

October 28, 2019

The Honorable Richard Shelby
Chairman
Senate Appropriations Committee
304 Russell Senate Office Building
Washington, DC 20510

The Honorable Patrick Leahy
Vice Chairman
Senate Appropriations Committee
437 Russell Senate Office Building
Washington, DC 20510

The Honorable Roy Blunt
Chairman
Senate Appropriations Subcommittee on
Labor, Health and Human Services, Education,
and Related Agencies
260 Russell Senate Office Building
Washington, DC 20510

The Honorable Patty Murray
Ranking Member
Senate Appropriations Subcommittee on
Labor, Health and Human Services, Education,
and Related Agencies
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Nita Lowey
Chairwoman
House Appropriations Committee
2365 Rayburn House Office Building
Washington, DC 20510

The Honorable Kay Granger
Ranking Member
House Appropriations Committee
1026 Longworth Office Building
Washington, DC 20510

The Honorable Rosa DeLauro
Chairwoman
House Appropriations Subcommittee on
Labor, Health and Human Services, Education,
and Related Agencies
2413 Rayburn House Office Building
Washington, DC 20510

The Honorable Tom Cole
Ranking Member
House Appropriations Subcommittee on
Labor, Health and Human Services, Education,
and Related Agencies
2207 Rayburn House Office Building
Washington, DC 20510

Dear Members of the Appropriations Committee:

Thank you for supporting global health research and development (R&D) in the fiscal year (FY) 2020 Labor, Health and Human Services, Education, and Related Agencies appropriations bills. As you advance these bills in conference, members of the Global Health Technologies Coalition (GHTC)—a group of more than 30 organizations advancing policies to accelerate the creation of new drugs, vaccines, diagnostics, and other health tools for neglected diseases and health conditions—wish to highlight the important work of the Biomedical Advanced Research and Development Authority (BARDA) to address naturally occurring and emerging infectious disease (EID) threats. Further, we encourage you to include language in the final bill report that supports BARDA's work in this area and requests a delineation of these investments in their annual five-year budget plan.

BARDA plays a critical role in advancing products that protect US health security interests and, by extension, bolster global health security. In response to outbreaks of Ebola and Zika in recent years, BARDA has mobilized its unique expertise in late-stage product development for medical countermeasures without robust commercial markets and its ability to forge innovative partnerships

with the private sector to accelerate the development of medical countermeasures for these threats. BARDA has supported multiple Zika vaccine candidates, two of which are now in clinical trials, and seven blood tests, diagnostics, and pathogen reduction technologies. Today, BARDA is supporting the late-stage development of two Ebola Zaire vaccine candidates, two Ebola Sudan vaccine candidates, three early-stage Marburg vaccine candidates, and the advanced development of two therapeutic candidates to treat Ebola, which are being made available in the ongoing Ebola outbreak in the Democratic Republic of the Congo as part of a randomized clinical trial. A rapid point-of-care diagnostic test developed with BARDA support is also helping to target response efforts for maximum impact in the DRC outbreak.

Since its founding in 2006, BARDA has been authorized to engage in the development of medical countermeasures for naturally occurring threats, including EIDs. This work was bolstered in the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019, which specifically authorized BARDA to implement “strategic initiatives” to develop countermeasures against EIDs, pandemic influenza, and antimicrobial-resistant pathogens. However, the majority of BARDA’s work in this space, including many of the examples cited above, has been funded through one-time, emergency supplemental appropriations. For BARDA to continue bridging the “valley of death” between basic research and advanced-stage product development for urgently needed medical countermeasures for the full spectrum of naturally-occurring threats, from EIDs to pandemic influenza to antimicrobial-resistant pathogens—an area where more traditional US government research enterprises do not operate and where private sector investment is scarce—increased funding, along with greater clarity into the use of existing funding streams and prioritization of disease threats, is needed.

For this reason, we urge House and Senate conferees to include the following language related to BARDA’s role in this space from your respective fiscal year 2020 Labor, Health and Human Services, Education, and Related Agencies appropriations bill reports in the final conference bill report:

From the House bill report:

Tuberculosis.—The Committee previously encouraged BARDA to support the development of new tuberculosis (TB) diagnostic tests, drugs and vaccines for drug resistant TB. The Committee requests a report on this issue within 180 days of enactment of this Act. *(In addition to the Senate language about tuberculosis listed below)*

Zika Vaccine Development.—The number of new Zika virus infections has dropped dramatically because much of the population in Zika-endemic areas has developed an immunity to the virus. However, like other similar mosquito-borne flaviviruses, the virus is likely to reemerge in these areas in several years, and could emerge unpredictably in isolated areas in the meantime, including within the US. Given the links between Zika virus infections and serious birth defects, and the length of time necessary to develop vaccines, the Committee believes it is prudent to continue efforts to develop a vaccine for the Zika virus. Within the total funding provided for BARDA, the Committee directs BARDA to continue to support research and development on a vaccine for the Zika virus.

From the Senate bill report:

Global Health Research.—The Committee requests an update in the fiscal year 2021 CJ on how CDC, FDA, BARDA, and NIH jointly coordinate global health research activities with specific measurable metrics used to track progress toward agreed upon health goals.

Infectious Diseases.—The Committee commends BARDA for supporting advanced development efforts to develop vaccines, diagnostics, drugs, and therapeutics to minimize serious threats of infectious diseases. BARDA is encouraged to continue to proactively prepare for emerging infectious disease outbreaks, including investing in rapid screening technology. The Committee encourages ASPR to delineate information on emerging infectious diseases, pandemic influenza, and AMR investments in its annual five-year budget plan for medical countermeasure [MCM] development to clarify how ASPR is considering such naturally occurring threats in relation to other priority areas of MCM development.

Tuberculosis.—The National Strategy for CARB identified drug resistant TB as a serious threat level pathogen and called for new diagnostic, treatment, and prevention tools to address this global health threat. The Committee encourages BARDA to support the development of new TB diagnostic tests, drugs, and vaccines through the CARB initiative, and the Emerging Infectious Disease program. *(In addition to the House language about tuberculosis listed above).*

As global health threats multiply around the world, supporting BARDA to invest in medical countermeasures for naturally occurring threats is critical to our national security—and to the health of communities worldwide where members of our coalition work. Thank you for your continued support for these life-saving investments.

Sincerely,

