again, or we will have to reconsider whether or not the product should remain on the market. But the agency is alert to Chloromycetin, and has exercised efforts over the years to hold its prescribing within bounds. There is no question that it did get out of bounds.

I was trying to address myself to the broader question of what have we done on the overall issue of promotion. In 1961, we put out requirements for full, complete disclosure to physicians on all promotional pieces. This made a drastic change in the information that went to the prescriber.

In 1962, Congress gave us authority over effectiveness claims, that was a program to review all the claims that had been approved over the years. The program of reviewing the claims is underway. Soon after the enactment of the 1962 amendments, we required drastic changes in the advertising. That is still a matter of controversy with us, but some steps have been taken to improve this, not enough, of course.

Senator NELSON. All I am saying, however, is the great and dramatic failure was chloramphenicol, because it continued to be prescribed indiscriminately. Nine out of 10 people for whom it was prescribed shouldn't have gotten it.

Mr. GOODRICH. Dr. Goddard could see to that when it came up.

Senator NELSON. What I am concerned about now is by what mechanics do we prevent it from happening again. The FDA, maybe through no fault of its own—whatever it required on the package labeling—was not effective. It didn't work. And I would have thought, knowing what the FDA did know, that your "Dear Doctor" letter should have gone out saying that nine out of 10 of you fellows prescribing this drug are prescribing it for nonindicated cases, and you had better stop. That is what I think should have been done. I assume that the FDA knew that people were dying from a drug that they shouldn't have received in the first place, and this went on for years and years and years. Just think of the tragedies. But FDA did nothing effective about it.

Yesterday we had Indocin, and the usage is contraindicated in children on the label clearly as can be. Yet 10 percent of pediatricians in a poll said they used it in children. They are misprescribing that drug. There is something wrong here, tragically wrong.

Senator HATFIELD. I have a couple of questions on the matter of restricting these drugs once they have been determined by your agency that they do not represent the truth, or to provide all the therapeutic value they claim. Take chloramphenicol.

Let's say that they decided to promote this drug again, and on the second go around you determine that it still lacks safeguards that you had prescribed or that you wanted placed on them. What would FDA do, negotiate, or what kind of action would FDA take against an industry or against a pharmaceutical house that violated what you considered to be appropriate safeguard requirements?

Dr. MINCHEW. Does your question pertain to total promotion or medical journal advertising or oral detailing?

Senator HATFIELD. Anything, any part of the promotional field which would tend to cause people to expect more and to submit themselves thereby to certain dangers than that which really exists?

Mr. GOODRICH. We have a variety of sanctions to deal with that, Senator. If the company made representations contrary to what had