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IDSA
Infectious Diseases Society of America

June 5, 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
241 Cannon House Office Building
Washington, DC 20515

RE: Comments on Discussion Draft (g:\VHLC\053118\053118.252.xml), 5/31/18

Dear Representatives Brooks and Eshoo:

The Infectious Diseases Society of America (IDSA) thanks you for your leadership and greatly appreciates the opportunity to offer comments on your discussion draft for the Pandemic and All Hazards Preparedness Reauthorization Act of 2018 (PAHPRA). The programs and authorities contained within Pandemic All Hazards Preparedness Act (PAHPA) reauthorization 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. 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 and safety. We are pleased to offer specific comments on the draft reauthorization bill and urge you to consider two additional provisions as you work toward introduction of the legislation: 1) to incent antibiotic research and development (R&D) for unmet needs, and 2) to provide loan repayment to encourage health professionals to enter the public health preparedness and response workforce. We look forward to an ongoing dialogue as you continue working on these important issues.

Sec. 104 National Disaster Medical System

IDSA recognizes the importance of the National Disaster Medical System (NDMS) 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 appreciates that the discussion draft would authorize a $4.7 million per year increase for this program.

Sec. 105 Volunteer Medical Reserve Corps

IDSA recognizes the importance of the Volunteer Medical Reserve Corps -- a group of medical and public health personnel who work to strengthen public health,

improve emergency response capabilities, and build community resiliency. Corps volunteers have supported vaccination clinics, emergency preparedness and response training, as well as disaster medical support. IDSA is concerned that the draft reauthorization bill would reauthorize this program at only $6 million each year, and we urge reauthorization at the currently authorized level of $11.2 million each year or greater. Such funding will ensure that the Corps maintains the ability to deploy volunteers as needed to support preparedness and response efforts.

Sec. 201 Public Health Emergencies

IDSA strongly supports the public health emergency response fund, but has concerns that the fund has not been adequately financed. 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, additional funding took nearly eight months.

IDSA believes that a public health emergency response fund should enable federal agencies to rapidly move forward with sufficient initial efforts to contain and track the spread of infections, to treat infected individuals, as well as to launch necessary research for vaccines, diagnostics, and therapeutics.

Current law authorizes “such sums as may be necessary”, but Congress has not maintained appropriations to meet the needs of public health emergencies. IDSA is concerned that the discussion draft authorizes the transfer of funds from existing programs, rather than establishing a new source of funding for rapid responses to public health emergencies. We are concerned that the transfer mechanism would either fail to provide sufficient resources to jumpstart an emergency response (if too few funds were transferred) or would come at the expense of other existing public health activities (if too many funds were transferred). We appreciate that the discussion draft limits discretionary fund transfers to no more than one percent. However, we caution that one percent can greatly impact existing programs with lean budgets. 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 is critical to protect 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 transmissable diseases (such as HIV, hepatitis C, and tuberculosis) among others. Public health budgets are already stretched. 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 funding for the public health emergency response fund that does not divert resources from existing public health priorities.

Sec. 202 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 by 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 continue to face severe—and, at times, unexpected--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). PAHPRA funding enables laboratories to test these select agents.

This provision also 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 $670 million, rather than the currently authorized level of $641.9 million, in part recognizing that community needs have grown. Noting that the 2006 PAHPA bill authorized $824 million, we urge you to consider providing a higher authorization for these important activities.

Sec. 203 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.

Many hospitals were 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 collaborate with health departments to coordinate influenza responses and share best practices. Without PAHPRA 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 discussion draft 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 note that the 2006 authorized level was $474 million and urge you to consider increasing the authorization for these activities.

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. 204 Revitalizing the Centers for Disease Control and Prevention

IDSA supports reauthorization of this provision and greatly appreciates the $23.5 million increase in authorized funding to support efforts including improving national communications regarding public health emergencies, modernizing public health situational awareness and biosurveillance and enhancing telehealth capabilities to support emergency responses.

Sec. 301 Strategic National Stockpile and Security Countermeasure Procurements

IDSA supports 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. 302 Biomedical Advanced Research and Development Authority (BARDA)

IDSA strongly supports 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 strongly encourages the inclusion of new incentives for antibiotic R&D for unmet needs.

