In other words, it is one thing to say that the Congress should legislate. But when it has legislated, and there is a broad discretion that has not been enforced, it is not our job.

Dr. McCLEERY. I do not think I could agree with you that it has not been enforced.

Mr. GROSSMAN. Section 502(n).

Dr. McCLEERY. 502(n) is the broad language, and includes as one of its parts the exclusion that except in extraordinary circumstances we should not require a company to preclear its ads, as a part of that section of the Kefauver-Harris amendment.

Mr. GROSSMAN. I will not pursue this.

I wonder if you can answer as to when you think an extraordinary situation exists?

Dr. McCLEERY. I believe that paragraph 1.105(j) is the paragraph of detail in the regulations which gives form to one view of "extraordinary circumstances." In the negotiations with the industry in 1963, at the time the regulations were being proposed to the industry, this was a prominent feature of difficulty in the industry's acceptance of the original regulations written on the basis of the amendment to the act. That the paragraph exists at all, I think, has had an effect which has been salutary in causing companies to be aware of the need to move more quickly, than they might otherwise, to get new warnings into advertising.

Mr. GROSSMAN. I would question whether they would act because of their fear of your implementation of it. We have not seen very many examples of it.

Senator NELSON. Mr. Goodrich, so that I have this clear in my own mind—we have referred several times to your authority to preclear ad copy and I think, in that context, you have always referred to new drugs.

Mr. GOODRICH. If so, I misspoke myself. The advertising provisions apply to all prescriptions.

Senator NELSON. That was my impression. So if a drug is on the market, no matter how long it has been there, and the company at some stage makes claims that extend beyond the authorized package insert claims, you do have authority in that case to preclear a future ad or ads.

Mr. GOODRICH. Yes—and even with drugs on which we have no approved package insert—that is the drugs on the market since 1938, without new drug clearance. If there should be discovered some new hazard about such a drug, it would be possible to preclear, and to require preclearance of the ad. Only, I believe, 2 years ago we reclassified a drug on the market in 1936 as a new drug, because of a newly discovered hazard in it, and did take regulatory action. It was not advertised broadly, so it was not necessary to preclear advertising. But we did require its reclearance through the new drug procedure. It was a product called Dipyrone, discovered to have some blood hazards.

Senator NELSON. You referred to drugs marketed before 1938. Do you approve a package insert from them?

Mr. GOODRICH. No; they are totally exempt from preclearance. They are required to have a package insert with full disclosure information in it. But we do no preclear it.