

Written Testimony prepared by Brise Tencer, Washington Representative of the Union of Concerned Scientists, on behalf of the following:

Keep Antibiotics Working ▪ Center for Science in the Public Interest ▪ Environmental Defense Fund ▪ Food Animal Concerns Trust ▪ Humane Society of the United States ▪ Institute for Agriculture & Trade Policy ▪ Lymphoma Foundation of America ▪ National Catholic Rural Life Conference ▪ Safe Tables Our Priority ▪ Union of Concerned Scientists ▪ Waterkeeper Alliance ▪ Alliance for Sustainability ▪ Alliance for the Prudent Use of Antibiotics ▪ American Academy of Pediatrics, District II ▪ American Academy of Pediatrics, NY Chapter 2 ▪ American Academy of Pediatrics, NY Chapter 3 ▪ American Academy of Physician Assistants ▪ American Grassfed Association ▪ American Nurses Association ▪ American Society for the Prevention of Cruelty to Animals ▪ Animal Welfare Approved ▪ Arkansas Nature Alliance ▪ Blue Heron Environmental Network Inc. ▪ Breast Cancer Fund ▪ Butte Environmental Council ▪ California Public Health Association, North ▪ Catholic Healthcare West ▪ Chicago Physicians for Social Responsibility ▪ Citizen Action of Wisconsin ▪ Citizens Action Coalition of Indiana ▪ Citizens for Pennsylvania's Future ▪ Citizens for Sludge-free Land ▪ Coast Action Group ▪ Colorado Academy of Family Physicians ▪ Consumers Union ▪ Earth Day Coalition, Cleveland ▪ Endangered Habitats League ▪ Fair Food ▪ Farms Without Harm ▪ Farmworker Justice ▪ Food & Water Watch ▪ Food Democracy Now! ▪ Friends of the Earth ▪ Georgia AIDS Coalition ▪ Grass-roots ▪ Halifax River Audubon ▪ Humane Farming Association ▪ Humane Society Veterinary Medical Association ▪ Illinois Citizens for Clean Air & Water ▪ Infectious Disease Association of California ▪ Iowa Association of Water Agencies ▪ Iowa Citizens for Community Improvement ▪ Iowa Environmental Council ▪ Iowa Farmers Union ▪ Izaak Walton League of America, Midwest ▪ Kentucky Resources Council ▪ Klamath Forest Alliance ▪ Maine Organic Farmers & Gardeners Association ▪ Maine Public Health Association ▪ Michigan Antibiotic Resistance Reduction Coalition ▪ Michigan Public Health Association ▪ Minnesota Citizens Organized Acting Together ▪ Montana Public Health Association ▪ National Anti-Vivisection Society ▪ National Latino Farmers & Ranchers Trade Association ▪ National Organic Coalition ▪ National Organization for Rare Disorders ▪ Naturesource Communications ▪ Network for Environmental & Economic Responsibility United Church of Christ ▪ New Mexico Environmental Law Center ▪ North Carolina Association of Pharmacists ▪ Northeast Organic Farming Association - Interstate Council ▪ Northeast Organic Farming Association - Massachusetts ▪ NY/NJ Environmental Watch ▪ Occidental Arts & Ecology Center ▪ Ohio Ecological Food & Farm Association ▪ Ohio Environmental Council ▪ Ohio Nurses Association ▪ Ohio River Foundation ▪ Oklahoma Chapter, American Academy of Pediatrics ▪ Oregon Pediatric Society ▪ Organic Consumers Association ▪ Pennsylvania Coalition of Nurse Practitioners ▪ Pennsylvania Farmers Union ▪ Pennsylvania State Nurses Association, Environmental Health Task Force ▪ Pew Campaign on Human Health & Industrial Farming ▪ Physicians for Social Responsibility-Los Angeles ▪ Preserve Wild Santee ▪ Protect Our Earth's Treasures ▪ Rivers Unlimited ▪ Rural Advancement Foundation International, USA ▪ Safe Food & Fertilizer ▪ San Francisco Bay Area Physicians for Social Responsibility ▪ San Francisco Medical Society ▪ South Carolina Nurses Association ▪ Southwest Environmental Center ▪ Stonyfield Farm, Inc. ▪ Sustain LA ▪ Sustainable Earth ▪ The Cornucopia Institute ▪ The Minnesota Project ▪ The Society of Infectious Diseases Pharmacists ▪ Trust for America's Health ▪ Upper Merrimack River Local Advisory Committee ▪ US Environmental Watch ▪ Washington Sustainable Food & Farming Network ▪ Western Nebraska Resources Council ▪ Wisconsin Chapter, American Academy of Pediatrics ▪ Women's Environmental Institute ▪ Women's Health & Environmental Network

