



Good morning Chairwoman Murray, Ranking Member Burr and Members of the Committee. My name is Phyllis Arthur and I am the Vice President of Infectious Diseases and Emerging Science Policy at the Biotechnology Innovation Organization, or BIO. Thank you for the opportunity to share our thoughts on the topic of the lessons learned from the COVID-19 pandemic.

BIO is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers and related organizations in the United States and over 30 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 proactively working to collect lessons learned from the COVID-19 pandemic and put forward legislation to prepare for future pandemics. As companies investing in novel therapeutics, vaccines, diagnostics, and platform technologies to help save lives from all types of biological 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 pandemic preparedness. To this effect, the global biopharmaceutical industry has initiated over 900 unique therapeutics and vaccines against COVID-19 since January 2020.

Our national biodefense enterprise supports medical countermeasure (MCM) development for a host of known and unknown threats: chemical, biological, radiological, and nuclear (CBRN), pandemic influenza, emerging infectious diseases, and antimicrobial resistance (AMR). Pandemic preparedness relies on the nation's ability to develop, procure, and deliver the necessary medicines and diagnostics to combat biological threats. The U.S. needs to maintain a robust stockpile of MCMs for each of these risks. We know that periodic threats, such as a 100-year pandemic like COVID-19, will occur but each individual threat has such a rare occurrence rate that commercial markets for such countermeasures do not exist. That is why the U.S. Government, through the Biomedical Advanced Research and Development Authority (BARDA), the Project BioShield Special Reserve Fund (SRF), and the Strategic National Stockpile (SNS), must invest in and procure the necessary MCMs to be ready for the next pandemic and other biological threats.

The Department of Health and Human Services (HHS) and the Department of Defense (DOD) work in partnership with the private sector on the development of vaccines, therapeutics, diagnostics, and platforms to protect the American people against these threats. As BARDA's portfolio has grown to include 61 approved products, funding levels for HHS Assistant Secretary for Preparedness and Response (ASPR) and BARDA initiatives have remained largely stagnant over the past decade. Recent iterations of the Public



Health Emergency Medical Countermeasures Enterprise (PHEMCE) Multi-Year Budget have shown increased projections of necessary funding for BARDA advanced research and development (ARD), pandemic influenza, Project BioShield, and the SNS, and BIO would expect further increases projected in the next iteration of the Multi-Year Budget.

Leadership

Role of the ASPR and the PHEMCE

Current statute clearly places authority for pandemic preparedness and response with the ASPR. The ASPR has the most appropriate expertise and statutory responsibilities for coordinating a public health emergency response, given their relationship across the healthcare supply chain, the pharmaceutical industry and public health preparedness leaders. This was the intent of the original Pandemic and All-Hazards Preparedness Act (PAHPA), which was further codified in PAHPA's subsequent bipartisan reauthorizations passed during the Obama & Trump Administrations. The ASPR should be empowered to lead the coordination of government preparedness initiatives, public health emergency and pandemic responses. Since the ASPR is intended to be the leader of the PHEMCE, in partnership with the DOD, other relevant agencies should work in collaboration and coordination with the ASPR.

The ASPR currently lacks the authority to clearly direct the actions of the PHEMCE. While we certainly applaud the success of both Operation Warp Speed and the current White House COVID-19 Taskforce in developing and distributing COVID-19 vaccines and therapeutics, BIO believes a stronger PHEMCE could have accomplished similar goals without the delays of building new organizational structures. The roles within the PHEMCE should be clearly defined, with a clear, centralized power structure, in advance of a public health emergency. Legislation ought to clarify the responsibilities and authorities of the many actors for pandemic preparedness and response and determine the chain of command so that directives come from a single top-down source or inter-agency group. Confusion regarding leadership undermined the government's ability to clearly communicate with industry during its COVID-19 response, and a proper pre-planned organizational structure and procedures could help prevent these issues from occurring in the future.

