Testimony of

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"Legislative Solutions to Bolster Preparedness and Response for All Hazards and Public Health Security Threats."

Summary of Testimony

Since the passage of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Project BioShield Act in 2004 and the Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006, our national preparedness and response capabilities against chemical, biological, radiological, and nuclear (CBRN), pandemic influenza, antimicrobial, and emerging infectious disease threats have been enhanced by the federal programs authorized and funded under this legislation.

As there are limited markets for CBRN medical countermeasures (MCMs), pandemic influenza products, and emerging infectious disease (EID) products, the federal government plays an important role to partner with industry on the research, development, and procurement of these products. The PAHPA legislation is an important signal to industry of the government's commitment to this space.
In the 2023 PAHPA reauthorization, BIO urges Congress to:

- Reauthorize an advanced appropriation for the Project BioShield Special Reserve Fund (SRF) at $1 billion annually to ensure that there is sufficient funding to cover the priorities outlined in the FY16-20 PHEMCE Multiyear Budget.
- Reauthorize funding for Advanced Research and Development (ARD) at BARDA at $1.6 billion, a level sufficient to cover the specific areas of MCM development under BARDA authority according to the PHEMCE Multiyear Budget.
- Authorize Pandemic Influenza product development and sustainment at levels sufficient to meet ASPR's projections in the PHEMCE Multiyear Budget, a minimum of $330 million annually.
- Authorize the Strategic National Stockpile (SNS) at an annual level of at least $1.8 billion to allow the ASPR to manage the full life cycle of all MCMs developed under BARDA. Congress should ensure funding and accountability within HHS for the procurement of FDA-approved or licensed MCMs developed by BARDA.
- Improve transparency and oversight of the Strategic National Stockpile (SNS) by sharing MCM requirements based on threat assessments with Congress and private sector partners on a regular basis. Additional oversight from Congress is needed to determine if requirements are being met.
- Eliminate the sunset of the MCM Priority Review Voucher (PRV) program.
- Establish a budget line within BARDA for the development of capabilities and medical countermeasures for Emerging Infectious Diseases authorized at $775 million and clarify BARDA authorities to enable a pathogen-agnostic Viral Family approach to research, development, manufacturing, and procurement.
- Establish a sustainable pull incentive program to spur the development of products to combat antimicrobial resistance through passage of the PASTEUR Act.
- Empower ASPR with authorities needed for robust preparedness and response that include expanded "Other Transaction" authority, expanded domestic manufacturing investment authority, authority for rapid procurement and acquisition, and direct hire.

- Authorize funding for increased surveillance capabilities at the Centers for Disease Control and Prevention (CDC) to better detect, monitor and respond to outbreaks and emerging pathogens of pandemic potential.
- Authorize funding for expanding and strengthening state immunization infrastructure, especially as it affects American adults, through increased partnerships with the CDC.

In reauthorizing PAHPA, Congress must continue to send a strong signal that it is committed to prioritizing national health security and health defense by providing the resources and authorities needed to fully prepare for and defend against biological threats. Investments in preparedness and medical countermeasure development will enhance our response efforts, save lives, and be more cost-effective in a biological emergency.

I – Introduction

Subcommittee Chairman Guthrie, Ranking Member Eshoo, and members of the Energy and Commerce Health Subcommittee, I want to thank you for inviting me to offer testimony today. My name is Phyllis Arthur and I am the Senior Vice President for Infectious Diseases and Emerging Science Policy at the Biotechnology Innovation Organization, or BIO. BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations across the United States and in more than 30 other nations. Our mission is to advance biotechnology innovation by promoting sound public policy and fostering collaboration, both locally and globally. Our members range from entrepreneurial companies developing their first product to Fortune 500 multinational companies.

BIO and our members appreciate that the Committee is committed to a bipartisan reauthorization of the Pandemic All-Hazards Preparedness Act, or PAHPA, legislation that is critical to our national health security. As companies investing in novel therapeutics, vaccines, diagnostics, and platform technologies to help save lives from all types of threats, our members are committed to continuing to strengthen the public-private partnerships enabling this critical research, development, and production, and we welcome the opportunity to provide comments on how to bolster our readiness and response capabilities.

