

**TESTIMONY OF**

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**Concerning**

**Advancements of Animal Health**

**Within the Livestock Industry**

**Before the**

**House Subcommittee on**

**Livestock, Dairy, and Poultry**

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Thank you, Mister Chairman and members of the Subcommittee on Livestock, Dairy, and Poultry, for providing the American Veterinary Medical Association (AVMA) with the opportunity to speak about the advances in animal health within the livestock industry.

My name is Dr. Christine Hoang, and I work as an Assistant Director in the Scientific Activities Division of the American Veterinary Medical Association. In addition to holding a doctorate in veterinary medicine, I also hold a master of public health degree with concentrations in veterinary public health policy, both national and international, as well as epidemiology<sup>a</sup>. The majority of my work focuses upon food safety, zoonotic disease<sup>b</sup>, and antimicrobial resistance. As a result, issues related to animal health, animal agriculture, and human health have not only become topics of interest, but are topics that require a great deal of intensive research and evaluation.

The AVMA represents nearly 77,000 U.S. veterinarians engaged in every aspect of veterinary medicine and public health. As veterinarians, our oath ethically charges us with promoting public health and protecting animal health and welfare. Thus, we share many of the same concerns as our human health counterparts. Among other things, our members protect the health and welfare of our nation's animals, help ensure food safety, and protect animal and human health through prevention and control of zoonotic diseases.

The AVMA supports the use of multidisciplinary and multi-hurdle<sup>c</sup> approaches<sup>1</sup> to address issues affecting public health and food safety. For instance, in addition to supporting improved animal husbandry and management practices, we also support the continued availability and judicious use of antimicrobials to safeguard the nation's food supply.

The veterinary profession strives to achieve optimal animal health as well as animal welfare and human health. The fundamentals of food animal medicine and population medicine<sup>d</sup> are the same as the fundamentals of public health – control and prevention of disease. While the end goal is the same for all medical professionals – good health – veterinarians are severely limited in our tools for disease control and prevention. Regulations for drug approvals are more stringent, therapeutic agents can be more difficult to develop, and there are fewer treatments available. Thus, veterinarians must rely on their knowledge of clinical medicine to determine the best course of treatment. Given the numbers of food animal species, in addition to the diversity of disease conditions that affect animals, a relative scarcity of labeled indications accompanying FDA approved drugs exists. Though the FDA, the AVMA and others have made and continue to make significant strides in enhancing drug availability, including legislative initiatives (such as the Minor Use and Minor Species Act), the numbers of FDA approved drugs are inadequate to meet veterinary medical needs, placing both animal health and welfare – and, potentially, human

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<sup>a</sup> Epidemiology is a medical discipline that is the study of the causes, distribution, and control of disease in populations and serves as the foundation and [logic](#) of interventions made in the interest of [public health](#) and [preventive medicine](#).

<sup>b</sup> Zoonotic diseases are diseases that can be transmitted from animals to humans. CDC estimates at least 60 percent of all human diseases and 75 percent of all newly emerging diseases are zoonotic.

<sup>c</sup> The multi-hurdle concept refers to the interaction of factors that affect microbial behavior in foods. Under some circumstances these effects are additive. Under others the implication is that synergistic interactions lead to a combined effect of greater magnitude than the sum of constraints applied individually.

<sup>d</sup> Population medicine is a medical discipline focusing on the concepts of public health and epidemiology. In veterinary medicine, these concepts are incorporated to make strategic decisions to advance animal and herd health.

health – at significant risk.

While it may seem intuitive to some that healthy animals are critically important for safe food, there are few who understand the intricacies of why. As an example, it is fairly intuitive that an effective antibiotic will help decrease the bacterial load in food. What many do not understand is that it is extremely difficult to ascertain whether or not a particular animal is carrying certain bacteria. Many bacteria, such as *Salmonella*, are shed intermittently, and cannot be easily detected by routine testing procedures. Animals can harbor types of bacteria in their intestinal tracts that have no effect on their health, but can cause illness in humans. Thus, we must rely on the combination of many different types of interventions to protect our food supply. These interventions would range from prevention and control of disease before it occurs in animals to post harvest interventions such as carcass rinsing to further minimize bacterial contamination in food. Another concept that is often misunderstood or overlooked is how seemingly unrelated illness, such as respiratory disease in a food animal, can affect the presence of enteric bacterial pathogens in the meat. For example, air sacculitis is a respiratory disease that affects poultry. It is a fairly common disease that can spread rapidly and often go undetected until slaughter. The disease causes tissues to become more friable<sup>a</sup> and difficult to remove during food processing. The increased handling and difficulty in processing increases the potential for damaging the intestines and contaminating the carcass with enteric pathogens that can be harmful to humans<sup>2</sup>. By controlling this disease through the use of antibiotics and/or other therapeutic agents, veterinarians assist producers in maintaining a healthy flock and a safe food supply. This example further illustrates the necessity to continually maintain and improve animal health in the preservation of food safety.

## **Veterinarian's Role**

Veterinarians evaluate whether a therapy's benefits would outweigh its risks to both the patient and to public health. Veterinarians have been trained to "do no harm" as they make therapy recommendations, and they have the duty to utilize such agents to promote animal health and welfare in such a way that safeguards the public health. In addition, veterinarians protect America's food supply by ensuring food animal health from "farm to fork," including their work in clinical practice, in state public health agencies, in the federal government, and in the corporate sector. Healthy animals make healthy food; for veterinarians to be effective in protecting our food supply, the appropriate tools for preventing, mitigating, and treating disease, which include antimicrobials, are paramount for veterinarians to be able to utilize.

