Journal of Pharmaceutical Sciences

DECEMBER 1974

VOLUME 63 NUMBER 12

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.

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QUANTITATIVE FORMULA DISCLOSURE

Last month in this column we wrote about "Drugs Anonymous," and we expressed our thoughts on the desirability of a requirement that the identity of the actual manufacturer of the drug product be included on the label of the article.

After that column had gone to the printer, but before its final publication, the Pharmaceutical Manufacturers Association announced a new policy adopted by its Board. Since PMA had formerly been the leading opponent to such a requirement, this change of policy—which now favors such a national legislative requirement—constitutes a very dramatic reversal on the part of this influential organization within the drug industry. Consequently, we are pleased to note this positive step forward and compliment the organization for its willingness to swallow pride and adopt this position which has been long advocated by APhA and a number of other pharmacy groups.

Consideration of this subject brings us to the next logical question. Namely, now that we know who makes a product, how do we know what is in it?

This latter problem has not been associated with prescription legend drug products, but it has been a significant shortcoming relative to the labeling of nonprescription or over-the-counter (OTC) drug products. The law requires only that active ingredients be named or listed in the drug label, and there is no obligation to provide quantitative information. Consequently, a very large proportion of OTC drug products have made no quantitative disclosure of their content.

Our February 1971 editorial was devoted to a discussion of this situation under the title "'Patent' Medicines vis-à-vis An Enlightened Society." That column specifically described the frequent difficulty in obtaining drug composition information for inclusion in the Association's publication the *Handbook of Non-Prescription Drugs*. It also criticized the intransigence of many firms within the proprietary drug industry: "... *furthermore, this practice (of keeping secret formulations) is tacitly supported, if not avidly defended, by much of the industry manufacturing these products.*"

APhA has persisted in its efforts to overcome this situation. It has done so by urging the proprietary drug industry voluntarily to adopt policies and practices which would accomplish the intended purpose and also by making such recommendations to legislative and regulatory agencies whenever the opportunity arose. For example, such a suggestion was included in the filing APhA made on the proposed regulations FDA issued concerning OTC antacid products. However, when the antacid regulations were issued in final form this summer, the Commissioner concluded that, despite its desirability, FDA did not have authority to issue such a requirement under present law. Hence, he could only request "... *that manufacturers voluntarily place such information on their label ...*."

But again there is welcome news. Late this past summer, APhA was informed that the Board of Directors of the Proprietary Association had made a policy decision to recommend to all PA member firms that they list the quantity of all active ingredients on the labels of all OTC medicines they market.

Whether as a result of their trade association recommendation or not—we have no way of knowing—we have already noted a decided swing toward inclusion of this information on OTC drug product labels.

Indeed, one major company's recent annual report repeatedly emphasized, in pictorial form and by way of prominently displayed quotations, their dedication to providing just this type of information. The entire front cover of this imaginatively prepared report is devoted to a one-sentence quote from the company's founder which was written forty-one years earlier, and starts out, "*Medicines should be good formulas, fairly priced and truthfully advertised ...*."

There is an implication that during the intervening years individual proprietary drug manufacturers may have deviated from these goals to varying degrees. Adoption of, and implementation of, the voluntary decision to reveal the quantitative formulas of their products indicate that this industry is recognizing its consumer and professional responsibilities. This first step is an encouraging sign; it is hoped that more will follow.

Edward G. Feldmann