



# ELI LILLY AND COMPANY

Corporate Responsibility Update 2014

**Our greatest contribution to society is making medicines that help people live longer, healthier, more active lives. But our company vision—to improve global health in the 21st century—demands that we do even more.** This report covers our activities across a range of areas, including Advancing Medical Science, Improving Global Health, Strengthening Communities, and Operating Responsibly.

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## Message from the CEO

Dear Reader,

For us at Lilly, there's an inherent connection between achieving our core mission and contributing to a healthier world.

Discovering new medicines means never being satisfied with what we've achieved. It demands determination to overcome failure and find solutions, no matter the odds. And it requires uniting our expertise with the creativity of research partners around the world. This same vision and resolve drive all our efforts to improve life for the people we touch. We're increasingly using our assets, expertise, and passion to find sustainable solutions to global health challenges, expand access for people who need our medicines, and strengthen communities.

“At Lilly, we hold steadfast to our long-standing values of integrity, excellence, and respect for people. We strive to create a culture that fosters engagement and teamwork, rewards diligence and ethical action, and inspires creativity.”

— John C. Lechleiter, Ph.D.  
Chairman, President, and Chief Executive Officer

This report reflects our commitment to fulfilling our mission and meeting our responsibilities as a corporation. In the pages that follow, you'll find a detailed report on our performance in four areas:

## ADVANCING MEDICAL SCIENCE

Colonel Eli Lilly, our founder, set out to establish public trust in medicine at a time when questionable characters were peddling untested potions. Throughout our company's history, we've earned that trust by bringing new and better medicines to people who need them—commercializing the first insulin, introducing important classes of antibiotics, revolutionizing the treatment of mental illness, making critical contributions in the treatment of cancer, and more. Today, we remain committed to pursuing innovative potential medicines for scourges such as diabetes and Alzheimer's disease, and we're working to change the way we perform research to reduce the time it takes to develop new therapies. All along the way—even when we fail—we advance medical science by learning more about disease pathways and human biology.

## IMPROVING GLOBAL HEALTH

At Lilly, we share the vision of a world where everyone is able to enjoy the basic health care that so many of us take for granted. Even as we develop strategies to bring medicines to more people around the world, our signature global health programs—the Lilly NCD

Partnership and the Lilly MDR-TB Partnership—are helping to improve health outcomes and expand access to medicines for people in need today. We also help providers, patients, and their families navigate the complexity of healthcare challenges through a variety of offerings, including TruAssist, which provides access to Lilly medicines for people in the United States who otherwise couldn't afford them. And Elanco, our animal health business, is focused on the important link between hunger and human health, and is working to break the cycle of hunger in 100 communities around the world by 2017.

## STRENGTHENING COMMUNITIES

In the late 1800s, Colonel Lilly took an active leadership role in efforts to improve life in Indianapolis, home to our global headquarters. Ever since, Lilly people have continued this legacy by strengthening the communities where we work and live and by assisting people who live in poverty. You can see this commitment on Lilly's Global Day of Service, which ranks among the largest single-day volunteer events of any global enterprise. The same spirit is manifested by Lilly volunteers who serve in vulnerable communities around the world as part of our Connecting Hearts Abroad program. And it drives our ongoing work to empower teachers, inspire students, and advocate for new approaches to ensure that every student has access to a great education.

## OPERATING RESPONSIBLY

At Lilly, we hold steadfast to our long-standing values of integrity, excellence, and respect for people. Our commitment extends through to our support for the United Nations Global Compact and its principles related to human rights, labor, the environment, and anti-corruption. We strive to create a culture that fosters engagement and teamwork, rewards diligence and ethical action, and inspires creativity. We're proud to be recognized as a company that works hard to support our employees, both inside and outside of work.

Our values—and our humanity—guide how we treat each other and those we serve, inspiring us to build trust through our commonalities, celebrate our differences, and seek out ways to keep making life better.

On behalf of everyone at Lilly, thank you for your interest in our company and in our efforts, outlined here, to be true to our mission and our legacy.



John C. Lechleiter, Ph.D.  
Chairman, President, and Chief Executive Officer  
May 2015

## About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [www.lilly.com](http://www.lilly.com) and [newsroom.lilly.com/social-channels](http://newsroom.lilly.com/social-channels).



### ABOUT ELANCO ANIMAL HEALTH

Elanco, a division of Lilly, provides comprehensive products and knowledge services to improve animal health in more than 70 countries. Elanco serves the diverse and evolving needs of our customers to help them address the global challenges we all face. At Elanco, we understand the powerful role healthy animals play in making life better. That's why Elanco initiated the ENOUGH movement to support food security ([www.ENOUGHmovement.com](http://www.ENOUGHmovement.com)) and supports the human-animal bond through partnership with Canine Assistants ([www.celebratethebond.com](http://www.celebratethebond.com)). Additional information about Elanco is available at [www.elanco.com](http://www.elanco.com).

## Our Approach to Corporate Responsibility

At Lilly, our greatest contribution to society is discovering and developing innovative medicines that make life better for people around the world. This is the core of what we do. And by doing this well, we are able to extend our reach and deepen the impact of our other activities.

This includes investing in areas traditionally seen as the domain of “corporate responsibility,” including philanthropy, community involvement and volunteerism, environmental programs, workplace initiatives, and patient programs, among others. At Lilly, no one person owns our corporate responsibility work. Rather, it is embedded into many facets of company operations and is expressed in countless ways in communities around the world.

Over the last decade, we have transformed our corporate responsibility efforts, sharpening our focus on improving the health of people in low- and middle-income countries and strengthening the communities where we work and live. We’re balancing traditional philanthropy—which dates back to the earliest days of our company—with novel approaches that put to work our scientific and business expertise, our resources, and the passion of our employees.

### EXPANDING ACCESS TO MEDICINES

Many people are interested in what pharmaceutical companies, including Lilly, are doing to help people get access to the medicines they need. We recognize that only an estimated 2 billion people out of the world’s total population of 7 billion have a reasonable opportunity to use a Lilly medicine today. And those 2 billion are typically in higher socio-economic classes or in developed countries with strong healthcare systems.

In the past, we have used traditional philanthropy—product donations and charitable contributions—to help reach more people in need of our medicines, including those living in low- and middle-income countries. Lilly will continue to make well-informed philanthropic investments. However, consistent with our mission to improve global health, Lilly is pursuing a number of different approaches to expand access to our medicines. These include our growing efforts to build strategic partnerships to find new solutions for people living in lower-income countries.

### GOVERNANCE

Given the growing importance and complexity of healthcare access issues, in 2012, Lilly named a senior director of global health programs and strategy, who works alongside the senior director of corporate responsibility. This operational structure allows for cross-functional collaboration on healthcare access and other corporate responsibility issues from a global perspective. Specifically, this role is responsible for Lilly’s engagement with key stakeholders interested in Lilly’s access to medicines strategy and also for leading strategic thinking at Lilly on broader access to medicine issues.

# Key Performance Indicators

	2010	2011	2012	2013	2014
<b>Financial Highlights</b>					
Worldwide Revenue (\$ millions)	\$ 23,076.0	\$ 24,286.5	\$ 22,603.4	\$ 23,113.1	\$ 19,615.6
U.S. Revenue	\$ 12,865.6	\$ 12,977.2	\$ 12,313.1	\$ 12,889.7	\$ 9,134.1
Europe Revenue	\$ 5,106.4	\$ 5,290.9	\$ 4,259.7	\$ 4,338.4	\$ 4,506.7
Other Foreign-Country Revenue	\$ 5,104.0	\$ 6,018.4	\$ 6,030.6	\$ 5,885.0	\$ 5,974.8
Stock Price (\$ at year end)	\$ 35.04	\$ 41.56	\$ 49.32	\$ 51.00	\$ 68.99
Dividend (\$ per share)	\$ 1.96	\$ 1.96	\$ 1.96	\$ 1.96	\$ 1.96
Research and Development (\$ millions)	\$ 4,884.2	\$ 5,020.8	\$ 5,278.1	\$ 5,531.3	\$ 4,733.6
<b>Workplace<sup>1</sup></b>					
Recordable Injury Rate (per 100 employees)	0.96	1.09	1.10	0.88	0.88
Lost-Time Injury Rate (per 100 employees)	0.41	0.47	0.49	0.36	0.35
Fleet Collision Rate <sup>2</sup> (percent of fleet)	24%	22%	21%	19%	18%
<b>Philanthropy Highlights<sup>3,4</sup></b>					
Product Donations (\$ millions)	\$ 373	\$ 549	\$ 645	\$ 695	\$ 550
Cash Contributions (\$ millions)	\$ 57	\$ 48	\$ 55	\$ 55	\$ 40
Total Contributions (\$ millions)	\$ 430	\$ 597	\$ 700	\$ 750	\$ 590

	2010	2011	2012	2013	2014
<b>Environmental Highlights<sup>5</sup></b>					
Greenhouse Gas Emissions (Scope 1 and Scope 2) (metric tonnes CO <sub>2</sub> e)	1,620,000	1,560,000	1,560,000	1,610,000	1,540,000
Greenhouse Gas Emissions Intensity (metric tonnes CO <sub>2</sub> e/1,000 square feet)	75.3	71.4	69.7	71.1	69.8
Energy Consumption (million BTUs)	11,200,000	10,800,000	10,900,000	11,200,000	10,700,000
Energy Intensity (million BTUs/1,000 square feet)	521	495	488	495	484
Water Intake (billion liters)	12.8	13.3	12.4	12.7	13.5
Water Intensity (million liters/million \$ revenue)	0.555	0.549	0.549	0.562	0.688
Waste Generation (metric tonnes)	228,000	242,000	281,000	307,000	292,000
Waste Generation Intensity (metric tonnes/million \$ revenue)	9.88	10.7	12.3	13.3	14.9
Waste to Landfill (metric tonnes)	15,900	10,900	12,300	8,900	6,300
Reportable Permit-Limit Exceedances <sup>6</sup>	11	8	8	5	3

<sup>1</sup> Read the [Health and Safety at Lilly](#) section to learn more about our new safety goals for 2020.

<sup>2</sup> In prior reports, we tracked the motor-vehicle collision rate (collisions per million miles driven). We now are tracking vehicle safety based on percent of fleet involved in a collision. Historical collision rates shown in this table have been restated.

<sup>3</sup> Total charitable donations include funding from both Lilly and The Eli Lilly and Company Foundation.

<sup>4</sup> In 2014, we saw a decrease in the number of people requesting assistance through our U.S. patient assistance programs following the implementation of the Affordable Care Act, which allows previously uninsured low-income Americans to obtain healthcare coverage. As a result, fewer people were in need of donations from Lilly.

<sup>5</sup> Following World Resources Institute guidance, energy use, greenhouse gas emissions (except Scope 3), waste, and water use data are reported on an adjusted basis accounting for mergers, acquisitions, and divestitures, as appropriate, to ensure comparability, unless stated otherwise.

<sup>6</sup> Lilly classifies an event as a reportable permit-limit exceedance if it involves an exceedance of a numeric permit or license limit that must be reported to the regulatory authority. The reporting may be immediate (e.g., within 24 hours) or in a routine compliance report. These exceedances do not necessarily result in harm to people or the environment.

## Corporate Responsibility Highlights

The Eli Lilly and Company Foundation and our animal health division, Elanco, together have contributed more than \$3 million to Heifer International, providing the gift of training and animals to break the cycle of hunger for families in China, India, Indonesia, and Zambia. Elanco's latest commitment supports the East Africa Dairy Development project, which aims to **provide sustainable livelihoods for more than 600,000 people** in Kenya, Tanzania, and Uganda by 2018.

*Working Mother* magazine has named Lilly as one of its **“Working Mother 100 Best Companies”** 20 years in a row.

The Lilly MDR-TB Partnership is our largest philanthropic effort ever—a **\$170 million commitment from 2003–2016**.

Through the partnership, we gave away our manufacturing technology and know-how for two antibiotics to other manufacturers. Lilly's experience and insights from this decade-long initiative are documented in a new white paper, [Seeking Solutions to a Global Health Crisis](#).

Through the Lilly NCD Partnership, we're investing **\$30 million over five years** to strengthen diabetes care for people in rural and urban settings in Brazil, India, Mexico, and South Africa.

Every year since 2006, Lilly has received a **100% rating on the Human Rights Campaign (HRC) Corporate Equality Index (CEI)** and has been named to HRC's "Best Places to Work" list.

Between 2007 and 2013, **we improved energy efficiency by 17% and reduced greenhouse gas (GHG) emissions intensity by 16%\***, surpassing our goals of 15% improvement during that timeframe. Through lower energy consumption, we saved \$175 million in energy costs during that period.

\*Each of these goals is per square foot of facility space.

## Our new 2020 environmental goals

target another 20% improvement in energy efficiency with a corresponding 20% reduction in GHG emissions intensity, a 20% improvement in waste efficiency, and a 15% absolute reduction of phosphorus emissions in wastewater.\*\*

## We reduced our waste sent to landfill by 72% from 2007 to 2013, surpassing our goal of a 40% reduction during that time.

This equals the amount of waste that would fill about 2,300 garbage trucks. Our total reduction in overall waste generation over that same period was about 19%.

In 2014, Lilly presented a gift of **\$12.7 million to United Way**—our company's largest ever United Way contribution.

The Asia-Pacific Economic Cooperation (APEC), in 2014, named Lilly as **one of the 50 Leading Companies for Women**, in recognition for our efforts to encourage women's participation and leadership.

**We reduced water intake** by 35% in absolute terms between 2007 and 2013, **exceeding our goal of a 25% reduction during that period.** The decrease of 6.9 billion liters would fill about 13,000 Olympic-sized swimming pools.

Over the last five years, Lilly has **committed more than \$6 million** in philanthropic donations to strengthen the educational landscape in Indiana and sent hundreds of employee volunteers to help in the schools.

For the fourth year in a row, in 2014, Lilly was named to DiversityInc's **"Top 50 Companies for Diversity"** list, which recognizes corporate diversity best practices.

Each year, Lilly **donates substantial amounts of products and cash—more than \$590 million in total in 2014**—and our employees volunteer their skills around the world.

\*\*These goals have a baseline of 2012, except for the reduction of phosphorus emissions in wastewater goal, which is 2014.

## About this Report

This is Eli Lilly and Company's 2014 Corporate Responsibility Report. It also serves as Lilly's annual Communication on Progress for the United Nations Global Compact (UNGC), of which Lilly is a signatory. The UNGC is a strategic policy initiative for businesses that are committed to aligning their operations and strategies with 10 universally accepted principles in the areas of human rights, labor, the environment, and anti-corruption. An index to the UNGC indicators in this report can be found on [page 113](#). More information about the UNGC can be found at [www.unglobalcompact.org](http://www.unglobalcompact.org).

Every year since Lilly joined the UNGC in 2010, we have reported on our commitments to the UNGC principles and our related activities and progress toward goals that we have set for ourselves. Since our initial UNGC Communication on Progress (COP) submission in 2010, we have integrated our COP content into our annual corporate responsibility report. This has enabled us to cover the UNGC principles alongside a range of other topics of interest to global stakeholders across all areas of our business. In 2014, we made the decision to adjust the timing of our annual corporate responsibility report, moving our annual publication date from November to May. This decision was based on a range of factors, including the desire to provide more timely updates on our corporate responsibility efforts, achievements, and challenges, as well as to align disclosures on Lilly's corporate responsibility goals and performance with our annual shareholders' meeting and the release of Lilly's annual report.

We feel the new timing for our report, issuing earlier in the calendar year, will help us to be more responsive and transparent to those interested in Lilly and our work. Indeed, it reflects a deepening and a strengthening of our commitment to communicating about our corporate responsibility in a more timely and coordinated way. This report, issued in May 2015, represents our first report to be issued on our new timeline. Moving forward, reports will be issued in May.

Data and other updates contained in this report are focused on the 2014 calendar year and include global operations, unless otherwise noted. We also discuss data and trends from previous years, where relevant, and include some significant events and initiatives that occurred in the first half of 2015. This report does not include joint ventures, partially owned subsidiaries, leased facilities, or outsourced operations.

Our financial information, which is prepared according to the generally accepted accounting principles (GAAP) in the United States, is subject to our own internal accounting control systems and to external third-party audits. (All dollar amounts given are in U.S. dollars.) In addition to those external third-party financial audits, Bureau Veritas provided independent, third-party verification of greenhouse gas emissions data for Scopes 1, 2, and 3. Bureau Veritas also verified the percentage decrease from both the baseline year (2007) and from 2013 compared to 2014 for the following metrics: energy intensity, waste to landfill, and water intake. Otherwise, the content and data in this report have not been externally verified.

To ensure appropriateness and accuracy, Lilly follows structured processes to collect, evaluate, and calculate the data we report. We consider external standards in deciding what data to collect and report. For example, following guidance from the World Resources Institute, we report progress toward environmental goals on an adjusted basis accounting for mergers, acquisitions, and divestitures, as appropriate, to ensure comparability, unless stated otherwise. Our global health, safety, and environment management system is certified by an independent, accredited auditor in accordance with the American Chemistry Council's Responsible Care Management System requirements.

We welcome feedback on this report, as it helps us to improve future reports.

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02

# Advancing Medical Science

- ▶ Discovering Medicines More Quickly
- ▶ Transforming Clinical Trials
- ▶ Bioethics
- ▶ Ensuring Quality Medicines

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At Lilly, our purpose is to make life better for people around the world. We focus on discovering and developing new medicines, improving the understanding and management of disease, and supporting people with serious illness and their families.

Throughout our history, we've been pioneers against some of the world's most devastating diseases. Our rich history includes industry breakthroughs, such as these:

- The development of insulin in 1923 with scientists from the University of Toronto;
- New classes of antibiotics—many of which are still being used today;
- Biosynthetic human insulin—the world's first biotech product for human use; and
- Prozac®, which revolutionized how doctors treat clinical depression.

But our legacy of improving human health is not done. Millions of people around the world continue to suffer from life-threatening diseases. And Lilly remains committed to the innovation-based research and development strategy that has distinguished us for more than 139 years.

In 2014, we launched a number of new medicines designed to treat diabetes and certain cancers. And our pipeline of potential new medicines is poised to deliver future treatments for other devastating diseases, including autoimmune disorders, Alzheimer's disease, pain, and more.

We focus our research on three core areas—diabetes, oncology, and neurodegeneration, including Alzheimer's disease. In addition, our research efforts will expand to include two emerging areas—immunology and pain—based on research opportunities and clinical data.

## BUILDING ON 139 YEARS OF EXPERTISE

For more than 139 years, Lilly researchers have worked tirelessly to discover medicines that make life better. From the development of insulin and the manufacturing of the polio vaccine to the discovery of medicines that treat mental illness, we have pioneered breakthroughs against some of humanity's most stubborn and devastating diseases.

### Milestones in Medical Research

- 1880s** Lilly was one of the first companies to initiate a genuine pharmaceutical research program, hiring a pharmaceutical chemist as its first scientist.
- 1920s** Our researchers collaborated with Frederick Banting and Charles Best of the University of Toronto to isolate and purify insulin for the treatment of diabetes, a fatal disease with no effective treatment options at the time. In 1923, the work resulted in Lilly's introduction of the world's first commercially available insulin product.

Lilly initiated a research program to find a treatment for pernicious anemia, a life-threatening blood disorder, and introduced a liver-extract product that served as a standard of therapy for decades.
- 1940s** Lilly was among the first companies to develop a method to mass-produce penicillin, the world's first antibiotic, marking the beginning of a sustained effort to fight infectious diseases.

**1970s** Ceclor® was launched and eventually became the world's top-selling oral antibiotic. Lilly also introduced Dobutrex®, an innovative and lifesaving cardiovascular product.

**1960s** Lilly launched the first of a long line of oral and injectable antibiotics and, over the next two decades, pioneered important chemical breakthroughs that allowed their large-scale production.

The company also introduced anticancer drugs, known as vinca alkaloids.

**1950s** The company introduced a powerful antibiotic that remains the last line of defense for patients suffering from serious hospital infections associated with certain types of resistant bacteria. Lilly also launched an antibiotic with a broad antimicrobial spectrum that expands the alternatives for penicillin-allergic patients.

Lilly was approached to produce a polio vaccine based on the one developed by Dr. Jonas Salk. Ultimately, more than half of all the Salk vaccine used in the United States bore the Lilly label.

**1980s** The most significant breakthrough in diabetes care since the 1920s was marked by Lilly's introduction of Humulin® insulin, which is identical to that produced by the human body.

Lilly launched Prozac®, the first major introduction in a new class of drugs for treatment of clinical depression.

**1990s** Lilly introduced a stream of innovative new products for the treatment of pancreatic and non-small-cell lung cancer, diabetes, and schizophrenia; the prevention of blood clots following certain heart procedures; and the prevention and treatment of postmenopausal osteoporosis.

**2000s** Since the turn of the century, Lilly has continued to develop and launch new medicines to treat or reduce the risk for a range of diseases and conditions, including osteoporosis, attention-deficiency hyperactivity disorder, bipolar depression, male erectile dysfunction, severe sepsis in adult patients, malignant pleural mesothelioma, ovarian cancer, invasive breast cancer, diabetes, and thrombotic cardiovascular events.

As we continue to focus on some of the most prevalent diseases affecting our society, we also recognize that for patients in need of treatment now, the drug discovery and development process can seem to cost too much and take too long. From start-to-finish, it's not uncommon for this process to take more than 10 years and to cost in excess of \$1 billion for each new medicine approved.

## Discovering Medicines More Quickly

Biopharmaceutical research takes determination. Once a molecule is invented, it goes through rigorous tests in our labs, followed by clinical testing at sites all over the world, to understand if it could potentially be effective and safe when used in humans.

How can we find innovative ways to improve the speed and quality of this development process so that new medicines reach the people who need them faster?

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### LILLY'S PIPELINE: MEDICINES IN DEVELOPMENT

Lilly is focused on some of the world's most prevalent and devastating diseases, including cancer, diabetes, and neurodegenerative disorders like Alzheimer's disease. Our science is focused on developing a complementary mix of small molecules (oral medications) and large molecules (often given by injection) to address the diverse needs of the people we serve. Our interactive pipeline website provides information on potential new medicines in clinical development: [www.Lilly.com/Pipeline](http://www.Lilly.com/Pipeline).

“The secrets of science inspire me. I went into this field because I always wanted to know the answer to the questions. But once I got here, it became more about the people who need new medicines, the people suffering from conditions that have no good treatment options. I see how we change people's lives in oncology and diabetes, the promise we have for Alzheimer's disease and autoimmune disorders. That inspires me. It makes me get up every morning, ready to come to work.”

— Carl Garner, Ph.D., Lilly Regulatory Scientist



“The single greatest motivation to work in the pharmaceutical industry is the knowledge that there are patients who are waiting for the medicines that we are making, who need the therapies that we can create for them.

When I was young, I developed a case of rheumatic fever after a bout of strep throat. It had an effect on my heart and, as a child in third grade, I was unable to play with other children. In fact, I had to lie in a bed for months and be carried. It was a medicine that I took that allowed me to get up again, and it was a medicine made by the company that I now work for. That’s why I joined the pharmaceutical industry.

There are two ways to beat the odds in the discovery of new drugs: strong data and a good dose of passion. To work against the odds for the good of the people who need the medicine—that’s what makes the difference.”

— Andrew M. Dahlem, D.V.M (h.c.), Ph.D., Vice President, Lilly Research Laboratories Operations, Lilly Research Laboratories Europe

Above all, it takes people, committed to excellence, working together, to make it happen. Our 6,000 R&D scientists are working not only to discover and develop new medicines, but to do it faster than ever before. Our scientists combine their deep knowledge of human biology, disease, chemistry, and genomics with computer models and the insights we've gained from people affected by disease to identify new potential medicines.

We build specialized computer programs, screening labs, and other tools to help us process information, develop new experiments, and test our hypotheses as efficiently as possible while maintaining a high standard of quality. During the drug development process, we might conduct 10,000 experiments to find one compound that has the potential to become a new medicine. The commitment and expertise of our scientists, who publish some 8,000 scientific articles annually based on their research, continue to drive forward the development of potential new medicines and contribute to society's overall base of scientific knowledge.

## OUR APPROACH TO DISCOVERY AND DEVELOPMENT

Lilly is evolving the way we discover and develop medicines in order to bring new medicines to the people who need them even faster. We can accomplish this in many ways, including these techniques:

- Science-driven adaptive programs that improve our quality and speed through use of analytics and modeling, along with patient input, in plan development, clinical study design, and decision-making;
- Patient-centric tools and approaches that make it easier for people to find, enroll, and participate in clinical studies;

- Continuous improvement in the quality of our clinical study design during the study, rather than evaluation of the study design at the end; and
- Improvements to our chemistry, manufacturing, and control processes to ensure flexible supply chains and product development plans throughout the development process.

### Our Partnerships

Some of the best scientific breakthroughs happen through collaboration. Particularly in today's complex healthcare environment, we must be innovative in our science, as well as in our approach to [partnerships](#). We never stop searching for the best potential medicines, new ways to address unmet medical needs, and treatments that provide better outcomes for patients, healthcare providers, and payers.

In addition to traditional partnerships, we find and facilitate medical innovations through [Lilly Ventures](#) and the capital funds portfolio [Lilly Asia Ventures](#). These funds invest in start-up biopharmaceutical and medical technology companies via early expansion-stage investments.

Lilly also collaborates with external scientists to complement our internal efforts. Lilly's Open Innovation Drug Discovery (OIDD) program provides external researchers with a point of entry into Lilly's drug discovery process. OIDD uses a unique web-based platform that aims to remove barriers to sustainable innovation with a novel transactional model between Lilly and external scientists. The platform provides external investigators with direct access to Lilly's scientific infrastructure and talent; Lilly provides quality

science as an in-kind contribution that the investigators can use in their work (e.g., publications, grants). Promising results may become the basis for further collaborative agreements.

## Bioethics

Bioethics—which focuses on the ethics of biomedical and clinical research and public policy in biomedical fields—is becoming an increasing area of attention for the pharmaceutical industry, with more companies posting bioethics position statements and making public statements about bioethics. At Lilly, we believe that bioethics is an integral component of corporate integrity and pharmaceutical R&D excellence. We embrace a comprehensive, systemic approach and offer an increasing variety of resources and educational offerings to help employees navigate ethical scenarios and empower them to apply bioethics principles in their daily work.

Our aim is to address bioethics issues proactively and make bioethics discussions more informed and commonplace throughout the company. Most importantly, we encourage our employees to adopt ethics-focused thinking, which is based on values and principles, in addition to compliance-focused thinking, which is based in legal regulation. This kind of ethics-focused thinking helps guide employees when they are faced with a situation that is not explicitly covered by regulation, such as continued access to an investigational medicine, stem cell research, or implications of providing individual results to clinical trial patients.

We also believe in contributing to a strong bioethics practice across our industry, so we engage external stakeholders through presentations at professional and academic conferences, post and communicate our bioethics position statements, and serve on industry, academic, and government committees that address bioethics issues related to biomedical research.

## LILLY BIOETHICS STRUCTURE AND MANAGEMENT

In 1999, Lilly became one of the first pharmaceutical companies to establish a standing bioethics committee to systematically identify, evaluate, and communicate bioethics issues. In 2008, we established the Lilly Bioethics Program, which is committed to promoting bioethics excellence across the company.

The bioethics program is an independent organizational unit reporting to the chief medical officer and includes a senior leader and full-time staff members with pharmaceutical industry expertise and specialized training in bioethics. These individuals serve as resources for the company and are responsible for the program's development, deliverables, and oversight.

In addition to this full-time effort, employees from across the company participate in key bioethics program activities beyond their regular work responsibilities. Employees get involved for a number of reasons: to broaden their own understanding, to create a network of additional resources, and to integrate bioethics concepts throughout Lilly. These "extracurricular" activities include:

- **The Bioethics Advisory Committee**, a cross-functional committee composed of senior leaders from across the company, as well as two external academic experts in the field of bioethics who offer guidance on projects and consultations;
- **The Lilly Bioethics Network (BEN)**, a virtual community of more than 150 Lilly employees who are interested in building their knowledge in bioethics through training opportunities and attendance at lectures, seminars, case discussions, and other activities sponsored by the Bioethics Program;
- **The Bioethics Specialist Team**, a subgroup of the BEN composed of Lilly employees with specialized knowledge and skills in bioethics and an ongoing commitment both to develop in this area and to support the Lilly Bioethics Program through participation in bioethics activities and projects; and
- **The Bioethics Leadership Academy (BELA)**, an internal, nine-month, experiential training program designed to establish a cohort of Lilly employees with distinct bioethics skills. See below for more about the academy.

## ENGAGING EMPLOYEES IN BIOETHICS

Our aim is to involve more and more employees in bioethics training—creating a network of specialists capable of relating bioethical thinking and knowledge back to different functional areas across the company. When employees approach their work with a strong foundation in bioethics, we're better able to safeguard the integrity of our scientific process and protect the rights and well-being of research participants.

## CROSS-FUNCTIONAL COLLABORATION

As bioethics principles continue to be integrated throughout Lilly, we collaborate internally to bring bioethics issues to the forefront of our work. One example is the collaborative efforts between our bioethics and pediatrics teams. A member of the Bioethics Advisory Committee sits on the Pediatric Steering Committee and vice versa. This approach allows employees to effectively share ideas and expertise and led to the co-development of our bioethics position on [Pediatric Medicine and Device Clinical Development](#).

**Bioethics Consultations**

Since 1999, the Bioethics Advisory Committee has offered a consulting service, providing a forum for Lilly employees to ask questions and seek advice regarding bioethics and research ethics issues. The primary focus of the consultations is pharmaceutical research and development, but questions may also touch on interrelated aspects of clinical ethics, business ethics, and organizational ethics.

We have conducted more than 200 consultations since 2008, when we started collecting metrics, and have seen rising interest over the past several years—starting with five requests per year in 2008 and increasing to approximately one per week in 2013. Results from a survey conducted by bioethics staff indicate that the consultation service is well regarded and viewed as approachable, helpful, and responsive. The service increases awareness about bioethics, empowers employees to raise bioethics concerns, and helps them reason through challenging issues.

For more information, read [“A Pharmaceutical Bioethics Consultation Service: Six-Year Descriptive Characteristics and Results of a Feedback Survey”](#)—an article about our experience with consultations and the benefits we’ve seen as a result of our consultation service.

**Bioethics Week**

In 2014, we hosted a companywide week of awards, lectures, presentations, and discussions related to bioethics. The event—themed “Bioethics in Action”—was jointly sponsored by Lilly’s Bioethics Program and our Animal Research 3Rs Initiative. Our goals for the week were to increase awareness of bioethics and its

implications for the pharmaceutical industry and Lilly, recognize those who have made contributions throughout Lilly in this area, provide employees with an opportunity to engage with experts in bioethics, and position Lilly to proactively address emerging bioethics issues. For more about our approach to animal research, see the [Animal Care and Use](#) section of this report or visit our [Animal Care and Use webpage](#).

**Bioethics Leadership Academy (BELA)**

Employees who are selected to participate in BELA dedicate a portion of their working time to bioethics training for nine months. Participants work through a curriculum, participate in bioethics program activities, and develop a project to help them respond to bioethics issues related to their functional role in the company and the pharmaceutical industry. This is just one way we’re increasing the number of employees throughout Lilly who make bioethics considerations a part of their daily work.

**Ongoing Employee Training**

In 2014, we introduced a computer-based training course to provide an overview of the bioethics program at Lilly and the resources available to help our employees effectively navigate bioethics issues. The training is mandatory for our medical directors and clinical research physicians and scientists. We plan to expand the training next year to help familiarize employees with our overarching bioethics framework (see below) and how it applies to their work.

**OUR POSITIONS ON CURRENT AND EMERGING BIOETHICS ISSUES**

The Lilly bioethics framework provides our researchers with guiding principles and practical tools by specifically describing and evaluating the ethics of developing,

conducting, analyzing, and disclosing results from studies involving human subjects. The framework incorporates company values, bioethics principles from widely recognized global guidelines, and scholarly literature.

The Lilly Bioethics Program employs the bioethics framework when conducting ethical analyses to answer consultation questions and to develop bioethics positions on relevant and emerging topics to assist Lilly teams contemplating challenging bioethics decisions.

For Lilly, conducting clinical trials in diverse locations around the world holds many benefits, including knowledge of how genetic and environmental diversity may impact the safety and effectiveness of our medicines. We understand that for many, the issue of how clinical trials are conducted in diverse locations around the world is of special interest, particularly with regard to the well-being of individual participants and the fair distribution of the benefit and burden of research across geographies. One of our most recently released position statements relates to [multinational clinical studies](#). The statement outlines:

- Reasons for conducting multinational clinical studies;
- Our global ethical standard for conducting clinical studies;
- Our commitment to the safety, rights, and well-being of all study participants;
- Our approach to choosing locations for clinical studies; and
- Our commitment to make the results and benefits of the study available to the host country or community.

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# Building Bioethics Leadership at Lilly: Three Perspectives from the BELA Program

“The foundation the BELA program provided is something I will carry with me throughout my career. I’m constantly referring back to the training I received and thinking about how bioethics principles apply to my work.”

— Sandra Prucka, M.S., Consultant Scientist, Tailored Therapeutics

## The intersection of bioethics and genetics research

Sandra Prucka is a consultant scientist in our tailored therapies area. Her expertise in informed consent and genetic education helps clinical trial investigators and research participants understand the role of biomarker research in helping to deliver the right medicine, to the right person, at the right time.

During the BELA program, Sandra focused on a question at the intersection of bioethics and medical research—the ethical implications of providing individual research results and incidental findings to individuals who have volunteered for clinical trials. As part of an industry research group, Sandra also focused specifically on the return of genetic research results and worked with others to develop a paper exploring this topic. Sandra’s participation in BELA has helped her to become a resource for her team at Lilly, offering important insights into bioethics issues that arise during the course of their work.

“With so many important things to do on any given day, I appreciate that Lilly gives employees an opportunity to devote a significant portion of time to the study of bioethics through the BELA program. The dedicated time to consider and study these issues has been invaluable for me, and I believe it will benefit my larger team and the patients we serve.”

— Elizabeth Stiegemeyer, M.A., Associate Consultant, Biomedicines, Clinical Development Information and Optimization

## A strong bioethics foundation for clinical trial teams

As an associate consultant on our clinical delivery team, Elizabeth Stiegemeyer helps improve the clinical trial experience for research participants. She evaluates data and collaborates with clinical trial teams to help them make decisions about enrollment timelines, study designs, and where to conduct trials. She also partners with those at Lilly who run clinical trial simulations to identify aspects of trials that may be burdensome for participants, so Lilly can address the issues before the studies begin.

Through BELA, Elizabeth proposed conducting a short workshop with the global clinical trial designers participating in the trial simulations. The workshop will help elevate bioethics issues and ensure the bioethical aspects of each specific trial are at the forefront of discussions during clinical trial development. Elizabeth plans to pilot the workshop by mid-2015 and roll it out more broadly throughout the year.

“The BELA program opened my eyes to bioethics issues in a way my previous medical training hadn’t. My entire way of thinking and the approach I take to my work have shifted significantly after going through the program.”

— Iris Goetz, M.D., M.S., Epidemiologist, Research Advisor, Global Patient Outcomes and Real World Evidence

## Supporting clinical trial patients with complex cases

Iris Goetz, M.D., works as research advisor on Lilly’s global patient outcomes and real world evidence team. She supports Lilly colleagues who design studies to help understand how a medicine will work outside of a controlled clinical trial environment. Iris and her colleagues also investigate how a given medicine may affect aspects of patients’ everyday lives, such as independence, quality of life, or the ability to work. Traditionally, this kind of “real-world” evidence can only be studied after a medication has been released commercially.

Iris is involved in a pan-European research project, running from 2013–2016, to evaluate how this knowledge can be gathered earlier in the process, for example, by opening clinical trial participation to patients who may not typically be considered, such as those with underlying health conditions. This ongoing work is helping Iris and others understand the bioethical implications associated with this approach to clinical trial design, and what additional considerations should be taken into account to support people with complex cases, who don’t fit the typical clinical trial profile.

All of our bioethics position statements are available on our [bioethics webpage](#), including [compassionate use of investigational medicines](#), [continued access to an investigational medicine](#), [human biological samples](#), and [stem cell research](#), among others.

## Transforming Clinical Trials

Learning how potential new medicines work for patients during clinical studies is essential to our ability to offer safe, effective medications. Therefore, it is critical that we work to understand the biggest barriers that prevent or deter people from participation in clinical trials and that we work to improve the clinical trial experience. This includes using technology to make trials more convenient for participants, integrating parent perspectives when children are involved, and increasing the diversity of participants across our studies.

### CREATING PATIENT-CENTRIC CLINICAL TRIALS

We believe study volunteers who have a positive experience are more likely to adhere to the study protocol, complete their intended study participation, and potentially be more positive when talking with others about their clinical study experience, which may speed enrollment in future studies.

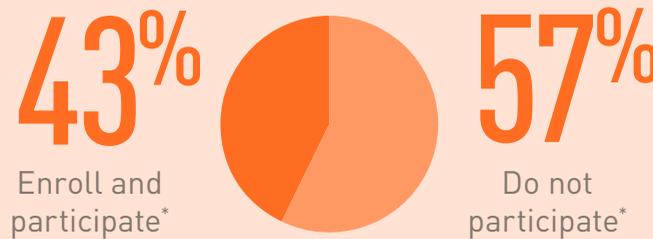
In Lilly's research, we have found that there are numerous reasons why people do—and do not—participate in clinical trials. A general lack of awareness among patients regarding their ability to participate in trials is a major issue. Once patients are aware of a clinical trial, several barriers may prevent them from enrolling—from fear that the new treatment won't be as good as what they are

# PATIENT PARTICIPATION IN CLINICAL TRIALS

FEW PATIENTS ARE AWARE THAT CLINICAL TRIALS ARE AN OPTION

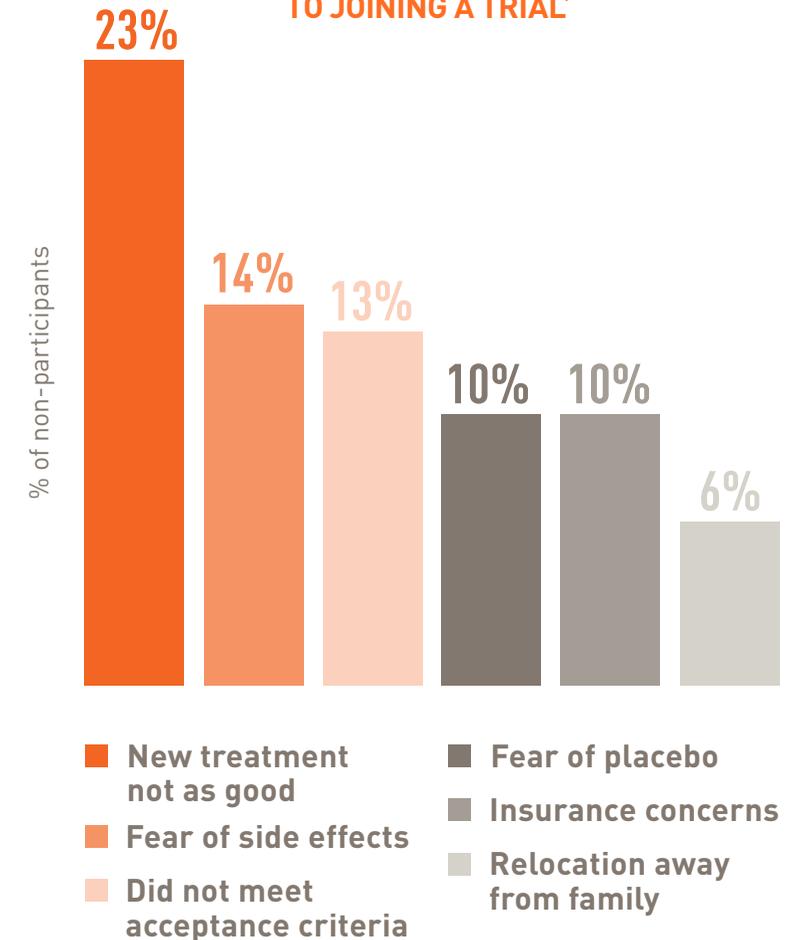
**16%** of cancer patients were aware of relevant clinical trials at the time they were considering treatment options\*

OF THE PEOPLE AWARE OF CLINICAL TRIALS:



**95%** of study volunteers would consider participating in another clinical research study\*\*

PATIENT-REPORTED BARRIERS TO JOINING A TRIAL\*



\*Fenton L, Rigney M, LICSW, Herbst, R Clinical trial awareness, attitudes and participation among patients with cancer and oncologists. 2006. [oncologypractice.com/co/journal/articles/0605207.pdf](http://oncologypractice.com/co/journal/articles/0605207.pdf).

