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July 10, 2023

Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building,
Washington, DC, 20510

Re: BIO Comments on the Reauthorization of PAHPA

Dear Chairman Sanders and Ranking Member Cassidy,

I write to you today on behalf of the Biotech Innovation Organization (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.

Thank you for the opportunity to submit comments on this draft of the 2023 Reauthorization of the Pandemic and All-Hazards Preparedness Act, or PAHPA. This historically bipartisan legislation 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.

Since the last PAHPA reauthorization in 2019 we have endured and emerged from a global COVID-19 pandemic, responded to outbreaks of Mpox, Marburg and Ebola, and are aiding our European allies with Chemical, Biological Radiological, and Nuclear (CBRN) countermeasures in response to the ongoing Russia-Ukraine war. To respond to these threats, and the inevitable next threat on the horizon, we must make substantive improvements to our Public Health Medical Countermeasure Enterprise (PHEMCE). Those improvements include robust funding for the PHEMCE (whose chronic underfunding fails to live up to its promise and mission to keep us safe), strong incentives to drive innovation in the medical countermeasure space and strengthening authorities today so structures like Operation Warp Speed (OWS) do not need to be rebuilt from scratch in an emergency and we will be prepared to respond to all hazards.

While BIO supports the reauthorization of expiring provisions and the addition of certain new polices in the discussion draft, it should be clear that we strongly oppose some of the draft's provisions because of the detrimental impact they would have on our nation's mission critical public-private partnerships to bring forward the medical countermeasures necessary to protect the American people**. If these "reasonable pricing" policies remain, BIO will strongly oppose its passage.**

TITLE I—STATE AND LOCAL READINESS AND RESPONSE

Sec. 101. Public Health Emergency Preparedness program.

- BIO supports this section.

Sec. 102. Improving and enhancing participation of EMS organizations in the Hospital Preparedness Program.

- BIO supports this section.

Sec. 103. Improving medical readiness and response capabilities.

- BIO supports this section.

Sec. 104. Pilot program to support State medical stockpiles.

- BIO supports this section.
- BIO requests that the committee use the original funding line in the bill rather than the "such sums" option on page 11 line 1.

Sec. 105. Enhancing domestic wastewater surveillance for pathogen detection.

- BIO supports this section.

Sec. 106. Reauthorization of Mosquito Abatement for Safety and Health program.

TITLE II—FEDERAL PLANNING AND COORDINATION

Sec. 201. All-Hazards Emergency Preparedness and Response.

- BIO supports this section. BIO recommends striking the word "advanced" on page 18 line 6 and amending the line to read "the research and development," to make sure that the provision is broad enough to include BARDA's work on all stages of development across its many programs.
- BIO recommends that the report described on page 21 be shared with industry stakeholders in attrition to the HELP committee. Additionally, the date for the report on page 21 line 2 is listed as March 15, 2020, since this date has passed, BIO recommends the committee use a date in the future, such as March 15, 2024.

Sec. 202. Strategic National Stockpile and material threats.

- BIO supports this section.

Sec. 203. Medical countermeasures for viral threats with pandemic potential.

- BIO supports this section with the following changes: Strike "(I) rapid diagnostics," and strike "(II) broad spectrum antimicrobials" as these product types already have dedicated programs within the BARDA Advanced Research and Development (ARD) portfolio, such as CARB-X and the Broad-Spectrum Antimicrobials (BSA) Program.
- BIO also recommends including an authorization of appropriations of $775 million, in line with the professional judgment.

Sec. 204. Public Health Emergency Medical Countermeasures Enterprise.

- BIO supports this section.

Sec. 205. Pilot program for public health data availability.

- BIO supports this section. BIO supports the inclusion of the bracketed [shall] on page 27.

TITLE III—ADDRESSING THE NEEDS OF ALL INDIVIDUALS

Sec. 301. Transition of certain countermeasures between compensation programs.

