

WHAT PEOPLE ARE SAYING ABOUT DRUG-RESISTANT BACTERIA AND THE NEED FOR NEW ANTIBIOTICS

LEGISLATORS, REGULATORS, SCIENTISTS AND ACADEMICS AGREE: WE ARE RUNNING OUT OF ANTIBIOTICS TO TREAT DRUG-RESISTANT INFECTIONS—AND WE NEED NEW ONES NOW. HERE IS WHAT LEADING VOICES ARE SAYING ABOUT HOW ECONOMIC, SCIENTIFIC AND REGULATORY FACTORS ARE IMPEDING THE DEVELOPMENT OF NEW ANTIBIOTICS, AND WHAT WE CAN DO ABOUT IT.

Antibiotic-resistant infections are a serious threat to human health

“People infected with antimicrobial-resistant organisms are more likely to have **longer, more expensive hospital stays**, and may be **more likely to die** as a result of the infection . . . Antibiotic resistance has been called **one of the world’s most pressing public health problems**. Almost every type of bacteria has become stronger and less responsive to antibiotic treatment when it is really needed. These antibiotic-resistant bacteria can quickly spread to family members, schoolmates, and co-workers—threatening the community with a new strain of infectious disease that is more difficult to cure and more expensive to treat. For this reason, **antibiotic resistance is among CDC’s top concerns.**”

— Centers for Disease Control and Prevention, “Antibiotic/Antimicrobial Resistance” and “Antibiotic Resistance Questions & Answers” web pages, March 14, 2011

“**The achievements of modern medicine are put at risk by antimicrobial resistance.** Without effective antimicrobials for care and prevention of infections, the success of treatments such as organ transplantation, cancer chemotherapy and major surgery would be compromised.”

— World Health Organization, Fact Sheet No. 194, February 2011

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“The stakes could not be higher. **Without action, deaths and morbidity from antimicrobial resistance will continue to increase and the drug development pipeline will run dry.** There is a moral obligation to patients and to the nation to prevent the unthinkable outcome of a return to the preantibiotic era and to ensure that these precious resources are available for future generations.”

— James M. Hughes, M.D., Infectious Diseases Society of America (IDSA),
“Commentary: Preserving the Lifesaving Power of Antimicrobial Agents,” *Journal of the American Medical Association*, February 22, 2011

We are running out of antibiotics

“**We need new and better drugs . . . and we need them now.** Yet the R&D pipeline is distressingly low. The number of newly approved antibiotics—not just new formulations of previously existing drugs—has fallen steadily since the 1980s. And **the range of new antibiotics is disturbingly limited** in terms of the types or classes of antibiotics available and the diseases they can treat.”

— The Honorable Margaret A. Hamburg, M.D., Commissioner of the U.S. Food and Drug Administration, October 6, 2010, National Press Club Speaker Luncheon

“We know **the cupboard is almost bare**, and of the limited drugs in development, most of them, if not all, will never see approval. Any investment in antibiotics is not likely to match that of traditional drug development.”

— Rep. John Shimkus (R-IL), hearing on “Promoting the Development of Antibiotics and Ensuring Judicious Use in Humans,” U.S. House of Representatives, Subcommittee on Health, Committee on Energy and Commerce, June 9, 2010

“**Only five new antibiotics were approved by the FDA from 2003 through 2007, down from 16 in the period from 1983 to 1987.** A survey last year by European health authorities found only 15 antibiotics in clinical trials that offered some promise of going beyond what is available today.”

— “Antibiotics Research Subsidies Weighed by U.S.,” Andrew Pollack, *New York Times*, November 5, 2010

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Market forces deter innovation

“New forms of antibiotics must be available if we are to effectively deal with this emerging [resistance] problem. Today, **the high cost of drug development and short treatment courses have caused a decreasing number of companies to pursue antibiotic development.** In other words, their success has led to the fact that there is a shortage now of antibiotics. Any solution geared towards addressing future bacterial infections must ensure that proper incentives are identified and supported that will encourage greater antibiotic development.”

