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A Report of the CSIS Global Health Policy Center

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GLOBAL HEALTH INTERVENTIONS FOR U.S. FOOD AND DRUG SAFETY

*Thomas J. Bollyky*¹

Overview

In 2007, a series of high-profile scandals involving contaminated blood thinner, toxic toothpaste, and melamine-laced pet food demonstrated the threat that unsafe food and drug imports pose to U.S. public health and international trade. Contaminated and adulterated products have sickened and killed U.S. consumers, fueled protectionism, raised business costs, and destabilized markets. A 2008 public opinion poll found that 67 percent of Americans are worried about food safety, ranking it higher than concerns about pandemic flu or natural disasters.²

Food and drug safety also has the attention of U.S. policymakers. In 2007, the Bush administration convened an Import Safety Working Group that called for an increased focus on prevention, more resources and greater mandates for the Food and Drug Administration (FDA) and other U.S. regulators, and increased engagement with trading partners and industry. President Obama appointed a cabinet-level Food Safety Working Group and requested the largest-ever budget increase for FDA food programs. The House of Representatives recently passed food safety legislation to modernize the authorities of the FDA and improve the ability of the FDA to trace and register facilities that import food, issue mandatory food recalls, and conduct border surveillance and enforcement. The Senate is scheduled to take up the food safety legislation in the coming weeks. Drug safety bills, pending in the House and Senate, would increase the mandate and resources for the FDA to conduct inspections of foreign drug suppliers.

Increasing the resources and mandate of U.S. regulators to conduct border and foreign risk-based inspections are positive and necessary steps, but insufficient. There are legal and practical limits to

¹ Thomas J. Bollyky is a visiting fellow at the Center for Global Development in Washington, D.C. He thanks those colleagues, particularly Paul Bollyky, MD, DPhil, and Phil Nieburg, MD, who kindly commented on drafts of this paper.

² Lisa Shames, “FDA Has Provided Few Details on the Resources and Strategies Needed to Implement Its Food Production Plan,” testimony before the Committee on Energy and Commerce, U.S. House of Representatives, June 12, 2008, GAO-08-909T.

the ability of U.S. regulatory authorities to conduct inspections of foreign food and drug producers and suppliers. The scale and complexity of the global trade in food and drugs overwhelm traditional methods of border control and inspection at ports of entry. Ensuring the safety of U.S. food and drug imports requires new approaches as well as new resources for traditional interventions.

A necessary first step toward formulating a new U.S. government approach to ensuring the safety of food and drugs is recognizing that it is not exclusively a U.S. domestic public health concern. Food and drug safety are global health problems and require strategies and tools similar to those used to address other global health threats. Drawing lessons from successful public health interventions, this paper makes the following observations and recommendations:

1. Inspection and quality control of goods destined for global trade must occur closer to their place of origin. U.S. border and port surveillance can supplement but not replace oversight, control, and surveillance by local regulators and industry.
2. More resources should be directed toward the development of food and drug regulatory capacity in developing countries. Resources should be prioritized and allocated to countries that export the highest volume and highest-risk food and drug products to the United States and targeted to address their specific challenges and comparative regulatory advantages.
3. The United States must engage on the broader global health food and drug safety agenda and incorporate developing country exporters' needs and interests if it is to gain cooperative action on the safety of U.S. food and drug imports. This can be accomplished by a combination of carrots and sticks that offer competitive advantage in the U.S. marketplace to purveyors of goods that are confirmed to meet relevant U.S. safety and efficacy standards.
4. Efforts to build local regulatory capacity and monitor food and drug safety should be coordinated regionally and internationally with multilateral and intergovernmental institutions and integrated into U.S. international trade and economic policies. The United States should support global efforts on regulator interoperability, information exchange, and cooperation.

Challenges in Ensuring Safety in the Global Trade in Food and Drugs

The mobility of manufacturing and ever-improving distribution systems mean that food and drug products can be produced and widely distributed across the globe. The globalization of the food and drug trade has brought many benefits to U.S. consumers—accessible, affordable, and, usually, safe drugs and foods that meet the demands of U.S. consumers and patients. Food exports are also important to developing countries as many have a comparative advantage in agricultural production. Drug manufacturing has been an engine of economic development and employment in developing countries like China and India.

The global trade in food and drugs also presents challenges. U.S. regulators do not have adequate authority or resources to enforce U.S. food and drug regulations extraterritorially. The scale and

complexity of the global food and drug trade overwhelms traditional public health interventions of border control and inspection at ports of entry. Ensuring the safety of food and drug imports is also increasingly beyond the ability of many U.S.-based retailers and manufacturers to resolve through monitoring of their supply chains—however well motivated they may be by the threats of litigation, expensive recalls, loss of consumer confidence, and business interruptions. Unsafe food and drug products continue to cross national boundaries. Below are some of the reasons why.

More Foreign Sources of U.S. Food and Drug Imports

The proliferation of foreign sources of food and drug imports stresses limited and under-resourced U.S. government foreign inspection regimes.

The success of U.S. regulation of food and drugs depends heavily on the ability of regulators to monitor and regulate the processes and procedures by which those products are produced.³ Post-market product inspections cannot reliably determine the safety of finished dosage forms of drugs or many foods.⁴ The risks of products are often only observable once they have harmed consumers. Even then, negative health effects may only surface after a long period of time and be difficult to attribute to a particular product. Accordingly, the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA), which regulates the safety of meat, poultry, and processed egg products, and the FDA, which regulates the safety of all other foods and the safety, efficacy, and security of human drugs, both mandate that private firms adopt procedures, risk assessments, and manufacturing processes before drugs and high-risk foods may leave the plant or reach the market.⁵

³ Kenneth A. Bamberger and Andrew T. Guzman, “Keeping Imports Safe: A Proposal for Discriminatory Regulation of International Trade,” *California Law Review* 96, no. 1 (December 2008): 1405, 1411–15.

⁴ U.S. Department of Health and Human Services (HHS), *HHS Task Force on Drug Importation: Report on Prescription Drug Importation* (Washington, D.C.: HHS, December 2004), 21: “[a] fundamental principle of drug regulation is that quality cannot be tested into a product,” but must instead be “built into the product through the manufacturing process” to ensure a product’s purity and potency, that it was manufactured pursuant to best industry practices, stored under appropriate conditions, and not expired or counterfeit.

