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 efforts range from focusing on sustainable design and bioethics during research and development, to efficient use of energy and materials during manufacturing and transport, to appropriate product advertising and promotion, and finally, responsible repair, refurbishment and recycling at product end-of-life.

In combination with its history of innovation, Baxter has programs to ensure high standards in quality, safety and product integrity.

The following graphic illustrates the breadth and depth of Baxter’s approach.
### Sustainability Issues Across the Product Life Cycle

#### R&D and Design

<table>
<thead>
<tr>
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<th>Approach</th>
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<tr>
<td>Sustainable Design</td>
<td>Product Sustainability Review &gt; Life cycle assessment &gt; Device Center of Excellence</td>
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<td>Bioethics</td>
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<td>Clinical Trials</td>
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<td>Animal Welfare</td>
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<table>
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<tr>
<td>Materials Selection/Reduction/Innovation Restricted Materials</td>
<td>Product Sustainability Review &gt; Supplier screening &gt; Evaluation of chemicals of concern &gt; Product stewardship software application &gt; Compliance with RoHS and REACH Directives &gt; Non-PVC and non-DEHP materials</td>
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#### Manufacturing

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<tr>
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<tr>
<td>Environmental Impacts</td>
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#### Product Transport

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<td>Intermodal transport and modal shift &gt; Increased capacity utilization &gt; Technology innovation &gt; U.S. Renal truck fleet &gt; Pallet programs &gt; Environmentally responsible transportation partnerships</td>
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#### Packaging

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<th>Issue</th>
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<tr>
<td>Minimizing Packaging Materials Selection</td>
<td>Materials reduction &gt; Materials substitution &gt; Packaging reuse</td>
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### Product Use

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<th>Issue</th>
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<tr>
<td>Advertising and Promotion</td>
<td>Compliance with promotional regulations companywide &gt; U.S. and international policies for interactions with healthcare practitioners, medical institutions and patient organizations</td>
</tr>
<tr>
<td>Safe Handling and Use</td>
<td>Material Safety Data Sheets &gt; Clinical education</td>
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<tr>
<td>Access to Healthcare</td>
<td>Product development &gt; &quot;Base of the Pyramid&quot; initiatives &gt; Strategic product donations</td>
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### Product End-of-Life

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<td>Responsible Reuse, Recycling and Disposal</td>
<td>Product take-back, repair and recycling programs &gt; Minimization of customer waste &gt; Industry collaborations</td>
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</table>
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 in this area. 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 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 preventative 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 if it might leverage the improvements on a broader basis.
Safety

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. The company also collaborates with hospitals to assess their processes to address patient safety, 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
- Focusing on Decreasing Medication Errors
- Addressing Parenteral Nutrition Safety
- 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 does 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 reduce pathogens, many hospitals, particularly in developing countries, continue to use open systems. The compatibility of the Baxter IV System with both infusion pump therapy and gravity applications can help nurses maintain a closed IV system that meets safety standards for IV replacement. Baxter’s IV Standard Set Closed System can reduce the number of set-ups and teardowns which can decrease the risk of touch contamination.

Baxter works with governments and healthcare providers to help conduct studies, set standards and implement conversion to closed IV systems in numerous markets to improve public health. For example, Baxter worked with the government of Brazil, which now requires all of the country’s nearly 8,000 hospitals to use closed IV systems, to convert to closed systems throughout the country. In Colombia, where the government now recommends closed systems, approximately 75% of hospitals have converted. In 2010, Baxter worked with four Ministry of Health-affiliated hospitals in Mexico to implement closed systems.

In 2008, Baxter launched the V-LINK with VitalShield protective coating device, the first needle-less IV connector with an antimicrobial coating. In vitro testing has shown that the device killed at least 99.99% of six common pathogens known to cause catheter-related bloodstream infections, including MRSA. The reduction in colonization or microbial growth on the device has not been shown to correlate with a reduction in infections. The antimicrobial agent is not intended to be used as a treatment for existing infections. VitalShield protective coating is contraindicated in patients with hypersensitivity to silver or silver components.
Focusing on Decreasing Medication Errors

The Institute of Medicine in the United States estimates that medication errors injure 1.5 million people each year, and that 7,000 die annually as a result. Other research shows even more severe mortality statistics in other countries.

Baxter helps address potential medication errors in several ways. The company’s premixed IV drugs are ready to use so hospital pharmacists do not have to prepare these critical drugs 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.

