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Backgrounder

Food and Drugs: Can Safety Be Ensured in a Time of Increased Globalization?

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Every aspect of the world's food, drug, and medicine supply chain has globalized, often to such a degree of complexity that it is difficult to determine where a given agricultural component in a food product was grown, from what source a specific chemical used in pharmaceutical formulation originated, or through which channels particular medicines were packaged and distributed. The scale and pace of transformation of food and drug production and distribution has far outstripped the capacity of national regulatory agencies or law enforcement offices to verify authenticity and safety. In a single generation countries that have, for centuries, been self-reliant for food have become net importers. On a similarly rapid timetable, drug and vaccine manufacturers that were once entirely domestically based have morphed into global webs of subcontractors and chemical plants located all over the world.

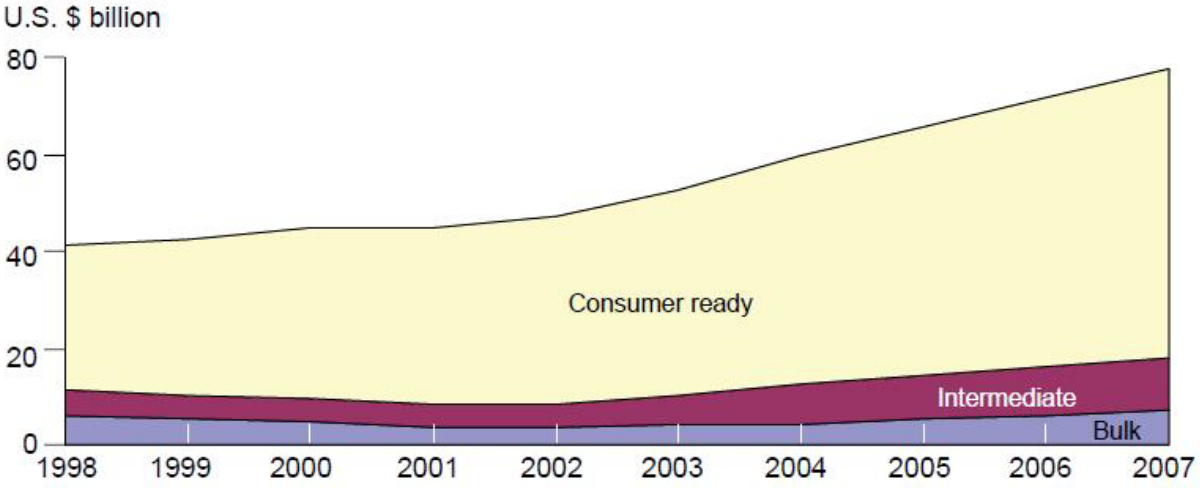
Most of the twentieth-century institutions created to guarantee food and drug authenticity and safety are nation-state functions that focus on domestic inspection and surveillance activities. Violators of national regulations are typically identified through domestic regulatory and law enforcement mechanisms and reprimanded, fined, or imprisoned based on national law and justice protocols. Agricultural inspectors visit local slaughterhouses, granaries, and food processing centers. Drug inspectors investigate some facilities around the world, but their resources are limited and the bulk of their inspections are domestic. Though many countries lack the resources to execute such actions on a routine basis, the food and drug safety and regulatory systems in wealthy and middle-income nations have functioned reasonably well most of the time, limiting human health catastrophes and disease spread.

As we enter the second decade of the twenty-first century, however, the national regulatory and health systems of all nations, regardless of their comparative wealth, are hard-pressed to meet the challenge of globalized food and drug production, processing, and distribution. In the absence of viable forms of global governance in food and drug manufacture and trade, the risk to public safety is rising all over the world.

The Scale of the Problem: Food

In 1999, the United States imported $41 billion worth of food. By 2009 that figure reached $77 billion.[1] U.S. fish and shellfish imports rose over that time from 1.7 million metric tons (MMT) to 2.3 MMT.[2] Vegetable importation jumped from 4.6 MMT to 7.2 MMT and vegetable oils from 2.5 MMT to 4.7 MMT.[3] The largest increase has been in foods grown and processed outside the country, delivered as packaged or ready-for-labeling products.[4]

U.S. food imports rose rapidly during fiscal years 1998-2007; consumer-ready products grew fastest



Notes: Includes only food products. Products are classified per USDA Bulk Intermediate and Consumer Oriented groups with fish and seafood added to consumer-ready products. See appendix for description.
Source: Compiled by ERS using data from U.S. Department of Commerce, Census Bureau.

