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IDSA
Infectious Diseases Society of America

July 15, 2021

The Honorable Diana DeGette
2111 Rayburn House Office Building
United States House of Representative
Washington, D.C 20515

The Honorable Fred Upton
2183 Rayburn House Office Building
United States House of Representatives
Washington, D.C 20515

Dear Representatives DeGette and Upton,

The Infectious Diseases Society of America (IDSA) thanks you for developing the Cures 2.0 Act discussion draft and for this opportunity to provide comments. We greatly appreciate your longstanding leadership in support of biomedical research and public health, and we thank you for incorporating some of our previous feedback in your discussion draft. We specifically offer our enthusiastic support for Sec. 105, Developing Antimicrobial Innovations, which we believe will significantly strengthen the pipeline of urgently needed antimicrobial drugs and promote their appropriate use. We hope our feedback on the discussion draft will be helpful and look forward to working with you on this important legislation.

Sec. 101: Further Understanding the Implications of Long COVID

IDSA recognizes that long COVID is a serious issue for many patients, impacting their ability to return to normal activities. We support your proposal to better understand the health coverage, long-term care coverage and disability coverage needs of these patients. We also support your proposal to develop a multisector long COVID learning collaborative.

- Additionally, we recommend the development of a national biobank for long-haul adult and pediatric COVID patients to enable the sharing of samples within the research community.

Sec. 102: National Testing & Response Strategy for Future Pandemics

IDSA strongly supports the development of a national strategy to prevent and respond to future pandemics and other public health emergencies, leveraging lessons learned from the COVID-19 pandemic. To ensure the strategy is informed by the best available information, we recommend that the secretary consult with a diverse group of nongovernment experts.

- Suggested language (page 4, line 20): "and (3) consult with appropriate non-government experts, including adult and pediatric clinicians, laboratorians, public health professionals and researchers."

We agree with the contents of the strategy, as specified in the discussion draft, and offer the following recommendations to strengthen the contents based upon key challenges from the COVID-19 pandemic:

- Include the manufacture and appropriate distribution of personal protective equipment (PPE) and testing supplies (including reagents, equipment, swabs and pipette tips). Suggested language (page 5, line 12): insert a new paragraph "(5) Modernizing and expanding domestic manufacturing and distribution of personal protective equipment and testing supplies, including reagents, equipment, swabs, and pipette tips."
- Include utilization of all appropriate expert partners to maximize testing capacity and prevent bottlenecks that slow turnaround time. Suggested language (page 4, line 24): "Strategies for testing (including point-of-care testing and testing at nonmedical sites) that appropriately leverage state and local health departments, private industry, and academic medical laboratories, to foster expedient results and personalized medical responses for patients and communities, including medically underserved populations."

Sec. 104: Vaccine and Immunization Programs

Support for the development and uptake of vaccines is critical to combatting COVID-19 and future outbreaks, and IDSA supports the appropriation of additional funding to strengthen vaccine awareness and immunization information systems (IIS).

- We recommend that efforts include assessing current IIS gaps and improving interoperability to ensure the accessibility of vaccine records for patients and providers across states, jurisdictions and health care facilities.

Sec. 105: Developing Antimicrobial Innovations

IDSA strongly supports this section and thanks you for working with the sponsors of the *Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act*. An innovative financing mechanism, as provided in the discussion draft, is essential to revitalize the antibiotic and antifungal pipeline and ensure the availability of urgently needed therapies to treat multidrug-resistant infections. Increasing antimicrobial resistance threatens our ability to safely provide modern medical care, including cancer chemotherapy, transplants, other surgeries and care of complex patients such as those hospitalized with COVID-19. De-linking antimicrobial drug payments from their use provides the necessary predictable return on investment and also aligns with antimicrobial stewardship principles.

We greatly appreciate that the discussion draft would provide grants to support antimicrobial stewardship programs, which, when appropriately resourced, are highly effective at reducing inappropriate antibiotic use, improving patient outcomes and reducing health care costs. During the COVID-19 pandemic, stewardship teams were also leaders in managing the complex administration of therapeutics such as remdesivir and monoclonal antibodies.

Sec. 203: Increasing Diversity in Clinical Trials

IDSA strongly supports the goal of increasing diversity in clinical trials. We agree that reports from the Food and Drug Administration (FDA) and Government Accountability Office (GAO) will be

helpful to inform further efforts, and we would also highlight the important roles of the National Institutes of Health (NIH) and especially the National Institute of Allergy and Infectious Diseases (NIAID), given the important intersection between health inequities and pandemic preparedness. NIH and NIAID have made important strides in diversifying participation in biomedical research, but further efforts are needed to identify best practices and gaps and to strengthen our clinical trial infrastructure to promote greater racial and ethnic diversity in clinical trials as well as inclusion of women, pregnant people and children.

