Scrutiny of livestock antibiotic use pressures veterinary profession

Part 1 of 4: Scrutiny of livestock antibiotic use pressures veterinary profession

Part 2 of 4: FDA: Food-animal antibiotic consumption dwarfs human medical use

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Editor's Note: This is a first in a four-part series on the struggle over the use of antibiotics in the livestock industry, the threat of antibiotic-resistant pathogens and the veterinary profession's role in safeguarding animal and public health. Today's story explores policy controversies in Washington, D.C. and within the American Veterinary Medical Association.

The U.S. Food and Drug Administration (FDA) is moving to corral the use of antibiotics in food animals, challenging organized veterinary medicine to grapple with an issue on which it has long resisted change.

The FDA is worried that antibiotics on farms may breed drug-resistant pathogens that could endanger public health. The agency is now at work on a new policy document that stands to be the federal government's strongest-ever position on the issue. As indicated in a draft policy guidance released in June 2010, the FDA supports two main changes:

- Restrictions on certain antibiotics meant to spur growth in livestock;
- Increased veterinary oversight of food-animal antibiotic use, in particular the vast quantities of non-prescription drugs now administered as "medicated feed" with no requirement for veterinary supervision.

For years, the American Veterinary Medical Association (AVMA), the largest veterinary professional organization, has opposed restrictions on food-animal antibiotic use. In public statements and Congressional testimony, the group has argued that there's no proof that using antibiotics in food animals presents a significant public health risk and has maintained that restrictions on the drugs would imperil animal health and food safety. This stance aligns the AVMA with drug makers and the meat industry and draws criticism from the human medical and public health communities.

"It's an embarrassment to the profession," said Ellen Silbergeld, a professor of environmental health sciences at the Johns Hopkins Bloomberg School of Public Health and a leading critic of antibiotic practices in the meat industry. "I don't know of anyone that adopts this perspective apart from industry and the AVMA."

The organization also is under pressure from within the profession. During the past three years, public debates at the AVMA annual meeting and among members of a special task force on the issue have shown that many veterinarians

question the wisdom of some routine uses of antibiotics in livestock and would like to see veterinarians play a more significant role in supervising the use of drugs in food animals.

"I think veterinarians should have the primary responsibility in deciding when it is appropriate to use antibiotics, rather than producers or feed companies," said AVMA member Dr. Susan Chadima, a companion-animal veterinarian in Topsham, Maine. "As medical professionals, we need to be directly involved in the choice and use of antibiotics in animals."

Since 2009, several discussions on the Veterinary Information Network (VIN), an online community for the profession, have focused on this issue as well, with some VIN members supporting status quo uses of antibiotics in livestock and others calling for restrictions.

Lately, the AVMA has come to recognize that by refusing to budge, it risks being left out of the national debate on farm-animal antibiotics. A prime example: The AVMA was not consulted during the preparation of the FDA's June 2010 draft policy guidance.

"We were not aware that it was coming," acknowledged Dr. Christine Hoang, AVMA assistant director of scientific activities.

Less than five weeks after the FDA document was released, the AVMA's House of Delegates passed a resolution calling for the group to "be at the forefront of discussions that may impact drug availability, such as regulatory changes in veterinary oversight especially pertaining to antimicrobial use." (Antibiotics are a subset of antimicrobial drugs; other antimicrobials include antivirals and antifungals.) In November, the AVMA Executive Board followed up by creating a five-member steering committee to work with the FDA on policies concerning increased veterinary oversight of antibiotic use. The committee's members were named in April.

"The idea is that AVMA should become involved in these discussions proactively," Hoang said. "It's a new way of doing things for us."

The issues surrounding food-animal antibiotic policy are not simple. Scientific uncertainty about the risk the drugs pose to human health clouds the debate. Arguments about antibiotics in livestock are wrapped up in larger battles over industrial-scale meat production. The number of food-animal veterinarians is declining, raising questions about the logistics of expanding veterinary oversight of drug use. The pharmaceutical industry's marketing power, political influence and threats of litigation complicate matters further.

