

Center for
**Health
Security**

**Response to the US Senate Request
for Information (RFI) on PAHPA
Reauthorization, as Submitted by the
Johns Hopkins Center for Health Security**

March 29, 2023



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Center for Health Security

Introduction

On March 29, 2023, the Johns Hopkins Center for Health Security provided feedback and recommendations 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. Senate Health, Education, Labor, and Pensions Committee Chair Sen. Bernie Sanders (I-VT), Ranking Member Sen. Bill Cassidy (R-LA), and Sens. Robert P. Casey, Jr. (D-PA) and Mitt Romney (R-UT) issued the RFI earlier in March. This submission follows the [Center's response to a US House of Representatives RFI](#) issued by Reps. Richard Hudson (R-NC) and Anna Eshoo (D-CA) on the same topic.

PAHPA is a groundbreaking piece of legislation that was first signed into law in 2006. PAHPA was reauthorized in 2013 and 2019, 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 emergencies. 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.

As with the US House RFI, 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 following is the Center’s RFI response, including cover letter and recommendations with explanation.

March 29, 2023

Senator Bernie Sanders
428 Senate Dirksen Office Building
Washington, DC 20510

Senator Bob Casey
393 Russell Senate Office Building
Washington, DC 20510

Senator Bill Cassidy
428 Senate Dirksen Office Building
Washington, DC 20510

Senator Mitt Romney
354 Russell Senate Office Building
Washington, DC 20510

Re: Request for Information on PAHPA Reauthorization

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 preparation for the upcoming reauthorization of the Pandemic and All-Hazards Preparedness Act (PAHPA), including by responding to the Request for Information (RFI) released by your committee. The Johns Hopkins Center for Health Security recommendations focus on 5 policy issues: (1) establishing a ‘Disease X’ Medical Countermeasures Program at BARDA; (2) supporting innovative next-generation reusable respirators for the SNS; (3) requiring mandatory screening of gene synthesis orders and customers; (4) 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 strengthen health security and national security and save lives. Our research focuses on improving organizations, systems, and tools to prevent and respond to outbreaks and other public health crises. We advance policies and practice addressing significant challenges, including emerging infectious diseases, a continued risk of pandemic flu, major natural disasters, and the potential for biological accidents or intentional threats. Our PAHPA recommendations reflect our analysis of the legislative changes that would substantially diminish the consequences posed by biological threats, including those that pose potentially catastrophic biological risks to the US and the world.

COVID-19 remains among the top 10 leading causes of death in the US, and more than a million lives have been lost in the US, with many more millions lost around the world. The pandemic cost the US between [\\$10 to \\$22 trillion](#). As terrible as COVID-19 has been, it is not the worst-case pandemic scenario. The world needs to be prepared for a ‘Disease X,’ a pandemic pathogen that could cause greater mortality and societal disruption—whether such a pathogen emerges naturally or via manipulation in a laboratory and subsequent accidental or deliberate release. This is the first PAHPA reauthorization that has come in the wake of a major pandemic, so it is an extraordinary

opportunity and obligation for the country to make critical reforms that will diminish the risks posed by future biological threats.

The Center's highest priority PAHPA reauthorization recommendations are the following:

1. **'Disease X' Medical Countermeasures (MCM) Program:** Congress should require Biomedical Advanced Research and Development Authority (BARDA) to establish a ['Disease X' MCM program](#) to protect against unknown viral threats.
2. **Next-generation reusable respirators:** 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.
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 require the implementation of a National Diagnostics Action Plan (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 that would substantially increase the capacity to identify the source of future pandemic events. This includes assigning these responsibilities to an HHS office; identifying existing funding levels and future funding requirements; and tracking the research and development around technologies that are key to this work.

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

Sincerely,



Tom Inglesby, MD

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Professor, Environmental Health and Engineering
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RFI Response

The below comments reflect the Center's RFI response to the Senate Health, Education, Labor, and Pensions (HELP) Committee. RFI headings without comments are not included and original RFI language appears in italics.

