

“While the FDA delays taking action, people continue to become ill from cephalosporin resistant infections.”

WASHINGTON – Congresswoman Louise Slaughter (NY-28), Ranking Member of the House Rules Committee today pushed the U.S. Food and Drug Agency (FDA) to implement an extra-label ban on a class of antibiotics in light of the growing public health threat of antibiotic resistance.

“It has now been almost three years since FDA determined that extra-label cephalosporins as currently used in food producing animals creates a public health risk,” Slaughter wrote today. “While the FDA delays taking action, people continue to become ill from cephalosporin resistant infections. Given the critical importance of the cephalosporin class of drugs to human medicine, we ask that you quickly reissue the prohibition on the extra-label use of cephalosporins in food producing animals.” Cephalosporin usage in agriculture has serious public health implications and is one of seven classes of antibiotics Slaughter has argued should be proactively fed to healthy farm animals. “The urgency of cephalosporin stewardship is highlighted by recent news of a strain of gonorrhea that may be initiating “a new era of untreatable gonorrhea,”” Slaughter continued. “For years, cephalosporins had been the only class of antibiotics that could effectively treat gonorrhea. However, the H041 strain is highly resistant to cephalosporins—the last line of antibiotics. Without treatment, gonorrhea can cause infertility and birth defects such as blindness. “Cephalosporins are considered critically important by the World Health Organization and are one of the most important lines of defense against severe Salmonella and Shigella infections in children,” she wrote. “In addition, cephalosporins treat a wide variety of other dangerous bacterial infections including Enterobacter, E. Coli, Staph, pneumonias as well as many hospital acquired infections.”

The full text of her letter is included below.

Slaughter is the only microbiologist in Congress. Since 2007, she has been the author of legislation titled The Preservation of Antibiotics for Medical Treatment Act (PAMTA), designed to ensure that we preserve the effectiveness of antibiotics for the treatment of humans.

[For more on her work to protect public health, click here](#) .

Text of Slaughter’s letter to the FDA

July 21, 2011

The Honorable Margaret A. Hamburg, M.D., Commissioner

U.S. Food and Drug Administration

10903 New Hampshire Avenue

Silver Spring, MD 20993

Dear Commissioner Hamburg:

I appreciate your commitment to curtail antibiotic use in agriculture, and I urge you to finalize the rule to prohibit the extra-label use of the critically important cephalosporin class of antibiotics for use in food producing animals. While an extra-label ban on cephalosporins is not a substitute for a comprehensive oversight system, it will help us to protect the effectiveness of this vital drug class.

In July 2008, the FDA announced it would implement a rule to prohibit the extra-label use of cephalosporins. While this rule was withdrawn, the agency has repeatedly told Congress and the public that it intends to implement the order. Most recently, the FDA indicated its plan to move forward on the extra-label ban in a November 2010 response to Congressional inquiries, in its 2011 Strategic Priorities: Strategic Goals and Long-Term Objectives, and in "A Public Health Action Plan to Combat Antimicrobial Resistance".

It has now been almost three years since FDA determined that extra-label cephalosporins as

currently used in food producing animals creates a public health risk.

While the FDA delays taking action, people continue to become ill from cephalosporin resistant infections. Given the critical importance of the cephalosporin class of drugs to human medicine, we ask that you quickly reissue the prohibition on the extra-label use of cephalosporins in food producing animals.

The urgency of cephalosporin stewardship is highlighted by recent news of a strain of gonorrhea that may be initiating “a new era of untreatable gonorrhea”. For years, cephalosporins had been the only class of antibiotics that could effectively treat gonorrhea. However, the H041 strain is highly resistant to cephalosporins—the last line of antibiotics. Without treatment, gonorrhea can cause infertility and birth defects such as blindness.

Furthermore, Cephalosporins are considered critically important by the World Health Organization and are one of the most important lines of defense against severe Salmonella and Shigella infections in children. In addition, cephalosporins treat a wide variety of other dangerous bacterial infections including Enterobacter, E. Coli, Staph, pneumonias as well as many hospital acquired infections.

Despite their importance to human medicine, antibiotics –including cephalosporins –are used on livestock and poultry regularly and with few restrictions. According to analyses by the Food and Drug Administration, 41,328 kilograms of cephalosporins were sold for use in food-producing animals in 2009. A review of available data suggests extensive extra-label usage. For example, FDA conducted inspections at U.S. poultry hatcheries in 2001, and found that six of eight hatcheries using ceftiofur – a cephalosporin – were using it in an extra-label manner.

Cephalosporin usage in agriculture has serious public health implications.

A recent study from the Netherlands reveals that food producing animals contribute to serious cephalosporin resistant extra intestinal E. coli infections in humans consuming animal products. A study in Canada found that the voluntary withdrawal of the cephalosporin medication ceftiofur “effectively reduced the number of ceftiofur-resistant Salmonella Heidelberg infections in humans.”

"In 2008, the Food and Drug Administration noted that "FDA is concerned that the extra-label use of cephalosporins in food-producing animals is likely to lead to the emergence of cephalosporin-resistant strains of foodborne bacterial pathogens. If these drug-resistant bacterial strains infect humans, it is likely that cephalosporins will no longer be effective for treating disease in those people." Animal products have been the cause of cephalosporin resistant Salmonella outbreaks since at least 2002, with the most recent known outbreak associated with frozen turkey patties.

Unfortunately but not surprisingly, increasing numbers of pathogens are resistant to cephalosporins. The Centers for Disease Control and Prevention (CDC) reports that almost 3 percent of human Salmonella isolates submitted in 2009 for testing were cephalosporin resistant. Given that there are over one million Salmonella cases in the United States each year, it is likely that there are at least 30,000 cephalosporin-resistant Salmonella infections each year.

Due to their importance in human medicine, multiple governmental agencies have recommended a ban of extra-label usage of cephalosporins. In September 2006, the FDA's Veterinary Medicine Advisory Committee recommended that extra-label restrictions be placed on the use of 4th generation cephalosporins if these drugs were to be used in food producing animals. On November 7, 2008, the CDC wrote to the FDA in support of the extra-label prohibition.

The time for delays is over. I urge you to finalize the extra-label ban on cephalosporins.

Sincerely,

Louise M. Slaughter
MEMBER OF CONGRESS