\*\*Center for Information and Study on Clinical Research Participation. 2013 Perceptions & Insights Study, Public and Patient Perceptions of Clinical Research: Report on Clinical Trial Information Seekers; [www.ciscrp.org/wp-content/uploads/2014/01/2013-CISCRP-Study-Clinical-Trial-Information-Seekers.pdf](http://www.ciscrp.org/wp-content/uploads/2014/01/2013-CISCRP-Study-Clinical-Trial-Information-Seekers.pdf). Accessed January 22, 2015.

receiving to insurance concerns. However, the vast majority of those who do participate have a positive experience and would consider participating in another research study.

Lilly works to ensure that those who participate in our clinical trials have a positive experience and would consider enrolling in future trials or recommending the experience to others. In 2012, we launched our “Volunteer/Patient Experience Measures” program, in collaboration with the nonprofit Center for Information and Study on Clinical Research Participation, to help us understand and improve the experiences of research volunteers in our clinical studies. Our goal was to gain a better understanding of why volunteers enter clinical trials in the first place, what their fears and expectations are, what contributes to their level of satisfaction at various points during the trial, how their experience affects their behavior, and why they may choose to drop out.

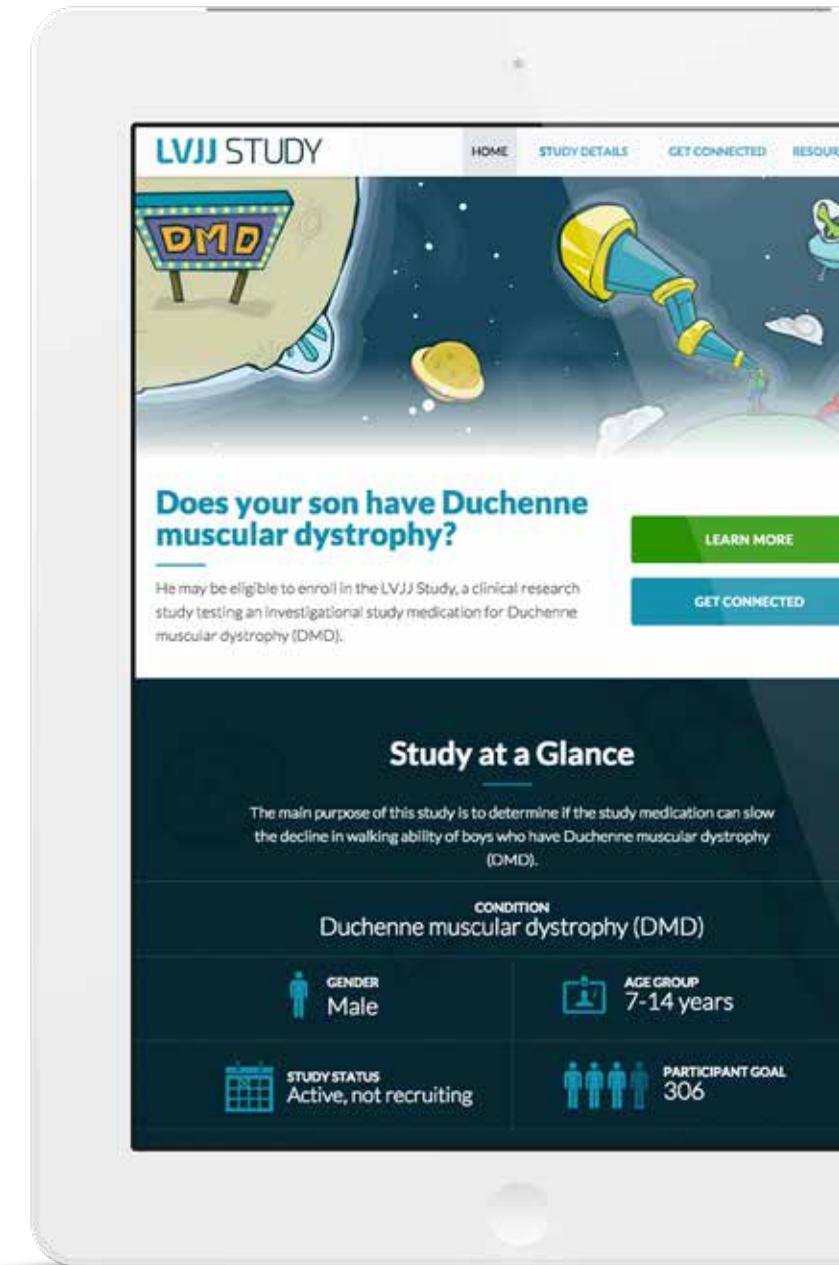
Using the insights gained from a comprehensive literature search and group discussions with volunteers, Lilly developed a quantitative survey to collect information about volunteer experiences throughout the clinical study process. This information can help us measure the success of efforts designed to improve recruitment, retention, and overall volunteer experience. Eight clinical trial sites plan to distribute this survey to participants in 2015. Early results are already helping us better understand how to measure patient satisfaction with clinical trials in the future.

In a separate program, which also aims to improve volunteer experiences with clinical research, Lilly has begun to incorporate the parent perspective in study design processes for pediatric research. Through the program, which began in 2013, Lilly employees who are parents of children with medical conditions volunteer to be contacted when a need arises to provide a parent’s perspective on a pediatric study protocol. The questions cover topics such as the frequency and duration of visits, the appropriateness of formulations and dosing, and what potential barriers to participation exist. After piloting the project with Lilly parent volunteers, the program will be expanded to include non-employees, such as parents from advocacy groups.

### Using Technology to Improve Clinical Trials for Participants

The Lilly clinical open innovation team explores the future of clinical trials—looking at how to improve clinical trial matching, the integration of mobile tools, and Internet-based studies. These are exciting possibilities as technology advances and clinical trial models evolve. The clinical open innovation team is also working on solutions that can improve the clinical trial experience for patients today.

One area that can benefit from immediate changes is the way in which we inform patients about clinical trials. According to the Center for Information and Study on Clinical Research Participation, the Internet is the primary way that people find out about clinical research.<sup>1</sup> However, sponsor websites, ClinicalTrials.gov,



<sup>1</sup> Center for Information and Study on Clinical Research Participation. 2013 Perceptions & Insights Study, Public and Patient Perceptions of Clinical Research: Report on Clinical Trial Information Seekers; [www.ciscrp.org/wp-content/uploads/2014/01/2013-CISCRP-Study-Clinical-Trial-Information-Seekers.pdf](http://www.ciscrp.org/wp-content/uploads/2014/01/2013-CISCRP-Study-Clinical-Trial-Information-Seekers.pdf). Accessed January 22, 2015.

and private third-party websites provide patients with limited information. Our discussions with patients and caregivers have taught us that these sources do not answer the questions that truly matter to them, such as these:

- How much time will I need to take off of work or school to participate?
- Will I need to fast before my visits?
- What can I expect to happen at these visits?
- Will this study interfere with my upcoming travels?

Patients don't get the answers to these important questions until they contact a research site and begin the formal informed consent process. Given patient interest in accessing clinical trial information online, sponsor websites are an excellent opportunity to do just that. As a result, we've revisited the study website to look for areas where we and other sponsors can do better. We've incorporated these ideas for improvement into a pilot project—a study website for our [Duchenne muscular dystrophy trial](#). The study website is designed for parents of boys with Duchenne muscular dystrophy to explore and simulate what participation in the trial would be like. Using the website, parents can begin to answer the questions that matter most to them—before initiating contact with a research site.

For instance, the “study details” section provides both general and specific study visit information. General

visit information includes average study visit duration, study length, and the total number of visits. The specific visit information provides details for individual study visits, including visit length, visit before and after instructions, and a visit assessment list. In addition, the “Get Connected” section allows caregivers to select a potential study start date and view a tentative schedule of visits for the entire study. Our intention is to use this website as a model for future study websites, improving upon the model as we learn.

### INCREASING DIVERSITY IN CLINICAL TRIALS

The impact of disease isn't the same for everyone. Research has shown that health disparities exist between different ethnic and racial groups. In the United States, members of minority groups often suffer a disproportionately higher incidence of certain diseases, such as stroke and diabetes, compared with whites. For example, we know that African Americans are twice as likely to be diagnosed with diabetes as non-Hispanic whites, and Hispanics are almost twice as likely as non-Hispanic whites to be diagnosed with diabetes.<sup>2</sup>

Responses to medicines can vary depending on a number of factors, including someone's genetic background, ethnicity, and lifestyle. That's why it's critical that Lilly has diverse representation in clinical trials—to gain the insights necessary to make medicines that will be the most effective for all people who use them. Unfortunately, minority populations have

historically and consistently been underrepresented in clinical trials. As a result, important information about how medicines work in minority populations is not always available.

In response, Lilly promotes initiatives, such as the [I'm In campaign](#), that are working to increase the diversity of clinical trials on a broad scale. We also strive to increase the enrollment of minority populations in our own clinical trials.

Lilly has developed a clinical trial diversity strategy to better understand patient differences that may affect clinical outcomes and to help increase the enrollment of racially and ethnically diverse populations in U.S. clinical trials. The ultimate goal of our clinical trial diversity strategy is to improve health outcomes for individual patients. The strategy includes:

- Translating patient materials into Spanish,
- Providing physician-education materials that include background on the different needs of distinct patient groups,
- Partnering with advocacy organizations and professional societies to raise awareness about health disparities and the need for diversity in clinical trials, and
- Actively recruiting investigators to work with diverse patient populations.

<sup>2</sup> Diabetes data from The Office of Minority Health ([minorityhealth.hhs.gov/](http://minorityhealth.hhs.gov/)). Accessed January 2015.

### Training Minority Clinical Trial Investigators

One important variable in increasing the diversity of clinical trials is increasing the diversity of the physicians who conduct the trials (called “investigators”). One in five African Americans and one in three Hispanic Americans prefer a doctor of the same race or ethnicity.<sup>3</sup> While this is not a majority, it is still a sizeable percentage and can impact enrollment in clinical trials if there is a lack of diversity among the physicians conducting the trials. When there is less minority representation among physicians in certain specialties, it makes it even more difficult for us to increase the diversity of our investigators. (For example, there are approximately 10,400 oncologists in the United States, but just about 1 to 2 percent are African American and approximately 2 to 3 percent are Hispanic.)

To address this issue specific to oncology, Lilly is partnering with The Center for Drug Development and Clinical Trials at Roswell Park Cancer Institute in Buffalo, New York, to conduct a three-day clinical research workshop to train minority physicians to become clinical trial investigators. It is Lilly’s hope that by increasing participation by minority physicians, we will be able to increase the diversity of clinical trial participants and improve clinical research.

The workshop, titled “Reducing Cancer Disparities through the Training of a Diverse Workforce,” is offered to oncologists across the country who hail from minority groups. This training program, the first of its kind in the

### GLOBAL DIVERSITY AND INCLUSION AWARD

Yoko Tanaka received a Global Diversity and Inclusion Award from Lilly’s diversity office in 2014 for her work to provide a more culturally relevant view of clinical trial data, including increased diversity in data monitoring committees and greater inclusion of various cultural perspectives.

Lilly conducts clinical trials in the countries where we intend to sell the medication being investigated, so we can get the most accurate information possible about the effects on the people who will be taking the drug. Yoko helps provide training for data monitoring committees in Japan that review clinical trial data and advise trial sponsors on the safety of continuing the trial.

Traditionally this work has been performed mostly by American, Canadian, and European personnel. However, Yoko has worked through a Harvard University project to involve and train experts from other areas of the world. In April 2014, Yoko organized a training that prepared a Japanese affiliate to set up a Japanese-led data monitoring committee for a study in Japan rather than having it led by our U.S.-based team.

pharmaceutical industry, aspires to develop a broader base of diverse investigators who understand the principles of good clinical trial design and have the tools to conduct trials that are relevant to underrepresented populations.

Participants arrive with a concept in mind for an ongoing project in diverse clinical trial research. During the course of the workshop, they complete a clinical trial protocol—describing the objectives, design, methodology, statistical considerations, and organization of the clinical trial—to support their research and ensure data integrity and participant safety. The oncologists also participate in lectures, small breakout discussions, one-on-one sessions, and self-study—all facilitated by expert faculty who guide participants in the development of their research concept and continue to mentor

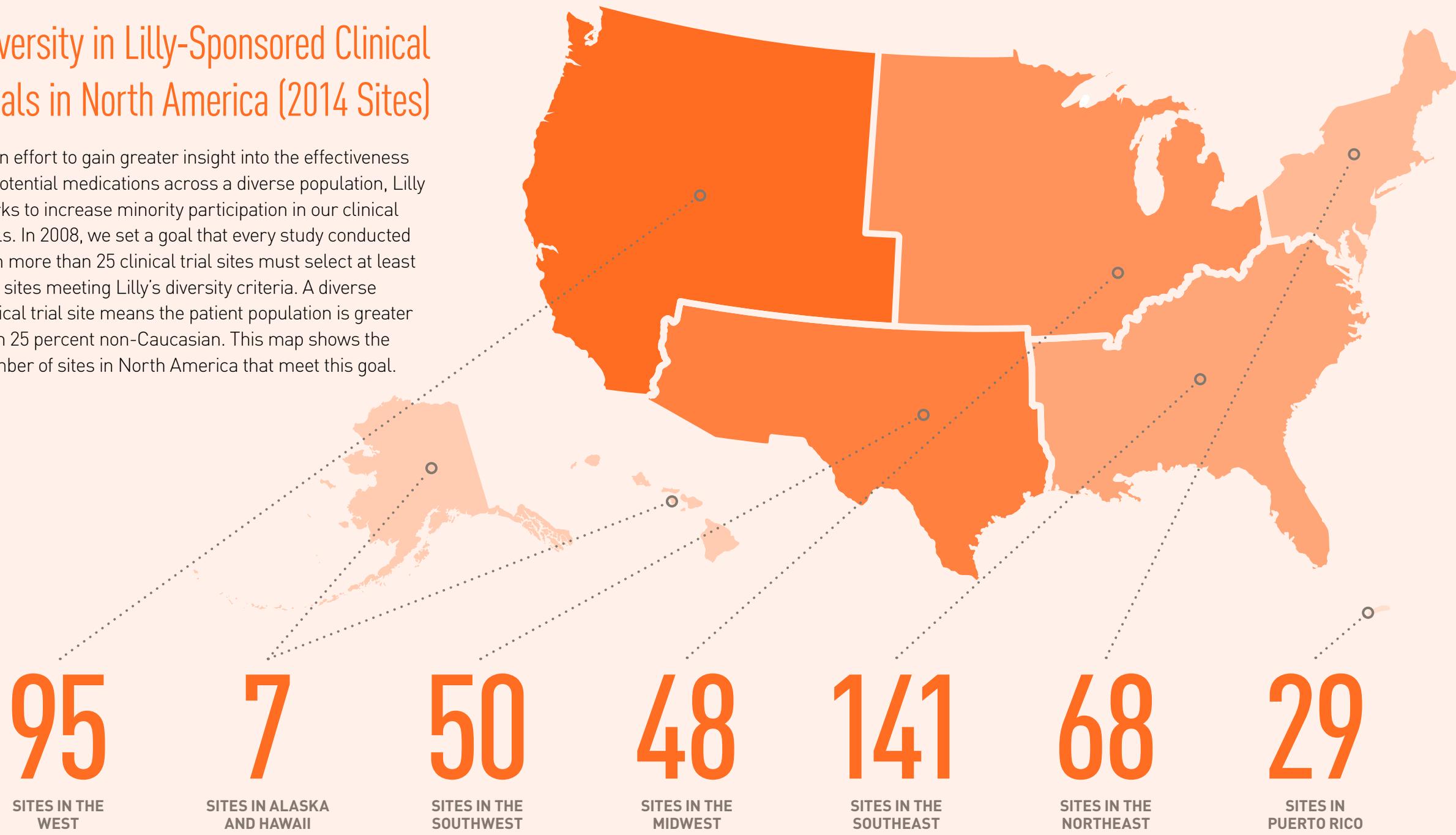
them after the completion of the workshop. The first workshop took place in March 2014, with 20 physicians in attendance. We are aiming for the same number of participants in 2015, with the goal of training 75 to 150 minority oncologists by 2016.

Coleman Obasaju, M.D., Ph.D., senior medical director, and global leader of diversity in clinical research for Lilly Oncology, is heading up Lilly’s efforts in this area. For his work, Dr. Obasaju has been awarded the prestigious Scroll of Merit by the National Medical Association for increasing minority participation in clinical trials. In addition, his team conducting the workshop received an award from Lilly’s Global Diversity and Inclusion Office for its work to increase clinical trial diversity in the United States.

<sup>3</sup> University of Alabama Minority Health & Health Disparities Research Center. Study: Minorities Prefer Same-Race Doctors ([mhrc.dopm.uab.edu/news/MinoritiesPrefer.html](http://mhrc.dopm.uab.edu/news/MinoritiesPrefer.html)). Published March 2005. Accessed January 2015.

## Diversity in Lilly-Sponsored Clinical Trials in North America (2014 Sites)

In an effort to gain greater insight into the effectiveness of potential medications across a diverse population, Lilly works to increase minority participation in our clinical trials. In 2008, we set a goal that every study conducted with more than 25 clinical trial sites must select at least two sites meeting Lilly's diversity criteria. A diverse clinical trial site means the patient population is greater than 25 percent non-Caucasian. This map shows the number of sites in North America that meet this goal.



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# Ensuring Quality Medicines

Lilly’s global quality team is an independent organization within Lilly, comprising about 2,200 individuals, including scientists, pharmacists, and other technical quality professionals. The team is involved in the entire life cycle of the molecules we develop, working across all phases of drug development. The team’s goal is to provide effective guidance and quality oversight, collaborating with colleagues in research and development and manufacturing, to assure regulatory and Lilly’s quality standards and controls are followed.

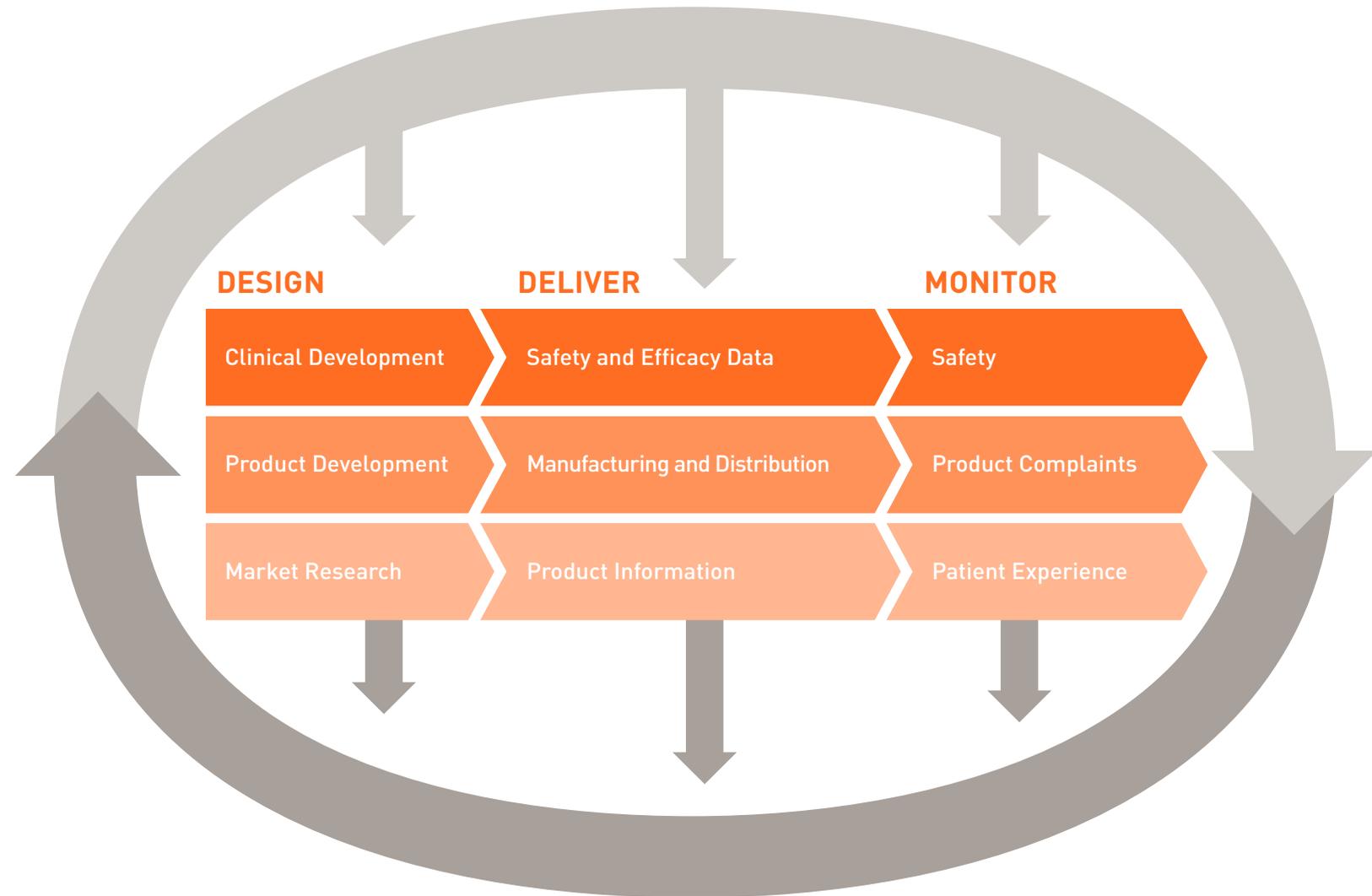
## LILLY QUALITY: PUTTING PATIENTS AT THE CENTER OF EVERYTHING WE DO

Lilly is known for superior quality—in our clinical trials, our products, and the information we provide to our customers. Producing quality medicines is our chief responsibility, and it is what protects the bond of trust between Lilly and our customers. Every day, we work to make sound decisions consistent with current regulations, science, and the best interests of patients. Our goal is to always carefully listen to patients and customers and to respond through continuous improvement.

To meet the expectation of quality that is Lilly’s hallmark, our quality team updates and manages the Lilly Quality System, providing the foundational quality requirements for processes throughout the product development cycle. An integrated structure of standards, business processes, organizational controls, and management controls, the Lilly Quality System is designed to assure that high-quality

### QUALITY ACROSS THE MEDICATION LIFE CYCLE

We work tirelessly to make our medications safe and effective—from the early stages of design and drug development through ongoing monitoring and understanding of the patient experience once a medication is on the market. Attention to detail and rigorous quality control across many interrelated areas of our company are necessary to ensure a high-quality product.



medicine and information get to every patient, every time. The system harmonizes quality approaches, as needed, among internal and external (contract) manufacturers of Lilly medicines and provides the overall quality direction across the company.

To ensure we are able to meet these standards, Lilly's quality organization provides on-site support as well as conducts an annual risk-based audit to oversee both internal Lilly and external partner operations. Audit results provide us with the knowledge we need to continue to make improvements to our quality controls and systems.

### LILLY GLOBAL MANUFACTURING

Approximately 9,200 individuals—about 22 percent of our employee base—compose Lilly's global manufacturing organization. The group operates 24 company-owned sites on five continents and manages relationships with more than 100 contract manufacturing organizations in 45 countries. Global manufacturing's mission is to ensure a continuous supply of the safe, high-quality medicines for which the Lilly brand is known.

The organization works across Lilly's businesses to achieve company objectives and optimize value through a commitment to scientific excellence, quality, efficiency, and integrity. All told, our global manufacturing function makes, packages, and distributes about 3,500 variations of our products (including different formulations, dosages, packaging configurations, and label languages) for diverse markets around the world—60 percent associated with our human pharmaceutical portfolio and 40 percent associated with Elanco, our animal health division.

We believe that focusing intently on both safety and quality leads to improved performance and productivity. To maintain continuous improvement, global manufacturing invests in the people, processes, technology, and facilities needed to ensure that Lilly and Elanco products provide the quality people expect. The organization constantly measures performance and productivity against its own stringent standards and best manufacturing practices. We also use the Six Sigma process-improvement system, originally developed by Motorola, as a tool for ongoing improvement.

### GLOBAL PATIENT SAFETY

Beginning with the discovery of a potential new medicine, our goal is to ensure that the benefits and risks of the medicines we market are continuously monitored and well-understood by regulators, healthcare providers, and patients. Lilly's global patient safety organization, consisting of more than 300 physicians, pharmacists, nurses, and other professionals, is dedicated to the collection, monitoring, evaluation, and reporting of safety information.

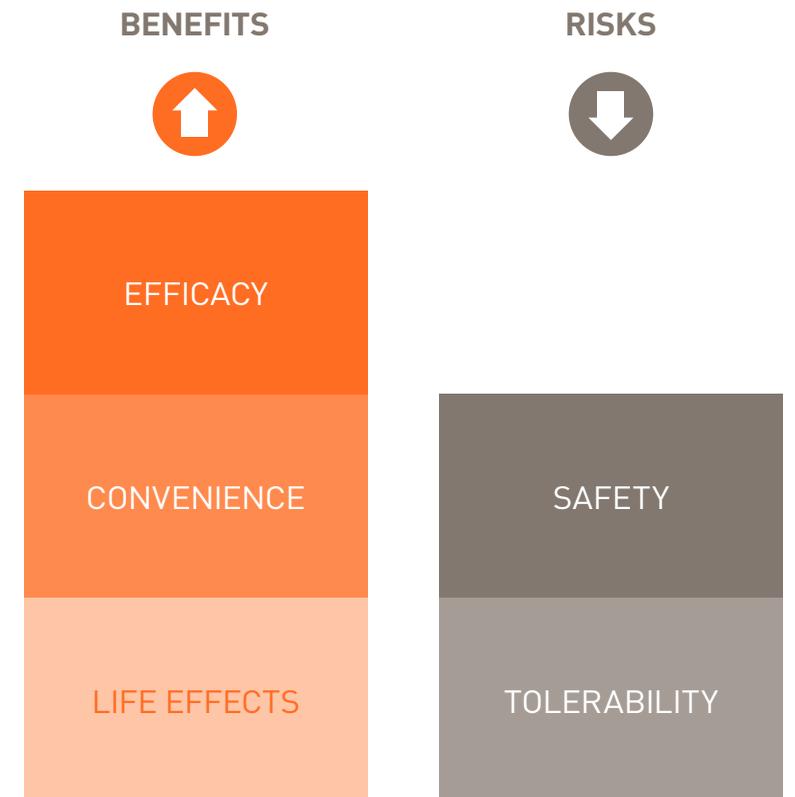
#### Assessing the Benefits and Risks of Medications

Well before a medicine is approved by regulatory authorities, it is rigorously assessed through carefully designed clinical trials to better understand its benefits and risks. The results of these studies are shared with regulators, such as the Food and Drug Administration in the United States, so they can conduct their own assessment before approving the drug for wider use.

When the regulatory agency approves a drug, it concludes that the drug's benefits outweigh its risks for the conditions outlined on the product label and that there is a public health benefit from the medication.

On its own, however, this data does not predict whether an individual patient will specifically benefit from a particular medicine. Once patients begin using the medication, they are monitored by their healthcare professionals to evaluate how the drug actually performs. Even as physicians become experienced at identifying individual patients who will more likely benefit from a specific drug therapy, it is still not always possible to predict whether the drug will have the expected therapeutic benefit or whether side effects will occur in an individual patient.

### BALANCING BENEFITS & RISKS OF MEDICATION



## Risk Management Plan

Lilly develops a risk management plan (RMP) for our medications. The RMP outlines the specific plan to further understand the safety profile of that product. It also outlines, when applicable, how Lilly plans to go about minimizing risks that may be associated with the medication. For example, it may require training for physicians that will teach them what specific actions should be taken to lessen certain risks.

After a drug receives approval and is made available to patients, the RMP continues to be updated as additional information becomes available that impacts the safety profile or benefit/risk balance of the product. Updates are submitted to the regulatory authorities.

## Collecting Safety Information Throughout the Life Cycle of a Medication

Learning how individual patients react to a medication is essential for the ongoing development of better treatment practices. Often, infrequent side effects can only be observed after a medication has been approved and used across a large, diverse patient population for an extended period of time.

For this reason, safety evaluation does not stop when a medication reaches the market. After the completion of pre-marketing clinical trials, Lilly continues to carefully monitor for new safety findings. In fact, the monitoring increases—through collection of information from post-marketing clinical studies and spontaneous adverse

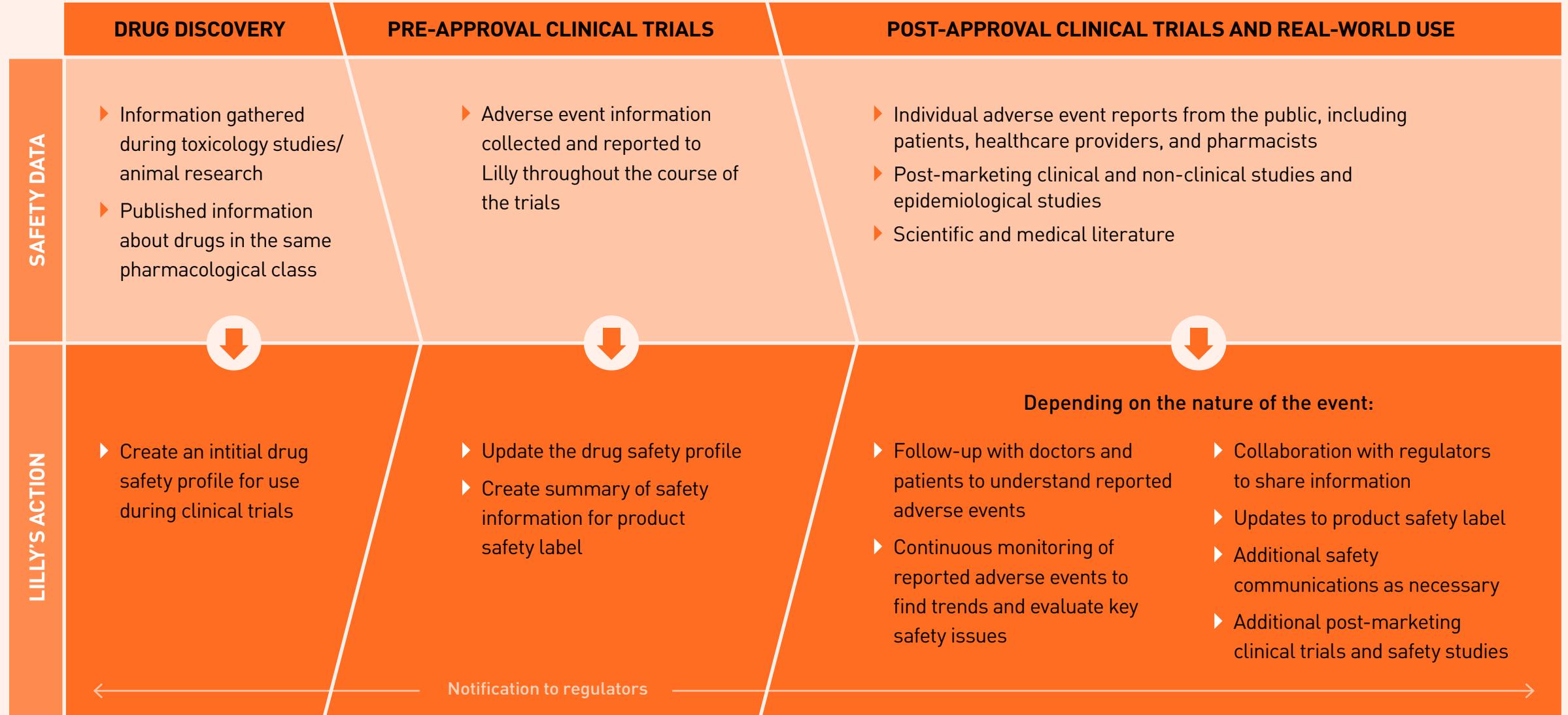
event reports voluntarily reported directly from the public, including healthcare providers and patients who are using a medicine.

New safety findings and emerging concerns are shared openly with regulators and healthcare providers to appropriately manage risks associated with the use of our medicines. We also work diligently to combat drug counterfeiting, which poses serious health threats to patients.

The Patient Safety section of Lilly's website is available to educate key external stakeholders about the role the pharmaceutical industry, regulators, physicians, and patients play in ensuring medicines are safe and effective.

# Pharmacovigilance: The Continuous Monitoring of Product Safety

Lilly collects, monitors, and evaluates safety information throughout the life cycle of each medication. This system is designed to maintain and evaluate the product's benefit/risk profile. When important safety issues arise, Lilly communicates them to doctors, patients, and regulatory agencies in various ways depending on the nature of the adverse event.





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# Improving Global Health

- ▶ Our Role in Healthcare Policy
- ▶ Our Global Health Programs
- ▶ Hunger Relief
- ▶ Responding to Ebola
- ▶ Product Pricing and Affordability
- ▶ Product Donations
- ▶ Patient Programs

For all our human ingenuity and medical advances—which have extended lifespans and improved the quality of life for billions of people—far too many have been left behind. Remedying that situation is not only a moral imperative, but also a very practical one. The pharmaceutical industry has an important role to play in addressing global health challenges and expanding access to quality care.

To be sure, expanding access to medicines is one important aspect. But at Lilly, we recognize that we also need to think bigger—beyond the medicines we provide—to identify ways we can work with others to help meet the health challenges of our time.

Lilly has a rich tradition of philanthropy, dating back to the earliest days of the company. And we remain committed to giving back to society, sharing our financial resources and time to help make life better for others. Yet we know that philanthropy alone is no match for the scale of global health problems facing us today. Many countries lack even the basic infrastructure and healthcare facilities needed to get the right treatment to those who need it. We need collaboration on a greater scale than ever before. At Lilly, this means seeking out partnerships that help us amplify our resources and impact. It means lending our voice to important debates on health care. And it also means focusing strategically on the areas of public health where we feel we can make the greatest impact, while understanding that the diversity of the challenges before us means we need to use a wide variety of engagement strategies.

Our global health programs, including the Lilly NCD Partnership and the Lilly MDR-TB Partnership, are helping to expand access to medicines to people today in low-income communities, with the potential to help millions more as solutions are replicated and scaled. In 2013, Lilly joined other industry leaders in support of a new U.N. framework around access to health care, and in early 2015, we announced a new commitment of \$1 million to our partner AMPATH in Kenya, helping to equip an oncology center, hire staff, and train local

healthcare workers. Our animal health division, Elanco, is focused on the link between hunger and poor health, and is dedicated to breaking the cycle of hunger in 100 communities by 2017. Our patient assistance programs provide free or reduced-price medicine to those who cannot afford to pay, including just over \$527 million in product in the United States, and Lilly product donations help thousands of people each year around the world, especially in times of disaster. Through a variety of patient programs, we work to make the healthcare system more accessible and effective, helping to educate those receiving care, caregivers, and others who impact patient outcomes, both directly and indirectly.

## Our Role in Healthcare Policy

There's a growing body of evidence that suggests in developing countries, health does not follow wealth—it's the other way around. A report by the World Health Organization (WHO) Commission on Macroeconomics and Health concluded that health is both a creator and pre-requisite of societal development. The Commission underscored that extending the coverage of health services and a small number of critical interventions to the world's poor could save millions of lives, reduce poverty, spur economic development, and promote global security. Likewise, a study from researchers at Harvard University estimated that one extra year of life expectancy raises a country's per capita GDP by about 4 percent. Evidence such as this of the profound benefits of investing in robust healthcare systems informs Lilly's engagement in healthcare policy.

## GUIDING PRINCIPLES ON ACCESS TO HEALTHCARE

The complexity of the world's global health challenges requires collaboration across the private sector, governments, non-governmental organizations (NGOs), donors, academia, and care providers. In this spirit, Lilly, along with 12 other major healthcare companies, signed on to the Guiding Principles on Access to Healthcare during the U.N. General Assembly in September 2013. As a set of industrywide principles and approaches, the document recognizes the importance of five core areas: collaboration, research and development, expanding availability of healthcare services, developing health systems resources, and respecting human rights.

Universal healthcare coverage (UHC) is a concept that is also attracting increasing attention. In March 2014, Lilly joined in another industrywide effort to voice support for the concept and to articulate some guiding principles for consideration. Lilly is committed to working with multiple stakeholders to shape action and

implementation toward achieving UHC. We believe the perspectives of the pharmaceutical industry, including our technical knowledge and experience in providing access to high-quality medicines and other health solutions, makes us valuable partners in this discussion.

As countries work toward achieving UHC, we hope the principles we advocate may offer guidance to policy makers, industry members, and other stakeholders who seek to improve health care and meet the health needs of all citizens. While every country is unique and tailored approaches will be required, there are some common challenges and opportunities faced by countries at all stages of implementing UHC. Based on these areas of shared experience, the guiding principles focus on eight key areas to inform the design of global UHC policies:

- Equitable Access
- Efficiency
- Quality
- Inclusiveness
- Availability
- Adaptability
- Choice
- Innovation

“At its core, universal health coverage (UHC) is the idea that people should be able to gain access to the health care they need without experiencing financial hardship as a result. UHC has become an increasingly salient issue for developed and developing countries alike in the context of the global economic crisis, increasing healthcare demands, and still unmet medical needs. There is increasing recognition that providing quality UHC is an investment in socio-economic well-being and a key contributor to the wealth and economic productivity of countries.”

— Innovative Biopharmaceutical Industry Perspectives on UNIVERSAL HEALTH COVERAGE  
March 2014, Proposed Public Policy Principles, March 2014



“What a boon it would be to the world if all of the earth’s people had access to basic health care and modern medical innovation.”

— John C. Lechleiter, Ph.D., Lilly Chairman, President, and Chief Executive Officer

## ADVOCATING FOR COLLECTIVE IMPACT THROUGH THE SHARED VALUE INITIATIVE

Another way that Lilly participates in dialogues about global health impacts and outcomes is in conjunction with the [Shared Value Initiative](#), a collaboration of organizations committed to creating measurable business value by identifying and addressing social problems by applying business expertise.

