



New products hold the key to health improvement worldwide

To meet the global health needs of tomorrow, US investment in today's research is critical to ensure that effective health tools are available when we need them.

The US government has long played a leading role in the development of new health technologies for global populations. In fact, the US government is the [largest supporter](#) of global health research and development (R&D) in the world, supporting the development and delivery of breakthrough technologies such as vaccines, drugs, diagnostics, microbicides, and devices.

At the same time that research and innovation are spurring development of new health tools, the political and economic environment in the United States puts even the most essential programs at risk, including funding for global health research and product development.

Past US investments resulted in tools that save millions worldwide

US government support has increased the number of global health products under development or already available for populations in low- and middle-income countries.

- [Each year](#), approximately 45 percent of the total investment in global health R&D and 70 percent of public-sector funding worldwide comes from the United States.
- Between 2000 and 2010, the US government was involved in the development of 24—or 53 percent—of the 45 vaccines, drugs, diagnostics, and devices introduced for global health.

Much of the US government support for global health R&D is done through nonprofit product developers (NPPDs). NPPDs partner with governments, the private sector, and philanthropies to create health tools for low- and middle-income countries. As of 2013, NPPDs and their partners contributed to the development, evaluation, and/or introduction of 42 global health technologies.

Due in large part to US government investment (see Figure 1), some of the biggest breakthroughs in global public health have been made possible. US support contributed to recent developments such as:

- MenAfriVac™, a vaccine that protects against meningitis A. The vaccine has been delivered to more than [151 million people](#) in Africa's meningitis belt since its launch in 2010.
- GeneXpert, a new diagnostic test for tuberculosis (TB), launched in 2010. The test [offers the potential](#) to more rapidly identify drug-resistant tuberculosis (TB), allowing individuals to start treatment more quickly, thus slowing the disease's spread.
- Coartem® Dispersible, a new pediatric antimalarial drug. Since 2009, [250 million treatments](#) have been delivered to children suffering from malaria in 50 endemic countries.

The global health R&D pipeline has never looked more promising

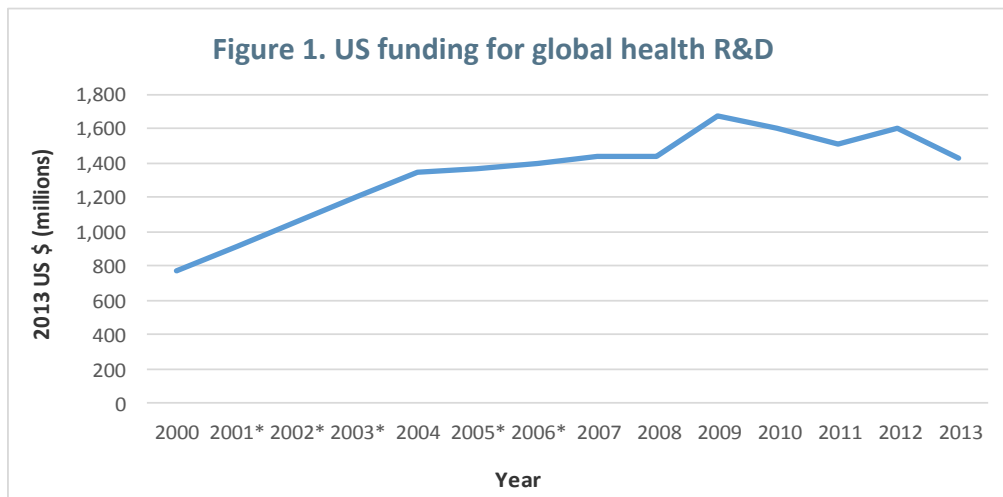
Existing tools to combat global diseases have made tremendous progress, but more are needed to stop the spread of life-threatening illnesses. There are currently more global health products in the research pipeline than ever before—with more than [365 new tools](#) under development as of April 2012. With increased investment and support from the US government, further gains are achievable. Technologies currently under development which offer great promise include:

- **New drugs and novel drug regimens to treat TB**, including those focused on treating children and patients with drug-sensitive and drug-resistant forms of the disease. New drug regimens currently in clinical testing have the potential to shorten treatment times by up to 75 percent for drug-resistant TB and reduce the costs of treatment by up to 90 percent.
- **New vaccines for neglected tropical diseases (NTDs)**—such as leishmaniasis, schistosomiasis, hookworm, dengue fever, and Chagas disease, currently under development, including several in clinical trials. These diseases are the most common infections of the world’s poor, while Chagas disease is now endemic in the southern United States.
- **Modern reproductive health technologies** that hold the key to lowering maternal mortality by enabling women to practice healthy timing and spacing of their pregnancies. An estimated 222 million women in developing countries want to delay the birth of their next child or limit the size of their family but are not using contraception. Many new technologies will become available in the near future, helping to improve reproductive health for women.
- **A preventative malaria vaccine** that could help put an end to this disease. According to the World Health Organization, more than 20 vaccine candidates are currently being evaluated in clinical trials or are in advanced preclinical development.



PATH/Gabe Bienczycki

US investments in global health R&D have created tools already making a difference in lives worldwide.