**House Committee on Appropriations Subcommittee on Agriculture, Rural
Development, Food and Drug Administration, and Related Agencies, March 19, 2010**

Antibiotic-resistant infections have been identified by the Centers for Disease Control and Prevention (CDC) as one of the top public health challenges in the United States. Massive use of medically important antibiotics like penicillin and tetracycline in food animal production is a significant contributor to this problem.¹ Antibiotic-resistant pathogens, which are found in and on food animals, can be transferred to humans through several pathways, including handling of farm animals², movement through ground and surface water, and most commonly on contaminated food.³ Animal food products can become contaminated during slaughter and processing and food and crops can become contaminated with resistant bacteria in the field or during food processing. Infections caused by foodborne pathogens are more severe and more costly to treat than those caused by susceptible bacteria. The existence of resistant bacteria also means that more cases of infection will occur than would otherwise be the case.⁴

As recently reported in *The New York Times*, some infections caused by resistant bacteria now cannot be treated. There simply are no longer antibiotics that work. There are 5,815 hospitals in the U.S. registered with the American Hospital Association. The yearly cost associated with antibiotic-resistant patient infections in one U.S. hospital has been estimated at \$13.5 million.⁵

Additional research and data are critical to understanding how to address the public health and food safety concerns associated with such uses. As you consider fiscal year 2011 appropriations, we would like to propose three appropriations that will help research, monitor, and find solutions to the problem of antibiotic resistance. The requests below are in priority order:

Request #1: \$5 million of funds from the FDA's Transforming Food Safety Initiative to finish, update, and publish reviews on the safety of antimicrobials important in human medicine currently used for nontherapeutic purposes in food-producing animals for their role in the selection and dissemination of antibiotic-resistant foodborne pathogens.

Request #2: \$3 million to fund Research and Education Grants for the Study of Antibiotic Resistant Bacteria as authorized in Section 7521 of the 2008 Farm Bill.

Request #3: \$10 million for the FDA/USDA/CDC National Antimicrobial Resistance Monitoring System (NARMS) in order to expand data collection by \$3 million beyond current annual funding of approximately \$7 million.

The rationale and background for each of these requests are detailed below.

Request #1: \$5 million of funds from the FDA's Transforming Food Safety Initiative to finish, update, and publish reviews on the safety of antimicrobials important in human medicine currently used for nontherapeutic purposes in food-producing animals for their role in the selection and dissemination of antibiotic-resistant foodborne pathogens.

Requested accompanying report language: *In conducting these post-market safety reviews, the FDA shall use the same standards and methodology currently used in pre-market safety evaluations. The Committee directs the FDA to report the findings of the safety reviews to Congress within two years and to include a time line of any regulatory action steps needed to address drug uses found not to be safe. Congress directs the FDA immediately to report to Congress on any post-market safety reviews of animal antimicrobials already completed, but not yet made public.*

Background: The FDA’s Center for Veterinary Medicine is responsible for reviewing the safety of animal drugs, including antibiotics, and has the authority to approve, withdraw, or restrict drugs based on their safety. Since 2003, the FDA has required that the pre-approval safety review for all new antibiotic veterinary drugs include an evaluation of the likelihood that the proposed drug use in animals will lead to resistant infections in humans.

Because almost all antibiotics being used for growth promotion and other nontherapeutic purposes in livestock production were approved by the FDA before 2003, most have either not undergone reviews with respect to antibiotic resistance or have undergone reviews that are inconsistent with current standards. In order to ensure that these drugs meet current safety standards, it is now critical to conduct post-market safety reviews of those antibiotic classes important to human medicine that are also being used for routine nontherapeutic purposes in animal agriculture.

