GHTC
global health technologies coalition

advancing **innovation** to save lives

November 5, 2021

Rebecca Haffajee
Acting Assistant Secretary for Planning and Evaluation
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

Dear Dr. Rebecca Haffajee:

The Global Health Technologies Coalition (GHTC)—a group of 38 organizations advancing policies to accelerate the creation of new vaccines, drugs, diagnostics, and other health tools for enduring and emerging global health challenges—writes in response to the request for public comment on the Department of Health and Human Services (HHS) Draft Strategic Plan for Fiscal Years 2022-2026.

US government support for the development of new health products is essential to addressing the world's most pressing health challenges. Neglected diseases, which disproportionately affect people in poverty, offer few commercial incentives for the private sector to invest in research and development (R&D). Adding to this disparity, people in poverty often live in low-resource settings, where it is difficult or even impossible to implement tools that were designed for places with consistent access to electricity, sanitation, refrigeration, expertise, and reliable supply chains. Within this context, HHS agencies, including the National Institutes of Health (NIH), the Centers for Disease Control and Prevention, and the Biomedical Advanced Research and Development Authority (BARDA) have historically been core sponsors of product innovations that have opened new pathways for progress in global health.

We appreciate that the HHS Draft Strategic Plan includes a focus on global health and product development for defeating infectious diseases. Below, we provide comment on Strategic Goal 2: Safeguard and Improve National and Global Health Conditions and Outcomes, Strategic Objective 2.1 and Strategic Objective 2.2.

Within Strategic Objective 2.2, we are highly supportive of the following goals:

> ***Develop and deliver evidenced-based safe, effective, testing, treatments, therapeutics, medical devices, vaccines, and prevention strategies***
>
> - *Mobilize resources and collaborations, including domestic, international, and public-private partnerships to support the research, development, testing, manufacture, and equitable distribution of safe and effective prevention strategies, diagnostics, vaccines, therapeutics, and medical devices for non-communicable and infectious disease.*
>
> ***Invest in innovative technology and development to ensure supply and availability of safe and effective diagnostics, treatments, therapeutics, medical products and devices, and vaccines***
>
> - *Support the development of new, safe, and effective medical products with improved delivery characteristics, such as easier storage conditions, longer shelf-life, and reduced*

dosing, for the treatment, prevention, and diagnosis of non-communicable and infectious diseases.

- *Support the application and use of innovative technologies, including mobilizing industry to advance manufacturing (including flexible on demand and point-of-care manufacturing) and artificial intelligence to accelerate research and manufacturing, to improve quality, address shortages, and speed time-to-market for new diagnostics, treatments, therapeutics, medical products, and vaccines.*
- *Advance the research and development of accessible, point of care diagnostic testing to detect non-communicable and infectious diseases to ensure that timely, safe, and effective treatments and therapeutics can be delivered equitably to all communities when needed, including underserved communities, tribes, and territories.*

Leverage resources and collaborations to support and apply research, evaluation, and data insights about non-communicable and infectious disease

- *Build and maintain partnerships, including federal, non-federal, academic and industry partnerships, to promote the development, implementation, evaluation, and availability of vaccines and other treatments to combat antimicrobial resistance and microbial threats.*

Related to the strategy above, "Invest in innovative technology and development to ensure supply and availability of safe and effective diagnostics, treatments, therapeutics, medical products and devices, and vaccines," and its reference to development of technologies with improved deliverability, we recommend the HHS Draft Strategic Plan specifically reference development of technologies for low-resource settings and in health areas that lack commercial markets:

1. **Prioritize development of products that are deployable in low-resource settings in the United States and around the world and require minimal infrastructure and health worker training for delivery.**

   Justification: COVID-19 has highlighted how first-to-market medical technologies are rarely appropriate for all geographies. HHS and its agencies, such as BARDA, should explicitly recognize such realities in their grant-making processes. Tools developed for well-resourced health care settings often do not meet the needs of low-resource settings, and COVID-19 has reaffirmed that many low-resource settings—including rural communities in the United States—face challenges implementing technologies that require robust health care infrastructure, such as vaccines that require ultra-cold chain storage and multiple doses, oxygen therapies that can only be administered in acute care settings, monoclonal antibodies that require intravenous delivery, and diagnostics that require expensive laboratory equipment. With focused funding, first-line tools could be designed for implementation in low-resource settings, obviating the challenges commonly faced in those regions. In other fields, this is typically called "designing to the edges," or designing products that will work for the most extreme cases—which leads to better products for everyone.

