Medical Product Development

DOING BUSINESS DIFFERENTLY

To improve the health and security of all U.S. citizens—and to ensure sustainable thriving of the world population—the United States must maintain its leadership in global health through forward-looking policies, a long-term vision, and continued investment. Where should U.S. investments and attention be focused? The report *Global Health and the Future Role of the United States* highlights four priority global health challenges and identifies four opportunities to do business differently.

Why is Medical Product Development an Opportunity?

Current and future global health threats can not be overcome without new drugs, vaccines, devices, and diagnostics. However, many of these diseases are concentrated in low- and middle-income settings, where markets fail to generate sufficient private investment. Thus, government investment and involvement in strengthening capacity, and creating market incentives for the private sector, are crucial to catalyze innovation.

Furthermore:

- Partnerships are critical. It can take up to **15 years** and cost up to **$2.5 billion** to develop a new drug and enter the market when undertaken by industry alone.
- Robust pipelines are needed. With less than **10 percent** of all new drugs that reach Phase 1 clinical trials achieving FDA approval, de-risking private investment is key.
- The pipeline does not reflect the burden. Between 2000 and 2011, only **4 percent** of all new drugs developed were aimed at neglected diseases.
- The cost of not acting is staggering. Addressing a pandemic can cost **$570 billion** globally, while implementing recommendations for increased R&D capacity would cost **$1 billion** per year.

What's the Big Picture?

Safe and effective medical products are needed to address global health priorities and stem the tide of dangerous outbreaks. Yet unattractive markets, costly regulatory processes, and limited lab and manufacturing capacity in low- and middle-income countries present challenges. The U.S government can create better incentives to enable industry, academia, and others to accelerate the development of new life-saving tools, quickly, cost-effectively, and with the end user in mind.

CASE STUDY FROM THE REPORT
NIGERIAN EBOLA RESPONSE

When Ebola hit West Africa in late 2013, regions that had previously invested in R&D capacity, assisted by the United States, were much better prepared to control outbreaks, minimizing lives lost and economic impact. In Nigeria, the African Center of Excellence for Genomics of Infectious Diseases was able to accurately diagnose the index case of Ebola, allowing containment of the spread before it could become an outbreak in their extremely populous country. Public health surveillance and detection were rapidly mobilized, supported by previous investments in emergency response for polio.

Conversely, in Guinea, where significantly less investment in R&D has been made, the initial investigation conducted by the Ministry of Health mistakenly concluded that the case was cholera. This impeded a swift and appropriate public health response, leading to unnecessary deaths and greater economic burden for the country.

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Key U.S. Agencies and Programs

- Biomedical Advanced Research and Development Authority (BARDA)
- U.S. Centers for Disease Control and Prevention (CDC)
- U.S. Department of Defense (DoD)
- U.S. Food and Drug Administration (FDA)
- National Institutes of Health (NIH)

RECOMMENDED ACTIONS

Accelerate Medical Product Development

Why? The pipeline of innovations is inadequate to address existing and emerging global health threats. The U.S. government can design and expand mechanisms to help develop, introduce, and scale needed technologies. This could help avoid the catastrophic loss of life and economic burdens that result from the lack of these innovations.

Through such assistance, the U.S. can also foster the ability of low- and middle-income countries to conduct clinical trials and use their own workforces and facilities. This unlocks a more efficient, sustainable long-term approach and paves a path toward less reliance on donor nations. Investment in local research capacity, research literacy, and training of local workforces will enable countries to better address their own health issues.

How? U.S. government agencies should invest in a targeted effort to reduce the costs and risks of developing, licensing, and introducing vaccines, therapeutics, diagnostics, and devices needed to address global health priorities.

This effort should include:

- **Enabling innovative approaches for trial design;**
- **Streamlining regulation;**
- **Ensuring production capacity;**
- **Creating market incentives;** and
- **Building international capacity for R&D**

OTHER BRIEFS IN THIS SERIES

The report highlights four priority global health challenges and four key opportunities to do business differently.

DOING BUSINESS DIFFERENTLY

- Digital Health Technology
- Financing
- Global Health Leadership

PRIORITIZING GLOBAL HEALTH CHALLENGES

- Women's and Children's Health
- Global Health Security
- HIV/AIDS, Tuberculosis, and Malaria
- Cardiovascular Health and Cancer Prevention

SPOTLIGHT ON: **Medical Product Development and Global Health Security**

Funding for research and development of critical medical products, for threats like Ebola and Zika, is highly reactionary. Adequately protecting U.S. citizens from health threats requires strong capabilities to detect the potential for a pandemic, ensure the availability of needed medical products, and provide necessary capacity in the nation's hospitals and health departments—all of which is currently insufficient.

To read the full report and other related resources, including all of the briefs in this series, please visit **nationalacademies.org/USGlobalHealth.**