Discussions of the

Antimicrobial Use Task Force

Introduction

The AVMA established the Antimicrobial Use Task Force in response to increasing concerns of antimicrobial use in animal agriculture. The AVMA recognized that not only was public concern growing, but its membership was also becoming increasingly aware of internal and external forces that had the potential to impact veterinary practice. At the 2009 Annual Session of the AVMA House of Delegates (HOD), members began a discussion on veterinary oversight of antimicrobials and the judicious use of antimicrobials. Following the AVMA House of Delegate's recommendation, the AVMA Executive Board (EB) charged the Task Force to evaluate all uses of antimicrobials and clarify the veterinarians' role in those uses. The report of the Antimicrobial Use Task Force includes background information, discussion points, and observations of the group. It is representative of the diversity of perspectives that emerged throughout the discussions. In some respects, there were points of agreement and in other respects, there were very divergent views. The report is not a consensus report, rather it reflects the breadth of the discussion and the many facets of the issue.

Background

In the late 1990s, voluntary and mandatory changes in antibiotic use were taking place in Denmark and the European Union (EU), as a resistant strain of *Salmonella* Typhimurium, known as "DT 104," was emerging in the EU. The same strain subsequently emerged in the United States. Also during the same period of time, the Food and Drug Administration's (FDA) controversial decision to approve a fluoroquinolone for use in food animal production fueled stiff opposition from the Centers for Disease Control and Prevention (CDC) and other public health groups. Each of these events precipitated increased scrutiny of antimicrobial uses in food animal production.

The AVMA quickly recognized the potential for development and transmission of antimicrobial resistance as a result of veterinary use. The AVMA believed veterinarians should strive to optimize therapeutic

efficacy and minimize resistance to antimicrobials to protect public and animal health. This series of events prompted the AVMA to form the Steering Committee on Judicious Therapeutic Use of Antimicrobials (SCJTUA) in 1998. The outcome of the SCJTUA was the current AVMA policy titled "Judicious Therapeutic Use of Antimicrobials" and species-specific policies similarly titled also addressing judicious use.

Current Regulatory Oversight and Legislative Activities

In veterinary medicine, antimicrobials are largely used for treatment of disease in the presence of clinical signs. Antimicrobials are also utilized for control of disease when clinical signs of disease are present in a certain percentage of the herd or flock to control further spread of disease. Additionally, antimicrobials are used to prevent disease when prior history or medical knowledge would indicate that a disease condition is expected to occur. Other FDA-approved uses include administration of antimicrobials to food animals to improve rate of gain or feed efficiency.

Regulatory Oversight

Approvals

The Food and Drug Administration regulates the classification of antimicrobials in veterinary medicine, administering three types of approvals: over the counter (OTC), prescription (Rx), and Veterinary Feed Directive (VFD).

Withdrawals

Although there is no periodic review process, the FDA has the authority to withdraw a drug approval if there is a significant harm to human health. The FDA's risk management options include the following:

- 1) withdrawal of approval for a drug product.
- 2) continued approval of use.
- 3) review by the Veterinary Medicine Advisory Committee.
- 4) limitations of use such as use in only certain species or changing to a Veterinary Feed Directive drug.

Voluntary drug withdrawals can also occur if the sponsor of the product agrees to voluntarily remove their product from the market. Some pharmaceutical companies are exploring ways to ensure drug availability and maintain claims for treatment, control, and prevention while voluntarily withdrawing the improved rate of gain and feed efficiency claims.

Classifying Prescription and Over-The-Counter Animal Drugs

FDA is responsible for determining the marketing status (prescription, over the counter (OTC), or VFD) of animal drug products based on whether or not it is possible to prepare "adequate directions for use" under which a layperson can use the drugs safely and effectively. Prescription (Rx) products can be dispensed only by or upon the lawful written order of a licensed veterinarian. Safe use includes safety to the animal, safety of food products derived from the animal, safety to the persons associated with administering the drug to the animal, and safety in terms of the drug's impact on the environment. Effective use of a drug product assumes that an accurate diagnosis can be made with a reasonable degree of certainty, that the drug can be properly administered, and that the course of the disease can be followed so that the success or lack of success of the product can be observed.

The same drug substances can be marketed in a number of different dosage forms, intended for use by different routes of administration, and in different species of animals. Thus, these drug products may be appropriately labeled Rx in some cases and OTC in others. Rx products must bear the legend:

"Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian"

Veterinary Feed Directives

The Animal Drug Availability Act of 1996 (ADAA) established a new category of drugs, veterinary feed directive (VFD) drugs. A drug intended for use in or on feed, which is limited by an approved application to use under the professional supervision of a licensed veterinarian, is a VFD drug.

The VFD regulations differ from those of prescription drugs in that the regulations explicitly state that the veterinarian must operate within the confines of a valid veterinarian-client-patient relationship (VCPR)—examining and diagnosing animal conditions and determining whether a condition warrants use of a VFD drug. Additionally, extralabel use (use in a manner that is not in accordance with the approved labeling) of a VFD drug is not permitted by anyone, including the veterinarian.

Allowed antimicrobial uses in animals

OTC:

The vast majority of feed-grade antimicrobials and some veterinary drug dosage forms, such as injectable, are available without veterinary prescription or VFD. Some feed-grade antimicrobials are labeled strictly for therapeutic uses (treatment, control, and prevention), and some are used for improved rate of gain (growth promotion) and feed efficiency. All antimicrobials labeled for improved rate of gain or feed efficiency are available without veterinary prescription or VFD and are administered exclusively in feed. No antimicrobials have been approved for therapeutic or production use in feed as over-the-counter products for several decades. However, all of these approvals are for a specific use for a specified period of time with a specified period of withdrawal. Any deviation from these labels with respect to the use of feed-grade antimicrobials is illegal. Deviations from the label for other dosage forms require a valid VCPR and must meet conditions defined for extralabel drug use.

Prescription:

Prescription antimicrobials for food animals can come in the forms of injectable medications and oral medications (largely water soluble medications). These dosage forms are labeled strictly for therapeutic uses (treatment, control, and prevention) only. Any deviation from the label (of either prescription products or over-the-counter products) without veterinary direction is unlawful.

VFD:

Of the antimicrobials available in feed, there are only two drugs that require a VFD. All feed mills authorized to produce medicated feeds are heavily regulated to ensure adherence to labeled indications

and compliance with federal regulations. Additional regulations are imposed on feed mills that produce feeds containing VFD-regulated drugs.

Current Thinking by FDA

The current FDA administration has clearly expressed its desire to eventually eliminate growth promotion and feed efficiency uses of antimicrobials that are important in human medicine. Additionally, the Center for Veterinary Medicine office of the FDA has articulated that veterinarians are professionally educated, trained, and licensed and as such should have greater oversight in the use of important antimicrobials. The FDA believes that antimicrobials are used broadly, with an unknown level of veterinary supervision, and without knowledge of a specific disease risk. Key elements of improving judiciousness as indicated by the agency would be to minimize use, limit use to disease therapy (treatment, control, and prevention), and increase veterinary oversight. Although the agency has not clarified how they might envision the greater oversight, it is understood that FDA is open to future discussions and innovative solutions.

