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October 19, 2009

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:

I write on behalf of the Infectious Diseases Society of America (IDSAs) to follow up on the National Institutes of Allergy and Infectious Diseases' (NIAID) recent external consultation on infectious diseases clinical research infrastructure. First, we very much appreciate your kind invitation asking IDSAs to send a representative to this important meeting, and we are very much appreciative to Dr. William Burman for his excellent service on IDSAs's behalf in this role. As you know, IDSAs is extremely committed to supporting NIAID in any way that we can to advance infectious diseases research, especially in strengthening the institute's clinical trials infrastructure. Much has been accomplished in this area, and much more needs to be done.

IDSAs supports the proposal discussed at the external consultation to expand the NIAID's clinical trials networks. Our support extends to NIAID's plans to expand networks to study tuberculosis, hepatitis, and influenza, which Drs. Hugh Auchincloss and Clifford Lane highlighted at the recent NIAID Advisory Council meeting. Additionally, Dr. Auchincloss mentioned antimicrobial resistance as a possible network focus that NIAID is exploring. As you know, IDSAs is strongly supportive of clinical research on drug resistance and on drug-resistant bacteria in particular. We applaud NIAID for considering a clinical trials network in this critical area.

The impact of antibacterial resistance is great and growing. The emergence of highly drug-resistant bacteria (e.g., extended spectrum beta-lactamase producing *Klebsiella pneumoniae*) has highlighted the deficiencies in our knowledge of the treatment of resistant bacterial infections. In addition, more virulent forms of other pathogens, such as methicillin-resistant *Staphylococcus aureus* (MRSA) and the BI-NAP strain of *Clostridium difficile*, have spread widely and caused tremendous morbidity and mortality. Many uncertainties constrain our efforts to prevent, control and treat resistant bacterial infections. Remarkably, we do not yet know the optimal drug, drug combination or treatment duration for invasive MRSA infections nor how best to use an old drug, colistin, to treat highly drug-resistant gram-negative infections. Well-conceived and executed clinical trials to evaluate interventions to prevent and treat resistant bacterial infections are essential.

The field of tuberculosis is now at a key juncture. The increased incidence of *Mycobacterium tuberculosis*, driven by HIV-related immunodeficiency, and the emergence of drug-resistant strains of *M. tuberculosis* threaten its global control. This time of great need reveals great opportunities. Promising new diagnostic tests and potent new drugs, based on investments in basic science by NIAID and others, hold the potential to revolutionize the treatment of both drug-resistant and drug-susceptible tuberculosis. In addition, novel vaccine candidates to replace the Bacillus Calmette-Guérin (BCG) vaccine are now entering clinical trials. Global tuberculosis clinical trials capacity is increasing, but is still woefully inadequate to allow prompt and robust evaluation of these promising new tests, drugs and vaccines.

Chronic viral hepatitis has become a common cause of morbidity and mortality among persons with HIV disease and in the general population. The estimated 3.2 million cases of Hepatitis C exceed those of HIV in the U.S. Enhancing the tolerability and efficacy of treatment for Hepatitis C, particularly genotype 1, is increasingly feasible as new drugs become available for clinical trials.

This year's global pandemic of the H1N1 strain is a striking reminder of the importance of research on influenza. Without accurate surveillance and the ability for rapid production of vaccine, the toll of H1N1 would have been worse. However, additional efforts are needed to allow even more rapid vaccine production and the identification of additional therapies for influenza.

In summary, NIAID-funded clinical trials networks have developed the key requirements for the performance of high-quality clinical trials; experienced investigators and study sites, robust statistical support, specialized laboratories (e.g., pharmacokinetics, immunology) and organizational structures to support clinical trials. New clinical trials groups can contribute substantially to the critical need for advancements in the diagnosis and treatment resistant bacterial infections, tuberculosis, chronic viral hepatitis and influenza. IDSA urges NIAID to include all four of these important areas in the expanded purview of its funded clinical trials networks.

Sincerely,



Anne A. Gershon, MD, FIDSA
IDSA President

cc: Hugh Auchincloss, Jr., MD, Principal Deputy Director, NIAID
H. Clifford Lane, MD, Director, Office of Clinical Research (OCR)/NIAID
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