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IDSA
Infectious Diseases Society of America

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Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
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31 Center Drive, Room 7A03
Bethesda MD 20892-2520

Julie L. Gerberding, MD, MPH
Director, Centers for Disease Control and Prevention &
Administrator, Agency for Toxic Substances and Disease Registry,
Department of Health and Human Services
Room 12316, Building 21
1600 Clifton Road N.E.
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Dear Drs. Fauci and Gerberding:

We are writing to inform you of the Infectious Diseases Society of America's (IDSA) strong endorsement of the "Strategies to Address Antimicrobial Resistance (STAAR) Act," which we are told Representative Jim Matheson (D-UT) plans to introduce this week. IDSA believes the STAAR Act provides a common-sense and comprehensive approach to addressing antimicrobial resistance and strengthening antimicrobial and other product discovery.

IDSA members are immensely indebted to both of you for the important work you have accomplished in advancing the study of infectious diseases and the practice of medicine. Moreover, we are grateful for the important research and surveillance efforts related to antimicrobial-resistant organisms that the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC) currently support. We believe, however, that more must be done to address this critical patient safety and public health issue.

To this end, IDSA is very supportive of two research-related provisions contained in the STAAR Act that are of particular relevance to NIH and CDC. These provisions, Section 101(i) and 103 (both enclosed), call for the:
1) development of an antimicrobial resistance strategic research plan to strengthen existing epidemiological, interventional, clinical, translational and basic research efforts, and
2) creation of a network of 10 or more geographically distributed sites, known as the Antimicrobial Resistance Clinical Research and Public Health Network.

The network would perform clinical and basic research devoted to optimizing antimicrobial therapy, defining natural histories, and testing new products; conduct public health research and sentinel surveillance to assist in describing and confirming new resistance patterns; and, test new ideas for improved prevention and control. These two proposals are further discussed below.

1.) Antimicrobial Resistance Strategic Research Plan

IDSA leaders believe that existing NIH and CDC antimicrobial resistance-related research activities can be better coordinated, funded, and strengthened. In the absence of a strategic plan on resistance research and product development, (including new antimicrobials, diagnostics, biologics and devices), key research areas remain unaddressed. IDSA strongly supports the STAAR Act's proposal that the NIH and CDC develop a strategic research plan that supports a robust, well-directed, and targeted antimicrobial resistance program and defines high-priority research needs and addresses scientific challenges. Such a plan would clarify goals and set benchmarks for evaluating progress particularly in the areas of:

- basic research to better understand the molecular basis for antimicrobial resistance;
- epidemiological research to better understand the transmission and emergence of resistance;
- interventional research to evaluate and determine the best strategies for preventing the spread of resistance; and
- clinical and translational research to define appropriate antimicrobial therapy for infectious diseases, to study the effects of antimicrobial therapy for different diseases and to identify and develop much-needed drugs, biologics, diagnostics, and devices.

IDSA also hopes NIH and CDC explore mechanisms to coordinate their ongoing and future activities in the areas of antimicrobial therapy and resistance, including the possibility of joint Study Sections in relevant areas.

2.) Antimicrobial Resistance Clinical Research and Public Health Network

To support and expand the outcomes envisioned under the strategic research plan, IDSA believes the NIH and CDC should establish a network that co-locates research, surveillance, and prevention research activities and leverages off of the expertise and resources found in existing sites across the country as well as potential new sites.

Section 103 of the STAAR Act would accomplish this by establishing the Antimicrobial Resistance Clinical Research and Public Health Network (ARCRPHN) to accelerate progress on the understanding and control of resistance. Per the STAAR Act, these ARCRPHN sites would be geographically distributed across the United States and could be housed in a variety of locations, including academic centers. These 10 or more sites would work closely with the CDC and NIH.

IDSA supports the ARCRPHN concept. We believe that multiple sites are needed to capture geographic variation and allow broad testing of ideas. Each site could bring together expertise on surveillance, prevention, and research. Because many experts in antimicrobial resistance already possess expertise in all three endeavors, co-locating these activities within the ARCRPHN sites would create efficiencies and speed translation of surveillance findings into research, for example. The ARCRPHN sites would act as an important "extension" of the NIH and CDC.

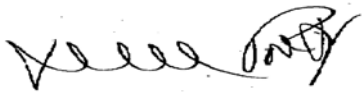
Of significance, ARCRPHN sites would pursue clinical research with a strong focus on identifying the optimal duration of antimicrobial therapy as well as establishing natural histories of infectious disease. IDSA believes that this type of clinical research is urgently needed. Similar clinical research networks have been successfully used by NIH to study HIV/AIDS, vaccines, and other matters requiring rapid, multi-pronged study of complex and urgent issues. Antimicrobial resistance falls within this category.

IDSA leaders believe the creation of the strategic plan and network described above would significantly improve and strengthen existing efforts in this critical area. We see no reason other than constrained funding as to why these two concepts cannot begin to take shape immediately. Regarding funding, IDSA is ready to work quickly and aggressively to advocate for funding to make these ideas a reality—but we realize we cannot make that happen without the shared support of our friends at the NIH and CDC. We hope we can all work together to bring these ideas to fruition. IDSA stands ready to assist you in any way that we can.