Veterinarians are actively involved in research, continually looking for new and better ways to improve animal and human health. Some veterinarians work in research through universities, private corporations, or through government projects, and many are actively involved in field research. It is through this process that we have learned so much about the nature of infectious diseases. It is through this same process of careful study that veterinarians evaluate and determine the efficacy of products and interventions that safeguard our nation's food supply. With limited tools, our profession has made many advances in animal health and food safety,

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<sup>a</sup> Friable is a term used in pathology to describe tissues that are brittle, fragile, and easily damaged.

including the development and implementation of animal disease control programs, pre- and post harvest interventions, and areas of biotechnology. Other successes through collaborative efforts include a decline in foodborne illness from meat and poultry products<sup>3</sup> as well as a decline in the prevalence of foodborne pathogens (including Salmonella) associated with meat and poultry<sup>4</sup> and resistance of those organisms<sup>5</sup>. These are all a result of improvements in animal health and the joint efforts of stakeholders.

Veterinarians are in the best position to prescribe and administer the most appropriate therapies for their patients. Veterinarians are licensed by state authorities to practice veterinary medicine and are authorized by both state and federal government entities to handle potent medical agents in the course of their professional practice. While there is governmental and regulatory oversight, veterinarians use professional judgment to determine the best therapy for their patients:

- Specifically, the Drug Enforcement Administration (DEA) entrusts registered veterinarians to prescribe controlled substances for animals, i.e., those drugs that are not available to the general public due to the potential for abuse and addiction.
- The Environmental Protection Agency (EPA) allows veterinarians to use both restricted-use and conventional pesticides in the course of their professional practice.
- The United States Department of Agriculture (USDA) recognizes veterinarians as professionals who may vaccinate animals to advance national animal disease control and eradication programs.

Of the tools that are available to veterinarians, one of the most important tools that veterinarians use to protect animal health and human health is the judicious use of antimicrobials. The continued availability of safe, effective antimicrobials for veterinary medicine, including the retention of currently approved drugs and future approvals of new drugs, are critical components of ensuring a safe food supply and essential to the improvement of animal health and welfare.

The exact quantity of antimicrobials that are used in animal agriculture remains unknown and estimates vary greatly depending upon the source and the classification of antimicrobials. The Union of Concerned Scientists (UCS) estimates 24.6 million pounds of antimicrobials were used for non-therapeutic uses (defined by UCS to include uses for prevention and control of disease as well as for growth promotion) in cattle, swine, and poultry in 1999.<sup>6</sup> However, The Animal Health Institute (AHI) has reported a general downward trend in total antibiotic use between 1999 and 2004, and estimates 95% therapeutic use (which includes disease control and prevention)<sup>7</sup>, and therefore about 1.2 million pounds for growth promotion or feed efficiency. Antibiotic use estimates are equally confusing and inconsistent when evaluating human use data. AHI reported in 2000 that 32.2 million pounds of antibiotics are used annually in human medicine.<sup>8</sup> However, the UCS estimate for human use (for inpatient and outpatient disease treatment and as topical creams, soaps, and disinfectants) was 4.5 million pounds. But the real issue is not the quantity of antimicrobials that are used but the outcomes of use.

Despite all of these figures and other available data, no one knows for certain what role animal agriculture plays in the ecology of antimicrobial resistance. What we do know is that we need to be able to have as many tools as possible to uphold our oath.

The number and supply of animals that is necessary to keep up with human demands for animal protein is rapidly increasing. The world's population is growing, and expected to increase by a third exceeding 9 billion by 2050.<sup>9</sup> With that population growth, comes an increased demand for a safe, healthy supply of food. Ban Ki-Moon, the United Nation's secretary general, has noted in multiple venues that global food production must increase by 50% by 2030 to meet those demands.<sup>10</sup>

In 2000, 9.7 billion animals were slaughtered for human consumption in the United States. In that same year, the US census bureau reported a population of approximately 281 million. The US population today is well over 300 million, and the world's population is rapidly approaching 7 billion.<sup>11</sup> Red meat production alone in the US totaled 48.8 billion pounds last year.<sup>12</sup> Today, the European Union's population is nearly 500 million, but in 2007 slaughtered only 42 million animals for food<sup>13</sup> compared to the US's nearly 10 billion animals slaughtered annually. While the United States is often compared to the European Union in the discussion of differing husbandry and management practices, few recognize the vast difference in per capita production and that the United States has the most affordable, abundant, safe, and healthy food supply in the world.

With the large number of animals produced for food in this country, the topic of antimicrobial use in food production often becomes a topic of debate. Much of the discussion revolves around a category of antimicrobial use commonly known as growth promotion or a group of antimicrobial uses that are poorly categorized as "non-therapeutic." The term "non-therapeutic" has no meaning in federal regulation or common usage. The FDA approves antimicrobials for four purposes: disease treatment, disease prevention, disease control, and growth promotion/feed efficiency. The FDA does not approve antimicrobials for "non-therapeutic" uses. Also, the various organizations and people who use the term "non-therapeutic," use it inconsistently. For example, the Pew Commission on Industrial Farm Animal Production (PCIFAP) provides an unclear definition of "non-therapeutic" that is different than H.R 962, the Preservation of Antibiotics for Medical Treatment Act of 2007 (PAMTA). Additionally, the definitions use terms that are undefined, such as "routine preventive uses and other routine uses." As a result, the term is not commonly understood. The use of exclusionary terms, such as "non-therapeutic", that are ill-defined serves to further confuse the issue. We caution against the use of this term.

Instead, we believe the FDA labeled uses of antimicrobials should be used as the terminology, i.e., treatment, prevention, control, or growth promotion/feed efficiency. Alternatively, we advocate using the definitions of the Codex Alimentarius Commission (an organization of the World Health Organization and the Food and Agricultural Organization of the United Nations), the FDA, and AVMA. All three organizations classify treatment, prevention, and control of disease as therapeutic uses.

