July 10, 2023

SUBMITTED VIA EMAIL to PAHPA2023Comments@help.senate.gov

Dear Members of the Senate HELP Committee,

The Pharmaceutical Research and Manufacturers of America (PhRMA) is pleased to submit comments on the discussion draft of the reauthorization of the many programs and initiatives under PAHPA. Timely reauthorization of PAHPA is critical given the centrality of these programs to ensuring pandemic preparedness, supporting a robust biodefense, and supporting resiliency in medical countermeasures.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to researching and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA's member companies have invested more than $1.1 trillion in the search for new treatments and cures, including an estimated $102.3 billion in 2021 alone.

A once-in-a-century global pandemic reinforced the value of the scientific advances that America's research-based biopharmaceutical industry makes possible. The breakthroughs in vaccine research and therapeutics to combat COVID-19 were built on a collaborative ecosystem that drives scientific discovery and resulted in the approval and authorization of numerous vaccines and therapeutics. During the pandemic biopharmaceutical companies made substantial investments to ramp up manufacturing capacity while simultaneously conducting necessary research and development (R&D) despite the high degree of uncertainty as to whether their research efforts would yield products authorized or approved by the U.S. Food and Drug Administration. PhRMA's member companies were central to the U.S. and global response to COVID-19 in large part due to the decades of investments in infectious disease, vaccine manufacturing expertise and capacity, and robust supply chains.

PhRMA's members rapidly screened vast global libraries of medicines to identify potential treatments, assessed previously failed research projects as well as whether currently approved medicines should be further researched, supported clinical trials around the globe, collaborated with government agencies in and outside of the United States, hospitals, doctors, and public health workers to donate supplies and medicines around the world, and worked with governments and insurers to ensure that treatments were available and affordable for patients. As the COVID-19 pandemic ends, over 16 billion doses of COVID-19 vaccines have been delivered around the globe.

The benefit of collaboration between the public and private sectors to address urgent public health needs is evident. Over $24 billion was spent by the biopharmaceutical industry, government, and academia on the clinical trials for COVID-19 vaccines and treatments in the United States, supporting about 100,000 U.S. jobs.[1] As of February 2023, manufacturers had delivered over 16 billion vaccines globally. Between December 2020 and March 2022, U.S. vaccination efforts prevented 2.3 million deaths, 66 million infections, and saved $899 billion in health care costs.[2]

To inform future pandemic preparedness, it is important that we build upon lessons learned from across the public health supply chain during the pandemic. While we can collectively take great pride in the efforts that ended the COVID-19 pandemic, it is critical that we also prepare for the challenges presented by potential future pandemics and other public health emergencies. PhRMA and our members are committed to continuing to bolster pandemic preparedness and health care resiliency to make sure our country and American patients are stronger, healthier, and better prepared for the next public health emergency. This is integral to American national security, the health of the American public and future economic stability and growth.

Given the high costs and length of time to research and develop new medicines and vaccines, as well as to invest in manufacturing facility enhancements and to invest in new facilities, IP rights have been critical to providing the potential for returns and spurring companies to make the investments needed to ensure supply chain resiliency and, in many cases, boost redundancies and the ability to respond to all manner of public health emergency. Manufacturers need the certainty and predictability provided by IP protections to make the decades long investments in new technologies, infectious disease expertise, increased resiliency, and security measures, and in building new or expanding existing facilities. IP protections are also critical to fostering public-private partnerships and other forms of collaboration to support the development of medical countermeasures to respond to the full range of chemical, biological, radiological, and nuclear threats that could threat our nation's public health and national security.

Our responses to select questions are provided below.

Feedback on the proposed policy to require that all BARDA and CDC-supported products be sold to the Federal Government or in the U.S. commercial market at the lowest price among G7 countries (Canada, France, Germany, Italy, Japan, and the United Kingdom) and at a reasonable price.

[1] Sources: Informa data used to identify clinical trials for COVID-19 vaccines and treatments in the United States. Evaluate data used to estimate clinical trial costs. PhRMA analysis of U.S. Department of Commerce (BEA) RIMS II (Type II) multipliers used to estimate the total (direct and indirect impact) of clinical trial spending in the United States.

