



February 1, 2018

The Honorable Susan Brooks
United States House of Representatives
1030 Longworth House Office Building
Washington, DC 20515

The Honorable Anna Eshoo
United States House of Representatives
231 Cannon House Office Building
Washington, DC 20515

RE: Comments on PAHPA draft, g:\VHLC\112117\112117.193.xml, November 21, 2017

Dear Representatives Brooks and Eshoo:

The Infectious Diseases Society of America (IDSA) and the Pediatric Infectious Diseases Society (PIDS) greatly appreciate the opportunity to offer comments on draft legislation to reauthorize the Pandemic and All Hazards Preparedness Act (PAHPA). The programs and authorities contained within PAHPA provide essential leadership and resources for communities and health care facilities to prepare for and respond to public health threats as well as critical support for the research and development of life-saving medical countermeasures, including vaccines, diagnostics, and antimicrobial drugs.

IDSA represents over 11,000 infectious diseases physicians and scientists, and PIDS represents about 1,100 pediatric ID physicians. Many of our members work on the frontlines of public health emergencies, including bioterror attacks, outbreaks, and natural disasters such as hurricanes that carry significant infectious diseases risks. We support swift congressional action to reauthorize sufficient resources to safeguard our nation's health. We are pleased to offer specific comments on the draft reauthorization bill and recommend two new provisions we urge you to consider: 1) to incent antibiotic R&D, and 2) to provide loan repayment for people entering the public health preparedness and response workforce. We look forward to an ongoing dialogue as you continue working on these important issues.

Sec. 2(a) Public Health Emergencies

IDSA and PIDS strongly support the establishment of a public health emergency response fund, although we have concerns with the specific approach included in the draft legislation. Over the last few years, this country has repeatedly confronted public health emergencies that required swift responses. However, federal agencies experience significant delays in receiving resources necessary to respond. For example, despite bipartisan recognition of the need to address the Zika virus outbreak, Congress took nearly eight months to provide funding.

IDSA and PIDS believe that a public health emergency response fund should enable federal agencies to move forward with sufficient initial reactions to contain and to track the spread of infections, to treat infected individuals, and to launch necessary research for vaccines, diagnostics, and therapeutics. We believe this provision could be strengthened by including a mechanism for the rapid distribution of funding during an emergency. Funding could be triggered by a section 319 PHSA public health emergency declaration by the Secretary of Health and Human Services (HHS), activation of the Centers for Disease Control and Prevention (CDC)

Emergency Operations Center, or a declaration of a public health emergency by the World Health Organization (WHO).

IDSA and PIDS are concerned that the draft legislation does not establish a new source of funding for rapid responses to public health emergencies, but instead authorizes the transfer of funds from existing programs during a public health emergency. In our view, resources to respond to emergencies must not come at the expense of other essential public health activities. Emergency responses are just one sector of the many critical duties performed by our public health system. Current funding of federal, state and local public health agencies protects the health of U.S. citizens through many mechanisms. Examples include providing surveillance of antimicrobial resistance, tracking foodborne illnesses and other infectious diseases, vaccine promotion, screening for transmissible diseases such as HIV, hepatitis C, and tuberculosis. Public health budgets are already stretched. The CDC core budget declined by \$580 million from 2010 to 2016 adjusted for inflation. We understand that there are significant pressures placed upon the federal budget, and we appreciate your mindfulness regarding new federal spending. However, given the central role of public health in securing the safety of Americans, we urge you to advance a public health emergency response fund that does not divert resources from existing public health priorities.

Sec. 2(b) Improving State and Local Public Health Security

Local and state public health agencies provide the initial responses to infectious disease outbreaks that occur every year in this country. The year-long 2017-2018 hepatitis A outbreak in San Diego caused over 500 illnesses and 20 deaths locally and triggered outbreaks in other parts of California, Arizona, Utah, Michigan, and Kentucky. Outbreaks can only be contained by case identification and epidemiologic tracking, rapid laboratory testing, public communications about threats and providing advice on how individuals can protect themselves, such as offering vaccinations to those at risk. State and local health departments must be adequately funded to perform these functions and be ready daily to assure a rapid, effective first response.

The 2014-2015 Legionella outbreak in Flint, Michigan demonstrates what happens when delayed health department responses occur due to diminished resources. From June 2014 to November 2015, at least 87 county residents developed Legionnaires' disease, and ten died. This stands in comparison to the 6 to 13 cases annually in the four preceding years. Adequate resources, including expert staff, are needed to rapidly identify the causes of outbreaks and take swift actions to limit the spread of infection. States and communities are facing severe threats including influenza, Zika, and the consequences of infectious diseases arising from hurricanes, floods, and other natural disasters.

