Global Health Technologies Coalition

Advancing innovation to save lives

Improving health at home and abroad

How the US Food and Drug Administration can maximize its global impacts

In today's increasingly interconnected world, the US Food and Drug Administration (FDA) must work across borders to safeguard the health of Americans. Through these efforts, the FDA also plays a vital role in global health issues by ensuring the safety and effectiveness of health products that prevent, diagnose, and treat diseases that affect millions of people worldwide.

Already, the FDA has demonstrated its commitment to leading global health regulatory efforts that help ensure the health and well-being of populations globally. During the last two decades, the FDA has increased its global health regulatory engagement through the establishment of initiatives that support broad US government activities, such as the US President's Emergency Plan for AIDS Relief (PEPFAR) as well as its own priorities. It also intensified its involvement with organizations and cross-sector groups working to improve regulatory capacity within developing countries and align regulatory standards across the globe.

But, while some FDA global health programs continue to grow and make an impact today, others wane and remaining gaps present opportunities to substantially improve global health. To capitalize on progress made to date, US policymakers within and outside of the FDA must continue to prioritize global health initiatives at the agency.

Spotlight: Improving access to lifesaving ARVs

HIV/AIDS is preventable and treatable, yet it continues to claim the lives of women, men, and children, primarily in developing countries. To improve the health of millions of people across the globe and reduce deaths, PEPFAR was launched in 2003 with a focus on delivering lifesaving antiretroviral drugs (ARVs) to those most in need.

Recognizing the importance of quality assurance in this program, the FDA partnered with PEPFAR in 2004 to provide regulatory support. Through the use of a "tentative approval" process for generic drugs, FDA indicates if a generic ARV drug produced abroad meets the same safety, efficacy, and manufacturing standards as those used in the United States. Since the FDA began supporting PEPFAR, more than 150 drugs have received tentative approval and PEPFAR has supported lifesaving treatment for more than 5.1 million people across the globe.

Recommendations for US policymakers

The FDA has demonstrated noteworthy leadership and interest in global health. Still, the agency can play an even greater role by leveraging its expertise to address regulatory issues worldwide. This brief offers actionable recommendations that the FDA can implement to strengthen the United States' legacy in global health—and save lives.

To maximize US investments in—and impact on—global health, the FDA should continue to elevate relevant issues in its mandate by:

- Creating an office of neglected diseases.
- Strengthening partnerships with global regulatory stakeholders.
- Ensuring its authority to review health products for all neglected diseases.
- Increasing transparency of its neglected disease activities.
- Strengthening its internal capacity on global health.

Where it has appropriate budget and programmatic authority, the FDA should sustain robust investments in the delivery of new tools for public health worldwide.

Coordinating global health activities

Today, the FDA leads numerous international programs from its headquarters in the United States and operates offices and posts in ten countries across the globe, which opened during the last decade.

As the agency expands and deepens its contributions to global health through the international regulatory enterprise, it is essential to ensure FDA's activities contribute to an agency-wide strategy. By creating an office of neglected diseases, the FDA can better drive coordination among its centers and offices to maximize its global—and domestic—health impacts.

To ensure that neglected diseases and global health issues are consistently elevated at the leadership level, this new program should be housed within the FDA's Office of the Commissioner. By formalizing the agency's global health activities, better oversight can help eliminate redundancies and ensure related programs and initiatives contribute to a unified goal.

Ultimately, this office should issue a strategic plan for global health regulatory activities that outlines steps to achieve greater coordination and partnership among stakeholders representing companies, nonprofits, governments, and multi-lateral organizations. This plan should also recognize the global impacts of many diseases on the health of Americans and on national security by expanding FDA's authority to review products for neglected diseases that do not widely impact Americans. Without sufficient resources and authority to review products that address neglected diseases, delays, and bottlenecks are likely to prevail.

Coordinating neglected disease activities across the agency and ensuring the FDA's authority in global health affairs and neglected diseases will not only improve the health of Americans, it will provide the FDA with the flexibility and authority it needs to respond quickly to medical concerns in a dynamic world.

Spotlight: Coordinating research and product development to deliver health solutions faster

Recognizing a decline in the number of new innovative medical products submitted for approval, the FDA established the Critical Path Initiative (CPI) in 2004 to close the gap between early-stage biomedical research and product development. To do this, the FDA called for greater partnership among regulators, researchers and product developers across all sectors to improve testing methods and processes to evaluate the safety and effectiveness of new medical products.

FDA recognized that coordination would be an essential ingredient to ensuring the success of this new initiative. To support tighter collaboration among the many stakeholders, the agency published the Critical Path Opportunities List, which identified 76 projects that could significantly improve medical product development.

Through this collaboration and coordination, CPI has led to gains in modernizing product development through new biomarker development and qualification, advances in clinical trials and processes, and improved product safety. It also sparked the creation of the Critical Path Institute: a public-private partnership devoted to developing desperately needed medical products, including treatments for tuberculosis—a disease that disproportionately impacts people in developing countries.

