# Food and Drug Regulations as they Affect the Practicing Veterinarian

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The veterinary practitioner today is faced with a number of conditions which affect his daily operations that those of us in practice 20 years ago, or even 10 to 15 years ago, did not even consider. The most important of these are:

1. Loss of drugs routinely used in practice for many years;
2. The long delays in approval of new products due to increased demands by FDA for safety and effectiveness data;
3. In food animal medicine, the public announcements of dangers from residues in animal source food products and the practitioner's moral and legal responsibilities to prevent residues;
4. The great changes in livestock operations where the size of the operation necessitates first diagnosis, and most treatment, by employees at the livestock operation; and
5. The public awareness of malpractice and the trend toward many more court claims against veterinary practitioners.

Before discussing further the five changes mentioned, I do not aim to apologize for, or justify, the actions of FDA. However, many of the actions taken by FDA are the result of changes in the laws which were made by Congress. FDA does not make the laws but we are required to try to enforce them.

The only way major changes could be brought about in FDA's program of drug review and approval, and philosophy of enforcement, would have to come about after changes in the laws by Congress.

*Loss of Drugs Routinely Used for Many Years*

To get back to the changes in practice conditions, number one was loss of drugs routinely used by the practitioner. There are a number of reasons for this including:

A. The manufacturer no longer finds it profitable to manufacture the product due to reduced sales. (This is usually due to approval of a new or superior product by the manufacturer or a competitor).

B. New government laws including: the passage of the Food Additive Amendments in September 1958. These prohibited use of new food additives until the sponsor established safety. Ordinary therapeutic drugs become food additives if, after use, residues remain in milk, meat, or eggs. The previous 1938 revised Food, Drug and Cosmetic Act required safety data only for therapeutic drugs.

The 1962 Keefauver-Harris Amendments required for the first time that drug manufacturers must show effectiveness of their products. The 1962 Act also included the Delaney Amendment which is proving to be a real monster. This amendment specifies that no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal. This means that none of the product or its metabolites can be present in the final food for man or animals, or if present there is proof the product is safe. This is very difficult to prove since cancer is an insidious disease and may develop over a period of months or years with the cause unknown.

Due to sophistication of analytical methods, many products can now be found in fractions of parts-per-billion. In other words, no matter how miniscule the amount, or how meaningless it is, if it is a carcinogen it cannot be present in food.

Another Act that caused the non-availability of drugs to veterinarians and further restrictions in use was the Drug Abuse Amendments passed in July 1965. This Act is administered by the Department of Justice and regulates three groups of dangerous drugs–depressants, stimulants, and hallucinogens.

C. All of the above legislative acts affected the legal removal of drugs from the market–but little was done until FDA contracted with the National Research Council and the National Academy of Sciences to evaluate effectiveness of drugs marketed between 1938 and 1962. This evaluation was done in the late 1960's and the drugs were classed as: not effective, possibly effective, probably effective, and effective. The non-effective drugs were quickly removed from the market. However, the manufacturers of the possibly effective or probably effective drugs were given the opportunity to submit data to the Bureau of Veterinary Medicine, FDA, to prove the effectiveness of their product.

If the data was not available; if it would require prolonged and expensive trials to develop the data; and if the product was no longer a volume sale item, the manufacturer would choose to withdraw the drug from the market.

**On October 11, 1972, Federal Judge Bryant rendered a decision that established a four-year timetable for FDA to act on the NAS/NRC Drug Efficacy Reports. The agency was required to provide an opportunity for a hearing within 60**

**days for all drugs classified as ineffective. If a hearing was not requested, the final order was to be issued within 150 days. The possible effective, probably effective, and effective drugs rulings were to be made over the next 42 months. As a result of this, a number of products have gradually been removed from the market during the last four years.**

*Long Delays in Approval of New Drug Products*

Item two in practice condition changes is the long delay in approval of new products. The same legislative changes mentioned in item one also apply here:

(a) The safety and effectiveness data must be extensive and include documented, controlled studies;

(b) There must be documentation of effective dosages for all species and conditions of use for which claims are made on the label;

(c) Warnings of adverse effects or contra-indications from use of the drug;

(d) Proof that the drug is not carcinogenic or its use would not result in carcinogens in the final food.

