COUNCIL *on* FOREIGN RELATIONS

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

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Over the last two decades, the scale of global food and drug trade has expanded dramatically. During his opening remarks, **Richard Haass**, president of the Council of Foreign Relations, said that "from 1990 to 2008, global food imports rose in value from $350 billion to over $1 trillion… and globalization has had an even more significant impact on the pharmaceutical market. Today, drug manufacturers located outside the United States and Europe command 80 percent of the global market, up from 10 percent just two decades ago." However, global governance and regulatory capacity have not grown to meet the challenges presented by this increased trade. As globalization has increased, so have the number of cross border food contamination events and food-borne illness. The global trade in counterfeit, falsified, and substandard medicines has been estimated to be in the realm of hundreds of billions of dollars.

In December 2010, the U.S. Congress passed the Food Safety Modernization Act, a bill which empowers the U.S. Food and Drug Administration (FDA) to expand its surveillance and inspection efforts. Despite this success **Margaret Hamburg**, commissioner of the FDA, reiterated her conviction that no amount of national legislation could ensure food safety. Hamburg stated that, "we have to recognize this isn't a problem that our nation or any other nation can inspect is way out of. It really is a problem that requires a fundamental shift in how we think about the problem and how we work together as two partners across nations and governments, as well as across sectors." **Paul Orhii**, director-general National Agency for Food and Drug Administration and Control (NAFDAC) in Nigeria asserted that food and drug safety is a "life-and-death issue" for his compatriots and a challenge that they cannot face without substantial cooperation and support from the international community.

The overarching consensus of the meeting was that effective food and drug safety at the national and local levels would require a new scale of global cooperation focused on the harmonization of safety principles, the sharing of information, and the building of regulatory capacity, especially in the

developing world. This new coalition would need to go beyond government officials and incorporate industry leaders, consumer advocates, and multilateral organizations. Hamburg issued a call for a new way forward:

> This is a moment for leaders around the world to create a new vision of how we regulate. We have a shared interest in assuring the safety and quality of food and medical products, and a shared responsibility for safety and quality. By working together to monitor and to improve safety and quality globally, we will benefit all of the citizens of the world. What I envision for the future is a public health safety net for consumers around the world that is created, supported, and maintained by a global alliance of regulators, working closely with all our critical stakeholders.

There are, however, significant obstacles blocking such achievements. Though a relative consensus was established during the meeting, with experts agreeing that the public health fight against counterfeit drugs should be decoupled from issues of intellectual property, significant disagreements over specific definitions of counterfeit, substandard, and falsified medicines remained. Additionally, the food sector has established international safety standards but suffers from insufficient implementation. **Caroline Smith DeWaal**, food safety director at the Center for Science in the Public Interest argued that "we need to recognize that some of the tools to accomplish [better food safety] already exist and need to be strengthened and further developed."

Laurie Garrett, senior fellow for global health at the Council on Foreign Relations stated in her final remarks:

> I began earlier talking about the question of global governance. One of the interesting possibilities as you look at this food and drug space is that every human being on planet Earth has a stake in seeing this resolved. This is not an abstract problem like climate change, where many people can convince themselves that either it's not occurring, or it's too big and they are just a little person, what can they do about it, et cetera. Every single person on the planet takes drugs, depends on medicines, has injections, and eats food. It doesn't get much more bottom line than that.
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> And if there is any opportunity to really mobilize some sense of what global governance might look like, this I think is an ideal place to begin—to begin to think about a different scale and way of organizing that involves private players, public players, multilateral players, donor players and consumers, average citizenry, and some new kind of yet-to-evolve sense of what global governance could look like.

Session One: The Scale of the Challenge: Overview and Case Studies

Richard Besser, chief health and medical editor at ABC News, led the first discussion, asking why it might not be possible to, as Hamburg had asserted, "inspect our way out of this problem."

Orhii responded that the "the culture of chasing counterfeiters within a country is not sustainable in the long run" as globalization had radically changed trade and supply routes and require global regulatory capacity and governance. In an example of how countries need to work together in order to ensure product safety, Orhii described a case in which substandard Chinese drugs were imported into Nigeria mislabeled as originating in India. Working with Chinese and Indian officials, NAFDAC was

able to track down the drugs' origin, resulting in the arrest and subsequent Beijing-ordered execution of six Chinese counterfeiters.

