

Mr. GOODRICH. Perhaps so.

Senator HATFIELD. I couldn't be less interested in their logistical problem, if this film were inaccurately portraying a drug that you said should not be portrayed that way. You had a responsibility to deny them the use of that film.

I think, too, on the top of page 5, "the final review developed the fact that we did not have a firm understanding with Pfizer." I mean to me this is filled with procedures or practices that showed either lack of a strong position posture in other activities that I hope is not typical of FDA, because frankly from the testimony in this case, and I don't know why the staff chose this one, because it didn't help their side of the case at all in my opinion, this was not a case that would be typical, I would hope would not be typical.

What I would like to see is the aggressive posture of FDA in handling any of this advertising and promotional material on which they have doubts. And then, also, on the basis of equity as it relates to other companies, other competing pharmaceutical houses. But that is just a point of view that I have that I wanted to make sure that I understood and that I held on a certain basis of fact and that it is not an improper or not a factual understanding.

I would like to suggest, too, that on this whole matter, where we do have staff inadequacies, as indicated awhile ago, legal inadequacies or other such, I know that Senator Nelson is keenly interested in this matter. I, too, share his interest. There are many other Senators on the Appropriations Committee, and others, who would share the interests that we have.

We certainly would feel very pleased if you would indicate to us that we could become an ally to you in behalf of your financial needs before the Appropriations Committee, because we are interested in a policy and in the policing and the other activities of this agency. If you are inadequately staffed, you can't come before us and fulfill your responsibilities here. We have no reason to demand anything more than you are capable of performing.

But if you do have the law, and as you indicate to me, you have the adequacy of law to enforce, to administer, to police, then it seems to me there might be a review as to the philosophy of your agency's attitude toward these laws, philosophy and attitude toward these laws and administrative responsibilities, because I do feel that we should be most aggressive in this field, most aggressive.

Mr. GOODRICH. I would agree with you. Vibramycin, the big, the salient point that comes through, however, is that here is a drug which was introduced on the proper basis, once all these negotiations went through. Perhaps there was some laxity or unsatisfactory procedures as you see it, where we did not have a firm understanding. But the critical fact is that before this drug was launched to the medical profession, an accurate, informative, reliable statement of its place and its hazards was presented both in the labeling and in the promotional material.

Dr. MINCHEW. I would like to make one comment in regards to the first paragraph on page 5. The impact of this statement was not that it just all of a sudden dawned on us that we didn't have a final understanding. It was when this visual aid material was presented that the promotional thrust of the material did not reflect that we had reached this understanding in the negotiation of the package insert.