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Infectious Diseases Society of America

May 3, 2018

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United States Senate
455 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Richard Burr
United States Senate
217 Russell Senate Office Building
Washington, DC 20510

RE: Comments on the "Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018" Discussion Draft

Sent electronically to PAHPA2018@help.senate.gov

Dear Chairman Alexander, Ranking Member Murray, Senator Burr, and Senator Casey:

Thank you for your leadership in developing the draft *Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2018 (PAHPAI)*, which reauthorizes and strengthens the Pandemic All-Hazards Preparedness Act (PAHPA). The programs and authorities contained within PAHPA provide essential 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 (R&D) of life-saving medical countermeasures (including vaccines, diagnostics, and antimicrobial drugs).

IDSAs 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 (e.g., 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 the addition of two new provisions: (1) to incent antibiotic R&D further, and (2) to **provide loan repayment** for people entering the public health preparedness and response workforce. We look forward to an ongoing substantive dialogue as you continue working to advance these important issues.

The Honorable Patty Murray
Ranking Member, HELP Committee
United States Senate
154 Russell Senate Office Building
Washington, DC 20510

The Honorable Robert Casey
United States Senate
393 Russell Senate Office Building
Washington, DC 20510

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Request to Add Provisions

Further incent antibiotic R&D to address unmet needs

IDSA strongly encourages you to include a new incentive for antibiotic R&D in the PAHPA reauthorization bill. While the **Biomedical Advanced Research and Development Authority** (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, the 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, BARDA-supported 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 antibiotic-resistant infections and, thereby, 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.

Loan repayment to strengthen the public health workforce

IDSA urges you to take an additional step toward securing our public health workforce by providing loan repayments for the Centers for Disease Control and Prevention (CDC) Epidemic Intelligence Service (EIS) officers. A loan repayment program will assist CDC in recruiting qualified individuals and make a career path in public health more financially feasible for new physicians.

A successful response to a public health emergency depends upon skilled personnel. 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 was created in the 1950's in response to concerns about bioterror linked to the Korean War, and EIS officers have since been integral to responses to public health emergencies including the recent Ebola and Zika outbreaks, the 2017 hurricanes, the September 11, 2001 terrorist attacks, and the 2001 anthrax attacks among others. EIS is *the* state-of-the-art training ground for many of our nation's public health leaders. However, EIS is experiencing a significant decline in physician applicants, as considerable medical school debt drives many physicians to higher paying opportunities.

Statutory authority for the CDC under section 317S of the Public Health Service Act (42 USC 247b-7) establishing a student loan repayment program (authorized from FY 1995 to FY 2002) has lapsed. Although the program was authorized, funds were not appropriated and, therefore, the authority has never been used. Beyond the appropriation issue, this 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, increasing the maximum amount of loan repayment to be consistent with that of NIH and HRSA loan repayment programs (i.e., \$50,000), 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.

Suggested language follows:

SEC. ____ . IMPROVEMENT OF LOAN REPAYMENT PROGRAM.

Section 317E of the Public Health Service Act (42 U.S.C. Sec. 247b-7) is amended—

(a) in subsection (a)(1)

(1) by inserting “, including rapid response to major health threats,” after “conduct prevention activities”; and

(2) by striking “\$35,000” and inserting “\$50,000”;

(b) in subsection (a)(2)(B) by striking “3 years” and inserting “2 years”;

(c) in section (c)

(1) by striking “1994” and inserting “2019”; and

(2) by striking “1995 through 2002” and inserting “2020 through 2023”.

Specific Comments on PAHPAI Discussion Draft

Sec. 101 National Health Security Strategy

Zoonotic disease, food and agriculture

IDSA supports the provision to improve coordination among federal, state, local, and tribal entities to prevent, detect, and respond to outbreaks of plant or animal disease (including zoonotic disease). We greatly appreciate your recognition of the potential impact of plant or animal infectious diseases on human health. A One Health approach is important to provide broad surveillance, prevention and response capabilities across the spectrum of human, animal and environmental health.

