

Center for
**Health
Security**

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

March 13, 2023



JOHNS HOPKINS
BLOOMBERG SCHOOL
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Center for Health Security

Introduction

On March 13, 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. House Energy and Commerce Committee members Rep. Richard Hudson (R-NC) and Rep. Anna Eshoo (D-CA) released the RFI in February 2023.

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.

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.

RFI Response

The below comments reflect the RFI response as submitted to Reps. Hudson and Eshoo. RFI headings without comments are not included.

Hospital Preparedness Program (HPP)

Next-Gen Reusable Respirators

Integrate next-generation reusable respirators into the HPP.

We recommend 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 health care 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 “Administration for Strategic Preparedness and Response (ASPR)” and “Strategic National Stockpile (SNS).”

Public Health Situational Awareness and Biosurveillance Network Programs

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, we recommend that the US government (USG) 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 the Centers for Disease Control and Prevention (CDC)/Department of Health and Human Services (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.

The PREVENT Pandemics Act made efforts to improve data sharing between public health agencies and clinical laboratories, but even more can be done to establish a uniform and standardized system. Congress should ensure that burdens on data providers are manageable and streamlined given the critical role that such providers play during a public health emergency. In particular, the PREVENT Pandemics Act added the new PHSA section 310B that requires the Secretary to “provide information on the content, form, and manner” in which public health data related to communicable diseases, including demographic data, should be reported from entities, including clinical laboratories. Congress should add additional clarification to ensure that HHS does not simply announce new data reporting requirements, as it did under section 18115 of the CARES Act, without consideration for other data reporting requirements from state, local, and tribal agencies, and regardless of whether clinical laboratories have access to the requested data. Indeed, when section 18115 of the CARES Act was implemented, HHS mandated that clinical laboratories report certain demographic information with test results, such as patient race, ethnicity, and sex, that clinical laboratories did not always have access to because it was not consistently collected by ordering health care providers. These federal data reporting requirements therefore intensified the burden on laboratories—already working to provide important services during the public health emergency—to satisfy variable data reporting requirements.

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.

Assistant Secretary for Preparedness and Response (ASPR)

Next-Gen 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 stockpile. 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 the 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.

We recommend that Congress ensures planning around personal protective equipment (PPE) stockpiling requirements and approaches include scenarios in which the mortality risk is greater than with COVID-19, since this 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 the COVID-19 pandemic. 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 Food and Drug Administration (FDA) and National Institute for Occupational Safety and Health (NIOSH) 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 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.

Public Health Emergency Medical Countermeasures Enterprises (PHEMCE)

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).”

Strategic National Stockpile (SNS)

Next-Gen Reusable Respirators

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

To build upon Congress’ actions in the [FY23 Omnibus](#) under the heading “Ensuring the Availability of Next Generation Masks and Respirators,” we recommend 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 this 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 with COVID-19. This recommendation is consistent with the [2022 National Biodefense Strategy and Implementation Plan](#).

During the COVID-19 pandemic, healthcare 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, there is reason to believe that a future pandemic or large-scale bioattack could once again overwhelm our ability to protect essential workers.

Widespread use of improved, next-generation reusable respirators would: (1) be more cost effective; (2) better protect healthcare 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 communicate through, manufacturers are not incentivized to invest significant capital in R&D without a demand signal from hospitals or the USG. There are also very substantial regulatory hurdles to getting new medical products approved through the FDA and NIOSH and to market.

We recommend 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 NIOSH/FDA 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. We recommend that Congress directs 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. This recommendation may 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 newly 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 that they would be produced in quantities that would make them available to other essential services, and even the public, in the event of a severe, prolonged pandemic or other public health emergency.

We recommend 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 USG 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, we recommend 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) the maintenance of 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.