Data sources: (1) Saving lives and creating impact: Why Investing in global health research works. *GHTC and Policy Cures*. 2012; (2) Neglected Disease Research and Development: Emerging Trends. *Policy Cures*. 2014. * estimates

- **New tools to prevent and treat malaria**, including medicines that will both protect against the disease and prevent its transmission. As of 2014, the malaria drug portfolio included over 65 projects. Recently, several compounds to counter drug-resistance to current antimalarials advanced through the pipeline, and tafenoquine, a promising treatment for relapsing malaria, which was granted Breakthrough Therapy designation by the US Food and Drug Administration (FDA), entered phase III clinical trials.
- **New insecticides**, which could help control insects that spread diseases, such as dengue fever, Chagas, filariasis, and leishmaniasis. These diseases are among the major causes of death in developing countries.
- An **antiretroviral-based microbicide** that offers hope for women's HIV prevention. A monthly, long-lasting microbicide ring is currently in late-stage clinical trials with results expected in early 2016. In sub-Saharan Africa, where the epidemic has hit hardest, women 15 to 24 years old are at least [twice as likely](#) to be infected with HIV as young men.
- A **new oral drug for African sleeping sickness**, fexinidazole, which is in late-stage clinical trials. As a simple, short-course oral pill, [fexinidazole](#) could transform care for sleeping sickness, which is fatal without treatment, and could potentially reduce its incidence among the most afflicted populations and accelerate elimination of the disease.
- Several candidates for a **new vaccine to prevent TB** that are in various phases of clinical trials around the world. Preventing TB is one of the most cost-effective ways of reducing the disease's burden in endemic countries, especially with the rise of multidrug-resistant and extensively drug-resistant TB.



New global health tools are now under development and need continued support.

- A **preventive HIV vaccine**. Researchers are currently expanding on results of a 2009 trial that demonstrated for the first time that a vaccine can reduce the risk of HIV infection, as well as pursuing other groundbreaking vaccine research. An effectively rolled-out AIDS vaccine that provides 70 percent protection could reduce new annual infections by 40 percent in its first decade and by almost half in 25 years—up to 19 million infections averted by 2050.
- **Cost-effective diagnostics** for malaria, TB, and NTDs. These diagnostics could be administered in a variety of health care settings and could rapidly and accurately identify sick patients.
- New **child-friendly HIV medicines**. Current options for children are difficult to take and store in developing countries. **Highly sensitive point-of-care diagnostic tools** are also being developed that can accurately test children born to mothers living with HIV.
- **Renewed interest for drug development** for lymphatic filariasis (elephantiasis) and onchocerciasis (river blindness). While current treatments prevent infection by killing juvenile filarial worms, clinical research has begun on new drugs that kill adult worms and provide a cure for these debilitating diseases.

Budget cuts could undermine critical advancements in global health

US investments have helped create the largest global health R&D pipeline in history, full of promising solutions to fight infectious diseases and other global health challenges at home and abroad. However, for the past several years, US policymakers have had difficulty agreeing on a long-term budget for the federal government, which has led to widespread and damaging cuts to global health R&D, produced by sequestration and a government shutdown.

With so many promising global health tools entering later stages of the product development process where costs escalate, it is more critical than ever that the US government continue to sustain investments in global health R&D. Repetitive cuts to agencies' budgets and the repercussions of sequestration have the potential to halt promising developments.

In particular, five federal agencies that make significant contributions to global health R&D could see damaging cuts to their budgets.

- Budget cuts and sequestration could affect the **Centers for Disease Control and Prevention's** (CDC's) grants and cooperative agreements around the world. One of CDC's many global health R&D projects is the TB Trials Consortium that includes a global network of clinical trials in nine countries. The agency also builds in-country capacity and enhances rapid response to infectious diseases in developing countries.
- Cuts to the **Department of Defense** budget could postpone or halt research taking place at the Walter Reed Army Institute of Research, the Naval Medical Research Center, and the military

HIV Research Program. These programs support research to develop tools for NTDs, malaria, and HIV/AIDS.

- Through the **FDA**, the United States has an important role in regulating global health products, which helps ensure that safe and effective health tools reach people in need worldwide. Indiscriminate budget cuts could slow the FDA's ability to review products and delay patients' access to them.
- The **National Institutes of Health** (NIH), the largest funder of global health R&D in the world, was forced to cut US\$1.71 billion from its budget during the 2013 sequester. NIH contributes to [almost half](#) of global health discovery and preclinical funding, and the agency supports domestic research jobs all over the United States.
- The **US Agency for International Development** (USAID) is a key supporter of global health research. With a presence in over 100 countries, USAID is often the best-suited federal agency to support the clinical trials needed to ensure that basic research is translated into appropriate health products. Budget cuts could severely hinder USAID's ability to continue as a leading supporter of global health product development, including for microbicide, HIV vaccine, and device research.

There is too much at risk if policymakers allow political gridlock and difficult fiscal circumstances to undermine America's leadership in global health R&D. US leaders should seize upon the recent successes in global health R&D and pass a forward-looking budget that ensures America's legacy as a leader in innovation and science.

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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, 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.