Leadership and Management of the Strategic National Stockpile

Another specific area of concern is leadership of the SNS. As we learned during the COVID-19 pandemic, the SNS is vital for many healthcare products from personal protective equipment (PPE) to generic essential medicines to complex biologicals and vaccines. BIO strongly believes that the SNS must remain under the ASPR's jurisdiction with funding levels that account for the breadth of products in the Stockpile and the complexity of managing the myriad roles the SNS must play. For many MCMs, such as smallpox vaccines, anthrax antitoxins, and pandemic influenza products, the federal



government is the primary customer through procurements by the SNS and the SRF. The ASPR is best equipped to manage all of the products included in the Stockpile, especially MCMs, given the role of the office in setting requirements, coordinating responses to many types of health emergencies, leading BARDA investments in product development, and planning lifecycle management and stockpile operations. For MCMs, future stockpiling strategies must be applicable to each specific product being procured, based upon characteristics such as the market size, use, timelines for manufacturing, and the speed of pathogen spread for the different medical countermeasures.

With respect to state and hospital-based stockpiles, BIO believes that they may be suitable for some products such as PPE, antibiotics, or threats endemic to the region, but they are not replacements for the national stockpile for specific MCMs for national security threats, like anthrax. Investment in state and hospital stockpiles does provide value to the preparedness of the nation, though money spent on any potentially new state stockpiles should not come at the expense of the investment in, or replenishment and maintenance of, classic or non-commercial MCMs within the federal SNS.

Communications With Stakeholders

The ASPR and PHEMCE leadership need to strengthen communications systems surrounding pandemic preparedness. Clarity on the distribution plan of an MCM is important for federal, state, and local response to public health emergencies, and industry often has a role to play in communicating around and facilitating product distribution. Federal, state, and local government public health responses are intimately interconnected. There must be the infrastructure and resources to allow seamless communication and coordination between all parties for the fastest possible response. The ASPR and the Centers for Disease Control and Prevention (CDC) must be unencumbered in their ability to ensure coordination and communication between federal, state, local, and industry partners when time matters most.

Threat Assessment and Awareness

Congress must take steps to ensure its awareness of the threat assessments that drive PHEMCE's MCM requirements and decisions. Currently, this information is not regularly shared with Members of Congress, even though statute requires an annual submission of a threat-based review to Congress. To our knowledge, the threat-based review report required by the most recent PAHPA reauthorization has never been submitted to the appropriate Congressional committees. BIO believes that a better understanding of these threat assessments would help Congress better understand the role played by the PHEMCE and the changes in the threat matrix on a year-to-year basis. Regular visibility into the threat assessment process would assist Congress in evaluating appropriate levels of funding to ensure the PHEMCE fulfills its statutory requirements. Congress would also



be better able to perform its oversight role with an improved understanding of all biological threats, whether naturally occurring, deliberate, or accidental.

Commitment to Public Private Partnerships

Private sector partners must be treated as true partners rather than vendors. This means understanding the business needs of partners so that the private sector can be sustained and therefore all products can be available over time. These relationships should not be only transactional.

Clear Communication on Product Requirements

Industry partners need clarity around product requirements, plans for product replenishment, and when the U.S. Government thinks that a requirement or threat is fulfilled or completed. When there are changes in prioritization, those changes must be communicated with industry partners in a timely manner. The ASPR should use the Multi-Year Budget process to communicate the short- and long-term strategy and priorities of the U.S. Government for the development and procurement of MCMs.

Staffing for BARDA Contracting

Another key aspect of the public-private partnership is the length and complexity of contracting timelines. Legislation should facilitate ASPR/BARDA to quickly bring in contracting staff from other federal agencies or other implement other solutions for expedited contract reviews. This was recommended by the Bipartisan Commission on Biodefense and implemented by the last Administration. Contracting authority should principally remain with BARDA.

The billions of dollars recently appropriated to ASPR and BARDA for COVID-19 response necessitates an increase in BARDA support staff. Limited contracting staff is a bottleneck to rapidly issuing contracts and other agreements to accelerate development of drugs, vaccines, and diagnostics that can save lives during a public health emergency. Additional contracting staff can enable not only a standard review process but an expedited process that is badly needed.

