Towards the Responsible Use of Veterinary Drugs

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The citizens of this world are immersed in a chemical society, a social fabric largely held together by the intelligent use of agricultural chemicals, drugs, and other useful compounds. Paradoxically, the world order is today threatened by the irresponsible use of certain of these substances.

The gravity of the problem becomes apparent as one surveys recent developments. Narcotic and alcohol abuse are of course old stories, but disclosures regarding drug abuse by athletes including, unbelievably, anabolic steroids shock the sensibility of all.

In the microcosm within a macrocosm that is livestock agriculture, we have been shocked and appalled by the DES Scandal of 1980 wherein half a million beef cattle were implanted with a known carcinogen and the Veal Calf incidents of this year involving the injection of DES in over a thousand calves intended for human consumption. Sandwiched in between these two episodes has been a hue and cry from the veterinary profession and other constituencies about misuse of prescription drugs by both the laity and the veterinarian. Our incredulity has been further exercised by being furnished proof from the legitimate pharmaceutical industry of drug counterfeiting, patent infringement by companies that had simply eschewed the FDA approval process, and blatant drug smuggling. These and other trends prompted the Bureau of Veterinary Medicine (BVM) to proceed to assess the situation in early 1982.

The first step in the fact-finding process was the imposition of an import alert ordering U.S. Customs inspectors to specifically look for the unauthorized importation of veterinary drugs. The import alert confirmed our suspicions—unapproved drugs were being imported for use in various species of animals in the U.S.

The second step involved an FDA survey of cattle feedlots. Twenty-five percent of surveyed feedlots stocked unapproved drugs on a routine basis including prescription compounds. A survey conducted under the aegis of USDA's Residue Avoidance Program drew the same essential conclusions.

Third, diversion of prescription drugs, unapproved chemicals, drugs approved for other species, and other similar deviations as reported to BVM/FDA were increasing at an appreciable rate. No one here today is unaware of the practice of the advertising and sale of these compounds directly to the livestock industry and everyone is likewise aware that veterinarians are sometimes involved.

These findings dictated an increased level of regulatory activity in order to protect the public health. Prescription drugs become prescription drugs because adequate directions cannot be written for lay use. Analytical methods generally do not exist for drugs not intended for use in food-producing animals. The safety to man and to animals of unapproved drugs has either not been established or it has been established and potential harm has been demonstrated.

In August of 1983, we re-directed compliance activities in two important ways. First, since unexpected and unapproved drugs were being used in food-producing animals, we could not wait for a residue to occur because we had no methodology in most cases for finding the residue of unapproved drugs. Second, distribution of prescription drugs without a prescription and/or a client-veterinarian-patient relationship had to be curtailed.

We then circulated to the veterinary medical profession the following statement:

> Although it has been and remains the policy of the Food and Drug Administration not to interpose itself into the practice of veterinary medicine, this policy does not extend to situations where the public health may be adversely affected. The extra-label use of drugs in food-producing animals (use for species or conditions or at levels not recommended on the label or failure to observe withdrawal times) may adversely affect the public health because such use may expose consumers to residues that have not been shown to be safe. Both producers and veterinarians may be subject to prosecution under the Food, Drug, and Cosmetic Act for such extra-label use, particularly when it results in violative residues in edible products of treated animals.

