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June 15, 2011

The Honorable Phil Gingrey, MD  
U.S. House of Representatives  
Washington, D.C. 20515

### **SUBJ: H.R. 2182, the Generating Antibiotic Incentives Now (GAIN) Act**

Dear Representative Gingrey:

I write on behalf of the Infectious Diseases Society of America (IDSAs), a medical society comprised of more than 9,300 Infectious Diseases physicians and scientists, to thank you again for participating in the World Health Day Press Conference on Antimicrobial Resistance and to applaud your leadership in introducing H.R. 2182, the Generating Antibiotic Incentives Now (GAIN) Act of 2011. The Society highly values your commitment to address the critical problem of antimicrobial resistance—an urgent and growing problem that threatens patient safety and public health worldwide. The World Health Organization (WHO) has identified antimicrobial resistance as one of the three greatest threats to human health.

To begin to reverse the impact on public health, save lives, and reduce healthcare expenditures, last year, IDSAs launched a collaboration titled the “**10 x '20 initiative**”, which aims to create a sustainable global antibacterial drug research and development (R&D) enterprise with the power in the short-term to develop 10 new, safe, and effective systemic antibiotics by 2020. The 10 x '20 initiative builds upon the goals outlined in IDSAs's 2004 *Bad Bugs, No Drugs* report, which recommended the adoption of statutorily-defined incentives to stimulate new antibiotic development.

Recent reports by IDSAs as well as the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) demonstrate that there are few candidate drugs in the pipeline to treat infections due to highly-drug-resistant bacteria. An ECDC/EMA report, for example, found only 15 antibacterial drugs for 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.

The GAIN Act provides an excellent starting point for discussing the right combination of incentives necessary to jumpstart novel antibiotic (and related diagnostic) R&D, and IDSAs supports H.R. 2182 as a foundation for achieving this—our shared goal. We are pleased to have had the chance to work with you and your staff on this critically important legislation and are eager to work with

you to further strengthen the bill and secure its passage. H.R. 2182 contains promising ideas to encourage antibiotic and related diagnostics R&D, including provisions that will:

- extend the period of exclusivity for new antibiotics to treat many of the drug-resistant pathogens of greatest concern;
- encourage companion diagnostics R&D by extending the period of exclusivity for an antibiotic for which the manufacturer identifies a companion diagnostic test;
- require the Food and Drug Administration (FDA) to provide expedited review for qualified antibiotics;
- provide fast track consideration for qualified antibiotics; and
- establish deadlines and other requirements for the development of clinical trial guidance related to antibacterials.

As you know, identifying incentives that sufficiently stimulate the development of novel antibiotics while also ensuring their appropriate use once approved is a complex undertaking due to the nature of the antibiotic resistance problem. For that reason, we plan to continue to review the bill and discuss its provisions with other stakeholders to ensure that, as drafted, the bill will achieve its intended goal.

As you move forward in further refining your legislation, IDSA strongly encourages you to consider these additional modifications:

- Establish a **panel of experts** to document and regularly update the list of qualifying pathogens against which statutory incentives will be targeted and expand the initial list to include influenza and gonorrhea (for which oral therapies currently are urgently needed);
- Explore **additional language to ensure the incentives target the highest priority drugs** (i.e., new classes of antibiotics, drugs approved through superiority trials rather than non-inferiority trials, drugs that target multiple high priority pathogens) as well as lead to the prudent use of these drugs once approved;
- Insert language to **extend the length of an antibiotic's patent term** post-approval, which we understand to be critically important to spurring manufacturers to invest in antibiotic R&D;
- Provide **additional safeguards** that will encourage FDA to permit **accelerated, conditional approval** of antibiotics in rare, appropriate instances where urgent medical need exists;
- Allow for **expedited review of relevant diagnostics**; and
- Create a **self-sustaining infectious diseases clinical specimen repository** at the National Institute of Allergy and Infectious Diseases (NIAID) to support R&D of novel molecular diagnostic tests. The repository would be paid for in part by companies purchasing specimens.