As seen during the COVID-19 pandemic, insufficient testing capacity—including limited staffing and on-site availability of supplies—can significantly limit access to diagnostic testing for patients. Therefore, the SNS authorities should be clarified to **expressly authorize HHS to contract with commercial clinical laboratories that have national reach and demonstrated expertise in developing tests, facilitating patient sample collection and transport, maintaining an expert workforce to perform tests, and efficiently delivering results at national scale.** Commercial laboratories could reserve laboratory services to fulfill surge capabilities, from test development support to sample collection and transport, as well as capacity to ramp up and sustain an agreed upon level of weekly testing within ~30 days, with targeted turnaround times to results reporting.

Additionally, the SNS distribution policies should be refined to ensure that critical testing supplies reach clinical laboratories faster. In particular, processes need to be implemented so that supplies from the SNS and vendor-managed inventory (as established under the PREVENT Pandemics Act) can be transferred directly to clinical laboratories in need. In the past, several instances saw supplies transferred to states and localities, which then needed to transfer the supplies to clinical laboratories, creating complexities, delays, and inefficiencies. Instead, **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.**

Medical Countermeasure Budget Plan

Disease X

Include funding for a ‘Disease X’ Medical Countermeasures Program.

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

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' 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 be right around the corner. 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, we recommend Congress explicitly require a medical countermeasures strategy and dedicated program at BARDA focused not on single agents, viral and non-viral, 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. We recommend 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.** These products, and the strategy needed to rapidly develop them, are vital to our country's public health preparedness, our citizens' health, and national security.

Next-Gen Reusable Respirators

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

We recommend that Congress require BARDA 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 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.”

Genomic Engineering Technologies

Mandatory Gene Synthesis Screening

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 all purchasers of gene sequences to order only from providers and manufacturers who perform such screening.

We recommend 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 regards 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 (DOC) in crafting such a regulatory regime. We understand **that there is a mandatory gene synthesis screening bill circulating among congressional staffers and 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 about to the Office of Science and Technology Policy \(OSTP\) and National Security Council \(NSC\)](#) last year.

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 (ie, scientists and research labs), including customers 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 in order 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. Unfortunately, screening of both gene synthesis orders and customers remains only voluntary and does not prevent dangerous synthesized DNA from getting into the hands of bad actors, who could potentially use such DNA to create a novel, synthesized virus capable of being both highly deadly and highly 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. 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 prevent the ease with which potential bad actors can currently get their hands on synthesized DNA that could result in global catastrophe.

Accordingly, we recommend 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 clarity that they are authorized to make such rulemaking and clarify that they may also harmonize their existing guidelines with a new rulemaking requiring mandatory gene synthesis screening. However, in the absence of such authority, Congress should grant such authority to ASPR and require that they take action.

Medical Countermeasure Innovation Partner (MCIP) Program

Disease X

[Establish a 'Disease X' Medical Countermeasures Program.](#)

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

Other Policy Suggestions

The following information was submitted under the RFI section stating, “If you have a policy suggestion that does not fit within one of the currently authorized programs or initiatives, please provide information about that request. If you are seeking statutory changes to a public health preparedness program that has been appropriated, but not authorized, please make that distinction.”

Bioattribution

We recommend Congress enhance the government’s bioattribution capabilities as part of PAHPA reauthorization. GAO recently conducted a [technological assessment](#) on pandemic origin investigations and identified policy options to address cross-cutting challenges that hinder pandemic origin investigations, including improving US coordination and collaboration with domestic and international partners and 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’s 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:

1. 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.

2. The development of assignments, milestones, timelines, and budgets necessary to establish the strongest possible national capacity for bioattribution.
3. 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).
4. Coordination with the Intelligence Community.
5. 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:

1. 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.
2. Task OSTP with undertaking efforts that encourage and enable increased biosurveillance capabilities that provide data accessible to the federal government.
3. 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.

Top 3 Priorities

The following information was submitted under the RFI section stating, “Finally, please submit your top three priorities for the 2023 PAHPA reauthorization in order of preference.”

1. **Disease X:** Congress should require BARDA to establish a ‘Disease X’ Medical Countermeasures Program.
2. **Next-gen 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. **Mandatory gene synthesis screening:** 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 all purchasers of gene sequences to order only from providers and manufacturers who perform such screening.

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