

ONE HUNDRED ELEVENTH 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**

**June 7, 2010**

**To: Members of the Subcommittee on Health**

**Fr: Committee on Energy and Commerce Staff**

**Re: Subcommittee Hearing on Antibiotic Resistance**

On Wednesday, June 9, 2010, at 10:00 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled “Promoting the Development of Antibiotics and Ensuring Judicious Use in Humans.” The hearing will focus on two issues. First, it will examine how we can best safeguard the effectiveness of antibiotics once they are on the market. Second, it will explore various ways to ensure adequate development of new, safe and effective antibiotics. The subcommittee expects to hold a subsequent hearing on the use of antibiotics in animals.

**I. JUDICIOUS USE IN HUMANS**

Antibiotics are critically important tools for fighting bacterial infections. In many cases, they save lives. However, the more frequently antibiotics are used, the more bacteria develop the ability to resist the effects of those antibiotics. To avoid the development of widespread antibiotic resistance, antibiotics must be prescribed only when necessary.<sup>1</sup>

There are growing concerns that many physicians are prescribing antibiotics more than necessary. For example, because so many patients have become accustomed to taking antibiotics, physicians may inappropriately prescribe antibiotics when a patient actually has a viral – not a bacterial – infection.<sup>2</sup> Additionally, because of the lack of readily accessible

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<sup>1</sup> CDC, *Testimony for the Committee on Energy and Commerce, Subcommittee on Health Hearing on Antibiotic Resistance and the Threat to Public Health Statement of Thomas Frieden, M.D., M.P.H.* (April 28, 2010) [hereinafter “CDC testimony”] (online at: [energycommerce.house.gov/index.php?option=com\\_content&view=article&id=1974:antibiotic-resistance-and-the-threat-to-public-health&catid=132:subcommittee-on-health&Itemid=72](http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1974:antibiotic-resistance-and-the-threat-to-public-health&catid=132:subcommittee-on-health&Itemid=72)).

<sup>2</sup> NIH, *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,*

diagnostic information at the time of a patient's visit, physicians often prescribe antibiotics "just in case" an infection is present, without an actual diagnosis of a bacterial infection.<sup>3</sup>

Another contributor to antibiotic resistance occurs when patients themselves fail to take the antibiotics as directed. It is not at all uncommon for patients to stop taking the drugs once their symptoms have resolved, instead of completing the entire course of antibiotics.<sup>4</sup>

Many have called for increased efforts to curtail the inappropriate use of antibiotics in an effort to safeguard their effectiveness, or, in other words, to promote antibiotic stewardship. CDC has been at the forefront of this work. It has instituted an educational campaign called "Get Smart: Know When Antibiotics Work."<sup>5</sup> Through the campaign, CDC develops clinical guidance and principles for appropriate antibiotic use in the prevention and control of upper respiratory infections.<sup>6</sup> Associated with this effort have been a 20 percent decrease in prescribing antibiotics for upper respiratory infections and a 13 percent decrease in prescribing antibiotics for all office visits.<sup>7</sup>

In order to measure how much and where antibiotics are used, sophisticated data surveillance systems are necessary. CDC has an initiative to enhance the National Healthcare Safety Network (NHSN), which is a web-based surveillance tool for hospitals and state health departments that monitors healthcare-associated infections (HAIs) to accept data on antibiotic use from healthcare facilities through electronic medical records.<sup>8</sup>

## II. DEVELOPMENT OF NEW ANTIBIOTICS

In recent years, a decreasing number of pharmaceutical companies have been engaged in the development of antibiotics.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> In fact,

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*M.D.*, (April 28, 2010) [hereinafter, "NIH testimony"] (online at: [energycommerce.house.gov/index.php?option=com\\_content&view=article&id=1974:antibiotic-resistance-and-the-threat-to-public-health&catid=132:subcommittee-on-health&Itemid=72](http://energycommerce.house.gov/index.php?option=com_content&view=article&id=1974:antibiotic-resistance-and-the-threat-to-public-health&catid=132:subcommittee-on-health&Itemid=72)).

<sup>3</sup> *Id.*

<sup>4</sup> NIH testimony, *supra* n.2, at 6.

<sup>5</sup> CDC testimony, *supra* n.1, at 13.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> CDC testimony, *supra* n.1, at 14-15.

<sup>9</sup> NIH testimony, *supra* n.2, at 10.

<sup>10</sup> NIH testimony, *supra* n.2, at 11.

<sup>11</sup> *Id.*

when antibiotics are prescribed judiciously, they should be used infrequently. In this way, antibiotics are unlike medications for chronic diseases which patients take for longer time periods.

Certain witnesses at the hearing will discuss proposals for promoting the development of new antibiotics.

### **III. WITNESSES**

The following witnesses have been invited to testify:

#### **Panel One:**

**Janet Woodcock, MD**

Director  
Center for Drug Evaluation and Research  
Food and Drug Administration

**Robin Robinson, MD**

Director  
Biomedical Advanced Research and Development Authority  
Department of Health and Human Services

#### **Panel Two:**

**Brad Spellberg, MD FIDSA**

Associate Professor of Medicine  
David Geffen School of Medicine at UCLA  
Member: Infectious Diseases Society of America (IDSA)'s  
Antimicrobial Availability Task Force

**Sandra Fryhofer, MD**

Council on Science and Public Health  
American Medical Association

**John S. Bradley, MD**

American Academy of Pediatrics  
Chief, Division of Infectious Diseases  
Department of Pediatrics  
University of California, School of Medicine  
Clinical Director, Division of Infectious Diseases at Rady Children's Hospital

**Barry Eisenstein, MD, FACP, FIDSA**

Senior Vice President, Scientific Affairs,  
Cubist Pharmaceuticals

**Jeffrey Levi, PhD**  
Executive Director  
Trust for America's Health