

Summary of Johns Hopkins Center for Health Security RFI Submission for PAHPA Reauthorization to US Senate



The Johns Hopkins Center for Health Security recently provided feedback and suggestions in response to a [Request for Information](#) (RFI) in preparation for the upcoming Pandemic and All-Hazards Preparedness Act (PAHPA) reauthorization due by September 30, 2023. The Senate Health, Education, Labor, and Pensions (HELP) Committee released the RFI on March 15, 2023. This submission follows [the Center's response to a US House RFI](#) issued by Rep. Richard Hudson (R-NC) and Rep. Anna Eshoo (D-CA) on the same topic.

PAHPA is a groundbreaking piece of legislation first signed into law in 2006, and the next round of reauthorization is rapidly approaching. PAHPA is now widely considered a “must pass” bill that bolsters the nation’s medical and public health preparedness and response capabilities against deliberate, accidental, and natural biological threats, as well as other crises. Previous iterations of PAHPA have authorized the Administration for Strategic Preparedness and Response (ASPR) and the Biomedical Advanced Research and Development Authority (BARDA) and provided new authorities for a variety of other programs.

The Center for Health Security’s recommendations consist of 5 categories of policy recommendations: (1) establishing a ‘Disease X’ Medical Countermeasures Program at BARDA; (2) supporting innovative next-generation reusable respirators for the Strategic National Stockpile (SNS); (3) requiring mandatory screening of gene synthesis orders and customers; (4) implementing a National Diagnostics Action Plan; and (5) improving US bioattribution capabilities.

The Center’s top 5 priorities for the 2023 PAHPA reauthorization include:

1. **‘Disease X’ Medical Countermeasures (MCM) Program:** Congress should require BARDA to establish a [‘Disease X’ MCM program](#) to protect against unknown viral threats.
2. **Next-generation reusable respirators:** Congress should require 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.
3. **Gene synthesis screening:** Congress should require the Department of Health and Human Services (HHS) to prescribe a regulation requiring gene synthesis providers and manufacturers to screen all customers and incoming orders of gene sequences and to require all purchasers of gene sequences to order only from providers and manufacturers who perform such screening.
4. **National Diagnostics Action Plan:** Congress should implement a National Diagnostics Action Plan, such as the one co-authored by the Center for Health Security and the American Clinical Laboratory Association (preprint [here](#)).
5. **Bioattribution:** Congress should task the Office of Science and Technology Policy (OSTP) with coordinating federal bioattribution efforts across and outside of government, as well as with establishing a working group to maximize existing databases and data resources for bioattribution purposes. Congress should also authorize funding for the improvement of current, or the development of new, bioattribution technologies.

In taking these actions, Congress can ensure that critical gaps in national pandemic prevention and preparedness are filled and that our health, economic, and national security are hardened.

High-Level Recommendations

High-level recommendations for each policy priority within the RFI's listed programs are as follows:

(Superscript numbers represent 1 of the 5 categories of the Center's policy recommendations as enumerated above.)

- **HHS:** Establish a permanent public-private National Testing Coordination Forum focused on preparedness and response to disease emergencies and use it to plan to: (1) rapidly provide clinical samples to private-sector test developers during the earliest phase of a new epidemic; and (2) quickly share clinical research to inform test development.⁽⁴⁾
- **ASPR:**
 - Create target product profiles (TPPs) for next-generation reusable respirators and a process of recurring competitive bidding for products meeting increasingly stringent TPPs.⁽²⁾
 - Require ASPR to prescribe a regulation requiring gene synthesis providers and manufacturers to screen all customers and incoming orders of gene sequences and to require all purchasers of gene sequences to order only from providers and manufacturers who perform such screening.⁽³⁾
- **SNS:**
 - Provide assured market for next-generation reusable respirators once they are developed.⁽²⁾
 - Facilitate transparent, bilateral contracts between the US government and testing manufacturers and laboratories before a disease emergency.⁽⁴⁾
- **BARDA:**
 - Establish a 'Disease X' Medical Countermeasures Program.⁽¹⁾
 - Work with industry partners to foster further development of improved, next-generation reusable respirators, leading to their eventual purchase for the SNS.⁽²⁾
- **Public Health Emergency Medical Countermeasures Enterprise (PHEMCE):** Members should integrate their programs with a 'Disease X' approach at BARDA.⁽¹⁾
- **Emergency Use Authorizations (EUA):** Refine regulatory requirements for pre-EUA and EUA processes to swiftly bring testing to scale.⁽⁴⁾
- **Hospital Preparedness Program (HPP):** Integrate next-generation reusable respirators.⁽²⁾
- **Biosurveillance and Public Health Situational Awareness:** Reduce redundant reporting mechanisms for public health data and minimize burden on reporting entities.⁽⁴⁾
- **Gaps in the PAHPA Framework:**
 - The PAHPA framework does not adequately protect against novel or future threats.⁽¹⁾
 - The PAHPA framework currently lacks dedicated attention to bioattribution.⁽⁵⁾
- **Gaps in HHS capabilities:** Significant gaps exist in coverage of tests for new pathogens of concern.⁽⁴⁾
- **How can states and localities, community-based organizations, and private sector and nongovernment stakeholders be better supported in appropriately engaging with the federal government to understand available resources, capabilities, and expectations prior to, during, and following a public health emergency?** Establish a permanent public-private National Testing Coordination Forum focused on preparedness and response to disease emergencies and use it to plan to: (1) rapidly provide clinical samples to private sector test developers during the earliest phase of a new epidemic; and (2) quickly share clinical research to inform test development.

For more detailed information on each program and recommendation, please see the Center's [full RFI response](#).