

Mr. GORDON. How many civil and criminal cases have been brought against drug firms in the last couple of years for false and misleading advertising?

Mr. GOODRICH. Seven or eight. I would have to get the exact figure for you.

Mr. GORDON. Are these criminal?

Mr. GOODRICH. Some criminal and some seizures.

Mr. GORDON. What has been the disposition of these?

Mr. GOODRICH. The seizures? I believe there were three of them. All four of them were settled by consent decree. One of them may not have been finally settled—in any event, we have worked up a consent decree with them and it will be the fourth.

One of the criminal cases was settled on a plea of *nolo contendere*, and the other three or four are pending on motions to dismiss in that kind of a setting.

Dr. GODDARD. We will provide this information, as you will recall, in response to Senator Javits' question as well.¹

Mr. GORDON. Which publication has been most prominent in the carrying of false or misleading medical advertising?

Dr. GODDARD. We have not made any study of publications. One would have to really carry on a comprehensive analysis of this. I cannot answer that question intelligently, because we have not carried out such a study.

Now, of course, you realize that most of these advertisements that we were striking at were carried by many publications. You know, the editors' plight is really a difficult one, because it takes our staff 3 to 4 man-days as a minimum, and usually around 10 man-days, to analyze an ad completely and to provide me with a report.

Mr. GORDON. In reading the complaints of the Justice Department, I notice that one name stands out among others. That is the Journal of the American Medical Association.

Dr. GODDARD. Well, I am told they have the largest paid advertising receipts of any journal published, so that does not really surprise me. But I would not limit it to the JAMA. It is not solely their problem. It is a tough problem for the editor to contend with.

We have worked very closely with the Drug Research Board of the National Academy of Sciences, which has also vigorously supported this concept. We have urged the leading trade associations of the drug industry to underwrite the costs of the compendium in the interests of better medical therapy and with the possibility of a more rational approach to the package insert by both industry and Government.

Senator Nelson, FDA is making every effort to make sure that the claims for a drug and the guidance for its proper usage, will be in the hands of all those who prescribe or compound or otherwise are responsible for drug therapy. Thus far, neither industry nor organized medicine has come forward to undertake such a compendium. We have had to make a start in this direction on our own.

This cartridge of microfilm, Senator Nelson, is our beginning effort in the production of a drug labeling compendium for our own agency's use. We are putting into this film record updated package inserts, to make sure that only approved inserts are accompanying the drug products coming off the production line.

¹ See pp. 751, 752.