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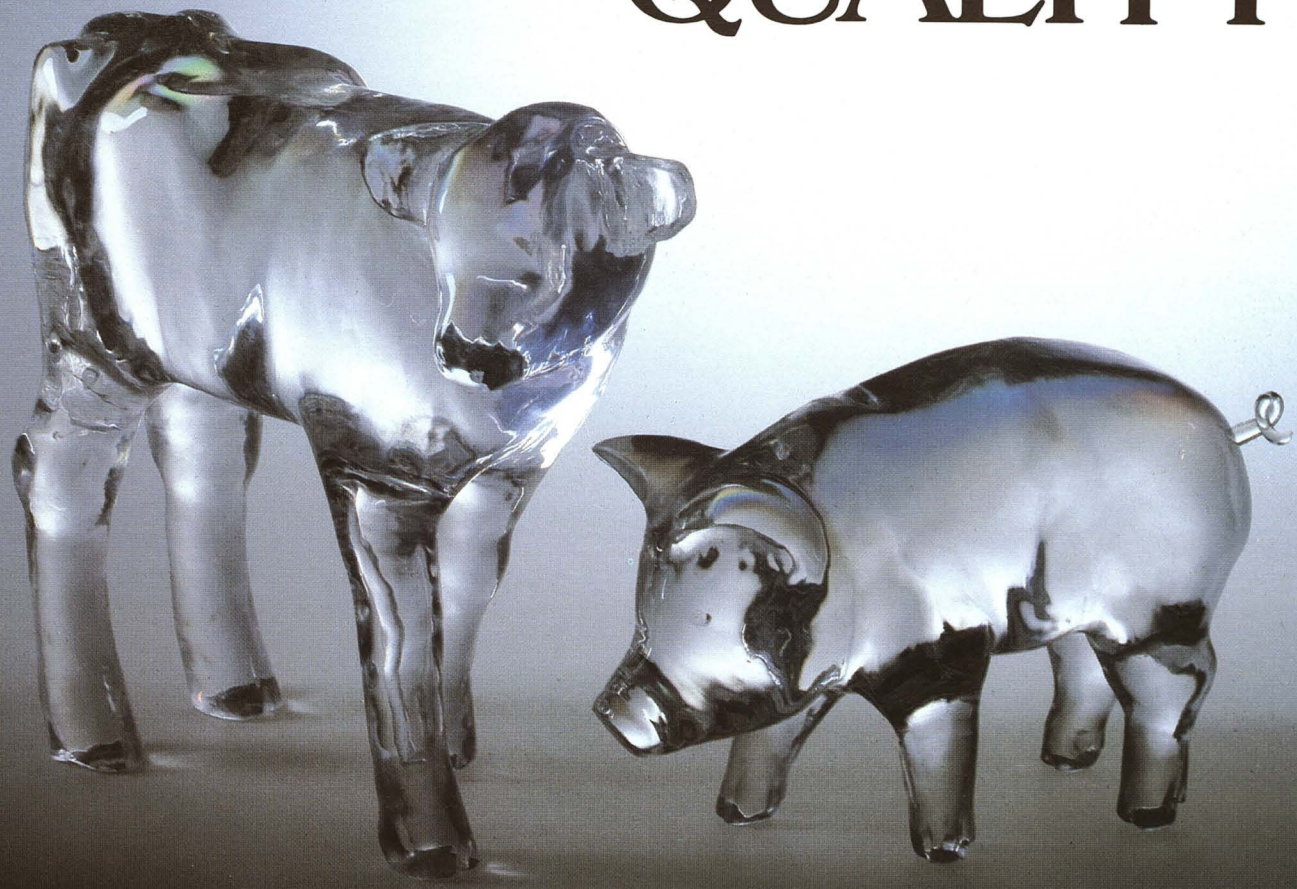

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In so doing we acknowledged legitimate practicing veterinarians operating within a bona fide veterinarian-client-patient relationships would not likely be subject to regulatory action. This took the form of our stating that BVM would take the following clinical circumstance into consideration when considering regulatory action:

(1) Was the severity of the disease a factor in using the drug?
(2) Were any drugs labeled for the specific use available?
(3) Were such drugs used first and was the change in extra-label use clinically necessary?

Since the August, 1983 statement, the American Veterinary Medical Association has succeeded in achieving an exquisitely sensitive definition of the veterinarian-client-patient relationship:

An appropriate veterinarian-client-patient relationship will exist when:

(1) The veterinarian has assumed the responsibility for making medical judgments 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 reaction or failure of the regimen of therapy.