Starting in 2013, Lilly and more than 20 corporate leaders and global health experts came together at the behest of the Shared Value Initiative to tackle the challenge of measuring the outcomes of shared value programs in health care. Sessions continued over the course of the year. A [summary document](#) provides a guide for corporation practitioners. Participants in this dialogue included two distinct groups with different, but complementary, perspectives:

- Representatives from pharmaceutical, medical device, nutrition, technology, and telecommunications companies that are pursuing shared value initiatives at various stages of implementation. These companies see measurement as a critical barrier to fostering wider adoption and scale-up of shared value, but are still learning how to do it well.



- Global health experts including NGOs, academic institutions, and government agencies that bring long experience in measuring health outcomes and recognize the vast potential of corporate innovation to address public health challenges.

For more on Lilly's work in health policy, see the [Ethics and Transparency](#) section of this report.

## Our Global Health Programs

Historically, pharmaceutical companies such as Lilly have sold their products in markets that have well-functioning healthcare systems and the economic means to pay for innovative products. Philanthropic donations have helped to further expand access to medicines and improved health care to a relatively limited number of people living in low- and middle-income countries. Faced with growing, aging populations, and already-strained healthcare budgets, however, governments are desperately looking for new, sustainable solutions that improve overall health outcomes and lower costs.

Lilly recognizes that we must continue to pursue a variety of strategies when it comes to making our medicines available to patients more broadly. We are actively seeking ways to serve those:

- Who do not have access to quality healthcare delivery systems;

- Who live where there is a shortage of health care, where there is a shortage of healthcare professionals, or where drug supply chains break down;
- Who are inhibited by stigma from seeking treatment; or
- Who could not afford our medicines even if they were otherwise available to them.

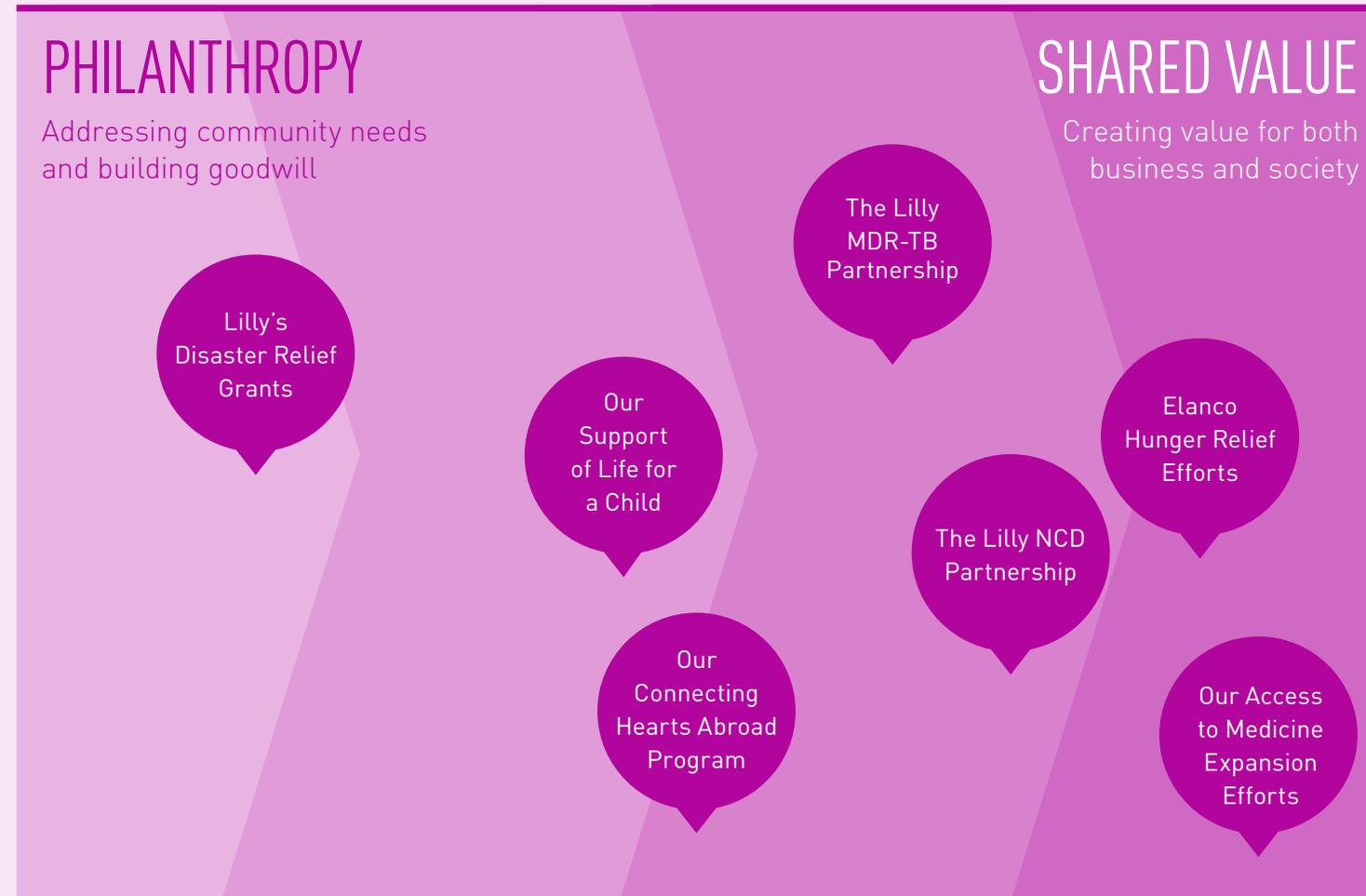
Like other actors in the global healthcare world, we are one entity amid a much larger ecosystem. In seeking innovative solutions to healthcare challenges—whether they are access, affordability, or quality of care—no single organization can solve these problems alone. That's why we partner with leading organizations at both the international and local level to tackle tough challenges and use a variety of approaches, tools, and tactics.

## OUR AMPATH PARTNERSHIP

Lilly is proud to play a small role in supporting the work of AMPATH, or Academic Model Providing Access to Healthcare. AMPATH is led by Moi Teaching and Referral Hospital and the Moi University School of Medicine in Eldoret, Kenya, and a consortium of North American academic health centers, led by Indiana University. Created in 2001 as a response to the HIV crisis, AMPATH has since grown into a highly respected international research and care consortium, serving more than 3.5 million people who previously lacked access to basic health care in Kenya and surrounding countries.

# A Spectrum of Involvement: Lilly's Global Health Programs

We know that the philanthropic efforts of Lilly and others in our sector are vitally important, and this will remain a fixture of our global health portfolio. Increasingly, however, even our philanthropic efforts are being evaluated and fine-tuned to create deeper and more sustainable impact over time. Our efforts to improve global health span a spectrum ranging from traditional philanthropy, to donations of products and employee volunteerism, to strategic global health partnerships, and even to shared value strategies that link activities to Lilly's business operations.



One of Lilly's long-running partnerships, AMPATH is a great example of a philanthropic partnership that is strongly outcomes-based and has set a high bar for quality healthcare management and innovation in a resource-constrained setting. AMPATH provides care based on individual needs—from treating diabetes to preventing hunger-related complications—and has been nominated three times for the Nobel Peace Prize. Since 2002, Lilly has donated approximately \$60 million in medicines to the program. In early 2015, we committed \$1 million to help fund a new oncology center and hire healthcare workers, allowing AMPATH to treat and provide palliative care to more people. Watch this [video](#) to learn more about our partnership with AMPATH.



## THE RISING BURDEN OF NCDs

Non-communicable diseases (NCDs) are a complex and growing public health threat, accounting for approximately 36 million deaths each year, according to the World Health Organization (WHO). Commonly mistaken for diseases that mainly afflict affluent countries, NCDs—which include diabetes, cancer, cardiovascular diseases, and chronic respiratory diseases—disproportionately affect the most vulnerable. In fact, a staggering 80 percent of these deaths occur in low- and middle-income countries.

This impact is exacerbated by the fact that healthcare systems in these countries have traditionally been oriented toward infectious diseases and other areas, including maternal and child health. Amid scarce resources and competing healthcare system demands, many people with NCDs are diagnosed late—if at all. And for those who are diagnosed, care is variable at best. More than 16 million deaths attributed to NCDs occur before the age of 70. As these diseases take lives, they also diminish opportunities. Poverty grinds on. Development stalls. Struggling communities weaken even further. And families face the loss of loved ones, lost income, and potentially catastrophic healthcare expenditures.

There are few successful models and limited international funding for NCDs, but recognition of the challenge is increasing, and global health organizations, governments, and other stakeholders are mobilizing to address the human, financial, and societal toll of these diseases. The WHO Global Action Plan for the Prevention and Control of NCDs 2013–2020 provides a road map and a menu of policy options for cross-sector collaboration that, when implemented, will attain nine voluntary global targets, including a 25 percent reduction in premature deaths from NCDs by 2025. Achieving these targets would save millions of lives.

## LILLY'S SIGNATURE HEALTH PROGRAMS

In recent years, we have sharpened our thinking and our focus for our global health programs, and challenged ourselves to ask the big question: How can we find long-term, sustainable solutions that have the potential to not just help hundreds or thousands of people, but millions?

The answer we have repeatedly found is that only through collaboration can we maximize the overall impact of our work. Increasingly, we are using a “collective impact” approach to help address global health issues that disproportionately afflict people living in lower- to middle-income countries. This approach is best illustrated by Lilly’s two signature global health programs: the Lilly NCD Partnership and the Lilly MDR-TB Partnership.

Through these two programs, we are actively engaged with nearly 50 leading health and governmental organizations to tackle two stubborn diseases: diabetes and tuberculosis. Our ultimate goal is to find solutions that can be scaled up and replicated around the world, creating ripple effects that touch even more lives. You can read more about our global health initiatives, including specific progress in target countries, in our [Global Health Programs Report](#).

## The Lilly NCD Partnership

The Lilly NCD Partnership was launched in 2011 to help stem the rising tide of non-communicable diseases, which include cancer, cardiovascular disease, chronic respiratory diseases, and diabetes. Collectively, NCDs are by far the leading cause of deaths worldwide. After consulting with key global health stakeholders at the international, national, and local levels, we determined that we could best contribute by primarily focusing on diabetes, which particularly affects those who are socially and economically disadvantaged. For more than 90 years, Lilly has been a world leader in pioneering diabetes solutions. Given our history, deep expertise, and current product portfolio and pipeline, diabetes was a natural choice as the first area of focus for the Lilly NCD Partnership.

As part of our commitment, Lilly is investing \$30 million over five years to strengthen diabetes care for people in rural and urban settings in Brazil, India, Mexico, and South Africa. In those four countries alone, 91 million people live with diabetes, the equivalent of one-quarter of the population of the United States. We are working with our partners to develop and evaluate approaches that strengthen the early detection and timely treatment of diabetes—with the goal of sustainably improving patient and health systems outcomes and possibly even lowering costs. Evidence shows that investments in early intervention efforts can improve health outcomes and reduce the need for more expensive treatment later, typically at far greater cost to families, communities, and society.

## Here are some highlights of our work:

### India

We work with three organizations in India—the Public Health Foundation of India (PHFI), Population Services Incorporated (PSI), and Project HOPE. With PHFI as the program lead, we are implementing a program designed to help prevent, detect, and reduce the risk of diabetes and hypertension, and collecting operational research on the effectiveness of the intervention.

The program, known as UDAY, is the largest comprehensive, community-based diabetes initiative of its kind in India. It has the potential to reach more than 400,000 people living in two pilot areas, significantly improve patient and health system outcomes, and modernize diabetes and hypertension care—while reducing overall cost to the healthcare system.

Our UDAY partners have established a research program to collect data and understand an array of factors that contribute to the spread of diabetes and hypertension—from prevalence to patient knowledge base, to healthcare provider practices. Based on this data, we, along with our partners, are implementing and evaluating a multifaceted intervention program through 2016.

### Mexico

Our partner in Mexico is the Carlos Slim Foundation (CSF), a nonprofit organization that finds new solutions for key health issues afflicting Latin America and Mexico's most vulnerable populations. Through the partnership, we have collaborated with the foundation to help standardize, monitor, and evaluate a pilot of its Casalud healthcare model. The model offers an innovative, comprehensive approach to address NCDs at primary care clinics with a focus on diabetes and hypertension.

In October 2013, Mexico's Ministry of Health adopted the CSF's model as part of its strategy against obesity and diabetes. The Casalud model was scaled and implemented across nearly all of Mexico by the end of 2014. Through our ongoing partnership with CSF, we will continue to evaluate the implementation of this model in two states and the resulting patient outcomes. We will use the data to further validate the model, improve it, and facilitate its implementation nationally.

### South Africa

In Johannesburg, South Africa, we're partnering with Project HOPE on a five-year community-based project that is addressing gaps in care for people at risk of—or already living with—diabetes. Further south, in the vast rural stretches of South Africa's Eastern Cape, we're working with the Donald Woods Foundation to build on its success with home-based HIV programs by adding diabetes and hypertension screening and care to its existing model.

### Brazil

In Brazil, the Lilly NCD Partnership works on two projects that are helping address gaps in the country's approach to diabetes. With the Institute for Children with Diabetes, we are seeking to improve long-term healthcare outcomes for young people with type 1 diabetes. With the Medical Foundation of Rio Grande do Sul—Federal University of Rio Grande do Sul, we are focusing on finding replicable approaches to reduce the incidence of type 2 diabetes in women who have previously been diagnosed with gestational diabetes.

### GLOBAL STAKEHOLDER DIALOGUE ON NCDS

Finding enduring solutions to treat NCDs requires smart collaboration from diverse stakeholders. To ensure that we can leverage learnings around our work in NCDs, we actively share our approaches and key outcomes on an ongoing basis as well as every year at the Lilly NCD Partnership Summit, a gathering for all of our partners. In 2014, Lilly also collaborated with other companies, international nonprofit federations, and foundations focused on NCDs to organize two "NCD cafés" during major health conferences. These forums helped to facilitate dialogue among prominent global health leaders on key NCD topics and included representatives from the WHO and the United Nations.

“We’re open to making a small difference, however we can, today. And we’re open to the possibility that through the work of Project HOPE and Lilly, we collectively can make a big difference in the years to come.”

— Amy Sousa, Communications Advisor,  
Lilly Research Laboratories

## Connecting Hearts Abroad in South Africa

Amy Sousa is one of 20 Lilly ambassadors who have served with the Lilly NCD Partnership in South Africa through the Lilly volunteer program, Connecting Hearts Abroad. These volunteer teams include doctors, pharmacists, and diabetes educators, as well as specialists in communication, training, and information technology. They help with community health screenings, patient education, and other services at the HOPE Centre.

## At a Glance: the Lilly MDR-TB Technology Transfer

Over the course of a decade, Lilly partnered with seven manufacturers—four in countries with high burdens of MDR-TB—to create a reliable supply of capreomycin and cycloserine, and to improve local access to medicines. In the process, Lilly:

- ✓ Gave away its manufacturing know-how for capreomycin and cycloserine
- ✓ Used external contract manufacturers to expand supply of capreomycin during technology transfer to ensure continuity of supply chain
- ✓ Committed the time and expertise of multiple staff members over the lifetime of the project
- ✓ Offered on-site technical and quality assistance
- ✓ Funded local facility upgrades or the purchase of specialized equipment aimed at minimizing future manufacturing costs for our partners
- ✓ Worked to improve process efficiency so that partners could reinvest in local staff and facilities
- ✓ Helped partners build additional manufacturing capacity to strengthen long-term sustainability

### THE LILLY MDR-TB PARTNERSHIP

Collaboration also powers the Lilly MDR-TB Partnership, which was launched in 2003 to fight multidrug-resistant tuberculosis (MDR-TB). This hard-to-treat form of TB is preventable and curable if patients get the right medicine at the right time. But too often that's not the case: MDR-TB needlessly kills more than 150,000 people each year. It develops when a TB patient doesn't know he or she has the disease or doesn't adhere to the proper course of treatment, and the TB strain evolves into MDR-TB—a much harder-to-treat form of TB that can require up to 24 months of treatment.

The Lilly MDR-TB Partnership is our largest philanthropic effort ever—a \$170 million commitment from 2003–2016. The partnership began when Lilly gave away the manufacturing technology and know-how to produce two Lilly antibiotics, capreomycin and cycloserine, to manufacturers in China, India, Russia, and South Africa—four MDR-TB “hot spots”—to help create a more reliable supply of these critical medicines. We also worked with other partners to strengthen healthcare systems so they could better respond to the MDR-TB threat, and to fund drug discovery efforts for badly needed new medicines. Lilly's experience and insights from this decade-long initiative are documented in a white paper released in 2014, [Seeking Solutions to a Global Health Crisis](#) [video ▶](#). Lilly's experience is also detailed in a video released with the report.

The need is as pressing as ever: The WHO notes that more than 450,000 people contracted MDR-TB in 2013 alone. Combatting MDR-TB effectively requires a comprehensive approach to address multiple social,

economic, and medical issues simultaneously. Today, our partnership is composed of more than 25 health organizations; academic institutions; and corporations, including the Global Fund to Fight AIDS, TB, and Malaria; and the WHO. Together, we've trained more than 100,000 healthcare professionals and nurses, distributed guidelines and toolkits to more than 45,000 hospitals and clinics, provided messages about TB to millions of people in high-risk populations through innovative public awareness campaigns, and educated more than 350 journalists about the disease.

### **TB Drug Discovery Efforts**

As part of the Lilly MDR-TB Partnership, we are committed to supporting research for greatly needed new TB medicines. Most current medicines used to treat TB are at least 50 years old, take too long to work, and have potentially debilitating side effects.

#### **The Lilly TB Drug Discovery Initiative**

We launched the Lilly TB Drug Discovery Initiative in 2007 as a not-for-profit, public-private partnership with a mission to accelerate early-stage drug discovery. Headquartered in Seattle, Washington, the initiative brings together representatives from governments, philanthropic organizations, pharmaceutical companies, universities, and other research institutions to search for new TB treatments. The most important goal of the initiative is filling the pipeline with new TB medicines. The initiative's founding members represent a unique consortium linking private, not-for-profit, and public sectors—including Lilly, the Infectious Disease Research Institute (IDRI), and the National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health. In 2009, Academia Sinica

(National Academy of Sciences of Taiwan) joined the initiative as a contributing member.

#### **Infectious Disease Research Institute**

We partner closely with IDRI, located in Seattle, to support its research efforts to find new TB medicines. We've committed more than \$20 million in funding and in-kind contributions to IDRI from 2008–2016. Initially, we provided start-up funding and helped to establish IDRI's fully equipped high-efficiency screening and chemistry laboratories. We also provide access to Lilly research tools and our corporate compound library to enable the screening of more than 800,000 molecular entities for activity against TB. Lilly scientists volunteer time to assist IDRI with its discovery efforts, contributing their scientific and technical expertise—and passion—for finding new TB medicines. Learn more about our partnership with IDRI in this [video ▶](#).



#### **TB Drug Accelerator**

Lilly is a member of a groundbreaking collaboration between eight pharmaceutical companies and seven research organizations known as the TB Drug Accelerator. The partnership, aided by nearly \$20 million from the Bill and Melinda Gates Foundation, was

launched in 2012 and is targeting the discovery of new TB medicines by collaborating on early-stage research. The goal of this partnership is to shorten treatment time for TB from the current minimum of six months to two months, which would keep an additional 1 million people on treatment each year, reducing deaths and slowing the development of drug resistance.

The partnership is unique because it breaks from traditional research and development practices. Instead of competing, members work together to develop the best prospects, regardless of where they originated. The structures of lead compounds identified through the program will ultimately be placed in the public domain. The first round of screening for new TB drug candidates has been completed, and compounds are advancing rapidly.

#### **Global Stakeholder Engagement on MDR-TB**

Lilly is actively involved with global conversations on MDR-TB, especially how to address market barriers to ensure the timely and efficient distribution of high-quality medicines to those who need them most. Through our engagement efforts, we are in discussions and collaborations with organizations on the front lines of fighting TB, including the Center for Strategic and International Studies, the USAID Center for Accelerating Innovation and Impact, the Centers for Disease Control, the Global Health Council, the Food and Drug Administration, the Global Fund, the European Parliament, Doctors without Borders, the WHO, Partners in Health, and the Stop TB Partnership, among others. At the country level, we work closely with important national institutions, including national TB control programs and leading TB research institutions.

## Hunger Relief

The world's population is expected to soar from 7 billion today to 9 billion by 2050. At Elanco, Lilly's animal health division, our vision is a food-secure future—a world where everyone has access to enough nutritious and affordable food.

Over the next few years, the world will experience the fastest growth of the global middle class in history. An increase in income typically leads to an increase in a family's intake of meat, milk, and eggs. Yet, based on today's production trends, the world might not have enough resources to meet demand. The gap is widening between what society will need and what farmers are able to produce.

We believe every person on earth deserves a minimum of a glass of milk and an egg a day—a modest, but achievable, goal. Elanco has been developing the tools and technologies that protect animals from infectious disease, reduce the environmental impact of livestock production, enhance animal well-being, and eradicate food-borne illness. These, in turn, enable farmers and producers to provide greater amounts of food—safely and sustainably.

Elanco is dedicated to improving animal health, including the health of animals raised for food. In other words, we're very much in the business of feeding the world. That's why it makes sense for us to focus our sustainability strategy on reducing hunger and improving access to food.

Through global partnerships and volunteer efforts in our own backyard, we support community programs

“Food security is an issue we can start to solve now. If we focus on the need, rely on a science-based approach, and take leadership, we can create a food-secure future—one in which 9 billion people have access to enough nutritious, affordable food.”

— Jeff Simmons, Elanco President

and initiatives that provide food to those who need it and promote awareness of hunger and the related problem of food insecurity. Our commitment focuses on three areas: employee engagement, community engagement, and sustainable development, with a goal of nutritious food that is accessible and affordable to all.

We have pledged to “break the cycle of hunger” in 100 communities<sup>1</sup> around the world by 2017, and we’re working with a range of partner organizations, from food banks to Heifer International (see [page 44](#)). Breaking the cycle means making at least 100 people more food secure for at least one year. By the end of 2014, we had made food more secure in 53 communities around the world through philanthropic partnerships, company-sponsored donation programs, and volunteer initiatives that deliver food, dollars, and Elanco capabilities to those who need it most.

In addition, we have set a simultaneous goal of engaging 100 percent of our employees so they are invested in the hunger cause. In 2014, we engaged 65 percent of our people in volunteer activities, up from 57 percent in 2013, and 87 percent of employees said they were proud of our company’s efforts around food security. In 2014, Elanco employees committed approximately 20,000 hours of volunteer time; by 2017, we expect that Elanco employees will have volunteered 100,000 hours over a period of four years.



### SUSTAINABLE DEVELOPMENT

“We will be a global leader in sustainable food-security initiatives.”



### EMPLOYEE ENGAGEMENT

“We are personally invested in the hunger cause.”



### COMMUNITY ENGAGEMENT

“We will break the cycle of hunger in our communities.”

“Everyone has a basic right to food. In the past 30 years, China has made significant progress to advance food security. Unfortunately, there are still 200 million people in China today who struggle for their meals. Elanco is helping to make a difference by working to provide more affordable, abundant, and nutritious food.”

— Yang Yunfeng, Senior Corporate Affairs Manager and Elanco Hunger Ambassador, Beijing, China

<sup>1</sup> We have defined a community as one that includes 100 or more people.

# Growing Middle Class Drives Need for New Sources of Food

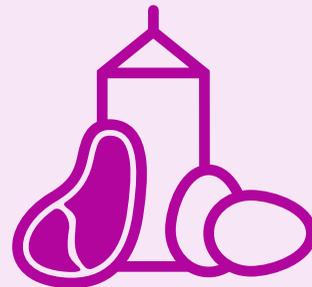


\* Food & Agriculture Organization (FAO). "How to Feed the World in 2050" Rome. 12-13 October 2009. pg. 1-6 [www.fao.org/fileadmin/templates/wsfs/docs/expert\\_paper/How\\_to\\_Feed\\_the\\_World\\_in\\_2050.pdf](http://www.fao.org/fileadmin/templates/wsfs/docs/expert_paper/How_to_Feed_the_World_in_2050.pdf).

\*\* Kharas, Homi. "The Emerging Middle Class in Developing Countries." Global Development Outlook. OECD Development Center. Working Paper No. 285. January 2010. [www.oecd.org/dev/44457738.pdf](http://www.oecd.org/dev/44457738.pdf).

## INCREASING DEMAND FOR MEAT, MILK & EGGS

WE WILL NEED  
**60%**  
MORE ANIMAL-SOURCED FOODS\*\*\*



\*\*\* Food & Agriculture Organization (FAO). "World Livestock 2011: Livestock in Food Security." Rome, 2011.

## FEEDING MORE WITH LESS

BY OVERUSING OUR RESOURCES, IT TAKES  
**1.5**  
YEARS FOR THE EARTH TO REGENERATE ANNUAL CONSUMPTION\*\*\*\*



\*\*\*\* World Wildlife Fund (WWF). "Living Planet Report 2012: Biodiversity, biocapacity and better choices."

“We live in a world of extremes—from extreme excess to extreme poverty. Food is a commodity that many of us take for granted and yet so many go hungry and battle for every mouthful. Elanco’s hunger cause is critical because food is something we all need. It’s about redressing that balance and making that difference. And Elanco is indeed making a difference by harnessing our technical expertise to manufacture products that can and do make a difference toward putting food on the table.”

— Julie Ann MacCluskey, Public Relations and Communications Associate and Elanco Hunger Ambassador Speke, United Kingdom

We give all of our people an opportunity to use a half day per quarter, on company time, to volunteer with a local hunger project. We want our employees to connect on a personal level to the problems of world hunger so that they can contribute to solutions. Across our company, we have a team of approximately 60 “hunger ambassadors” who help to coordinate on-the-ground volunteer activities with their Elanco peers in 23 different countries. Programs range from providing backpacks filled with food for children facing food insecurity at home to stocking shelves at local food pantries.

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#### THE “ENOUGH” REPORT

Read our recent [report](#) on the realities and solutions available to achieve global food security. Written by Elanco President Jeff Simmons, “Enough: The Fight for a Food-Secure Tomorrow” highlights the urgency to act now. Simmons advocates for farmers to have access to innovative tools and practices that will enable them to feed a growing global population and save natural resources.

“We have—either right now or in the pipeline—the technology that would enable us to meet consumer demand in 2050. But we need to give farmers the ability to access and utilize this technology and ensure that proven innovation and farm practices which maintain health and productivity are available for use,” Simmons said.



“As a food animal veterinarian, my career is based around knowing that animals and their byproducts will eventually be involved in feeding and clothing humans. Access to available protein for growth and health of children and adults is a key part of agriculture. I am proud to be a veterinarian who plays a role in the improved health and growth of animals so that humans around the world can have a better diet. Feeding the most impoverished people in the world and making food more affordable for them is something all of us at Elanco can be proud of.”

— Christopher Dale Ashworth, Doctor of Veterinary Medicine and Elanco Hunger Ambassador, Arkansas, United States

#### OUR WORK WITH HEIFER INTERNATIONAL

Elanco has had a strategic relationship with the nonprofit Heifer International since 2007, part of an ongoing program to lift 100,000 families, or 600,000 individuals, out of hunger. We have committed a \$1.5 million matching challenge to the organization’s East Africa Dairy Development (EADD) project, which aims to provide sustainable livelihoods for more than 600,000 people in Uganda, Tanzania, and Kenya by 2018. Funding for the matching challenge was provided by The Eli Lilly and Company Foundation.

Overall, Elanco has contributed more than \$3 million to Heifer projects that include contributions of animals and training for families in Indonesia, Zambia, and China.

Launched in 2008, EADD focuses on empowering small dairy producers to move beyond subsistence toward sustainable livelihoods. Farmers receive extensive training on dairy husbandry, business practices and operations, and marketing of dairy products. Phase II of the project will employ new technologies and practices around feed production, alternative energy sources, and milk transport systems. The project ultimately will reach 136,000 smallholder dairy farmers, giving them—and their families—opportunities to achieve financial independence. The program will also give more people in the region better access to dairy products.

Elanco’s commitment includes the donation of products that will help dairy farmers improve the health of their cows, the talents of Elanco employees to provide on-site training in cow health, and financial support through 2018.



## Responding to Ebola

In our scientific discovery, we follow where the science leads us. That means that about every 10 years, Lilly's portfolio changes, and over time our therapeutic areas of focus change as well. Decades ago, our portfolio included vaccines and other antivirals, the types of products most likely to be effective in treating Ebola, but those products are not part of the Lilly portfolio today. Nonetheless, in 2014, as news of the outbreak spread, Andrew Dahlem, Ph.D., Lilly's vice president for Lilly Research Laboratories operations, led an analysis of Lilly's molecule library and portfolio to see if any of our molecules might prove active against Ebola.

Lilly may not have a recent history with the kinds of treatments that might prove effective against Ebola, but we do have capabilities and assets that may be useful as further scientific understanding of the virus and host response unfolds. Lilly has been actively involved in other efforts to understand and combat Ebola:

- Tim Garnett, M.D., Lilly's chief medical officer, is a member of the Ebola response coordination team from the Pharmaceutical Research and Manufacturers of America that will coordinate the unified response to the crisis by member companies.
- An Eli Lilly and Company Foundation grant of \$100,000 made in 2014 to long-time partners Project HOPE and Direct Relief International will support aid efforts in the most affected West African countries. Thanks to this support, Project HOPE has sent shipments of medicines and supplies to Sierra Leone. Lilly's grant has also supported a logistics assessment team in

Sierra Leone. In addition, the Lilly Foundation support helped Direct Relief International make emergency shipments to aid medical responders in more than 60 facilities.

- Lilly employees worldwide who contribute \$25 or more to Ebola relief projects are automatically matched by the Lilly Foundation. Through the Lilly Global Giving program, as of the end of 2014, Lilly employees and the Lilly Foundation had donated nearly \$42,500 to Ebola relief.

## Product Pricing and Affordability

Medicines play an important role in making life better for people. When used appropriately, medications can help us live longer and healthier, slow the progression of disease, improve management of chronic conditions, enhance our quality of life, prevent or minimize complications and side effects of disease, or even eliminate the need for costly or painful hospitalizations and surgeries. But the role of medicines in making life better extends well beyond the people who use them directly. Families, caregivers, the broader healthcare system, and society all benefit from the use of new medicines. By helping people prevent and manage disease, medicines can reduce overall health spending, enhance the productivity of our workforce, and improve public health. When compared against other healthcare interventions, medicines are by far one of the most cost effective.

At Lilly, we recognize that people are concerned about the cost of medicines. We share this concern and are working in several ways to address it. Increasingly, we are

exploring ways to help people at different income levels get access to the Lilly medicines they need. At the same time, we need to protect the work of discovery that is not possible without solid intellectual property protection, the lifeblood of any enterprise generating value from ideas.

On average, it takes nearly 10 years and \$1 billion to bring a new medicine from the drawing board to the pharmacy. Without the ability to protect Lilly's intellectual property (IP), medical innovation would not be sustainable. And the benefits of IP protection include not only breakthrough medicines, but, over time, a broad range of low-priced generic medicines, which are an important legacy of the innovative research-based industry.

## Product Donations

In addition to our financial contributions to organizations working to support global health initiatives, Lilly donates medicines in a variety of settings, including through partnerships with aid organizations, nonprofits, and governmental bodies.

### INSULIN PARTNERSHIP WITH LIFE FOR A CHILD

Between 2008 and 2015, Lilly has committed to donating more than 800,000 vials of insulin to the International Diabetes Federation's Life for a Child program—one of our largest single-product donations. Today, the IDF's program provides support to 15,000 children and youths with diabetes in 46 of the world's poorest countries.

## DISASTER RELIEF

When disasters strike, Lilly responds with cash and product contributions to help people in desperate situations. Every disaster is different, prompting a wide variety of needs. When responding, we take great care not to overburden the local infrastructure, so that our product donations are meaningful. We donate items that are specifically requested by relief agencies, partnering with them to best leverage our support. In 2014, Lilly gave \$1.9 million in cash and product donations in the wake of natural disasters.

## PATIENT ASSISTANCE PROGRAMS

It's important to us to make sure that those who can benefit from our medicines have access to them. The majority of our product donations are made through [Lilly TruAssist](#), which serves as the umbrella program for Lilly's many patient assistance efforts. In the United States, Lilly TruAssist provides access to products for people who might not otherwise be able to afford our medicines. In addition to product donations, some programs featured on Lilly TruAssist connect patients to co-pay programs, or offer information and assistance with therapies. See this [video](#) to learn more.



## Impact of the Affordable Care Act

When the U.S. economy began its downward turn in 2007, many patients found themselves lacking prescription insurance coverage and experienced hardship in obtaining access to Lilly medications. This trend continued through 2013. With the implementation of the Affordable Care Act in 2014, we began to see a change in the use of our programs. For the first time in seven years, our programs saw a decrease in demand. Many patients previously needing assistance in our programs now found themselves eligible for medical coverage from other sources.

## Patient Programs

Here at Lilly, we want to do what we can to create a more accessible healthcare system with better treatment options and better care. We believe we can play a role in educating patients and family members, as well as leaders and other decision makers who can potentially impact health outcomes.

We work cooperatively across sectors to promote access to medicines, including sponsoring patient assistance programs. Such programs demonstrate our desire to improve patient outcomes by helping patients meet the challenge of obtaining access to Lilly medications. Thanks to the variety of patient assistance programs supported by Lilly, a wide portfolio of valuable medications is available to eligible patients.

In the United States, for example, Lilly TruAssist provides access to products for eligible patients through several patient assistance programs. The majority of

our product donations are made through TruAssist, which serves as the umbrella program for our many patient assistance efforts.

Our patient assistance programs align with our business objectives, focusing on our core areas of expertise, including Alzheimer's disease, cancer, diabetes, and mental illness. Our programs help us gain valuable patient insights while offering individuals the best treatments possible.

We support many programs, including the following examples.

## DIABETES PROGRAMS

### Diabetes Conversations

Created by Healthy Interactions in collaboration with the International Diabetes Federation, Lilly Diabetes sponsors the Diabetes Conversations program, featuring Conversation Map™ education tools. This innovative education method uses a unique, visual approach to facilitate interactive group participation and empower people with diabetes to become actively involved in managing the disease. The education tools, available in 38 languages, have been launched in more than 121 countries since 2008.

### Diabetes Camps

For more than a decade, Lilly has been one of the largest providers of insulin and glucagon, educational materials, volunteers, scholarships, and special guests to diabetes camps through the comprehensive Lilly Camp Care Package. In 2014, 129 diabetes camps participated in the Camps in Color program, an art therapy-based initiative for children. Requesting camps received \$3.89 million

in insulin product and 151,000 educational book packs. Lilly also provided \$91,000 in camperships through its partnership with the American Diabetes Association. Learn more about diabetes camps in this [video ▶](#).



Lilly sees the value that camps bring to children with diabetes. Since 2001, the company has donated \$25 million in medications, 170,500 educational book packs with materials on diabetes management, and, since 2008, \$623,000 in camp scholarships.

### **Type 1 Diabetes: Collaboration with Disney**

A child's diagnosis of type 1 diabetes (T1D) can be overwhelming, and caregivers often question if they will ever be able to get their families back into any kind of daily routine. Both parents and the child may feel the diagnosis is the end of their future hopes and dreams. This understanding of a family's situation served as the foundation for Lilly Diabetes to collaborate with one of the most recognizable brands in the world: Disney. Lilly pairs its deep expertise in diabetes care with Disney's magical storytelling to encourage and inspire families coping with a diagnosis of T1D for a child.

Launched in 2011, the Lilly Diabetes and Disney collaboration offers healthcare providers and families

a variety of fun and educational printed resources including a book series for younger children featuring Coco, the first Disney character with T1D. Most of the books, including the flagship book, *Coco and Goofy's Goofy Day*, are now available through many pediatric endocrinologist and other healthcare provider offices in 50 countries and 30 languages around the world. In the United States, the collaboration also offers the books online, along with other unique content that provides advice and practical tips, recipes, and activities for families affected by T1D at [www.T1EverydayMagic.com](http://www.T1EverydayMagic.com).

### **ALZHEIMER'S PROGRAMS**

#### **"Worried About Your Memory?" Campaign**

To help people who have concerns about dementia, Lilly has partnered with the Alzheimer's Society on the "Worried About Your Memory?" campaign. The campaign encourages people concerned about their memories to visit their doctors and seek diagnoses. Together, we have enabled 1.7 million leaflets, 17,000 campaign posters, and 60,000 information booklets to be distributed to surgical centers, health centers, and hospitals in the United Kingdom.

### **ONCOLOGY PROGRAMS**

#### **Oncology On Canvas<sup>SM</sup>**

The Lilly Oncology On Canvas: Expressions of a Cancer Journey Art Competition and Exhibition honors the journeys people face when confronted with a cancer diagnosis. The biennial competition invites individuals diagnosed with any type of cancer—as well as their families, friends, caregivers, and healthcare providers—to express, through art and narrative, the life-affirming changes that give their cancer journeys meaning.

The result is a compelling art collection that provides insights into the wide range of emotions experienced by those touched by cancer. For more information, see the [Lilly Oncology On Canvas website](#).

#### **PACE**

Lilly Oncology is dedicated to helping improve the cancer policy environment—specifically those decisions that impact the development of treatments and patient access to care. In 2012, Lilly Oncology launched PACE (Patient Access to Cancer care Excellence), an initiative that aims to encourage public policies and healthcare decisions that speed the development of new medicines, assure cancer treatments respond to the needs and qualities of individual patients, and improve patient access to the most effective cancer medicines. For more information, see the [PACE Network website](#).

### **MENTAL HEALTH PROGRAMS**

#### **Lilly Reintegration Scholarships**

Over the past 15 years, Lilly Reintegration Scholarships have assisted students living with mental illness by directing more than \$4 million to cover their tuition, lab fees, and books at nearly 350 schools across the United States. The program specifically benefits individuals living with schizophrenia, schizoaffective disorder, bipolar disorder, or major depressive disorder who wish to attain a certificate or degree from an accredited institution to help them secure employment and reintegrate into society. Approximately 1,200 students have received assistance from the scholarship—in pursuit of all levels of education, from high school equivalency degree to Ph.D.—attending state and private universities, community colleges, and trade schools.

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# Strengthening Communities

- ▶ Giving at Lilly
- ▶ Volunteerism at Lilly
- ▶ Education Initiatives

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Our company vision—making a significant contribution to humanity by improving global health in the 21st century—calls on us to give back to the world around us. In addition to our work finding and developing new medicines, we fulfill this vision by using our financial resources, our time, and our expertise to make a meaningful, measurable, and sustainable difference in the communities where we operate.

Each year, Lilly donates substantial amounts of products and cash—more than \$590 million in total in 2014—and our employees volunteer their skills around the world. Many of our donations, including those provided through The Eli Lilly and Company Foundation, focus on improving patient outcomes and enhancing quality of life.

Our commitments to helping those in need started with our founder, who aided the poor and unemployed in Indianapolis. In 1937, the Lilly family established the Lilly Endowment, which has since grown to become one of the largest and most important foundations in the country. The family members were also major donors to the Community Fund, which eventually became known as United Way. That relationship continues today; in 2014, Lilly presented a gift of \$12.7 million to the nonprofit—our company’s largest ever United Way contribution.

