Sustainability at Baxter
2012

Product Responsibility

Baxter
Product Responsibility

Baxter develops, manufactures and markets products for people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions. The company’s products are infused, injected or inhaled more than two billion times annually, to treat life-threatening acute or chronic conditions.

While delivering products that save or sustain lives, Baxter also works to address environmental and social issues across the product life cycle. These range from sustainable design and bioethics during research and development, to energy and materials efficiency during manufacturing and transport, to responsible advertising and promotion, and finally, product repair, refurbishment and recycling for electronic products as appropriate at end-of-life. Baxter also has programs to ensure high standards in quality, safety and product integrity.

To further these efforts, Baxter launched a new Product Sustainability Program in 2012, building on extensive partnership with the R&D, marketing and supply chain groups. The program team initiated new projects to define life cycle environmental impacts for both individual products and entire therapies.

The following graphic illustrates the breadth and depth of the company’s approach.

Sustainability Issues Across the Product Life Cycle

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Product Sustainability Trends

The importance of product sustainability to Baxter’s ongoing success continues to grow, due to several factors:

- Increasing customer requirements, expectations and concerns (see Case Study: Engaging with Stakeholders on Product Environmental Performance);
- New and expanding regulatory requirements globally (see Case Study: Materials Restrictions); and

[Table with issues and approaches for materials use, manufacturing, product transport, packaging, product use, and product end-of-life]
• Ongoing pressure from non-governmental organizations to improve product environmental and social performance.

To better understand these trends, in 2012 Baxter commissioned a third party to conduct an in-depth analysis. This included benchmarking of peer companies, customers and key market leaders, as well as interviews with internal representatives from research and development, supply chain, marketing, and other areas. The study also reviewed product sustainability tools to possibly integrate into the company's product stewardship program.

Key findings included the following:
• The two leading customer product sustainability issues are decreasing materials of concern (such as PVC, DEHP and mercury) and reducing waste (packaging and disposables);
• Customer focus on product sustainability varies significantly by region (with customers in Europe and California demonstrating the strongest interest);
• Companies have opportunities across the life cycle to influence and improve product sustainability performance, from identifying customer requirements and educating R&D professionals to engaging suppliers and communicating product benefits to customers; and
• Companies across the healthcare industry are responding to similar pressures, with varying levels of focus and investment.

Baxter is using these findings to inform enhancements of its Product Sustainability Program during the coming year.

Quality

Every day, Baxter products make the difference between life and death for millions of patients worldwide. The company’s reputation and ongoing success depend on the quality of Baxter’s products and services. Therefore, uncompromising dedication to quality is a guiding principle of the company's culture and is among its shared values.

Baxter's global quality management system (called "1QSys" for "one quality system") provides a single, global Baxter-wide standard for quality. 1QSys offers a consistent approach to managing quality across the product life cycle, including design, development, manufacturing, sterilization, labeling, packaging, distribution and promotion. 1QSys helps to address the complexities of managing across interconnected businesses, regions and manufacturing operations, enhancing the company's ability to meet quality standards and adapt to changes in a complex regulatory environment.

Baxter regularly evaluates and reviews its quality management system to identify and correct issues that may affect product and service quality, and pursues continuous improvement through a range of data-driven methodologies. One focus is simplifying processes, which increases efficiency and prevents potential quality issues from occurring.

Baxter also assesses its suppliers of raw materials, components and finished goods to track and enhance their performance. After products are launched, the company executes post-market surveillance to monitor the safety, efficacy and quality of products while in use. See Safety for more for more information.

When Baxter identifies a potential quality or safety issue with one of its products or determines that products manufactured or marketed by the company do not meet company specifications, published standards or regulatory requirements, it investigates and takes appropriate preventive and corrective actions. This may include providing notice to the customer of revised labeling, correction of the problem at the customer location, withdrawal of the product from the market and/or other actions. See Safety for detail.

Baxter takes any self-identified quality or safety issues or finding by regulatory authorities very seriously, and establishes comprehensive plans to address the specific findings. As these plans are executed, Baxter also evaluates the identified corrective actions to determine potential to leverage the improvements on a broader basis.

Safety

Promoting patient safety is at the core of everything Baxter does. The company was founded in 1931 on its ability to produce safe intravenous (IV) solutions for hospitals at a time when most hospitals were not equipped to prepare their own.

Today, Baxter focuses on safety across the product life cycle, from product development and enhancements, to post-market research and via pharmacovigilance and post-market surveillance. For example, Baxter's Pharmacovigilance department identifies and confirms pre- and post-market drug safety signals and then communicates these potential issues. Through product labeling or risk management activities, the department identifies and executes approaches to promote a positive benefit-risk balance of Baxter's therapeutic drug products.
The company also collaborates with hospitals to assess their patient safety processes, and partners with customers and third parties to develop patient and clinician educational materials and raise safety standards worldwide. This section includes examples of these efforts, as well as other ways the company enhances patient safety worldwide:

- Supporting Reduction of Pathogens
- Improving Product Design
- Focusing on Decreasing Medication Errors
- Addressing IVIG Safety
- Educating Nurses on Safe Practices
- Complying with Government Regulations
- Addressing Product Safety Issues

Supporting Reduction of Pathogens

In 1971, Baxter introduced the first flexible, plastic IV bag. As the first "closed system" IV container, the bag did not require venting during administration. This keeps the solution from contacting outside air, helping to minimize contamination.

Despite evidence that use of closed systems can help reduce pathogens, many hospitals in developing countries continue to use open systems. The compatibility of the Baxter IV System with both infusion pump therapy and gravity applications helps meet safety standards for IV replacement. Baxter's IV Standard Sets help reduce the number of set-ups and teardowns which may decrease the risk of touch contamination.

Baxter works with governments and healthcare providers to help conduct studies, set standards and implement conversion to standard set technology in numerous markets to help improve efficiency and waste.

For example, in 2012, Baxter honored the first recipient of the Baxter Colombia Patient Safety Prize, Hospital Pablo Tobon Uribe in Medellin. Launched in 2011, the award recognizes leading hospitals for outstanding efforts in preventing hospital-acquired infections. Representatives from Joint Commission International and Baxter held a training session for more than 60 multidisciplinary teams from across the region on improving medication practices for patient safety.

Improving Product Design

Baxter Healthcare Corporation recently expanded its IV (intravenous) connector portfolio to include the ONE-LINK needle-free IV connector, launching in Canada in 2011 and in the United States in 2012. The ONE-LINK connector features neutral displacement and is intended for single patient use with a vascular access device for the administration of drugs and solutions without needles and can be used to aspirate blood. It builds upon the INTERLINK system, promoting a needle-free platform that Baxter pioneered more than 20 years ago to help protect healthcare workers from needle sticks.

