Statement by the Animal Agriculture Alliance Coalition on Antimicrobial Resistance

Farmers, ranchers and veterinarians take this issue of antimicrobial resistance very seriously. Nothing is more important to us than public health, animal health and well-being and a safe food supply. If a problem existed, those most likely to be affected are those of us who work on the farm and our families.

Although most scientists agree that improper use of antibiotics in human medicine is the greatest contributing factor in the formation of resistant bacteria affecting humans, the government, animal health industry, farmers and ranchers have implemented multiple steps to ensure antibiotic use in food producing animals does not affect human health.

Antibiotic use practices in food animals is based on years of veterinary directives, practical experience, scientific analyses, and risk assessments that work to ensure both animal health and public health.

Technical Report Overview

On March 11, 2008, the Pew Commission on Industrial Farm Animal Production (NCIFAP) released "Antimicrobial Resistance and Human Health," which attributes a large portion of antibiotic resistant bacteria in humans to the use of antibiotics in livestock production. The report is authored by Dr. Ellen Silbergeld, Professor of Environmental Health Sciences and Environmental Health Engineering at Johns Hopkins Bloomberg School of Public Health.

The report includes the following claims:

- *"…the preponderant use of antimicrobials—which is in food animal production—must be a significant source of antimicrobial resistance."*
- *"…the source of resistance from outside the hospital is largely determined by this larger community reservoir of resistance (which for many reasons discussed in this paper, is driven in large part by the magnitude of agricultural uses and affects dietary pathways of exposure through…consumer meat and poultry products."*

It may be possible, but the science shows it is highly improbable that antibiotic resistant bacteria can develop in animals as a direct result of antibiotic use and can cause foodborne infections in humans that are more difficult to treat, . Despite the low probability, the FDA and USDA, along with the veterinary community, animal health companies, farmer and rancher organizations and other stakeholders have put in place several layers of human health protections during the past decade to further reduce risks associated with antibiotic use in animals. These measures, or layers of protection, include:

- A stringent animal health product approval process that was made markedly more rigorous in 2003 when FDA finalized an additional safety measure requiring a risk assessment to be applied to all new and existing antibiotics.
- Post-approval risk assessments that have been conducted and published by the FDA, product manufacturers and researchers.
- Food safety monitoring programs that have been established by government agencies and product manufacturers to track the development of antibiotic resistant bacteria.
- Responsible use programs that are specific to the different poultry and livestock species to give veterinarians, farmers and ranchers specific guidelines to safely and properly use antibiotics in their health management systems.
- Pathogen reduction programs that have successfully led to documented reductions in pathogens on meat, therefore contributing to decreased food-borne illness.

Key Points:

- Animal agriculture has a long standing commitment to protect the health and safety of our animals, our families, our employees, and consumers

- The FDA rigorously reviews all antibiotics prior to approval and then conducts a stringent post-approval risk assessment

- The FDA requires specific withdrawal times for antibiotics to ensure all meat, milk and eggs in the food supply are antibiotic-free

- Antibiotics are used to treat, prevent and control disease and to increase nutritional efficiency, providing environmental benefits

- Responsible use of antibiotics is crucial to ensuring the well-being of animals and consumers

-Numerous public and private systems are established for early detection of antimicrobial resistance with control measures

- The agricultural community has gone beyond the legal requirements of safe antibiotic use & created guidelines for producers to ensure antibiotics are used effectively to control and treat animal disease while safeguarding public health.

Overall, using antibiotics to keep animals healthy is a critical policy issue that deserves serious attention. Responsible use of antibiotics by veterinarians, farmers and ranchers is essential in ensuring the health and well-being of the animals, as well as the families who are eating the food products. The Animal Agriculture Coalition shared with the Commission the best scientific articles known from prestigious peer-reviewed journals and it appears they were ignored in this report.

Additional specific claims from the Silbergeld research include:

- "*Most estimates suggest that non-therapeutic, agricultural use, accounts for between 60% and 80% of total AM production in the US… "*
  - The estimated amounts of antibiotics used in the report are inaccurate, according to the companies that make the antibiotics. Each year, those animal pharmaceutical companies report the amount of antibiotics sold for use in animals to the Animal Health Institute. The most recent figures, for calendar year 2007, show that 87 percent of the antibiotics sold were for the therapeutic uses of treatment, control and prevention, and 13 percent was for nutritional efficiency (growth promotion).