Funding authorized by this provision supports laboratory response networks in state and local health departments that are responsible for investigation of suspicious specimens. When hospitals encounter an organism that may be an agent of bioterrorism, such as plague, anthrax, smallpox, or tularemia, they send samples to these specialized laboratories for identification. In addition, all white powder testing is performed at these laboratories under the direction of the Federal Bureau of Investigation (FBI). PAHPA funding enables laboratories to test these select agents.

This provision authorizes funding to train public health experts to respond to communicable disease events. IDSA and PIDS appreciate that the draft bill reauthorizes this provision at the 2017 appropriated level of \$666.6 million, rather than the currently authorized level of \$641.9 million, in part recognizing that community needs have grown. We urge you to consider reauthorizing this provision at the level of the 2006 PAHPA bill, \$824 million.

Sec. 2(c) Partnerships for State and Regional Hospital Preparedness to Improve Surge Capacity

Federal funding to support hospital preparedness and response capabilities is essential. Hospitals must have the workforce and the resources to care for patients during public health emergencies. During such crises, hospitals may face not only their patients from communities they typically serve but also displaced patients from outside areas where healthcare facilities are over capacity or damaged by the emergencies. Hospital resources for infection prevention and control are essential, not only when the emergency is an outbreak. Any disaster event that results in significant injuries such as wounds or burns can present serious risks for infection.

Currently, many hospitals are overwhelmed due to the 2017-2018 seasonal influenza season. In advance of influenza season, hospitals and health departments developed and implemented preparedness plans to help contain the spread of infection and support appropriate treatment for infected patients. Throughout the country, hospitals are collaborating with health departments to coordinate influenza responses and share best practices. Without PAHPA funding, much of this planning and coordination would not be possible, and our responses to influenza would be less robust. IDSA and PIDS are concerned that the draft bill would authorize only \$227.2 million for hospital preparedness, a significant cut from the current authorized level of \$347.7 million and the 2017 appropriated level of \$254 million. We urge reauthorization at the 2006 authorized level of \$474 million.

As many hospitals routinely operate at near capacity for economic survival, this inherently limits the identification and staffing of additional beds during a time of national crisis. Additional planning and resources must be directed to build contingencies to meet surge capacity needs.

Sec. 2(e) Strategic National Stockpile and Security Countermeasure Procurements

IDSA and PIDS support your bill's proposed increase in authorized funding for the Strategic National Stockpile and security countermeasure procurements. These funds are essential to ensure that medical countermeasures (such as vaccines, diagnostics, and therapeutics) are available to deploy during a public health emergency.

Sec.2 (f) Biomedical Advanced Research and Development Authority (BARDA)

IDSA and PIDS strongly support a robust reauthorization of BARDA. We applaud the vital role BARDA has played advancing research and development of medical countermeasures. Antibiotic resistance is a severe threat to our security and therefore should be a top priority for PAHPA reauthorization. As you revisit BARDA's authority, IDSA and PIDS strongly encourage the inclusion of new incentives for antibiotic R&D.

Antibiotic Resistance and Antibiotic Research and Development

We are particularly supportive of BARDA's broad spectrum antimicrobials program. This led to a crucial victory in 2017 when the first BARDA-supported antibiotic—Vabomere™ (meropenem/vaborbactam) from The Medicines Company—received Food and Drug Administration (FDA) approval. As you may know, most large pharmaceutical companies have retreated from antibiotic research and development (R&D). IDSA greatly appreciates the longstanding leadership by the Energy and Commerce Committee on this issue. In 2012, the Generating Antibiotic Incentives Now (GAIN) Act, passed as part of the FDA Safety and Innovation Act (FDASIA). It provided an important first step to spur antibiotic R&D. In 2016, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act passed as part of the 21st Century Cures Act. This act reduced regulatory burdens to facilitate antibiotic R&D. While these efforts have yielded modest market improvements, the antibiotic pipeline remains fragile and insufficient to meet current needs, let alone needs that can arise during an emergency.

Antibiotic resistance is a serious threat to our security and should be a priority for PAHPA reauthorization. If an antibiotic resistant pathogen were weaponized and used against the U.S. population, we are ill-prepared to deal with such a crisis. Further, antibiotic resistance can significantly complicate responses to many other emergencies. For example, significant wounds and burns resulting from a terrorist attack can quickly become infected. Increasing rates of antibiotic resistance and inadequate antibiotic innovation leave us with frighteningly few options and in some cases, no available treatment for these highly resistant infections. As another example, many influenza deaths are attributable to secondary bacterial pneumonia. Treatment of bacterial pneumonia has become increasingly challenging due to antibiotic resistance and our limited antibiotic arsenal.

