birth weights, and has promoted breastfeeding.

With funding from the NOC program, the Circle of Life Children's Center Pediatric Palliative Care in Elizabeth, New Jersey, was able to retain two clinical positions, a bilingual pediatric nurse and a social worker, to provide direct services to seriously ill children and their families.

A grant to the Hunterdon Medical Center Foundation in New Jersey enabled the institutionalization of the program *Nurses Improving Care to Health System Elders (NICHE)*.

The Somerset Medical Center in New Jersey utilized grant funds to support the El Poder Sobre Diabetes, a community outreach program that provides diabetes prevention and disease management education and services to underserved Hispanic populations.

#### Social Services

With support from Merck, the New Jersey-based organization Heightened Independence and Progress provided direct assistance to individuals with vision loss. The *Adjustment to Vision Loss* project facilitated the development and maintenance of an extensive network of peer-support groups in the 14 counties of northern and central New Jersey.

A grant to Hunterdon Prevention Resources was used to provide health and wellness self-management tools to senior citizens and to increase knowledge about cyber-bullying and drug abuse among local youth in Hunterdon County, New Jersey.

A grant to the Elkton, Virginia, Family and Children's Medical Center supported a wellness program designed to develop a "Biggest Loser" peer network program to improve the fitness and nutrition of children and their families.

A Neighbor of Choice grant through Merck's Charlotte, North Carolina, facility in 2012 was awarded to A Child's Place of Charlotte, Inc. The grant supports crucial social work services provided to homeless elementary and middle-school students in the Charlotte-Mecklenburg schools in North Carolina. Merck's donation was used to help underwrite services at Walter G. Beyers Academy,

which has one of the highest homeless student enrollments in the county.

With NOC funding, Merck has been able to support A Secret Safe Place for Newborns of Tennessee, an organization working to promote education and awareness to help prevent the abandonment of newborn babies. Newborn abandonment is a phenomenon that has no socio-economic, age, race or income boundaries. The mission of the organization, located near Merck's Memphis, Tennessee, facility, is to protect infants.

## Education

In October 2012, Teach for America was awarded a Neighbor of Choice grant with the goal of placing 55–60 additional STEM teachers, who would join 175 total Teach for America STEM teachers in northern New Jersey; maximize their impact on the achievements of 9,300 students; and fostering the leadership of over 550 alumni as a force for change during the 2012–2013 school year.

In Memphis, Tennessee, a grant to the Brinkley Heights Urban Academy supported the Infusionomics program, which improves the economic prospects of at-risk urban youth from low-income communities by increasing students' financial literacy and teaching them entrepreneurship skills. Students launched school-based businesses and engaged in hands-on, personal-money management through a mini-economy that trains them in such critical skills as budgeting, saving, investing and credit management.

In San Juan, Puerto Rico, a grant to Centro de Enseñanza para la Familia was used to provide enrichment in science and mathematics for more than 1,000 students.

An NOC grant to the Academy of Natural Sciences in Pennsylvania is helping that organization maintain its commitment to its long-standing *Women in Natural Sciences (WINS)* Program. WINS is a highly successful after-school science enrichment and mentoring program for young women in grades 9–12 from underserved schools and families in Philadelphia. With Merck's help, WINS continues to achieve its outstanding graduation and college placement rates for its participants, helping to make it possible for these young women to pursue science-related majors in college.

## Environment

A grant to the Nature Conservancy aimed at creating rainwater collection systems and rain gardens in the city of Camden, New Jersey, helps to reduce storm-water runoff in the city's combined sewer and storm-water system.

Merck's Stonewall, Virginia, manufacturing plant is supporting an effort by the Virginia Wilderness Committee, together with the U.S. Forest Services and others, to protect a young forest habitat, the Beech Lick Knob Wilderness Area in the George Washington National Forest (GWNF) in northern Rockingham County, Virginia. The grant supports the establishment of a large national scenic area and several new wilderness areas that are part of the GWNF on Shenandoah Mountain. The area contains the largest concentration

of "un-roaded" wild lands in the eastern United States and is the watershed for thousands of valley residents who get their drinking water from the Shenandoah River downstream.

## Arts

A grant to the Paper Mill Playhouse in Milburn, New Jersey, was used to help fund the Theater for Everyone's sensory-friendly performances, which makes live performing arts and its many benefits available to children with autism (and other cognitive and developmental disabilities) and their families.

## Civic

Through the *Domestic Violence Legal Representation Program*, New Jersey-based Partners for Women and Justice provides legal assistance to low-income victims of domestic violence seeking restraining orders, safe visitation and custody arrangements, and financial support. Representation is provided by a highly trained staff attorney funded by the Neighbor of Choice program.

## International

In 2012, the Neighbor of Choice program was piloted in the following MSD sites: France, Ireland, the Netherlands, Singapore and the United Kingdom. Among the nongovernmental organizations (NGOs) supported were: the National University of Singapore School of Medicine, to improve the health outcomes of elderly patients living with chronic disease; the Children's Sunshine Home and Laurel Lynne House in Ireland, to build a soft play area for its respite-care unit, where medically fragile children with

life-limiting and life-threatening conditions can move and play; and Basc Enterprises, also in Ireland to improve the learning and social education of children with learning disabilities by using iPads to aid speech development, expression through various applications, engagement and social inclusion.

## DISASTER RELIEF

### Merck provides disaster-relief assistance during major disasters and supports efforts in disaster preparedness and recovery.

Merck’s Office of Corporate Philanthropy serves as the central clearinghouse for information regarding Merck’s companywide response to major disasters, and works with the Office of Corporate Responsibility to make decisions related to the company’s donations of cash and/or medicines and vaccines in a disaster situation.

### Hurricane Sandy (United States) (October 2012)

In response to Hurricane Sandy, Merck made cash donations that exceeded \$1.3 million, in addition to Merck employee donations. A large percentage of the employee donations were from those in the northeastern United States, the area impacted by the storm.

Cash contributions were made to the following nonprofit organizations: a \$250,000 donation to the American Red Cross; \$150,000 to Save the Children, \$150,000 to the Children’s

Health Fund; \$150,000 to New Jersey Futures; \$150,000 to Community Health Charities; \$100,000 to the Hurricane Sandy New Jersey Relief Fund; \$50,000 to Direct Relief International; \$50,000 to AmeriCares; and \$30,000 to Volunteer Lawyers for Justice. Approximately \$606,000 in product inventory was also donated, via the Merck Medical Outreach Program, to Direct Relief International, AmeriCares and the New York Police Department Foundation to assist with relief efforts.

At Merck, we believe that indiscriminate responses to urgent requests for assistance can be counterproductive. Therefore, we follow the long-standing recommendation by the Office of U.S. Foreign Disaster Assistance that a company’s response be made on the basis of a firsthand assessment of need by local authorities and/or a designated relief agency. In major disaster situations, donations of Merck medicines are often made directly by the local Merck subsidiary or manufacturing facility. Where appropriate, and in consultation

with local Merck management, the Office of Corporate Responsibility may donate pharmaceuticals and vaccines through the disaster and emergency relief component of the **Merck Medical Outreach Program**.

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, Merck neighbors and relief agencies
- Evaluate continued assistance through recovery stages
- Evaluate the need for, and feasibility of, providing support for important disaster preparedness efforts

Disaster and Emergency Relief Summary	2009	2010	2011	2012
Disaster relief efforts assisted	7	6	13	6
Total giving value of disaster relief contributions (cash and products, US\$M)	1.5	24	13.8	2.7 <sup>1</sup>

<sup>1</sup> Includes products that were donated for disaster relief in 2012, but will be used for disaster relief in 2013.

**American Red Cross**

Merck is a long-standing member of the American Red Cross Annual Disaster Giving Program (ADGP). The Merck Foundation has pledged \$2 million over four years (2010–2013) 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 partnership with local agencies.

**International Support**

In 2012, the Foundation partnered with the International Centre for Diarrhoeal Disease Research Bangladesh (icddr), the world leader in cholera/acute watery diarrhea (AWD) management with an initial contribution of \$372,000. This grant was envisioned to ensure timely response to international requests for support—through standing capacity of appropriate supplies and expertise—during the critical early stages of a cholera outbreak.