That definition and the constructive comments of the consumer movement, the academic community, the National Milk Producers Federation, the American Association of Sheep and Goat Practitioners, the Livestock Conservation Institute, the American Association of Swine Practitioners, the American Association of Bovine Practitioners, the National Cattlemen's Association, the Academy of Veterinary Consultants, the National Wool Growers Association, Professional Veterinary Consultant, the National Pork Producers Council, the National Grain and Feed Association, and the Kansas Livestock Association, have added a measure of renewed assurance that a more responsible attitude regarding the use of drugs in food-producing animals now prevails. Accordingly, we are including the following amended statement in BVM/FDA instructions to the field on the use of drugs in food-producing animals:

> We do not intend to interfere with responsible veterinary practice where individual animals diagnosis and treatment dictates drug therapy for a condition for which there is no approved drug and when scrupulous precautions are taken to maintain adequate animal identity, and an exaggerated time period is followed before meat, milk, or eggs are marketed for food. The Agency acknowledges, therefore, that occasional extra-label use is necessary in the course of veterinary practice.

There are still "many more miles to go before we sleep..." We need more drugs approved for a wider variety of uses. Things are improving in this area. BVM approved 25 new animal drugs in 1982—the most approvals in any year since 1976. Of the 25, 11 single and 9 combination drugs were approved for food animals and 4 single drugs and 1 combination product for non-food animals. Among the new approvals were 7 products never approved before in this country in any form for animal use—the largest number of new entities since 1972.

It is gratifying to report that the pattern of an increased number of approvals is being sustained. BVM currently has 26 drugs on fasttrack or expedited review. Of these, 5 are minor species drugs—needed medications for sheep, goats, fish, game birds, and the like.

Realistically, however, it will be a long time, if ever, before we have all the drugs we need. In the meanwhile, organized veterinary medicine must work with local, state, and federal officials to continue to guard against illegal residues, contamination incidents, and the perception of an adulterated meat supply. Whenever instances are found wherein veterinary drugs are being sold or used with flagrant disregard, get involved and work out a strategy for dealing with the problem. Every state has adequate laws for dealing with this problem, and the FDA Regional Office closest to you also will be pleased to help.

We at BVM have not received one letter on this subject over the past two years denying there is a veterinary drug misuse problem in the U.S. Most correspondents encourage FDA to take a stronger stand. The present problem has the potential to:

(1) Result in a large-scale food contamination incident or incidents that could undermine the public's confidence in the safety of the meat supply;
(2) Place in jeopardy the status of prescription drugs;
(3) Thwart the best efforts of the American pharmaceutical industry to enhance the veterinary medical armentarium;
(4) Precipitate a legal backlash wherein tougher laws, regulations, and enforcement are demanded by individual states and, perhaps, the nation.

The key to capitalizing on the mutual concern AABP shares with FDA in encouraging proper drug usage is to sustain the degree of liaison we have established over the past few months. I would be remiss if I did not publicly thank Jenks Britt, Glen Hoffsis, and George Washington for what can only be called spirited liaison.

Our problem in interacting with any special interest group is that we are compelled to counterbalance that interaction with commentary from those holding opposing views, if such be known. To that end, I am pleased to announce BVM has been given tentative permission by the Office of

Management and Budget to constitute an official advisory committee. Until that decision last week, we had gone 15 years without an advisory committee, and I believe it has been at the root of many of our problems. The composition of the committee will include representatives from the fields of companion animal medicine, food animal medicine, avian medicine, microbiology, biometrics, toxicology, pathology, pharmacology, animal science, and chemistry.

AABP will be asked to nominate a member and that member, if appointed, will become heavily involved in the affairs of BVM. Moreover, the committee will be asked their advice on each and every policy decision to come before me, and they will be fundamentally in the essential programs of BVM:

Human Food Safety
Research
Scientific Evaluation
Surveillance and Compliance
Voluntary Compliance and Management Operations

A new day is dawning and I must congratulate this administration for approving the advisory committee plan and Gerry Guest for devising the plan.

Let me close by thanking AABP for inviting me here and by congratulating the Association on its excellent record of progress. I am persuaded this organization has materially enhanced the art and the science of bovine medicine. I am more persuaded that AABP is as much or more concerned with the proper use of veterinary drugs as is any other element of American society. You have a legacy of leadership in the profession regarding responsible drug usage that has served this nation well. One need only go back to Alexandre F. Liautard, who fathered the American Veterinary profession and who considerably furthered the cause of bovine medicine, to obtain adequate inspiration and energy for dealing with "unscrupulous empirics." **For what, therefore, you have done and will continue to do, I salute you.**