Organized Veterinary Medicine Representing the Interests of the Bovine Practitioners

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The previous speakers at this general session, "Consumer Concerns, Producer Demands, the Veterinarian's Responsibility", have provided you with a comprehensive overview of the generic subject of food safety from the view of drug use in bovines and as it applies to the bovine practitioner. It remains for me to provide you with an overview of organized veterinary medicine's role in providing for the interests of practitioners in this scenario.

For purposes of this discussion, organized veterinary medicine is defined to mean the American Veterinary Medical Association (AVMA) and all of the constituent and allied organizations which legislatively govern AVMA through actions of its House of Delegates (HoD). The American Association of Bovine Practitioners (AABP) delegate to this body is Dr. Bob Keith; alternate delegate is Dr. Harold Amstutz.

Since extra label use of drugs (ELUD) is the focus of attention for bovine practitioners, it may be appropriate to take a retrospective look at the matter of ELUD. Just prior to the 1983 AVMA Convention in New York, the Food and Drug Administration's (FDA) Bureau of Veterinary Medicine, i.e. the current Center for Veterinary Medicine (CVM) elected to change a long standing extra lable veterinary drug use policy which had governed the conduct of use of pharmaceuticals by food animal practitioners. The policy which was rescinded simply stated that a food animal practitioner could use any pharmaceutical agent which could be legally obtained provided that there was an assumption of responsibility on the part of the veterinarian and owner of the treated animal for any violative residue or adverse reactions that might result from such use. From this policy envolved the FDA Compliance Policy Guide 7125.06, Nov. '86 (copy attached) to which food animal practitioners and producers must adhere. This policy, with which we are all familiar, is recognized to be more restrictive than that which it replaced. Nonetheless, it gives practitioners a clear perception of that which is expected of them, delineates clearly certain responsibilities which the food animal practitioner must accept if drugs are to be used in an extra label fashion, includes the profession's long accepted AVMA (1) definition of a veterinarian-client-patient relationship and enunciates clearly that professionally unauthorized ELUD is prohibited. It would be my opinion that those responsible for effecting the policy change actually had in mind that the new ELUD policy would provide the consumer of food of animal origin, an assurance that food animals treated in an ELUD manner were free of violative residues before they entered the food chain. This would also be true for milk. Organized veterinary medicine played a consultant role to FDA/CVM in their efforts to allow veterinary practitioners to continue to use drugs in an extra label manner. When one recognizes that the veterinary provisions of the Food, Drug and Cosmetic Act (FDCA) does not provide legal language for ELUD in veterinary medicine, it comes as no surprise that the information Dr. Held presented to you represents a very significant effort by AVMA. To achieve statutory recognition for a procdure which most of us find to be a necessity in bovine practice will place the bovine practitioner on much firmer footing than is currently the case under FDA Compliance Policy Guide 7125.06 (Nov. '86) for then we will not be practicing "illegally".

In 1988 the efforts of organized veterinary medicine successfully achieved statutory recognition for the class of drugs we know as veterinary prescription drugs (Rx drugs), i.e. those drugs which bear the FDA legend, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarinan". This subject has already been addresed. The only comment that will be added, is to state that this legislative accomplishment set the stage for the ELUD legislative initiative and also provided veterinary practitioners with one-half of the legislative authority to practice in a manner to which our colleagues in human medicine are privileged. The extra label use of drugs is the other half of this privilege. As we are aware, the difference that exists in human medicine is that physicians have the authority under the FDCA to use a pharmaceutical in a manner for which the drug was not approved, provided the patient agrees to that form of therapy. The veterinarian's ability to use drugs off-label is not authorized under FDCA. Understandably ELUD is an extremely more complicated issue in food animal medicine for ELUD must equate to a safe human food supply.

