

Mr. GOODRICH. The law was passed in 1963. It required that before we could do anything on advertising, we had to promulgate the regulations. We set to work promptly at that. We promulgated the regulations effective in 1964—after confrontation with the industry. The regulations became effective at that time. The original enforcement actions were—some were taken, but it was not until Dr. Goddard became Commissioner that this program was sharply stepped up, and I believe since certainly March of 1966—he came in February or March—I forget which—but soon after he came, it became one of his most—one of his highest priority programs. It has been a high-priority program since.

Senator NELSON. So the regulations were promulgated about 4 years ago.

Mr. GOODRICH. Yes, sir. As a matter of fact, we now have under consideration—we have had over about the past year—an improvement in those regulations in terms of making them much more specific. This improvement will be carried out very shortly. But meanwhile, we think the regulations are entirely adequate to deal with the major problems of advertising. We are revising them simply to be more specific and to avoid any contention on the part of the pharmaceutical industry that they did not understand what was required, or what our attitude towards specific kinds of advertising practices were.

Senator NELSON. Have there been any cases where the penalties under the law were levied against any of the companies?

Mr. GOODRICH. Yes. There has been one prosecution involving a product called Pree MT. There have been a number of others under discussion back and forth with the Department of Justice. Several of them are in controversy.

Senator NELSON. Do I understand you to say the penalty is a thousands dollars?

Mr. GOODRICH. Yes, sir—for each shipment of the drug. So there is a possibility of a substantial penalty.

Senator NELSON. We are talking about advertising in a journal now.

Mr. GOODRICH. Yes. But the offense is in terms of an interstate shipment of a supply of the drug.

Senator NELSON. The liability under the law is what?

Mr. GOODRICH. The introduction into interstate commerce of a misbranded drug, and the drug is misbranded because its advertising failed to comply with the regulations.

Senator NELSON. And what is the effective date from which you start measuring the penalty—the date of the publication of the ad?

Mr. GOODRICH. Yes—the ad must be related to a shipment made after the date the ad appeared.

Senator NELSON. And then the penalty is based upon the number of shipments, not the quantity?

Mr. GOODRICH. Yes, sir.

Senator NELSON. So if an ad were run on April 1 that violated the regulation by making claims that were not approved in the package insert, and one shipment of drugs was made after that, the maximum penalty would be a thousand dollars, is that correct?

Mr. GOODRICH. Yes, sir. Regardless of the size.

Senator NELSON. Do I understand you to say that in the last year and a half there have been 22 "Dear Doctor" letters sent out?