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IDSA
Infectious Diseases Society of America

May 21, 2018

The Honorable Lamar Alexander
Chairman, HELP Committee
United States Senate
455 Dirksen Senate Office Building
Washington, DC 20510

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

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

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

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

Thank you for your leadership in introducing S. 2852, the *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. Further, PAHPA provides critical support for the research and development (R&D) 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 (e.g., hurricanes that carry significant infectious diseases risks). **We support PAHPAI's efforts to strengthen our capacity to prepare for and respond to public health emergencies**, and thank you for increasing the authorized levels of appropriations for many of the essential programs in this bill. We also hope to continue working with the Committee on the attached proposals to incent antibiotic R&D, such as a market entry reward, and to provide loan repayment to help the Centers for Disease Control and Prevention (CDC) recruit individuals to train and serve as Epidemic Intelligence Service (EIS) officers. The EIS is a program established in 1951 in response to the threat of biological warfare.

IDSA thanks you for authorizing new strategic initiatives under the Biomedical Advanced Research and Development Authority (BARDA) to address emerging infectious diseases, pandemic threats, and antibiotic resistance and particularly for increasing BARDA's authorization of appropriations to $611.7 million – a nearly $200 million increase over the currently authorized level. Increased funding is essential to ensure that BARDA can meaningfully impact emerging threats while

continuing its equally important current activities. IDSA shares the hopes expressed by other industry and public health stakeholders that we can continue to work together to further expand BARDA's budget in order to meet our medical countermeasure needs.

IDSA strongly supports the availability of a robust public health emergency fund that may be used to facilitate coordination of response activities; accelerate research and development of vaccines, diagnostics and antimicrobial drugs in advance of emergent needs; strengthen biosurveillance capabilities and laboratory capacity; and support initial emergency operations. We greatly appreciate that you modified that provision to include communication with relevant international entities. As we have seen repeatedly through outbreaks of Ebola, Zika, SARS, MERS-CoV and others, infectious diseases do not respect borders, and international coordination of responses are essential to protect our health security and prevent dangerous infectious diseases from reaching our shores.

As noted in our earlier comment letter on the discussion draft of this legislation, IDSA also supports the bill's provisions aimed at global health security as well as outbreaks of plant or animal diseases, including zoonotic diseases. We also support the creation of federal guidelines for regional systems of health care facilities and public health. As leaders of bioemergency preparedness programs at our institutions, our members stand ready to offer their clinical and programmatic expertise to inform the development of these guidelines and regional systems.

Once again, IDSA thanks you for your dedication to our nation's health security and looks forward to continuing to work with you on these important issues.

Sincerely,

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

Attached:
Draft legislative proposal to provide loan repayment to CDC EIS officers
Draft legislative proposal to provide market entry rewards to stimulate antimicrobial R&D

Infectious Diseases Society of America
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Arlington, VA 22209

CDC Loan Repayment Program

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".

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§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, including rapid response to major health threats[i], 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[ii] 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 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[iii] 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) of this section, 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~~2019, and such sums as may be necessary for each of the fiscal years ~~1995~~ 2020 through ~~2002~~2023[iv].

(d) Availability of appropriations

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

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[i] Intended to highlight the EIS program

[ii] Sec. 2002, 21st Century Cures Act (PL 114-255) increased similar authority for NIH from $35,000 to $50,000

[iii] Authority was not previously used because the CDC's EIS program is only 2 years

[iv] Request that authorization dates match PAHPA reauthorization

Working Group on US Market Entry Rewards, Convened by IDSA
Draft Principles 11/3/17
Developed by the Infectious Diseases Society of America, GlaxoSmithKline, Merck, Society of Infectious Diseases Pharmacists, Spero Therapeutics, _____

Note: The proposal below reflects the best current thinking of the above organizations. However, it is still a draft and we welcome the opportunity to work with congressional champions to consider and refine these ideas.

Provide base market entry rewards to eligible antimicrobial products

- Series of milestone payments over a five-year period, beginning after successful registration of a new qualifying antibiotic. Payments should be $500 million-$1 billion over 5 years, front-loaded with higher payments occurring in the earlier years.
- Payments would be administered by BARDA and funded with new sustainable resources to reflect long and risky R&D lifecycles.
- BARDA should have the authority to make additional smaller rewards for further prioritized new indications.
- In order to provide predictable availability of funds, funding for market entry rewards should be derived from a sustainable source that does not require annual appropriations.
- BARDA should be directed to develop a streamlined mechanism to administer market entry rewards rather than relying solely on existing contractual approaches.
- Companies retain all intellectual property.
- Separate funding shall also be made available through BARDA to support the development of antimicrobial susceptibility test devices and other rapid diagnostics that can support stewardship.
- The Secretary shall coordinate with other countries as feasible and appropriate to help promote global investment, in addition to US leadership, in antimicrobial R&D.

