



December 9, 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) is pleased to support the Cures 2.0 Act (H.R. 6000) and is particularly grateful for its inclusion of the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act. We greatly appreciate that Cures 2.0 includes many of the recommendations we have previously shared with you, and we applaud your transparent and inclusive process in developing this important legislation. Below we are pleased to highlight some of the provisions of greatest importance to IDSA and our members.

### **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. This provision to increase our understanding of long COVID is timely and important to help patients recover.

### **Sec. 104. Vaccine and Immunization Programs**

Vaccines are one of our most transformative public health tools. With vaccine hesitancy threatening to undermine decades of progress against infectious diseases and hampering our ability to end the COVID-19 pandemic, the Cures 2.0 provision to improve vaccine public education activities is timely and critical. In addition, strengthening capacity for our Immunization Information Systems (IIS) will improve our ability to track vaccinations across care providers, maximizing opportunities to keep everyone up to date on recommended vaccinations.

### **Sec. 105. Developing Antimicrobial Innovations**

Antimicrobial resistance (AMR) is a public health crisis capable of unraveling modern medicine. Advances from cancer chemotherapy to transplantation, from joint replacements to other surgeries all carry a risk of serious infection and thus rely on the availability of safe and effective antimicrobial drugs. Our antimicrobial arsenal is diminishing due to growing resistance and lack of innovation. Concurrently, economic challenges unique to antimicrobials have driven the pharmaceutical industry away from this field. Antimicrobial drugs must be used judiciously to protect their efficacy and are typically prescribed for a short duration, making it extremely difficult for innovators to earn a return on investment (ROI) in antimicrobial research and development (R&D).

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The PASTEUR Act, included in Cures 2.0, provides the novel financing mechanism needed to revitalize antibiotic R&D. Under this policy, the federal government would pay for the value that truly novel antimicrobials provide to society, rather than simply paying for the volume of antimicrobials prescribed. By allowing the federal government to enter into contracts with antimicrobial innovators and provide set payments for supplies of novel antimicrobials regardless of the amount prescribed, this policy provides the predictable ROI necessary to sustain the antibiotic pipeline and aligns with principles of appropriate antibiotic use.

The bill creates a new grant program to support antimicrobial stewardship programs in hospitals, with priority given to rural, critical access and safety net hospitals. Stewardship programs have demonstrated tremendous effectiveness in reducing inappropriate antibiotic use, improving patient outcomes and lowering health care costs. During the COVID-19 pandemic, these teams have led the complex administration of COVID-19 therapies, often grappling with optimizing use of limited supplies and developing creative approaches to the complicated administration of infusion therapies. Despite the central importance of stewardship teams to modern medicine and our pandemic response, these teams are consistently understaffed and under resourced. Cures 2.0 will help ensure the investments necessary to realize the full patient and public health benefits of antimicrobial stewardship.

### **Sec. 203. Increasing Diversity in Clinical Trials**

The COVID-19 pandemic has shined a spotlight on longstanding health disparities and the importance of including diverse populations in clinical trials. We appreciate that Cures 2.0 requests an update from the Food and Drug Administration (FDA) on progress made in diversifying clinical trial participation as well as a Government Accountability Office (GAO) study on barriers to clinical trial participation. While we understand there are some key barriers — such as geographic locations of trial sites, lack of transportation and lack of hours outside the standard 9-5 workday — both approaches in Cures 2.0 will allow us to more comprehensively assess lessons learned from efforts to recruit diverse participation in COVID-19 clinical trials and will help ensure that national conversations on this important issue continue. We look forward to the FDA update and GAO study and encourage you to utilize their findings to inform future policymaking with the goal of increasing diversity in clinical trials.

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

IDSA supports the provision to provide funding for incorporating complex adaptive and other novel trial designs into clinical protocols and applications for drugs. This effort can support the creation of trial designs that are ready to be used quickly in the event of a pandemic or epidemic caused by a new pathogen. 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 infections caused by multidrug-resistant pathogens.

### **Sec. 403. Extending Medicare Telehealth Flexibilities**

We appreciate that Cures 2.0 includes the Telehealth Modernization Act, which would permanently remove Medicare's geographic and originating site restrictions that require a patient to live in a rural area and be physically in a doctor's office or clinic to use telehealth services. It would also allow the

Secretary of Health and Human Services (HHS) to permanently expand the types of health care providers that can offer telehealth services and the types of services that can be reimbursed under Medicare. These policies will help extend the reach of clinicians and expand access to care for many patients.

### **Sec. 501. Advanced Research Projects Agency for Health**

IDSa is enthusiastic about the promise of the Advanced Research Projects Agency for Health (ARPA-H) and is pleased that Cures 2.0 would establish this effort. As much remains to be known about exactly what ARPA-H will do, IDSA appreciates that Cures 2.0 would require ARPA-H to submit a report to Congress on its strategic vision. IDSA is also pleased that the bill directs ARPA-H to coordinate with relevant HHS agencies and to ensure it does not duplicate the efforts of other agencies. IDSA looks forward to engaging with ARPA-H to share our ideas for transformative research in the area of infectious diseases, and thanks you for authorizing ARPA-H to consult with relevant professional and scientific societies.

### **Sec. 502. Research Investment to Spark the Economy (RISE)**

IDSa welcomes the inclusion of the RISE Act in Cures 2.0 to provide additional resources to support research in a wide array of areas. This funding would provide relief to U.S. researchers working to reinvigorate federal research projects that were stalled due to the pandemic.

We thank you for your longstanding leadership in support of biomedical innovation, public health and pandemic preparedness and look forward to working with you to advance Cures 2.0. Please feel free to contact Amanda Jezek, IDSA Senior VP of Public Policy & Government Relations at [ajezek@idsociety.org](mailto:ajezek@idsociety.org) if we can ever be of assistance to you.

Sincerely,



Daniel P. McQuillen, MD, FIDSA  
President, IDSA