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IDSAs Headquarters

1300 Wilson Boulevard
Suite 300

Arlington, VA 22209

TEL: (703) 299-0200

FAX: (703) 299-0204

EMAIL ADDRESS:

info@idsociety.org

WEBSITE:

www.idsociety.org

December 17, 2007

Honorable Edward M. Kennedy
Chairman,
Committee on Health, Education, Labor and Pensions
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

I write on behalf of the Infectious Diseases Society of America (IDSAs) to urge your support for improving incentives for antibiotic research and development. IDSAs greatly appreciates your attention to the issue of antimicrobial resistance and hopes that Congress will address exclusivity for "old" antibiotics this year. As you may recall, this provision from the Senate-passed bill was eliminated from the Food and Drug Amendments Act (FDAAA) conference report and we urge you to address the issue on another vehicle to ensure timely passage.

The provision from the Senate-passed bill -- Section 261 of S.1082, entitled "Incentives for the Development of, and Access to Certain Antibiotics" -- was an important step forward to help spur research on new indications/uses for antibiotics originally submitted to the Secretary before 1997. The inequity for these "old" antibiotics was the result of a transition when antibiotic regulation was shifted from Section 507 to 505 in the 1997 Food and Drug Administration Modernization Act (FDAMA). Today, "old" antibiotics continue to be treated less favorably than other pharmaceutical products regulated under Section 505.

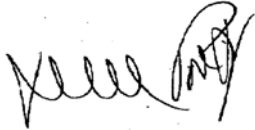
As you know, many pharmaceutical companies are abandoning or scaling back antibiotic research and development in favor of more profitable drugs that treat chronic conditions. This is a regrettable, but understandable, development as market forces that would lead companies to consider investing in new antibiotic development are weak. Because antibiotics work so well and so fast, in most cases, they are prescribed for only one or two weeks. That means they don't have as large a market as drugs that patients take for years.

Federal policy to reduce the threat of antimicrobial resistance should include incentives to strengthen the antibiotic pharmaceutical pipeline. Unless we improve incentives for antibiotic research and development, there is no promise of treatments for the increasing number of resistant microbes we face. As you know, research and development takes time and money. Any policies implemented today will take more than a decade to realize. In the meantime, resistance to existing antibiotics will continue to increase.

PAGE TWO—IDSA Incentives Letter to Chairman Kennedy

IDSA stands ready to work with you. As infectious diseases specialists, we believe keeping up with the “Bad Bugs” is in the best interest of our Nation’s and global health. Should you have any questions, please contact Robert J. Guidos, JD at 703-299-0202 or RGuidos@idsociety.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Donald Poretz", with a stylized flourish at the end.

Donald Poretz, MD
IDSA President