⁵ USDA and FDA have mandated adoption of Hazard Analysis and Critical Control Point (HACCP), a science-based system of quality control for food manufacturing, for the meat, poultry, fish, egg, and juice industries and have instituted voluntary HACCP programs for fresh fruits and vegetables. See Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation, 74 Fed. Reg. 33,030 (July 9, 2009); Pathogen Reduction: Hazard Analysis and Critical Control Point (HACCP) Systems, 61 Fed. Reg. 38,806 (July 25, 1996); Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products, 60 Fed. Reg. 65,096-202 (December 18, 1995); Peter Barton Hutt et al., *Food and Drug Law: Cases and Materials*, 3rd ed. (New York: Foundation Press, 2007), 344–55. The *Food, Drug, and Cosmetic Act* deems drugs to be “adulterated” if they are not manufactured in accordance with current FDA-mandated good manufacturing practices (GMPs). 21 CFR § 501(a)(2)(B).

Both the FSIS and the FDA also conduct regular tests and on-site inspections to enforce those requirements and prevent harm to consumers.⁶

There are, however, both legal and practical limits on the ability of U.S. regulatory authorities to conduct the inspections necessary to regulate the production of food and drug imports.

Regulators of an importing state are not entitled to conduct extraterritorial inspection of the facilities of exporting manufacturers without prior notice and consent. Regulators cannot demand access or information from the foreign firms they wish to inspect. The FDA and FSIS may condition access to U.S. markets on cooperation with inspections, but doing so requires detailed knowledge of supply chains in order to ensure that products are not falsely represented outputs of an approved facility.⁷

U.S. government inspections of foreign drug and food production facilities also cost more than inspections of domestic facilities because of travel, translation, and other logistical hurdles.⁸ A 2008 U.S. Government Accountability Office (GAO) report estimated that, at current inspection cost estimates, if the FDA were to inspect each of the 189,000 registered foreign facilities that manufacture, process, pack, or hold foods for export to the United States, it would cost approximately \$3.16 billion.⁹ A 2007 GAO report estimated that it would take the FDA, at the rate it was conducting foreign inspections between 2002 and 2007, more than 13 years to inspect each registered foreign drug facility once, assuming that no additional establishments require inspection.¹⁰

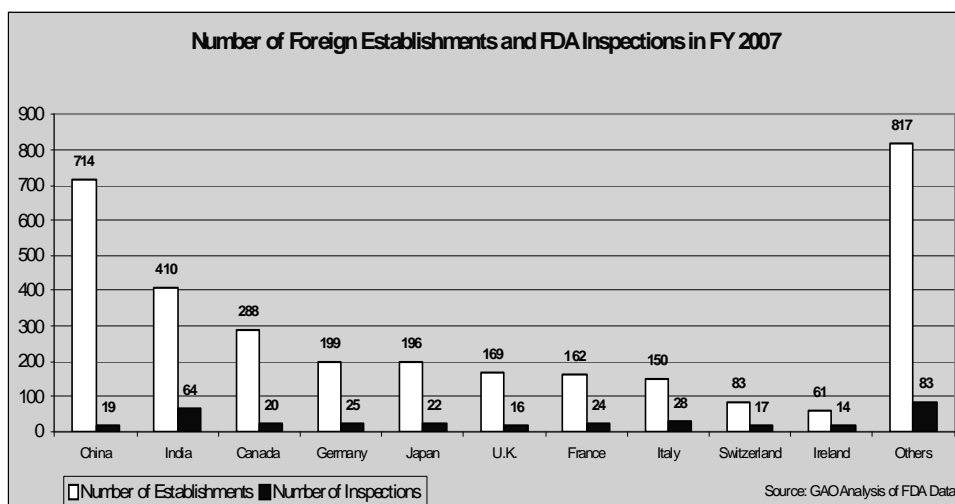
⁶ USDA has a statutory mandate to inspect every carcass passing through slaughter establishments and to inspect every meat and poultry processing plant every day. See *Federal Meat Inspection Act*, 21 U.S.C. § 604 (2000); *Poultry Products Inspection Act*, 21 U.S.C. § 455 (2000). FDA is required to inspect each U.S. drug manufacturer every two years and ensure all drugs are produced in accordance with current GMPs. 21 CFR § 820.1 et seq. The FDA also conducts periodic, risk-based inspections and post-market surveillance for the FDA-regulated food supply. See also Hutt et al., *Food and Drug Law*, 343.

⁷ Bamberger and Guzman, “Keeping Imports Safe,” 1420.

⁸ See, for example, Janet Woodcock, FDA, statement before the House Agriculture, Rural Development, Food and Drug Administration and Related Agencies Appropriations Subcommittee, February 27, 2008, describing the “fundamental challenges of many different languages and protocols” arising from “the globalization of the supply chain [to include] an ever-growing number of brokers.”

⁹ Shames, “FDA Has Provided Few Details.”

¹⁰ Marcia Crosse, “Preliminary Findings Suggest Recent FDA Initiatives Have Potential, but Do Not Fully Address Weaknesses in Its Foreign Drug Inspection Program,” testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, House of Representatives, April 22, 2008, GAO-08-701T.



Growing Volume of U.S. Food and Drug Imports

The exponential growth of U.S. food and drug product imports makes efforts to identify and seize noncompliant food and drug products at the border largely infeasible.

U.S. agricultural imports in 2000 were worth approximately \$38 billion; in 2008, they were worth approximately \$80 billion¹¹ and represented 16 percent of all foods consumed in the United States.¹² Imports account for a high share of the foods that are most often linked to microbial food-borne illness in the United States. An analysis of 5,000 food-borne disease outbreaks between 1990 and 2004 found that the food category linked to the most U.S. outbreaks was seafood; imported fish and shellfish account for 80 percent of U.S. consumption of these foods.¹³

Both the FSIS and the FDA have authority to examine and refuse entry to items that fail to comply with relevant U.S. product standards. In 2008, however, the FDA had only 450 port inspectors to examine the almost 20 million annual shipments of food, drug, and other products that fall within its jurisdiction. While the FDA regulates 80 percent of the U.S. food supply,¹⁴ it only examines approximately 1 percent of the food presented for import.¹⁵

¹¹ See U.S. Department of Agriculture, “Foreign Agricultural Trade of the United States (FATUS),” <http://www.ers.usda.gov/Data/FATUS/#calendar> (September 8, 2009).

¹² Ibid.