One of the most common types of noninfectious complications with central venous catheters (CVCs)—a catheter placed into a large vein in the neck or chest—is that blood can back up into the catheter and form a clot that could occlude the catheter, which may lead to complications. As many as one in three CVCs will become occluded. The ONE-LINK connector is designed to help prevent reflux of blood back into the tip of the catheter upon connection or disconnection. This may help reduce the risk of thrombotic occlusions compared to other devices with higher reflux volumes.

Focusing on Decreasing Medication Errors

Baxter helps address potential medication errors in several ways, including by providing innovative tools for in-house compounding, updating labeling for premix solutions, producing smart infusion pump technology and supporting programs that reduce medication errors.

Baxter also continues to improve product packaging and labeling to help reduce the potential for medication errors due to incorrect drug selection. For example, the company voluntarily redesigned the labels of six existing intravenous (IV) premix drug labels based on data from practicing healthcare providers and human factors research. By decreasing the clutter and treating information more simply and consistently, Baxter sought to improve readability and product differentiation. The new labels take advantage of increased white space and reduced clutter. In addition, key information—including the medication's name, total strength per total volume, strength per mL, and container total volume—were placed in a hierarchical format.

"Harmful medication errors not only jeopardize a patient’s safety, but also lead to longer hospital stays and higher healthcare costs. I commend Baxter for working to prevent errors and potential patient harm by continually monitoring actual and potential medication errors. 
errors related to its products and identifying ways to improve the medication-use system," said Michael R. Cohen, RPh, MS, ScD, FASHP, president of the Institute for Safe Medication Practices, a non-profit healthcare organization that specializes in understanding the causes of medication errors and providing error-reduction strategies to the healthcare community, policy makers, and the public. Baxter’s new labels are an important step in reducing confusing and non-distinct drug labeling; two factors that significantly contribute to medical errors, Cohen said.

Compounding remains an important part of the pharmacy process. Some compounds are unstable and thus require mixing in the pharmacy based on the exact specifications and needs of each patient, while others can be premixed outside of the pharmacy. Baxter produces premixed IV drugs so hospital pharmacists do not have to prepare these critical medications themselves. Baxter was the first company to work with other pharmaceutical firms to premix their drugs in IV solution, and is the only manufacturer of frozen premixed drugs for compounds that are not stable at room temperature. Based on the company’s experience in sterile manufacturing of critical medications, Baxter uses specialized processes to ensure the sterility of its manufactured products.

For IV drugs that must be administered in a very specific dose or have other special requirements, Baxter operates pharmacy compounding centers in some countries. Hospital pharmacies transmit prescriptions electronically to the Baxter compounding center, where pharmacists and technicians prepare patient-specific doses under sterile conditions and deliver them to the hospital ready for administration. Baxter also continues to improve product packaging and labeling to help reduce the potential for medication errors. The company was the first to develop a readable bar code for clear, flexible IV bags.

Baxter also offers pharmacy technology that enhances the efficiency and safety of oral and IV dose preparation and delivery. For example, the DoseEdge Pharmacy Workflow Manager, an integrated system for managing IV and oral dose preparation activities, has delivered nearly 16.5 million error-free doses as of the end of 2012. Of these, 4% were identified as potential medication errors and caught prior to administration. DoseEdge prevents approximately 6,300 potential medication errors per week. Following Baxter’s 2011 acquisition of Baxa Corporation, other products now in its portfolio include the ExactaMix Compounder, a device that automates multi-ingredient solution compounding; ExactaMed Syringes, dispensers that provide greater accuracy for dosing oral liquid medications; and the NeoThrive Enteral Feeding System, enteral syringes and accessories.

In April 2012 Baxter completed its purchase of SIGMA International General Medical Apparatus, LLC (SIGMA). SIGMA develops and manufactures smart infusion pump technology including the Spectrum large volume pump (LVP), which provides advanced safety and clinician-friendly features. The Spectrum smart infusion system features Dose Error Reduction Software with hospital-defined Drug Libraries including dosing limits and clinical advisories. When a clinician programs an infusion, the software verifies that the dose meets facility-determined parameters. If the programmed infusion is outside of the pre-determined dosing limits, the pump will alert the clinician before the infusion begins. In conjunction with the SIGMA transaction, Baxter acquired SIGMA’s product development pipeline, which includes a platform of multiple infusion technologies with advanced safety capabilities.

Baxter's Medical Products business also helps hospitals through its Connections Portfolio of programs, which focus on three key principles — simplification, streamlining and standardization. These programs, administered by Baxter clinical experts, are based on objective observational, interview, and data collection methodologies that identify opportunities for improvement in practice and product utilization. In addition, these offerings help to increase staff productivity and patient safety by providing specific recommendations and action plans to improve alignment with nationally recognized regulations, standards and guidelines.

Addressing IVIG Safety

Thromboembolic events (TEE) can occur during the administration of intravenous immune globulin (IVIG) products. It has been reported that pro-coagulant activity, during which blood clots, can be introduced into IVIG products during the manufacturing process. Baxter uses quality procedures to measure thromboembolic impurities throughout its manufacturing processes, including systematic and extensive characterization studies and global and specific tests to demonstrate the effective removal of pro-coagulant activity. Data indicate that process analysis, combined with quality measures throughout the manufacturing process, is the best way to minimize levels of pro-coagulant activity in the final product.

To further understand the role of pro-coagulant activity in IVIG, Baxter—along with other manufacturers of IVIG products and representatives from regulatory agencies (FDA, Paul-Ehrlich-Institut, National Institute for Biological Standards and Control, and the organization now known as the National Agency for the Safety of Medicines and Health Products), academia and organizations involved in the use of IVIG—participated in a 2011 workshop held by the Plasma Protein Therapeutics Association and Food and Drug Administration (FDA) during which regulators from national and international agencies and members of industry convened to discuss risk mitigation strategies in this area.
Based on this meeting, the FDA published a paper in 2012 in the journal Transfusion on the development of TEE in patients, based largely on data presented at the workshop. It suggested that multiple risk factors can contribute to the development of TEE, including the product manufacturing process, patient age, a history of thromboembolic events and the presence of a hypercoagulable state.

Educating Nurses on Safe Practices
Baxter offers education programs that provide training and guidance to nurses in the safe and proper use of its products, including:

- An educator network of nurses that was available for the first year after FDA approval of the subcutaneous administration of GAMMAGARD LIQUID to train other nurses on the administration of both intravenous and subcutaneous infusion, as well as to provide extensive materials to help nurses train patients to self-administer the therapy. Nurses are available by phone to answer GAMMAGARD LIQUID administration questions from both nurses and patients.
- The Baxter-sponsored Canadian Institute of Nutrition Excellence (CINE), composed of stakeholders dedicated to improving clinical support practice, patient outcomes and patient safety in nutrition therapy.
- A program of continuing education courses about peritoneal dialysis (PD) launched by Baxter’s renal team in Chile for adult and pediatric nurses across the country, aimed at keeping nursing professionals informed of the latest studies and best practices in PD. Courses in 2012 focused on topics such as the role of the nurse in patient selection and education as well as the prevention of peritonitis.

