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Infectious Diseases Society of America

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### IDSAs Headquarters

66 Canal Center Plaza  
Suite 600

Alexandria, VA 22314

TEL: (703) 299-0200

FAX: (703) 299-0204

EMAIL ADDRESS:

info@idsociety.org

WEBSITE:

www.idsociety.org

July 5, 2005

The Honorable Barbara Cubin  
1114 Longworth House Office Building  
House of Representatives  
Washington, D.C. 20515

Dear Representative Cubin:

I am writing to express the appreciation of the Infectious Diseases Society of America (IDSAs) and our membership for the leadership that you have shown in introducing H.R. 3154, the "Infectious Diseases Research and Development Act of 2005." This important bill, if signed into law, will motivate the research and development (R&D) of critical new drugs, vaccines, and diagnostics that will better protect Americans against the growing threats posed by infectious diseases. As such, IDSAs supports the bill and pledges to closely work with you and your staff to ensure that this important legislation is further strengthened and enacted this year.

IDSAs represents 8,000 infectious diseases physicians, researchers, and other health care professionals dedicated to promoting health through excellence in infectious diseases research, education, prevention, and patient care. For the past several years, IDSAs has sought the enactment of novel legislation to spur the development of new products to protect patients against an increasing number of antibiotic-resistant infections, pandemic influenza, and other emerging infectious diseases. We are grateful to have had the opportunity to work with you and your staff in developing this solid, pragmatic bill.

Reports of antibiotic-resistant infections have been steadily increasing in the scientific literature and these infections are having an impact throughout the country. At the same time, the pipeline of new antibiotics has been drying up. Many communities are reporting a significant increase in methicillin-resistant *Staphylococcus aureus* (MRSA) and other serious drug-resistant infections among people with no known risk factors, such as healthy children, athletes, and military recruits. In addition, 2 million hospital-acquired bacterial infections result in 90,000 deaths each year in the United States; approximately 70 percent are resistant to at least one antibiotic. At the same time, several major pharmaceutical companies have abandoned antibiotic research and development altogether in favor of more profitable drugs for chronic conditions like heart disease and arthritis. IDSAs has documented the problem in a report published last July called *Bad Bugs, No Drugs: As Antibiotic Discovery Stagnates ... A Public Health Crisis Brews*, which is available at [www.idsociety.org/badbugsnodrugs](http://www.idsociety.org/badbugsnodrugs).

H.R. 3154 adopts many of the ideas that IDSA suggested in our *Bad Bugs* report, including the restoration of patent time lost during the Food and Drug Administration’s (FDA) review of antibiotics and other “qualified infectious diseases products;” a “wild-card patent extension” provision that could extend the patent time on a company’s separate, FDA-approved product, if the pharmaceutical company successfully produces a “qualified infectious diseases product;” and fast-tracking FDA’s review of these products. The patent extension and other provisions found in the bill will go a long way toward reinvigorating the antibiotic pipeline.

Concerns about the product pipeline are not limited to drug-resistant infections, however. Last fall’s influenza vaccine shortage demonstrated how unprepared the nation is for the next influenza pandemic. The Centers for Disease Control and Prevention estimates that a flu strain as deadly as the one that caused the 1918 pandemic could kill as many as 2 million people in the United States alone. However, the nation lacks the manufacturing capacity to produce enough influenza vaccine or necessary antivirals to protect the American people. H.R. 3154 helps to address this problem by, among other things, establishing tax credits for the research, development, manufacturing, and distribution of “qualified infectious diseases products,” such as influenza vaccine and antivirals.

With regard to antiviral drugs for influenza, IDSA is very concerned that the United States does not have nearly enough antivirals on hand to fight a coming influenza pandemic. When the next pandemic hits, antivirals will be our only defense for at least the six to nine months it takes to make sufficient doses of a new vaccine. Currently, the Department of Health and Human Services (HHS) has only 2.3 million treatment courses of oseltamavir (Tamiflu) available. IDSA calculates that HHS should have at least 52 to 84 million courses available to treat those who become sick with flu. At least another 15 to 40 million courses would be needed to provide preventive treatment to even a small set of essential health care workers and emergency responders. Although your bill includes language that begins to address this problem, we hope to have the opportunity to work with you and your staff further to strengthen this provision before the bill is enacted.

Finally, IDSA applauds the creation of a Commission on Infectious Diseases Product Development (CIDPROD), through which infectious diseases experts will work to identify the most dangerous infectious disease pathogens that are or are likely to become significant public health threats. H.R. 3154 will not delay action until CIDPROD issues its first report. Instead, the legislation wisely provides an initial list of targeted “bad bugs” for the U.S. Department of Health and Human Services to work on, including:

- community-acquired methicillin-resistant *Staph aureus* (CA-MRSA)
- life-threatening gram negative bacteria, such as *Escherichia coli* (*E. coli*), *Acinetobacter* (which is threatening soldiers returning from Iraq), *Klebsiella species*, and *Pseudomonas aeruginosa*
- influenza

IDSA Letter Regarding H.R. 3154, "Infectious Diseases Research and Development Act"  
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In the future, IDSA expects the "Infectious Diseases Research and Development Act" also will help to encourage the development of new vaccines, anti-infectives, and diagnostics to prevent, treat, and detect other significant infectious disease pathogens such as HIV/AIDS, tuberculosis, malaria, and neglected diseases; and frightening emerging diseases such as severe acute respiratory syndrome (SARS), West Nile virus, and Ebola and Marburg hemorrhagic fevers.

H.R. 3154 provides a valuable opportunity to limit the United States' vulnerability to the many "bad bugs" that threaten American children, our elderly, and even healthy adults. We look forward to working with you to see that this important legislation reaches the President's desk this year.

Should you have any questions, please feel free to contact Robert J. Guidos, JD, IDSA's director of public policy and government relations at (703) 299-0200.

Sincerely,

A handwritten signature in black ink, appearing to read "Walter Stamm". The signature is fluid and cursive, with the first name "Walter" and last name "Stamm" clearly distinguishable.

Walter E. Stamm, MD  
IDSA President