

April 18, 1985

Section II - 5:30-6:00 Open Discussion

**Dr. Aronson:** At this moment I would like to request our speakers take a place at the table and we will move on to the discussion section. At this point the floor is now open to discussion and I would invite any comments you may have, any questions you may have to our panel. Do I have any?

**Dr. Muser:** I would like to address Dr. Francis on one of the things he said in his presentation about the need for clinical studies as compared to closely controlled, more limited studies. As I understood what everybody was saying today, we have certain types of animal drugs that can be evaluated in a model or in an experimental disease in the target species, something that cannot be done in human medicine. Therefore, human drugs have to be studied in larger numbers of real patients. What I heard everyone say today is that it should be permissible to replace closely controlled clinical studies by closely controlled small scale studies and then use the drug in clinical studies that are less controlled but encompass a larger number of animals. I would really be concerned if that wasn't clearly coming out of today's discussions.

**Dr. Francis:** Are you saying you would prefer to see or we would prefer to see it done in a model rather than go to the field in smaller numbers?

**Dr. Muser:** What I am trying to say is there are examples where we do have models and I do not think there is any question that FDA would accept those models as valid. I am not saying we need a model for every disease. I am not saying that. But if we do have a model that is acceptable by everybody's standards, I do not see the need for extensive clinical well controlled studies. They should only be needed when we do not have a model. Because, again, I believe we are copying things that have been developed with human drugs in mind.

**Dr. Francis:** It is my understanding that when there is a model that is well designed, that is our policy. That we would prefer to have a model and the limited field study.

**Dr. Swenson:** Could I comment on that. I have some concern about a small number of what are relatively superficial clinical studies. I think I would have to ask what were your objectives on those studies and can you really say that you are answering that objective with those studies. Would they not be better addressed with, say, a couple of well controlled studies at maybe two locations, whether they are in a model or whether they are in a naturally occurring disease such as Dr. Brandt used with calf pneumonia that he reported on at the last symposium.

**Dr. Muser:** The only thing I am saying is we should choose the easiest path that leads us to the goal. Is it a laboratory study with an acceptable model and then some extensive clinical studies, let us do that but let us not get to a point where we have to check every box! If we have a laboratory model, we have to do the clinical studies too. I think we should apply some reason. I do not think Dr. Francis said that this is

a reasonable approach accepted by FDA. I just wanted to be sure that we do not leave this meeting without understanding this point.

**Dr. Francis:** I think what I am really saying is under those circumstances, why have them at all. Why use resources unnecessarily.

**Dr. Aronson:** Any additional comments on this particular point. Dr. Francis, I understand you to say that there is sometimes a need to demonstrate by means of additional studies that a drug can be used safely and properly by a layman in the case of a OTC product. Would you care to comment on the nature of these additional studies and just what would be required in this case.

**Dr. Francis:** Since we have to have the safety and efficacy data before us before we can actually classify a drug, it would seem to me that in order to classify it OTC, in addition to the safety and efficacy data, there would have to be additional data (which would be an additional study) to generate the data to demonstrate that the layman can use the drug safely and effectively and that is to what I was referring.

**Dr. Aronson:** What would be the nature of this type of study?

**Dr. Francis:** If I understand the point of your question, it would be the use of a paste, anthelmintic paste, under the supervision of a trained veterinarian out there in the field. It would still be under the supervision of a trained person.

**Dr. Aronson:** OK, I guess this is the point I was really trying to address. Additional comments, please.

**Dr. McCracken:** Different topic. We are interested in the case of food animal studies where there are lots of animals in collecting data on-line. I am wondering if anyone in the Food and Drug Administration has addressed this issue, of the acceptability of electronically recorded and stored data as raw data. The advantage being, if it is done right, higher quality data with less errors. And also if there was a standard format that the FDA would agree that they would accept data in. Then it could be provided in that format and the Food and Drug Agency regulatory agency could access that data literally instantly, validate our statistics, validate all of our data and be able to work with a lot more of our data a lot more quickly. Has anything been done in that regard?

**Dr. Aronson:** Do we have someone from the agency here to respond to that?

**Dr. Norcross:** No, we are not in the mode at this moment of routinely, collecting, utilizing, reviewing and responding to firms in that fashion, not at all. However, it is certainly a given in my opinion of things to come. We are fairly well on-line in house. We need a pharmaceutical firm now that will cooperate with us. We would like to do exactly what you are talking about, i.e., bring in the information electronically, store it in CVM electronically, do all the reviews electronically, shift the paperwork internally electronically, by modems, terminals, etc. and then respond to

the firm in the same fashion. I think we are talking about the same idea here and if you are interested --

Dr. McCracken: I will give you my card.

Dr. Norcross: --in participating in this experiment, we would like to talk to you. We would like to participate with you in such an experiment. At the moment, it would have to be in addition to the hard copy because we can not do anything without hard copy at this time. We are all for it.

Dr. Aronson: Thank you, it was just going through my mind, what happens if there is a power failure? But when you qualified this, in addition to the hard copy, I see we have a built in safety factor to be considered here.

Dr. Aronson: Do we have additional comments or questions either from our panel members or from the audience? I would like to take this opportunity to thank each of our speakers who have been on our program today and each of the chairmen. It is really quite unusual when at the end of the day we find ourselves running ahead of schedule. Usually it is the other way around and we are hurrying to make up time. So, again, thank you to each and every one of you for your cooperation. Before you get up and leave, John Paul has some important information for you.