During the first six months of the grant, icddr:

- Responded to the cholera outbreak in Sierra Leone in October 2012, providing supplies, building capacity of Ministry of Health and government laboratories, and training clinicians in the hardest-hit districts
- Performed a follow-up training in the Horn of Africa
- Continued to use the Dhaka Hospital as a dynamic laboratory for testing and refining effective treatment protocols

**OTHER COMMUNITY GRANTS**

**New Jersey Performing Arts Center (NJPAC)**

NJPAC is the home of the nation’s largest and most comprehensive arts education program. 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 over 1 million children, families and educators since its inception in 1992.

Merck’s support in 2012 marked the fourth year of a multiyear, \$1 million grant to help NJPAC fulfill its mission of offering impressive programming ranging from in-school and after-school performances, in-school residency programs, and arts training and scholarship for children throughout the Garden State.

**Philadelphia International Festival of the Arts (PIFA) at the Kimmel Center**

Merck is 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 500,000, with almost 200,000 coming from outside of Philadelphia.

In 2012, Merck partnered with the Kimmel Center for *PIFA 2013*, a month long celebration of Philadelphia’s vibrant cultural sector involving over 50 arts

and cultural partners. With Merck support, the Kimmel Center hopes to serve its mission of “transforming lives daily through the arts” across a broad spectrum of artistic disciplines, price points and diverse communities.

**New Jersey Symphony Orchestra (NJSO)**

The Merck Foundation continued its support of the New Jersey Symphony Orchestra in 2012 with a multiyear grant to nurture young minds, inspire creativity and promote lifelong learning through the experience of live music. Merck 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.

# EMPLOYEE ENGAGEMENT

**At Merck, we believe that employee giving benefits our employees, their communities and our company. Across the globe, Merck employees take an active role in giving back to their communities through a variety of programs offered by the company.**

Merck's leading-edge Global Employee Volunteerism Policy provides each employee with the opportunity to take up to 40 hours' paid time off to engage in traditional and/or skills-based volunteering opportunities. Additionally, Merck offers a dollar-for-dollar matching gifts program for U.S.- and Puerto Rico-based active and retired Merck employees through which they can support eligible nonprofit organizations in their communities.

- Volunteering
  - RTC Fellowship for World Health
  - Signature Volunteer Programs
  - 365 Merck Days
- Partnership for Giving (P4G)
- Join My Village

## VOLUNTEERING

**Effective January 2013, Merck has enhanced its Global Volunteer Policy by doubling the number of hours, from 20 to 40, that employees may take as paid time off per calendar year.**

We instituted this change in policy in response to an increasing number of requests from employees for multi-day volunteering trips as well as to pave the way for the company to introduce new volunteer opportunities, such as week-long service trips. In 2012, more than 12,000 employees volunteered approximately 220,000 hours. Overall, 12 percent of Merck's employee population worldwide took paid time off (PTO) to volunteer.

### **Richard T. Clark Fellowship for World Health**

In 2012, Merck launched the **Richard T. Clark (RTC) Fellowship for World Health**—a global program designed to apply the skills and talents of Merck employees to help build and support the efforts of humanitarian organizations to address the health needs of the underserved.

The program aims to:

- Strengthen the capacity and reach of nonprofit organizations with technical and human capital support, not just funds
- Provide rich professional development experiences for Merck employees
- Bring together the passion, purpose and commitment of dedicated, talented people to achieve measurable outcomes

### **Signature Volunteer Programs**

**Merck's Pro Bono Legal Program**—This nationally recognized pro bono program began modestly in 1994,

and now includes nearly 200 Merck attorneys, paralegals and administrative associates who provide pro bono legal services to residents of New Jersey and Pennsylvania who could not otherwise afford legal representation. Merck is currently handling pro bono cases in the areas of guardianship, landlord-tenant disputes, bankruptcy, family law, domestic violence, military veteran benefits, social security disability benefits and special education law. By the end of 2012, Merck's Pro Bono Legal Program had provided approximately 3,000 hours of pro bono legal services for the year.

**Reach Out and Read**—This program prepares America's youngest children—especially those growing up in poverty—to succeed in school by partnering with doctors to prescribe books for reading and to encourage families to read together. The program recruits pediatricians and nurse practitioners to make literacy a standard part of well-child visits for children ages six months through five years. Physicians distribute new books to children at each visit and advise parents on the importance of reading aloud to their children. They also provide parents with literacy strategies for each developmental stage. In 2012, 21 Merck employees helped model good literacy practices by reading aloud to children in "literacy-rich" waiting rooms.

**Making Positive Choices**—Making Positive Choices is an initiative created in partnership between Merck and the Pro Bono Institute. The program engages Merck employees interested in using their unique professional knowledge to make a difference in the lives of

children and young adults. The Making Positive Choices program provides an opportunity to make a positive and long-term impact while fostering relationships with local youth through Prevention and Youth in Transition programs. Merck volunteers teach law, health, community safety, career planning and advocacy to middle- and high-school students, and youth who are aging out of the foster care system. The program focuses on helping young people understand the importance of being a good citizen and encouraging personal, academic and professional growth.

### 365 Merck Days

The 365 Merck Days program is a global volunteer program that supports the efforts of our employees by providing them with ways to search for volunteer opportunities in their communities and a mechanism by which they can log their volunteer hours and share their experiences through videos and photos, with colleagues anywhere in the world.

Merck has numerous volunteer programs in place around the world that address a variety of societal challenges. Here is a sample of those programs:

**St. Baldrick's Foundation** (North Plainfield, New Jersey, USA)—Five Rahway colleagues (Vincent Williams, Frank Wanger, Frank Juricic, Scott Kiss and Andrew Aitken pictured below) gave new meaning to the phrase “bald is beautiful” by shaving their heads in March 2012 as part of the annual St. Baldrick's Event, which helps raise money to find cures for childhood cancers.



Bald is Beautiful (Rahway, New Jersey)

Similarly, 36 MSD employees in Singapore shaved off their hair for children with cancer at the second annual “Hair for Hope” event, benefiting the Children's Cancer Foundation.



Ng Lai Peng, MSD Singapore, makes a brave, bald statement.

**Companywide Volunteer Activities**— Many MSD country offices conducted volunteer events in 2012. Among them, MSD Taiwan's Volunteer for Butterfly Conservation; Jordan's renovation of the Maymouna Bit Al Hareth Primary School; the EEMEA region's continued participation in the Lucerne Marathon Winter Run for a Good Cause, in

Switzerland, benefiting the Chronic Disease Clinic in Ifakara, Tanzania, Africa, and the institution “Haus für Mutter und Kind” (House for Mother and Child), in Hergiswil, Switzerland. Overall, MSD companywide volunteer activities in 2012 involved up to 85 percent employee participation in some countries.

*“I am proud to be here with the amazing MSD Jordan team. We believe in our community and our company and will do all within our power to support the development of the communities we live in.”*

**Omar Rifi**  
Managing Director, MSD Jordan

*“Corporate social responsibility is an integral part of MSD’s strategy, and this project represents a perfect opportunity for the company’s employees to be part of a humanitarian project.”*

**Nidal Fakhoury**  
Managing Director, MSD in the Middle East

For a number of years, MSD France employees have supported an Alzheimer’s program in Paris, called ARTZ. ARTZ is committed to improving the quality of life for people living with Alzheimer’s disease, or other forms of dementia, through engagement with art throughout museums in Paris. MSD France has embraced ARTZ wholeheartedly through the participation of several hundred of our employees in France.

A number of country offices received awards for their generous employee volunteerism in 2012:

- MSD Korea’s Mapo District Chief Officer Award for Volunteerism in Korea—for citizens’ well-being and social welfare

- MSD Thailand’s award, for the second year running the American Chamber of Commerce for its Corporate Social Responsibility programming and particularly for the MSD “IN-STEP” Program, an inquiry-based science and technology education program for secondary schools, in Thailand’s Phang Nga province
- MSD Hong Kong’s recognition as a “Caring Company” for its continuous service to the community since 2002
- MSD China’s China Children Charity Award, in recognition of its dedication to children in the community

**Team Volunteering**—Volunteer teams at Merck/MSD pride themselves on giving back to their communities. Hundreds of teams all over the world from Sales, Marketing, Finance, Research, Manufacturing, Information Technology, Global Support Services, Legal and many other divisions and departments gather throughout the year to build homes and

playgrounds, harvest farm vegetables, stock food bank pantries and shelves, serve meals to the homeless, visit the elderly—the list goes on.

