Denver Post
January 16, 2007

DANGERS OF AGRICULTURAL ANTIBIOTICS
Sue Jarrett and David Wallinga, M.D.
guest commentary

Recently, something completely unprecedented happened at the U.S. Food and Drug Administration that should be of interest to beef industry representatives attending the U.S. Department of Agriculture's Marketing Service listening session in Denver on this week on marketing claims for naturally raised livestock.

For years, medical experts have warned that the widespread use of antibiotics in raising the animals that we eat - cattle, chickens, pigs - hurts the effectiveness of these drugs in fighting serious bacterial infections in people. Using these antibiotics in agriculture promotes bacterial resistance to these drugs and reduces their effectiveness in human medicine.

In light of human health concerns, an FDA panel of experts has rejected a proposal by the maker of a new antibiotic for selling the drug to treat respiratory disease in beef cattle. The decision was the first rejection of its kind by the FDA's Veterinary Medicine Advisory Committee (VMAC) and an important step towards protecting the efficacy of antibiotics in human medicine.

Cefquinome, the drug rejected by VMAC, is a fourth-generation cephalosporin. This class of antibiotics includes the important human drug cefepime, used to treat pneumonia and resistant infections, especially in children. The panel said that using such a drug in cattle could not be considered safe for human health.

Given the increased scrutiny on the FDA and its drug approval processes, VMAC's action is both surprising and welcome. The U.S. Centers for Disease Control and Prevention calls antibiotics resistance "one of the world's most pressing public health problems."

In Europe, cefquinome has already been approved and is being used in livestock under the brand name Cobactan. Since its approval, resistance to this drug has emerged among E. coli and Salmonella bacteria isolated from livestock, two major causes of food poisoning. In the U.S, where fourth-generation cephalosporins have not been approved for use in animal agriculture, this resistance has not been detected in animals and has very rarely been found in humans.

Last year, the FDA re-examined the human health impact of using the antibiotic Baytril to treat respiratory disease in poultry and found that this use in animals was undercutting the effectiveness of the antibiotic Cipro to treat serious bacterial illness in humans. After a five-year process complicated by legal challenges by Baytril's manufacturer, Bayer, the FDA withdrew approval for this use.

If the FDA, which has said it will render a decision this month, heeds these experts' findings, that using Cefquinome in beef cattle is not safe, then the two decisions could signal the emergence of a new FDA, one that is aggressive in preserving the effectiveness of antibiotics in treating human disease.

VMAC includes both human and animal health experts. It is an independent scientific body created by the FDA as a reality check on its decisions, so the FDA rarely ignores its recommendations. However, there is a chance that the FDA may reject the independent scientific advice that it sought from VMAC, as it has done before during the Bush administration. If that happens, the FDA would continue a recent disturbing trend of placing science and human health second to commercial interests. Concern about the FDA's decision prompted the chairwoman of the House Rules Committee, U.S. Rep. Louise Slaughter, D-N.Y.,

the only microbiologist in Congress, to send a letter this week to the FDA, urging it to follow its scientific advisory committee's recommendation.

Regardless of its decision on Cefquinome, the FDA has yet to take action to curtail the much more widespread use of antibiotics important in human medicine as farm animal feed additives. The Union of Concerned Scientists estimates that 70 percent of all antibiotics used in the U.S. - nearly 25 million pounds annually - are used as feed additives for chicken, hogs and beef cattle.

Antibiotic feed additives are used to promote slightly faster growth and to compensate for overcrowded and unhealthy conditions in industrial-scale concentrated animal feeding operations. The FDA continues to allow these non-therapeutic uses, even though such use appears to violate the safety standards in the FDA's own official guidance on agricultural antibiotics. More than half of these drugs belong to classes of antibiotics that are important in human medicine.

Only three new classes of antibiotics have been developed during the last 25 years. We must preserve the few we have left in order to protect human health.

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Washington Post
Sunday, March 4, 2007; A01

FDA RULES OVERRIDE WARNINGS ABOUT DRUG
Cattle Antibiotic Moves Forward Despite Fears of Human Risk
By Rick Weiss

The government is on track to approve a new antibiotic to treat a pneumonia-like disease in cattle, despite warnings from health groups and a majority of the agency's own expert advisers that the decision will be dangerous for people.

The drug, called cefquinome, belongs to a class of highly potent antibiotics that are among medicine's last defenses against several serious human infections. No drug from that class has been approved in the United States for use in animals.

The American Medical Association and about a dozen other health groups warned the Food and Drug Administration that giving cefquinome to animals would probably speed the emergence of microbes resistant to that important class of antibiotics, as has happened with other drugs. Those super-microbes could then spread to people.

Echoing those concerns, the FDA's advisory board last fall voted to reject the request by InterVet Inc. of Millsboro, Del., to market the drug for cattle.

Yet by all indications, the FDA will approve cefquinome this spring. That outcome is all but required, officials said, by a recently implemented "guidance document" that codifies how to weigh the threats to human health posed by proposed new animal drugs.

The wording of "Guidance for Industry #152" was crafted within the FDA after a long struggle. In the end, the agency adopted language that, for drugs such as cefquinome, is more deferential to pharmaceutical companies than is recommended by the World Health Organization.

Cefquinome's seemingly inexorable march to market shows how a few words in an obscure regulatory document can sway the government's approach to protecting public health.

Industry representatives say they trust Guidance #152's calculation that cefquinome should be approved. "There is reasonable certainty of no harm to public health," Carl Johnson, InterVet's director of product development, told the FDA last fall.

Others say Guidance #152 makes it too difficult for the FDA to say no to some drugs.

"The industry says that 'until you show us a direct link to human mortality from the use of these drugs in animals, we don't think you should preclude their use,' " said Edward Belongia, an epidemiologist at the Marshfield Clinic Research Foundation in Wisconsin. "But do we really want to drive more resistance genes into the human population? It's easy to open the barn door, but it's hard to close the door once it's open."

The FDA knows how hard it can be to close that door. In the mid-1990s, overriding the objections of public health experts from the Centers for Disease Control and Prevention (CDC), the drug agency approved the marketing of two drugs, Baytril and SaraFlox, for use in poultry. Both are fluoroquinolones,

a class of drugs important for their ability to fight the bioterror bacterium that causes anthrax and a food-borne bacterium called campylobacter, which causes a serious diarrheal disease in people.

Before long, doctors began finding fluoroquinolone-resistant strains of campylobacter in patients hospitalized with severe diarrhea. When studies showed a link to poultry, the FDA sought a ban. But while Abbott Laboratories, which made SaraFlox, pulled its product, Baytril's manufacturer, Bayer Corp., pushed back.

"They fought this tooth and nail. It took years," said Kirk Smith, an epidemiologist at the Minnesota Department of Health.

Finally, late in 2005, Bayer gave up, but not before fluoroquinolone resistance had spread even further.
A Question of Resistance

Microbes are constantly mutating, and some of those mutations happen to confer immunity to one drug or another. Exacerbating the problem, bacteria constantly exchange bits of DNA with each other, spreading that resistance.

Given those realities, experts agree that all antibiotics should be used judiciously.

"If a drug is used less, then less resistance emerges," said Patricia Griffin, chief of intestinal disease epidemiology for the CDC.

Prudence is especially important for medicines of last resort, which is why the cefquinome application stirred such a storm.