Not all antimicrobials or all their uses are equal in their probability of developing resistance or creating a risk to human health. The EU's Scientific Committee on Animal Nutrition has agreed that *possible* theoretical human health concerns related to animal agricultural use of antimicrobials continue to be the focus while *probable* and scientifically based benefits to human and animal health are largely ignored.<sup>14</sup>

There is little debate on the use of antimicrobials for treatment of disease in animals. However, few understand the importance of disease control and prevention, and even fewer have a clear understanding of growth promotants. Prevention and control of disease are key elements in the practice of veterinary medicine, particularly in animal agriculture, where the focus is on population health. This concept of disease prevention and control through herd health is analogous to public health efforts. Additionally, some of the growth promoting antimicrobials have no human health equivalent and thus no human health impact. In fact, studies show a potential health benefit from the use of growth promoting antimicrobials.<sup>15,16,17,18,19,20,21,22</sup>

## **Danish Experience**

The Danish experience has taught us that there can be serious negative consequences in animal health and welfare following the withdrawal of growth promoting antimicrobials and few, if any, improvements or positive human health impact.

In the late 1990s, Denmark instituted a voluntary ban on the use of antimicrobials for growth promotion (AGPs). (A complete ban of AGPs was initiated in 2000.) The use of antimicrobials in feed and water for controlling and treating disease was not banned. The following has been observed as a result of the ban on the use of antibiotics for growth promotion in Denmark:

- There is little evidence to demonstrate a general decline in antimicrobial resistance in humans and there is no evidence of an improvement in clinical outcomes of antimicrobial treatment of humans, the desired consequence of the antibiotic ban in livestock. The results have been mixed. In fact, resistance in humans to some of the banned drugs has increased dramatically.
- There has been increased death and disease in the swine herds, especially at the weaning stage (information inferred from DANMAP 2005 and other reports on pigs). According to published news reports, there was a relative increase of 25% in the number of pigs that died from illnesses from 1995 to 2005.
- While the total quantity of antimicrobials used in food animals has decreased by 27%, the increase in disease has resulted in a 143% increase in the quantity of antimicrobials used for therapeutic purposes. And the antimicrobials now used are classes such as tetracyclines that are also used in humans.<sup>23</sup>
- Resistance to some antibiotics has decreased in some animals while resistance to other antibiotics has increased

The ban on antibiotic growth promoters in Denmark has not resulted in a significant reduction of antibiotic resistance patterns in humans. It has, however, resulted in an increase in disease and death in the swine herds and an increase in the use of antimicrobials for therapeutic uses in swine herds that discontinued the use of antibiotic growth promoters.

Some important resistance trends reported by DANMAP:

- *Salmonella* Typhimurium from human isolates<sup>a</sup> has shown 34-49% *increase* in resistance to tetracycline, sulfonamides, and ampicillin from 1997-2006; increases in resistance to nalidixic acid and ciprofloxacin were 3.8% from 1997-2006
  - In contrast, during the same period of time, poultry isolates have shown only minimal increases (2-6%) in resistance to the same antimicrobials.
  - Isolates from pigs have also shown a lesser increase (25-27%) in resistance to tetracycline and ampicillin than human isolates during that time.
- *Campylobacter jejuni* from human isolates<sup>f</sup> has shown 5-11% *increase* in resistance to tetracycline, nalidixic acid, and ciprofloxacin from 1997-2006.
  - In contrast, during the same period of time, poultry isolates have shown lesser increases (4-6%) in resistance to the same antimicrobials.
- *Enterococcus faecium* isolates from healthy human volunteers has shown no increase in resistance to vancomycin (the equivalent of avoparcin) from 1997- 2006, and remains at 0%.
- However, resistance to virginiamycin (quinupristin/dalfopristin, e.g., Synercid) had been steadily increasing (up to 25%) from 1997 to 2005 until the definition of resistance was changed in 2006, bringing the level of resistance down to 0%.<sup>b</sup>
  - When the definition of resistance is standardized to the United States definition used by CDC and the level of resistance in humans in Denmark to Synercid is compared to the United States, we find that the level is 10 times higher in Denmark in spite of the Danish ban in 1998 of use in animals and the continued use in the United States.
- During the same period of time, *Enterococcus faecium* isolates from pigs and poultry has shown 8-20% *decrease* in resistance to avoparcin<sup>c</sup>, virginiamycin, erythromycin and tetracycline from 1997- 2006 (using the same definition of resistance as the human isolates from 1997-2005)

Even though the results of the Danish experiment with antimicrobial growth promotant drug bans is very mixed, proposals within the United States go far beyond the Danish example by proposing to ban uses for the prevention and control of disease in addition to uses to promote growth and feed efficiency. Evidence shows that the Danish ban has caused animal health and welfare problems, without improving human health.

Based on the results of a limited ban enacted in Denmark (i.e., the banning of growth promotants, not uses to prevent and control disease), we do not believe the public would benefit

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<sup>a</sup> domestically acquired clinical cases

<sup>f</sup> domestically acquired clinical cases

<sup>b</sup> The rationale for this change is unknown, but appears to introduce bias in reporting. DANMAP decided to use a preliminary European Committee on Antimicrobial Susceptibility Testing breakpoint instead of the previously used breakpoint established by the Clinical and Laboratory Standards Institute.

<sup>c</sup> avoparcin has never been approved for use in the United States

from such limitations on the use of antimicrobials. The loss of approved uses of antimicrobials will negatively impact animal health and welfare without significantly or predictably improving public health. Non-science based, broad bans of preventive uses of antimicrobials have the potential to harm public health, such as through increased foodborne disease.

Significant decisions regarding animal health need to be science- and risk-based decisions. Decisions made without the benefit of veterinary input as well as a thorough evaluation of risks and benefits have the potential to further divert resources away from more appropriate disease control measures.

## **Actions Advancing Livestock Animal Health**

### **AVMA's Efforts**

The AVMA has acted with three objectives in mind:

1. Safeguarding public health,
2. Safeguarding animal health, and the
3. Continued availability of effective therapeutic agents, including antimicrobials for veterinary medicine and the retention of currently approved, safe drugs and biologics as well as future approvals of new therapeutic agents.