Specific activities in 2012 included:

- A team of 15 employees from Global Compliance harvested 6,000–7,000 pounds of corn, tomatoes and peppers with *Americas Grow a Row* in New Jersey for area food pantries
- Teams at the Merck Arcibo and Barceloneta Manufacturing Sites in Puerto Rico held a volunteer activity benefiting the *Asilo San Rafael*, a home for the aged, by building a roof for the laundry area, painting all bedrooms, washing all windows and screens, cleaning and, most importantly, sharing time and stories with elderly residents in the home
- The MSD U.K. Specialty Care team provided some much needed repairing, painting and decorating at *Valleys Kids*, a community development charity in Wales that serves disadvantaged children and young people. And Aaron Corona organized many of his colleagues in Merck Research Laboratories Project Management to participate in several volunteer activities throughout the entire year. Here’s a video highlighting their 2012 service.





Children's Smiles, Kenya

**Overseas Volunteering**—Merck/MSD has an ever growing commitment to overseas service and volunteerism. Employees commit a few days or several weeks to serving others.

- Mandy King, an Illinois-based customer sales representative, spent extended volunteer time with *Globe Aware* in Orosi Valley, Costa Rica, to help with the repair and rebuilding of a grade school
- A team of 10 from MSD Singapore Shared Business Services and Finance embarked on a two-day, self-funded volunteering mission that supported more than 70 displaced children under the *Green Gecko Project* in Cambodia by planting organic vegetables and fruits as well as building a compost house for organic fertilizers
- Antiena Van de Pol, a senior customer representative in Northern California, served as a Medical Ambassador in Chirramos, Guatemala, teaching healthcare classes to the community and running an on-site pharmacy

- The EEMEA Extended Leadership Team continued its tradition of service with *Children's Smiles* in Kenya by helping with the maintenance and renovation of this center for AIDS-orphaned children outside of Nairobi, Kenya



Children's Smiles, Kenya

**Relief Efforts**—In the aftermath of the floods in Thailand, more than 80 MSD Thailand employees provided hands on volunteerism for the continued recovery effort in 2012 by helping rebuild the Pranakornsri Ayuthaya Hospital. And when Hurricane Sandy hit the northeastern United States, many teams and individuals across New Jersey, Pennsylvania and Connecticut volunteered in the relief, cleanup and rebuilding efforts. Merck/MSD also continues to run blood drives at many of its sites around the world. For more information on our efforts, visit the disaster relief tab on this page.

## PARTNERSHIP FOR GIVING

**The Merck Partnership for Giving (P4G) program is Merck's year-round matching fund that gives U.S. and Puerto Rico-based active and retired Merck employees the opportunity to support eligible health and human services agencies, accredited educational institutions, arts and culture, and animal welfare and environmental organizations of their choice.**

The Merck Foundation matches employee and retiree contributions of up to \$30,000 per year.

To recognize and thank the many people and organizations that have made a difference in our own lives and the lives of our families, U.S.-based employees are invited each year to nominate nonprofit agencies to receive a \$1,000 "thank you" grant through "Touched by An Agency," a Merck P4G program. Employees share their personal stories about these agencies on the P4G website, marking the kickoff of the Partnership for Giving Enrollment Campaign.

Community Giving Summary (US\$)	2009	2010	2011	2012
<b>Partnership For Giving</b>				
Art	673,000	774,000	980,000	<b>966,000</b>
Education	3,648,000	3,449,000	4,261,000	<b>4,543,000</b>
Human Health Services	5,754,000	4,383,000	7,902,000	<b>7,114,000</b>
<b>TOTAL<sup>1</sup></b>	<b>12,467,000</b>	<b>11,209,000</b>	<b>15,808,000</b>	<b>13,033,000</b>

<sup>1</sup>Grand total also includes giving to animal welfare and environmental organizations.

## JOIN MY VILLAGE

**Join My Village (JMV)** is a “click-to-commit” social change initiative through which Merck/MSD employees can help Merck’s efforts in making charitable donations that increase access to healthcare and provide education and economic development opportunities for women and girls in Malawi and India to help mitigate the effects of poverty. JMV empowers women and girls by increasing access to classroom education, economic opportunities and better healthcare. JMV is a partnership with the Merck Foundation, the General Mills Foundation and CARE. In February 2012, JMV launched in India supporting two CARE programs: one in Uttar Pradesh, India’s most populous state, where more than half of the women and girls suffer from anemia and malnutrition; the other in Haryana, where healthcare is more likely to be withheld from girls and women with limited means. In total, General Mills and Merck donated \$1.5 million in 2012 as a result of employee “click-to-commit” efforts. To learn more about Join My Village, you can also visit their [Facebook page](#).

## PERFORMANCE

Employee Engagement Summary	2008	2009	2010	2011	2012
# Employees who volunteered <sup>1</sup>	NA	NA	NA	9,605	12,333
% of total Merck population <sup>1</sup>	NA	NA	NA	11%	15%
# Employees who used Paid Time Off (PTO) <sup>1</sup>	NA	NA	NA	8,058	9,732
% of total Merck population <sup>1</sup>	NA	NA	NA	9.5%	12%
Total volunteer hours (TVHs) <sup>1</sup>	NA	NA	NA	213,000	221,050
PTO Hours <sup>1</sup>	NA	NA	NA	130,900	142,082
Ratio of PTO/TVH	NA	NA	NA	61%	64%
<b>Partnership for Giving (P4G)</b>					
Total contribution (US\$M) <sup>2</sup>	25	22	21	27	27
Number of organizations that benefited	7,048	6,777	7,406	10,037	10,172
Number of Merck employees who gave	12,289	11,222	14,112	16,208	14,572
Touched by an Agency grants	15	15	15	18	20

<sup>1</sup> Figures for employees who volunteered in 2011 have been adjusted to reflect new data. Figures are based on data collected, reported and estimated worldwide. Merck population figures are based on an estimated workforce of 86,000 in 2011 and 83,000 in 2012. PTO = paid time off. TVH = total volunteer hours. NA = Not Available.

<sup>2</sup> Contributions through P4G included direct giving, donations made through payroll deductions and Dollars for Doers, and matching gifts from Merck.

## RTC FELLOWSHIP FOR WORLD HEALTH

**Merck’s mission to improve and save lives underpins the idea behind the Richard T. Clark Fellowship for World Health.**

In recognition of retired Chairman and CEO, Dick Clark, and his philosophy of “Passion, Purpose and Commitment to Corporate Responsibility,” Merck’s Office of Corporate Philanthropy created the Richard T. Clark (RTC) Fellowship for World Health—a global program designed to apply the skills and talents of Merck and MSD employees to help build and support the efforts of humanitarian organizations’ to address the health needs of the underserved.



What really excites me is the chance the Fellowship gives employees to apply their dedication, skills and abilities to put Merck’s mission into action. Working with humanitarian organizations around the world in this way allows us to have a truly unique effect on people’s lives and better understand the future of healthcare.

**Richard T. Clark**  
Retired Merck Chairman & CEO

The programs aims to:

- Strengthen the capacity and reach of nonprofit organizations with technical and human capital support, not just funds
- Provide rich, professional development experiences for Merck employees
- Bring together the passion, purpose and commitment of dedicated, talented people to achieve measurable outcomes

While providing unique career development opportunities that help expand employees’ understanding of critical needs in different parts of the world, the program works to improve health literacy, increase access to health services and products, enhance access to health education and improve health outcomes.

