


FY22 Report Language Request Outcomes

R&D-related language included in Senate FY22 State, Foreign Operations, and Related Programs report

 = language similar to that submitted by GHTC

Senate

[Under HIV/AIDS] *Vaccine*.—USAID shall continue to support research and development of a vaccine to combat the AIDS virus.

[Under Malaria] The Committee recommends \$800,000,000 for programs to combat malaria, and continues to encourage USAID to support public-private partnerships; research and development; diagnostic and vector control tools; access and delivery of anti-malarial medicines, including new, effective pediatric formulations and alternative therapies to counter resistance; and continued efforts to develop new insecticides and a malaria vaccine.

[Under Malaria] *Vaccine*.—The Committee notes progress in the development of an effective malaria vaccine and again encourages USAID to support this effort, as well as the development of next-generation vaccines, including vaccines that interrupt malaria transmission.

[Under Neglected Tropical Diseases] The Committee continues to support research and development on NTDs, and notes the essential contributions of the private sector in improving diagnostic and therapeutic tools, and product innovation, to treat patients with NTDs.

[Under Neglected Tropical Diseases] *Leprosy*.—The Committee is informed that every two minutes someone is diagnosed with leprosy and four million people live with lifelong disabilities from this marginalizing disease. The Committee encourages USAID to support research and development of a vaccine to protect against nerve damage among those diagnosed with leprosy, the most serious complication of the disease.

[Under Other Global Health Issues] *Childhood Cancer*.—The Committee supports public-private partnerships, including in coordination with multilateral organizations and research entities, to strengthen public health systems in developing countries that are currently unable to provide life-saving treatment for childhood cancers. Not later than 60 days after enactment of the act, the USAID Administrator shall consult with the Committees on Appropriations on opportunities for such partnerships

[Under Other Global Health Issues] *Research and Development*.—Not later than 60 days after enactment of the act, the USAID Administrator shall update the report required under this heading in Senate Report 116–126 on USAID’s health-related research and development strategy.

The USAID Administrator shall also develop a new multi-year strategy on global health research and development, which shall be posted on the USAID website. Such strategy should include: (1) how USAID will work across programs to implement a comprehensive research and development approach; (2) plans to collect and use input from the Global Health Bureau, consultations with nonprofit and other private sector partners, and the heads of other relevant Federal agencies, including CDC, the National

Institutes of Health, and the Biomedical Advanced Research and Development Authority; (3) plans to coordinate with such stakeholders in support of innovative global health product development; and (4) specific investment and target goals for research and product development across GHP-funded disease areas.

R&D-related language included in Senate FY22 Labor, Health and Human Services, Education, and Related Agencies report

[Yellow highlight] = language similar to that submitted by GHTC

Senate

HHS – Office of the Secretary

Global Health Research.—The Committee requests an update in the fiscal year 2023 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.

Office of the Assistant Secretary for Preparedness and Response

Antimicrobial Resistance [AMR].—The Committee directs the Office of the Assistant Secretary for Health, NIH, ASPR/BARDA, CDC and AHRQ to jointly brief the Committees on Appropriations of the House of Representatives and Senate no later than 30 days after the enactment of this act detailing how HHS and its agencies are coordinating their AMR-related efforts.

Biomedical Advanced Research and Development Authority [BARDA]

Infectious Diseases.—The Committee commends BARDA for supporting advanced development efforts to develop vaccines, diagnostics, drugs, and therapeutics to minimize serious threats of infectious disease. The Committee supports robust funding for enhanced work by BARDA in this space to proactively prepare for emerging infectious disease outbreaks and other naturally occurring threats to American and global health security. 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, particularly given their inclusion in the Strategic Initiatives section of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act (Public Law 116–22)

Tuberculosis [TB].—Drug-resistant TB is identified as a serious threat level pathogen to the United States by the National Strategy for Combating Antibiotic-Resistant Bacteria. As drug resistant TB cases are on the rise globally, the threat to the United States also grows. BARDA’s investments in new TB diagnostics, drugs, and vaccines are critical. The Committee requests an update on BARDA’s investments in drug resistant TB research in the fiscal year 2023 CJ.

Centers for Disease Control and Prevention

National Center for Emerging Zoonotic and Infectious Diseases (NCEZID)

Advanced Molecular Detection [AMD].—The Committee recognizes the critical role of CDC’s AMD program to bring cutting edge technology to the front lines of public health by harnessing the power of next-generation sequencing and high performance computing with bioinformatics and epidemiology expertise to study pathogens. The COVID–19 pandemic highlighted the importance of laboratory

capacity to respond to emerging infections and apply novel technologies like next-generation sequencing.

[Under *Antimicrobial and Antibiotic Resistance*.—] CDC is directed to expand laboratory and epidemiological surveillance of bacterial and fungal infections, increase research on infection prevention and the emergence and spread of AR infections—including global surveillance and research activities—and to develop new tools to help prevent healthcare-associated infections. The Committee strongly encourages CDC to develop new or expanded educational training guidelines, outreach and awareness activities to healthcare providers on best practices for using antibiotics responsibly, stopping the spread of AR, and preventing infections to improve national outpatient antibiotic use and the use of antibiotics across healthcare settings and communities. The Committee encourages CDC to competitively award research activities that address aspects of antibiotic resistance related to a “One Health” approach to public academic medical centers including Minority Serving Institutions, veterinary schools, including those with agricultural extension services, and public health departments whose proposals are in line with CDC’s strategy for addressing AR bacteria.

Mycotic Diseases.—The Committee provides an increase of \$1,000,000 for mycotic diseases and encourages CDC to fully utilize its clinical trial partners and the Mycoses Study Group to address the growing threat from mycological infection in the United States and around the world.

