

October 24, 2019

Tammy R. Beckham  
Director  
Office of Infectious Disease and HIV/AIDS Policy  
U.S. Department of Health and Human Services  
330 C Street, S.W., Suite L100  
Washington, D.C. 20024

Dear Dr. Tammy Beckham:

The Global Health Technologies Coalition (GHTC)—a group of 30 organizations advancing policies to accelerate the creation of new vaccines, drugs, diagnostics, and other health tools for neglected diseases and global health conditions—writes in response to the request for information from non-federal stakeholders to inform the development of the 2020 National Vaccine Plan (NVP).

US investment in the development of new vaccine technologies is essential to addressing the world's most pressing health challenges—achieving an AIDS-free generation; ending malaria, tuberculosis (TB), and neglected tropical diseases (NTDs); ending preventable maternal and child deaths; and preventing pandemics. And this investment brings dividends for the United States—creating jobs and economic growth at home, expanding US R&D capacity, leveraging non-US government funding, promoting cost-savings in health treatment and services, and protecting American health and security.

The need for US leadership in vaccine research and development (R&D) for global public health was emphasized in the 2010 NVP, which referenced the unignorable connections between global health and US domestic health priorities. Below, we detail our support for maintaining many of the goals, objectives, and strategies related to vaccine R&D for global health in the 2010 NVP and to suggest updated objectives and strategies for the 2020 NVP.

### **GHTC Priority 1: Maintain and build upon the goals, objectives, and strategies that encourage vaccine R&D for global public health concerns**

Since 2010, there has been significant progress in R&D for vaccines that address global public health concerns. Several vaccines for emerging infectious diseases and biothreats, including Ebola, Marburg, and Middle East respiratory syndrome, are in development or near regulatory review. In 2016, NIH-sponsored research showed for the first time that an HIV vaccine was possible. And as of this year, the first malaria vaccine in history was approved by the FDA. Continued progress is possible—but not inevitable, and long-term investments and coordination between partners on vaccine R&D are needed to advance global public health. Without continued leadership and guidance from the US government, such as with the 2020 NVP, key missing technologies will remain undeveloped, and global health issues will continue to threaten and weigh on the lives of people living in the US and around the world.

Below we have listed the goals, objectives, and strategies from the 2010 NVP that GHTC would like to see maintained in order to uphold US leadership in this critical area:

#### **Goal 1: Develop new and improved vaccines.**

- **Objective 1.1:** Prioritize new vaccine targets of domestic and global public health importance.

- **Objective 1.2:** Support research to develop and manufacture new vaccine candidates and improve current vaccines to prevent infectious diseases.
  - Particularly **strategies 1.2.2, and 1.2.5** related to emerging infectious diseases and new approaches to vaccine manufacturing.
- **Objective 1.3:** Support research on novel and improved vaccine delivery methods
  - Particularly **strategy 1.3.1** related to new delivery methods for immune response, safety, effectiveness, and/or efficiency.
- **Objective 1.5:** Support product development, evaluation, and production techniques of vaccine candidates, and the scientific tools needed for their evaluation
  - Particularly **strategies 1.5.2 and 1.5.5** related to developing flexible and agile R&D and manufacturing and stronger public-private partnerships.

**Goal 5:** Increase global prevention of death and disease through safe and effective vaccination.

- **Objective 5.1:** Support international organizations and countries to improve global surveillance for vaccine preventable diseases (VPDs) and strengthen health information systems to monitor vaccine coverage, effectiveness, and safety.
  - Particularly **strategies 5.1.1, 5.1.3, and 5.1.5** related to WHO certification quality surveillance, strengthening global laboratory networks, and developing new field- and laboratory-based diagnostics.
- **Objective 5.3:** Collaborate with global organizations and partners to accelerate clinical testing and licensure in developing countries of vaccines already licensed in developed countries, where appropriate.
  - Particularly **strategy 5.3.5** related to vaccine reference strains and candidate vaccines.
- **Objective 5.5:** Support the development of regulatory environments and manufacturing capabilities that facilitate access to safe and effective vaccines in all countries.
  - Particularly **strategy 5.5.2** related to building regulatory capacity in low-resource countries.
- **Objective 5.6:** Build and strengthen multilateral and bilateral partnerships and other collaborative efforts to support global immunization and eradication programs.
  - Particularly **strategy 5.6.2** related to strengthening international collaborations for R&D and training the next-generation researchers, especially in VPD endemic areas.