Program Effectiveness

What specific changes could Congress make to improve the efficiency and effectiveness of:

The responsibilities and authorities of the Secretary of Health and Human Services (HHS) prior to or during a public health emergency (PHE)?

National Diagnostics Action Plan

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.

As described in our National Diagnostics Action Plan (preprint [here](#)), co-authored with the American Clinical Laboratory Association, the Johns Hopkins Center for Health Security recommends that a public-private National Testing Coordination Forum (Forum) be established to focus on preparedness and response to disease emergencies. The Forum would meet regularly and be empowered to provide recommendations to the HHS Secretary, White House, and Congress on both preparedness and response matters. The Forum would comprise leaders from public health sector agencies and departments integral to diagnostic testing (eg, CDC, CMS, FDA, NIH), and representatives of public sector laboratories, hospital laboratories, commercial laboratories, private sector organizations that represent diagnostic manufacturers, and healthcare product distributors.

The Forum would serve as the primary coordinating hub for public and private sector stakeholders executing diagnostic testing plans to ensure real-time information sharing, swift development and scale-up of tests and testing capacity, and clear communications to the public on the state of testing. The Forum also would identify serious national testing challenges and provide recommendations for solving them. For example, in the earliest stages of an emergency, when access to patient samples is limited, the Forum would support the work of CDC, FDA, and NIH to facilitate high-value allocation of samples to test developers under contract with the federal government to develop and scale up manufacturing and testing capacity. The Forum would also work with the federal government to ensure the sharing of clinical research findings relevant to developing diagnostics for new pathogens of concern, in collaboration with CDC, providers, test developers, public health offices, and others.

The authorities, duties, and functions of the Assistant Secretary for Preparedness and Response (ASPR)?

Next-Generation Reusable Respirators

Create target product profiles (TPPs) for next-generation reusable respirators and a process of recurring competitive bidding for products meeting increasingly stringent TPPs.

The [FY23 Omnibus](#) directs ASPR to submit to Congress a report on its activities with regards to an assessment of its stockpile of reusable respirators and scenario-based modeling studies to determine the appropriate amount needed for the Strategic National Stockpile (SNS). Congress also urged ASPR in the Omnibus to consider creating target product profiles (TPP) for respirators and masks and a process of recurring competitive bids for products meeting increasingly stringent TPPs. Over time, as there is more innovation, the TPPs should evolve in the areas of filtration, ease of breathing, fit, comfort, and other areas as needed and technologically feasible.

The Center for Health Security recommends that Congress directs that planning around PPE stockpiling requirements and approaches include scenarios in which the mortality risk is greater than COVID-19, since this is not the most severe respiratory threat the country could face. High-consequence biological events in the future (eg, involving higher mortality rates, a longer period of uncontrolled spread prior to vaccine availability, and a prolonged pandemic) could put much more stress on the N95 supply chain and require even greater national capacity for respiratory protection than was needed during COVID-19. This recommendation is consistent with *Goal 3.3 Resilient and Scalable Supply of PPE* in the [2022 National Biodefense Strategy and Implementation Plan](#).

Congress should require ASPR and BARDA to work closely with industry partners to encourage and support their development of these next-generation respirators so that new products can successfully come through advanced development and be able to get NIOSH/FDA approval so that they are fit for procurement and stockpiling. BARDA already plays this role for other medical countermeasures and has operational know-how in this regard. We agree with Congress' recommendation in the FY23 Omnibus and recommend that ASPR create TPPs for reusable respirators and a process of recurring competitive bidding for products meeting increasingly stringent TPPs. This recommendation may also be consistent with or complementary to ASPR's PAHPA priorities of expanded Other Transaction Authority (OTA) and expanded General and Innovative Procurement and Acquisition authorities.

Mandatory Gene Synthesis Screening

Congress should 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.

