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Rep. Slaughter Urges FDA to Heed Its Scientific Advisory Committee's Recommendation on Drug Used to Treat Life-Threatening Infections *New Science Confirms That New Animal Drug Use Will Promote Resistance to Similar Vital Human Drugs*

Washington, DC – The incoming chair of the House Rules Committee, U.S. Rep. Louise Slaughter (D-N.Y.), sent a letter this week to the U.S. Food and Drug Administration (FDA), urging it to follow its scientific advisory committee's recommendation to reject the use of an animal drug because this use would spur resistance to similar drugs that are important in human medicine. The drug, cefquinome, is a fourth-generation cephalosporin, which is part of a class of drugs highly valued in human medicine as treatment for serious and life-threatening infections.

On September 25, the FDA's Veterinary Medical Advisory Committee (VMAC) recommended against approving cefquinome for the treatment of respiratory disease in cattle out of concern that the new use of the drug would erode the effectiveness of related human drugs. So far the manufacturer of the drug, Intervet, has not withdrawn its application to the FDA, suggesting that the Agency intends to approve the drug despite the opposition of the VMAC.

"Over the past several years, the integrity of FDA's drug review process has been called into question amid allegations that your agency has put the interests of industry and politics above science," said the letter by Rep. Slaughter, the only microbiologist in Congress (see full text of letter at http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=96925). "Given the recent outbreaks of *E. coli* and other food borne illnesses across the nation, it is hardly the time to ignore the advice of scientists, and potentially impair our ability to treat deadly infections."

Two recently published scientific studies have heightened concern about animal use of cefquinome. The two studies show that traits which can confer resistance to fourth generation cephalosporins have become widespread in food animals in Europe, where the drug is widely used. In the United States, where fourth-generation cephalosporins have not yet been approved for use in animal agriculture, resistance traits to these drugs are rare. The Keep Antibiotics Working coalition sent a letter this week opposing the approval of cefquinome, citing these facts, to FDA Commissioner and the Director of the FDA's Center for Veterinary Medicine (see letter at: www.keepantibioticsworking.com/new/resources_library.cfm?RefID=96916).

"We urge FDA officials not to endanger human health by repeating the same mistake their counterparts made in Europe," said Dr. David Wallinga, director of the Food and Health Program at the Institute for Agriculture and Trade Policy in Minnesota and a member of the Keep Antibiotics Working coalition. "Fourth generation cephalosporins are too important in human medicine to put at risk by widespread use in cattle."

KAW has reason to be concerned that the FDA may ignore VMAC's advice. Two years ago, in a vote on another cattle drug, tulathromycin, the VMAC's recommendations favored restricting the use of tulathromycin to species and purposes listed on the drug label. But FDA went ahead and approved extra-label uses anyway.

Proposed federal legislation, The Preservation of Antibiotics for Medical Treatment Act, sponsored by incoming Senate Health Committee Chairman Edward Kennedy (D-MA), would phase out the use of antibiotics that are important in human medicine as animal feed additives within two years. The American Medical Association, the Infectious Diseases Society of America, and the American Academy of Pediatrics are among the more than 350 health, agriculture and other groups nationwide that have endorsed this bill.