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June 24, 2005

Senator Richard Burr, Chair
Subcommittee on Bioterrorism and Public Health Preparedness
U.S. Senate Committee on Health, Education, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman Burr:

The Infectious Diseases Society of America (IDSA) wishes to thank you for your hearing, *Crossing the Valley of Death: Bringing Promising Medical Countermeasures to Bioshield*, on June 9, to focus attention on very important problems facing the nation. We also want to thank your staff, Dr. Bob Kadlec, for taking time after the hearing to discuss with us your plans for introducing legislation related to Bioshield II. IDSA, which represents nearly 8,000 infectious disease physicians and scientists, is ready to provide assistance to you in whatever way that we can.

In the drafting of any new legislation on Bioshield, IDSA would like to emphasize the crucial importance of including in your bill a "wild-card" patent extension for companies that develop and receive approval for a priority antibiotic that treats a targeted bacterial pathogen. As you know, the wild-card concept would allow a company developing an approved priority antibiotic to extend its market exclusivity for another of the company's FDA-approved drugs for a defined period of time, e.g. six months. IDSA proposes that the availability of the wild-card provision also could be tied to a company's commitment to invest a portion of the profits derived during the extension period back into antibiotic research and development (R&D).

IDSA believes that the wild-card provision is critically needed to save countless lives and to protect national security. Antibiotics simply are not as profitable as drugs that treat chronic conditions that require drug therapy for the rest of a patient's life, and, for this reason, they are not being developed by drug companies. A recent study has found only five new antibiotics in the R&D pipeline out of more than 506 drugs in development among 15 major pharmaceutical companies with a track record in antibiotic development and seven major biotechnology companies. Since 1998, the Food and Drug Administration has approved very few antibiotics and only a small proportion of these were truly novel; that is, they have a new target of action, with no cross-resistance with other antibiotics.

Because antibiotics work as well and as fast as they do (antibiotics are commonly prescribed for seven to 14 days), they produce a weak return on investments for manufacturers. Furthermore, antibiotic R&D is hampered by technical challenges; the discovery of new antibiotics is not as easy as once believed, the Institute of Medicine noted recently. Finally, because many antibiotics are used to treat various types of infections, the drug approval process requires clinical trials for each type. These three problems—limited demand, the high cost of basic research, and the regulatory process—have led major pharmaceutical companies to conclude that costs outweigh benefits and that research dollars are better invested in other areas.

To concerns being raised about the wild-card patent extension idea, we respond that any short-term profits that a drug company receives as a result of developing a priority antibiotic would be more than offset by inpatient, emergency room, and physician visit costs that would be incurred for treating the growing number of patients with resistant bacterial infections for which there are no licensed, effective antibiotics.

To get to the question of what would constitute a "priority antibiotic" valuable enough to trigger the application of a wild card patent extension, IDSA envisions the establishment of an independent commission to identify ahead of time those targeted pathogens that are (or are likely to become) a significant threat to public health due to drug resistance and other factors. The commission would make recommendations directly to the Secretary of the Department of Health and Human Services (HHS) and would be comprised of leading representatives of the infectious diseases medical, research, and pharmaceutical and biological communities; and leaders in law, health policy, and economics. The commission also should include as ex officio members the Secretary of HHS, the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, the Director of the Centers for Disease Control and Prevention, the Assistant Secretary of Defense for Health Affairs, the Chief Medical Director of the Department of Veterans Affairs (or the designees of such officers).

For more than two years, IDSA has investigated the serious decline in new antibiotic R&D. In our discussions with government officials, executives from leading pharmaceutical and biotechnology companies, as well as representatives from public-private partnerships that are focused on infectious diseases-related products, we learned that a number of different incentives are necessary to correct the serious imbalance in industry's commitment to antibiotic R&D and the country's need for cures for new infections and the growing resistance to known bacteria. None of the solutions that we found is as critical as the establishment of a wild-card patent extension.

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We would be pleased to talk to you further about this whenever it may be convenient to do so. Please feel free to contact Robert J. Guidos, JD, at 703-299-0202.

Sincerely yours,

A handwritten signature in black ink that reads "Walter Stamm". The signature is written in a cursive style with a large, prominent initial "W".

Walter E. Stamm, MD
President