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. In August 2011, for example, Baxter partnered with Cho Ray Hospital in Ho Chi Minh City, Vietnam, to establish a center for compounding IV therapy, the first of such a facility to be located in a Vietnam hospital. The new Vietnam IV Admixture (VIVA) Center is dedicated to compounding IV chemotherapy for about 80 patients a day.

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, which present challenges for conventional bar-code technology.

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 feature capabilities. Within the pipeline is a syringe infusion pump that has been submitted to the U.S. Food and Drug Administration (FDA) for review and clearance. The 510(k) is pending and the pump is currently for available for sale in the U.S. Syringe pumps are small infusion pumps used to deliver more precise amounts of IV medications and fluids to patients.

Baxter’s Medical Products business also helps hospitals through its Connections Portfolio, which focuses on three key principles - simplification, streamlining and standardization. These programs, administered by Baxter clinical experts, are based on objective observational, interviewing, and data collection methodology that identify opportunities for improvement in practice and product utilization. In addition, the clinical offerings help to increase staff productivity and patient safety and includes specific recommendations and action plans to improve alignment with nationally recognized regulations, standards and guidelines. In 2011, Baxter launched the Tubing Misconnections Self-Assessment for Healthcare Facilities, designed to help institutions identify products and practices that pose a risk of inadvertent tubing misconnections. The objectives are to:

- Identify and prioritize devices and practices vulnerable to tubing misconnections,
- Establish processes and device selection protocols to safeguard against misconnections.
Addressing Parenteral Nutrition Safety

Parenteral nutrition (PN), commonly referred to as IV nutrition, is one way that people receive nutrition when they cannot eat. Instead, nutrition is supplied through an IV tube inserted directly into the veins. The amount, type, and method of nutrition are tailored to each patient to meet their nutritional needs. Preparing and delivering this type of nutrition involves complex sterile preparations which must be performed in a carefully controlled environment with quality control measures in place from prescription to formulation and delivery. When these quality control measures are not in place, product sterility, stability and compatibility can be impacted, potentially putting patients at risk.

In September 2011, leaders from several major safety associations came together to organize a PN Safety Summit. Baxter, a leading maker of PN therapies, sponsored the summit, hosted by the American Society for Parenteral and Enteral Nutrition (ASPEN). At the event, experts in clinical nutrition discussed safety issues surrounding PN and developed recommendations for improvement, including increased standardization of prescription processes, order review and verification and formulation processing, as well as additional education for PN prescribers.

One of the safety issues covered was the ongoing shortage of vitamins, electrolytes and other IV nutrition ingredients that has critically impacted hospitals nationwide. A 2011 study by the American Hospital Association found that 89% of U.S. hospitals have experienced nutrition product shortages. Further, drug shortages within a six-month period led to 58% of patients requiring IV nutrition receiving a nutritional formulation that may not have addressed all of their nutritional needs and 32% experiencing an adverse outcome. Organizations such as ASPEN and Baxter are working to address these shortages to ensure patients continue to receive the life-sustaining therapies they need.

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 Food and Drug Administration (FDA), the Drug Enforcement Agency (DEA), the Environmental Protection Agency (EPA), the Occupational Health and Safety Administration (OSHA), the Department of Agriculture (USDA), the Department of Labor, the Department of Defense (DOD), Customs and Border Protection (CBP), 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, as well as other governmental agencies worldwide, administers 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 notification of revised labeling, correction of the problem at the customer location, withdrawal of the product from the market and/or other actions.

For example, Baxter’s COLLEAGUE Volumetric Infusion Pump is an electronic device that controls the flow of IV drugs to patients. In 2005, Baxter notified customers of several issues that had the potential to disrupt the delivery of therapy and placed a hold on shipments of new pumps until these problems could be corrected. The FDA classified this as a Class 1 recall, the most serious type of recall, with potential for death and injury. In June 2006, Baxter announced a consent decree with the FDA under which the company pursued remediation of the pumps.

Additional Class 1 recalls related to remediation and repair and maintenance activities of COLLEAGUE infusion pumps were addressed by the company in 2007 and 2009. Pursuant to the consent decree, in July 2010, the FDA ordered removal of all COLLEAGUE infusion pumps in the United States by July 14, 2012. Baxter has been executing the removal these pumps, offering eligible customers a refund or an option to replace them.

