

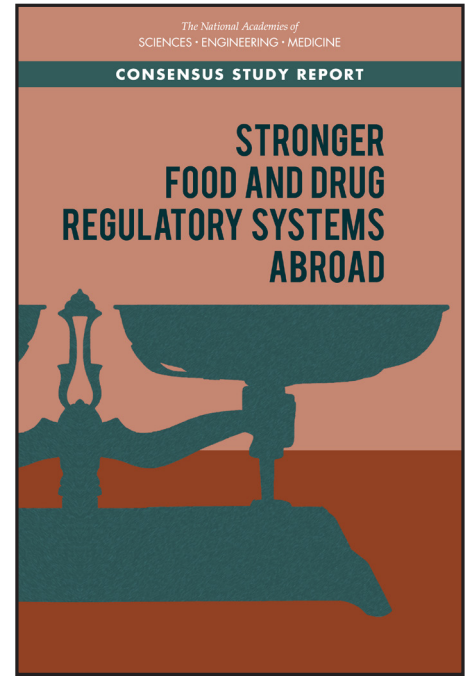


January 2020

## Stronger Food and Drug Regulatory Systems Abroad

By recent estimates, unsafe food kills over 400,000 people a year—a third of them children under 5, mostly in low- and middle-income countries. In sub-Saharan Africa alone, poor quality medicines cause about 70,000 excess deaths from childhood pneumonia and roughly 8,500 to 20,000 deaths from malaria every year. Ensuring the safety and quality of food and medicines in a country is an important role of government and essential for public health.

The capacity of regulatory systems abroad is of special interest to the U.S. Food and Drug Administration (FDA) Office of Global Policy and Strategy, the office that commissioned this study and a similar one released in 2012. This report discusses changes in the field since the 2012 study and outlines a strategy to strengthen food and medical products regulatory systems in low- and middle-income countries, recommending actions at the global, national and agency levels ([see condensed recommendations table](#)).



### REGULATORY SYSTEMS, HEALTH, AND DEVELOPMENT

The last two decades have seen considerable health gains in low- and middle-income countries. Child mortality and infectious disease prevalence have fallen and nutrition has improved. While donors deserve credit for this progress, it is also a function of increasing global prosperity and national investments in health systems and other social programs. Functional regulatory systems are necessary for continued progress. Growing demand for safe food and medicines is also a consequence of increased prosperity.

Modern food and medicines production are global enterprises, and product regulation is an increasingly global task. International collaboration has therefore been cited as a minimum function of the regulatory agency. International meetings, such as the International Conference of Drug Regulatory Authorities, make it easier for regulators to work across borders. However, there is no standing international venue for food regulators to interact with their counterparts abroad. A formal, standing meeting for food regulators is an investment in food safety and emergency response, and something the report recommends the World Health Organization (WHO) and the Food and Agriculture Organization (FAO) convene.

### A ROLE FOR DEVELOPMENT PARTNERS

United Nations (UN) agencies such as the WHO and FAO, and other global health and development organizations can influence policy in ways that encourage strong regulatory systems. Development assistance is one tool to this end. Investing in low- and middle-income countries' regulatory systems builds institutions in the recipient country and helps ensure a vibrant market for safe food and effective, quality medicines. Still, regulatory systems have not been a high priority for most donors, who have traditionally preferred projects that promise measurable success on a

relatively short timeline. The recent development benchmarking tools for regulatory systems can help change that calculation, defining clear parameters to measure how well the systems function. A benchmarking assessment identifies the relative strengths and weakness in countries' systems, as well as a plan and timeline for improvement. Donors can encourage countries to go through such an assessment and target their assistance to priority areas identified in the assessment.

Global organizations can also encourage stronger systems through capacity building and regulatory cooperation. The WHO Prequalification of Medicines program provides regulatory assessment, inspection, and ongoing quality control for certain medical products procured through the UN or other large donors. Prequalification can help manage the combination of limited regulatory capacity and foreign procurement that many regulators struggle with. Prequalification also helps regulators work more efficiently, allowing them to give more attention to work that adds the greatest value and avoid redundant effort. The report calls for the expansion of prequalification to include products used in the treatment of cancer, diabetes, and other diseases with a high global burden.

The report discusses the limits of the regulator's power to improve quality if industry is not investing in quality. Sometimes the business case for meeting regulatory standards is not clear to producers, distributors, and retailers. Even when clear, if the capital available comes at too high a price, business calculations are not likely to favor improving their processes. Development banks and bilateral development finance can adjust this calculation, both through their advisory services and their concessional financing. With this in mind, the report recommends these organizations help manufacturers of screening technologies expand their manufacturing and distribution systems in the low- and middle-income countries where there is need for such products. The report also emphasized the role development finance can play in helping all actors on the distribution chain meet regulatory standards.

From the regulator's perspective, a lack of evidence to support regulatory policy complicates their job. Advanced agencies have ways to collaborate with academia on pressing scientific questions, such as the FDA Centers of Excellence in Regulatory Science have done. That model of dedicated research centers run in collaboration with universities could be adapted globally, which the report recommends National Institutes of Health (NIH), FDA and the U.S. Agency for International Development (USAID) take on.

## THE ROLE OF THE NATIONAL GOVERNMENT

The capacity of the regulatory system is partly determined by the willingness of the national government to support it. Much of the regulatory agency's effec-

tiveness, efficiency, and independence are determined by a country's political leaders, who are ultimately responsible for creating an environment conducive to product safety. Political leaders need to provide a legal framework to protect food and medical products in their countries, defining the institutions that make up the regulatory systems, the ways they are involved, and their ability to enforce rules. Their legal mandates should give special attention to provisions for independence, sustainable financing, and international cooperation.

Regulatory agencies around the world are facing the limits of their resources, driving an imperative to make good use of available funding and staff time. Work sharing with foreign agencies can improve efficiency, and it is important to ensure that support for international cooperation is in place. Considerations of the agency's financing must be made, balancing the tradeoffs and feasibility of support from taxes, fees on industry, earmarks, or some combination thereof.

## THE ROLE OF THE REGULATORY AGENCY

Regulatory work is highly technical and complicated and, when done properly, invisible to the consumer. This poses a barrier to public appreciation for the regulatory agency, but one that can be overcome with effective communication. Regulators need to be able to advocate for their work, quantifying its health and economic benefits.

Regulators can improve their efficiency by making use of global tools that can support their decisions, by determining what work can be shared internationally, and by determining what work should be devolved to local authorities. There is no universal blueprint to guide the coordination of multiple levels of government. Developing technical capacity at the local level and governance capacity (the skills that allow levels to work together) at all levels is important for effective delegation.

Steps taken to mitigate the risks of informal markets will have disproportionate returns for the agency because they depend on local context. Jobs that do not yield better understanding or control of local risks are best approached with an eye to making use of the work of other trusted authorities.

To read the full text of the committee's recommendations, visit [nationalacademies.org/StrongerRegulatorySystems](https://nationalacademies.org/StrongerRegulatorySystems).

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To read the full report, please visit  
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