The Center for Health Security recommends that Congress require ASPR to create and implement a regulatory process for ensuring that gene synthesis providers and manufacturers screen all incoming customers and orders before fulfilling them and that all purchasers of gene sequences only order from providers and manufacturers that perform such screening. To ensure compliance with regard to international exports and imports, Congress should require ASPR to collaborate with the Office of the Director of National Intelligence (ODNI) and the Department of Commerce in crafting such a regulatory regime. We understand **there is a mandatory gene synthesis screening bill circulating among congressional staffers and we recommend its introduction and inclusion in PAHPA.**

This is an issue of national security. Pathogens—particularly small viruses—can be assembled from scratch in a lab, evading the regulatory regimes that the US and many other nations have in place to control unauthorized access to dangerous pathogens. The National Academies of Sciences, Engineering, and Medicine listed the synthesis of known pathogens, particularly small viruses, as one of the most pressing biodefense risks in a 2018 report. There are also new risks of synthesizing unknown pathogens or novel viruses using artificial intelligence, as a recent [Nature article](#) pointed out and which [Rep. Eshoo wrote to OSTP and NSC](#) about last year. Bad actors could use genome synthesis products to create a synthesized virus that is both lethal and contagious. The skills and costs of technology required to do such a thing continue to decline, making it easier for malicious actors to do harm.

Some commercial gene synthesis companies already voluntarily screen orders to ensure they are selling to scientists who work in regulated research institutions and comply with laws that govern the possession of dangerous pathogens. But some gene synthesis companies, to reduce costs or for other reasons, do not screen gene sequence orders from their customers, including customers (ie, scientists and research labs) based outside of the United States. This can create market conditions that favor gene synthesis companies that do not take necessary safety and security precautions. A mandatory gene synthesis screening regulatory regime would start leveling the playing field for responsible companies within the US, which are at a relative competitive disadvantage to companies that do not screen. It would also provide the US with soft power abroad and increase the possibility that companies outside of the US would start to screen gene sequence orders to sell to the substantial US market, further protecting our own nation's health security. The gene synthesis industry has a global market valued at more than \$200 million in 2017 and is projected to grow to \$5.2 billion by 2027. Many larger companies belong to an organization called the International Gene Synthesis Consortium (IGSC) that requires companies to screen their orders, but screening is not universal and a recent review by Gryphon Scientific presented at a symposium on gene synthesis screening found that enforcement is nearly nonexistent.

ASPR's recent issuance of proposed [Revised Guidance](#) for the DNA synthesis industry is laudable and of utmost importance to a safe, secure, and productive biological research ecosystem capable of addressing the great societal challenges of this time.

However, on its own, it is insufficient. This is because screening of both gene synthesis orders and customers would remain only voluntary. By ensuring that industry groups manufacturing and selling synthesized DNA sequences do both “know your customer” and “know your order” checks, and by ensuring that liability can be placed upon both providers/manufacturers and purchasers, HHS can substantially lower the risks that genome synthesis products could lead to the creation of viruses that could lead to epidemics, pandemics, or even catastrophic biological events.

Accordingly, the Center for Health Security recommends that Congress ensure that ASPR create and implement a regulatory process for ensuring that gene synthesis providers and manufacturers screen all incoming customers and orders before fulfilling them and that all purchasers of gene sequences only order from providers and manufacturers that perform such screening, as well as establish a punitive regime for violations. Such a congressional mandate would provide ASPR with statutory authorization to make such rules and clarify that they may harmonize existing guidelines with a new rule requiring mandatory gene synthesis screening.

The Strategic National Stockpile (SNS)?

Next-Generation Reusable Respirators

The SNS should provide some level of assured market for next-generation reusable respirators once they are developed.