Cefquinome is a fourth-generation cephalosporin, the most recent of several steadily improving versions of the cephalosporin family of antibiotics. Only one medicine from that family has been approved in the United States -- a powerful human drug called cefepime (brand name Maxipime), which is the only effective treatment for serious infections in cancer patients and a reliable lifesaver against several other nearly invincible infections.

InterVet developed cefquinome to treat bovine respiratory disease, the most common disease in cattle. Recognizing the potential public health implications of using a close cousin of cefepime in animals, the FDA's Center for Veterinary Medicine, which oversees animal drug approvals, convened its expert advisers in September.

One of the first things the group learned was that more than a dozen medicines are already on the market for the respiratory syndrome, and all are still effective.

"If we have no susceptibility problem, why do we need one more new drug?" asked James E. Leggett Jr., a professor of medicine at Oregon Health & Science University, whom the FDA brought in as a consultant on the cefquinome question.

The panel also learned that the disease would be a relatively minor issue but for the stressful conditions under which U.S. cattle are raised, including high-density living spaces and routine shipment on crowded trains for hundreds or thousands of miles. Those "production dynamics" suppress the animals' immune systems, explained feedlot consultant Kelly Lechtenberg of Oakland, Neb., and virtually guarantee that bovine respiratory disease will be a major problem.

Yet Stephen Sundlof, head of the FDA's Veterinary Medicine Center, told the panel members that under agency rules they should ignore those issues and consider only the language in Guidance #152.

Flaws Seen in Rules

Guidance #152 is essentially a checklist of points to consider when weighing the potential human impact of a new animal drug.

After the Baytril debacle, the public health community embraced the idea of a guidance document. A formalized risk-assessment process promised to minimize the chances of making a bad regulatory call.

But a struggle ensued when the FDA hosted meetings to spell out the criteria to be used for measuring risk, often with veterinarians and veterinary drug companies on one side and doctors and public health experts on the other.

When differences could not be resolved after repeated drafts and months of work, the agency sidestepped some tough issues and adopted language that both sides agree can block approval of the most worrisome drugs -- those such as Baytril that are put in animal feed or water, and so are easily overused. But public health experts say the wording tilts the playing field toward industry for other kinds of drugs. They want to see it revised.

Most glaring, they say, is that the guidance makes it almost impossible to say no to a new animal drug unless it is likely to threaten the effectiveness of an antibiotic that is a critical player against food-borne illnesses. By contrast, the World Health Organization recommends saying no if approval would spur resistance to any antibiotic that is important for fighting "serious human disease" -- not just food-borne illnesses.

Cefquinome's primary threat is that it may undermine the usefulness of the closely related human drug, cefepime. But as it turns out, the FDA does not consider cefepime a front-line drug against food-borne infections. So although it is a highly important drug in human medicine generally -- and although the Infectious Diseases Society of America even recommends it against some food-borne bacteria -- that risk does not count under the terms of Guidance #152.

A related problem is that the guidance's definition of "food-borne" is conservative, said Margaret Mellon of the Union of Concerned Scientists, a science policy advocacy group. For example, most urinary tract infections are caused by intestinal bacteria acquired from food, and cefepime is prescribed for those infections. If the FDA counted those infections as food-borne, then the guidance's formula would call for rejecting cefquinome for cattle.

"But FDA didn't do that," Mellon said. "That restricted the analysis right there."

Moreover, the guidance does not take into account that when microbes become resistant to fourth-generation cephalosporins, they often gain resistance to third-generation versions, too.

Third-generation cephalosporins are among the only effective therapies for serious gastrointestinal diseases in children and are the sole therapies for many cases of meningitis. That means the emergence of resistance to fourth-generation cephalosporins "could have a much more far-reaching effect" than is considered under the terms of Guidance #152, John H. Powers, a medical officer at the FDA's Center for Drug Evaluation and Research, told the agency's panel of experts.

How Great a Risk?

Richard Carnevale, vice president for scientific and regulatory affairs at the Animal Health Institute, which represents veterinary drugmakers, said critics should not presume that a dozen drugs effective against bovine respiratory syndrome is enough.

"It's not a question of whether there is a need or not," Carnevale said. "The answer is, there's always a need."

The institute argues that the risk to human health posed by animal antibiotics has been overblown.

Officials at InterVet declined several requests to be interviewed. In a statement, the company said it "fully supports the prudent use of antibiotics in animals."

The statement also says that in Europe, fourth-generation cephalosporins similar to cefquinome have been used in animals for the past decade "without compromising the interests of public health."

Yet recent European data indicate that resistance against this class of antibiotics is on the rise.

An analysis of E. coli bacteria in pigs and other animals in Spain, published in December, found high levels of the resistance that renders fourth-generation cephalosporins useless. A January report from Britain documented similar resistance patterns emerging at 10 farms.

Microbes resistant to fourth-generation cephalosporins have also begun to pop up in European patients. Such resistance is virtually unknown in the United States, where fourth-generation cefepime has been used in patients since 1997. That suggests that the resistance emerging in Europe is a result of veterinary use, said Steve Roach of the Food Animal Concerns Trust, a Chicago public interest group.

Roach says he is concerned that history is about to repeat itself. U.S. cattle were free of bacteria resistant to third-generation cephalosporins in 1997, but by 2003 one of every five samples was resistant. "This is exactly what should be avoided with cefquinome," he said.

Merely Suggestions

At the FDA advisory meeting in September, the agency's experts defied Guidance #152 and voted 6 to 4 against approval of cefquinome. But that day, and in follow-up interviews, Sundlof, the agency's veterinary chief, made it plain that the vote was "not binding."

"I think we all agreed . . . that Guidance for Industry #152 would be the criteria against which we would base our decisions on safety," Sundlof said at the meeting.

Concerned that the FDA is poised to approve cefquinome, Congress's only microbiologist recently wrote to the agency.

"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," wrote Rep. Louise M. Slaughter (D-N.Y.), who chairs the House Rules Committee.

Yet being realists, the FDA advisers in September said more than just no. They told the FDA that if it approves cefquinome, then it should at least impose limits to minimize the potential consequences. One suggestion was to explicitly preclude "off label" use of the drug -- that is, to tell veterinarians that it can be used only for bovine respiratory disease.

But Sundlof said that under FDA rules, those decisions must be left up to veterinarians unless there is clear evidence that wider use is causing harm.

"We have to take a fairly legal interpretation," Sundlof said in an interview. "If we have no evidence of a problem, or sparse evidence, we would not be able to make the prohibition prior to approval."

But he added: "As soon as we have the first glimpse of evidence that off-label use of a drug is causing resistance, we have the authority to prohibit off-label use."

The advisers also urged that as a condition of approval, the FDA should demand that InterVet provide annual reports on how much cefquinome was used and in which animals -- data that would help scientists detect links between the drug's use and patterns of resistance that emerge in people.

"Without reliable, meaningful data on the quantity of use, the purpose of use, the type, number and location of animals treated, it will be exceedingly difficult to interpret fluctuations in rates of resistance," said Susan Prolman of the Union of Concerned Scientists.

But Sundlof offered little hope for that outcome.

"That is information that would be useful to have," he said. But the agency does not have the authority to demand it.

“FDA RULES OVERRIDE WARNINGS ABOUT DRUG” was syndicated nationally and ran in at least 20 additional newspapers.

