Testimony before the

House Committee on Energy and Commerce, Subcommittee on Health

United States House of Representatives

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Chairman Pitts, Ranking Member Pallone and members of the Health Subcommittee, thank you for the opportunity to submit testimony about the essential steps Congress must take to stimulate the development of new antibiotics that we urgently need to fight serious and life-threatening bacterial infections.

We wish to thank Rep. Gingrey, Rep. Green and their fellow co-sponsors of H.R. 2182, the Generating Antibiotic Incentives Now (GAIN) Act, for their bipartisan leadership on this vital issue. We appreciate the broad support this bill has received in both chambers of Congress and on both sides of the aisle.

Based on research and critical analysis, the Pew Health Group (Pew) seeks to improve the health and well-being of all Americans by reducing unnecessary risks to the safety of medical and other consumer products and supporting medical innovation. Pew's Antibiotics and Innovation Project addresses the growing public health challenge of multidrug-resistant infections by supporting policies that stimulate and encourage the development of new antibiotics to treat life-threatening illnesses.

Introduced more than 75 years ago, antibiotics have profoundly transformed healthcare. Thanks to these drugs and to advances in vaccines and infection control, many formerly devastating bacterial illnesses can be cured or contained. Antibiotics also help make surgery, chemotherapy, and other medical procedures possible by reducing their once-prohibitively high risk of infection.

However, unlike other drugs, antibiotics gradually lose their effectiveness as bacteria develop resistance.

Unfortunately, the pipeline of new antibiotics is running dry. In the 1980s, the U.S. Food and Drug Administration (FDA) approved 29 new systemic antibiotics. That number dropped to 23 in the 1990s and to nine in the 2000s.[i]

The results of an October 2011 survey soon to be published in a leading infectious disease journal, *Clinical Infectious Diseases*, underscore the urgency of this growing problem. More than 500 infectious diseases specialists across the country identified the limited number of new antimicrobials under development as the greatest challenge in the treatment of multidrug-resistant infections. Sixty-three percent of respondents reported caring for a patient with an infection resistant to all available antibiotics and 56 percent felt that the number of untreatable infections is increasing.[ii]

As a result, we find ourselves on the brink of what the Centers for Disease Control and Prevention Director Dr. Thomas Frieden has called a "post-antibiotic era."[iii] In this world, bacterial infections are increasingly difficult and costly to treat and common medical procedures are excessively risky. Children, seniors, and military personnel are at disproportionate risk of infection compared to the general population, so they would be unduly harmed if we fail to develop new antibiotics.

In September 2011, Pew partnered with the Infectious Diseases Society of America (IDSA) and the Pharmaceutical Research and Manufacturers of America (PhRMA) to convene a meeting of physicians, scientists, business leaders, economists, and policymakers entitled, "Reviving the Pipeline of Life-Saving Antibiotics: Exploring Solutions to Spur Innovation." At this conference, experts discussed the obstacles to antibiotic innovation. Among the regulatory challenges noted were the difficulty of finding appropriate test subjects for clinical trials, which is complicated by the lack of good diagnostic tools, and unresolved questions about how to demonstrate an antibiotic's effectiveness in clinical trials.

Some of these impediments are inevitable. For example, there are natural tensions between creating a predictable regulatory pathway and ensuring that the criteria for drug approvals reflect the most up-to-date science, which can evolve quickly. FDA recognizes these challenges and we are encouraged by the agency's ongoing efforts to address them.

Among the economic challenges, participants noted that new antibiotics are used sparingly in order to slow the evolution of resistant bacteria and that they tend to produce lower revenues than many other types of drugs. For example, a treatment course of even the newest antibiotic is less expensive than that of a new cancer drug or a medication for a chronic illness. As a result, when pharmaceutical companies and investors consider where to put their R&D dollars, other therapeutic areas are often more appealing investment targets.

The GAIN Act would create an economic incentive for drug makers to discover, develop, and introduce new antibiotics by allowing qualifying drugs to be on the market without generic competition for an additional five years. Pew is working with Members of Congress to ensure that the bill squarely targets the development of the most-needed new drugs—those to treat serious or life-threatening diseases, such as healthcare-associated and community-acquired pneumonia, complicated skin, intra-abdominal and urinary tract infections, sepsis, tuberculosis, meningitis, and other infections of vital organs and systems.