To build upon Congress’s actions in the [FY23 Omnibus](#) under the heading “Ensuring the Availability of Next Generation Masks and Respirators,” the Center for Health Security recommends that Congress **require ASPR to assess its stockpile of reusable respirators within the SNS and conduct scenario-based modeling studies to determine the appropriate amount needed for the stockpile.** These studies should include scenarios in which the mortality risk is greater than with COVID-19, since it is not the most severe respiratory threat the country could face. More high-consequence scenarios (eg, involving higher mortality rates, a longer period of uncontrolled spread prior to vaccine availability, and a prolonged pandemic) will put much more stress on the N95 supply chain and will require greater national capacity for respiratory protection than was needed in COVID-19. This recommendation is consistent with the [2022 National Biodefense Strategy and Implementation Plan](#).

During the COVID-19 pandemic, healthcare and other essential workers depended largely on the availability of disposable respirators. These single-use products require a very robust supply chain that proved to be unreliable, and stockpiles were quickly depleted—leaving countless essential workers inadequately protected. Although the SNS has been replenished and the normal supply chain now meets current demand, given underlying conditions and the anticipated great surge in demand in pandemic settings, it should be assumed that future pandemics or a large-scale bioattack could again overwhelm our ability to protect essential workers using a single-use product approach to masks.

Widespread use of improved, next-generation reusable respirators would: (1) be more cost effective; (2) better protect healthcare and other essential workers; and (3) reduce our nation's dependence on an uncertain supply chain during a severe public health crisis. As a side benefit, such novel respirators could be relied upon for a range of respiratory threats such as SARS, MERS, influenza, and RSV. Although some innovation is occurring in the design of reusable medical respirators to make them easier to wear for prolonged periods and to communicate through, manufacturers are not incentivized to invest significant capital in R&D without a demand signal from hospitals or the federal government. There are also substantial regulatory hurdles to getting new medical products approved by the FDA/NIOSH.

The Center for Health Security recommends that BARDA work closely with industry partners to encourage and support the development of these next-generation respirators so that new products can successfully come through advanced development and be able to get FDA/NIOSH approval so they are fit for procurement and stockpiling. BARDA already plays a similar role for medical countermeasures and has operational know-how in this regard. The Center for Health Security recommends that Congress direct ASPR to create target product profiles (TPPs) for respirators and then a process of recurring competitive bidding for products meeting increasingly stringent TPPs. Over time, as there is more innovation, the TPPs should evolve in the areas of filtration, ease of breathing, fit, comfort, and other areas as needed. The development and procurement of next-generation reusable respirators would also be an effective use of the flexible \$400 million increase requested in the FY24 President's Budget for ASPR to prepare for pandemics and biological threats. This recommendation may further be consistent with or complementary to ASPR's PAHPA priorities of expanded Other Transaction Authority (OTA) and expanded General and Innovative Procurement and Acquisition authorities.

A commitment by the federal government, including the SNS, Department of Defense, and Department of Veterans Affairs health system, to a substantial procurement over several years of next-generation reusable respirators would incentivize industry to invest in the needed research and development, regulatory approval process, and manufacturing. If the government provides industry with a base market, manufacturers are more likely to want to expand production by promoting these new improved products to private sector healthcare facilities. In this way, government commitment could help drive change across the healthcare system. If next-generation reusable respirators become more wearable and practical for regular use, and more available in healthcare settings, it is more likely they would be produced in quantities that would make them available to other essential services and even to the public in the event of a severe, prolonged pandemic or other public health emergency.

The Center for Health Security also recommends that Congress **require the SNS to evaluate and implement mechanisms for rotating protective personal equipment (PPE), including masks and respirators, through public and private healthcare facilities, so they do not expire in the SNS.** This would maintain a market for the new improved devices and ensure that healthcare facilities are familiar with the products in the SNS.

Congress should clarify that the SNS has this authority and mandate that they take action. If ASPR disagrees that it has this authority, Congress should grant this new authority to the SNS.

National Diagnostics Action Plan

Facilitate transparent, bilateral contracts between the federal government and testing manufacturers and laboratories before a disease emergency.

As described in our National Diagnostics Action Plan (preprint [here](#)), co-authored with the American Clinical Laboratory Association, the Center for Health Security recommends that, for the purpose of maintaining the SNS, HHS should be expressly permitted to contract with clinical laboratories before a disease emergency to ensure reserve capacity to fulfill surge capabilities.