In December 2010, Baxter informed the Medicines and Healthcare products Regulatory Agency (MHRA) and other EU Authorities that endotoxins had been detected in some batches of its peritoneal dialysis (PD) solutions manufactured at its Castlebar, Ireland facility. In PD patients, endotoxins can potentially cause an inflammatory reaction known as sterile peritonitis. While only a very small proportion of bags were likely to contain endotoxins, these could not be identified. In response to this finding, Baxter shut down production of the solutions at this plant to investigate the problem, and the European Medicines Agency (EMA) recommended that all potentially affected PD solutions be withdrawn as soon as replacement product became available to meet patients’ need. The company worked closely with EMA and its Committee for Medicinal Products for Human Use (CHMP) to ensure the production of endotoxin-free PD solutions. In October 2011 following its inspection of the Castlebar site, the Irish Medicine board confirmed the reinstatement of the facility’s good manufacturing practice status, authorizing it to resume the release of PD solution products.

Additional details on regulatory matters currently being addressed by the company are available under the heading “Certain Regulatory Matters” in Baxter’s most recent filing with the U.S. Securities and Exchange Commission on Form 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 SEC filing on 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.

3 Preventing Medication Errors,” Institute of Medicine, July 2006.
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.

![Diagram of Product Integrity]

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 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, adverse event 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, including restrictions in some markets regarding the destruction of product packaging.

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, Pharmaceutical Security Institute, 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.
Product Sustainability Review

The design stage offers a unique opportunity to shape a product’s environmental, health and safety (EHS) performance across the life cycle. During this phase, decisions are made regarding materials selection, characteristics including energy use that influence carbon footprint, features that affect recyclability, and other factors.

For this reason, Baxter includes Product Sustainability Review (PSR) during the early stages of the product development process. PSR is a two-step assessment of a product’s projected EHS impacts. 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).

The second step is a comprehensive review that identifies improvement opportunities across the life cycle. This process 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 has historically 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.


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In 2011, the company continued to expand use of PSR to therapeutics products in its BioScience business. Beginning in 2012, the product development process for these products will include a requirement to conduct a PSR. When fully implemented, nearly all new products Baxter introduces will complete the PSR process.

PSR also provides a process to integrate compliance considerations for existing and upcoming product regulations. In 2008, Baxter enhanced the PSR screen for toxic chemicals, and updates this screen periodically to reflect changes in regulation and other factors. This enhancement helps the company meet growing customer demands to limit these substances and also helps Baxter prepare for potential chemical restrictions under the European Union REACH (Registration, Evaluation, Authorisation and Restriction of Chemical substances) regulation. Through the PSR process, requirements regarding materials selection are documented in the product design history file. See Case Study: Materials Restrictions for more information about Baxter’s approach related to product materials.

PSR has yielded positive results. Several reviews have influenced materials selection, and Baxter requires that all new machines under development meet the European Union Restriction of Hazardous Substances (RoHS) Directive restrictions regarding heavy metals. Even though these products are currently exempt, medical devices will fall under the scope of the revised RoHS Directive in 2014. Recent reviews also stipulate that new product designs should limit the use of "Substances of Very High Concern" as listed under REACH regulation.

**Life Cycle Assessment**

Supplementing PSR, Baxter also uses formal 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, carbon footprint and waste generation.

During 2011, Baxter used LCA to take environmental impacts into account in 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 new family of XENIUM+ dialyzers is 13-22 percent lighter than earlier versions, which offers the potential for reduced fuel consumption in shipping and biohazard waste removal. XENIUM+ dialyzers also use approximately one-third less cardboard in their packaging, reducing natural resource use and waste removal requirements. 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, see below, was the first).

In 2009, Baxter completed several externally verified LCAs demonstrating the significant environmental benefits of FLEXBUMIN [Albumin (Human)] - the first and only human albumin solution in a flexible, plastic container - compared to a similar product in a glass bottle. In addition to enhancing convenience for customers and users, the FLEXBUMIN container system has a 55-77% smaller carbon footprint, depending on product size and geography. (See Case Study: FLEXBUMIN Life Cycle Assessment for more detail).

**Engaging with Customers**

Customers in Europe and the United States increasingly require information related to product environmental performance in requests for proposal and consider that information in vendor selection. Baxter reflects these requirements in the PSR process, such as the need to avoid certain chemicals of concern. The company responds to targeted customer requests and engages with customers as...
appropriate to share information about products. Baxter also provides access to a searchable database of Materials Safety Data Sheets for all relevant products, in more than 25 languages.

