distributor. It requires only that such material be issued *or caused to be issued* by the manufacturer, etc.

We think it is clear from the dictionary meanings of "cause" that Merck caused the *Pageant* article to be issued. For example, a pertinent meaning is that "cause applies to any event, circumstance, or condition or any combinaation of these that brings about or helps brings about a result."

There are several statements in the article that could not possibly have been made unless the information had been furnished by Merck; thus, it is apparent that the firm can be considered to have caused the article to be issued.

Additionally, the article itself contains direct confirmation of Merck's participation in causing the article to be issued. For example, on page 8, the authors state:

> ". . . many of them [patients] are moved to sit down and write about their experiences with the drug to its producer, Merck, Sharp and Dohme of West Point, Pennsylvania."
>
> "The following are some samples of these letters to the pharmaceutical firms: . . ."

C. In our opinion, the *Pageant* article by Phyllis and Robert P. Goldman misbrands Indocin, a prescription drug, under section 502(n) of the Act.

Having "caused" the article to be issued, Merck then had the obligation to insist that it meet the requirements of section 502(n). Merck did not meet this obligation. For example, the article fails to contain a true statement of information in brief summary relating to side effects, contraindications and effectiveness as required by section 502(n)(3) and regulations 1.105(e) and 1.105(f)(1).

We believe that a most serious aspect of this misbranding situation is the flagrant appearance of claims in the article that go far beyond the indications for use approved in the package insert. For example, use of Indocin for "bursitis," "trick knee," "tennis elbow," and "a host of other less common disorders characterized by pain and swelling in and around the joints" has not been approved in labeling for the drug. To demonstrate Merck's direct responsibility in causing such unapproved claims to be published in the offending article, the following sample of a letter furnished to the writers by Merck is quoted:

> "From Minneapolis: 'Because of bursitis I had to give up golf two years ago. But with your wonderful medicine I'm in good enough shape now to play golf once again . . .'"

II. Three-Page Ad in the July 4, 1966, Journal of the American Medical Association

A. *Promotional Copy* (re effectiveness)

1. The headline, "extends the margin of safety in long-term management of arthritic disorders," is misleading since:

a. It implies that sufficient experience has been obtained to establish Indocin's long-term safety. This is neither the case, nor does the approved package insert (FPL) contain such an affirmation.

b. It contains an implication that Indocin is safer than all other effective anti-arthritic agents for long-term therapy. This is neither proved, nor does the FPL contain such an affirmation.

c. The claim, ". . . of arthritic disorders," is too broad. It extends the FPL indications by implication to other arthritic disorders which have not been approved for inclusion in the FPL. At least it should be modified by a word such as certain."

2. The use of the quote from the Hart and Boardman article (attachment #1), under the caption "rheumatiod arthritics," is misleading since:

a. It is taken out of the context of the article which reveals that the very impressive phrase, ". . . in most cases of active rheumatoid arthritis," refers to the small number of 8 out of a total of 15 cases.

b. It fails to reveal that dosages far in excess of those approved in the FPL were employed (see pages 966 and 968), at least in the early phases of therapy; e.g., 200–300 mg./day versus the FPL's upper initiating limit of 75 mg./day.

c. It fails to reveal, for fair balance, that approximately 60% of the patients with rheumatoid arthritis got side effects, and that all of these got more than one side effect (pp. 969–970).

d. The duration of therapy (p. 966) in these patients was far too short to support the layout's implication that this paper supports the headline's claim of long-term safety.