- *"…the source of resistance from outside the hospital is largely determined by this larger community reservoir of resistance (which for many reasons discussed in this paper, is driven in large part by the magnitude of agricultural uses and affects environmental and dietary pathways of exposure through drinking water)..."*
  - The discussion about the environmental impacts of antibiotic use is speculative and ignores the science. FDA requires sponsors to perform an assessment of the environmental impact of the use of an antibiotic as part of the review process. A 2002 survey by the U.S. Geological Survey (USGS)[i] focused on the water bodies most likely to contain contaminants. It found no veterinary pharmaceuticals at many of the sampling sites, and of those veterinary products detected, the frequency of detection was low and the concentrations of detections were very low. A more recent University of Minnesota study[ii] demonstrated that the very low levels of antibiotics found in the rural waters in the USGS study did not have any impact on the development or persistence of resistance to the antibiotics tested.

The Animal Agriculture Coalition and its members understand and share the concerns of the public regarding the responsible use of antibiotics. This is why there are significant check-and-balance systems in place. America's veterinarians, farmers and ranchers use FDA-approved antibiotics to treat, prevent and control disease, ensuring the health and well-being of animals and the safety and healthfulness of the food that consumers are eating. In addition, FDA-approved antibiotics are used to increase nutritional efficiency which provides environmental benefits through reduced feed consumption by livestock which, in turn, results in less manure for the producers and ranchers to manage.

It is essential that careful scientific risk assessments be conducted as the basis for regulation and public policy in order to prevent politically-motivated decisions from being made. Decisions made without careful assessments can lead to harmful health risks. Emerging evidence documents the unintended consequences that can result when policy decisions about antibiotic use are not driven by science and risk assessment. Studies indicate that the risk of food borne bacteria on meat increases when antibiotics, which help suppress animal disease, are removed.

There is clear evidence from Denmark[iii] that the removal of antimicrobial growth promoters resulted in more animal death and disease, increased use of antibiotics to treat animal disease, and little evidence that antibiotic resistant rates in humans were decreased. According to the World Health Organization review panel's evaluation, "… clinical problems in humans related to resistance to antimicrobial growth promoters were rare in Denmark before and after termination" and "… direct effects of the termination of growth promoters on resistance in Gram-negative bacteria (e.g. *E. coli*, *Salmonella*) were neither expected nor observed."[iv]

Additional evidence can be found in the results from changes in the use of growth promoters in the Netherlands. The use of growth promoters was completely phased out by 2006, however, the therapeutic use of antibiotics increased to the same level of overall use of antibiotics in 1999. The result has been an increase in resistance in Salmonella to penicillin and tetracycline in The Netherlands. At the same time those same. resistances in the U.S. have gone down and are about half the level of those in The Netherlands.

Key Points

- Antimicrobials provide for good health of animals entering the food chain.[v]
- In Europe, the elimination of antibiotics for growth promotion resulted in increased animal illness and more therapeutic antibiotic applications.[vi]
- Experts say that the best way to make sure resistant bacteria are not transferred to humans by food is to implement policies focused on reducing all food borne bacteria. To date, industry has worked hard to achieve this, and data from the government shows good progress.

Current Antibiotic Use Programs

There are currently several programs in place throughout federal agencies and in the various specific segments of agriculture to address the needs and precautions for each species related to antibiotic use. Several public and private monitoring and surveillance systems have been established to watch for the emergence of antibiotic resistance. These systems allow for early detection and the implementation of management and control measures, when appropriate.

The National Antimicrobial Resistance Monitoring System (NARMS)[vii] is a multi-agency program consisting of three federal agencies.

1. The Food and Drug Administration (FDA) coordinates the programs and monitors for resistant bacteria in retail meats (http://www.fda.gov/cvm/narms_pg.html)
2. The Centers for Disease Control and Prevention (CDC) collects isolates, or samples, from public health laboratories to monitor for the emergence of antibiotic resistant food borne pathogens in humans. (www.cdc.gov/narms)
3. The USDA Agricultural Research Service (ARS) collects samples from slaughter and processing facilities to monitor for antibiotic resistance trends in farm animals. www.ars.usda.gov/main/site_main.htm?modecode=66120508

So far, the NARMS program has produced seven years of data representing *Salmonella* isolates from over 50,000 animals and 11,000 humans. Human isolates tested against most drug classes potentially related to animal usage have shown stable or declining trend patterns through 2004. Most of the multiple-drug resistance types, such as *Salmonella Typhimurium* DT104 show stable or declining prevalence in both food animals and humans since 1996.

- The Collaboration on Animal Health and Food Safety Epidemiology (CAHFSE) is a program within the USDA's Animal and Plant Health Inspection Service that provides more real-time, active surveillance data (www.aphis.usda.gov/cahfse). The program is designed to collect comprehensive, specific information on a variety of farm practices, including antibiotic use, and track animals through processing for food to provide specific management information to the producer.

