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IDSA
Infectious Diseases Society of America

May 6, 2020

The Honorable Diana DeGette
United States House of Representatives
2111 Rayburn House Office Building
Washington, D.C. 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) thanks you for issuing the 21st Century Cures 2.0 Concept Paper and specifically for its focus on public health and pandemic preparedness and response, including testing, vaccines and antimicrobial resistance. As the COVID-19 pandemic is demonstrating, infectious diseases can devastate our health and economy, and it is critical that we strengthen our national infrastructure to prepare for and respond to infectious diseases threats. IDSA is pleased to support several of the policies outlined in your concept paper and to offer recommendations that we believe would strengthen your proposals and more effectively address the challenges you have articulated. At this time, our comments are limited to Titles I and IV, as we believe these are specifically relevant to the COVID-19 pandemic. We plan to provide comments on other Titles in the future. We look forward to working with you to advance our shared goals in Cures 2.0.

Title I: Public Health

National Testing and Response Strategy for Current and Future Pandemics

IDSA strongly supports the allocation of federal funding and resources to improve U.S. surveillance and testing capabilities for enhanced outbreak response both now and in the future. Without the implementation of a flexible, prospective, evidence-based national testing infrastructure, the U.S. will remain overtly 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 strategy from a diverse group of experts across the testing, public health, policy, and clinical landscapes.

Testing Strategies

With regard to testing, we recommend that the national strategy include a federal plan to ensure the manufacture and appropriate distribution of adequate testing supplies, including personal protective equipment (PPE), reagent, equipment and swabs. In addition, we ask that Cures 2.0 call for the strategy to directly address how to get the critical tests to marginalized groups and those that have been

disproportionately impacted by COVID-19 (e.g., African-American and Native American communities). We applaud the concept paper's consideration of medically underserved populations and areas but caution that success will require corresponding infrastructure development (e.g., point-of-care testing and non-medical site development, sufficient trained personnel, etc.).

Surveillance

Establishing data sharing methods to improve pathogen surveillance and response is a critical but resource-heavy task that must be undertaken simultaneously with the expansion of the public health workforce. State and local public health departments currently operate woefully under capacity and will be unable to increase data collection efforts without significant additional support. We further commend the development of an evidence-based plan to help Americans relax physical distancing requirements safely and recommend that this be developed with a coalition of infectious diseases experts, clinical laboratory personnel, supply chain experts, and public health stakeholders. IDSA outlined recommendations for a safe reopening process to help inform federal efforts.

Domestic Drug Manufacturing

IDSA strongly supports the inclusion of domestic drug manufacturing expansion and modernization in the national strategy for pandemic preparedness and response. Antibiotic shortages have been a persistent and pervasive problem for several years, frequently requiring physicians to prescribe suboptimal therapies that may negatively impact patient outcomes and increase antibiotic resistance. COVID-19 has significantly disrupted supply chains, worsening antibiotic shortages at a time when patients—particularly the most seriously ill patients with COVID-19 who are hospitalized and placed on ventilators—need them most. The Center for Drug Evaluation and Research at the Food and Drug Administration (FDA) is asking manufacturers to evaluate any components that may be impacted due to the COVID-19 pandemic; the agency is currently reporting shortages of several critical antibiotics.

In October 2019, the Food and Drug Administration released a report that identified three root causes for drug shortages: lack of incentives for manufacturers to produce less profitable drugs; lack of reward for quality systems that focus on continuous improvement and early detection of supply chain issues; and logistical and regulatory challenges that make it difficult for the market to recover from a disruption. IDSA concurs with these findings and encourages the national strategy to build on this work to implement solutions.

Plan to Develop and Administer Vaccines and Therapeutics

IDSA strongly supports the establishment of a plan to develop and administer vaccines and therapeutics. It may take months to have sufficient supplies of a COVID-19 vaccine distributed around the country for all who require it. Federal, state and local leaders should review pandemic influenza vaccine distribution plans as a basis for preparing for COVID-19 vaccine distribution and address any existing regulatory or logistical barriers to provider and patient access to a novel coronavirus vaccine. Plans should account for resource needs for the provision of routine immunization efforts and annual flu vaccine efforts. **IDSA recommends that Cures 2.0 direct the prioritization of vaccine supply distribution based on Advisory Committee on Immunization Practices (ACIP) recommendations that address potential access barriers for vulnerable populations.**

Pandemic Preparedness Program for Patients

IDSA supports your provision to provide grants to organizations to help support patients and families for the current or a future pandemic. We have seen firsthand the significant suffering of patients who struggle to access medical care. We also recognize that COVID-19 is disproportionately impacting communities—including the African American and Native American communities—who were already facing significant health disparities. **We recommend that a portion of these grants be targeted to organizations who specifically work with communities or populations disproportionately impacted by the pandemic.**

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

Policy

IDSA strongly supports your proposal to provide HHS, through the Assistant Secretary of Preparedness and Response (ASPR), resources and authorities necessary to effectively address the commercial market challenges that are impeding antibiotic innovation. As you note, secondary bacterial infections are a key concern in the COVID-19 pandemic and antibiotics are essential to our response as well as for routine medical care and preparedness for future pandemics.