In 1989, the United States imported $22 billion worth of foodstuffs, about 20 percent of which came from the countries that today comprise the European Union. The next eight most significant food exporters to the United States in 1989 were, in order, Canada, Mexico, Brazil, Australia, New Zealand, Colombia, Indonesia, and Philippines.[5]

In 2009, the United States imported $77 billion worth of foodstuffs, with Canada the major exporter, contributing 20 percent. The next eight largest exporters were, in order, the European Union, Mexico, China, Brazil, Australia, Chile, Indonesia, and Colombia.[6] Not only is the United States increasingly dependent on foreign producers for the country's food supply; it has expanded its trade with exporters, especially China and India, and Latin American companies.

The globalization of food supply has also lengthened the supply chain. Given the complex sourcing of food ingredients and the lack of cooperation between food processors and their overseas suppliers, it is increasingly difficult to fully trace food "from farm to fork." Furthermore, globalization of food supply chains creates the so-called Wal-Mart effect: the huge buying power of large, vertically integrated multinational corporations and their razor-thin profit margins lead to cost-cutting pressures so strong that overseas suppliers and manufacturers searching for ways to use cheaper materials turn to unsafe or substandard products, particularly in the absence of significant local safety regulation.

With fewer than 1,800 inspectors in its employ, who are spending more than half of their time dealing with food and agriculture and are also responsible for drugs and medicines, the U.S. Food and Drug Administration (FDA) does not have sufficient personnel to test and scrutinize domestically produced foods, much less the increasing burden of imported foodstuffs.[7] In 2009, it is estimated that the FDA was able to inspect 1 percent of imported foods (compared to Japan's 15 percent inspection rate), and was granted the right to inspect a handful of the reckoned 200,000 food production sites outside the country that export to U.S. prepared and raw food distributors.[8]

The U.S. Centers for Disease Control and Prevention (CDC) estimates that 48 million Americans in 2009 took ill as a result of ingesting contaminated food and drinks, 128,000 of them were hospitalized, and 3,000 died.[9] Because of the complexity today in food production, the CDC is unable to determine what percentage of these contamination incidents is entirely of domestic origin versus imported.

The conundrum the United States faces in trying to guarantee the safety of its increasingly globally derived food supply is mirrored, to varying degrees, all over the world. According to the United Nations Food and Agriculture Organization (FAO), global food imports were valued at $351 billion in 1990.[10] By 2008, the FAO estimated that number had soared to $1.1 trillion.[11] Few countries have the capacity to meet their populations' food demands based solely on domestic production, not only because of the vagaries of agricultural production and increasing human population size, but also due to the positive improvements in dietary intake, as an increasing percentage of the world's people can afford protein in the form of milk and meat. In 1980, in the world's poor countries, the average adult consumed 14 kg/year of meat (compared to 73 kg/year in developed countries). [12] By 2015, that is projected to reach 32 kg/yr in poorer countries, compared to 83 kg/yr in developed nations. Milk consumption had climbed from 34 kg/yr per person in poorer countries in 1980 to 55 kg/yr by 2010 (still far shy of the projected 203 kg/year per person in 2015 in wealthy nations).[13]

The global trade in raw and processed foods, estimated to have topped $1 trillion in 2009, has increasingly been a target for market speculation and resultant price inflation.[14] While the G20 finance ministers are focusing with urgency in 2011 on worldwide mechanisms of cost control for this massive uptick in food commodities trade, the safety of that escalated trade and limited inspection capacity for all nations has not yet garnered the institution's formal attention. The G8 Muskoka Summit (2009) commitment to food security and the White House "Feed the Future" initiative provide potential opportunities to better link food production with food safety and strong regulatory systems.

The biggest food importers are multinational retail grocers and prepared-food chain restaurants, such as Wal-Mart, McDonald's, Costco, Safeway, Burger King, and Kentucky Fried Chicken. Many such companies now run their own laboratory and inspection operations, entirely separate from government activities inside exporting and importing nations.[15] Health experts at the World Health Organization (WHO) and other institutions have expressed serious concern that in the absence of systems of globally agreed-upon governance and inspection executed by the *public* sector, private corporate standards of safety will supersede, and even render useless, governance structures aimed at the food supply.