Legislative Activities on Oversight

The Preservation of Antibiotics for Medical Treatment Act (PAMTA), which is seen as a passable bill in Congress, seeks to eliminate the "nontherapeutic" use of antibiotic drugs considered important for human health in order to decrease the development of antibiotic-resistant bacteria in humans. PAMTA purports to preserve the effectiveness of medically important antibiotics used in the treatment of human and animal diseases by withdrawing specified classes of antibiotics for "nontherapeutic" purposes in food-producing animals unless they can be proven to pose no harm to human health. Within the text of the bill, "nontherapeutic use" is defined as use of a drug as a feed or water additive for an animal in the absence of any clinical sign of disease in the animal for growth promotion, feed efficiency, weight gain, routine disease prevention, or other routine purpose.

The AVMA opposes this legislation because of the strong likelihood of increasing animal disease and death without assurance of improving human health. PAMTA not only seeks to remove growth promotion and feed efficiency uses, but will also disallow prevention and potentially control uses in feed or water.

This type of broad-based ban is contrary to the practice of veterinary medicine and is not based upon actual risks. AVMA has urged Congress and regulators to make decisions based upon science when considering actions concerning the use of antibiotics in animal agriculture. Meanwhile, the public remains largely unaware of the current role of veterinarians in the use of antimicrobials for food producing animals, both when there is a requirement for direct veterinary oversight (e.g., VFD and Rx) and when there is not (e.g. OTC).

As the FDA cannot lobby Congress, FDA has implied neither support nor nonsupport of PAMTA, but has testified that the agency's current thinking is as described above.

AVMA Policies and Recent AVMA Statements

AVMA's current policy is very clear in terms of therapeutic uses of antimicrobials. The FDA, AVMA, and Codex Alimentarius Commission (the international standard setting body for food safety) defines therapeutic uses as treatment, control, and prevention. While some groups use terms such as "nontherapeutic" or "subtherapeutic," the AVMA has refrained from using such terminology because they are ill defined and used inconsistently.

Judicious Therapeutic Use of Antimicrobials

In 1998, the SCJTUA developed and the AVMA EB approved the AVMA's original Judicious Therapeutic Use of Antimicrobials (JTUA) Policy. The JTUA and subsequent species-specific guidelines were developed in conjunction with AVMA's allied organizations and with input from collaborators including the Infectious Diseases Society of America (IDSA), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and United States Department of Agriculture (USDA). Working closely with allied organizations, the AVMA's Councils and Committees have continued to review and revise the policy and guidelines as needed, most recently in 2008.

Among the many statements contained within the current JTUA policy supporting the judicious uses of antimicrobials (such as "therapeutic exposure to antimicrobials should be minimized and be confined to

appropriate clinical infections"), the policy also clearly states that "veterinarians should work with those responsible for the care of animals to use antimicrobials judiciously regardless of the distribution system through which the antimicrobial was obtained." The policy's intent was to be inclusive of all antimicrobials used for treatment, control, and prevention that may be available over the counter or by other means.

Antimicrobials in Livestock Feeds

AVMA has recently revised the policy titled "Antimicrobials in Livestock Feeds" to indicate that all regulatory or legislative actions should be transparent and based on scientific risk analysis. The livestock feeds policy also recognizes that more data are needed to complete a risk analysis on the public health significance of many antimicrobial uses in livestock feeds and urges the FDA and other public health agencies as well as veterinarians, livestock producers, and pharmaceutical companies to cooperatively support scientific studies needed to close the data gaps. The AVMA has sought input and support for a concerted and coordinated effort to obtain the data necessary to conduct assessments to enable risk-based decisions concerning use. Some believe that many data gaps still exist and no further scientific risk analyses have been completed to facilitate regulatory or legislative action.

Other Relevant AVMA Policies

- AVMA Strategy regarding Antimicrobial-Resistant Bacteria.
- Approval and Availability of Antimicrobials for Use in Food Producing Animals.
- Aquatic Animal Therapeutic Agents.
- Guidelines for Veterinary Prescription Drugs.
- American Association of Avian Pathologists Guidelines to Judicious Therapeutic Use of Antimicrobials in Poultry.
- American Association of Equine Practitioners Prudent Drug Usage Guidelines.
- American Association of Feline Practitioners/American Animal Hospital Association Basic
 Guidelines of Judicious Therapeutic Use of Antimicrobials.
- American Association of Swine Veterinarians Basic Guidelines of Judicious Therapeutic Use of Antimicrobials in Pork Production.

- Judicious Use of Antimicrobials for Treatment of Aquatic Animals by Veterinarians.
- American Association of Bovine Practitioners Prudent Drug Usage Guidelines for Cattle.

Recent AVMA Statements

From the AVMA response to the PEW Industrial Farm Animal Production report:

"The AVMA believes that a veterinary consultation should occur and that a veterinarian should be involved in the decision-making process prior to the implementation of any treatment therapy or regimen, including but not limited to the use of antimicrobials."

Development of the Antimicrobial Use Task Force and Its Charge

In 2009, the New Jersey Veterinary Medical Association, the Association of Avian Veterinarians, and the Washington State Veterinary Medical Association submitted Resolution 3 (Appendix A) for introduction at the 2009 Annual Session of the House of Delegates to revise the JTUA Policy. The revision, if approved, would state that one of the principles of judicious therapeutic use is that judicious use of antimicrobials should meet all requirements of a VCPR.

The House of Delegates' Reference Committee #7 (Scientific Activities) recommended, and the House approved, that Resolution 3 be referred to the EB with the following recommendations:

- 1) That the Executive Board reconvene a multidisciplinary entity similar to the Steering Committee on Judicious Therapeutic Antimicrobial Use,
- 2) That the entity should consider revising the policy ("Judicious Therapeutic Use of Antimicrobials") to clarify the veterinarian's role in the judicious therapeutic use of antimicrobials,
- 3) That the Executive Board provide the recommendation of the entity to the House of Delegates for final consideration, and
- 4) That the policy recommendation be presented to the House of Delegates for its consideration no later than the 2010 Annual Session.

In crafting the entity description for the Antimicrobial Use Task Force (AUTF), consideration was given as to whether an existing AVMA entity could fulfill the recommendation of the HOD or if an existing entity could be leveraged to fulfill the recommendation. It was determined that the multidisciplinary representation needed for this assignment would be best achieved by the establishment of a task force whose membership mirrored that of the 1998 Steering Committee on Judicious Therapeutic Antimicrobial Use that created the policy titled "Judicious Therapeutic Use of Antimicrobials."

Representatives from several AVMA entities were included in the AUTF membership in order to provide specific expertise and to allow continuity of information flow within the AVMA once the Task Force was sunset.

