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Via Electronic Submission - cures.rfi@mail.house.gov

The Honorable Diana DeGette 2111 Rayburn House Office Bldg. 2313 Rayburn House Office Bldg. Washington, DC 20515

The Honorable Larry Bucshon, MD Washington, DC 20515

August 2, 2024

RE: Request for Information on Next Generation CURES Bill

Dear Representatives DeGette and Bucshon,

On behalf of the Society for Healthcare Epidemiology of America (SHEA), the leading professional society dedicated to the prevention of healthcare-associated infections (HAIs) and antimicrobial resistance (AMR), I welcome the opportunity to respond to your inquiry on finding the next generation of life-changing treatments. SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology, infection prevention, and antimicrobial stewardship. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality, and the cost of care linked to HAIs and AMR.

Below we comment on the pandemic preparedness and antibiotic resistance provisions included in the CURES 2.0 legislation and suggestions on how these important provisions should be updated. We look forward to working with you and your staffs on enacting this important legislation.

Pandemic Preparedness

CURES 2.0 required that the President develop and implement a national strategy to "prevent and respond to pandemics and other public health emergencies for which a declaration is made." SHEA greatly supports the provisions included in the legislation and further recommends action in five key areas to ensure the healthcare system is adequately prepared for a future pandemic: building a strong and resilient healthcare workforce; mitigating supply chain shortages; improved surveillance for emerging infectious diseases threats; creating robust approach to pandemic data collection, maintenance and release, and enhancing communication during infectious diseases outbreaks.

The COVID-19 pandemic exposed many of the preexisting problems within the US healthcare system, including a lack of capacity to manage a large influx of contagious patients while simultaneously maintaining routine and emergency care to non-COVID patients; a "just in time" supply network that led to shortages and competition among hospitals, nursing homes, and other care sites for essential supplies; and longstanding inequities in the distribution of healthcare and the healthcare workforce. The decades-long shift from manufacturing to a

reliance on global supply chains has compounded ongoing gaps in preparedness for supplies such as personal protective equipment and ventilators.

Ultimately, the lessons of COVID-19 illustrate the need to better prepare for the next pandemic. SHEA suggests the following areas be addressed to adequately be prepared for the next crisis.

- Healthcare workforce shortage: An already understaffed healthcare workforce was further exposed during the COVID-19 pandemic. Cross training additional professionals in infection prevention and epidemiology, as well as strengthening the relationships between public health, frontline workforce, and infection prevention specialists will be necessary to ensure appropriate responses during similar crises.
- **Medical supply chain:** While maintaining an uninterrupted supply of medical equipment involves preparedness on federal, state, and institutional levels, it also relies upon a unique and ever-changing global supply chain, which has a direct impact on the ability to procure a reliable supply of personal protective equipment at the institutional level during times of disruption. Adequate and timely access to medical supplies for patient care and personal protective equipment for healthcare personnel requires a transparent and accessible national stockpile.
- Surveillance: An improved network of surveillance systems and multiple health agencies must be coordinated to detect potential pandemics at an early stage. Additional research for pandemic preparedness, such as in vaccine development and understanding the interplay between animals, humans, and the environment remains crucial. Healthcare must play a role not only in training providers to respond to these threats, but in reducing the emergence of such pathogens through antimicrobial stewardship, climate change mitigation, and reducing socioeconomic disparities.
- Healthcare data: Streamlining and reporting of data between healthcare entities and multiple agencies must be thoughtfully redesigned and implemented to ensure that the greatest amount of standardized data are collected and organized. This also means data should be as widely available and transparent as possible, while able to remain relevant and funded for the long term, regardless of the next pandemic pathogen.
- Health disparities: Addressing inequities in COVID-19 outcomes, vaccine uptake, and provision of therapeutic agents among persons of color, marginalized populations, and vulnerable groups such as those who reside in skilled nursing facilities or rural areas is paramount to reducing disparities in healthcare outcomes. Healthcare professionals have a duty to address the need for equitable outcomes, not only in times of crisis, but during routine surveillance and prevention for healthcare associated infections.

Antibiotic Resistance

HAIs, especially those caused by multidrug resistant organisms (MDROs), are a significant threat to patient safety and public health. Deaths from HAIs are among the top preventable conditions. According to the Centers for Disease Control and Prevention (CDC) 2022 National and State HAI Progress Report, approximately one in 31 U.S. patients and one in 43 nursing home residents contracts at least one infection in association with their healthcare, underscoring the need for improvements in patient care

practices in U.S. healthcare facilities¹. CDC also reports that more than 3 million Americans acquire an antimicrobial-resistant infection or *Clostridioides difficile* infection each year and nearly 50,000 people die from these threats². HAIs prolong hospital stays and increase mortality, with the estimated cost to the U.S. healthcare system of the most common HAIs ranging from \$8-12 billion annually.³

