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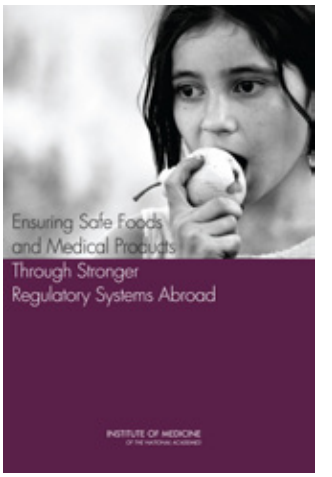
Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad



Suspect scallions from Mexico. Catfish from China and Vietnam laced with prohibited antibiotics. Contaminated ingredients, also from China, used in the blood thinner heparin. The Food and Drug Administration (FDA) is intimately familiar with the daunting task of policing the safety of food and medical products faced by regulators abroad.

The agency's regulatory oversight has grown in fits and starts over decades, often in response to such product safety problems. Yet the FDA is responsible for protecting American consumers from unsafe food, medicines, biologics, and medical products that now originate from many different countries—including some with weak regulatory systems—and that are transported through complex supply chains.

Imports of food and drug products regulated by the FDA have increased by more than 13 percent per year since 2002, resulting in a threefold increase of products produced outside of the United States. Almost 40 percent of the fruits and nuts and 85 percent of the seafood that Americans purchase come from abroad. More than 80 percent of active pharmaceutical ingredients—the building blocks of medicines—are imported, and 40 percent of medicines are imported as finished products. Further, U.S. imports of medical devices quadrupled over the last 10 years.

Since the late 1930s, when a sweetened elixir laced with poison killed more than 100, U.S. law has required drug manufacturers to prove safety before the FDA permits sale of their products. Decades later, the exact same poison has been implicated in product safety crises around the globe. But many regulatory peers abroad lack the legal framework, funding, training, and oversight that have helped to transform the FDA into one

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of the world's top-notch regulatory agencies.

Against this backdrop, the Institute of Medicine (IOM) convened a committee of experts at the FDA's request to identify the core elements of food, medicine, medical product, and biologics regulatory systems in developing countries; to pinpoint the main gaps in these systems; and to design a strategy to leverage the expertise of the FDA and other stakeholders to strengthen regulatory systems abroad.

Weak Regulatory Systems in Developing Countries

There are more than 150 developing countries in the world. The committee's report, *Ensuring Safe Foods and Medical Products Through Stronger Regulatory Systems Abroad*, identifies shared themes and challenges among them, while also giving special attention to the emerging economies that trade heavily with the United States: Mexico, Brazil, South Africa, India, Thailand, and China.

In such countries, regulatory authorities and industry both face numerous hurdles to protecting consumer safety, according to the IOM committee. Barriers include unreliable transportation and communication systems, along with inadequate access to clean water, electricity, and broadband Internet.

Further, regulatory agencies in developing countries often have few staff positions, difficulty hiring and retaining qualified workers, outdated equipment, and skeletal surveillance systems to track and monitor products.

In some of the poorest countries, no law governs product safety; other countries have a weak legal foundation for regulation. Finally, product safety is not a high priority in countries with overwhelmed health systems, poor sanitation, and high mortality rates. The committee finds that developing countries are unlikely to have robust regulatory systems due to these infrastructure and resource limitations.

Modern Regulatory Systems for a Global Marketplace

In its report, the IOM committee identifies specific actions that the FDA should take to improve product safety for consumers. The FDA needs management systems that enable the agency to target resources to the greatest risks. It is neither good management nor good sense to divide resources equally among all regulated products, the committee reasons.

While the passage of the 2011 Food Safety Modernization Act strengthened the FDA's ability to prevent and respond to outbreaks, the FDA cannot continue to do its job well without substantive improvements in the capacity of counterpart agencies in emerging economies, the committee writes.

The committee also recommends that to close critical gaps, the FDA work closely with industry, other regulatory agencies, and international organizations to ensure that only safe food and medical products reach American consumers. Because everyone has a stake in product safety, everyone needs to take action to build regulatory systems.

The FDA's traditional method of ensuring product safety—periodic inspections at factories and 300 ports of entry—is impractical when 20 million types of FDA-regulated goods arrive from more than 300,000 factories in 150 different countries. With this in mind, the FDA created the Pathway to Global Product Safety and Quality—a strategic plan that broadens the FDA's safety focus for imports beyond the U.S. borders. A focus abroad is consistent with the agency's new responsibilities outlined in the Food Safety Modernization Act. More will be required.

Since 2008, the FDA has used a risk-based process to rank foreign manufacturers needing inspection. The committee suggests that enterprise risk management guide the FDA's training, regulatory, and surveillance efforts in the developing world. Enterprise risk management aggregates information about risks from across the FDA to give agency leaders a comprehensive analysis of threats. Agency officials then direct resources to the most

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pressing vulnerabilities. This analysis should be applied across domestic and foreign operations.

The FDA should use partnerships to drive improvements in supply chain management. The committee recommends that the FDA work with strong regulators in other countries to plan inspections and pool data. There is no need for American and European inspectors to duplicate each other's work, especially when a vast number of facilities go uninspected. Also, the FDA should enhance incentives offered to importers that make sure their supply chains fully adhere to U.S. standards. One promising initiative is the two-year FDA Secure Supply Chain pilot program, which rewards firms that trace their products thoroughly from manufacture to entry into the United States. If it is successful, the committee recommends expanding this pilot to include a greater number of importers and food.

International Cooperation to Build Regulatory Capacity

Successful regulatory systems meet the highest standards: they are responsive, focus on outcomes, are predictable, allocate controls proportionate to risk; and they are independent, not unduly influenced by politics or money. The FDA took generations to achieve its status as an internationally respected, science-driven regulator, and the challenge is even greater for developing countries. Low- and middle-income country regulatory authorities are not able to execute all of these responsibilities.

With the help of international partners, the FDA, and U.S. governmental agencies, low- and middle-income countries should work toward achieving core regulatory capabilities. As a starting point, the committee recommends the minimum components for regulatory systems abroad:

- A rule-making process that enables all stakeholders to comment on proposed regulations
- A protocol for different regulatory agencies to share information and oversight along the supply chain
- A method to identify when regulatory actions, such as an order to stop production due to unsanitary conditions, are necessary.

In international partnerships, the FDA can leverage its considerable leadership and expertise to improve product safety. These partnerships should involve other regulatory agencies, foundations and other donors, universities, international organizations, and non-governmental organizations, such as consumer and industry groups.

One priority for the FDA and its international partners should be to expand education and training about regulatory science and policy in countries that are high-volume exporters of high-risk goods to the U.S. market. Similarly, the FDA should work with other U.S. governmental agencies and international organizations to strengthen surveillance systems in developing countries. The FDA and U.S. Department of Agriculture should engage government and private funders

to research and develop inexpensive tools and procedures to effectively monitor products—tracking, verifying, and preventing fraud—from development through distribution. The economical technologies developed in these collaborations could benefit small- and medium-sized producers in both developed and developing countries.

Conclusion

International trade can turn the product safety failures of the poorest countries into liabilities for the richest ones. Globalization can benefit U.S. consumers, as Americans fill shopping carts and medicine chests with food and medical products imported from other countries. But globalization also uniquely challenges the FDA's ability to assure product safety in the United States.

Food and medical product safety is a dynamic problem that requires agile systems. The committee's proposed international actions will increase investment in regulatory systems; encourage open dialogue among government, industry, and academia; work toward voluntary sharing of inspection results; and support surveillance. In time, these actions would do much to improve product safety in the United States, as well as improve public health around the world.

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