Forcing debate within AVMA

To a significant degree, Dr. Robert Gordon, the New Jersey Veterinary Medical Association (NJVMA) delegate to the AVMA House of Delegates, is responsible for pushing the AVMA into open discussion on food-animal antibiotic use.

Spurred by his own investigations while studying for a Master of Public Health degree, Gordon, a companion-animal veterinarian, brought controversial resolutions on behalf of the NJVMA to the House of Delegates in 2008 and 2009. The first resolution called for the AVMA to support a ban on the use of antibiotics to promote growth; the second asked the organization to advocate a veterinarian-client-patient relationship for all uses of antibiotics in food animals.

While Gordon's measures failed to pass, they prompted vigorous debates and led to the creation of a 15-member AVMA task force on the judicious use of antibiotics. The task force members represented a range of veterinary expertise — including companion-animal and food-animal medicine and public health, epidemiology and food safety. The group was charged with "clarifying the role of the veterinarian and level of involvement in all uses of antimicrobials," including growth promotion.

The June 2010 final report of the task force revealed differences of opinion within the profession. While the members of the task force agreed that "veterinarians should be involved in the decision-making process for the use of antimicrobials," they did not agree on the degree of that involvement. They also disagreed on a number of points concerning the use of antibiotics for growth promotion, and acknowledged that there are sharply differing interpretations of the existing research concerning the link between food-animal antibiotic use and the development of disease-resistant pathogens.

To help bridge some of these divides, the task force suggested AVMA undertake a systematic review of the existing research on the link between antimicrobial use in animals and antimicrobial resistance in humans. The House of Delegates and the AVMA Executive Board, however, did not choose to pursue such a review.

"Creating and operating such an entity would be an enormous, extremely costly and time-consuming undertaking," said AVMA's Hoang in an e-mail message. "And there was discussion among members of both the Executive Board and the House of Delegates as to whether funding such an entity would be an appropriate use of AVMA member dues."

The broader public debate over food-animal antibiotic use is characterized by disagreements over basic issues as well. In published documents on food-animal antibiotic use — such as the 2008 report of the Pew Commission on Industrial Farm Animal Production; the AVMA's response to the Pew report; and fact sheets on the issue posted on the AVMA website — the public health and food-animal communities differ on many facts:

- What quantities of antibiotics are fed to food animals to promote growth or prevent disease;
- Whether the use of growth-promoting antibiotics saves consumers a significant amount of money and is necessary for the meat industry to remain economically viable;
- What current science shows about the risk that food-animal antibiotic use poses to humans;
- Whether food-animal antibiotic use significantly benefits food safety;
- What lessons the United States can take from countries such as Denmark, where growth-promoting antibiotics have been restricted since the mid-1990s.

Subsequent articles in this VIN News Service series will explore these contested areas.

What's at stake

Like most calls from public health advocates for restrictions on animal-antibiotic use, the FDA's draft policy guidance focuses on two of the four FDA-labeled uses. There's little discussion of seriously restricting the uses for disease control and disease treatment.

The two disputed uses are:

- Growth promotion/feed efficiency. Such uses are meant to increase an animal's rate of growth and/or the weight it gains per unit of feed consumed. These uses are also known as "production" uses because, in the words of the FDA, they "are not directed at any identified disease but rather are expressly indicated and used for the purpose of enhancing the production of animal-derived products."
- Disease prevention. Such uses help prevent infections common in food-animal operations.

Antibiotics for growth promotion and disease prevention typically are purchased as "medicated feed" and do not require a prescription or other veterinary oversight.

Antibiotics for disease control and treatment generally are mixed into animals' water supply or administered individually, for instance by injection. These drugs may be available with or without a prescription, depending on the FDA's judgment about whether they can be used safely and effectively without veterinary oversight.

A given drug may be labeled for more than one type of use. It may, for instance, be administered at a low dose for growth promotion and at a higher dose to treat

disease.

All four of the FDA's animal antibiotic use categories include a number of drug classes that are also used in human medicine.

In the draft policy guidance, the FDA states its position to be that "the use of medically important antimicrobial drugs in food-producing animals for production purposes … represents an injudicious use of these important drugs."

Regarding disease prevention, the agency states that some such uses are "necessary and judicious," and that veterinary involvement is important to ensure that such drugs are used appropriately.

In addition, the agency states that, as a general principle, "The use of medically important antimicrobial drugs in food-producing animals should be limited to those uses that include veterinary oversight or consultation."

Promoting growth with antibiotics

Animal nutrition researchers first noticed that antibiotics could foster growth in the late 1940s, in studies of chickens. By 1950, trials in turkeys and pigs had confirmed that antibiotics promoted growth in those species as well, and in 1951, antibiotic-supplemented livestock feeds formulated for that purpose were on the market.

It was unclear in 1951 precisely why antibiotics boosted growth, and that's still the case today. Several mechanisms may be at work, experts say. Among other possibilities, the drugs may help to reduce low-grade infections, reduce inflammation, stimulate metabolic processes and inhibit the growth of microbes in the digestive tract that compete for nutrients.

By the late 1960s, concerns that routinely incorporating antibiotics into animal feed might pose a risk to human health were strong enough to prompt major government-funded reviews. A report to the British Parliament in 1969 warned of the potential for antibiotic-resistant pathogens to pass from livestock to humans, prompting restrictions in that country on growth-promotion uses of drugs used in human clinical medicine.

The FDA first appointed a task force to review the antibiotic-resistance issue in 1970 and has revisited the issue many times. The agency repeatedly has expressed concerns about the development of antibiotic-resistant pathogens due to the use of antibiotics in animals, and in 2003 it added an antibiotic-resistance risk assessment requirement to the animal drug approval process.

However, to withdraw an already-approved animal antibiotic based on its potential to generate antibiotic resistance, the FDA must meet a high standard of

proof. The agency has successfully used drug-resistance concerns to force the withdrawal of only one animal antibiotic, enrofloxacin (brand name Baytril), which was pulled in 2005 following a five-year legal battle with its sponsor, Bayer Corp. Baytril was used for the treatment of respiratory diseases in poultry. No antibiotic labeled for growth promotion or disease prevention has ever been withdrawn in the United States because of concerns about drug resistance.

Next steps in Washington

The FDA currently is reviewing the more than 1,200 unique comments it received on the draft policy guidance and "determining next steps," according to a spokeswoman. The agency has not announced when it will release the final policy guidance. Dr. William Flynn, deputy director for science policy at the FDA Center for Veterinary Medicine, stressed that the final guidance will not include concrete regulations.

"This is a broad vision of where we would like to go," Flynn said. "Our intention is to follow up with some more specifics."

Dr. Michael Blackwell, a veterinarian and consultant and former deputy director of the FDA Center for Veterinary Medicine, said any enforceable regulations on growth-promoting antibiotics are likely to be years away, unless Congress intervenes. Because new FDA restrictions stand to be challenged by drug makers in court, the agency is likely to move cautiously, Blackwell said.

In recent years, some Democrats in Congress have supported legislative action to restrict growth-promotion and disease-prevention uses of antibiotics in food animals, but the bills have never progressed beyond committee. Rep. Louise Slaughter, D-N.Y., who in 2009 introduced the Preservation of Antibiotics for Medical Treatment Act, or PAMTA, reintroduced a similar bill in the current legislative session. But with Republican control of the House, chances of passage appear slim; in the 2009-2010 session, all of the bill's 117 co-sponsors were Democrats.

AVMA's Hoang said FDA officials have been receptive to the organization's efforts to increase veterinary involvement in the policy-making process.

Gordon, the New Jersey companion-animal veterinarian, said he is pleased that AVMA's leadership appears to be serious about constructively engaging with regulators on the issue.

"I think ultimately we're going to get to a point where either we step up and take a leadership role, or the role will be filled by others, and regulation or legislation will come about that is not necessarily in the direction that AVMA would like," he said.

Next up: A look at how public-health advocates and food-animal interests have attempted to sway public opinion with wildly divergent claims about the quantities of antibiotics used on U.S. farms.