

Several weeks ensued. Mr. Goldman did not visit the company or talk with anyone in the company about the drug or the story he was writing. Then he called Mr. Fletcher again, said his story was essentially finished, said he had a lot of anecdotes to liven it up, and asked if the company could provide additional anecdotal material to personalize it still further.

Mr. Fletcher supplied him with four or five letters from our files, deleting the names of the correspondents. They dealt with approved claims.

There is, as I understand it—and I will check it if this is material—an attribution of a nonapproved claim in the article. This was not among the cases supplied to him by Merck & Co.

Senator NELSON. What is an approved claim?

Mr. GADSDEN. The four that were enumerated earlier, sir, which have to do with various aspects of arthritis.

Senator NELSON. What is an approved claim?

Mr. GADSDEN. When we make a submission to Food and Drug, as we discussed earlier, we request—let us call them indications. Perhaps that is a more precise term than “claims,” meaning for what disease conditions use of the drug is indicated. The FDA must approve these indications. The thrust of the criticism is that we were seeking through lay publicity to publicize and popularize the use of this drug for conditions—indications—which had not been approved.

Senator NELSON. I see.

Mr. GADSDEN. I will continue, sir, if I may.

We were altogether unprepared for the appearance of this Pageant article, with the name of the drug as the title of the article, and a subtitle that enumerated its value for a number of conditions for which we had no claim.

Senator NELSON. That will go into the record immediately following this letter so that they will both appear in the appropriate place in the record.

Mr. GADSDEN. Counsel reminds me, sir, that contrary to the statement that is contained in the letter which has gone into the record, Mr. Fletcher did not see the article until after it was printed.

Mr. CUTLER. Also, Mr. Chairman, the article itself, as I understand it, refers to one letter which the author says he got from Merck relating to the use of the drug for an unapproved claim. No such letter was furnished by Merck.

Senator NELSON. Thank you.

Again, thank you, Doctor.

Dr. LAWRASON. Before introducing the two outside witnesses, Dr. Calabro and Dr. Smyth, the two physicians, who will summarize their views and the views of physicians who are treating patients with arthritic disorders, I have with me an even broader representation of medical opinion concerning the values and limitations of indomethacin that we hereby submit to you with the request that it be made part of the official record.

Senator NELSON. Would you identify what it is?

Mr. CUTLER. It is this green folder which you should have up there, Senator Nelson.

Dr. LAWRASON. This exhibit, Mr. Chairman, consists of letters and telegrams from distinguished rheumatologists and experienced physi-