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

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attention to your packaging. They will not allow a company to package a drug that is intended for dogs and cats in a package large enough that would be attractive marketing wise to use in cattle and this is because they say that you can not prove otherwise and therefore you are a bunch of crooks!

Q. Is the use of DES still legal?

A. My understanding is that, effective November 1, the *use* of DES is no longer allowed. That is the use. The manufacture of DES was banned in the summer, July or August, then the other date that I mentioned is November 21, where they no longer were requiring that producers certify that they have, or have not, used DES in the production of their animals. The use was banned November 1.

Q. What about in small animals; DES tablets are still available to them. Is there any regulation on that?

A. That comes under the category of what we call extra label drug use and we all know that in our practices we use a lot of human label products and that is going to your source of DES tablets primarily for use in a dog and cat prictice and it would not be an implant but a table and that is a perfectly legitimate part of your practice.

Q. What is a lobbyist, Dr. McDonald?

A. I am a card-carrying, paper filing lobbyist and if you think you have to turn in paperwork to get new drugs approved, you have to see the paper you have to turn in to be a lobbyist. What I call a lobbyist is that person who is a teacher. You have a different audience. I enjoy teaching, I had an opportunity to do it at LSU, also at Texas A & M. The audience that I try to educate now is all the way from the regulatory people, naturally, to the politicians. I think that some real good points were made here this morning as far as the veterinary profession becoming more involved in trying to help your clients. I firmly believe that part of the responsibility of veterinarians in the service that they give their clients is to take the time and try to educate all the way from the consumer to your local representative to the different bureaucrats that are out there trying to affect your client's business, namely the producers. I am extremely pleased that the veterinary profession has become more involved in this direction and David Bechtol, your new president has spent a lot of time on that. I had made the comment earlier about Mr. Garner who has been Deputy Commissioner of FDA under three different commissioners. David Bechtol was instrumental in getting him, along with their legal counsel, to come to the Texas panhandle. We took them out and showed them what was going on in the country. I do encourage you to do one thing though. Whenever you bring them to the country or when you visit with them, always maintain your credibility, don't go off half cocked and continually bad mouth them without coming up with a solution. It won't do you any good; it won't help the situation at all. We know that there is some DES still available but I think that we have to go ahead and live with the system. We don't like it and we don't like the idea of it being banned, but it has been banned. As far as the fellow who still has it on his shelf, he is taking a big risk in my opinion. He needs to get it off his shelf and out from under his inventory. So, to answer your original question, a lobbist is a person who teaches. We have a different audience, but instead of a classroom of students, we have a classroom of regulatory people as well as politicians and I guarantee you Dan, at Kansas State, after you continue to work with the Drug Availability Committee that you will get to where you will enjoy that more than trying to teach some students. There are 16 regulatory agencies so FDA is just one of the 16.

Q. The question was raised about defensive research in the drug industry. Could you talk about that?

A. Dr. Upsom commented that it would be nice if we had some exact figures on the percentage of research dollars that are being devoted to defensive researches in contrast to research and development of new products. Basically, the total amount of research that the pharmaceutical industry directs towards research and development and defense is approximately 11% of the total sales dollar and that is the most recent accounting period amounted to more than one hundred million dollars a year. The defensive part of research has been increasing ever since the efficacy requirements were enacted and now since you are seeing much more concern over the need for absolute safety, the efficacy part was first directed towards the combination antibiotic products and a great deal of money was expended during the 60's until these products were eventually removed from the market in the early 1970's. The low level antibiotics have resulted in millions and millions of dollars being spent by the companies in defensive research. What it has shifted from is where you had, say, in the early 60's virtually 10% of a budget being spent on defensive research to now some companies are spending upwards of 60% of their total research budget on defending existing products. The net effect of this will be that in the years ahead you will have fewer new products.

Q. What about extra label drug use?

A. The question relates specifically to the use of a drug that is labeled for one species and used in another species not labeled and what are the responsibilities here as far as the residue are concerned. I don't really know how to answer that. Let me say that it coincidental that next week in Chicago the AVMA is sponsoring a colloquium on clinical pharmacology and it is also very coincidental that their program committee made the same kind of a mistake that the Bovine Practitioners committee made and I have been asked to give a paper and the title of that paper is Extra Label Drug Use.[1] So,