## MEET THE FELLOWS

### 2013 Richard T. Clark Fellows



**Jennifer Abrevaya**

Associate Director, Marketing  
West Point, PA

**PSI**

*It's exciting to know that the training skills I developed at Merck will be put to use to make a positive health impact around the world. I'm so honored and humbled to have this opportunity.*

*Plus it's a reminder to me that the work all of us do at Merck, no matter what our role, has an effect on patient health somewhere down the line.*



**Jessica Carideo**

Associate Director,  
Global Marketing  
Whitehouse Station, NJ

**PSI**

*This Fellowship offers us a unique opportunity to contribute simultaneously to the mission of Merck and the mission of a humanitarian organization also*

*dedicated to improving health outcomes. I'm excited to use skills I've developed at Merck to make a meaningful difference in my assignment and to return with an expanded perspective both personally and professionally.*



**Darwin Cox**

Director, Business Consulting  
Whitehouse Station, NJ

**Physicians for Peace**

*What an amazing opportunity we are given to partner with a humanitarian organization in such a noble cause. I'm sure this experience will open my eyes and my heart to the challenges people*

*face in the developing nations.*



**Hilde Jagers**

Associate Director,  
Learning & Development  
Kriens, Switzerland

**PSI**

*The RTC Fellowship concept is fabulous! Everybody wins: the patient, the NGO, our company and the Fellows. I'd love to keep in touch and share these exciting*

*experiences with my Merck colleagues. Together, we could make a difference and start changing the world.*



**Nandini Konar**

Associate Director,  
Project Management  
North Wales, PA

**Drugs for Neglected Diseases Initiative**

*I am overjoyed with the opportunity to meet my personal philanthropic goals through my workplace while simultaneously*

*expanding my professional horizons by this exposure to broader healthcare needs (who could ask for more?). I am very excited about helping to fulfill Merck's mission in a new way and am looking forward to working on neglected diseases with our nonprofit partners.*



**Myla Maloney**

Associate Director,  
Learning & Development  
Lansdale, PA

**PSI**

*In countries with more sophisticated medical infrastructures like the United States, we go to the doctor for a runny nose or a headache,*

*but much of the world suffers through ailments that could be resolved with basic medical attention. I believe that the Richard T. Clark Fellowship helps to solve for this worldwide epidemic by aligning our resource rich and experienced organization with a non-profit in need of support. I am truly honored to be a Fellow.*



**Skipper Kozelsky**

Customer Manager, Sales  
Scottsdale, AZ

**PSI**

*I see the Richard T. Clark Fellowship as another opportunity to help those most in need. Nothing is more noble than this mission.*



**Sowmnya Murthy**

Associate Director,  
Strategic Planning  
Whitehouse Station, NJ

**Physicians for Peace**

*Setting organizational strategy requires leadership and vision to look within, look around and leverage unique capabilities to make an enduring difference.*

*I eagerly look forward to working with Physicians for Peace to make a lasting impact through local education and self-empowerment that will improve healthcare delivery and patient access in the developing world.*



**Nancy Pietroski**  
Senior Specialist, Medical Affairs  
North Wales, PA

**Medicines for Malarial Ventures (MMV)**

*I consider the Fellowship a privilege and a wonderful opportunity to leave the Merck mother ship for a period and literally travel outside the box—to*

*explore new territory, expand my world view, and gain skills and fresh perspectives in a different arena... a nonprofit organization. While on assignment, I hope to be able to capitalize not only on my Merck experience, but my life experiences as well. Learning firsthand about the work that Merck is doing to help the world be well is something we can all feel good about.*



**Pam Rizos**  
Specialist, Project Management  
Rahway, NJ

**PSI**

*The Fellowship has given us a unique opportunity to take part in changing the world. I am excited and grateful that I will be able to expand my knowledge, push my boundaries, and grow*

*professionally and personally while improving the health and lives of those in need.*



**Phieng Siliphaivanh**  
Principal Scientist, Chemistry  
Boston, MA

**MMV**

*I am very excited for the opportunity to contribute to the Medicine for Malaria Venture (MMV) Pathogen project. This is an occasion to use all of my training and expertise I have learned at*

*Merck to have an impact on multiple neglected disease areas.*



**Suan Swenson**  
Senior Account Manager,  
Account Management  
North Wales, PA

**Physicians for Peace**

*The need to impact the greater good is foundationally what Merck is about and for me personally, a conscious way in which I live my life. Being able to represent Merck*

*as a member of the RTC Fellowship program will afford me the opportunity to build a sense of community, despite geography, with people in need all over the world.*



**Marjorie Waters**  
Director,  
Financial Planning & Analysis  
Rahway, NJ

**Save the Children**

*This will be a life changing experience for everyone involved. As Fellows, we will take on new challenges and gain new perspectives. Through our*

*contributions to the nonprofit organizations, we are also positively impacting the lives of the people they serve.*

## ALUMNI

### Andreas Berg

Managing Director, MSD Norway

#### Centre for Development and Population Activities (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 non-profit 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 Safe Water Network (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.*



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**Linda Nelsen**

Senior Principal Scientist, Epidemiology

**SWN**

*The images and experiences of the three months in India are still with me every day. I think of my new colleagues at Safe Water Network, the villages we worked in, the opening celebration around a safe water station and the amazing friendships that the Fellows developed in our time living, working and traveling together. Through all the connections I made on the assignment—the people at Safe Water Network, the rural villagers, local government officials and water experts—I learned several important lessons. Because of this experience, I am better able to focus on single tasks and minimize the distractions inherent in our daily routine, be flexible and creative with the resources available to me, and appreciate the range of perspectives of those that I am working with.*

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**Swapna Purani**

Associate Director, Marketing

**SWN**

*I will cherish my Fellowship experience for a lifetime. I am proud of the work we did to further Safe Water Network's mission and support Merck's purpose of improving and saving lives. The extent of my personal and professional growth is priceless, and I'm honored to have served with my other Fellows. Although my Fellowship assignment is over, my commitment is not. I will continue to work with the Safe Water Network's mission so that we can continue to reach and enrich more lives.*

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**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.*

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**Nand Kumar**

Specialist, Marketing Operations

**International Centre for Diarrhoeal Disease Research, Bangladesh (icddr,b)**

*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.*

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**Alicia M. Bartolozzi**

Specialty Account Executive, Managed Markets & Policy

**Population Services International (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!*

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**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.*

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**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.*

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**Jan Nissen**

Established Products Business Unit Leader, 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.*

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**Julia Shoff**

U.S. 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**



DNDi is a collaborative, patients’ needs-driven, nonprofit drug research and development (R&D) organization that is developing new treatments for patients suffering from the most neglected communicable diseases. Acting in the public interest, DNDi bridges existing R&D gaps in essential drugs for these diseases by initiating and coordinating drug R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry, and other relevant partners.



Medicines for Malarial Ventures (MMV) is a nonprofit public-private partnership, established as a foundation in Switzerland in 1999. Its mission is to reduce the burden of malaria in disease-endemic countries by discovering, developing and facilitating delivery of new, effective and affordable antimalarial drugs.



**Physicians for Peace** engages compassionate world citizens to deliver training and support to healthcare teams in underserved regions. They work with local health professionals to introduce skills and fill specific training gaps, while mobilizing targeted equipment and supplies that are scarce in the developing world. Regardless of the country or region, their goals are the same: self-sufficiency and better health.



**PSI** is a global nonprofit organization dedicated to improving the health of people in the developing world by focusing on serious challenges like a lack of family planning, HIV/AIDS, maternal health, and the greatest threats to children under five, including malaria, diarrhea, pneumonia and malnutrition. PSI has operations throughout Asia, Africa and Latin America and has more than 16,000 franchises delivering services to 6.4 million clients.



**Save the Children** is a leading independent organization for children in need, with programs in 120 countries, including the United States. The organization aims to inspire breakthroughs in the way the world treats children, and to achieve immediate and lasting change in their lives by improving their health, education and economic opportunities. In times of acute crisis, Save the Children mobilizes rapid assistance to help children recover from the effects of war, conflict and natural disasters.

# REPORTING INDICES



**Since the release of our first corporate responsibility report in 2005, Merck 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 data collection challenges and the harmonization process following the merger with Schering-Plough, Merck has utilized the GRI as well as the Access to Medicines Index (ATMI), the United Nations Global Compact Communication on Progress (UNGC COP), and the UN Millennium Development Goals (MDG) as our overall framework for corporate responsibility reporting. Our 2012 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

**In preparing Merck’s disclosures relating to access to medicines 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 medicines 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 Merck disclosures can be found on the Merck website in relation to the ATMI criteria.