### **Veterinary Oversight, Judicious Use, and VCPRs**

Since 1998, the AVMA has actively worked to mitigate the development of antimicrobial resistance related to the use of antimicrobials in food animals. The AVMA Guidelines for the Judicious Therapeutic Use of Antimicrobials were developed to safeguard public health by providing specific recommendations for responsible and prudent therapeutic use of antimicrobials. With support and input from the CDC, Infectious Diseases Society of America, the FDA, and the USDA, the guidelines were developed in collaboration with our species specific allied veterinary organizations. These guidelines were based upon carefully reviewed, scientifically sound research, and we believe that our members conscientiously adhere to the principles of judicious therapeutic use of antimicrobials to ensure the protection of human health, as well as animal health and welfare.

We have actively encouraged and assisted our allied veterinary organizations to use the AVMA general principles as a template to develop more detailed guidelines appropriate to each species, disease and type of client. The AVMA also worked with these groups to develop and deliver a continuing education program to raise awareness within the profession and to encourage utilization of the principles. Fundamentally, the guidelines encourage scientifically based therapeutic practices, the use of antimicrobials only when needed, and compliance with all existing regulatory requirements when antimicrobials are used.

Veterinarians also strongly encourage a veterinarian-client-patient relationship (VCPR) and veterinary consultation when implementing any treatment regimen. Dispensing or prescribing a prescription product (including antimicrobials) requires a VCPR. The VCPR is the basis for interaction among veterinarians, their clients, and their patients.

The veterinarian must have sufficient knowledge of the animal(s) to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s). This means that the veterinarian has recently seen and is personally acquainted with the keeping and care of the animal(s) by virtue of an examination of the animal(s), or by medically appropriate and timely visits to the premises where the animal(s) are kept.

Veterinarians making treatment decisions must use sound clinical judgment and current medical information and must be in compliance with federal, state, and local laws and regulations. The veterinarian must also include consideration of: judicious use principles; food safety and public health; and producer education as a part of the treatment plan. After considerations have been made for animal, human, and the environmental health impact, veterinary authorization is required prior to dispensing of the prescription product.

There are older antimicrobials that are available in medicated feeds that can be purchased without a veterinary prescription. These are called over-the-counter or OTC drugs. OTC drugs have been approved for marketing without a veterinary prescription and include adequate directions for use under which a lay person can use the drugs safely and effectively. To our knowledge, no new classes of antimicrobials have been approved by the FDA as an OTC drug since the 1980s. A newer category of drugs, the Veterinary Feed Directive (VFD) Drug category, was created by the Animal Drug Availability Act of 1996 to provide veterinary control for certain animal pharmaceuticals for use in feed that are not suitable for OTC status. Any animal feed bearing or containing a VFD drug shall be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian in the course of the veterinarian's professional practice.

Veterinarians must balance the need for animal health and welfare with the need of human health. We are supportive of measures to mitigate risks to human health. Risk management measures can include any of the following: advisory committee review of an existing approval or application for a new animal drug approval; post-approval monitoring through systems such as the National Antimicrobial Resistance Monitoring System (NARMS); limitations on the extent of use (e.g., individual animals only for short duration of use); limited or broad extra-label use restrictions in some cases or all cases; antimicrobial use through prescription or VFD drugs only; and, finally, non-approval or withdrawal of a previously approved antimicrobial.

Although there are critical shortages in the veterinary workforce, particularly in food supply veterinary medicine and veterinary public health, veterinarians provide oversight and advice on the use of medications, including OTC antimicrobials, on a significant percentage of animal operations. *Feedlot '99* reports that all large operations and nearly all (96.5%) small operations used the services of a veterinarian. Large operations were more likely to use a veterinarian that made regular or routine visits or employ a full-time veterinarian on staff than small operations. Conversely, small operations were more likely to use a veterinarian when the need for one arose. Veterinarian recommendations had strong or moderate influence on selection of an antimicrobial for nearly 100% of feedlots. Laboratory test results influenced 58.8% of feedlots strongly or

moderately. Veterinarian recommendations and laboratory test results were more likely to strongly influence selection of antimicrobials on large feedlots than small feedlots. Almost three out of four feedlots provided formal training in areas related to antimicrobial use.<sup>24</sup>

The *USDA Swine 2006* reports approximately seven of 10 sites (69.1%) used a veterinarian during the previous year. A higher percentage of large and medium sites (88.1 and 85.0%, respectively) used a veterinarian during the previous year compared to small sites (60.8%). Nearly 5 of 10 large sites (46.8%) used an on-staff veterinarian. A similar percentage of large sites (42.5%) used a local practitioner. Overall, approximately half of the sites (49.5%) used a local veterinarian during the previous 12 months. About one of four sites (24.7%) was visited by a veterinarian five or more times. Producers used the services of a veterinarian for many purposes during the previous 12 months. A higher percentage of large sites used a veterinarian for blood testing, production record analysis, employee education, and quality assurance compared to small sites. For sites that had at least one veterinary visit during the previous 12 months, the highest percentage of sites used a veterinarian to treat individual pigs (63.8%) and to provide drugs or vaccines (62.6%). These are followed by vaccination consultation (48.6%), quality assurance (47.9%), blood testing (47.6%), nutritional consultation (19.8%), environmental consultation (19.0%), and employee training/education (18.0%).<sup>25</sup>

We believe that these numbers can be improved through the resolution of the critical shortage of the veterinary workforce by identifying resources and developing solutions in collaboration with key stakeholders to ensure that veterinary needs are met. Further studies should appropriately address the availability of veterinary services.

### **Data Collection and Review; Monitoring and Surveillance Systems**

The AVMA has also continually advocated for improved, more robust monitoring and feedback systems for foodborne disease and antimicrobial resistance such as FoodNet and NARMS. It is unfortunate that reporting by NARMS is not timelier. For example, the most recent Centers for Disease Control and Prevention NARMS report that is available to the public is for 2004 – four years ago.