The PREVENT Pandemics Act amended the SNS authority to authorize HHS to enter into contracts with vendors, including manufacturers or distributors of medical products, to: (1) enable vendor-managed inventory of medical products; and (2) maintain domestic manufacturing capacity and capabilities of medical products to ensure additional reserved production capacity and capabilities are available. **Congress should clarify this authority by expressly authorizing HHS to contract with clinical laboratories to maintain testing capacity and capabilities to ensure additional reserve testing capacity and capabilities are available.**

Agreements should allow for a 6-month supply of testing components/materials/test kits to either be kept onsite at commercial laboratories with national reach or dedicated to these laboratories but held by manufacturers for swift shipment to laboratories.

The Biomedical Advanced Research and Development Authority (BARDA)?

‘Disease X’

Establish a ‘Disease X’ Medical Countermeasures Program.

Last Congress, a stakeholder letter of 17 academic institutions, think tanks, and industry groups urged Congress to include the Disease X Act (Baldwin, S.2640) in the PREVENT Pandemics Act (Alliance for Biosecurity, Big Cities Health Coalition, BioOhio [now Ohio Life Sciences], Biotechnology Innovation Organization [BIO], Coalition for Epidemic Preparedness Innovations [CEPI], Coherus BioSciences, FluGen Inc., Ginkgo Bioworks, Helix, Infectious Diseases Society of America, Institute for Progress, Johns Hopkins Center for Health Security, Securing America’s Medicines and Supply, The Gerontological Society of America, Tonix Pharmaceuticals, US Biologic, and Vir Biotechnology).

We expect the *Disease X* Act will have a bipartisan, bicameral reintroduction in the coming weeks and strongly recommend its inclusion in PAHPA. The reintroduced text

may have language that would be consistent with or complementary to ASPR's PAHPA priorities of expanded Other Transaction Authority (OTA) and expanded General and Innovative Procurement and Acquisition authorities. It also builds upon Congress's FY23 Omnibus report language encouraging BARDA to engage in public-private partnerships to support advanced research and development of innovative platform technologies and medical countermeasure programs focused on, but not limited to, vaccines, therapeutics, and other medical countermeasures for emerging infectious diseases, including novel pathogens and viral families with pandemic potential.

The next fast-moving, novel infectious disease pandemic could happen at any time, without prior notice. However, there is no sustained funding, program, or strategy dedicated to accelerating the development of medical countermeasures for previously unidentified infectious disease threats, referred to here as 'Disease X.' Existing programs at HHS are primarily directed towards specific, known, high-priority health security threats (including chemical, biological, radiological, nuclear threats, and pandemic influenza). The accelerated development of new vaccines and treatments for COVID-19 has shown the promise of innovative platform technologies paired with significant, dedicated emergency funding, and a focused public-private partnership. However, the US will need to move even faster to develop and deploy medical countermeasures to save lives and safeguard the economy when the next deadly pathogen emerges.

Not all pathogens can cause a disruptive infectious disease emergency—let alone a pandemic—and viruses, because of their mutability, rapid replication rates, and the relative infeasibility of a broad-spectrum antiviral, are the pathogen class that currently poses the greatest threat to the human species. To increase resiliency against these 'Disease X' threats, the Center for Health Security recommends Congress explicitly require a medical countermeasures strategy and dedicated program at BARDA focused not on individual known viral agents and other pathogens, but specifically on **viral families** from which a threat—known or unknown—is most likely to cause a pandemic or major epidemic. Accordingly, BARDA's statutory authority should be augmented and durably funded in order to undertake these activities proactively, rather than having to wait for specific congressional emergency supplemental funding that often comes late. The Center for Health Security recommends that Congress therefore **add a specific requirement for accelerated advanced development and manufacture of flexible medical countermeasures for viral families with pandemic potential and previously unknown pathogens at BARDA.** This recommendation is in accordance with the White House's proposed \$10.5 billion in mandatory funding for FY24 to ASPR that would support "end-to-end" advanced development and manufacturing scale-up of prototype vaccines and therapeutics against the highest priority viral families. These products, and the strategy needed to rapidly develop them, are vital to our country's public health preparedness and national security.

