STATEMENT OF DR. ROBERT S. McCLEERY, ACTING DIRECTOR, DIVISION OF MEDICAL ADVERTISING, BUREAU OF MEDICINE, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY DR. HERBERT L. LEY, DIRECTOR, BUREAU OF MEDICINE, FDA; AND WILLIAM W. GOODRICH, GENERAL COUNSEL, FDA

Dr. McCLEERY. Mr. Chairman, I appreciate this opportunity of appearing before you this morning to discuss our experience with the advertising of Indocin.

Shortly after Dr. Goddard became Commissioner of Food and Drugs, in early 1966, the agency's interests in prescription drug advertising were sharply accentuated. It was felt that manufacturers had had time enough to adjust to new requirements concerning advertising. Dr. Goddard spoke to the presidents of pharmaceutical firms, to their medical directors and to their advertising agencies to note what we regarded as a continuation of advertising abuses that had been so largely responsible for the enactment in 1962 of the Kefauver-Harris drug amendments and the promulgation in 1964 of the first advertising regulations.

Senator NELSON. Doctor, do you have any examples that you would like to give us of what you consider to be advertising abuses, in addition to those you have already mentioned?

Dr. McCLEERY. The case we are describing today is in our view a case typical of some of the major abuses. We could submit for the record the actions we have taken against drugs in the past in terms of the use of the sanctions for criminal prosecutions—the use of seizure of products for bad advertising and for a large number of "Dear Doctor" remedial letters which have been sent, roughly 20 in number.

Senator NELSON. I would like to have the examples you referred to.

Do I understand you to say that the case you are talking about today is quite typical of other instances that you have of the same kind of advertising abuses?

Dr. McCLEERY. Well, in some sense, yes, in that it contains a number of faults which are common to many other ads against which we have acted, and these were present during the introduction and the subsequent advertising of the drug under your interest here today.

Senator NELSON. The point I am interested in having clear for the record is whether or not this is an isolated case, or whether it is a general problem that you have to deal with.

Dr. LEY. Senator Nelson, may I suggest that we submit for the record the examples of what the FDA considered misleading advertising which were presented in October of 1966 by Mr. Goodrich, and secondly, a file of "Dear Doctor" letters stimulated by the FDA over the past year. I believe this will set the picture in proper perspective.

Senator NELSON. All right. If you would submit that for the record.

(The material to be furnished for inclusion in the record follows:)

THE STATE OF THE LAW AND COMPLIANCE*

(Address of William W. Goodrich, Assistant General Counsel, Department of Health, Education, and Welfare, Washington, D.C.)

Three years have passed since FDA first entered the world of prescription drug advertising.

We are more intrigued with what we see today, than we were by our first viewing. To borrow a quote: "We are reading more now and enjoying it less."

*Presented at "A Morning With FDA," Pharmaceutical Advertising Club, Roosevelt Hotel, New York City, Oct. 20, 1966.