

ONE HUNDRED THIRTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

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MEMORANDUM

September 17, 2014

To: Committee on Energy and Commerce Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Subcommittee Hearing on “21st Century Cures: Examining Ways to Combat Antibiotic Resistance and Foster New Drug Development”

At 9:00 a.m. on September 19, 2014, in 2123 Rayburn House Office Building, the Subcommittee on Health will hold a hearing titled “21st Century Cures: Examining Ways to Combat Antibiotic Resistance and Foster New Drug Development.” The following memo supplements information provided in the Republican memo circulated on September 17, 2014.

I. BACKGROUND ON ANTIBIOTIC RESISTANCE

According to the U.S. Centers for Disease Control and Prevention (CDC), antibiotic resistance is “the ability of bacteria or other microbes to resist the effects of an antibiotic. Antibiotic resistance occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to cure or prevent infections.”¹ Every time antibiotics are used, sensitive bacteria are killed and resistant forms of the bacteria may survive.² These resistant bacteria can then flourish and infect others.

Antibiotic resistance has been called one of the world’s most pressing public health problems.³ The CDC observes that “the number of bacteria resistant to antibiotics has increased in the last decade. Many bacterial infections are becoming resistant to the most commonly

¹ Centers for Disease Control, *Get Smart: Know When Antibiotics Work—Antibiotic Resistance Questions & Answers* (online at <http://www.cdc.gov/getsmart/antibiotic-use/antibiotic-resistance-faqs.html#define-antibiotic-resistance>).

² *Id.*

³ Centers for Disease Control, *Fast Facts: Facts About Antibiotic Resistance* (online at <http://www.cdc.gov/getsmart/antibiotic-use/fast-facts.html>).

prescribed antibiotic treatments.”⁴ Each year in the United States, at least 2 million people become infected with bacteria that are resistant to antibiotics and at least 23,000 people die each year as a result of these infections.⁵ According to the National Institute of Allergy and Infectious Diseases (NIAID), “many infectious diseases are increasingly difficult to treat because of antimicrobial-resistant organisms, including HIV infection, staphylococcal infection, tuberculosis, influenza, gonorrhea, candida infection, and malaria.”⁶ Numerous press reports have highlighted the decreased ability of modern antibiotics to control deadly diseases.⁷

Each year between 5 and 10 percent of all hospital patients in the United States get an infection in a hospital, and about 90,000 die as a result of these infections.⁸ More than 70% of the bacteria that cause hospital-acquired infections are resistant to at least one of the antibiotics most commonly used to treat them.⁹ People infected with drug-resistant organisms are more likely to have longer hospital stays and require more complicated treatment.¹⁰

In addition to these public health impacts, antibiotic resistance adds considerable costs to the U.S. healthcare system. Some studies have estimated that antibiotic resistance adds between \$20 billion in excess direct health care costs, with additional costs to society for lost productivity as high as \$35 billion per year.¹¹

⁴ *Id.*

⁵ Centers for Disease Control, Threat Report 2013 (online at <http://www.cdc.gov/drugresistance/threat-report-2013/index.html>).

⁶ National Institute of Allergy and Infectious Disease, *Antimicrobial (Drug) Resistance* (online at www.niaid.nih.gov/topics/antimicrobialResistance/Understanding/Pages/quickFacts.aspx).

⁷ See, e.g., Andrew Pollack, *Rising Threat of Infections Unfazed by Antibiotics*, New York Times, (Feb. 26, 2010) (online at http://www.nytimes.com/2010/02/27/business/27germ.html?_r=0).

⁸ National Institute of Allergy and Infectious Disease, *Antimicrobial (Drug) Resistance: Quick Facts* (online at www.niaid.nih.gov/topics/antimicrobialResistance/Understanding/Pages/quickFacts.aspx).

⁹ Federal Drug Administration, *Battle of the Bugs: Fighting Antibiotic Resistance* (online at <http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143568.htm>).

¹⁰ National Institute of Allergy and Infectious Disease, *Antimicrobial (Drug) Resistance: Quick Facts* (online at www.niaid.nih.gov/topics/antimicrobialResistance/Understanding/Pages/quickFacts.aspx).

¹¹ Centers for Disease and Control, *Untreatable: Report by CDC details today's drug-resistant health threats* (Sept. 16, 2013) (online at <http://www.cdc.gov/media/releases/2013/p0916-untreatable.html>).