## GHTC Priority 2: Add new objectives and strategies that anticipate the future of vaccine R&D for global health needs

As the health and safety of populations improve, global health challenges shift, and new goals, objectives, and strategies are required. Certainly, the next five years of global health will have dynamics different from those of the last decade. In anticipation, GHTC is submitting several recommended objectives and strategies for the 2020 NVP:

- **Strengthen public-private partnerships for vaccine R&D with a focus on lowering transaction costs.** The 2010 NVP included a strategy to strengthen public-private partnerships, and countless partnerships have formed in the last decade. But the cost of public-private partnership is still prohibitive for many organizations. Innovation and government policy change are needed to lower the high transaction costs of R&D partnerships.
- **Advance regulatory science that anticipates near-future technologies.** New, transformative technologies—such as self-administered, printed vaccine patches; solid-state, extended-dose vaccines; mobile microscale manufacturing; and new DNA and live recombinant vaccines—are

on the horizon. Regulatory science in the US and in other countries will need to keep pace to ensure innovation is not suppressed.

- **Continue to promote R&D on technologies that improve vaccine access, distribution, and equity in low-resource countries and in the US during an emergency.** Such technologies include thermo-stable adjuvants, self-administered vaccines, microscale manufacturing, transport, and technologies that help target and reach underserved, subnational populations.
- **Incentivize, finance, and de-risk investment in vaccine R&D for commercial areas with high uncertainty to ensure sustainable financing throughout the R&D pipeline and post-approval market success.** Sustainable financing has previously focused on bringing high-need, low-profit products through the first valley of death. But once these products are approved, they often face a second valley: lack of market demand. This can lead to insolvent companies and shelved products. There are ways to address this issue, such as by working with rising-income countries to bolster their health infrastructure and regulatory systems in order to foster new, robust vaccine markets.
- **Work with foreign partners to strengthen international laboratory networks and clinical trials sites.** Preparing the US and the world for future epidemics depends on having clinical trial sites available for faster evaluation of new vaccines. Bolstering international partnerships and maintaining laboratory networks and clinical trials sites can lower the cost and timeline of clinical trials by lowering start-up costs.
- **Recognize the need for new vaccines as part of global health security.** Since 2010, global health security has increasingly been recognized as an essential component of US national security. This year, the US Global Health Security Strategy mentioned that “in-country research to develop new prevention measures, especially vaccines,” is critical for the prevention of infectious diseases. Some of the most significant threats to global health security are emerging infectious diseases (EIDs), which are emerging at a rapid rate and continue to pose significant risks to American public health preparedness. Robust work in the area, however, has mostly come through emergency funding from responses for Ebola in 2014 and Zika in 2016. The 2020 NVP should not only coordinate with the Global Health Security Strategy but should emphasize the importance of sustainable funding for vaccine R&D for global health security challenges.
- **Coordinate with the WHO Immunization Agenda 2030, specifically recognizing strategic priority six: research and innovation.**

Vaccine R&D for global public health is critical. Not only will new vaccines help end endemic health issues in low-resource settings, they will also strengthen global health security and protect the health of people living in the US. Given this, while drafting the 2020 National Vaccine Plan, we hope that you will consider GHTC’s priorities.

Please do not hesitate to contact Jamie Bay Nishi at [jnishi@ghtcoalition.org](mailto:jnishi@ghtcoalition.org) or (202) 540-4393 if you have questions or need additional information.

Sincerely,

Jamie Bay Nishi  
Director, Global Health Technologies Coalition