We are particularly pleased that your proposal explicitly covers federal support for new antibiotics in the pre-approval and post-approval periods. Current mechanisms to provide pre-approval support are critical and should be strengthened. However, they are insufficient. Post-approval support is necessary, as the small companies responsible for the vast majority of current antibiotic innovation typically lack the resources to scale up the infrastructure necessary to bring a newly approved antibiotic to market. **IDSA also encourages you to specify in Cures 2.0 that support may be provided to any antibiotics that address unmet medical needs, not only those products with a specific biothreat indication.**

To ultimately ensure the robust and renewable antibiotic pipeline needed to meet current and future patient needs, new antibiotic developers must have a way to earn a fair and reasonable return on their investments. Post-approval support through ASPR may play a critical role in meeting this goal, but additional policies recommended below may also be needed.

Additional Recommendations

Subscription Model

The challenges facing the antibiotic pipeline exist, in part, because antibiotics must be used judiciously to prevent the development of resistance, which significantly limits the ability of antibiotic developers to earn a return on their investments. As a result, several experts, including IDSA, are calling for a new business model for antimicrobial drugs based on a subscription model. Such an approach would provide a contract mechanism to guarantee predictable return on investment for antibiotic developers without tying that revenue to volume of sales, helping to ensure that these drugs are properly conserved for the patients who need them. **We urge you to include a** subscription model **for new antibiotics in Cures 2.0.**

Reimbursement Reform

We appreciate that Title VI seeks to modernize Medicare coverage of new therapies and wish to note that reimbursement reform could also help address the challenges facing the antibiotics market. The current Medicare reimbursement system hinders patient access to new antibiotics, which in turn further limits antibiotic revenues. The Medicare Diagnosis Related Group (DRG) for many infectious syndromes is often too low to cover the cost of new antibiotics, which are more expensive than generics but far less expensive than new drugs in other therapeutic areas. As a result, it can be challenging to add new antibiotics to hospital formularies and make them available even to patients for whom they are clinically appropriate. The bipartisan DISARM Act (H.R. 4100) would address this challenge by carving new antibiotics out of the DRG and reimbursing for them separately. The bill also includes stewardship provisions to help ensure that this mechanism does not drive inappropriate use of new antibiotics. **We encourage you to include reimbursement reform for antibiotics, such as what is proposed in DISARM, in Cures 2.0.** Recognizing that it may take more time for HHS to launch a subscription model even after legislation is enacted, reimbursement reform could provide more rapid relief for the antibiotics market.

Stewardship

We greatly appreciate that the Cures 2.0 concept paper includes a national strategy to get ahead of drug resistance in the future. In addition to new antibiotic innovation, stewardship and surveillance are equally critical. IDSA greatly appreciates that CMS finalized in 2019 a new requirement for hospitals to implement antibiotic stewardship programs. Significant data demonstrate that stewardship programs are highly effective at improving patient outcomes, reducing inappropriate antibiotic use and reducing the development of resistance. However, many hospitals—particularly rural, community and critical access hospitals—lack the resources necessary to optimize stewardship programs. Outpatient facilities still often lack coordinated approaches to antibiotic stewardship. **IDSA recommends that Cures 2.0 provide new grant funding to support the implementation of antibiotic stewardship programs.**

Data on antibiotic use and resistance are critical to measure and drive our progress. **IDSA recommends that Cures 2.0 require hospitals to report antibiotic use and resistance data to the CDC National Healthcare Safety Network (NHSN) and provide new grant funding to hospitals to support reporting.**

Vaccine and Immunization Programs

Vaccines are one of the most important tools of public health, and IDSA strongly supports provisions to strengthen vaccine infrastructure and access with the ultimate goal of increasing vaccination rates. The current COVID-19 pandemic demonstrates how devastating an infectious disease can be with no vaccine. The policies proposed in the Cures 2.0 concept paper will help our nation prepare for an effective rollout of a future COVID-19 vaccine and increase uptake of existing vaccines—both critical public health goals.

