Mr. GOODRICH. Where the product has a possibility of serious adverse effects or of causing fatalities. This was one of the issues that was in dispute when the Kefauver-Harris drug amendments were passed. There was a strong feeling on the part of the industry that we should not have routine preclearance. Of course we did not want that. But we said it would be necessary in some circumstances to have advance preclearance. As the regulations worked out, a provision was inserted to require preclearance when a newly discovered serious hazard or fatality came about, and we have a mechanism through which the company itself, on being notified by us of this new hazard and requirement of preclearance, can submit a program for their advertising that will assure prompt transmission of this important information to the profession through the company's promotional efforts.

Senator NELSON. You referred to a new drug?

Mr. GOODRICH. Any prescription drug, Senator, whether it be a new drug, or certified antibiotic, or even a prescription drug that has been on the market for a long time, and is under the grandfather protection for effectiveness. If we should learn that even an old drug suddenly had been discovered as a causative factor in serious adverse experience or fatalities, we have the authority to require preclearance of ads and to make sure the profession is notified through all mechanisms of this new hazard.

Senator NELSON. Supposing it is a new or an old drug and it is on the market; it is a very toxic drug, has dramatic side effects, such as this one or chloramphenicol, or any one of many, many more, and the company continues to put in its advertisements, such as this one, claims that extend beyond what is authorized in the package insert—do you have the authority, when that happens, to say, "From now on we will insist on preapproval of the ad"?

Mr. GOODRICH. Yes.

Senator NELSON. Have you ever exercised that authority?

Mr. GOODRICH. We have not. In this case, as Dr. McCleery's statement shows, we met with the firm on November 11, 1966, which was less than a month after we challenged this ad, this promotional practice, publicly, and the firm immediately developed a program to change its advertising practice. It was not necessary for us to require a preclearance. We have the authority to do so.

Senator NELSON. If I understand your testimony and other previous testimony before the committee, there have been a number of cases where the advertising for a drug has made a claim beyond the claims approved for the package insert; is that correct?

Mr. GOODRICH. Yes. And our reaction to those ads has been prompt and decisive in calling the company in, Dr. Goddard himself meeting with the companies to go over the defects, and to make sure that the company does and will immediately communicate with the profession to call attention to these defects. There have been, I believe, 21 or 22 letters in the last year and a half involving these advertising practices. We will put those into the record for you, so that you can see both the details of the advertising abuses that called for the letters, and the mechanisms that we used to require the companies to communicate this information to the profession.

SENATOR NELSON. What puzzles me a little bit is that this has been the law since 1963, has it not?