Recommendation for New Antibiotic Market Entry Incentive

IDSA and PIDS strongly encourage you to include a new incentive for antibiotic R&D in the PAHPA reauthorization bill. While BARDA currently supports antibiotic R&D by providing funds for costly clinical trials, private investments in antibiotic R&D are still needed. Unfortunately, because antibiotics are typically taken for a short duration and must be used judiciously to protect their utility, high sales volume of any new antimicrobial drug is extremely unlikely and in fact would be counter to goals of restraining the inappropriate use of last-resort agents. Therefore, industry has limited or no opportunity to earn a return on investment in antibiotic R&D, making antibiotic R&D unattractive for many companies. As an example, The Medicines Company announced it would no longer pursue antibiotic R&D, just shortly after the launch of its new antibiotic Vabomere last year.

IDSA and PIDS urge you to provide a new targeted antibiotic incentive in PAHPA reauthorization that will provide for a return on industry investment. Specifically, we propose a substantial market entry reward for new antibiotics that treat serious or life-threatening resistant infections that address unmet medical needs. Companies that receive such rewards should be required to commit to antimicrobial stewardship goals to slow the emergence of antimicrobial resistance to the new drug. Pharmaceutical companies may well be open to such options as witnessed by the TB Alliance-supported effort that helped produce bedaquiline by Janssen (Johnson and Johnson) for drug-resistant tuberculosis

Pandemic Influenza Program

IDSA and PIDS recognize the ominous threat of pandemic influenza. We commend the inclusion of a new provision in the draft bill directing BARDA to establish a pandemic influenza program. For your consideration, we offer suggested edits to the text of this provision to maximize the potential for innovation. In particular, we stress the fundamental need to enhance vaccine manufacturing capacity and the ability to rapidly deliver influenza vaccine in a pandemic. Please see suggested additional language for this provision (p. 8, lines 10-23) below in red:

- “(1) supports research and development activities for qualified pandemic or epidemic products (as defined in section 319F–3(i)), **including improved antiviral drugs and vaccines, and** by developing innovative technologies to enhance rapid response to threats relating to pandemic influenza;
- “(2) ensures readiness to respond to pandemic influenza **threats by improving the ability to rapidly produce vaccine in a pandemic, including improving the capacity for rapid manufacture of vaccines,** supporting the development and manufacturing of influenza virus seeds, clinical trial lots, and stockpiles of novel influenza strains; and
- “(3) sustains and replenishes ~~pandemic~~ **stockpiles of vaccines for potential pandemic strains, including stockpiles** of bulk antigen and adjuvant material, including annually testing the potency and shelf-life potential of all existing pandemic stockpiles held by the Department of Health and Human Services.

Emerging Infectious Disease Program

IDSA and PIDS strongly support the provision in the draft bill directing BARDA to establish a program supporting research and development for emerging infectious diseases. As emerging infectious diseases present a continuously evolving threat, we must remain vigilant. Waiting until a serious outbreak occurs to initiate research and development of vaccines, diagnostics, and therapeutics dramatically hampers our ability to respond on a timely basis that leads to a clear cost of lives lost and survivors maimed. **We recommend that your legislation direct BARDA to consult with infectious diseases experts to help determine which emerging infectious diseases should have priority. We further recommend that this program consider both domestic and global infectious diseases threats.** Since infectious diseases do not respect national borders, threats in other parts of the world can quickly become threats in the U.S. and our national security. Stopping a threat abroad is often the most effective way to keep a fatal pathogen from reaching our shores.

Sec. 2(i) National Disaster Medical System

IDSA and PIDS recognize the importance of the National Disaster Medical System that sends teams of medical personnel to support community responses to public health emergencies when local health care professionals are overwhelmed. The NDMS fills essential gaps, helping to ensure that all individuals in need during a public health emergency can receive care. IDSA and PIDS are concerned that the draft reauthorization bill would reauthorize this program at only \$49.8 million, and we urge the reauthorization level instead be at no less than the current authorized level of \$52.7 million.

Sec. 2(j) Volunteer Medical Reserve Corps

IDSA and PIDS recognize the importance of the Volunteer Medical Reserve Corps, a group of medical and public health personnel whom work to strengthen public health, improve emergency response capabilities and build community resiliency. Corps volunteers have supported vaccination clinics, emergency preparedness and response training, and disaster medical support. IDSA and PIDS are concerned that the draft reauthorization bill would reauthorize this program at only \$6 million, and we urge reauthorization at the currently authorized \$11.2 million or greater. Such funding will ensure that the Corps maintains the ability to deploy volunteers as needed to support preparedness and response efforts.

