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GETTING TO KNOW THE FDA

If the average pharmacist is asked what he or she thinks about the federal Food and Drug Administration, the answer is apt to be anything from a blank stare to a stream of profanity.

And why not? This shouldn't be very surprising because there is very little that health care practitioners—pharmacists, physicians, dentists, nurses, and others—really know about the agency, its workings, and its operations. There is a rather vague understanding that this is an all-powerful governmental arm that decides, among other things, what we shall have available to eat as well as what will be made available to us as medication.

Although this perception is partially accurate, there is little knowledge of how the agency operates, how much it initiates actions, how broad is its scope of responsibility, and the like.

As a result, there often is public furor over some FDA action; health care professionals may have a foggy understanding of the scientific reason for the action, but even they rarely have any concept of the legal aspects of the action. Whatever their merits on scientific grounds, FDA initiatives regarding saccharin, laetrile, phenformin, cyclamates, combination antibiotic products, and the many other rhubarbs that have been in the news over the past 20 years have been based upon FDA implementation of some law which was not of its own doing. Rather, these actions are the result of the agency attempting to do its assigned job as it interprets various statutes that Congress has enacted. We shall freely grant that, in the process, FDA has had some rather strained and unusual interpretations of what it believes Congress has said, but the courts are available to bring challenges when someone feels that the agency is overstepping its bounds. And the halls of justice have sustained the FDA in a high proportion of such cases.

At any rate, even today recent graduates of our pharmacy, medical, and other professional schools rarely have been given more than the most superficial exposure to the role of FDA as it relates to professional practice.

Well, we were pleased to read recently that this is an information gap that someone is doing something to correct. Specifically, in the last issue of the *American Journal of Pharmaceutical Education*, R. W. Jacobs and J. C. King of the School of Pharmacy at the University of the Pacific published a report entitled "Development of a Course of Study in FDA Drug Regulatory Procedures."

What they set about to do can be neatly summed up in a quote from their article:

> *"If one acknowledges the fact that the agency works to control the quality but cannot assure the absolute quality of drugs, then the pharmacist must share some responsibility for drug quality with the FDA. The need for a comprehensive understanding of the drug regulatory procedures of the FDA can be met by providing a course as a component of the curriculum in pharmacy school.*
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> *"There exists an apparent lack of understanding of the functions and responsibilities of the Food and Drug Administration, the drug regulator, by the pharmacist, the drug dispenser. Since the common goal of both is to assure that only safe, effective, and good quality medications reach the patient, an interface between the FDA and the pharmacy profession needs to be created. While the FDA law is slighted in most pharmacy jurisprudence courses, there is need to expand course scope to include the implementation of the regulations associated with the various FDA programs."*

The Jacobs and King article describes the development of a residency program as a cooperative experience between the FDA and the school of pharmacy, from which evolved a syllabus for future residencies as well as textual material for a didactic course in FDA regulatory procedures. As an addendum to their report, the authors provide an outline of the residency program and the various units within the FDA operation which were studied for a minimum of one to two weeks each. These included the Bureau of Drugs, Pharmaceutical Research and Testing, Biometrics and Epidemiology, Compliance, Regional Operations, New Drug Evaluation, and Drug Monographs.

It was the conclusion of the authors that the insight gained from such a program and course serves to broaden the scope of cooperation between pharmacy and the FDA. Specifically identified in this regard are: drug recalls, the drug product defect reporting system, current good manufacturing practices, drug efficacy study implementation, over-the-counter drug evaluation, antibiotic and insulin certification, methadone monitoring, drug product packaging and stability, maximum allowable cost and bioequivalence regulations, and selected aspects of the IND/NDA new drug procedures.

As the form of pharmacy practice changes and as the role and responsibility of the pharmacist evolves, there appears to be increasing need for the pharmacist to be informed in these matters as part of the formal education process. Consequently, we hope that other schools will review the experience of this group and consider such a course for current students as well as a pragmatic subject for continuing education.

It may not result in pharmacists growing to love the FDA, but at least they will be able to deal with issues involving the FDA in a knowledgable rather than emotional way. And, as an added bonus, it will certainly help pharmacists to understand—and perhaps even to appreciate—the basis for many of the actions taken by their national professional society on various FDA matters. —EGF