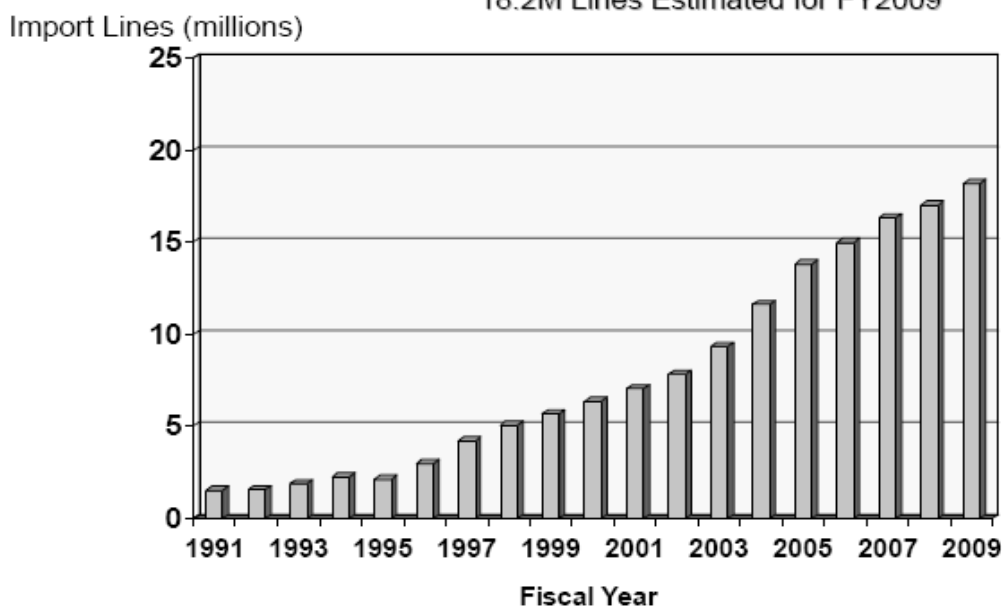
¹³ Ibid.

¹⁴ Lisa Shames, “Federal Oversight of Food Safety: FDA’s Food Protection Plan Proposes Positive First Steps, but Capacity to Carry Them Out Is Critical,” testimony before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, January 29, 2008, GAO-08-435T.

¹⁵ GAO, “Consumer Safety: Better Information and Planning Would Strengthen CPSC’s Oversight of Imported Products,” report to congressional committees, August 2009, GAO-09-803, 32.

Import Volume History

18.2M Lines Estimated for FY2009



Source: FDA. Import lines, referenced in this exhibit, are a measurement of volume of imported goods. An import line is the portion of an import shipment that is listed as a separate item on an import entry document. Classification codes, or tariff lines, apply to traded goods. Items in an import entry that fall under different tariff lines must be listed separately.

Increased Complexity of Products, Manufacturing, and Supply Chains

Food and drug products are increasingly not “from” any one place or any one manufacturer or producer, but rather consist of parts and components from any number of countries, suppliers, manufacturers, handlers, and producers. Multinational corporations produce food and manufacture drugs through multiple supply chains, fragmented across several countries. U.S. food and drug retailers and manufacturers may not always know the identity of all their suppliers, let alone be able to provide comprehensive monitoring and oversight of them.¹⁶ Foods are often

¹⁶ See, for example, Nicholas Zamiska and David Kesmodel, “Growing Concern: Tainted Ginger’s Long Trip from China to U.S. Stores,” *Wall Street Journal*, November 19, 2007, describing a product recall in which a U.S. firm that packaged and distributed fresh ginger tainted with a banned and potentially fatal pesticide could not identify its suppliers because it purchased its supplies from Chinese intermediaries. Since 2005, the FDA has required certain food facilities to maintain records on the sources, recipients, and transporters of food products so that it may better trace public health threats in a food emergency. *Food, Drug, and Cosmetic Act* § 414(a), 21 U.S.C. § 350c(a) as amended by the *Public Health Security and Bioterrorism Act of 2002*, P.L. No. 107-188, § 306. These regulations do not apply to farms or foreign entities operating outside of the United States. 21 CFR § 1.327. A 2009 report by the HHS’s Office of Inspector General concluded that 59 percent of U.S. food facilities were not meeting the FDA’s requirements on maintaining records about their

processed and drug products are more sophisticated; the safety of such products is harder to determine. Entities along a supply chain may adhere to strict quality control procedures, only to have those efforts undone by an inadvertent contamination of one component or the malfeasance of a single participant in the supply chain.¹⁷

Increased Imports from Developing Countries with Less-Developed Regulatory Systems

U.S. food and drug imports increasingly involve ingredients produced and components manufactured in countries with less-developed regulatory systems. Fresh and processed fruits and vegetables, fish, meat, nuts, and spices collectively account for more than 50 percent of food exports from developing countries.¹⁸ Twenty percent of finished generic and over-the-counter drugs sold in the United States and more than 40 percent of the active ingredients in U.S.-made medications are produced in China and India.¹⁹ Exporting developing countries are working to strengthen border control and regulatory oversight, but face capacity, resource, and governance challenges.²⁰

Lack of Coherence in International, National, and Private Food and Drug Standards and Regulation

International drug and food standards and regulation are spread out among a large number of national authorities and private and nonprofit organizations with overlapping, sometimes interdependent, often competing roles—none of which necessarily has the final word. World Trade Organization (WTO) Agreements on Application of Sanitary and Phytosanitary Measures (SPS) and Technical Barriers to Trade (TBT) promote harmonization and strongly encourage, but do not

suppliers, recipients, and transporters. Office of the Inspector General, HHS, “Traceability in the Food Supply Chain,” OEI-02-06-00210 (March 2009).

¹⁷ See, for example, Walt Bogdanich and Jake Hooker, “From China to Panama, a Trail of Poisoned Medicines,” *New York Times*, May 6, 2007, tracing the supply chain for a batch of counterfeit glycerin used in cough syrup manufactured in Panama and responsible for approximately 365 deaths from the Panamanian port of Colón, back through various trading companies in Barcelona, Spain, and Beijing, China, to a place near the Yangtze Delta that the local people called “chemical country.”

¹⁸ Agriculture and Rural Development Department, *Food Safety and Agricultural Health Standards: Challenges and Opportunities for Developing Country Exports*, Report No. 31207 (Washington, D.C.: World Bank, January 2005).

¹⁹ Marc Kaufman, “FDA Scrutiny Scant in India, China as Drugs Pour into U.S.,” *Washington Post*, June 17, 2007.

²⁰ See, for example, Covington & Burling LLP, “China Enacts New Food Safety Law, Effective June 1, 2009,” *Food & Drug E-Alert*, March 30, 2009, describing China’s 2009 Food Safety Law, which replaces its 1995 Food Hygiene Law, restructures government agencies’ responsibilities with regard to food safety, and provides broader enforcement powers and harsher penalties for violations. See also Bamberger and Guzman, “Keeping Imports Safe,” 1426, noting that there may be incentives to maintain low-quality food and drug regulation in states competing for foreign investment and in circumstances in which food and drugs are produced primarily for export.