Under usual circumstances, contract timelines at BARDA have been lengthy. At best, new contracts have taken about 60 days for very small awards (under \$750,000) for BARDA's Division of Research Innovation and Ventures (DRIVE) program. For larger awards under routine BARDA programs, contract decisions can take 6-9 months.

This is a bureaucratic issue but also fundamentally a staffing issue. Over the last several years (before COVID-19), companies interfacing with BARDA have experienced a severe



shortage of experienced contracting staff within the agency. Several companies have reported up to four contracting manager changes in under a year.

Increasing Domestic Biopharmaceutical Manufacturing

The public-private partnerships for MCM research & development, manufacturing, and stockpiling are critical to the health security of the U.S. Neither the U.S. Government nor industry would be successful in this effort alone, and the investments made by the U.S. Government are important to sustaining and bolstering our national preparedness. The health security provided by a robust domestic market for medical products, along with the economic impact of high paying jobs, is of the utmost value to the United States. Fair and competitive markets are important for maintaining the rigor and vitality of the industry, and Executive Order 14005 (Ensuring the Future Is Made in All of America by All of America's Workers) includes many provisions to improve upon the economic ecosystem.

There is a need to incentivize future investment in U.S. manufacturing capabilities, to ensure that the United States is the best place in the world to locate global biomanufacturing facilities. BIO recommends that Congress consider providing targeted incentives to grow and maintain the U.S. domestic biopharma manufacturing sector. Legislation should require clarity from the U.S. Government related to the requirements for MCMs, so Congress has needed visibility and private sector partners can accurately assess the government's needs.

One model to consider strengthening is the Centers for Innovation in Advanced Development and Manufacturing (CIADM) program, which was created in 2012. This program, which had seen inadequate government investment over many years, has unfortunately resulted in the sale and exit from the program of one of the three facilities due to the unsustainability of the model as actually funded & supported.

The American Jobs Act proposes investment in both the U.S. supply chain and domestic production, and currently the House Ways and Means Committee has several bills, including the "Start-Ups for Cures Act," the "More Cures Act," the "Infectious Disease Therapies Research & Innovation Act," and the "IP Repatriation Act" that seek to incentivize onshoring and continued investment in domestic medical manufacturing. Passage of these bills would help ensure that the U.S. has a robust medical supply chain and the necessary domestic manufacturing capacity needed to combat the next pandemic.

Investments also should be made in workforce development and training. Onshoring and growing the domestic manufacturing industry is more than just a health security priority, it is also a jobs and economic priority. One of the United States' major national strengths has been the high-quality workforce that manufactures our medicines and supply chain inputs through a diverse network of job training and occupational expertise respected around the world.



We believe the United States should create a national industry/academic preparation clearinghouse focused on new curricula and programs that incentivize an adequate supply of management, sales, marketing, and regulatory personnel experienced in manufacturing for the biotechnology industry.

The US must also invest more significantly in science and Science, Technology, Engineering, and Math (STEM) education at all levels but especially at the college and graduate level. The rapid evolution of life science knowledge is a driving force in the biopharmaceutical industry and should be viewed as a core national security and domestic policy priority. These efforts should be complemented with a sound foundation of immigration policies that attract and retain the best technologists, scientists, and innovators from around the world.

BIO supports increasing U.S.-based manufacturing of critically needed medicines, but not a broad mandate requiring MCMs, essential medicines, and related active pharmaceutical ingredients (API) to be made in the United States. There are numerous challenges to relying solely on U.S. manufacturing, including lack of access to certain raw materials, gaps in specialized workforce needs, and governmental regulations that would make it extremely challenging to produce in the United States without significant regulatory changes and cost considerations. This is especially important for those MCMs targeted to specific biological threats with limited demand. These medicines are generally made in one facility and shifting them to a U.S. production site may cause undue cost, delays, and manufacturing inefficiencies. Also, any changes would take significant time for companies to implement, as supply chains, including the facilities for manufacturing API, often are established years in advance of a product's launch, from the base of global regulatory filings/approvals, and are designed with global access and resiliency in mind.

