

Summary of Center for Health Security RFI Submission for PAHPA Reauthorization to US House of Representatives



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. House Energy and Commerce Committee members Rep. Richard Hudson (R-NC) and Rep. Anna Eshoo (D-CA) released the RFI last month.

PAHPA is a groundbreaking piece of legislation that was 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 programs.

The Center for Health Security’s recommendations consist of 5 categories of policy recommendations (in descending order of priority): (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.

- **ASPR's Hospital Preparedness Program (HPP):** Integrate next-generation reusable respirators.⁽²⁾
- **Public health & biosurveillance:** Reduce redundant reporting mechanisms for public health data and minimize burden on reporting entities.⁽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⁾
- **Public Health Emergency Medical Countermeasures Enterprises (PHEMCE):** Members should integrate their programs with a 'Disease X' approach at BARDA.⁽¹⁾
- **Strategic National Stockpile (SNS):**
 - Provide assured market for next-generation reusable respirators once they are developed.⁽²⁾
 - Facilitate transparent, bilateral contracts between the USG and testing manufacturers and laboratories before a disease emergency.⁽⁴⁾
- **MCM budget plan:** Include funding for a 'Disease X' Medical Countermeasures Program.⁽¹⁾
- **BARDA:**
 - Work with industry partners to foster further development of improved, next-generation reusable respirators, leading to their eventual purchase for the SNS.⁽²⁾
 - 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 all purchasers of gene sequences to order only from providers and manufacturers who perform such screening.⁽³⁾
- **Other:**
 - Task the Office of Science and Technology Policy (OSTP) with coordinating bioattribution efforts across the federal government.⁽⁵⁾
 - Task OSTP with coordinating the federal government's bioattribution efforts with related efforts in academia, industry, and other entities outside the federal government.⁽⁵⁾
 - Establish a working group to develop standards for bioattribution database management and information sharing.⁽⁵⁾
 - Authorize and allocate funding for the improvement of current, or the development of new, bioattribution technologies.⁽⁵⁾

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