

top priority item in the Bureau of Medicine. We understand its importance in having drugs prescribed. As Dr. Jennings testified yesterday, the promotion of this drug was in part responsible for its tremendous use. It was launched with a message with which we cannot agree. So we adopted in March or June of 1966, a program of monitoring the initial promotion for every new drug approved to make sure the drug was launched on the right foot, and promoted to the profession for the conditions for which we had actually approved it.

Senator NELSON. Are you saying that you preexamine the advertising for all new drugs?

Mr. GOODRICH. We require them to submit, as soon as the first promotion is run—we do not require it to be submitted before it is run—submit that to us. Dr. McCleery's office processes that. If it is not in accordance with the conditions for which the drug has been approved, we then take action to be sure that it is.

Now, trying to preclear the ads at what you call the viewing board stage—this is just not a practical thing that we have felt we could do so far. We are calling for the ads to be submitted as soon as they are first placed. We are exercising care to make sure they are promptly reviewed.

Senator NELSON. Well, I do not know what the problem would be in preclearing all ads. I assume it would be massive. I am not talking about that. An ordinary layman such as myself can look at the ad promoting Indocin for gout, and knowing what I do about it, see the misleading point there, when they use the phrase "drug of choice." I know why they did it. I know why their highly paid advertising experts sat all day long figuring out the best phrase they could use to convince the doctors to prescribe their product.

The company knows that. So I do not know why you should not say to the company, "This is an overt, gross violation, and you know it, and you are the one company that is going to spend the next year submitting your ads for preclearance from us." I think if you did that once or twice, you would end up with very, very few "Dear Doctor" letters, and then you would not be permitting the misleading of the medical profession by ads such as this one.

My question is, Why don't you really get tough with these firms?

Mr. GOODRICH. I think we have been as tough as possible within the limits of our people. This is a good suggestion. But if spending time to preclear all the advertising—

Senator NELSON. Just a minute. I have never said that. I have suggested that you notify the industry that in clear cases of ads where the claims for a drug go beyond the package insert, the FDA will preclear the ads of this particular firm for the next 6 months or the next year. Then you are not going to have very many violations to bother with; that is my point. And if you told them also that they are going to have to send the ad to all doctors and tell the medical profession in the "Dear Doctor" letter, "We misled you in that ad; we made claims not permitted in the package insert and the FDA has told us to send you this ad and correct the ad," in my judgment you would not have much problem with this any more. The medical profession would no longer be subjected to misleading ads of the sort that caused Dr. Goddard to say of chloramphenicol, "I am at my wits end as to how to effectively warn the profession." I know why. Because the industry