Other Placements on March 4:
- Bradenton Herald, FL front page tease
- Contra Costa Times, CA
- Fort Wayne Journal Gazette, IN
- Fort Worth Star Telegram, TX front page
- Houston Chronicle, TX
- Hutchinson News, KS
- Kansas City Star, KS
- Minneapolis-St. Paul Star Tribune, MN
- San Francisco Chronicle, CA
- St. Petersburg Times, FL front page tease
- The Spokesman Review, WA
- Seattle Times/Seattle Post Intelligencer, WA front page

Placements on March 5:
- amNew York, NY
- Boston Globe, MA
- Charleston Daily Mail, WV
- Columbus Dispatch, OH
- Delaware News Journal, DE
- New York Sun, NY
- Pittsburgh Post Gazette, PA

Placements on March 6:
- San Jose Mercury News, CA

The story also appeared online in 255 different sites, including
- Slate - Today's Papers
- Huffington Post
- Slashdot

Also, both Reuters and UPI put the story out on their wires.

Sacramento Bee
Editorial: CHAIN OF FOOLISHNESS
FDA shouldn't approve cattle antibiotic

Published Wednesday, March 7, 2007

In deciding whether to approve new pharmaceuticals, the federal Food and Drug Administration must often weigh risks versus benefits, depending on test results that contain varying levels of uncertainty.

For drugs that could treat human diseases, these decisions can sometimes be exceedingly difficult. If the FDA errs in approving a product that hasn't been fully tested, it can sicken or even kill people the drug was intended to help. Yet if the agency is overly cautious, it can reject a promising medication that potentially could save lives.

The risk-benefit equation is less challenging, however, when the FDA evaluates medications aimed at increasing production of cattle and other livestock. If the FDA errs in rejecting one of these drugs, certain industries and farmers may lose potential profits, but no one is directly harmed. Yet if it errs in approving a drug that could find its way into the food chain, the consequences to consumers could be staggering.

By all indications, the FDA isn't sufficiently weighing these consequences as it prepares to approve a highly potent cattle antibiotic called cefquinome. As the Washington Post reported Sunday, the American Medical Association and about a dozen other health groups have warned that cefquinome could speed the emergence of cattle microbes resistant to certain antibiotics. If consumers were to ingest the microbes in large quantities while eating meat, it could increase their resistance to commonly prescribed antibiotics used to treat diseases and infections.

Despite the warnings, the FDA appears to be close to approving cefquinome, which is made by a Delaware company called InterVet Inc. to treat cattle lung infections. According to the Post, an internal policy document called Guidance Document #152 makes it difficult for the FDA to say no to cefquinome, even though the FDA's advisory board recommended rejecting the drug last fall.

The agency's march toward approval is doubly troubling, because the federal government has a mixed history of keeping potentially dangerous antibiotics out of the food supply. In the mid-1990s, the FDA allowed poultry to be treated with two antibiotics containing a class of drugs called flouroroquinolones. Only after bacteria resistant to flourorquinolones started showing up in patients with severe diarrhea did the agency pull the antibiotics from the market.

While bovine respiratory disease is highly common and extremely expensive for the cattle industry, experts say effective medicines are already on the market to treat this disease. Moreover, indications are the industry could reduce the spread of this disease by not packing cattle so closely into feedlots and train cars.

Clearly, the risks of cefquinome outlined by the FDA's advisory board outweigh the benefits. Until InterVet can demonstrate otherwise, the federal government should keep this drug off the market.

“CHAIN OF FOOLISHNESS” ran on March 7
- also appeared in Ft. Wayne News Sentinel, IN March 8
- also appeared in Belleville News Democrat, IL March 8
- also appeared in Merced Sun-Star, CA March 9
- also appeared in Wilkes Barre Times Leader, PA March 10

Columbus Dispatch
Thursday, March 08, 2007

JUST SAY NO
Approval of antibiotic for cattle could endanger important human drug

Once again, the Food and Drug Administration might ignore the recommendation of one of its advisory panels, this time regarding an antibiotic for animals that some health groups fear could pose a danger to humans. The advisory group recommended against approval for cefquinome, a highly potent antibiotic that would be used against bovine respiratory disease. The drug is part of a class of antibiotics that "are among medicine's last defense against several serious human infections," according to a Washington Post story in Monday's Dispatch.

Experts, including the American Medical Association, are worried that if cefquinome is given to cattle, that would hasten the development of drug-resistant microbes that then could spread to humans.

In spite of the advisory panel's recommendation, FDA officials say they have little choice but to approve the proposal, because of a guidance document approved in 2003 that lays out how to evaluate potential effects of animal drugs on human health.

But that document, Guidance for Industry No. 152, is not a regulation, according to a news release announcing its publication on the FDA's Web site. The guidance document itself says: "This guidance represents the Food and Drug Administration's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public."

Clearly, the FDA has some wiggle room that it ought to take advantage of.

The FDA has approved only one drug from this family for human use, cefepime, which is the only treatment for cancer patients who have serious infections. And it's also a big gun that is counted on to fight other serious infections. Such weapons are too valuable to put at risk.

Also, cefquinome is a fourth-generation drug in the family of cephalosporin. If a bug becomes resistant to a fourthgeneration drug, it could become resistant to third-generation drugs, too. That would endanger medications for meningitis and serious gastrointestinal diseases.

Because few new classes of antibiotics have been developed in recent years, current ones have to be protected.

More than a dozen drugs to treat bovine respiratory disease are in use, and all are still effective. The FDA has no reason to put an important human drug in danger to add another animal drug to the shelf. The agency should heed its advisory panel and reject cefquinome.

Walla Walla Union-Bulletin
March 8, 2007

DRUG COMPANY PROFITS CAN'T BE PUT AHEAD OF HUMAN LIVES
A loophole - created by lobbying from the pharmaceutical industry - could lead to the release of a drug to treat cattle that experts believe will result in the creation of supermicrobes.

By the Editorial Board of the Union-Bulletin

Drug company profits can't be put ahead of human lives A loophole - created by lobbying from the pharmaceutical industry - could lead to the release of a drug to treat cattle that experts believe will result in the creation of supermicrobes.
By the Editorial Board of the Union-Bulletin

New pharmaceuticals can easily be worth millions if they fill the right niche. That holds true whether the drugs target disease in animals or humans.

Drug companies often rush them to market so they can cash in. But these drugs can have dangerous side effects.

And this is why it is critical that the federal government, through the Food and Drug Administration, test and monitor the new drugs for safety.

Unfortunately, the system isn't foolproof - humans are involved. Greed can too easily cause the health and welfare of the public to be minimized, if not ignored.

This appears to be what's happening as InterVet Inc. pushes to get a new antibiotic to treat a pneumonia-like disease in cattle on the market.

The drug, cefquinome, is a highly potent antibiotic that medical experts classify as the last line of defense against a number of serious human infections. The Washington Post reports that no drug from that class has ever been approved for use in animals.

The reason for that is simple. As antibiotics are used on animals - or people - the microbes become resistant to those drugs over time. The fear is that if this powerful antibiotic is used on animals it will speed the emergence of supermicrobes that will spread to humans.
The American Medical Association and a variety of other groups concerned about human health have urged the FDA not to approve the use of cefquinome for cattle. The FDA's advisory board agreed and rejected InterVet's request.