Any policies to incentivize U.S. medical supply manufacturing must be targeted and recognize the complex nature and inherent global aspects of the biopharmaceutical supply chain. The medical supply chain is incredibly delicate and complex. The many products in supply chain are unique and have their own market intricacies, and so BIO would caution against any one-size-fits-all or product-blind policy for managing the supply chain. At the same time, there is, of course, a need for redundancy built into the supply chain. When determining where redundancy is required, it is important to keep in mind production capability and the complexity of certain products.

Investment across the whole supply chain, along with an incentive structure that rewards market entry as well as rewards those who choose to stay in the MCM market, is needed to create a domestic supply chain that is sustainable and secure.

Private companies have solutions related to supply chain and manufacturing challenges, but the U.S. Government must be a transparent, communicative, and cooperative partner. The U.S. Government must work with industry to find strategies for maintaining some



level of excess capacity for emergencies, a sustainable infrastructure that can surge during a public health crisis. To reserve manufacturer capacity to use when needed, the government would need to pay for that reserved capacity and ensure it is not double-booked for other clients. To ensure adequate capacity is achieved, the U.S. Government should pursue multiple partnerships, build excess manufacturing capacity into the system, and pay for capacity on top of existing demand – not supplant existing demand. These manufacturing partnerships should be viewed as a cost-effective insurance policy for national preparedness. Additionally, public-private partnerships to stockpile ancillary materiel such as glass vials and syringes that will be needed for fill-finish capabilities for a variety of products should also be utilized.

Strategies That Support MCM Development

Platform Technologies for Vaccines and Therapeutics

COVID-19 will not be the last emerging infectious disease that the U.S. will need to respond to. Support for capacity and capability building for MCMs and our public health system is critical to protecting our national health security from emerging infectious disease threats. Investments must be made now in new technologies to ensure our national health security through preparedness and quick resolution of an outbreak when any emerging pathogen arises. The 2019 Pandemic and All-Hazards Preparedness and Advancing Innovation Act (PAHPAIA) included clear authorities for ASPR and BARDA related to strategic innovation in countermeasures for emerging infectious diseases, especially through support of novel platform technologies and manufacturing advancements. The PHEMCE Multi-Year Budget has long highlighted the need for dedicated emerging infectious disease funding, but neither Congress nor multiple Administrations have called for annual investments to better address this critical need. Funding during a crisis is often too late, as development of drugs, vaccines, diagnostics, and platform technologies takes time. Even with accelerated timelines during the COVID-19 pandemic, biotechnology innovations took the better part of a year to bring to FDA authorization. As COVID-19 demonstrated, that delay risks lives and causes trillions of dollars in losses to our economy -- considerably more than any upfront investments in these MCMs and rapid response capabilities.

Establishing flexible partnerships with industry, particularly those with established vaccine, therapeutic, and diagnostic platforms, to then work on developing MCMs for a pre-determined set of emerging infectious diseases and families of viruses that have pandemic or even regional outbreak potential, will shorten the development timelines for the next outbreak or pandemic. When an outbreak of a novel pathogen occurs, companies can then pivot to applying that platform to the novel pathogen.

Congress should specifically authorize funding within BARDA to allow for investments in numerous platforms (such as mRNA, protein subunit vaccines, 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 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, including the SNS, to ensure the U.S. can meet a surge in demand when outbreaks occur.

Additionally, Congress should work with FDA to clarify the regulatory mechanisms by which platforms can be authorized or approved in a timely manner for the next pathogen. Platforms that are tested and proven for a certain pathogen hold the promise of potentially shortening timelines for other pathogens, but FDA’s thinking about how they are viewing regulatory considerations for the base platform in addition to review and approval for specific products could help spur further innovation in novel technologies.