Next-Generation Reusable Respirators

Work with industry partners to foster further development of improved, next-generation reusable respirators leading to their eventual purchase for the SNS.

The Center for Health Security recommends that Congress require BARDA to work closely with industry partners to encourage and support their development of these next-generation respirators so that new products can successfully come through advanced development and be able to get FDA/NIOSH approval so that they are fit for procurement and stockpiling. BARDA already plays a similar role for medical countermeasures and has operational know-how in this regard. For more information, please see the entry under “Strategic National Stockpile (SNS).”

The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) and related strategy, implementation plan, and budget plan?

‘Disease X’

PHEMCE members should integrate their programs with a ‘Disease X’ approach at BARDA.

For more information, please refer to the [‘Disease X’-related entry under “Biomedical Advanced Research and Development Authority \(BARDA\).”](#)

Emergency Use Authorizations (EUA) and related authorities?

National Diagnostics Action Plan

Refine regulatory requirements for pre-EUA and EUA processes to swiftly bring testing to scale.

As described in our National Diagnostics Action Plan (preprint [here](#)), co-authored with the American Clinical Laboratory Association, the Center for Health Security recommends that the pre-EUA and EUA processes should be refined to ensure swift access to validated testing in future emergencies. Ideally, at the beginning of a potential emergency, when a pathogen of concern is identified, certain test developers already under contract with the federal government could access patient samples and swiftly develop and launch tests for patient care in a pre-EUA environment (ie, prior to an EUA declaration being made).

The Hospital Preparedness Program (HPP) Cooperative Agreements?

Next-Generation Reusable Respirators

Integrate next-generation reusable respirators into the HPP.

The Center for Health Security recommends that Congress require ASPR to incorporate the purchase and stockpiling of next-generation reusable respirators into the HPP guidance for its cooperative agreements to improve the surge capacity of the healthcare system, to respond to large-scale emergencies and disasters, and to make it less susceptible to supply chain shocks. For more information, please see

the recommendations under “[The authorities, duties, and functions of the Assistant Secretary for Preparedness and Response \(ASPR\)](#)” and “[The Strategic National Stockpile \(SNS\)](#).”

Biosurveillance and Public Health Situational Awareness?

National Diagnostics Action Plan

Reduce redundant reporting mechanisms for public health data and minimize burden on reporting entities.

As described in our National Diagnostics Action Plan (preprint [here](#)), co-authored with the American Clinical Laboratory Association, the Center for Health Security recommends that the federal government facilitate the establishment of a uniform, single, national, accurate, actionable public health data reporting policy that standardizes data sets and delivery mechanisms for data. Under such a system, appropriate entities would report public health data to CDC/HHS depending on their access to and control over the requested data. Then CDC/HHS could make the data available to state and local authorities simultaneously, removing the burden on states and localities to establish separate requirements and mechanisms, and relieving the burdens on data providers to comply with the variable and duplicative requirements of today’s patchwork system.

To address these challenges and ensure a clear process is utilized, **the newly added PHSA section 310B should be amended to: (1) require that the public health data collected by CDC/HHS as per the Secretary’s requirement is made available to state and local authorities simultaneously, removing the burden on states and localities to establish separate requirements and mechanisms; (2) ensure that clinical laboratories are not penalized for the inability to report certain information that was not received from the ordering health care provider; and (3) preempt State, local, and Tribal public health agencies from imposing additional or different data reporting requirements than those established by the Secretary.** With these changes, the country would be meaningfully closer to achieving a uniform, standardized data reporting policy.