- BIO supports this section and suggests the following revisions:

- BIO asks that the committee remove the language under CICP on page 35, lines 23-25 and page 36, lines 1-5, "(B) Exclusion of Injuries Caused by Vaccines on the Vaccine Injury Table" because it could result in unintended consequences in the future should a

previously approved vaccine be used off-label during a pandemic where such use would actually fall under the Public Readiness and Emergency Preparedness (PREP) Act.

- BIO asks that the committee strike "under paragraphs (2) and (3) of section 2111 (c)." on page 37 lines 8 and 9. The supporting documentation described in Section 2111(c)(1) is an important part of having a complete petition, and Section 2111(c)(3) mitigates the potential concerns about the breadth of records required under (c)(1). Section (c)(3) allows a petitioner to identify "any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability." Requiring a petitioner to either provide the records called for under both paragraphs (1) or (2) or explain why the records are not available as permitted by paragraph (3), would not impose an unreasonable burden on petitioners and would help ensure that VICP works as intended.

- BIO supports the bracketed language on page 37 starting on line 22. BIO asks that the committee clarify if Covid vaccines under EUA will also move to VICP along with other licensed vaccines? BIO encourages the Committee to ensure that the language is clear that when the first vaccine in a class has FDA approval that meets the statutory criteria for VICP all of the vaccines in that class will transition to VICP regardless of their FDA status.

Sec. 302. Accelerating injury compensation program administration and ensuring program integrity.

- BIO supports this section.

Sec. 303. Review of regulations.

- BIO supports this section.

Sec. 304. Supporting individuals with disabilities during emergency responses.

- BIO supports this section.

Sec. 305. National advisory committees.

- BIO supports this section.

Sec. 306. Research and coordination of activities concerning the long-term health effects of SARS–CoV–2 infection.

- BIO supports this section, and suggests striking "continue to," on page 52 line 6, and the to insert, "research, development, testing and evaluation of therapies and diagnostics," on page 52 line 8 following "translation research" and adding a "," before inserting. This would strengthen the effort to be more wholistic and go beyond the existing program at the NIH.

TITLE IV—STRENGTHENING BIOSECURITY

Sec. 401. Treatment of genetic variants and synthetic products of select agents and toxins.
Sec. 402. Establishment of no-fault reporting system.
Sec. 403. Evaluation of the Federal Select Agent Program and related policies.
Sec. 404. Supporting research and laboratory surge capacity.

- BIO supports the provisions in Title IV.

TITLE V—ADDITIONAL REAUTHORIZATIONS AND TECHNICAL AMENDMENTS

Sec. 501. Epidemic Intelligence Service loan repayment program.

Sec. 502. Temporary reassignment of State and local personnel during a public health emergency.
Sec. 503. Vaccine tracking and distribution.
Sec. 504. Regional health care emergency preparedness and response systems.
Sec. 505. Emergency system for advance registration of volunteer health professional.
Sec. 506. Limited antitrust exemption.
Sec. 507. Trauma care.
Sec. 508. Military and civilian partnership for trauma readiness.
Sec. 509. National Disaster Medical System.
Sec. 510. Volunteer Medical Reserve Corps.
Sec. 511. Epidemiology-laboratory capacity grants.
Sec. 512. Veterans Affairs.
Sec. 513. Technical amendments.

- BIO supports the provisions in Title V.

TITLE VI—ADDITIONAL POLICIES OUTSIDE THE STAFF AGREEMENT FOR STAKEHOLDER FEEDBACK
Subtitle A—Chair Sanders Staff Proposal
Sec. 601. BARDA reasonable pricing requirements.
Sec. 602. CDC reasonable pricing requirements.

- **BIO strongly opposes the proposals in this subtitle.**
  After 9/11 and the 2001 anthrax attacks, Congress rallied together in a bipartisan fashion to create project BioShield and subsequently BARDA to meet the national security needs outlined by the new Department of Homeland Security (DHS). Project BioShield is the procurement mechanism; BARDA is the advanced research and development partner which was designed to foster trusted public-private partnerships with private sector innovators to bridge the "valley of death" in medical countermeasure development and drive investment toward otherwise unmet critical needs with no existing market. BARDA also partners with the DOD to align research and development priorities that affect the warfighter and civilian population. This model, as it stands today, has been overwhelmingly successful. It has led to 77 Food and Drug Administration (FDA) approved countermeasures.