— Rep. Phil Gingrey (R-GA), hearing on “Promoting the Development of Antibiotics and Ensuring Judicious Use in Humans,” U.S. House of Representatives, Subcommittee on Health, Committee on Energy and Commerce, June 9, 2010

“**There is a market failure.** We need to look at ways to spur development of this market.”

— Rep. Henry Waxman (D-CA), “Antibiotics Research Subsidies Weighed by U.S.,” Andrew Pollack, *New York Times*, November 5, 2010

We need policies to incentivize antibiotic development

“The AMA proposes a multi-faceted approach to combating antibiotic resistance that includes . . . **incentivizing research and development to create novel antibiotics** for clinical use.”

— American Medical Association (AMA), press release, “AMA: Antibiotic Resistance a Major Public Health Problem,” June 9, 2010

“When there is market failure to address a major public health concern, it becomes incumbent upon the government to create the climate and, if need be, provide the resources to address this challenge . . . **This is a public health problem that requires immediate national and international attention and . . . incentives for the best minds and the most successful companies** to invest their talents and their capital in finding new diagnostics and new antimicrobial agents.”

— Jeffrey Levi, Ph.D., Executive Director, Trust for America’s Health, hearing on “Promoting the Development of Antibiotics and Ensuring Judicious Use in Humans,” U.S. House of Representatives, Subcommittee on Health, Committee on Energy and Commerce, June 9, 2010

“The AAP [American Academy of Pediatrics] supports the many and diverse antimicrobial resistance programs within the CDC, National Institutes of Health (NIH), and Food and Drug Administration (FDA), as well as public-private partnerships, global collaboration, and work in the pharmaceutical and diagnostics industries to **incentivize the development of new antimicrobial agents.**”

— John Bradley, testifying on behalf of the AAP, hearing on “Promoting the Development of Antibiotics and Ensuring Judicious Use in Humans,” U.S. House of Representatives, Subcommittee on Health, Committee on Energy and Commerce, June 9, 2010

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“A concerted effort is needed to provide short-term relief and long-term solutions to the problem of antibiotic resistance. **The public health and biodefense interests of this effort call for the Federal government to take the lead** in providing the necessary support and incentives to restore the commercial antibiotic pipeline and ensure the continuous availability of effective drugs to treat all bacteria that cause human disease.”

— Robin A. Robinson, Ph.D., Deputy Assistant Secretary of the U.S. Department of Health and Human Services and Biomedical Advanced Research and Development Authority (BARDA) Director, “BARDA Efforts to Counter Antimicrobial Resistance,” Hearing on “Promoting the Development of Antibiotics and Ensuring Judicious Use in Humans,” U.S. House of Representatives, Subcommittee on Health, Committee on Energy and Commerce, June 9, 2010

We need a clearer regulatory pathway to spur antibiotic development

“**We need better, more advanced strategies for evaluating the effectiveness of new antimicrobials** once they are in development. This includes new clinical trial designs that reflect the need for important and robust scientific answers but are realistic about constraints such as the number of patients, the size and length of studies, and the cost of the trials . . . And at FDA, we will also continue efforts to **streamline and modernize our regulatory pathways** so that we can **expeditiously review applications** for new antimicrobial drugs, diagnostics, and vaccines when they come before us.”

— The Honorable Margaret A. Hamburg, M.D., Commissioner of the U.S. Food and Drug Administration, “FDA’s Efforts to Facilitate Antibiotic Approvals,” IDSA World Health Day event, April 7, 2011

“We certainly understand that the process for developing clinical trials at the FDA is extremely complex . . . but we do need to **explore ways to provide incentives** for pharmaceutical companies as well as trying to **make the system less complex** but also ensuring safety.”

— Rep. Ed Whitfield (R-KY), hearing on “Promoting the Development of Antibiotics and Ensuring Judicious Use in Humans,” June 9, 2010, U.S. House of Representatives, Subcommittee on Health, Committee on Energy and Commerce

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The Pew Health Group’s Antibiotics and Innovation Project develops and advocates for policies that will spur the creation of new antibiotics to protect Americans’ health.