Investment in Novel Antivirals and Therapeutics

Investments in novel mechanisms for developing antivirals as well as treatments for the secondary consequences of infections can make future public health emergency responses more efficient and potentially faster. Almost 20% of the therapeutics tested against SARS-CoV-2 were repurposed from other fields and served as a model for not only quickly understanding the virus but also for directing the development of novel clinical products designed specifically to counter the unique nature of the virus.

BIO is encouraged by important programs like the Antivirals Program for Pandemics and the University of North Carolina Rapidly Emerging Antiviral Drug Development Initiative (READDI). These programs will help invest in new antiviral technologies through partnerships between government, academic, and industry scientific leaders. These programs must be accompanied by funding at BARDA for later stage development and manufacturing support for the most promising technologies, especially those that could be applied to both commercial and pandemic pathogens.

While there is a need for more R&D in versatile products that can address an array of threats, such as antivirals, the government must continue to stockpile and invest in MCMs for *specific* CBRN and biologic threats so that the nation is prepared for all possible predictable scenarios. Novel therapeutics for the treatment of the severe consequences of a serious infection should be supported and developed as well. Many of these products developed during the COVID-19 pandemic may be effective for treating the same or similar consequences of other respiratory illnesses, like a bad influenza season. BARDA and the SNS must balance their investment between specific countermeasures and versatile ones to fully prepare for any future threat.



Additionally, investments in novel and more accessible delivery systems for MCMs can improve the emergency response of the nation and provide better outcomes for patients. Less invasive MCMs and easier delivery mechanisms improve access for Americans, especially in underserved or rural communities where, for example, access to infusion centers may be difficult to reach.

Pandemic Influenza Strategy

Pandemic influenza remains as likely a threat as it has ever been, and investments through BARDA, NIH, and the CDC are critical to preparing the nation and the world for a pandemic influenza event. The development and manufacturing of influenza vaccines, therapeutics, and diagnostics by industry is dependent on federal funding to support the scale and scope of U.S. government requirements. There is no commercial market for pandemic influenza 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. Further 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 Executive Order with respect to preventing the spread of influenza viruses and protecting the United States from future pandemics.

Antimicrobial Resistance (AMR) as a National Security Threat

Antimicrobial resistance (AMR) represents a major public health and national security threat. The CDC estimates almost 3 million Americans suffer from AMR-relevant infections annually, with over 48,000 deaths resulting from those infections. As the COVID-19 pandemic continues, a sizable minority of patients are suffering from secondary infections, with the CDC identifying resistant secondary infection outbreaks in COVID-19 units. This reinforces the urgent need for access to effective antimicrobial products as a part of our pandemic preparedness and response.

A key component of addressing AMR is to address the market challenges that have caused a deterioration of the antimicrobial medicines pipeline. The Government Accountability Office (GAO)’s 2019 “Antibiotic Resistance Report” concluded that pull incentives as well as reimbursement reform are needed to ensure the nation has the AMR medicines it needs. While BARDA’s CARB-X program makes investments to help support R&D, HHS has indicated it does not have the authority to implement the policies to reform these market challenges. However, Congress has put forward two pieces of legislation, the Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act of 2021, which address reimbursement barriers to patient access, as well as The Pioneering



Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act, which creates a sustainable return on successful R&D investments into AMR. BIO believes both policies are key steps to address the market challenges of AMR and should be included in any pandemic preparedness package.

MCM Marketplace and SNS Investments

For many MCMs, the SNS is the only market. Industry partners have invested in these technologies in part due to the guarantee that there is a sustained government market. In order for the SNS to be properly prepared for the next pandemic, it must be fully funded. For the last ten years, funding of the SNS has been flat while new FDA approved MCMs have been added to the Stockpile. Though the President's FY 22 budget and the draft budget in the House do propose an increase in funding, it still lags behind the amount recommended by the professional judgment in the PHEMCE Multi-Year Budget. 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. Adequate, sustainable funding for the SNS keeps the MCM manufacturers in the countermeasure space, allows for companies to properly plan for long-term development, and propels competition and innovation.