Similarly, governments increasingly set environmental criteria for “greener” public procurement. For example, nearly all tenders in the United Kingdom include EHS-related questions. Throughout all of Europe, EHS-related questions can represent up to 20% of the total weighting of tenders.

Representatives from Baxter’s EHS and Supply Chain teams met with diverse audiences across the company during 2011 to provide background about the evolving customer landscape, as well as related regulatory trends, and how to best respond to these emerging information needs and legislation. Building on this, in 2012 meetings are planned on these issues with each Baxter franchise globally as well as the company’s Research and Development organization.

Baxter believes that leadership in this area will represent an increasing source of competitive advantage, and proactively communicates information about product environmental performance. Recent examples include:

• Baxter has continued the global marketing roll-out of FLEXBUMIN [Albumin (Human)], which is the world’s first medical product to receive Carbon Reduction certification from the Carbon Trust (in 2009, re-certified in early 2012).

• In 2011, Baxter also received Carbon Trust certification for Baxter’s new family of XENIUM+ synthetic dialyzers.

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


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

3 Human albumin, which is an essential protein found in human plasma, is used to treat critically ill patients by replacing lost fluid and maintaining adequate blood pressure and volume.
Bioethics

At Baxter, bioethics covers a range of issues, including Animal Welfare, Clinical Trials, 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. Baxter’s senior leadership considers these principles, in addition to the advice of scientific and ethical advisors, to determine whether to proceed in areas requiring consideration of bioethical issues. To be justified, the potential benefits to individual subjects and society must be equal to or exceed possible risks.

For more information, see Baxter’s Bioethics Position Statements.
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 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) and are in compliance with Public Health Service Policy as governed by the Office of Laboratory Animal Welfare of the U.S. Department of Health and Human Services. 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 is sponsored by the company’s Chief Science and Innovation Officer Norbert G. Riedel, PhD, and 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.


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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.

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
- American Society of Laboratory Animal Practitioners
- Council on Research for American Veterinary Medical Association

**Europe**
- The European Partnership for Alternative Approaches to Animal Testing
- Society for Laboratory Animal Science;
- Federation of European Laboratory Animal Science Associations

**International**
- The Association for Assessment and Accreditation of Laboratory Animal Care International
- The International Association of Bioethics

**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 several implemented in 2011 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 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 investigating 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.

Animal Welfare Regulations and Guidelines

Baxter complies with relevant animal welfare regulations and guidelines:

United States

- U.S. Animal Welfare Act Standards; and
- Health Research Extension Act (based on The Guide for the Care and Use of Laboratory Animals).

Europe

- European Treaty Series No. 123 (ETS 123) 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

\(^1\) In-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 a legally required part of the research process for many Baxter products. Baxter protects the safety, well-being and privacy of clinical trial participants, as well as the completeness and integrity of data obtained from these studies. The company is committed to sharing results from its clinical trials with the scientific and medical community and the broader public via publications in peer-reviewed journals, presentations at scientific and medical conferences, as well as postings on U.S. Food and Drug Administration or European Medicines Agency-authorized public repositories. Baxter’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;
- International Ethical Guidelines for Biomedical Research Involving Human Subjects;
- European Union Medical Device Directives and U.S. Code of Federal Regulations Part 812 on medical devices;
- 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 require the prior written approval by an Independent Ethics Committee/Institutional Review Board. Before any study-related activities or assessments occur, study subjects must provide informed written consent.

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 will register the trial at www.clinicaltrials.gov within three weeks after the first subject has been recruited.
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 (see Case Study: Materials Restrictions). Customers are also interested in which materials are recyclable, such as in product 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 2011, Baxter purchased more than 150,000 metric tons of major commodities for use in its products and packaging, in addition to pre-manufactured components (see Major Materials Used in Manufacturing). The company continues working to improve the efficiency of its materials use. Baxter implemented projects that reduced total packaging by 1,100 metric tons and corrugated cardboard consumption by 732 metric tons in 2010-2011, on an annualized basis (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. This includes an enhanced screen for toxic chemicals, which Baxter works to eliminate when feasible. For example, new devices under development are designed to meet the European Union's Restriction on Hazardous Substances (RoHS) Directive guidelines worldwide and to avoid chemicals from the REACH (Registration, Evaluation and Authorisation and Restriction of Chemicals) Directive list of "Substances of Very High Concern" as is appropriate.

