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The Campaign to End Antibiotic Overuse

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Four Leading Medical Organizations Tell FDA to Reject Animal Drug Used to Treat Life-Threatening Infections in Humans

Urge FDA to Heed Recommendation of Scientific Advisory Committee

Washington, D.C. – Four of the nation's top medical organizations have each sent letters to the U.S. Food and Drug Administration (FDA), urging it not to approve an antibiotic for use in animals which could elicit resistance to antibiotics vital in human medicine. The animal drug, cefquinome, is a fourth-generation cephalosporin, which is one of a class of drugs highly valued in human medicine as treatment for serious and life-threatening infections.

The American Medical Association (AMA), Infectious Diseases Society of America (IDSA), American Academy of Pediatrics (AAP) and American Public Health Association (APHA) have called on the FDA to heed the advice of its Veterinary Medical Advisory Committee (VMAC). It recommended in September against approving cefquinome out of concern that the use of the drug for the treatment of respiratory disease in cattle would erode the effectiveness of related human drugs. The manufacturer of the drug, Intervet, has not yet withdrawn its application to the FDA, suggesting that the agency intends to approve the drug despite the opposition from the VMAC.

"As our human antimicrobial armamentarium dwindles, it is essential that we preserve the remaining agents and, as such, we should not take actions that could diminish the efficacy of cefepime [the only fourth-generation cephalosporin used in the humans in the United States, often used as a drug of last resort for many severe infections]," wrote Dr. Martin J. Blaser, immediate past president of IDSA in its letter (http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=98030). "A strong and compelling need is necessary to justify such a risk to human health, and the sponsor has failed to justify that need."

The letter from Dr. Michael D. Maves, AMA executive vice president, pointed out that the introduction of 3rd generation cepahlosporins in the U.S. has already led to increased resistance to important human drugs (see letter at http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=97841). "With the unrestricted use of ceftiofur [the only 3rd generation cephalosporin approved for use in animals in the United States], data from the National Antimicrobial Resistance Monitoring System indicate that ceftriaxone-resistant *Salmonella* and *E. coli* have emerged and spread in the United States."

AAP President Dr. Jay E. Berelhamer acknowledged that antibiotic resistance has severe implications for the health of children, who depend more on crucial antibiotics to combat serious infections because their immune systems are less developed than those of adults.

"Cephalosporins are one of the most widely used classes of antibiotics in children, second only to the penicillins," said Berkelhamer in the letter to FDA Commissioner Andrew C. von Eschenbach, M.D., a former Director of the National Cancer Institute (see letter at www.keepantibioticsworking.com/new/resources_library.cfm?RefID=98077). "Because there is limited resistance to cefepime here in the United States, it is frequently given to children with cancer who are highly immuno-compromised, as well as to children with severe bacterial infections caused by bacteria resistant to other commonly used antibiotics. If widespread use of cefquinome leads to resistance to it and cefepime, the consequences could be severe for our most vulnerable patients."

"APHA urges the FDA to reject the application for the use of cefquinome in cattle," wrote APHA Executive Director Dr. Georges C. Benjamin in the letter. "It is prudent to limit the use of this important class of antibiotics *now* rather than after a problem arises." The APHA letter is available at: http://www.keepantibioticsworking.com/new/resources_library.cfm?RefID=97927).

The FDA has already approved the use of 14 other drugs in eight different drug classes to treat cattle respiratory diseases. The Intervet application aims to add cefquinome – and fourth-generation cephalosporins – to this list, despite strong objections from the medical and science communities.

"Experience gives us good reason to worry that the FDA may ignore the scientific advice of its own expert advisors," said Dr. David Wallinga, physician-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. "We hope Commissioner von Eschenbach will heed the advice from the nation's leading public health professionals and physicians: Sick human patients rely on these life-saving drugs too much to put them at risk by using them in cattle."

U.S. Rep. Louise Slaughter (D-N.Y.), chair of the House Rules Committee and the only microbiologist in Congress, also sent a letter to the FDA in January, urging it to follow VMAC's recommendation. Proposed federal legislation, the Preservation of Antibiotics for Medical Treatment Act, sponsored by Senate Health Committee Chairman Edward Kennedy (D-MA) and Senators Olympia Snowe (R-ME), Susan Collins (R-ME), Sherrod Brown (D-OH) and Jack Reed (D-RI) in the Senate (S. 549) and Rep. Slaughter and 11 other House members in the House of Representatives (H.R. 962), would phase out the use of antibiotics that are important in human medicine as animal feed additives within two years. AMA, IDSA and AAP are among the more than 350 health, agriculture and other groups nationwide that have endorsed this bill.

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