IDSA
Infectious Diseases Society of America

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

The Honorable Larry Bucshon
2313 Rayburn House Office Building
United States House of Representatives
Washington, DC 20515

Dear Reps. DeGette and Bucshon,

The Infectious Diseases Society of America (IDSA) thanks you for the opportunity to provide comments on the request for information regarding Cures 2.0. IDSA represents over 13,000 infectious diseases (ID) physicians, scientists and other public health and health care providers specializing in the prevention, diagnosis and treatment of infectious diseases. We greatly appreciate your longstanding leadership in support of biomedical research and public health, including efforts to stem the tide of antimicrobial resistance (AMR).

Inclusion of PASTEUR in Cures 2.0

IDSA strongly supported the inclusion of the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act in the previous iteration of Cures 2.0. The PASTEUR Act is an innovative solution that will address the failing antibiotic and antifungal pipeline while providing much needed support to hospitals and long-term care facilities to address AMR. **IDSA strongly urges the sponsors to include PASTEUR in any future version of Cures 2.0.**

The AMR threat has increased sharply and threatens the ability of doctors to treat patients effectively. Antibiotics are the foundation of modern medicine that treat common infections as well as facilitate the safety of procedures like cancer treatment, complex surgeries and transplants. The pipelines of antibiotic and antifungal therapies are extremely slim. Nearly all large pharmaceutical companies have exited antibiotic research and development, leaving small companies that struggle to stay afloat as the ones conducting 95% of this vital work.

Clinicians prescribe antibiotics only as needed to protect their efficacy. This approach is necessary to ensure the effectiveness of the medicines but limits sales volume, which has led to companies closing and backing away from researching and developing the next antibiotic. PASTEUR will solve this problem by delinking federal payments for antimicrobial drugs from use. The passage of PASTEUR will ensure that patients covered by Medicare and other federal payers will have access to these medications. We greatly appreciate the launch of ARPA-H, and we are grateful that it is supporting some AMR research. However, ARPA-H is not positioned to ensure the sustainable development and availability of novel antibiotics in partnership with industry, highlighting why PASTEUR is crucial. Further, improvements by the Food and Drug Administration (FDA) to the regulatory environment are also welcome, but without an economic incentive like PASTEUR, companies are unable to make use of new regulatory opportunities.

The second part of PASTEUR provides resources for antibiotic stewardship programs in rural, critical access and safety-net hospitals and long-term care facilities to guide optimal antibiotic use. Stewardship programs have proven, when appropriately resourced, to be highly effective at reducing inappropriate antibiotic use and health care costs while improving patient outcomes.[1]

Preparedness and Response to Public Health Security Threats

The RFI highlights that since the Cures 2.0 Act was introduced, there have been advances in our national preparedness and response infrastructure, including strategies for testing. The need for accurate, timely diagnostic capacity in a public health emergency and in everyday clinical settings cannot be overstated.

IDSA has provided comments to FDA in response to changes in its oversight of laboratory-developed tests (LDTs). We believe that the LDT final rule as put forth by FDA will dramatically curtail patient access to testing, with devastating outcomes for patients with serious infections.

We welcome the opportunity to work with you on legislative avenues to better protect diagnostic innovation and patient access to testing. **LDTs are used in a wide array of ID practice areas, including testing for organism identification, antimicrobial susceptibility, HIV and hepatitis virus drug resistance, and tick-borne diseases like Lyme and *Ehrlichia*, as explained in our comments to FDA.** The FDA final rule would create barriers to the continued development of tests to determine the most effective treatment for AMR pathogens. Additionally, the rule included a grandfathering provision for existing LDTs, but ID LDTs are frequently modified to keep pace with evolving pathogens and needs for additional specimen types, and it remains unclear how such modifications will be assessed by FDA and what criteria will be used to determine if modified tests are subject to review. FDA also included some narrow exemptions for specific LDTs, but they are likely too narrow to have a significant impact.

In addition, there is further attention needed to the diagnostics capacity required to respond to a pandemic or other public health emergency (PHE). IDSA has previously commented on pandemic preparedness needs, including in response to the White House Pandemic Preparedness Plan. Congress should encourage FDA, the Agency for Strategic Preparedness and Response, the White House Office of Pandemic Preparedness and Response and other appropriate agencies to collaborate on the establishment of predefined and funded reference and academic laboratory networks preauthorized by FDA to quickly develop ID diagnostics in outbreak and pandemic conditions and begin biorepositories.

Such a “warm base” for reference labs and others to be ready to perform tests in an emergent situation would provide the ability to rapidly scale testing and provide diagnostics with optimal turnaround time as a PHE is building. Labs also require easy access to sequences, extracted relevant nucleic acid, samples and quality assurance standards (e.g., controls) to quickly build, validate and utilize tests. Supply chain bottlenecks need to be anticipated and prevented so that a breakdown in availability of a particular component needed for testing does not delay or inhibit needed diagnostic capacity. In addition, FDA and other agencies should collaborate to designate pandemic assessment centers, i.e., institutions partnered with state health departments, to coordinate activities to improve responses and alleviate supply chain issues. These partnerships can work strategically to maximize utilization of existing resources and decrease turnaround times on testing.

