October 7, 2011

Dear Representative _____:

We are writing to share our perspective on a recent letter from public health organizations regarding the issue of antibiotic use in food animals. Our members, who raise and care for food-producing animals or provide products and services for those who do, play a major role in public health by protecting the health and well-being of these animals. As a result, we believe it is important to correct the record and share our perspective on the science regarding antibiotic use to keep food animals healthy.

Correcting the Record

Contrary to assertions in the letter, the Food and Drug Administration (FDA) has taken a series of actions to address the potential threat of antibiotic resistant bacteria being transferred from animals to humans. While these actions do not include the type of legislative ban on use sought by some, our view is that these actions have been overly conservative in building protections against the extremely low risk of the transference of antibiotic resistant bacteria. These actions include the following:

1. In 1996, Congress passed the Veterinary Feed Directive (VFD) legislation to accommodate an FDA policy that all new feed-grade antibiotics must be restricted to use by the order of a veterinarian. This action was taken specifically due to concerns about antibiotic resistance.
2. In 1998, FDA implemented the National Antimicrobial Resistance Monitoring System (NARMS) in cooperation with the U.S. Department of Agriculture and the Centers for Disease Control and Prevention to track antibiotic resistant bacteria in animals, people and foods.
3. In 2003, FDA issued Guidance for Industry #152, applying new restrictions on the use of antibiotics in food animals based on the estimated risk of antibiotic resistance in those antibiotics deemed important to human health.
4. Last year FDA published Guidance #209, proposing to phase out growth promotion claims and to restrict the use of all medically important antibiotics in feed by the order of a veterinarian. Additional guidance and proposed rules on these issues is expected from the agency in the coming months.

In addition to these major actions, the "U.S. Public Health Action Plan to Combat Antimicrobial Resistance" details dozens of individual actions taken by public agencies to address this issue.

We strongly object to the use of antibiotics to keep animals healthy being characterized as "misuse." The products our members rely on to keep their animals healthy have been approved by FDA as safe and effective. FDA mandates the directions for use that are on the label and it is unlawful to administer any antibiotic in feed outside of the labeled indications. In addition to these mandated protections, the species groups have

implemented an array of programs aimed at educating their members on the proper use of antibiotics.

We wish to highlight FDA warnings about comparing available animal antibiotic sales data to available human antibiotic data. On at least three occasions FDA has warned against the validity of these comparisons: In the April 19, 2011 letter to Rep. Louise Slaughter (D-NY), in a caution document posted on its website, and most recently in a response to a court petition. Comparisons of currently available data on human and animal use of antibiotics are not valid and are in no way indications of the risk of those uses.

What the science says about risk

Antibiotic resistance can result from the use of antibiotics in both animals and humans. However, the development and dissemination of resistant bacteria is a complex process subject to a variety of factors. The mere presence of resistance does not necessarily mean that the resistance arose from antibiotic use. Nor does the fact that particular types of antibiotic resistance are serious problems in human medicine mean that use in animals is responsible.

The real question is, "What is the level of risk of specific kinds of antibiotics use in food animals to human health?" This specific question has been quantitatively addressed in numerous peer-reviewed risk assessments on virtually all classes of antibiotics important to human medicine that are also used in animal feed, and the measured risk has been found to be vanishingly small. Some examples:

- **Public Health Consequences of Macrolide Use in Food Animals: A Deterministic Risk Assessment**. *Hurd, et. al., Journal of Food Protection, Vol. 67, No. 5, pgs. 980-992, 2004.* According to the results of an Iowa State University study, the probability of someone in the U.S. experiencing a treatment failure due to the acquisition of resistant food borne bacteria from eating meat from animals treated with macrolide antibiotics (tylosin, tilmicosin) is less than one in 10 million for resistant *campylobacter*, and less than one in 3 billion for resistant *Enterococcus faecium*. As one of the scientists said: "People would be more likely to die from a bee sting than for their antibiotic treatment to fail because of macrolide-resistant bacteria in meat or poultry."

- **Assessing Potential Human Health Hazards and Benefits from Subtherapeutic Antibiotics in the United States: Tetracyclines as a Case Study.** *Cox and Popken, Risk Analysis, 2010.* An assessment of the risk of using tetracycline in food animals concluded that reducing tetracycline use in food animals in the United States should not be expected to cause any improvements in human health or to reduce the risks of tetracycline-resistant infections.

- **Human Health Risk Assessment of Penicillin/Aminopenicillin Resistance in Enterococci Due to Penicillin Use in Food Animals**. *Cox, et. al., Risk Analysis, Vol. 29, No. 6, 2009.* A risk assessment of penicillin used in animal feeds concluded the use of these drugs was unlikely to seriously impact human health from antibiotic-resistant bacteria.

Additionally, the FDA's own studies reinforce the results of these and other independently conducted risk assessments. For example, FDA's risk assessment on the use of virginiamycin, a common antibiotic, found that "assuming a food pathway attribution of 10 percent, the average risk to a random member of the U.S. population of having SREF (streptogramin-resistant *E. faecium*) attributable to animal uses of virginiamycin and that may result in impaired Synercid therapy ranges from 7 chances in 1 billion to 14 chances in 100 million in one year."

Real world experience provides evidence to question the proposed link between animal antibiotic use and public health. In the wake of the European ban on the use of antibiotics for growth promotion, the World Health Organization (WHO) concluded antibiotic resistance problems in humans due to growth promoters were rare in Denmark before or after the ban (Impact of antimicrobial growth promoter termination in Denmark, Foulum, Denmark, 6-9 November, 2002). The recently released General Accounting Office Report (GAO-11-801) stated "*Danish officials told us that Denmark's resistance data have not shown a decrease in antibiotic resistance in humans after implementation of the various Danish policies, except for a few limited examples*." The one example the report went on to cite was for an antibiotic compound never approved for use in animals in the United States. The point is that the political ban on some uses of antibiotics in Europe had negative impact on animal health with no measured improvement in human health –the stated intent of the ban.

FDA is properly managing the risk

The letter incorrectly suggests the options for responding to this issue are "do nothing" and "legislatively ban products." In fact, despite decades of science generated on this issue, there is no conclusive evidence the use of antibiotics to keep food animals healthy harms public health. As a result, even the agency testimony cited in the letter relies on terms like "it is likely," "may have," and "might serve" which indicate that while there is evidence of a potential link, there are no reports that can actually cite direct cause-and-effect situations where the animal use of an antibiotic was determined to have caused harm to human health. This does not mean no action should or has been taken. In fact, as described above, the agency has taken a series of actions and continues to take action as the scientific evidence dictates.

Our organizations are participating with FDA in the voluntary stakeholder process. We believe this process is the appropriate way to institute change without suffering the unintended and negative consequences that resulted from a legislative ban in Europe. At the same time, our members are working every day to raise healthy animals in order to

produce the safest possible food supply. Judicious and responsible antibiotic use is an important tool in that process.

Should you have questions or need additional information, please contact Ron Phillips at rphillips@ahi.org.

Sincerely,

American Association of Avian Pathologists
American Association of Bovine Practitioners
American Association of Swine Veterinarians
American Farm Bureau Federation
American Feed Industry Association
American Meat Institute
American Veterinary Medical Association
Animal Health Institute
National Chicken Council
National Grain and Feed Association
National Milk Producers Federation
National Turkey Federation
National Pork Producers Council