## Giving at Lilly

Philanthropy will always be a hallmark of Lilly. But we’re also exploring ways we can extend our impact by tapping our business expertise to create new partnerships and make significant strides in several key focus areas. That’s one reason why we’ve sharpened our focus on improving health for people in low- and middle-income countries and strengthening the communities where we work and live, especially through improvements to education.

We’re partnering with leading health organizations and governments to explore new approaches to complex global health challenges, as discussed in more detail in the [Improving Global Health](#) section of this report. Our Elanco animal health division, meanwhile, is working to [break the cycle of hunger](#) in communities around the world.

# Charitable Donations\*

In 2014, we saw a decrease in the number of people requesting assistance through our U.S. patient assistance programs following the implementation of the Affordable Care Act, which allows previously uninsured low-income Americans to obtain healthcare coverage. As a result, fewer people were in need of donations from Lilly.

	2012	2013	2014
<b>Product Donations</b>	\$645M	\$695M	\$550M
	+	+	+
<b>Cash and In-Kind Contributions</b>	\$55M	\$55M	\$40M
	=	=	=
<b>Total Contributions</b>	<b>\$700M</b>	<b>\$750M</b>	<b>\$590M</b>

\*Total charitable donations include funding from Lilly and the Lilly Foundation.



## THE CIVIC 50

In 2014, Lilly was named to The Civic 50, an annual list of America's most community-minded companies. An initiative of Bloomberg LP and Points of Light, The Civic 50 was created in 2012 to measure corporate civic engagement and to recognize companies that incorporate socially responsible practices and community leadership into their cultures.

## Charitable Giving: Highlights

In 2014, we gave more than **\$590 million in charitable contributions** (including cash, products, and other in-kind donations) to organizations around the world.

We gave approximately **\$1.9 million in cash and product donations** in 2014 following **natural disasters**.

Lilly has invested a total of **\$170 million** since 2003 to fight multidrug-resistant tuberculosis through the **Lilly MDR-TB Partnership**.

We have committed to donating more than **800,000 vials** of insulin to the International Diabetes Federation's **"Life for a Child"** program between 2008 and 2015. The program is currently reaching 15,000 children and youth with diabetes in 48 countries.

**The Lilly NCD Partnership** provides **\$30 million** over five years (2012–2016) to fight the rising burden of non-communicable diseases (NCDs) in developing nations, with a focus on diabetes.

Since its launch in 2011, Lilly employees have raised more than **\$1.1 million** through **Lilly Global Giving**, supporting more than 800 projects in the areas of health, hunger, education, and the environment.



“Connecting Hearts Abroad is one of the best ways to engage our employees. People come back energized, excited, and appreciative of the opportunities we have—as individuals and as a company—to help improve people’s lives.”

— Stacy Burdett, Senior District Sales Manager, Cardiovascular, Kansas City, Kansas, and Lilly Ambassador to Thailand

## Volunteerism at Lilly

Lilly actively encourages employees to volunteer and give back, and we develop programs that enable them to do so. Our robust tradition of volunteerism is often cited as a reason why people come to work for our company.

Our annual Global Day of Service (GDOS) is among the largest single-day volunteer initiatives of any U.S. company. In 2014, some 24,000 Lilly employees, dressed in signature Lilly red T-shirts, fanned out across communities in nearly 60 countries, accomplishing in one day what might otherwise take months or even years. Since our first GDOS in 2008, Lilly employees have contributed more than 725,000 volunteer hours through these daylong efforts.

Activities ranged from working in food pantries to outdoor beautification projects to developing activities for special needs students. In Indianapolis, Lilly attorneys and the Wills for Heroes Foundation partnered with two U.S. laws firms to provide free wills to 100 police officers, firefighters, and other first responders.

Another flagship volunteer program at Lilly is Connecting Hearts Abroad, which sends employees on two-week assignments in impoverished communities around the globe. Since we began the program in 2011, more than 600 employees, representing all job levels and roles at our company, have participated in what many have described as a life-changing experience.

Working alongside local partners in some of the world’s most impoverished communities, these Lilly ambassadors have the opportunity to view the world through a different lens, applying their energies and

# Global Day of Service Around the World

On October 2, 2014, more than **24,000** Lilly employees in nearly **60** countries took part in Lilly's seventh annual **Global Day of Service**.

For more information, visit our [website](#).

**ONE OF THE LARGEST SINGLE-DAY  
VOLUNTEER PROGRAMS IN THE WORLD**

**2014 MARKED THE 7TH ANNUAL  
LILLY GLOBAL DAY OF SERVICE**

**SINCE 2008, EMPLOYEES HAVE  
VOLUNTEERED MORE THAN 725,000 HOURS**



passions toward improving health for those living in low- and middle-income countries. The employees selected for the program get to see firsthand the day-to-day challenges that confront people living in poverty. They come back with insights and inspiration that make us a better—and more globally aware—company.

In 2014, Lilly volunteers worked on assignments in Costa Rica, Ghana, Guatemala, India, Peru, South Africa, Tanzania, and Thailand. About 30 of the ambassadors volunteered at global health sites associated with the [Lilly NCD Partnership](#) in India and South Africa, where we're working to improve the diagnosis and treatment of diabetes and other non-communicable diseases.

## Education Initiatives

As a company built on scientific discovery, we recognize the pivotal role that education plays in preparing children for successful careers, including in science, technology, engineering, and mathematics (STEM) fields.

Our local philanthropic portfolio in recent years has focused on education, particularly in our headquarters state of Indiana. We have been placing special emphasis on improving outcomes for low-income students and helping excite all kids about science and math.

In Marion County, where we are headquartered, more than 20 percent of people live below the poverty line. As a major corporation with deep roots here, we believe that we have an obligation to address this. Access to

high-quality education is critical to breaking the cycle of poverty, and it must include investments in high-quality early education, which pays big dividends for students, schools, and communities. Studies have shown that every dollar invested in early education provides returns of up to \$16 for society.

That's one reason why we enthusiastically championed the Indianapolis Early Education program, which the city's legislature approved in the fall of 2014. Lilly pledged to raise \$10 million over three years from the business community, including \$2 million from the Lilly Foundation, to invest in preschool programs. The funds are part of a broader \$40 million investment from public and private funding sources that will help ready more students for kindergarten by expanding the number of quality early education providers and making access more affordable to low-income families.

Improving education in Indianapolis not only strengthens our city; it also strengthens our business. By investing in our children, we are building a future pool of talented individuals who may one day work for Lilly. Today's student could be tomorrow's scientist or doctor. Moreover, a stronger, more vibrant community will help us recruit, retain, and engage talent from our home state and from around the world.

While high-quality early education is necessary, it cannot be the end of the story. We have to ensure that every child has access to a great school, regardless of where the child lives. Over the last five years, Lilly

has committed more than \$6 million in philanthropic donations to improve the educational landscape in Indianapolis. Some examples are detailed below and can be seen in this [video](#) of our education support.



### The Mind Trust

Lilly has partnered with The Mind Trust, an Indianapolis-based nonprofit, to attract more great leaders and teachers to local schools and to encourage more innovation and school-level autonomy. Most recently, we have helped support The Mind Trust's Innovation School Fellowship. The Fellowship is a partnership with the Indianapolis Public Schools (IPS) and the City of Indianapolis to help IPS create high-quality "Innovation Network Schools" within the school system. These schools are autonomous public schools that will operate under a contract with IPS, but will be free from many regulations and bureaucratic burdens, giving principals and teachers the autonomy and accountability that are hallmarks of high-performing schools.

**The Indiana Science Initiative (ISI)**

This initiative helps public school teachers (kindergarten through eighth grade) effectively integrate inquiry-based learning curricula into their classrooms. The Lilly Foundation provided \$1.5 million in funding to support the program and extend its reach. More than 130 schools, 1,900 teachers, and 53,000 students will participate in ISI through 2017. In addition to the funding from the Lilly Foundation, Lilly employees also volunteer as coaches, getting children excited about science and math. The 10 public schools that have participated in ISI for two full years have improved their performance, surpassing the state average on the most recent statewide science test.

**The IPS Business Alliance**

The IPS Business Alliance, which launched in the fall of 2014, pairs low-performing schools with businesses like ours to help improve student outcomes. Lilly is one of about a dozen companies that have pledged support for principals and staff in this first-of-its-kind partnership between Indianapolis public schools and the business community. Lilly has been matched with the Joyce Kilmer Academy, where we will focus on innovation, early intervention, and fostering exceptional leaders.

**SUPPORTING AND EMPOWERING TEACHERS**

Many of our efforts focus on ways to empower teachers and give them extra support for their daily activities.

**Teach Plus**

The Lilly Foundation is providing a \$1 million grant to support the implementation of teacher-led school turnaround initiatives at three public schools in Indianapolis. The four-year grant is in partnership with the nonprofit Teach Plus, which puts teacher leaders at the center of school- and system-level reform. Teach Plus will place 24 experienced, high-performing teachers in cohorts at the schools starting in the fall of 2015, using a program known as T3: Turnaround Teacher Teams Initiative. Designed by teachers, T3 addresses the problem of inequitable access to high-performing teachers in the highest-need schools and is founded on the premise that empowering exceptional teachers is the key to improving our nation's schools.

**Teacher's Day**

Every year since 2000, Lilly has hosted an annual "Teacher's Day" event, inviting teachers and administrators to "shop" for science equipment—for free. Nearly 100 schools are invited to participate and select from items such as glassware, microscopes, test tubes, flasks, beakers, hot plates, and more. The total estimated value of the equipment and supplies each year is \$100,000. Access to these much-needed supplies enables teachers to stretch their budgets and continue to advance science in their classrooms. The event also helps prevent our company from sending nearly 50,000 pounds of equipment to landfills each year.

**Life Science Coaches**

The Lilly Life Science Coach program assigns Lilly scientists to teachers to help them with classroom experiments, to talk about real-world science, and to serve as role models for students. In 2014, 65 Lilly employees volunteered as Life Science Coaches.

A portrait of De'Amonte McKinnis, a young Black man with long dreadlocks, wearing a blue polo shirt. He is looking slightly to the right of the camera with a neutral expression.

**De'Amonte McKinnis**  
Student, Shortridge Magnet High School

## Lilly Lawyers Head to the Classroom

De'Amonte McKinnis, a student at Indianapolis' Shortridge Magnet High School, was skeptical when he heard that a group of Lilly lawyers would be teaching his class lessons in civil law. But he quickly changed his mind after going through the Street Law course, a national program that pairs inner-city schools with corporate legal departments to boost students' knowledge of and interest in the law and legal careers.

"At first, I thought lawyers were always serious, but they came in and they were cool and mellow—and I like that. I really liked the experience," he said.

Since 2011, nearly 200 students have gone through the Street Law program at Shortridge. Several Lilly attorneys volunteer in the classroom, teaching the students concepts that are typically covered in the first year of law school. Although the classes have been adapted to a high school level, the lessons give the students exposure to legal and critical thinking, as well as current events.

The curriculum offers the students "real, authentic experiences," said Stanley Law, Shortridge's principal. "It gives them some insight into what they might want to do as a career path in their lives."

At the same time, the program provides Lilly's lawyers a chance to meet groups of young people with whom they may not otherwise get a chance to connect. The program also helps to address an overarching lack of diversity in the legal profession, encouraging minority students to choose the law for a career.

"Lilly has a very strong law division," said Ponce Tidwell, assistant general counsel at Lilly. "We will need diverse talent, and so it's very important for us to ensure that, at an early stage, we're priming the pipeline."

Learn more about the program in this [video ▶](#).

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# Operating Responsibly

- ▶ Ethics and Transparency
- ▶ Supply Chain
- ▶ Counterfeit Medicines
- ▶ Animal Care and Use
- ▶ Workplace
- ▶ Environmental Stewardship

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At Lilly, *how* we do business is as important as *what* we do. We demonstrate our values through responsible business practices that reflect our commitments to strong governance principles. This includes our efforts in, and approaches to, promoting ethics and transparency; instilling responsible supply chain management; tackling counterfeit medicines; ensuring the ethical care and use of animals in research; promoting an inspiring and inclusive workplace; and fostering environmental stewardship.

## Ethics and Transparency

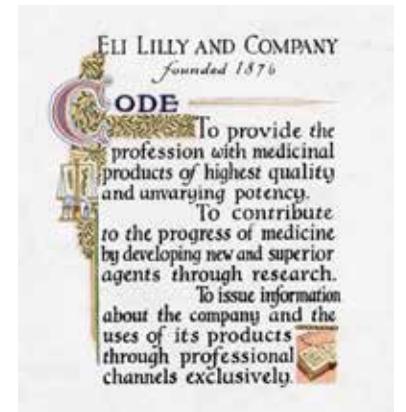
For more than 139 years, the people of Lilly have approached our company's business with a deep sense of responsibility to those we serve—patients, physicians and other healthcare providers, shareholders, suppliers, business partners, our workforce, and the communities in which we operate. Our actions are grounded in our core company values of integrity, excellence, and respect for people. These values are not simply platitudes; they are infused into the Lilly culture and guide all that we do.

### ETHICS, COMPLIANCE, AND GOVERNANCE

Our commitment to ethics and compliance is born of our commitment to integrity. Our policies, our Code of Business Conduct (which we call *The Red Book*), our compliance management systems, and our training

#### THE LILLY CODE

The Lilly Code, established in 1899 and illustrated in this 1932 version of the Code, served as the company's first mission statement and code of conduct. The Code established three areas of focus that endure to this day.



programs reinforce ethical behavior. As a global leader in the development, manufacturing, and sale of pharmaceutical products, we have implemented—and we continue to refine and improve—programs designed to promote ethical conduct and instill a culture of integrity. We train all of our employees in ethical business practices and have systems in place to detect potential violations of the law and company policies.

We have invested significant resources in our ethics and compliance programs, among them programs that focus on privacy, anti-corruption, and appropriate product promotion. The elements of each program include training and communications designed to prevent potential issues from arising, as well as reporting, auditing, and monitoring to detect potential compliance gaps. We also have a robust investigation process and develop corrective and preventive action plans to address issues that are identified.

### **Ethics and Compliance Program Oversight**

Responsibility for ethics and compliance at Lilly starts at the very top and cascades to all levels of the organization. Our board of directors' public policy and compliance committee, consisting of five independent director members, exercises direct oversight of Lilly's global ethics and compliance program. The board's audit committee has direct oversight of financial matters and some compliance-related audit matters.

Our chief executive officer routinely sets “the tone from the top” by speaking directly to employees about ethics and compliance issues through his blog, through audio and video messages, and through global town hall meetings. The global ethics and compliance organization

is charged with providing support for and assessment of compliance with global company policies that apply cross-functionally. The organization is headed by the senior vice president of enterprise risk management, who is also Lilly's chief ethics and compliance officer. This position reports to the CEO and has direct access to the board of directors' public policy and compliance committee.

### **Code of Conduct, Policies, Standards, and Procedures**

Our ethics and compliance programs include policies, standards, and procedures. We communicate our key compliance-related expectations through the following vehicles:

#### ***The Red Book.***

We regularly update and disseminate our Code of Business Conduct, *The Red Book*. Available in 23 languages, this document emphasizes the company's values and the importance of ethical decision-making, summarizes key principles from global company policies, and provides examples for employees to practice applying these principles to their decisions and actions. *The Red Book* is designed to provide foundational guiding principles to help our employees navigate an increasingly complex global business environment.

#### **Policies, Standards, Procedures, and Related Materials.**

The information summarized in *The Red Book* is amplified by policies, standards, and procedures accessible to employees on the company's intranet. These documents govern Lilly's actions with respect to specific areas, including anti-corruption, privacy, product promotion, safety, medical research, communications, securities trading, record keeping, international transactions, ethical interactions with external parties, interactions

with government and public officials, payments, grants and donations, meetings with healthcare providers, gifts, product samples, and many other topics. We also have functional policies, standards, and procedures that apply specifically to particular areas of our business.

### **Reporting, Monitoring, and Auditing**

To detect possible compliance violations, we maintain an internal disclosure system that includes a mechanism for anonymous reporting. We also review business actions through a system of monitoring and audits.

#### **Internal Reporting.**

Lilly employees are required to report to the company any known or suspected violations of the law, *The Red Book*, company policies, or official orders or decrees applicable to our business. Employees are also encouraged to report any other ethical concerns or issues. Our toll-free Ethics and Compliance Hotline is staffed by an independent firm, 24 hours a day, seven days a week. Due to differences in local law, local reporting processes can vary.

#### **Monitoring.**

Lilly maintains an ethics and compliance monitoring program. Its purpose is to evaluate whether the following have occurred:

- Compliance policies and procedures have been implemented,
- Employees have been trained on these policies and procedures, and
- Management is providing sufficient oversight of business processes and related results to support compliance with company policies, standards, and government laws and regulations.

The program has been standardized to include a global monitoring strategy, a risk assessment and monitoring plan with standard tools, and a process for reporting metrics to business leaders and key company stakeholders.

#### **Corporate Auditing.**

Our internal auditing function, corporate audit services (CAS), conducts both financial and nonfinancial audits of all Lilly affiliates globally to evaluate compliance with various company policies and procedures. CAS audits include reviews of our anti-corruption program and our policies that govern ethical interactions. Other groups at Lilly routinely audit additional regulated functions (e.g., manufacturing, environment, and safety), as described elsewhere in this report.

#### **Training and Communications**

We believe training is a necessary part of promoting ethical behavior because all employees play a role in the success of our ethics and compliance program. The company's commitment to training and communication is visible through many of our activities, including the following:

- Each year, all Lilly employees (and certain company contractors) must complete training on *The Red Book* and certify that they have received, read, understand, and will abide by its requirements.
- Employees receive targeted ethics and compliance training related to their specific job responsibilities.
- New employees in the ethics and compliance group participate in a training and education curriculum that focuses on understanding and implementing the elements of an effective compliance program globally. Training continues on a periodic and as-needed basis.

- Our leaders communicate regularly with employees to reinforce that they all must conduct company business in an ethical and compliant manner, making decisions and taking actions in line with the company's values of integrity, excellence, and respect for people.

#### **Investigations and Corrective Actions**

We take all reports of known or suspected violations of company policies, standards, and procedures seriously, and we appropriately investigate all claims of potential wrongdoing that are brought to our attention. We seek to address inappropriate conduct as early as possible and to prevent future recurrences. To accomplish this, a five-stage investigation process is in place globally to conduct timely, thorough, and professional investigations. All investigators are trained to understand and follow this process and to meet local procedural and privacy requirements.

#### **Anti-Corruption Due Diligence**

Lilly uses anti-corruption due diligence processes to assess the appropriateness of interactions with certain external parties, including the following:

- External parties whom Lilly may authorize to interact with government officials on the company's behalf,
- Prospective recipients of grants and donations, and
- Prospective business development partners.

Lilly also uses an institutional notification process to mitigate risk relating to healthcare providers whom Lilly pays for services, including clinical trial research, or to whom Lilly provides other items of value, such as educational opportunities.

## **PRIVACY**

At Lilly, we are committed to complying with privacy laws in all parts of the world and to acting ethically in our privacy practices. We work hard to meet our objectives of operating with transparency and protecting the privacy rights of all of those with whom we interact. We have a comprehensive global privacy program, including a global privacy office and a chief privacy officer, designed to protect the privacy rights of patients, consumers, healthcare professionals, our workforce, medical research subjects, and others. As a part of this global program, we have adopted robust privacy policies. These policies govern the collection of personal information necessary to our business operations and innovation. Our goal is to ensure that we always deliver on the promises we make to individuals whose personal information we collect and use.

*For more information on our privacy policies, see [www.lilly.com/Pages/privacy.aspx](http://www.lilly.com/Pages/privacy.aspx).*

## **TRANSPARENCY AT LILLY**

Lilly is a leader in transparency because we believe that this will help us to build trust with the public and with other stakeholders. Collaboration and partnerships between pharmaceutical companies, healthcare professionals, and healthcare organizations continue to be important and necessary for the development of new and lifesaving treatments and medical innovations. Some of these partnerships have raised concerns regarding potential conflicts of interest where a healthcare professional's judgment or actions regarding a patient may be influenced by relationships with industry. The need for greater and

more detailed transparency about industry relationships with healthcare professionals and organizations has evolved over the past decade. In the United States, Lilly complies with disclosure requirements at both the state and federal levels. Outside the United States, Lilly participates in voluntary disclosure codes under the European Federation of Pharmaceutical Industries and Associations (EFPIA), impacting 33 European countries, Russia, Ukraine, and Turkey, as well as legislated requirements within and outside of Europe. Lilly views our transparency as an opportunity to ensure that patients, healthcare professionals, and business partners feel confident when engaging with Lilly.

Lilly's transparency journey began in 2004 when we voluntarily began to disclose results from all of our clinical trials online—even the unfavorable ones. In 2007, Lilly added a registry of grants and charitable contributions made by the company. In 2009, as a requirement of our five-year Corporate Integrity Agreement (see detail under Marketing Practices section in this chapter), Lilly began to disclose payments, reimbursed expenses, and all transfers of value to U.S.-based physicians on the [Lilly Physician Payment Registry](#). Lilly publicly reports its financial support to patient organizations based in Europe and our company's U.S. political contributions.

These experiences have helped Lilly prepare to meet new obligations under the U.S. "Open Payments" regulations (implementing the [U.S. Sunshine Act](#)) and are also preparing Lilly to meet similar obligations under the EFPIA transparency initiative. Lilly also engages in dialogue directly with healthcare providers and others about transparency questions through our EthicsPoint

healthcare partners hotline (1-877-237-8197) or the Lilly EthicsPoint website.

In line with transparency disclosure, Lilly believes that fair compensation is due to healthcare professionals for services rendered in the drug development process, for research, for medical education, and/or to support product promotion and commercialization. Transparency has challenged, and continues to challenge, us to view our business practices through the lens of external stakeholders. By listening to stakeholders' concerns, we strive to continuously examine and improve the way we do business.

## MARKETING PRACTICES

Our commitments to ethical business practices are reflected in how we market our products. We introduce a medicine to the market only if we believe it addresses unmet patient needs. Once a product is approved for use, we communicate its benefits and risks, market it in compliance with company policies and applicable legal requirements, and monitor for safety concerns. Providing trusted, timely, and accurate information about our products is a vital part of our engagement with customers. We communicate product information to our customers in several ways. These include the following:

- Direct interaction between our sales representatives and prescribers, as well as account managers and public and private healthcare administrators;
- Information provided to patients and physicians through package labels and inserts; and
- Product websites and direct-to-consumer communications in some markets (see next page).

All communications about our products are reviewed and approved internally (before use) for compliance with company policies and applicable legal requirements; in some jurisdictions, they are also submitted to regulatory authorities. We are committed to following leading trade association codes of conduct regarding appropriate sales and marketing practices and interactions with healthcare professionals. These include international, regional, and country-specific codes such as the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) (for emerging markets), the European Federation of Pharmaceutical Industries and Associations (EFPIA) (for Europe), and the Pharmaceutical Research and Manufacturers of America (PhRMA) code (for the United States) (see [www.phrma.org/code-on-interactions-with-healthcare-professionals](http://www.phrma.org/code-on-interactions-with-healthcare-professionals)).

## U.S. FOREIGN CORRUPT PRACTICES ACT INVESTIGATION

**In August 2003, we received notice that the staff of the U.S. Securities and Exchange Commission (SEC) was conducting an investigation into the compliance by Lilly's Polish subsidiary with the U.S. Foreign Corrupt Practices Act (FCPA). Subsequently, we were notified that the SEC had expanded its investigation to other countries and that the U.S. Department of Justice was conducting a parallel investigation. In December 2012, we announced that we had reached an agreement with the SEC to settle its investigation. The settlement relates to certain activities of Lilly subsidiaries in Brazil, China, Poland, and Russia from 1994 through 2009. Without admitting or denying the allegations, we consented to pay a civil settlement amount of \$29.4 million and agreed to have an independent compliance consultant conduct a 60-day review of our internal controls and compliance program related to the FCPA. This review has been completed, and Lilly has implemented recommended enhancements to its anti-corruption program.**

## Direct-to-Consumer Communications

Given the increasingly complex healthcare system, patients are seeking more information about diseases and treatments as they prepare to consult with their healthcare providers about their healthcare needs. As a company responsible for developing new, innovative medicines, we are committed to providing consumer-focused communications that are truthful, accurate, and balanced. We believe that direct-to-consumer (DTC) disease-state communications help to raise awareness of diseases and conditions that are often undiagnosed, untreated, or undertreated.

For similar reasons, we engage in DTC product advertising in the United States, where we adhere to PhRMA's Guiding Principles on Direct to Consumer Advertisements about Prescription Medicines and additional internal Lilly principles on DTC communications.

## THE IMPORTANCE OF STAKEHOLDER ENGAGEMENT

At Lilly, our engagement with a wide range of stakeholder groups provides a basis for developing innovative medicines and enhances our collective ability to improve patient outcomes, both of which are important to our business.

Participating in dialogue and partnerships with groups beyond our own company allows us to understand different viewpoints, explain our positions, and address differences when they arise. We approach these discussions through several departments at Lilly: public policy; government affairs; advocacy; health, safety, and environment; and communications. This Corporate Responsibility report and our related website are also part of that stakeholder dialogue. This section of the report describes our engagement with advocacy organizations and provides examples of our stakeholder groups and engagement channels.

## ENGAGING WITH PATIENT AND CONSUMER ADVOCACY ORGANIZATIONS

We interact with advocacy organizations to address global healthcare challenges and to help shape the healthcare environment in ways that support patients. We believe that our role within this environment is discovering and developing breakthrough medicines, as well as providing information about these medicines and the diseases they treat to healthcare professionals, patients, and their caregivers. Lilly values the independence of external organizations, and we recognize that an advocacy group's scientific or educational agenda, perspectives, and legal

obligations may differ from our own. We follow our company principles and industry codes when interacting with third-party patient and consumer advocacy groups. Our principles are built upon compliance with legal requirements, open and honest communications, transparency, and funding a diversity of recipients. We seek to establish collaborative partnerships that achieve the following:

- Engage stakeholders on matters involving public policy, improving patient access to treatment options, and supporting market-oriented solutions to the healthcare issues we all face;
- Build awareness about various disease states, treatment options, and the importance of adherence to treatment recommendations;
- Provide educational information, tools, and resources;
- Improve medical standards of care and foster productive communication between patients and their healthcare providers; and
- Serve varied populations and provide educational materials that are culturally appropriate and that respect the diversity of patients and caregivers.

## U.S. CORPORATE INTEGRITY AGREEMENT

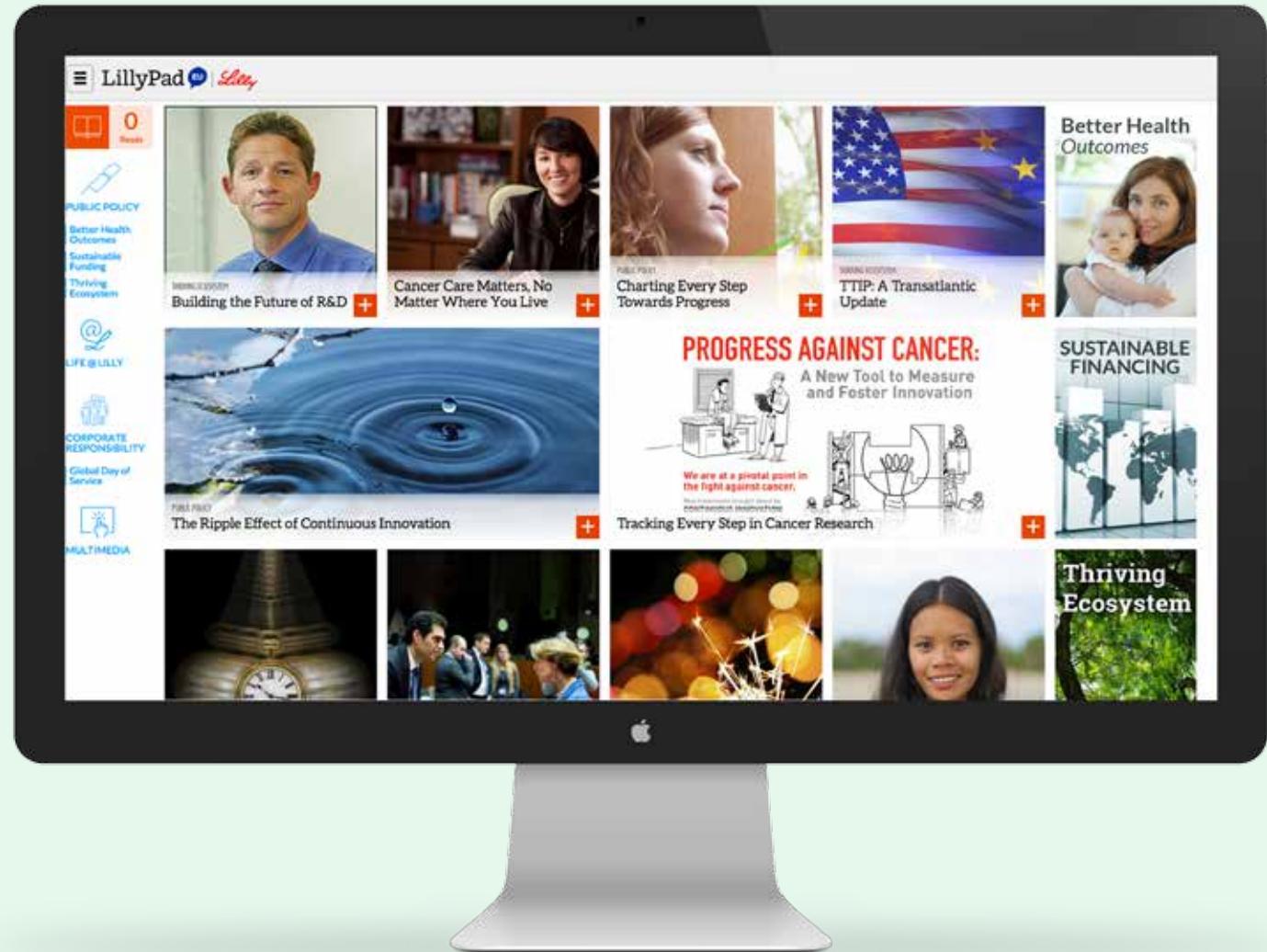
In January 2009, as part of the resolution of a government investigation related to our U.S. marketing and promotional practices with respect to Zyprexa®, we entered into a Corporate Integrity Agreement (CIA) with the U.S. Department of Health and Human Services Office of the Inspector General, which required us to maintain our compliance program and to undertake a set of defined corporate integrity obligations for five years. The agreement also provided for an independent third-party review organization to assess and report annually on the effectiveness of the company's ethics and compliance program. This information was used, along with other information, to build enhancements into our ethics and compliance program. Lilly satisfied the requirements of the CIA in 2014.

## ADDRESSING PARENTS' ADVERTISING CONCERNS

Since October 2010, we have participated in an initiative in the United States with the Parents Television Council (PTC) to alert parents to broadcast television programs that will contain advertisements for erectile dysfunction drugs. Lilly sends to the PTC weekly broadcast schedules of Cialis® advertisements. The PTC publishes advertising schedules for erectile dysfunction drugs on the PTC's website here: [w2.parentstv.org/Main/Toolkit/Ed\\_Sched.aspx](http://w2.parentstv.org/Main/Toolkit/Ed_Sched.aspx).

## LillyPad

LillyPad, the official blog of Eli Lilly and Company, aims to start a dialogue on today's most pressing topics that impact people around the world, such as health, medical discovery, and public policy. It also describes our corporate responsibility initiatives, advocacy efforts, and the work that our employees do every day to make the world a healthier place in which to live. Visit [lillypad.lilly.com](http://lillypad.lilly.com) or follow @LillyPad on Twitter to join the discussion.



## WHO ARE OUR STAKEHOLDERS?

Stakeholder Groups and Examples of Engagement Channels

### HEALTHCARE PROFESSIONALS

- Online medical information resources
- Disease-state educational programs
- Advisory boards
- Sales force interactions
- Direct-mail communications
- The Lilly Answers Center telephone line
- Medication guides and package inserts
- Online registries
- Publications (manuscripts, posters, and abstracts)
- Medical letters
- Patient support programs
- Lilly-sponsored symposia and scientific exchange meetings
- Medical and commercial booths at congresses
- Interactions with Lilly physicians, scientists, and medical liaisons
- Contracting for clinical trial investigation work
- Lilly-sponsored mobile apps that provide physicians with easy-to-access research and clinical trial information

### INVESTORS

- Daily interactions through our investor relations' function
- Industry investor conferences
- Meetings in Indianapolis and major global cities
- Quarterly earnings communications
- Annual meeting of shareholders
- Annual report and other financial disclosures
- Periodic investment community update meetings

### SUPPLIERS

- Green procurement program
- Product stewardship standard
- Supplier self-assessments and qualifications
- Supplier audits that Lilly performs
- Supplier risk-assessment process
- Policy advocacy conversations with vendors

### EMPLOYEES<sup>1</sup>

- Live "global town hall" meetings
- Intranet social collaboration/networking tools, including CEO blog
- Employee resource groups
- Employee surveys
- Electronic newsletters
- Hotline for ethics, compliance, and privacy questions/concerns

### PATIENTS

- Healthcare provider discussions
- Educational materials and programs
- Product package inserts and medication guides
- Patient advocacy groups
- Patient support and assistance programs
- Online product resources
- The Lilly Answers Center telephone line

### NON-GOVERNMENTAL ORGANIZATIONS

- Partnerships to support patients and families
- Partnerships to raise awareness about certain diseases
- Advisory board participation
- Participation in annual conferences/exhibitions
- Company communications
- Memberships

Our business partners, including those involved in research, development, commercial, and manufacturing alliances, are also important stakeholders. Our office of alliance management performs about 15 "Voice of Alliance™" surveys per year of more than 2,000 respondents, asking both our business partners and the Lilly employees involved in those partnerships how the collaborations could be improved.

### GOVERNMENT AND REGULATORY ORGANIZATIONS

- Policy education materials
- Published policy research
- Responses to written requests for information
- Oral and written testimony
- Written comments on proposed regulations
- Policy discussions
- Advisory boards
- Meetings and conferences
- Communication of studies
- Lobbying activities
- Educational briefings
- Direct legislator and policy-maker engagement

### PUBLIC AND PRIVATE HEALTHCARE ADMINISTRATORS

- Account-manager interactions
- Disease-state educational programs
- Advisory boards
- The Lilly Answers Center telephone line
- Online medical information resources

### COMMUNITY MEMBERS

- Employee service on boards and committees of local organizations
- Participation in local volunteer opportunities
- Employee-directed philanthropy

<sup>1</sup> Approximately 39,000 employees as of December 31, 2014.

## IMPROVING PATIENT OUTCOMES THROUGH HEALTH LITERACY

A number of factors are making health-related decisions more complex, including the economic pressure of rising healthcare costs and the growing prevalence of chronic disease. Increasingly, patients are the primary decision makers in their own care, driving major decisions about the healthcare they receive. Without clear communications, however, patients cannot make fully informed decisions and take actions that will best protect and promote their health. The efforts of Lilly and others to promote health literacy are designed to help.

Health literacy relates to one's ability to interact with the healthcare system to get the information needed to manage one's health. Recently, healthcare organizations have been placing increasing emphasis on reducing the complexity of decision-making by making healthcare communications easier to understand.

Lilly believes that clear health communication is a vital component of the healthcare delivery system in which pharmaceutical companies play an important role. We have made a strong commitment to improve our healthcare communications and to better connect with patients in ways that are both meaningful and actionable.

It's not about oversimplifying our patient resources; it's about communicating in plain "living room" language so

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### THE INSTITUTE OF MEDICINE DEFINES HEALTH LITERACY AS:

"... the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions."

## IMPROVING HEALTH THROUGH ENGAGEMENT WITH FAITH-BASED GROUPS

Lilly has long recognized that churches and other faith-based groups are powerful allies for improving health. We work with several religious communities to engage stakeholders. Our ongoing relationships with the National Baptist Convention, Church of God in Christ, and the religious arms of organizations like the NAACP, reach more than 8 million people, most of them African American, and have achieved some excellent results. Several years ago, we started working with leaders of these organizations to distribute educational materials focused mostly on healthy and active lifestyle choices. Requests for these materials have been overwhelming, and we have now given out more than 1 million pieces of literature and provided resources regarding Lilly's patient assistance programs.

Individual churches have also become more engaged in keeping their congregations healthy. Many of the churches now run comprehensive wellness programs and include diabetes-screenings that are founded upon Lilly's principles of prevention and ongoing adherence to treatment regimens. Some have revamped the menus in their church kitchens to offer healthier meals. And some have applied for grants through First Lady Michelle Obama's "Let's Move!" program. These churches are truly investing in the well-being of their members, and we are glad that Lilly has played a small role in their success.

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ordinary people can understand medical information and play a more active role in making appropriate decisions about their health. One way we have begun to do this is by partnering with nationally recognized health literacy experts to train employees and to help us assess, test, and implement new, clear communication standards for the materials and resources that we share with patients.

In 2013, Lilly sponsored a pilot project about the pamphlets detailing potential risks that accompany Lilly medicines. The study found that this risk information often exceeds patients' abilities to understand and effectively act on it. This research was developed into a manuscript and is now published online in the journal *Therapeutic Innovation & Regulatory Science*.

As a result of work like this, Lilly has been a member of the Institute of Medicine's Roundtable on Health Literacy since 2013. The Roundtable brings together leaders from academia, industry, government, foundations and associations, and representatives of

patient and consumer groups that have an interest in improving overall health literacy. By participating on the Roundtable, we have an opportunity to continue to make a difference on the national level and to directly support the National Action Plan to Improve Health Literacy as outlined by the U.S. Department of Health and Human Services. We look forward to continuing to report on these efforts and other health literacy initiatives in the future.

## ADVANCING PUBLIC POLICY

As a biopharmaceutical company that treats serious diseases, we play an important role in public health and related public policy debates. We believe it is important for our company to participate in global policy discussions and form partnerships with various stakeholders to create innovative solutions to global health challenges. Our engagement in the public policy arena focuses on issues that will help increase access to medicines. As such, we develop policy positions with the needs of patients foremost in our minds.

# Expanding Our Diabetes Outreach

At Lilly, expanding our definition of diversity to include people with a wide range of healthcare, social, and situational needs makes sense to us. Both in the United States and globally, we are expanding our outreach and education for people with diabetes who fast during the Muslim holiday of Ramadan. Up to 1.5 billion people worldwide practice the Muslim faith, and the number of people with diabetes is growing at an alarming rate in many areas with large Muslim populations.

Fasting during the holy month of Ramadan is an obligation for healthy adult Muslims, and some experts suggest that up to 50 million people with diabetes worldwide observe the Ramadan fast.

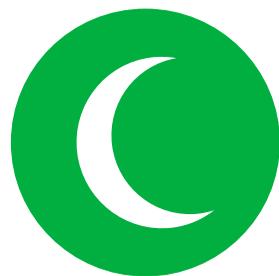
For many people with diabetes, skipping or reducing meals can quickly result in serious complications. Since we recognize that many Muslims with diabetes wish to stay healthy while they fast, Lilly provides Ramadan-focused educational materials.

The materials for Ramadan cover how people with diabetes can safely fast, using a tool called Conversation Maps™. These visual “road maps” facilitate group discussions so people with diabetes can get more involved in managing their disease. The Ramadan-focused Conversation Maps were developed with the International Diabetes Federation and were expanded in 2014 into more than 42 countries and translated into more than 35 different languages. Read more about our Conversations Maps in the [Patient Programs](#) section.