Case Study: Heparin

The recent heparin episode is illustrative of the challenges facing food and drug safety regulators. In 2008, batches of counterfeit heparin, a blood thinner used typically in kidney dialysis and patients undergoing heart surgery, caused 19 deaths and hundreds of allergic reactions in the United States and nearly 250 deaths worldwide. The supply chain for the heparin in the United States was as follows. The active pharmaceutical ingredient (API) in heparin derives from proteins found in the intestines of pigs. Half of the world's pigs are now in China. Small, rural farms in China harvest pig intestines and sell them to Chinese intermediaries—often small, family-run businesses themselves—that process the intestines into crude heparin. In this case, two medium-sized Chinese firms served as the intermediaries and purchased the crude heparin from a dozen or so farms. Scientific Protein Laboratories LLC (SPL), a U.S.-based firm, had a joint venture with a Chinese firm, Changzhou-SPL, which purchased the crude heparin from the intermediary firms and processed it into the API for heparin at the Changzhou-SPL factory in China. SPL imported that heparin API into the United States and supplied it to Baxter International, a large U.S.-based multinational health care company. Baxter manufactured the finished dosage form of heparin in the United States and sold it to hospitals and U.S. patients.

Prior to the heparin-related deaths, the FDA had not inspected the Changzhou-SPL factory. Nor had the SFDA, China's regulator, which did not, at the time, inspect manufacturers providing drug products solely for export. Baxter inspected the factory and reviewed its quality systems and capabilities in November 2007. After the heparin-related deaths, the FDA inspected the Changzhou-SPL factory, but was denied consent to inspect the intermediaries that manufactured the crude heparin. After months of investigation, the FDA determined that one or more entities along the supply chain substituted a chemical, over-sulfated chondroitin sulfate (OSCS), for crude heparin. OSCS costs \$20 per kilogram; crude heparin costs \$2,000 per kilogram. Conventional laboratory tests could not reveal the difference between OSCS and crude heparin. There is no evidence that Baxter or SPL were aware of the substitution, and months later, they were still unsure where the contamination occurred. Months of negative press attention followed for Baxter and Chinese exporters generally. At least 60 U.S. lawsuits have been filed in the aftermath.

require, member states' use of international food and drug standards. Many states have different structures for enforcing standards, reflecting their prevailing legal and administrative mechanisms and practices. Subnational and local governments may impose additional requirements beyond those set by the national government. Businesses increasingly rely on private or nonprofit organization standards, voluntary third-party certifications, and their own safety and quality management systems to regulate their suppliers. The resulting incoherence in the global system of food and drug product regulation undermines compliance and enforcement, prevents effective cooperation among regulators, and limits information sharing across borders.

Current U.S. Initiatives to Address Global Food and Drug Safety

The need for a more global approach to food and drug safety is not news to U.S. policymakers and regulators. In the last two years, the United States has announced numerous international initiatives to address the safety of U.S. food and drug imports. Most notably, the United States has:

- Completed a 2007 Import Safety Action Plan that calls for shifting the primary emphasis for import safety from intervention to a risk-based prevention with verification model. Recommendations include: creating a common vision and better collaboration among U.S. government agencies; establishing a more consistent FDA global presence; U.S. support for regulatory capacity building in other countries; international standards development and harmonization; an increase in timely U.S. government foreign inspections; sharing inspection reports with other competent regulatory authorities; and third-party certification.²¹
- Negotiated two memoranda of agreement (MOAs) with the People’s Republic of China in 2007 aimed at improving the safety of Chinese food and drug products exported to the United States.²² These MOAs allow the United States to inspect food and drug production facilities that export to the United States, require Chinese companies manufacturing drug components to register with Chinese drug regulators, and permit foreign third-party certification.
- Launched the Beyond Our Borders Initiative in 2008—an effort to establish a continuous FDA presence in strategic countries as determined by the volume of imports and the risks of products; opportunity for bilateral capacity building or resource leveraging; and potential for fostering relationships with counterparts. Congress awarded \$20 million to initiate the program. By the end of 2010, the FDA intends to engage and post 43 U.S. nationals and 20 local staff members in FDA offices in China, India, Costa Rica, Belgium, and the Middle East. The Beijing FDA office opened in November 2008; the New Delhi office opened in January 2009.
- Engaged in the EU-U.S. Bilateral Technical Working Group on Medicines Quality and Manufacturing in 2008 to explore the exchange of nonproprietary data for inspections of manufacturing plants by the European Union or United States.
- Participated in multilateral food safety talks in the Asia-Pacific Economic Cooperation (APEC) forum in 2008 and pushed for the launch of an APEC Training Institute Network to leverage resources and expertise from industry and academia to support food safety regulatory needs as identified by APEC governments.

The Obama administration is working in close collaboration with the U.S. Congress on legislation to increase resources for U.S. regulators and to modernize their mandates. In July 2009, the U.S. House of Representatives passed the Food Safety Enhancement Act of 2009, which requires, among

²¹ Interagency Working Group on Import Safety, *Action Plan for Import Safety: A Roadmap for Continual Improvement* (Washington, D.C.: HHS, November 2007), <http://www.importsafety.gov/report/actionplan.pdf>.

²² “Agreement between the Department of Health and Human Services of the United States of America and the General Administration of Quality Supervision, Inspection and Quarantine of the People’s Republic of China on the Safety of Food and Feed,” December 11, 2007, <http://globalhealth.gov/news/agreements/ia121107b.html>; “Agreement between the Department of Health and Human Services of the United States of America and the State Food and Drug Administration of the People’s Republic of China on the Safety of Drugs and Medical Devices,” December 11, 2007, <http://globalhealth.gov/news/agreements/ia121107a.html>.

other items, the registration of all facilities supplying food to the U.S. market, foreign as well as domestic, and empowers the FDA to bar the import of products from unregistered importers.²³ The FDA has expressed concern, however, that the bill's requirements for FDA-conducted foreign inspection are unrealistic and cost-inefficient, favoring third-party inspection and limited risk-based FDA foreign inspections instead.²⁴

In important respects, however, the U.S. strategy on food and drug safety remains a work in progress. It is not feasible for the FDA, or any U.S. regulator, to ensure the necessary control and oversight on its own. Preventing unsafe food and drugs from entering the U.S. market and causing harm to consumers and patients necessarily depends heavily on the inspection and quality control of goods by foreign governments and local industry. Unfortunately, however, the strategies put forward in the 2007 Import Safety Action Plan and the FDA's 2007 Food Protection Plan on foreign regulatory capacity building and developing country government and industry collaboration are the least-defined components of those Plans.²⁵

The Action Plan did not offer a strategy on foreign regulator capacity building or improvement of international food and drug safety governance. Instead, that Plan calls only for a long-term U.S. State Department–led review of how and whether existing U.S. foreign assistance efforts on rule of law and trade and regulatory capacity building could be used to address product safety standards and compliance.²⁶ It is unclear whether that review has occurred, but a review of U.S. trade capacity building data does not suggest a long-term health-oriented strategy focused on countries that export high-risk food and drug products (those that have been most often associated with repeated instances of serious health problems or death to humans from contamination and adulteration) to the United States.