Complying with Government Regulations
Baxter's operations and products are subject to extensive regulation by numerous governmental agencies worldwide. In the United States, the federal agencies that regulate the company's facilities, operations, employees, products (their manufacture, sale, import and export) and services include: the FDA, the Drug Enforcement Agency, the Environmental Protection Agency, the Occupational Health and Safety Administration, the Department of Agriculture, the Department of Labor, the Department of Defense, Customs and Border Protection, the Department of Commerce, the Department of Treasury and others. Because Baxter supplies products and services to healthcare providers that are reimbursed by federally funded programs such as Medicare, the company’s activities are also subject to regulation by the Center for Medicare/Medicaid Services and enforcement by the Department of Health and Human Services. State agencies also regulate the facilities, operations, employees, products and services of the company within their respective states.

Outside the United States, Baxter products and operations are subject to extensive regulation by governmental agencies, including the European Medicines Agency in the European Union. International governmental agencies also regulate public health, product registration, manufacturing, environmental conditions, labor, imports, exports and other aspects of the company’s global operations.

The FDA and other governmental agencies worldwide administer requirements covering the testing, safety, effectiveness, manufacturing, labeling, promotion and advertising, distribution and post-market surveillance of Baxter’s products. The company must obtain approval or clearance from the FDA before it can market and sell its products in the United States. Other countries have similar pre- and post-market registration requirements. Even after the company obtains regulatory approval to market a product, the product and the company’s manufacturing processes are subject to continued review by regulatory authorities.

Addressing Product Safety Issues
When Baxter identifies a potential quality or safety issue with one of its products or determines that products manufactured or marketed by the company do not meet company specifications, published standards or regulatory requirements, it investigates and takes appropriate corrective action, such as revising labeling, correcting the problem at the customer location, withdrawing the product from the market and/or other actions.

In another example, Baxter undertook initiatives in 2012 to alert patients and clinicians about the risk of Extraneal—a specialty peritoneal dialysis solution containing icodextrin, which is metabolized into maltose—to falsely elevate blood glucose readings when non-specific glucose monitoring systems are used. Since December 2008, when the FDA requested that Baxter submit a Risk Evaluation and Mitigation Strategy (REMS) as a precautionary, patient safety endeavor, Baxter has enacted efforts to inform patients and clinicians who treat patients who use Extraneal about the potential for this serious issue. These efforts have included proactively engaging trade media and associations as well as creating a website with detailed safety information (www.glucosesafety.com). Through these efforts, the company aims to educate patients so they can inform health care providers as they receive medical treatment outside of a dialysis clinic, and physicians, so that they use the correct glucose monitoring system. Additional details on regulatory matters currently being addressed by the company are available under the heading "Certain Regulatory Matters" in Baxter’s most recent periodic report filed with the U.S. Securities and Exchange Commission (SEC) on Form 10-K or 10-Q. Details on product liability, patent, commercial and other legal matters currently being addressed by Baxter are available in the note to the company’s...
consolidated financial statement entitled "Legal Proceedings" in Baxter’s most recent periodic report filed with the SEC on Form 10-K or Form 10-Q.

The devices referenced within are Rx only. For safe and proper use of all devices please refer to the complete Instructions for Use. Full prescribing information for Extraneal can be found here.

3 Hadaway LC. Reopen the pipeline for IV therapy. Nursing. 2005;35(8):54-61

Infection and occlusion rates were monitored four months before (June - Sept. 2011) and four months after (Nov. - Feb. 2012) ONE-LINK connector implementation.

Infections were recorded per one thousand catheter days. Catheter occlusions were measured by extracting data from pharmacy issuing tPA. Catheter occlusions tracked four months prior to the ONE-LINK connector implementation showed an average rate of 5.47 occlusions requiring tPA/1,000 catheter days. Catheter occlusions tracked four months post ONE-LINK connector implementation showed an average rate of 4.04 occlusions requiring tPA/1,000 catheter days.

Product Integrity
Counterfeit and/or adulterated medical products pose growing risks to patient safety worldwide. Maintaining product integrity is a complex and multifaceted challenge, encompassing an array of supply chain, product design and packaging, and risk management strategies.

Baxter launched a formal, global product integrity program in 2008 to safeguard the company’s products from the threat of counterfeiting or adulteration. The company’s diverse product portfolio is manufactured in 27 countries and sold in more than 100 countries globally, and ranges in complexity from basic intravenous solutions to highly-specialized biologic derived therapies. Baxter’s product integrity measures take into account the differing levels of complexity and risk associated with individual products and markets.

The company has conducted a series of risk assessments, examining economic incentives, supply chain and product complexity, and other factors that may contribute to this issue. Based on that analysis, Baxter prioritized certain product lines and geographies for piloting and implementing various product authentication and security measures.

Risk Assessment and Ongoing Monitoring
Economic realities, manufacturing processes and supply chain dynamics vary considerably by product and market. Accordingly, the risk profile associated with a particular product can present distinct challenges. Baxter has conducted an extensive review of its product portfolio and geographic presence to assess the level of risk associated with individual products by market. The highest priority


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products and markets were earmarked for initial implementation of various product integrity measures, including multiple layers of product packaging features and serialization using GS1 standards, the most widely used supply chain standards system in the world. The GS1 information standards organization is dedicated to the design and implementation of global standards and solutions to improve the efficiency and visibility of supply and demand chains globally and across sectors.

Because changing economics, shifting political climates, new technologies and other world events can impact risk levels, the risk assessment process must be dynamic and informed by ongoing monitoring and information sharing among law enforcement and regulatory officials and industry players. In addition to these broader trends, Baxter monitors for patterns or anomalies within its own pharmacovigilance, product complaint reporting and customer order systems to spot and investigate potential events or product issues that may have resulted from or suggest adulteration or wrong-doing.

Supply Chain Measures
Maintaining a secure supply chain, all the way from Baxter to the end user of the product, is essential to ensuring product integrity. Direct selling and sole source agreements are one way the company can retain control and/or visibility of the product for much of its route. Baxter regularly monitors customer purchasing data and trends and has terminated or changed customer relationships after detecting actions that jeopardize supply chain integrity (e.g. resale of product, unexplained spikes or changes in ordering behavior that would suggest diversion). Baxter’s sales contracts include restrictions that support supply chain transparency and control, which may include restrictions or requirements related to the destruction of product packaging in some markets.

Additionally, the company was an early adopter of GS1 standards including the Global Trade Item Number (GTIN). A GTIN is a unique identification number tagged to a product that provides the link between the item and the information pertaining to it. GS1 standards are used to uniquely distinguish all products, trade items, logistic units, locations, assets, and relationships in the supply chain—from manufacturer to consumers. Baxter believes that global adoption of GS1 standards will facilitate greater use technologies that can help ensure that products are moved correctly and efficiently throughout the supply chain. Ultimately, adoption of these standards can help enable healthcare professionals to verify they are administering the right product to the right patient at the right time.