Antimicrobial products eligible for the base market entry rewards/milestone payments

- Antimicrobial products to treat a serious or life-threatening infection caused by a pathogen classified as "urgent" or "serious" on the antibiotic resistance threats list, developed by the CDC, would be eligible to receive a market entry reward. The CDC shall be directed to update the existing pathogen list within one year of enactment of market entry reward legislation, and the updated list shall be the first list utilized to determine eligibility for market entry rewards. The CDC shall update the pathogen list at least every two years, or sooner as determined by the Secretary. CDC's process for updating the pathogen (including the initial update) list shall:
    - Include input from relevant expert stakeholders, including clinicians, industry, public health, researchers, and patients
    - Coordinate as appropriate with relevant federal agencies, including NIH, FDA, BARDA, DoD
    - Coordinate as appropriate with relevant international bodies, including the WHO
    - Consider the following factors: all-cause mortality, healthcare and community burden, prevalence of resistance, 10-year trend of resistance, transmissibility, preventability in hospital and community settings, treatability and current pipeline.

- Before removing a pathogen from the list, the CDC shall consider number and utility of new drugs approved for that pathogen; and ensure a sufficient timeline to sunset a pathogen.

Process for determining eligibility for and receipt of base market entry rewards/milestone payments

- At any time from IND to NDA, drug sponsor would seek from FDA for a designation as an eligible antimicrobial product
- There is no limit on how many companies or products may receive designations for an eligible antimicrobial product. The Secretary shall have the discretion to limit the number of market entry rewards per pathogen, considering public health need and novelty of the product.
- Designation can be transferred from one sponsor to another in the case of a product transfer, and BARDA should establish a process that is not onerous on the entities involved.
- As provided in the GAIN Act, designation may be revoked if the Secretary finds that the request for the designation contained an untrue statement of material fact.
- Payments cease if product is withdrawn from US market, if supply is interrupted for more than 6 consecutive months, and/or if the stewardship requirements are not fulfilled for more than 6 consecutive months (but previously made payments will not be clawed back).
- Companies receiving the designation shall make reasonable efforts to study the antibiotic in patients with the targeted organism, including drug-resistant organisms, recognizing that it can be very challenging to enroll patients infected with drug-resistant organisms in clinical trials.
- After one year after the date of enactment, FDA should draft guidance on how to obtain label indication (sNDA) for resistant pathogens – utilizing data sources such as PK/PD, well-validated animal models, and post marketing trials – as traditional guidance pathways are not feasible. After a public comment period, FDA will finalize the draft guidance within six months of the close of the public comment period. (similar language in 21st Century Cures related to regenerative medicine)

Promoting Antibiotic Stewardship

- In order to receive the award, companies agree to the following:
    - Antimicrobial products receiving market entry rewards (and their active ingredients) shall be sold only for human use.
    - Company field sales representatives shall not be incentivized based upon the sales volume of the antimicrobial product.
    - At least 6 months prior to launching the antimicrobial product receiving the market entry reward, company shall appoint a Chief Stewardship Officer to oversee company's stewardship efforts. The Chief Stewardship Officer's duties shall include:
        - Responsibility for developing the vision and strategic direction for the company's AMS efforts, promoting corporate-wide, cross-functional alignment on AMS, driving execution through collaboration, and ensuring all AMS requirements are met

        - Regular interaction with executive leaders to ensure ongoing commitment to AMS efforts
        - Serve as the expert resource responsible for leading scientific and strategic interactions with company stakeholders, external thought leaders, and potential collaborators regarding AMS
        - Serve as the primary global point of contact for the company's AMS efforts
        - Identify and prioritize AMS initiatives to support corporate AMS strategic imperatives in consultation with functional AMS stakeholders
        - Explore opportunities for collaboration with external partners
    - Within 6 months of receiving the first payment, the sponsor must:
        - Develop and implement efforts to educate health care providers about antimicrobial resistance and appropriate use, implement a surveillance program to monitor resistance trends, and report resistance information to the Secretary and health care providers.
        - Track and monitor stewardship activities.
        - Make publicly available annual reports on implementation of stewardship activities.
- Stewardship activities described above should be continued throughout the patent life of the new antimicrobial product.
- When seeking designation, company shall develop and submit to the Secretary of HHS a plan to coordinate with appropriate device manufacturer(s) to support the timely availability of antimicrobial susceptibility test devices and other rapid diagnostics that can guide appropriate use of the new antibiotic. Plan should include making the appropriate drug material available to the diagnostic developers.
- The Secretary shall encourage all healthcare facilities that may utilize antibiotics receiving market entry rewards to establish antibiotic stewardship programs (ASP) that are aligned with the CDC Core Elements and to report antibiotic use and resistance data through CDC's National Healthcare Safety Network (NHSN).

Promoting Access to Antibiotics

- Any company receiving a market entry reward shall be required to develop and submit to the Secretary within three months of approval a plan to promote access to the antimicrobial product for US patients. This plan may include patient assistance programs, other tools, and collaboration with other entities. This effort shall be tailored to the capability of the individual company, recognizing that company size and manufacturing capacity will impact feasibility of access efforts.
- Any company receiving a market entry reward shall be required to develop and publish on their website a plan to promote global access to the antimicrobial product, including countries that have a high need for the antimicrobial and low and middle income countries. This plan may include patient assistance or donation programs, other tools, and collaboration with other entities.

Evaluation

- Five years after enactment, the Government Accountability Office (GAO) shall submit a study to Congress reporting on the impact of the new market entry rewards

on antimicrobial research and development. GAO should also make recommendations for additional incentives needed to ensure a robust and renewable antimicrobial pipeline. Review and recommendations should consider total numbers of antimicrobials for targeted pathogens in pre-clinical and clinical development, new antimicrobial classes, new antimicrobials with novel mechanisms of action, and areas of unmet need.