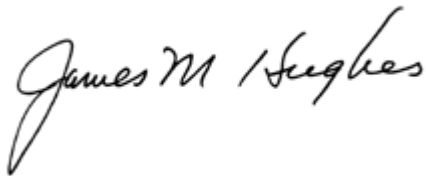
In addition, IDSA respectfully requests that you consider the suggestions we have outlined in the published report *Combating Antimicrobial Resistance: Policy Recommendations to Save Lives* (4/7/2011; [http://cid.oxfordjournals.org/content/52/suppl\\_5](http://cid.oxfordjournals.org/content/52/suppl_5)), as outlined in the enclosed document. As we prepared this document, we consistently heard from pharmaceutical companies and other stakeholders that a combination of push and pull incentives, such as the 50 percent R&D tax credit provided to orphan drugs coupled with the GAIN Act-type pull incentives, will be necessary to encourage antibiotic innovation.

As you know, the discovery of antibacterial drugs in the 1930s and 1940s represented a transformative moment in human history. Now, 70 years later, the challenges posed by infections caused by multiply-drug resistant pathogens continue to escalate, causing patient morbidity and mortality, as well as increasing healthcare costs.

We have a moral obligation to ensure, in perpetuity, that the treasure of antibiotics is never lost and that no infant, child or adult dies unnecessarily of an infection caused by the lack of effective and safe antimicrobial therapies.

Again, IDSA commends you for your leadership in advancing legislation to encourage the development of products to detect and treat antimicrobial-resistant infections. We stand ready to work with you and your staff to strengthen H.R. 2182 and work toward its passage to ensure that we achieve our shared goal of effective incentives that generate novel antibiotics and diagnostics. Should you have any questions or comments, please contact Robert J. Guidos, JD, IDSA's vice president for public policy and government relations at 703-299-0202 or [rguidos@idsociety.org](mailto:rguidos@idsociety.org).

Sincerely,

A handwritten signature in black ink that reads "James M. Hughes". The signature is written in a cursive, flowing style.

James M. Hughes, MD, FIDSA  
President

Enclosure: IDSA Recommendations to Address Antimicrobial-Resistant Infectious and Stimulate Research and Development of Novel Antibiotics and Related Diagnostics

## ENCLOSURE

### **IDSA Recommendations to Address Antimicrobial-Resistant Infectious and Stimulate Research and Development of Novel Antibiotics and Related Diagnostics**

The Infectious Diseases Society of America (IDSA), a medical society comprised of more than 9,300 infectious diseases physicians and scientists, encourages Congress to take action to reduce the threat of antimicrobial resistance. To begin to reverse the impact on public health, save lives, and reduce healthcare expenditures, last year, IDSA launched a collaboration titled the “**10 x '20 initiative**”, which aims to create a sustainable global antibacterial drug research and development (R&D) enterprise with the power in the short-term to develop 10 new, safe, and effective systemic antibiotics by 2020. To support the “10 x '20 initiative,” and IDSA’s broader efforts to reduce antibiotic-resistant infections, IDSA has proposed several key policy changes, as outlined in the published report ***Combating Antimicrobial Resistance: Policy Recommendations to Save Lives***<sup>1</sup>. These policy changes include the following:

#### Energy and Commerce/HELP Committee jurisdiction

-Provisions found within H.R. 2182, the Generating Antibiotic Incentives Now (GAIN) Act.

##### **In particular, IDSA supports the GAIN Act provisions to:**

- extend the period of exclusivity for new antibiotics to treat many of the drug-resistant pathogens of greatest concern;
- encourage the development of companion diagnostics by extending the period of exclusivity for an antibiotic for which the manufacturer identifies a companion diagnostic test;
- require the Food and Drug Administration (FDA) to provide expedited review for qualified antibiotics;
- provide fast track consideration for qualified antibiotics; and
- establish deadlines and other requirements on the development of clinical trial guidance related to antibacterials.