[2] Eric C. Schneider et al., "Impact of U.S. COVID-19 Vaccination Efforts: An Update on Averted Deaths, Hospitalizations, and Health Care Costs Through March 2022," *To the Point* (blog), Commonwealth Fund, Apr. 8, 2022. https://doi.org/10.26099/d3dm-fa91

PhRMA is strongly opposed to the proposal to add "reasonable pricing" requirements to all BARDA and CDC-supported products sold to the Federal Government or in the U.S. commercial market. Three years ago, at the start of the pandemic, America's biopharmaceutical companies made a commitment to fight COVID-19. Working around the clock, biopharmaceutical researchers conducted hundreds of clinical trials to identify potential treatments and vaccines, and increased investments into new technologies to speed the manufacturing of safe and effective medicines.

America's biopharmaceutical industry already had deep scientific knowledge gained from decades of experience with research and development to counter viruses such as Zika and related viruses causing MERS and SARS. It took several key advances in mRNA treatment engineering and extensive investment from the private sector to develop the technological advances to overcome early technical challenges for mRNA vaccines in particular. Biopharmaceutical knowledge combined with decades-long investments in mRNA and other advanced vaccine technologies by the private sector allowed the industry to collaborate with its partners in government and academia to respond in record time to the COVID-19 pandemic, and as a result the industry was able to deliver with unprecedented speed four vaccines and seven therapeutics during the public health emergency.

The biopharmaceutical industry has successfully partnered with the Biomedical Advanced Research and Development Authority (BARDA) in the development of medical countermeasures since it was first established in 2006. The National Institutes of Health (NIH) and BARDA routinely partner with biopharmaceutical companies to support medical countermeasure (MCM) development through funding, technical assistance, and core services like clinical trial site management and manufacturing scale-up. Several MCMs, such as monkeypox vaccines, smallpox antiviral drugs, H5N1 influenza vaccines and anthrax vaccines are maintained in the strategic national stockpile, where they can be made available in the face of a public health threat.[3] BARDA support is often aimed at supporting or accelerating research into potential medical products including vaccines, which have failure rates as high as 95 percent. Pipeline products being explored have potential but there is no guarantee they will ultimately receive FDA approval, and thus seeking to inject further uncertainty by setting an arbitrary price at the outset would simply serve to further chill critical R&D investments and collaborations between the public and private sectors with the end-result leaving the United States unprepared to quickly respond to emerging health threats.

Public-private partnerships with BARDA played a critical role in helping increase the availability of certain materials and supplies that were essential for the development of COVID-19 therapeutics and vaccines. Partnership between the government and the private sector is critical because each plays a fundamentally different but complementary role in the biopharmaceutical research and development ecosystem. The biopharmaceutical industry's unique role in the research ecosystem is to utilize its scientific and industrial expertise to take the necessary risks to build upon and further advance basic science research into safe and effective treatments that can be made available to patients. The federal government cannot research,

[3] https://aspr.hhs.gov/SNS/Pages/Requesting-SNS-Assets.aspx

develop and manufacture vaccines and other new treatments without the resources, scientific expertise, R&D, manufacturing and technological platforms from private sector biopharmaceutical companies. As the National Institute of Allergy and Infectious Diseases head stated during the pandemic "We always need a pharmaceutical partner… I can't think of a vaccine, even one in which we've put substantial intellectual and resource input, that was brought to the goal line without a partnership with industry."[4]

Policy proposals to place pricing restrictions on the private sector as a condition of partnering with the government have been tried before with disastrous results for patients and taxpayers. In 1989, the NIH imposed "reasonable pricing" conditions all Cooperative Research and Development Agreements (CRADAs) between federal labs and outside parties to conduct research or development. The policy was revoked in 1995 after public meetings were held with companies, patient advocates and researchers after which the agency concluded that these pricing conditions significantly chilled collaboration between the public and private sectors.[5] In his announcement of the decision, then Director of the NIH, Harold Varmus, M.D. 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," Dr. Varmus further said, "Eliminating the clause will promote research that can enhance the health of the American people." [6] After the removal of the clause, there was a subsequent rebound in CRADAs.