Seven classes of antibiotics considered by the FDA to be either critically or highly important for therapy of infectious diseases in humans are used for nontherapeutic purposes in livestock production. These are the penicillins, tetracyclines, macrolides, lincosamides, streptogramins, aminoglycosides, and sulfonamides. Nontherapeutic uses of these drugs include growth promotion and routine disease prevention in healthy farm animals.

In 1977 the FDA proposed to withdraw its approval for nontherapeutic uses of both penicillin⁶ and tetracycline⁷ in food animals because of then new evidence showing that such uses undercut the efficacy of human drugs and as such were not safe for humans. The FDA took no final action on either of these 1977 proposals.

In the interim since the proposed cancellations, the European Union has banned use of all medically important antibiotics to accelerate the growth of food animals, and Australia, Japan, and New Zealand do not allow the use of penicillin and tetracycline as growth promoters.⁸

Citing its still-pending 1977 regulatory proposal, in May 2004 the FDA wrote to three manufacturers of penicillin for animal use – Alpharma Inc, Pennfield Oil Company, and Phibro Animal Health – to express its concerns about their products’ “possible role in the emergence and dissemination of antimicrobial resistance” in humans.

In its July 2007 report on the FY 2008 appropriations bill, the House Committee on Appropriations expressed its concern that the use of antimicrobials in animals produced for food can also render less effective critically important human antibiotics, including those used to treat foodborne illnesses. The Committee was particularly concerned that the FDA had not finished its review of the safety for humans of using penicillin nontherapeutically in animal feed and directed the FDA to finish this review and make it public by June 30, 2008.

In September 2008 the FDA told Congress that it had completed its review of the “scientific literature for microbial food safety information for penicillin-containing products” and that it “continues to have safety concerns regarding the non-therapeutic use of antimicrobial drugs in food-producing animals.”⁹ The FDA has not, however, either made public the results of its penicillin review or taken any action on the other medically important antibiotics that are used to accelerate the growth of food animals.

In FY2009 and FY2010, the FDA received a significant amount of new funding to address food safety. An additional \$318.3 million and 718 new FTEs for the Transforming Food Safety initiative have been proposed for FY11. With the additional resources FDA should take a more aggressive approach to tackling the growing problem of antibiotic resistant foodborne pathogens.

Congress should ensure that the FDA finishes, updates, and publishes reviews on the safety of antimicrobials important in human medicine used for nontherapeutic purposes in food-producing animals.

Request #2: \$3 million to fund Research and Education Grants for the Study of Antibiotic Resistant Bacteria as authorized in Section 7521 of the 2008 Farm Bill.

Background: Antibiotic-resistant disease has been identified by the CDC as the number one public health challenge in the United States. Massive use of medically important antibiotics like penicillin and tetracycline in food animal production is a significant contributor to this problem. Research to develop animal production systems less dependent on antibiotics would help American producers address this crisis, add consumer value to their products, and position themselves advantageously in the global marketplace.

In 2004, the U.S. Government Accountability Office (GAO) released a report highlighting the looming trade implications for countries that do not improve their agricultural antibiotic-use practices. GAO found that two of our major competitors in world meat markets (New Zealand and Denmark) have already banned the use of medically important antibiotics for growth promotion in food animals, as has the European Union. In addition, Japan, a major market for U.S. meat exports, is now reviewing such uses and considering a ban. The international trend is clear. To keep up and maintain market share, U.S. meat producers need to have the option to raise animals with less dependence on antibiotics.

The 2008 Farm Bill addressed this need by creating a new competitive grant program called Research and Education Grants for the Study of Antibiotic-Resistant Bacteria. This program will provide the research needed to understand the phenomenon of antibiotic resistance and devise food animal production systems less dependent on antibiotic use. But, this important program will not get off the ground without funding. If U.S. meat producers hope to maintain a competitive advantage in the global market, funding is needed to support research to provide technical information on antibiotic-free production methods to all meat producers, and to enable those producers seeking to transition away from routine antibiotic use to do so smoothly. Accordingly, we urge the committee to appropriate \$3 million to launch the grant program.