But it now looks like a loophole - created by lobbying from the pharmaceutical industry - is going to result in the approval of cefquinome. FDA officials say their hands are tied by a guidance document - Guidance for Industry 152 - that codifies how to weigh threats to human health posed by proposed new drugs for animals.

The wording of the Guidance for Industry 152, as The Post reported, is more deferential to pharmaceutical companies than is recommended by the World Health Organization. In short, drug companies have a better lobby than the WHO.

``The industry says that `Until you show us a direct link to human mortality from the use of these drugs in animals, we don't think you should preclude their use,'" said Edward Belongia, an epidemiologist at the

Marshfield Clinic Research Foundation in Wisconsin. ``But do we really want to drive more resistant genes into the human population? It's easy to open the barn door, but it's hard to close the door once it's open."

In this case, the barn in question contains a very serious disease that would be devastating if unleashed. Let's not forget that the type of drug at issue here is the last line of defense to a life-threatening disease in humans.

Profits should never be put ahead of lives.

Action needs to be taken now to alter the FDA guidelines before microbes are altered and human lives are lost.

New York Times
March 9, 2007
Editorial

HEALTHY CATTLE AND HEALTHY HUMANS

Medical experts have long worried that the indiscriminate use of antibiotics in animal feed is yielding resistant strains of bacteria that may be ingested by humans and cause diseases that can't be cured. The main concern has been large-scale dosing of big herds or flocks. But an application now before the Food and Drug Administration raises the issue of whether injecting even individual animals may interfere with human medical treatments.

The human version, known as cefepime, is typically administered intravenously in a hospital to treat severe pneumonia or other serious infections. Now an animal health company wants to sell a veterinary version, known as cefquinome, to treat beef cattle that are suffering from bovine respiratory disease, the most common cause of illness in cattle.

There are many other veterinary antibiotics in this class already on the market, but the F.D.A. does not have the authority to evaluate whether a new drug is needed. The F.D.A. simply evaluates the drug's safety and effectiveness in animals and its potential impact on the effectiveness of drugs used in humans. There the evidence is murky. While an F.D.A. scientific assessment determined that the proposed new veterinary drug posed only a "medium" risk to human health — hardly a cause for alarm — an F.D.A. expert advisory committee voted 6 to 4 to reject the veterinary drug.

The agency needs to dig much harder. It needs to take another look at its judgment that the drug is only "highly important" to human medicine in light of the World Health Organization's judgment that it is "critically important." It also needs to determine just how much resistance to the drug has emerged in Europe, where it has been used in animals for many years. And it needs a better fix on the number of cattle apt to receive these injections, a factor affecting the likelihood that resistance will spread.

Before giving the go-ahead, the F.D.A. must make sure that this drug — of marginal importance to the cattle industry — will not undercut a drug vital to human medical care.

"HEALTHY CATTLE AND HEALTHY HUMANS" ran on March 9
- also appeared in Worcester Telegram & Gazette News, MA March 10
- also appeared in The Argus, (Fremont) CA March 12

San Jose Mercury News
March 9, 2007

FDA plan a danger to human health;
CONGRESS SHOULD PUT COMMON SENSE AHEAD OF PROFITS

Only the FDA's convoluted regulations would put the needs of cattle over that of people. Or more to the point, the profits of the cattle industry over the health of Americans.

The most apt word to portray the federal agency's plans to approve a new antibiotic for cattle is a common barnyard epithet. Medical experts, including the American Medical Association and the Union of Concerned Scientists, continue to express fears that the use of antibiotics in the animals Americans consume severely damages the effectiveness of antibiotics used by humans.

Congress should take action to force the FDA to abandon its plans to approve the use of the antibiotic cefquinome. It should start by pointing out that the FDA's own scientific committee recommended against granting the cattle industry permission to use the antibiotic.

Then Congress should look into the subject of why the cattle industry is so desperate to win approval of the powerful new drug.

According to a Washington Post report, the industry's common practice of packing cattle tightly together for train trips of hundreds or thousands of miles puts tremendous stress on the animals, so much so that it often suppresses the cattle's immune systems. The industry wants approval of the new, powerful antibiotic to protect their interests.

But scientists have demonstrated in the past that the use of antibiotics in chickens and pigs, for example, eventually sharply reduces the antibiotics' effectiveness for humans.

The FDA's regulations, according to the Post investigation, force the agency to prove that the drug would damage human's resistance to antibiotics -- an unrealistic approach because it can take years to develop.

Doctors have known for years that the number of effective antibiotics is in decline, and that it is becoming increasingly difficult for scientists to develop new medicines to fight infections. This means we must ensure the effectiveness of the antibiotics we have.

The benefits to the cattle industry are far outweighed by the potential needs of humans. If the FDA doesn't see the error of its ways, then Congress must step in and send the cattle industry packing.

Washington Post
Sunday, March 11, 2007

RESISTANT BUGS
Keeping antibiotics effective

EVER SINCE Ernst Chain and Howard Florey isolated penicillin in 1939, inaugurating the era of antibiotics, harmful microbes have steadily developed resistance to even the most robust bacteria killers. The more often a particular antibiotic is administered, the more likely that bacteria will adapt. So, along with the continual development of new antibiotics, the best way to preserve the efficacy of medications that treat dangerous infections is to use them as sparingly as possible. That's why your doctor might not prescribe a course of amoxycillin for your sniffles.

But The Post's Rick Weiss reported last week that the Food and Drug Administration might do the exact opposite. The FDA is considering approval of cefquinome, a powerful antibiotic, to treat a common bovine infection. Never mind that there are already 12 medications on the market to treat the illness, bovine respiratory disease, or that it would be more effective to simply house cows in more sanitary conditions. FDA officials are not supposed to discriminate against drugs because their purposes might overlap with others. Nor can they tell farmers how to raise their livestock.

What the FDA can do, however, is alter its self-imposed rules that prevent the agency from fully considering the public health risks of approving this antibiotic for use in animals. The FDA's current rules say that the agency can deny approval if giving the medication to livestock would threaten the efficacy of a major antibiotic in the treatment of food-borne illnesses in humans.

But overusing cefquinome might undermine a similar antibiotic for humans, cefepime, that is an essential medication for treating many infections that are not classified as food-borne but are nevertheless very dangerous. James E. Leggett Jr., an infectious-disease specialist whom the FDA brought in to advise on the cefquinome issue, points out that risk analyses compiled according to FDA guidelines do not consider whether giving cefquinome to cows would encourage resistance to it and other valuable antibiotics in some of the bacteria that live in -- and are excreted from -- the bovine gut, such as E. coli.

Instead of ignoring these risks, the FDA should adopt the more sensible standard that the World Health Organization recommends, which would allow the FDA to reject drugs that might undermine an antibiotic important in fighting "serious human disease," food-borne or not. With a fuller picture of how dangerous widespread use of cefquinome in cows might be, the FDA can make a better decision.

CBS Evening News

HUMAN VS. COW IN BATTLE OVER ANTIBIOTIC
New York, March 11, 2007

(CBS) It's a battle over the health of cattle versus humans.

The Food and Drug Administration is moving towards approval of an antibiotic drug call ed Cefquinome for use in cows being shipped for slaughter, reports CBS News correspondent Randall Pinkston.

But infectious disease experts are sounding an alarm.