  The creation of BioShield and BARDA was predicated on bipartisan agreement that it is critical for the federal government to be a reliable and trusted partner in these endeavors given the unique challenges in researching, developing, and commercializing medical countermeasures to protect the American people, as well as the necessity of doing so. Changing this model now is unwarranted, especially after COVID-19 showed us that rapid development and deployment of vaccines and therapeutics is critical to fighting a pandemic. Advancement of sections 601 & 602 would have the extreme consequence of subverting BARDA's ability, and subsequently the DOD's ability, to attract private interest in areas of unmet need for civilians and the warfighter alike.

  We are deeply concerned that these provisions would decimate the value of the BARDA model leading to fewer partnerships and drugs and platform technologies being developed. They are in stark contrast to the spirit and principles on which BioShield and BARDA were established, and affirmed, with every PAHPA reauthorization since their creation. If advanced, they would jeopardize the decades spent fostering public-private

partnerships and confidence in the federal government as a trusted partner in these essential endeavors, and ultimately the goal of bringing forwarded needed medical countermeasures to protect the American people.

It is also worth noting that the drugs and other medical products procured ASPR, BARDA, and the SNS all already go through open negotiation between the federal government and industry partners. This process has been successful in procuring these lifesaving products for the government at a negotiated price, but also allows for contracts to take into account the nuances of each individual product.

While we do not disagree that products that are critical to public health should be offered at a price that fosters access, the chilling impact of "Reasonable Pricing" clauses on public-private partnerships is already known. It was a failed experiment terminated by the Clinton Administration in 1995 because it halted the public-private partnerships that developed NIH-funded science into important cures. Then-NIH Director Harold Varmus said, *"An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public. One must have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment."* While public agencies like NIH and BARDA fund important research, it is the government's partnership with the private sector that transforms these discoveries into much needed therapies. Research America reports that, in 2018, the biopharmaceutical industry invested $102 billion in R&D, whereas the entire NIH budget for that year was $35.4 billion.

Here are some examples:
o Radiation/Nuclear: One of the greatest areas of unmet need has been in finding products to combat the multitude of symptoms that could come from radiation exposure, for example from a nuclear attack. BARDA has worked with numerous companies with important drugs used to treat cancer symptoms to conduct R&D on these products for use in the event of a nuclear attack or radiation exposure. These very specific indications help our government not just prepare for this type of terror threat in the US, it also helps us respond to our allies, like the Ukraine and other countries close to Russia, so that they can save lives in the event of a cataclysmic radiological event. Companies with commercial products that could be vital to our nuclear response would not conduct this very specific research without BARDA funds, but they will not risk those products with these provisions in place. This would leave both the American people and our allies without the necessary products for a robust response.

o Viral families: These provisions would hinder the development of pan-flu, pan-corona, or other viral family products that have been identified as a priority by the Federal Government, and by this very draft of PAHPA Reauthorization (see section 203). Companies working on these products that could prevent the next pandemic would be wary of accepting any federal funding to support that R&D since they have broad use implications for both pandemic and routine commercial markets. Companies may forgo investment in these products all together as public-private partnerships with BARDA are often a key factor in investment strategies and raising capital.

o Seasonal and Pandemic Influenza: Seasonal Flu will also be at risk as the CDC contract provision would impact those contracts and development processes. Seasonal flu vaccines operate on already thin margins, and price controls like this provision could lead to a collapse in the seasonal flu market. Additionally, seasonal flu developers rely on CDC for candidate virus samples, this non-monetary contribution could by itself qualify a seasonal flu vaccine for the price controls outlined in the bill, leading to privately funded vaccines to be forced into an unsustainable pricing scheme for simply developing a product that the CDC requests. It is also important to note that pandemic flu development is linked to the seasonal market, and any damage to the seasonal market would directly impact pandemic flu, the pandemic pathogen with the highest probability of occurrence.