The 2008–2009 Chair of Reference Committee #7 was recommended to chair the Task Force in order to enhance transmission of information from it to the House Advisory Committee and the House of Delegates. Additionally, the structure was to ensure neutrality by having an individual who did not represent a specialty organization serve as the chair of the Task Force.

The scope of the AUTF, as described in the entity description (Appendix B), was broadened from that recommended by the HOD. The HOD recommended that AVMA clarify the veterinarian's role in the "judicious *therapeutic* use of antimicrobials." "Therapeutic," by definition, includes uses for "prevention, control, and treatment of disease." Recognizing that the range of discussion within the House of Delegates extended beyond therapeutic uses and into production uses, the Task Force description as approved by the EB directed the members to address the veterinarian's role in *all* uses of antimicrobials, specifically including the production uses of antimicrobials for growth promotion and feed efficiency.

The reference in the Task Force charge to characterize the level of veterinarian involvement includes addressing the advisability of the availability of antimicrobials (dosage form and feed grade) over the counter versus via prescription only (or its equivalent) or via some other method.

The Task Force met twice in Schaumburg, III: first on November 12–13, 2009, and second on February 2–3, 2010. A professional facilitator was invited to the second meeting to ensure balanced participation and assist in gaining consensus.

Following two in-person meetings, two conference calls, the establishment of a subcommittee and additional conference calls, the Task Force chair and staff provided a status update to the EB at its April 2010 meeting. The EB expressed its desire for a narrative report to be written by staff and available by the June 2010 meeting. Following receipt of the Task Force's report, the EB will then forward its recommendation to the House of Delegates.

AUTF Discussions

Prior to the first meeting of the Task Force, the members were asked to review a number of scientific background documents as well as policy statements from AVMA stakeholder groups.

The Task Force attempted to clarify the veterinarian's role and level of involvement in all uses of antimicrobials.

In its discussions, some members of the Task Force stressed the importance of recognizing that over-the-counter availability of antimicrobials does not equate to a complete lack of veterinary oversight of these drugs. Veterinarians are often involved in the use of antimicrobials, but the extent of involvement has been difficult to define and qualify. Given the shortage of food animal veterinarians, some members of the Task Force believed that over-the-counter availability of antimicrobials was essential in ensuring animal health, especially for therapeutic uses.

Conversely, concerns were discussed surrounding over-the-counter antimicrobial availability and growth promotion/feed efficiency uses in particular and the perceived ability for the product to be used fairly arbitrarily and therefore injudiciously. Additional concerns surfaced regarding the use of antimicrobials in veterinary medicine that have human applications and were followed with suggestions for required

veterinary oversight for those antimicrobial products. However, without clearly defining oversight, the idea could not be explored any further. The AUTF expressed that increased scrutiny of these uses could lead to negative impacts such as a decline in drug availability. Yet, potential consequences, such as a loss of consumer confidence, that could occur as a result of failing to fully acknowledge and address the concerns could be equally devastating.

After thoughtful discussions on veterinary oversight, the Task Force universally agreed, "Veterinarians should be involved in the decision-making process for the use of antimicrobials regardless of the distribution channel through which the antimicrobial was obtained."

Following its discussions on the use of antimicrobials for growth promotion or feed efficiency, members of the AUTF came to consensus on several points:

- Veterinarians should be involved in the use of antimicrobials. Veterinarians should strive to improve their relationships with producers and clients as well as explore ways to better educate and communicate information on antimicrobial use.
- Although discussed and suggested by some members, there was no recommendation for additional veterinary supervision or oversight of antimicrobial use by those responsible for animal care. It was agreed that "oversight" could imply and engender additional regulation and responsibility without improving actual overall stewardship of antimicrobial use. Certain antimicrobials have no potential to impact human resistance patterns and therefore should not require additional veterinary oversight. Additionally, these products should be allowed to be used according to their labeled indications (including growth promotion and feed efficiency).
- It has been theorized that antimicrobials labeled for growth promotion or feed efficiency prevent subclinical disease and allow the animal to reach its full growth potential. Many agreed that in principle (with logistic barriers aside) drugs in this group that have been shown to have therapeutic efficacy (disease treatment, control, or prevention) should be reassessed and, if appropriate, relabeled accordingly. It was acknowledged that for disease prevention, the specific disease being prevented may not be easily identified from among the many that are probable and the mechanism by which

antimicrobials promote growth could remain unknown. There was also the understanding that over-the-counter availability is not necessarily equivalent to a lack of veterinary oversight.

- Investigation of over-the-counter antimicrobials that potentially have a demonstrable human health risk is warranted and could be evaluated by a risk assessment.
- Demonstration of significant human health risk associated with over-the-counter availability of antimicrobials should trigger a requirement for additional veterinary supervision.

Improving Veterinary Stewardship

Recognizing that the charge of the AUTF was to evaluate veterinary oversight of all uses of antimicrobials, the AUTF explored ways to improve veterinary "stewardship." Because no single definition of the term "oversight" was agreed upon, the Task Force had previously agreed to use the term "stewardship" for both its initial brainstorming sessions and its subsequent discussions.

While recognizing that no consensus was achieved regarding increased oversight, four processes that *might* enhance veterinary oversight emerged during discussions:

- Availability of antimicrobials only by prescription—A prescription-only process would require all antimicrobials to be authorized under a veterinary prescription or VFD. The current VFD process would require significant changes (such as electronic VFD forms, further education of veterinarians on the VFD process, and addressing other logistic barriers) to succeed as a mechanism to enhance veterinary stewardship. Additionally, the definition of VCPR may need to be further clarified and consistently applied to other prescription products in addition to VFDs and extralabel drug use.
- Certification requirement for access to antimicrobials—Several ideas regarding certification emerged, including various types and levels of certification:
 - Similar to the pesticide applicator licensure process, an antimicrobial use licensure process could allow a producer to purchase antimicrobials after meeting certain requirements.
 - Veterinarians could be certified to indicate that there was a certain level of understanding regarding the judicious use of antimicrobials.

- Producers could be certified by their veterinarian indicating that there is a valid VCPR, and some sort of documentation could be issued to allow purchase of antimicrobials (nonspecific to a drug).
- Tiered approach—This approach would endorse a prioritization of important antimicrobials (in human health) and increase the levels of veterinary oversight accordingly.
- Electronic/telemedicine approaches—Electronic medical records, diagnostic reports, and other electronic media could be used to supplement on-farm visits by the veterinarian and still satisfy the requirements of a VCPR.

Barriers to implementation of greater veterinary stewardship

In examining the potential barriers to implementing greater veterinary stewardship, three major contributing factors were discussed:

- Veterinary Workforce—With increased requirements for oversight of antimicrobials use, the current shortage of food supply veterinarians would suddenly become more pronounced.
- Veterinary Feed Directive (VFD)—VFDs are currently the only mechanism for a prescription-like drug administered in feed. Incorporation of feed-grade antimicrobials into the current VFD system would be burdensome, as technical and logistic concerns decrease usability of the current VFD process. Application of the VFD process to all antimicrobials in feed would require the FDA to address complicating factors, including drug combinations of antimicrobials and non-antimicrobials, and the need for education on regulations on use of VFD forms by veterinarians, feed mills, and producers.
- Veterinarian-Client-Patient Relationship (VCPR)—The AVMA's current definition of the VCPR is utilized as a model by FDA and state veterinary practice acts. Considering that VFDs require a VCPR, it is unclear whether the current definition of VCPR will best serve the profession if it were integrated as a requirement for the use of all antimicrobials in feed.

