



IDSAs

Infectious Diseases Society of America

2011-2012 BOARD OF DIRECTORS

President

Thomas G. Slama, MD, FIDSA
INDIANA UNIVERSITY SCHOOL OF MEDICINE
INDIANAPOLIS, IN

President-Elect

David A. Relman, MD, FIDSA
STANFORD UNIVERSITY SCHOOL OF MEDICINE
PALO ALTO, CA

Vice President

Barbara E. Murray, MD, FIDSA
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER
HOUSTON, TX

Secretary

Kathryn M. Edwards, MD, FIDSA
VANDERBILT UNIVERSITY MEDICAL CENTER
NASHVILLE, TN

Treasurer

Cynthia L. Sears, MD, FIDSA
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
BALTIMORE, MD

Immediate Past President

James M. Hughes, MD, FIDSA
EMORY UNIVERSITY
ATLANTA, GA

Upton D. Allen, MD, FIDSA

HOSPITAL FOR SICK CHILDREN
TORONTO, ONTARIO, CANADA

Paul G. Auwaerter, MD, FIDSA

JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE
BALTIMORE, MD

Johan S. Bakken, MD, PhD, FIDSA

ST. LUKE'S ID ASSOCIATES
DULUTH, MN

Helen W. Boucher, MD, FIDSA

TUFTS MEDICAL CENTER
BOSTON, MA

Michael L. Butera, MD

PULMONARY MEDICINE AND INFECTIOUS DISEASES
MEDICAL GROUP
SAN DIEGO, CA

Carlos del Rio, MD, FIDSA

EMORY UNIVERSITY
ATLANTA, GA

Stanley C. Deresinski, MD, FIDSA

STANFORD UNIVERSITY SCHOOL OF MEDICINE
PALO ALTO, CA

Andrew T. Pavia, MD, FIDSA

UNIVERSITY OF UTAH
SALT LAKE CITY, UT

Wesley C. Van Voorhis, MD,

PhD, FIDSA
UNIVERSITY OF WASHINGTON
SEATTLE, WA

Chief Executive Officer

Mark A. Leasure

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

November 22, 2011

Honorable Richard Blumenthal
United States Senate
Washington, D.C. 20510

Honorable Bob Corker
United States Senate
Washington, D.C. 20510

Dear Senators Blumenthal and Corker:

On behalf of the Infectious Diseases Society of America (IDSAs), a medical society comprised of nearly 10,000 infectious diseases physicians and scientists, I write to thank you for your leadership in introducing the Generating Antibiotic Incentives Now (GAIN) Act (S. 1734) to address the diminishing pipeline of new antibiotics and elevating this important public health and national security issue in the United States Senate. Your commitment to find solutions to this critical problem is highly valued by the hundreds of thousands of Americans who suffer from serious and life-threatening bacterial infections each year and the physicians who seek new medicines to treat them.

The GAIN Act provides an excellent starting point for discussing the right combination of incentives needed to jumpstart novel antibiotic and related diagnostic research and development (R&D). IDSAs supports several provisions in the GAIN Act that encourage antibiotic development, including those that encourage the development of companion diagnostics; provide expedited review and fast track consideration; and establish deadlines for release of antibiotic clinical trial guidance. Congressional action on these issues is particularly critical given the high health care and societal costs attributed to antibiotic resistance.

Like you, IDSAs is committed to achieving a robust antibacterial R&D effort. Each day, ID physicians are on the front lines in hospitals and communities across the country fighting bacterial infections including aggressive, antibiotic-resistant "bad bugs". We are frustrated with the lack of effective drugs available to treat our patients. Many companies have abandoned antibiotic R&D in the U.S. due to complex factors, chiefly economic disincentives and regulatory uncertainty. Today, alarmingly, there are only two large companies with strong and active antibiotic programs. Recent reports by IDSAs and the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) demonstrate that there are few candidate drugs in the pharmaceutical pipeline to treat infections due to highly-drug-resistant bacteria. The ECDC/EMA report, for example, found only 15 antibacterial drugs with systemic administration in the development pipeline and only five of these had progressed to clinical trials to confirm clinical efficacy (Phase III or later). Unfortunately, based on past experience, we know that few of these drugs are likely to make it to market.