Continuation of Telemedicine Services

[1] Centers for Disease Control and Prevention. Core Elements of Hospital Antibiotic Stewardship Programs. Atlanta, GA: US Department of Health and Human Services, CDC; 2019. Available at https://www.cdc.gov/antibiotic-use/core-elements/hospital.html

IDSA appreciates the focus you have placed in previous versions of Cures on the need for telemedicine services for patients, especially in rural and sparsely populated areas. IDSA supports the extension of telehealth flexibilities, such as those included in the *Preserving Telehealth, Hospital and Ambulance Access Act* (H.R. 8261) and *Telehealth Modernization Act* (H.R. 7623). Audio-only services are particularly important to avoid disadvantaging those without adequate access to video technology, including older individuals, those with lower incomes and those without adequate internet access.[2] Reimbursement must continue at rates similar to in-person visits for both video and telephonic visits to avoid reducing access to infectious disease services.

Access to Immunization Services

Vaccination provides a foundation for preventing infectious diseases in infants, children and adults. Infants and children have the highest morbidity and mortality due to vaccine-preventable diseases. Vaccine hesitancy and refusal are undermining decades of progress against infectious diseases. Support for public education activities while enhancing vaccine safety monitoring is timely and critical. A national immunization information system would facilitate vaccine administration by maximizing opportunities for timely administration and would enhance surveillance across location and lifespan. Public-private partnerships to facilitate vaccination both in and outside of the medical home enhances both physical and financial access. Funding to develop innovative approaches to enhancing vaccine access would offer outstanding return on the investment.

- **Resources to support state/local/tribal/territorial immunization programs in health departments.** Additional federal authorities and funding are needed to provide a stable and consistent framework of support for immunization data modernization efforts at the state and local level to address gaps in technology capabilities, including the following: compliance with the latest privacy, security, interoperability and reporting standards; upgrades to allow bidirectional reporting; establishment of policies that facilitate immunization data exchange across the life course; education and training for clinicians on the latest information technology systems; and efficient distribution of federal resources through the use of real-time data to monitor vaccine supply and ensure fair distribution across regions and communities.

- **Reimbursement to support vaccination.** Ensuring that clinicians are properly reimbursed is key to fostering a sustained environment for this high-value preventive service. Vaccinators continue to cite financial and other challenges impacting their ability to get vaccines to patients, including concerns with payment rates across clinician types and settings of care. Clinician vaccine product reimbursement and administration payment rates are intended to account for the cost to acquire a vaccine product as well as the time and resources required to administer vaccines to patients. These rates vary across insurance markets. Adequate payments for vaccine products, standalone vaccine counseling and vaccine administration — recognizing practice differences across the variety of care settings — are needed to improve vaccine access.

- **Enabling pharmacist vaccinators.** Pharmacists play a key role in vaccinating millions of Americans each year. The COVID-19 public health emergency temporarily eased restrictions that otherwise inhibit the ability of pharmacists and pharmacy technicians to immunize in community-based health care settings,

[2] Wendy S Armstrong, Allison L Agwu, Ernie-Paul Barrette, Rachel Bender Ignacio, Jennifer J Chang, Jonathan A Colasanti, Michelle Floris-Moore, Marwan Haddad, Lynsay MacLaren, Andrea Weddle, Innovations in Human Immunodeficiency Virus (HIV) Care Delivery During the Coronavirus Disease 2019 (COVID-19) Pandemic: Policies to Strengthen the Ending the Epidemic Initiative—A Policy Paper of the Infectious Diseases Society of America and the HIV Medicine Association, Clinical Infectious Diseases, Volume 72, Issue 1, 1 January 2021, Pages 9–14, https://doi.org/10.1093/cid/ciaa1532

such as federally qualified health centers and long-term care settings. Rural, underserved and patients at greater risk of adverse consequences from vaccine-preventable illness receive a range of important health care services through these sites of care. We urge your support for the complete vaccination neighborhood, including pharmacists.

Long COVID and Other Post-Acute Syndromes

The prevalence and scope of long COVID have increased awareness of the toll of post-acute syndromes on millions of Americans. We appreciate the establishment of the Office of Long COVID Research and Practice to enhance our understanding of and options for management of patients who suffer with long COVID.

Research into long COVID should address other post-acute syndromes, including myalgic encephalomyelitis/chronic fatigue syndrome (ME/CFS). Some patients experiencing long COVID also experience ME/CFS, which has significant overlap and similar pathophysiology. The study of additional post-acute syndromes may offer insight into long COVID.

- In addition to exploring off-label uses of current pharmaceutical products, research should study nonpharmaceutical interventions, including physical therapy and behavioral- and nutrition-focused changes.
- Funding should also support epidemiological studies to more accurately measure the incidence and prevalence of long COVID and trends in patients who suffer long COVID symptoms, including data on age, race/ethnicity, gender and other demographics.
    - Additionally, funding should support research into how COVID reinfection impacts patients who suffer from long COVID, the risk of long COVID from reinfection and implications for frequency of vaccination.
- To ensure broad expertise is harnessed to better understand treatment of long COVID, Congress should expand funding for long COVID adaptive platform repurposed drug trials, independent of the RECOVER mechanism.

In closing, we hope our feedback on the RFI is helpful and look forward to working with you in the future on these important issues. Please direct any questions to Eli Briggs, IDSA director of public policy, at ebriggs@idsociety.org.

Sincerely,

Steven K. Schmitt, MD, FIDSA, FACP
IDSA President