

13618 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

The American Medical Association rejected this as being completely false and misleading, yet 6 months later the same ad appeared in four widely used medical journals * * *

Here again, the criticism is directed to the false and misleading nature of the advertisement as a whole. The statements in the "message" portion of the advertisement were false and misleading. The addition of a "true statement" in a "brief summary" of side effects or contraindications or effectiveness might afford the physician other information on which to judge the drug, but could not itself correct the misleading effect of the advertisement. Certainly, the advertisement would be misleading if it asserts that "Tao" is superior to penicillin in the "message" portion even if the "brief summary" said that it was not. The total effect would be something less than a "true statement" of effectiveness of the drug.

Similarly, Representative Dingell described an advertisement for the drug "Medrol", as follows:

"I was surprised to find in my study of material involving one medical practitioner that an ad appeared in one of the standard publications on the subject showing the photographs of a patient who allegedly suffered from colitis. I was further surprised to find in my additional study that this so-called reputable manufacturer who was advertising had actually gone so far as to use X-ray photos of persons who had not received the drug. These two different photographs of two different patients appeared in the ad with statements in the advertisement purporting to indicate that it was the same patient on a before and after treatment basis, before and after he had received the drug Medrol."

"This is the kind of advertisement that the amendment to the drug advertisement section tries to correct, to assure that the doctor shall receive to the fullest extent possible the fairest and most complete statement of side effects, contraindications, and efficacy of the drug in simple form." 108 Cong. Rec. 21064 (Sept. 27, 1962). [Emphasis added]

The false illustrations in that advertisement occurred in the "message" portion, and would not be affected by a true statement of side effects, contraindications, or effectiveness, "in brief summary", or otherwise. From this example, the conclusion is inescapable that Representative Dingell believed that section 502(n) was intended to eliminate false and misleading statements throughout the advertisement.

The drug advertising examples given in debate demonstrate that Congress intended to promote truthful drug advertising in all aspects. The concept of truth in drug advertising would be meaningless if it were interpreted to apply to only a portion of an advertisement. Such an interpretation would illogically limit the meaning of the phrase "true statement" and would do violence to the understanding of the provision by Congress. Rather than preventing half-truths, the provision would enable advertisements to mislead, as has occurred in the instant case, by permitting truth to be mixed with fiction.

Certainly, Congress did not want this amendment to promote confusion to physicians. To limit regulation of the advertisement to examination of a portion of it—whether labeled "brief summary" or otherwise—could only have that result. Only if the entire advertisement be subject to the requirement of "a true statement" can 502(n) have the enforcement effect sought by Congress.

This very issue was taken up in the 1963 hearing to establish regulations on prescription drug advertising. The Commissioner stated and the Pharmaceutical Industry agreed that the "true statement" concept applied to the whole ad message. On October 1, 1963, Mr. Larrick wrote to Mr. Gesell, counsel for the industry, as follows:

I. *Fair Balance and Prominence.* It seems clear to us from the legislative history of section 502(n) that Congress intended this new section to deal completely, and not partially, with the problems of false and misleading advertising which had been called to its attention. The legislative history clearly shows that Congress intended the administering agency to have jurisdiction over the entire advertisement and that the phrase "brief summary" was introduced only to authorize use of a stripped-down statement of the drug's effectiveness, side effects, and contraindications when the sponsor wished to limit the size of his ad.

Our regulations are not intended to prohibit use of graphic presentations, headlines, or similar advertising techniques. Our basic purpose is to provide assurance that the advertisement will fairly present the message to the physician of what the drug will do, what its limitations are, and what side effects