It's a Small World, After All

These days, a trip to the supermarket or drugstore is like a trip around the world.

Many of the products you and your family buy, the medicines you use, and the foods you eat are from other countries. Did you know, for example, that 80 percent of our seafood and 80 percent of the active ingredients in medications consumed in the United States comes from abroad?

"Global Engagement" (*www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm298576.htm*), a new, in-depth report from the Food and Drug Administration (FDA), tells how the agency works to ensure that the imported foods, medical products, and other goods it regulates meet the same high standards for safety and quality set for products manufactured domestically.

The report was compiled to provide a face and voice to FDA's global work, which includes overseas inspections and collaborations with governments in other countries, says FDA's Mary Lou Valdez, associate commissioner for international programs.

Rather than focusing on the efforts of one FDA office or center, the report describes for the first time—through data, charts, vignettes, quotes, and narratives—the global engagement efforts taking place across the agency. The report also explains some of the challenges that FDA faces in fulfilling its mission.

"It truly is a different world for all of us working to ensure product safety," says Valdez. "We had to recognize the complexity of the world in which we're regulating."

From Farm to Fork

Take food. FDA regulates most food products in the United States, from the lettuce you put in your family's dinner salad, to the eggs and juice you serve for breakfast. As of 2011, roughly one in six FDA-regulated food products consumed in the United States comes from abroad. And the percentage is much higher in foods like fruits (about 50 percent) and vegetables (about 20 percent).

So the agency—empowered by the Food Safety Modernization Act signed into law in 2011—is focusing its efforts on making sure that foods from other countries meet U.S. safety standards before they reach the United States, and your family's dinner plates. Investigators with FDA's Office

FDA works with other countries to develop strong regulatory standards for medical products—such as vaccines for children around the world.

of Regulatory Affairs travel the globe to inspect facilities that produce food bound for the United States. Additionally, FDA's Office of International Programs has stationed investigators in multiple overseas posts to complement these inspection efforts.

"Consumers around the world, not just in the United States, expect and demand safe food, no matter its source," says Michael Taylor, FDA's deputy commissioner for foods.

The Global Drugstore

These strategies also apply to medical products, which include prescription and over-the-counter drugs, biologics (like vaccines and tissue), and devices that range from tongue depressors to complex diagnostic tools.

Forty percent of drugs—generic and prescription—consumed in the United States are now manufactured in other countries.

Globalization of the medical product industry presents regulatory challenges from product development to final use by the consumer:

- The clinical trials of all medical products required for FDA approval are increasingly conducted abroad, adding the complexity of the review process.
- Many U.S. consumers can purchase medicines via the Internet directly from foreign sources, increasing their potential exposure to unsafe or ineffective medical products.
- Many medical devices are sold in nearly identical forms around the world but are known by different trade names, making it difficult to warn medical professionals and consumers about potential dangers.

Global Strategies

The report outlines a variety of strategies to increase its engagement in the international public health community. These include:

- Opening new FDA posts overseas in key areas such as China, India, the Middle East, Europe, and Latin America. These help FDA build strong relationships with officials overseas and see first-hand how foreign-based facilities are operating.
- Developing strong and consistent international regulatory standards to allow countries to share a common foundation of science-based goals for product safety and quality. FDA's Office of International Programs works with FDA's centers and offices to share information, strategies and tools with other countries.
- Sharing and analyzing information and data in a way that will help regulatory agencies around the world use finite resources strategically.
- Working with other countries to monitor, prepare for, and respond to public health challenges, such as pandemics (widespread epidemics of infectious disease), natural disasters or broad distribution of tainted FDA-regulated products.
- Developing innovative strategies and tools for risk-based monitoring and inspection of imported products. An example is the PREDICT Application, a data-mining and pattern-tracing tool that FDA uses to screen imported products and identify those that pose the greatest risk to public health.
- Working with international partners to advance the science used to assess the safety and effectiveness of regulated products, which can lead to more cost-effective and timely product development. One example is the development of vaccine technology by FDA's Center for Biologics Evaluation and Research that was used, through an international partnership, to protect millions in Africa against meningitis.

"FDA is no longer a domestic agency," says Valdez. "We have gone global because consumers' products come from many corners around the globe. We have made significant contributions towards assuring global product safety and quality."

"And we will continue to make many more to promote the health and well being of the American people and our fellow citizens around the world," she says.

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