

Report: Stagnant US funding for tools against disease threats leaves world at serious risk

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Even as Congress grapples with the White House on how to fund an emergency response to fight Zika virus, a new report warns that overall underfunding for development of lifesaving tools against neglected global diseases is putting the United States and the world at risk, and that emergency funding can't be allowed to substitute for sustained US investment in research and development (R&D) of global health technologies.

"Current levels of US global health R&D financing do not match the scale of health challenges the world faces," said Erin Will Morton, director of the Global Health Technologies Coalition (GHTC)—27 nonprofit groups focused on accelerating the creation of new drugs, vaccines, diagnostics, and other health tools. "Political inaction in Washington could undermine two decades of landmark gains in global health and leave the world unprepared and unprotected against emerging health problems like Zika virus infection or antimicrobial resistance."

The GHTC report, Achieving a bold vision for global health: Policy solutions to advance global health R&D, was released today at a Capitol Hill briefing. In it, GHTC urges Congress and the Administration to recognize the United States' crucial role in accelerating R&D that both saves lives around the world and protects the health of Americans at home.



The report urges Congress to provide robust and sustained public financing for US agencies engaged in global health R&D, from the US Department of State and Department of Defense to the US Agency for International Development, National Institutes of Health, Centers for Disease Control, and Food and Drug Administration (FDA). It also calls for those agencies to then set a percentage of program budgets to be directed to global health R&D and for greater cross-agency coordination to accelerate health product development.

"The Ebola and Zika virus outbreaks have exposed the perils of waiting for an emergency to trigger investment in R&D for neglected diseases. Sustained, predictable funding is not only more cost-effective, it's a down payment to save lives from the diseases we'll face tomorrow," said Morton.

A recent study that examined the risk of infectious disease outbreaks projected that large-scale global disease pandemics could cost the global economy more than US\$60 billion a year, while investing in the interventions needed to protect against these outbreaks, including R&D, would cost only a fraction of that—\$4.5 billion—each year.

The GHTC report documents how past US support has led to breakthrough health solutions, like the first blood test for HIV/AIDS, a vaccine to prevent meningitis A in Africa, and new diagnostic tests to target drug resistant tuberculosis (TB), which have contributed significantly to major milestones in global health—since 1990, there has been a 53 percent drop in childhood deaths and a 45 percent decrease in maternal deaths.

US investment have also helped nurture a growing global pipeline which contains nearly 500 promising tools under development for neglected global diseases, including:



- For malaria, new drug candidates in the pipeline; second-generation vaccines, and a new class of insecticides;
- For TB, shorter treatments for drug-resistant strains, easier-touse, more rapid diagnostic tests, and efforts underway to develop a new vaccine;
- For Ebola, new vaccine and drug candidates moving through clinical trials;
- For drug-resistant superbugs, an entire new class of antibiotics;
- For HIV/AIDS, a new microbicide ring that has advanced through clinical trials and new hopes for a vaccine; and
- For neglected tropical diseases such as sleeping sickness, visceral leishmaniasis and Chagas disease, new drug cures and vaccines.

GHTC credits much of this progress to the catalyzing effect from the near-doubling of US funding for global health R&D between 2000 and 2010. Since peaking in 2009, however, funding has been largely stagnant or declining. With Ebola emergency funding removed, US investments in neglected disease R&D in 2014 actually fell 2 percent from the year before and fell nearly 13 percent, or \$221 million, from the 2009 peak.

Despite uncertain year-over-year funding from the United States, the report says, developers around the world have contributed to a global health R&D pipeline today with nearly 500 products, up from 365 in 2012. The United States is the lead funder of this R&D, contributing around 70 percent of public investment and 45 percent of all global investment, including private and philanthropic funding. More specifically, the United States is the lead funder of R&D for 26 of the 30 most neglected diseases.

"It is critical not to pull back US investments now and put this arc of progress at risk," said Morton. "As promising global health products move from laboratory testing through clinical trials, costs escalate. So with great promise and success also comes a more pronounced need for



funding to see these products to the finish line."

The GHTC report offers an example of cuts in US funding for Ebola R&D in 2012 that permanently stalled development of a promising vaccine, leaving the world empty-handed when an epidemic flared in West Africa. Policymakers could once again stall Ebola R&D if they redirect emergency funds allocated for Ebola R&D to fight Zika before we've completed development of Ebola diagnostics, vaccines, and other tools to curb future outbreaks.

"We're missing a generation of biomedical interventions against neglected and emerging infections, and it's becoming increasingly clear that to solve this problem we'll need new partnerships and new strategic plans," said Dr. Peter Hotez, dean of the National School of Tropical Medicine at Baylor College of Medicine, president of the Sabin Vaccine Institute, and a US Science Envoy. "The partnerships must include industry, developing country manufacturers, and nonprofit product development partnerships, with increasing financial and strategic support from the G20 nations, including the US government."

Recognizing that many of the diseases in question are ones of poverty, the GHTC report not only calls for robust public <u>investment</u> in global health R&D, but also suggests adoption of policies to incentivize the private sector to act in the absence of viable commercial markets. For example, prizes, small business innovation awards, priority review vouchers, advance market commitments, and tax credits could help leverage US investments. New financing mechanisms like social impact bonds or pooled funds could attract diverse and non-traditional funding partners. Investing in strengthening the R&D sector of fast-developing countries so they can address their own health challenges could also lessen US share of funding over time.

Right now, however, the GHTC report insists the US cannot fall behind



on its investments.

Working together to get to the finish line faster

Beyond funding, the report's second goal is to direct greater cooperation and coordination across US agencies, which could close gaps and accelerate development of drugs, vaccines, diagnostics, and other tools. To achieve such coordination, the report recommends that Congress establish a whole-of-government R&D strategy, which could include a designated coordinator appointed to oversee it. It also calls for existing cross-government global health initiatives like the Global Health Security Agenda (GHSA) to adopt R&D as a core goal in dealing with future health crises.

The third and final US goal recommended by the report is to deploy US expertise and resources to strengthen regulatory pathways to help get global health products into the hands of the people who need them more quickly. Regulatory capacity is often weak in the countries where new drugs, vaccines, and devices are meant to be deployed. The report recommends that Congress direct the FDA to establish a mechanism to offer a formal scientific opinion on medical products intended for markets outside the US, which would give authorities in countries lacking resources the trusted scientific guidance needed to make regulatory decisions. It also calls for greater support for programs to strengthen regulatory capacity in low- and middle-income countries and harmonize regulatory requirements.

"When the US government and R&D sector strategically unleash their ingenuity and resources, there is no global health goal out of our reach," said the GHTC's Morton.

Provided by Global Health Technologies Coalition



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