

And the use of only those promotional claims which have been approved in advance upon the clearance of the drug for the market as a "new drug" or as a certified antibiotic, or, for drugs that required no preclearance, claims of effectiveness that are generally recognized as true or which are supported by substantial evidence, consisting of adequate and well-controlled investigations or adequate clinical experience on the basis of which it can fairly and responsibly be concluded that the drug will have the effectiveness claimed.

This is not a very big order.

Simply stated, drugs may be promoted only on the basis of proven effectiveness.

The total advertising message must be fair and frank in discussing both the usefulness and the hazards that may attend the administration of the drug.

And the layout of the ad must deal fairly with the scientific data that underlies the message.

As Dr. Goddard said in his Chicago speech to the Midwest PA Club, we have difficulty in understanding how a group of creative people with the talents you so regularly display should have any difficulty at all in understanding the advertising restrictions of our regulations.

"Fair balance", "reasonably close association", and the "same relative degree of prominence" are words of ordinary English.

No more inflexible words were used because the Agency wanted to move with the drug industry and the creative people in correcting what was an indefensible state of drug promotion.

If these concepts in the present regulations seem perplexing—we offer the memoranda of understanding which passed between us and the industry back in October, 1963. And we offer also a statement we made public in 1964 calling attention to the most common failings in drug promotion. More recently, at the medical section meeting of the Pharmaceutical Manufacturers Association on March 30, 1966, we described in great detail the basic premises underlying our evaluation of advertising and promotional labeling.

Bearing in mind Ben Franklin's comment that "Laws too gentle are seldom obeyed; too severe, seldom executed", we are preparing to move the informal comments in the memo of understanding and in the policy announcement into the positive provisions of regulations. And we will continue to examine the performance of all advertisers under our rules, so that misunderstanding and non-compliance can be promptly corrected.

With this background as to the state of the law, let's turn to the state of compliance by examining a few cases of actual performance.

Remembering that "all things that hurt, instruct", I apologize in advance for any injured feelings that may flow from a critical examination of some examples of your most recent work.

We would like to view with you the ads for the "big eight"—all of the eight new 1965 model drugs that entered the list of the 200 most prescribed during the first years of their introduction.

They are:

Aventyl—Eli Lilly
C-Quens—Eli Lilly
Indocin—Merck Sharpe Dohme
Lincocin—Upjohn
Oracon—Mead Johnson
Peditamycin—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 * * *'