Policies enabling the government to determine the "reasonable price" of medicines developed with support from the Centers for Disease Control and Prevention (CDC) and BARDA fail to recognize that reducing the incentives for the private sector to invest in medical countermeasures could have serious unintended consequences. In addition, concerns that the biopharmaceutical industry will inappropriately price future vaccines or treatments are unfounded. In the face of the COVID-19 crisis, PhRMA member companies committed to collaborating with a wide range of partners including working with various governments to ensure that when new treatments and vaccines were approved, they would be available and affordable for patients. During the public health emergencies and pandemics, the biopharmaceutical industry has a track record of responsible pricing and actively partnering with the government to ensure availability and affordability of vaccines and therapeutics, and COVID-19 is no exception. The heads of NIH and NIAID have stated they are not aware of any situation where companies priced vaccines out of reach in pandemic situation.[7]

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[4] Lerman D & A Siddons. "Vaccine prices a flashpoint in coronavirus funding talks," Roll Call. February 27, 2020. https://rollcall.com/2020/02/27/vaccine-prices-a-flashpoint-in-coronavirus-funding-talks/

[5] National Institutes of Health. Reports of the NIH Panels on Cooperative Research and Development Agreements: Perspectives, Outlook, and Policy Development, December 1994. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH_%20CRADA_Report_on_Reasonable-Pricing_Clause_1994.pdf

[6] Press Release, NIH News, April 11, 1995. Available from: https://www.ott.nih.gov/sites/default/files/documents/pdfs/NIH-Notice-Rescinding-Reasonable-Pricing-Clause.pdf

[7] Lerman D & A Siddons. "Vaccine prices a flashpoint in coronavirus funding talks," Roll Call. February 27, 2020. Available at: https://www.rollcall.com/2020/02/27/vaccine-prices-a-flashpoint-in-coronavirus-fundingtalks/

For most Americans, affordable vaccine access for regular immunizations is already made possible through several federal and state policies and programs. Under the Medicare statute, Medicare Part B covers vaccines for influenza, pneumococcal, hepatitis B (for patients at medium or high risk of hepatitis B) and COVID-19 with zero cost sharing. The Medicare Modernization Act of 2003, which created the Part D program, provided that all adult vaccines not covered under Part B would be covered under Part D with out-of-pocket costs determined by the Part D plan. The federal Vaccines for Children (VFC) plan provides childhood vaccines at no cost to children who are Medicaid-eligible, uninsured, underinsured, American Indian or Alaska Native. To provide vaccines under the VFC plan, manufacturers negotiate vaccine prices with the CDC at levels that are typically substantially reduced relative to commercial list prices.[8] Under the Affordable Care Act (ACA), all vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) are required to be covered without cost sharing by non-grandfathered commercial health insurance plans and Medicaid expansion programs as part of preventive care services.[9] Additionally, Section 317 of the Public Health Service Act authorizes the federal government to purchase vaccine doses at CDC-negotiated public sector prices for distribution to states in limited numbers subject to Congressional funding levels, and these doses may be used to provide vaccine access to uninsured adults through mass clinics and at Federally Qualified Health Centers.[10]

During the COVID-19 pandemic the Coronavirus Aid, Relief, and Economic Security (CARES) Act required that products purchased by the federal government, such as vaccines and therapeutics developed using federal funds, would be acquired at a fair and reasonable price.[11] As Speaker Pelosi described the provision, "The legislation protects against price-gouging of these medicines developed with taxpayer dollars by ensuring that the federal government will only pay a fair and reasonable price for coronavirus vaccines and drugs and providing HHS the authority to ensure that they are affordable in the commercial market."[12]

Affordable vaccines are critical to the protection of Americans against emerging infectious diseases and to the approximately 18 vaccine-preventable diseases in the US today. As discussed, there are established policies and programs in place to ensure broad access to both vaccines for disease prevention and for coverage during a public health emergency. Any new additional policies that would give broad authority to set prices in the commercial market would make it significantly less attractive to collaborate with the federal government and would fundamentally set back the nation's ability to make long-standing investments in our emergency response infrastructure or respond quickly in times of future global health emergencies. This is particularly short-sighted in the wake of the hugely successful COVID-19 response, which

[8] https://www.healthaffairs.org/content/forefront/ensuring-covid-19-vaccine-affordability-existing-mechanisms-should-not-overlooked
[9] https://www.healthcare.gov/preventive-care-adults/
[10] https://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html#
[11] Coronavirus Aid, Relief, and Economic Security (CARES) Act. Available at: https://www.congress.gov/bill/116th-congress/house-bill/748
[12] Pelosi Statement on Coronavirus Emergency Response Bill," March 4, 2020. Available at: https://www.speaker.gov/newsroom/3420

demonstrated that existing mechanisms work well. In light of this, we strongly urge the Committee not to adopt this short-sighted policy.