In addition, the withholding of approval, and sometimes withdrawal, is due to lack of development of a dependable analytical method to test the active ingredients for potency and tissue residue analytical methods for food animal drugs (example: Nitrofurans).

**I often feel that many of the staff at the Bureau of Veterinary Medicine are extremely cautious nit-pickers and are afraid to make decisions. In government the non-decisionmaker seldom gets fired. On the other hand, FDA takes daily broadsides from several legislators in Congress (who feel they gain votes by harassing FDA) and the would-be decisionmakers have become gun-shy.**

*Drug Residues and Drug Administration by Laymen Employees*

The third and fourth major changes in conditions of practice are the problems of drug residues in meat, milk products, and eggs and the hugh livestock production operations where the treatment of animals is largely done by laymen. These are closely related and I will discuss them together.

I personally feel that the dangers from the minute residues occasionally found in animal source food products are greatly exaggerated. However, the highly vocal health food fadists, Ralph Nader, and consumer advocate groups have ready access to the press. The stories and reports are often not based on well designed scientific trials, are inaccurate, biased, and should not have been printed or broadcast, but the reports will continue as long as producers and veterinarians misuse drugs and residues are found.

**In the United States there are quantities of fresh milk, other dairy products, and meat supplies condemned daily for residues. The veterinary practitioner must operate in a manner to alleviate personal responsibility for these condemnations.**

The practitioner must be aware of withdrawal times and give warnings (preferably written) when he uses drugs that require withdrawal for food producing animals. If he supplies or aids in securing medical supplies for use by livestock owners or their employees, he must determine that individuals administering the drugs are properly trained to administer the drugs and informed of withdrawal requirements.

The food animal veterinarian needs to have a close working association with management in order to assure a good treatment regimen, with the indicated drugs for the condition. Personnel at livestock operations will make mistakes such as use of the wrong product, wrong route of administration, improper withdrawal, or failure to properly identify the treated animals. I repeat–the practitioner must take steps to prevent personal responsibility for these errors.

*Malpractice Claims*

Many of you may be aware that malpractice insurance costs are increasing nationwide. This is due in part to greater interest by opportunistic attorneys who see veterinary malpractice tort claims as an added, or supplemental, source of income. Claims are filed more frequently and for greater amounts. In California alone two attorneys are working almost full-time on veterinary malpractice cases.

In some cases the malpractice suit is brought about by gross negligence on the part of the veterinarian in diagnosis or treatment, and in some recent cases it has been due to concoctions mixed in the veterinarian's office and used on a client's animal.

Here are some examples of malpractice cases where claims were paid by the AVMA Group Insurance Trust:

1. A veterinarian mixed nicotine sulfate for use on cattle–the mix given was an overdose and cattle were lost;
2. Swine were given oral triple sulfa into the peritoneal cavity–45 deaths and $5,000 paid;
3. Rotenone dust was prescribed for sows–70 little pigs died from exposure to the dust;
4. A veterinarian misread the label and five times overdose of an arsenical compound was given–42 calves were lost;
5. The veterinarian mixed an antibiotic and used a disinfectant for diluent. There were multiple abscesses–105 calves lost and $2,000 paid;
6. Tylan was prescribed by a veterinarian at an overdose level–25 calves were lost;
7. Cow lost–from oral sulfa given IV. There were several other claims paid where an oral drug was injected;
8. Two cattle died from Ripercol injectable wormer. Dosage was given at five times recommended dose.

Here are three examples of more recent cases that were real or potential malpractice cases:

1. A veterinarian mixed food-grade DES with propylene glycol and used it to abort heifers; 300 of 700 developed prolapses.

2. A veterinarian mixed IBR and anaplasmosis vaccine and injected cattle. The mixture resulted in 50% abscesses.

3. A third example was the practitioner who bottled a mange medicine for dogs containing a pesticide and sold it for mange in hogs. The residue resulted in need to hold the hogs to approximately 400 lbs. until the residue dropped to a level where the hogs could be sold.

A veterinarian is more liable when using drugs not labeled for veterinary use, or drugs not labeled for specific species use. In using this type of product or a product labeled for human use he must use sound professional judgment, assure a long enough withdrawal time, and observe the animal closely for any unexpected side reactions. There is no company backup if adverse reactions occur when the product is not used according to labeling.

