THE STATE OF THE LAW AND COMPLIANCE*

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Three years have passed since FDA first entered the world of prescription drug advertising.

We are more intrigued with what we see today, than we were by our first viewing. To borrow a quote: "We are reading more now and enjoying it less." And we are more convinced than ever that there is much room for needed improvement.

Getting to know you is a refreshing experience. It has been said of you that you have a unique ability to make a virtue out of a serious side effect.

The Kefauver investigations highlighted many excesses in drug promotion. But they suggested no remedies. The Executive Branch's first reaction was to strengthen the Federal Trade Commission Act. But the Congressional response was to require stronger control under the Federal Food, Drug, and Cosmetic Act. Instead of orders to cease and desist, new sanctions of seizure, injunction and criminal penalties were provided to do this job.

While the legislative developments were fast moving—and the legislative history is relatively thin—the message was loud and clear that there had to be some basic changes in this phase of drug promotion.

President Kennedy recommended—and the Congress enacted—provisions intended to "help assure the American people . . . that the promotional material [for Rx drugs] tells the full story . . . [the] possible bad effects as well as the good—and the whole truth about therapeutic usefulness."

This is the guideline that controls our operations.

The only concession made for the special needs of advertising was that the essential information might be presented "in brief summary." This requires the presentation of information in your ads which will fairly show the effectiveness of any drug, along with any side-effects, contraindications, precautions and warnings, in a form that is brief but neither false nor misleading. The central idea is to be sure that the message that comes through to the profession strikes a proper balance in telling what the drug is for, what the limitations are upon its usefulness, and what hazards may attend its use.

Lest there be any question as to precisely what is required—the law provides that every prescription drug advertisement and any other descriptive matter issued to promote sales shall contain a true statement of—

The formula;

The established name of the drug along with the trade name;

And "such other information in brief summary relating to side effects, contraindications and effectiveness as shall be required in regulations" issued by the Secretary.

Preclearance of ads is not required except in extraordinary circumstances. The Department was authorized to specify which promotional material is labeling (requiring full disclosure) and which is advertising (requiring the brief summary).

The regulations applicable to ad content were promptly issued—but only after a confrontation with both the pharmaceutical industry and the medical profession. Both professed to believe that advertising was not educational—that it served only a reminder role—and played no part in the physician's choice of drugs when he began to write on his prescription form.

We took the more realistic view that if advertising does not sell drugs it will not continue to run.

Therefore, the major issue requiring resolution was whether the regulatory controls would extend to the entire ad—or just to the little part that the advertiser might designate as the "brief summary."

Resolution of that issue was accomplished by final regulations, supplemented by a memorandum of understanding about their intent. The whole ad was controlled.

The regulations themselves are simple indeed. They were offered as the first step in public supervision of this very vital means of communication between

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