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INSTILLING SCIENCE IN THE REGULATORY PROCESS

When mention is made of the U.S. Food and Drug Administration among pharmacists or pharmaceutical scientists, the image that apparently comes to mind for most of them is that of police officers—the "cops who watch over drugs."

Such an image is not at all inappropriate because the monitoring and surveillance of drug product quality is one of the most important responsibilities of the FDA. But FDA has often gotten undeservedly low marks as a science-based agency. Overall, the FDA staff has not enjoyed a strong reputation within the scientific community.

This is unfortunate, because the agency has long benefitted from the presence of some truly outstanding individuals among its cadre of staff scientists, and in recent years the number and general quality of its scientific component have grown greatly. A similar conclusion may also be found in the various critical studies or commissioned reviews of the FDA operation that have been conducted over the past few years.

However, as in the case with most federal regulatory agencies, the FDA is often constrained by laws, regulations, and judicial processes which necessitate that it go about its business in certain legalistic or regulatory-oriented manners. This is in contrast to the freedom enjoyed in the private sector by academic-based scientists or even by scientists employed by industry. Indeed, scientists within other government agencies, such as the National Institutes of Health and the National Bureau of Standards, suffer none of the operating constraints that are commonplace for their FDA colleagues.

But observers of the Washington scene have also felt that FDA could do more than it has in the past to institute procedures that would effectively draw upon and utilize science resources both within and outside of the agency.

Recently, however, the agency announced an action that we would classify as a major step in this direction. Specifically, early this summer FDA announced that sometime this year it would be convening *"a scientific Board of Inquiry to recommend to the Commissioner whether to approve the artificial sweetener aspartame."*

To the calorie-conscious, the big news here was the prospect of an artificial sweetener to replace their lost cyclamate and the threatened loss of saccharin. As to those not calorie-conscious, probably little, if any, attention was paid to this announcement.

To us, however, this represented a significant development. FDA's own news release states it quite well in the following excerpt: *"This will be the first Board of Inquiry ever convened by the Agency. The Board of Inquiry system was established as a means for helping the Commissioner resolve scientific issues; it is an alternative to a formal evidentiary hearing before an administrative law judge. It is designed to provide a forum in which scientific issues can be considered by scientists without the legal formalities of an evidentiary hearing. The procedure is experimental and FDA will evaluate its success after the aspartame hearing has been completed."*

The board will consist of three members selected from respective lists of nominees submitted by interested private parties, by the manufacturer of aspartame (G. D. Searle Company), and by FDA staff.

The procedure for the board's operation was also spelled out in the FDA announcement: *"It is expected that the board will be selected and begin its deliberations by late summer or early fall. The board will hear oral presentations from anyone it believes can contribute valuable information. After evaluating the information, the board will render an 'initial decision.' The participants will be given time to file 'exceptions' or objections to the Commissioner, after which time he will decide whether to approve or permanently withdraw approval for aspartame."*

Chemically, aspartame is a simple dipeptide, L-α-aspartyl-L-phenylalanine methyl ester. Its manufacturer received news of the FDA action with apparent mixed emotions. Although "encouraged" and "pleased" that FDA is moving forward with its evaluation of aspartame, the firm felt that existing data were sufficient for the agency to take action to approve the agent without the need for further assessment.

Despite this difference of opinion on the adequacy of the proof of safety of aspartame—or perhaps *because* of it—the effectiveness, usefulness, and credibility of the Board of Inquiry as a mechanism for considering scientific issues by this regulatory agency will be subjected to the acid test. We are hopeful and optimistic that this trial will prove to be successful in fulfilling its objectives.