NARMS data, when combined with FoodNet data, demonstrates that the case rate of human infections with multidrug resistant *Salmonella* spp. has decreased 49% between the NARMS baseline years of 1996-98 and 2004 (the most current, publicly available human data from NARMS). In addition, there has been a 65% reduction in the case rate of penta-resistant *Salmonella* Typhimurium infections. The case rate for *Campylobacter* infections in humans that are resistant to ciprofloxacin have remained constant over that period.<sup>26</sup>

Additional important resistance trends<sup>a</sup> reported by NARMS<sup>27</sup> (Isolates from humans with clinical disease):

- *Salmonella* spp. (non-Typhi) – ½ as likely to be resistant in 2004 as in 1996

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<sup>a</sup> Odds ratios were calculated based upon available data from NARMS assuming the reported isolates were representative of the bacterial population.

- a highly significant<sup>a</sup> improvement in susceptibility<sup>b</sup> (20% relative increase in susceptibility, from 66.2% in 1996 to 79.6% in 2004)
- *Salmonella* Typhimurium – less than ½ as likely to be resistant in 2004 as in 1996
  - a highly significant<sup>j</sup> improvement in susceptibility<sup>k</sup> (60% relative increase in susceptibility<sup>k</sup> from 37.9% in 1996 to 60.7% in 2004)
- *Campylobacter* – only 0.03 times more likely to be resistant in 2004 compared to 1997
  - a marginally significant<sup>j</sup> increase in resistance (2% relative increase in resistance from 53% in 1997 to 54% in 2004)
  - However, campylobacter was significantly less likely to be resistant in 2003 when compared to 1997; there was a significant<sup>j</sup> improvement in relative resistance (8.2% decrease from 53% in 1997 to 49% in 2003)
- *E. coli* O157 – 1/3 as likely to be resistant in 2004 compared to 1996
  - a highly significant<sup>j</sup> improvement in susceptibility<sup>k</sup> (10% relative increase in susceptibility)

In addition to trends of improved susceptibility, trends<sup>i</sup> regarding multi-drug resistance<sup>l</sup> also showed improvement:

- *Salmonella* spp. (non-Typhi) – nearly ½ as likely to be multi-drug resistant<sup>c</sup> in 2004 when compared to 1996
  - a highly significant<sup>j</sup> improvement (44% relative decrease) in multi-drug resistance<sup>l</sup> (decreased from 27.0% in 1996 to 15.0% in 2004)
- *Salmonella* Typhimurium – nearly ½ as likely to be multi-drug resistant<sup>l</sup> in 2004 when compared to 1996
  - a highly significant<sup>j</sup> improvement (34% relative decrease) in multi-drug resistance<sup>l</sup> (decreased from 56.2% in 1996 to 37.2% in 2004)
- *Campylobacter* – slightly less likely to be multi-drug resistant<sup>l</sup> in 2004 when compared to 1997
  - a marginally significant<sup>j</sup> improvement (10% relative decrease) in multi-drug resistance<sup>l</sup>

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<sup>a</sup> “Marginally significant” indicates a p-value between 0.05 and 0.10; “significant” indicates a p-value between 0.01 and 0.05; “highly significant” indicates a p-value of less than 0.01

<sup>b</sup> no resistance detected to any of 5 subclasses of antibiotics

<sup>i</sup> Odds ratios were calculated based upon available data from NARMS assuming the reported isolates were representative of the bacterial population.

<sup>j</sup> “Marginally significant” indicates a p-value between 0.05 and 0.10; “significant” indicates a p-value between 0.01 and 0.05; “highly significant” indicates a p-value of less than 0.01

<sup>k</sup> no resistance detected to any of 5 subclasses of antibiotics

<sup>c</sup> resistant to 2 or more antibiotic subclasses

(decreased from 15.7% in 1997 to 14.1% in 2004)

- However, when comparing 1997 to 2003, isolates were half as likely to be multi-drug resistant<sup>1</sup> and there was a highly significant<sup>1</sup> improvement (46% relative decrease) in multi-drug resistance<sup>1</sup> (decreased from 15.7% in 1997 to 8.5% in 2003)

Most foodborne infections do not require treatment with antimicrobials. Information shows that there is a decreasing trend of foodborne diseases, thereby decreasing the potential numbers of treatments.<sup>28</sup> The trends of increasing susceptibility/decreasing resistance mean more successful treatments when needed. This information indicates that there is not a public health crisis related to human pathogens that are thought to originate in animals.

We have also advocated for more research to support scientifically based therapeutic practices, such as epidemiological studies, that assess the effects of antimicrobial use. In addition, we advocate for increased resources for the FDA's Center for Veterinary Medicine (CVM) so the agency can adequately implement its regulatory authority.

We support the scientifically valid and meaningful collection and review of data for all uses of antimicrobials and other pharmaceuticals used in humans and animals. We urge that such data be collected in concert with other data necessary to explain or inform fluctuations in use, e.g., disease prevalence, regional data, populations of animals, etc. An example is the USDA program, Collaboration for Animal Health, Food Safety and Epidemiology, that is attempting to study the use of antimicrobials on farms correlated with disease occurrence, and the effects of antimicrobial use on antimicrobial resistance as measured both on the farm and during processing of the meat from the specific farm. Unfortunately, the program has not received adequate funding and is therefore not completed or ongoing.

The AVMA provided start-up funding for projects to create a nationally coordinated laboratory system to test for and report on resistance in animal pathogens and to create a decision support system to assist veterinarians when making antimicrobial use decisions. Unfortunately, while this project received follow-on funding by the FDA, it has not been sustained or completed.

## **The FDA Role and Actions**

The FDA approves antimicrobials for four purposes:

1. Treatment of disease,
2. Prevention of disease,
3. Control of disease, and
4. Growth promotion or feed efficiency.

The first three uses are classified as therapeutic uses by the FDA, the AVMA, and Codex Alimentarius Commission (an organization of the World Health Organization and the Food and Agricultural Organization of the United Nations), and the fourth has also been shown to have

health-promoting effects.

