

We do not agree with the allegations of fact, charges, and conclusions contained in Dr. McCleery's testimony on a number of detailed aspects of our advertising of 'Indocin', such as his extensive discussion of the reference in our advertisement to an article by Hart and Boardman in the *British Medical Journal* of October 18, 1963. We have presented to the Food and Drug Administration detailed factual and legal responses to these charges. In our view, the advertising statements the Company used did not misrepresent the status of the drug, intentionally or otherwise. In any event, the criticized statements have not appeared in any Merck advertisement since 1966.

As Mr. Goodrich testified before your Subcommittee, this matter is now pending before him for a decision on whether further legal proceedings should be recommended. While the matter is in this status—and since the issues involved require lengthy analysis and interpretation of the criticized quotations, the scientific data on which they were based, and the articles from which they were taken—we believe it would be inappropriate to comment on the issues in this forum.

We do feel, however, that we should note our exception to one specific point about our advertising raised by Dr. McCleery, since it suggests knowing misrepresentation on our part. In commenting on an advertisement in the July 18, 1966, edition of the *Journal of the American Medical Association*, he said that the advertisement "... featured the claim of one of the participants in a Merck-sponsored symposium. This is attributed to Dr. Englund—they featured a claim, quoting from him at this symposium that [he] had had 500 patients on the drug for three years, when Merck's own records would have told them this was not true." (Page 4733)

The advertising to which he referred contained this statement:

"I have had some 500 patients on indomethacin now for about three years. I find it an extremely helpful drug. I think there are certain areas where it will be without question [a] drug of choice. One of these is osteoarthritis of the hip."

This quotation was taken from a statement made by Dr. DeWitt W. Englund in response to a question from the chairman of an international symposium on Non-Steroidal Anti-Inflammatory Drug Therapy in Rheumatic Diseases conducted September 26-28, 1965, in New York City, by the Excerpta Medica Foundation.

We do not believe that Dr. McCleery's criticism of the Company for using the statement "when Merck's own records would have told them this was not true" is warranted. Merck could properly have relied on Dr. Englund's recorded and published statement as the factual observation of an eminent and leading rheumatologist. Our records did show that Dr. Englund had treated at least 500 patients by that time. The information was contained in Merck's first quarterly report to the FDA after the approval of the New Drug Application on June 10, 1965. It was sent to the Agency about the middle of September, 1965, and should also be in its records.

In another portion of his testimony, Dr. McCleery described his understanding of our connection with a lay article about the drug in *Pageant* magazine. (Pages 4716-20) We consider this also to be fundamental because, according to Dr. McCleery, it led the FDA to conclude that this Company "might not be scrupulous in its advertising to the medical profession."

We are therefore setting forth in detail what took place with regard to the *Pageant* article:

1. On February 15, 1966, Mr. Robert P. Goldman, who has been a science writer since the late 1940's, telephoned John E. Fletcher, Director of Public Relations for Merck, stating that while in France his wife had been given a prescription for "Indocin" for the treatment of tennis elbow. Mrs. Goldman and her doctor felt that the treatment had been successful. When Mr. Goldman inquired of the doctor as to the source of the drug, he was surprised to learn that it had been originated by an American company, namely Merck. Mr. Goldman chided Mr. Fletcher about the fact that there had been no publicity about the drug. He said he planned to write an article about indomethacin and asked the company to provide him with some background material on it.

2. On February 17, 1966, Mr. M. T. Noar, a member of the Company's public relations staff, at the request of Mr. Fletcher, sent Mr. Goldman appropriate background information, including a "background" containing medically and scientifically authenticated information about the drug, its genesis, and the disease conditions for which it is approved; a package circular; relevant papers by scientists from Merck and other laboratories; and a bibliography.

3. Sometime within the next month, Mr. Goldman called Mr. Fletcher stating that he would like to have some human interest stories to increase readability