Nor has there been an upsurge in the U.S. commitment to food and drug regulator capacity building. The United States obligated \$6.6 million in SPS trade capacity building in 2008, which is roughly the same amount as in 2007, but is otherwise the lowest amount since 2000.²⁷ The \$1.8 million obligated for TBT capacity building in 2008 was the least the United States had obligated for

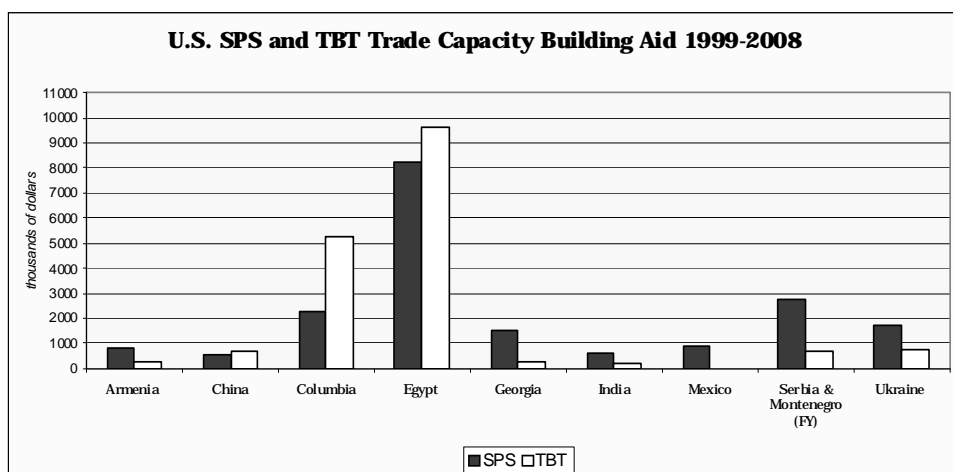
²³ *Food Safety Enforcement Act of 2009*, H.R. 2749 §§ 101, 204.

²⁴ Michael Taylor, FDA, testimony before House Committee on Agriculture, July 16, 2009, <http://www.fda.gov/NewsEvents/Testimony/ucm172576.htm>.

²⁵ Interagency Working Group on Import Safety, *Action Plan for Import Safety*, 20–21, 24–25; FDA, *Food Protection Plan: An Integrated Strategy for Protecting the Nation's Food Supply* (Washington, D.C.: HHS, November 2007), <http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132565.htm>.

²⁶ Interagency Working Group on Import Safety, *Action Plan for Import Safety*, 24–25.

²⁷ U.S. Agency for International Development (USAID), “United States Trade Capacity Building Database,” <http://tcb.eads.usaidallnet.gov> (October 16, 2009), data for U.S. SPS capacity building, 2000–2008.



that purpose since 1999.²⁸ The FDA provides significantly less support for SPS and TBT capacity building (\$2,957,000 between 1999 and 2007) than the USDA (\$25,811,000 over the same period), despite being responsible for a much larger volume of food and drug imports, and a small fraction of the trade capacity building assistance provided by other U.S. agencies.²⁹

The FDA also has relatively few formal collaborative arrangements with its developing country counterparts. The FDA has negotiated 61 memoranda of understanding or other cooperative agreements with the governments of 26 different countries; only 5 of these agreements are with developing country regulators other than Mexico—China (3), the Philippines (1), and Vietnam (1).³⁰ The FDA has negotiated 34 confidential information-sharing agreements with the governments of 19 countries; only 1 of these agreements is with a developing country regulator other than Mexico—South Africa.³¹

The current administration recognizes the need for new international approaches to the food and safety problem. FDA commissioner Margaret Hamburg stated in a recent speech on food safety that the FDA “will never be in all sites that are producing and handling food” for import into the United States, but that duty cannot be delegated to foreign governments without adequate laws or capacity.³² Hamburg emphasized that it is “very, very important” the FDA and other relevant U.S. regulators think about potential international activities and working partnerships with foreign

²⁸ Ibid., data for U.S. TBT capacity building, 1999–2008.

²⁹ Ibid., comparing data for trade capacity building for 1999–2007 by U.S. government agency.

³⁰ The FDA has 4 MOUs with Mexico only and 2 MOUs with Mexico and Canada jointly. See FDA, “Memoranda of Understanding and Other Cooperative Arrangements,” <http://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/default.htm>.

³¹ The FDA has two confidentiality commitments with Mexico. See FDA, “Confidentiality Commitments,” www.fda.gov/InternationalPrograms/Agreements/ConfidentialityCommitments/default.htm.

³² “Hamburg Says New Authorities, Capabilities Key to Improving Food Safety,” World Trade Online, September 11, 2009, http://www.insidetrade.com/secure/display.asp?f=&dn=9112009_hamburg.

regulatory agencies and industry in order to move toward harmonized standards, better information sharing, and a sharing of responsibilities.³³

Food and Drug Safety Is a Global Health Problem

A necessary first step toward formulating a new U.S. government approach to ensuring the safety of food and drugs is recognizing that it is not exclusively a U.S. domestic public health concern. Food and drug safety are global health problems. Unsafe foods and drugs cross national boundaries with travel, trade, and technology. In this context, the health of U.S. citizens is interdependent on the health of other states' citizens. Given the increasing complexity and volume of international trade, the FDA, or any national regulator alone, cannot ensure the safety of food and drugs used by its citizens. Sustainable progress on the issue depends on the cooperation of not only trading partners, but all entities involved in the international commerce and regulation of food and drugs: industry, health and trade intergovernmental institutions, private and nonprofit standard-setting organizations, scientists, and academic centers.³⁴

Unsafe food and drugs exact a significant human and economic toll in developed and developing countries alike. Outbreaks of food-borne disease have occurred on every continent over the last decade.³⁵ Approximately 76 million Americans—one in four—are sickened by food-borne diseases each year.³⁶ Of these, an estimated 325,000 are hospitalized and 5,000 die.³⁷ The burden of unsafe food is even greater elsewhere in the world. The World Health Organization (WHO) estimates that 2.2 million people die every year from diarrhea, much of which is caused by microbiologically contaminated food.³⁸ The WHO estimates that one-third of the population in industrialized countries suffers from food-borne disease each year.³⁹ Such disease most seriously affects children, pregnant women, the elderly, and people already suffering from disease. Nearly 2 million of the people who die each year from diarrhea are children.⁴⁰

Chemical contamination in food is likewise a significant source of food-borne illness. Chemical contamination can affect health after a single exposure or after more long-term use. While the

³³ Ibid.