- The SENTRY Antimicrobial Surveillance Program, initiated in 1997, is the most comprehensive human surveillance program in the world (www.jmilabs.com). SENTRY data shows that the resistant organisms that pose the greatest risk for poor therapy outcomes in patients have little link to the usage of animal antibiotics. This data is reflected by other members of the medical community who have concluded that that the contribution of animal use to resistant infections is less than 5 percent (Bywater R. and Casewell M., Journal of Antimicrobial Chemotherapy 2000; 6:643-645).

Animal health companies support these surveillance and monitoring programs, which are important and necessary for monitoring the health and well-being of animals and humans. The data is also important for use in risk assessments to measure and/or predict the public health impact of the use of particular antimicrobials. In addition to these programs, the agricultural community has gone beyond the legal requirements of safe antibiotic use and created guidelines to give producers an additional tool to use in making proper decisions about the use of antibiotics.

The American Veterinary Medical Association, specie-specific veterinary groups, livestock producer groups and the Food and Drug Administration have collaborated to produce guidelines for safe and responsible use of antimicrobials. These guidelines were designed to minimize the need for antibiotic use and maximize their effectiveness when needed and can be found at http://www.avma.org/reference/jtua/default.asp.

These guidelines are used as the basis of food animal production education programs. For example, The National Pork Board has instituted the Take Care – Use Antibiotics Responsibly Program (www.pork.org). Similar guidelines are used in the beef industry's Beef Quality Assurance Program (www.bqa.org).

Another program to guide safe drug use is the Food Animal Residue Avoidance Databank (FARAD). FARAD is a National Food Safety Project administered through USDA's Cooperative State, Research, Education, and Extension Service. It is a computer-based decision support system designed to provide producers, extension specialists and veterinarians with practical information on how to avoid environmental contaminant residues and antibiotic residues in food (www.farad.org).

The Center for Disease Control and Prevention (CDC) sponsors the Get Smart: Know When Antimicrobials Work on the Farm Program aimed at responsible use of antimicrobials on the farm. (http://www.cdc.gov/narms/get_smart.htm). The program is the companion of CDC's Get Smart program designed to promote responsible use of antibiotics in human medicine. Get Smart on the Farm is aimed at reducing emergence of resistant food borne pathogens that could be transferred to people via food or environmental sources.

> *"The banning of any antibiotic usage in animals based on the 'precautionary principle' in the absence of a full quantitative risk assessment is likely to be wasted at best and even harmful, both to animal and human health."* - Journal of Antimicrobial Chemotherapy, Volume 53, © 2004

Resources

American Veterinary Medicine Association
www.avma.org

Centers for Disease Control
www.cdc.gov/narms

Food and Drug Administration
www.fda.gov

Food Animal Residue Avoidance Databank
www.farad.org

Get Smart on the Farm
http://www.cdc.gov/narms/get_smart.htm

National Pork Board
www.pork.org

National Cattlemen's Beef Association
www.bqa.org

SENTRY Program
www.jmilabs.com

USDA Ag Research Service
www.ars.usda.gov

USDA Animal and Plant Inspection Service
www.aphis.usda.gov

These programs represent public and private voluntary efforts designed to ensure antibiotics are used effectively to control and treat animal disease while at the same time safeguarding public

Animal Agriculture Alliance Coalition Members

American Farm Bureau Federation
Animal Agriculture Alliance
Animal Health Institute
American Meat Institute
National Chicken Council
National Milk Producers Federation
National Pork Board
National Pork Producers Council
National Turkey Federation
United Egg Producers
U.S. Poultry & Egg Association
United Soybean Board

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Sources

[i] USGS Fact Sheet 027-02: Pharmaceuticals, Hormones, and other Organic Wastewater Contaminants found in U.S. Streams. 2002. Accessed at: http://toxics.usgs.gov/pubs/FS-027-02/

[ii] Munoz-Aguayo J, et al. 2007. Evaluating the effects of chlortetracycline on the proliferation of antibiotic-resistant bacteria in a simulated river water ecosystem. Applied Environmental Microbiology. 73:5421-25.

[iii] Agence France-Press. 2005. World-leading Pork Exporter Denmark Sees Sharp Increase in Pig Mortality. http://archive.wn.com/2005/09/06/1400/copenhagenbusiness/

[iv] The World Health Organization review panel's evaluation of the termination of the use of antimicrobial growth promoters in Denmark: http://www.who.int/salmsurv/links/gssamrgrowthreportstory/en/

[v] IFT Expert Report: Antimicrobial Resistance: Implications for the Food System.

[vi] Ibid

[vii] USDA National Animal Health Monitoring System. Swine 2000, Swine 2006. Accessed at: http://www.aphis.usda.gov/vs/ceah/ncahs/nahms/swine/index.htm