MAY 1978
VOLUME 67 NUMBER 5

JOURNAL OF PHARMACEUTICAL SCIENCES

The *Journal of Pharmaceutical Sciences* is published monthly by the American Pharmaceutical Association at 2215 Constitution Ave., N.W., Washington, DC 20037. Second-class postage paid at Washington, D.C., and at additional mailing office.

Offices Editorial, Advertising, and Subscription Offices: 2215 Constitution Ave., N.W., Washington, DC 20037. Printing Offices: 20th & Northampton Streets, Easton, PA 18042.

Annual Subscriptions—United States and foreign, industrial and government institutions $50, educational institutions $50, individuals *for personal use only* $30; single copies $5. All foreign subscriptions add $5 for postage. Subscription rates are subject to change without notice. Members of the American Pharmaceutical Association may elect to receive the *Journal of Pharmaceutical Sciences* as a part of their annual $70 (foreign $75) APhA membership dues.

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DEVIOUS ROUTES TO GOVERNMENTAL REGULATION

So-called "Big Business" has long suffered from a public perception as being devious in many of its approaches and actions. It has been common to expect that business interests often will not be completely open and above board in their motives and objectives.

On the other hand, it is only in recent years that the public has come to view with comparable suspicion various proposals and actions involving government agencies, particularly at the federal level. Presumably, in a Democratic society, government is the people and honesty in government has been—or, more accurately, *had been*—taken for granted. However, the "Watergate affair," among other things, has done a good deal to change public attitudes rather drastically in this regard.

This may seem like a rather strange introduction to the subject of Food and Drug Administration regulations, but in our view there is a rather decided connection.

For example, on the surface, the concept of patient package inserts is very appealing. When one delves into the subject, a number of pragmatic considerations do arise, such as who will prepare them, who will distribute them, at what reader level will they be written, and so on. However, none of these questions would suggest that any ulterior motives may be involved on the part of the FDA in proposing that such inserts be provided with a given class of drugs.

Well, last fall the FDA published a notice with regard to amphetamines. The contemplated action would recognize the usefulness of these drugs in treating narcolepsy and minimal brain dysfunction but would eliminate the treatment of obesity as a recognized or approved use. Furthermore, it was also proposed that a patient package insert would be required and that such "patient labeling" would be given to the patient at the time the drug is dispensed.

What makes this proposal unusual is that the FDA would further mandate that the wording of the insert must include "warnings in layman's terms about using these drugs in weight reduction." But since weight reduction is not to be one of the approved uses, such a warning is academic and meaningless to any patient for whom the drug has been prescribed in accord with either of the approved uses. Obviously, therefore, this is a back-door approach on the part of FDA to exert a degree of control over the prescribing practices of physicians through subtle pressures brought to bear *via* the patient.

Inasmuch as the FDA has no jurisdiction over the practice of medicine—authority in this area residing with state government agencies—any FDA efforts to control physician prescribing for individual patients, albeit well intentioned, is improper. Consequently, it appears that this proposed wording requirement is nothing more than a devious effort to accomplish such control.

We have also heard similar concerns expressed by some research investigators.

Again, FDA has no direct authority, as such, to control drug research. However, when the agency does have the authority to monitor research subjects, to register clinical investigators, and to approve study protocols, it is a very short step indeed to cross over the line and to dictate how the research itself will be conducted.

Regulations, controls, and surveillance are recognized as very necessary safeguards for the public at large as well as for individual patients or test subjects. There can be little quarrel when the agency charged with responsibility in this area applies such rules properly and as they are intended. When, and if, that agency bends and distorts them in a manner to serve other purposes for which they were not intended, then there is legitimate cause for strong objection. Unfortunately, in resorting to such practices, the agency also damages whatever respect and credibility it may have previously enjoyed.

Edward G. Feldmann