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Lawrence A. Tabak, DDS, PhD Principal Deputy Director Office of the Director National Institute of Health Building 1, Room 126 Bethesda, MD, 20892

# **Re: NOT-OD-15-118: "Request for Information (RFI): Inviting Comments and Suggestions on a Framework for the NIH-wide Strategic Plan"**

Dear Dr. Tabak,

The Infectious Diseases Society of America (IDSA) is pleased to offer comments to the National Institutes of Health (NIH)'s request for information on its NIH-wide Strategic Plan. As biomedical research has become more interdisciplinary, the need for an objective set of NIH-wide principles to guide cross-cutting research topics has become clear. IDSA firmly believes this strategic plan will enable the NIH to guide and prioritize its resources to more effectively deliver lifesaving medical advances urgently needed by many patients. Below, we offer specific comments within the topics listed in the announcement.

# Potential benefits, drawbacks/challenges, and areas of consideration for the current framework

IDSA supports the framework's statement that measures of disease burden should be a factor, but "not the only factor" when setting research priorities. The NIH's investments must be cognizant of which research opportunities have the highest impact on the many diseases facing patients. For example, while threats from some infectious diseases, such as antimicrobial resistance, may currently incur a moderate disease burden in the U.S., without sustained investment into improved treatments, they can escalate into major public health crises.

Infectious diseases also know no boundaries. While antimicrobial resistance is already a well-documented problem in the U.S., new and even more highly resistant bacteria, such as those containing the New Delhi metallo-beta-lactamase (NDM) enzyme, continue to be imported into the U.S., significantly worsening the impact of resistance on patients. As the recent outbreaks of Ebola virus disease, MERS-coronavirus, and Chikungunya fever have illustrated, new and emerging infectious diseases may have low incidence in the U.S. but nevertheless pose high public health risks. Strong research investment is essential to address these global threats before they can incur a heavy disease burden to the American public, and IDSA urges the NIH to ensure they remain high priority for research investment.

### 2: IDSA comments to the NSABB

Co-morbidities are another important cross-disciplinary consideration. For example, patients who have undergone transplantation, are being treated for cancer, or are suffering from heart disease, are more prone to other diseases, including infection. Improved treatments for infections can decrease the disease burden for these patients who are most at risk. In addition to prioritizing research that aims to directly address diseases with a heavy public burden, we urge the NIH to consider the value of research that may lead to treatments that indirectly improve other diseases.

IDSA also strongly supports the strategic plan's statement that the value of eradicating a pandemic should be considered when prioritizing research. The robust investment by the NIH into developing therapeutics to HIV has saved millions of lives, and IDSA urges the NIH to continue its strong support of efforts to eradicate the HIV/AIDS pandemic. IDSA also recommends prioritizing vaccine research programs, all of which hold great potential to eradicate or significantly reduce the risks of pandemics. For example, in addition to ongoing seasonal influenza vaccine research, the development of a universal influenza vaccine that can generate multi-season protection should remain a NIH priority. IDSA also recommends that the NIH considers the value of research that improves existing vaccines, such as to pertussis, where outbreaks in recent years highlight the need for improved vaccines.

Finally, IDSA strongly agrees with the NIH inclusion of early diagnosis and detection within its area of opportunity for "Health Promotion and Disease Prevention." Improved diagnostics are essential to improving other areas of the healthcare spectrum, such as antimicrobial stewardship. Since common diagnostic technologies can improve testing for multiple disease burdens, IDSA urges the NIH to prioritize cross-cutting diagnostic research so these new tests can improve patient care.

## Additional concepts in ICO strategic plans that are cross-cutting and should be included in this trans-NIH strategic plan

IDSA is pleased to see the NIH lists the need for partnerships for breakthroughs in its areas of opportunity. IDSA has strongly supported NIH public private partnerships (PPP) such as the Accelerating Medicines Partnership (AMP), and believes that AMP should be expanded to better take advantages of untapped partnership opportunities such as antimicrobial drug development and rapid diagnostic technologies. IDSA urges that the NIH consider similar PPP models for prioritization, such as the biopharmaceutical incubator called for by the National Action Plan for Combating Antibacterial Resistant Bacteria (CARB) to promote antimicrobial development.

Our society also supports the NIH's inclusion of reducing administrative burden in its "enhancing stewardship" focus area. As this strategic plan focuses on cross-cutting efforts, IDSA believes this is an excellent opportunity for the NIH to consider a systematic plan to develop, in collaboration with its institutes and centers as well as funded academic institutions, standard metrics or best practices that focus on the most efficient policies to ensure regulatory compliance without creating undue burden.

### 3: IDSA comments to the NSABB

### Future opportunities or emerging research needs

IDSA is pleased to see the NIH include recruiting and retaining an outstanding biomedical research workforce in its focus areas to sustain the biomedical research enterprise. As the NIH moves to more cross-disciplinary research, the unique perspectives of physician-scientists, who sit at the intersection between basic and translational/clinical research, will only become more valuable to biomedical research. IDSA urges that the NIH prioritize the strengthening of the physician-scientist workforce to enable the cross-cutting research the strategic plan endorses.

IDSA appreciates the opportunity to provide its recommendations to the NIH as it further develops its NIH-wide strategic plan to strengthen the biomedical research enterprise. Should you have any questions or concerns about these comments, please feel free to contact Greg Frank, PhD, IDSA Program Officer for Science and Research Policy, at <u>gfrank@idsociety.org</u> or 703-299-1216.

Sincerely,

Steplen B. Calderwood

Stephen B. Calderwood, MD, FIDSA IDSA President

### About IDSA

IDSA represents over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA) vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as *Acinetobacter baumannii, Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*, and, finally, emerging infectious syndromes such as Ebola virus fever, enterovirus D68 infection, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), and infections caused by bacteria containing the New Delhi metallo-beta-lactamase (NDM) enzyme that makes them resistant to a broad range of antibacterial drugs.