Gaps in Current Activities & Capabilities

What gaps do you see in the PAHPA framework, or how it has been implemented to date? (These gaps could be related to any of the programs noted above, or other aspects of the public health and medical preparedness and response ecosystem that are otherwise currently unaddressed.)

‘Disease X’

The PAHPA framework does not adequately protect against novel or future threats.

The Center for Health Security recommends that one of the best improvements Congress can make through this PAHPA reauthorization is to protect against novel strains of pathogens for which the US currently lacks strong defenses. For instance, wastewater monitoring capabilities allow us to know when a known pathogen is circulating within a population, but wastewater monitoring against a novel pathogen is still nascent. Programs at BARDA develop diagnostics, therapeutics, and vaccines against various known pathogens, but we don't have a dedicated program to develop such medical countermeasures against a novel pathogen.

Since the costs and skills required to create a novel pathogen and release it are declining, the threat landscape is broader than during previous iterations of PAHPA. The US must protect against not only nation states with the resources required to create a novel pathogen, but also the threats that could be posed by rogue groups or individuals seeking to do harm. The US needs to invest in protecting itself against novel strains of pathogens, whether they arise naturally, via accident, or through deliberate use. For these reasons, this PAHPA reauthorization should not only aim to take all of the lessons from COVID-19 and incorporate them but should also accomplish what health security experts have been recommending for years and better protect Americans against novel and future pathogens. One major improvement Congress could make to address this issue would be to **establish a 'Disease X' Program at BARDA**. For more information, please refer to the 'Disease X'-related entry under "The Biomedical Advanced Research and Development Authority (BARDA)."

Bioattribution

The PAHPA framework currently lacks dedicated attention to bioattribution.

The Center for Health Security recommends that Congress enhance the government's bioattribution capabilities as part of the PAHPA reauthorization. GAO recently conducted a [technological assessment](#) on pandemic origin investigations and identified cross-cutting challenges that hinder pandemic origin investigations, including US coordination and collaboration with domestic and international partners by augmenting or developing a national strategy for pandemic origin investigations. We also participated in a [roundtable event](#) recently hosted by OSTP regarding bioattribution, which largely informs the below recommendations.

Possessing a strong ability to identify the cause of a biological incident and attribute who, if anyone, is responsible serves multiple national security and public health interests of the United States. Such an ability, termed "bioattribution," would serve as a deterrent to intentional misuse of biological agents. For natural events, an understanding of the cause can support efforts and actions to prevent them from occurring again. For deliberate or accidental events, the ability to attribute responsibility for a biological incident (bioattribution) helps to ensure that the deliberate use of biological weapons or lab leaks may be fully prosecuted and those responsible are held accountable. Investigations that serve to determine the origin of

a pandemic are one type of bioattribution effort. Notably, information used to help determine the origin of a pandemic should be collected prior to the outbreak being designated as a pandemic. As such, it is important to establish and maintain the capability to perform bioattribution on a routine basis and not just when an outbreak has reached a global scale. These scientific capabilities need to be strengthened within the federal government. We recommend that Congress strengthen the federal government's bioattribution capabilities through the following actions:

1) Task the Office of Science and Technology Policy (OSTP) with coordinating bioattribution efforts across the federal government.

As it currently stands, it is not clear which offices across the federal government are responsible for different aspects of bioattribution, how much funding is allocated to them for bioattribution purposes, and to what extent they do or are able to coordinate. To rectify this, we recommend that Congress require OSTP to lead coordination of bioattribution efforts across the federal government. Such coordination should include:

- Identification of which specific bioattribution responsibilities, including pandemic origin investigations, reside in each of the lead agency/program offices in the federal government, the nature of routine bioattribution activities within each, and the budgetary support allocated within each. Gaps in funding should be identified.
- Development of assignments, milestones, timelines, and budgets necessary to establish the strongest possible national capacity for bioattribution.
- Interfacing among executive agencies, including, but not limited to, the Department of Health and Human Services (HHS), the Department of State (DoS), the Department of Justice, the Department of Defense, and the Department of Commerce (DoC).
- Coordination with the Intelligence Community.
- Routine exercise of the capabilities of the federal government to perform bioattribution activities.

