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August 19, 2010

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

Dear Dr. Fauci:

We write on behalf of the Infectious Diseases Society of America (IDSAs) for two important reasons. First, to express IDSAs leaders' sincere gratitude for the keynote talk you presented to launch the July 26-27, 2010 Food and Drug Administration/ National Institute on Allergy and Infectious Diseases (NIAID)/IDSAs Public Workshop on Antibacterial Resistance and Diagnostic Device and Drug Development Research for Bacterial Diseases. Your excellent presentation lent additional gravitas to the important issues discussed during the workshop and started the workshop on a very high note. Your presentation slides and a video of your talk have been posted on IDSAs's website at www.idsociety.org/ARWorkshop.html. IDSAs hopes the joint workshop will inspire strengthened research in the area of antibacterial-resistant infections.

Second, we write in response to NIAID's recent solicitation for input on the future structure and objectives of NIAID's clinical trials infrastructure. In a letter to you of October 2009, IDSAs urged NIAID to expand the purview of its clinical trials groups in four areas: influenza, serious bacterial infections, tuberculosis, and hepatitis C. IDSAs views the clinical trial infrastructure we proposed as fitting squarely within and being supportive of the Department of Health and Human Services' (HHS) new initiative: [Public Health Emergency Medical Countermeasures Enterprise \(PHMCE\) Review: Transforming the Enterprise to Meet Long-Range National Needs](#), which HHS Secretary Kathleen Sebelius, Assistant Secretary for Preparedness and Response (ASPR) Nicole Lurie, you and other HHS leaders announced this morning. IDSAs believes the establishment of an NIAID-funded clinical trials infrastructure, which addresses high priority, life-threatening infections and that is similar in scope to the National Cancer Institute's (NCI) clinical trials infrastructure, which spans across the spectrum of cancers, is urgently needed. We are gratified to see steps being taken towards this goal, such as the recent expansion of the AIDS Clinical Trials Group's (ACTG) tuberculosis research portfolio. We believe the needs in this area have become even more urgent due to the elimination of two clinical trials groups: the Mycoses Study Group and the Collaborative Antiviral Study Group.

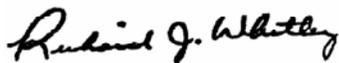
In an effort to better understand the position of NIAID leadership on its plans to expand its current clinical trial network infrastructure, including how this enhanced infrastructure could best support the new HHS' PHMCE initiative, and given your previous invitation to meet with you and NIAID leadership, IDSA is extremely interested in participating in a meeting to discuss the Institute's plans for clinical studies of these infections going forward and to provide input on possible mechanisms the Institute might use to organize them. As you know, there is much to be learned from NCI's experience in support of cancer clinical trials, including inefficiencies and frustrations to avoid, as were highlighted in a recently released Institute of Medicine report: *A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program* (Executive Summary and Overview of Conclusions and Recommendations enclosed).

Clinical trials are urgently needed to compare treatments for drug-resistant infections. For example, a variety of possible interventions have been suggested to improve the outcomes of invasive methicillin-resistant *Staphylococcus aureus* (MRSA) infections (e.g., higher-dose vancomycin, higher-dose daptomycin, use of adjunctive antibiotics). Similarly, despite the growing prevalence of extensively-resistant Gram-negative pathogens, there is an almost complete lack of randomized trials of possible therapeutic agents for these infections (e.g., colistin, tigecycline, fosfomycin).

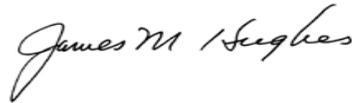
Clinical trials also are needed to address other important infections, for example those caused by viruses, such as influenza (both seasonal and pandemic), parainfluenza viruses, respiratory syncytial virus, cytomegalovirus, and herpes simplex virus, as well as those caused by important fungi such as *Candida* and *Aspergillus*. Decisions as to which infections to investigate, in both children and adults, might be decided under the leadership of the proposed new clinical trials organization, as was done with the ACTG. Such an NIAID clinical trials infrastructure should be flexible and agile, with the ability to rapidly respond to new or re-emerging infections as they arise. Further, it must balance both pediatric and adult unmet infectious diseases needs.

We appreciate your consideration of IDSA's meeting request and look forward to further discussions on the future of NIAID's clinical trial networks.

With warmest wishes,



Richard J. Whitley, MD, FIDSA
President



James M. Hughes, MD, FIDSA
President-Elect

Enclosure: Summary and Recommendations from [IOM 2010 Report: A National Cancer Clinical Trials System for the 21st Century: Reinvigorating the NCI Cooperative Group Program](#)

cc: Nicole Lurie, MD, MSPH, HHS ASPR
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