

March 15, 2013

President Barack Obama  
The White House  
1600 Pennsylvania Avenue, NW  
Washington, DC 20500

Dear President Obama:

As organizations committed to protecting public health, animal health, and food safety, the undersigned groups seek your continued leadership in addressing the urgent and growing epidemic of antibiotic resistance. Specifically, we ask that you move forward with stalled U.S. Food and Drug Administration (FDA) actions to reduce the overuse and misuse of antibiotics in food animal production, including strengthening and finalizing voluntary guidelines and moving forward with mandatory withdrawals of unsafe uses of antibiotics. We also ask you to support improvements to reporting requirements for livestock antibiotic sales in legislation currently before Congress.

According to the Infectious Diseases Society of America, nearly two million Americans each year develop hospital-acquired infections, resulting in 99,000 deaths—with a steadily increasing number due to antibacterial-resistant infections. The Director General of the World Health Organization last year warned that, “[t]hings as common as strep throat or a child’s scratched knee could once again kill. . . . A post-antibiotic era means, in effect, an end to modern medicine as we know it.”<sup>1</sup> Currently, medically important antibiotics sold for food animal use constitute more than 70 percent of total reported sales of medically important antibiotics in the United States.

We were dismayed in 2011 when the FDA formally declined to use its regulatory authority to withdraw approvals for certain uses of penicillins and tetracyclines in animal feed—something it first proposed to do in 1977 after finding that these uses threaten public health by contributing to the crisis of antibiotic resistance. Given the rapid rate at which many antibiotics are becoming ineffective for treating human disease and the limited number of new antibiotics in development, the FDA should take bold steps to rein in overuse and misuse. We ask you to ensure that FDA moves immediately to use its regulatory authority to withdraw approvals for the non-therapeutic use (i.e., use of antibiotics for purposes other than disease treatment and disease control) of all medically-important antibiotics from food animal production, thus preserving their use for treating sick animals and people.

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<sup>1</sup> Dr. Chan, Margaret. Keynote Address: “Antimicrobial resistance in the European Union and the World,” Copenhagen, Denmark, March 14, 2012, [http://www.who.int/dg/speeches/2012/amr\\_20120314/en/index.html](http://www.who.int/dg/speeches/2012/amr_20120314/en/index.html)

The FDA has instead issued voluntary draft guidance for the pharmaceutical industry (Guidance for Industry #213) that establishes guidelines by which it is encouraging the phase-out of growth-promoting uses of antibiotics in livestock and poultry, an economic use designed to speed animal growth and reduce feed costs. While the guidance cannot replace a regulatory path that would guarantee an end to these and other non-medically necessary uses of antibiotics in food animals, it could be improved to be more helpful, and we have shared with FDA our two primary concerns to be addressed in the final Guidance #213:

- 1) it must clearly limit the use of antibiotics for “disease prevention” in animals. “Disease prevention” is often a catch-all term covering many uses in the absence of clinical disease. The Guidance should provide a more restrictive definition to ensure appropriate use of antibiotics; and
- 2) it should include a plan to monitor progress in reducing antibiotic use and antibiotic resistance. Data collection on antibiotic use is virtually non-existent, and data on antibiotic sales is insufficient to measure the effectiveness of the guidance program.

We seek your help in strengthening and then advancing these policies quickly. We recommend that by the start of the summer the FDA issue a finalized and strengthened Guidance #213 that limits routine use of antibiotics for disease prevention and establishes tracking mechanisms so the public health community, pharmaceutical companies, and the public in general have the fullest picture of how your Administration plans to address the agricultural contribution to the antibiotic resistance crisis.

Finally, we ask that you support stronger reporting requirements for agricultural antibiotic sales and distribution as part of this year’s reauthorization of the Animal Drug User Fee Act (ADUFA), which can help illustrate current use patterns, explain resistance trends, and monitor progress in assuring responsible animal antibiotic use. The American people need your help to ensure that these essential medicines will be effective in protecting our children into the future.

We are eager to help in any way we can. Thank you for your consideration.

Sincerely,

Alliance for the Prudent Use of Antibiotics  
American Academy of Pediatrics  
American College of Preventive Medicine  
American Nurses Association  
American Public Health Association  
Applegate

Assateague COASTKEEPER  
Association for Politics and the Life Sciences  
American Society for the Prevention of Cruelty to Animals  
Bon Appetit Management Company  
Brown's Ranch  
Center for Foodborne Illness Research and Prevention  
Center for Food Safety  
Consumers Union  
Dignity Health  
Environmental Working Group  
FamilyFarmed.org  
First Focus Campaign for Children  
Food Animal Concerns Trust  
Food and Water Watch  
Fresh Direct  
Health Care Without Harm  
Humane Society Veterinary Medical Association  
Infectious Diseases Society of America  
Institute for a Sustainable Future  
Institute for Agriculture and Trade Policy  
Johns Hopkins Center for a Livable Future  
Keep Antibiotics Working  
March of Dimes  
Michigan Antibiotic Resistance Reduction (MARR) Coalition  
National Research Center for Women & Families  
National Consumers League  
Natural Resources Defense Council  
Organic Consumers Association  
Niman Ranch Pork Co.  
Pediatric Infectious Diseases Society  
Pitman Farms  
School Food FOCUS National Office  
Society of Infectious Diseases Pharmacists  
STOP Foodborne Illness  
The Humane Society of the United States  
The Pew Charitable Trusts  
Trust for America's Health  
Union of Concerned Scientists  
Waccamaw RIVERKEEPER  
WATERKEEPER Alliance  
Yadkin RIVERKEEPER

Cc: The Honorable Kathleen Sebelius, Secretary, Department of Health and Human Services  
The Honorable Tom Vilsack, Secretary, Department of Agriculture  
The Honorable Margaret Hamburg, Commissioner, Food and Drug Administration