³⁴ See David Fidler, "The Globalization of Public Health: The First 100 Years of International Health Diplomacy," *Bulletin of the World Health Organization* 79, no. 9 (2001), comparing the characteristics of "global" versus international health issues.

³⁵ World Health Organization (WHO), *WHO Strategy for Food Safety: Safer Food for Better Health* (Geneva: WHO, 2002).

³⁶ Paul S. Mead et al., "Food-Related Illness and Death in the United States," *Emerging Infectious Diseases* 5, no. 5 (September-October 1999), <http://www.cdc.gov/ncidod/eid/vol5no5/mead.htm>.

³⁷ Ibid.

³⁸ WHO, *World Health Report 2008: Primary Health Care: Now More Than Ever* (Geneva: WHO, 2008).

³⁹ WHO and WTO, *WTO Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat* (Geneva: WHO and WTO, 2002), 63.

⁴⁰ WHO, *World Health Report 2008*.

health impact of chemically contaminated food is thus difficult to estimate, its potential effects are global and have been amply demonstrated.⁴¹

Substandard, adulterated, and contaminated drugs impede patient recovery, undermine disease control and prevention, increase drug resistance, and, if toxic, sicken or kill patients. One expert has estimated that deaths from substandard, adulterated, and contaminated drugs within China number as high as 300,000 annually.⁴² The substitution of ethylene glycol (antifreeze) for pharmaceutical-grade glycerin in an elixir killed 365 people in Panama and others in Nigeria, India, South Africa, and Argentina.⁴³

Deliberately and fraudulently misidentified shipments or mislabeled drugs thwart customs and regulatory systems designed to protect patients and monitor drug safety, efficacy, and quality. In doing so, these counterfeit medicines pose a twofold public health risk to developed and developing countries alike. First, the counterfeit medicines themselves pose greater health risks than products that have been screened by regulatory and customs systems. Second, the trade in counterfeit medicines undermines rule of law and the integrity of regulatory and customs systems generally, which poses systemic risks for patients and health governance. The incidence of counterfeiting is highest in countries and regions where regulatory and enforcement systems are the weakest—Africa, parts of Asia and Latin America, and countries of the former Soviet Union.⁴⁴

Beyond their health implications, unsafe food and drugs also have economic consequences. Food-borne illnesses cost the United States \$37 billion in medical costs and lost productivity in 1997 and likely considerably more today.⁴⁵ Consumer anxiety accumulates with each new product scandal and erodes consumer confidence in regulatory governance, depresses trade, and undermines the economic development of exporting developing countries.

Global Health Solutions for Global Health Problems

The challenge of protecting one's borders from unsafe food and drugs has similarities with the challenge of screening for individuals infected with contagious diseases in this era of globalization. The regulatory challenges posed by the volume and complexity of international trade and travel are analogous, as are the potential consequences for local economies and human health. Further, both realms require solutions that are adaptable to a heterogeneous collection of developed and developing countries.

⁴¹ See, for example, Bill Powell, "Heparin's Deadly Side Effects," *Time Magazine*, November 13, 2008, citing the 2008 melamine milk contamination that killed 6 and sickened 296,000 in China and led to product recalls in 11 countries.

⁴² William K. Hubbard, Alliance for a Stronger FDA, statement before U.S. Senate Committee on Health, Labor, and Pensions, April 24, 2008.

⁴³ Bogdanich and Hooker, "From China to Panama."

⁴⁴ WHO, "Counterfeit Medicines," fact sheet (2009).

⁴⁵ WHO, "Food Safety and Foodborne Illness," fact sheet (2007).

Given the structural similarities involved in protecting the public from imported food and drug threats and imported diseases, it is worth looking to past public health successes to inform present U.S. efforts in food and drug safety.

One lesson from public health is that surveillance and regulation should take place at the source. The approach of neglecting the root of the problem and instead opting for containment—essentially quarantine—can only hope to succeed temporarily for small-scale problems. Viewed in this way, the current challenges in imported food and drug safety represent the collapse of a de facto quarantine regime previously made possible by oceans and long transit times. In the case of infectious disease control, the most effective long-term approach has been to promote local public health and surveillance such that infectious disease outbreaks are identified and controlled before they arrive at our borders.

A second hard-learned lesson from public health is the value of indigenous investment. Such support compounds any centralized investment and is applied to the source of the problem in a manner cognizant of local conditions. Donald Henderson, MD, the individual who led the successful smallpox eradication campaign, attributes that program's success to the fact that it "functioned within existing health service structures and took advantage of available resources."⁴⁶ He contrasts this to contemporaneous malaria eradication programs managed centrally by the WHO, which were more costly and unsuccessful. Of the national health apparatuses built from the ground up to support smallpox eradication, Henderson writes "they provided valuable training and experience for health service staff and, most important, would create a skeleton framework permitting other activities to be added....[by] 1990, this culminated in...the nominal achievement of the goal of vaccinating 80% of the world's children against six major diseases."⁴⁷

The third lesson is the need for local government and grassroots support. If potential participants do not realize that an intervention is in their interest, it will not happen. Corollary to this is that the intervention must in fact be in their interest; without this precondition efforts to marshal public participation are moot.

A fourth lesson from successful public health interventions is the necessity of central coordination and clarity of purpose. While public health interventions are won or lost at the local level, their success is predicated on the ability of a central body to coordinate and galvanize the organization. Adequate funding is essential to these efforts.

⁴⁶ Donald A. Henderson, "Eradication: Lessons from the Past," *Morbidity and Mortality Weekly Report* 48, supp. 01 (December 31, 1999): 16–22, <http://www.cdc.gov/mmwr/preview/mmwrhtml/su48a6.htm>.

⁴⁷ *Ibid.*

Case Study: SARS

The first case of SARS occurred in Guangdong, China, in November 2002. The patient died soon after but other cases followed. The Chinese government did not inform the WHO of the outbreak until February 2003, by which time several neighboring countries were already affected. Despite the quarantine of thousands of individuals and the closure of international borders, the outbreak spread to 37 countries around the world. There were 8,096 known cases and 774 deaths worldwide. The economic impact was tremendous.