Federally supported infrastructure should provide an integrated framework to link individuals to appropriate trials and encourage large-scale collaboration across many different types of facilities, including settings outside the traditional urban tertiary care academic centers. Such an approach will increase the reach of trials of promising therapeutics to populations that are typically omitted from studies.

- We recommend that in addition to requesting reports from FDA and GAO on the issue of diversity in clinical trials, you also request a similar report from NIH and NIAID to ensure a complete review of this issue, including existing efforts, progress, gaps and recommendations.

Sec. 205: Ensuring Coverage for Clinical Trials Under Existing Standard of Care

IDSA supports this provision to allow Medicare to cover the costs of their beneficiaries in Patient-Centered Outcomes Research Institute (PCORI)-funded clinical trials. This coverage will help alleviate financial burdens that could prevent individuals from participating in clinical trials and will hopefully increase diversity in clinical trials.

- We recommend you also extend this coverage in Medicaid as well, to facilitate the participation of individuals who rely on Medicaid (including children and pregnant people) in PCORI-funded clinical trials.

Sec. 302: Grants for Novel Trial Designs and Other Innovations in Drug Development

IDSA supports the provision to provide funding to support incorporating complex adaptive and other
novel trial designs into clinical protocols and applications for drugs. We believe this effort should include trial designs that are ready to be used quickly in the event of a pandemic or epidemic caused by a new pathogen, e.g., lottery-based randomization of a scarce therapeutic agent with means for rapid follow-up. Novel trial designs are also important to facilitate the study of drugs for less common indications that can be life-threatening and difficult to treat, such as ventilator associated pneumonia and other infections caused by multidrug-resistant pathogens.

In addition, it is important to pay greater attention to the stages of an acute illness when testing antimicrobial agents. Using trial designs from chronic diseases is problematic due to the differences in time periods that should be studied. When studying antimicrobial drugs, accounting for day of infection and stage of immunologic response in trial design or interpretation would be beneficial.

Sec. 304: Increasing Use of Real-World Evidence

IDSA supports provisions calling for HHS to outline approaches to maximize and expand use of real-world evidence and to encourage patients to engage in the generation of such evidence and in post-approval studies. Antibiotics to treat multidrug-resistant infections often must be approved for indications that are most feasible to study, such as urinary tract and skin and soft tissue infections, rather than for indications more urgently in need of treatments that can be extremely difficult to study. For example, enrolling patients with ventilator associated pneumonia or bone and joint infections in clinical trials can be very challenging due to the complexity of these patients and small patient populations. Real-world evidence can fill important gaps in knowledge and provide physicians with critical data to guide optimal use of therapies.

It is important to note that the collection of real-world evidence will require new resources, increased access to data and an expansion of our biomedical research workforce, including data scientists with clinical trial backgrounds. We recommend the following:

- Direct the Real-World Evidence Task Force to identify the resources necessary to facilitate the collection of real-world evidence. Suggested language (page 64, line 11): (B) Identify the resources necessary to facilitate the collection of real-world evidence, including workforce and infrastructure needs and gaps.

Sec. 401 and Sec. 405: GAO and HHS Reports on Coverage for Innovative Technologies

IDSA appreciates the discussion draft's attention to the issue of Medicare coverage for innovative technologies. Rapid diagnostic and screening tests for infectious diseases are critical to support optimal patient care and prevent the spread of infections. However, they are often not adequately reimbursed, which limits their use. In particular, screening tests for emerging pathogens, such as *Candida auris* or carbapenem-resistant Enterobacterales (CRE), are often not performed in hospitals due to prohibitive costs. This can limit our ability to detect deadly, difficult to treat pathogens and prevent outbreaks.

Sec. 403: Extending Medicare Telehealth Flexibilities

IDSA strongly supports this provision to permanently remove Medicare's geographic and originating site restrictions, which require a patient to live in a rural area and be physically in a doctor's office or clinic to use telehealth services. During the COVID-19 pandemic, telehealth has been a critical tool to expand access to care, and beyond the pandemic it should continue to be leveraged.

Sec. 501: Advanced Research Projects Agency for Health (ARPA-H)

Thank you for seeking input on the development of ARPA-H. We are pleased to provide feedback on the questions you posed and look forward to ongoing conversations as ARPA-H continues to be designed.