Center for Global Health

[Under Global Public Health Protection] The Committee continues to support CDC’s work to protect American and global health security through programs that detect, prevent, and respond to infectious diseases and other health threats. The Committee supports CDC’s continued work on the development of new tools, especially diagnostics, the application of advanced molecular detection for the identification and tracking of infectious diseases and disease variants at home and abroad, and the agency’s core technical contributions to developing and validating tools for use by U.S. bilateral and multilateral global health programs and laboratory efforts to monitor and combat infectious diseases, including antimicrobial drug and insecticide resistance.

National Institutes of Health

National Institute of Allergy and Infectious Diseases

Antiviral Drug Discovery Initiatives.—The Committee supports NIAID’s ongoing efforts to establish public-private partnerships focused on global pandemic preparedness and antiviral drug discovery, leveraging the best of academia and industry to develop and deliver broad-spectrum antiviral drugs, address rapidly emerging public health threats, be better prepared before the next virus creates another global catastrophe, and encourage close collaboration with BARDA.

Responding to Infectious Diseases.—The Committee supports NIAID’s efforts to continue responding to the COVID–19 pandemic and prepare for future outbreaks while carrying out its broader role in infectious diseases research, including research on antimicrobial resistance. To that end, the Committee provides no less than \$550,000,000, an increase of \$25,000,000, to support NIAID research to combat antimicrobial resistance. In particular, the Committee recommends NIAID devote the additional funding to expand research on mechanisms of resistance, therapeutics, vaccines and diagnostics; support the development of a clinical trials network to reduce barriers to research on difficult-to-treat infections; and support the training of new investigators to improve AMR research capacity as outlined in the 2020–2025 National Action Plan to Combat Antibiotic-Resistant Bacteria. As part of the latter effort to

expand and diversify the infectious diseases research workforce, the Committee recommends NIAID expand the number of K, T, and F awards, and Early Investigator Awards. The Committee directs the Office of the Assistant Secretary for Health, NIH, ASPR/ BARDA, CDC and AHRQ to jointly brief the Committees on Appropriations of the House of Representatives and Senate no later than 30 days after the enactment of this Act detailing how HHS and its agencies are coordinating their AMR-related efforts. The briefing should include a comparison of actual performance against the national targets for 2020 established in the March 2015 National Action Plan for Combatting Antibiotic-Resistant Bacteria and whether those goals were sustained in 2021. Agencies are directed to outline the focus of their plans for fiscal years 2022–2023 and how these are connected to longer-term objectives included in the follow-on National Action Plan released in October 2020. In addition, NIAID should detail the focus of its initiatives to strengthen and diversify the ID/HIV research workforce for fiscal years 2022–2023

Vaccine Development.—The Committee recognizes the importance of being able to quickly, efficiently, and safely develop and manufacture vaccines against emerging infectious diseases. Vaccines play a pivotal role in host protection against infectious diseases and have significantly reduced mortality worldwide. Older methods of developing vaccines are no match for a host of emerging and reemerging pathogens that call for a tailored and speedy response, such as the developing coronavirus variants. Today, innovations in how vaccines are developed enable faster production of platforms capable of making and initially testing a new vaccine in less than 120 days that then are tailored to specific pathogens as manufacturing begins, based on science and data, not speculation. Such rapid vaccine platform technologies can vastly decrease the time it takes to develop, manufacture, and distribute vaccines. The Committee encourages NIAID to support research and development of rapid vaccine platform technologies. The Committee directs NIAID to brief the Committee within 180 days of enactment on progress.

Fogarty International Center

Global Health Research.—COVID–19 has shown the importance of FIC’s essential role in global health research training, pandemic preparedness, and global health security by assisting low- and middle-income countries [LMIC] in advancing their own research and health solutions and tools. These investments strengthen research capacity across a wide range of diseases and cross-cutting public health needs, including infectious diseases, non-communicable diseases, environmental health, trauma and injury, and mobile technologies—all of which are critical to improving economic and global health security. The COVID–19 pandemic illustrates the importance of FIC’s efforts to strengthen country capacity to enable cutting edge research at the origin of outbreaks, improving the likelihood that emerging diseases can be addressed at their source—ultimately protecting American health security. The Committee believes these long-standing relationships and unique capabilities position FIC to play an important and expanded role in pandemic preparedness, including developing a network of modeling hubs and joint research programs to engage LMIC investigators to collaboratively train for pandemic preparedness. The Committee requests information from FIC in their annual budget justification about how FIC training programs and research collaborations have, and with additional resources can, increase efforts to advance global health security and pandemic preparedness. The Committee is particularly interested in understanding FIC’s unique capabilities and capacities as well as coordination with other Federal government agencies engaged in these efforts.

Office of the Director

Research Involving Enhanced Potential Pandemic Pathogens.— Understanding the origin of pandemics is important for identifying potential sources of future epidemics or pandemics. The possibility that the

SARS-CoV-2 virus leaked from a laboratory cannot be excluded, though there is no evidence to suggest that it was engineered. The Committee notes that research involving enhanced potential pandemic pathogens is critical to public health preparedness, but such work must be conducted safely and securely, no matter where in the world it is conducted. The Committee supports a robust evaluation of whether the HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogen Care and Oversight [P3CO] has achieved its intended purpose and whether the scope of research it covers is sufficient. The Committee directs HHS and NIH to convene the National Science Advisory Board for Biosecurity [NSABB] and conduct such a review. Further, the Committee strongly encourages NIH to suspend funding for any and all existing and future studies under the Framework that are being conducted or proposed to be conducted in settings outside the United States until such time as the NSABB review of that process is complete.

Note: Significant language included on the Advanced Research Projects Agency for Health, but nothing of note for its potential global health impact.