Global Health Technologies Coalition
455 Massachusetts Ave NW, Suite 1000
Washington, DC 20001

July 16, 2021

The Honorable Diana DeGette
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

The Global Health Technologies Coalition (GHTC) is pleased to submit the following responses to your request for information (RFI) on the authorization of the Advanced Research Projects Agency for Health (ARPA-H) in the 21st Century Cures 2.0 discussion draft. GHTC is a coalition of 38 nonprofit organizations, academic institutions, and aligned businesses advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other tools that bring healthy lives within reach for all people. We are eager to share the perspective of our coalition on this exciting proposal for a new entity to develop breakthrough health technologies and platforms "focused on solving practical problems that advance equity," as stated in the initial factsheet on ARPA-H shared with the discussion draft of Cures 2.0.

To ensure it has the biggest impact, on what activities or areas should ARPA-H focus? What activities or areas should ARPA-H avoid?

GHTC believes there is a strong case for ARPA-H to focus on poverty-related and neglected diseases (PRNDs), such as HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, and antimicrobial resistance—a health area "ripe for major transformation with the right support and collaboration," as described in the factsheet. If the goal for ARPA-H is to produce transformative innovation where there otherwise would be none, few areas offer as much potential for R&D impact as PRNDs, for three main reasons:

First, as afflictions associated with conditions of poverty globally, including in the United States, **PRNDs offer little commercial incentive for the private sector to develop medical products to diagnose, treat, or prevent them. This market failure has led to historic under investment relative to the societal burden that these diseases produce.** In 2016, the global private pharmaceutical sector spent approximately $159.9 billion on R&D for health *overall*, but only $511 million—less than one-third of one percent—on R&D for neglected diseases.[i] In contrast, the private sector is investing heavily in R&D on treatments for cancer and Alzheimer's disease. According to the Congressional Budget Office, in 2018, there were more than twice as many ongoing clinical trials for cancer and nervous system disorders (such as Alzheimer's) than the next three biggest disease classes combined.[ii] While more

resources are needed for R&D in many health areas that affect American and global health, leveraging the unique capabilities of the proposed ARPA-H model for PRNDs creates an opportunity to make a major impact in eliminating or even completely eradicating some diseases that are unlikely to be a focus of other stakeholders.

Second, even though past US investments from different R&D agencies have produced laudable scientific advances against some PRNDs, **a considerable number of high-impact innovation gaps remain**: the world still awaits a vaccine and cure for HIV/AIDS, a single-dose cure for the deadliest form of malaria, shorter tuberculosis treatment regimens, better diagnostics for neglected tropical diseases, highly effective vaccines for tuberculosis and malaria, and many other innovations that could transform global health. Defeating these global health challenges remains a lofty goal, but as with COVID-19 in the United States, the right mix of resources and ingenuity—including through game-changing initiatives like ARPA-H—could create bridges to a healthier future for all.

Third, if the goal of ARPA-H, like DARPA, is to foster transformative, sector-defining breakthroughs, then policymakers should note that **investments in infectious disease research have historically paid dividends across the health R&D landscape**. For instance, investments in HIV/AIDS research led to the immunological breakthroughs critical to understanding the pathogenesis of COVID-19. Research on malaria has produced anti-malarial drugs that are being evaluated as promising anti-cancer treatments.[iii] And a one-hundred-year-old tuberculosis vaccine is now being evaluated for its potential therapeutic and protective effects against Type 1 Diabetes, Alzheimer's, and other diseases.[iv] In short, investments in infectious disease research have historically nourished a rich soil of scientific knowledge from which innovations for other disease areas have blossomed. It is clear that investing in PRND R&D closer to the level of need through support from ARPA-H would yield a harvest of health advancements across the entire landscape of pressing needs.

In calling for the creation of ARPA-H, President Biden has cited the success of the Defense Advanced Research Projects Agency (DARPA) and expressed his belief that ARPA-H should be similar. Please provide specific details on which aspects of DARPA ARPA-H should replicate and why this would lead to similar success.

GHTC supports an ARPA-H framework that closely mirrors that of DARPA. This framework should include policies that would give APRA-H program managers maximum flexibility in how they distribute funding—enabling them to place high-risk, high-reward bets with strategic partners. For instance, if freed from the burdens of the typical NIH funding process, ARPA-H program managers could more easily collaborate with product development partnerships (PDPs)—partnerships that combine expertise, resources, and funding from the public, philanthropic, and private sectors to create products that address specific public health goals. With flexible funding capacities, ARPA-H program managers could leverage PDPs and other aligned partners as a powerful tool for solving the most difficult public health challenges.

We understand that designing ARPA-H, and authorizing it in the final iteration of Cures 2.0, will require a thoughtful negotiation between congressional oversight and the flexibility necessary to foster innovation, as well as a thoughtful balance among many competing disease priorities rising to the fore

based on public health need, scientific neglect, ripeness for breakthroughs, and other factors. We believe that a focus on PRNDs—an area of historic market failures—holds the greatest potential for ARPA-H's societal impact and that flexible funding capacities designed to foster partnership are essential for its success. We stand ready to work with you on the design and authorization of this exciting initiative. Please do not hesitate to contact Emily Conron, the US policy officer for GHTC, at econron@ghtcoalition.org if you have questions or requests for additional information.

Sincerely,

Emily Conron
US Policy and Advocacy Officer
Global Health Technologies Coalition

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[i] West DM, Villasenor J, Schneider J. Private Sector Investment in Global Health R&D: Spending Levels, Barriers, and Opportunities. Washington, DC: Brookings Institution; 2017. https://www.brookings.edu/wp-content/uploads/2017/09/private-sector-investment-in-globalhealth-rd_final.pdf.

[ii] Congressional Budget Office. *Research and Development in the Pharmaceutical Industry*. Washington, DC: Congressional Budget Office; April 2021. https://www.cbo.gov/publication/57126.

[iii] Ellis T, Eze E, & Raimi-Abraham B. Malaria and Cancer: a critical review on the established associations and new perspectives. *Infectious Agents and Cancer*. 16, 33 (2021). https://doi.org/10.1186/s13027-021-00370-7.

[iv] Keener A. A repurposed TB vaccine shows early promise against diseases like diabetes and MS. *ScienceNews*. June 2, 2021. https://www.sciencenews.org/article/bcg-tb-vaccine-diseases-diabetes-multiple-sclerosis.