Impeding safety are serious inefficiencies in current international institutions charged with setting international food standards, notably the Codex Alimentarius Commission and the World Trade Organization (WHO), which often "take a very long time to reach resolution" according to **Gary Kushner**, partner and lead of the food and agriculture practice area at Hogan Lovells. On the industry side, the hazard analysis and crucial control point program (HACCP) has been the cornerstone of food industry's safety standards, which Kushner characterized as largely successful.

The paramount challenge in creating a global coalition focused on combating fake drugs has been the striking inability of the international community to cut through trade disputes, reaching an agreed definition of "counterfeit" medicines. Since WHO took up the issue of drug safety thirty years ago, the definitions of the various types of harmful drugs have been hotly contested because of concerns about intellectual property rights. Describing the results of a recent meeting held by Chatham House in December 2010, **David Heymann**, head and senior fellow at the organization's Centre on Global Health, suggested it is easier to define "substandard drugs and vaccines." He described this category of drugs as "those that don't meet regulatory requirements in the country in which they're produced or in the country in which they're imported." This definition applies to both patented and generic drugs. However, within the category of substandard drugs, there are two subcategories that continue to generate controversy: falsified drugs and counterfeit drugs. Heymann argued that counterfeit drugs constitute issues of copyright and have an established framework. However, it is falsified medicines that lack clear definition. The Chatham House meeting developed definitions for each of these three categories which Heymann hopes will help the World Health Organization overcome this dispute. Orhii suggested that the discussions of intellectual property had been "deliberately used to confuse the issues." Both speakers agreed that counterfeit drugs in the regulatory framework should be defined solely in the public health context. However, **Charles Clift** of Chatham House noted that some countries, Brazil in particular, had narrow definitions of "counterfeit" drugs that focus on intellectual property. Brazilian officials instead prefer to use the term "falsified" medicines in the public health context.

Developing countries are most at risk from violations of food and drug safety. Unfortunately, they also have the least resources and regulatory capacity to deal with the ever increasing tide of food and drug imports. Orhii said that 60 to 70 percent of essential medicines sold or distributed in Nigeria are purchased in China or India, with as much as 40 percent of all medicines being counterfeit. Without technical assistance and training in addition to increased resources, it will be impossible for countries like Nigeria to ensure the safety of their populations' food and drug supply. Orhii noted the limited capacity that Nigeria has to regulate the huge number of imported food and drug products coming into the country stating that "the borders are vast, [and] poorly managed because of lack of funds." Besser underscored the danger faced by regulators in the developing world, highlighting the fall 2010 assassination attempt on Orhii.

Shifting to food safety, Kushner described the new Food Safety Modernization Act as a "very, very important step forward in helping to harmonize regulation and ensure the safety of products coming into the United States." However, the FDA remains underfunded and under staffed with fewer than two thousand inspectors for both food and drugs. In comparison, the U.S. Department of Agriculture (USDA) has nearly seven thousand investigators for meat and poultry alone. Though some observers insist that greater efficiency in food regulation could be realized by merging USDA, FDA, and other

agency operations, Kushner did not believe that it was realistic that a single food regulating agency would be established in the United States. Instead, the food industry lawyer suggested that the current agencies to work under a central "approach or philosophy."

Trade concerns are also important to the food safety debate as countries are often accused of creating regulations "in the guise of food safety standards to protect their local industries and keep products out," according to Kushner. The protectionism versus safety tension is particularly salient in Europe. Heymann cautioned that the European Union does not speak with a single voice on food and drug safety and that many countries in the region lacked their own regulatory capacities until recently.

Experts have had a difficult time agreeing on how to sanction "bad actors" in the food and drug trade that seem to have less interest in consumer safety. Using the example of the SARS epidemic and the World Health Organization's criticism of China's response, Heymann argued that it was possible to elicit behavior change by calling out governments that were noncompliant and essentially embarrassing them on the world stage. Changing attitudes at the local level is also essential to increasing adherence to safety standards, as top-down approaches have not shown the desired results. Heymann argued that a "multi-pronged approach," incorporating both political policy shifts and individual behavior change, was necessary.

Session Two: Policy Challenges in a Globalized Era

Susan Dentzer, editor of *Health Affairs*, asked the speakers to detail case studies that illustrate the complexities of a world where international food and drug trade is growing and increasingly complex, but national capacity remains inadequate and current global governance is insufficient.