Should you have any questions or wish to set up a meeting with IDSA leaders to further discuss these ideas, please contact Robert J. Guidos, JD, IDSA's director of public policy and government relations at 703-299-0202 or rguidos@idsociety.org.

Our best regards to you both,

Martin J. Blaser, MD, FIDSA
Immediate Past President



Donald M. Poretz, MD, FIDSA
President-Elect

Enclosure: Sections 101(i) and 103 of the STAAR Act

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RELEVANT RESEARCH-RELATED PROVISIONS FROM
"THE STRATEGIES TO ADDRESS ANTIMICROBIAL RESISTANCE ACT"

1.) SECTION 101(i): ANTIMICROBIAL RESISTANCE RESEARCH AND DEVELOPMENT OF ANTIMICROBIAL DRUGS, BIOLOGICS, DEVICES, AND DIAGNOSTICS.—
The Secretary, through the Office of Antimicrobial Resistance (NOTE: This would be a new office within the HHS Assistant Secretary of Health's Office), the Centers for Disease Control and Prevention and the National Institutes of Health, and in consultation with other federal agencies shall develop an antimicrobial resistance strategic research plan that strengthens existing epidemiological, interventional, clinical, translational and basic research efforts and funds directly or through the awards of grants or cooperative agreements to public or private entities the conduct of research, investigations, experiments, demonstrations, and studies that advance our understanding of:

(1) the development, implementation and efficacy of interventions to prevent and control the emergence and transmission of antimicrobial resistance;
(2) the epidemiology, pathogenesis, mechanisms and genetics of antimicrobial resistance;
(3) the natural histories of infectious diseases (including defining the disease, the diagnosis, the severity, and the time course of illness);
(4) how best to optimize antimicrobial effectiveness while limiting antibiotic pressure for the emergence of resistance, including but not limited to addressing issues related to duration of therapy, effectiveness of therapy in self-resolving diseases, and determining populations most likely to benefit from antimicrobials;
(5) the development of new therapeutics, including antimicrobial drugs, biologics, and devices against resistant pathogens, and in particular diseases for which few or no therapeutics are in development;
(6) the development and testing of medical diagnostics to identify patients with infectious diseases and identify the exact cause of infectious diseases syndromes, particularly with respect to the detection of pathogens resistant to antimicrobial drugs;
(7) the extent to which the use of antimicrobial products in humans, animals, plants and other uses accelerates development and transmission of antimicrobial resistance; and
(8) the sequencing of the genomes, or other DNA analysis, or other comparative analysis of priority pathogens (as determined by the advisory board), in collaboration with the Department of Defense and the Joint Genome Institute of the Department of Energy.

To the extent practical, such research shall be conducted in conjunction with the Antimicrobial Resistance Clinical Research and Public Health Network.

2.) SECTION 103: ANTIMICROBIAL RESISTANCE CLINICAL RESEARCH AND PUBLIC HEALTH NETWORK

(a) IN GENERAL—The Secretary, through the Director of the Centers for Disease Control and Prevention and the National Institutes of Health, shall establish at least 10 Antimicrobial Resistance Clinical Research and Public Health Network sites to strengthen the national capacity to do the following:

(1) describe and confirm regional outbreaks through surveillance of locally available clinical specimens;

(2) rapidly assess, integrate, and address local and national antimicrobial resistance patterns;

(3) facilitate research concerning prevention, control and treatment of resistant organisms; and

(4) serve as a clinical trials network for optimizing antimicrobial effectiveness.

(b) GEOGRAPHIC DISTRIBUTION—The 10 or more sites shall be geographically distributed across the United States, based in academic centers, health departments and existing surveillance sites.

(c) RESPONSIBILITIES—The persons employed at these sites shall:

(1) monitor the emergence and changes in the patterns of antimicrobial resistant pathogens in people;

(2) study the molecular epidemiology of these pathogens;

(3) evaluate the efficacy and effectiveness of new and existing interventions to prevent or limit the emergence of antimicrobial resistance throughout the geographic region of the site;

(4) provide to the Centers for Disease Control and Prevention isolates of resistant pathogens, and in particular pathogens that show new or atypical patterns of resistance adversely affecting public health;

(5) conduct clinical research to develop natural histories of infectious disease and to study duration of antimicrobial use related to resistance development; and

(6) conduct basic antimicrobial resistance-related research.

(d) COORDINATION—These 10 or more network sites shall be authorized to share data and cooperate with the Centers for Disease Control and Prevention and National Institutes of Health.

(e) DATA ACCESS—The Directors of the Centers for Disease Control and Prevention and the National Institutes of Health shall ensure that summary reports data obtained by the Antimicrobial Resistance Clinical Research and Public Health Network sites are made accessible to the Antimicrobial Task Force for review on an on-going basis.