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IDSA
Infectious Diseases Society of America

April 20, 2021

The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

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

Dear Representatives DeGette and Upton:

The Infectious Diseases Society of America (IDSA) greatly appreciates your longstanding leadership in support of biomedical innovation, public health and pandemic preparedness. As you continue working to develop and advance Cures 2.0, we would like to reiterate the support and recommendations we provided in our May 2020 comments and offer updated feedback below. Given your leadership in sponsoring H.R. 869, the *Research Investment to Spark the Economy (RISE) Act*, we also would like to share our recommendations to strengthen the infectious diseases research workforce. As you continue working on the next draft of Cures 2.0, we would welcome the opportunity to answer any questions you may have. Once the draft is released, we look forward to providing feedback to you and your staff.

Cures 2.0

Title I: Public Health

Public Health National Testing and Response Strategy for Current and Future Pandemics

IDSA continues to support increased allocation of federal funding and resources to improve U.S. surveillance and testing capabilities for enhanced outbreak response. Without the implementation of a flexible, prospective, evidence-based national testing infrastructure, the U.S. will remain overly vulnerable to biological threats. We recommend that your legislation direct the U.S. Department of Health and Human Services (HHS) to seek input in developing the national testing and response strategy from a diverse group of experts across the testing, public health, policy and clinical landscapes.

Testing Strategies

We recommend that a national testing strategy include a federal plan to ensure the manufacture and appropriate distribution of adequate testing supplies, including personal protective equipment (PPE), reagents, equipment and swabs. In addition, we ask that Cures 2.0 call for the strategy to directly address how to ensure testing access for marginalized groups and those who have been disproportionately impacted by

COVID-19 (e.g., Black/African-American, Latinx and Indigenous communities). Successful efforts to reach medically underserved populations will require corresponding infrastructure development (e.g., point-of-care testing, non-medical site development and sufficient trained personnel).

Improving U.S. Pandemic Preparedness and Response Through Support of Antimicrobial Resistance Product Commercialization

IDSA reiterates our support for your proposal to provide HHS, through the Assistant Secretary for Preparedness and Response (ASPR), resources and authorities necessary to effectively address the commercial market challenges that are impeding antibiotic innovation. We also continue to support the *Developing an Innovative Strategy for Antimicrobial Resistant Microorganisms (DISARM) Act*.

In our previous comments on Cures 2.0, we recommended a subscription model for novel antibiotics. We are delighted that Reps. Doyle and Ferguson introduced legislation in Fall 2020 that would implement such a model, and we expect this bill to be reintroduced this spring. The *Pioneering Antibiotic Subscriptions to End Upsurging Resistance (PASTEUR) Act* would allow the federal government to enter into contracts with antibiotic developers to provide set payments for a supply of a new antibiotic instead of paying for the volume of new antibiotics used. This approach would help revitalize antibiotic innovation in a manner consistent with stewardship. The bill would also establish a new grant program to support implementation of antibiotic stewardship programs in hospitals, which have been shown to improve antibiotic usage and result in better patient outcomes, reduced cost and reduction of antimicrobial resistance (AMR). We strongly encourage you to work with Reps. Doyle and Ferguson to advance the shared priority of a comprehensive federal response to AMR.

Title IV: Clinical Trials

Diversity in Clinical Trials

IDSA continues to agree that additional federal efforts to promote diversity in clinical trials are critical. Lessons learned from COVID-19 provide a crucial opportunity to strengthen our clinical trial infrastructure with a focus on diversity, inclusion, equity and access. Key strategies should be centered around the need to increase engagement with community-based organizations and leaders; address barriers to health care; optimize the clinical trial infrastructure to be more inclusive of key populations and community-based clinical trial sites; and foster an inclusive and diverse research workforce.

We are engaging with the National Institute of Allergy and Infectious Diseases (NIAID) and have shared with them this set of recommendations to strengthen our clinical trial infrastructure in a manner that promotes greater diversity in clinical trials. 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. IDSA supports the expansion of pragmatic trials networks to reach more participants through community-based settings and run larger, simpler trials.

Trial Sites at Care Sites

We recommend that Cures 2.0 include a provision directing NIAID to report to Congress regarding progress made in increasing diversity in clinical trials and addressing remaining barriers, and authorizing additional funding to support new initiatives to advance diversity in clinical trials. Specific needs include additional funding for transportation to and from trial sites, as well as additional staff to support extended hours outside of the 9-5 workday. While we appreciate the Cures 2.0 concept paper suggestion for HHS to publicize clinicaltrials.gov and other resources through the Medicare Explanation of Benefits, the utility of these tools remains limited for individuals who lack regular internet access or do not speak English. Additional funding is needed for community outreach, engagement and translation services.

Title VI: Centers for Medicare and Medicaid Services (CMS) Modernization

IDSA agrees with the Cures 2.0 concept paper's assertion that modern and systemic approaches to coverage and reimbursement are essential to support the development of lifesaving new technologies and treatments. In particular, coverage modernization for diagnostic testing is needed to keep pace with innovation. Multiplex respiratory panels that can simultaneously detect over 20 pathogens in only a few hours are currently the only FDA-approved assays to diagnose SARS-CoV-2 following the expiration of the Public Health Emergency. These panels are also often the only way to detect uncommon respiratory viruses and determine etiology, thereby helping to guide proper treatment — including appropriate antimicrobial use. Standard microbiology tests often require two days for results. More rapid results lead to better care and patient outcomes. However, Medicare Administrative Contractors have historically declined to cover testing for panels with more than 3-5 pathogen targets. We recommend that Cures 2.0 direct CMS to develop a plan, in consultation with clinicians, laboratories and other relevant experts, to modernize coverage for essential diagnostic testing in line with rapidly emerging new technologies.

***Research Investment to Spark the Economy Act (RISE) Act* (H.R. 869)**

IDSA is pleased to support the RISE Act and greatly appreciates your leadership in efforts to increase funding for research. 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. Infectious diseases as a specialty only filled 75% of programs in the 2020 match (compared to most other specialties that filled all or nearly all programs). 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 these recommendations, which include providing more resources for mentorship, greater opportunities for clinicians in non-academic settings to participate in clinical trials and more funding to support early stage investigators, particularly from underrepresented groups. We would welcome the opportunity to work with you on legislation that would direct

NIAID to enhance ID physician-scientist training programs and authorize additional funding to address these goals.

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, IDSA