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Keep Antibiotics Working Praises FDA's First Ever Ban of Agricultural Drug Due to Antibiotic-Resistance Effects in Humans

Ban on Cipro-like Drugs in Poultry Initiated During Clinton Administration

Washington D.C. — The Keep Antibiotics Working (KAW) coalition commended newly confirmed U.S. Food and Drug Administration (FDA) Commissioner Lester Crawford for today issuing a precedent-setting, final decision to withdraw approval for use of Cipro-like antibiotics in poultry (see FDA decision at <http://www.fda.gov/oc/antimicrobial/baytril.pdf>). This action is the first time that FDA has ever withdrawn an agricultural antibiotic from the market because of concerns about antibiotic resistance affecting human health. The ban was proposed in October 2000, but took nearly five years to finalize because of numerous procedural delays created by Bayer Corp., the only manufacturer of the drug, whose trade name is Baytril. Both Baytril and Cipro are members of the fluoroquinolone class of antibiotics.

FDA has shown that use of Baytril in poultry reduces the effectiveness of Cipro in treating *Campylobacter*, one of the most common causes of severe bacterial food poisoning. The most recent data from the Centers for Disease Control and Prevention show that resistance to Cipro in *Campylobacter* in humans has risen to 21 percent as of 2002; when Cipro-like drugs were first approved for use in poultry in 1995, such resistance was negligible. Although Bayer claims that Baytril is critical for poultry production, most top poultry producers have announced that they no longer use these drugs in chickens produced for human consumption, including Tyson, Gold Kist, Perdue, Foster Farms, and Claxton. Major chicken purchasers, including McDonald's, Wendy's, Dairy Queen, Burger King, Domino's, Hardee's, Popeye's, Subway and Bon Appetit, have instructed their suppliers to stop using fluoroquinolones in chickens they purchase.

"We applaud Commissioner Crawford and the FDA for acting decisively to protect the public's health," said David Wallinga, M.D., MPA, a senior scientist and director of the Antibiotic Resistance Project at the Institute for Agriculture and Trade Policy. "Cipro is an essential antibiotic and we cannot allow its effectiveness to be compromised by squandering it on poultry."

The decision takes effect September 12, 2005, but implementation could be delayed if Bayer requests a stay from FDA or from the courts.

"This proceeding has dragged on for nearly five years, during which time resistance has continued to climb," said Karen Florini, senior attorney with Environmental Defense. "It would be simply irresponsible for Bayer to seek a stay at this point, or for FDA to grant one pending judicial review."

“This is a very important decision because it is the first time FDA has cited antibiotic resistance as the reason for banning use of a drug,” said Margaret Mellon, Ph.D., J.D., Director of the Food and Environment Program at the Union of Concerned Scientists. “But FDA also needs to take additional steps to address inappropriate antibiotic use in agriculture, particularly use of medically important antibiotics as feed additive uses.”

The Union of Concerned Scientists estimates 70 percent of all antibiotics used in the U.S. — about 25 million pounds annually — are routinely fed to poultry, swine, and beef cattle not to treat illness but rather to promote slightly faster growth and to compensate for overcrowded and unhealthy conditions in concentrated animal feeding operations. More than half of these drugs are identical or similar to antibiotics that are important in human medicine. Use of antibiotic feed additives spurs the development and spread of antibiotic resistant bacteria in our food supply and the environment.

In April, KAW members Environmental Defense, Food Animals Concerns Trust, and the Union of Concerned Scientists, along with the American Academy of Pediatrics and the American Public Health Association, petitioned FDA to ban the use of medically important antibiotics as feed additives for chickens, hogs, and beef cattle. The petition is based on a detailed analysis showing that such use violates the specific safety criteria in FDA's official Guidance on agricultural antibiotics (see FDA guidance at <http://www.fda.gov/cvm/guidance/fguide152.pdf> and see petition at http://www.keepantibioticsworking.org/new/resources_library.cfm?RefID=70402). The American Medical Association and nearly 300 other groups have joined in supporting the bipartisan ‘Preservation of Antibiotics for Medical Treatment Act,’ legislation that would end the use of medically important antibiotics as feed additives *unless* FDA finds that they are safe.

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