Supplementing PSR, Baxter also uses formal life cycle assessment 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, 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 complying with these regulations 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 and REACH Directives. To date, the company has gathered information from more than 1,000 suppliers for about half of its product components (out of a total of tens of thousands of parts overall). Ensuring compliance will require heightened levels of supplier engagement, working with new suppliers, and potentially modifying product designs.

Baxter is implementing a product stewardship software application to manage this environmental and other information related to new and existing products. This system will interface with other company product information systems as well as supplier information systems.

Materials Innovations

To meet the preferences of some customers and address drug compatibility issues in specific clinical applications, Baxter has invested significant resources to develop a variety of materials that meet the unique technical, design, regulatory, clinical and commercial requirements of individual product lines and markets. 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.

Broader Impacts

Baxter recognizes the interrelationship between materials choices and other environmental issues. The company estimates that in 2011 the greenhouse gas emissions in Baxter’s supply chain attributable to Baxter’s business equaled 1,121,000 metric tons carbon dioxide equivalent (CO\(_2\)e), 23.1% of Baxter’s total GHG emissions footprint. This included an estimated 266,000 metric tons CO\(_2\)e for Baxter’s first-tier suppliers, and 855,000 metric tons CO\(_2\)e for emissions from sub-tier suppliers, including 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.

1 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 during the manufacture of Baxter’s products.

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 more than 10,000 filled pallets or a workforce of 100 or more people. Manufacturing, research and development, and distribution sites that have achieved third-party ISO 14001 certification generally also pursue third-party Occupational Health and Safety Assessment Series (OHSAS) 18001 certification, as it helps improve a facility’s health and safety programs. As of year-end 2011, 66 Baxter locations (including all but one meeting the criteria outlined above) have met the requirements of ISO 14001 and are covered by Baxter’s group certificate, and 50 Baxter locations were certified to OHSAS 18001. See EHS Management Systems and Certifications for detail.

In 2011, Baxter continued to improve its environmental and health and safety performance in manufacturing. See Environment, Health and Safety for more detail.

Baxter also influences its suppliers’ manufacturing and other operational practices through its Ethics and Compliance Standards for Baxter Suppliers and the company’s e-impact program. See Supply Chain for more detail about Baxter's activities in this area.
Baxter transports large amounts of raw materials and more than 100 million cases of finished products each year throughout the company’s global supply chain. In some instances, Baxter directly operates its product distribution system. For example, Baxter manages its own private, and third party fleets, to transport its frozen therapies and to home deliver Renal products, and it distributes some of its products in selected regions, such as Europe. In other cases, Baxter partners with third-party vendors and carriers.

Baxter uses several approaches to decrease the environmental impact, including associated greenhouse gas (GHG) emissions, of product transport:

- Intermodal Transport
- Capacity Utilization and Technology Innovation
- U.S. Renal Truck Fleet
- Pallet Programs
- Environmentally Responsible Partnerships
- Measuring Performance

Intermodal Transport

Different modes of transport - such as air, ocean, river barges, trucks and rail - have varying levels of environmental impact. This is largely because they use different amounts of fuel per ton of product shipped. Given Baxter’s current product mix and global reach, intermodal transport, which combines multiple modes for a single shipment, offers the greatest opportunity for the company to save costs and reduce GHG emissions related to product transportation.

Baxter has increased its use of intermodal transport in Europe and the United States since 2002 to shift toward more energy-efficient modes. Shipping containers are moved from manufacturing plants by truck and then transferred to more efficient and cost-effective rail or barge transport for longer distances, and then shifted back to truck for final delivery. This increases fuel efficiency per ton of product transported, decreases costs and reduces emissions.

<table>
<thead>
<tr>
<th>Annual GHG Emissions Reductions from Total Shipments Using Intermodal Transport in the United States*</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermodal Loads</td>
<td>6,750</td>
<td>7,620</td>
<td>7,800</td>
</tr>
<tr>
<td>Calculated Fuel Savings (liters)**</td>
<td>6,671,900</td>
<td>7,325,610</td>
<td>7,354,830</td>
</tr>
<tr>
<td>Metric Tons of carbon dioxide equivalent (CO₂e) Emissions Reduced</td>
<td>18,010</td>
<td>19,780</td>
<td>19,860</td>
</tr>
</tbody>
</table>
In 2011, Baxter revised its methodology to track intermodal shipments in the United States. As a result, the company updated the data in this table for 2009-2010.

** Calculated fuel savings is the difference between the total calculated fuel use of intermodal shipments versus truck shipments on the same routes.