The example of the SARS pandemic is instructive to our discussion of global food and drug safety. First, the SARS outbreak emphasizes the difficulty of maintaining an effective quarantine in an era with greatly increased global trade and travel. This is as much the case for infected individuals as it is for counterfeit Viagra. Second, the SARS outbreak highlights the global threat posed by individual systems closed to oversight. Third, it highlights the degree to which weaknesses in one nation's infrastructure (in this case, health care) can amplify and spread.

The subsequently successful containment of SARS also provides valuable lessons for designing systems to address other threats that might cross international borders. First is the need for local surveillance. The initial clue of the outbreak appeared when the WHO's Global Outbreak and Alert Response Network (GOARN) picked up reports of a "flu outbreak" in China through Internet media monitoring and analysis. However, the GOARN network had language limitations, since corrected, that impaired the rapid dissemination of information about the outbreak in the most relevant countries. This illustrates the point that such surveillance systems must be bidirectional. Nonetheless, GOARN subsequently provided timely information about the virus and containment procedures to a global audience. Second is the value of international cooperation. WHO set up a network for doctors and researchers dealing with SARS consisting of a secure Web site to study chest x-rays and teleconferences. These efforts ensured that cases were rapidly identified and isolated to prevent further transmission. An international laboratory network was also established; within a month participating scientists collectively announced conclusive identification of the SARS virus. These results illustrate the power of international collaboration supported at the highest political level.

Recommendations

Drawing lessons from successful public health interventions, this paper makes the following observations and recommendations:

- 1. Inspection and quality control of food and drug products destined for international trade must occur at their place of origin. U.S. border and port surveillance can supplement, but not replace, oversight, control, and surveillance by local regulators and industry.**

An effective U.S. long-term strategy on food and drug product safety must address prevention, surveillance, and control throughout the supply chain for these products. Such an approach requires, first, a risk-based determination of the most likely sources—countries or industries—of unsafe food and drug products based on the volume of imports and the type of imported food or drug (those that have been most often associated with repeated instances of serious health problems

or death to humans from contamination and adulteration). Once identified, U.S. policymakers must, second, pursue a strategy, particular to the country and the parties involved, to promote local regulatory governance and product safety surveillance such that unsafe food and drug products are identified and controlled before they circulate in U.S. or international commerce. U.S. policymakers must, third, ensure adequate systems are in place to allow for the bilateral exchange of surveillance data (such as product alerts and inspection reports) between U.S. agencies and their local regulatory counterparts. U.S. policymakers should, finally, take appropriate steps to encourage stronger regulation and monitoring by U.S.-based manufacturers and retailers of their local producer and supplier partners.

The United States need not have a regulatory presence in every market, but it does require a global strategy to identify the highest-risk markets for food and drug products and the resources and authority to promote local regulatory and industry oversight, control, and surveillance, as well as bilateral regulator exchange of critical information. Congress, as part of its ongoing overhaul of the resources and authorities of the FDA, should take four steps to empower the FDA to pursue that strategy.

First, Congress should increase the funding and mandate of the Beyond Our Borders Initiative, direct the FDA to seek sustained regulatory cooperation with local and national authorities in markets responsible for the highest volumes of U.S. food and drug imports or highest-risk products, and provide the FDA with the resources to do so.

Second, Congress should direct the FDA to pursue information-sharing arrangements with national regulators in countries that are the most likely sources of unsafe food and drug products and provide the FDA with the resources to do so. The FDA has relatively few information-sharing arrangements with its developing country counterparts, even though those countries are responsible for increasing volumes of U.S. imports. This should change.

Third, Congress should remove the prohibition on the FDA sharing proprietary information as part of such bilateral regulator information exchanges. Steps may be taken to ensure the confidentiality of that information without continuing to hamper regulator-to-regulator communication about important public health risks.

Fourth, Congress should consider steps to encourage U.S.-based retailers and manufacturers to adopt stronger prevention, surveillance, and control of their supply chains and supplier and producer partners. Retailers and manufacturers are in the best position and best equipped, particularly in the near term, to regulate their local producer and supplier partners. Firms may demand contractual product specifications and safety and quality assurances, limit themselves to the suppliers and producers from which those assurances are most credible, and insist on an on-site presence at or regular inspections of production facilities. Congress should consider encouraging such efforts by imposing a higher risk and increased certainty of liability on importers for unsafe food and drugs, such as by amending the Food, Drug, and Cosmetic Act to grant the FDA broader

authority to seek civil penalties, and by providing more resources for enforcement efforts.⁴⁸

Congress should also empower the FDA to require importer-funded, mandatory third-party safety inspection of foreign producers and suppliers of high-risk food and drugs. Shifting some inspection costs to U.S.-based importers would be justified in light of the higher inspection costs imposed on U.S. government regulators when drug and high-risk food products are sourced abroad.

- 2. More U.S. resources should be directed toward the development of food and drug regulatory capacity in developing countries. Resources should be prioritized and allocated to countries that export the highest volume and highest-risk food and drug products to the United States and targeted to address their specific challenges and comparative regulatory advantages.**

Expanded efforts are needed to help strengthen the capacity of regulators in developing countries. It is impossible for the FDA to establish the necessary point-of-origin regulatory control, oversight, and surveillance on its own. It must rely on the inspections and quality control of food and drug products by local regulatory authorities and industry. The regulatory authorities or local businesses in many developing countries, however, do not have the resources and expertise to conduct the necessary stringent regulatory reviews or establish adequate quality and safety management systems. It does little good for the United States to enter into agreements or memoranda of understanding with a national regulator that does not have the resources or capacity to effectively implement the agreement.

Congress, as part of its ongoing overhaul of the resources and authorities of the FDA, should create specifically funded mandates and ensure that the FDA has the necessary budgetary and

⁴⁸ See *Food Safety Enforcement Act of 2009*, H.R. 2749 § 135. Given the high costs of litigation, the easy access to courts, and the vigor of the products liability plaintiffs' bar in the United States, there are significant incentives for U.S.-based retailers and manufacturers to monitor and control supplier and producer partners. In some circumstances, however, U.S. firms may be able to avoid liability and reputational risks from harm caused by products from foreign sources. See Bamberger and Guzman, "Keeping Imports Safe," 1415–16, 1433, noting that U.S.-based firms may be able avoid product liability if it cannot be demonstrated that they knew or should have known or could have known about their producer/suppliers partners' acts, and it may be difficult for consumers or consumer groups to assign blame for unsafe products produced via long, complicated supply chains. Congress could address that gap by making importers subject to civil penalties under the *Food, Drug, and Cosmetic Act*. The FDA could also issue stringent, binding guidance for importers of high-risk drugs and foods, including unannounced inspections and maintaining an employee of the importer full-time in each foreign production facility. See, by way of comparison, FDA, "Good Importer Practices (Draft Guidance)," <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125805.htm>, for nonbinding, broad guidance that applies across a wide range of products. Other scholars have recommended other approaches. See Bamberger and Guzman, "Keeping Imports Safe," 1432–34, proposing a system of discriminatory strict liability for unsafe food and drug imports with higher civil damages, administratively determined according to the relative risks posed by the product and exporting country; Tom Baker and David Moss, "Government as Risk Manager," in *New Perspectives on Regulation*, ed. David Moss and John A. Cisternino (Cambridge, MA: Tobin Project, 2009), 100–101, proposing bonded warranties obliging sellers to pay statutory damages to consumers injured by unsafe product imports.