If a DVM is sued due to adverse reactions from use of a drug not approved for the specific use, it may or may not result in a settlement against the veterinarian. These cases are settled out of court or tried before a judge or jury. If the veterinarian defendant's peers can and will testify that the treatment was an established, safe, and effective treatment commonly used by practitioners, the judgment may go in favor of the veterinarian. Example:

> I think it would be very difficult to get veterinarians to testify in the case of mixing of feed-grade DES with propylene glycol.

*Illegal Sale of Veterinary Prescription Drugs*

In the over nine years in my present position in San Francisco, the illegal sale of veterinary Rx drugs has been the greatest problem and of the most concern to the profession. Any company can become a licensed distributor of veterinary drugs. In California an employee of a company (in a management position) may take a simple test regarding the pharmacy laws and become licensed by the Board of Pharmacy. This license permits the firm to wholesale prescription drugs to other licensed firms or to sell directly to licensed veterinarians. Legally, a veterinary drug manufacturer cannot refuse to sell to a licensed veterinary drug distributor or veterinarian without documented just cause. To do so would leave the manufacturer subject to legal actions by the firm or person refused the product.

The main problem with illegal sales is the veterinarian who orders for, or sells directly to, producers who are not his clients or to veterinary supply firms who resell to producers without a veterinarian/patient relationship.

Unfortunately (unless they have recently changed their policy), we have some members of the California VMA who are still selling drugs illegally in and out of the state of California. The patient/veterinarian relationship means very little to these individuals compared to volume sales and profits.

**I am happy to say that I feel we are making some progress against illegal prescription sales in California. This is a three-pronged attack with the California Board of Pharmacy and the California Department of Agriculture (section which registers non-prescription animal remedies) cooperating with FDA. Without the cooperation of the other agencies it is very difficult for FDA to act.**

FDA cannot make outright seizures and must have ample documentation of wrongdoing and then act through the courts. Documentation (to stand up in court) should include an illegal purchase of a prescription product by an FDA inspector, or an affidavit from a layman buyer admitting purchasing without a veterinarian/patient relationship.

An FDA investigator can occasionally make an over-the-counter buy of a prescription drug. However, the veterinary supply firms have a fairly steady clientele and know the personnel of the livestock producers. More often than not, they become suspicious of the FDA employee. When we do make the buy the firm then cries "entrapment."

The non-veterinarian-operated supply firms must be licensed by the California Board of Pharmacy to handle prescription items. If sales are made without a veterinarian's order, or shipments made of prescription veterinary drugs by non-licensed personnel of the supply firm, the Pharmacy Board can act against the facility where the violation was made. The revocation or threatened revocation of the pharmacy license seems to be quite effective.

Last March a practitioner from Kingsburg, Calif., noticed a sales slip from Anchor-Fresno made out in his name to the swine producer. He noticed that the product was ocytocin and that he had not ordered the drug for the producer. He alertly put the sales slip in his pocket and called the Fresno FDA office. Two of our investigators visited the swine producer and Walco offices in Fresno and Porterville and documented the illegal sale and one other similar sale.

The swine producer admitted the purchase but would not sign an affidavit and claimed that all the product had been used so that we could not seize a sample representing the illegal sale. He also became very irate with out investigators. The veterinarian signed an affidavit documenting the sale without his order and the information was turned over to the California Board of Pharmacy. A hearing was held for Walco International on May 12, 1976.

Walco International was charged by the Pharmacy Board with two instances of sale of a prescription drug without authorization by a veterinarian. They were also charged with stocking and sale of legend drugs from their Fresno facility with no one present at the facility who was registered with the Board of Pharmacy to handle legend drugs.

*Legal Actions Against Veterinarians or Veterinary Supply Firms*

In addition to malpractice claims or indemnity claims due to loss of animals or animal source food products, a veterinarian can be sued by the FDA. This would usually be due to illegal sale of legend veterinary drugs or causing adulteration, with drugs or chemicals, of food shipped in interstate commerce. The adulteration could be caused by administration of the drugs by the veterinarian or furnishing the product to the livestock producer without sufficient instructions and warnings.

Penalties can run from a simple warning in writing to a hearing where the defendant is asked to show cause why he should not be prosecuted, to prosecution, to an injunction barring the veterinarian or company from selling prescription drugs.