As part of the above effort, Baxter has increased the use of intermodal transport at to replenish its U.S. distribution network from 24% in 2009 to 27% in 2011.

Baxter also conducts route-by-route analysis in Europe to assess and implement possible shifts to intermodal transport. Changing from truck to other modes of transport in the region reduced GHG emissions by approximately 10,000 metric tons CO\textsubscript{2}e in 2011 based on changes implemented in 2010 and compared to what emissions would have been otherwise. These initiatives now cover 75% of replenishments in Europe, with 11,000 short sea loads reducing CO\textsubscript{2}e emissions by 80% and 4,000 rail loads decreasing CO\textsubscript{2}e emissions by 60% during the year.

**Capacity Utilization and Technology Innovation**

Baxter also improves transport efficiencies by increasing capacity utilization. For example, use of double-deck trucks to replenish distribution centers across Europe has enabled Baxter to transport loads in two trucks that have historically required three. In 2011, this reduced CO\textsubscript{2}e emissions by 101 metric tons. Baxter also works to ensure that trucks are at maximum load capacity, including through collaboration with business partners, reducing the number of trucks required.

In Northampton, United Kingdom, Baxter worked with third-party logistics providers to utilize a highly aerodynamic teardrop-shaped truck design, which features a full-length curved roof with rounded corners that improve air flow and reduce drag force. The design decreases CO\textsubscript{2}e emissions by approximately 18% while increasing cubic storage volume by 10%. Currently, approximately 50% of Baxter’s dedicated fleet in the United Kingdom use this model.

**U.S. Renal Truck Fleet**

As the largest part of Baxter’s internally managed product transport system, the company’s U.S. Renal truck fleet provides home delivery of peritoneal dialysis (PD) supplies to thousands of PD patients each day. During the last few years, improvements with environmental benefits have included the following:

- Requiring new trucks to use nose cones that improve aerodynamics and increase fuel efficiency;
- Installing onboard computers to monitor and reduce truck idle times, and incorporating a second-generation system with revised fleet delivery software to enhance efficiency;
- Capping fleet speeds at 62 miles per hour to optimize fuel usage; and
- Replacing approximately 20% of the existing fleet with newer, more efficient vehicles annually (for example, in 2011 Baxter replaced five existing vehicles with more fuel efficient trucks utilizing Selective Catalytic Reduction (SCR) technology, which neutralizes nitrogen oxides (NOx) in the exhaust stream and improves fuel efficiency by up to 5%).

These initiatives reduced total U.S. Renal fleet emissions by approximately 1.1% and increased fuel economy by 1.1% in 2011 compared to 2010. Baxter also increased the monthly number of deliveries per driver from 141 in 2009 to 149 in 2011.
Baxter also added several new safety features to five of its trucks in 2011 that will help reduce work-related injuries among its drivers. These include cameras to assist drivers while reversing, front fender mirrors for better blind-spot visibility, ergonomically placed grab handles on door to help reduce back muscle strain, and lift-gate switches on both sides of the truck that allow drivers to operate safely away from traffic on either side of the vehicle. Additionally, all field management teams and drivers completed a safety training course in 2011. Read more about Baxter’s efforts in this area in the Health and Safety Performance and Safety Program Management and Initiatives sections of the report.

Pallet Programs

Wooden pallets are used to consolidate cases of products for transport and to move products within Baxter facilities. Baxter works to use pallets more efficiently to save materials and cost. In Europe, for example, pallet programs within and across Baxter facilities, mainly in the United Kingdom and Spain, improved pallet utilization and enabled the company to reuse more than 80,000 pallets in 2011, saving nearly $600,000. In Europe, Baxter also plans to recover pallets from the customer facing distribution cycle in Poland and France.

In the United Kingdom, Baxter’s Northampton distribution center uses "loadhogs" - reusable plastic caps that fit over pallets - as an alternative to shrink-wrap when shipping boxes of dialysis solutions to home patients. Baxter plans to test their use in additional facilities in Europe in 2012.

In the United States, Baxter will explore in 2012 the feasibility of using a light weight plastic pallet when shipping by air for certain international shipments. The new pallet weighs approximately 30 pounds less than the wooden pallets currently used and is reusable and recyclable.

Environmentally Responsible Partnerships

Baxter is one of a select number of companies that participate in the U.S. Environmental Protection Agency (EPA) SmartWay® program as both a Carrier Partner and a Shipper Partner. SmartWay is a partnership between the EPA and industry to reduce air pollution and GHG emissions through cleaner, more fuel efficient product transport.

Baxter became a SmartWay Carrier Partner in 2009 with its own U.S. Renal truck fleet, and achieved the highest possible score of 1.25, recognizing the company's "outstanding" commitment to utilizing commercially available fuel-saving options and actively evaluating emerging technologies that help reduce the environmental impact of its fleet.

Besides the company’s own Renal fleet, Baxter works with shipping carriers to deliver other products. In January 2011, Baxter was also accepted into the SmartWay Partnership as a Shipper. Since 2009, Baxter requires all of its carriers in the United States to be SmartWay members.

In 2011, Baxter partnered with FedEx to use its Healthcare Shared Network to transport products with specific temperature requirements in select locations in the United States. This service provides Baxter a time-definite, temperature controlled, less-than-truckload delivery service designed for the pharmaceutical and diagnostics industries, eliminating the need for special packing materials previously used to keep shipments at required temperatures. In 2011, Baxter used this service to ship more than 2,100 orders, saving Baxter approximately 35,000 coolers and 124,000 gel packs. These orders would have otherwise been shipped via air.
Through this initiative, Baxter eliminated the need for 144 metric tons of packaging material in 2011. Baxter is exploring opportunities to include additional delivery locations in the United States.

In Europe, Baxter also encourages product transportation programs that reduce GHG emissions, and considers such initiatives when awarding contracts to carriers.

In 2011, Baxter and healthcare company UCB agreed to combine their shipments to optimize product transport efficiencies in Europe. The companies believe this will help both organizations increase the speed and frequency of medicine delivery to patients, while reducing carbon footprint by 30% and cost by 10% on average per shipment, depending on the destination and the potential for transport synchronization. The initial pilot program began with destinations in Eastern Europe.

In June 2011, Baxter and its partners UCB, Tri-Vizor and H.Essers received the Innovation Award at the fourth European Supply Chain Awards ceremony organized by the World Trade Group and Supply Chain Logistics. The award recognized Baxter and the other organizations for their innovative approach to freight transportation through this program.

Measuring Performance

In 2010, Baxter redesigned its process for collecting global transportation information to measure fuel usage and calculate GHG emissions related to product transport. The company regularly reports to Baxter’s Sustainability Steering Committee on regional activities to describe the company’s efforts in this area and encourage global participation.

Baxter plans to utilize a UPS supply chain solutions model to develop a global emissions measurement system to track GHG emissions from Baxter’s product transport worldwide. Through this model, Baxter will capture product shipments made by truck, rail, air and ocean globally.
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 2011 that reduced total packaging on an annualized basis by 402 metric tons. Total annualized savings since 2007 equals 4,300 metric tons.¹

China

Baxter’s facility in Guangzhou, China, decreased the packaging associated with one of its parenteral nutrition products, without impacting product protection and usability. Reducing the thickness of the aluminum cap and stopper and eliminating the plastic hanger produced annualized savings of 44 metric tons of a combination of aluminum and plastic material.

Europe

In 2008, Baxter and its corrugate supplier in Castlebar, Ireland, initiated a project to optimize corrugate use. Weekly calls to review the previous week’s performance incorporated with daily measurement of scrap at the carton manufacturing, and weekly inventory counts of corrugate helped save approximately $79,000 annually between 2009 and 2011. The total corrugate reduction from 2008 to 2011 was 99 metric tons. After introducing a new board grade in 2011, Baxter saved an additional $300,000.

In Lessines, Belgium, Baxter implemented a process to reduce the sheeting thickness of the extrusion process for many product codes, while maintaining overall specifications and ensuring quality standards. Depending on the product code, the company reduced sheeting thickness between 1% and 2.8%, saving $318,000 and 5.3 metric tons of plastic annually.

Latin America

Projects implemented in Latin America in 2011 to reduce packaging include:

- In São Paulo, Brazil, Baxter decreased the thickness of an overpouch for 500mL bags by 0.001 inch saving approximately 25 metric tons of plastic and $100,000 on an annual basis. In addition, a second project to reduce the box size will also save a metric ton of corrugate and an additional $116,000 on an annual basis.

- Baxter’s facility in Cali, Colombia, initiated a project in 2011 to reduce the packaging size of peritoneal dialysis (PD) solution cartons. A new design decreases the amount of corrugated material per carton by 40 grams while improving box strength. The project will save approximately 34 metric tons of corrugated material on an annual basis. The site also redesigned a product’s direction insert, reducing paper use by 85%, equaling 2.5 metric tons of annualized savings.