The FDA process for the evaluation of food animal antimicrobials is at least as stringent as, and often more stringent than, the approval process for human antimicrobials. In addition to the testing for efficacy and safety to the individual (human or animal) receiving the drug that is common to the human and animal drug approval process, each food animal antimicrobial undergoes an assessment for human and environmental safety as part of the review by the FDA. The FDA's Center for Veterinary Medicine uses a very strict safety assessment approval process that requires sponsors to submit data proving the antibiotic is safe for both humans and animals. This is a zero-risk procedure for human safety – benefits to animals are not weighed to offset risks to humans, but rather, drugs that possess risks beyond “a reasonable certainty of no harm” to human health are rejected.

Another safety measure was instituted in 2003 (Guidance for Industry #152, “Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern,”) that outlines a comprehensive, evidence-based approach to preventing the emergence and selection of antimicrobial-resistant bacteria that may adversely affect human health. The Guidance requires antimicrobial manufacturers to provide information to the FDA showing that a proposed animal drug will not harm public health. The current FDA risk assessment on a drug-by-drug basis provides a scientifically sound process to protect human health. In the event that a determination is made that human health is jeopardized, FDA will not approve the antimicrobial or may limit the use of the antimicrobial in order to mitigate the adverse effect.

We support GFI #152 while recognizing that it is very conservative in ensuring that preference is given to protection of human health without consideration of benefits to animal health and welfare. We also recognize that the ranking of antimicrobial drugs according to their importance in human medicine adds additional difficulty for approving animal drugs because the ranking design includes treatment of human diseases that are not in any manner associated with food animals. These diseases include gonorrhea, tuberculosis caused by *Mycobacterium tuberculosis*, neurosyphilis, meningitis, neutropenic fever, and Legionnaire's disease.

In addition, we also recognize that the design of GFI #152 makes it extremely difficult or impossible for FDA to approve antibiotics for use in feed or water for treatment of groups of animals if those antibiotics are also used in humans. This is because the extent-of-use limitations table assigns a high ranking for intended administration to flocks or herds of animals regardless if the duration of use is short (less than 6 days) or long (more than 21 days).

Since the mid-1990s, the FDA has coordinated the NARMS in cooperation with the CDC and the USDA. NARMS is a multi-agency program that includes monitoring for resistant bacteria in retail meats by the FDA, monitoring for resistant foodborne pathogens in humans by the CDC, and monitoring for resistant bacteria in animals on farms and animal products in slaughter and processing facilities by the USDA. NARMS has provided a great deal of useful information since 1996.

Therefore, the AVMA does not believe that the FDA needs new authority to regulate the human

safety of animal drugs. Instead, the FDA needs additional resources to fulfill its existing mission.

## **The USDA Role and Actions**

USDA Animal and Plant Health Inspection Services (APHIS) regulates veterinary biologics (vaccines, bacterins, antisera, diagnostic kits, and other products of biological origin) to ensure that the veterinary biologics available for the diagnosis, prevention, and treatment of animal diseases are pure, safe, potent, and effective. According to the USDA, which regulates vaccines and other biologics for animals, over 80 billion doses of approved vaccine were produced last year.<sup>29</sup>

USDA also has oversight over many national programs for animal health monitoring and surveillance. Veterinarians in both public and private practice actively participate in these national programs and AVMA has consistently advocated for funding to maintain and continually improve all of these programs.

### **National Programs**

[National Animal Health Surveillance System \(NAHSS\)](#) - NAHSS integrates animal health monitoring and surveillance activities conducted by many federal and state government agencies into a comprehensive and coordinated system.

- [U.S. status for reportable diseases](#) as reported to the World Organization for Animal Health (OIE)
- [NAHSS Outlook](#) - Articles on U.S. animal health surveillance issues and developments.

[National Animal Health Monitoring System \(NAHMS\)](#) - National studies on animal health and health management practices of U.S. livestock and poultry.

[National Animal Health Reporting System \(NAHRS\)](#) - Information on the presence of reportable animal diseases in the United States.

[National Animal Identification System \(NAIS\)](#) - This program coordinates and expands animal identification programs and practices in livestock and poultry.

[National Animal Health Laboratory Network \(NAHLN\)](#) - This network of state animal health laboratories provides, among other things, laboratory data to meet epidemiological and disease reporting needs.

[National Poultry Improvement Program \(NPIP\)](#) - National poultry health monitoring and surveillance.

[National Aquaculture Program \(NAP\)](#) - National aquaculture health monitoring and surveillance.

[U.S. Animal Health and Productivity Surveillance Inventory](#) - Search for surveillance programs, studies, and related information.

[Impact Assessments on Animal Health Events](#) - Reports on trade and production impact of animal disease occurrences in the U.S. and foreign countries.

[Emerging Animal Disease Notices](#) - Information sheets on new and emerging animal diseases.

[National Surveillance Unit](#) - organization within APHIS tasked with coordinating activities related to animal health surveillance.<sup>30</sup>

## **FARAD Role and Actions**

The Food Animal Residue Avoidance Databank (FARAD) program was developed by pharmacologists and toxicologists at the university of California, Davis, University of Florida, North Carolina State University and the University of Illinois as a complement to the USDA Food Safety and Inspection Service (FSIS) Residue Avoidance Program (RAP) to reduce the rate of animal residue violations through education, and residue mitigation rather than enforcement.

Whenever drugs are used to treat sick animals or prevent disease or when animals are exposed to chemicals in the environment, there is a potential that remnants of the drugs can be found in the meat or other animal products (often known as residues). The FDA establishes tolerances for drug residues to insure food safety. The FDA also establishes “withdrawal times” or “withholding periods” which are times after drug treatment when milk and eggs are not to be used for food, and during which animals are not to be slaughtered. This allows time for the animals to metabolize and eliminate the drugs that had been used for treatment.