ATMI Criteria	Report Location
<b>General Access to Medicine Management</b>	
ATM Governance	Access to Health
ATM Management System	Access to Health
Stakeholder Engagement	Stakeholder Engagement
<b>Public Policy and Market Influence</b>	
Advocacy and Lobbying	Public Policy & Advocacy
Competitive Behavior	Sales & Marketing
Market Behavior	Sales & Marketing
<b>Research and Development</b>	
Innovative R&D	Research & Development R&D for Low- & Middle-Income Countries
Adaptive R&D	Research & Development
Intellectual Property Sharing	Public Policy & Advocacy

ATMI Criteria	Report Location
<b>Equitable Pricing, Manufacturing and Distribution</b>	
Marketing Approval	Product Registration Access to Health
Equitable Pricing	Pricing Access to Health
Manufacturing and Distribution	Manufacturing & Supply Chain Access to Health Committed to Improving Access to HIV Care Vaccines Women's Health
<b>Patents and Licensing</b>	
Patents	Manufacturing & Supply Chain Access to Health Committed to Improving Access to HIV Care Vaccines Women's Health
Non-Exclusive Voluntary Licensing	Manufacturing & Supply Chain Committed to Improving Access to HIV Care

ATMI Criteria	Report Location
<b>Capability Advancement in Product Development and Distribution</b>	
Capacity Building in Research and Development	Research & Development Access to Health
Capacity Building in Quality Management and Distribution	Quality & Safety Standards
<b>Product Donations and Philanthropic Activities</b>	
Donations	Patient Assistance Program Product Donations Merck Medical Outreach Program Community
Philanthropy	Giving at Merck

# GRI INDEX

Merck reports in accordance with the **Global Reporting Initiative (GRI) G3.1 guidelines** on our corporate responsibility (CR) website.

The voluntary guidelines offer a useful framework 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.

This report has been prepared according to the GRI Guidelines, at Application Level A.

The table on the right summarizes where the disclosures can be found on the Merck website.

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART I: Profile Disclosures</b>		
<b>1. Strategy and Analysis</b>		
1.1	Statement from the most senior decision-maker of the organization.	Letter from the CEO
1.2	Description of key impacts, risks, and opportunities.	Letter from the CEO
<b>2. Organizational Profile</b>		
2.1	Name of the organization.	Merck & Co., Inc.
2.2	Primary brands, products, and/or services.	Our Business
2.3	Operational structure of the organization, including main divisions, operating companies, subsidiaries, and joint ventures.	Our Business
2.4	Location of organization's headquarters.	Whitehouse Station, New Jersey, USA
2.5	Number of countries where the organization operates, and names of countries with either major operations or that are specifically relevant to the sustainability issues covered in the report.	81 countries
2.6	Nature of ownership and legal form.	2012 10-K
2.7	Markets served (including geographic breakdown, sectors served, and types of customers/beneficiaries).	Our Business 2012 10-K



GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART I: Profile Disclosures</b>		
2.8	Scale of the reporting organization.	<b>Economic Impact</b> 2012 10-K
2.9	Significant changes during the reporting period regarding size, structure, or ownership.	<b>About This Report</b> 2012 10-K
2.10	Awards received in the reporting period.	<b>Awards &amp; Recognition</b>
<b>3. Report Parameters</b>		
3.1	Reporting period (e.g., fiscal/calendar year) for information provided.	<b>About This Report</b>
3.2	Date of most recent previous report (if any).	2011
3.3	Reporting cycle	Annual
3.4	Contact point for questions regarding the report.	<b>Contact Us</b>
3.5	Process for defining report content.	<b>Our Approach</b> <b>About This Report</b> <b>Materiality</b>
3.6	Boundary of the report.	<b>About This Report</b>
3.7	State any specific limitations on the scope or boundary of the report.	<b>About This Report</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART I: Profile Disclosures</b>		
3.8	Basis for reporting on joint ventures, subsidiaries, leased facilities, outsourced operations, and other entities that can significantly affect comparability from period to period and/or between organizations.	About This Report
3.9	Data measurement techniques and the bases of calculations, including assumptions and techniques underlying estimations applied to the compilation of the Indicators and other information in the report.	About This Report
3.10	Explanation of the effect of any re-statements of information provided in earlier reports, and the reasons for such re-statement.	See specific performance metrics for details
3.11	Significant changes from previous reporting periods in the scope, boundary, or measurement methods applied in the report.	See specific performance metrics for details
3.12	Table identifying the location of the Standard Disclosures in the report.	GRI Index
3.13	Policy and current practice with regard to seeking external assurance for the report.	Report is not currently externally assured

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART I: Profile Disclosures</b>		
<b>4. Governance, Commitments, and Engagement</b>		
4.1	Governance structure of the organization, including committees under the highest governance body responsible for specific tasks, such as setting strategy or organizational oversight.	<b>Corporate Governance</b> <b>CR Governance</b>
4.2	Indicate whether the Chair of the highest governance body is also an executive officer.	<b>Corporate Governance</b>
4.3	For organizations that have a unitary board structure, state the number and gender of members of the highest governance body that are independent and/or non-executive members.	<b>Corporate Governance</b> <b>Diversity &amp; Inclusion</b>
4.4	Mechanisms for shareholders and employees to provide recommendations or direction to the highest governance body.	<b>Contact Us</b> <b>Employee Engagement</b>
4.5	Linkage between compensation for members of the highest governance body, senior managers, and executives, and the organization's ESG performance.	<b>Corporate Governance</b>
4.6	Processes in place for the highest governance body to ensure conflicts of interest are avoided.	<b>Corporate Governance</b> <b>Policies of the Board</b> <b>Ethics &amp; Transparency</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART I: Profile Disclosures</b>		
4.7	Process for determining the composition, qualifications, and expertise of the members of the highest governance body and its committees, including any consideration of gender and other indicators of diversity.	<b>Corporate Governance Policies of the Board</b>
4.8	Internally developed statements of mission or values, codes of conduct, and principles relevant to economic, environmental, and social performance and the status of their implementation.	<b>Corporate Governance Ethics &amp; Transparency Views &amp; Positions</b>
4.9	Procedures of the highest governance body for overseeing the organization's identification and management of economic, environmental, and social performance, including relevant risks and opportunities, and adherence or compliance with internationally agreed standards, codes of conduct, and principles.	<b>CR Governance</b>
4.10	Processes for evaluating the highest governance body's own performance, particularly with respect to economic, environmental, and social performance.	<b>Corporate Governance</b>
4.11	Explanation of whether and how the precautionary approach or principle is addressed by the organization.	<b>Our Approach</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART I: Profile Disclosures</b>		
4.12	Externally developed economic, environmental, and social charters, principles, or other initiatives to which the organization subscribes or endorses.	<b>About This Report</b>
4.13	Memberships in associations and/or national/international advocacy organizations in which the organization has positions in governance bodies; participates in projects or committees; provides substantive funding beyond routine membership dues; or views membership as strategic.	<b>Public Policy &amp; Advocacy</b>
4.14	List of stakeholder groups engaged by the organization.	<b>Stakeholder Engagement</b>
4.15	Basis for identification and selection of stakeholders with whom to engage.	<b>Stakeholder Engagement</b>
4.16	Approaches to stakeholder engagement, including frequency of engagement by type and by stakeholder group.	<b>Stakeholder Engagement</b>
4.17	Key topics and concerns that have been raised through stakeholder engagement, and how the organization has responded to those key topics and concerns, including through its reporting.	<b>Stakeholder Engagement</b> <b>Stakeholder Feedback</b> <b>Working with Patient Groups</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART II: Disclosures on Management Approach (DMAs)</b>		
<b>DMA EC</b>		
Aspects	Economic performance	<b>Our Business 2012 10-K</b>
	Market presence	<b>Our Business 2012 10-K</b>
	Indirect economic impacts	<b>Our Business 2012 10-K</b>
<b>DMA EN</b>		
Aspects	Materials	<b>Product Stewardship</b>
	Energy	<b>Energy Use &amp; Climate Change</b>
	Water	<b>Water</b>
	Biodiversity	This is not a highly material indicator for our activities and products.
	Emissions, effluents and waste	<b>Emissions, Effluents &amp; Waste</b>
	Products and services	<b>Product Stewardship</b>
	Compliance	<b>EHS Management &amp; Compliance</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART II: Disclosures on Management Approach (DMAs)</b>		
	Transport	Energy Use & Climate Change
	Overall	Environmental Sustainability
<b>DMA LA</b>		
Aspects	Employment	Employees
	Labor/management relations	Positive Work Environment
	Occupational health and safety	Employee Safety
	Training and education	Training & Education
	Diversity and equal opportunity	Diversity & Inclusion
	Equal remuneration for women and men	N/A
<b>DMA HR</b>		
Aspects	Investment and procurement practices	Human Rights External Supplier Network
	Non-discrimination	Human Rights Diversity & Inclusion
	Freedom of association and collective bargaining	Human Rights

