

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.¹

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

¹(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]