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LOUISE M. SLAUGHTER
CONGRESS OF THE UNITED STATES
28TH DISTRICT, NEW YORK

December 29, 2010

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hamburg:

I appreciate your strong support for public health and your efforts to ensure the judicious use of antibiotics. As you know, surveillance is necessary to protect the effectiveness of antibiotics. Therefore, I recommend that the Food and Drug Administration (FDA) expand its tracking and reporting of antibiotic usage in three ways, specifically: 1) expand public reporting on antibiotic usage in the agricultural sector by providing more detail on classes critical to human medicine; 2) increase reporting on the route of antibiotic administration in order to shed light on the pervasiveness of sub-therapeutic usage in agriculture; and 3) enhance reporting on antibiotics produced for human use.

Every year, two million Americans acquire bacterial infections during their hospital stay, and nearly 100,000 die from them. 70 percent of these infections are resistant to the drugs commonly used to treat them.

Recent research provides further evidence of the need for careful stewardship of antibiotics. In February, Michael A. Kohanski, Mark A. DePristo, and James J. Collins authored a journal article in *Molecular Cell*, which demonstrated that low doses of antibiotics significantly increase gene mutation in bacteria. The increase in gene mutation creates "superzoos" of mutant bacteria that are resistant to a wide range of antibiotics. Unfortunately, the use of sub-lethal doses of antibiotics is common in the production of food animals. This research serves as yet another reminder of the need to protect the effectiveness of antibiotics by limiting their use.

The successful stewardship of antibiotics requires surveillance of antibiotic usage patterns. As you know, Section 105 of the Animal Drug User Fee Amendments of 2008 directed FDA to publish data on antibiotic use in food animals. Prompted by the FDA's recent release on the amount of antibiotics given to food animals in 2009 (29 million pounds in domestic sales and distribution), I write to ask for two types of additional information so that these data will be more useful to both Congress and the general public.

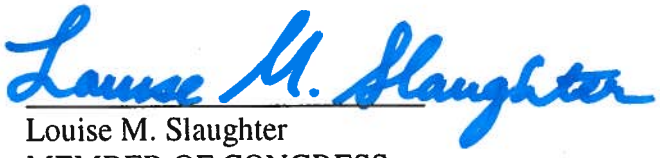
First, Congress required the FDA to summarize antibiotic distribution data by class except when there are less than three distinct sponsors for a single class. FDA made public distribution data for eight separate classes that had at least three sponsors but lumped together into one group the nine classes that had less than three distinct sponsors. This had the effect of lumping critically important classes, such as fluoroquinalones and diaminopyramidines, with classes not used in human medicine. It is my understanding that fluoroquinolones and diaminopyrimidines each have two distinct sponsors. Accordingly, I request distribution data on: (1) fluoroquinolones and diaminopyrimidines combined, and (2) the combination of medications with less than three distinct sponsors used only in animal medicine.

Second, the FDA collected – but did not make public – information based on the approved labels which states the route of administration and dose form for each antibiotic. FDA therefore has information on the amounts of antibiotics distributed in 2009 for administration in feed, water, or by injection. As FDA acknowledged in draft Guidance #209, administering antibiotics to whole groups of animals, as is done in feed or water, creates a qualitatively higher human health risk than when antibiotics are administered to individual animals by injection. Accordingly, I request data on the amounts of antibiotics administered in 2009 to food producing animals: (1) in feed, (2) in water, and (3) by injection. These data should be subdivided into the four groups of antibiotics that the FDA has established: critically important in human medicine, highly important in human medicine, important in human medicine, and not used in human medicine.

In addition to better clarifying the usage of antibiotics in the agricultural sector, I urge you to publicly report on the quantity and type of antibiotics used in human medicine. While the overwhelming majority of antibiotics in human medicine are prescribed at therapeutic levels and therefore may be less likely to generate antibiotic resistance, we must better understand their usage in humans.

Thank you for your commitment to the stewardship of antibiotics. As you know, antibiotics are one of the greatest treasures of modern medicine.

Sincerely,



Louise M. Slaughter
MEMBER OF CONGRESS