## RAMADAN AND LILLY DIABETES

### What is Ramadan?

During Ramadan, Muslims fast during the day from food, drink, and medicine



In 2015, Ramadan Starts  
**JUNE 17 AND ENDS JULY 17**  
(varies with region)

### Muslim Populations



There are up to  
**1.5 billion**  
Muslims worldwide\*



By 2030, Muslims will  
make up more than a  
quarter of the global  
population\*\*

Diabetes is becoming an epidemic around the world, including in countries with large Muslim populations, such as

**INDONESIA AND PAKISTAN**

### What is the Conversation Map® “MANAGING DIABETES DURING RAMADAN”?

Educational tool to help patients with diabetes

Reminds Muslims with diabetes to consider all of their circumstances to help them achieve a **safer** Ramadan experience

Help patients to help themselves if complications arise during Ramadan

Encourages conversation surrounding the importance of a Ramadan management plan



**42** INTRODUCED  
IN 42 COUNTRIES



**35** TRANSLATED  
INTO MORE THAN  
35 DIFFERENT  
LANGUAGES

\*Al-Arouj B, Bouguerra, Radha, et. al. Recommendations for Management of Diabetes During Ramadan. *Diabetes Care*. September 2005 vol. 28 no. 9; 2305.

\*\*Lugo L, Cooperman C, et al. The Future Global Muslim Population: Projections for 2010–2030. January 2011. [www.euro-muslims.eu/future\\_global.pdf](http://www.euro-muslims.eu/future_global.pdf). Accessed on May 14, 2014.

## COMMUNITY CONVERSATIONS

Lilly is committed to helping improve health outcomes for people with chronic conditions. In the United States, one of our initiatives is Community Conversations. Focused on people with Alzheimer's disease and their families, this initiative pulls together stakeholders in local communities to identify, discuss, and address systemic issues related to Alzheimer's, such as the need for better detection and diagnosis and medical system barriers that can stand in the way of effective treatment.

Lilly is the facilitator for the "community conversations," which provide an opportunity for people to meet, learn about best practices from an expert trained in Alzheimer's policy and care, and then create an action plan to address specific areas of need locally. Since the program's launch in 2005, when it had a broader focus on mental health generally, we have seen the program create new partnerships, advance priorities around the management of the disease, and build links and connections to resources.

During 2014, Lilly brought together stakeholders to discuss what can be done to address the unique challenges posed by Alzheimer's disease. Representatives from advocacy and community groups, health systems, public health clinics, senior housing, and law enforcement agencies are some of the stakeholders that have participated in Community Conversations events. The result has been increased collaboration between these groups, better integration of community resources, increased training programs for those who provide care, and a platform for ongoing knowledge sharing and problem solving.

At Lilly, our public policy efforts center on areas that we feel are critical for sustainable innovation, including intellectual property protection, sound healthcare delivery, pricing and reimbursement issues, a favorable regulatory system, and securing the legitimate supply chain. Lilly focuses on conducting policy research, taking positions on key issues, and improving stakeholder dialogue around topics important to our company, our industry, and the people we serve. More detailed information on key issues is available at [www.lilly.com](http://www.lilly.com).

## POLITICAL ENGAGEMENT

When engaging in lobbying efforts or making political contributions, we comply with the laws that govern such activities. All financial support and lobbying activity are overseen at the board level by the public policy and compliance committee, which is composed entirely of outside directors. All decisions are made without regard for the private, personal preferences of the company's officers and executives. All of our employees must also comply with our global policies, core values, and legal obligations, which are outlined in our written Code of Business Conduct, *The Red Book*.

Our annual report of Political Financial Support provides details of our company's U.S. political contributions, our memberships in organizations that report lobbying activity to the U.S. government and to which we contribute \$50,000 a year or more, and the activities of our Political Action Committee, the Lilly PAC, which is funded solely by U.S. employee contributions.

In the United States, we are committed to backing candidates of any party who support public policies that contribute to pharmaceutical innovation and the health needs of patients. When reviewing U.S. candidates for support, we consider a number of factors, including these examples:

- Has the candidate historically voted or announced positions on issues of importance to Lilly, such as pharmaceutical innovation and health care?
- Has the candidate demonstrated leadership on key committees of importance to our business?
- Does the candidate demonstrate potential for legislative leadership?
- Is the candidate dedicated to improving the relationship between business and government?
- Does the candidate represent a state or district where Lilly operates a facility or has a large concentration of employees or retirees?
- Would Lilly support have an impact on his or her campaign?

Eligible Lilly employees in the United States may choose to make voluntary contributions to the Lilly PAC. Lilly PAC donations, which are made in accordance with its budget, are determined annually by the Lilly PAC governing board, which is composed of 13 U.S.-based employees from various groups within the company. Support is divided between the federal and state levels and allocated among various candidates according to specific recommendations from Lilly's government affairs department and employee PAC members. Lilly PAC meets all disclosure requirements and is audited annually by Ernst & Young.

## MEMBERSHIPS

In addition to direct political contributions, Lilly maintains memberships in organizations that report lobbying activity to the U.S. federal government. We support organizations that champion public policies that contribute to pharmaceutical innovation, healthy patients, and a healthy business climate. Our annual report of Political Financial Support also notes our memberships in trade associations that report lobbying activity to the U.S. government and to which we contribute \$50,000 per year or more. What follows is a list of U.S.-based organizations that conduct lobbying activities to which Lilly contributes a minimum of \$50,000 a year. Organizations with which Lilly holds a board seat are noted to reflect our greater degree of involvement in setting priorities for these organizations.

### MEMBERSHIPS IN 2014

#### Board seat:

- American Feed Industry Association
- Animal Health Institute
- Biotechnology Industry Organization
- Greater Indianapolis Chamber of Commerce
- Healthcare Leadership Council
- Indiana Chamber of Commerce
- National Association of Manufacturers
- Pharmaceutical Research and Manufacturers of America

#### Non-board seat:

- Business Roundtable
- U.S. Chamber of Commerce

## IN 2014, LILLY SPENT THE FOLLOWING AMOUNTS:

A total of

**\$1,683,525**

in political financial support (United States):  
**\$420,100** in corporate contributions and  
**\$1,263,425** through the Lilly Political  
 Action Committee (Lilly PAC).

**\$8,066,000**

on federal lobbying activities in the  
 United States. This information is reported  
 to the U.S. Congress in accordance with the  
 Lobbying Disclosure Act of 1995.

### ANTI-COUNTERFEITING MEASURES

To ensure patients have access to trusted medicines, a secure supply chain is a necessity. The global problem of counterfeit medicines requires a sustained, long-term commitment. Despite the ongoing efforts of law enforcement and health authorities throughout the world, as well as the efforts of the pharmaceutical industry to increase the integrity of the supply chain and support transnational law enforcement cases, the rate of counterfeiting continues to increase significantly. Collaboration and cooperation are critical to stop this dangerous trend. Lilly is committed to working with a wide range of public and private partners to reduce the threat to patients. To learn more, see [Counterfeit Medicines](#). To read more about critical elements within trade agreements, see our trade agreements policy.

## Supply Chain

Ensuring our products are available wherever and whenever patients need them is one of our top priorities. As worldwide attention has increasingly focused on the need to monitor global supply chains to ensure reliability and safety, we at Lilly have continued to refine our efforts in this area. Through better integration of Lilly-owned facilities and external suppliers, we have been able to provide a consistent flow of materials so we can manufacture our medicines in a more efficient and effective manner. We view our supply chain as an extension of our operations, and we strive to instill our company's operating principles within our supplier network. These include our support of the United Nations Global Compact principles, adherence to labor laws, development of a diverse supply base, and the promotion of sustainability efforts to minimize our environmental impact. To learn more about our environmental impacts and how we work to mitigate them, see [Environmental Stewardship](#).

As part of Lilly's ongoing supply chain risk management, Lilly suppliers in Tiers B and C are expected to complete a supplier self-assessment questionnaire aligned with the [Pharmaceutical Industry Principles for Responsible Supply Chain Management](#) (also known as PSCI principles, see detail later in this section) and be

available for audits, at Lilly's discretion. Tier A supplier contracts contain language indicating the supplier supports the [PSCI principles](#). For those Tier A suppliers that are not under a contract, we expect adherence to our [Supplier Code of Conduct](#).

### MAINTAINING AND MONITORING QUALITY, SAFETY, AND SECURITY OF SUPPLY

Our ability to manufacture quality medicines for the people we serve depends on the quality and availability of the materials used in the manufacturing process. In 2014, our active pharmaceutical ingredient manufacturing relied heavily on Lilly-owned and Lilly-partner facilities located in the United States, Puerto Rico, and Europe. Finishing operations, including labeling and packaging, occur at various Lilly-owned and Lilly-partner facilities as well as several third-party sites globally. Distribution and warehousing activities are strategically located to serve their specific markets.

Because Lilly manufactures medicines that people rely upon and that can be critical for health, we have a responsibility to safeguard both the materials needed to manufacture these medicines as well as the supply chain logistics that help to ensure their availability. Before they enter the Lilly system, our raw material suppliers are evaluated for patient, commercial, and health, safety, and environment (HSE) impacts. For those suppliers deemed to have a higher risk in any of these areas, additional

evaluations are conducted. These evaluations are separate from, and in addition to, evaluations of Tier A, B, and C suppliers from a supply risk perspective.

Our manufacturing policy committee oversees the maintenance of Lilly's inventory of essential raw materials. Inventory levels of these materials are monitored weekly to allow for proactive intervention, as needed, to avoid any interruptions of supply. To supplement these inventory action plans, we also have additional mitigation plans in place for our drug product components, including materials critical to manufacturing finished drug products. For these components, we have identified secondary sources, as well as additional existing inventory in our supply chain. This analysis has permitted us to further refine our overall risk strategy.

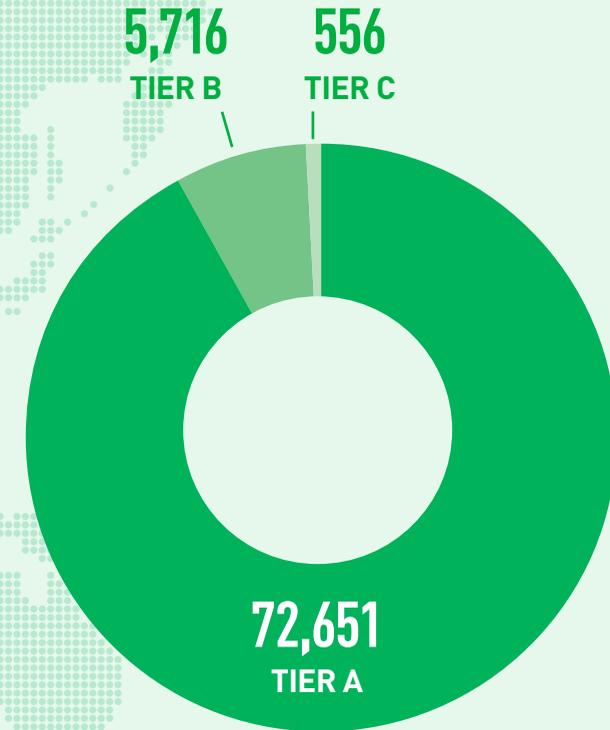
### UPHOLDING HUMAN RIGHTS THROUGHOUT THE SUPPLY CHAIN

**Lilly maintains a long-standing practice of complying with local minimum-age laws and requirements and does not employ child labor, or forced or compulsory labor, in any of our facilities globally. In 2011, Lilly revised our global standards and procedures to include specific language about human rights, including our expectation that vendors to Lilly abide by Lilly's human rights standards as one piece of our Supplier Code of Conduct. To view the current Lilly Supplier Code of Conduct, visit [supplierportal.lilly.com/Suppliers/Pages/ConductCode.aspx](http://supplierportal.lilly.com/Suppliers/Pages/ConductCode.aspx).**

## Lilly's Supply Chain at a Glance

In 2014, Lilly used the services of just under approximately 79,000 suppliers of materials and services. To help identify the potential impact to Lilly's business from any disruption of services or materials, we categorize all of our suppliers into three tiers, using a supply risk\* perspective lens. Supplier data include Elanco, our animal health division.

## SUPPLIERS IN 2014 BY TYPE



### TIER A

Includes suppliers of a lower supply risk profile. These include vendors providing goods and services across general business functions, including general office supplies, travel services, IT equipment, catering, and other routine services.

### TIER B

Includes suppliers of a medium-level of risk. Suppliers in this tier provide raw materials and other common commodities used for packaging and manufacturing operations. These include packaging materials, waste disposal services, and energy.

### TIER C

Includes suppliers deemed to pose the greatest risk for supply chain interruptions. Suppliers provide active pharmaceutical ingredients, including specialty chemicals. Suppliers in this tier include contract manufacturers and research and development labs.

\*Supply risk is the risk associated with Lilly's dependence on a third party for services or materials that are critical to the operation of our business. Supply risk can come from many factors, including but not limited to supplier financial stability, the ability to produce or provide services in a quality manner, or the impact of a natural disaster on the supplier's site. This risk is monitored on an annual basis, and mitigation plans are implemented and monitored to minimize it.

TOC

01

02

03

04

05

Shipping pharmaceutical products requires extra precautions that typical freight shipping does not, including precise temperature controls. Shipments of medicines can also be subject to tampering and interference from drug counterfeiters, leading to very serious consequences. Therefore, the security of our supply chains and our extended distribution network remains a key focal point for Lilly. We have chosen to integrate high standards to help safeguard our products during transport, integrating what are known as Transported Asset Protection Association, or TAPA, standards into our security framework. We actively monitor our supply chain using TAPA standards to ensure a high level of performance for our transportation carriers and warehouse and distribution centers. See [Counterfeit Medicines](#) to read more about our broad-based anti-counterfeiting efforts, including product serialization and traceability.

## PHARMACEUTICAL SUPPLY CHAIN INITIATIVE (PSCI)

**PSCI** is an industry body formed by the pharmaceutical sector and facilitated by Business for Social Responsibility (BSR), whose members share a vision for responsible supply chain management, with an ultimate goal of facilitating better social, environmental, and economic outcomes in the communities where purchases are made. Lilly joined PSCI in 2009 and remains an active member, aligned to the mission and vision of the organization. In October 2014, Lilly was pleased to host PSCI's annual general meeting in Indianapolis at our corporate headquarters.

Lilly is committed to following the Pharmaceutical Industry Principles for Responsible Supply Chain Management, which PSCI created, together with member companies. These principles, established to provide the pharmaceutical industry with a consistent standard of measurement for vendors in the areas of ethics, labor, health and safety, the environment, and related management systems, were designed to be consistent with the United Nations Global Compact. The principles themselves and related information can be found at the PSCI website: [www.pharmaceuticalsupplychain.org/principles/introduction](http://www.pharmaceuticalsupplychain.org/principles/introduction).

Lilly's participation in PSCI has provided a much-appreciated opportunity to engage with our PSCI colleagues around supply chain management, and we have found much common ground in our collective support for the values that PSCI advocates. Our involvement with PSCI has helped us to sharpen our supply chain management practices and delivered business value through enhanced understanding of the environments in which our vendors operate. PSCI has also provided Lilly with some valuable tools, including:

**Common auditing practices** – As our industry increasingly adopts the standardized PSCI questionnaires, our suppliers can more easily anticipate questions we might have about their practices and learn to manage their operations with the rigor required by Lilly and other major manufacturers. These questionnaires cover adherence to high standards of HSE performance, labor practices, human rights, and

ethics. Lilly has also used joint audits performed by PSCI to supplement our own supplier assessment process. Through this process, we have been able to help our suppliers improve their internal capabilities by identifying areas for improvement.

### Vendor trainings for knowledge and capability building

– Lilly has also participated in webinars and workshops, facilitated by PSCI, to help pharmaceutical suppliers better understand and improve social and environmental practices across their own supply chains. For example, PSCI held a capability-building workshop in China in September 2014, bringing together more than 150 Chinese suppliers. Over a two-day period the suppliers received presentations on topics including process safety, industrial hygiene, and environmental control, as well as labor practices and ethics. Further workshops in other global locations are planned for 2015.

## CONFLICT MINERALS

Lilly is concerned with the variety of human rights violations that occur throughout the world. We are aware that the ongoing conflict in the Democratic Republic of Congo (DRC) and the surrounding countries is understood to be financed, in part, by the mining and trade of certain minerals, including tungsten, tantalum, tin, and gold. We are committed to making every effort to ensure we understand our supply chain and the potential downstream impacts of our supply and purchasing decisions as they relate to the minerals at issue.

Lilly, along with other companies covered by the Securities and Exchange Commission's Conflict Minerals Rule, is required to annually report whether products that we manufacture or have contracted to manufacture contain certain defined minerals, and whether those materials may have come from sources in the DRC region.

As a part of this process, we examine the raw material content of all of our global commercial products and seek to identify the origin and source of these raw materials. Our goal is to ensure that the materials we use cannot be traced back to areas where proceeds from the mining of the materials may have been used to support armed conflict in the DRC region.

Lilly's expectation is that our suppliers will source their materials responsibly and abstain from procuring materials from areas or sources that might promote conflict in the DRC, and that our suppliers conduct their own due diligence regarding the source of any materials they provide to us in order to ensure those materials are conflict free.

Our due diligence process for 2013 revealed that we use very minimal amounts of the minerals at issue. We filed our Conflict Minerals [disclosure documents](#) with the Securities and Exchange Commission (SEC) in May, which include additional details regarding our diligence process and findings. As of that date, aside from one supplier that could not provide us with sufficient information to enable us to definitively determine the source of the minerals it provides to us, we were able to determine that none of our products use minerals sourced from the DRC or surrounding region.

“At Lilly, we strive to ensure that our global operations contribute to a cleaner, safer, and more sustainable environment. This includes our interactions with key suppliers and business partners across the globe. We are very pleased to be a contributing stakeholder of PSCI and believe that the collective influence we have as an industry is accelerating advancements in capability and performance across the globe.”

— Edward Canary, Vice President, Health, Safety, and Environment

We have established an action plan to ensure the supplier at issue is able to provide us with the required information as a part of next year's diligence process, and we will include updated information in our next Conflict Minerals Report to the SEC in May 2015.

Lilly is committed to continue to understand the origin of these materials and will take appropriate action to avoid the inadvertent support of business associated with human rights violations.

## Counterfeit Medicines

Counterfeit medicines, often produced and distributed by global criminal networks, are an increasing threat to patient safety. In fact, The World Health Organization estimates that as much as 30 percent of the medicines sold in parts of Asia, Africa, and Latin America are counterfeit. But counterfeit medicines aren't confined to one region; they have been found in all therapeutic areas in every region of the world. Counterfeits put patients at risk of further illness, disability, or even death; and they can also undermine a patient's confidence in the medicines they are prescribed, as well as the credibility of healthcare providers.

During 2013, the Pharmaceutical Security Institute documented 2,193 incidents of pharmaceutical crime across 124 countries, a nearly 9 percent increase over

2012. According to data from the World Economic Forum, worldwide counterfeit drug sales generate an estimated \$75 billion to \$200 billion in illicit profits annually.<sup>2,3</sup> One expert estimates that a \$1,000 investment in counterfeit prescription drugs can result in a \$30,000 return—which is 10 times the profit return from trafficking heroin.<sup>4</sup>

Every year, healthcare providers, health authorities, and law enforcement agencies must spend an increasing amount of resources to combat this growing threat. Lilly faces this same challenge. We employ a variety of anti-counterfeiting tactics for our medicines and are actively engaged in efforts to combat counterfeiting to protect patients and the Lilly brand.

Counterfeiting is an issue that has historically affected many developing countries, but the Internet has exacerbated the problem by serving as a platform to increase the availability of these dangerous products globally. In the European Union (EU), approximately 19 percent of all counterfeit goods detained in postal traffic in 2013 were medicines.<sup>5</sup> Today, counterfeit medicines are exported across borders using conventional and unconventional trade routes and shipping methods that change frequently in response to regulatory and law enforcement actions. Products are often made in one country, trafficked through other countries, and ultimately sold to consumers in yet another country.

Ensuring that patients can continue to benefit from safe medicines requires innovative approaches to expose and outwit counterfeiters—and a broad, coordinated effort among many stakeholders to give patients confidence in the safety and efficacy of the medicines they take. Lilly has made a sustained, long-term commitment to address this problem. Our anti-counterfeiting strategy is composed of three key objectives:

- Securing the integrity of Lilly medicines through the legitimate supply channels;
- Deterring major counterfeiters of Lilly medicines through targeted investigations, Internet monitoring, and legal actions; and
- Partnering with governments, non-governmental organizations, and trade associations to raise awareness and to strengthen, enact, and enforce anti-counterfeiting laws.

### LILLY'S WORK TO SECURE THE LEGITIMATE SUPPLY CHAIN

For many years, Lilly has used various types of anti-counterfeiting and tamper-evident technologies as part of its overall strategy to protect patients. We are also putting systems in place to meet emerging pharmaceutical "track and trace" standards around the globe. These standards, while not a "silver bullet," are designed to help patients, pharmacists, and others determine if a given medicine is a fake or the real thing.

<sup>2</sup> World Economic Forum. Global Risks 2011. Sixth Edition. An Initiative of the Risk Response Network. January 2011.

<sup>3</sup> The Center for Medicines in the Public Interest. Counterfeit Drugs and China. [www.cmpi.org/in-the-news/testimony/counterfeit-drugs-and-china-new](http://www.cmpi.org/in-the-news/testimony/counterfeit-drugs-and-china-new). Last accessed December 18, 2014.

<sup>4</sup> Ehrenberg R. Counterfeit crackdown. *Science News*. 2011;179:22-25.

<sup>5</sup> Report on EU customs of enforcement of intellectual property rights, Results at the EU border. Publication Office of the European Union © 2014. [ec.europa.eu/taxation\\_customs/resources/documents/customs/customs\\_controls/counterfeit\\_piracy/statistics/2014\\_ipr\\_statistics\\_en.pdf](http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/2014_ipr_statistics_en.pdf). Last accessed January 12, 2015.

Serialization, the unique identification of individual packs of medications, is a particularly promising technology. As each batch of finished product is packaged, a globally unique two-dimensional code is assigned and physically marked on the product's packaging. To track and trace the movement of individual packs, serial numbers can be recorded and electronically linked to deliveries to customers. As a result, some countries have begun to require serialization, including pharmacy validation that a serial number is valid, before dispensing a given medicine to patients. By requiring not only manufacturers, but also wholesalers and pharmacies, to record shipments and receipts of serialized products, a documented chain of custody can be established. When implemented correctly, serialization will help secure the legitimate supply chain, while simultaneously offering other benefits to patients and the healthcare providers who serve them. These other benefits include automated checking of expiry dates, providing a way to record the batch number of specific medicines in a patient's electronic medical records, and reducing fraudulent reimbursement claims for medicines not actually dispensed to patients.

To help secure the legitimate supply chain for its products even further, Lilly has been making considerable investments in packaging operations, distribution centers, and information technology infrastructure, including adding new technology to more than 30 packaging

assembly lines around the world. The incremental cost of meeting "track and trace" standards is significant: a roughly \$100 million investment. Additionally, Lilly is working closely with other organizations to advocate for common serialization standards in the United States and globally. These standardization efforts will help doctors, pharmacists, and patients around the world trust the legitimacy of the medicines they prescribe, dispense, and receive.

### WORKING TO DETER COUNTERFEITERS ONLINE AND IN THE FIELD

According to the National Association of Boards of Pharmacy, 96 percent of online drug sellers do not meet Food and Drug Administration (FDA) standards.<sup>6</sup> And yet the FDA notes that nearly 1 in 4 Internet users has bought from an online pharmacy.<sup>7</sup> The vast majority of pharmacy websites do not require a valid prescription to sell a medicine; others issue an on-the-spot "prescription" after a visitor completes an online questionnaire. This setting provides the perfect haven for counterfeiters to sell counterfeit and illegal medicines. Lilly is deeply engaged in efforts to close off such illegitimate channels on the Internet.

Lilly is a founder and board member of the Alliance for Safe Online Pharmacies (ASOP), a broad coalition of stakeholders with an interest in protecting patient safety and ensuring patients have access to safe and legitimate

online pharmacies. In Europe, we are an active partner in the European Alliance for Access to Safe Medicines and ASOP EU to further educate patients about the dangers of counterfeit medicines and encourage Internet stakeholders to take voluntary action to tackle the problem of illegal online pharmacies.

Lilly is also working collaboratively with European stakeholders (pharmacists, wholesalers, and parallel distributors) on implementation of the EU Falsified Medicines Directive. The Directive is designed to safeguard public health by regulating pharmaceutical supply chains and monitoring activity to help prevent counterfeit medicines from being dispensed to patients through legitimate EU supply chain channels. In addition, Lilly supports prosecutors and other law enforcement personnel in the criminal prosecution of counterfeiters around the world by gathering evidence, testing samples, testifying in court, and filing civil actions. Lilly also participates in the World Customs Organization's Interface Public-Members (IPM) database, a secure online tool serving as an interface between front-line customs officers and the private sector. IPM is used by customs agents globally to help identify counterfeit products that cross national borders.

<sup>6</sup> National Association of Boards of Pharmacy. Internet Drug Outlet Identification Program Progress Report for State and Federal Regulators. [www.nabp.net/programs/consumer-protection/buying-medicine-online/not-recommended-sites](http://www.nabp.net/programs/consumer-protection/buying-medicine-online/not-recommended-sites). Last accessed December 10, 2014.

<sup>7</sup> US Food and Drug Administration. FDA campaign aims to protect consumers from the risks of fake online pharmacies: survey data shows lack of confidence in purchasing drugs over the Internet. Press release. September 28, 2012. [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm321470.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm321470.htm). Last accessed January 5, 2015.

## PARTNERING WITH GLOBAL STAKEHOLDERS

In March 2013, Lilly was proud to join with INTERPOL and 28 of the world's leading pharmaceutical companies to launch a landmark agreement to combat counterfeit medicines. The three-year initiative is funded by a combined investment of nearly \$5.9 million from the companies involved and is designed to forge strong partnerships between law enforcement and industry to enhance the global response to pharmaceutical crime. The program targets multiple issues, including combating branded and generic drug counterfeiting, as well as identifying and dismantling organized crime networks linked to this illegal activity. Lilly was a leader in the formation of this important public-private partnership.

Lilly also endorses the Fight the Fakes campaign ([www.fightthefakes.org](http://www.fightthefakes.org)), which aims to raise awareness about the dangers of fake medicines. The campaign gives a voice to those who have been impacted personally by counterfeit drugs and shares the stories of those working to put a stop to this threat to public health. It seeks to build a global movement of organizations and individuals who will shine light on the negative impact that fake medicines have on people around the globe and to reduce the negative consequences on individuals worldwide. The website also serves as a resource for organizations and individuals who are looking to support this effort by outlining opportunities for action and sharing what others are doing to fight fake medicines.

“An important collaboration to build trust in our medicines is the “Fight the Fakes” campaign, an innovative partnership between the International Federation of Pharmaceutical Manufacturers & Associations and other partners representing physicians, nurses, pharmacists, patient organizations, international financial organizations, leading foundations, and the private sector—all working to raise awareness of the dangers of counterfeit medicines.”

— John C. Lechleiter, Ph.D., Lilly Chairman, President, and Chief Executive Officer

## Animal Care and Use

Animal studies are a critical component in the discovery and development of innovative medicines for both humans and animals. In biomedical research, animals have significantly contributed to the development of lifesaving treatments in the areas of cancer, diabetes, vaccines, high blood pressure, and neurological disorders, to name just a few. We believe we have a moral, ethical, and scientific responsibility to ensure the welfare of animals used in research, and we have strong principles and policies in place to ensure that animal research at Lilly is conducted in line with our values.

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### WHY DO WE CONDUCT STUDIES ON ANIMALS?

Regulations that govern the approval of new medicines for human and animal use dictate that all potential treatments be evaluated in animals prior to testing in humans. The reason for this lies in biochemistry. Human and animal physiology is so complex that current non-animal research models simply cannot tell us all we need to know about how a potential new treatment will function in a living organism. Therefore, without some animal experiments to understand the safety and efficacy of potential medicines, it would not be possible to bring these new medicines to the people and animals that need them.

More than 96 percent of the animals used in pharmaceutical research for Lilly—including at third-party facilities—are rats and mice. We have established company guidelines for the use of non-human primates. Lilly has not used chimpanzees in research since the late 1980s, and careful consideration to alternative approaches is given prior to initiating studies using other non-human primate species.

### LILLY'S APPROACH TO ANIMAL TESTING

Lilly embraces the industry standard for the ethical treatment of animals known as the 3Rs. This approach prioritizes strategies for the *reduction*, *refinement*, and *replacement* of animal use within biomedical studies conducted on behalf of Lilly.

We continually work to integrate the 3Rs into the processes and practices used by Lilly and third parties on our behalf. Since we established a formal 3Rs initiative in 2012, we have seen advances in several areas. For instance, during the drug discovery phase, we test chemical or biological entities that have the potential to become future medications to see if they have the desired therapeutic activity and corresponding safety profile. Using 3Rs principles, Lilly scientists have been able to *reduce* or *replace* live animal tests by using cell-based (e.g., primary tissue cultures) to screen compounds that can be used for potential future medications.

We are also working to improve the predictive value of computer models to *reduce* the number of animals needed. For instance, in neuroscience, we can use

PET-like methodologies (similar to clinical PET-imaging technology for people) with rodents during the discovery process to determine if the target in the brain is being engaged. If there is no effect, we know that it is unnecessary to test that chemical or biological entity further.

We also believe it's important to engage with others to advance our own understanding of, and to promote the ethical treatment of, animals in quality research. Nationally, we participate in the 3Rs Leadership Group at the Innovation and Quality Consortium. We also participate in or collaborate with the American Association of Laboratory Animal Science, the American Society of Laboratory Animal Practitioners, the American College of Laboratory Animal Medicine, and the American Veterinary Medical Association, among others. Internationally, Lilly has associations and supporting roles with several organizations, including the European Federation of Pharmaceutical Industries and Associates, the Federation of European Laboratory Animal Science Associations, and the National Center for 3Rs, among others.

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### THE 3RS AWARD

We work to increase employee understanding of and encourage adoption of the 3Rs across the company through communication of strategies for reduction, refinement, and replacement of animal use within the company; awareness training; and information sharing. Each year, we also honor individuals and teams who demonstrate incorporation of one or more of the 3Rs principles into an ongoing research project in a significant way.

In 2014, an oncology team received the 3Rs award for their innovative work in reducing and replacing animal use in cancer therapy research. The team collaborated with local hospitals to receive skin surgically removed from patients (who gave consent for use of their tissue for biomedical research) undergoing mastectomy or skin tucks following significant weight loss. By testing compounds directly on human skin tissue during the drug development process, the need to test compounds in live mice is dramatically reduced.

Lilly sites that conduct animal research are guided by an Institution Animal Care and Use Committee—an ethical oversight committee—which approves and oversees animal research activities and care programs and ensures that people conducting tests with animals are appropriately qualified. Committee members undergo intense training, and the committees include volunteers who are not affiliated with Lilly to represent the public. Committees meet monthly to review animal use protocols and regularly to conduct program or facility reviews.

### **Lilly Animal Care and Use Policies and Principles**

All personnel conducting studies for Lilly must adhere to the following principles, which provide the foundation for our care and use of animals:

**Living conditions** for research animals must be appropriate for their species and contribute to their health and well-being.

**Personnel** who care for animals or who conduct animal studies must be appropriately qualified for the proper care and use of animals in research.

**Studies** involving animals must be designed and conducted in accordance with applicable country and local regulatory guidance and the following widely recognized principles of animal care and use:

- with due consideration of the study relevance to human or animal health and the advancement of scientific knowledge,
- selecting only animals appropriate for that study,

- using the minimum number of animals required to obtain valid results,
- using alternative methods instead of live animals where appropriate, and
- avoiding or minimizing discomfort and distress to the animals.

In addition, personnel must comply with our Global Policy on Care and Use of Research Animals, which covers compliance, design and conduct of animal studies, care of animals, training of personnel, reporting concerns, and contracts with animal suppliers and research service providers. Personnel must also follow other related animal research policies that apply to their particular area of expertise.

Our policies and standards are based upon the [U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#).

### **Accreditations and Inspections**

All Lilly-owned animal testing facilities are accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC). The AAALAC provides independent review and confirmation of appropriate animal care and use. Lilly also uses the services of third-party facilities located at various sites around the world. These third parties include contract research organizations or third-party operations that conduct research on behalf of Lilly, supply animals to Lilly, or supply feedstuffs to animals at Lilly.

All animal facilities are subject to external review and inspection. In the United States, our facilities are subject to unannounced site inspections by the United States Department of Agriculture. In Europe, local and national authorities regularly inspect animal facilities. In addition, we self-inspect regularly, including semiannual program review and facility reviews. In situations where we have recently acquired another company, we work closely with that group to ensure that animal welfare standards align with our policy and principles. We also maintain a global oversight program of all animal research and supply companies that we do business with, including visits by trained specialists to conduct welfare examinations.

Lilly requires all employees and all third parties involved in our research to adhere to all applicable country and local laws, regulations, and standards regarding the care and use of animals. Moreover, we require Lilly researchers and contractors to adhere to the Lilly Animal Care and Use Principles, even if these principles are more stringent than applicable local laws. Lilly also encourages animal research and animal supply companies globally to obtain and maintain accreditation from the AAALAC.

More information about our commitment and activities in this area is available on our [Animal Research website](#).

## Workplace

At Lilly, we work to improve the world around us. Our values—integrity, excellence, and respect for people—guide our efforts as we discover, develop, and deliver life-changing medicines and enhance the understanding and management of diseases.

Respect for people has been central to the Lilly culture since our start nearly 140 years ago. Colonel Eli Lilly, our founder, charged his son to “Take what you find here and make it better and better.” His words continue to hold true today. Whether this takes the form of discovering new medicines, finding new ways to support people and patients, or aiding our communities, we strive to improve the lives of the patients we serve.

### EMPLOYEES\*

**10,700**

Indianapolis

**21,918**

Outside United States

**1,055**

Indiana (excluding Indianapolis)

**39,136**

Worldwide Total

**5,463**

United States (excluding Indiana)

**8,042**

Employees engaged in Lilly R&D activities

\*As of Dec. 31, 2014.

## WORKFORCE SUPPORT AND DEVELOPMENT

We invest in competitive compensation and benefit programs, training and development, and opportunities for our employees to serve in their communities and the world at large. We believe in offering benefits that are designed to promote individual well-being while contributing to the health of our organization as a whole.

Lilly compensation and benefits programs are designed to recognize and reward employees for their hard work and contributions. Flexible work arrangements and generous time-off programs strive to balance the multiple dimensions of personal well-being, including physical, financial, and social health. We want Lilly to be a place where our employees enjoy meaningful work, build successful careers, and make important contributions to society.

Lilly employees participate in required training each year to ensure they maintain the technical qualifications expected to perform their work so our company can remain viable in an increasingly competitive environment. In addition, employees have access to a robust suite of learning and development programs that can increase performance and assist individuals in achieving their career aspirations.

In 2014, we implemented a new performance management process focused on helping our employees learn, develop, and achieve their goals. The simplified approach promotes ongoing, quality conversations between employees and supervisors, and encourages employees to prioritize and focus their efforts to align with our goals for the business overall. As part of this process, we invested in education for all employees with

emphasis on our supervisors and further developing their coaching skills so they, in turn, can better support employees’ progress.

At the most fundamental level, the new process is designed to help people doing good work get even better. It’s important to note that the new performance management process was introduced at a time when our company had been working to overcome significant obstacles and create sustainable growth. We continue to be faced with a demanding healthcare environment, an uncertain global economy, and the ongoing challenges of patent expirations. In order to seize the opportunities ahead, we all must perform at our best.

That is why we announced plans in September 2014 to streamline our business, lower our operating expenses, and more tightly focus our innovation strategy. We made the tough decision to reduce the layers of management in our company to facilitate faster decision-making and reduce bureaucracy. As a result, we saw reductions in the number of management positions, from vice president to first-line supervisor. While most of the impact was felt in 2014, work continued in many areas in the first quarter of 2015. In addition, we had reductions in staff across many parts of the company as a result of rigorous prioritization of work. While difficult, these changes were necessary to enable us to advance our pipeline.

We also announced plans to close facilities in Puerto Rico and Egypt, impacting 100 and 130 employees, respectively. In Puerto Rico, the employees will be offered positions at other Lilly plants on the island. In Egypt, we discontinued operations at our Cairo

site as part of our efforts to align global capacity and capabilities with long-term business needs. We expect to transfer ownership of that facility to Medical Union Pharmaceuticals, a subsidiary of Arab Company for Drug Industries & Medical Appliances, in 2015.

## EMPLOYEE ENGAGEMENT

Effective employee collaboration is critical to Lilly's success, and we work to engage our employees by fostering and promoting teamwork. We know that Millennials in particular embrace employers who devote significant time, dollars, and resources on corporate responsibility programs and volunteerism. These are important areas for effective employee engagement. Even in a difficult business environment, we believe employees should have opportunities to connect with Lilly's corporate responsibility vision and mission.

Connecting Hearts Abroad is a great example. Since the launch of this program in 2011, more than 600 Lilly employees have served as Connecting Hearts Abroad ambassadors, volunteering for two weeks of paid leave in some of the world's most impoverished communities. The Lilly volunteers are providing hands-on support in four categories: health care, caregiving for children and the elderly, teaching, and community development. Our colleagues who participate in the signature program return home as better employees and stronger leaders. Many of the participants describe their experiences as "life changing." (See the [Strengthening Communities](#) section on [page 52](#).)

Diversity must act as "the lens through which we're able to understand, test ideas, challenge assumptions, and respond to patients' needs."

– John C. Lechleiter, Ph.D., Chairman, President, and Chief Executive Officer

One area we're particularly proud of is our work supporting Science, Technology, Engineering, and Mathematics (STEM) education initiatives. As a company built on scientific discovery, we recognize the important role that early education programs in STEM play in preparing children for scientific careers. We provide funding and volunteers for a number of programs in schools in our home state of Indiana. In addition to boosting the skills of young people, our efforts are also helping to develop a future pipeline of potential talent for our own company.

For example, the Lilly Life Science Coach program assigns Lilly scientists to teachers to help them with classroom experiments, to talk about real-world science, and to serve as role models for students. (See the [Strengthening Communities](#) section on [page 52](#) of this report for more on our volunteer efforts, including our Global Day of Service and additional examples of our STEM work.)

## DIVERSITY AND INCLUSION

To succeed as a company in the 21st century, we believe it is imperative to include and value diversity and inclusion in every aspect of our operations. An inclusive culture helps to derive the scientific, clinical, and customer insights that fuel innovation.

An important measure of our efforts to foster diversity and inclusion is our ability to attract and retain exceptional employees who feel comfortable being themselves at work. Our record as a diverse employer is consistently recognized by independent organizations. For example, in 2014, for the fourth consecutive year, we were named one of *DiversityInc's* Top 50 Companies for Diversity. (See a more complete list on [page 81](#).) As a company whose culture is built on improving the lives of others, being recognized for our commitment to diversity and inclusion is an honor we value highly.

We executed many important steps in 2014 to increase the diversity of our global workforce, as well as to create a more inclusive culture that embraces and values diverse ideas and perspectives. It's important to note these efforts have occurred during a period of patent expirations and financial constraints that have impacted our workforce. We have a strong talent management process in every business unit to develop and promote diverse talent. Beginning in 2015, we will be adding a metric to our corporate objectives to measure our progress in the area of diversity and inclusion. When staffing management roles, supervisors must have a diverse pool of candidates. Leaders also must expect a diverse slate of candidates for external hires.

