Journal of Pharmaceutical Sciences

MARCH 1974

VOLUME 63 NUMBER 3

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.

All expressions of opinion and statements of supposed fact appearing in articles or editorials carried in this journal are published on the authority of the writer over whose name they appear and are not to be regarded as necessarily expressing the policies or views of the American Pharmaceutical Association.

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. 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 $55 APhA membership dues.

Claims—Missing numbers will not be supplied if dues or subscriptions are in arrears for more than 60 days or if claims are received more than 60 days after the date of the issue, or if loss was due to failure to give notice of change of address. The Association cannot accept responsibility for foreign delivery when its records indicate shipment has been made.

Change of Address—Members and subscribers should notify at once both the Post Office and the American Pharmaceutical Association, 2215 Constitution Ave., N.W., Washington, DC 20037, of any change of address.

DR. JEKYLL AND MR. HYDE

Schizophrenia is a serious mental disorder disrupting the lives of many persons. But schizophrenic behavior can also creep into the operating procedures of institutions; in their sphere of influence, the effects of "institutional schizophrenia" can be equally devastating, but presumably this condition should be immensely more amenable to treatment.

The Food and Drug Administration's (FDA) schizophrenia relative to pharmacy, and specifically related to the role of the pharmacist in the health-care system, appears to have been developing for several years. Particular isolated examples might have been dismissed as petty or picky, but a recent action seems to constitute an especially acute episode.

The publication in the *Federal Register* of the "General Conditions for OTC Drugs" and "Tentative Final Order for Antacid Products," regulations related to the general review of over-the-counter (OTC) drugs and specifically the proposed antacid monograph, suggests that FDA's institutional schizophrenia has taken a decided turn for the worse.

Currently available FDA-generated consumer information repeatedly and explicitly suggests that the consumer utilize the expertise of the pharmacist. Although an entire series of comparable examples could be cited from various FDA publications, news releases, consumer-oriented information, exhibits, approved prescription drug product package inserts, and so on, for purposes of illustration we will quote from just one of these. An FDA brochure entitled *Medicines without Prescriptions* states:

"*Your pharmacist and doctor are trained in drug therapy. They know what a drug is supposed to do and what adverse effects you can expect. Whenever you are in a pharmacy buying an OTC drug, ask your pharmacist's advice....*

"*Ask your pharmacist whether he can recommend a drug that will relieve the symptoms but that will not cause the adverse reaction....*

"*Before using any combination of drugs—prescription drugs with OTC drugs, or several OTC drugs together—it is important that you ask your doctor and follow his advice. Your pharmacist can also advise whether certain drugs can safely be taken at the same time.*"

However, when a recommendation was made by the FDA's own OTC panel on antacids to include on certain product labels the statement "Do not take this product concurrently with a prescription drug except on the advice of your physician or pharmacist," the FDA Commissioner elected to drop the "or pharmacist" from the wording. While the panel's recommendation applied to antacid products containing activated charcoal, the Commissioner's rewording would apply to all instances where a statement of this nature was deemed appropriate for any category of OTC product. His accompanying statement in part stated:

"*...His [the pharmacist] precise role in clinical health care, however, is the subject of intense interest and debate as part of the larger issue of the future of the entire health care delivery system. The Commissioner concludes that such an important matter should be resolved in the context of broad health policy deliberations and not as a part of the OTC drug review, and thus that no reference should be made to pharmacists in OTC drug labeling at this time.*"

Such ambivalence on the part of FDA in promoting the pharmacist as an advisor on drugs to the consumer, while simultaneously refusing to recognize this expertise in product labeling and other professional areas, is blatantly contradictory and absurdly confusing to everyone. It may be true that the questions concerning the pharmacist as an advisor on OTC drugs, on prescription drugs, and as to his future role in the health-care system are complex, comprising economic, legal, professional, and consumer aspects.

However, it is not our purpose or interest here to comment on any of these points. Instead, our purpose is to focus on the apparent tactic chosen by FDA to present one position to the public and another position to the relevant professions. This tactic, if successful, would establish a serious precedent for the future; that is, official recognition or sanction of two dichotomous positions, on the part of a single federal regulatory agency. To us, this would not only assure continued confusion, but also present a dilemma for the regulated industry and professions—an altogether unattractive prognosis.

For FDA's schizophrenic condition, we prescribe a large dose of internal consistency, in order to overcome its multiple personalities. Any further perpetuation of the current FDA approach to the role of the pharmacist could have long-term detrimental effects on the entire health-care system.

Edward G. Feldmann