FARAD personnel collate residue avoidance information from many sources. These data are then reviewed by residue experts to insure accuracy and consistency, and further analysis is done by FARAD personnel at North Carolina State University to explore novel ways in which the data may be used to prevent residue problems. FARAD maintains an up-to-date computerized compilation of:

- Current label information including withdrawal times on all drugs approved for use in food animals in the United States and on hundreds of products used in Canada, Europe and Australia.
- Official tolerances for drugs and pesticides in meat, milk, and eggs.
- Descriptions and sensitivities of rapid screening tests for detecting chemical residues in meat, milk, and eggs.
- Data on the fate of chemicals in food animals.

FARAD has been a chronically under-funded resource used by veterinarians, livestock producers, and state and federal regulatory and extension specialists to ensure that drug, environmental, and pesticide contaminants do not end up in meat, milk, and eggs. AVMA has been a strong supporter of FARAD and has worked diligently with Congress on the 2008 Farm Bill to include authorization for a \$2.5 million annual appropriation for the Food Animal Residue Avoidance Databank from 2008 through 2012.<sup>31</sup> However, if funding is not appropriated before September 30, 2008, this vitally important asset to ensure food safety may be forced to close its doors—permanently. Not only does FARAD ensure the safety of our meat, milk, and eggs, but

the U.S. researchers from FARAD launched a global FARAD (gFARAD) initiative in response to an increasing need from foreign countries for residue data and requests made to FARAD to duplicate this successful program in other countries.

FARAD's efforts in establishing gFARAD have, to date, been financed entirely by local funds in participating countries, and in the US by private donations and use of facilities made available by the three U.S. Universities housing the FARAD program. These exciting developments, which have attracted collaborations (but no funding) from the Food and Agricultural Organization (FAO) and Commonwealth Agricultural Bureaux International (CABI), have far reaching implications for the safety of foods imported into the United States as well as upon global food safety and the harmonization of standards and procedures. Since 2003, the United Kingdom, France, and Spain have initiated gFARAD sites. The Canadian gFARAD became fully operational with significant, recurring support from the government of Canada in 2003. In recent years, FARAD has provided training in gFARAD techniques and databases for China, as well as hosted the Taiwanese gFARAD consortium and South Korean delegate visits to FARAD.

The funding lapses of U.S. FARAD in 2007 and the continued lack of recurring support for US FARAD places the entire program in jeopardy. In addition, the lack of continued funding and support compromises US leadership in the continued development of a program initiated by our own researchers. In 2007, gFARAD may have been able to assist in mitigating the Chinese melamine crisis, however, it was a necessity for funds to be utilized to maintain essential personnel and no funds were available for U.S. FARAD to leverage the gFARAD consortium. Global food safety and security will continue to be a concern for decades to come. Support for a strong U.S. FARAD is a critical investment in continuing relationships with our trading partners and global information sharing between governments to mitigate agroterrorism concerns and ensure a safe, abundant food supply.

## **Risk Assessments/ Human Health Impact**

### **Antibiotics as a tool to prevent and control disease in animals and humans**

The use of drugs in animals is fundamental to animal health and well-being. Antibiotics are needed for the relief of pain and suffering in animals. For food animals, drugs additionally contribute to the public health by helping keep animals healthy and thereby keeping bacteria from entering the food supply. The hypothesis, supported by scientific information, is that a reduction in the incidence of food animal illness will reduce bacterial contamination on meat, thereby reducing the risk of human illness.<sup>32,33,34,35,36,37,38,39</sup>

Several risk assessments have been performed that demonstrate a very low risk to human health from the use of antimicrobials in food animals, and some of the models predict an increased human health burden if the use is withdrawn. The unique farm-to-patient risk assessment performed by Hurd demonstrates that the use of tylosin and tilmicosin in food animals presents a very low risk of human treatment failure because of macrolide resistance, with an approximate

annual probability of less than 1 in 10 million with *Campylobacter* infections and approximately 1 in 3 billion *E. faecium* infections.<sup>40</sup> Cox performed a quantitative human health risks and benefits assessment for virginiamycin and concluded that there would be a significant human health risk if virginiamycin use is withdrawn. There would be 6,660 excess cases per year of campylobacteriosis, which far outweighs the 0.27 per year reduction of cases of streptogramin-resistant and vancomycin-resistant *E. faecium* (VREF) resulting from the withdrawal.<sup>41</sup> Cox also performed a risk assessment regarding macrolide and fluoroquinolone use and concluded that withdrawal is estimated to cause significantly more illness days than it would prevent.<sup>42</sup> Cox also examined the impact of the use of penicillin-based drugs in food animals on penicillin/aminopenicillin resistant enterococcal infections and concluded that not more than 0.04 excess mortalities per year (under conservative assumptions) to 0.18 excess mortalities per year (under very conservative assumptions) might be prevented in the whole U.S. population by discontinuing current use of penicillin-based drugs in food animals. The true risk could be as low as zero.<sup>43</sup> This equates to one potentially preventable mortality in the U.S. population roughly every 7-25 years. Alban's risk assessment concluded that the risk associated with veterinary use of macrolides in Danish pigs resulted in a low risk to human health.<sup>44</sup>

Others have estimated that risk management strategies that focus on eliminating resistance are expected to create < 1% of the public health benefit of strategies that focus on reducing microbial loads in animals or on foods.<sup>45</sup> In another paper, the authors concluded, "We came to some surprising conclusions that were robust to many uncertainties. Among these were that antimicrobials that benefit animal health may benefit human health, while regulatory interventions that seek to reduce antimicrobial resistance in animals may unintentionally increase illness rates (and hence antimicrobial use and resistance rates) in humans. . . . In conclusion, our analysis suggests that the precautionary-principle approach to regulatory risk management may itself be too risky."<sup>46</sup>

Information derived from studies of organic or antibiotic-free production practices compared to traditional production practices is inconclusive, but there are indications that organically grown meat may have less-resistant organisms but greater prevalence and quantities of pathogens on the meat. Therefore, the greater risk of foodborne illness is somewhat offset by an increased likelihood of treatment success if treatment is necessary.<sup>47,48,49,50</sup>

The question of what the nature and magnitude of the risk to humans is can only be answered by performing systematic risk assessments. Such risk assessments must include identification of the endpoints of concern (e.g., increased illness or mortality caused by bacteria resistant to antibiotics used to treat the disease in humans), the nature of the treatment protocols in food animals, the potential routes of exposure, characterization of the population at risk, and the probability of occurrence.