2. **Expand focus on product development and translational research for health areas that lack a commercial market.**

   Justification: Neglected diseases are so named because their disproportionate impact on the world's poorest leads to a lack of commercial incentives strong enough to attract private-sector investment in R&D. The challenge is similar for emerging infectious diseases with epidemic potential: there is no market of patients until an outbreak occurs, and even then, the number of patients remains limited. Developing new tools to address these diseases is unfeasible without initial public sector funding. HHS through its agencies, especially NIH, focus most resources on basic research that supports the development of new medical products, which works well for disease areas where private-sector companies will eagerly invest to bring nascent discoveries from government-funded laboratories to market. For neglected and epidemic-risk diseases, though, fewer companies are willing to take the risk of funding the late-stage development of new products. HHS via its agencies should build on its existing funding of late-stage research for emerging infectious diseases, like COVID-19 and Ebola, and select neglected diseases like HIV/AIDS, malaria, and tuberculosis. By expanding funding or co-funding of late-stage development of new products for the full spectrum of neglected diseases, HHS agencies could provide the final push required to get these innovations across the finish line.

In addition, we support the language and intent of Strategic Objective 2.1 and note its strategies to support global coordination and R&D for medical countermeasures. Neither Strategic Objective 2.1 nor 2.2, however, specifically include support for multilateral R&D coordination or international R&D capacity building for global health or global health security. We recommend the following strategies be included in either Strategic Objective 2.1 or Strategic Objective 2.2:

1. **Advance commitment to innovative financing models and unlock investment from international financial institutions to strengthen R&D capacity in low- and middle-income countries, including through alignment with the Global Health Security Agenda.**

   Justification: A largely untapped source of new sustainable financing for global health R&D is international financial institutions, including the World Bank. Health R&D has the potential to both multiply the outcomes of development investments and foster new hubs of health innovation. The Biden-Harris administration is pushing for a global Financial Intermediary Fund (FIF) to support mechanisms to provide financing for global health security capacity-building. This fund should include support for R&D capacity strengthening in low- and middle-income countries, which could improve both global and local resilience to persistent and emerging global health challenges. Given HHS' strong leadership role in the Global Health Security Agenda (GHSA), it should explore ways to connect R&D capacity gaps identified through the GHSA R&D Task Force with pandemic preparedness financing mechanisms such as the FIF.

2. **Hold convenings that elevate global health research and principles of equity; the right to science; and needs-driven, country-led approaches in R&D.**

   Justification: Global health and life sciences research, generally, is at a turning point. COVID-19 has further exposed a deficit of equitable funding for health research that meets the actual needs of affected communities, as they themselves define them, rather than the perceived needs of patients and communities as determined by scientists and policymakers from afar. The United States is recognized for its expertise in R&D and can underscore that expertise by actively demonstrating an ethical and needs-based approach to that work. HHS should spearhead global convenings that work to decentralize and redistribute power within the global health sector and promote a global health research ecosystem whose agenda and priorities are set by communities that experience a disproportionate burden of disease. These convenings should be established through a health equity lens that critically examines how US scientific resources can equitably and ethically support the most marginalized communities around the world.

3. **Coordinate with USAID in setting R&D strategies for global health and medical countermeasures.**

   Justification: In 2020, the US Agency for International Development (USAID)—the only US agency with a mandate to focus on global health and development—was largely excluded from high-level strategic planning for the COVID-19 response. The agency was not included in either the White House Coronavirus Task Force or Operation Warp Speed, creating a disconnect between the tools and efforts needed to confront the pandemic domestically and globally. USAID's deep expertise in global health and development is essential for engineering a US global response to COVID-19 and future pandemics. USAID should be included alongside HHS agencies in high-level planning for all future global health emergencies, and more proactive coordination between HHS and USAID on shared R&D priorities ought to be built into the Strategic Plan.

4. **Promote collaboration between the Food and Drug Administration, the World Health Organization, and other international partners to improve regulatory coordination and harmonization to facilitate product approvals.**

   Justification: Strong regulatory systems play a critical role in global health R&D. As new global health innovations move further through the pipeline, regulatory bodies are required to ensure they are safe and effective and ultimately approve them for use in a timely manner to ensure populations have access to new tools as soon as possible. The Food and Drug Administration (FDA) is a global leader in the safety, efficacy, and security review of biomedical products and regulates products marketed in the United States—and it could play a stronger role in providing more technical support to under-capacitated national and regional regulatory authorities.

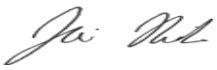
   HHS should support FDA in deploying its expertise to strengthen global regulatory pathways in low- and middle-income countries, such as by providing technical support and work product

sharing with international partners through improved global clinical data interoperability, evidence sharing, mutual recognition agreements, and increased coordination and harmonization, especially with WHO.

R&D for neglected and emerging infectious diseases is a force multiplier for global health—but a recommitment to US innovation leadership is needed to solve the health challenges of today and prevent the health crises of tomorrow. We thank you for considering our recommendations for the HHS Draft Strategic Plan to better align it with the needs of our research community and global health.

Please do not hesitate to contact Jamie Bay Nishi at jnishi@ghtcoalition.org if you have questions or need additional information.

Sincerely,



Jamie Bay Nishi
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