This is an important moment for our nation as we emerge from a, hopefully, once in a generation pandemic allowing us to take stock of lessons learned. The important question to ask is, are we more prepared today than we were in 2019? Unfortunately, it is not evident that we are. While our response to the COVID-19 pandemic was incredible in scale, and successful in its aims to rapidly and, in record time, safely develop vaccines and therapeutics to a novel pathogen, there is no guarantee that we could replicate that success again without making permanent the pieces of the response that facilitated that success.

Following the terror attacks of September 11th, the United States government acted swiftly to change the world. It built new structures, new organizations, new facets of American life, and new funding streams to invest in new ways to keep us safe. Similarly following the anthrax attacks of 2001, Congress acted to create Project BioShield and later BARDA. For the medical countermeasure space, these represented the important structural and financial change needed to prepare and respond to an ever-present threat of a natural, accidental, or deliberate biothreat.

Since that time, the world has remained a scary place. In the last year alone, the US continued its COVID-19 response, responded to an MPox outbreak, supported European allies request for Chemical, Biological, Radiological, and Nuclear (CBRN) medical countermeasures in response to the Russian invasion of Ukraine, and has supported an international response to outbreaks of Ebola and Marburg. Over the past decade, we faced numerous other biothreat events and near-miss pandemics from SARS to Zika. The response to these programs was led by industry innovation and supported by public-private partnerships.

During the height of the COVID-19 pandemic the United States had death tolls from the virus that equated to a September 11th sized attack, every day, for months. Despite this staggering loss of life, fundamentally nothing has changed. Our nation's health defense programs, BARDA and the Strategic National Stockpile, are still underfunded, and our surveillance tools are still underdeveloped. Now is the time to act and make an impactful and lasting change.

In order to respond to the next inevitable threat, we must make substantive improvements to our Public Health Medical Countermeasure Enterprise (PHEMCE). In my testimony today I will advocate for robust funding for the PHECME, whose chronic underfunding fails to live up to its promise and mission to keep us safe. I also ask that authorities be established now so that the nation is ready to respond at any moment, and that structures like Operation Warp Speed (OWS) do not need to be rebuilt from scratch in an emergency. Lastly, I will share my thoughts on some new programs that can improve our national health defense and fill some crucial gaps in our preparedness.

II - Funding a Robust Medical Countermeasure Industry

A robustly funded biodefense budget is the nation's best protection against future threats, naturally occurring or deliberate. Public-private partnerships deliver lifesaving products to the American people, and for those partnerships to be successful, the government must provide sustainable long-term funding and treat their industry counterparts as partners and not just vendors. Investments made today have the capability to save time, money, and lives during the inevitable next health crisis.

BIO recommends the following funding authorizations for the key programs of the PHEMCE:

Authorize the SNS at an annual level of at least $1.8 billion. This level of funding will allow the ASPR to manage the full life cycle of all MCMs (medical countermeasures) developed under BARDA. Industry partners have invested in these technologies in part due to the guarantee that there is a sustained government market. For many MCMs, the SNS is the only market and therefore must be well funded for investment in the development of these critical products to continue. For nearly 10 years, funding of the SNS has been largely flat while new FDA approved MCMs have been added to the Stockpile. Because of this deficit in funding, many products have not been replenished as they should have been. This is particularly true for MCMs against biological threats like smallpox and anthrax. Areas of investment needed to prepare for a potential future surge in demand include capital equipment/infrastructure; raw materials; human resources; and investments in industry partnerships. One important lesson from the MPox response has been the importance of maintaining and replenishing the SNS. The SNS allowed much of its smallpox vaccine stockpile to expire without any plan to replenish. This made the response to the global MPox outbreak more complicated given the smallpox vaccines and therapeutics are vital for both a deliberate smallpox attack *and* a natural outbreak of an Orthopox virus. The threat to the nation's health security was real and we were not prepared despite

decades of planning. The SNS has been chronically underfunded, and to be prepared for all potential threats, the U.S. needs the SNS to have the capabilities for which it was designed. This means it needs to be able to stockpile new countermeasures, maintain the products already in the stockpile, and replenish expiring products in an efficient manner.

More responsibilities within the SNS will result in higher operating costs but the replenishment of MCMs must remain a top priority for these funds to manage all aspects of lifecycle management and stockpile operations.

