# AVMA Drug Availability Committee

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For your information, the Drug Availability Committee is really an outgrowth of the activities of two of the councils of the AVMA, the Council of Veterinary Service and the Council on Biologic and Therapeutic Agents. Both of these groups were working in the area of concern for the availability of drugs to our profession. The Council of Biological and Therapeutic Agents because of their title deal with the drug problem in our profession and Council Veterinary Services because they felt that the lack of available drugs had an inhibiting factor on the quality of veterinary service that they could offer. It went through some molting procedures but at the present time the makeup of the Drug Availability Committee includes two members from the Council of Veterinary Service, one is a small animal practitioner, the other is a swine practitioner, there are two members of the Council of Biologic and Therapeutic Agents, both of which are pharmacologists in academia. There is a representative from the following recognized specialty groups within the AVMA—the American Association of Bovine Practitioners, and your organization's member is Dr. David Bechtol, there is a representative from the Equine Practitioners, Swine Practitioners, Sheep and Goat Practitioners, the Association of Industrial Veterinarians, and Avian Pathologists. I might say, as an aside, that the original drug availability committee were all members of the two AVMA councils and now the members from the allied groups outnumber the committee members from the councils. I think that this is healthy, but some of my colleagues feel that this may be a problem at some point. Many of us ask what is AVMA doing for any of us? I want you to recognize that the Drug Availability Committee is a function of and supported by the Executive Board of the AVMA and I feel we have done some things that have been helpful, but we have a lot left to do. Under this heading, allow me to go over some of these areas. I am not going to try to list everything that we have been involved in but I would answer any specific questions that you might have.

Primarily I see our purpose is to establish adequate lines of communication and have good dialogue with governmental agencies. In other words, take the identifiable problems from all of our allied people representing different segments of the veterinary profession, identify the problems and then take them to the appropriate governmental agency and see if we can have an influence in rectifying any of these problems. We were advised early that there are certain procedures that one needs to follow to have good dialogue with government and that is not go over people's heads, in other words, start at the appropriate level and if you do not find a good communication there, move to the next step, and if you find that you do not like what they tell you, go to the next step. We have done this, for example, we have had audience with people from the bureau of foods in Schamburg with the Council and the Committee. The next step we had a meeting in Washington with the Bureau of Foods and met with the then Acting Director and certain of his staff. Later we had a meeting with the Commissioner of Food and Drugs and at that meeting Dr. Les Crawford was present. He was new on the job and there were other members of the staffs of FDA, Bureau of Foods and Bureau of Veterinary Medicine. If you have followed these at all, you will know that our initial statement to the Commissioner was published in the Journal of the AVMA and the response that was written concurrently by Drs. Kennedy and Crawford also appeared in the AVMA Journal. I personally was a little disappointed in their response, but I recognize, however, the constraints that they operate within. I would agree whole heartedly with the statements made by my colleagues earlier. Let me look at these in a little bit different light.

In my association with the Drug Availability Committee I see first of all a problem of the bureaucratic system and I am not pointing fingers at people. I am talking about the system. Dr. Crawford has inherited many constraints and many problems that he would like to do something about and can't. It is my opinion that he has some staff members that are very, very in-efficient. They have what my old basketball coach used to call tunnel vision, they can only see what is right directly in front of them. They are not that knowledgeable. That sounds rather harsh but I really believe that. There are some people that Dr. Crawford has on his staff that just do not have adequate information at their disposal to make the decisions that they ultimately have to make. Lastly, I think that some of them make decisions based on trying to justify their own positions and even to the

point of trying to make enough waves to be recognized in order to enhance their position.

