Global Health Technologies Coalition

Advancing innovation to save lives

The FDA's role in global health

Helping safe, effective health tools reach people in need worldwide

The US Food and Drug Administration (FDA) is best known for its work to protect the health of US consumers, but the agency has a history of leveraging its expertise to benefit people worldwide and is playing an increasingly vital role in global health issues. As US leaders continue to prioritize global health and development, the FDA can play an important role in efforts to ensure the safety of health tools to prevent, diagnose, and treat infectious diseases that affect millions of people worldwide every year.

The need to regulate health tools

When health products undergo rigorous clinical trials to demonstrate their safety and efficacy, local authorities must monitor these trials to ensure that they are conducted in an ethical and safe manner. Additionally, before new health products can be licensed for use, they must be assessed and approved by authorized regulatory agencies, similar to the FDA's review of products intended for US consumers. These regulatory processes are designed to ensure that products are safe and effective before they are widely distributed.

In the developing world—where infections such as HIV, tuberculosis, and malaria are endemic—some countries lack the expertise or resources to appropriately review new health tools. When a nation does not have the capacity to determine the safety and efficacy of a medical product, the health of its people suffers. In addition, a lack of regulatory capacity to review new health products can result in lengthy delays in distributing crucial tools to the patients who need them most.

FDA's role in global health

The FDA's vast expertise can be used to address complex regulatory issues worldwide, and the agency is positioned to heighten this role even further. As FDA Commissioner Margaret Hamburg noted, "We no longer view ourselves or describe ourselves as a domestic agency. We believe that we have to be a global agency with a global mission and with partnerships … that are global as well."

A history of global engagement

The FDA has demonstrated through several recent actions that it can expedite the introduction of global health tools. These include:

- The FDA's program to review HIV/AIDS drugs delivered in the developing world through the US President's Emergency Plan for AIDS Relief.
- The release of a document that outlined the FDA's willingness to review vaccines for diseases not endemic to the United States.
- The agency's partnership with global bodies, such as the World Health Organization, to enhance access to medicines for neglected diseases and assist other countries in bolstering their regulatory capacity.
- The FDA's priority review voucher program, which awards a voucher for future expedited product review to the sponsor of a newly approved drug or biologic that targets a neglected tropical disease.
- The release of documents from FDA centers that aim to increase partnerships with global regulatory stakeholders and aid product sponsors in developing drugs for neglected diseases.

Poised for further engagement

During the last two decades, the FDA has taken several steps that demonstrate its continued commitment to global health.

In 2011, Commissioner Hamburg announced an agency-wide reorganization, through which a new directorate for Global Regulatory Operations and Policy was established. Today, the directorate is working with authorities worldwide to increase transparency and accountability in the global supply chain, improve enforcement of regulatory laws and policies, and facilitate greater collaboration among all regulatory stakeholders—from companies to governments and other third parties.

Similarly, the FDA opened international offices and posts in 10 countries, greatly enhancing its ability to lead and engage in global health activities. For instance, in South Africa, FDA officials are working to increase clinical trials capacity among researchers and institutions across sub-Saharan Africa. In partnership with the Southern Africa Development Community, which represents 15 African nations, the FDA offers trainings and technical assistance before, during, and after clinical trials. Similarly, FDA worked through its India Office to establish a "train-the-trainers" program, requested by the Indian regulatory authority to improve its ability to certify regulatory professionals in clinical trials inspections.

It is critical that the FDA builds upon these and other recent global activities to make the biggest possible impact on the lives of people around the world.

Recommendations for US policymakers

The FDA can continue to bolster its role in global health. The agency should:

- **Strengthen partnerships with regulatory authorities.** For example, the FDA should consider a formal arrangement with the World Health Organization so they can conduct simultaneous reviews of global health products, thereby speeding access to much-needed new health tools worldwide.
- **Build its internal capacity in neglected disease.** The FDA needs sufficient resources to provide training opportunities and to hire additional staff with expertise in neglected diseases. The agency should also include experts from endemic countries on the FDA advisory boards when products for neglected diseases will be reviewed.
- **Create an office of neglected diseases in the Office of the Commissioner**. As the agency expands and deepens its contributions to global health and international regulatory affairs, it is essential to ensure FDA's activities contribute to a shared strategy. By creating an office of neglected diseases, the FDA should better drive coordination among the agency's centers and offices to maximize its global—and domestic—health impacts.
- **Increase transparency by reporting on neglected diseases activities**. The FDA is already heavily engaged in global health, but without formalized reporting and oversight mechanisms the potential outcomes of this work can wane in the face of other priorities and funding constraints. To increase transparency and accountability for its global health commitments, the FDA should take steps to establish formalized processes to report to Congress on its neglected disease activities.

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About the Global Health Technologies Coalition

The Global Health Technologies Coalition (GHTC) is a group of more than 25 nonprofit organizations working to increase awareness of the urgent need for tools that save lives in the developing world. These tools include new vaccines, drugs, microbicides, diagnostic tests, and other devices. The coalition advocates for increased and effective use of public resources, incentives to encourage private investment, and improved regulatory systems. Learn more at www.ghtcoalition.org.

July 2013