Thanks to the FDA's leadership in rallying important stakeholders along the product development lifecycle, new emphasis has been placed on improving scientific processes and getting important lifesaving health technologies to patients faster than before.

Building global regulatory partnerships

Even the most safe and effective medicine cannot save and improve peoples' lives if it never reaches those in need. But before new health technologies can be marketed and used they must be reviewed, approved, and licensed by national regulatory authorities.

Regulatory review of products designed for use in the developing world can be particularly challenging, especially when the national regulatory authorities do not have the capacity or resources to

manage the reviews. This strain on national agencies may intensify as additional products are developed specifically for low-income countries.

To equip national governments and scientific professionals with the skills and resources they need to independently facilitate medical product reviews in the future, the FDA offers trainings and contributes to global efforts to improve regulatory harmonization. For example, the FDA established the International Scientist Exchange Program that invites students, regulators, and academics from developing countries to its Arkansas-based research facility for additional training in regulatory science.

The agency also supports a variety of global regulatory initiatives, including the International Medical Device Regulators' Forum, the Regulators' Forum of the International Conference on Harmonization, and the African Medicines Regulatory Harmonization Program to strengthen regulatory coordination and capacity across the globe.

But this is just the beginning. To realize the positive impacts of these investments, FDA should continue to contribute to and expand these efforts, placing additional emphasis on coordination across regulatory agencies and training the next generation of product regulators across the developing world, ensuring greater regulatory capacity abroad.

Increasing accountability and transparency

Already the FDA has taken great steps to increase its engagement in global health and international affairs. But without formalized reporting and oversight mechanisms the potential outcomes of this work can wane in the face of other priorities and funding constraints. Alternatively, when positive gains are made, it is difficult to recognize the FDA's accomplishments and reap the greatest rewards of its efforts without external communication.

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. Those reports can also provide guidance to other key stakeholders and improve coordination and alignment across global health and product development leaders in all sectors.

Spotlight: Strengthening FDA's engagement in international affairs

To improve its international engagement efforts at the FDA, the agency established the Office of International Programs (OIP) to coordinate and oversee the many individual efforts that were initiated over time.

After multiple public health crises were caused by imported food and medical products in 2007 and 2008, OIP's capacity increased significantly when Congress granted FDA the authority to establish international offices and posts in strategic locations. These efforts aimed to better ensure the safety of products bought and used in the United States, but they also offer a unique opportunity for FDA to engage in important global health initiatives.

In South Africa, for example, 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.

Just as important as expanding regulatory capacity is ensuring that regulatory processes and standards are aligned among countries. Through OIP, the FDA works with European regulators and others to align and improve medical product regulation standards, guidelines, and processes across the globe.

The Office of International Programs is an essential structure to maintaining the health of Americans and improving the lives of people abroad, and it can increase its impact with additional support from agency leadership and Congress.

Strengthening internal global health capacity

While its first priority is the health of Americans, it is essential that the FDA arms itself with global health experts who can help carry out a comprehensive plan for regulatory affairs that includes international activities. To strengthen the work already being conducted in the agency's international offices and posts, FDA should dedicate additional staff members and resources to global health engagement.

Specifically, these resources could support the establishment of a comprehensive US strategy for global health regulatory activities that drives not only the FDA's international engagement but also related efforts by other agencies within the US Department of Health and Human Services. Operating under a united objective will help the United States make the most of its global health investments.

Sustaining global health investments

During more than a decade of fiscal constraints, it is understandable that the FDA's global health initiatives often surge and subside as resources appear and diminish. But without consistent attention and effort, nascent initiatives and programs are often unable to fully develop. This cycle significantly limits the potential impact of US government investments on health domestically and abroad.

Where it has budget authority, FDA should sustain robust investments in the delivery of new tools for public health worldwide. Furthermore, Congress should ensure that it is robustly funded to carry out its work without significant setbacks or delays.

Miguel Alvarez

Through international exchange programs and investments in workshops across the globe, the FDA supports the development of regulatory capacity abroad. These efforts equip professionals in developing countries to lead their nations to a healthier future independently.

Conclusion

Already the FDA has demonstrated the importance of its global regulatory engagement. Through capacity-building efforts, opening offices across the globe, and improving regulatory harmonization, the FDA has taken important steps to safeguarding the health of individuals across the globe as well as in the United States. Still, more can be done.

But the agency cannot do this alone. Because the FDA needs support from Congress to carry out its global health work, Congress should provide the agency with sufficient funding and authority to do so. In addition, the agency should use its position as a leading regulatory agency to establish clear strategies for neglected diseases and coordinate global health activities across the agency to drive health improvements worldwide.

Global Health Technologies Coalition
455 Massachusetts Avenue NW
Suite 1000
Washington, DC 20001 USA

ph: 202.822.0033
www.ghtcoalition.org

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, as well as the most effective policies and programs needed to develop and deliver new health tools. These tools include new vaccines, drugs, microbicides, diagnostics, insecticides, and devices. The coalition advocates for increased and effective use of public resources, incentives to encourage private investment, and streamlined regulatory systems. The GHTC is housed at PATH. Learn more at www.ghtcoalition.org.

September 2013