## Employee Resource Groups (ERGs)

Employee resource groups are more vital than ever to our company's success. About 12,500 of our employees—nearly one-third of our overall workforce—are members of these nine groups in more than 60 chapters, which are located at Lilly offices around the world. Our ERGs offer strong support networks for their members and help our company develop talented individuals for future leadership roles at Lilly. In recent years, they have been expanding their grassroots activities into areas that have more direct ties to Lilly's business impact.

Put simply: ERGs support a richer, more inclusive workplace culture while partnering with the business to better serve our diverse marketplace. They provide valuable insight as we develop programs and relationships that help us improve lives.

For example, the Africa Middle East & Central Asia Network ERG consulted on an educational tool to help Muslims with diabetes during Ramadan. Both the Lilly India Network and the Chinese Culture Network offer regular cultural awareness training classes for U.S. Lilly employees who are preparing for work assignments to India and China or working closely with colleagues there. And, in July 2014, the field chapter of the Organization of Latinos at Lilly (OLA) held its first summit at Lilly headquarters in Indianapolis. Approximately 135 attendees, representing all business units, participated in workshops that focused on addressing the healthcare needs of the Latino community. OLA also has mobilized its representatives in the field for outreach to healthcare providers with large numbers of Latino patients.

In addition, ERGs participate in recruiting events with our human resources department to help find interns and new employees from colleges, universities, and career fairs. They frequently consult on marketing and workplace programs and help to serve as language translators during company meetings. They also assist with corporate executive training programs on topics such as cultural bias and inclusion.

### EMPLOYEE RESOURCE GROUPS: IMPACTING THE BUSINESS\*

Employee resource groups are critical in driving our diversity and inclusion strategy across our company.

The bottom line:

9

Employee  
Resource Groups

12.5K

Members

60

Satellite Groups  
Globally

12K

Internal  
Volunteer Hours

8K

External  
Volunteer Hours

\*2014 data.

## FREEDOM INDIANA

In 2013 and 2014, Lilly actively participated in a statewide alliance called Freedom Indiana, which opposed a proposed amendment to the state constitution to ban same-sex marriages and civil unions. We contributed financial resources, volunteer hours, and strategic oversight to a campaign that ultimately resulted in court decisions allowing same-sex marriage in our home headquarters state.

Being part of a diverse community, which produces a stronger, more diverse workforce, is important to Lilly. We vigorously fought against the amendment because we want our current and future employees to live in a state that is welcoming to all people.

Our efforts to ensure a diverse and inclusive environment for our employees and those we serve span the globe. We've created programs in many countries, including Saudi Arabia, Japan, Korea, and others, to help grow the ranks of female employees and female leadership (see [page 83](#) for more information). Our global locations are constantly formulating new ways to hire, train, and develop underrepresented groups in our workforce. For example, our European affiliates will be conducting the first European Diversity Summit in June 2015 to accelerate programs there, including introducing more employee resource groups (ERGs).

Yet while we are proud of our progress, we know we must do more. At a time when Lilly is poised for growth, we need all employees to feel included, empowered, and valued so they can do their best work and deliver great results for the people we serve. To accomplish this, we must intensify our efforts to become more diverse and inclusive here at home.

## GENDER DIVERSITY

In 2014, we spotlighted gender diversity, celebrating the successes of women at our company through a Women@Lilly campaign. Our recognitions range from inclusion in the 50 Leading Companies for Women in the Asia-Pacific Economic Cooperation, to a "Best of the Best" award from *Professional Woman's* magazine, to 20 consecutive years on *Working Mother* magazine's "Best Companies" list.

While times are changing, Lilly recognizes that work-life balance is a challenge for many of our female, as well as male, employees. In acknowledgment of this reality, Lilly offers programs, such as part-time employment and childcare services, that give all our working parents the flexibility they need to support their families while advancing their careers.

We are executing extensive efforts for the promotion and development of women at our corporate headquarters and at our locations around the world, including those countries where there have not been strong gains in the workplace. Some of these initiatives have been industry leading.

For example, in Japan in 2004, we introduced the first phase of a "females in leadership" diversity strategy. In the decade since, we have refined this strategy to include the establishment of a diversity council and introduction of new programs to develop female leaders. Culture change takes time, particularly in more traditional societies. Progress has been slow yet steady as Lilly Japan works to increase the number of women in leadership roles. Lilly Japan implemented a number

of new programs, including childcare support, expanded work-from-home programs, and childcare financial support, among others, to make our company more attractive for women. Since we began this initiative, Lilly Japan has made the "Best Companies to Work For" list.

## WORKPLACE AWARDS, 2014–2015

- Best Places to Work for Lesbian, Gay, Bisexual, Transgender (LGBT) Equality. Human Rights Campaign's Corporate Equality Index
- Top 50 Companies for Diversity. *DiversityInc*
- Top 10 Company for LGBT employees. *DiversityInc*
- Top Company for Working Families. *DiversityInc*
- 100 Best Companies. *Working Mother* magazine (20 consecutive years)
- Top 20 Employer Science Careers. *Science* magazine
- Best Adoption-Friendly Workplaces. Dave Thomas Foundation
- "Best of the Best," Top Pharmaceutical & Biotech Company. *Hispanic Network* magazine
- "Best of the Best," Top Disability-Friendly, Top LGBT-Friendly Company. *Black Equal Opportunity Employment Journal*
- Latino 100. *Latino* magazine
- Top 25 Global Companies for Leaders. Aon Hewitt
- 50 Leading Companies for Women, Asia-Pacific Economic Cooperation
- Top Companies for Executive Women. National Association for Female Executives

For a more comprehensive list of awards, visit [Lilly.com](http://Lilly.com).

## The Bump Group

They called themselves the “Bump Group”—nine Lilly Indianapolis-based marketing employees who all delivered babies around the same time. The women gathered weekly during their maternity leaves and continued to meet as they returned to work. Although it’s not an official employee resource group, it’s just one example of how Lilly people support each other both inside and outside the workplace.

Lilly encourages flexibility, including working remotely, something the Bump Group members especially appreciate when it comes to balancing work and family. “Lilly does an amazing job of providing the benefits and flexibility that working parents need to stay in the workplace,” says Kate Dempsey Leiser, a Bump Group member.

Tara L. Walton is a Lilly brand manager who organized the Bump Group. She says she felt lucky to find eight other women, all in marketing roles across the organization, with due dates within three months of each other.

“The goal of the Bump Group is simple: to build a support network of women at Lilly that champion each other both in and out of work,” Walton says. “I can honestly say that I am a better person, colleague, mother, wife, and friend because of the Bump Group ladies. They’ve supported and inspired me in so many ways and will continue to play a huge role in my life, even after newborn troubles are long gone.”



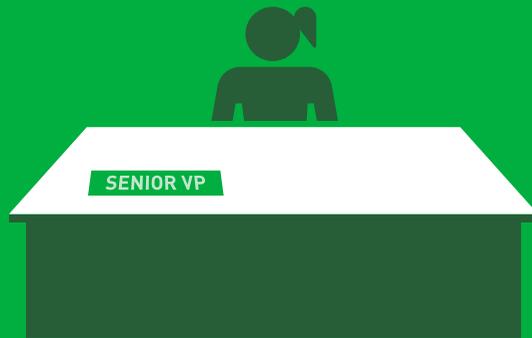
# Gender Diversity at Lilly

There are four women on the board of directors—about **29%**.

The average for Fortune 500 companies is just under **17%**.



Lilly also has four women on its executive committee—also **29%**.



■ FEMALE ■ MALE



**36%**  
of management positions are held by women.



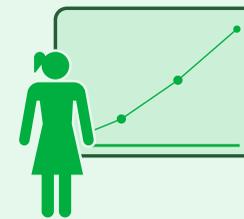
**46%**  
of the 39,000 global employees are women, 54% are men.



**47%**  
of U.S. employees are women, 53% are men.



**4,500 women** participate in the Global Women's network (WN), including networks in Asia, Canada, Central America, the European Union, South America, and the United States. WN strives to provide support, voice, and advocacy to women as employees, patients, consumers, and healthcare decision makers.

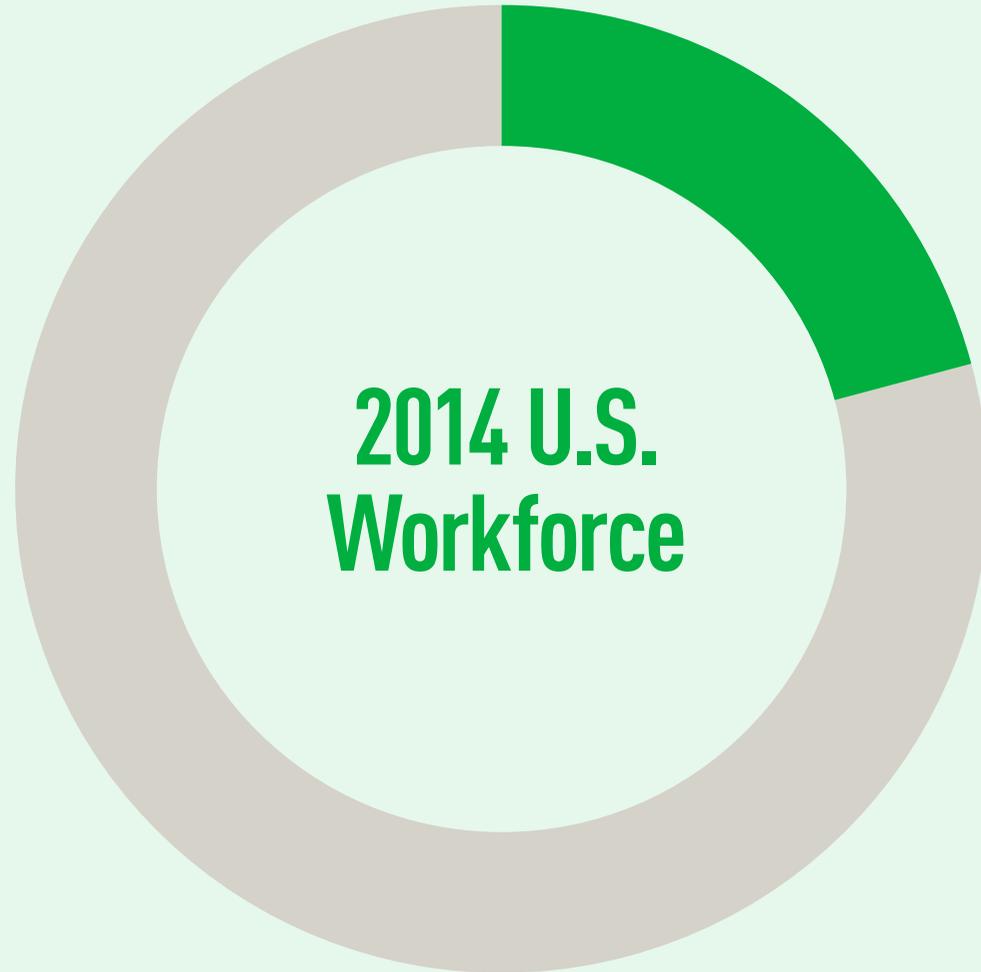


Lilly Saudi Arabia has transformed its workforce. Three years ago, it had no female employees; now it has 37—**20% of its total workforce**.



**68%** of Lilly Korea's operational committee members are women.

# Diversity at Lilly



# 21%

## Minority Employees\*



Although we are proud of the progress we have made in diversity and inclusion, we know we must work to continually improve so that each individual feels ever more valued and respected.

\*Percentage is approximate.

## HEALTH AND SAFETY AT LILLY

As a leading developer of medicines, we aim to make lives better and that includes for our own employees. Keeping our people safe at work is one of our highest priorities and aligns directly with our company values of excellence, integrity, and respect for people. Our philosophy is that no employee should be hurt while doing his or her job at Lilly.

Our employees can be exposed to a variety of on-the-job risks, including injuries from dangerous materials and equipment, exposure to chemicals, ergonomic injuries, and motor vehicle accidents for those who spend many hours a week driving.

We had established an aggressive goal in 2007 to reduce injuries, including total recordable injury rate, lost-time injury rate, and motor vehicle collision rate—each by 50 percent—by the end of 2013. We made very strong progress between 2007 and 2013: Our total recordable injury rate fell by 37 percent; our lost-time injury rate dropped by 38 percent; and our motor vehicle collision rate went down by 16 percent.

Although we fell short of the aggressive targets we had set for ourselves, we learned a lot about the complex interaction of a number of factors that influence injury rates, including improved reporting of injuries and accidents, changes to employee behavior, and conformance to procedures and regulations. During

<sup>8</sup> The *total recordable injury rate* is defined by the number of work-related injuries and illnesses that require medical treatment beyond immediate first aid per 100 employees working full-time for a year. The *lost-time injury rate*, which reflects the severity of serious injuries, equals the number of serious injuries that result in an employee missing at least one day of work per 100 employees working full-time for a year.

this time, we implemented many programs that have had a direct impact on reduced injury rates, including the following:

- A companywide initiative on injury prevention to address the most common injury types,
- hseDIRECTIONS to address motor vehicle safety, and
- A formal safety culture program.

We also learned that attaining our goals requires cooperation across all aspects of our global business.

Thus, in 2014, we developed a new suite of goals to take effect in January 2015. To set our new goals, we gathered input from a variety of internal stakeholders, including a cross-functional review from all business areas at our company. The new goals to 2020 (using a 2014 baseline) are as follows:

- A total recordable injury rate<sup>8</sup> of 0.7, or a 20 percent improvement from 2014's rate of 0.88;
- A lost-time injury rate of 0.25, a 30 percent improvement from 0.35 in 2014; and

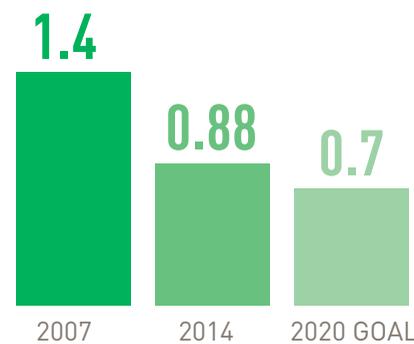
- A fleet collision rate of 12 percent, a 33 percent improvement from 18 percent in 2014.

As part of the new goal-setting process, we also changed the motor vehicle safety metric from one based on collisions per million miles to one based on percent of fleet involved in a collision. We believe the new fleet collision rate metric is easier to understand and measure across the globe.

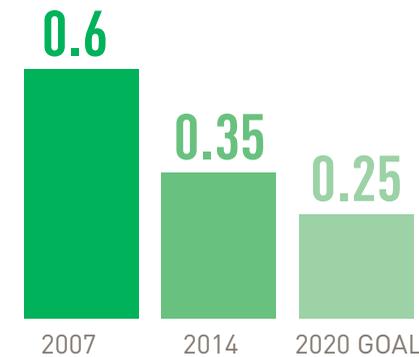
To achieve our new goals, it is imperative that we make progress in injury reduction across all areas of the company. World-class health and safety performance requires focus and excellence in three key categories: leadership, programs, and process and structure.

**Leadership.** Increasing leadership effectiveness is critical for us to drive continued improvement in our health and safety culture. Further integration of health and safety into business processes, decisions, and actions will take us to the next level of performance. Leaders at all levels of the organization will be expected to model safe behaviors while prioritizing health and safety.

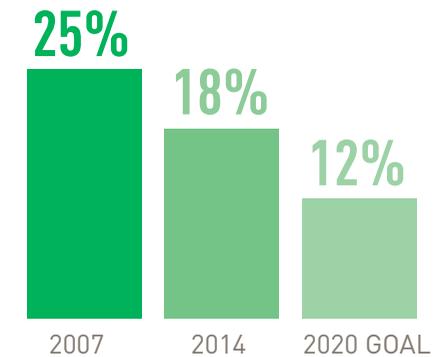
**TOTAL RECORDABLE INJURY RATE**



**LOST-TIME INJURY RATE**



**FLEET COLLISION RATE**



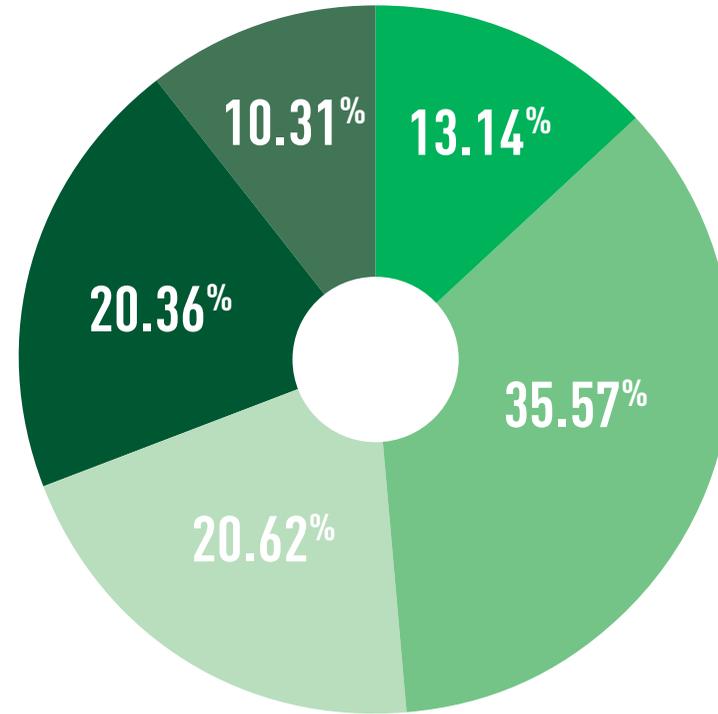
**Programs.** The Health, Safety, and Environment (HSE) department and staff members have the primary responsibility for program definition and establishment. This team works companywide to understand our future product portfolio and the programs required to reduce health and safety risks. We will continue to refine and support the implementation of our current programs to advance safety culture and prevent catastrophic events, chronic illness, and injury.

**Process and structure.** Process and structure is a shared responsibility between Lilly senior leadership and HSE. We continue to develop and mature across each of our business functions and areas, as demonstrated by the recent formation of a new HSE governance council made up of top leaders from our four biggest business areas at Lilly. Further integration of health and safety into our decision-making and governance forums will be required to increase visibility and priorities for Lilly overall.

**Motor Vehicle Safety Program**

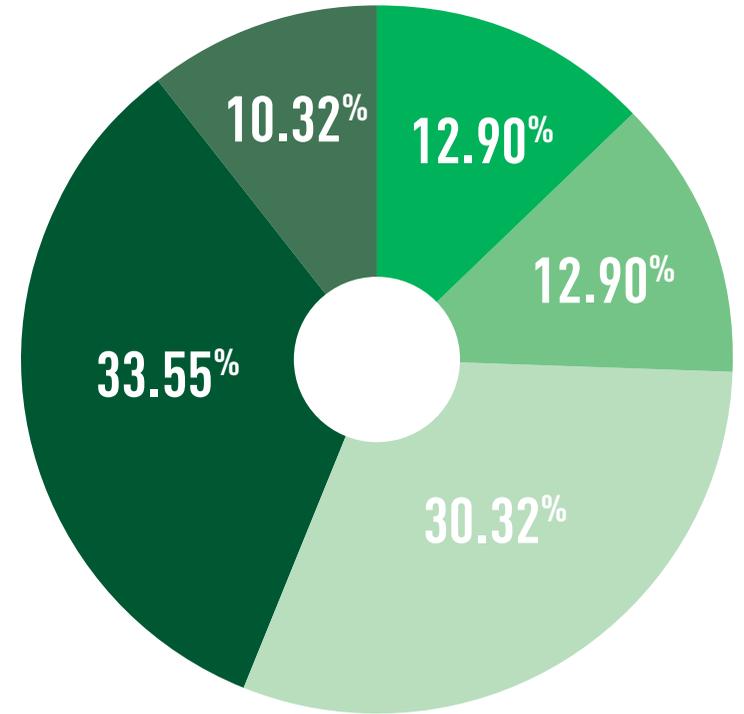
Here at Lilly, sales and marketing employees represent about 30 percent of our global workforce. Their jobs require them to spend large amounts of time driving. Motor vehicle accidents pose very real risks—risks that are often out of their control. In 2010, we launched a motor vehicle safety program, called hseDIRECTIONS, designed specifically for the thousands of Lilly employees who are on the roads every day, visiting physicians, hospitals and clinics, and other customers.

**TOTAL RECORDABLE INJURIES BY ACCIDENT CATEGORY 2014\***



- Contusion/Laceration
- Ergonomic
- Motor Vehicle Collisions
- Slip/Trip/Fall
- Other

**LOST-TIME INJURIES BY ACCIDENT CATEGORY 2014\***



- Contusion/Laceration
- Ergonomic
- Motor Vehicle Collisions
- Slip/Trip/Fall
- Other

\* Company injuries are divided into accident categories so that we can analyze, communicate, and act upon global trends consistently.

The program focuses on four key areas:

- Motor vehicle safety, collision prevention, and injury reduction;
- Ergonomic risk reduction;
- Injury prevention; and
- Improving energy conservation with eco-driving behaviors.

Over recent years, we have stepped up our programming to further reduce the rate of motor vehicle accidents. In 2013, unfortunately, two work-related motor vehicle fatalities occurred. (Two additional fatalities involved Lilly employees operating Lilly vehicles during non-work-related activities.) In 2014, there were no work-related motor vehicle fatalities.

Following an analysis of motor vehicle collisions and related injuries, we added requirements for all new fleet vehicles in the United States and Europe to be equipped with collision-avoidance technologies. We expect these technologies to result in a significant reduction in rear-end collisions—the most common type of accident leading to employee injuries.

We also focused our fleet safety program on ergonomic training, e.g., aligning the seat correctly and reducing the amount of time spent in the same position. We added new makes and models of vehicles to our fleet choices that provide greater varieties of seating options and ergonomically friendly technologies, such as hands-free trunk lifting that reduces the risk of back injuries while inserting heavy containers into vehicles.

Energy conservation is another area where we can have an impact. We encourage eco-driving behaviors and have expanded the choices of fleet vehicles with lower emissions.

### Health and Wellness

Our company's wellness and productivity team has direct responsibility for U.S. wellness strategy, work-life operations, health management and promotion, and employee activities, as well as leaves and disability. There are similar wellness teams at several of our international affiliates.

The mission of the wellness and productivity team mirrors the Lilly Promise—uniting caring with discovery to make life better, including for our own employees.

When people hear the term “wellness,” they often think about the physical aspects of health and fitness. To fulfill our promise to employees, we have a broadened view of wellness promoting the multiple dimensions that contribute to personal well-being: physical, financial, social, career, and community. Our Fit for Life program offers a set of tools and resources to help employees not only better manage their health but also to identify those things that can contribute to a healthier and more active life. Fit for Life benefit offerings include free health screenings, well-being assessments and plans, fitness trackers, health and clinical coaching, smoking cessation, and access to a network of nearly 9,000 fitness centers nationwide.

In the United States, Lilly offers health plan coverage to employees, retirees, and their eligible dependents; plan participants may obtain some Lilly-manufactured medicines at no cost. In the United States, Lilly provides coverage for preventive-care services (such as annual physicals and cancer screenings) that go well beyond the requirements established under federal healthcare reform. Outside the United States, we deliver competitive benefit packages and health coverage that vary depending upon location. In many countries, our employees receive government-provided medical benefits.

At our Indianapolis headquarters, we have several on-site fitness centers for individual and group fitness activities. We have worked with our food service vendors to provide a wider range of healthier dining choices and snacks—some of which are subsidized. We provide showers and bike racks for our more than 150 Indianapolis employees who commute to work by bicycle. We have also made our headquarters smoke-free.

Other efforts to support employee physical and emotional health include free gym memberships (both on-site and off campus), support groups for new mothers, health coaching, and a comprehensive employee-assistance program, including on-site psychologists. We also promote financial well-being through a variety of online financial tools and financial advisory programs. Many of the benefit offerings are available to spouse/domestic partner and qualified dependents as well.

## Environmental Stewardship

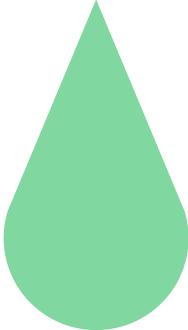
The medicines we make require the use of valuable resources, such as energy, water, and raw materials. We know that how we operate our business today can have a long-lasting impact on people and the planet. That's why Lilly takes a broad approach to understanding and managing our environmental impacts across the product life cycle. We're committed to conducting our business in a patient-centered and an environmentally, socially, and financially responsible manner.

### OUR COMMITMENT AND APPROACH

Lilly's progress toward meeting our environmental goals demonstrates the company's commitment to reduce our environmental footprint (see [page 90](#)). We believe implementing innovative, cost-effective, and more sustainable solutions creates ongoing business value. This section covers the broad range of our environmental activities, from our approach and management systems, to our work addressing environmental issues across our business, to performance data and examples illustrating progress.

#### A Life Cycle Focus

Each stage of the pharmaceutical product life cycle includes distinct environmental, health, and safety impacts and offers opportunities for improvement. The graphic on the next page provides an overview of our work to reduce the potential impacts from our operations.

210  
MILLION 

LITERS OF WATER USE REDUCED  
PER YEAR THROUGH NEW PROJECTS  
INITIATED IN 2013 AND 2014



A HEALTHIER ENVIRONMENT, A HEALTHIER WORLD [video ▶](#)

Data referenced in this video cover 2007–2013.

45% 

PERCENTAGE OF ELECTRICITY  
PROVIDED BY A NEW 9.95 MW  
PHOTOVOLTAIC (PV) SOLAR  
SYSTEM ADJACENT TO  
OUR BRANCBURG,  
NEW JERSEY, SITE

16 

NUMBER OF LILLY SITES  
GLOBALLY THAT REPORTED  
"ZERO-LANDFILL" STATUS  
IN 2014

(indicating that they send less  
than 0.5 percent of generated  
waste to landfill)

# Managing Environmental Performance across the Product Life Cycle

MATERIALS, WATER, AND ENERGY, HSE MANAGEMENT SYSTEMS AND STANDARDS



## Research and Development

We consider environmental factors from the earliest stages of design and development. We use the 12 principles of green chemistry, environmental product risk assessments, and an Environmental Development Review process to evaluate potential environmental issues and opportunities during the scale-up of human health pharmaceutical production to manufacturing levels. For more information, see [page 94](#).



## Materials and Natural Resources

Lilly, customers, and governments worldwide are increasingly focused on the materials and chemicals used to make products. We work to reduce our use of materials, water, and other natural resources when possible. For more information, see [page 90](#).



## Manufacturing

Our manufacturing health, safety, and environment (HSE) committee oversees compliance and sustainability with applicable HSE regulations, policies, procedures, and standards while making certain we continually measure, report, and reduce Lilly's environmental impacts throughout the manufacturing organization. For more information, see [page 98](#).



## Sales and Marketing

At many Lilly sales and marketing offices worldwide, we've established projects to improve environmental performance while increasing employee awareness and action. Lilly continually works to enhance the fuel efficiency of our sales force vehicles. Each affiliate periodically reviews its fleet and is encouraged to reduce associated greenhouse gas (GHG) emissions.



## Product Transport and Packaging

Lilly tracks the GHG emissions of our product transportation and distribution vendors, and we work with them to reduce those impacts while also ensuring product integrity. We consider many factors in selecting product packaging, including sustainability dimensions such as materials use and recyclability. We require packaging vendors in China, Europe, and the United States to certify that they source all paper and cardboard used to package our products from sustainable forests. For more information, see [page 96](#).



## Product Use

Lilly is committed to understanding the potential effects of pharmaceutical products in the environment. We support using science-based evaluations to assess and reduce the environmental risks of our pharmaceutical products. Through collaborations with industry partners, academic researchers, and regulatory agencies, we continually work to further understand and proactively address any potential impacts from our products. For more information, see [page 96](#).



## Product End of Life

Due to patient safety considerations and medicine regulations, typical product stewardship concepts of reuse and recycling are not applicable to our products. We are working with customers and business partners to ensure cost-effective approaches are available for product end-of-life disposal that balance environmental risk, patient privacy, legal compliance, and security. For more information, see [page 97](#).

## SCOPE OF HEALTH, SAFETY, AND ENVIRONMENT DATA IN THIS SECTION

- Data in this section cover Lilly's global operations, including wholly-owned subsidiaries, unless stated otherwise.
- Data may be revised compared to prior reports due to changes in calculation methodology and other factors.
- Following World Resources Institute guidance, energy use, greenhouse gas (GHG) emissions (except Scope 3), and water-use data are reported on an adjusted basis accounting for mergers, acquisitions, and divestitures, as appropriate, to ensure comparability, unless stated otherwise.
- Years are calendar years, unless stated otherwise.
- Bureau Veritas provided independent, third-party verification of GHG emissions data for Scopes 1, 2, and 3. In addition, Bureau Veritas verified the percentage decrease from both the baseline year (2007) and from 2013 compared to 2014 for the following metrics: energy intensity, waste to landfill, and water intake.



# Lilly's 2013 Environmental Goals

(BASELINE OF 2007 UNLESS OTHERWISE NOTED)\*

In 2008, Lilly established several performance goals to minimize our impact on the environment. We achieved our water-intake and waste-to-landfill reduction goals significantly ahead of the target date and reset our goals for these measures, demonstrating our drive for continuous improvement. We exceeded our updated waste-to-landfill reduction goal as well as our reduction of energy intensity and GHG emissions intensity goals. We fell short of our updated reduction in water-intake goal, due to increased production over this time period. We continue striving to make progress in that area. For information about progress toward our health and safety goals, see [page 85](#).



## REDUCTION IN GREENHOUSE GAS EMISSIONS INTENSITY\*\*,\*\*

**Progress through 2013**  
16% reduction



## REDUCTION IN ENERGY INTENSITY\*\*

**Progress through 2013**  
17% reduction



## REDUCTION IN WATER INTAKE\*\*\*\*

**Progress through 2013**  
35% reduction  
Goal achieved in 2009, four years early

**Updated goal (2010 baseline)**  
Reduce water intake by 5%\*\*\*\*  
Progress through 2013: 1% reduction



## REDUCTION IN WASTE TO LANDFILL\*\*\*\*,†

**Progress through 2013**  
72% reduction  
Goal achieved in 2009, four years early

**Updated goal (2010 baseline)**  
Reduce waste to landfill by 20%\*\*\*\*,†  
Progress through 2013: 44% reduction

\*Following World Resources Institute guidance, progress toward environmental goals is reported on an adjusted basis accounting for mergers, acquisitions, and divestitures, as appropriate, to ensure comparability, unless stated otherwise.

\*\*Per square foot of facility space.

\*\*\*This goal covers Lilly's Scope 1 and Scope 2 emissions.

\*\*\*\*In absolute terms.

†Lilly's waste goals do not include materials that are deemed "reused" without extensive processing. Examples include coal ash reused for mine reclamation or road base, and mycelia and urea reused for fertilizer.

# Lilly's 2020 Environmental Goals

(BASELINE OF 2012 UNLESS OTHERWISE NOTED)\*

To motivate Lilly to continually decrease our environmental impacts, we've launched a new set of goals for 2020. As in the past, we'll continue to report our progress transparently.



**REDUCTION IN GREENHOUSE GAS EMISSIONS INTENSITY\*\*,\*\***

**Progress through 2014**  
Essentially no change



**IMPROVEMENT IN ENERGY EFFICIENCY\*\***

**Progress through 2014**  
1% improvement



**REDUCTION OF PHOSPHORUS EMISSIONS IN WASTEWATER (WITH A BASELINE OF 2014)\*\*\*\***



**IMPROVEMENT IN WASTE EFFICIENCY† WHILE INCREASING RECYCLING RATE ABOVE 70% AND DECREASING WASTE TO LANDFILL BELOW 10% OF TOTAL WASTE**

**Progress through 2014**  
33% decrease in efficiency

\*Following World Resources Institute guidance, progress toward environmental goals is reported on an adjusted basis accounting for mergers, acquisitions, and divestitures, as appropriate, to ensure comparability, unless stated otherwise.

\*\*Per square foot of facility space.

\*\*\*This goal covers Lilly's Scope 1 and Scope 2 emissions.

\*\*\*\*In absolute terms.

†Per unit of production or relevant index. Lilly's waste goals do not include materials that are deemed "reused." Examples include coal ash reused for mine reclamation or road base, and mycelia and urea reused for fertilizer.

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## How We Manage Environmental Issues

### Policies and Standards

Several policies and standards define our commitments and guide our efforts:

- Our **Global Health, Safety, and Environment Policy** sets environmental expectations related to compliance and environmental protection for our people and operations.
- Our **Environmental Standard** provides more detailed requirements and establishes the core governance requirements to manage significant environmental and energy-related aspects of our operations.
- Our **Management System Standard and Verification and Corrective Action Standard** define requirements to ensure compliance with Lilly HSE standards, applicable

regulatory requirements, and other external HSE standards to which the corporation subscribes.

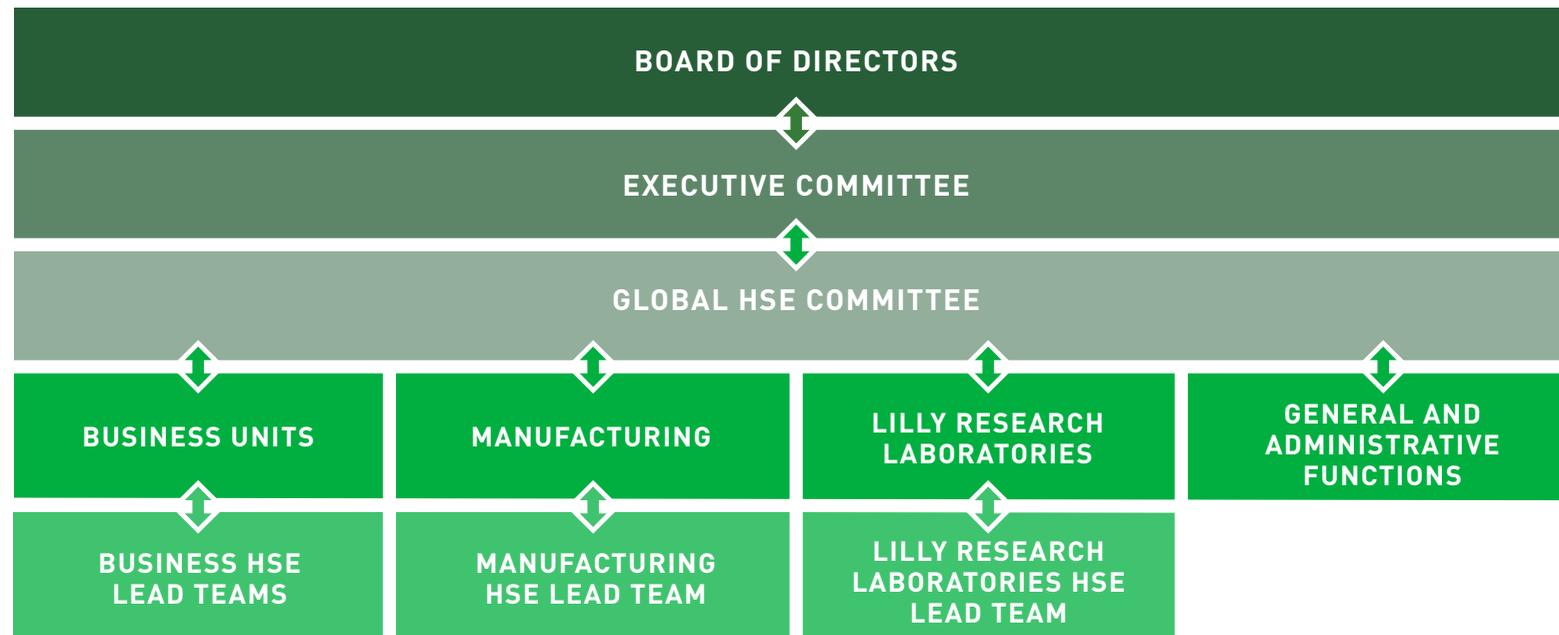
- Our **Global Engineering Standards** govern many environmental aspects of our operations, such as energy use and GHG emissions.
- Our **Product Stewardship Standard** provides a systematic way to manage product and process risks in our supply chain and our operations, and during the use of our products.

### HSE Governance

Lilly's formal HSE governance structure (see graphic) ensures that management of HSE issues is integrated companywide. Our global HSE committee—which includes senior executives from key areas of the

business—ensures proper oversight and plays a central role in monitoring corporate performance and ensuring continuous improvement. The vice president of global HSE works closely with the global HSE committee to set appropriate metrics and goals, assess company performance, and oversee compliance with all HSE regulations, policies, procedures, and standards globally. The manufacturing HSE committee supports these efforts and drives ongoing improvement throughout the manufacturing organization. Executives and lead teams in each of our business groups and manufacturing, as well as Lilly Research Laboratories and general and administrative functions, manage governance for HSE in those areas.

## LILLY HEALTH, SAFETY, AND ENVIRONMENT GOVERNANCE STRUCTURE



### LILLY'S HEALTH, SAFETY, AND ENVIRONMENT POLICY

Encourages and expects each employee to be environmentally responsible and to conduct work practices in a safe manner in accordance with established policies, standards, and procedures. These practices are considered an essential measure of performance for all employees.

Builds health, safety, and environment considerations into all phases of the business, including product and technology discovery and development, facility design, operation and maintenance, and product delivery.

Strives for an injury-free workforce and minimizes environmental impact through implementation of programs in our facilities and the surrounding communities that reduce risks to employees, neighbors, the public at large, and the environment.

Encourages and promotes waste minimization, the sustainable use of natural resources, recycling, energy efficiency, resource conservation, and resource recovery.

### Management Systems

Relevant business areas have an HSE management system aligned with our Management System Standard, which is consistent with third-party standards such as International Organization for Standardization (ISO) 14001, Occupational Health and Safety Assessment Series (OHSAS) 18001, and the American Chemistry Council's Responsible Care Management System (RCMS®). Our global HSE management system is also certified to RCMS, and almost half of our manufacturing locations are certified to either ISO 14001, OHSAS 18001, Voluntary Protection Programs, or RCMS.

### Audits

To assess performance, we audit a significant portion of our sites globally each year following the protocols outlined for each of our Global HSE Standards. We use a risk-based approach to determine which sites to audit and then reassess those sites every one to five years. Both external and internal auditors participate in each audit conducted.

### Energy, Waste, Water, and Natural Resource Use Reduction Fund

Making capital investments in technology and physical plant operations can have a substantial, positive environmental impact. However, these projects compete for funding with other essential projects at each facility. To address this challenge, we established an Energy, Waste, Water, and Natural Resource Use Reduction Fund. The Fund helps pay for capital projects at our facilities globally and promotes the development of environmentally superior, efficient technologies, and best-practice sharing across our facilities.

A total of more than \$35 million has been approved for investment in more than 135 projects since 2006. This is in addition to the amounts spent by those facilities independent of the global fund. These projects collectively save more than 850 billion BTUs of energy annually, avoiding about 106,000 metric tonnes carbon dioxide equivalent (CO<sub>2</sub>e) of GHG emissions each year and saving almost \$19 million on an annual basis. In 2014, examples included the following:

- Boiler enhancements and heating, ventilation, and air conditioning improvements in Carolina, Puerto Rico;
- Cooling tower upgrades in Kinsale, Ireland;
- Variable speed drive implementation on well pumps in Clinton, Indiana, United States;
- Boiler and heating hot water improvements in Erl Wood, United Kingdom; and
- Sub-metering implementation at several locations worldwide including in Sesto, Italy, and at the Lilly Corporate Center in Indianapolis, Indiana.

