

Senator HATFIELD. Mr. Chairman, then we ought to deal with the question of staffing. I don't think that is any excuse. I think after all that if they have that kind of a problem, that they ought to come in here with the kind of budget that is going to let them maintain a current workload so they can deal in a reasonable time with all of these companies on all of the products.

Senator NELSON. I wouldn't quarrel with that. I think they have been asking for more staff and desired more staff for a long time, but haven't been able to get it out of the Congress. But in any event, in chloramphenicol, for example, you moved forthwith after the hearings here with a letter to 200,000 doctors, and I assume that is because you put aside anything of lesser importance, lesser priority.

The question that still remains, however, and which bothers me, is once you have decided with Vibramycin that in the labeling that would—when did that drug go on the market by the way?

Dr. MINCHEW. August of 1967 it was approved. Now I could not comment when the industry first got it in interstate commerce.

Senator NELSON. Once you made the decision that it was significant enough to require the package labeling of Vibramycin, I think the question raised by Senator Hatfield raises this point. You had already made that decision. It isn't necessary to carry on a dialog back and forth with the rest of the companies on their labeling. It would seem to me he has made the point that once you have made that decision you ought to order the other companies in their future package labeling to make this amendment without any delay. I think that is a valid point raised. Is there any response you have to that?

Dr. MINCHEW. Yes, sir. The only point I would make here, though I certainly in no way disagree with the desire which you obviously have, is that we have also to be as efficient as is possible and as equitable as possible. The particular labeling changes which we are talking about far exceed just the animal pharmacology section. They did involve other matters which we felt that it was fair and equitable to discuss with the industry in terms of a format for presenting the indications for the drug and this type of thing.

It did involve a lot more variables than just simply establishing the edict that animal pharmacology sections shall be present. We did also discuss some of these with our Medical Advisory Board.

Senator NELSON. The point raised here, if there are competing products, and I agree when a New Drug Application is made and you decide upon the package insert, you use the most up-to-date information you have. You notify the doctor. But it seems to me in any competing product, once you have made that decision, you certainly ought to move as expeditiously as possible in directing an amendment to the package insert of the other products, or it is subject to, I think, a valid complaint.

Dr. MINCHEW. And we agree that the time period is certainly longer than we would prefer. In the interest of giving the doxycycline as equitable a treatment as is possible in this regard, the package insert does state that the animal toxicities which are observed and described in their labeling occur with other tetracyclines.

Senator HATFIELD. May I ask one more question? Could you tell me what your requests were in the budget for additional staff for this year that were denied you, the numbers that were denied you or the dollars that were denied you?