There is currently an ongoing activity by organized veterinary medicine and the Animal Health Institute in regard to flexible labeling. The CVM is involved in this effort in a consultant manner. One of the hopeful end-points of this cooperative endeavor is to establish a veterinary label which has a basis in pharmacokenetics that allows veterinarians to exercise scientific judgement in the use of phar-

maceuticals in the course of treating animals within the scope of their practice. Another of the results of the committee's efforts might be a label entity for veterinary medicine that currently exists for human medicine. This is a professional label which cites restricted uses for over-the-counter (OCT) products. As an example, aspirin, a human OTC drug, contains restricted label information for physicians which pertains to use of this drug in preventing heart disease. To conclude this topic it would be well to cite the charge to which the AVMA Committee on Flexible Labeling is responsible "...to describe the scientific data requirements, the rationale for these requirements and to identify the necessary changes in the regulatory process that would allow revision of labeling criteria for animal drugs used under the supervision of a veterinarian". Such would preclude that the professional activity authorized by such a professional label would be conducted under the authority of a bonafide veterinarian-client-patient relationship and with emphasis on food safety. In concert with the activities regarding flexible labeling are the efforts of AABP in working with two pharmaceutical manufacturers to attempt to achieve bovine indications on dosage labels for two commonly used OTC drugs, this is yet another example of organized veterinary medicine working to resolve pharmaceutical issues which are important to bovine practitioners.

Another effort involving organized veterinary medicine in regard to pharmaceutical issues and veterinary practice focuses on dairy practice and the human food that results from dairy production, milk and wholesome meat from cull dairy cows. This activity which has been ongoing for over a year now, demonstrates a cooperative effort by National Milk Producers' Federation (NMPF) and AVMA to establish a drug use quality assurance program for the dairy industry and to address pharmaceutical use, storage and related matters as these issues interact with the Pasteurized Milk Ordinance (PMO). AABP has representation in this effort. Practicing veterinarians will be highly visible in this milk quality assurance activity and play an important role in its implementation.

The Guidelines for Supervising Use and Distribution of Veterinary Prescription Drugs (2) which the AVMA House of Delegates approved in 1988 provides further evidence of organized veterinary medicine in action. These Rx guidelines were developed by AVMA's Council on Biologics & Therapeutic Agents (CoBTA) with input from a variety of professional organizations and provide for the practitioner a management scheme for handling Rx drugs and ELUD. CoBTA has the responsibility to identify and study and to suggest policy action to AVMA's Executive Board on matters relating to drugs and biologics. The Drug Availability Advisory Committee serves as an advisory role to CoBTA and has representation on it from all of the species allied associations such as AABP.

One could continue to give additional evidence of the efforts of organized veterinary medicine in behalf of the bovine practitioners, the issue of sulfamethazine and milk and organized veterinary medicines responses at FDA hearings, liaison activities of AVMA's Food Animal Task Force (FAVOR) to aid in communicating the profession's views to producer organizations are two additional examples and there are more that could be cited.

In closing, let me share with you this thought regarding organized veterinary medicine. Ladies & gentlemen, we are not a large profession, numbering in the U.S. somewhere in the 50 thousands. AVMA membership stands at nearly 49,000 and AABP about 4800+. Each of us speaking individually results in a mere murmur. When we speak in unison, as organized professionals, the many voices become a sound that commands recognition. A profession as small and as diverse in species' responsibility and interest as ours is, mandates that issues must be decided by sound rational thought provoking processes and equally sound decisions must be rendered to determine which organization is most qualified to orchestrate those many voices into a single voice that warrants a response. This requires that all of the individual professional organizations that make up the infrastructure of organized veterinary medicine, recognize their various roles and excercise a willingness to recognize their limitations, to compromise by accepting a reasonable solution to problems, structure committees and task force groups to enable responsible liaison between professional organizations to occur and finally to cooperate as one profession with a single voice that can be heard.

References

1. AVMA Directory, pg. 693. 2. JAVMA, Oct. 1, 1988

FOOD AND DRUG ADMINISTRATION COMPLIANCE POLICY GUIDELINES

SUBJECT: Extra-Label Use of New Animal Drugs in Food-Producing Animals

BACKGROUND

Concern over the extra-label use of drugs in treating food-producing animals and the possibility that human food may become adulterated with illegal drug residues from such misuse has prompted a revision in the Center for Veterinary Medicine (CVM) extra-label drug use policy. Under the revised policy, a finding of illegal drug residues no longer will be a prerequisite for initiating regulatory action based on extra-label drug use of drugs in food-producing animals.

For the purpose of this policy, "extra-label use" refers to the actual or intended use of a new animal drug in a food-producing animal in a manner that is not in accordance with the drug labeling. This includes, but is not limited to, use in species or for indications (disease or other conditions) not listed in the labeling, use at dosage levels higher than those stated in the labeling, and failure to observe the stated withdrawal time.