National Preparedness and Response Science Board

IDSA and PIDS are concerned that the draft legislation does not reauthorize the National Preparedness and Response Science Board (formerly the National Biodefense Science Board), as established by PAHPA in 2006 and reauthorized and renamed in 2013. We believe this body provides valuable expertise and guidance for the Assistant Secretary of Preparedness and Response. A mechanism that provides regular input from non-government experts is essential for informing our preparedness and response policies. We are not recommending any changes to the statutory authority of the Board, only that Congress not allow its authority to expire.

New Recommendation for Additional Provision to Strengthen the Public Health Workforce: Reinstating and Improving Loan Repayment Opportunities

IDSA and PIDS urge you to take an additional step toward securing our public health workforce by providing loan repayments for the CDC Epidemic Intelligence Service (EIS) officers that will make this career path more financially feasible for new physicians

A successful response to a public health emergency depends upon skilled personnel. A sufficient number of appropriately trained individuals is necessary to ensure a ready response, including surveillance, research, and patient care. Infectious diseases physicians are a central component of the public health preparedness and response workforce. Their unique training and experiences provide superb abilities to prevent, detect, track, contain, manage and treat infectious diseases in a variety of community and healthcare settings.

Unfortunately, fewer young physicians now pursue infectious diseases (ID) as a specialty. By 2016, infectious disease fellowship training programs experienced a 21.6% decline in applicants over the prior five years. IDSA surveyed internal medicine residents during this time and found that many expressed a strong interest in infectious diseases, yet few elected ID training. The most common reason for this decision was financial. The average salary of an infectious diseases physician (according to the IDSA 2017 compensation survey) is \$100,000 less than the median salary of a specialty physician (according to the 2017 Medscape Physician Compensation Report). For ID physicians working in public health, there is an additional \$30,000 gap. Pediatric ID physicians have an even greater compensation disparity with other subspecialty pediatricians. One study considered the cost of training, the impact of delayed time to a first faculty position, and the age-specific net incomes--finding that pediatric ID specialists are the lowest earners among pediatric subspecialists. In fact, the study found that a graduating third

year pediatric resident would need a lump sum payment of \$870,000 to make pediatric ID training financially neutral compared to a career as a general pediatrician. According to the American Association of Medical Colleges, average medical school debt now stands at approximately \$200,000, placing tremendous pressure on young physicians to pursue more lucrative specialties.

As fewer physicians choose the infectious diseases specialty, even fewer physicians are attracted to careers in public health, all in large part due to financial reasons. The CDC Epidemic Intelligence Service (EIS) is a two-year fellowship program in which participants receive on-the-job training to respond to infectious disease outbreaks and other public health emergencies. EIS is the state-of-the-art training ground for many of our nation's public health leaders. However, EIS continues to experience a significant decline in physician applicants, as considerable medical school debt drives many physicians to higher paying opportunities.

CDC had statutory authority, under section 317S of the Public Health Service Act (42 USC 247b-7) for establishing a student loan repayment program from FY 1995 to FY 2002. Although a program was authorized, funds were not appropriated and therefore the authority has never been used. Beyond the appropriation issue, this now-expired authorization required a longer three-year service agreement than the EIS fellowship itself (3 years vs. 2 years), meaning that an individual taking part in two-year programs such as the CDC EIS fellowship would not be eligible for loan repayment due to the three-year service requirement.

We propose modifying the CDC student loan repayment statutory provision by reducing the three-year service agreement to two years as well as reauthorizing and funding the modified provision. The reduction in the service year agreement will allow public health trainees in the CDC two-year fellowships, such as EIS, to be eligible for student loan repayment. This reauthorization and service-year modification will allow CDC to effectively recruit physicians for critical public health preparedness and response roles.

IDSA and PIDS thank you for your leadership and commitment to public health emergency preparedness and response. Protecting the public from threats such as bioterrorism and infectious diseases outbreaks is a critical federal government responsibility. IDSA and PIDS stand ready to assist you in reauthorization of PAHPA. We appreciate your consideration of our recommendations. If you have any questions or we can be of any further help, please do not hesitate to contact Amanda Jezek, IDSA's Senior Vice President for Public Policy and Government Relations at 703-740-4790 or ajezek@idsociety.org.

Sincerely,



Paul G. Auwaerter, MD, MBA, FIDSA
President, IDSA



Paul Spearman, MD, FPIDS
President, PIDS