"We're squandering this," says Dr. Martin Blaser, an infectious disease specialist. "W e're wasting one of our most powerful antibiotics."

Cefquinome is a member of a very potent class of antibiotics, oftem a medicine of last resort for humans.

"It's used to treat a number of infections that plague cancer patients and other very seriously ill patients," says Rebecca Goldberg, an environmental biologist.

If Cefquinome is used in cows, infectious disease experts believe it could create bact eria that become resistant to the drug. The resistant bacteria could then be passed on to humans who eat undercooked beer of dairy products, add Pinkston.

"Antibiotic resistance is just increasing and increasing," says Dr. Blaser.

In a statement, the FDA insists, "If there is credible scientific evidence that use of an antibiotic in livestock poses a health threat to people, the FDA will take every possible measure to protect human health, including not approv ing a new antibiotic for livestock."

Critics say the FDA's own guidelines make it likely that Cefquinome will be approved o ver the objections of the American Medical Association and the FDA's own scientific advisory panel.

That's what happened a decade ago, reports Pinkston, when, under different guidelines, the FDA approved an antibiotic for poultry, which created an antibiotic resistant form of salmonella

"The FDA should say 'no' to any drug if there is a risk to human health," says Goldber g.

After proof that food poisoning victims were resistant to antibiotics similar to the p oultry drug, the FDA did a 180 and banned its use. This time around, critics are hoping history doesn't repeat itself with he new antibiotic for cattle.

Buffalo News
March 12, 2007

LIMIT USE OF LIVESTOCK DRUGS
Too much reliance on cattle antibiotics could compromise human medicines

What's more important — the health of your child or the health of the cow your child might eat? And how surprising is it to learn that favoring one might harm the other?

U.S. Rep. Louise M. Slaughter is among those who aren't surprised at all. Her degrees in microbiology and public health help her see that the way cattle are raised in modern America, and the way they are heavily medicated because of it, pose a long-term threat to human health. And her experience in politics tells her what steps are necessary to see to it that people who make drugs for cattle do not have more effective lobbyists than your children do.

Thus Slaughter, a Democrat from Western New York, is arguing that the Food and Drug Administration should not allow the use of new drugs for cows when that use could threaten the effectiveness of similar drugs that might save the lives of people.

The reason the health of people and the health of animals are in conflict, rather than complementary, flows from the wholly unnatural way in which the industrial food system brings beef to most of our tables. By cramming cattle into trucks, rail cars and feedlots and feeding them stuff the bovine digestive tract was not evolved to properly digest, disease and bacteria that threaten the animals have to be fought off with an ever-growing arsenal of drugs.

But evolution cannot be tricked forever. The germs that make cattle sick, or that might poison the people who eat them, develop a resistance to whatever vaccines and treatments we might throw at them. People then invent a new drug, forcing the Darwinian rise of the next superbug.

The most recent example of that phenomenon is called cefquinome. It's a new antibiotic developed for cattle that is up for FDA approval. Because FDA rules presume that such usages should be approved absent an imminent threat to human health, experts fear that approval will be given and the countdown will begin toward a day when similar drugs will lose their ability to cure horrible infections in people. Those experts include the panel of scientists appointed by the FDA itself, whose recommendation against approving cefquinome for cattle is about to be ignored.

In the case of cefquinome, the move is doubling maddening because, while there are other medicines to treat common lung infections in cattle, none are now as effective as a related drug, cefepime, in treating kinds of infections that human cancer patients are vulnerable to. But once cefquinome gets into the biosphere, cefepime's days are numbered.

Oh, sure, they'll invent another drug. But do you want to be the one suffering from a life-threatening infection while they are still working on it?

Slaughter has petitioned the FDA to follow its expert panel's advice, and has also introduced legislation that would change the process so that the agency would have to give a lot more weight to scientific concerns about antibiotic resistance and comparatively less to industry pressure. That's just the shot in the arm the FDA needs.

The Baltimore Sun
Editorial March 13, 2007

BUGGED

The warning to sausage-eaters, about not watching it be made, should also direct the gaze of other meat-eaters away from factory-style cattle, pig or poultry farms. Exposure to the cruel and cramped conditions in which the animals are kept as well as the poor quality of their feed might well upset lunch.

But what's downright unconscionable is the use by farmers of powerful antibiotics, partly to combat the ill effects of the animals' living conditions. The practice poses the risk of negating the antibiotics' healing effects on humans.

Congress should move quickly to phase out the routine use of human antibiotics for feed animals and to block an anticipated move by the Food and Drug Administration to approve a highly potent new drug, cefquinome, for treatment of a pneumonia-like disease in cattle. Especially in an era when there's so much concern about pandemics, it makes no sense to weaken medicine's best defenses against infection simply to protect the commercial interests of the pharmaceutical and meat industries.

Medical experts have complained for years that widespread use of most human antibiotics as feed additives for chicken, hogs and beef cattle - both to promote growth and to compensate for unhealthy surroundings - diminishes the effectiveness of these drugs in humans.

The American Medical Association and other scientific and consumer groups are particularly alarmed at the prospect of cefquinome being approved for cattle. It would be the first of a still powerful class of antibiotics to be given to animals, and they fear it would spur development of super-resistant microbes, which could be passed on to humans through food, air and water.

Yet The Washington Post reported last week that the FDA is poised to ignore such warnings, even from its own advisory committee, and grant the approval this spring. Such a move by an agency already seen as too cozy with the pharmaceutical industry at the expense of the public should give added momentum to a legislative drive intended to sharply curtail this casual exploitation of a tool so important to human health.

Diseases caused by resistant germs bring with them more severe symptoms and longer hospitalizations, medical experts say.

Ponder that over your next hamburger or chicken fingers.

Palo Alto Daily News
Monday Mar 26

LOCAL FOOD COMPANY HAS BEEF WITH ANTIBIOTICS By Kristina Peterson

A Palo Alto-based food company has found a new tool in battling the phenomenon of increasingly antibiotic-resistant bacteria: the hamburger.

Last week, Bon Appetit Management Company announced that under a new policy, it will only buy beef that has never been exposed to antibiotics or growth hormones. The on-site catering firm also recently became the first major food service company to oppose the Food and Drug Administration's pending approval of allowing cattle to be fed cefquinome, an antibiotic used to treat human illnesses.

Bon Appetit, which operates more than 400 cafes in 28 states, will now serve 100,000 all-natural hamburgers each month. Locally the company operates restaurants at Stanford's Graduate School of Business, Oracle, Yahoo and the de Young museum in Golden Gate Park.

Executive Chef Andrew Roybal, who runs the dining hall at Palo Alto-based TIBCO Software, said natural beef cooks differently and produces a better-tasting, healthier burger.

"Natural hamburger patties don't shrink down as much as your standard ones," Roybal said.

Bon Appetit spokeswoman Maisie Greenawalt said that when cattle are fed antibiotics and hormones, the animals grow faster by adding water weight. "So when you cook the meat, it releases a lot of water and with that goes flavor, so you end up with a drier hamburger," she said.

Greenawalt said the company has found that a five-ounce conventional patty cooks to the same size as a four-ounce natural beef patty.

And Roybal noted that the natural beef tastes better than "something that's been fed a processed cornmeal product."

Moreover, limiting the use of antibiotics in cattle may make human illnesses easier to treat, said Rebecca Goldburg, senior scientist at the nonprofit Environmental Defense.