### Sustainable Culture at Lilly

Our employees play a key role in the ongoing success of our environmental efforts. Hundreds of employees, passionate about sustainability, make up dozens of "green teams" globally. With the support of HSE representatives and management, these teams work to reduce environmental impact at Lilly sites and in their communities. The green teams also engage internal and external experts to provide insight on environmental issues at work and at home. These teams implement projects such as employee carpooling programs, energy-efficiency initiatives, and beverage container and cardboard recycling. The green teams present ideas for

management approval and demonstrate projects' cost-effectiveness and environmental benefits.

Green teams engage in many activities to celebrate Earth Day each April. In 2014, more than 80 employees at one manufacturing plant site in Indianapolis, Indiana, partnered with a local environmental group to pick up debris along the White River near Lilly's recreational park. Employees at several sites also brought in a total of several metric tonnes of televisions, printers, computers, and other electronics for responsible recycling by a local organization that provides workforce training to former inmates. Globally, employees took a "No Print Challenge" for the week and reduced the number of pages printed and copied on site by more than 20 percent.

The green team at our site in Morumbi, Brazil, held its second annual Environment Week to raise employee awareness about the importance of environmental protection. Three days of activities included presentations on topics such as the 4Rs of waste management (rethink, reduce, reuse, and recycle), waste segregation, and water conservation. Employees also participated in a trivia competition covering those and other topics.

To extend the benefits of strong environmental performance beyond our operations, we also encourage employees to act as better environmental stewards outside of their work and provide them with information and resources to do so. Examples include increasing composting and recycling in their homes, upgrading to more efficient lighting at home, and using public transportation when feasible to decrease impacts from commuting.

## PRODUCT STEWARDSHIP

Lilly takes a broad approach to understanding and managing possible HSE issues across the product life cycle (see [page 89](#)). This improves our own performance and demonstrates our values, while also meeting the expectations of customers and other stakeholders who are increasingly focused on Lilly's progress in this area.

Lilly's Product Stewardship Standard defines our HSE requirements for assessing Lilly products (see box). Numerous Lilly business areas and functional groups contribute to implementing this standard across the entire value chain—from product discovery and development; through manufacturing, sales and marketing, distribution and use; to final disposal. The scope covers both internal and external value chain elements globally. This approach is intended to integrate product stewardship deeply into Lilly's business.

We focus on the following areas:

- Using green chemistry and engineering to reduce the use of energy, water, and hazardous materials in our development and manufacturing processes;
- Reviewing materials used in devices to reduce their environmental footprint;
- Developing more sustainable packaging practices;
- Using science-based environmental risk assessments to evaluate the potential impact of our products in the environment; and
- Supporting responsible product disposal at end of life.

### Design for Environment

For pharmaceuticals, the majority of product environmental impacts are determined at the development stage, during which we consider environmental factors associated with the product. We take into account the materials and processes we will use to make products and their packaging. This integrated approach enables us to identify opportunities to improve product environmental performance.

### Innovations in Green Chemistry

Traditionally, pharmaceutical manufacturers viewed the use of hazardous materials as a necessary part of making medicine. Green chemistry, by contrast, works to reduce or eliminate the use of hazardous materials, where possible, so protection, controls, and treatment are reduced or are no longer needed.

The potential benefits of finding new and better ways to make pharmaceutical products are substantial. Lilly's approach to green chemistry in our human health pharmaceuticals is twofold:

- We seek improvements by reducing the amount of hazardous material used to make a product, increasing overall materials efficiency, evaluating chemical alternatives, and avoiding use of the most hazardous substances.
- We strive to advance the underlying chemistry and engineering technologies used to make medicines through innovation, both internally and externally through partnerships.

To support these efforts, we have established guidelines for the quantity of materials needed to synthesize new products. These guidelines also restrict the

### LILLY'S PRODUCT STEWARDSHIP STANDARD

Reflecting the breadth of product-related sustainability issues, our Product Stewardship Standard covers the following areas:

- **Emerging issues:** Identifying, analyzing, and managing new and emerging issues;
- **Procurement:** Considering environmental factors in purchasing decisions;
- **Product discovery:** Reviewing internal and external research operations to foster high HSE standards;
- **Product development:** Using inherently safer design principles such as green chemistry, as well as engineering innovations, to identify and reduce HSE hazards from new production processes where possible;

- **Product packaging:** Reducing the amount of packaging and using environmentally preferable materials, when possible, while satisfying regulatory and customer requirements, meeting marketing objectives, and preserving product integrity;
- **Distribution:** Ensuring safe product transport and warehousing while reducing associated environmental impacts;
- **Marketing and sales:** Working with customers to enhance the patient experience related to product environmental performance;
- **Suppliers, contract operations, and alliances:** Evaluating and influencing the HSE performance of suppliers, contract operations, and alliances (see [page 69](#) for more information about supplier management); and
- **Supply chain management:** Establishing plans to ensure business continuity and appropriate emergency response, if needed.

use of materials that could significantly increase the environmental and safety risks of a process. These guidelines, along with other design criteria, are a part of the Process by Design methodology used to develop and assess the suitability of new processes for future manufacturing. We then evaluate success in implementing these standards and share feedback with the development teams (see Environmental Development Review on this page).

We have integrated the routine use of green chemistry principles in our human health business. Our product development objectives include the expectation to use green chemistry, along with other important criteria such as quality and cost. Development teams are accountable for process efficiency and safety from the point when they select candidate molecules through the development of a manufacturing process, and we monitor progress at major development milestones. We outsource a significant amount of development work, so we share guidelines with our partners to ensure consistent expectations between internal and external processes.

We have developed several innovative processes that improve environmental performance and enhance process safety by reducing the scale of the most hazardous manufacturing steps by more than one hundredfold. We measure progress in green chemistry at critical steps in the human health product development process with material use efficiency metrics including process mass intensity (PMI), a ratio of the total mass of raw materials (including water) used for every kilogram of drug produced.

We set PMI targets based on molecular complexity and predicted product demand, helping us to identify the highest return opportunities for waste reduction. In 2013, for example, we applied this strategy to a development project. Compared to the prior year, we reduced PMI for this project by 95 percent. As a result, during initial active pharmaceutical ingredient (API) production in 2013, we avoided nearly 450 metric tonnes of waste generation.

Another target of our green chemistry efforts was halomethylation chemistry, which generates by-products that are highly hazardous at all stages of operation. During 2013 and 2014, we developed and implemented a lower environmental impact methodology that can be used to synthesize API starting materials for two products in development.

Lilly also focuses on the use of greener and safer solvents. We have replaced several hazardous solvents with safer alternatives over the years, and, in 2014, we completed a Six Sigma project focused on several additional solvents to replace. Following this initiative, we issued new internal solvent selection and solvent replacement guides. The latter includes case studies on successful replacement of solvents to meet requirements of the European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulations. We have also made significant efforts to limit the use of dichloromethane (a hazardous air pollutant), including the development of an amino acid-based approach to produce a key pharmaceutical intermediate. This process uses environmentally benign solvents and is considered nearly carbon neutral. This new approach has decreased solvent-related GHG emissions from the process by 69 percent.

Lilly has been a leader in the American Chemical Society Green Chemistry Institute Pharmaceutical Roundtable since it co-founded the Roundtable in 2004. During 2011–2013, we co-chaired its workgroup on green chemistry and engineering and contributed to several guides published by the group.

Lilly also worked through the IQ Green Chemistry working group, sponsored by the International Consortium for Innovation and Quality in Pharmaceutical Development, to co-author the article "Seven Important Elements for an Effective Green Chemistry Program: An IQ Consortium Perspective," published in *Organic Process Research & Development* in 2013. The document includes six examples from the company that demonstrate aspects of a strong green chemistry program. It also provides a blueprint for other companies to develop green chemistry and engineering programs.

### Environmental Development Review

Lilly uses an Environmental Development Review (EDR) process in our human health pharmaceutical business to evaluate potential environmental issues and opportunities during the scale-up of medicine production to manufacturing levels. The EDR process helps us identify and address potential impacts of manufacturing and waste treatment, suggest process improvements, and share learning as new medicines come through the pipeline and transition into manufacturing.

An EDR conducted in 2013 identified significant opportunities for the recovery and reuse of solvents for the manufacture of a product in our pipeline.

Compared to incineration of these solvents, this reuse would decrease predicted GHG emissions by more than 83 percent (equivalent to 4,300 metric tonnes CO<sub>2</sub>e per year), while recovering solvent worth up to \$5 million annually. The review of production at a contract manufacturer that makes an intermediate for this same process uncovered additional solvent recovery opportunities that would decrease predicted GHG emissions from incineration by 87 percent (equivalent to 3,700 metric tonnes CO<sub>2</sub>e per year) at that facility, while saving \$3 million annually. See more information about our environmental performance in manufacturing on [page 98](#).

### Global Chemical Management

Lilly, customers, and governments worldwide are increasingly focused on the chemical substances used in products. Governments across many of the regions where we operate have developed chemical management legislation, such as the European Union (EU) REACH regulation, which requires manufacturers and importers of chemicals to collect and register information about the chemicals they manufacture or use. These regulations may also require replacing the most hazardous chemicals with safer alternatives when available.

We continue to assess the impact of these new and emerging global chemical management regulations on substances we manufacture and on our raw materials. We are committed to ensuring our facilities and supply chain remain in compliance with all relevant laws.

### Materials Use

Lilly assembles injection devices that patients use to administer some of our medicines—products that

demand the highest standards of quality, sterility, and reliability to ensure patient safety. Assuring these high standards are met consistently is our top priority. Although our environmental design and materials selection efforts extend to this area, we use only virgin raw materials in manufacturing to meet the standards for these devices and minimize the possibility of any impurities.

### Packaging

Pharmaceutical packaging is highly regulated and must fulfill many functions, including protecting product integrity during transit and storage, providing information, resisting counterfeiting, and protecting contents from tampering or access by children. Packaging is also a source of cost and waste. Through our sustainable packaging efforts, we continually review packaging technologies and practices to reduce the amount of packaging used; utilize lower environmental impact materials, such as recycled content; enhance recyclability; and reuse or recycle packaging

throughout the supply chain. We're also collaborating with our distributors, retail pharmacies, and healthcare providers to better understand the overall pharmaceutical packaging footprint and practical ways to reduce it.

Our Product Stewardship Standard also supports these efforts. It requires that in our procurement processes we consider the use of post-consumer recycled materials, products from certified sustainable forests, and materials derived from renewable resources. All of Lilly's paper stock suppliers in China, Europe, and the United States have met our requirement to certify that they source materials from sustainable forests as accredited by Forest Stewardship Council or equivalent entities.

### Pharmaceuticals in the Environment

Advanced analytical testing technologies enable scientists around the world to measure trace residues of pharmaceutical products in the environment that were previously undetectable. These trace residues are

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## IMPROVING PACKAGING AND LOGISTICS FOR CLINICAL TRIAL MATERIALS

Each year, we ship about 30,000 orders of clinical trial materials to investigators in North America and Europe. Due to quality requirements, the materials were historically packaged in single-size foam boxes, with 10 cooling gel packs, inside a heavy cardboard box. Investigators would then discard packaging after use.

In 2014, we qualified four different package sizes with superior cooling medium, vacuum-sealed panels, and corrugated plastic protective shells. The variety of sizes allows for smarter shipping and has reduced the average number of packages per order from 1.4 to less than 1.1. The lighter and smaller containers reduce shipping costs and are 100 percent reusable.

We also implemented a reverse logistics process for returns of the packaging from the investigator sites. Last year, about 96 percent of the boxes were returned to a refurbishment center, where they were inspected, cleaned, and returned to inventory.

The new solution reduces landfill waste by more than 300 metric tonnes each year and is projected to save Lilly \$1.8 million dollars over the next five years.

widespread and found mainly in streams, rivers, and other water bodies. The primary source of these residues is from humans after use; trace amounts of medicines pass through the human body without being metabolized and reach surface waters via municipal wastewater treatment systems.

Reported concentrations are extremely low—in some cases, less than one part per trillion (equivalent to about one teaspoon of sugar dissolved in more than 3,300 Olympic-sized swimming pools). Despite the very low concentrations, the presence and biological potency of pharmaceuticals raise questions about how to best evaluate associated human and environmental risks. Many of these pharmaceuticals have been available for treatment of patients for decades prior to their detection in the environment.

At the levels currently detected, risks to human health are considered very unlikely. The World Health Organization (WHO) evaluated investigations conducted in Australia, the United Kingdom, and the United States and concluded that exposure to trace quantities of pharmaceuticals in drinking water is highly unlikely to pose risks to human health. WHO has cautioned interested parties to not let concerns over pharmaceuticals in the environment divert the attention and resources of water suppliers and regulators from other water quality priorities.

Lilly applies product stewardship principles to manage potential environmental risks from the manufacture and use of medicines. This process utilizes enhanced environmental risk assessment, increased awareness of related research, and control of effluent emissions from manufacturing.

Lilly is working on a project to support collaborative research on pharmaceuticals in the environment with the Innovative Medicines Initiative (IMI), Europe's largest public-private collaboration, jointly undertaken by the EU and the European Federation of Pharmaceutical Industries and Associations. Using input from industrial and academic experts, participants in the IMI project will develop a predictive framework to identify potential risks in this area. Tools from this project could eventually be used to more effectively target environmental testing requirements at the early stages of drug development, to better assess the environmental safety of new products, and to prioritize legacy pharmaceuticals for testing and monitoring.

In 2012, we began to assess the ability of our programs to further reduce potential risks related to wastewater discharges at external partners involved in active pharmaceutical ingredient production. We continue to evaluate program effectiveness and, following these assessments, provide recommendations regarding related business process improvements.

Lilly supports industry efforts to make information about pharmaceuticals in the environment and the environmental characteristics of medicines readily available. Our scientists have published articles on these topics, presented at conferences, and participated in meetings held by the U.S. National Academies National Research Council, WHO, the U.S. Environmental Protection Agency, and European governmental sponsors. Summary results from environmental fate and effect studies are available in our [Safety Data Sheets](#) and are routinely updated.

### Product End of Life

Medicines are intended to be used in their entirety by patients. Even when this does not occur, regulatory requirements do not support the use of recovered materials in our products. As a result, typical models of consumer take-back programs designed to capture value from reused and recycled products (such as paper, beverage containers, or electronic equipment) after use do not apply to our industry. With this in mind, we continue to work with customers and partners to better understand and ensure an effective approach to product end-of-life issues.

We promote science-based policy decisions regarding the disposal of unused medicines, and we support educating patients and caregivers on how to properly dispose of unused medicines. See [Lilly's Position Statement on the Disposal of Unused Medicines in the United States](#).

We also support the proper disposal of syringes, needles, and other sharps used in home settings to mitigate potential public health and safety risks. Based on feedback from patients and healthcare providers, we believe that education offers the greatest opportunity to improve disposal practices for sharps. We are working to more effectively communicate this information to patients through product user manuals, patient education programs, improved sales force awareness, and updated information at The Lilly Answer Center.

## PERFORMANCE IN OPERATIONS

We are committed to continually improving environmental performance across Lilly’s operations. This includes what we consider our most significant areas of environmental impact—energy use, GHG emissions, water use, and waste. We are also dedicated to maintaining compliance with applicable legal standards, advancing our green procurement, reducing non-GHG air emissions, and supporting biodiversity efforts in communities where we operate. As a fundamental part of our approach, we establish, work toward, and share progress against HSE performance goals (see [page 90](#)).

### Greenhouse Gas Emissions

Climate change is compelling governments, companies, and citizens worldwide to act. We’ve responded to climate

change by setting and making progress toward aggressive targets for improved energy efficiency and reduced GHG emissions. These efforts improve our environmental performance and decrease energy use, which represents one of the most substantial operational costs for our research, manufacturing, and distribution activities (see [page 99](#)). Recognizing the connection between GHG emissions and water use, we have also conducted evaluations of water-stressed areas where we operate (see [page 103](#)).

During 2014, the company’s Scope 1 and Scope 2 GHG emissions equaled 1,540,000 metric tonnes CO<sub>2</sub>e, 4 percent less than in 2013 (see graph on [page 99](#)). Lilly’s GHG emissions intensity improved by 16 percent through 2013 compared with 2007, surpassing the company’s goal of a 15 percent improvement by that year.<sup>9</sup> The decrease

## CLIMATE CHANGE-RELATED RISKS AND OPPORTUNITIES

Lilly faces various climate change-related issues, risks, opportunities, and impacts in its global operations, which we integrate into the framework of our Corporate Responsibility and Enterprise Risk Management (ERM) strategies.

We regularly assess climate change-related regulatory risks and opportunities through our global environmental affairs team, and physical and other climate change-related risks through our ERM process. Information from these assessments informs our business strategies across multiple components within the business.

One set of risks and opportunities that Lilly focuses on relates to the production of animals used for human food consumption, due to our Elanco animal health product portfolio. Food animal production has a sizable impact on global GHG emissions, and our products and services help producers sustainably deliver more food and address hunger globally while using fewer

resources. This decreases climatic and other environmental impacts while making food safer, more affordable, and more abundant. For example, between 1977 and 2007, efficiency-enhancing technologies reduced the carbon footprint per kilogram of beef produced by 18 percent, while also decreasing related water usage by 14 percent and associated land usage by 34 percent.<sup>10</sup>

To increase awareness about these benefits, we analyze and communicate how improved animal productivity and health can help to reduce GHG emissions and the use of natural resources such as land, water, and fossil fuels. We share this information with food animal industry organizations; various non-governmental organizations; multistakeholder groups such as Global Roundtable for Sustainable Beef, U.S. Dairy Innovation Center, and National Pork Board; as well as companies operating within the sector’s retail supply chain.

## IF WE IMPROVE ENERGY EFFICIENCY AND REDUCE OUR GHG EMISSIONS

# 20% BY 2020, WE’LL:



reduce CO<sub>2</sub>e, the equivalent of planting

**20,000,000**  
trees\*



save more than

**\$160,000,000\***



avoid the use of energy equivalent to about

**78,000,000**  
gallons of gasoline\*

\*Based on information available at [www.epa.gov](http://www.epa.gov).

<sup>9</sup> This goal covers Lilly’s Scope 1 and Scope 2 emissions per square foot of facility space.

<sup>10</sup> Capper, J. July 2010. “Comparing the Environmental Impact of the U.S. Beef Industry in 1977 to 2007.” Abstract presentation at the American Society of Animal Science meetings.

in Scope 1 and Scope 2 GHG emissions between 2007 and 2013 is equivalent to the annual emissions of more than 48,000 passenger vehicles.<sup>11</sup> The company's GHG emissions intensity remained essentially flat from 2012 through 2014, not on track to meet our new goal of a 20 percent reduction by 2020.<sup>12</sup> Greenhouse gas emissions will continue to be a key area of focus given our ongoing emphasis on energy efficiency.

This year, we again reported several categories of Scope 3 GHG emissions, as included in the Environmental Performance Indicators table on [page 111](#) (and not included in the graph on this page). We are committed to continually expanding the scope and quality of our disclosure in this area. To support these efforts, we have initiated a project to gather energy and GHG data from our key suppliers to more effectively assess our Scope 3 emissions and overall carbon footprint.

In 2014, Lilly achieved a CDP (Carbon Disclosure Project) climate change disclosure score of 85, compared to the average score of 75 in the healthcare sector and our company's score of 65 in 2012. Our performance band remained B. See Lilly's recent [CDP climate change submission](#) for additional detail about the company's approach and performance in this area.

**Decreasing Environmental Impacts in Sales and Marketing**

We use a scorecard at our sales and marketing affiliates in the Americas, Canada, and Europe to identify and assess progress reducing GHG emissions, energy use, water consumption, waste, and transportation. Each year, these affiliates look for opportunities to enhance their environmental performance by identifying and implementing new projects and setting targets across more than 40 dimensions. In 2013 and 2014, 26 affiliates assessed their performance level (the levels include Beginner, Follower, Good Citizen, Leader, and Best in Class). Based on this analysis, 80 percent improved

performance through new initiatives. Six affiliates achieved the "Best in Class" level, and more than 90 percent reached at least the "Good Citizen" level.

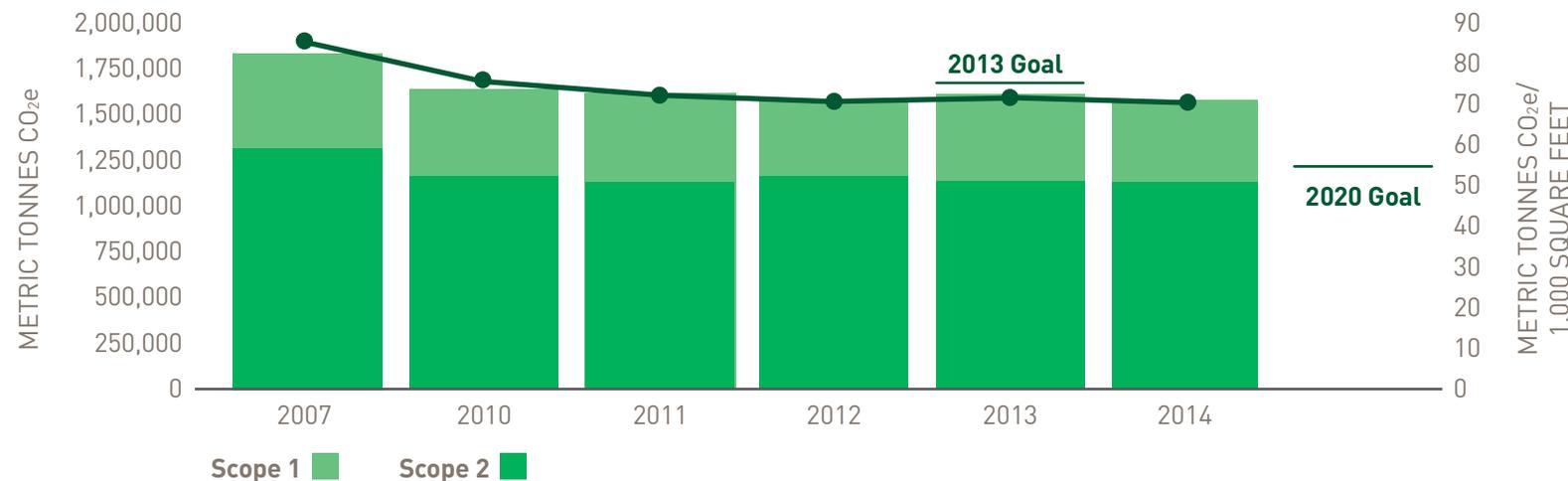
During 2015, we plan to complete the replacement of all company cars in Europe, and we will manage those vehicles across the continent instead of at the affiliate level. This will decrease costs and allow for more consistent implementation of strong safety and environmental standards. We anticipate that the new average emissions will decrease to approximately 100 grams CO<sub>2</sub>e per kilometer, 30 percent less than the rate in 2015.

**Energy Use**

Improving energy efficiency and reducing overall energy use to save money and reduce our climate impact are key priorities in our operations. Energy assessments are central to our approach. Since 2006, we have conducted 32 assessments at our most energy-intensive sites, which we have used to identify and prioritize energy conservation measures.

Additionally, Lilly has implemented several global strategic initiatives to support these efforts, such as energy sub-metering to enable monitoring and benchmarking of facilities and utility equipment, use of the Laboratory Energy Efficiency Profiler assessment tool, and retrocommissioning<sup>13</sup> of laboratory and administrative facilities.

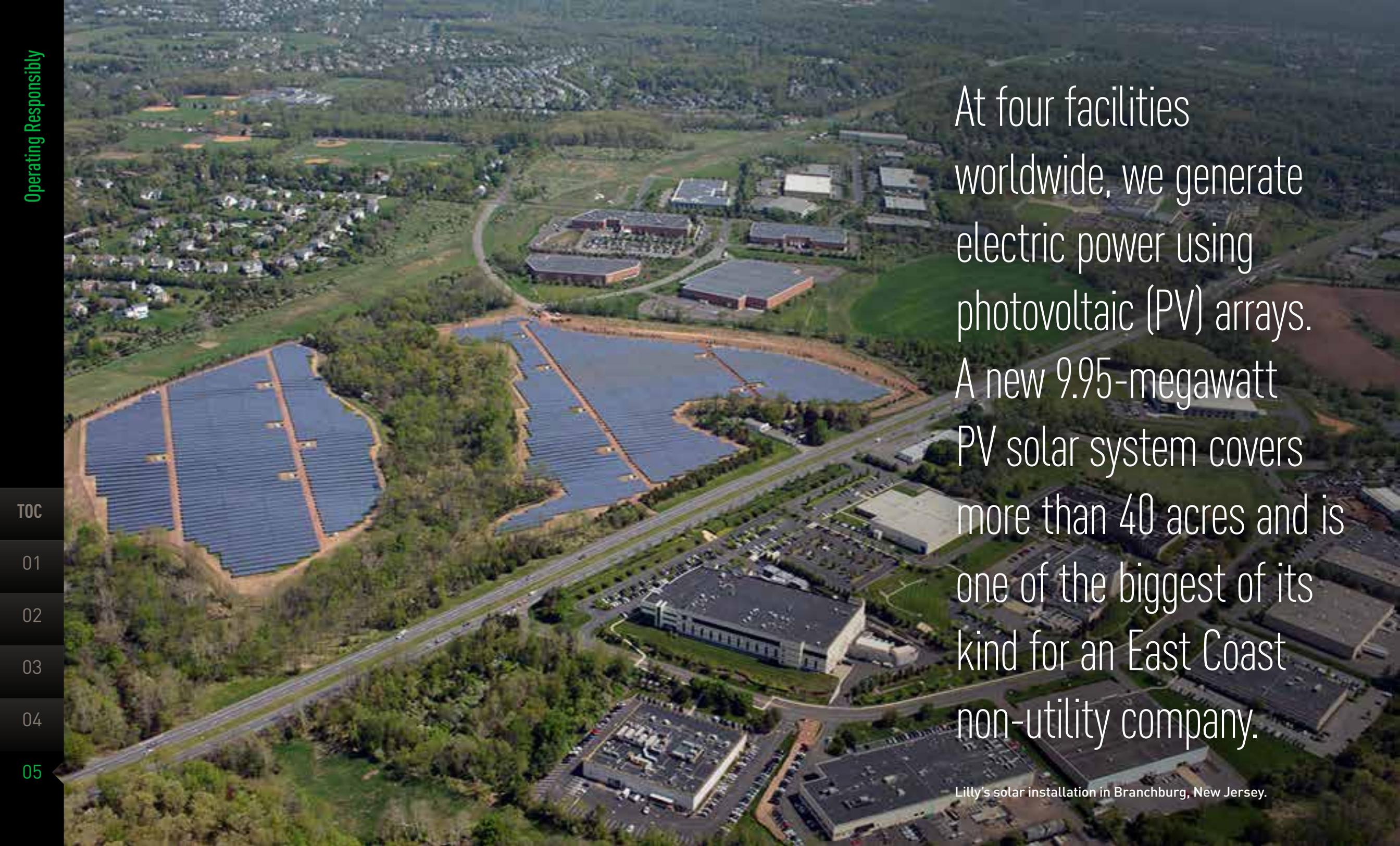
**PROGRESS TOWARD GOAL—GREENHOUSE GAS EMISSIONS**



<sup>11</sup> According to [www.epa.gov/cleanenergy/energy-resources/refs.html](http://www.epa.gov/cleanenergy/energy-resources/refs.html).

<sup>12</sup> This goal covers Lilly's Scope 1 and Scope 2 emissions per square foot of facility space.

<sup>13</sup> Retrocommissioning refers to a structured process for identifying suboptimal performance in an organization's lighting, heating, cooling, and other systems and making adjustments as needed.



At four facilities worldwide, we generate electric power using photovoltaic (PV) arrays. A new 9.95-megawatt PV solar system covers more than 40 acres and is one of the biggest of its kind for an East Coast non-utility company.

Lilly's solar installation in Branchburg, New Jersey.

We continue to use renewable energy to diversify our energy sources and decrease GHG emissions globally, using direct generation as well as direct and indirect purchases of renewable energy from local utilities. At four facilities worldwide, we generate electric power using photovoltaic (PV) arrays. A new 9.95-megawatt PV solar system, completed in 2014, adjacent to our subsidiary in Branchburg, New Jersey, covers more than 40 acres and is one of the biggest of its kind for an East Coast non-utility company. The system generates 12.6 million kilowatt hours of electrical energy per year and will provide 65 percent of the power needs of the largest facility on-site. That is roughly equal to the electricity used by 1,500 homes and will avoid 3,900 metric tonnes of CO<sub>2</sub>e emissions annually.

Cogeneration, which involves using a combustion source to generate electricity on-site while also recovering usable heat from the process, is another important part of our approach. We currently feature three sites with 10-MW, 4.3-MW, and 2.7-MW cogeneration units in operation. A fourth site is constructing an 8-MW unit.

Over the past two years, we've installed electricity sub-meters at several locations worldwide. This technology enables us to measure energy consumption at specific

locations within facilities, helping us to more effectively monitor processes and identify new energy-saving projects.

To expand benefits companywide, Lilly employees share energy-efficiency best practices through channels such as our regional networks and Engineering Technical Center. The latter is a group of experienced engineers who provide consultation on operational issues, including energy forecasting and efficiency initiatives to manage projected demand. We also conduct a yearly internal awards presentation for HSE performance (which, similar to the initiatives described earlier in this paragraph, also addresses water savings and waste reduction).

Other educational opportunities include the following:

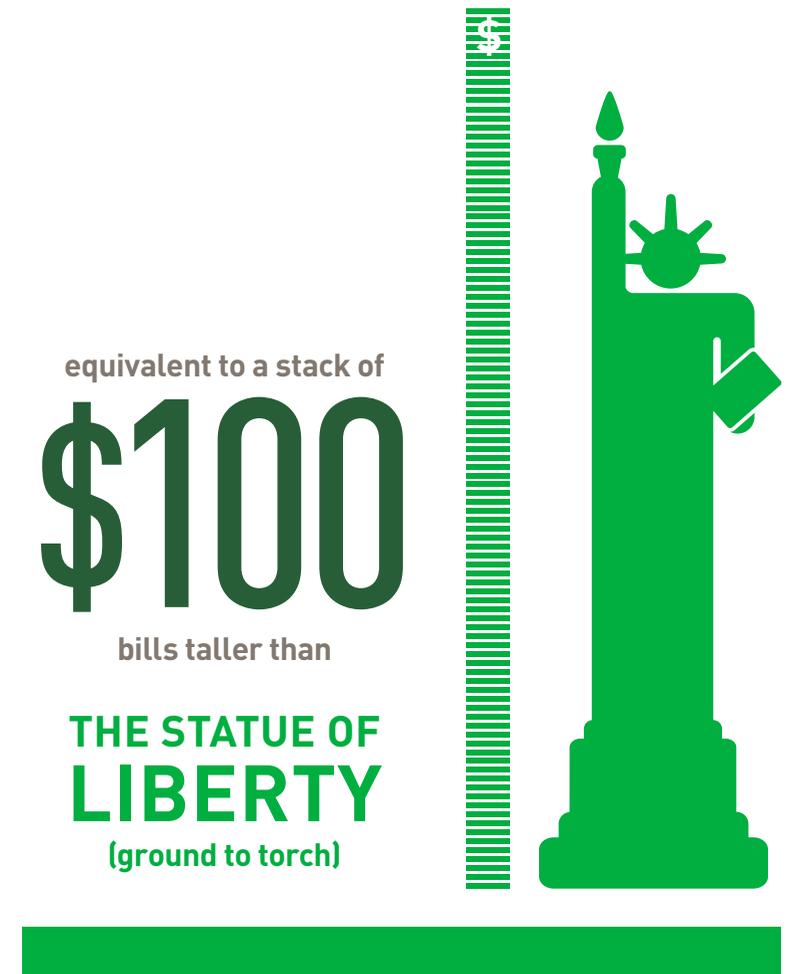
- Energy-focused webinars and collaboration sites on the Lilly intranet,
- Use of our internal social networking site to share best practices and make suggestions, and
- Global Energy Day, a widely attended annual employee event that includes poster presentations, videos, contests, guest speakers, and energy-focused informational booths to promote awareness of and progress toward Lilly's companywide energy goal.

### ENERGY PROGRAM

We are committed to using energy in an efficient, cost-effective, and environmentally responsible manner. To do so, we establish energy-efficiency goals and implement energy management practices globally. Our approach includes the following elements:

- Design for energy efficiency in new or updated processes and facilities;
- Operate our facilities and equipment efficiently;
- Monitor and report energy consumption and resulting GHG emissions;

- Conduct energy assessments and implement initiatives to enhance energy efficiency;
- Utilize alternative energy sources, new technologies, and best practices; and
- Participate in local, regional, and/or national forums to influence responsible and cost-effective decision-making and policy development relative to energy.



In 2014, Lilly's energy use totaled 10,700,000 million BTUs, 4 percent less than 2013 (see graph). Our energy intensity<sup>14</sup> improved by 17 percent from 2007 through 2013, exceeding the company's goal of a 15 percent reduction.<sup>15</sup> The company's energy efficiency improved 1 percent from 2012 through 2014, as we work to meet our new goal of a 20 percent improvement by 2020.<sup>16</sup>

**Improving Energy Efficiency in Carolina, Puerto Rico**

We improved heating and cooling efficiency by setting target temperature for laboratories, offices, and exercise rooms when they are unoccupied. In addition, we are installing motion sensors on fume hoods to decrease airflow when personnel are not detected. These changes will save more than 3 million kWh of energy yearly, decreasing GHG emissions by over 2,700 metric tonnes CO<sub>2</sub>e and saving greater than \$300,000 on an annual basis.

**Developing Energy Management Capabilities in Suzhou, China**

Our East Lake Branch Office in Suzhou, China, began commercial production of insulin in 2013. To support the launch of the facility, we established a Six Sigma team to track energy usage on a daily basis, analyze and manage consumption, assess trends, and determine savings opportunities. The team identified and implemented two heating, ventilation, and air conditioning projects to reduce energy use. Together, these initiatives have reduced energy consumption at the site by about 7 percent, reducing GHG emissions by more than 600 metric tonnes CO<sub>2</sub>e and saving nearly \$110,000 each year.

<sup>14</sup> Per square foot of facility space.  
<sup>15</sup> Following World Resources Institute guidance, progress toward environmental goals is reported on an adjusted basis accounting for mergers, acquisitions, and divestitures, as appropriate, to ensure comparability, unless stated otherwise.  
<sup>16</sup> Per square foot of facility space.

**Water Use**

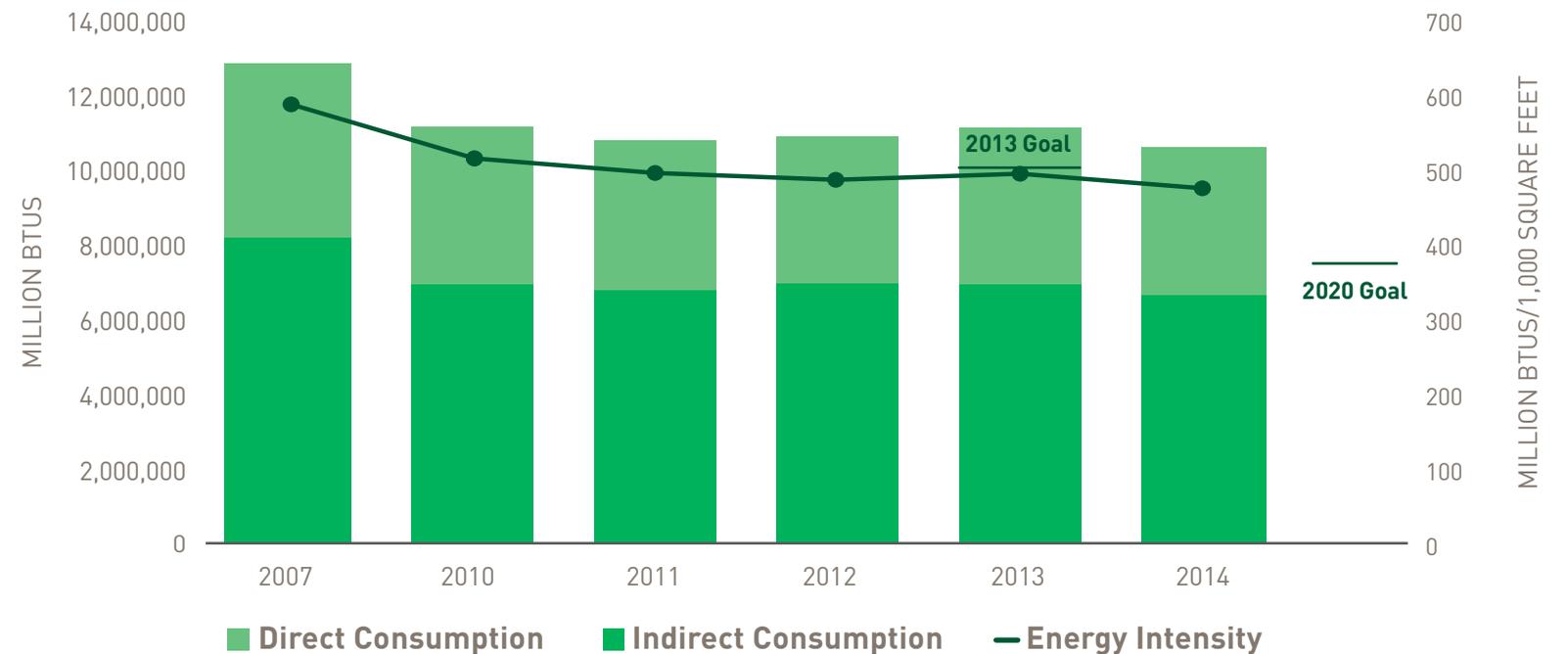
Water is a key input to our products and manufacturing processes and is essential to our business. Predicted future regional water scarcity, increased costs, and climatic changes have only strengthened our commitment to use this resource wisely.

Manufacturing operations account for the majority of the water consumed by Lilly. Our operations that produce injectable products require exceptionally high-quality water, while our utility operations use substantial amounts of water for cooling and to support steam boilers. Some sites have updated to waterless cooling systems, and others have installed technology that reclaims water for this purpose. To a lesser extent,

we consume water for domestic uses in our offices (such as cafeterias, bathrooms, and landscaping). Our Engineering Technical Center helps our sites to identify water-saving technologies, and the sites can apply for capital funding for projects through Lilly's Energy, Waste, Water, and Natural Resource Use Reduction Fund.

In 2014, we used the World Business Council for Sustainable Development's Global Water Tool<sup>®</sup> and the United Nations Environment Programme's Vital Water Graphics tool to evaluate water stress-related risks to our contract manufacturing. Using business-interruption criteria, we estimated potential financial impacts for each type of risk and assessed whether it is significant to the company.

**PROGRESS TOWARD GOAL—ENERGY USE**



We evaluated more than 100 contract manufacturing sites to determine business risks that could arise if the sites experienced extended droughts. This analysis covered a range of operations, from bulk active ingredient production sites that require the largest amounts of water to packaging sites that consume the least. Through this assessment, we determined that extended periods of drought should not significantly impact our human health business. We use inventory management practices to mitigate these types of risks, and each of our facilities creates a local business continuity plan that considers many possible sources of business interruption, including water availability.