Collaboration with Officials and Industry Partners
Baxter collaborates with regulatory and public health officials and industry experts on an ongoing basis to share intelligence, insights and experience regarding the integrity of products and supply chain. Groups such as GS1, Parenteral Drug Association and Rx360 have facilitated exchange of industry expertise and collaboration with regulatory authorities to develop and raise standards, drive voluntary adoption of new processes and technologies, and implement new measures to advance product integrity and protect patients and clinicians.

Product Packaging and Design
Over the last several years, Baxter has implemented several enhancements to product and container design and labeling to enable and expand product authentication and the ability to identify tampering. These measures may include multiple levels of closure and packaging, elaborate closure systems and the use of unique materials. Due to the openness of global trade and the increasing sophistication of counterfeiters, companies must vary their approaches and continue to evolve specific technologies or materials used.

Preventing and overcoming the many threats to product integrity that exist today and will arise in the future requires a comprehensive approach that incorporates many elements. Industry-wide, global adoption of GS1 standards are important building blocks in securing the supply chain. Baxter looks forward to expanding its implementation of the GS1 standards, furthering its product integrity efforts and driving greater security and efficiency in the delivery of our products to healthcare providers and patients around the world.

R&D and Design
The research and development and design stages offer unique opportunities to shape a product’s sustainability performance across the life cycle. To address environmental, health and safety issues such as materials selection, energy use, and features that affect recyclability, Baxter includes Product Sustainability Review during the early stages of the product development process.

Baxter also has policies and programs to address a range of bioethics issues, from Animal Welfare and Clinical Trials to genetically modified organisms and the cloning and use of human embryos. The company's Bioethics Policy includes Baxter's Bioethics Guiding Principles that address topics such as product safety and efficacy, stakeholder concerns, risk-benefit analysis, legal and regulatory compliance, vendor conformance to Baxter's standards, clinical trials, animal welfare and biodiversity. The company's senior leadership considers these principles, in addition to the advice of scientific and ethical advisors, to determine whether to proceed in research activities.
requiring consideration of bioethical issues. To be justified, the potential benefits to individual subjects and society must equal or exceed possible risks. For more information, see Baxter's Bioethics Position Statements.

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Product Sustainability Review

Baxter recognizes the essential role that product design has in determining the environmental, health and safety (EHS) performance of products, from materials extraction through end-of-life. Reflecting this, the company includes Product Sustainability Review (PSR) during the early stages of the product development process. This allows Baxter to fully consider and address EHS factors such as materials selection, energy use and features that affect recyclability.

As part of the process, an initial screen at the product concept phase reveals high-level sustainability risks and opportunities in areas such as regulations and customer and other stakeholder requirements (see graphic). Later in the process, a comprehensive review identifies improvement opportunities across the life cycle. This includes life cycle assessment-related computer modeling of a proposed product, and may involve comparison to existing products. Designers use this assessment to inform material choices and evaluate product end-of-life options and other factors. Baxter uses these results to confirm product feasibility, help establish product requirements and minimize potential product impacts to human health and the environment.

PSR is focused on medical devices, ranging from intravenous solution containers to dialysis machines, reflecting the greater potential environmental impact of these compared to other Baxter products. Since 2005, Baxter has used PSR to evaluate all new medical devices reaching the concept stage of development (more than 15 products so far), and currently has several devices under review. PSR has yielded positive results, and several reviews have influenced materials selection.

PSR also provides a process to address compliance considerations for existing and upcoming product-stewardship regulations, and Baxter periodically updates the PSR toxic chemicals screen to reflect changes in legislation and other factors. This helps the company meet growing customer demands to limit these substances and prepare for potential chemical restrictions under the REACH Directive. Through the PSR process, materials requirements are documented in the product design history file. See Materials Use and Case Study: Materials Restrictions for more information about Baxter's approach related to product materials.

Life Cycle Assessment

Supplementing PSR, Baxter also uses life cycle assessment (LCA) to evaluate the environmental performance of its products and determine ways to reduce environmental footprint. This may include decreasing the presence of chemicals of concern and reducing life cycle water or energy consumption, greenhouse gas emissions and waste generation.

Examples during recent years include the following:

- During 2011, Baxter used LCA to inform the development of its next-generation home hemodialysis system.
- In 2010, Baxter undertook a streamlined LCA that compared two generations of dialyzer products to evaluate how material changes affect environmental performance. The company’s family of XENIUM+ dialyzers is 13-22% lighter than earlier versions, which offers the potential for reduced fuel consumption in shipping and biohazard waste removal. XENIUM+ dialyzers also use approximately one-fourth less cardboard in their packaging. Also, all materials used in XENIUM+ are free of bisphenol-A. In 2011,
the product received certification from the Carbon Trust Footprinting Certification Company, the second medical product to receive this certification (FLEXBUMIN was the first). See Case Study: FLEXBUMIN Life Cycle Assessment.

Baxter is pursuing LCAs of several additional products during 2013.

1Dialyzers are filters used during hemodialysis to eliminate waste products from the blood of people with end-stage kidney disease.

Animal Welfare

Baxter supports the conscientious use of animals in research only when no other acceptable scientific alternative exists to demonstrate the safety and effectiveness of the company's life saving and sustaining products and therapies. Baxter believes that it has an ethical responsibility to ensure the well being and humane care of animals it uses in product development and testing. In the substantial majority of cases where Baxter uses animal testing, it is required by health authorities to do so.

Consistent with Baxter's Bioethics Position Statement, the company is committed to using and developing alternative protocols, methodologies and models which reduce or replace the use of animals. Baxter also works to refine current test systems to improve animal welfare while ensuring sound data. For decades, the company has supported pre-clinical testing involving humane animal use that complies with all relevant local, national and transnational laws and regulations (as verified by regular inspections by the respective authorities/ agencies) as well as additional voluntary guidelines.

Veterinary professionals with specialty training operate Baxter's research animal facilities, which are overseen by Animal Care and Use Committees as well as local authorities. These Animal Care and Use Committees review research and testing protocols to ensure that they are appropriately designed, that the information derived is essential and full consideration for is given to animal welfare. Baxter's animal research facilities are fully accredited by the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC), which evaluates organizations that use animals in research, teaching or testing. In the United States, the company's facilities are registered and inspected regularly by the U.S. Department of Agriculture (USDA). Outside the United States, Baxter's animal facilities and programs are regularly inspected by relevant government agencies and comply with all applicable laws and regulations.

All animals used within Baxter's research facilities are from sources that Baxter's veterinary professionals select carefully and monitor regularly. Contract research organizations that Baxter uses to assess the safety of its medical products must follow similar animal care and welfare standards, and are reviewed as part of Baxter's overall quality and regulatory compliance program.