The Scale of the Problem: Drugs, Pharmaceuticals, and Vaccines

Every aspect of drug manufacture, packaging, and distribution has globalized in recent years. According to the Government Accountability Office, non-U.S. and non-European drug manufacturing increased from 10 percent to 80 percent in the past two decades.[16] In 2008, 40 percent of the foreign drug manufacturers registered with the FDA were Chinese and Indian, representing a 30 percent increase from 2002.[17] The United States now imports some 40 percent of its drugs.[18] Chemical, mineral, and biological raw materials used in drug manufacture come

from all over the world, and production and packaging are now handled by a vast network of companies, large and small, that may ultimately sell their materials to multinational companies. These products cover everything from aspirin to advanced genetically engineered bio-products and sophisticated vaccines. A product may bear the label of a Swiss or German company, though all of its components and formulation may have been executed outside of Europe. In this sense the drug and medicine industries' trends merely mirror those seen with other types of manufacturing from computer software to automobiles. As is the case with those other industries, the drug business has witnessed a surge in importation from China and India. Combined, India and China now control 20 percent of the global generic drug and over-the-counter (nonprescription) markets.[19]

While this shift in origins of raw materials, chemical formulation, and packaging makes good business sense for the relevant companies and spreads the wealth of the industries across a broader swath of nations, it renders much of drug safety regulation and inspection extremely challenging. No country is able to inspect all of the foreign factories that are supplying its products, and very few governments have shared inspection agreements of any kind. The burden of ensuring the authenticity and purity of raw materials exported from Country A to a chemical formulation plant in Country B falls on the receiving company.

Complicating efforts to address vulnerabilities of globalized supply chains for drugs and medicines is an ongoing dispute over definitions of such terms as "counterfeit," "fake," "falsified," and "substandard" drugs. Counterfeiting and substandard drugs pose significant public health risks. Yet the 2010 Anti-Counterfeiting Trade Agreement (ACTA) frames "counterfeiting" as a trade and intellectual property issue, which may be appropriate in the context of trade but complicates the landscape from a public health perspective. ACTA is viewed by many humanitarian groups and governments as blurring distinctions between intellectual-property-right theft from patent holders and criminal acts involving deliberate sale of fake, fraudulent, or contaminated products. It is difficult to evaluate data pertaining to counterfeit drugs because of global differences in definition.

For the sake of clarity in this discussion "counterfeit drugs" will be defined as products that claim to be manufactured by Company A, for example, but were actually made by Company B and therefore bear false labeling. In such a definition, "counterfeit" drugs may be only partially effective, or be ineffectual and dangerous but clearly represent a form of public health fraud and harm. They may contain too many, too few, no, or wrong ingredients. This definition is in concurrence with that of the WHO: "Counterfeit medicines are medicines that are deliberately and fraudulently mislabeled with respect to identity and/or source."[20]

"Fake and substandard" products cover a broader range of drugs, vaccines, and medicines, as they may include products legitimately made by the company that claims their manufacture (and are therefore not, technically, "counterfeit"). What distinguishes this category is that the products represent a clear potential safety hazard, as they either make false claims regarding effectiveness of the drug, contain chemicals or biologicals that are fraudulent or hazardous, have no active ingredient, represent repackaging of long-expired medicines, or are deliberately diluted in order to allow the seller to garner greater profit by stretching supplies of active ingredients.

Drug Counterfeiting

Sale of counterfeit drugs, vaccines, or medicines has been confirmed in at least 90 countries worldwide, accounting for 8 to 10 percent of the world's pharmaceutical market.[21] Sales are heavily skewed toward developing countries, with confirmed counterfeiting constituting just 1 percent of the developed-world pharmaceutical and drug market. Most sales of counterfeit drugs in wealthier countries transpire on the Internet. According to the WHO, counterfeit drugs have been found in over 50 percent of the medicines sold online from illegal sites.[22] Both branded and generic products have been counterfeited. Indeed, all kinds of medicines, from "lifestyle" drugs (e.g., Viagra, diet pills) to "mainstream" use drugs, including inexpensive generic drugs (e.g.,

painkillers, antihistamines) and medicines for the treatment of life-threatening conditions (e.g., cancer, diabetes, malaria) are subject to counterfeiting. According to the Center for Medicine in the Public Interest, global sales of counterfeit drugs totaled approximately $75 billion—an estimate that is close to the WHO reckoning of $72 billion.[23]

