



July 10, 2023

The Honorable Bernie Sanders, Chair
Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Bob Casey
393 Russell Senate Office Building
Washington, DC 20510

The Honorable Bill Cassidy, Ranking Member
Committee on Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Mitt Romney
354 Russell Senate Office Building
Washington, DC 20510

Re: Request for Comment on PAHPA Reauthorization Discussion Draft

Dear Chair Sanders, Ranking Member Cassidy, and Senators Casey and Romney,

Thank you for the opportunity to provide feedback and suggestions to the Senate Health, Education, Labor, and Pensions (HELP) Committee in response to the discussion draft for the upcoming reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA). As we previously communicated to the Committee in our [response](#) to the Committee's Request for Information (RFI) regarding PAHPA, the Johns Hopkins Center for Health Security's highest priority recommendations focus on 5 policy issues: (1) establishing a 'Disease X' Medical Countermeasures Program at BARDA; (2) requiring the Department of Health and Human Services (HHS) to regulate the screening of gene synthesis orders and customers; (3) supporting innovative next-generation reusable respirators for the Strategic National Stockpile (SNS); (4) developing and implementing a National Diagnostics Action Plan; and (5) improving the country's bioattribution capabilities.

The Johns Hopkins Center for Health Security examines how new policy approaches, scientific advances, and technological innovations can help prevent and prepare for pandemics, accidents, and deliberate biological events in order to strengthen both health security and national security, and therefore save lives. Our recommendations for amendments to this discussion draft reflect our analysis of the legislative changes that would increase opportunities to prevent biological threats from occurring, as well as substantially diminish the consequences posed by those threats, including those that pose potentially catastrophic biological risks to the US and the world.

The Center provided edits and comments on a discussion draft document that has been submitted directly to Committee staff. The highest priority comments on the marked-up discussion draft are as follows:

1. **'Disease X' Medical Countermeasures (MCM) Program (§ 203):** We strongly support the establishment of a ['Disease X' MCM program](#) to protect against unknown viral threats and appreciate the inclusion of this section. However, we are concerned that the amending language is situated within a clause that governs threats that *consistently exist or continually circulate* and have a significant potential to become a pandemic—a program established with those requirements could not protect against unknown viral threats with pandemic potential, and therefore would not be significantly different from the status quo. Accordingly, we recommended 2 alternative approaches in the marked-up draft. We also strongly support the language and dedicated funding in S.2093, [Disease X Act of 2023](#).
2. **Gene synthesis screening (Title IV):** Congress should require HHS to prescribe a regulation requiring gene synthesis providers and manufacturers to screen all customers and incoming orders of gene sequences and to require purchasers of gene sequences to order only from providers and manufacturers who perform such screening. We included a 1-page background document to Committee staff on this issue and urge a closed member briefing on this important and urgent issue.

3. **Next-generation reusable respirators (Title II):** Congress should require the Administration for Strategic Preparedness and Response (ASPR) to create target product profiles (TPPs) for [next-generation reusable respirators](#) and a process of recurring competitive bidding for products meeting increasingly stringent TPPs to create demand-side incentives for next-generation reusable respirators. We included a 2-page background document to Committee staff on this issue and recommended possible amending language to achieve this.
4. **National Diagnostics Action Plan (Title II):** Congress should require that ASPR develop and implement a [National Diagnostics Action Plan](#), including the establishment of a permanent public-private coordination forum for diagnostic testing. We are supportive of the [Diagnostic Testing Preparedness Plan Act](#) introduced in the House by Representatives Pence, Schrier, Bucshon, and Susie Lee and believe it could be further strengthened with the establishment of a public-private coordination forum for diagnostic testing. We included a 1-page background document to Committee staff highlighting several other recommendations that would strengthen US diagnostic testing preparedness.
5. **Bioattribution (Title II):** Congress should require ASPR to establish a Bioattribution Strategy to include the following:
 - Identification of the specific bioattribution responsibilities, including pandemic origin investigations, that reside in each of the federal agency/program offices, the nature of routine bioattribution activities within each, and the budgetary support allocated within each.
 - Development of assignments, milestones, timelines, and budgets necessary to establish the strongest possible national capacity for bioattribution.
 - Interface among executive agencies, including, but not limited to, HHS, the Department of State, the Department of Justice, the Department of Defense, and the Department of Commerce.
 - Coordination with the Intelligence Community.
 - Routine exercise of the capabilities of the federal government to perform bioattribution activities.We included a background document to Committee staff highlighting several other recommendations that would improve the country's bioattribution capabilities.

In addition to these Center priorities, we are very supportive of the requirements for public health data reporting in Section 205 of the discussion draft. We included suggestions for how to make that program as effective as possible.

In taking these actions, we can ensure that critical gaps in national pandemic prevention and preparedness are filled to make the country's public health, economy, and national security more resilient. If the Johns Hopkins Center for Health Security can provide any technical assistance or other resources as you consider these issues, please contact us. The Center for Health Security stands ready to be a resource to the HELP Committee members and your offices.

Sincerely,



Tom Inglesby, MD

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Professor, Environmental Health and Engineering
Johns Hopkins Bloomberg School of Public Health
Joint Appointment, Medicine, Johns Hopkins School of Medicine