Feedback on the proposed policy to incentivize the development of more medical countermeasures (MCMs) by extending the Priority Review Voucher program through the duration of PAHPA and (1) providing a new, non-transferrable priority review voucher to companies that develop new MCMs on top of the transferrable voucher they currently receive; and (2) including threats to the Armed Forces.

We encourage a more fulsome engagement with manufacturers of MCMs and other stakeholders to assess the adequacy of existing incentives, including the use of priority review vouchers (PRVs). PRVs alone are insufficient as an incentive to invest in new MCMs, particularly given the lack of a guaranteed market, high scientific uncertainty, uncertainty around ultimate FDA approval, and significant uncertainty around the potential market. We would note that as eligibility for PRVs has expanded over time, the value of PRVs has fluctuated but overall has declined significantly over time. Numerous stakeholders have raised concern regarding continuing expansions resulting in further declines in value and have raised concerns regarding FDA resources. The FDA has also noted that the demands of the PRV program may require it to shift resources away from other public health priorities.

Feedback on Section 301 – Transition of Certain Countermeasures Between Compensation Programs

PhRMA strongly encourages the Committee not to include the bracketed language proposing new 42 U.S.C. 360aa-14(e)(4). This proposed language would preclude HHS from revising the Vaccine Injury Table to include a vaccine for which CDC has issued a recommendation for routine use in children or pregnant women until at least one application for such vaccine has been approved under section 351 of the Public Health Service Act. Including this language would run contrary to the overarching intent of the VICP of encouraging development of vaccines.

By excluding certain vaccines from the Vaccine Injury Table, for instance vaccines authorized under an Emergency Use Authorization (EUA), manufacturers could face standard tort liability for these products. This, in turn, could disincentivize manufacturers from seeking EUAs – products by nature intended for emergency situations – or from seeking use in the most vulnerable populations (i.e., children and pregnant women). Further, manufacturers of existing authorized product may face difficult choices of continuing to market vaccines under an EUA or to limit distribution.

Accordingly, we strongly encourage the Committee not to include this bracketed proposed language to ensure that applicable vaccines marketed under EUAs – products critical to responding to emergencies – come within scope of the VCIP.

Inclusion of Incentives to Advance Treatments for Antimicrobial Resistance in PAHPA

PhRMA and our members are committed to bolstering pandemic preparedness and health care resiliency to make sure our country and American patients are stronger, healthier, and better prepared for the next public health emergency. Having a robust pipeline of medicines to address antimicrobial resistance (AMR) is a key part of pandemic preparedness, and we urge further consideration of the fundamental challenges to developing new medicines to target antimicrobial resistance; unlike most other medicines, the market is inherently limited by design.

To help address the AMR crisis over 20 leading biopharmaceutical companies, global foundations and development banks came together to create the AMR Action Fund, a groundbreaking partnership that seeks to strengthen and accelerate the research and development of antibiotics through investment and provision of industry resources and expertise to biotechnology companies. The broad alliance of industry and non-industry stakeholders also encourages governments to advance policies that will create market conditions that will encourage a sustainable pipeline of new antibiotics to fight the highest priority bacterial threats over the long term. To slow and control continued antimicrobial resistance, newer medicines are frequently used only in a limited set of circumstances and in only the most necessary cases. Antibiotic stewardship programs are designed to limit the use of new antibiotics specifically for this reason and thus limit the commercial viability of new antimicrobials, making it difficult for companies to sustain R&D investments to address AMR.

If we fail to address this growing crisis, many modern medical advances that depend on antibiotics – such as routine surgery, cancer therapy and treatment of chronic diseases – may be jeopardized. New treatments for increasing levels of Valley fever, a serious fungal infection that is on the rise in the western part of the United States, are desperately needed.[13] Policy reforms, such as the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act of 2023"[14] are still needed to create a more sustainable environment for antimicrobial research and development to ensure a robust pipeline for future treatments.

We look forward to ongoing dialogue on these issues. Please free to reach out to Jocelyn Ulrich, Deputy Vice President, Policy and Research, at julrich@phrma.org with any questions or for additional discussion.

[13] https://www.vox.com/the-highlight/23673211/valley-fever-cocci-fungal-infections-colorado-river-dust

[14] https://www.congress.gov/bill/118th-congress/senate-bill/1355/text?s=1&r=15