

the drug had been on the market, the more serious adverse experience information was reported.

The ad quoted apparently-authoritative sources without the full impact of the limited experience contained in the actual articles. And it featured, for example, one reference which on checking proved to be only a 2-inch abstract of a 1964 speech. The ad quoted the author's opinion that "... results have been uniformly excellent or good in ankylosing spondylitis." The same abstract also included the author's view that, while "Excellent results have also been obtained in some cases of rheumatoid arthritis . . . there have been striking failures as well." It is, perhaps, not surprising that, while the advertiser included this author's favorable remark regarding his experience with spondylitis, the ad turned to another author for a more favorable quote concerning the possible value of the drug on rheumatoid arthritis.

It offered the drug for "arthritis disorders," rather than solely for the four conditions for which it had been approved.

It characterized the drug as non-steroid—which of course it is—but failed to disclose in this connection that it had some of the major side effects of the steroids, e.g., an ulcerogenic effect.

It claimed that the drug extended the margin of long-term safety, without any evidence to support the claim—it quoted from isolated pieces of literature—one an excerpt from a symposium sponsored by the company—to claim that the drug was the drug of choice in gout and osteoarthritis of the hip, neither of which claims had been approved.

It quoted from two leading English authorities to the effect that the drug was useful in most cases of rheumatoid arthritis, when these authors had used the tablet and not the marketed capsule, and when their actual opinion, known to Merck, was that the drug was useful in only selected cases of rheumatoid arthritis.

It featured the claim of one of the participants in a Merck-sponsored 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.

And finally in the "Brief Summary" of information on side effects and contraindications some of the major warning information was left out—such as the fact that indomethacin itself had caused ulcers, and that the drug should not be administered to children.

This exemplifies what may be called the euphemistic style of revealing warning information. The ad's "Brief Summary" translated the package insert's warning, "INDOCIN itself may cause peptic ulceration . . ." into the area of causal doubt in this manner: "Ulceration of the stomach, duodenum, or small intestine have been reported . . ." Further, the package insert's directness, regarding administration of the drug to children, became the "Brief Summary's" statement that "Safety in pregnancy and pediatric age groups has not been established."

Deficiencies in the ad were publicly noted in a speech before the Pharmaceutical Advertising Club in New York on October 20, 1966, by our General Counsel, Mr. Goodrich.

The firm protested and shortly thereafter, on November 11, 1966, a sort of armistice day, the firm's principal officers met with Dr. Goddard and his staff to go over the problem.

The firm reported that it had immediately ordered the ad discontinued after the October meeting and was taking a close look at all of its promotional efforts. Later, its physician and counsel responsible in the area of advertising came down to go over some ads for other products with us.

Soon after this episode, Merck began to show significant improvements in its advertising practices for prescription drugs but not before it ran, in the November 1966 issue of the *American Journal of Medicine*, another ad which contained most of the faults of the original ad, plus some additional new faults.

I will expand on this. While the authors, in 1963, had published the report quoted, we felt that Merck had no right to adopt the quotation in their 1966 advertising.

The quotation from an article by Hart and Boardman (Hart, F.D. and Boardman, P.L.: *British Medical Journal*, 2:965, October 18, 1963) and used under the ad caption "rheumatoid arthritis," namely, "... the first non-corticosteroid agent which produced a predictable and measurable reduction in joint swelling in most cases of active rheumatoid arthritis."

Our comments in reference to the quotation are that it: