

Dr. MINCHEW. We have taken immediate steps in terms of initiating an effort to get this done. At the same time, we could not——

Senator HATFIELD. How long has it taken?

Dr. MINCHEW. This is a highly variable thing. There are several manufacturers of the tetracyclines. We wrote all of the manufacturers, I believe in the spring of 1967 or the winter, I would have to check that date, requested a meeting with them to discuss class labeling of the tetracyclines.

Senator HATFIELD. December 1967.

Dr. MINCHEW. I would have to check the date. It was either in the winter or early spring of 1967.

Senator HATFIELD. You get worse mail delivery and mail service than we do, don't you?

Dr. MINCHEW. I don't know the condition of yours. Ours does have problems.

Senator HATFIELD. You mean you are almost a year involved in this thing?

Dr. MINCHEW. In changing the class labeling of tetracyclines, yes, sir.

Senator HATFIELD. Is this typical of your bureaucracy?

Dr. MINCHEW. I would not say it is typical. It certainly is an example of our efforts to handle a large number of manufacturers with a very complex question of making uniform labeling.

Senator HATFIELD. How much longer do you think it will take?

Dr. MINCHEW. I can't say because it will be dependent upon some degree of concurrence being reached by a variety of people, and I could not honestly give you an estimated date of completion.

Senator HATFIELD. In other words, you want Pfizer under this special regulation that you have not yet implemented on these other pharmaceutical houses.

Dr. MINCHEW. For this particular product, yes, sir. I think, for example——

Senator HATFIELD. But these other products of these other houses have been on the market and are still on the market.

Dr. MINCHEW. And including some of Pfizer's; yes, sir.

Senator HATFIELD. And you claim some of the same factors are involved in their product that should be labeled as you now require Pfizer; is that correct?

Dr. MINCHEW. And I just would like to make a point also——

Senator HATFIELD. And you have been almost a year in not getting this implemented on the other houses; is that correct?

Dr. MINCHEW. And Pfizer; yes, sir.

Senator NELSON. May I ask a question here? Does the Pfizer package insert include this specific reference to animal thyroid effects now?

Dr. MINCHEW. In the Vibramycin. Pfizer has other tetracycline products currently on the market that do not have it, which will have to have it when we are able to implement across-the-board changes.

Senator NELSON. So Pfizer with its other tetracyclines along with all the other companies with their dosage forms, do not now——

Dr. MINCHEW. Have this animal pharmacology section, that is correct.

Senator NELSON. But in this Vibramycin, issue is raised prior to approval of marketing of the drug?