o Chemical: Alteplase is an approved tissue plasminogen activator in wide use for the treatment of conditions including stroke and embolisms. BARDA is partnering with the manufacturer to conduct studies to demonstrate the use of the drug to dissolve obstructive airway casts caused by sulfur mustard (mustard gas) exposure. It is in Phase 2/3, and if successful, BARDA's support of Alteplase will yield the first drug approved to treat sulfur mustard inhalation/pulmonary exposure. Pursuing the chemical threat indication helps defend our nation's warfighters, but if this pricing provision is passed, then manufacturers may have to discontinue this type of research to protect their commercial application. This would leave BARDA and the DOD without the approved product they have been pursuing.

Subtitle B—Ranking Member Cassidy Staff Proposal

Sec. 611. Priority review to encourage treatments for agents that present national security threats.

- **BIO strongly supports the reauthorization of the Medical Countermeasure Priority Review Voucher.**
  BIO recommends that the committee reauthorize and strengthen the Medical Countermeasure Priority Review Voucher (MCM PRV) Program by eliminating the sunset to best prepare the federal government to align procurement with the urgency of known threats. The MCM PRV program creates a powerful pull incentive for industry to develop products on the material threat list. These products generally have limited or no commercial market when developed in advance of a known threat, and this incentive is key to the development of these products. This program supports the medical countermeasure needs of the DOD to protect the warfighter and should remain to be a priority.

  BIO acknowledges and appreciates the unique needs of the warfighter. Provided the proposed changes in the draft which appear to align eligibility for the MCM PRV program with those needs. BIO appreciates the limited scope of those changes and would underscore the need for the MCM PRV program to remain targeted, and narrow, so as to maintain the power of the incentive that it creates. Throughout the program's life, it has been a success, leading to the issuance of seven vouchers. The small number of vouchers is key to this success, having helped to maintain the value and importance of the incentive. Notably, the program has zero cost for the Government according to past

CBO reports. But, for the recipient (or transferee) it can be used to cut down a product's time to market, particularly for those second to market, increasing competition and downward pressure on drug prices.

As drug development takes an average of 10+ years, eliminating the 5-year sunset date for the MCM PRV program would stabilize and strengthen the incentive by providing a signal to spur and support earlier stage innovation. **Reauthorizing the MCM PRV Program and eliminating the sunset are crucial to preserving that incentive for research and development.**

BIO asks that the committee reauthorize essential programs from previous PAHPA bills that were omitted in this draft:

1) 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.

2) 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

3) 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.

BIO asks the committee to please include the following legislation in the reauthorization of PAHPA:

1) PASTEUR Act of 2023

   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.

2) PHEMCE Advisory Committee Act of 2023

   Included in the House package of bills considered for PAHPA reauthorization, this bill establishes an advisory committee to seek input from external stakeholders on issues central to the mission of the PHECME. Improved transparency, communication, and stakeholder engagement is greatly needed for stronger preparedness and response, particularly when the PHEMCE seeks to partner with industry. Having industry partners and stakeholders in an advisory role will lead to better coordination, planning, and stronger public-private partnerships, all of which keep the American people safer.

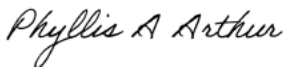
3) FLASH Act of 2023

   Included in the House package of bills considered for PAHPA reauthorization, this bill strengthens the ASPR's ability to invest in innovative technologies and enhances its

ability to pursue partnerships with industry. Facilitating prototype deals will fill a much-needed gap within the ASPR partnership system and enable innovation that will make the nation more prepared for the next emerging threat.

Thank you for the opportunity to submit comments on the draft bill and your consideration of our feedback. Reauthorizing PAHPA is an essential part of our national health defense, and the public-private partnership that it supports help keep the American people safe. BIO is committed to working with the committee on reauthorization and is always available as a resource.

Sincerely,



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