Last year, IDSAs launched a global collaboration titled the "10 x '20 initiative," to provide a measurable goal for our Bad Bugs, No Drugs campaign. The 10 x '20

initiative, which is supported by 33 medical societies in the U.S and Europe, aims to create a sustainable global antibacterial drug R&D enterprise with the power in the short-term to develop 10 new, safe, and effective systemic antibiotics by 2020. Efforts like those envisioned by the GAIN sponsors are necessary to begin to reach this life-saving achievement.

We understand the difficulty of funding new efforts at a time when Congress is grappling with the need to reign in federal spending and address the deficit. As the clinical and research experts in this field, IDSA leaders look forward to working with you toward passage of the GAIN Act and encourage you to further strengthen the bill in three critical areas, which we believe complement the current provisions. Our suggestions include:

(1) providing targeted market exclusivity incentives that begin at the end of all existing patent and exclusivity periods. Given congressional concern regarding overall cost of any proposals, **it is important to note that exclusivity incentives crafted in this way would likely not produce a score within the next decade or two** given the average patent life that remains available for most antibiotics at the time of approval. Further, these incentives may be targeted to areas of greatest need (e.g., to spur the development of new classes of antibiotics—experts report only one new class of antibiotics has been approved in the past thirty years—and to spur research needed to bring new indications onto the label for approved antibiotics). Please refer to the **enclosure** for more information on IDSA’s exclusivity proposals.

(2) ensuring the appropriate use of antibiotics once approved. We want to be sure antibiotics are used at the right time and for the right bacteria post-approval to preserve their effectiveness for as long as possible by protecting against the development of antibiotic resistance. Appropriate use of antibiotics not only promotes high quality care, but will help protect the federal investment necessary to jumpstart innovation as well as protect precious Medicare and Medicaid dollars by limiting the development of resistant bacteria that cause costly infections.

(3) designating a lead federal agency to explore options for public private collaborations focused on antibiotic discovery research and to report back to Congress within 1 year. This initiative could be undertaken at little to no cost and could yield significant results. Companies have acknowledged the value, and perhaps necessity, of working closely together and with governments to overcome the unique scientific and economic challenges to antibiotic innovation. Collaborative public private partnerships already are moving forward in Europe. Last week, the European Commission, recognizing the urgent need for a “new business model” for antibiotic R&D, announced an “unprecedented collaborative” effort¹ whereby the government will work together with companies to bring new antibiotics to patients. If the U.S. fails to support similar collaborative efforts, we run the risk of further eroding our competitive edge, not to mention losing more U.S. jobs and intellectual capital.

Antibiotic-resistant infections significantly increase both health care and societal costs and hospital stays as demonstrated by an analysis of antibiotic-resistant infection data from a study

¹“Communication from the Commission to the European Parliament and the Council; Action Plan Against the Rising Threats from Antimicrobial Resistance”. Pages 8-9. November 17, 2011.
http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf

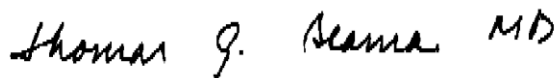
conducted at Chicago Cook County Hospital (*Clinical Infectious Disease*, October 2009). Extrapolating that analysis nationwide, the authors concluded antibiotic-resistant infections cost the U.S. health care system in excess of \$20 billion annually, \$35 billion in societal costs, and more than 8 million additional days spent in the hospital. The cost to society of antimicrobial-resistant infections in terms of lives lost and the economy will only rise as antimicrobial resistance continues to spread.

Strengthened investment in new antibiotics also is essential for U.S. national security. An October 2011 Bio-Response Report Card issued by the Bipartisan WMD Terrorism Research Center—chaired by former Senators Bob Graham and Jim Talent—concluded that a terrorist armed with an antibiotic-resistant pathogen could produce a large-scale event with “catastrophic consequences,” resulting in a “potentially uncontrollable number of illnesses and/or deaths,” “civil and political unrest in the affected region,” and a “global economic impact”.