- In 2011, Baxter’s facility in Cuernavaca, Mexico, redesigned the cardboard boxes for Baxter’s Mini-bag, 50mL, and 100mL intravenous (IV) bags configuration. The changes will save 32 metric tons of packaging annually.
In 2011, Baxter partnered with FedEx to use their Healthcare Shared Network to transport products with specific temperature requirements. This service provides temperature controlled delivery for the pharmaceutical and diagnostics industries, eliminating the need for packing materials such as coolers and gel packs to maintain required temperatures. Through this initiative, Baxter has reduced packaging by an estimated 144 metric tons on an annualized basis.

¹ This 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, scientific symposia and 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 product risks and benefits. The company’s approach takes into account regulations and standards which vary by region:

- In the United States, Baxter’s advertising and promotion standards for all business groups incorporate best practices from inside and outside the company and comply with the U.S. Code of Federal Regulations.
- In Europe, Baxter ensures that marketing materials for distribution in the region comply with the European Federation of Pharmaceutical Industries and Associations (EFPIA) Code 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.
- In 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.
- In Latin America, Baxter applies advertising and promotion standard review procedures to ensure compliance with local and regional marketing promotion codes and regulations.

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 2011, no enforcement actions were initiated against Baxter by the FDA.

<table>
<thead>
<tr>
<th></th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011</th>
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</tr>
<tr>
<td>Warning Letters</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

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.

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Access to Healthcare

Worldwide, many people lack access to Baxter’s products due to insufficient resources, inadequate healthcare infrastructure, disruption caused by natural disasters and other crises, and other factors. Baxter works to increase access to healthcare globally through product development, initiatives targeted specifically at the “base of the pyramid”\(^1\), product donations and philanthropic giving. See Access to Healthcare for more detail.

\(^1\) The term “base of the pyramid” refers to the approximately 4 billion people who each live on less than $1,500 per year, mostly in developing countries.
Product End-of-Life

The responsible treatment of healthcare products after customer use is an 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 but may be responsibly recycled to recapture 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 uses repair and refurbishment, which extends a product’s useful life and decreases the environmental impacts associated with product disposal and the manufacture of new products.

At times, reuse is not feasible and regulations worldwide reflect the recent focus on electronic product recycling. For example, the European Union 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 a range of Baxter products in Europe, including dialysis machines, IV pumps and other electronic devices. Baxter is in full compliance in all EU member states where the regulations have been adopted. In 2011, approximately 100 metric tons of electronic products were recovered on Baxter’s behalf through these programs in Europe.

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

Baxter continues to look for 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.

Baxter won the Repak Best Practice in Industry Award in 2011 for its innovative program in Ireland offering services to pick up and responsibly process waste for home renal and oncology patients. Contractors collect, process and dispose of the products as
required by law, while protecting patient confidentiality and privacy. The program also collects recyclable materials such as cardboard from patients’ homes where local authorities don’t offer this service, decreasing the amount of these materials that go to disposal. In 2011, Baxter provided waste-collection services to more than 590 home patients in Ireland through this program, collecting a total of 86 metric tons of waste.

Global Audit Program

Baxter has a global audit program covering all regulated or medical waste recycling or disposal sites that Baxter 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 200 regulated or medical waste recycling or disposal sites through this program.

1 Oncology products are classed as “hazardous” waste in Ireland which requires specialized incineration. Non-hazardous medical waste, such as over renal product pouches, bags, cassettes and shields, is classed as “ clinical” waste and is sterilized and shredded before the material is accepted for landfill.

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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.

The RoHS2 Directive was recently released. Medical devices are no longer exempt and will fall within the scope of the directive beginning in July 2014. After that time, medical devices that contain, subject to certain thresholds, the substances listed above will no longer be allowed on the EU market. Furthermore, countries such as China, South Korea, Taiwan and some U.S. states such as California have already implemented legislation similar to RoHS2. Baxter is implementing a global strategy to respond to these regulations worldwide, and requires that all new machines under development meet RoHS Directive restrictions regarding heavy metals.

Baxter is also working to ensure it meets the European Union’s REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) Directive. 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’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 in Europe 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. A global EHS team also monitors similar regulations worldwide.

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 legislation, “presence” equals at least 0.1% of the total product mass.