2) Task OSTP with coordinating the federal government's bioattribution efforts with related efforts in academia, industry, and other entities outside the federal government.

Bioattribution efforts rely on tools developed, data collected, and analysis performed by entities outside of the federal government. During the COVID-19 pandemic, academics contributed significant insights to the discussion on the origin of the pandemic. To ensure a strong USG ability to interface with entities outside the federal government, including academia and industry, and to improve the federal government's bioattribution capabilities, we recommend that Congress:

- Task OSTP with the responsibility of coordinating the federal government’s bioattribution efforts with related efforts in academia, industry, and other entities outside the federal government.
- Task OSTP with undertaking efforts that encourage and enable increased biosurveillance capabilities that provide data accessible to the federal government.
- Allocate funding to HHS to build relationships with external stakeholders and encourage the transition of technology to government, for example through advanced contracting or other means.

3) Establish a working group to develop standards for bioattribution database management and information sharing.

Many existing databases provide value to bioattribution efforts, but their value could be enhanced by standardizing the way in which data and metadata are represented and what data and metadata are included. We recommend Congress task OSTP, with support from HHS and DoC, to maximize the utility of existing databases that are commonly used in bioattribution efforts by developing standards. Congress may consider requiring OSTP to engage with federal policymakers, scientists, database administrators, and other key stakeholders through the creation of a working group. The purpose of the working group could be to support the development of more efficient, standardized approaches to database submission, storage, management, metadata requirements, information sharing, and similar such practices for the purpose of bioattribution (eg, for pathogen characteristics, genetic sequence data, evolutionary data, epidemiologic data, and others). In creating such a working group, Congress may require the working group to engage with developers and owners of critical databases around the world.

4) Authorize and allocate funding for the improvement of current, or the development of new, bioattribution technologies.

Developments in the complementary fields of genomics, proteomics, metabolomics, and data analytics provide opportunities for development of improved bioattribution capabilities that may provide more conclusive answers with less underlying data in a shorter time frame and at lower cost. Additionally, existing capabilities can be matured to higher technology readiness levels to support fielded use. We recommend Congress authorize and allocate funding to HHS, including funding to:

- Develop machine learning and data analytics tools for bioattribution.
- Curate and manage data.
- Operationalize or “field” developed tools and technologies domestically and internationally.
- Develop proteomics methods for bioattribution.
- Jointly, with DoS and DoC, leverage epidemiological data and pathogen characterization data.

- Develop new approaches to data sharing from multiple sources that do not require disclosing proprietary information.

Additionally, aside from currently authorized programs and activities, what gaps exist in HHS' capabilities, and what types of activities or authorities are necessary for HHS to fulfill the intent of PAHPA and related laws?

National Diagnostics Action Plan

Significant gaps exist in coverage of tests for new pathogens of concern.

As described in our National Diagnostics Action Plan (preprint [here](#)), co-authored with the American Clinical Laboratory Association, the Center for Health Security recommends the rapid establishment of medical billing codes, coverage, and national payment rates for new tests to ensure robust provider and patient access to tests across all modalities (laboratory-based and point-of-care, including at-home and over-the-counter tests). While expedited processes for coding are established, the US lacks durable policy to rapidly develop comprehensive coverage and payment to private-sector testing partners. CMS should develop a mechanism to set and communicate broad, national coverage and payment for testing of new pathogens of concern.

Partnerships

What specific steps could Congress take to improve partnerships with states and localities, community-based organizations, and private sector and non-government stakeholders, such as hospitals and health care providers, on preparedness and response activities? For example:

How can these entities 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?

National Diagnostics Action Plan

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 information, please refer to the entry under “[responsibilities and authorities of the Secretary of Health and Human Services \(HHS\) prior to or during a public health emergency \(PHE\)](#).”