Just as in humans, resistant bacteria can and do develop in animals. However, many of the important details regarding the transfer of that resistant bacteria, or even resistance genes – to the environment or humans – still remains in question. Simply because resistance exists in animals, it does not necessarily equate to a human health risk. First, the bacteria or its resistance determinants may not effectively transfer to humans through the food chain. Secondly, the pathogen may not colonize in humans to create a foodborne disease. Third, if a disease does

occur, antimicrobial therapy may not be needed, and the disease resulting from the resistant bacteria is in effect no different than any other bacteria. In the majority of cases, treatment is not needed. Supportive therapy, such as fluids, is the only treatment that is needed for most *Salmonella*, *Campylobacter* and *E. coli* infections. In fact, antimicrobial therapy of *E. coli* O157 infections is contra-indicated because such treatment makes the effects of the disease worse. Lastly, if antimicrobial therapy is needed, the pathogen may be susceptible to the drug of first choice. The Therapy Guidelines for Enteric Infections for non-typhi *Salmonella* are, “In uncomplicated infections antimicrobial therapy is not indicated because it has no effect on clinical illness and prolongs carriage and excretion of the organism. . . . Treatment recommended only for young infants (< or = 6 m) and immunocompromised individuals. Resistance is common. Agents that can be used include a fluoroquinolone or a third-generation cephalosporin such as ceftriaxone for 5-7 days. Ampicillin and co-trimoxazole can be used if the infecting organism remains susceptible.”<sup>51</sup> NARMS<sup>52</sup> reports the following resistance percentages of non-typhi *Salmonella* to fluoroquinolone (ciprofloxacin) – 0.2%, third-generation cephalosporin (ceftriaxone) – 0.6%, ampicillin – 12.0%, and co-trimoxazole (trimethoprim-sulfamethoxazole) – 1.8%. These resistance levels do not indicate a public health crisis associated with foodborne *Salmonella*.

## Conclusion

The American Veterinary Medical Association is committed to ensuring a safe and healthy abundant food supply. Among other things, our profession is dedicated to improving animal health, further safeguarding public health and food safety, and to maintaining the long-term effectiveness of antibiotics. The AVMA established a profession-wide initiative to create and implement judicious use guidelines for the therapeutic use of antimicrobials by veterinarians, and we launched an educational campaign to raise the awareness of the profession to the issue. Today, we continue to review and update those guidelines to reflect current practices and actively encourage compliance.

Foodborne illness and the spread of antibiotic resistance is a public and animal health concern. There is no question that the public demands a safe food supply and that the human medical profession is facing extreme challenges because of hospital- and community-acquired resistant human pathogens. The human medical problem with resistant nosocomial and community-acquired infections has increased the concern of possible development of resistant pathogens in animals that could be transferred to humans through the food supply or environment.

The AVMA shares the concerns of the human medical community, the public health community, governmental agencies, and the public regarding the potential problem of resistant foodborne pathogens developing in animals and then being transferred to humans. However, we emphasize the importance and primacy of using these medicines to prevent and treat diseases before they enter our food supply. Pre-emptive bans of veterinary antimicrobials before science-based studies and risk-based evaluations are performed would be detrimental to animal and human health. Inappropriate reactions to a perceived problem could have unknown and unintended consequences that negatively affect animal health and welfare, and ultimately, could create other public health risks, such as increased foodborne illness.

The AVMA does not believe that additional regulation of the uses of antimicrobials or other therapeutic agents in veterinary medicine and animal agriculture are necessary. Additional legislation and further regulation can put animal health and welfare and public health at risk. The FDA has adequate authority for oversight but lacks the resources to accomplish its many priorities.

An analysis that compared the regulatory strategy of the European Union to ban or restrict animal antibiotic uses with the United States' approach of continued prudent use to prevent and control animal infections, together with measures to improve food safety, has some pertinent conclusions. Among these, prudent use of animal antibiotics may actually improve human health, while bans on animal antibiotics, intended to be precautionary, inadvertently may harm human health.<sup>53</sup>

The AVMA supports the ongoing scientific efforts of monitoring and surveillance of foodborne disease and resistant foodborne pathogens; education; development of new antimicrobials, biologics, and other treatment options; and other research to better define the challenges presented by animal agriculture. Increased data collection and surveillance of disease, as well as continued veterinary input (including the appropriate use of pre- and post-harvest interventions, and compliance with judicious use guidelines for veterinarians and producers), may be sufficient to protect human health against the current small risks without compromising the health of food animals.

We also support adequate funding for all efforts to improve animal health and food safety, including efforts to combat antimicrobial resistance. These efforts were high-priority tasks in the 2001 version of the Public Health Action Plan to Combat Antimicrobial Resistance that was created by a Federal Interagency Task Force on Antimicrobial Resistance. The Action Plan reflected a broad-based consensus of federal agencies and stakeholders on actions needed to address antimicrobial resistance and provided a blueprint for specific, coordinated federal actions that included the full spectrum of antimicrobial use: human medicine, veterinary medicine and animal agriculture. We are disappointed that the Action Plan was not adequately funded and prioritized by Congress. We are also concerned that the new Action Plan under development appears to not be as collaborative, broad-based or acceptable to the diverse community of stakeholders.

The AVMA is committed to working in concert with the CDC, FDA, and USDA to provide consumers – not only in the United States, but all over the world - with the safest food possible. The judicious use of antimicrobials is but one of the essential components of the process that enables animal agriculture to meet that demand. Other components include veterinary care, good management practices, biosecurity, proper nutrition and good husbandry.

Thank you for the opportunity to appear before you today and speak on behalf of our profession.

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