Authorize funding for Advanced Research and Development (ARD) at BARDA at $1.6 billion, a level sufficient to cover the specific areas of MCM development according to the PHEMCE Multiyear Budget. BARDA funding is essential to our nation's ability to prepare for, respond to, and recover from public health emergencies, both naturally occurring and deliberate. The BARDA pipeline currently includes over 200 candidate MCMs such as broad-spectrum antimicrobials, rapid diagnostics, and next-generation products to address chemical, biological, radiological and nuclear (CBRN) threats and emerging infectious diseases (EID). Increased funding for BARDA activities is needed to advance MCMs currently in the BARDA pipeline, provide funding for additional MCMs reaching the critical later stages of clinical development, invest in novel manufacturing capabilities, and support products to address antimicrobial-resistant threats through the Broad-Spectrum Antimicrobials (BSA) and CARB-X programs. The ability to respond to the next pandemic relies on a well-funded BARDA.

Reauthorize appropriations for the Project BioShield Special Reserve Fund (SRF) at $1 billion annually to ensure that there is sufficient funding to cover the priorities outlined in the PHEMCE Multiyear Budget. When Project BioShield was enacted in 2004, Congress provided a 10-year advanced appropriation of $5.6 billion to create a guaranteed market for the procurement of MCMs for DHS-identified national security threats, before they are approved by FDA. The SRF was needed to encourage private sector investment in MCM research and development where no commercial market exists. For example, the U.S. government is the only significant purchaser of vaccines and treatments to protect Americans against anthrax or smallpox. This advanced appropriation expired in 2013. The 2013 and 2018 PAHPA reauthorizations did not create an advanced appropriation, but rather extended the authorization of funding over a five-year period. Since then, Appropriators have continued to fund the SRF on an annual basis. The reauthorization of PAHPA is an opportunity to reauthorize and increase the funding authorization and reconsider the original advanced appropriation construct.

Authorize Pandemic Influenza product development and sustainment at levels sufficient to meet ASPR's projections in the PHEMCE Multiyear Budget, a minimum of $330 million annually.
The development and manufacturing of pandemic influenza vaccines, therapeutics, and diagnostics by industry is dependent on Federal funding to support the scale and scope of USG requirements. There is no commercial market for products like H5N1 or H7N9 vaccines. Continued investment is necessary to maintain a robust R&D pipeline and sustain the capabilities the U.S. has developed. The September 2019 "Executive Order on Modernizing Influenza Vaccines in the United States to Promote National Security and Public Health" acknowledges that the current domestic enterprise for manufacturing influenza vaccines has critical shortcomings. Increased funding for BARDA's pandemic influenza activities will support work on the development of more effective, longer lasting vaccines, as well as novel antivirals and therapeutics and rapid diagnostics. These additional funds are critical to meeting the needs and

objectives expressed in the EO with respect to preventing the spread of influenza viruses and protecting the United States from future pandemics.

Prioritize sustained investments in advanced research and development in Emerging Infectious Diseases (EID), viral families, and multiple types of platform technologies, specifically through a direct funding line for EID of a $775M, to ensure that there are sustained investments made for advanced research and development in the EID space to achieve the 100 Day Mission. Inevitably there will be another emerging infectious disease requiring a robust national response. Support for capacity and capability building for MCMs is critical to protecting our national health security from EID threats. Investments must be made now to ensure quick resolution of an outbreak when any EID arises. Funding during a crisis is often too late, as development of drugs, vaccines, diagnostics, and platform technologies takes time. The COVID-19 pandemic demonstrated that upfront investments in MCMs and rapid response capabilities save lives, resources and our economy.

BARDA's current funding constraints, BARDA has had to choose priorities within its limited budget. This means that investments in MCMs for viral families with pandemic potential, emerging infectious diseases, and platform technologies have historically gone unfunded. For the U.S. to be better prepared, BARDA will need to direct investments in numerous platforms (such as mRNA, protein subunit, DNA vaccines and medicines, monoclonal antibodies) so that the U.S. has the most "shots on goal" to be able to respond quickly and effectively to any potential threat. BARDA should, in collaboration with the National Institutes of Health (NIH) and the Department of Defense (DoD), create a prioritized list of emerging infectious diseases and viral families with outbreak potential, including vector-borne diseases. This list should be incorporated into the MCM advanced research and development and procurement programs at HHS and DoD to ensure the U.S. can more rapidly respond.