1. **What activities or areas should ARPA-H focus on, and what should it avoid?**

ARPA-H provides an unprecedented opportunity to bring together groups of scientists who have not historically collaborated to solve complex global issues. For example, to combat the rise of

antimicrobial resistance — a leading cause of death in the U.S.[1] and one of the most significant risks facing the world — ARPA-H could fund multidisciplinary research helmed by infectious diseases physician-scientists, environmental ecologists, chemists, engineers, agricultural scientists and computational biologists. **Funding awards could require interdisciplinary participation and a focus on issues that require multiple stakeholders.**

Pandemic preparedness and health inequities are also important, cross-cutting issues to which ARPA-H should devote resources. Translational research, patient-oriented studies with a short path to application, advanced diagnostics and biochemistry studies in humans that yield candidate drug targets would all help address gaps in existing research. **We suggest that ARPA-H avoid basic science studies,** as these are well supported by NIH; excessive reliance on mouse models; and descriptive genomics studies with tenuous connection to application.

2. **How should ARPA-H be designed to operate both independently and transparently?**

It is important that ARPA-H have an explicit mission and clear goals from the start. It will be important for ARPA-H to have broad engagement with a diverse array of stakeholders, particularly individuals in medically underserved areas. **We recommend that frontline physicians be given a strong voice in setting research priorities**, as they are highly attuned to emerging patient needs. ARPA-H should continue engaging frontline physicians in research, which in turn will expand clinical trial opportunities to broader and more diverse patient populations who may not have access to academic medical centers. To secure NIH funding, physicians must typically devote significant time to research and often be housed at an academic medical center. By engaging more community physicians in research, ARPA-H could complement NIH by tapping a more diverse array of experts. ARPA-H can use NIH's scoring criteria for grants as a model and revise as necessary to fit ARPA-H's structure and goals.

3. **How should ARPA-H coordinate with existing federal entities involved in health care-related research and regulation?**

Engagement in multi-agency committees will be important to ensure efforts are appropriately coordinated to address key priorities, to identify and address gaps in research, to share information and to avoid duplication.

4. **How should ARPA-H work with the private sector?**

Engagement with industry should be conducted in a transparent manner, with clearly defined shared goals and deliverables. ARPA-H should have clear mechanisms to support and encourage engagement with smaller companies.

5. **What is the appropriate funding level for ARPA-H and how to prevent funding at NIH's expense?**

Funding for **ARPA-H must supplement, not supplant, NIH funding**. For ARPA-H to have a net positive impact, the availability of funding for research must grow to accommodate ARPA-H

[1] https://www.cambridge.org/core/services/aop-cambridge-core/content/view/C9B09A787FCCA1EA992AF45066F3FF7C/S0899823X18003045a.pdf/div-class-title-re-estimating-annual-deaths-due-to-multidrug-resistant-organism-infections-div.pdf

without reducing funding for existing federal research agencies. NIH excels in supporting basic research but does not always have the capacity to support sufficient translational research. ARPA-H could distinguish itself by focusing on pathways to application and engaging community physicians beyond academic medical centers.

Sec. 502: Research Investment to Spark the Economy

IDSA supports this provision. Strengthening our pipeline of scientists is a central component of efforts to bolster research. While the current pandemic has reportedly increased interest in infectious diseases careers, translating increased interest into recruitment and retention of infectious diseases physician-scientists remains a challenge. Unlike most specialties, infectious diseases remains unable to fill fellowship slots during the annual match. This challenge is driven by factors such as low salaries relative to other medical specialties (and low reimbursement for cognitive specialties more generally); high medical school debt combined with the requisite extra years of fellowship training; and the need to obtain funding for scientific faculty positions.

IDSA is engaging with NIAID to discuss opportunities to strengthen the ID research workforce, and we have offered several recommendations, which include providing more resources for mentorship, greater opportunities for clinicians in nonacademic settings to participate in clinical trials and more funding to support early stage investigators, particularly from underrepresented groups. Given that pandemic preparedness relies more heavily on infectious diseases physician-scientists than most other specialties, we recommend that Cures 2.0 include language directing NIAID to enhance ID physician-scientist training programs and authorizing additional funding for this purpose.

Once again, we thank you for your leadership and commitment to biomedical research, public health and pandemic preparedness and look forward to working with you to advance shared priorities. Please feel free to reach out to us by contacting Amanda Jezek, IDSA Senior Vice President of Public Policy & Government Relations, at ajezek@idsociety.org.

Sincerely

Barbara D. Alexander, MD, MHS, FIDSA, President