

For the purpose of convenience in this discussion, I will use the word advertising in reference to graphic presentations to physicians which are readily identifiable as commercially sponsored sales messages. By promotion I mean all other communications aimed at promoting the sales, use and acceptance of The Pill by the medical profession and by the public.

Advertising of The Pill to the medical profession has been characterized by many statements that tend to be misleading. For example, in Enovid Bulletin No. 20, published in 1964, under a section headlined "The responsibility of leadership" is this statement:

... few drugs in any category have ever been subjected to clinical tests as exhaustive as those already undergone by Enovid.

The reader was expected, no doubt, to understand that statement as applying to safety as well as to efficacy. In fact, the "exhaustive" testing was applicable to efficacy but not to safety. In that same bulletin:

In the mass of data now on hand, there is *no* evidence that long-term inhibition of ovulation with Enovid impairs post-treatment fertility. . . .

Again, a statement implying that exhaustive work relevant to the subject had been done.

Ambiguous language has been employed many times to take away the sting from information which should have had a warning impact on the physician. For example, in Physicians' Product Brochure No. 62, printed March 16, 1964:

There is no direct evidence that Enovid alters the diabetic state. However, in a few instances some degree of difficulty in the management of diabetic patients has been reported in connection with Enovid therapy. . . .

They may be expected to return to their pretreatment manageability on discontinuance of the drug.

Obsolescence of statements in advertising, amounting to untruthful misrepresentation, has occurred from time to time, as newer knowledge superseded older. Such were not restricted to the early days of aggressiveness, however; an outstanding example of this practice appeared in the past year. This was at a time when past events and warnings should have made everyone more vigilant than ever to be promptly forthright with physicians and their patients. This relates to the British statistical data, first published in 1967 as preliminary findings, then in 1968 as firm conclusions, about the increased risk of thromboembolism in Pill users. In May 1968 that data was added to the labeling on The Pill, all brands, as an emergency measure. However, the manufacturers successfully persuaded the F.D.A. to allow a neutralizer in the material. The impact of the British data was in fact negated, in the minds of many American physicians, by this language:

No comparable studies are yet available in the United States. The British data, especially as they indicate the magnitude of the increased risk to the individual patient, cannot be applied directly to women in other countries in which the incidences of spontaneously occurring thromboembolic disease may differ.

In November 1968 Drs. Markush and Siegel of N.I.H. disclosed that their study of mortality data "indicate an association of oral contraceptives with an increase in mortality from diseases of the veins. . ." Although that study was not comparable in technique, it was certainly comparable in conclusion, and American physicians should have been told about it in the labeling. It has not been included, perhaps because it would have helped debunk the language quoted above. The results of the Sartwell study, reported in the Second Report on Oral Contraceptives by the Advisory Committee, were known in the spring of 1969, were circulated widely in mimeographed form in August, released to the press in September, but as late as the issue of J.A.M.A. for December 29, 1969, had not been incorporated in the labeling. Physicians who took solace in the cleverly worded detour around the British data—and there were many who seriously believed that nonsense—were deprived of the comparable American information, unless perchance they read it in the lay press. At the very least, this represents a five month delay in disseminating the new information.

The tone of much of the advertising has been to suggest to the doctor that he is indeed in a supreme position to order and manipulate life with his prescription pad. The doctor's ego has been pampered so that he may not realize he is being treated like a door-to-door salesman for the drug company, who shows him how to get his foot in the door and close the sale.