For all of these reasons, IDSA is eager to see success in your efforts to encourage antibiotic R&D. We stand ready to assist you and hope you will carefully consider how the three suggestions included above can encourage antibiotic innovation and serve to complement the current GAIN Act provisions.

Again, thank you for your commitment and leadership on this important public health issue, which the World Health Organization (WHO) has identified as one of the three greatest threats to human health.

Sincerely,

Handwritten signature of Thomas G. Slama MD in black ink.

Thomas G. Slama, MD, FIDSA
President

Cc: The Honorable Tom Harkin, Chairman
U.S. Senate Health, Education, Labor and Pensions Committee
The Honorable Michael Enzi, Ranking Member
U.S. Senate Health, Education, Labor and Pensions Committee
GAIN Act Co-sponsors

Enclosure: GAIN Act Exclusivity Proposals

Enclosure: GAIN Act Exclusivity Proposals

Exclusivity: To provide economic benefit and thus spur antibiotic research and development (R&D), exclusivity must be applied at the end of all remaining exclusivity and patent time to keep competitors' drugs off the market longer. **Structured in this manner, the exclusivity proposals discussed below will likely not produce a score for the next decade or two,** given the average amount of patent life typically remaining on new antibiotics at the time they are approved. As currently drafted, GAIN exclusivity attaches to the end of existing Hatch/Waxman data exclusivity and would run concurrent with most antibiotics' existing patent terms. As such, GAIN will keep competitors off the market only in limited cases when the original drug's development period took so long that less than 10 years of patent life remains available post-approval. For the average antibiotic, 10 to 12 years of patent time typically remains post-approval. Thus, GAIN's exclusivity incentive's primary benefit will be to protect companies from patent infringement suits during the additional 5 years of exclusivity. While companies want to be protected from infringement suits, and, thus, support GAIN, the value of this incentive likely is not sufficient to stimulate new antibiotic R&D—our common, critical goal. Major companies, including GlaxoSmithKline (GSK) and Pfizer, agree with IDSA's assessment. To strengthen GAIN's exclusivity provision, consider the addition of (1), (2), and (3) below in descending order of priority:

- (1) A 5-year period of exclusivity that attaches to the end of all existing exclusivity and patent periods, thereby prohibiting the approval of competitors' drug applications during the protected period. In its first 10 years (1997-2007), pediatric exclusivity generated more than 300 pediatric studies and over 115 products have undergone labeling changes for pediatric use—demonstrating that exclusivity at the end of patent life is a model worth considering. Both GSK and Pfizer have modeled this incentive and agree that it would provide substantial additional benefit over the current GAIN exclusivity provision.
- (2) An additional 3-year period of exclusivity at the end of all existing exclusivity and patent periods if the antibiotic is the first of a new class because, for example, the active moiety of the product achieves its therapeutic effect through a new mechanism of action or targets a site on the infectious pathogen not targeted by products previously approved. For purposes of this new provision, the Food and Drug Administration will need to define in regulations the term "antibiotic class" as this term currently is not defined. However, many experts agree only one new class of antibiotic has been approved since the 1970s. New classes of antibiotics can provide valuable new protections against drug-resistant pathogens. Creating new antibiotic classes should be a priority for GAIN.
- (3) Any exclusivity period extended pursuant to the GAIN Act should be further extended by one year of exclusivity at the end of all existing exclusivity and patent periods for each subsequent approval an antibiotic receives for treating an additional infection or pathogen where FDA deems the subsequent approval(s) address a critical unmet need. It makes sense to consider limiting this incentive, e.g., no antibiotic could receive more than three such one year extensions. This incentive will spur companies to conduct additional research on approved antibiotic drugs, thus, providing valuable effectiveness and safety information about how these drugs work in patients suffering these infections; without such additional studies physicians will not have access to this critical information.