In 2008, the U.S. Food and Drug Administration was confronted with cases of food-borne illness around the country which were eventually confirmed to have been caused by salmonella contaminated tomatoes and peppers imported from Mexico. Commissioner Hamburg described the incredible epidemiological and logistical hurdles that the FDA faced during the outbreak, which resulted in an incredible cost to both consumers and industry. The example was instructive of how no single nation could maintain food safety on its own. Going forward, both prevention and outbreak response will require cross border and cross sector collaboration.

The International Medical Products Anti-Counterfeiting Taskforce (IMPACT) has been the World Health Organization's most ambitious and controversial effort to combat fake medicines. **Howard Zucker**, former assistant director-general at the World Health Organization, described difficulties during his tenure in the founding leadership of IMPACT.

Divided by deep disputes over intellectual property issues versus drug safety concerns, IMPACT struggled for years. Zucker contended that the "counterfeit" definition should consider intent and whether someone was moving "something forward in the supply chain of medicines" with a "guilty mind." **Dirceu Barbano**, director-chairman of Brazil's National Agency of Sanitary Surveillance, acknowledged that "the discussion of falsified and substandard products is of great interest to the Brazilian government" making no reference to counterfeit medicines. Later in his talk, the Brazilian regulator acknowledged that Clift had accurately described the Brazilian position and that his government did not see counterfeits as a public health issue but as part of an intellectual property debate. Building on the relative consensus that the intellectual property issues should be resolved separately from the public health challenges, Zucker agreed that until this is done, international collaboration would remain difficult.

Barbano offered the Brazilian case study focused on the need for local capacity to advance food safety. Using the example of acai berry contamination in 2007, Barbano described the steps that the Brazilian government took to identify the source of Chagas disease in the Amazon region, eventually linked to the consumption of the fruit. Barbano said that "this case is very interesting because it shows that in many instances, global efforts will be insufficient." His point reflected statements made earlier by Orhii about the development of national regulatory capacity and Heymann on the need for bottom-up approaches. Barbano also discussed the need for regulatory autonomy so that government officials would be able to resist pressures from interest groups. Hamburg suggested that it was in the self interest of the United States to invest in the regulatory capacity of other countries, to ensure that there is a "minimum threshold of standards for food products around the world."

Dentzer asked whether public outrage might drive governments' investments in regulatory capacity. Hamburg noted that food and drug safety was one of the few areas where nearly everyone, regardless political affiliation or ideology, could agree that government should have a lead role. "They want to know that the drugs that they are taking and giving their family are safe as well. And I think for the most part in the United States, people assume that to be true." But Hamburg said public outrage is typically reactive rather than proactive and consumers take for granted that the products they consume are safe. However, the commissioner pointed to the Food Safety and Modernization Act as a reason for optimism at it represents a rare instance of consumer groups, industry, and government coming together to demand better regulation.

Zucker suggested that he too felt that greater grassroots activism was needed on this issue. This assertion was challenged by **Jean Hollaran** of Consumers Union who pointed out that consumers in many countries were constrained by governments more interested in political repression than food safety, noting the case of jailed Chinese parents in the wake of that country's infant formula scandal. **Ashifi Gogo** of Sproxil, a new firm working on drug monitoring in Africa, asked about using consumer reports to build a database of contamination events and suspect companies. However, Hamburg noted that this would be somewhat difficult in the area of medicines as consumers are often unaware that they are taking fake drugs. Barbano offered the example of a new model being developed in Brazil that will use barcodes to track medicines. He also referenced a project launched by the Organization of American States, the Consumer Safety and Health Network, a new international database of health alerts. Dentzer noted that given Brazil's success, there is hope that other resource limited countries might be able to create capable regulatory systems.

Session 3: Potential Solutions

Garrett led the final panel focusing on mechanisms that could move global food and drug regulation to greater harmonization and safety.

In 2006, Interpol began to partner with WHO's IMPACT initiative to coordinate law enforcements activities and in 2010 established the Medical Products Counterfeiting and Pharmaceutical Crime Unit (MPCPC). **Aline Plançon**, head of MPCPC, said that "the countries where we've been interacting are starting with nothing, with not knowing even one another when we did some meetings between the policy, the health, and the customs [officials]." What is really required, Plançon insisted, is "thinking differently, thinking outside the box" and focusing on global collaboration**.**

Unfortunately for organizations like Interpol, criminals are increasingly sophisticated and have begun to move from the illicit drug and narcotics trade to creating counterfeits of legitimate pharmaceutical

products. **Greg Simon**, senior vice president for worldwide policy at Pfizer, noted that the incentive for criminal counterfeiting will only increase as the focus in the developing world moves from neglected tropical disease and infectious disease to noncommunicable disease, which require long-term, often lifelong treatment. Additionally, as pharmaceutical companies make advances in medical technology to allow for easier implementation, like the new PATH meningitis-A vaccine, criminals will find it easier to create imitations. This will require the pharmaceutical industry to continually innovate to stay ahead of counterfeiters, according to Simon. The fact that many, if not most of these drugs are sold on the Internet also presents a huge challenge as criminals can quickly change servers and restart websites that have been brought down by organizations like Interpol. However, coordination between law enforcement and internet service payment providers has already shown results, suggests Plançon.

