

Court orders FDA action on antibiotic use on farms

March 23 2012, By MATTHEW PERRONE , AP Health Writer

(AP) -- A federal court judge has ordered the Food and Drug Administration to take action on its own 35-year-old rule that would stop farmers from mixing popular antibiotics into animal feed, a practice which is widely believed to have led to a surge in dangerous, drug-resistant bacteria.

In 1977, the FDA concluded that the [overuse of antibiotics](#) in livestock, poultry and other [animals](#) weakened the treatment's effectiveness in humans. The agency issued an order that would have banned non-medical use of penicillin and tetracycline in farm animals, unless drugmakers could show the drugs were safe. But the rule was never enforced, following vigorous pushback from [members of Congress](#) and lobbyists for farmers and drugmakers. Farming groups have long argued the drugs are needed to keep animals healthy, though many natural [food producers](#) dispute such claims.

In a ruling handed down Thursday, Judge Theodore Katz said the FDA must begin steps to withdraw approval of the two [antibiotics](#) for routine use in animals, siding with four [consumer safety](#) groups that brought a lawsuit against the agency.

"Today we take a long overdue step toward ensuring that we preserve these lifesaving medicines for those who need them most - people," said Avinash Kar, attorney for the [Natural Resources Defense Council](#).

The FDA has 60 days to appeal the ruling.

The court ruling will not immediately halt the use of antibiotics on farms. The FDA must first give drug companies a chance to respond and schedule a public hearing.

"If, at the hearing, the drug sponsors fail to show that use of the drugs is safe, the 'FDA' commissioner must issue a withdrawal order," concludes Katz, a judge in the U.S. District Court of Southern New York.

Antibiotics were one the most key medical discoveries of the last century, used to heal everything from infected wounds to strep throat. Since their commercial introduction in the 1930s, antibiotics have become a ubiquitous part of medical practice. Most medical experts agree overprescribing of the drugs has played a role in bacteria's growing resistance to them.

The FDA approved antibiotic use in animals in 1951, before concerns about drug resistance were recognized.

Public health advocates have been pushing the federal government to put more restrictions on antibiotics for decades. Nearly 80 percent of all antibiotics sold in the U.S. are given to [farm animals](#) used in food production, according to a recent estimate by the FDA. Farmers mostly use the drugs in healthy animals to spur growth or to keep them from getting sick in crowded, unsanitary feedlot areas.

However, after constant use some animals develop germs that are immune to antibiotics. These germs, often called superbugs, can then pass to farmworkers and their families. In other cases germs blow into neighboring communities in dust clouds, run off into lakes and rivers during heavy rains, or sometimes contaminate steaks and chops that end up on kitchen tables.

The Natural Resources Defense Council sued the FDA in May 2011 to

compel the agency to act on its 35-year-old order. The FDA countered that the 1977 ruling was outdated and that the agency had already issued more recent proposals to curb antibiotics, such as a 2010 recommendation that veterinarians be consulted before antibiotics are given to animals. The FDA is expected to finalize those recommendations, which would not be binding, next week.

But Katz said the more recent actions don't overrule the agency's previous judgment that "the drug products are not shown to be safe," for non-medical use in animals.

"The FDA has not issued a single statement since the issuance of the 1977 'decision' that undermines the original findings that the drugs have not been shown to be safe," states the opinion.

FDA spokeswoman Siobhan DeLancey said Friday the agency is "studying the opinion and considering appropriate next steps."

Throughout President Obama's first term in office, FDA officials repeatedly said antibiotics in agriculture pose a serious public health threat and said they would act on the issue. In January, the agency took its first step on the issue, ordering farmers to limit the use of cephalosporins, which are given to some cattle, swine, chickens and turkeys. The drugs are not as widely used as penicillin and other common antibiotics.

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