Clarify BARDA's authority to enable research, development, and procurement of versatile products that target viral families to help ensure that the pipeline remains robust and that products are available when an unknown threat emerges.

This PAHPA reauthorization is an opportunity for Congress to create a procurement mechanism and stockpile model for emerging infectious disease MCMs which may also be able to be rotated to support international responses to infectious disease outbreaks overseas.

III - Authorities to Facilitate Medical Countermeasure Development and Deployment

The success of Operation Warp Speed (OWS) was due in large part to the expanded authorities the program received from the Department of Defense, FEMA, and the Public Health Emergency (PHE). To replicate that success in the future, we should not rebuild OWS from scratch. The Assistant Secretary for Preparedness and Response (ASPR) is the leader of the PHEMCE and should have all the authorities it needs to be able to fully prepare for, and ramp up a response to, any next crisis.

The following are BIO's recommendations for strengthening the ASPR and PHEMCE so that preparedness and response capabilities are available during peace time and in emergency situations:

Empower ASPR with direct hire, asset acquisition and contracting authority similar to that of DoD. Ensuring that ASPR has the tools, authorities, and personnel it needs to be able to contract effectively with industry will better allow ASPR to improve its preparedness and response activities. Many of the

types of contracts used by ASPR during the PHE are not available to HHS outside of a PHE. Granting these authorities will make sure that, in pursuing the preparedness goals of ASPR, the government is able to leverage the necessary public-private partnerships in advance of and during an emergency. Similarly, having a fully staffed ASPR will eliminate administrative delays in contracting and resource allocation.

Increase Congressional oversight and transparency to industry stakeholders on funding, requirements, and replenishment activities.
While current statute requires ASPR to deliver an annual threat-based review of the contents of the SNS, this review does not provide transparency into the requirement-setting process necessary for congressional oversight or private sector planning. Requirements include the type of product (Target Product Profile) as well as the number of doses and delivery format needed. Better insight into these requirements would improve the forward-planning required for the SNS to meet its targets while allowing industry to better plan their development and manufacturing of key MCMs. Specifically, BIO recommends that the Committee include new statutory language in PAHPA mandating that the PHEMCE engage in a formal requirement-setting process for all material threat determinations that 1) is based on the most up-to-date assessment of risks to the U.S. public and to national security and 2) is not influenced by budgetary decisions.

ASPR requirements need to be updated on a scheduled basis (i.e., every three years, or within six months if informed by USG intelligence sources of a material change to the threat landscape), and they should be shared with the Committees of jurisdiction and shared with private sector partners in a manner that does not compromise national security.

Authorize new statutory language in PAHPA that would require ASPR to conduct an annual meeting with each private sector partner with an existing countermeasure contract to discuss additions, modifications, and replenishments in all countermeasures, consistent with the requirements above.

Extend the ASPR authorization to provide State grants to support state strategic stockpiles for 5 years.
Section 2409 of the PREVENT Pandemics Act authorized a pilot program to support state medical stockpiles (Section 319F-2(i) of the Public Health Service Act). State and local health departments are the front line of defense against infectious disease threats and must be equipped to quickly respond on the ground. Empowering states to hold their own stockpiles will improve their ability to protect their populations. States may have specific needs (mosquito-borne diseases such as dengue and chikungunya and natural disaster preparedness) outside the federal SNS that can be better managed through their own stockpiles. The authorization for the program only covers FY23 and FY24; however, the legislation did not pass in time for funding to be allocated in FY23.

Expand BARDA's funding authorization and authorities to allow for procurement and use of Other Transaction Authorities for construction in their Industrial Base Expansion programs.
To achieve the lofty goals of the USG and the G7 nations to manufacture vaccines for the US population in 100 days, investments must be made today in industrial base expansion and supply chain security. To do so, BARDA needs the resources to make those investments coupled with expanded Other Transaction Authorities (OTAs) and procurement authorities to facilitate those manufacturing investments.