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I would defer part of my answer to the time in which my paper is in print because I think that you have to develop this a step at a time so that I would not be misunderstood, but in essence, my position is that a veterinarian should be given the priviledge of using anything in his practice that he may legally purchase. Secondly, it implicitly says that this is used by, or on the order of, the veterinarian and that implicitly implies a doctor and his patient relationship and I sat down and tried to define that. You ought to try that sometime. My definition is going to read something like the veterinarian either is seeing or has recently seen the animal or the animal handling and care unit is totally familar with via periodic visits, and that these animal or animals have been examined by the veterinarian either at his clinic, hospital or in the premises where they are housed. If those criteria are met, then it is my position that the veterinarian today is trained in safety, the efficacy of these products, how they work, how long they stay in the animal, and all aspects and should be given the privilege of using them as he sees fit, extra label or otherwise. Second, along with that and a part what I think needs to be developed just as strongly is that when there are given privileges there are always responsibilities and it is my contention that the veterinary profession is ready to accept those responsibilities and that means that you, before you put something in an animal, as was stated by Sir William Osler, do not pour strange medicines in your patients, and that means know the drug before you use it. If you do know it and know its function, its toxicities and what nots, then use it extra label. That is my position.

Q. What can we do about consumer education?

A. I don't know if I have an answer. I did try to end mine on a positive note regarding the future, and that is that I think the consumer, Kenny Monfort also touched on this, has now heard so many opinions on TV and have read so many opinions in the press about how cancer prone mice were injected with a potential cancer-causing product which in fact did produce cancer, that they believe it. That does not surprise anybody. When you have got an inbred mouse strain, they forget to give us the details but they finally get leaked out. The only difference between the controls and tests was about 5%; most of the controlled mice get cancer too. So this type of cutting off at the pockets is one of them. I think that this is a place that I can plug something that I wanted to and that is the Beef Referendum. The Beef Referendum is an Act that has been passed now and is going to be up for vote by membership and again you as veterinarians dealing with your clients are in an excellent position to promote, educate and hopefully assist in passing the Beef Referendum act. An Act that will generate about 40-50 million dollars a year to do research in marketing, to do research in the scientific aspects of production, such as some of the things that we have talked about here today. To do research to come up with some positive things about dietary goals that will have some teeth in it and some documentation instead of just opinions. It is money that will come from a check-off system from the cattle industry so it is self-supported and I feel that that is the way it should be. We should use our own dollars to support our own industry to prove that our own product is in fact healthy, that beef does not cause cancer and that beef does not cause heart disease and that beef does not have all these terrible things in them. I think that that should be one thing that we can do. If many of you have a chance to speak, never leave a crowd without taking the opportunity to give a plug for agriculture. Give them the statistics that 6%, or less of the working disposal income is spent on food. I have been keeping a little running tally as I travel around the country just asking airline stewardesses or asking the guy you are sitting with and visiting with at the airport of which anymore of them anymore, unfortunately, do not have very close ties to agriculture, what they think about food prices. I am running about a 95% versus 5% that know that in fact food is 6% cheaper. What a terrible job we have done educating the most important person that we serve, the consumer. We have got to do better and it is support for this program that I have just mentioned. We can generate funds to do that very thing. So, never miss the chance to stand up and tell the consumer these facts and you have got credibility with them and they will listen to you and they will tell their friends and they will tell their friends, and so on.

Thank you Doctor Horton.

Q. How soon can we expect to see cyclic review?

A. The document has not yet been issued even in a proposal stage. The Bureau of Foods people have scheduled the first stage of cyclic review for publication early in 1980. What they will outline in that first stage is the priorities of how many drugs, which drugs, and how soon will you have to provide the answers on these drugs. There have been a lot of changes in FDA recently that may affect their expectations that will come out in 1980. Donald Kennedy's leaving may have de-emphasized the desire for absolute safety. The inroad that the Bureau of Veterinary Medicine has been making into the food safety assessment aspects is seen in the form of Dr. Jerry Guest who was recently appointed as a food safety coordinator. He is working daily with the Bureau of Foods people. The progress that is being made there may eventually lead to the Bureau of Foods activities being brought over into the Bureau of Veterinary Medicine. If this were to occur, rather than having a systematic cyclic review that will eventually cover all drugs, they may go to a causal review where only those drugs that have some reason of being suspected of causing a problem will be reviewed.

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This would be a much more acceptable approach. I think that everyone involved would agree with this. The answer is that we are expecting something in 1980 but there is a lot of discussion going on right now that might change that.

Dr. Bechtol: If any of you would like to serve on the Food and Drug Committee of the AABP, please let me know.

Special Session — Mexican Colleagues

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