General Session I

"Consumer Concerns, Producers Demands: The Veterinarian's Responsibility"

Moderator: **Steve Vaughn**

Summary of Activities of the FDA/CVM Advisory Committee 1984-1988

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It is an opportune time to reflect on the VM/AC activity inasmuch as four years have elapsed since the recreated committee convened. I was privileged to serve this first committee as chairman. My selection indicates in part the confidence CVM places in the AABP.

The committee was very active during the years I served as chairman. I think it acted in a manner which has been helpful to the agency as well as the regulated industries and the American public. The issues considered by the committee were primarily requested from CVM. The following is a recap of some of the issues discussed by the committee along with its recommendations.

1. The committee was asked to consider the efficacy and labeling requirement for antimicrobial agents used in veterinary medicine.

   The committee recommended very specific criteria for generation of efficacy data in support of product label claims. In general, the recommendations favored increased flexibility in the generation of efficacy data in support of label clains. It also recommended the labels incorporate pharmacokinetic and other technical data which would accomodate a wider use of professional judgment in the use of these products. We saw this implemented with one or two small animal products.
2. The committee discussed the extra-label use of drugs in food producing animals and made the following reommendations.
   a. The committee acknowledged that at the present time extra-label drug use is needed and is unavoidable in providing humane and appropriate therapy for food aniamls.
   b. Found that current drug labeling is inadequate to fully direct drug usage in modern veterinary therapeutics.
   c. Recommended the development and application of methods to validate the absence of unsafe residues in food products.
   d. Encouraged CVM to work with veterinarians, producers, and drug manufacturers to develop improved methods and systems of assuring consumers that food producing products entering the retail market are free of violative residues.
3. The committee was asked to consider ways to improve the credibility and respect for the prescription veterinary legend.
   a. The committee recommended that the term "prescription" be replaced with the term "restricted" when referring to animal drugs to indicate the group of products for use exclusively under the direction of a veterinarian. It was not possible for this recommendation to become implemented even though it gained wide support including AHI.
   b. Recommended the NADA approval number be printed on the label.
   c. Recommended the prescription legend be highlighted and accompanied by a distinctive uniform logo and possibly colored-coded.
   d. Recommended that other confusing labels such as "for veterinary use only" be banned from product labels.
4. The committee was asked to critique a revision of the Rx/OTC labeling policies for Rx and OTC drugs. The committee recommended that products be approved only as Rx or OTC with none labeled as both, but if dual labeling was necessary, that CVM provide all label claims in the Rx product label for those products which are approved for both Rx and OTC designation.
5. The committee was asked to consider the criteria for determining Rx/OTC designation.
   a. Dual labeling - some drugs Rx and OTC - The committee approved in principle the concept of

designating those drugs used for therapy as prescription products and those products used for production enhancement as over-the-counter products.

b. The final action of the committee was the unanimous recommendation that:
   1. Designation of therapeutic drugs as Rx and production drugs as OTC become a major, although not exclusive, criterion in the Rx/OTC decision.
   2. The current guidelines for determining the classification of drugs (1240, 2220) be strictly implemented.
   3. A mechanism be instituted whereby drugs currently marketed OTC could be reviewed and reclassified as Rx if residue or other problems occurred.
   4. Compliance and enforcement activity be increased coincident with implementation of this recommendation.
   5. Residue testing and traceback activity increase.

c. The committee called upon producer groups, veterinarians, and federal agencies to give increased attention to the development of rapid screening testing for drug residues on the farm at slaughter or processing plants to develop improved means of identifying animals and animal products reaching the market so as to permit tracback of residues to their source to increase the frequency and sophistication of animal product testing. CVM should also consider the feasibility of requiring a rapid screening method for detection of drugs as part of the approval process and/or through a mechanism such as USDA's IR4 program.

Interspersed among the specific issues discussed were briefings by the agency about various aspects of the operation for the information of the committee members. Along the way numerous research protocols were also critiqued.

My overall assessment of the committee's activities during the 4 years I served as chairman is very positive. First, as I just reviewed, the committee made a significant number of very specific recommendations to CVM. Many of these have already been incorporated into the policies and procedures of the agency. Secondly, the committee has served as a forum for the discussion and hearing of views from a wide range of interested individuals and organizations. This was an unexpected benefit of committee activity the importance of which should not be underestimated. All meetings of the committee are open to the public and thereby provide a rare opportunity for everyone interested to enter into discussion with the management of the agency through its advisory committee.