Increasingly, vaccines and essential medicines donated through humanitarian organizations are being stolen, diluted, and sold on the black market. Garrett highlighted this problem illustrating an investigation she conducted on drugs sold in the former Soviet Union which had been trafficked from humanitarian relief operations in Ethiopia. Combating this problem will require a change in mentality on the part of donors and recipient countries and an emphasis on developing a monitoring system, according to Plançon.

The pharmaceutical industry has devoted considerable resources to fighting counterfeit drugs and in many ways is leading the effort. Pfizer has worked with the U.S. government to help train officials in anticounterfeiting in its Groton, Connecticut lab. Simon described counterfeit drugs as less of an attack on the Pfizer brand than an obstacle to achieving their mission of "the ethical production of medicines that help improve the health of people all over the world." He described counterfeit and falsified drugs as an "assault" on consumers who are expecting a healing product but instead get something that has no affect and potentially breeds microbial resistance or causes actual direct harm.

The speakers agreed that it was an essential responsibility of industry to ensure the safety of their own products. Both Simon and **Michael Robach**, vice president for corporate food safety and regulatory affairs at Cargill, suggested that industry does, and should spend more on safety than government. They contended that it would be impossible for national regulators to inspect every plant of every company in every locale. Food companies have set up manufacturers' alliances to ensure that bad products are not turned away from one plant only to be accepted at another. Despite these established networks, panelists concluded that there was no single authority, or "911" as termed by Laurie Garrett, which could receive and respond to reports of contamination or counterfeiting.

In contrast to drug safety, food regulation has a long established global body, the Codex Alimentarius Commission, which is charged with setting global standards and widely accepted. Smith DeWaal, food safety director at the Center for Science in the Public Interest, argued that Codex is an important standard setting regime but that a framework for implementation is lacking. Like most global organizations where each country gets a singular vote, the Codex process is often slow and thus, ineffective. Additionally, Smith DeWaal noted that arguments between the United States and the European Union often divide the global body, preventing it from conducting necessary work over what should be bilateral discussions.

One study has suggested that a single cheese burger could be composed of components from as many as 54 different countries. Robach described the incredibly complex food chain supply lines that have developed over the past several decades. "It's not simple. And it takes an awful lot of work, not only

within the company, but then also with our suppliers, and our suppliers' suppliers, to really be able to focus in on what's really important from the positive public health standpoint."

Already established principles of Codex and HACCP should be applied universally and can serve as the basis for improving food safety globally, Robach and Smith DeWaal agreed. Additionally, understanding the differences from region to region, which require unique responses, is necessary if the United States is to be successful in ensuring food safety. Smith DeWaal argued that "if the U.S. tries to manage food safety risks based on the standards that are important to food produced in the U.S. we'll be missing the mark when it comes to imports."

Smith DeWaal noted that there is wide variation across the United States in the scale and quality of safety investigation. Internationally, she said, the variation is even more pronounced. Many African governments, for example, report large scale contamination events and outbreaks but lack much useful epidemiological data. The World Health Organization has begun to set up regional laboratories to increase monitoring capacity, which will require greater resourcing. However, increased surveillance will only be useful if governments and others act on the data. In 2007, melamine was found in the United States in pet food imported from China, sickening or killing several thousand pets. A year later, the same substance was found in milk formula in China. According to Smith DeWaal, this information was not acted upon. "We need to listen to the surveillance, we need to recognize the canaries, and we need to take action a lot faster than I think we are today."

When asked by the presider what she would ask of White House aides planning next year's G20 agenda, Plançon commented that just getting the issue of pharmaceutical crimes on the agenda would be important. Mike Robach contended the governments could reallocate spending to focus on areas of real need and transition to preventive public health. Greg Simon wanted a small amount of money to create a global tracking system for drugs that could be based on the credit card monitoring model. Smith DeWaal argued for a sharp increase in funding for capacity building in the developing world.