Unintended Consequences

The Task Force also examined potential unintended consequences of implementing greater veterinary stewardship over the use of antimicrobials and found several possible ramifications:

- Diminished veterinary workforce—Greater responsibilities and potential liability risks associated with violative residues or other antimicrobial use—associated concerns could deter interest in food supply veterinary medicine. In addition, alienation of producers who may not favor additional costs associated with greater veterinary involvement and reduction in profitability of animal agriculture as a whole may further deter food supply career interests.
- Reduced economic viability of food animal stakeholders—Greater veterinary stewardship of antimicrobial access and use has the potential to adversely affect some small producers, who currently can purchase and treat their own animals (with a limited number of older over-the-counter antimicrobials) when a veterinarian is unattainable for whatever reason (cost, physical proximity, or timing). Small feed mills who cannot comply with new regulations might be forced to shut down, further affecting producers' efficiency or ability to feed their animals.
- Decreased animal health and welfare—Overly stringent regulations or cumbersome requirements may delay delivery of medicated feeds, thereby allowing animal disease and suffering to progress. The delay of timely medication and subsequent decline in animal health may also impact food availability and safety. With an insufficient workforce, the added burden of recordkeeping and other logistics has the potential to shift focus from animal care to recordkeeping activities.
- Negative perceptions of veterinarians—The decision to increase veterinary stewardship may be perceived as an admission of guilt or an acceptance that greater oversight will improve resistance levels in humans. Increased stewardship also may be perceived as an effort to generate more income for veterinarians. Lastly, the use of paraprofessionals may be seen as an unwelcome necessity.
- Circumvention of the VCPR—A strict requirement for a VCPR may serve as an impetus for some clients to seek other routes for obtaining antimicrobials without any veterinary involvement.

Potential Benefits

Benefits of increased veterinary stewardship were also weighed:

• Enhanced consumer confidence—Greater veterinary stewardship has the potential to communicate to the public and others that the veterinary profession is addressing the concerns of antimicrobial resistance, thereby improving consumer confidence in the food supply and potentially

deterring further efforts to minimize or eliminate important uses of antimicrobials. Such stewardship may also facilitate understanding by consumers that feed administration is an appropriate route of administration for antibiotics in food animals.

- Improvement in animal and human health—Improvement in animal health and human health may be achieved as a result of the increased veterinary involvement. Enhanced stewardship could also drive the exploration of alternative husbandry practices and non-antibiotic therapies in addition to the reduction of violative residues.
- Increased funding for veterinary workforce needs—An increasing demand for food supply veterinarians may lead to increased funding in support of initiatives and incentives aimed at increasing the veterinary workforce.
- Increased clarification of the VCPR—Although many states address the VCPR, in federal regulations, it is only defined with regard to extralabel drug use and the VFD. Increasing veterinary stewardship may inherently require the VCPR definition to be applied more broadly or be further clarified.
- Facilitation of antimicrobial use monitoring—Through greater stewardship, data collection specific to antimicrobial use may be easier, providing a basis for continued research and data collection. There may also be a reduction in antimicrobial use or improvement in strategic uses as a result of monitoring.

Possible Effects of Veterinary Stewardship on Relevant Stakeholders

In addition to possible effects of increased stewardship on food supply veterinarians, the AUTF believed it was important to understand how other stakeholders are currently affected by growth promotion and feed efficiency uses, since production uses could be impacted by changes in stewardship. The AUTF asserted that by examining the issue through different "lenses" or points of view, a strategy that was mindful of all stakeholders and interest groups could be developed. The six stakeholders or interest groups that were identified were the public, producers, regulators, legislators, human and public health officials, and veterinarians. The Task Force weighed both positive and negative perceptions, concerns, and opinions by stakeholders, regarding antimicrobial use for growth promotion and feed efficiency. A number of ways forward were identified to meet the needs of each stakeholder group. Some consistent themes emerged

that would maximize the benefits while minimizing the risks associated with the continued use of these products.

In the facilitated group discussion, the following stakeholder groups were identified by the Task Force:

- The public—American Medical Association, Infectious Diseases Society of America, and the American Society for Microbiology.
- Federal agencies—Centers for Disease Control and Prevention, USDA-Animal and Plant Health Inspection Service-Veterinary Services, and the FDA Center for Veterinary Medicine.
- Producers—National Pork Producers Council, National Milk Producers Federation, United Egg
 Producers, National Cattlemen's Beef Association, National Chicken Council, American Feed Industry
 Association, National Turkey Foundation, American Sheep Industry Association, and the National Pork
 Board.
- Species groups—American Association of Avian Pathologists, American Association of Bovine Practitioners, Association of Avian Veterinarians, American Association of Feline Practitioners, American Animal Hospital Association, American Association of Equine Practitioners, American Association of Swine Veterinarians, and the American Association of Small Ruminant Practitioners.
- AVMA Councils/Committees—Aquatic Veterinary Medicine Committee, Council on Biologic and Therapeutic Agents, Food Safety Advisory Committee, and the Council on Public Health and Regulatory Medicine.
- Specialty groups—American Academy of Veterinary Pharmacology and Therapeutics and the National Association of State Public Health Veterinarians.

Production Uses of Antimicrobials

The sections that follow are reflective of observations and potential ways forward by members and invited representatives of the Task Force as they considered the issue of production uses of antimicrobials. The Task Force first explored the potential public perceptions; followed by perceptions of producers, legislators, regulators, and human health and public health professionals; and then finally the veterinary perspective.

Public Perception

The group believed that some members of the public may have an understanding of some positive characteristics of growth promotion and feed efficiency antimicrobial use in food production animals:

- Presently, the use of antimicrobials in food animals provides for a reduced cost for food of animal origin. A reduction in the amount of animal feed consumed and resulting reduced cost to the farmer translates to savings to the consumer. Price is often the primary driver in the consumers' purchase of foods of animal origin.
- Antimicrobial use could decrease the potential for animal suffering and promote well-being.
- Increased feed efficiency decreases the need for crops grown for animal feed and lessens the amount of animal waste, thereby reducing the animals' carbon footprint.

However, the Task Force also acknowledged that members of the public may be entirely unaware of the distinction between the different uses of antimicrobials and that this sector may overlook any benefits of these uses.

