Global Health
Technologies Coalition

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Advancing innovation to save lives

April 1, 2016

The Honorable Harold Rogers
Chairman
House Appropriations Committee
2406 Rayburn House Office Building
Washington, DC 20510

The Honorable Nita Lowey
Ranking Member
House Appropriations Committee
2365 Rayburn House Office Building
Washington, DC 20510

The Honorable Robert Aderholt
Chairman
House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
235 Cannon House Office Building
Washington, DC 20510

The Honorable Sam Farr
Ranking Member
House Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
1126 Longworth House Office Building
Washington, DC 20510

Dear Members of the Appropriations Committee:

As members of the Global Health Technologies Coalition (GHTC)—a group of more than 25 nonprofit organizations working to increase awareness of the vital role health technologies play in saving lives in the developing world—we write to highlight the critical role of US global health research and development (R&D) efforts and thank you for your support of programs that enhance global health R&D at the US Food and Drug Administration (FDA).

US investments in R&D for vaccines, microbicides, drugs, devices, diagnostics, and other tools have led to significant breakthroughs in addressing diseases and health conditions that afflict people living in some of the poorest countries around the world. The FDA plays a vital role in this equation, helping ensure that new tools are safe and effective before they reach people in need. **We respectfully urge you to sustain and protect funding for this important work by funding the FDA at $2.9 billion for fiscal year 2017.**

While the FDA is well-known for its role in regulating food and drug safety for US citizens, it also plays a less visible but important role in ensuring that safe and effective new tools to prevent, diagnose, and treat global diseases reach those who are most in need. This ensures that US investments in the development of new tools to treat endemic health challenges like malaria, tuberculosis, and neglected tropical diseases are translated into tools that meet stringent standards for clinical trials, testing, and efficacy. For example, the agency's work to evaluate generic antiretroviral medications to treat HIV/AIDS was essential to make sure the President's Emergency Plan for AIDS Relief (PEPFAR) programs delivered safe, cost-effective treatments to people in need.

The FDA also plays a vital role in building regulatory capacity of national governments in low- and middle-income countries. Partnerships between the FDA and partner governments work to ensure that countries have the skills and expertise needed to effectively evaluate new health technologies for

themselves before products enter the market—which helps eliminate gaps between product approval in the United States and approval in low-resource settings where global health tools are most critical.

Recent examples of FDA support for the development of new health technologies for low-resource settings include:

- Supporting the expedited development and availability of treatments, vaccines, and diagnostic tests for Ebola.

- Supporting streamlined regulatory review for generic medications through PEPFAR which has improved access to lifesaving antiretroviral therapy in developing countries.

- Issuing guidelines in 2007 and official guidance in 2008 and 2011 on how the FDA will handle vaccines and drugs for neglected diseases affecting developing countries.

- Increasing senior-level staff capacity within the FDA to more effectively manage its global health portfolio.

- Supporting capacity building among regulators in developing countries through collaborations with international and regional regulatory networks, such as the African Vaccine Regulatory Forum, which strengthens the ability of countries to provide safe technologies to their citizens.

- Partnering with the National Institutes of Health and the Centers for Disease Control and Prevention to support the development of tools such as biomarkers and animal models to better evaluate and register new tools to combat tuberculosis.

- 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.

In addition, programs at the FDA that support the development of technologies to address rare or orphan diseases or diseases of public health importance play a critical role in streamlining the review of urgently needed global heath innovations. Tafenoquine—an innovative single-dose treatment for *P.vivax* malaria—has been granted breakthrough designation by the FDA, which helped facilitate its path through clinical trials and made the delivery of a simpler treatment for malaria a near-term reality.

The FDA's work to facilitate review of health technologies for global health concerns also directly benefits US citizens. As our world becomes more interconnected, the health of Americans is interdependent with the health of populations abroad. Health threats know no borders, and protecting the well-being of Americans now requires a globally-focused approach. Many diseases are only a plane ride away, or in some instances, beginning to re-emerge as health threats to US citizens. For example, there are currently more than 300,000 cases of Chagas disease in the United States, indicating that a disease that has long plagued Latin America is now increasingly a health threat in the United States. The mosquito-borne Zika virus, which has historically been limited to equatorial regions, is now a major public health issue in South America and projected to spread throughout the hemisphere. Investments to ensure that new products to diagnose, prevent, and treat global diseases are safe and effective not only play a vital role in saving lives around the world, but are also critical to the health of Americans and global health security.

To bolster and continue the FDA's vital work in global health R&D, we strongly recommend that you fund the agency as robustly as possible. This includes at minimum $2.9 billion for the FDA.

We stand ready to work with you to advance US leadership in global health and global health innovation, and ask that support for global health R&D at the FDA not come at the expense of other programs that prioritize neglected health conditions. Now more than ever, Congress must make smart budget decisions. Global health research that improves the lives of people around the world—while at the same time protecting the health of Americans—is a win-win.

Please do not hesitate to contact GHTC Director Erin Will Morton at ewmorton@ghtcoalition.org or (202) 540-4379, if you have questions or need any additional information.

Sincerely,

Aeras

American Society of Tropical Medicine and Hygiene

AVAC: Global Advocacy for HIV Prevention

Drugs for Neglected Diseases *initiative*

Elizabeth Glaser Pediatric AIDS Foundation

Global Health Council

HarvestPlus

International AIDS Vaccine Initiative

Infectious Diseases Society of America

IVCC

International Vaccine Institute

Medicines for Malaria Venture

PATH

Sabin Vaccine Institute

Treatment Action Group

TB Alliance

Washington Global Health Alliance