

3. The use of the quote from the Rothermich reference (attachment #2), under the caption "ankylosing spondylitis," is potentially misleading:

a. The quote seems to come from a scientific article. This is not the case—it is from a 2-inch abstract apparently of a talk presented at the "American Rheumatism Association" meeting in 1964.

b. The quote is accurate, but it is surprising that the company used this abstract as a reference when almost certainly the full details have been published as a regular article later in 1964 or early in 1965. (We have not yet located this article.)

c. The use of the abstract is also potentially misleading since long-term results (re the headline's claim for safety) and dosages were not included. Therefore, dosages that produced these results may well have been in excess of FPL limits.

d. For fair balance, against the quote of good results described in the Hart article above, the company could have included Rothermich's results in rheumatoid arthritis. In this same abstract, he stated that although "Excellent results have also been obtained in some cases of rheumatoid arthritis . . . there have been striking failures as well . . ."

4. The use of the quote from Englund, under the caption "degenerative joint disease (osteoarthritis) of the hip," is at least potentially misleading:

a. It gives the appearance of being from an article in a symposium-book. Such are not widely distributed, nor easily available.

b. It was not available in BuMed Library. Dr. Standard of DSB/DMR made a trip to the NIH Library, which had a copy.

c. There was no reference to Dr. Englund's work on page 27, as cited.

d. There was no reference to an article by him in the symposium, either in the index or table of contents.

e. We did locate a physician by that name, in the AMA directory, practicing in Phoenix, Arizona.

f. We will search further to try to find the quote. It could be seriously misleading if Dr. Englund did not, as seems likely, have all "500 patients on indomethacin for about three years" (*italic added*).

5. The use of the quote from the same Hart and Boardman article (attachment #1), under the caption "gout," is misleading and shows a serious lack of "fair balance."

a. The quote from a seemingly authoritative source from a leading foreign medical journal implies that this opinion must have been based on a large experience (unspecified in quote), and that it was consistent with the general experience of experts using the drug according to the FPL.

b. It was not:

(1) The implied claim that indomethacin is the drug of choice in acute gout is not supported by the FPL.

(2) A reasonable source of early consensus on a relatively new drug, about which "drug of choice" claims are being made, is the view of the AMA Council on Drugs. Its view is expressed in *New Drugs* (1966)—"Because it has produced relief in acute attacks within 48 hours, and because it lacks the untoward effects of colchicine, some clinicians consider it to be the drug of choice for these attacks; however, controlled trials are needed to determine how its effectiveness compares with that of colchicine."

If the company wanted properly to use the authors opinion, it should have included the dosage they used and the number treated. Even then, "fair balance" would still require inclusion of an authoritative opposite or consensus view if such existed.

(3) The experience was not large—the authors report on a study of only 15 cases treated for relatively short periods (see pages 966 and 967).

(4) The "good" results, that led the authors to make the quoted statement, were based on dosages far in excess of permitted (150 mg./day) upper FPL dosage limits—they administered 200–500 mg./day for several days (see pages 966 and 967).

(5) Their opinion was not based on a well-controlled experience. In only 7 patients were any direct comparisons made, and that only to one drug, phenylbutazone (see Table II, page 967). Even here, 3 patients out of 7 preferred phenylbutazone to Indocin.

c. It is very misleading that the company should employ this quote to imply it represents an accepted view of Indocin's effectiveness compared to all other drugs, especially when they know it is based on a very limited (15 patients) and uncontrolled experience—and when the results achieved are based on dosages far