**I don't know whether those of you who have not been involved in this situation recognize how important is one point that Doctor Brunton made and that is when Congress enacts certain laws, what they intended in enacting the law may bear no resemblence whatsoever to the policies and regulations promulgated by agencies and that is a real problem today. Congress did not intend the Delaney Clause to end up the way it is being interpreted and regulated today. I am sure of that and I can go on and on, about everywhere you turn, the agencies do not have to respond back to Congress. The only hold that Congress has on them is budgetary and I don't think that they really do their homework well enough when they study these budgets. This gap between Congress and intent and what happens by the agencies is a problem.**

Next, I think that we have a problem that has to do with scientific thinking, Dr. Horton mentioned this. I call it scientific thinking of the opeate quality. That means that you just hallucinate and out of your hallunications there is some little idea that what you come up with then is a potential problem and I get so tired of reading and hearing about potential problems. Did you know that it is potentially possible for this roof to fall in on us? It certainly is, I don't think that there is one person in this room who has thought about this. If you think about this long enough, you may get up and leave because you are going to opeate yourself into such a state that you are scared to death and you will be out through the door. We are bombarded with this. I encounter it when I attend and sit across the table from people in these governmental agencies. It would just scare you the way some of these people think and I submit to you that the Bureau of Foods has to be the world's worst. They are so busy applying the very latest of scientific technology. If it is scientifically possible, then it is important. They are going to have these people chasing residues of metabolites. They don't care whether there are two or 30 metabolites, they are going to require that you chase them all and again in parts per trillion. Cyclic review is another good example. Political problems that we recognize. You just cannot vote for cancer. You just can't go home and tell your constitutents that you voted for cancer.

Along with this, I would say a problem is inconsistency. At the same time they were in the process of banning DES as a feed additive that had never been found in skeletal muscle, had been found only in livers and only at two parts per million, in the same fell swoop they approved the morning after conceptive pill for human use as 50 milligram tablets. There is no way that that is consistent scientific thinking. That is opeate thinking. Lastly, the problem is defensive research in the industry. I was hoping Jerry that you might have brought some figures to show the relativity of the amounts of money that corporations in their research and development budgets are having to shift from new product research and development to defensive research of those that are already on the market. I do not have any idea of the percentages, but I do know that it is staggering and it is very inhibitory for us ever getting any new products on the market and as you all are aware, we are losing products much faster than they are being added.

What has the Drug Availability Committee done sepcifically? First of all, we have been involved for quite some time and recently supported the minor use of drugs in animals. I want you to be aware that there are two different facets to that. One is the use of drugs in minor species and the other is minor uses in major species. A minor use in major species would be those drugs that we use only on special occasions, such as the treatment of liver flukes. The Drug Availability Committee has had a great deal of correspondence and has been pressing BVM to bring a liver fluke treatment on to the market very quickly. Hopefully this will be accomplished and I think that we have played a part in bringing this about. We have made a very strong pitch to PVM that neonatal pigs and neonatal calves not be considered food producing animals. Early we received a lot of encouragement that this was going to come about. Right now I am a little more pessimistic than I was that we would get any relief in this area. We have appealed that there be more scientific and realistic judgments made and that benefit versus risk be a consideration. I want you to listen carefully because I am going to give you a statement that I firmly believe. **With the exception, several years ago of penicillin residues in milk, that caused human allergic problems, with those exceptions, there has NEVER been a human health disease traced to a residue from an animal drug. Not one.** There is not one documented case in the human literature. That is why I say that I am getting awfully tired of these "potential" hazards. I can dream up any number of potential medical and veterinary medical hazards. That is not hard to do. Scientific judgement. We have asked that in some of these areas, for example, DES low level antibiotic feedings, they have extramural committees appointed and then render judgements on these problems. These would be people selected from outside the agencies. We are laboring with the concept of new drug versus not new drug. There is a subcommittee of the American College of Veterinary Pharmacology and Therapeutics at the insistence of the Association of Equine Practitioners. This subcommittee has a single purpose to try to find an old drug that has been removed from the market and resubmit it under what is called the monograph system. What we would try to do is to establish a precedent that there is such a thing as "an old drug." Right now, FDA says that everything is a new drug if you are going to use it and you must follow the same procedures.