In 2014 and 2015, Lilly worked with the University of California, Santa Barbara (UCSB), to conduct a water stress analysis of one of our major pharmaceutical products using supply chain data. UCSB provided an in-depth evaluation of contract manufacturing in water-stressed areas using the World Resources Institute (WRI) Aqueduct tool and other reporting guidelines. We may be able to use this information to better understand water risks within our supply chain, to

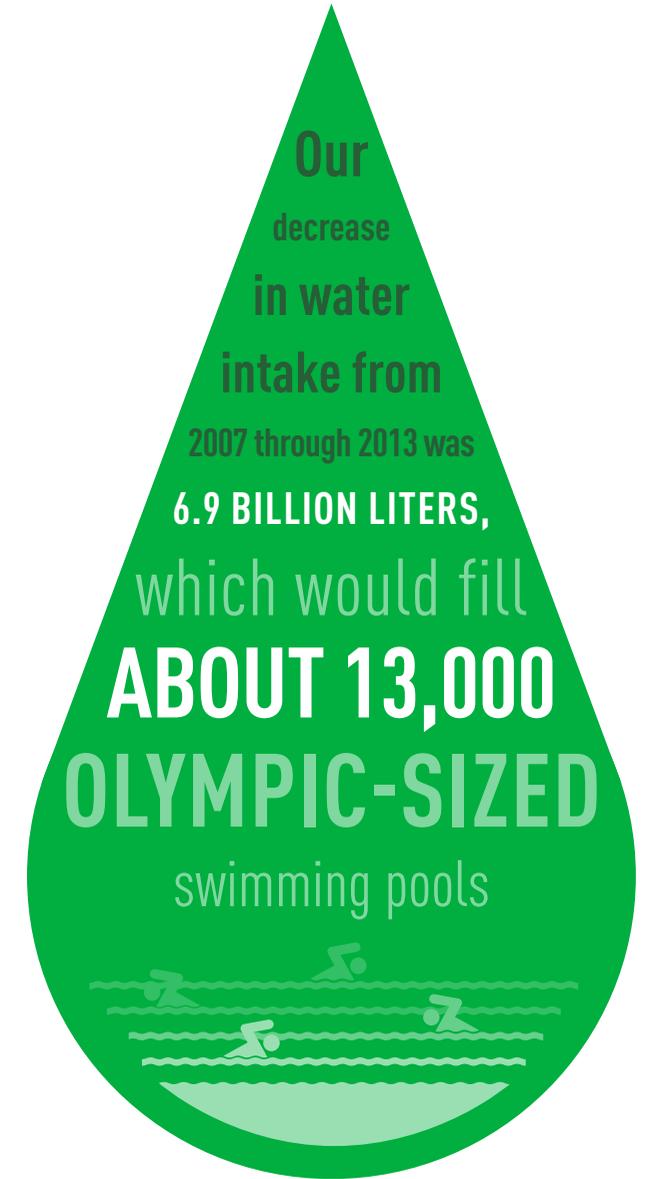
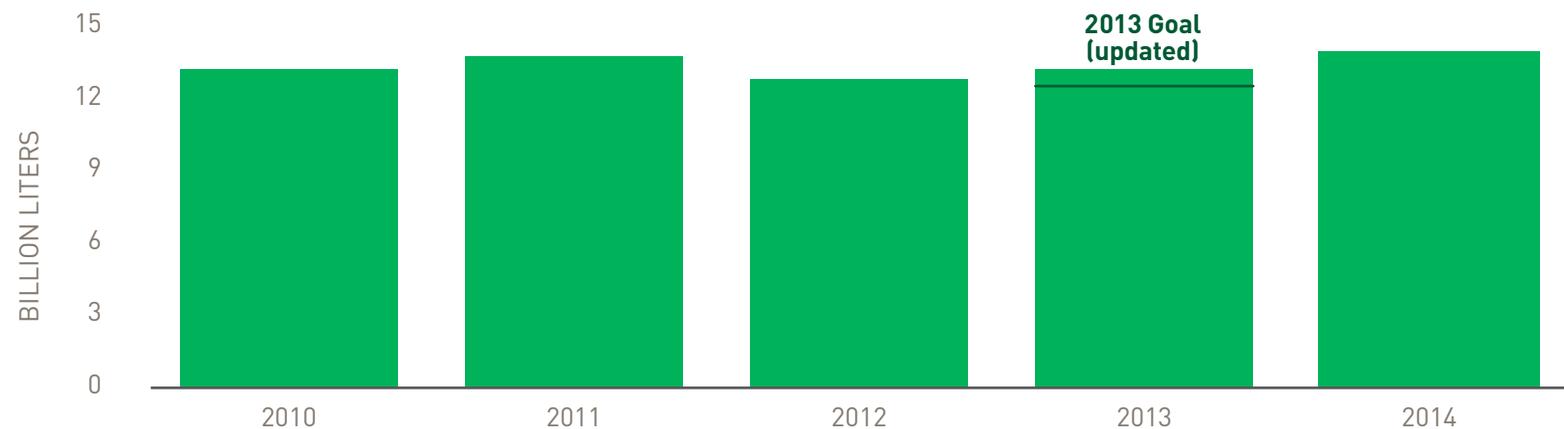
assess if the company’s current risk management practices are adequate, and to determine if additional data is needed to support sound risk management decisions. This evaluation is still under way, and we plan to report findings in future CDP water submissions and corporate responsibility reports.

[Learn more](#) in Lilly’s 2013 CDP water submission.

In 2014, Lilly’s water intake<sup>17</sup> was 13.5 billion liters, a 6 percent increase from 2013 and a 31 percent reduction since 2007 (see graph below). This slight increase in water intake was primarily due to production increases. We will continue to look for opportunities to decrease our water usage and will communicate our performance in our corporate responsibility reports, the CDP water submission, and other disclosures.

In 2013, we introduced a new water quality goal to reduce absolute phosphorus emissions in wastewater discharge by 15 percent by 2020, compared to 2014. This will address an issue that is increasingly important to communities, regulators, and investors. We believe that

**PROGRESS TOWARD GOAL—WATER INTAKE**



<sup>17</sup> “Water intake” is the total amount of water coming into a facility, including water pumped from bodies of surface water and groundwater, as well as water provided by a utility. It includes water used in processes, utilities, and other ancillary operations, such as irrigation. The term does not include groundwater pumped solely for treatment to satisfy regulatory actions or requirements (e.g., remediation activities where the water is not used for another purpose). Values do not include the water extracted from wells solely for the purpose of lowering the groundwater table(s) to maintain the physical and structural integrity of building foundations.

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significant source reduction will require phasing out and replacing cleaning agents with non-phosphorus based alternatives. Technical teams at Lilly are evaluating existing cleaning processes and will apply learnings to key sites worldwide.

#### Reusing Process Water in Carolina, Puerto Rico

At our insulin manufacturing facility in Carolina, Puerto Rico, we use a filter system to remove water from liquid process waste. This system used significant amounts of potable water to maintain filter press operations. To save resources, in 2013 we installed a system that receives reject water from the filtering process and supplies it back into the system. This reuse eliminated the need for potable water, decreasing annual use by 23,000 cubic meters compared to 2012 and saving more than \$50,000 each year.

#### Conserving Water in Sesto, Italy

In recent years, our site in Sesto, Italy, has increased its focus on conserving water, a primary input in insulin production at the facility.

The location has adopted a multipronged strategy to decrease water use:

- Using collected rainwater (instead of well water) for landscaping,
- Optimizing cleaning cycles,
- Reusing clean industrial water for cooling towers and other purposes, and
- Reusing reverse osmosis water discharges for other processes.

Since 2011, the site has improved its water-intake efficiency while increasing its production significantly. This saves money while preserving on-site water resources, which will be increasingly important due to planned production increases in the coming years.

To inform its approach moving forward, the site has also installed about 45 water meters throughout its operations to track correlations between production levels and water consumption. Lilly will use that information to determine when to modify its water systems, for example, by adding new wells or upgrading its wastewater treatment plant.

#### Decreasing Environmental Impacts in Insulin Production

In 2014, after performing a detailed environmental assessment, we launched a streamlined manufacturing process in Indianapolis, Indiana, for the active pharmaceutical ingredient in one of our insulin products. The new process aimed to increase manufacturing capacity to meet projected future demand for this lifesaving drug. These changes reduced purified water usage and aqueous process waste both by 30 percent, each decreasing by about 160 cubic meters per day. The new process, with 50 percent higher throughput than the former approach, decreases the need to build additional facility capacity and will avoid corresponding energy use and GHG emissions.

## Waste

Lilly uses the following hierarchy to manage waste:

- Eliminate or reduce the amount of waste produced,
- Reuse materials when possible (often multiple times),
- Recycle used materials to make new products,
- Recover energy from waste,
- Treat waste to reduce toxicity and volume, and
- Send waste to landfill only when the options above are not feasible.

Total waste generation decreased by about 5 percent from 2013 to 2014, primarily due to a reduction in demolition construction waste (see graph on [page 106](#)). Between 2007 and 2014, however, total waste generation decreased by 23 percent.

During 2014, Lilly sent 6,300 metric tonnes of waste to landfill, 29 percent less than in 2013 and an 80 percent reduction from 2007 (see graph on [page 106](#)).<sup>18</sup> During the year, 16 Lilly sites globally reported “zero-landfill” status (indicating that they send less than 0.5 percent of generated waste to landfill).

In 2013, we introduced a new waste goal to achieve a 20 percent improvement in waste efficiency<sup>19</sup> by 2020, compared to 2012, while increasing our recycling rate above 70 percent and decreasing waste to landfill<sup>20</sup> below 10 percent of total waste. In 2014, Lilly achieved a landfill diversion rate of 13 percent of total waste.

<sup>18</sup> These data do not include construction and demolition debris, biosolids from wastewater treatment plants, incinerator ash, coal ash if reused for mine reclamation or road base, and mycelia and urea reused for fertilizer.

<sup>20</sup> Lilly’s waste goals do not include materials that are deemed “reused” without extensive processing. Examples include coal ash reused for mine reclamation or road base, and mycelia and urea reused for fertilizer.

<sup>19</sup> Per unit of production or relevant index.

From 2012 through 2014, our waste efficiency decreased by about 33 percent. This was primarily due to a short-term operational issue at a large site. Material that was previously reused was temporarily sent for disposal due to a permitting issue. We will resolve this issue in 2015 and resume our normal reuse of this material.

**Increasing Non-Hazardous Waste Recycling in Indianapolis, Indiana**

In 2013, Lilly removed more than 10,000 trash cans and recycling bins from our Indianapolis, Indiana, offices, cubicles, and workstations, and replaced these with a greatly reduced number of centralized bins for recycling and waste. The objective was to increase our recycling rate, save money by decreasing custodial visits, and further embed waste reduction and recycling in our corporate culture. As a result, can and bottle recycling increased at these locations by nearly 50 percent, and overall non-hazardous waste decreased by 20 percent. These efforts also saved the company hundreds of thousands of dollars over the year and improved employee practices related to office waste. Watch this [video ▶](#) to learn more.



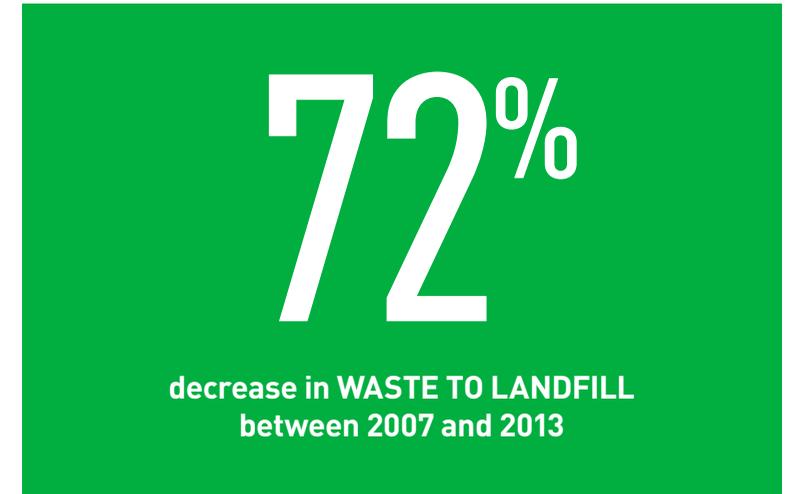
**Promoting Recycling and Vocational Training in Indianapolis, Indiana**

At our headquarters in Indianapolis, Indiana, Lilly works with Noble of Indiana to process cardboard for recycling from our research and cafeteria operations. Noble of Indiana provides small work crews of individuals with developmental disabilities, supervised by a Noble staff member, to collect and compact cardboard. In 2014, the crew sorted and processed more than 90 metric tonnes of material for recycling. The benefits are not only environmental. Noble employees also develop valuable pre-vocational job and social skills that enrich their lives and our community. Watch this [video ▶](#) to learn more.

**Reducing Waste to Landfill in Speke, United Kingdom**

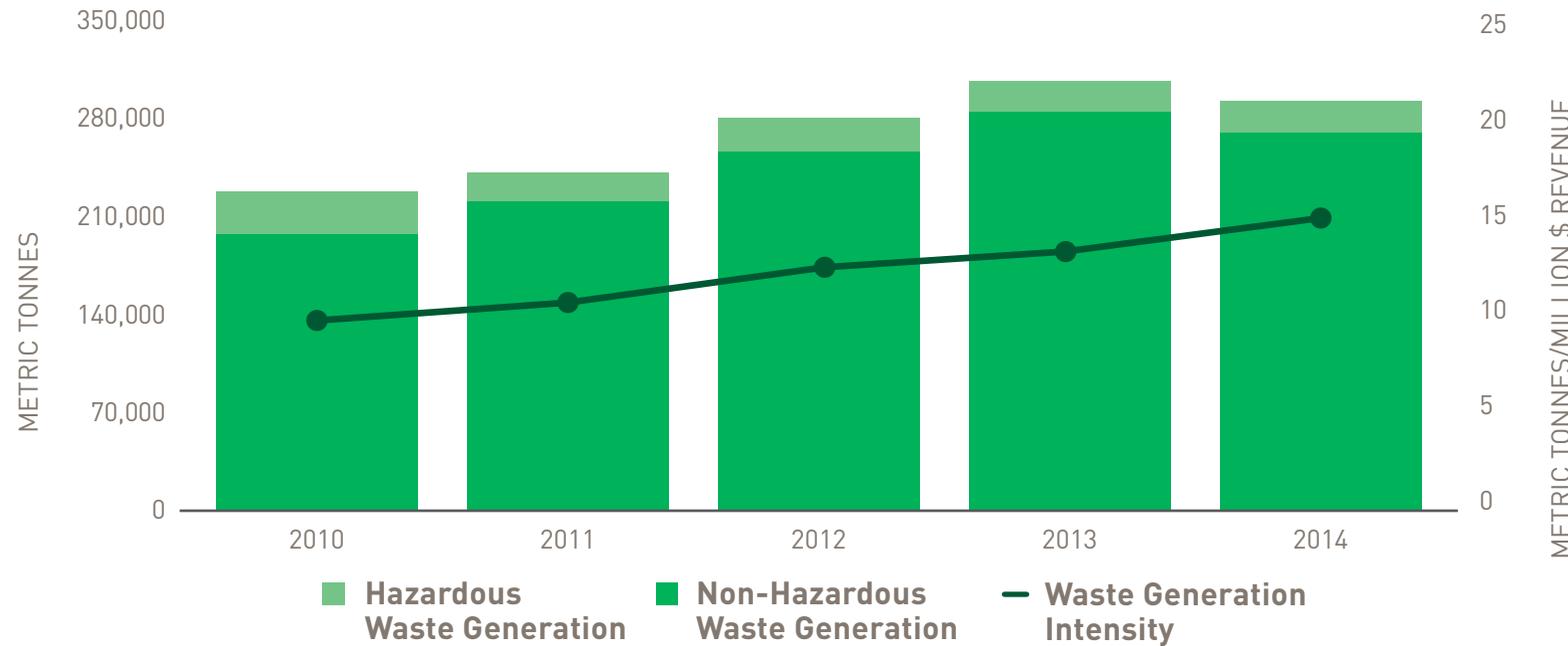
Our site is Speke, United Kingdom, which produces an animal health antibiotic, is one of Lilly's largest contributors of waste to landfill. In 2012, the site sent 77 percent of the production waste it generated to landfill, more than 99 percent of which was mycelia (the leftover cell mass as a result of fermentation). This facility will play a key role in helping the company meet its goal to reduce overall waste to landfill to less than 10 percent of total waste by 2020.

Energy recovery is not a viable option with mycelia, due to handling issues related to its chemical properties. To assess the possibility of composting mycelia waste (an option that had been rejected previously by the local environmental agency), the company worked with an external consultant to conduct a detailed environmental assessment. This analysis demonstrated that the material was acceptable for composting and offered some agricultural benefits, due to the presence of carbon, organic nitrogen, phosphorus, and potassium.



\*This assumes each garbage truck has a capacity of about 10 metric tonnes.

## WASTE GENERATION



After identifying an appropriate site to process the material, Lilly conducted several months of successful tests to confirm the new approach. In 2014, compared to 2012, the site reduced its mycelia waste to landfill from 100 percent to less than 10 percent and its total production waste to landfill from 77 percent to 7 percent.

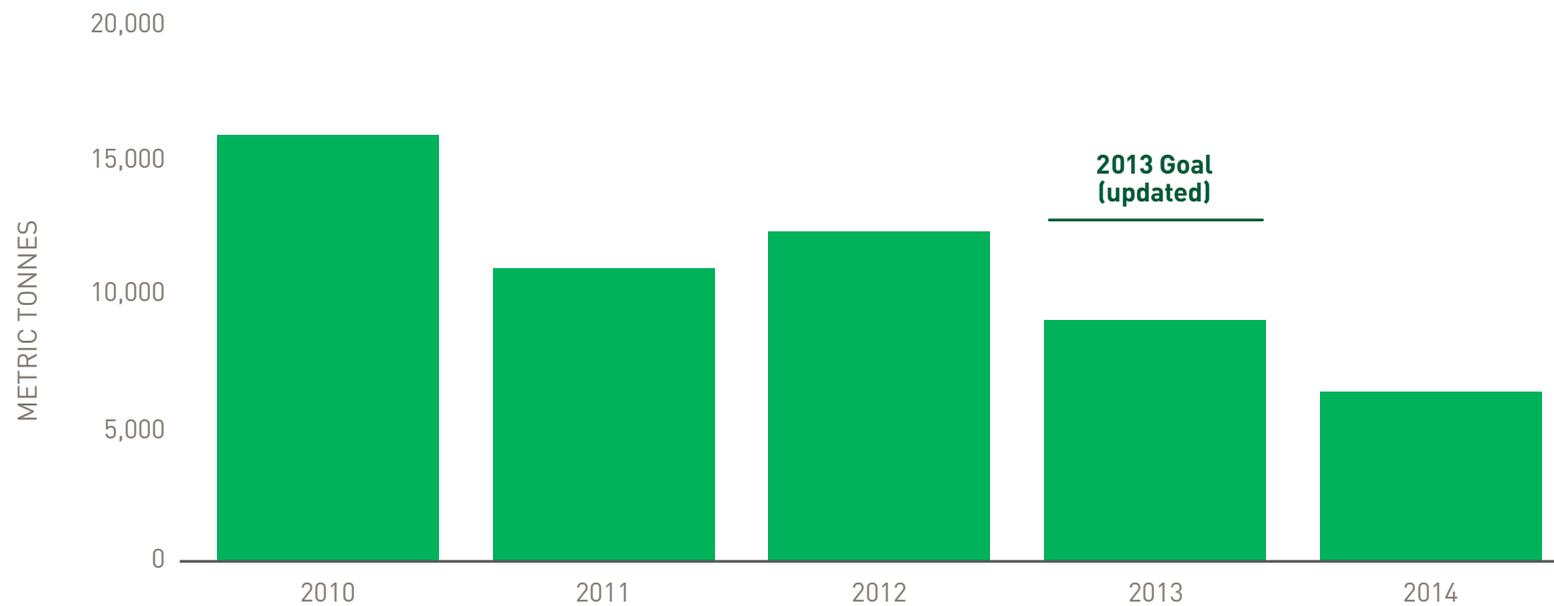
### Green Procurement

Lilly continues to expand its green procurement efforts to decrease the company's environmental impacts and support markets for green products. Office supplies remain an area of focus. We offer online purchasing tools globally that inform employees who order office supplies if items with recycled content are available.

Our Master Services Agreement outlines the principles that we encourage our partners to follow, including those related to energy, water, and waste. Many of our key suppliers have reduced their environmental footprints through initiatives in logistics, materials, and services provided. We benefit from these efforts when we travel, buy equipment, and use products provided by these partners.

Since 2013, we have reduced printing and paper purchases at our U.S. locations by almost 20 percent. Contributing factors included converting our sales force to tablet devices (and reducing paper documentation), encouraging employees to reduce the amount and type of information they print, and expanding use of technologies that support paperless operations.

## PROGRESS TOWARD GOAL—WASTE TO LANDFILL



We have expanded our green procurement program to cover areas such as product transport, manufacturing, and research. For example, in 2012 we transitioned our approach to shipping products related to clinical trials requiring refrigeration from one-way shipping containers to reusable packaging. See details on [page 96](#).

**Other Air Emissions**

Lilly tracks emissions of compounds that can affect air quality. Currently, the company’s most significant air emissions, other than GHGs, include volatile organic compounds (VOCs) as well as sulfur dioxide (SO<sub>2</sub>) and nitrogen oxides (NO<sub>x</sub>) resulting from the combustion of natural gas, oil, and coal.

Between 2007 and 2014, our total air emissions (not including GHGs) decreased by 36 percent, largely driven by changes in manufacturing processes. NO<sub>x</sub> and SO<sub>2</sub> emissions in 2014 decreased by 16 percent and 8 percent respectively compared to 2013. VOCs and particulate matter each increased by 5 percent, resulting from increased production and improved calculations.

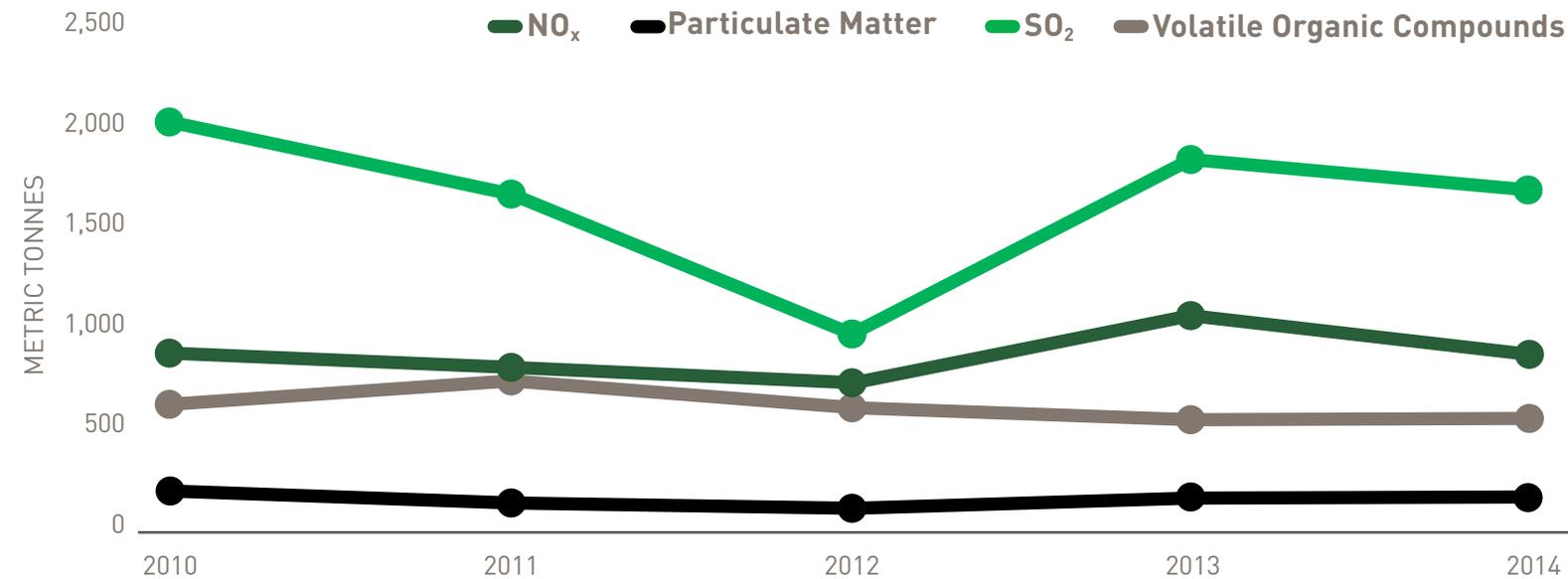
**Biodiversity**

Lilly has a long history of working collaboratively to protect habitat and reduce the impact of our operations on ecosystems. We pursue a decentralized approach, recognizing that biodiversity challenges and opportunities vary based on location, and we engage in conservation projects and habitat enhancements at many sites worldwide. We also support conservation efforts in the communities where our facilities are located.

Examples include the following:

- Kinsale, Ireland – Our manufacturing facility launched a long-term initiative in 2013 to protect, maintain, and enhance biodiversity on 152 acres at the site through various efforts. One project nearly doubled the number of butterfly species at the site during the first two years by planting wildflowers to serve as natural habitats.
- Guayama, Puerto Rico – Since 1991, our manufacturing facility has designated about 10 acres of its grounds as a habitat conservation area to help preserve and restore vibrant plant life. The space is divided into three main areas focused on education, reforestation, and preservation. Trained employees provide interpretive services at the site as a part of guided environmental tours.
- Indianapolis, Indiana, United States – As a part of Lilly’s annual Global Day of Service, the company started a multiyear project in 2012 to educate our employees and the communities where we operate about local water resources. Part of a larger citywide collaboration called “Reconnecting to Our Waterways,” this project helped Indianapolis meet U.S. Environmental Protection Agency requirements by adding markers to 302 drains in 23 subdivisions. Participants also removed invasive species and improved aesthetics along several waterways. About 8,000 of our employees have participated each of the last three years.

**OTHER AIR EMISSIONS**





In Kinsale, Ireland, our manufacturing facility launched a long-term initiative to protect, maintain, and enhance biodiversity on 152 acres at the site through various efforts. One project nearly doubled the number of butterfly species at the site during the first two years by planting wildflowers to serve as natural habitats.

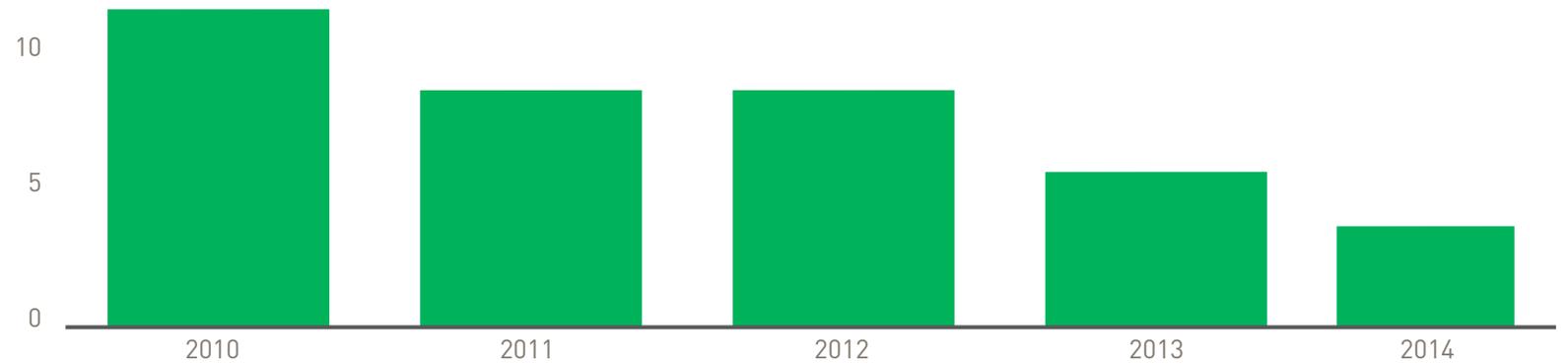
## ENVIRONMENTAL COMPLIANCE

Lilly's Health, Safety, and Environment Policy requires compliance with applicable regulations wherever we do business. Where existing laws and regulations are inadequate, Lilly applies its standards consistent with this policy. We believe compliance is fundamental to maintaining our facilities' "right-to-operate" in local communities. (For more information about our HSE policies, standards, and management systems, see [page 92](#).) If it is determined that we are out-of-compliance, we work to remedy the situation as quickly as possible and to continuously improve our performance.

Using environmental capability assessments based on sophisticated statistical techniques, we routinely review more than 50 environmental compliance-related processes across Lilly. We use the results to continually improve these processes and maintain compliance.

Reportable permit-limit exceedances decreased from 43 in 2007 to 3 in 2014, a 93 percent reduction that equals the lowest level ever reported by the company. The three exceedances in 2014 had to do with water-related permits. See the Environmental Performance Indicators table on [page 110](#) for detail.

## TOTAL REPORTABLE PERMIT-LIMIT EXCEEDANCES



## Environmental Awards and Recognition



Climate change disclosure score of 85, performance band B (2014)



Recognition of carbon-management programs for United Kingdom operations (2014)



Recognition of outstanding environmental performance in recycling (2014)

# Environmental Performance Indicators<sup>21,22</sup>

	2007	2010	2011	2012	2013	2014
<b>Greenhouse Gas Emissions</b>						
Greenhouse Gas Emissions (Scope 1 and Scope 2) (metric tonnes CO <sub>2</sub> e)	1,840,000	1,620,000	1,560,000	1,560,000	1,610,000	1,540,000
Scope 1	527,000	479,000	446,000	426,000	476,000	445,000
Scope 2	1,310,000	1,160,000	1,130,000	1,160,000	1,130,000	1,100,000
Greenhouse Gas Emissions Intensity (metric tonnes CO <sub>2</sub> e/1,000 square feet)	84.7	75.3	71.4	69.7	71.1	69.8
Greenhouse Gas Emissions Intensity (metric tonnes CO <sub>2</sub> e/million \$ revenue)	98.7	70.2	64.3	69.0	69.6	78.8
<b>Energy Use</b>						
Energy Consumption (million BTUs)	12,900,000	11,200,000	10,800,000	10,900,000	11,200,000	10,700,000
Energy Intensity (million BTUs/1,000 square feet)	594	521	495	488	495	484
Energy Intensity (million BTUs/million \$ revenue)	692	486	445	482	485	545
Direct Energy Consumption (million BTUs)	4,670,000	4,200,000	4,000,000	3,900,000	4,210,000	3,990,000
Coal (million BTUs)	1,410,000	1,280,000	1,170,000	690,000	1,340,000	1,300,000
Natural Gas (million BTUs)	2,480,000	2,230,000	2,300,000	2,770,000	2,430,000	2,250,000
Fuel Oil (million BTUs)	768,000	676,000	459,000	435,000	435,000	424,000
Liquid Propane (million BTUs)	18,600	23,000	15,900	700	700	2,400
Indirect Energy Consumption (million BTUs)	8,240,000	7,000,000	6,830,000	7,000,000	7,000,000	6,700,000
Purchased Electricity (million BTUs)	4,630,000	4,310,000	4,200,000	4,320,000	4,230,000	4,280,000
Purchased Steam (million BTUs)	2,990,000	2,200,000	2,240,000	2,200,000	2,310,000	2,430,000
Purchased Chilled Water (million BTUs)	619,000	491,000	445,000	491,000	450,000	4,500

	2007	2010	2011	2012	2013	2014
Scope 3 Emissions (not included in metrics above) <sup>23</sup>						
Employee Business Travel (personal car, taxi, rental car, rail, and air travel) (metric tonnes CO <sub>2</sub> e)	65,000	72,000	67,000	99,000	94,000	68,000
Employee Commuting (metric tonnes CO <sub>2</sub> e)	76,000	72,000	71,000	72,000	71,000	72,000
Product Transportation and Distribution (contracted) (metric tonnes CO <sub>2</sub> e)	30,000	43,000	50,000	45,000	30,000	18,000
Waste Generated in Operations (metric tonnes CO <sub>2</sub> e)	103,000	68,000	72,000	74,000	88,000	103,000
Non-Kyoto Compound Emissions (refrigerants, VOCs, etc.) (metric tonnes CO <sub>2</sub> e)	14,000	23,000	55,000	15,000	17,000	28,000
<b>Water Use</b>						
Water Intake (billion liters) <sup>24</sup>	19.6	12.8	13.3	12.4	12.7	13.5
Municipal (billion liters)		6.5	6.6	6.0	6.6	6.8
Surface (billion liters)		0.0	0.0	0.0	0.2	0.0
Groundwater (billion liters)		6.3	6.8	6.5	6.1	6.7
Water Intensity (million liters/million \$ revenue)	1.05	0.555	0.549	0.549	0.562	0.688
<b>Waste</b>						
Waste Generation (metric tonnes)	379,000	228,000	242,000	281,000	307,000	292,000
Hazardous Waste Generation (metric tonnes)	53,800	31,000	22,000	23,900	22,700	23,300
Non-Hazardous Waste Generation (metric tonnes)	325,000	197,000	220,000	257,000	284,000	269,000
Waste Generation Intensity (metric tonnes/million \$ revenue)	20.3	9.88	10.7	12.3	13.3	14.9
<b>Waste Disposition</b>						
Beneficially Reused (metric tonnes)	253,900	148,800	176,200	211,300	235,000	206,400
Recycled (includes incineration with energy recovery) (metric tonnes)	31,500	45,000	35,500	33,700	32,000	46,000
Treated (includes incineration without energy recovery) (metric tonnes)	49,100	12,300	13,300	16,300	18,200	28,600

	2007	2010	2011	2012	2013	2014
Landfilled (metric tonnes)	44,700	22,100	17,000	19,800	21,600	11,200
Landfilled (related to goal) (metric tonnes) <sup>25</sup>	32,000	15,900	10,900	12,300	8,900	6,300
<b>Other Air Emissions</b>						
Volatile Organic Compound Emissions (metric tonnes)	526	626	735	606	532	560
Particulate Matter (metric tonnes)	311	200	146	113	167	175
SO <sub>2</sub> Emissions (metric tonnes)	3,137	2,015	1,660	975	1,844	1,694
NO <sub>x</sub> Emissions (metric tonnes)	1,205	877	794	741	1,057	885
Ozone-Depleting Substances Potential (kg CFC-11 equivalent)	1,425	790	3,718	1,168	995	1,830
<b>Environmental Compliance</b>						
Reportable Permit-Limit Exceedances <sup>26</sup>	43	11	8	8	5	3
Number of Significant Spills <sup>27</sup>	0	0	0	0	0	0
Environmental Fines Paid (\$)	\$ 96,900	\$ 1,200	\$ 340,000 <sup>28</sup>	\$ 732	\$ 0	\$ 0
<b>Energy, Waste, Water, and Natural Resource Use Reduction Fund</b>						
Expenditures (\$ millions)	\$ 0	\$ 4.1	\$ 0.8	\$ 1.1	\$ 1.8	\$ 1.6

<sup>21</sup> Data may be revised compared to prior reports due to changes in calculation methodology and other factors. Some segments do not add up to totals due to rounding.

<sup>22</sup> Following World Resources Institute guidance, energy use, greenhouse gas emissions (except Scope 3), waste, and water use data are reported on an adjusted basis accounting for mergers, acquisitions, and divestitures, as appropriate, to ensure comparability, unless stated otherwise.

<sup>23</sup> These data do not include sales force travel using company vehicles, use of Lilly aircraft, or product distribution with Lilly vehicles. Those items are Scope 1 and included in the data above.

<sup>24</sup> "Water intake" as used in evaluating our progress toward our 2013 water reduction goal is the total amount of water coming into a facility, including water pumped from bodies of surface water and groundwater, as well as water provided by a utility. It includes water used in processes, utilities, and other ancillary operations, such as irrigation. The term does not include groundwater

pumped solely for treatment to satisfy regulatory actions or requirements (e.g., remediation activities where the water is not used for another purpose). Values do not include the water extracted from wells solely for the purpose of lowering the groundwater table(s) to maintain the physical and structural integrity of building foundations. Data for breakdown of water intake by source are not available prior to 2010.

<sup>25</sup> Lilly's waste goals do not include materials that are deemed "reused" without extensive processing. Examples include coal ash reused for mine reclamation or road base, and mycelia and urea reused for fertilizer.

<sup>26</sup> Lilly classifies an event as a reportable permit-limit exceedance if it involves an exceedance of a numeric permit or license limit that must be reported to the regulatory authority. The reporting may be immediate (e.g., within 24 hours) or in a routine compliance report. These exceedances do not necessarily result in harm to people or the environment.

<sup>27</sup> "Significant spill" in this report refers to any unexpected, unintended, abnormal, or unapproved dumping, leakage, drainage, seepage, discharge, or other loss of a substance that resulted in damage to the environment (i.e., human health, aquatic life, or wildlife) or a material event requiring reporting to the U.S. Securities and Exchange Commission. Damage means the actual or imminent alteration of the environment so as to render the environment harmful, detrimental, or injurious.

<sup>28</sup> During routine inspections in 2006 and 2007, the U.S. Environmental Protection Agency identified potential weaknesses in our leak detection and repair program at our Lilly Technology Center facility in Indianapolis, Indiana. In addition, in 2006 we voluntarily reported to the state and city environmental agencies that we had exceeded an annual limit for air emissions. In response to these events, we have implemented numerous corrective actions and enhancements to our environmental programs. We paid a penalty of \$337,500 in early 2011 to settle the case. There was no harm done to employees, neighbors, or the environment as a result of these events.

# Support for the United Nations Global Compact Principles (UNGC)

Eli Lilly and Company is proud to voice our continued support for the UNGC principles. Our website, [www.lilly.com](http://www.lilly.com), contains detailed information about our company policies, procedures, and programs that are related to the UNGC, including information on our workplace policies, ethics, and transparency, as well as our environmental impacts and programs.

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## Human Rights

Principle 1 - Businesses should support and respect the protection of internationally proclaimed human rights

Principle 2 - Make sure that they are not complicit in human rights abuses

Relevant Report Content: [Managing Our Supply Chain, page 69](#)

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## Labor

Principle 3 - Businesses should uphold freedom of association and effective recognition of the right to collective bargaining

Relevant Report Content: [Supporting Strong Workplace Practices, page 78](#)

Principle 4 - The elimination of all forms of forced and compulsory labor

Principle 5 - The effective abolition of child labor

Relevant Report Content: [Managing Our Supply Chain, page 69](#)

Principle 6 - Eliminate discrimination in respect of employment and occupation

Relevant Report Content: [Diversity and Inclusion, page 79](#)

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## Environment

Principle 7 - Businesses should support a precautionary approach to environmental challenges

Principle 8 - Undertake initiatives to promote greater environmental responsibility

Principle 9 - Encourage the development and diffusion of environmentally friendly technologies

Relevant Report Content: [Environmental Stewardship, page 88](#)

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## Anti-Corruption

Principle 10 - Businesses should work against all forms of corruption, including extortion and bribery

Relevant Report Content: [Conducting Our Business Ethically and Transparently, page 58](#)

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2017