In order for the agency to be understood and to have the support of the regulated industries, it must have a high level of voluntary compliance with its policies. This requires continual education and communication with all segments of the public with whom CVM interacts and impacts. The committee has helped with this task. This is an added benefit of the committee and one which I had not anticipated. This communication has taken place primarily as a result of the large number of media people who have regularly attended the meetings. Committee activities (CVM activities) have been widely reported in the press and have helped immeasurably in informing the public as well as enhancing feedback to the agency via the committee.

Because of the open forum format, all who personally attended the meetings have become better informed on the major issues facing the agency as well as hearing the discussions from agency employees and advisory committee members. The committee members themselves are afforded an opportunity to become very well informed about the operation of the agency and to consider its most pressing problems. Through the years these former committee members who come from all types of professional endeavors and from all geographic areas can provide an additional resource for support of and continued advice to the agency.

In the words of Director Guest there is a "quiet revolution" afoot in the country toward the end of achieving a higher degree of responsible drug use particularly in food producing animals. A large portion of this revolution is fueled by the interests of the livestock producers themselves as evidenced by the fact that producer groups such as the National Pork Producers and the National Milk Producers Federation have called for a voluntary ban on the use of sulfamethazine in swine and the National Cattlemen's Association who earlier called for a voluntary ban on penicillin and tetracycline. The committee should continue to play a large role in helping formulate and direct the policies which will achieve a higher level of responsible drug usage in animals and accomplishing it with the least disruption to production systems and in a cost effective manner. The agency itself is also evolving and has demonstrated a receptiveness to innovative thinking in the drug approval process specifically the idea of accommodating a "therapeutic window" for Rx products.

It should be remembered that the FDA can only control and direct a portion of the regulation pertaining to animal drugs. Many aspects are not under their jurisdiction and are completely out of their control. This means that we cannot totally blame FDA for deficiencies we see in the

drug delivery system, and that we must interact with more agencies than just FDA in affecting changes in this system.

Many initiatives are currently underway from a wide variety of sources with the aim of achieving more responsible and accountable animal drug use. Examples of these initiatives are: the Quality Assurance Program being developed by the major livestock producer organizations. These are coming about as a result of planning by National Milk Producers Federation in conjunction with the AVMA, the American Veal Association, National Pork Producers Association, Academy of Veterinary Consultants, and the National Cattlemen's Association. In addition the Association of Food and Drug Officials (AFDO), the organization of drug control agencies within the various states, has produced a model drug code which they are suggesting would be adopted in amended form in the various states. The AVMA has published guidelines for the use and distribution of prescription veterinary drugs. The Animal Health Institute has published a program specifically targeted at problem animal drugs and would involve education and regulatory control. Finally, CVM has devoted considerable time to evaluating the criteria for determining the Rx or OTC status of a new approved product.

It is interesting that nearly all of these initiatives rely heavily upon the food animal practitioners for implementation. In the final analysis it makes little difference if involvement of the veterinarian in achieving more responsible and accountable drug use occurs as a result of drug products being classified as Rx, involvement in quality assurance programs, or there is mandated involvement as a result of pharmacy laws within a state. The end result achieved remains pretty much the same. It is gratifying to realize that new programs envision and already implemented rely heavily on the practicing veterinarian for drug use supervision and for education of livestock producers.

It is unlikely that any single program will make a major impact. However, collectively all of these initatives including a gradual movement by CVM towards more prescription designation of newly approved animal drugs will likely have a major influence on achieving more responsible drug use with ultimate reduction in violative drug residues in livestock products. The veterinary medicine advisory committee has been an avenue by which programs can be launched, viewpoints can be developed, and trends can be started. It is my opinion and my hope that the VM/AC can continue to provide this type of forum.

The AABP must decide how much responsibility, control, and influence they wish to have and how great a role they wish to assume for bovine practitioners in the therapeutic use of pharmaceutical drugs in livestock production. These new and existing programs should be evaluated in this context and a decision reached as to which it wishes to support. The opportunity for AABP to influence the animal drug use system has never been greater. It is very important that the AABP recognizes the full spectrum of opportunities that exist. It is convenient for bovine practitioners to divorce themselves from all of the animal drug use controversies and remain in the loftier areas of production medicine and management, and let the animal drug system fend for itself. However, it is my judgement that bovine practitioners need to be positioned front and center, squarely in the middle of responsible and accountable drug use, taking a lead in directing how the animal drug use system should work and in implementing it. What did the VM/AC accomplish? It is difficult to assess after such a short time period. Moving the FDA and altering an industry such as the livestock industry is like moving a battleship. You don't get much movement by firing a few vollies across the bow and backing off. We can continue to make progress only by being presistent, accountable, responsible, persuasive, and by being positioned correctly for the best interest of the consuming public and the livestock industry we serve.