Establish an HHS program that facilitates public access to products authorized for emergency use.
One problem faced during the height of the COVID-19 pandemic was a lack of patient access to EUA-authorized and government-procured treatments. At least two monoclonal antibody treatments were

authorized before vaccines were widely available while several treatment options were available during the worst stages of the pandemic yet securing access was a challenge for many U.S. patients. While government communications reasonably focused on vaccinations, the public was not adequately aware of treatment options. Those who were aware had difficulty accessing the medicines because it was not clear where and how to access the therapies. This appeared to contribute to many people assuming there were no options and likely factored into a persistently high case fatality rate even after treatments were available**. Accordingly, a group or program should be established within HHS to facilitate public access to EUA-authorized treatments during public health emergencies, including through proactive public communication about what they should do in an emergency.**

Amend the PREP Act declaration language to ensure that countermeasures developed during an emergency retain their PREP Act protection after they are transitioned to commercial channels.
The PREP Act provides immunity from liability (except for willful misconduct) for claims of injury or loss resulting from the use of medical countermeasures. However, based on how HHS's PREP Act declaration for COVID-19 is currently written, the upcoming expiration of other federal emergency declarations in May 2023 could result in the expiration of PREP Act protections for commercially distributed products. For COVID-19 and future public health emergencies, **HHS should draft/amend PREP Act declarations to ensure that countermeasures that remain necessary in the long run will maintain their PREP Act protection for as long as the PREP Act declaration is in place even after they are transitioned to commercial channels.** Without this change, eventual transition to commercial distribution could serve as a disincentive for the development of important vaccines and therapeutics for public health emergencies.

IV - Other Programs to Sustain Medical Countermeasure Innovation

Lastly, BIO would like to share our recommendations related to other programs that can help strengthen the medical countermeasure marketplace:

Renew the MCM PRV program and eliminate the sunset.
BIO asks Congress to renew the MCM PRV program and eliminate the sunset. The program creates a powerful pull incentive for industry to develop products on the material threat list. These products have limited or no commercial market, and this incentive is key to the development of these products. Additionally, the program supports the medical countermeasure needs of the Department of Defense to protect the warfighter. BIO has long supported the MCM PRV program, and throughout the life of the program it has been a success, leading to the issuance of 7 vouchers. The low number of vouchers has helped maintain the value and importance of this incentive. The program has zero cost for the Government according to past CBO reports but for the recipient or user of a can be used to cut down time to market, particularly for those second to market, thus increasing competition and decreasing prices. Reauthorizing and eliminating the MCM PRV program sunset is crucial to preserving that incentive for research and development. Should there be any changes to the program, the scope must remain narrow to preserve the value of the vouchers and to maintain the power of the incentive that it creates.

Include the PASTEUR Act in the reauthorization of the Pandemic and All-Hazards Preparedness Act
The growing crisis of antimicrobial resistance (AMR) undermines U.S. public health preparedness and significantly hampers our nation's ability to respond to a wide range of threats, including pandemics,

outbreaks, natural disasters, and bioterror attacks. PASTEUR would increase our nation's resilience by strengthening the antibacterial and antifungal pipeline to ensure clinicians and other medical professionals have the innovative products they need to treat patients, and ensuring antimicrobials are used appropriately. Every day we wait to address the crisis in the antimicrobial ecosystem is another year patients and providers must wait to have access to life-saving medicines.

In 2019, an estimated 1.27 million deaths worldwide were directly caused by AMR, and AMR played a part in nearly 5 million deaths. This makes AMR a leading cause of death globally.[1] The AMR crisis was further exacerbated by the COVID-19 pandemic. In 2020, U.S. hospitals experienced a 15% increase in AMR infections and deaths, though pandemic-related data gaps suggest that the total national burden of AMR may be much higher. Experts do not expect a return to pre-pandemic levels without concerted action.[2] Any emergency resulting in high levels of hospitalization, particularly high levels of ventilator use, creates a ripe opportunity for the spread of secondary drug resistant infections.

