veillance, both by us and by the manufacturer, of clinical experience to keep advertising messages in step with the realities for safe and effective prescribing of new drugs as more experience is developed during their marketing history.

Thank you. I will be glad to answer any questions.

(The complete prepared statement and supplemental information submitted by Dr. McCleery follows:)

STATEMENT OF DR. ROBERT S. MCCLEERY, ACTING DIRECTOR, DIVISION OF MEDICAL ADVERTISING, BUREAU OF MEDICINE, FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman, I appreciate this opportunity of appearing before you this morning to discuss our experience with the advertising of Indocin. For the sake of brevity, and with your permission, I will submit for the record a statement of my educational and professional background.

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.

The Fountain Subcommittee, House Committee on Government Operations, had reviewed with the Commissioner our programs in this important area of our public responsibilities. In short, industry's attention was brought emphatically to promotion excesses in many ways.

In June 1966, the Director of Public Relations for Merck & Co., Mr. John E. Fletcher, wrote to Theodore O. Cron, our Assistant Commissioner for Education, enclosing a print of an article that was about to appear in the July 1966 issue of *Pageant* magazine.

The story featured Indocin as useful for "bursitis," "trick knee," "tennis elbow" and "a host of other less common disorders characterized by pain and swelling in and around the joints." The support for these claims was largely lay testimonials some of which, according to the article and the firm, were made available to the writers by the sponsor of the drug.

Mr. Fletcher said that the firm was in no way responsible for the article, that the authors had heard of stories about the drug from a variety of sources and wanted to do an article about it, and that the firm had simply responded to this inquiry from responsible science writers. Mr. Fletcher said the article was in no way promotional and wanted to so assure the Agency.

The drug, of course, had not been approved for use for the above-mentioned conditions for which it was claimed to be effective in the *Pageant* article. We knew also that a popular article of this sort is apt to create a demand for the drug by the patients who read it. My office, the Division of Medical Advertising in the Bureau of Medicine, was asked to review the article for possible violation of the law, and to review also the advertising of this drug in medical journals to determine if the drug was being promoted to the medical profession on the basis of unapproved claims.

Our concern was that if the firm would make these data on unauthorized uses available to a free-lance team of writers, it might not be scrupulous in its advertising to the medical profession.

Identical advertisements which appeared in the *Journal of the American Medical Association* issues of July 4, 1966 and August 15, 1966, were found to be featuring the theme that the drug "extends the margin of safety in the long-term management of arthritic disorders." At the same time, the Office of Marketed Drugs was negotiating with Merck for changes in the labeling to emphasize the newly recognized hazards that had emerged during the first year of clinical experience since original approval of the drug.

The *JAMA* ads in July 4 and August 15, 1966 issues were analyzed and found to be defective, in our opinion, in several respects. I will first mention generally the major defects of this ad and then will be more specific regarding the details of our objections to certain of the features of this and of a later ad which appeared in November 1966. The basic theme of greater long-term safety in the ads was not supported by the clinical experience. To the contrary, the longer