

in excess of approved dosages. Both of these important and material factors are concealed from the reader of the ad.

B. *Re: the "Brief Summary"*

The following important warning ideas in the FPL are omitted from the ad's "brief summary":

1. "As with other anti-inflammatory agents, Indocin may mask the signs and symptoms of peptic ulcer." (see Contraindications)
2. "Indocin itself may cause peptic ulceration . . ." (see Contraindications)
3. ". . . Indocin may cause [single or multiple] ulceration of the stomach, duodenum, or small intestine." (see Precautions and Adverse Reactions)
4. "The possible potentiation of the ulcerogenic effect of these drugs [steroids, salicylates or phenylbutazone] cannot be ruled out at present." (see Precautions and Adverse Reactions)
5. A summary of the following cautionary information (see Precautions and Adverse Reactions):

"Rare reports where it is not known whether the effects can be attributed to the drug include bleeding from the sigmoid colon either from a diverticulum or without a known previous pathologic condition, and perforation of pre-existing sigmoid lesions (diverticulum, carcinoma). In other rare cases a diagnosis of gastritis has been made while Indocin was being given. One patient developed ulcerative colitis and another regional ileitis while receiving Indocin."

III. RECOMMENDATION

Seizure, with or without such injunctive measures as may be feasible.

When Mr. Goodrich called, he asked that we expedite our review of the ad and article while they are still current. He felt that the two items might be joined in one regulatory action. For this reason, they are both included in this one memo.

R. S. McCLEERY, M.D.

MERCK SHARP & DOHME,
West Point, Pa., September 22, 1966.

Hon. L. H. FOUNTAIN,
Chairman, Intergovernmental Relations Subcommittee, Committee on Government Operations, House of Representatives, Washington, D.C.

DEAR MR. FOUNTAIN: This is in reply to your letter of September 7, 1966, enclosing an ad from the August 15, 1966, issue of the Journal of the American Medical Association for Indocin (indomethacin, Merck).

This advertisement and the labeling of the drug have been undergoing review by this agency. In our opinion, the ad is inconsistent with the prescription drug advertising provisions of the law. Further, we regard the quotes from the medical literature used in this ad as not being in conformity with the guidelines described in my statement to your Subcommittee on May 25, 1966.

We are proceeding to take corrective action in this matter.

Sincerely yours,

JAMES L. GODDARD, M.D.,
Commissioner of Food and Drugs.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
October 31, 1966.

FRED BARTENSTEIN, JR.,
Administrative Vice President,
Merck & Co., Inc.,
Rahway, N.J.

DEAR FRED: This acknowledges your letter of October 26, 1966, about my speech at the PAC in New York City, October 20.

My points were based on a medical evaluation of your Indocin ad. Our Philadelphia District has been instructed to issue citation to your firm. This involves both the Pageant article and the ad. You will, of course, have the opportunity to make your points in response to the citation.

We feel that the effectiveness of the drug and its safety in use have been misstated. The things I pointed out involved the approved brochure (before the recent revision) and the ad which is still running. We do not agree that the "profile" of "Indocin" remains the same today as it appeared when the new drug application was approved.