CURES 2.0 recognized the threats that HAIs and AMR pose, and as such required the Secretary of HHS to establish a Committee on Critical Need Antimicrobials to develop a list of infections for which new antimicrobial drug development is needed, taking into account organisms, sites of infection, and type of infections for which there is an unmet medical need. The legislation also included the Pioneering Antimicrobial Subscriptions to End Upsurging Resistance (PASTEUR) Act to encourage innovative drug development targeting the most threatening infections, improve the appropriate use of antibiotics, and ensure domestic availability of antibiotics when needed. *In addition to pursuing new therapeutic treatments, SHEA urges you to consider including provisions that would enhance and prioritize research focused on antimicrobial stewardship and preventing infections.* Specifically, we recommend that the National Institute of Allergy and Infectious Diseases (NIAID) enhance their research infection prevention portfolio to increase our understanding of which strategies or combination of strategies are most effective and how these strategies should be implemented to achieve the greatest impact. Factors such as an aging population, an increase in vulnerable populations, and the growing emergence of multidrug resistant organisms (MDROs) amplify the critical need to prioritize funding of this research.

Infection prevention and antibiotic stewardship are the most effective strategies for slowing the spread of MDROs

In October 2020, the US Government released the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB), 2020-2025⁴ which outlined "coordinated, strategic actions that the US Government will take in the next five years to improve the health and wellbeing of all Americans by changing the course of antibiotic resistance." One of the five goals of the National Action Plan was to "Accelerate Basic and Applied Research and Development for New Antibiotics, Other Therapeutics, and Vaccines." The Action Plan stated that support for basic and applied research was required to "improve our understanding of the many factors that contribute to the emergence, spread, and persistence of antibiotic resistance and can support new strategies for preventing and mitigating infections." *SHEA believes an opportunity exists for NIH to further support this goal by extending its research funding to infection prevention and health services research.*

¹ 2022 National and State Healthcare-Associated Infections Progress Report." Antimicrobial Resistance & Patient Safety Portal, Centers for Disease Control and Prevention, Nov. 2023, arpsp.cdc.gov/profile/national-progress-2022/united-states. Accessed April 9, 2024.

² 2022 National and State Healthcare-Associated Infections Progress Report." Antimicrobial Resistance & Patient Safety Portal, Centers for Disease Control and Prevention, Nov. 2023, arpsp.cdc.gov/profile/national-progress-2022/united-states. Accessed April 9, 2024.

³ Antibiotic Resistance Threats in the United States, 2019." CDC Antimicrobial Resistance, Dec. 2019, www.cdc.gov/drugresistance/pdf/threats-report/2019-ar-threats-report-508.pdf. Accessed April 9, 2024.

⁴ "National Action Plan for Combating Antibiotic-Resistant Bacteria, 2020-2025." Office of the Assistant Secretary for Planning and Evaluation (ASPE), 8 Oct. 2020, aspe.hhs.gov/reports/national-action-plan-combating-antibiotic-resistant-bacteria-2020-2025. Accessed May 20, 2024

Comprehensive infection prevention programs and antimicrobial stewardship initiatives play a vital role in ensuring patient safety and halting the spread of MDROs, which pose a significant threat to the delivery of routine and complex healthcare services. Over the years, the healthcare epidemiology and antimicrobial stewardship research communities have demonstrated their ability to develop and implement effective strategies through rigorous studies, thereby reshaping clinical practices to combat HAIs and the proliferation of MDROs. This research has shown the preventability of many HAIs and highlighted the existence of effective interventions to mitigate patient risks. However, despite significant strides, the landscape continues to evolve, presenting ongoing challenges and persisting knowledge gaps.

NIAID's Antibiotic Resistance Research Framework lays out the agency's strategic approaches for AMR research across several portfolios including, but not limited to, basic, translational research, and preventative research.⁵ These portfolios currently do not include a robust representation of research that adequately addresses the mechanisms of transmission of HAIs and MDROs in healthcare settings. To be successful in tackling our most critical global health threats, NIAID must undergo a paradigm shift in its approach to addressing knowledge gaps that are critical to fighting the growing threat of AMR. The CDC and the Agency for Healthcare Research and Quality (AHRQ) have prioritized research in preventing HAIs and MDROs, but there are limitations in their scope and capabilities. NIAID is best positioned to support the type and scale of foundational research needed to fill these gaps. *SHEA urges the next CURES legislation to include provisions that would enhance and prioritize this research.*

Conclusion

We appreciate the opportunity to provide comment on this very important legislation. Please do not hesitate to reach out with questions to Lynne Batshon, Director of Policy and Practice, at (703) 684-0761 or lbatshon@sheaonline.org.

Sincerely,

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Thomas R. Talbot, III, MD, MPH, FSHEA President, SHEA

⁵ NIAID's Antibiotic Resistance Research Framework." Antimicrobial (Drug) Resistance, 2019, www.niaid.nih.gov/sites/default/files/AR2019.pdf. Accessed May 20, 2024