

This could lure the unsuspecting physician into not looking much further. While the incidence is mentioned later of the common side effects, it's a bit too late.

* * * * *

"All in all, the sins in this ad are those both of omission and commission. They include poor arithmetic, poor terminology, invention of psychiatric terms, and an overwhelming intent to 'snow' the practicing physician."

As the medical officer's comment shows, we share the responsibility for some of the defects in this ad, because we approved the package insert. That does not make the ad any better.

Aventyl was offered for a new psychiatric disorder, discovered right here on Madison Avenue. While this makes excellent ad copy, it does not promote the drug for the conditions for which it has been approved. Instead, it uses a new catch phrase to cover a host of "target" symptoms, so that the drug is indicated and prescribed for the ordinary frustrations of daily living to reach a much larger patient population than the scientific data will support.

C-Quens and Oracon were approved as new sequential oral contraceptives.

The central theme of the ad for Oracon is that it is safer than and superior to other oral contraceptives because it is so close to nature—that it is physiological, neutral, and normal.

These claims are unsupported by scientific facts. Thus far, there is no substantial evidence that any oral contraceptive is either more effective or safer than any other that has been approved for the market.

This ad also make a point that Oracon was "the first sequential oral contraceptive". It fails to inform the physician that it was approved only 13 days before C-Quens. The apparent purpose of the claim is to bolster the asserted, but unsupported, superiority.

The theme of the ad for C-Quens is directed to a single side effect of the oral contraceptives—weight gain.

The claim that women using sequential oral contraceptives experience less significant weight gain is ungrounded in scientific fact, and the ad is thus misleading in its major implication. Yet, it may serve its purpose of influencing the physician to shift a patient to this product on the basis of this illusory promise.

This ad, like the one for Oracon, claims "other advantages of therapy"—presumably less side effects, and this is bolstered by a claim that it contains "the smallest amount of hormone substance". The latter claim is literally false, and the claim of lower incidence of side effects has no scientific support.

The truth about the oral contraceptives is reported in an FDA publication, available from the Government Printing Office. It is that there is no adequate scientific data, at this time, proving these compounds unsafe for human use. There are nonetheless some very infrequent but serious side effects and some possible theoretic risks suggested by the experimental data. The physician must decide for his patient whether to accept the risk—small though it may be. And the Committee which advised us said: The physician "can do this wisely only when there is presented to him dispassionate scientific knowledge of the available data."

We leave with you the question whether these two ads present the physician with "dispassionate scientific knowledge".

Indocin has been marketed for slightly more than one year. Like most new drugs offered to replace established products, this one was offered as safer and more effective. As new experience with the drug has been gained, more side-effects have been noted and more warning information has been required. Only a few days ago, the sponsor mailed a new revised brochure to the profession, with new cautionary information in heavy print. Yet the current ad continues the headline "extends the margin of safety in long term management of arthritic disorders".

There is not yet enough experience to support the claim for greater long-term safety. To the contrary, the longer the drug is used the more side-effect information appears.

This ad quotes authoritative sources, without the full impact of the actual articles. And it uses one reference which is from a 2-inch abstract, apparently of a 1964 speech. This latter reference is used to support a claim for "ankylosing spondylitis", but the ad does not inform the reader that this same abstract also states "Excellent results have also been obtained in some cases of rheumatoid arthritis . . . there have been striking failures as well."

The claim for gout is not supported by the package insert or by the scientific data.

And, finally, the "Brief Summary" omits some very important warning information that is required in the package insert—and thus in the ad.