##### **IDSA supports further strengthening the GAIN Act with:**

- additional incentives (including extending the antibiotic’s patent term post-approval) to stimulate antibiotic and related diagnostics R&D, and specifically, the highest priority drugs (i.e., new classes of antibiotics, drugs approved through superiority trials rather than non-inferiority trials, drugs that target multiple high priority pathogens);
- an expert panel to identify and regularly update the list of priority pathogens/infections for the purpose of targeting incentives;
- safeguards to ensure approved antibiotics are used appropriately;
- safeguards that will encourage FDA to permit accelerated, conditional approval of antibiotics in rare, appropriate instances where urgent medical need exists;
- an allowance for expedited review of relevant diagnostics; and
- a self-sustaining clinical specimen repository established by the National Institute of Allergy and Infectious Diseases (NIAID) to support R&D of novel molecular diagnostic tests.

-As outlined by the Strategies to Address Antimicrobial Resistance (STAAR) Act (H.R. 2400 in the 111<sup>th</sup> Congress), Congress should strengthen on-going federal efforts such as antimicrobial resistance data collection, surveillance, research and prevention and control efforts by establishing a director of the existing Interagency Task Force on Antimicrobial Resistance and an advisory board of non-government

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<sup>1</sup> 4/7/2011; [http://cid.oxfordjournals.org/content/52/suppl\\_5](http://cid.oxfordjournals.org/content/52/suppl_5)

experts both of which will provide vital input, renewed energy, increased transparency and accelerated progress to the federal effort.

-As outlined in Administration's Public Health Emergency Medical Countermeasure Review (PHEMCE) review issued in August 2010, the Independent Strategic Investment Firm should be formally authorized. In addition, the formation of an antibiotic-focused public private partnership should be explored.

-To fund new antibiotic development and antimicrobial stewardship activities, Congress should create an "Antibiotic Innovation and Conservation (AIC) Fee."

-Congress should consider opportunities to support career development to reverse the "brain drain" that has occurred in antibiotic and microbiology research in both academia and industry.

-The Preservation of Antibiotics for Medical Treatment Act (PAMTA) (H.R. 965 in the 112<sup>th</sup> Congress) should be enacted and other measures (including FDA regulations) adopted to end the use of antibiotics for growth promotion, feed efficiency, and routine disease prevention purposes in animal agriculture.

#### Ways and Means/Finance Committee jurisdiction

-Congress should create a 50% R&D tax credits for qualifying infectious disease products similar to those that exist for orphan drug products. Companies have emphasized the need for such push incentives in addition to GAIN Act-type pull incentives.

-Value-based reimbursement strategies in federal health programs that encourage antibiotic and related diagnostics development must be pursued. (Depending on the specific proposal, portions also may be under the jurisdiction of Energy and Commerce Committee.)

-Congressional leaders should consider novel and innovative ways to strengthen antimicrobial resistance prevention and control efforts including through the establishment and support of antimicrobial stewardship programs in all health care settings (e.g., hospitals, long-term care facilities, long-term acute care facilities, ambulatory surgical centers, dialysis centers, outpatient clinics, private practices), which should be required as a condition of participation in the federal Medicare and Medicaid programs or through another regulatory mechanism.

#### Appropriations Committees

-Congress should increase the number and size of federal research grants, contracts, and other transactions available to promote the development of priority antibiotics and diagnostics by the NIAID, Biomedical Advanced Research and Development Authority, Department of Defense, and the FDA including through the establishment of an antibiotic public private partnership.

-Congress should fund the implementation of the revised (March 2011) Action Plan of the existing Interagency Task Force on Antimicrobial Resistance, including through targeted funding to the Centers for Disease Control, NIAID, FDA, US Department of Agriculture and other agency members of the task force.