

February 22, 2012

The Honorable Harry Reid  
Senate Majority Leader  
522 Hart Senate Office Building  
Washington, DC 20510

The Honorable Mitch McConnell  
Senate Minority Leader  
317 Russell Senate Office Building  
Washington, DC 20510

The Honorable Richard Durbin  
Senate Majority Whip  
711 Hart Senate Office Building  
Washington, DC 20510

The Honorable Jon Kyl  
Senate Minority Whip  
730 Hart Senate Office Building  
Washington, DC 20510

The Honorable Tom Harkin  
Chairman of the Senate Committee on  
Health, Education, Labor and Pensions  
731 Hart Senate Office Building  
Washington, DC 20510

The Honorable Michael Enzi  
Ranking Member, Senate Committee on  
Health, Education, Labor and Pensions  
379A Russell Senate Office Building  
Washington, DC 20510

Dear U.S. Senate Leaders:

We, the undersigned organizations representing patients, health care providers, health systems, veterans, women's health, children's health, seniors, and other key stakeholders urge you to address the serious and growing problems of antimicrobial resistance and the dry pipeline for antibiotic research and development (R&D) in upcoming Food and Drug Administration (FDA) user fee legislation. A growing number of patients are suffering from and succumbing to antimicrobial-resistant infections, because we have too few, and in some cases no, antibiotics to treat them. Ironically, as the number of patients succumbing to resistant infections rises, the number of new antibiotics in development is plummeting.

If Congress does not enact strong solutions, we face a future that resembles the days before these miracle drugs were developed, one in which people died of common infections, and where many medical interventions that we take for granted—including care for premature infants, surgery, cancer chemotherapy, organ transplantation, and even dentistry for some patients—become impossible. Antimicrobial resistance also is placing a significant burden on our health care system—costing over \$20 billion annually in health care costs according to one study. To save patients' lives, we support U.S. efforts that strive to achieve the laudable goal of approving ten new systemic antibiotics by 2020. Read more about *The 10 x '20 initiative* (<http://www.idsociety.org/10x20>) on the Infectious Diseases Society of America's website.

In 1990, there were nearly 20 pharmaceutical companies with large antibiotic R&D programs. Today, alarmingly, only a few companies remain. Not only does the tumbling private investment in antibiotics R&D jeopardize the development and availability of sorely needed new antibiotics in the United States, it also drains indispensable jobs and intellectual capital as companies seek to do business in other countries. For example, the regulatory environment for antibiotics in the European Union (EU) is viewed much more favorably by pharmaceutical

companies and antibiotic public/private collaborations are being pursued as part of the EU's Innovative Medicines Initiative.<sup>1</sup>

Antibiotics' R&D poses unique scientific, regulatory and economic challenges. One company reports that over a 10 year period, it took 72 lead candidate antibiotic compounds in the early discovery phase to yield one FDA-approved product; other drug categories only took 15 leads to yield an FDA approval. Antibiotics also provide less financial reward for companies as they are used for a short duration, typically are priced low, and must be held in reserve to protect against the development of drug resistance, rather than used widely as most other drugs are.

We are encouraged that Congress has shown a strong interest in addressing the antibiotic crisis, as evidenced by the development of a U.S. Senate working group, past hearings in the U.S. House of Representatives, and pending antibiotic R&D incentives legislation. We call upon Congress to follow through with action that will spur new antibiotic R&D. A combination of push and pull incentives is needed to sufficiently raise the net present value of antibiotics so that they may compete on a level playing field with other drug categories for companies' R&D resources.

It is also vitally important for Congress to incentivize the development of new related diagnostics, and we are pleased that pending antibiotic R&D incentives legislation begins to address this issue. Better diagnostics can reduce the costs of new antibiotic development by identifying patients who are eligible for clinical trials. Diagnostic tests also are important for conducting surveillance for the patterns of antimicrobial resistance and recognizing emerging drug resistance. In addition, rapid diagnostic tests improve physicians' ability to prescribe antimicrobial drugs appropriately, which is critical to limit the development of resistant bacteria and preserve these important drugs' effectiveness for as long as possible. Congress should strengthen federal efforts to promote the appropriate use of antibiotics in health care facilities.

We are gravely concerned about the increasing number of patients with serious, life-threatening infections who cannot be treated due to a lack of effective antibiotics. These cases result in longer hospital stays, readmissions, increased healthcare costs and even deaths. Losing antibiotics entirely—which is where we are heading without urgent action—will undermine the way medicine is practiced and have devastating consequences for patients. We have an obligation to our children and grandchildren to invest in the development of new antibiotics and related diagnostic tests and to preserve antibiotics' effectiveness for the long term.

Sincerely,

Alliance for Aging Research  
Alliance for the Prudent Use of Antibiotics  
American Academy of Allergy, Asthma and Immunology  
American Academy of Neurology  
American Academy of Ophthalmology

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<sup>1</sup>([http://www.imi.europa.eu/sites/default/files/uploads/documents/Future\\_Topics/IMI\\_AntimicrobialResistance\\_Draft20120116.pdf](http://www.imi.europa.eu/sites/default/files/uploads/documents/Future_Topics/IMI_AntimicrobialResistance_Draft20120116.pdf)).

American Academy of Orthopaedic Surgeons  
American Academy of Otolaryngology-Head and Neck Surgery  
American Academy of Pediatrics  
American Association of Hip and Knee Surgeons  
American Association of Neurological Surgeons  
American College of Emergency Physicians  
American College of Medical Quality  
American College of Rheumatology  
American College of Surgeons  
American Congress of Obstetricians and Gynecologists  
American Geriatrics Society  
American Physical Therapy Association  
American Public Health Association  
American Society for Microbiology  
American Society of Hematology  
American Thoracic Society  
American Urological Association  
Association for Professionals in Infection Control and Epidemiology  
Center for Hospital Innovation and Improvement  
Children's Hospital Association  
Coalition of State Rheumatology Organizations  
Congress of Neurological Surgeons  
Department for Professional Employees of AFL-CIO  
First Focus  
Food Animal Concerns Trust  
Heart Rhythm Society  
HIV Medicine Association  
Immune Deficiency Foundation  
Infectious Diseases Society of America  
National Alliance to Advance Adolescent Health  
National Association of County and City Health Officials  
National Association of Nurse Practitioners in Women's Health  
National Association of Pediatric Nurse Practitioners  
National Association of Veterans' Research and Education Foundations  
National Coalition of STD Directors  
National Family Planning & Reproductive Health Association  
National Foundation for Infectious Diseases  
Pediatric Infectious Diseases Society  
Premier  
Renal Physicians Association  
Society for Healthcare Epidemiology of America  
Society of Infectious Diseases Pharmacists  
Society of Critical Care Medicine  
Treatment Action Group  
Trust for America's Health

[A similar letter has been sent to U.S. House leaders]