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May 7, 2012

The Honorable Fred Upton
Chairman
House Energy and Commerce
Committee

2183 Rayburn House Office Building
Washington, DC 20515

The Honorable Joe Pitts
Chairman
Subcommittee on Health
House Energy and Commerce
Committee

420 Cannon House Office Building
Washington, DC 20515

The Honorable Henry Waxman
Ranking Member
House Energy and Commerce
Committee

2204 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Ranking Member
Subcommittee on Health
House Energy and Commerce
Committee

237 Cannon House Office Building
Washington, DC 20515

Dear Representatives:

The Infectious Diseases Society of America (IDSAs), which represents nearly 10,000 infectious diseases physicians and scientists, **supports Title VIII, Subtitle C—Generating Antibiotic Incentives Now**—of the House Energy and Commerce Committee's Food and Drug Administration (FDA) Prescription Drug User Fee Act (PDUFA) reauthorization legislation.

IDSAs's members care for patients of all ages with serious infections, including an increasing number of patients with serious and life-threatening antimicrobial-resistant infections against which we have frighteningly few, and in some cases no, effective therapeutics available. Addressing the anemic antimicrobial pipeline and combating antimicrobial resistance have been IDSAs's top policy priorities for the past decade and have included our launch of the "Bad Bugs, No Drugs" advocacy campaign in 2003; "the 10 x '20 initiative" in 2010, which seeks the development of ten new systemic antibacterial drugs by 2020; and recently a new website, www.AntibioticsNow.org, that highlights the growing number of patients succumbing to serious and life-threatening infections.

As the committee considers the FDA reauthorization, IDSAs respectfully requests a few minor modifications to the Committee draft.

- Shortening the deadline for the report on antibiotic incentives (Sec. 834);
- Studying feasibility of establishing a biorepository of prospectively collected specimens (Sec. 834);
- Adopting the definition of "qualifying pathogen" and "qualified infectious disease product" used in the Senate bill (Sec. 831); and
- Inserting Sec. 906, Independent Study on Medical Innovation Inducement Model from Senate bill.

Fixing the significant regulatory and economic barriers to antibiotic research and development (R&D) will require a combination of push and pull incentives and other reforms. To this end, we support the 5-year exclusivity provision included in the Committee’s bill. Moreover, the Department of Health and Human Services (HHS) report called for in Sec. 834 of the draft legislation will provide policymakers valuable information on additional incentives needed to address the urgent antibiotic R&D crisis. IDSA is pleased to support this provision. We are particularly pleased that the HHS report will explicitly focus on public private collaborations, a potentially valuable incentive, as well as on a review of antibiotic stewardship programs, which are critical to ensure that antibiotics’ effectiveness is protected. However, we are concerned that **the five-year deadline provided in Sec. 834 for HHS to complete its report does not recognize the urgency of the Bad Bugs, No Drugs problem and risks missing an opportunity for the HHS report to be produced in time to impact the next PDUFA reauthorization.** Specific to the elements of the report to be focused on additional antibiotic incentives, including public private collaborations, IDSA strongly recommends that HHS be given 12 months for their completion as some of these incentives may be initiated without legislation (i.e. prior to the next user fee bill reauthorization).

IDSA also recommends that Sec. 834 (B) be further modified to direct HHS to work with FDA and the National Institutes of Health to determine the value and feasibility of a centralized biorepository to accelerate diagnostics R&D. One way to achieve this within the existing language is as follows:

“(B) on whether any additional program (such as the development of public-private collaborations to advance antibiotic innovation and the establishment of a biorepository of prospectively collected specimens to advance related diagnostics innovation) or changes to the incentives under this subtitle may be needed to promote the development of antibiotics.”

Diagnostic tests are desperately needed to help physicians appropriately prescribe antibiotics, as well as to help identify eligible patients for antibiotic clinical trials. Again, HHS should be given 12 months to report back on its findings concerning the biorepository proposal.

IDSA also supports the Committee’s efforts to hasten the review and revision of FDA clinical trial guidance documents, many of which currently pose significant challenges for antibiotic R&D. We are particularly pleased to see Sec. 835 of the legislation, which requires FDA to issue guidance regarding efficient and streamlined pathogen-focused antibacterial drug clinical trials for serious and life-threatening infections. IDSA has long championed the need for a new approval pathway for drugs to treat these infections, and this guidance is an important step forward.

Moreover, IDSA strongly recommends that the Committee adopt the definition of “qualifying pathogen” and “qualified infectious disease products” adopted by the Senate Health, Education Labor and Pensions (HELP) Committee. We applaud the Committee’s inclusion of antifungal drugs in the definition, but continue to emphasize that the Senate definition provides the necessary flexibility to target incentives to serious and life-threatening infections while keeping pace with emerging infectious threats. IDSA supports the Senate bill’s inclusion of experts in infectious disease and antibiotic resistance among the stakeholders who must be consulted regarding the list of qualifying pathogens and the requirement that methodology for developing

the list be made public. The Senate approach also provides companies with the certainty they need to proceed with R&D.

We also support Section 906 in the Senate bill, which asks the National Academies of Science (NAS) to evaluate the feasibility and possible consequences of using innovation inducement prizes to reward successful medical innovations in antibiotic development. We encourage the Committee to include Section 906 in the House bill—with one suggested change—that NAS experts also are asked to consider how public private partnerships might advance antibiotic development.

Finally, as you know, IDSA also seeks inclusion in PDUFA of our highest priority proposal—establishment of the Limited Population Antibacterial Drug (LPAD) product approval mechanism, which strongly complements current PDUFA provisions. LPAD will provide companies a new regulatory approval pathway that will allow them to benefit from PDUFA's other incentives. It is not feasible for antibacterial drugs that treat serious infections due to highly resistant bacterial pathogens to be developed using traditional, large scale clinical trials due to the limited numbers of patients in which such serious infections occur. Instead, under the LPAD mechanism, a drug's safety and effectiveness would be studied in substantially smaller, more rapid, and less expensive clinical trials. LPAD products then would be narrowly indicated for use in small, well-defined populations of patients for whom the drugs' benefits have been shown to outweigh their risks. Fourteen antibacterial companies and 23 health and medical groups have supported LPAD's inclusion in PDUFA.

Once again, IDSA is proud to support the House Energy and Commerce Committee's PDUFA legislation to address the dry antibiotic pipeline and to offer the few modifications highlighted above. IDSA looks forward to working with you to advance policies to bring needed antimicrobials to patients and help protect these new investments from the development of resistance.

For further information, please contact Robert Guidos, JD, IDSA's vice president of public policy and government relations at rguidos@idsociety.org.

Sincerely,



Mark A. Leasure
Chief Executive Officer

Cc: The Honorable Phil Gingrey
The Honorable Gene Green