

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

Majority (202) 225-2927
Minority (202) 225-3641

MEMORANDUM

July 12, 2010

To: Members of the Subcommittee on Health
Fr: Committee on Energy and Commerce Staff
Re: Subcommittee Hearing on Antibiotic Resistance

On Wednesday, July 14, 2010, at 2:00 p.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Health will hold a hearing entitled “Antibiotic Resistance and the Use of Antibiotics in Animal Agriculture.” The hearing will focus on the use of antibiotics in food-producing animals and the impact of this use on human health.

I. BACKGROUND ON ANTIBIOTIC RESISTANCE

Antibiotics are critically important tools for fighting bacterial infections. These medicines save countless lives and reduce the complications associated with many diseases and infections.¹

“Antibiotic resistance” refers to the ability of a bacteria or microbe to grow despite the presence of an antibiotic that would usually kill or limit the growth of that bacteria.² Resistance occurs wherever and whenever antibiotics are used, whether in the community, on the farm, or in a healthcare setting.³ This is because when antibiotics kill off all the “sensitive” bacteria, the only microbes left are resistant. As a result of antibiotic resistance, many existing antibiotics have lost their effectiveness, and pathogens that are not susceptible to commonly available drugs

¹ 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 S. Fauci, M.D., M.P.H.* (April 28, 2010) [hereinafter, “NIH Testimony”] at 2.

² *Id.*

³ Centers for Disease Control and Prevention, *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”] at 1.

have emerged.⁴ Physicians are often left with limited treatment options, and patients are at greater risk of serious complications or death.⁵ Additionally, resistant microorganisms can be spread to other patients, further complicating this problem.⁶

To avoid promoting antibiotic resistance, antibiotics must be used only when necessary.⁷

II. ANIMAL USE OF ANTIBIOTICS

Antibiotics are used in veterinary medicine and animal agriculture.⁸ The Center for Veterinary Medicine (CVM), a part of the Food and Drug Administration (FDA), is charged with regulating the manufacture and distribution of all drugs given to animals, including food animals. In agriculture, antibiotics are used in four primary ways: (1) growth promotion/feed efficiency; (2) disease prevention; (3) disease control; and (4) disease treatment.⁹ With the exception of a few classes of antibiotics such as ionophores, the majority of antibiotics used in animal agriculture are also used in human medicine.¹⁰

Out of a concern about antimicrobial resistance generated by agricultural uses of antibiotics, on June 28, 2010, FDA released a draft document to provide guidance to the public on the agency's current thinking about how medically important antimicrobial drugs can be judiciously used in food-producing animals.¹¹ In that document, FDA set forth two principles

⁴ NIH Testimony *supra* n. 1 at 3.

⁵ CDC Testimony *supra* n. 3 at 2.

⁶ *Id.*

⁷ *Id.*

⁸ *Id.* at 14.

⁹ Food and Drug Administration, *Testimony for the House Committee on Rules Hearing on the Preservation of Antibiotics For Medical Treatment Act of 2009, Statement of Joshua M. Sharfstein, M.D.* (July 13, 2009) (online at: www.fda.gov/NewsEvents/Testimony/ucm171715.htm).

¹⁰ *Id.*

¹¹ Food and Drug Administration, *Draft Guidance: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (June 28, 2010) (online at: www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm217464.htm) (hereinafter "FDA Draft Guidance"). This draft guidance uses the term "antimicrobial" instead of antibiotic. In that document, FDA states: "The term 'antimicrobial' refers broadly to drugs with activity against a variety of microorganisms including bacteria, viruses, fungi, and parasites. Antimicrobial drugs that have specific activity against bacteria are referred to as antibacterial or antibiotic drugs. However, the broader term 'antimicrobial,' commonly used in reference to drugs with activity against bacteria, is used in this document interchangeably with the terms antibacterial or antibiotic. Antimicrobial resistance is the ability of bacteria or other microbes to resist the effects of a drug. Antimicrobial resistance, as it relates to bacterial organisms, occurs when bacteria change in some way that reduces or eliminates the effectiveness of drugs, chemicals, or other agents designed to treat bacterial infections."

for judicious use. First, FDA stated that medically important antimicrobial drugs should be limited to uses in food-producing animals that are considered necessary for assuring animal health.¹² Specifically, FDA indicated that the use of such antimicrobials for “production purposes” such as promoting growth and improving feed efficiency represents an injudicious use of such drugs. FDA also listed certain factors to consider when determining the appropriateness of the use of medically important antimicrobials for disease prevention purposes.¹³ The second principle is that medically important antimicrobial drugs should be used in food-producing animals only with veterinary oversight or consultation.¹⁴

III. THE DANISH EXPERIENCE

Denmark, the world’s largest exporter of pork, has taken some of the most aggressive steps in the world in limiting antibiotic use in food-producing animals and in collecting data to evaluate the effects of those steps. From the beginning of 1995 to the end of 1999, the Danish government and Danish animal producers effectively ended the use of antimicrobials for routine prophylaxis (disease-prevention) and growth promotion and took additional steps to discourage unnecessary antimicrobial uses.¹⁵ This resulted in a significant reduction in total quantity of antimicrobials used in food-producing animals, although the reduction was not uniform across all classes of antimicrobials.¹⁶ Overall, the total amount of antimicrobials given to food-producing animals in 2001 was less than half that given in 1994, and the time period during which these

¹² *Id.*, at 16.