The Task Force also identified what negative public views may exist regarding the use of growth promotion and feed efficiency antimicrobial use in food production. At the forefront of the discussion is the potential human health risks associated with agricultural uses of antimicrobials:

- In general, it can difficult for the public to understand why antimicrobials are given to animals that are not obviously sick.
- There is a commonly held belief that anything extraneous in human food is inherently bad. This, coupled with a lack of understanding of withdrawal times, results in the public's assumption that antibiotics given to animals are contained in the animal products and are readily consumed by the public.
- Many believe that the use of growth promotion and feed efficiency antimicrobials is only necessary due to bad management practices and poor animal husbandry. Recent news reports are a good example of the negative perception of modern agricultural farms often referred to as "factory farms."

- While the consumer generally trusts small family farmers, there seems to be distrust of the larger food producers and intensive farming systems, citing a lack of transparency as the cause. The belief that growth-promoting antibiotics provide an economic incentive for producers and pharmaceutical companies only adds to consumer mistrust.
- There is currently mixed messaging presented to the public regarding antimicrobial use, and the various marketing terms ("naturally raised," "raised without antibiotics," etc) can add to the confusion.

The Task Force identified two focus areas for the AVMA to communicate to the public the benefits and costs related to growth promotion and feed efficiency uses:

- 1) Proactive communications—Relay honest, objective, and transparent communication regarding risks and benefits of growth promotion/feed efficiency antimicrobial use in animals.
- 2) Reactive communications:
- Coordinate responses to the concerns of the public regarding antimicrobial issues. The Task
 Force finds that there is no clear definition of acceptable risk related to use of antimicrobials in animal agriculture. Perhaps by increasing media communications for education and outreach to the consumers, acceptable risks can be further defined and risks even mitigated.
- Involve non-food animal veterinarians in educational and outreach efforts as these veterinarians are well recognized as knowledgeable health professionals and have significant interaction with the public.
- Consider gaining assistance of an independent third party that is trusted by the public to relay accurate information.

The Task Force believes that members of the public at large may not know or understand the true risk factors associated with antimicrobials used in food animals. Thus, for the most part, those perceptions shape their reality.

Producer Perspective

The Task Force discussed the current issues facing producers in regards to growth promotion and feed efficiency antimicrobial use:

- Various interpretations of the Danish experience, where antibiotic growth promoters were banned, were included in both positive and negative characteristics of production uses.
- Positive characteristics include increased efficiency, healthier animals, increased profitability, low mortality, more environmentally friendly, and improved growth rates—less feed per pound of gain.
- Negative characteristics relative to growth promotion and feed efficiency antimicrobial use were also discussed:
 - Public perceptions—Segments of the public believe that growth promotion and feed efficiency
 antimicrobial uses are inherently wrong and that producers are large corporations with only
 economic gain in mind. This negative perception lends the potential for increased liability due to
 human health concerns.
 - Contribution to antimicrobial resistance—Producers also recognize that growth promotion and feed efficiency antimicrobial use can contribute to increased levels of resistance in food animals but are also uncertain of the role it may play in human resistance trends and the environment.
 - Costs associated with the use of antimicrobials—Discussion targeted cost of the drugs themselves. Additional costs that are associated with not using the antimicrobials (increased feed costs, increased waste, and management costs) are often overlooked. Furthermore, smaller producers may not have the same resources as larger producers, may incur relatively greater costs per unit of production, and are potentially unable to compete with the niche of "antibiotic-free" producers.

To enhance the understanding of producers' use of growth promotion and feed efficiency antimicrobials, the Task Force identified several goals for the AVMA:

- Provide objective, scientific evidence.
- Promote the use of biotechnology and other novel tools.
- Promote innovative production practices as an alternative.

- Illustrate support for the benefits of antimicrobial use by advocating for healthy animals, safe food, and healthy people.
- Recognize that a healthy, economically viable livestock industry can be accomplished through intensive farming practices and by promoting positive aspects of those practices using more positive terminology.
- Advocate for changes to the formal curriculum for veterinary students and continuing education for veterinarians to encompass a broader spectrum of livestock systems.
- Exhibit objectivity regarding production animal health and welfare practices yielding antibiotic-free food. Remain objective on the issues allowing the AVMA to curtail any misconceptions of favoring industry.

Legislative Perspective

Legislators represent the public at large. Consequently, many of their individual views on this issue are similar to those of the public as discussed earlier. Given that legislators are also the voice of their constituent groups, a legislator from an agricultural area is more likely to have the needs and consideration of the producers at the forefront of the discussion, whereas a legislator from a non-agricultural or urban area is less likely to have an appreciation of food producers' issues.

Communication of accurate information is vital. Reports on this topic from the media and other popular information sources have raised concerns among legislators:

- Wastewater runoff from large farms has escalated environmental concerns to include discharge of antimicrobials.
- Continued use of growth promotion and feed efficiency antimicrobials might restrict certain exports, impact trade, and have a negative financial impact on the US economy.
- Lack of definitive proof that the use of growth promotion and feed efficiency antimicrobials in food animals does not contribute to resistant infections in humans is especially disconcerting to the legislators.

The Task Force agreed that clarity and framing of context in communication efforts with the legislative group is paramount. Furthermore, the AVMA must continue to advocate for objective research to inform all policy makers.

Regulators Perspective

The Task Force discussed its appreciation for the intentionally thoughtful deliberate pace of federal regulatory processes, which allow the agencies to make careful and well-informed decisions. Once federal agencies promulgate Final Rules, there is extreme difficulty in altering those regulations.

Therefore, Task Force members agreed that it is important to build a healthy relationship with regulators whereupon further engagement, communication, and outreach are necessary to be more effective. Regulators often seek professional input to ensure a thorough understanding of issues. In addition, studies are rarely black and white and do not clearly elucidate cause and effect, which is why some members of the Task Force believed there was a need for clear, concise communication for regulators where:

- The AVMA could be available to provide regulators with the data and science needed to support and enforce regulations, in addition to information that may be contrary to proposed regulations.
- Communication could comprise an acknowledgment that significant human health hazards are or are not associated with the current use of growth promotion and feed efficiency antimicrobials.

Human Health and Public Health Perspectives

As the One Health concept has gained greater recognition and support, human health professionals have expressed a strong desire to be engaged and discuss these issues. The Task Force meetings revealed human health professionals are often vocal regarding their concerns of antimicrobial use in animal agriculture, including how antimicrobial use affects food security and the availability of affordable, nutritious, and sustainable food animal products.

Barriers to open dialogue and communication between veterinarians and their human medical counterparts still exist. Although several organizations invited to the Task Force meetings have current policies in place specifically opposing use of antimicrobials for certain purposes, including growth promotion and feed efficiency in food producing animals, for other organizations, it is unclear if any therapeutic uses would also be unacceptable. These organizations are open to revisiting policies relative to food animal health and the use of growth promotion and feed efficiency antimicrobials based on scientific information. In addition, most health professionals present at the Task Force meetings recognized that human use of antimicrobials is the primary driver of human resistance, yet the extent of the contribution to human resistance from the use of antimicrobials in animal agriculture continues to be unknown and heavily debated. Another grave concern expressed by the human health community is the availability of antimicrobials without a prescription and limited or no oversight of a veterinarian.