Baxter's Global Animal Welfare Committee

Baxter's Global Animal Welfare Committee (GAWC) is composed of internal veterinary professionals and animal scientists whose goals are to enhance current programs and to identify and develop new opportunities to optimize animal welfare. The committee oversees standards of animal welfare across Baxter's global operations and contract research organizations including academic institutions.

The GAWC focuses on:

• Further developing and implementing programs that will advance the 3Rs (replace, reduce and refine), and other animal use initiatives;
• Encouraging the identification, investigation and validation of alternative test methods when opportunities exist and regulations permit;
• Setting universal standards of animal care and welfare across all Baxter animal research sites and external collaborators;
• Reviewing Baxter's animal use, animal welfare programs, and related policies and standards regularly; and
• Updating internal animal welfare education and training programs.

The committee provides ongoing assessment and support of Baxter's animal testing programs to harmonize processes and tools globally. The committee's recommendations are guided by the Association for Assessment and Accreditation of Laboratory Animal Care International's system of program accreditation. To help ensure Baxter maintains the highest standards practice, committee members participate in leading professional organizations where they receive continuing education and share best practices. Examples include:

United States

• Academy of Surgical Research
• American Association for Laboratory Animal Science
• American College of Laboratory Animal Medicine

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Replace, Reduce and Refine

Baxter is committed to enhancing animal welfare through the 3Rs - replacement, reduction and refinement. The company applies a range of innovations in this area, including those as noted in the lists below.

Replacement

Baxter implements new technologies and processes to substitute animal with non-animal tests.

- For both new product development and established products, Baxter is replacing animal safety testing with cell-based alternative in vitro methods where regulations will allow. In vitro test systems are being validated and registered, which will substantially reduce the use of animals for in-process and final product quality release tests.
- Building upon its expertise in developing cell-based methods of vaccine production, Baxter is using its proprietary cell line system with next-generation production methods which do not require large quantities of fertilized chicken eggs.
- When permitted, Baxter uses cell-based tests to determine the antibody content for specific antibody-based products. For example, for its liquid immune globulin intravenous (IGIV) products that help people with compromised immune systems fight disease, Baxter has replaced animal-based potency testing with a cell-based test, recently approved in the United States.
- Baxter uses thromboelastography (a non-animal, in-vitro test to assess blood clotting) to assess how quickly clots form on new products designed to stop bleeding. This screening test helps to minimize the number of animals needed for efficacy studies.

Reduction

When Baxter is required to conduct animal testing, researchers use enhanced data collection and analysis methods to reduce overall animal use.

- In 2012, Baxter increased the amount of information collected per study by combining study activities, for example, so that fewer animals were used overall.
- Baxter participates in the Extractables and Leachables Safety Information Exchange and utilizes other databases of test methods to share toxicity data to minimize the use of animals.
- In 2011, Baxter further reduced the number of animals used in quality testing of certain biotherapeutic drugs and vaccines.
- In 2011, Baxter increased the amount of information collected per animal that reduced the number of animals necessary to fulfill specific regulatory requirements.
- When feasible, Baxter uses automated blood sampling techniques and enhanced analytics to ensure high-quality samples every time which reduces animal procedures per study and related animal stress.
- Baxter uses non-invasive, state-of-the-art technologies such as CT scans, fluorescent imaging, advanced ultrasound and fluoroscopy to decrease the need for invasive testing.
- As new testing methods become available, methods must be validated and approved in cooperation with government regulators prior to medical use of the product. Baxter adopts new, approved methods, applies new testing models and thereby reduces animal testing wherever possible. For example, Baxter is implementing strategies to reduce intermediate test steps using the rabbit pyrogen (fever-producing) test, and when possible combines lot runs to minimize the use of control test animals used in a number of product safety and potency tests.
Baxter uses a combination of animal based toxicology, pharmacology, pharmacokinetics and local irritation tests to minimize animal use, where possible.

Refinement
Baxter researchers work closely with other scientists and industry organizations to share best practices and demonstrate continual improvement. The company also supports organizations that aim to reduce the need for animal testing and promote animal welfare.

- Baxter supports the American Association for Laboratory Animal Science and the American College of Laboratory Animal Medicine to investigate alternatives and refinements to laboratory animal use.
- The company invests in enhanced animal housing to improve comfort and reduce stress.
- Baxter continues to adopt or advance in-vitro techniques to test the efficacy of its products that help stop bleeding in patients in life-threatening situations.
- When possible, the company uses positive reinforcement to condition animals used in studies to enable administration of test materials and collection of blood samples without the use of physical restraint or anesthetics, minimizing stress and improving data quality.
- Baxter evaluates and ensures consistently high standards for all animal housing methods and cage-level enrichments.
- Baxter is exploring using antibody levels in the blood of vaccinated animals as a surrogate marker to evaluate viral-based vaccine potency, instead of measuring the ability to resist infection with a live virus, thereby avoiding the illness stage of the test.
- Baxter adopted technology with greater detection and quantification of biological parameters to reduce the frequency and volume of samples taken from animals.

Baxter Applies Voluntary Animal Welfare Guidelines

Baxter complies with relevant animal welfare regulations and guidelines:

United States
- U.S. Animal Welfare Act Standards; and
- The Guide for the Care and Use of Laboratory Animals

Europe
- European Treaty Series No. 123 (ETS123) European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes; and
- European Directive 86/609/EEC on the protection of animals used for experimental and other scientific purposes, which will be replaced by Directive 2010/63/EU as of January 1, 2013.

International
- World Health Organization Council for International Organizations of Medical Sciences International Guiding Principles for Biomedical Research Involving Animals
- Association for the Assessment and Accreditation of Laboratory Animal Care International
- National Research Council: Guide for the Care and Use of Laboratory Animals (revised 2011 version); and

1In-vitro tests are performed on individual cells in a lab environment versus in a living organism.

Clinical Trials
Clinical trials play an essential role in the development of new medical products and are legally required for the majority of Baxter products. The company protects the safety, well-being and privacy of clinical trial participants, as well as the completeness and integrity of data obtained from these studies. Baxter is committed to sharing results from its clinical trials with the scientific and medical communities and the broader public via publications in peer-reviewed journals, presentations at scientific and medical conferences, and postings on U.S. Food and Drug Administration or European Medicines Agency-authorized public repositories. The company's Clinical Trials Policy defines the requirements for clinical trials, studies and investigations involving human subjects that use investigational and/or marketed medicinal products and/or medical devices. The policy applies to all Baxter-sponsored studies worldwide.

Baxter adheres to standards including, but not limited to, those found in the following:
- The International Conference on Harmonization Guidelines for Industry Governing Good Clinical Practice, Good Laboratory Practices, and Good Manufacturing Practices;
• Principles that have their origin in the Declaration of Helsinki;
• Applicable privacy and data protection standards and regulations such as the U.S. Health Insurance Portability and Accountability Act regulations and other country-specific requirements; and
• The laws and regulations of the applicable country.