"The chief threat is that the use (in cattle) of antibiotics also used in human medicine increases the chance that when that antibiotic is used to treat human infections, it won't work," Goldburg said. She described cefquinome as "a very advanced form of penicillin."

In September, the Infectious Diseases Society of America said in a statement to the FDA that approving cefquinome use for cattle poses a threat to people because "resistance genes may be transferred to humans through the food supply and ultimately cause treatment failure..." The society also pointed out that the antibiotic is often the "sole therapy or one of few alternatives to treat serious human disease."

"Bon Appetit is the first major food company to say 'We don't want this either.' We want food to be safe," Goldburg said.

Greenawalt said the company already has similar all-natural policies in place for chicken and turkey breast. It took until 2007 for the company to find enough natural beef suppliers to meet their national demand, she said.

She said the company is now working on finding natural pork suppliers and increasing their percentage of beef from all-grass-fed cattle.

Roybal said his diners already enjoy the change.

"There is nothing like something coming from a real farm," he said.

This story also ran in the Contra Costa Times.

Minneapolis Star Tribune
April 05, 2007

CAN A CURE BE A CURSE?
Dairy farmers want new, powerful antibiotics, despite fears about the impact on human health.

By Matt McKinney, Star Tribune
EMERALD, WIS. - It's late morning at Emerald Dairy farm, and class is in session: Adolescent cows line up in the computerized milking parlor. Soon they'll be here every day. For now they're learning how to work with the machines.

Hooves pound the damp cement floor. Beefy sides shudder and then relax. Radio frequency identification tags on each cow talk to a computer as a farmhand, the only person in the parlor, cleans.

It's a point of pride for dairy farmer John Vrieze that at his farm, technology reigns.

"If she gets sick and needs an antibiotic, we ought to be able to give her the latest, best, technologically advanced antibiotic we can," said Vrieze, who runs the 2,600-head dairy farm.

And yet it's his diligence for the latest and the best that has Vrieze caught in a controversy in which some are accusing farms like his of endangering human health.

The issue is cefquinome, a new antibiotic from a class considered the most powerful known to science. It soon may win federal approval for use in cows.

The drug has been assailed by medical doctors and by a panel that advised the Food and Drug Administration (FDA) against approving the drug. They say it may encourage creation of a supermicrobe that could pose a threat to people by advancing a biological race between bacteria and antibiotics, a race that bacteria eventually would win.

"You're climbing up a ladder until you get to where there's only a few drugs left" to kill the toughest germs, said Steve Roach, public health director of the Food Animal Concerns Trust, a Chicago-based nonprofit group that has been lobbying against FDA approval.

The case has found attention among consumers who in recent years have taken more interest in things formerly left up to the farmer, from how food is grown, to whether or not pesticides were used, to animal welfare.

The FDA declined to comment specifically for this report, offering a previous statement that the agency continues to collect information about cefquinome. Agency observers say the director of the FDA's Center for Veterinary Medicine, Stephen Sundlof, has signaled that cefquinome may be approved with some limitations.

Battling illness

If cefquinome (pronounced "sef-kwi-nome") is approved, veterinarians would use it against a pneumonia-like illness commonly found in cows. Sometimes called "shipping fever," the sickness tends to creep up in cows as they're moved from farm to farm. Other antibiotics work against the illness, said large animal veterinarian Kevin Funk. He said vets "don't really need" cefquinome, but in general, they need more approved antibiotics to fight the sicknesses they see on farms.

"Our choices are really limited," he said.

Mastitis, an infection of the milk ducts, is a good example. It's very common among cows and yet there's no injectable antibiotic for it, he said. If veterinarians use an antibiotic on mastitis they have to do so "off-label," the term used for the legal practice of using an drug normally prescribed for something else.

Some are concerned that if cefquinome were approved for use on shipping fever, it eventually would be used for other things in an off-label fashion.

"There's kind of a loophole in the way that they approve these things, in that if they do gain this initial approval for cattle, it's going to be far easier for them to get expanded use in a number of different species," said Kirk Smith, a state epidemiologist. "It may not be a huge deal right now, but this might open the floodgates for much more use down the road."

Veterinarians and farmers both say human doctors overprescribe antibiotics, too, and some said they feel like the cefquinome case is punishing them for practices that go on in hospitals. The debate shouldn't be about whether animals or people deserve the best antibiotics, said veterinarian Matthew Boyle, a member of the Minnesota Veterinarian Medicine Association's Food Animal Pharmaceutical Committee.

"Prescribing prudent antibiotic use is more paramount than where we're using them," he said.

Losing potency

Cefquinome works by blowing apart invasive bacterial cell walls to make sick cows healthy again. And yet, like many antibiotics, it could become less effective over time if nature develops microbes capable of defeating it.

That's the process that has steadily weakened the power of penicillin, which 40 years ago was a cure-all for meningitis and middle-ear infections. Today, doctors use other antibiotics because penicillin no longer is effective against either illness.

"You use an antibiotic in people, or in animals, it's kind of a natural thing for it to select for resistance," Smith said.

Against that history, the FDA's advisory committee on cefquinome last September urged the agency to reject the antibiotic. The Veterinary Medicine Advisory Committee said that in its application, drugmaker Intervet Inc. of Millsboro, Del., did not supply the most up-to-date information to the agency, including reports of cefquinome resistance in Spain and England where the drug has been legal for a decade.

The American Medical Association (AMA), the Infectious Disease Society of America and the Union of Concerned Scientists all have warned against animal use of cefquinome. They worry that approval could ultimately weaken the effectiveness of its human analog, a drug known as cefepime that's sold under the brand name Maxipime. Cefepime is used on infections in cancer patients and against tough infections that do not respond to other antibiotics.

"I think FDA failed in this," Roach said. "They weren't critical enough of Intervet's assessment."

A stronger E. coli

Farmers and some large-animal veterinarians say the FDA's system for detecting resistance, begun more than a decade ago and run by the Centers for Disease Control, would give some warning if cefquinome was creating a resistant microbe.

But, critics say, the FDA has done little to counteract already-approved antibiotics showing signs of resistance. A team of scientists reported in the latest issue of Veterinary Microbiology that E. coli from chickens is now resistant in 5 percent of all cases to an antibiotic widely used in poultry farming, the third-generation cephalosporin drug ceftiofur. The human version of the drug, ceftriaxone, is commonly used for severe infections in people.

"Given the recent outbreaks of E. coli ... and salmonella in this country, this increase in resistance is particularly troubling," wrote Michael Maves, AMA executive vice president, in a letter sent to the FDA last month.

To dairy farmer Vrieze, it makes no sense to ignore biotechnology advances. "I tell people that don't want us to use therapeutic antibiotics on these cows: 'I use it on my kids, and I use it on my pets; why wouldn't I use it on my cows?' "

Federal regulations require keeping cows recently given a therapeutic antibiotic out of the milking parlor long enough that the drug washes out of the cow's body. "If there's antibiotic resistance," Vrieze said, "it's not coming from the dairy industry."

Vrieze, the dairy farmer quoted in the article, is the president of the Wisconsin Dairy Association. His affiliation was not mentioned.

