

Mr. GORDON. In view of the care that the FDA exercised in regard to the detailing of misleading statements by Pfizer detail men, do you regard the matter as serious?

Dr. MINCHEW. The matter of the details over which we were discussing?

Mr. GORDON. Yes.

Dr. MINCHEW. Yes; I do. The difference of opinion that we had in regard to the antibacterial spectrum, I would consider serious. Any misinformation which the physician might have that this drug would be effective in treating staphylococcal infections which indicated resistance to other tetracyclines could be very serious.

I would also consider the tooth staining problem certainly serious. If the physician were misled into thinking that this were a tetracycline which did not stain teeth and he used it without this consideration, I think it would be a serious matter.

Mr. GORDON. If you believe this matter was serious why did you select the kind of regulatory action you took rather than some other forms of action?

Dr. MINCHEW. From the medical standpoint, the seriousness of this was such that we felt the most important corrective measure was to take steps to be certain that the physician did not get this misinformation, or it did not continue. It apparently had taken place at the American Academy of Pediatrics. This is why we took this step to most expeditiously determine as far as we could that the misinformation and oral detailing did not continue.

Now in terms of other legal steps that might have been available, I would like Mr. Goodrich to comment, if he cares to.

Mr. GOODRICH. The decision in this case was made by Dr. Goddard to call the president of Pfizer about the detailing. The Pfizer president immediately reacted to say that he would send a telegram the same day to all of this force to bring about correction.

That was done, and that was satisfactory to Dr. Goddard, who was responsible for the agency at that time. It was concurred in by me and by others.

Senator HATFIELD. Who made the decision to permit this visual aid material to be used?

Dr. MINCHEW. For the purpose of informing the detail men?

Senator HATFIELD. Yes.

Dr. MINCHEW. This was a decision made in the Bureau of Medicine.

Senator HATFIELD. By whom?

Dr. MINCHEW. Dr. Ley and me.

Dr. McCLEERY. Mr. Gordon, may I have the microphone again?

Senator HATFIELD. Just a minute. He had a series of questions. Just 1 second.

Dr. McCLEERY. Yes. I asked him if he would yield the microphone, Senator.

Senator HATFIELD. Well, I happen to be chairman.

Dr. McCLEERY. May I ask you?

Senator HATFIELD. Just a moment. Just as soon as Mr. Gordon completes. Will you finish your questions first and then we will be happy to.

Dr. McCLEERY. Thank you.