The AVMA must acknowledge that discordant policies exist and an existing framework should be utilized to implement changes in policy across organizations. Therefore, the Task Force agreed that antimicrobial resistance should be a key topic related to the One Health Initiative, which comprises both AVMA and human medical organizations:

- The One Health Initiative could serve as a conduit to strengthen collaboration on scientific issues with other health professional organizations such as the American Medical Association. Furthermore, the One Health approach could be utilized to gain other professional perspectives and share the veterinary profession's positions more broadly.
- In addition, the Task Force supports the concept of an entity created to consider conducting or facilitating a rigorous scientific analysis evaluating risks from continued use and discontinued use of growth-promoting antimicrobials. The Task Force recognized that the ability to conduct such studies remains unknown but acknowledged that illustration of benefits of antimicrobial use could foster relationships and understanding by our human health colleagues. Such studies could also facilitate use of consistent terminology and definitions among the relevant medical-oriented organizations.

Veterinary Perspective

The Task Force discussed division among veterinarians' views on use of antimicrobials for the purpose of growth promotion and feed efficiency:

- There is a lack of consensus on whether growth promotion and feed efficiency uses are judicious. The AVMA has policy clearly stating that it does not support broad-based bans of antimicrobials which would include growth promotion and feed efficiency use, yet it does not have clear policy indicating whether or not such uses are judicious. There are concerns among veterinarians that growth promotion and feed efficiency antimicrobials may not be a judicious use of these valuable products.
- Beyond whether production uses are judicious, a variety of views exist on the responsibility of growth promotion and feed efficiency uses. Scientifically, there is no doubt that there are a multitude of benefits and strong evidence supporting the use of antimicrobials for animal health and welfare as well as food protection. However, concerns remain that unacceptable risks may still be posed to human health if these uses are a significant driver of the development or transmission of resistance. Similarly, there are also concerns of risks posed to animal health even though some risk assessments have shown a minimal risk to humans.
- An additional view held by some veterinarians comprises the appreciation of the direct relationship between economic viability for producers and economic viability for veterinarians. Some among the Task Force also noted a benefit in antimicrobial use as a means to conserve animal resources.
- A general lack of knowledge regarding the use of antimicrobials for weight gain or feed efficiency also exists within the veterinary profession. When coupled with a lack of understanding of drug availabilities and distribution processes, the discussion of increasing veterinary oversight and the potential for prescription-only antimicrobials becomes considerably more complex.

Following the conclusion of the second in-person meeting, the Task Force recognized that although the many perspectives had been well elucidated, different opinions surrounding production uses remained. As a result, a subcommittee of four Task Force members representing the most divergent viewpoints was appointed to continue the work of the Task Force. Two subcommittee reports reflected

the work of the subcommittee, providing background and justification for: 1) potentially phasing out the use of antimicrobials (specifically those important in human medicine) for production uses, and 2) for veterinary involvement and potential increased oversight of all uses of antimicrobials. In spite of the diligent efforts of both the subcommittee and the entire Task Force, consensus on the issue of growth promotion and feed efficiency uses of antimicrobials was not reached. The Task Force recognized strong differing views among its members on this issue. When this conclusion was presented to the AVMA Executive Board at its April meeting, the Board requested that AVMA staff draft a report on the activities of the AUTF for Task Force members to review. The AUTF members have reviewed and approved this report.

Status of the Science of Antimicrobial Resistance

The Task Force agrees that the use of antimicrobials can select for altered populations of bacteria and that resistant bacteria can be transmitted from animals to humans in several ways (including via food). Although the use of antimicrobials in humans is the major driver of human antimicrobial resistance, whether or not illness in humans due to resistant bacteria can also be linked to growth promotion or feed efficiency uses of antimicrobials in food animals continues to be debated. Some studies suggest a relationship between such use in food animals and human resistance trends while other studies and risk analyses find no such relationship. Therefore, the AUTF came to consensus on the need for an evaluation and continued monitoring of health effects of veterinary-administered antimicrobials on both veterinary and human therapeutic efficacy.

The Task Force discussed the need for judicious use of all antimicrobials that are important for therapeutic uses in both human and veterinary medicine, regardless of how they were obtained.

Therefore, the Task Force supports AVMA's creation of an entity charged with performing a structured and systematic review of relevant data related to antimicrobial use in animals and its impact on animal and public health.

The Task Force believed that an entity charged with reviewing previous published reviews and relevant data related to antimicrobial use in veterinary medicine would serve the purpose of empowering veterinarians, stakeholders, and representatives of the AVMA to develop positions based on the best possible information and interpretation. Furthermore, they identified a need to determine the magnitude and duration of the changes in antimicrobial resistance (exposures exerting selection pressure and adding to development or transmission of resistance) in addition to identifying the effects that those changes may have on the ability to treat diseases.

The AUTF recognizes that this undertaking will require more resources than typically expended for several Task Force meetings, yet the importance of this topic has the potential to recruit significant outside funding from partners. Some have advocated for a more detailed evaluation (risk assessments) based upon specific drug, regimen, and pathogen combinations rather than broad general discussions that were the focus of the AUTF. Such risk assessments would serve as a starting point to develop a scientifically rigorous policy including the definition of "acceptable risk." Additionally, some individuals had proposed that demonstrating animal health and food safety benefits and separating the growth promotion aspects from the therapeutic (prevention, control, and treatment) could mitigate risks of losing other applications of these antimicrobials. As an aside, veterinary students and veterinary colleagues could also benefit from learning specifics on both the positive and negative aspects of growth promotion and feed efficiency uses as a basis of understanding from which to formulate their opinions.

Although the efforts cannot provide definitive answers as to the drivers of antimicrobial resistance, it can provide an awareness of the complexity of the issue and an understanding of the data in addition to various perspectives and interpretations. Furthermore, as the debate continues with some believing there is a preponderance of evidence and others believing more data are needed, an objective assessment of current literature prior to investing in and initiating an extensive risk analysis protocol would be prudent.

Outcome

The Task Force discussed a wide variety of issues relative to its charge and objectives. The members agreed that there is a significant lack of data and a lack of understanding among our profession as well as the public and other stakeholders regarding the use of antimicrobials in food animal production. These gaps, coupled with inconsistent information from varying sources, clouds the decision-making process. Data gaps and differing interpretations drive distinct causal attributions and potentially contrasting conclusions.

While attempting to characterize the level of veterinary involvement as mandated by its charge, the Task Force found that terms such as veterinary "involvement," "oversight," and "stewardship" had no clear definitions. The only terms clearly understood and agreed upon by the Task Force are defined in federal regulations. For example, "over the counter" refers to drug availability, not veterinary involvement. Prescription-only products place additional restrictions on drug availability on the prescription or other order of a licensed veterinarian. The Task Force discussed that restricting antimicrobials to prescription-only use does not guarantee improved veterinary involvement or a valid VCPR, nor does it guarantee an improvement in judicious uses or resistance levels. Furthermore, attempts to require a veterinary prescription for all antimicrobials has the potential for multiple challenges and unintended consequences. Some among the Task Force relayed that veterinarians with their unique training, knowledge, and expertise are the only animal caretakers who have the ability to decide when antimicrobial use is appropriate and judicious. Regarding stewardship, the Task Force could only agree that veterinarians should be involved in the use of antimicrobials but it could not characterize the level of involvement needed.