<u>Antibiotic Resistance and Antibiotic Research and Development</u>
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 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 law 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 strongly encourages 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 time 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 urges 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.

At a minimum, we urge you to include the following language from **Section 404 of S. 2582, the Pandemic and All Hazards Preparedness and Advancing Innovation (PAHPAI) Act**, as approved by the Senate Health, Education, Labor and Pensions Committee and authorize explicit new funding for BARDA to implement an initiative aimed at antimicrobial resistance, similar to the draft bill's approach to pandemic influenza and emerging infectious diseases programs at BARDA:

> SEC. 404. PREPARING FOR PANDEMIC INFLUENZA, ANTIMICROBIAL RESISTANCE, AND OTHER SIGNIFICANT THREATS.
>
> Section 319L(c)(4) (247d–7e(c)(4)) is amended by adding at the end the following:
>
> "(F) STRATEGIC INITIATIVES.—The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs, supporting innovative candidate products in preclinical and clinical development, to address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of, countermeasures and products, as applicable, to address areas including—
>
> "(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious disease, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.".

Pandemic Influenza Program (p. 17-18)

IDSA recognizes 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 and particularly appreciate the authorization of new funding to support this important effort. 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. 18, lines 8-21) 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 (pp. 18-20)

IDSA strongly supports the provision in the draft bill directing BARDA to establish a program supporting research and development for emerging infectious diseases, and we particularly appreciate the authorization of new funding to support this important effort. As emerging infectious diseases present a continuously evolving threat, we must remain vigilant. Waiting until a serious outbreak occurs to to initiate research and development of vaccines, diagnostics, and therapeutics dramatically hampers our ability to respond in a timely manner that leads to a clear cost of lives lost and potentially 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.

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

IDSA urges you to take an additonal step toward securing our public health workforce by providing loan repayment for the CDC Epidemic Intelligence Service (EIS) officers to 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. The CDC’s 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 was established in the 1950s in response to the threat of bioterror during the Korean War. Since then, EIS officers have been on the frontlines of responses to public health emergencies including the September 11, 2001 attacks, anthrax attacks, Ebola, Zika, and the 2017 major hurricanes. 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 versus 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. Below please see the provision with our proposed modifications.

42 U.S. Code § 247b–7 - Loan repayment program

(a) In general

(1) Authority

Subject to paragraph (2), the Secretary may carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct prevention activities, as employees of the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry, in consideration of the Federal Government agreeing to repay, for each year of such service, not more than ~~$35,000~~ $50,000 of the principal and interest of the educational loans of such health professionals.

(2) Limitation

The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

(A) has a substantial amount of educational loans relative to income; and

(B) agrees to serve as an employee, such an Epidemic Intelligence Service Officer, of the Centers for Disease Control and Prevention or the Agency for Toxic Substances and Disease Registry for purposes of paragraph (1) for a period of not less than ~~3~~ 2 years.

(b) Applicability of certain provisions

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of this subchapter, the provisions of such subpart shall, except as inconsistent with subsection (a), apply to the program established in this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated ~~$500,000 for fiscal year 1994, and such sums as may be necessary~~ $1,000,000 for each of the fiscal years ~~1995~~ 2019 through ~~2002~~ 2023.

(d) Availability of appropriations
Amounts appropriated for a fiscal year for contracts under subsection (a) shall remain available until the expiration of the second fiscal year beginning after the fiscal year for which the amounts were appropriated.

IDSA thanks 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 stands 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

Cc: The Honorable Greg Walden
Chairman, U.S. House of Representatives Energy & Commerce Committee

The Honorable Frank Pallone, Jr.
Ranking Member, U.S. House of Representatives Energy & Commerce Committee

The Honorable Michael Burgess, MD
Chairman, Subcommittee on Health, U.S. House of Representatives Energy & Commerce Committee

The Honorable Gene Green
Ranking Member, Subcommittee on Health, U.S. House of Representatives Energy & Commerce Committee