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART II: Disclosures on Management Approach (DMAs)</b>		
	Child labor	Human Rights
	Prevention of forced and compulsory labor	Human Rights
	Security practices	Human Rights
	Indigenous rights	Human Rights
	Assessment	Human Rights
	Remediation	Human Rights
<b>DMA SO</b>		
Aspects	Local communities	Supporting Our Communities Community
	Corruption	Ethics & Transparency
	Public policy	Public Policy & Advocacy Our Views & Positions
	Anti-competitive behavior	Ethics & Transparency Manufacturing & Supply Chain
	Compliance	Compliance



GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART II: Disclosures on Management Approach (DMAs)</b>		
<b>DMA PR</b>		
Aspects	Customer health and safety	Patient Safety Adverse Event Reporting Chief Medical Officer
	Product and service labeling	Product Safety
	Marketing communications	Sales & Marketing
	Customer privacy	Global Privacy Office
	Compliance	Compliance
<b>STANDARD DISCLOSURES PART III: Performance Indicators Economic</b>		
<b>Economic Performance</b>		
EC1	Direct economic value generated and distributed, including revenues, operating costs, employee compensation, donations and other community investments, retained earnings, and payments to capital providers and governments.	Our Business Positive Work Environment Compensation & Benefits Product Donations Community 2012 10-K

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
EC2	Financial implications and other risks and opportunities for the organization's activities due to climate change.	<b>Environmental Sustainability</b> <b>Energy Use &amp; Climate Change</b>
EC3	Coverage of the organization's defined benefit plan obligations.	<b>Compensation &amp; Benefits</b> <b>2012 10-K</b>
EC4	Significant financial assistance received from government.	<b>2012 10-K</b> We do not receive financial assistance from the government
<b>Market Presence</b>		
EC5	Range of ratios of standard entry level wage by gender compared to local minimum wage at significant locations of operation.	We do not currently track this information
EC6	Policy, practices, and proportion of spending on locally-based suppliers at significant locations of operation.	<b>Supplier Diversity</b> <b>External Supplier Network</b>
EC7	Procedures for local hiring and proportion of senior management hired from the local community at significant locations of operation.	

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Indirect Economic Impacts</b>		
EC8	Development and impact of infrastructure investments and services provided primarily for public benefit through commercial, in-kind, or pro bono engagement.	Community Investment Giving at Merck Community Employee Engagement
EC9	Understanding and describing significant indirect economic impacts, including the extent of impacts.	Our Business Economic Impact Access to Health Community
<b>Environmental</b>		
<b>Materials</b>		
EN1	Materials used by weight or volume.	Emissions, Effluents & Waste Solvent Use
EN2	Percentage of materials used that are recycled input materials.	Emissions, Effluents & Waste Solvent Use
<b>Energy</b>		
EN3	Direct energy consumption by primary energy source.	Energy Use & Climate Change
EN4	Indirect energy consumption by primary source.	Energy Use & Climate Change

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
EN5	Energy saved due to conservation and efficiency improvements.	We estimate that 218,582 MMBtu per year of energy will be saved due to energy conservation and efficiency improvement projects completed in 2012.  <b>Energy Use &amp; Climate Change</b>
EN6	Initiatives to provide energy-efficient or renewable energy based products and services, and reductions in energy requirements as a result of these initiatives.	Not relevant
EN7	Initiatives to reduce indirect energy consumption and reductions achieved.	<b>Energy Use &amp; Climate Change</b> <b>CDP Climate Change</b>
<b>Water</b>		
EN8	Total water withdrawal by source.	<b>Water</b> <b>CDP Water Disclosure</b>
EN9	Water sources significantly affected by withdrawal of water.	Merck's water withdrawals do not meet any criteria defined as significantly affecting a water source.
EN10	Percentage and total volume of water recycled and reused.	<b>Water</b> <b>CDP Water Disclosure</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Biodiversity</b>		
EN11	Location and size of land owned, leased, managed in, or adjacent to, protected areas and areas of high biodiversity value outside protected areas.	We have only one facility that is adjacent to an area of high biodiversity value, in Elkton, Virginia, which is located near the Shenandoah National Park.
EN12	Description of significant impacts of activities, products, and services on biodiversity in protected areas and areas of high biodiversity value outside protected areas.	This is not a highly material indicator for our activities and products.
EN13	Habitats protected or restored.	This is not a highly material indicator for our activities and products.
EN14	Strategies, current actions, and future plans for managing impacts on biodiversity.	This is not a highly material indicator for our activities and products.
EN15	Number of IUCN Red List species and national conservation list species with habitats in areas affected by operations, by level of extinction risk.	A 2011 desktop assessment concluded that we have 28 sites in eco-regions that have between one and nine critically endangered species. We have not concluded whether our operations are impacting any of these species.

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Emissions, Effluents and Waste</b>		
EN16	Total direct and indirect greenhouse gas emissions by weight.	Energy Use & Climate Change CDP Climate Change
EN17	Other relevant indirect greenhouse gas emissions by weight.	Energy Use & Climate Change CDP Climate Change
EN18	Initiatives to reduce greenhouse gas emissions and reductions achieved.	Energy Use & Climate Change CDP Climate Change
EN19	Emissions of ozone-depleting substances by weight.	Energy Use & Climate Change CDP Climate Change
EN20	NOx, SOx, and other significant air emissions by type and weight.	Energy Use & Climate Change Emissions, Effluents & Waste CDP Climate Change
EN21	Total water discharge by quality and destination.	Emissions, Effluents & Waste CDP Water Disclosure
EN22	Total weight of waste by type and disposal method.	Waste Prevention & Management