Policy (Vaccines education)

IDSA supports policies to improve education around the importance of vaccines. Educational initiatives should be evidence-based and culturally appropriate to build confidence in vaccines and clearly communicate the risks and costs of vaccine-preventable illnesses. It is particularly important to target populations most likely to forego or delay vaccines and those at risk for adverse health outcomes from

vaccine-preventable diseases. Improved surveillance of vaccine uptake, as proposed in the bipartisan VACCINES Act (H.R. 2862) will be important to help public health authorities more rapidly and effectively target at-risk communities and prevent outbreaks of vaccine preventable diseases. In addition, new research should be supported to identify the messages and communications tools and strategies that will be most effective in boosting immunization rates.

Policy (Vaccines surveillance)
IDSA supports strengthening and supporting Immunization Information Systems (IIS) capacity to improve vaccination rates through confidential, population-based data tracking. Enhancements for IIS should include accelerated and expanded provider registration, vaccine distribution, vaccine accountability, dose administered reporting, patient recall if a second dose is needed, and adverse event tracking. IIS standards should be uniform across states and should support cross-jurisdictional information sharing.

Additional Policy Recommendation (Vaccines access)
IDSA encourages the inclusion of additional provisions to increase vaccine access to effectively meet the ultimate goal of improving vaccination rates in the U.S. Barriers to vaccine access include cost-sharing and limited workforce capacity.

- *Cost-sharing*: When faced with an additional expense for a vaccine, patients are more likely to forgo the immunization. This is particularly important for Medicare beneficiaries, who are at higher risk for adverse health consequences from vaccine-preventable diseases. Vaccines covered under Medicare Part D, including Tdap and shingles, typically require out-of-pocket costs for patients, while vaccines under Part B by contrast require no cost-sharing. **IDSA supports the inclusion of a provision to eliminate out-of-pocket costs for Medicare Part D vaccines in Cures 2.0 so vaccines can be equally accessible among all insured populations. Such a provision could be modeled after the "Protecting Seniors Through Immunization Act" (H.R. 5076).**

- *Limited workforce capacity:* The state and local public health workforce is stretched extremely thin. Providers who serve all populations, but especially those at high risk for serious SARS-CoV-2 disease outcomes, need to be identified and enrolled as vaccinators and staffing plans must be developed for mass vaccination clinics. Additionally, adequate staffing must be maintained to manage routine vaccination activities in order to prevent and contain ongoing outbreaks of seasonal influenza, measles, hepatitis, pertussis and other vaccine-preventable diseases. **IDSA recommends that Cures 2.0 direct HHS to develop a plan to increase the number of vaccine providers to distribute a novel coronavirus vaccine and to maintain routine vaccination activities. Additional funding should also be provided for this activity.**

Title IV: Clinical Trials

Diversity in Clinical Trials

IDSA strongly supports the inclusion of a section in Cures 2.0 focused on improving diversity in clinical trials, particularly given the rapid advent of personalized medicine. From an ID perspective, the heterogeneity of many clinical disease presentations and the unknowns inherent in emerging outbreaks require data from a wide array of patient populations and care settings. Expanding trial access for marginalized, underserved, and differently abled populations is critical, and lessons can be learned from current initiatives within HHS agencies. For example, the National Institutes of Health's (NIH) *All of Us* Research Program – which aims to have at least 50% of its million-subject cohort comprised of traditionally underrepresented patients – has successfully recruited diverse participants by developing multilingual program materials; partnering with advocates and leadership from underrepresented groups; building provider engagement; and targeting community health centers. The NIH Office of Equity, Diversity, and Inclusion has also laid a strong evidence-based foundation for tackling medical and clinical trial disparities that can inform current policy needs.

These tools can be utilized to increase awareness and understanding of clinical trials in addition to publicizing clinicaltrials.gov and other resources. While the cultivation of a more user- and patient-friendly experience for the clinicaltrials.gov site is a valuable effort, many prospective participants do not have regular internet access or speak English as a first language; we therefore recommend the proposed task force consider additional comprehensive and community-based resources for patient outreach.

Since the passage of 21st Century Cures, multidisciplinary and team science have only continued to accelerate. **IDSA strongly supports the formation of a diverse expert task force as outlined in the concept paper, as well as additional university-government-industry partnerships to address current and future clinical trial participation needs and challenges.**

Trial Sites at Care Sites

IDSA appreciates the addition of a provision addressing access barriers to covered medical services at clinical trial sites. In addition to convening a partnership between the Centers for Medicare and Medicaid Services (CMS), FDA, NIH, and principal investigators, **we recommend the requirement of a federal report within a specified period of time outlining current barriers, proposed solutions, implementation timelines, impact analyses, and outstanding needs.**

Once again, IDSA thanks you for your leadership on issues critical to our nation's health. We are happy to serve as a resource to you as you advance this critical legislation. If you have any questions, please contact Amanda Jezek, IDSA's Senior Vice President for Public Policy and Government Relations at ajezek@idsociety.org.

Sincerely,

Thomas M. File, Jr., MD, MSc, FIDSA
President, IDSA