New Era for Nonprescription Drugs

The law says that drugs must be "safe and effective" if they are to be legally on the market.

But it was not always so.

Specifically, less than 50 years ago, it was neither a legal requirement nor an actuality that drugs in the American marketplace were generally safe and effective.

The Federal Food, Drug, and Cosmetic Act of 1938 formally established safety as a condition of drug approval and marketing. The Drug Amendments of 1962 did likewise regarding drug effectiveness.

However, it takes more than just a vote in Congress and the signature of a President to transform the objective into the reality. Recognizing that the criteria of safety and effectiveness could be applied rather readily in evaluating *new* drugs as a condition of their approval by the federal Food and Drug Administration, it remained to develop some system for the review and evaluation of those drugs *already* on the market—particularly, for the effectiveness evaluation of pre-1962 drugs.

And so it was in the mid-1960's that the FDA—working along with the National Academy of Sciences/National Research Council—undertook the Drug Efficiency Study Implementation (DESI). This was a massive program over a 10-year period to evaluate the effectiveness of virtually all drug products marketed prior to 1962.

Very early in this project, it became evident that the complete task was impossible and certain limitations would need to be applied. The most fundamental of these adjustments was the decision to concentrate on the prescription drug products, of which there were almost 10,000, and to set aside the nonprescription drug products, which numbered over 300,000. In view of the fact that not only was a much smaller and manageable a universe involved, but also that the drugs were more important in the sense of being used to treat more serious health problems and conditions, this decision made a great deal of sense to all concerned.

And eventually, the DESI project ground to its inevitable conclusion, with many products forced off the market, others reformulated, and still others relabeled as to claims and conditions for use. Although the process was long and stressful, the general consensus appears to be that the net result has been beneficial to the public health and welfare, and that both consumers and health care professionals now can have a high level of confidence that prescription drug products will perform in accord with their claims.

But what about those several hundred thousand nonprescription drug products?

Under law, they must be just as safe and effective for their labeled purposes and claims as their prescription legend cousins. The only real difference between these two drug classes is that the former are judged to be suitable for use without professional supervision, while the latter—for one reason or another—are judged to necessitate such professional practitioner involvement.

As the DESI project was proceeding on track during the very late 60's and early 70's, the FDA concluded that the nonprescription drugs would require a different approach logistically. Instead of considering them on a product-by-product basis, the FDA decided to approach the project on a drug active ingredient basis. With active ingredients totaling less than a thousand, in contrast to the several hundred thousand products, this alternative was clearly more practical and manageable.

And so was conceived the FDA's "OTC Drug Review" which has now been in process for some 11 to 12 years, depending upon when one regards the starting date to have occurred. In contrast to the DESI project, in which the FDA contracted with the NAS-NRC to conduct the fact-finding aspect, the OTC Drug Review was organized and operated by FDA itself. A series of 17 advisory panels—composed of about 250 outside nongovernment drug experts—were established with each panel responsible for a particular therapeutic or pharmacologic class of drugs. The panels, which were staffed by FDA, reviewed 20,000 volumes of data, held 508 meetings over 1,047 days, and participated in innumerable phone conferences, exchanges of correspondence, and other activities relating to their deliberations.

On October 7 of this year, the FDA and its parent Department of Health and Human Services, proudly announced that a most important milestone had been reached in this monumental project. The 58th, and last, report of the advisory panels was publicly released.

Although agency officials pointed out that much work still remains to be done to convert the final panel recommendations into regulatory action, they emphasized that major strides had already been made "in improved products, greater safety, and reduced medical costs."

HHS Secretary Margaret M. Heckler concluded her statement with the comment that, "The review has begun to transform the nonprescription drug market." And the accompanying FDA summary cited ample statistics and examples to document her assessment.

What impact will this all have on pharmacy and the pharmaceutical sciences?

Nonprescription drugs and drug products have long had an image of being nothing more than harmless, ineffective nostrums at best, and potentially harmful quack remedies at worst.

But the FDA's OTC Drug Review has changed that. The products on the market now and in the future have been established as safe and effective. And professional organizations have been making great efforts to educate practitioners and the public in the proper selection and use of such products.

In particular, the American Pharmaceutical Association has contributed enormously in this regard through publication of its highly respected *Handbook of Nonprescription Drugs*, which is now in its 7th Edition. APhA has also been conducting a whole host of other efforts, including workshops and seminars, to support an active and effective role for the pharmacist with regard to self-medication by the public.

And in recent years the nonprescription drug industry has generally assumed a high sense of public responsibility for the products it produces as well as their proper use. Indeed, the Proprietary Association, which is the major trade organization of nonprescription drug manufacturers, currently is closely cooperating with APhA in efforts to produce a consumer version of APhA's *Handbook*.

Finally, the general public today is much more health conscious than ever before; it has a keen interest in knowing as much as possible about self-treatment; and it wants to feel confident that the therapeutic agents it uses are safe and reliable.

Consequently, the entire picture as to contemporary perceptions and attitudes regarding nonprescription drugs is dramatically different from that which prevailed just a few short years ago. And the resultant shift in emphasis will greatly affect not only pharmacy practitioners but also pharmaceutical educators and scientists as well.

—EDWARD G. FELDMANN
American Pharmaceutical Association
Washington, DC 20037

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