Mr. GOODRICH. Well, I think we have been doing most of the acting to initiate these meetings. I am sure we have.

Mr. GROSSMAN. I think that the companies have done some things that have forced you to react to them. What—I am trying to say—in other words, as far as we are concerned, this section 502(n) is really worthless—it has never been used, and you do not think there have ever been indications that the——

Mr. GOODRICH. I do not think that is so at all. This preclearance proviso in the section, which Congress told us not to routinely preclear ads——

Mr. GROSSMAN. I did not say you should routinely preclear. In other words, there is authority for you here to use preclearance, as I understand it, in hazardous situations. Now, I want to know what you consider hazardous. Obviously this was not a hazardous situation. Chloramphenicol—has there been anything you can think of that might be hazardous? In other words, how many deaths do you require?

Mr. GOODRICH. This was a serious situation, and we did get the company in within 2 weeks after the ad, and required the "Dear Doctor" letter shortly thereafter.

Mr. GROSSMAN. Do you require preclearance on all their advertising now?

Mr. GOODRICH. No. But they have been over—after we first had our discussion about this, their lawyer and their physician in this area came down to Washington, and went over a series of their ads with us, to make sure that they did fully understand what we intended, and their performance and behavior since that time has been improved.

Mr. GROSSMAN. Dr. McCleery, do you have anyone in your division who is assigned to decide when a drug is hazardous, and should become part of the section 502(n) proceedings?

Dr. MCCLEERY. No, I have no one specifically assigned. The information of the kind that you are talking about would be developed principally in the area of the Office of Marketed Drugs. If they, in their work in surveillance of the reports of new adverse reactions of drugs on the market, would find an instance of this kind that they felt was not generally known—that the profession had not been prominently and widely informed, then at that point we would be able to enter in and to act as agents of this particular requirement of the law. We would not develop the information.

Mr. GROSSMAN. Is it fair to say that the committee could interpret that since 1964, since section 502(n) went into effect, there have been no cases of hazardous drugs which would qualify for preclearance? There have not been any?

Dr. MCCLEERY. The paragraph in the regulations which give form to this section of the law that Mr. Goodrich talks about, is paragraph 1.105(j), and we have not as an agency invoked the provisions of that paragraph of the regulations.

We have, on the other hand, precleared many ads.

Mr. GROSSMAN. I am just thinking back to what Mr. Goodrich was discussing before—there are a lot of questions on which Congress has gone far enough. I just wonder whether 502(n) does not give us authority; and whether authority that you have could be used and has not been used.