Industry representatives at our September 2011 conference noted that they are focusing their antibiotics R&D efforts on drugs to treat such infections.

This Act builds on precedents set by laws such as the Orphan Drug Act, which, in part, used narrowly targeted exclusivity extensions to boost the development of nearly 400 medicines used to treat rare diseases.

We urge Congress to include the GAIN Act with the Prescription Drug User Fee Act reauthorization, which we hope the legislature will pass this year to ensure FDA continues to receive the funds it needs to allow safe and effective medications to reach the market in a timely manner.

Pew is proud to stand in the company of many organizations that support the GAIN Act, including a broad array of drug developers, children's hospitals, professional medical societies, and organizations representing veterans and their families. Among the organizations that have written to Congress in support of the GAIN Act are: Achaogen (South San Francisco, Calif.), American Medical Association (Chicago, Ill.), American Society for Microbiology (Washington, D.C.), American Urological Association (Linthicum, Md.), Associated Industries of Massachusetts (Boston, Mass.), AstraZeneca (Waltham, Mass.), Boston Chamber of Commerce (Boston, Mass.), California Healthcare Institute (La Jolla, Calif.), Cempra (Chapel Hill, N.C.), Children's Hospital Association

of Texas (Austin, Texas), Children's Memorial Hospital (Chicago, Ill.), Children's National Medical Center (Washington, D.C.), Cubist (Lexington, Mass.), Defense Technology Initiative (Waltham, Mass.), Durata (Morristown, N.J.), East Tennessee State University (Johnson City, Tenn.), Georgia Bio (Atlanta, Ga.), GlaxoSmithKline (Philadelphia, Pa.), Infectious Diseases Society of America (Arlington, Va.), Indiana Health Industry Forum (Indianapolis, Ind.), Johnson & Johnson (New Brunswick, N.J.), LeBonheur Children's Medical Center (Memphis, Tenn.), MassBio (Cambridge, Mass.), Massachusetts High Technology Council (Waltham, Mass.), Massachusetts Hospital Association (Burlington, Mass.), Medicines Co. (Parsippany, N.J.), Merck (Whitehouse Station, N.J.), Military Families United (Washington, D.C.), National Association of Children's Hospitals (Alexandria, Va.), National Military and Veterans Alliance (Springfield, Va.), Optimer (San Diego, Calif.), Paratek (Boston, Mass.), Pediatric Infectious Diseases Society (Arlington, Va.), PolyMedix (Radnor, Pa.), Rib-X (New Haven, Conn.), Society of Infectious Diseases Pharmacists (Austin, Texas), St. Jude Children's Research Hospital (Memphis, Tenn.), TB Alliance (New York, N.Y.), Tetraphase (Watertown, Mass.), Texas Children's Hospital, Baylor College of Medicine (Houston, Texas), Theravance (South San Francisco, Calif.), and University of Tennessee, Health Science Center (Memphis, Tenn.).

We again thank the leadership of the House Energy and Commerce Committee, its Health Subcommittee, the sponsors of the GAIN Act, their fellow Members of Congress, and their staffs for working to address this urgent public health problem.

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[i] John Powers, M.D., "Scientific and Regulatory Issues in Studying Experimental Antibiotics; Doing Better with More Efficient Studies" (presented at Pew-IDSA-PhRMA conference "Reviving the Pipeline of Life-Saving Antibiotics: Exploring Solutions to Spur Innovation," Washington, DC, September 22, 2011.) N.B. Systemic antibiotics are those designed to treat infections throughout the body.

[ii] A. L. Hersh, J. G. Newland, et al., "Unmet Medical Need in Infectious Diseases," *Clin Infect Dis* (2012) In Press.

[iii] *Antibiotic Resistance and the Threat to Public Health, before the Committee on Energy and Commerce, Subcommittee on Health, United States House of Representatives*, 111th Congress, 2nd Session (2010) (statement of Thomas Frieden, M.D., M.P.H., Director, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services).