full misleading character of the promotional drive can be assessed only by considering the full text of the bulletins. The setting of substantial quotas and reports of sales suggest that the promotional scheme was successful. The extent to which the sales instructions were followed, or what extrapolation the Merck detail men may have given to the bulletin instructions, in their oral presentations is, of course, unknown to us. But we do know that "Indocin" has been promoted for conditions outside the approved labeling. We have no reason to doubt that the promotional instructions contributed to prescribing of the drug for unapproved uses.

We appreciate your making the bulletins available to us for examination.

Please let us know if we may be of further assistance.

Sincerely yours,

PAUL A. PUMPIAN,
Director, Office of Legislative and Governmental Services.

Senator NELSON. But let me quote a few passages from this letter:

The 1965 bulletins suggest generally to the detail men that they promote use of Indocin beyond approved indications, and play down side effects and other warnings present in the labeling. * * *

As you know, there was a series of events that occurred between 1965 and 1967 which involved our dealing with the firm regarding their advertising and promotion of Indocin. Merck was cited in regard to Indocin advertising, conferences were held with the firm's management in 1966 and the Assistant General Counsel of the Department spoke publicly regarding the misleading nature of an Indocin advertisement appearing in the Journal of the American Medical Association, and elsewhere. With such notice, the firm did take action to correct its forms of promotion which are subject to our control. Notwithstanding such notice, however, we find in 1967 Indocin bulletins: The expansion of indications for open-ended uses. * * * The continued minimization of side effects and warnings. * * *

The setting of substantial quotas and reports of sales suggest that the promotional scheme was successful. The extent to which the sales instructions were followed, or what extrapolation the Merck detail men may have given to the bulletin instructions, in their oral presentations, is, of course, unknown to us. But we do know that "Indocin" has been promoted for conditions outside the approved labeling. We have no reason to doubt that the promotional instructions contributed to prescribing of the drug for unapproved uses.

We will hear now from the witness. Our witness this morning is Dr. Robert S. McCleery, Acting Deputy Director, Bureau of Medicine, Food and Drug Administration of the U.S. Department of Health, Education, and Welfare.

Dr. McClerry, we appreciate your appearance here this morning very much, and you may proceed to present your statement. I assume that you would have no objection to interruptions for questions from time to time.

Dr. MCCLEERY. No, sir.

Senator NELSON. Please go ahead, Dr. McCleery.

STATEMENT OF DR. ROBERT S. McCLEERY, ACTING DEPUTY DIRECTOR, BUREAU OF MEDICINE, FOOD AND DRUG ADMINISTRATION; ACCOMPANIED BY DR. B. HARVEY MINCHEW, ACTING DIRECTOR, BUREAU OF MEDICINE, FDA; HARRY CHADDUCK, DEPUTY DIRECTOR, DIVISION OF MEDICAL ADVERTISING, BUREAU OF MEDICINE, FDA; WILLIAM W. GOODRICH, GENERAL COUNSEL, FDA; AND MORTON M. SCHNEIDER, ASSISTANT DIRECTOR, OFFICE OF LEGISLATIVE AND GOVERNMENTAL SERVICES, FDA

Dr. MCCLEERY. Mr. Chairman, on May 2, as you mentioned, I appeared before you at your request to discuss our experience with the