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
EN23	Total number and volume of significant spills.	<b>EHS Management &amp; Compliance</b>
EN24	Weight of transported, imported, exported, or treated waste deemed hazardous under the terms of the Basel Convention Annex I, II, III, and VIII, and percentage of transported waste shipped internationally.	<b>Emissions, Effluents &amp; Waste</b>
EN25	Identity, size, protected status, and biodiversity value of water bodies and related habitats significantly affected by the reporting organization's discharges of water and runoff.	Merck's discharges and runoff do not meet any of the criteria for significantly affecting a water source.
<b>Products and Services</b>		
EN26	Initiatives to mitigate environmental impacts of products and services, and extent of impact mitigation.	<b>Product Stewardship</b> <b>Emissions, Effluents &amp; Waste</b>
EN27	Percentage of products sold and their packaging materials that are reclaimed by category.	Approximately 40 percent of the insulated Vaccine Shippers sent out in the U.S. with return shipping labels are returned for recycling into other products. <b>Product Stewardship</b> <b>Packaging</b> <b>Environmental Goals</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Compliance</b>		
EN28	Monetary value of significant fines and total number of non-monetary sanctions for non-compliance with environmental laws and regulations.	<b>EHS Management &amp; Compliance</b>
<b>Transport</b>		
EN29	Significant environmental impacts of transporting products and other goods and materials used for the organization's operations, and transporting members of the workforce.	<b>Energy Use &amp; Climate Change</b>
<b>Overall</b>		
EN30	Total environmental protection expenditures and investments by type.	We report on some of our environmental protection expenditures in the <b>2012 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#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Social: Labor Practices and Decent Work</b>		
<b>Employment</b>		
LA1	Total workforce by employment type, employment contract, and region, broken down by gender.	<b>Positive Work Environment</b> <b>Economic Impact</b>
LA2	Total number and rate of new employee hires and employee turnover by age group, gender, and region.	<b>Positive Work Environment</b>
LA3	Benefits provided to full-time employees that are not provided to temporary or part-time employees, by major operations.	<b>Compensation &amp; Benefits</b>
LA15	Return to work and retention rates after parental leave, by gender.	N/A
<b>Labor/Management Relations</b>		
LA4	Percentage of employees covered by collective bargaining agreements.	<b>Human Rights</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
LA5	Minimum notice period(s) regarding significant operational changes, including whether it is specified in collective agreements.	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 4 weeks to 6 months.
<b>Occupational Health and Safety</b>		
LA6	Percentage of total workforce represented in formal joint management-worker health and safety committees that help monitor and advise on occupational health and safety programs.	<b>Wellness</b> <b>Employee Health</b> <b>Employee Safety</b>
LA7	Rates of injury, occupational diseases, lost days, and absenteeism, and number of work-related fatalities by region and by gender.	<b>Employee Safety</b>
LA8	Education, training, counseling, prevention, and risk-control programs in place to assist workforce members, their families, or community members regarding serious diseases.	<b>Employee Health</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators Economic</b>		
LA9	Health and safety topics covered in formal agreements with trade unions.	<p>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.</p> <p><b>Employee Health</b></p> <p><b>Employee Safety</b></p>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Training and Education</b>		
LA10	Average hours of training per year per employee by gender, and by employee category.	<p><b>Positive Work Environment</b></p> <p><b>Training &amp; Education</b></p> <p><b>Office of Ethics</b></p> <p><b>Global Privacy Program</b></p> <p><b>EHS Management &amp; Compliance</b></p> <p><b>Sales &amp; Marketing</b></p> <p>We conduct extensive training programs worldwide, however we do not currently track these by gender.</p>
LA11	Programs for skills management and lifelong learning that support the continued employability of employees and assist them in managing career endings.	<p><b>Training &amp; Education</b></p> <p><b>Merck Careers</b></p>
LA12	Percentage of employees receiving regular performance and career development reviews, by gender.	<b>Positive Work Environment</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Diversity and Equal Opportunity</b>		
LA13	Composition of governance bodies and breakdown of employees per employee category according to gender, age group, minority group membership, and other indicators of diversity.	Diversity & Inclusion
<b>Equal Remuneration for Women and Men</b>		
LA14	Ratio of basic salary and remuneration of women to men by employee category, by significant locations of operation.	N/A
<b>Social: Human Rights</b>		
<b>Investment and Procurement Practices</b>		
HR1	Percentage and total number of significant investment agreements and contracts that include clauses incorporating human rights concerns, or that have undergone human rights screening.	Human Rights External Supplier Network Business Partner Code of Conduct
HR2	Percentage of significant suppliers, contractors and other business partners that have undergone human rights screening, and actions taken.	Human Rights External Supplier Network Business Partner Code of Conduct

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
HR3	Total hours of employee training on policies and procedures concerning aspects of human rights that are relevant to operations, including the percentage of employees trained.	Office of Ethics Code of Conduct
<b>Non-Discrimination</b>		
HR4	Total number of incidents of discrimination and corrective actions taken.	Office of Ethics
<b>Freedom of Association and Collective Bargaining</b>		
HR5	Operations and significant suppliers identified in which the right to exercise freedom of association and collective bargaining may be violated or at significant risk, and actions taken to support these rights.	Human Rights Business Partner Code of Conduct
<b>Child Labor</b>		
HR6	Operations and significant suppliers identified as having significant risk for incidents of child labor, and measures taken to contribute to the effective abolition of child labor.	Human Rights Business Partner Code of Conduct

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Prevention of Forced and Compulsory Labor</b>		
HR7	Operations and significant suppliers identified as having significant risk for incidents of forced or compulsory labor, and measures to contribute to the elimination of all forms of forced or compulsory labor.	<b>Human Rights</b> <b>Manufacturing &amp; Supply Chain</b> <b>Business Partner Code of Conduct</b>
<b>Security Practices</b>		
HR8	Percentage of security personnel trained in the organization's policies or procedures concerning aspects of human rights that are relevant to operations.	The nature of our business does not require extensive security personnel in our global operations.
<b>Indigenous Rights</b>		
HR9	Total number of incidents of violations involving rights of indigenous people and actions taken.	Our operations do not significantly impact indigenous communities.
<b>Assessment</b>		
HR10	Percentage and total number of operations that have been subject to human rights reviews and/or impact assessments.	N/A

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Remediation</b>		
HR11	"Number of grievances related to human rights filed, addressed and resolved through formal grievance mechanisms."	<b>Office of Ethics</b> We have an internal grievance mechanism in place that allows employees and our business partners to report any suspected human rights violations (or other ethical or policy violations).
<b>Social: Society</b>		
<b>Local Communities</b>		
SO1	Percentage of operations with implemented local community engagement, impact assessments, and development programs.	<b>Supporting Our Communities</b> <b>Community</b> <b>Pharmaceuticals in the Environment</b>
SO9	Operations with significant potential or actual negative impacts on local communities.	N/A
SO10	Prevention and mitigation measures implemented in operations with significant potential or actual negative impacts on local communities.	N/A



GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Corruption</b>		
SO2	Percentage and total number of business units analyzed for risks related to corruption.	Code of Conduct Sales & Marketing Interacting with Healthcare Professionals
SO3	Percentage of employees trained in organization's anti-corruption policies and procedures.	All employees are required to take mandatory training related to anti-corruption policies & procedures. Code of Conduct Sales & Marketing Interacting with Healthcare Professionals
SO4	Actions taken in response to incidents of corruption.	Ethics & Transparency Code of Conduct Sales & Marketing Interacting with Healthcare Professionals

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Public Policy</b>		
SO5	Public policy positions and participation in public policy development and lobbying.	Public Policy & Advocacy Views & Positions
SO6	Total value of financial and in-kind contributions to political parties, politicians, and related institutions by country.	Transparency Disclosures Public Policy & Advocacy
<b>Anti-Competitive Behavior</b>		
SO7	Total number of legal actions for anti-competitive behavior, anti-trust, and monopoly practices and their outcomes.	2012 10-K
<b>Compliance</b>		
SO8	Monetary value of significant fines and total number of non-monetary sanctions for non-compliance with laws and regulations.	EHS Management & Compliance Ethics & Transparency

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Social: Product Responsibility</b>		
<b>Customer Health and Safety</b>		
PR1	Life cycle stages in which health and safety impacts of products and services are assessed for improvement, and percentage of significant products and services categories subject to such procedures.	Research & Development Manufacturing & Supply Chain Quality & Safety Standards Product Stewardship Patient Safety
PR2	Total number of incidents of non-compliance with regulations and voluntary codes concerning health and safety impacts of products and services during their life cycle, by type of outcomes.	Transparency Disclosures Manufacturing & Supply Chain Quality & Safety Standards
<b>Product and Service Labeling</b>		
PR3	Type of product and service information required by procedures, and percentage of significant products and services subject to such information requirements.	Transparency Disclosures Clinical Research Quality & Safety Standards Sales & Marketing Patient Safety

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
PR4	Total number of incidents of non-compliance with regulations and voluntary codes concerning product and service information and labeling, by type of outcomes.	<b>Sales &amp; Marketing</b> <b>Manufacturing &amp; Supply Chain</b>
PR5	Practices related to customer satisfaction, including results of 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.
<b>Marketing Communications</b>		
PR6	Programs for adherence to laws, standards, and voluntary codes related to marketing communications, including advertising, promotion, and sponsorship.	<b>Sales &amp; Marketing</b>
PR7	Total number of incidents of non-compliance with regulations and voluntary codes concerning marketing communications, including advertising, promotion, and sponsorship by type of outcomes.	<b>Sales &amp; Marketing</b>

GRI#	Description	Report Location/ Direct Answer
<b>STANDARD DISCLOSURES PART III: Performance Indicators</b>		
<b>Economic</b>		
<b>Customer Privacy</b>		
PR8	Total number of substantiated complaints regarding breaches of customer privacy and losses of customer data.	<b>Global Privacy Program</b>
<b>Compliance</b>		
PR9	Monetary value of significant fines for non-compliance with laws and regulations concerning the provision and use of products and services.	<b>Sales &amp; Marketing</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, Merck 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 Merck is contributing to the MDGs.