Clinical trials at Baxter require the prior written approval by an Independent Ethics Committee/Institutional Review Board. Study subjects must provide informed written consent before any study-related activities or assessments occur.

For any clinical trial that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome, Baxter registers the trial at www.clinicaltrials.gov.

Materials Use

Customers, governments and other stakeholders are increasingly focused on the materials and chemical substances used in products and packaging. With regard to medical products, stakeholders are especially focused on health and safety and environmental impacts, especially at product end-of-life. In some countries, legislation restricts the use of specific substances in products. Customers are also interested in which materials are recyclable, such as in packaging.

Baxter carefully considers the potential impacts of the materials it uses in its products and packaging, and takes a disciplined approach to identifying materials for possible restriction. The company focuses on the amount as well as the types of materials used, working to eliminate hazardous substances wherever possible. For its electronic products, Baxter also works to maximize product service life, reuse and recycling as appropriate. This decreases the demand for virgin materials to produce new products.

In 2012, Baxter purchased more than 215,000 metric tons of major commodities for use in its products and packaging, in addition to pre-manufactured components (see Major Materials Purchased for Manufacturing). The company continues working to improve the efficiency of its materials use. Baxter implemented projects that reduced total packaging by 850 metric tons in 2012, on an annualized basis1 (see Packaging for details). Because plastic scrap from manufacturing is Baxter’s largest waste stream, generating roughly one-third of the company’s non-hazardous waste, reducing plastic waste and increasing recycling is another key focus (see Waste for details).

Product Design

Baxter’s research and development and manufacturing operations work with environmental, health and safety (EHS) specialists to ensure that new products meet robust environmental design principles, comply with environmental regulations and satisfy customer requirements. As part of the company’s product development process, Baxter applies a Product Sustainability Review (PSR) to all new medical devices, assessing EHS impacts across the product life cycle, including those related to materials selection and use. For example, new electrical and electronic devices under development are designed to meet the European Union’s Restriction on Hazardous Substances (RoHS) Directive guidelines wherever they are sold worldwide. All devices are screened for the presence of chemicals from the REACH (Registration, Evaluation and Authorisation and Restriction of Chemicals) Regulation list of “Substances of Very High Concern” (SVHCs) and are considered for elimination.

Supplementing PSR, Baxter also uses formal life cycle assessment to evaluate the environmental performance of its products and determine ways to reduce their environmental footprints. This may include decreasing the presence of chemicals of concern and reducing life cycle water or energy consumption, carbon footprint and waste generation. See Product Sustainability Review for more detail.

Reporting Material Use

Customers and governmental regulations increasingly require companies to disclose information about materials and chemical substances used in products and manufacturing. However, effectively tracking and reporting this data is complex given the number and evolution of these standards, and since a product may contain components from numerous suppliers worldwide.
To better meet this challenge, Baxter is implementing a global project to determine and record in one resource the material chemical content of all substances and parts purchased for use in Baxter’s products. The project also seeks to better understand what, if any, key chemicals of concern are present and to meet global regulations, such as the RoHS Directive and REACH Regulation (see Case Study: Materials Restrictions). To date, the company has gathered information from suppliers for about 44 percent of its product components (out of a total of tens of thousands of parts overall). Through this process, Baxter has identified the presence of SVHCs in some components and improved its understanding of which suppliers and components may pose a higher risk in this regard.

The next phase of the project, beginning in 2013, will target an expanded list of components and the substances included in the initial phase, as well as additional SVHC’s from the REACH Directive list, as it expands. In addition to materials restricted by regulations, the company is also gathering information about substances such as bisphenol-A (BPA) and latex, which are of interest to some customers.

As Baxter receives information from a larger percentage of its suppliers covering a higher proportion of components used in its products, the company anticipates that the quality of the data collected will continue to improve. Nonetheless, ensuring compliance will require ongoing expansion of supplier engagement, working with new suppliers, and potentially modifying product designs.

Additionally, the Dodd-Frank Act requires companies to file annual reports with the U.S. Securities and Exchange Commission beginning May 31, 2014, indicating if their products contain tantalum, tin, tungsten or gold originating from the Democratic Republic of Congo or adjoining countries (known as “conflict minerals”). Baxter has established an internal team that is working with its suppliers to ensure compliance with these regulations.

**Materials Innovations**

To meet the preferences of some customers and address drug compatibility issues in specific clinical applications, Baxter has invested and continues to allocate significant resources to develop a variety of materials that meet the unique and evolving technical, design, regulatory, clinical and commercial requirements of individual product lines and markets. The company’s research team, headed by world-leading experts in plastics technology, considers the distinct characteristics of the solutions to be held in the containers, the performance characteristics required, the scientific data supporting safe use, regulatory requirements, environmental impact, and other aspects.

The company now offers a portfolio of more than 300 intravenous medications, parenteral nutrition solutions, injectable drugs, biopharmaceuticals, IV sets and access devices and other products that use or are contained in non-DEHP [di-(2-ethylhexyl)phthalate] or non-PVC materials. See Baxter's position statement on PVC in medical products.

Baxter will continue its science-based approach toward the development and adoption of materials used in its products.

**Broader Impacts**

Baxter recognizes the interrelationship between materials choices and other environmental issues. The company estimates that in 2012 the greenhouse gas (GHG) emissions in Baxter’s supply chain attributable to Baxter’s business equaled 1,072,000 metric tons carbon dioxide equivalent (CO₂e), 23.0% of Baxter’s total GHG emissions footprint. This included raw materials extraction and processing as well as other activities (see Greenhouse Gas Emissions and Climate Change for more detail). These numbers do not include GHG emissions related to product transport (see Greenhouse Gas Emissions and Climate Change for more detail).

These savings represent the total savings attributable to identified projects across the company, counted only for the first year the packaging innovation is implemented.

**Manufacturing**

Baxter manufactures its products at more than 50 facilities in 27 countries worldwide. The company has extensive environmental, health and safety (EHS) programs to minimize environmental impacts and ensure employee safety.

Baxter generally requires third-party certification to the International Organization for Standardization (ISO) 14001 Environmental Management System Standard for the company’s manufacturing and research and development sites, and distribution sites with a capacity of at least 10,000 filled pallets or a workforce of 100 or more people. Sites that have achieved third-party ISO 14001 certification generally also pursue third-party Occupational Health and Safety Assessment Series (OHSAS) 18001 certification, which helps improve a facility’s health and safety programs. As of year-end 2012, 68 Baxter locations have met the requirements of ISO 14001 and are covered by Baxter's group certificate, and 57 company locations were certified to OHSAS 18001. See EHS Management Systems and Certifications for detail.
In 2012, Baxter continued to improve its EHS performance across its facilities globally, including in manufacturing. See Environment, Health and Safety for more detail.

