Congress of the United States Washington, DC 20515

August 30, 2010

The Honorable Margaret Hamburg Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dr. Joshua M. Sharfstein Principal Deputy Commissioner Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Dear Commissioner Hamburg and Deputy Commissioner Sharfstein:

We appreciate your strong support for public health and your efforts to curtail the overuse of antibiotics in agriculture, as reflected in your recently issued Guidance #209, The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals. This guidance document is an important step in the right direction and shows increased attention to the threat that overuse of antibiotics in agriculture presents for public health. However, we believe that it does not go far enough.

We have two concerns with the guidance. First, it does not clearly and explicitly call for the elimination of the routine use of antibiotics in healthy farm animals. Second, it is merely a recommendation and does not carry the force of law or regulation.

As the Food and Drug Administration (FDA) considers regulatory action, we urge the FDA to ensure that any regulatory action defines 'judicious usage' carefully. The guidance currently deems 'production uses' as inappropriate, but allows for some 'prevention uses'. This introduces a potentially significant loophole in the regulatory schema, permitting farms to continue to use antibiotics routinely for purposes other than treating disease. The continued sub-therapeutic usage of antibiotics will promote the spread of antibiotic-resistant pathogens. This approach is particularly concerning, given that antibiotics on the farm are regularly dispensed without veterinary oversight. Public health must be preeminent in any definition of the judicious use of antibiotics.

Given the public health implications of current practices of antibiotic usage in food animals, the FDA must act quickly to issue regulations. The scientific community has concluded that there is a powerful connection between non-therapeutic agricultural usage of antibiotics and the emergence of antibiotic resistant pathogens infecting humans. In 2003, the Institute of Medicine concluded, "Clearly, a decrease in the inappropriate use of antimicrobials in human medicine alone is not enough. Substantial efforts must be made to decrease inappropriate overuse in animals and agriculture as well." Federal agencies, public health organizations, and scientists are united by their

concern with the overuse of antibiotics, and its implications for human health. Thirty years have passed since the FDA first issued a warning call on agricultural usage of antibiotics, and we cannot wait any longer for regulatory action.

We look forward to working with you to preserve the effectiveness of antibiotics.

Sincerely yours,

Louise M. Slaughter

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