



June 4, 2013

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

Dear President Obama:

As medical and health care professionals, we seek your help 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 your administration to publicly report better data on livestock antibiotic sales to inform the public health community about emerging disease threats and to monitor the success of federal policies.

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.”¹ 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.

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

¹ 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

purposes other than disease treatment and disease control) of all medically-important antibiotics from food animal production, thus preserving their use for treating sick people.

The FDA has instead issued voluntary draft guidance for the pharmaceutical industry (Guidance for Industry #213) that establishes guidelines by which it is encouraging the phase-out of growth-promoting uses of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. We have two primary concerns we wish to see addressed in 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. Draft Guidance #213 is now over a year old. We recommend that by the start of the summer the FDA issue a finalized and strengthened guidance 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 your administration improve reporting of agricultural antibiotic sales and distribution, 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.

Thank you for your consideration.

Sincerely,

795 Health Professionals

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