Global health security

IDSA strongly supports the provision to assess current or potential health security threats from abroad to inform domestic public health preparedness and response capabilities. Infectious diseases do not respect borders. As we witnessed with recent outbreaks of Ebola and Zika, outbreaks anywhere in the world pose a threat to the U.S. and should be addressed before they reach our shores. Life-threatening antibiotic-resistant bacteria not uncommonly develop first abroad and then reach our shores. While including global health security in the National Health Security Strategy is important, IDSA also is calling for sufficient investment to maintain global health security activities across multiple countries. These efforts are essential to ensure surveillance and laboratory capacities needed to detect emerging health security threats quickly.

Sec 203 Regional public health emergency preparedness and response systems

IDSA appreciates the call in the discussion draft for federal guidelines for regional systems of health care facilities and public health. Such regional systems improve the rapid care of patients and increase medical surge capacity during and in advance of a public health emergency. In particular, we thank you for including individuals with expertise with emerging infectious diseases among those with whom the federal government should consult in developing these guidelines. Infectious diseases physicians often lead hospital bioemergency preparedness programs and are on the frontlines of responses to bioterror attacks, outbreaks and other public health emergencies. Their clinical and programmatic expertise will be important in informing the development of useful guidelines.

Sec 205 Strengthening and supporting the public health emergency [bridge] fund

IDSA strongly supports the availability of a robust public health emergency fund that may be used to facilitate coordination of response activities; accelerate advanced research and development of vaccines, diagnostics and antimicrobial drugs; strengthen biosurveillance capabilities and laboratory capacity; and support initial emergency operations. Given that some public health emergencies are global in nature, we suggest that (2)(A) be edited to reflect the possible need for the U.S. government to coordinate with international entities, such as the World Health Organization or other governments. For example, the language [p. 35, line 22] could be edited to include new text in red:

“(A) facilitate coordination between and among **international**, Federal, State, local, tribal, and territorial entities that the Secretary determines may be affected by a public health emergency, including further supporting programs under section 319C–1 or 319C–2;

Ultimately, the success of this fund will depend upon the availability of actual funding in the event of a public health emergency. We urge you to take any possible steps to ensure that sufficient funding is allocated for this fund, that a mechanism exists to allow for rapid distribution of the funds during a public health emergency, and that a mechanism exists to ensure the funds are replenished.

Sec 305 Reauthorizing the national advisory committee on children and disasters

IDSA thanks you for reauthorizing the National Advisory Committee on Children and Disasters and for including in the advisory committee’s membership individuals with expertise in treating children with infectious diseases. Pediatric infectious diseases physicians possess critical and unique expertise in addressing the needs of children during a public health emergency.

Sec 404 Preparing for pandemic influenza, antimicrobial resistance and other significant threats

IDSA thanks you for authorizing new strategic initiatives to address emerging infectious diseases, pandemic threats, and antibiotic resistance. Antibiotic resistance is a serious threat to our security and should be a priority for BARDA. 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.

While we appreciate the clear signal in the discussion draft that antibiotic resistance is an important component of BARDA's mission, we are concerned that this provision does not provide sufficient direction, detail or new resources to drive the necessary research and development of new antimicrobial drugs to address threats posed by multidrug-resistant organisms.

Authorization of appropriations

We understand that you are still working to determine appropriate authorization of appropriations levels for all of the programs and activities covered in the discussion draft. Given the central importance of PAHPA efforts to our nation's security, we urge you to authorize the highest possible funding levels for all programs included in this legislation. Specifically, we urge you to include a significant funding increase for BARDA to allow BARDA to undertake the newly authorized strategic initiatives, including for antimicrobial resistance, while maintaining current efforts.

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 the 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,

A handwritten signature in black ink, appearing to read "Paul Auwaerter". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

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