organizational resources required to pursue regulatory cooperation and capacity-building efforts with developing countries that export the highest volume and highest-risk food and drug products to the United States. This is not the case currently.

3. The United States must engage on the broader global health food and drug safety agenda and incorporate developing country exporters' needs and interests if it is to gain cooperative action on the safety of U.S. food and drug imports.

Food and drug safety must be in the interests of the producers of goods destined for export, as well as the interests of their governments.

This goal can be accomplished by U.S. policymakers, first, engaging food and drug product safety as a global health issue, rather than as a problem of a few exporting developing countries. The United States, like other developed countries, has its share of incidents with unsafe, domestically produced food and drugs. A global health approach would lessen claims of double standards and unfairly targeting countries like China and India to limit exports and offer opportunities for collaboration among importing and exporting countries.

U.S. policymakers should, second, ensure there is an adequate mix of carrots and sticks to offer competitive advantage in the U.S. marketplace to purveyors of goods that are confirmed to meet U.S. safety standards. One such promising initiative is the two-year FDA Secure Supply Chain pilot program that, when launched in 2010, will enroll 100 drugmakers to test a verification process that could expedite importation of eligible drugs that meet specific product and shipping criteria.⁴⁹ Such a program, if successfully and more broadly implemented, could allow the FDA to focus its resources on imported drugs outside of the program, which pose a greater risk of being adulterated, misbranded, or unapproved. The pilot project remains in the comment phase, but deserves support.

U.S. policymakers should, third, consider the legitimate expectations and needs of developing countries in formulating the United States' approach on food and drug safety. Agriculture is an important, and sometimes singular, area of comparative advantage for many developing countries. As part of its overall package on food safety, Congress should consider funding appropriate mitigation strategies, such as regional cooperative management and certification regimes, to reduce costs for small and medium-sized developing country producers to comply with stricter food standards.⁵⁰ Congress is also in the process of mandating much greater use of private certification; it is critical that these regimes be flexible and adaptive to the legitimate needs and demands of developing countries.

⁴⁹ FDA, "Secure Supply Chain Pilot Program: Notice of Pilot Program," 74 Fed. Reg. 2605 (January 15, 2009), <http://www.fda.gov/OHRMS/DOCKETS/98fr/E9-791.pdf>.

⁵⁰ See Keith Maskus et al., "The Cost of Compliance with Product Standards for Firms in Developing Countries: An Econometric Study" (World Bank Policy Research Working Paper No. 3590, Washington, D.C., May 2005), noting that compliance with standards and technical regulations on product safety adds fixed compliance costs that can be decisive factors in limiting exports for developing country companies.

- 4. Efforts to build local regulatory capacity and monitor food and drug safety should be coordinated regionally and internationally with multilateral and intergovernmental institutions and integrated into U.S. international trade and economic policies. The United States should support international efforts on regulator interoperability, information exchange, and cooperation.**

Long-term, sustainable success on the global health problem of food and drug product safety cannot be the responsibility of the FDA or, more generally, the United States alone.

Food and drug safety has been and must continue to be a U.S. government interagency effort. There should be improved coordination and better leveraging of scarce USDA, FDA, and other U.S. agency resources in conducting port and foreign inspections and inspector training programs.⁵¹ The U.S. Centers for Disease Control and Prevention (CDC) plays a critical role in monitoring food-borne disease outbreaks domestically and would be an essential part of any effort to build global surveillance capacity for food and drug safety. A coordinated approach of U.S. international health, trade, and economic tools on the global problem of food and drug safety maximizes the effectiveness of limited U.S. government resources, engages other sources of leverage and expertise, offers additional opportunities to address issues, and helps ensure consistency with U.S. trade and economic policy and international trade law. U.S. government interagency mechanisms have usefully driven regulatory capacity-building and cooperation efforts in the past.⁵²

U.S. efforts on food and drug safety must leverage and support international and intergovernmental resources and tools on these issues. While regulatory oversight, control, and surveillance of food and drug product safety must occur at the local level, their success requires international support and coordination. The United States must be joined by and work with the European Union and other developed importing countries in providing financial and technical support for the development of food and drug regulatory capacity in developing countries. Intergovernmental institutions like the WTO, WHO, Food and Agriculture Organization (FAO), and World Bank and regional institutions like APEC and the Association of Southeast Asian Nations (ASEAN) also have programs on food and drug safety, regulatory capacity building, and/or food-borne disease surveillance. These institutions and efforts, however, have been underutilized by U.S. policymakers, earning almost no mention in the 2007 Import Safety Action Plan. This should change. With

⁵¹ See GAO, "Oversight of Food Safety Activities: Federal Agencies Should Pursue Opportunities to Reduce Overlap and Better Leverage Resources," March 2005, GAO-05-213, recommending that: (1) FDA commission USDA officials, pursuant to the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, to conduct FDA-regulated food safety inspections at ports of entry; (2) FDA rely on USDA foreign inspection reports, FSIS food safety system equivalence determinations, and the National Marine Fisheries Service's voluntary, fee-for-service seafood product and processing facility inspections in determining where to conduct foreign risk-based inspections; and (3) pursue, where feasible and cost effective, joint FDA-USDA inspector training programs.

⁵² Raymond J. Ahearn, "Transatlantic Regulatory Cooperation: Background and Analysis," CRS report for Congress, RL34717, Congressional Research Service, October 22, 2008, 11.

appropriate U.S. support, such institutions could usefully address international regulator interoperability and coordination—issues the United States cannot address effectively on its own. Intergovernmental institutions, such as the WHO/FAO Codex Alimentarius Commission (the international food safety body), can generate international risk-based, commodity-specific performance standards for the production of high-risk foods and drugs and may be better vehicles for securing trading partners' buy-in than often-contentious bilateral negotiations of memoranda of understanding.