Goal	Description	Report Location
MDG 1	Eradicate extreme poverty and hunger	Health MerckCR Animal Health Merck Animal Health Website
MDG 2	Achieve universal primary education	Education
MDG 3	Promote gender equality and empower women	Diversity & Inclusion
MDG 4	Reduce child mortality	Public-Private Partnerships Vaccines Pediatric Treatments for HIV
MDG 5	Improve maternal health	Women's Health Merck for Mothers
MDG 6	Combat HIV/AIDS, malaria and other diseases	Committed to Improving Access to HIV Care Vaccines R&D for Low- & Middle-Income Countries Global Burden of Disease
MDG 7	Ensure environmental sustainability	Environmental Sustainability
MDG 8	Develop a global partnership for development	Public-Private Partnerships

## UN GLOBAL COMPACT

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

By signing on, the company confirms its commitment to support the 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 Merck disclosures can be found on the Merck website in relation to UN Global Compact principles.

### 2012 Communication on Progress

Principle	Description	Report Location
	Statement of continued support by the CEO	CEO Letter
<b>Human Rights</b>		
Principle 1	Businesses should support and respect the protection of internationally proclaimed human rights	Human Rights
Principle 2	Businesses should make sure that they are not complicit in human rights abuses	Human Rights External Supplier Network
<b>Labour</b>		
Principle 3	Businesses should uphold the freedom of association and the effective recognition of the rights to collective bargaining	Human Rights
Principle 4	Businesses should support the elimination of all forms of forced and compulsory labor	Human Rights
Principle 5	Businesses should support the effective abolition of child labour	Human Rights
Principle 6	Businesses should support the elimination of discrimination in respect of employment and occupation	Human Rights Human Rights of Our Employees Office of Ethics Diversity & Inclusion

Principle	Description	Report Location
<b>Environment</b>		
Principle 7	Businesses should support a precautionary approach to environmental challenges	Environmental Sustainability EHS Management & Compliance Manufacturing & Supply Chain Product Stewardship
Principle 8	Businesses should undertake initiatives to promote greater environmental responsibility	Environmental Sustainability EHS Management & Compliance Manufacturing & Supply Chain Product Stewardship
Principle 9	Businesses should encourage the development and diffusion of environmentally friendly technologies	Environmental Sustainability Product Stewardship Green Chemistry
<b>Anti-Corruption</b>		
Principle 10	Businesses should work against corruption in all its forms, including extortion and bribery	Ethics & Transparency Office of Ethics



# KEY PERFORMANCE INDICATORS (KPIs)



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 our business units with the exception of joint ventures.

KEY PERFORMANCE INDICATORS		
ACCESS TO HEALTH	2011	2012
<b>Research &amp; Development</b>		
Top 20 global burdens of illness addressed by our products and pipeline <sup>1</sup>	53%	55%
GCP/PV audits by regulatory agencies of Merck or clinical trial investigators that led to significant fines, penalties, warning letters or product seizures	0	0
Initiated (new) licenses for new technologies	52	61
Narrative of compounds provided to Product Development Partnerships <sup>2</sup>	Online	Online
<b>Manufacturing &amp; Supply</b>		
Product recalls in the United States	0	4
Countries we currently supply with our products	140	140
Local and regional manufacturing partnerships <sup>3</sup>	130	84
Products available via local and regional manufacturing partnerships	NA	34

<b>Registration</b>		
New product and device registrations <sup>4,5</sup>	334	437
Local regulatory agency GCP/PV training requests fulfilled that will help strengthen agency capabilities with their GCP/PV compliance oversight role <sup>6</sup>	Online	Online
Products submitted that have achieved WHO prequalification (cumulative)	10	10
<b>Commercialization</b>		
Products for which we have access pricing <sup>7</sup>	19	19
Countries where at least one product has intra-country pricing of public and private sectors <sup>8</sup>	49	49
Investment into patient- and provider-education programs	\$93.9M	\$91.1M
<b>Community Investment</b>		
Healthcare workers trained through major programs and partnerships <sup>9</sup>	51,600	38,166
Investment in partnerships for activities to address underlying barriers to health, such as health system strengthening and capacity building <sup>10</sup>	\$34.7M	\$23.8M
People reached through our major programs & partnerships <sup>9,11</sup>	255M	269M

ENVIRONMENTAL SUSTAINABILITY <sup>12</sup>	2011	2012
Greenhouse gas emissions (million metric tons of CO <sub>2</sub> e)	2.10	1.98
Emissions of volatile organic compounds (metric tons)	931	807
Water usage (billion gallons)	9.1	9.1
Waste generated (metric tons)	186,500	179,000
Waste recycling rate	54%	52%

EMPLOYEES	2011	2012
<b>Diversity &amp; Inclusion</b>		
Executive roles held by women <sup>13,14</sup>	35%	31%
Women on the Board	17%	17%
Underrepresented ethnic groups on the Board	11%	25%
Underrepresented ethnic groups in the workforce (U.S.)	29%	24%
<b>Well-Being</b>		
Response rate to Merck and MSD Voice Survey	63%	77%
Employees who completed health assessment (U.S.)	58%	58%
Overall turnover rate <sup>15</sup>	14%	11%
Lost-Time Injury Rate (LTIR) <sup>16</sup>	0.30	0.24
Recordable Injury Rate (RIR) <sup>16</sup>	0.74	0.59
<b>Volunteerism</b>		
Employees who took release time according to the global policy on employee volunteerism <sup>17</sup>	11%	15%
Volunteer hours <sup>17</sup>	213,000	221,000

ETHICS & TRANSPARENCY	2011	2012
Employees trained on our Code of Conduct	90%	92%
Substantiated allegations to concerns/issues raised	65%	60%
Reported concerns regarding privacy practices, breaches of privacy, and losses of personal data and devices that were substantiated <sup>18</sup>	68%	23%

NA: Not available.

<sup>1</sup> As defined by the WHO and excluding accidents, premature births and self-inflicted injuries.

<sup>2</sup> For information on product development partnerships, visit the "Partnerships" tab [here](#).

<sup>3</sup> The number of partnerships decreased in 2012 following the evaluation of the manufacturing capabilities needed to support and sustain our Access goals.

<sup>4</sup> Data includes new products and new indications.

<sup>5</sup> For information on new registrations by region, click [here](#).

<sup>6</sup> For information on local regulatory agency GCP/PV training requests, click [here](#).

<sup>7</sup> Differential pricing intended to facilitate access for the at-need population.

<sup>8</sup> Countries with an MSD trading equity.

<sup>9</sup> "Major" is defined as an investment by Merck's Office of Corporate Philanthropy and/or The Merck Foundation of more than \$300,000 per year and/or an engagement with a national government.

<sup>10</sup> Includes investments by Merck's Office of Corporate Philanthropy and/or The Merck Foundation; also includes funding for nutrition and access to clean water.

<sup>11</sup> Includes treatments approved for river blindness and lymphatic filariasis through the Merck MECTIZAN<sup>®</sup> Donation Program.

<sup>12</sup> For more details on our environmental metrics, please download the Excel spreadsheet on our [Downloads & Media](#) page.

<sup>13</sup> Beginning with 2012, data reported for women are global; previously, these data were limited to the U.S.

<sup>14</sup> "Executive" is defined as the Chief Executive Officer and two structural levels below.

<sup>15</sup> Overall turnover incorporate all types of turnover, including restructuring.

<sup>16</sup> LTIR/RtR: Calculated per OSHA methodology.

<sup>17</sup> Figures are based on data collected, reported and estimated worldwide.

<sup>18</sup> Privacy concerns include all concerns escalated to the Merck Privacy Office about the company's privacy practices.

Substantiated concerns are those that are determined to be inconsistent with Merck privacy standards or that involve loss, theft or unauthorized access to personal data.