Counterfeiting is most serious in regions with extremely weak regulatory systems and market controls. In Asia, Africa, and Latin America, 10 to 30 percent of the medicines on sale are believed to be counterfeit drugs. With up to 30 percent of its pharmaceutical market overtaken by counterfeit drugs, Kenya is named by the WHO as a "safe haven" for counterfeiters.[24] With the globalization of drug manufacturing and marketing, even industrialized countries with effective regulatory and enforcement capacities are seeing their drug supply systems compromised by the increasingly sophisticated activities of counterfeiters, often linked with organized crime. In December 2010, five British citizens, including a pharmacist, were accused of sourcing medicines from China via parallel imports and infiltrating the United Kingdom supply chain with counterfeit versions of medicines such as Sanofi-Aventis's heart medicine Plavix (clopidogrel), AstraZeneca's prostate cancer treatment Casodex (bicalutamide), and Eli Lilly's Zyprexa (olanzapine) used for schizophrenia.

The harm of drug counterfeiting extends beyond lost sales for legitimate drug makers. Because they have not been subjected to country safety inspection or regulation, the products may contain toxic materials, repackaged expired drugs, or insufficient or no active ingredients, thereby posing a serious public health risk. Their use may lead to treatment failure. According to a recent study conducted by the WHO and the United States Pharmacopoeia (USP), anti-tuberculosis and anti-malaria products falsely packaged in pharmaceutical labeling showed treatment failure rates as high as 70 percent in Nigeria, 60 percent in Ghana, and 50 percent in Cameroon.[25] A 2009 report from the International Policy Network estimated that 700,000 people are killed annually because of counterfeit and substandard malaria and tuberculosis drugs.[26] Eventually, drug counterfeiting undermines the credibility of national health and enforcement authorities.

In many cases, it is impossible to visually detect the differences between counterfeit drugs and the authentic version. Unlike substandard medicines, which may involve a known manufacturer, counterfeit medicines are made by people with the intent to mislead and misinform. In online marketing, the counterfeiters typically work with sites that conceal their locations and identities. Pharmaceuticals advertised as having come from the United Kingdom, for example, may actually be made in China and repackaged in the Bahamas. This multinational supply chain renders it extremely difficult to trace the manufacturing and distribution channels of counterfeit medicines. Worse, few national legal systems are equipped to address the serious consequences of drug counterfeiting, offering light penalties or jail sentences to those few criminals who are actually caught by law enforcement authorities. Health officials typically find law enforcement personnel uninterested in pursuing the complex, multinational chains of criminality involved in the production and distribution of counterfeited medicines, unless it can be proven that the products fatally poisoned a large number of people.

Improper Formulation and Contamination

According to the World Health Organization the burden of fraudulent "drugs" falls on poor countries, where upward of 25 percent of medicines are, WHO says, "counterfeit or substandard."[27] Critics charge that WHO is understating the impact of fake and substandard drugs in poor countries, which may amount to nearly one-third of all medicines distributed in those nations.[28] The underestimates may stem from the definitional issues, amid interchangeable use of "counterfeit," "substandard," and "fake." In one study of forty-six nonvalidated reports of counterfeit drugs, WHO found the following:

— Products missing active ingredients (32.1 percent of counterfeits)
— Products with incorrect quantities of active ingredients (20.2 percent)

— Products with wrong ingredients (21.4 percent)
— Products with correct ingredients and amounts but fake packaging (15.6 percent)
— Copies of original products (1 percent)
— Products that contain high levels of contaminants (8.5 percent)[29]

The WHO survey is small and leans on several nonvalidated studies, but it is the only such breakdown of medicine crime and contamination available. It reckons that the annual worldwide cost of such activity totals $431 billion. Assuming the nature of the frauds and their percentages of "counterfeit" trade are correctly estimated by the WHO, 83.4 percent of the criminal activity involves improper formulation, contamination, or fake drugs, for a total criminal activity cost of $359 billion—up since 2000 from an estimated $100 billion.

Fraudulent drugs can drive microbial resistance that eventually renders properly made and formulated medicines useless. For example, fake anti-malaria drugs sold in five Southeast Asian nations in 2008 either contained no active ingredient or suboptimal doses that could not protect users against the disease. New forms of drug-resistant malaria have now emerged in the region.[30]

During the 2009 swine flu pandemic, fake Tamiflu tablets containing no active ingredients were sold in many countries and over the Internet.[31] Anti-microbial resistance causes infections to fail to respond to treatment, results in extended periods of illness, and increases treatment costs, not to mention the risk of death.[32] In 2007, fake Xenical diet tablets composed of sugar and talc were sold over the Internet.