“CAN A CURE BE A CURSE?” appeared on the front page of the Minneapolis Star Tribune. It also ran on the AP wire and appeared in the following newspapers:
- Fond du Lac Reporter, WI
- Chippewa Herald, WI
- Appleton Post Crescent, WI
- West Central Tribune, MN
- The Forum of Fargo, ND
- Oshkosh Northwestern
- Winona Daily News, MN
- Janesville Gazette, WI
- LaCrosse Tribune, WI
- Oshkosh Northwestern, WI

Minneapolis Star Tribune
April 9, 2007

Editorial: Beware wider use of antibiotics in animals
FDA drug approval would make humans more vulnerable.

Wisconsin dairy farmer John Vrieze wants FDA permission to give his cows a powerful antibiotic, cefquinome, that is now the drug of choice and last resort for several difficult-to-treat human conditions. He shouldn't get that permission. That would be, as the Gold'n Plump billboards say about antibiotics and animals, a "cock-a-doodle-don't."

By all accounts, Vrieze is a very good dairy farmer who embraces advanced techniques for keeping his cows happy, healthy and producing. So when one of his cows comes down with bovine respiratory disease, he'd like to treat the animal with a powerful drug, cefquinome. The manufacturer of cefquinome has petitioned the Food and Drug Administration for permission to begin selling the drug for use in animal husbandry.

That has set up a tug of war between those opposed to wider use of antibiotics in animals and those who favor it. In this battle, the opponents are the good guys; they include the American Medical Association, other health groups and the FDA's own advisory panel.

The problem is that the disease-causing microbes which antibiotics attack constantly mutate. The wider the use of an antibiotic, the sooner one of those mutations will defeat the drug.

Widespread use of antibiotics in animals accelerates this process tremendously, leaving humans more vulnerable to diseases once controllable. That's what is behind a movement to reduce the use of antibiotics in animals, and why the Gold'n Plump billboard is an effective marketing device.

Enter cefquinome. A close cousin, cefepime, is the only effective treatment available for some serious infections. Worried that using cefquinome in animals puts the efficacy of cefepime at risk, the advisory board at the FDA's Center for Veterinary Medicine recommended against approving animal use.

The panel had two other reasons for voting the way it did: A dozen other, effective treatments already are on the market for bovine respiratory disease, and the incidence of that disease can be significantly reduced if the animals are treated right -- i.e., not frequently moved long distances and not packed tightly together.

Notwithstanding the common-sense judgment that drugs from the cephalosporin family should be reserved for humans, the FDA may still approve it for animals. The reason is one that has become common under the Bush administration: deference to industry.

FDA guidelines have been rewritten so that approval in a case like this is pretty much guaranteed unless opponents can prove a risk to a drug used in humans to fight a food-borne illness. Since that is not the case for cefquinome, dairy farmer Vrieze may get his wish and be allowed to use its close cousin on his sick dairy cows. His "Bossy" may be better off, but someone's very sick Aunt Millie eventually is going to pay the price. Something's wrong with that outcome.

This editorial also ran in the Pueblo Chieftain, CO, on April 23, 2007

Vrieze, the dairy farmer quoted in the article, is the president of the Wisconsin Dairy Association. His affiliation was not mentioned.

Honolulu Star Bulletin editorial
April 16, 2007

Our Opinion:
OVERUSE OF ANTIBIOTICS IMPERILS PUBLIC HEALTH

THE ISSUE
An antibiotic used to treat gonorrhea has been found no longer effective.

DRUGS first limited to treat a resistant strain of gonorrhea in Hawaii eight years ago have now been recommended for patients nationwide, an alarming development that furthers the argument for curbing nonhuman antibiotic applications.

Data show rapid spread of the "superbug" in 26 cities with dramatic increases in cases from 1 percent of all gonorrhea infections to more than 13 percent in less than five years. In Hawaii, resistant gonorrhea comprised 1.4 percent of cases in 1997 compared with more than 20 percent in 2006.

What's causing concern is that the antibiotic that was the first line of defense against the fast-evolving microbe no longer restrains the disease. The substitute antibiotic now recommended by the Centers for Disease Control and Prevention leaves just the one class of drugs for treatment, with no new antibiotics for gonorrhea being developed.

Antibiotics are one of the most profound achievements in medicine, but decades of widespread and indiscriminate use -- in cosmetics and soaps and food animal production -- has rendered many ineffective.

The practice continues. Last month, the Food and Drug Administration, despite counsel from its own experts and health groups, put on the approval track for treating cattle an antibiotic that is the fourth generation version of the one the CDC is now urging for gonorrhea.

The company that makes the antibiotic contends similar drugs have been used in animals in Europe without harm, but recent data indicate bacteria resistance has grown not only in food animals but in humans as well. Government and private health organizations agree that careful, limited use of antibiotics is crucial to public health as microbes become more and more resistant to them. The spread of gonorrhea is just one indication of the danger.

Boston Globe Editorial
April 23, 2007

CHEW CUD, NOT ANTIBIOTICS

ANTIBIOTICS, one of the great medical advances of the 20th century, are being threatened by their careless use in the 21st century. Time and again, disease-causing bacteria in humans become resistant to antibiotics because they are prescribed for the wrong conditions or because patients fail to complete the full course of the prescription. A third, highly avoidable cause of resistance is the use of antibiotics in poultry or livestock.

The Food and Drug Administration has before it now an application to use on cattle an antibiotic from a family of antibiotics crucial to treating humans. The agency should follow the advice of its veterinary advisory committee and turn thumbs down on this bid.

The antibiotic is cefquinome. Intervet, the world's third largest animal health company, wants to sell it for treatment of bovine respiratory disease, or "shipping disease," which occurs frequently when cattle are shipped in trucks or rail cars to feed lots and are then kept in close confinement. Intervet's application says the drug would be sold for therapeutic use in individual cases and not as a preventive, where the danger of resistance developing would be even greater as bacteria mutate and find ways to survive the drug.

But Margaret Mellon, director of the Food and Environment Program of the Union of Concerned Scientists, says that bovine respiratory disease is so endemic in feed lots that cefquinome's use would become routine. She said there are alternative drugs to use with cattle and the disease would be much less common if the industry would change the conditions under which cattle are raised and prepared for slaughter. Critics of cefquinome use for bovine respiratory disease also worry that once it becomes available for that purpose, it would be used for others as well.

Cefquinome belongs to a class of antibiotics known as cephalosporins. According to the president of the American Academy of Pediatrics, Dr. Jay E. Berelhamer, this class of drugs is widely used in children, who are particularly dependent on antibiotics in cases of infection because their immune systems are less developed than those of adults . In a letter to the FDA opposing approval of cefquinome for cattle, Berelhamer says a similar antibiotic is often prescribed for children being treated for cancer whose immune systems are weakened. "If widespread use of cefquinome leads to resistance to it . . . , the consequences could be severe for our most vulnerable patients," he wrote.

Other professional organizations that have opposed approval of cefquinome include the American Medical Association, the Infectious Diseases Society of America, and the American Public Health Association. The FDA should take the advice of the doctors and place the continued effectiveness of antibiotics above the profit margins of cattlemen.

Los Angeles Times editorial
April 26, 2007

PRESCRIPTION FOR TROUBLE
The FDA should deny a request to use a key human antibiotic on beef cattle. The risks are too great.