Baxter also influences its suppliers’ manufacturing and other operational practices through the company's Global Supplier Sustainability Program as well as its Supplier Quality Standard and Ethics and Compliance Standards for Baxter Suppliers. See Supply Chain for more detail about Baxter's activities in this area.

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Packaging

Baxter works to decrease the environmental impact of packaging by reducing the amount used and substituting for environmentally-preferable materials. The company implemented projects in 2012 that reduced total packaging on an annualized basis by 850 metric tons. Total annualized savings since 2007 equals 5,150 metric tons, exceeding Baxter's goal to eliminate 5,000 metric tons of packaging material from products sent to customers by 2015.¹

Europe, Middle East, and Africa

In Tunis, Tunisia, Baxter installed machinery with new pouch size molds that allowed the company to reduce the size of the outer plastic pouch by 20-40%, depending on the product's size, and then replace an inner plastic pouch with a paper band. The smaller size of the outer pouch allows Baxter to fit the same quantity of products into a smaller box. Using the new machinery, the company can also print product labels directly onto the packaging instead of printing a label separately and adhering it to the product.

In Ireland, Baxter designed a renal pack unit that reduces the waste generated by dialysis treatment centers and hospitals across the country. All materials and consumables are packed together at the Baxter facility in patient specific, bar-coded treatment packs. This reduces corrugated box use as well as customer storage needs. In 2012, Baxter received the EnviroCom Award for Best Example of Waste Prevention for the project.

In Kista, Sweden, Baxter implemented a project to reduce the packaging material used to distribute products with specific temperature requirements. Changing to a cooling truck for transport eliminated the need for approximately 3 metric tons of Styrofoam packaging and saved more than $50,000 in 2012. In Marsa, Malta, Baxter implemented a project to reduce primary packaging material, top web of paper and bottom web of plastic, with savings of $20,000 and 5.6 metric tons of material in 2012.

Latin America

Baxter's facility in Cali, Colombia, completed a project in 2012 to reduce the carton weight of its intravenous (IV) sets. The new design decreased corrugated material use for six carton codes, saving approximately 32 metric tons of packaging on an annualized basis.

United States

Baxter's facility in Mountain Home, Arkansas implemented several packaging reduction projects in 2012, including decreasing the high-density polyethylene (HDPE) sheeting used to make a product’s overpouch by reducing the thickness of the sheeting. This saved 11 metric tons of material and nearly $44,000 on an annualized basis. ¹This equals the total savings attributable to identified projects across the company, counted only for the first year after the packaging innovation was implemented.

Product Use

Advertising and Promotion

The U.S. Food and Drug Administration (FDA) and other governmental agencies worldwide regulate the advertising and promotion of pharmaceuticals, medical devices and biologics. Included in FDA's oversight are print and broadcast advertising, websites, press releases, sales brochures, convention booths, and other promotional materials and activities.

Baxter's Advertising and Promotion staff manage the company's compliance with promotional regulations companywide, reviewing marketing materials for accuracy and balance in terms of presentation of product risks and benefits. The company’s approach takes into account regulations and standards which vary by region:


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• United States - Baxter’s advertising and promotion standards for all business groups incorporate best industry practices and are reviewed rigorously for compliance with the U.S. Code of Federal Regulations.

• Canada - Baxter’s advertising and promotion standards incorporate industry best practices as per Pharmaceutical Advertising Advisory Board (PAAB) guidelines and are reviewed for compliance to Health Canada regulations.

• Latin America - Baxter applies advertising and promotion standard review procedures to ensure compliance with local and regional marketing promotion codes and regulations.

• Europe - Baxter ensures that marketing materials for distribution in the region comply with applicable laws and regulations as well as with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code of Practice on the promotion of prescription-only medicines to, and interactions with, healthcare professionals. The company’s procedures ensure review of marketing materials at the pan-European level, as well as at the country level for compliance with local codes of practice and national product licenses. Baxter also adheres to the EUcomed UNAMEC Code that covers medical devices.

• Asia Pacific - Baxter uses an electronic approval system that enables the company to comply with advertising and promotion codes, regulations and internal standards in 15 countries.

Compliance
If a company fails to comply with advertising and promotion regulations in the United States, the FDA or the Department of Justice may initiate civil or criminal enforcement actions. Enforcement actions can range from an untitled letter (the least serious) or a warning letter (an elevated action) up to a criminal indictment. In 2012 and 2011, no enforcement actions were initiated against Baxter by the FDA.

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Comparable information is not commonly available outside the United States.

See Priorities and Goals for information about Baxter’s progress against its goal to continue to champion internal and industrywide ethical sales and marketing practices.

See Access to Healthcare for information about Baxter’s approach to increasing access to healthcare globally.

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Product End-of-Life
The responsible treatment of healthcare products after customer use is an increasingly important issue worldwide. Because the appropriate approach varies by type of product, Baxter has a range of initiatives. For example, some of the electronic medical devices Baxter sells, such as renal automated peritoneal dialysis cyclers, are well suited to repair and refurbishment after the original customer has finished using them (see below). Many of the company’s other products, such as intravenous (IV) bags, cannot be reused due to regulatory, quality and safety reasons. However, they may be responsibly recycled to recover energy and materials for other uses.

Electronic Products
In some countries, Baxter leases most of its electronic medical products to customers, which helps ensure they will be returned to Baxter after a set period of time. As appropriate, the company repairs and refurbishes those products, which extends their useful life and decreases the environmental impacts of product disposal and new product manufacture.

At times, reuse is not feasible, and regulations in many countries worldwide promote responsible recycling. For example, the European Union (EU) Waste Electrical and Electronic Equipment (WEEE) Directive requires companies to arrange for the take-back of electronic products at end-of-life to enable the recovery and recycling of product components and materials. This regulation impacts certain Baxter products in the EU such as dialysis machines, IV pumps and other electronic devices. In 2012, approximately 100 metric tons of electronic products and batteries were recovered in the region on Baxter’s behalf.

During the year, regulators enacted a revision of the WEEE Directive that sets recovery and recycling targets for non-implantable, electronic medical devices sold in the EU. Those target rates, which can vary by country and apply to product categories as opposed to
Individual producers, will increase over time. The updated Directive also establishes requirements related to transnational shipments of used electronic products for manufacturers selling those products in the region.

Baxter’s WEEE website provides customers detailed information on WEEE and how to dispose of Baxter products in accordance with the Directive, in each of the European Union Member States.

When customers return products to Baxter that contain batteries, or when Baxter repairs those products on-site, Baxter sends the batteries to a recycler when feasible, or otherwise provides for responsible disposal.