Request #3: \$10 million for the FDA/USDA/CDC National Antimicrobial Resistance Monitoring System (NARMS) in order to expand data collection by \$3 million beyond current annual funding of approximately \$7 million.

Systematic collection and analyses of data are essential to addressing the growing problem of antibiotic resistant disease. NARMS has been funded at about \$7 million for the last several years and at that level has been unable to keep up with emerging new public health concerns, such as the Committee-recognized (in the report on the FY 2009 appropriations bill) threat of methicillin-resistant *Staphylococcus aureus* (“MRSA”). Additional funding will enable increased surveillance, to include additional bacterial species and numbers and/or types of samples as well as allow NARMS researchers to utilize more sensitive methods (e.g., antibiotic-supplemented

media and molecular assays). Furthermore, the additional funding should be used to initiate farm-level surveillance of antibiotic-resistant bacteria.

NARMS is a national public health surveillance system that tracks changes in the susceptibility of certain enteric bacteria to antimicrobial agents of human and veterinary medical importance.

The NARMS program was established in 1996 as a collaboration among three federal agencies: the FDA, the CDC, and the U.S. Department of Agriculture (USDA). NARMS is included in the FDA's budget, and the FDA then gives some of the appropriated funds to CDC and USDA.

NARMS also collaborates with scientists involved in antimicrobial resistance monitoring in other countries so that information can be shared on the global dimensions of antimicrobial resistance in foodborne bacteria. The NARMS program currently looks at only four pathogens: *Salmonella*, *Campylobacter*, *Escherichia coli*, and *Enterococci* on retail meats. However, the scientific literature on foodborne antibiotic-resistant bacteria shows that additional pathogens may be contaminating our food supply, such as *Staphylococcus aureus*.

As a public health monitoring system, the primary objectives of NARMS are to:

- Monitor trends in antimicrobial resistance among foodborne bacteria from humans (CDC), retail meats (FDA), and animals (USDA)
- Disseminate timely information on antimicrobial resistance to promote interventions that reduce resistance among foodborne bacteria
- Conduct research to better understand the emergence, persistence, and spread of antimicrobial resistance
- Assist the FDA in making decisions related to the approval of safe and effective antimicrobial drugs for animals

The NARMS program is important for identifying trends in antimicrobial resistance and for setting policy to address problems that are identified. For example, NARMS data have been used to support regulatory action such as the FDA's withdrawal in 2005 of the approval for fluoroquinolones in poultry and a proposed FDA ban in 2008 on the extralabel use of cephalosporins in food animals.

Thank you for your support of these priorities.

¹ Silbergeld, Graham, and Price. 2008. "Industrial food animal production, antimicrobial resistance, and human health," *Annual Review of Public Health* 29:151-69.

² Akwar et al. 2007. "Risk factors for antimicrobial resistance among fecal *Escherichia coli* from residents on forty-three swine farms," *Microbial Drug Resistance* 13(1):69-76.

³ WHO. 1997. "The Medical Impact of Antimicrobial Use in Food Animals," Report of a WHO Meeting. Berlin, Germany, 13-17 October. whqlibdoc.who.int/hq/1997/WHO EMC_ZOO_97.4.pdf

⁴ Anderson et al. 2003. "Public Health Consequences of Use of Antimicrobial Agents in Food Animals in the United States," *Microbial Drug Resistance* 9(4):373-379.

whqlibdoc.who.int/hq/1997/WHO EMC_ZOO_97.4.pdf

⁵ Roberts, 2009. "Hospital and Societal Costs of Antimicrobial-Resistant Infections in a Chicago Teaching Hospital: Implications for Antibiotic Stewardship," *Clinical Infectious Diseases* 49:1175-84.

⁶ 42 Fed. Reg. 43770 (August 30, 1977).

⁷ 42 Fed. Reg. 56264 (October 21, 1977).

⁸ General Accounting Office, *Antibiotic Resistance, Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals* (April 2004) at 44.

⁹ September 19, 2008 letter from FDA to Senator Kennedy (at 8).