Additionally, ASPR and BARDA play a critical role in managing the lifecycle of an MCM as the entities responsible for late-stage countermeasure development and procurement. When funded effectively, they facilitate the transition of every medical countermeasure from BioShield to sustainable procurement by the SNS, which is vital for the continued health of the MCM marketplace.

MCM Priority Review Voucher (PRV)

BIO is supportive of the Medical Countermeasure PRV program created by the 21st Century Cures Act and sees the program as an important incentive for the research and development of medical countermeasures. However, the current five-year sunset of the program will likely offset any incentive that the program offers. The program should be extended through the removal of the sunset.

Clinical Trials for Pandemic Response

During the COVID-19 pandemic, the NIH established the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) program, which is managed by the Foundation for the National Institutes of Health (FNIH) and includes BARDA, the CDC, FDA, DOD, the Department of Veterans Affairs (VA), "The Operation" (formerly known as Operation Warp Speed), the European Medicines Agency (EMA), and representatives from academia, philanthropic organizations, and numerous biopharmaceutical companies.



This public-private partnership seeks to develop a coordinated research strategy for prioritizing and speeding development of the most promising treatments and vaccines. The problem that it sought to address was that there were numerous products in development, all competing for patients to participate in clinical studies. ACTIV worked to coordinate and streamline processes to make the best use of biomedical research resources and testing of preclinical and clinical compounds. It also worked to prioritize the most promising candidates and move them into clinical trials in a way that was safe and efficient.

This coordination across agencies and with industry led to many of the successful products, especially the therapeutics, being used today to combat the pandemic. The fast-tracking framework gave needed guidance to industry, led to the development and use of master protocols, and also expedited the trials process while maintain the highest standards of safety and oversight.

Setting up and maintaining a permanent structure for a clinical trial framework to rapidly evaluate products for emergency situations is the best way to rapidly respond to emerging health threats. NIH, FDA and BARDA should lead, and coordinate with international partners (e.g., the Coalition for Epidemic Preparedness Innovations (CEPI), the Foundation for Innovative New Diagnostics (FIND), European Health Emergency Preparedness and Response Authority (HERA)), in the identification of priority pathogens and the creation of a global research agenda to accelerate the development of therapeutics, vaccines, and diagnostics against emerging infectious diseases. There is no reason to disassemble or abandon this successful program, only to have to rebuild it again sometime in the future. An ACTIV-like program as a long-term part of the pandemic preparedness infrastructure will ensure the fastest, safest, and best-planned pathways to vaccines, treatments and diagnostics in the future.

Also, diversity in clinical trials was an important aspect of the COVID-19 response and must be prioritized going forward. Prioritizing diversity in trials not only leads to better data generation and more effective outcomes, but it also strengthens the public confidence in the products across the many groups represented in the trials.

Strengthen and Clarify the Emergency Use Authorization (EUA) Process

The EUA process functioned largely as designed during the COVID-19 pandemic. Since going through the process in a pandemic setting, it may be of value to set up an emergency response framework to more rapidly get decisions made by FDA, NIH, CDC, and/or the Advisory Committee on Immunization Practices (ACIP). Expedient communication with industry and stakeholders is paramount to an effective EUA process. Making the process standardized and providing as much transparency to the public as possible will ensure a successful response in the future and help to combat vaccine hesitancy by helping to ensure the American people understand the safety, effectiveness,



and quality of any vaccines and therapeutics that receive EUA. This should be coordinated with promotional outreach efforts for EUA products that could help with the uptake or use of vaccines and therapeutics to directly combat misinformation.

However, the EUA process proved to be more complex and challenging in terms of providing requirements and authorization to a number of manufacturing facilities – even with a significant, frequent, and sometimes embedded presence from the FDA as well as Operation Warp Speed representatives from HHS and DOD.