Addressing AMR is important for bioterror preparedness as well, as agents used by bioterrorists may be genetically engineered to resist current therapeutic antimicrobials.[3] World Health Organization (WHO) has estimated that if 50 kg of *Y. pestis* were to be released as an aerosol over a city with a population of 5 million, 150,000 people might fall ill with pneumonic plague, 36,000 of whom would die.[4] Drug resistant strains of *Y. pestis* have been reported, which can increase mortality.[5] As another example, modeling suggests that deliberate release of aerosolized *F. tularensis* over London would result in an estimated 130,000 infections and 24,000 deaths.[6] Natural resistance is already observed in tularemia, and the overuse of fluoroquinolones in the last two decades has led to treatment failure and relapses in tularemia patients.[7]

Hurricanes and other natural disasters can also increase the spread of infections, including drug resistant infections. Loss of electricity increases the risk of food spoilage and foodborne illness. Interrupted access to safe water supplies can lead individuals to turn to rivers or other ad hoc water sources. This approach, along with the presence of floodwaters, can increase the risk of illness caused by waterborne pathogens. Studies have found higher levels of pathogenic bacteria and antibiotic resistance genes in floodwaters and soil in the Houston, TX area following Hurricane Harvey.[8][9] Conditions in crowded shelters and severely damaged homes can significantly increase the spread of infection as well. All these infections can trigger sepsis among victims and emergency workers.[10] Additionally, during natural disasters, those who are immunocompromised may not only lose access to crucial systems such as infusion or dialysis centers due to the loss of power but are also even more prone to these infections.

Despite the urgent and increasing need for novel antimicrobials to treat superbugs, the antimicrobial ecosystem is broken and unable to meet patient needs. The current pipeline has fewer than 50

[1] https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02724-0/fulltext
[2] https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf
[3] https://books.google.com/books?hl=en&lr=&id=IiGEDwAAQBAJ&oi=fnd&pg=PR1&ots=ZXqKRYXnRH&sig=39-Vf6uaisjn-zSVfBI-1p_9TT4#v=onepage&q&f=false
[4] https://apps.who.int/iris/bitstream/handle/10665/39444/24039.pdf
[5] https://journals.asm.org/doi/full/10.1128/AAC.00306-06
[6] https://www.liebertpub.com/doi/abs/10.1089/bsp.2011.0004
[7] https://ami-journals.onlinelibrary.wiley.com/doi/full/10.1111/j.1751-7915.2008.00063.x
[8] https://pubs.acs.org/doi/10.1021/acs.estlett.8b00329
[9] https://pubmed.ncbi.nlm.nih.gov/33077230/
[10] https://www.sepsis.org/sepsisand/natural-disasters/

antibacterial therapeutics in clinical development worldwide – only a handful of which are for the most threatening gram-negative pathogens – a critical area of need.[11] We know that the pipeline is already inadequate to address current resistant threats, let alone those that will come in the future.

Novel antimicrobials must be used appropriately to limit the development of resistance, so payment based on volume fails to drive innovation. PASTEUR's subscription model is an innovative way to pay for novel antimicrobials that will revitalize the pipeline and support appropriate use. Under PASTEUR, the federal government can enter into contracts with innovators to pay for a reliable supply of novel antimicrobials with payments that are decoupled from the volume of antimicrobials used. Importantly, the federal government only pays once – the subscription payment is all-inclusive, and PASTEUR only pays for success. Furthermore, PASTEUR is designed to pay for FDA approved treatments that are available to patients and meet unmet AMR needs– those that experts agree will most likely have a big impact for patients and public health.

The delinked approach is similar to Project Bioshield, which provides multi-year funding to support procurement of medical countermeasures (MCM) for national security. Antimicrobials, like MCM, have a very limited commercial market. PASTEUR will provide novel antimicrobial innovators with a more predictable return on investment necessary to revitalize the antimicrobial pipeline—just like Project Bioshield has done for MCMs.

PASTEUR would also provide new funding for health facilities including rural, critical access and safety net hospitals to support antimicrobial stewardship, to ensure that antimicrobials are used appropriately to limit the development of resistance, and to ensure that the vulnerable patients served by these hospitals can have access to the benefits of antimicrobial stewardship. Stewardship teams also typically play critical roles in preparedness and response, including managing administration of novel therapeutics during emergencies and managing antimicrobial drug shortages.