FDA in the past has not sanctioned extra-label uses of drugs in food-producing animals, but the agency has stated that it would refrain from

instituting regulatory action against licensed veterinarains for using or prescribing in their practices any drugs they could legally obtain. Nevertheless, it has been FDA's position that veterinarians may be subject to regulatory action for any violative drug residues in human food resulting from their prescriptions, recommendations, or treatments contrary to label instructions. Similarly, *anyone* in the producing or marketing chain who could be shown to have caused illegil drug residues through extra-label use of drugs in food-producing animals has been subject to regulatory action.

POLICY

The use or intended use of new animal drugs in treating food-producing animals in any manner other than in accord with the approved labeling causes the drugs to be adulterated under the Federal Food, Drug, and Cosmetic Act (the Act) (sections 501 (a) (5) and (6), 512 (a) (1) (A) and (B), 512 (a) (2)). The agency will consider regulatory action when such use or intended use is found, whether by a veterinarian, producer, or other person. Regulatory actions will also be considered against distributors and others who might cause adulteration of approved new animal drugs. Nevertheless, extra-label drug use in treating food-producing animals may be considered by a veterinarian when the health of animals is immediately threatened and suffering or death would result from failure to treat the affected animals. In instances of this nature regulatory action would not ordinarily be considered provided all of the following criteria are met and precautions observed:

1. A careful medical diagnosis is made by an attending veterinarian within the context of a valid veterinarian-client-patient realtionship[1];
2. A determination is made that, (a) there is no marketed drug specifically labled to treat the condition diagnosed, or (b) drug therapy at the dosage recommended by the labeling has been found clinically ineffective in the animals to be treated;
3. Procedures are instituted to assure that identity of the treated animals is carefully maintained; and
4. Significantly extended time period is assigned for drug withdrawal prior to marketing meat, milk, or eggs; steps are taken to assure that the assigned timeframes are met, and no illegal residues occur.

Extra-label use of drugs in treating food-producing animals may under this policy, therefore, be considered only in special circumstances. The "exempting" criteria do not include drug use in treating food-producing animals by the layman. Lay persons cannot be expected to have sufficient knowledge and understanding concerning animal diseases, pharmacology, toxicology, drug interactions, and other scientific parameters to use drugs in treating food-producing animals in any way other than as labeled.

Certain drugs may not be used in treating food-producing animals even under the cited criteria. This includes chloramphenicol. Extra-label uses of drugs in treating food-producing animals for improving rate of weight gain, feed efficiency, or other production purposes, or for routine disease prevention are inappropriate as is use for therapeutic purposes other than under the circumstances described above. Also, the criteria cited above do not sanction the sale and use, for any purpose, of new animal drugs that are not approved, such as diethylstilbestrol (DES). Furthermore, a drug ⋆(including a bulk drug)⋆ may not be mixed into feed for any use or at a potency level not specifically permitted by the regulations in 21 CFR Part 558, even if prescribed or ordered by a veterinarian.

REGULATORY GUIDANCE

The highest priorities for regulatory attention regarding extra-label use are:

- Instances where illegal residues occur.
- Use of chloramphenicol or diethystilbestrol (DES) in food animals.
- ⋆Use of dimetridazole, iproinidazole, or other nitroimidazoles in unapproved species such as swine.⋆
- Manufactuers and distributors who promote extra-label use of drugs. The mixing of drugs into medicated feeds intended for extra-label use. Extra-label use by laymen at their own initiative.

Further guidance for investigations and regulatory action recommendations will be issued separately.

[1]A valid veterinarian-client-patient relationship, as defined by the American Veterinary Medical Association is the following:

> "An appropriate veterinarian-client-patient relationship will exist when:
> (1) the veterinarian has assumed the responsibility for making medical judgements regarding the health of the animal(s) and the need for medical treatment and the client (owner or other caretaker) has agreed to follow the instructions of the veterinarian: and when (2) there is sufficient knowledge of the animal(s) by the veterinarian 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) and /or by medically appropriate and timely visits to the premises where the animal(s) are kept; and when (3) the practicing veterinarian is readily available for follow-up in case of adverse reactions or failure of the regimen of therapy."

⋆ Material between asterisks is new or revised⋆

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