The first offense is usually a misdemeanor; conviction can carry a penalty of up to $1,000 fine and/or one year in prison on each count. The second offense may comprise a felony with penalties up to $10,000 fine and/or up to three years in prison on each count.

Recently, the president of Chem-Vet in Fremont, Nebr., Dr. Wartig, was convicted on eight counts of selling veterinary legend drugs to persons not authorized to purchase the drugs. A preliminary injunction was issued to bar Dr. Wartig from selling legend drugs except to licensed veterinarians or persons having a legal prescription. A further hearing was to be held August 16, 1976.

In an earlier case, Dr. Vernon Cockerill of Schuyler Laboratories, Rushville, Ill., was convicted of illegal sales of new and prescription drugs in a state where he was not even licensed. He was convicted and fined, but the conviction was overturned by a judge due to a technicality.

In a case not involving a veterinarian, Vet-Pro Company of Ipswich, Mass., was fined $5,000 and the company president was given a one-year suspended sentence and three years probation for selling legend drugs over the counter.

*The Compounding or Manufacture of Drugs by the Practitioner*

Many veterinarians in practice mix products for their own clients. This is perfectly legal if he can purchase the bulk drugs or other pharmaceuticals. The practitioner can mix or use any product he can legally obtain for his clients. He must in turn accept the responsibility for use of non-approved drugs or for non-approved uses.

The mixing of products does not always prove to be a good practice as illustrated by some of the cases mentioned under the malpractice discussion.

Veterinarians have been concerned about the recent publicity concerning the mixing of bulk drugs. The following quote is from Dr. C. D. Van Houweling, director of the Bureau of Veterinary Medicine, FDA:

"We believe the veterinarian may use in the compounding of prescriptions for his private practice patients whatever bulk drugs or other pharmaceuticals he may lawfully purchase. We believe this falls under the general practice of veterinary medicine which is amenable to local or state laws in which we have no desire to interfere. This would, however, include only those bulk drugs which are not new drug substances or new animal drug substances. Bulk drugs which are deemed to be new drug substances or new animal drug substances may not be sold to, or purchased by, veterinarians or anyone else unless they are the holders of an approved new animal drug application or in connection with the sponsoring of an investigational new animal drug application.

"New animal drugs as you know are defined in the Federal Food, Drug, and Cosmetic Act as those drugs intended for animal use which are not generally recognized by qualified experts as being safe and effective for their intended purposes. To manufacture or compound a new animal drug one must have an approved new animal drug application (NADA) on file with the FDA.

"We believe that to authorize veterinarians or other professionals to operate outside of these NADA restrictions would be to fly in the face of the intent of Congress to prohibit the distribution and use of new drugs or new animal drugs prior to approval by the Food and Drug Administration and would be illegal."

**There are many problems involved in mixing and manufacturing drugs or chemical products. Examples are: need for adequate equipment for weighing, mixing, and sterilization; the need to know chemical compatibility of the ingredients; the mode of bacterial action of the different drugs; and factors such as synergism, inhibition, potentiation, antagonism, etc.; I am not convinced it is a good policy for veterinarians to become drug manufacturers.**

The present philosophy of the Bureau of Veterinary Medicine, FDA, is to place as many drugs (Rx status) in the hands of veterinarians as possible. This is difficult since Congress has always taken the stand that an animal owner should have the right to treat his own animals even if it resulted in destruction of the animal. In the past, FDA could not place a product in the prescription status unless adequate directions for use could not be given for the layman. (Example–anesthesia drugs.) Lately, we have been justifying placing other products in a prescription status if they have a long withdrawal period where it is more difficult to keep track of the treated animal and residues in food might occur.

Many practitioners advocate placing all veterinary drugs on a prescription basis. Many livestock producers advocate removal of the legend from all veterinary drugs.

**With the historical attitude of Congress and the livestock producer potential lobby, I see little opportunity for change in the Rx/OTC status of veterinary drugs.**

In conclusion, I can see little relief for veterinarians in the problems incurred by loss of drugs and the slow approval of replacement. The consumerist trend and the outcries of the food fadists will continue until the public becomes aware of the effect of the consumerist trend on the price of food. The public will then demand relief from Congress for excessive government regulation and unreasonable food and drug standards.

**In the meantime the veterinary practitioner must use animal remedies judiciously and protect himself from responsibility for losses of animals or animal-source food products.**