Disposable Medical Waste

Baxter has worked with customers, industry peers, and recycling and disposal vendors to facilitate the recycling and responsible treatment of disposable medical products. The company is a member of the Healthcare Plastics Recycling Council (HPRC), an alliance of global healthcare companies focused on the recycling of plastic products in hospitals. Baxter was one of 11 companies involved with HPRC to develop the Design Guidelines for Optimal Hospital Plastics Recycling, primarily intended for product designers and users of disposable medical devices.

Through an HPRC initiative, Baxter collaborated on a study with Kaiser Permanente Los Angeles Medical Center to conduct a value stream mapping of all waste generated at the hospital, including pre-patient disposable medical waste. The team used Lean principles to understand the critical processes that contribute to waste generation and to establish a materials and waste baseline. Based on this information, the group identified priority focus areas and plans for program design, implementation, measurement and reporting.

Baxter continues to seek other opportunities to partner with waste management and recycling firms to test the economic and logistical feasibility of more efficient management of wastes generated from Baxter IV products. Possibilities include creating products from recycled materials that can be reused in the medical supply chain, such as plastic pallets made from mixed IV bags or packaging.

For example, Baxter partnered with the Vinyl Council of Australia (VCA) to launch the VCA’s PVC Recovery in Hospitals program in Toongabbie in early 2013. This initiative collects used PVC medical products for recycling into new products, such as garden hoses. The organization initially introduced the program to hospitals in Sydney, and plans to roll it out countrywide.

Global Audit Program

Baxter’s global audit program covers all regulated or medical waste recycling or disposal sites that the company uses for waste generated internally. As part of this program, before using a medical waste recycling or disposal vendor, trained Baxter auditors assess the vendor for compliance with Baxter’s requirements. Repeat audits are then conducted at least once every four years. These audits examine all aspects of operations, including site history, regulatory compliance, financial conditions, insurance, and other factors. Baxter has audited and approved more than 230 regulated or medical waste recycling or disposal sites through this program.

Case Study: Engaging with Stakeholders on Product Environmental Performance

Product environmental performance is an issue of growing importance in the healthcare sector. Baxter works to understand customer needs in this area, and to reflect those in product design and communications when feasible. Due to the complexity of these issues, in some cases Baxter collaborates with other organizations to develop ways to improve performance across the industry.

Customer Environmental Requirements and Preferences

Customers and group purchasing organizations in most countries in Europe as well as the United States (especially California) increasingly require information related to product environmental performance in requests for proposal and consider that information in vendor selection. The two leading customer product sustainability issues are eliminating or decreasing materials of concern such as PVC, DEHP and mercury and reducing waste (packaging and disposables).

Similarly, governments increasingly set environmental criteria for “greener” public procurement. For example, nearly all tenders in the United Kingdom include Environment, Health and Safety (EHS)-related questions. Throughout Europe, EHS-related questions represent on average 5% of the total weighting of tenders that Baxter receives.
Baxter reflects these requirements and preferences in product design through its Product Sustainability Review process. The company responds to targeted customer requests and engages with customers as appropriate to share information about products. Baxter also highlights product environmental performance for two products using the Carbon Trust certification:

- Baxter has continued the global marketing roll-out of FLEXBUMIN [Albumin (Human)], which is the world's first medical product to receive Carbon Trust certification (in 2009, re-certified in early 2012).
- In 2011, Baxter also received Carbon Trust certification for the company's new family of XENIUM+ synthetic dialyzers.

In 2013, Baxter plans to highlight the enhanced environmental performance of an additional new product at launch.

To address specific questions that customers might have about materials, Baxter also provides access to a searchable database of Safety Data Sheets for all relevant products, in more than 25 languages.

**Industry Collaboration**

Reflecting the sizable environmental impacts of the healthcare sector, Baxter promotes improved performance across the industry. In 2009, the UK National Health Service (NHS) Sustainable Development Unit (SDU) conducted a carbon footprinting exercise and determined that the procurement of goods and services from the healthcare supply chain accounted for 65% of the total greenhouse gas (GHG) emissions of NHS England, with almost half attributable to pharmaceutical products and medical devices.

To encourage sound disclosure in this area, Baxter recently collaborated with the UK NHS SDU, Environmental Resources Management (ERM), and other industry representatives to create the first ever Pharmaceutical and Medical Device Sector Guidance for Product Life Cycle Accounting. Built upon the GHG Protocol Product Life Cycle Accounting and Reporting Standard methodology, the document provides sector-specific guidance to enable consistent and comparable reporting. The guidance publication was launched in late-2012.

"If healthcare providers are to meet demanding climate change targets, it's important that they gain a better understanding of the greenhouse gas emissions associated with all parts of a health system, and identify the carbon intensive "hotspots," said Sonia Roschnik from the NHS SDU. "I am confident that developing such guidance will help us to achieve this."

Additionally, in 2013 Baxter joined Practice Greenhealth, a nonprofit membership organization founded on the principles of positive environmental stewardship and best practices by organizations in the healthcare community.

**Case Study: Materials Restrictions**

The European Union (EU) Restriction on Hazardous Substances (RoHS) Directive seeks to phase out the use of lead, mercury, cadmium, hexavalent chromium and brominated flame retardants used in electronic products such as computers, televisions and mobile phones. This is principally aimed at minimizing negative environmental impacts from these substances throughout the product life cycle, in particular at product end-of-life.

Although exempt from the original Directive, medical devices will fall within the scope of the RoHS2 Directive beginning in July 2014. After that time, new medical devices that contain, subject to certain thresholds, the substances listed above cannot be placed on the EU market. To comply with the directive, manufacturers must provide documentation demonstrating conformity of relevant products to the requirements. Furthermore, countries such as China, South Korea, Taiwan and some U.S. states such as California have already enacted legislation similar to RoHS2. Baxter is implementing a global strategy to respond to these regulations worldwide, and requires that all new electrical and electronic equipment under development meet RoHS and RoHS2 Directive restrictions.

Baxter is also working to ensure it meets the European Union's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Regulation. Under the legislation, chemical suppliers, manufacturers or importers of more than one metric ton of a chemical substance in a given year must register the substance with the European Chemical Agency. The regulation expands significantly the number of substances that will require authorization for use, identifies "Substances of Very High Concern" that may face future restrictions, and requires companies to proactively inform customers about the presence of those substances in products. Baxter has registered all required substances and preparations following the regulation.

Baxter's cross-functional REACH team oversees the company's ongoing response to this regulation and explores further opportunities to eliminate hazardous substances. To keep informed of these sorts of trends, Baxter's global Environmental, Health and Safety (EHS) organization assesses existing, new and emerging environmental regulations to identify and prioritize critical business issues,
benchmarks Baxter’s performance against others in the industry, and helps the company develop positions and strategies aimed at improving its environmental performance

See Materials Use for more information.

1 As defined by the RoHS2 Directive, maximum concentrations allowed are 0.1% by weight of homogeneous material for all substances except for cadmium which is restricted to 0.01% by weight.

2 As defined by REACH Regulation, “presence” equals at least 0.1% of the total product mass.