As previously stated, antimicrobial growth promoters are available as over-the-counter products and, as such, are sometimes perceived as an injudicious use of antimicrobials. Yet, some would argue that over-the-counter availability is not equivalent to lack of oversight and thus not necessarily injudicious. Along those same lines, as judicious therapeutic use has been defined by AVMA to only include treatment, control, and prevention, some may interpret that to mean growth promotion and feed efficiency uses are not judicious because they are excluded from the definition of therapeutic. An alternative interpretation

would be that growth promotion and feed efficiency uses are simply not therapeutic, but no judgment is made on the judiciousness of such uses.

There were also a few philosophical components to the debate on the science of growth-promoting antimicrobials and how they should be used:

- One of the components hinges on the burden of proof. If clear evidence illustrating the harm to human health cannot be proven or if the harm to humans is insignificant, then continued use is appropriate given the societal benefits of these products. Converse views were relayed among the Task Force, stating that if clear evidence illustrating no harm is lacking, then continued use still is inappropriate given the potential for human harm, regardless of the benefits.
- A second component surrounds the perceived quality of evidence. While there is a body of evidence that supports one position, or the opposing position, or even both, much of the end result is dependent upon an individual's interpretation of the science and the preferred strategies. Attempts to remove growth promotion uses were seen by some as politically driven and not based upon scientific evidence, thus potentially secondarily impacting the ability to use antimicrobials for therapeutic purposes. Others among the Task Force indicated acceptance of the available data and viewed removal of these products as a logical way forward.

Conclusion

The AVMA Antimicrobial Use Task Force (AUTF) was convened to evaluate all uses of antimicrobials and clarify the veterinarians' role in those uses. Following two in-person meetings and many conference calls, the Task Force identified that the issues surrounding antimicrobial use in veterinary medicine are multifaceted, involving highly complex information as well as a multitude of scientific unknowns. Yet, the Task Force also recognized a less technical component of the issue wherein learned professionals can evaluate the same data and come to differing conclusions. The Task Force offered an opportunity for exchange of information, and the members gained greater understanding of differing perspectives. The purpose of the report of the AUTF is to share the breadth and complexity of the issues and identify the many perspectives.

Upon the AUTF's submission of its report to the EB, the EB will determine and forward its final recommendation to the House of Delegates for consideration at the 2010 Annual Session of the AVMA.

The AUTF will sunset at the close of the 2010 Annual Session of the House of Delegates.

AUTF Members

- Dr. Daniel E. Lafontaine, Chair
- Dr. John R. Brooks, Executive Board Liaison
- Dr. Michael D. Apley, American Academy of Veterinary Pharmacology and Therapeutics
- Dr. Henry E. Childers, American Animal Hospital Association
- Dr. Timothy S. Cummings, American Association of Avian Pathologists
- Dr. Virginia R. Fajt, American Association of Bovine Practitioners
- Dr. Keven Flammer, Association of Avian Veterinarians
- Dr. Donald E. Hoenig, Council on Public Health and Regulatory Veterinary Medicine
- Dr. Scott Hurd, Council on Biologic and Therapeutic Agents, Epidemiology
- Dr. Lorraine K. Jarboe, American Association of Feline Practitioners
- Dr. Harold C. McKenzie III, American Association of Equine Practitioners
- Dr. Mark Dr. Starr, National Association of State Public Health Veterinarians
- Dr. John T. Waddell, American Association of Swine Veterinarians
- Dr. E. P. Scott Weber III, Aquatic Veterinary Medicine Committee
- Dr. Christine B. Navarre, American Association of Small Ruminant Practitioners

AVMA Staff

- Dr. Christine Hoang, Assistant Director, Scientific Activities Division
- Dr. Kristi Henderson, Assistant Director, Scientific Activities Division
- Ms. Jennifer McBride, Staff Assistant, Scientific Activities Division

Facilitator

Dr. Kenneth Andrews, High Impact Facilitation

EB Agenda: E-1a ATTACHMENT 2

APPENDIX A RESOLUTION 3—2009—Annual

Submitted by
New Jersey Veterinary Medical Association
Association of Avian Veterinarians
Washington State Veterinary Medical Association

JUDICIOUS THERAPEUTIC USE OF ANTIMICROBIALS POLICY

RESOLVED, that the American Veterinary Medical Association (AVMA) revise the Judicious Therapeutic Use of Antimicrobials Policy as indicated below (deletions are struckthrough):

Judicious Therapeutic Use of Antimicrobials Position Statement

When the decision is reached to use antimicrobials for therapy, veterinarians should strive to optimize therapeutic efficacy and minimize resistance to antimicrobials to protect public and animal health.

Objectives

Support development of a scientific knowledge base that provides the basis for judicious therapeutic antimicrobial use.

Support educational efforts that promote judicious therapeutic antimicrobial use.

Preserve therapeutic efficacy of antimicrobials.

Ensure current and future availability of veterinary antimicrobials.

Strategies

Facilitate development and distribution of appropriate antimicrobial use guidelines by practitioner species-interest groups.

Improve scientifically based therapeutic practices through education.

Recognized Needs

Improved monitoring and feedback systems for antimicrobial use and resistance patterns.

Research to improve scientifically based therapeutic practices.

Judicious Use Principles

Preventive strategies, such as appropriate husbandry and hygiene, routine health monitoring, and immunization, should be emphasized.

Other therapeutic options should be considered prior to antimicrobial therapy.

Judicious use of antimicrobials, when under the direction of a veterinarian, should meet all requirements of a veterinarian-client-patient relationship.

Prescription, Veterinary Feed Directive, and extralabel use of antimicrobials must meet all the requirements of a veterinarian-client-patient relationship.

Extralabel antimicrobial therapy must be prescribed only in accordance with the Animal Medicinal Drug Use Clarification Act amendments to the Food, Drug, and Cosmetic Act and its regulations.

Veterinarians should work with those responsible for the care of animals to use antimicrobials judiciously regardless of the distribution system through which the antimicrobial was obtained.

EB Agenda: E-1a ATTACHMENT 2

APPENDIX A

Regimens for therapeutic antimicrobial use should be optimized using current pharmacological information and principles.

Antimicrobials considered important in treating refractory infections in human or veterinary medicine should be used in animals only after careful review and reasonable justification. Consider using other antimicrobials for initial therapy.¹

Use narrow spectrum antimicrobials whenever appropriate.

Utilize culture and susceptibility results to aid in the selection of antimicrobials when clinically relevant.

Therapeutic antimicrobial use should be confined to appropriate clinical indications. Inappropriate uses such as for uncomplicated viral infections should be avoided.

