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FDA: POLICEMAN OR TEACHER?

A few years ago, the big thing for the college age crowd was to dwell on the question, "who am I?"

Not only do persons undergo such identity crises but at times organizations and agencies also experience this type of traumatic soul-searching.

In a number of respects, the behavior of the Food and Drug Administration has appeared to this writer as suggesting that it is similarly uncertain as to its proper role or function. In particular, the Agency has often acted ambivalent and wavering as it has moved back and forth between at least two distinctly different roles: namely, that of a police officer and that of a teacher.

By law, the FDA has responsibility to oversee the purity, quality, identity, safety, usefulness, and related characteristics of the nation's food, drug, and cosmetic supply. With this legal mandate, the Agency is clearly a regulatory body and must operate in a manner to assure compliance.

But compliance itself can be achieved by at least two different routes. There is, of course, that of close supervision and monitoring combined with various enforcement measures. However, to rely solely on this approach would virtually necessitate one FDA agent for each person being monitored—clearly an unrealistic system.

This same problem is encountered in other aspects of day-to-day living; for example, adherence to traffic regulations and payment of income taxes. Both of these systems basically rely on voluntary compliance by the general public, coupled with spot checks of driving speed and sampling of tax returns for auditing. Similarly, the FDA must primarily rely on the voluntary compliance of those who operate within the professions and industries that are responsible for the products over which the FDA has jurisdiction. This voluntary compliance is encouraged by a parallel program of regulatory enforcement *via* product sampling, batch testing, marketplace surveys, plant inspections, and so on.

The relative emphasis which the Agency places on the voluntary route *versus* the enforcement route varies greatly from time-to-time depending upon a number of factors.

Among these is the "philosophic bent" of those persons who happen to be in the upper echelons of FDA at any given time. In particular, if the persons at the top are **enforcement oriented**, it can be expected that the general tenor of the Agency will reflect that leaning. Conversely, if they are **education oriented**, it is more likely that they will generally opt for policies that are persuasive toward voluntary compliance.

In Dr. Jere E. Goyan, the new Commissioner, we have someone with a long and distinguished background in health education. This is not to suggest that Dr. Goyan will be reluctant to use the regulatory enforcement approach if he feels it necessary; his past record shows that he can be forceful, decisive, and "hard-nosed" when he feels that such a manner is needed. However, we suspect that he will initially approach each problem with the perspective that education will frequently resolve such difficulties and make regulatory action unnecessary. Moreover, we are hopeful that this philosophy will permeate the entire Agency.

Again, there is an interesting corollary to be drawn from daily life. Society has learned that people's attitude regarding their police force is largely shaped when they are small children. It is far better if children can be taught that the policeman is there to help them and protect them than it is to make them fearful by scaring them with warnings that "the policeman is going to catch you!" By the same token, we expect that the police force will behave in a manner that warrants the trust and respect of both children and adults.

Similarly, if the FDA is to have both the trust and respect of those with whom it interfaces, then it too will need to conduct itself in a manner that encourages such an attitude.