Health Defense Operations (HDO) Budget Designation

Congress should authorize an HDO budget designation for a narrow set of programs, projects, and activities critical to our nation’s health security. The HDO designation would exempt certain programs from statutory (and deemed) budget caps to ensure Congress is able to appropriate sufficient sums to protect our national health security. In order to understand the true need of agencies, Congress should require agencies to provide a bypass professional judgment budget that is not constrained by spending caps.

Public Health Infrastructure

U.S. Surveillance Systems

As our nation’s public health agency, CDC is the lead for viral surveillance. 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, genomic sequencing, 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.

We must remain vigilant against other infectious diseases during the COVID-19 pandemic by increasing surveillance of seasonal and pandemic influenza and other novel viruses and bacteria.

To improve our understanding of emerging infectious diseases in the U.S., Congress should improve CDC surveillance by expanding the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Vector-Borne Diseases’ ArboNet system to enhance active data collection and analysis of vector-borne diseases, within our borders or from returning travelers into the U.S. and enhance collection of information on geographic and behavioral risk factors. In addition, Congress should ensure adequate funds are authorized for the CDC for the collection, sequencing, and analysis of viruses with outbreak or pandemic potential and improve overall data collection by directing the



CDC to request that States and territories include serious vector-borne diseases, as “reportable” diseases.

Data Generation

Over the course of the COVID-19 pandemic, ASPR worked closely with hospitals, public health departments, and other organizations to distribute therapeutics. However, the data systems used to track the distribution, availability, and use of COVID-19 medicines were not robust enough to help industry truly understand where, how, and in which populations federally-purchased doses of vaccines and therapeutics were being utilized.

HHS should invest in more robust systems that capture complex and important data on the location, utilization, and patient demographics for all MCMs.

Immunization Information Systems

Our national public health infrastructure is not only vital in “normal” times, it is the backbone of our pandemic response and recovery system. Investing in this infrastructure by increasing support for state, local, and territorial health departments and state data systems, like immunization registries, can help track immunization uptake, ensure individuals receive all of their necessary doses, and help restore our routine immunization rates. Taking action here will also enhance our ability to respond better to outbreaks of vaccine-preventable diseases as well responses to future pandemics.

One way that Congress can support public health is by strengthening the functionality and interoperability of state immunization information systems (IIS) by including H.R. 550, the “Immunization Infrastructure Modernization Act.” Immunization information systems 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. IIS are managed at the state level, creating a patchwork of these systems’ functionality across the country. Having immunization data systems that are able to 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 is essential to COVID-19 vaccine efforts, as well as routine vaccination efforts.

Strengthen the Adult Immunization Program

The COVID pandemic and mass vaccination efforts has driven substantial immunization infrastructure investments at the state and local level that includes systems, provider



recruitment and developing relationships and partnerships with community-based organizations that supports the diverse needs of adult populations. Adult immunization infrastructure improvements and investments in the CDC Immunization Program made during the pandemic must be sustained for routine vaccination beyond COVID-19. It is vital for public health and pandemic preparedness that adult immunization infrastructure remains a priority over the long-term if we are going to have a life course approach to immunization. This infrastructure is also critical to replicating the success of high childhood immunization rates for the adult population. It is important that communities can get vaccines to where people are, whether it's through a community provider, pharmacy, health care center, senior center, or through a mobile van that can go to remote areas or provide vaccine services to disabled and homebound individuals. This capability is essential not only during a pandemic, but also for routine immunizations, such as annual flu vaccine campaigns. Having a reliable immunization network for adults will also ensure that this form of preventive health is available those who otherwise would not be able to afford it.

Conclusion

Thank you for considering BIO's recommendations on pandemic preparedness. BIO, along with the rest of the country, learned a lot from the experience of COVID-19, and we hope that our insights shared here can help prepare us better for the next pandemic. BIO and our member companies are committed to working with the HELP Committee as it drafts legislation on these issues and would be happy to serve a resource. Thank you again for the opportunity to provide testimony for today's hearing.