In some cases, criminals copy pharmaceutical labeling with exquisite detail, even including batch and expirations numbers, to sell sugar pills or water. The result is that patients are treated with "medicine" devoid of active ingredients. There is evidence that this is a widespread practice among criminals vending fake anti-malarial drugs in East Africa.[33] The Nigerian National Agency for Food and Drug Administration and Control over a seven-year period (2001–2008) captured $16.25 billion worth of fake medicines, many of which were destined for export throughout Africa.

An epidemic of meningitis swept West Africa in 1994–95, creating opportunity for illegal "vaccine" makers in Nigeria. The Nigerian criminals made useless "vaccines," some of which were labeled with European pharmaceutical logos. Children in Nigeria died as a result, and the Abuja government donated 88,000 doses to neighboring Niger, leading to the deaths of another 2,500 children.[34] Supposed vaccines are a common target for criminal activity. In December 2010, eight "vaccine" makers were imprisoned in China for selling 530 doses of fake rabies vaccines. At least one child died of rabies after receiving six injections of the useless fake product.[35] A nursing home owner in Houston, Texas, was imprisoned in 2005 after he distributed fake influenza vaccines that were injected into 1,000 Exxon Oil Company employees and residents of one of his elder-care centers.[36]

Numerous incidents have involved substituting expensive or patented active ingredients for cheaper, poisonous ones. In 2007–2008, postoperative patients in hospitals in Europe and North America suffered anaphylactic episodes, and some 250 deaths (19 in the United States), after being treated with heparin blood thinner sold by the U.S. company Baxter International. Baxter purchased the raw ingredients from a Chinese company, Changzhou-SPL, which had substituted an expensive pig-derived compound for a synthesized, poisonous chemical.[37] The FDA discovered phony Alli diet pills in 2010 that had the wrong active ingredient and instead contained a dangerous heart stimulant.[38]

Ghana's Food and Drug Board (FDB) launched a campaign at the close of 2010 against fraudulent Chinese-made medicines that have flooded the West African country.[39] Ghanaian authorities say Chinese marketers starting dumping expired and phony medicines in their country after Beijing cracked down on fraudulent domestic sales in

early 2008. In 2007, in China some 329,613 illegal drug sales were reported domestically; in 2008 that figure fell to 297,500 following a national crackdown, especially on the aphrodisiacs trade. In Ghana in 2009 and 2010, sales of bad Chinese drugs—especially aphrodisiacs and male sexual performance enhancers, jumped dramatically—leading the country's FDB to charge that the Chinese companies simply dumped the domestically banned products on African markets.

Raw Ingredients

The United States imports about 80 percent of the raw active ingredients used by the country's drug manufacturers.[40] For certain chemicals and ingredients, dependency on foreign producers is greater. The United States imports 100 percent of wheat gluten supply.[41]

Two countries—China and India—have taken center stage in production of raw materials for drugs, medicines, and pharmaceuticals, having, prior to 1999, had virtually no contributors to global trade in this area. Since 2002, China has emerged as a major player, controlling about 50 percent of the global aspirin market, 35 percent of acetaminophen production, and nearly 100 percent of synthetic Vitamin C production.[42] In 2009, China boasted more than 4,100 manufacturers of analgesics, vitamins, and antibiotics, representing a $15 billion export market.[43]

The global marketplace for raw materials used in drug manufacture is so fluid and is shifting so rapidly (especially to Asian production sites) that it is difficult to accurately estimate its size, directions of market flow, or actual sources of essential chemicals and minerals. Trade now takes place online, linking importing companies with hundreds of potential exporters.[44] Made-in-China.com, for example, links potential importers with 703 raw material suppliers in that country.[45] Indiamart.com provides a similar service, linking potential importers to suppliers of 2,496 active ingredients, in addition to stabilizers, capsules and pill makers in India.[46]

Whether an importing company is in the Americas, Europe, Africa, or Asia, the burden of proof for compound authenticity and purity in purchasing raw ingredients falls on the importer. No national regulatory agency in the world has the capacity to follow or monitor this market.

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