ALMOST AS SOON as antibiotics came into widespread use during World War II -- allowing battlefield doctors to cure once-fatal infections -- bacteria started evolving to resist the miracle drugs. The medical profession further eroded antibiotics' effectiveness by prescribing them too blithely, sometimes for the wrong illnesses; patients chipped in by stopping their medications too soon.

Now a drug company wants to use an important human antibiotic on beef cattle, another major way in which antibiotic resistance is bred. The Food and Drug Administration should deny the request.

The drug, cefquinome, belongs to a class of antibiotics used as a last line of defense for patients with weakened immune systems, such as the elderly or children with cancer. The veterinary drug company Intervet wants to use cefquinome as a treatment mostly for bovine respiratory disease, a common illness in cattle that are shipped and corralled in feedlots. Crowded and stressed, these cattle are more susceptible to the disease.

Unlike other antibiotics that are routinely added to livestock feed to prevent disease and promote growth, cefquinome must be injected and could be used only with a prescription. But so-called shipping fever is common and costly enough in cattle that medical groups are rightly alarmed that the use of cefquinome would become routine or even preventive. The American Medical Assn. and American Public Health Assn. are among several health organizations opposing cefquinome as a treatment for cattle.

Changing farming practices would go a long way toward reducing the spread of the disease, but that's not on the livestock industry's agenda. Meanwhile, the industry already has a dozen other medications for bovine respiratory disease. The FDA's veterinary committee recommended against Intervet's application, but the agency's recently adopted guidelines make it difficult to block antibiotic use except in extreme cases. As a result, it's uncertain how the FDA will rule.

But the decision should be clear. On a scale that measures a steer's health against human safety, the ability to fight infection in frail people must win.

Chicago Sun-Times editorial
April 26, 2007

FDA TURNING RESISTANT TO THE PUBLIC INTEREST

There exists a class of super antibiotics never approved for use in animals, and for good reason: They are critically needed for treating certain serious life-threatening infections in humans, and any risk of weakening their ability to fight them -- of making bacteria more resistant to drugs through overexposure -- is one most doctors and scientists will not take. But now, despite dire warnings from health groups including the American Medical Association, and even though its own advisory board is against it, the Food and Drug Administration is poised to approve the use of one of those drugs to treat a common respiratory disease in cattle. Use of the drug, cefquinome, in animals also could undermine the effectiveness of a similar drug, cefepime.

"There is reasonable certainty of no harm to public health," the product development director of cefquinome's manufacturer, InterVet, assured the FDA last fall. While "reasonable certainty" is good enough for the people who stand to profit from the drug, it is disturbingly unreasonable for those concerned about individuals paying with their health. A similar scenario unfolded in the mid-'90s when the FDA approved the use of Baytril (produced by Bayer) and SaraFlox (Abbott Laboratories) in poultry. Subsequently, people treated with this antibiotic for a diarrheal disease found the germ began developing resistance to the drug, which also is prescribed for a bacterium that causes anthrax. SaraFlox was pulled from the market after the FDA sought a ban, but not until 2005, after much antagonism, was Baytril withdrawn. By that time, its resistance in humans had increased dramatically.

That InterVet has not withdrawn the drug, the advisory group's opposition notwithstanding, tells us the company has the FDA's assurance it will be approved. What makes the agency's willingness to give the green light to cefquinome even more objectionable is the availability on the market of other medicines that effectively treat the respiratory ailment in cattle. Why not use what is available rather than speed the emergence of microbes resistant to antibiotics that are looked upon as a last resort in humans? And how is it that the FDA is not planning to impose limits on the drug's application to minimize bad consequences?

With the medical and scientific communities angrily calling for the FDA not to approve cefquinome in cattle and pressure against its use in cattle building in Congress, there is a chance the agency will back down and do the right thing. If it thinks the poison pet food scare, which it is currently focused on, is a health crisis, wait until people who could have been saved by an unnecessarily weakened antibiotic start dying.

Columbus Dispatch
April 28, 2007

NOT CHICKEN FEED
Gonorrhea resistance shows why protecting antibiotics is important

Scientists have been saying for years that the indiscriminate use of antibiotics in animal feed is going to have a cost. Now, the toll is being felt.

Earlier this month, the national Centers for Disease Control and Prevention told doctors that they should stop using the class of antibiotics called fluoroquinolones to treat cases of gonorrhea, because so many strains of gonorrhea have become resistant to these drugs.

For a decade, fluoroquinolones were widely used in chicken feed to prevent respiratory problems in poultry flocks. The Food and Drug Administration withdrew its approval for such use in 2005.

But the damage has been done. An entire class of antibiotics has been sacrificed to the convenience of poultry and egg producers, leaving only one class of antibiotics to defend against gonorrhea.

The drug now recommended is ceftriaxone, a member of the family of cephalosporin.

At the same time, the FDA is contemplating approval of an antibiotic called cefquinome for use against respiratory disease in cattle. Cefquinome also is a cephalosporin. If that family of antibiotics were to be compromised, it would adversely affect medicines that fight meningitis and serious gastrointestinal diseases, as well as serious infections in cancer patients.

The American Medical Association, along with an FDA advisory panel, has recommended against approving cefquinome for cattle. Plenty of other drugs are effective at treating bovine respiratory disease. A class of drugs so important to humans should not be put at risk.

The FDA should not make the same mistake twice.

Hartford Courant
May 3 2007

FDA SHOULD REJECT CATTLE DRUG

If the federal Food and Drug Administration moves ahead with a plan to approve a new, potent antibiotic for use in cattle, it will risk undermining the effectiveness of an entire class of powerful antibiotics to treat humans. That's too big a gamble - especially for people who already rely on one of those drugs to fight life-threatening infections.

Cefquinome is specifically designed to treat bovine respiratory disease, a pneumonia-like illness common in cattle. It's the fourth generation of a highly powerful family of antibiotics - cephalosporins - none of which have been approved for use in animals.

Only one other medicine from that family is authorized for use in the United States. Called cefepime, it's the drug of last resort for humans suffering from infections that would otherwise be invincible.

The FDA appears poised to approve the use of cefquinome. In so doing, it will be going against the recommendations of its own advisory board, the American Medical Association and a dozen other health organizations, who have stated that the use of the drug in cattle may create super-resistant strains of bacteria that will ultimately end up infecting humans. Worse, it would render an entire class of important antibiotics useless.

In the mid-1990s (over the objections of the Centers for Disease Control and Prevention) the FDA authorized the marketing of two antibiotics for use in poultry, Baytril and SaraFlox. The drugs were useful in fighting the bacterium that causes anthrax and another, food-borne bacterium that causes severe diarrhea. Before long, doctors started seeing resistant strains of bacterium in patients being hospitalized with severe diarrhea.

The FDA's advisory board also notes that there are already more than a dozen medicines on the market for bovine respiratory disease and that all are effective. So the cattle industry doesn't even need cefquinome.

But the FDA is moving ahead, citing its own, industry-friendly policy that makes it almost impossible to reject a new animal drug unless it threatens the effectiveness of antibiotics critical to fighting food-borne illnesses exclusively. Cefquinome doesn't meet that standard.

Bad policy is no excuse for jeopardizing the interests of public health. The FDA should follow the advice of its own advisory board and various health organizations by rejecting the use of cefquinome in cattle. Otherwise, people suffering from virulent infections - including cancer patients - may lose a last, powerful ally in their struggles for survival.