Therapeutic exposure to antimicrobials should be minimized by treating only for as long as needed for the desired clinical response.

Limit therapeutic antimicrobial treatment to ill or at-risk animals, treating the fewest animals indicated.

Minimize environmental contamination with antimicrobials whenever possible.

Accurate records of treatment and outcome should be used to evaluate therapeutic regimens.

¹In this context, this principle takes into account development of resistance or cross-resistance to important antimicrobials.

Glossary:

*These terms are to be defined and utilized in the context of Judicious Therapeutic Use, with the intent of focusing on antimicrobials that may be of significance to human health. They are to be applied to the principles of Judicious Use outlined within the context of this document.

Antibiotic—a chemical substance produced by a microorganism which has the capacity, in dilute solutions, to inhibit the growth of or to kill other microorganisms.

Antimicrobial—an agent that kills microorganisms or suppresses their multiplication or growth.

Broad Spectrum Antimicrobial—a type of antimicrobial effective against a large number of bacterial genera; generally describes antimicrobials effective against both Gram-positive and Gram-negative bacteria.

Narrow Spectrum Antimicrobial—a type of antimicrobial effective against a limited number of bacterial genera; often applied to an antimicrobial active against specific families of bacteria.

Antimicrobial Resistance—a property of microorganisms that confers the ability to inactivate or elude antimicrobials or a mechanism that blocks the inhibitory or killing effects of antimicrobials.

Extralabel Use—actual use or intended use of a drug under veterinary direction, in an animal in a manner that is not in accordance with the approved labeling. This includes, but is not limited to, use in species not listed in the labeling, use for indications (disease or other conditions) not listed in the labeling, use at dosage levels, frequencies, or routes of administration other than those stated in the labeling, and deviation from the labeled withdrawal time based on these different uses.

Immunization—the process of rendering a subject immune or of becoming immune, either by conventional vaccination or exposure.

Monitoring—periodic health surveillance of the population or individual animal examination.

EB Agenda: E-1a ATTACHMENT 2

APPENDIX A

Therapeutic—treatment, control, and prevention of disease.

Veterinarian-Client-Patient Relationship (VCPR)—a relationship where all of the following conditions have been met:

- 1. The veterinarian has assumed the responsibility for making clinical judgments regarding the health of the animal(s) and the need for medical treatment, and the client has agreed to follow the veterinarian's instructions.
- 2. The veterinarian has 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.
- 3. The veterinarian is readily available for follow-up evaluation, or has arranged for emergency coverage, in the event of adverse reactions or failure of the treatment regimen.

Veterinary Feed Directive (VFD) Drug—category of medicated feeds created by the Animal Drug Availability Act of 1996 to provide an alternative to prescription status for certain therapeutic animal pharmaceuticals for use in feed. 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.

Statement about the Resolution

The organization representing the veterinary profession in the United States should have as organizational policy the clearly stated, unequivocal concept that veterinarians are the gatekeepers and decision makers regarding judicious use of antimicrobials. There should be no exclusion in policy that suggests or implies that judicious use is only appropriate when under the direction of a veterinarian. The veterinary professional education, knowledge, experience, and licensure render the veterinarian as the only, without exclusion, entrusted individual in ensuring judicious use of antimicrobials. To state that the judicious use only applies when such use is under the direction of a veterinarian suggests tacit approval of non-judicious use. Furthermore, the current policy states that judicious use should meet all requirements of a veterinarian-client-patient relationship but states that the relationship is not important when antimicrobial use is excluded from the direction of a veterinarian.

Once established as policy, this policy should supersede and be applied to all AVMA policies in which similar wording and/or intent is present.

The cornerstone of the veterinary oath is enhanced by AVMA policy statements. It is incumbent on the AVMA to pronounce that judicious antimicrobial use is uniquely the role of the veterinarian, without exclusion.

Financial Impact: None

	RECOMMEND APPROVAL	RECOMMEND DISAPPROVAL	REFER TO	NO RECOMMENDATIO N
Executive Board		Х		
House Advisory Committee		Х		
Reference Committee #7	REFER TO EB			####

(*Use this space for additional narrative, if needed.)

APPROVED	DISAPPROVED	REFER TO

APPENDIX A

		.*
HOD ACTION		EB

APPENDIX B

Antimicrobial Use Task Force

The Antimicrobial Use Task Force is charged to clarify the veterinarian's role and level of involvement in all uses of antimicrobials through a science based evaluation.

- Any recommendations must consider the practicality of and identify barriers to implementation.
- Where it is determined that a veterinarian needs to be involved, the level of involvement must be characterized.
- All AVMA policies that may be affected must be considered and, where necessary, revised.

Membership, Method of Appointment, and Representation

Each of the following organizations are invited to nominate a veterinarian to serve on the Task Force.

American Association of Avian Pathologists

American Association of Bovine Practitioners

American Association of Equine Practitioners

American Association of Feline Practitioners

American Animal Hospital Association

American Association of Swine Veterinarians

Association of Avian Veterinarians (representing AAV, Association of Exotic Mammal Veterinarians and Association of Reptilian and Amphibian Veterinarians)

American Academy of Veterinary Pharmacology and Therapeutics

Aquatic Veterinary Medicine Committee

Council on Public Health and Regulatory Veterinary Medicine

Council on Biologic and Therapeutic Agents, representing epidemiology

Food Safety Advisory Committee, also representing the American Association of Small Ruminant Practitioners

National Association of State Public Health Veterinarians

Chair of the 2008–2009 House Advisory Committee Reference Committee #7 (Scientific Activities)

The Executive Board Chair appoints the members of the Task Force. If the appointed member cannot attend a meeting of the Task Force, the nominating organization may send an alternate, pending approval of the Executive Board Chair.

Liaisons:

Executive Board Liaison

Invited Representatives (non-voting):

American Feed Industry Association

Animal Health Institute

American Medical Association

American Sheep Industry Association

American Society for Microbiology

Centers for Disease Control and Prevention

Food and Drug Administration, Center for Veterinary Medicine, representing science policy

Infectious Disease Society of America

National Aquaculture Association

National Cattlemen's Beef Association

National Chicken Council

National Grain & Feed Association

National Milk Producers Federation

National Pork Board

APPENDIX B

National Pork Producers Council
National Turkey Federation
United Egg Producers
United States Department of Agriculture, Animal and Plant Health Inspection Service, Veterinary Services

Chair

The chair of the 2008–2009 House Advisory Committee Reference Committee #7 (Scientific Activities) will chair the Task Force.

Meetings

The Antimicrobial Use Task Force is authorized to meet up to two times in Schaumburg.

Funding

Travel expenses are authorized in accordance with the AVMA Travel Policy.

Reports

The Task Force will provide its recommendation to the Executive Board. The Executive Board will provide a resolution to the House of Delegates for final consideration.

Life Expectancy

The Task Force will be sunset following action on the resolution by the House of Delegates at its 2010 Annual Session.

October 16, 2009