II. CAUSES OF ANTIBIOTIC RESISTANCE AND POTENTIAL WAYS TO ADDRESS THE PROBLEM

According to NIAID, the broader causes for resistance could include the following:

1. Inappropriate use by physicians;
2. Inadequate diagnostics, leading to use of broad spectrum antibiotics when a specific one might be better, or leading to the use of antibiotics to treat viral infections;
3. Hospital use, because of the heavy use and the close contact among sick patients; and
4. Agricultural use, particularly in animal feed, although NIAID acknowledges there is debate about the public health impact.¹²

CDC states that “widespread use of antibiotics promotes the spread of antibiotic resistance. Smart use of antibiotics is the key to controlling the spread of resistance.”¹³ Antibiotic stewardship refers to programs that help to ensure that patients receive the right antibiotics at the right time for the right duration.¹⁴ Numerous studies have shown that implementing antibiotic stewardship programs can save lives, as well as healthcare dollars.¹⁵

In addition to stewardship, there have been calls to find ways to encourage development of new antibiotics.¹⁶ In recent years, fewer pharmaceutical companies have been engaged in the development of antibiotics.¹⁷ Given the high cost of drug development, companies are often hesitant to enter the market when there is no guarantee that they will receive an adequate return on their investment.¹⁸ This is a concern in the case of antibiotics because these drugs are typically used in a small number of patients for relatively short treatment courses.¹⁹ In addition, doctors and patients are admonished to use antibiotics judiciously, which in part means they should use antibiotics less frequently. In this way, antibiotics are unlike medications for chronic diseases, which patients take for long time periods.

¹² National Institute of Allergy and Infectious Disease, *Antimicrobial (Drug) Resistance: Causes* (online at <http://www.niaid.nih.gov/topics/antimicrobialresistance/understanding/pages/causes.aspx>).

¹³ Centers for Disease and Control, *Get Smart: Know When Antibiotics Work—Antibiotic Resistance Questions & Answers* (online at www.cdc.gov/getsmart/antibiotic-use/antibiotic-resistance-faqs.html).

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ See, e.g., Institute of Medicine, *Microbial Threats to Health: Emergence, Detection, and Response* (2003).

¹⁷ National Institutes of Health, *Testimony for the Committee on Energy and Commerce, Subcommittee on Health Hearing on Antibiotic Resistance and the Threat to Public Health Statement of Anthony Fauci, M.D.* (Apr. 28, 2010) [hereinafter, “NIH testimony”] (online at <http://democrats.energycommerce.house.gov/sites/default/files/documents/Testimony-Fauci-HE-Antibiotic-Resistance-Threat-to-Public-Health-2010-4-28.pdf>).

¹⁸ *Id.* at 11.

¹⁹ *Id.*

At the hearing, witnesses are likely to discuss two examples of legislation aimed at creating incentives for antibiotic development.

First, in the 2012 FDA Safety and Innovation Act, provisions from the “Generating Antibiotic Incentives Now Act of 2011” or “GAIN Act,” introduced by Reps. Gingrey, Green, Whitfield, DeGette, Rogers, Eshoo, and Shimkus, were included.²⁰ That legislation extends by five years the exclusive marketing period for certain antibiotics to treat serious or life-threatening infections.

Second, another potential route to addressing the problem of antibiotic resistance is a bill introduced by Reps. Gingery, Green, Shimkus, Eshoo, Whitfield, DeGette, Blackburn, Engel, Griffith and Butterfield, H.R. 3742, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act. That bill seeks to accelerate the development of new therapies to treat antibiotic-resistant infections by establishing a “limited population approval pathway” that would permit FDA to approve drugs based on smaller and shorter clinical trials with fewer participants.

There will also likely be discussion of a study on antibiotic development, commissioned by the Assistant Secretary of Planning and Evaluation at the Department of Health and Human Services.²¹ That report evaluated various mechanisms to create incentives for the development of new antibiotics. The report concluded that only a combination of incentives has the potential to be effective and incentives provided early in the drug development process are likely to have the most significant impact.

II. WITNESSES

Panel I

Janet Woodcock, M.D.

Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Panel II

Kenneth Hillan, M.B. Ch.B.

CEO and CMO
Achaogen

Barbara E. Murray, M.D., FIDSA

President
Infectious Diseases Society of America

²⁰ P.L. 112-144. Title VIII—Generating Antibiotic Incentives Now.

²¹ Eastern Research Group, *Analytical Framework for Examining the Value of Antibacterial Products*, (Apr. 2014) (online at http://aspe.hhs.gov/sp/reports/2014/antibacterials/rpt_antibacterials.cfm).

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