**I would urge that if you know of a drug that you think would be a good candidate for us to try to get approval from FDA as an old drug under the monograph system, please let either Doctor Bechtol or myself know because we are having trouble finding a good candidate.** We have been encouraged by the Bureau of Veterinary Medicine to undertake this and

I think that they will be receptive to it but we have got to be careful about the drug. We would have trouble if it were a combination drug because FDA takes a very dim view of a combination drug. Along these same lines, our Drug Availability Committee has been table pounding in trying to get people to recognize that veterinary drugs and veterinary therapy and veterinary medicine are different from human medicine. We have a great deal of differences. So far we have not found anyone who really wants to listen to this but it is a tremendously important difference in the way we handle a patient, versus a feedlot. We have replied by letter to hearing clerks on several issues. One is the Sensitivity of Method and I might point out as a little additive of what Dr. Brunton mentioned to you about Sensitivity of Method. My big objection to that could be summarized by the fact that it was written by statisticians. You know that they think a great deal differently from other people. It has some real problems. We have replied on the minor use. We have supported, and you must listen carefully again here or you will misinterpret that I am in disagreeing with you Dallas, FDA in their attempts presently to have the opportunity under an imminent hazard situation to very quickly remove a drug from the market. The concept here is not to opeate thinking. It is as if there is scientific evidence that something that is on the market, because of some interaction etc. is really toxic to the target species, can be pulled off. An example would be the small animal worming agent that was on the market and just created havoc. They should have the ability to pull an imminent hazard off the market. We also included in our reply in support of their position in needing this that if this be so, then we submit that a drug ought to be put on the market quicker and then let clincial investigation by the veterinarian determine its safety and efficacy. This is a point that I feel is important and one that I think we should really push for and let the veterinarian's clinical investigations be the one that makes some of these decisions and not someone sitting in Washington who has never ever even seen a dairy barn, a slatted feeding floor for swine, or a feedlot, etc.

Lastly it is my opinion that ultimately we are going to have to go to Congress. It is very frustrating, however well meaning they mean to be, to both sides when you have conversations with people in Bureaus and try to get something done. They may feel your point is well taken but they can quote you ten regulations that say they cannot do it that way. As was pointed out, you must label that feed when it leaves the mill going to the pens of cattle, but cattle can't read! That is in some regulation somewhere and if you think that those people don't know those regulations, you are crazy. They may not know anything else but they know their regulations and they can quote them.

**I think we do have an opportunity in that, as was pointed out earlier, there are two or three different versions of Human Reform Acts. There are two different acts presently before Congress for the reform of the human drug bill and I think that we will have an excellent opportunity at that point to go in with an animal reform drug act. I think that BVM is aware obviously and I think that they would work with this. We have urged for a long time that the Bureau of Foods be separated from the approval process for new animal drugs. We have had some success but if a new animal drug act were written, we would have a good opportunity to separate this entirely and the Bureau of Veterinary Medicine would be the decision making body and I do believe that Dr. Les Crawford is the type of person that if you took his constraints from him, I think that he is a man you can sit down and talk with and he is scientifically knowledgable and he is knowledgable about veterinary medicine. A new act would not be easy, and again, when it comes to that time, we are going to be calling on a lot of people for help.**

# Discussion

Q. Not heard on tape.

A. The question has to do with our activities in trying to secure within the regulations a fact that the neonatal pig and the neonatal calf would not be considered food producing animals. Early in our conversations when we met in Washington we were encouraged, and now I am not that optimistic. One of the reasons that I am less optimistic, if you have noticed in the literature recently is, they are finding that mastitis therapy is leading to antibiotics being found in the colostrum. The colostrum is then passed on to the baby calves and they feel this is a potential for antibiotic and/or sulforamide residues in these young animals. We did studies to the best of our ability, and it is very difficult to get data on how much veal and baby pig are really consumed in the United States. I don't know what the total outcome of this is going to be. There is a precedent in that baby chicken is considered a non-food producing animal. So we are still working on this. Hopefully, it would be something that we can get accomplished. Along the same lines, I get very discouraged when people in the Bureau of Foods make very disparaging remarks about our profession and one of them is, if they allow any medication in any bovine animal, that veterinarians are not capable of handling this responsibility. They will abuse it and they believe that. You can get upset with them but you are not going to phase their thinking very much and this disturbs me a great deal. Just pay