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Infectious Diseases Society of America

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November 30, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Leader McConnell, Leader Reid, Speaker Ryan, and Leader Pelosi:

On behalf of the Infectious Diseases Society of America (IDSA), thank you for continued efforts to spur biomedical innovation through approval of the new 21st Century Cures Act. IDSA particularly appreciates measures within the bill that help address the public health crisis of antimicrobial resistance (AR), support the next generation of scientists, and deal with the opioid epidemic that is contributing to a surge in new HIV and hepatitis C infections. We urge Congress and the president to approve the legislation as soon as possible.

Antimicrobial resistance claims new victims every day and this threat continues to grow. More than 10 million deaths are expected annually by 2050 due to superbugs, according to the *Review on Antimicrobial Resistance, Tackling Drug-Resistant Infections Globally*. While AR has increased, research and development for new antibiotics and antifungals has dramatically decreased. Public health authorities and experts such as the Centers for Disease Control and Prevention, World Health Organization, and the President's Council of Advisors on Science and Technology have stated that the scientific, regulatory and economic obstacles to research and development for new antibiotics and antifungals must be addressed to effectively combat AR.

The latest version of 21st Century Cures legislation represents an important step forward to reduce regulatory barriers to antimicrobial research and development. The number of people who have a highly antibiotic-resistant infection at any given time may be relatively small and spread over a wide geographic area that makes it nearly impossible to adequately conduct a traditional large-scale clinical trial. For that reason, IDSA strongly supports the provision in the Cures Act that establishes a new FDA limited population approval pathway for antibiotics and antifungals that treat serious or life-threatening infections with unmet medical needs. The bill allows for conduct of smaller and more efficient trials while including necessary safeguards to guide their appropriate use.

IDSA also strongly supports the provision in the Cures Act that speeds the updating of antimicrobial susceptibility interpretive criteria, which are commonly referred to as ‘breakpoints.’ Breakpoints are used in antibiotic susceptibility testing (AST) devices that serve to instruct clinicians on which drugs appear to work against a given organism. Health care facilities rely on accurate AST devices to identify patients with dangerous, multi-drug resistant infections for whom certain infection control protocols must be activated to prevent the further spread of the resistant organism.

IDSA has identified the need for federal policy to attract and support the next generation of infectious diseases physician-scientists as important to combating existing and emerging public health threats. We are pleased that the Cures Act includes the creation of a Next Generation Researchers Initiative within the National Institutes of Health (NIH). Further, we believe that the increase in the NIH loan repayment annual maximum from \$35,000 to \$50,000 is a meaningful step towards making research careers more feasible.

While additional resources and legislative efforts are necessary to further these areas, we believe that the 21st Century Cures Act represents an important step forward. We strongly urge passage of the bill prior to the conclusion of the 114th Congress. Once again, thank you for the leadership demonstrated while advancing this important legislation.

Sincerely,

A handwritten signature in cursive script that reads "Bill Powderly". The signature is written in dark ink and is positioned above the printed name.

William G. Powderly, MD, FIDSA
President, IDSA