

July 24, 2009

Ms. Melody Barnes
Assistant to the President for Domestic Policy
The White House
Washington, DC 20500

Dear Ms. Barnes:

As organizations committed to protecting patients, public health, animal health, and food safety, the undersigned groups are writing to express our grave concern about the misuse of antibiotics in agriculture and our strong support for the Administration's new "public health approach to antimicrobial use in animals," which was articulated by the Food and Drug Administration (FDA) in its July 13th statement before the Rules Committee of the U.S. House of Representatives. The Obama Administration's leadership in providing a clear path forward on this highly politically charged issue is very much welcomed after decades of inertia.

Our combined memberships include the country's foremost scientific and medical experts and represent more than eleven million concerned Americans and health professionals. Our position is based on objective health interests and concerns that dangerous drug resistant infections are rapidly increasing in hospitals and community settings adding to the economic burden of the U.S. healthcare costs.

Specifically, we support the FDA's calls for phasing out the use of antimicrobial drugs for growth promotion and feed efficiency, and for requiring that all other uses of these drugs be carried out under the supervision of a veterinarian and within the boundaries of a valid veterinarian-client-patient relationship – which we expect will end over-the-counter sales of tons of antimicrobial drugs annually. We also support the agency's expressed intent to clearly define the limited instances where antimicrobials may be used judiciously in food animals for purposes of disease prevention and control and are eager to work with FDA to ensure that the policy developed is the most protective of public health. We also urge the agency to make the new antimicrobial policy mandatory, retroactive to already-approved drugs, and enforceable, in order to best guarantee a significant reduction in antimicrobial use. The Administration's statement clearly demonstrates a commitment to sound and science-based policies that are backed up by scores of scientific and medical publications and will protect the health of every American.

The development of antimicrobial agents to treat life-threatening infections has been one of the most notable medical achievements of the past century. Physicians, healthcare professionals, and public health and food safety advocates are greatly concerned about the growing body of scientific evidence demonstrating that antimicrobial drug use in livestock and poultry contributes to the spread of drug-resistant bacteria to people. Drug-resistant organisms are plaguing Americans, including otherwise healthy individuals, in healthcare settings and communities across the country. We are pleased that these concerns finally are being recognized and addressed by the federal government to forestall epidemics of untreatable infections.

Fundamental to FDA's new approach—and our support for it—are the principles that:

“protecting public health requires the judicious use in animal agriculture of those antimicrobials of importance in human medicine” and that “purposes other than for the advancement of animal and human health should not be considered judicious use.”

— Dr. Joshua Sharfstein, FDA's Principal Deputy Commissioner, July 13, 2009

The Administration's vision to eliminate non-judicious uses of antimicrobial drugs, including for purposes of growth promotion and feed efficiency and non-judicious disease prevention which have been practiced in animal agriculture for several decades, demonstrates a critical public policy shift that will better protect the public against resistant infections and preserve the power of existing antibiotics. In addition, we urge FDA to formalize its position on veterinary supervision of all antimicrobial uses and ending the over-the-counter sale of antibiotics for animal agricultural uses, which are long-overdue. The sale of antimicrobials for use in human medicine requires a prescription; there is no reason to permit a lower standard for agricultural purposes where considerably more antimicrobial drugs are used annually.

The Administration's new policy direction appears intended to reflect the concerns of a broad consensus of the scientific, medical, public health and international health communities. Such consensus is buttressed by the actions of expert bodies and governments. For example:

- Since 2002, the World Health Organization (WHO) has called upon all nations to shift from use of antimicrobials in non-human medicine.
- In 2003, the Institute of Medicine (IOM) of the National Academies of Science called on the FDA to ban the use of antimicrobials for growth promotion in animals, if those drugs were also used in human medicine.
- In 2006, the European Union banned non-therapeutic use of antimicrobials, because such use was found to raise food safety concerns, and the ban was instituted to protect against further development of antimicrobial resistance.

We recognize that phasing out of antimicrobials for non-judicious uses in animals will require changes in the agricultural industry. But protection of the public's health must come first, and the phase out can be conducted in a way that that minimizes costs to the agriculture industry. Farmers in Europe have adapted to such a policy without undue disruption of production or increased consumer costs; the United States can learn from that experience while also protecting American lives. In addition, the U.S. Department of Agriculture has recognized that various production methods used in the United States today are viable alternatives to non-judicious antimicrobial uses and such alternatives are employed with little negative – or even with somewhat positive – economic impact to producers¹.

We urge you to maintain the scientifically sound positions the Administration already has taken in support of phasing out growth promotion and feed efficiency uses, and to finalize a policy that will strictly manage a narrow set of prophylactic uses while mandating veterinary-patient relationships and eliminating the over-the-counter sale of antibiotics for use in animals.

¹ MacDonald, James M. and McBride, William D. *The Transformation of U.S. Livestock Agriculture: Scale, Efficiency, and Risks*, Economic Information Bulletin No. 43. Economic Research Service, U.S. Dept. of Agriculture. January 2009.

We remain committed to working with the Administration to implement these new approaches in ways that will best protect the lives and health of both humans and animals.

Sincerely, the

Alliance for the Prudent Use of Antibiotics
American Academy of Pediatrics
American Association of Critical-Care Nurses
American Medical Association
American Pharmacists Association
American Public Health Association
American Society of Health-System Pharmacists
Association for Professionals in Infection Control and Epidemiology
Food Animal Concerns Trust
Humane Society of the United States
Infectious Diseases Society of America
Institute for Agriculture and Trade Policy
Keep Antibiotics Working
Michigan Antibiotic Resistance Reduction Coalition
National Association of County and City Health Officials
Pew Campaign on Human Health and Industrial Farming
Premier, a healthcare alliance serving 2,100 nonprofit hospitals and 58,000 healthcare sites
Society of Infectious Diseases Pharmacists
Trust for America's Health
Union of Concerned Scientists

cc: Secretary Kathleen Sebelius, HHS
Secretary Tom Vilsack, USDA
Dr. Dora Hughes, Counselor for Public Health and Science, HHS
Dr. Peggy Hamburg, FDA Commissioner
Dr. Josh Sharfstein, FDA Principal Deputy Commissioner
Dr. Thomas R. Frieden, CDC Director
Dr. Howard Koh, Assistant Secretary for Health, HHS
Rep. Henry Waxman
Rep. Rosa DeLauro
Rep. Jack Kingston
Rep. Louise Slaughter
Senator Edward Kennedy
Senator Tom Harkin
Senator Saxby Chambliss
Senator Herb Kohl
Senator Sam Brownback
Rep. Collin Peterson
Rep. Frank Lucas