

Oracon—Mead Johnson
 Pediamycin—Ross
 Pre-Sate—Warner Chilcott
 Tegopen—Bristol Laboratories

Without implying that there has been a complete medical work-up as to the validity of all of the advertised claims for these drugs, I can say that I asked our medical staff—including some of the physicians who were primarily responsible for the clearance of the drugs for market—to comment on some current ads for these important new offerings of the pharmaceutical industry.

Here are the results.

"No doubt, this ad will sell huge amounts of Aventyl. It is pretty, impressive, and seems to pack quite an emotional wallop. However, the term 'behavioral drift' doesn't appear to be more than a Madison Avenue description. It certainly is not a bona fide psychiatric diagnosis.

"It is, from the ad, difficult to tell in the first 4 pages, whether Aventyl is primarily an anti-depressant, primarily a tranquilizer or what.

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"The first sentence under side effects in both the ad and the package insert states that 'No single side effect can be considered as occurring frequently * * *.' 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.

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"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, natural, 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 makes 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