PASTEUR has the broad support of over 230 stakeholder organizations representing health care providers, public health professionals, scientists, patients, and the pharmaceutical and diagnostics industries (https://www.fightinfectiousdisease.org/_files/ugd/b11210_4c0cfcf82850470794f2b9db8bc137c5.pdf?index=true). Additionally, in his September 2022 remarks to the World AMR Congress, Secretary Becerra reiterated the Administration's commitment to this issue, as evidenced by the inclusion of a proposal that aligns with PASTEUR in the President's budget request for 2024. At the end of 2022, PASTEUR also had over 60 bipartisan cosponsors. Delays in the passage of PASTEUR are delays in the development of novel antimicrobials to treat highly resistant, life-threatening infections—delays that erode our preparedness and that many patients, including those particularly susceptible to infections, such as patients with cystic fibrosis, cancer, or organ transplants, cannot afford. We urge you to include PASTEUR in the PAHPA reauthorization.

Bolster CDC surveillance, routine vaccination and data utilization

As the frontline of public health in the United States, the CDC plays a critical role in pandemic preparedness. As we saw with recent outbreaks and pandemics, our everyday public health systems

[11] https://www.who.int/publications/i/item/9789240047655

served as a base for pandemic infrastructure. A well-functioning routine public health system – immunization infrastructure, workforce, and disease surveillance - is pandemic preparedness.

- **Surveillance:** As our nation's public health agency, CDC is the lead for viral surveillance and testing. CDC's efforts help to provide early warnings of emerging infectious diseases and emergent variant strains of infectious diseases. More funding is needed to support and expand CDC's viral testing and surveillance capabilities so that we continue to have an accurate picture of disease epidemiology and circulating viral strains to properly direct public health response. This is pivotal to track the evolution of SARS-CoV-2 but also emerging infections, both viral and bacterial.
- **Immunization Program (Section 317):** Vaccinations are one of the most cost-effective public health approaches to reducing healthcare costs because they prevent disease before it occurs and spreads through our communities. CDC Immunization Program funds are used to not only purchase vaccines for those in need but also to provide critical support for the people and systems that make immunization programs work, including surveillance of vaccine-preventable diseases, outbreak response, immunization information systems (IIS), and vaccine safety monitoring. In recent years, the CDC Immunization Program has become reliant upon transfers from the Prevention and Public Health Fund. Given the importance of the program, dedicated funding for the Immunization Program is needed to provide CDC and state and local health departments that rely on CDC funding more certainty around the sustainability of the Program.
- **Immunization Information Systems:** Immunization information systems (IIS) are computerized, multi-faceted systems that operate in 62 jurisdictions, and have the ability to maintain immunization records across the lifespan. They can be used by providers to order vaccines and maintain an accounting of inventory, project what a patient needs based on what they have received previously (preventing both over- and under- vaccination), remind patients when they are due to receive a recommended vaccine, and, at a population level, track coverage and identify areas where there are low immunization rates so public health programs can develop targeted immunization efforts in response. These systems are managed at the state level, creating a patchwork of these systems' functionality across the country. Having immunization data systems that can efficiently and effectively manage vaccine ordering, inventory, and patient records, and securely exchange information across providers, health systems, and public health agencies in real-time will be essential to COVID-19 vaccine efforts, as well as routine vaccination efforts.

Support industrial base expansion and supply chain security.

BIO supports investments made to ensure a secure and stable medical supply chain as well as efforts to onshore and near-shore the production of medical countermeasures. Investment in the supply chain is critical to both ensure surge for MCM production and continuity of manufacturing of other biotechnology products during a public health emergency. Any program developed to create surge capacity needs to be based on a model of long-term sustainability. "Warm-basing," a manufacturing consortium, or an arrangement paying for excess capacity need to have clear and long-term financing along with transparent and robust IP protections. PAHPA reauthorization is an opportunity to make these investments.

V – Conclusion

Thank you for this opportunity to testify and allowing me to share the positions of the biotechnology industry. Making these investments and authoritative improvements will facilitate robust preparedness and rapid response. Health security is national security, and Congress must act now to ensure that our nation is able to respond to any threat, and partner with industry to do so. BIO and our member companies are committed to working with the Energy and Commerce Committee as it works to reauthorize PAHPA and would be happy to serve as a resource.