¹³ Such factors include: Whether there is veterinarian involvement, evidence of effectiveness, evidence that such a preventive use is consistent with accepted veterinary practice, evidence that the use is linked to a specific etiologic agent, evidence that the use is appropriately targeted, and evidence that no reasonable alternatives for intervention exist. FDA Draft Guidance, *supra* note 11.

¹⁴ FDA Draft Guidance, *supra* note 11, at 17.

¹⁵ *Information Note Regarding the Danish and EU Restrictions of Nontherapeutical Use of Antibiotics for Growth Promotion*; Ministry of Food, Agriculture and Fisheries, Danish Veterinary and Food Administration; August 12, 2009 [hereinafter, “DVFA Information Note”] (online at:

http://www.uk.foedevarestyrelsen.dk/nr/rdonlyres/63497aa7-8e8a-4c6a-9c74-e56c3383f26a/0/info_om_vaekstfremmerforbud_samt_oevrige_riskmanagement_str_uk.pdf).

¹⁶ *Id.*; DANMAP 2008, *Use of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Bacteria in Food Animals, Foods and Humans in Denmark*; Statens Serum Institut, Danish Veterinary and Food Administration, Danish Medicines Agency, National Veterinary Institute, Technical University of Denmark, National Food Institute, September 2009 [hereinafter, “DANMAP 2008”] (online at: www.danmap.org/pdfFiles/Danmap_2008.pdf)

animals were exposed to antimicrobials was significantly reduced.¹⁷ Usage has increased somewhat since 2001, but in 2008 was still only 60% of 1994 levels.¹⁸

In November, 2002, the World Health Organization (WHO) convened an international panel of experts to review the effects of the termination of use of antimicrobial growth promoters. WHO published its findings in a report entitled “Impacts of Antimicrobial Growth Promotion Termination in Denmark.”¹⁹ The report focused primarily on the impacts on pig and broiler chicken production, which together accounted for most growth promotion use in Denmark (pig production alone accounted for 80%). In summary, it found that Denmark’s termination of growth promoter use:

- Did not affect the levels of the major human pathogens in chickens or pigs,
- Reduced the rates of antibiotic resistance in one class of bacteria known as *enterococci*, noting that this thereby reduced the pool of antibiotic resistance genes that might otherwise be transferred to food-borne pathogens (*enterococci* ordinarily are not themselves food-borne pathogens).
- Was associated with both increases and decreases in rates of antimicrobial resistance in different food-borne pathogens (noting that the growth-promoting antimicrobials generally are not effective against these organisms, and so terminating their use would not be expected to have a direct effect on rates of resistance in these organisms).
- Did not result in adverse economic effects on chicken producers and had only an approximately 1% adverse economic impact on pig producers, primarily because of decreased weight gain and increased mortality in recently-weaned pigs.

IV. WITNESSES

The following witnesses have been invited to testify:

Panel One:

Joshua Sharfstein, MD
Principal Deputy Commissioner
Food and Drug Administration

¹⁷ DANMAP 2003, *Use of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Bacteria in Food Animals, Foods and Humans in Denmark*; Statens Serum Institut, Danish Veterinary and Food Administration, Danish Medicines Agency, Danish Veterinary Institute; July 2004 (online at: www.danmap.org/pdfFiles/Danmap_2003.pdf), at 12, 18.

¹⁸ DANMAP 2008, *supra* note 16, at 31.

¹⁹ World Health Organization, *Impacts of Antimicrobial Growth Promotion Termination in Denmark; The WHO International Review Panel’s Evaluation of the Termination of the Use of Antimicrobial Growth Promoters in Denmark*. November 6-9, 2002 (online at: www.who.int/gfn/en/Expertsreportgrowthpromoterdenmark.pdf).

Department of Health and Human Services

John Clifford, DVM

Deputy Administrator, Veterinary Services
Animal and Plant Health Inspection Service
United States Department of Agriculture

Rear Admiral Ali S. Khan, MD, MPH

Assistant Surgeon General and
Acting Deputy Director, National Center for Emerging & Zoonotic Infectious Disease Centers
for Disease Control & Prevention
Department of Health and Human Services

Panel Two:

Per Henriksen, DVM Ph.D.

Head, Division for Chemical Food Safety, Animal Welfare and Veterinary Medicinal Products
Danish Veterinary and Food Administration

James R. Johnson, MD

Director, Infectious Disease Fellowship Program
Professor of Medicine
University of Minnesota

Gail R. Hansen, DVM, MPH

Senior Officer
Human Health and Industrial Farming Group
Pew Charitable Trusts

Christine Hoang, DVM, MPH, CPH

Assistant Director, Scientific Activities Division
American Veterinary Medical Association

Randall Singer, DVM, MPVM, PhD

Associate Professor of Epidemiology
Department of Veterinary and Biomedical Sciences
University of Minnesota

Richard Carnevale, DVM

Vice President, Regulatory, Scientific and International Affairs
Animal Health Institute

Stuart Levy, MD

Professor of Molecular and Microbiology
Professor of Medicine
Tufts University