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DRUG QUALITY: POTENTIAL PROBLEMS *VERSUS* ACTUAL EXPERIENCE

Scientists frequently are chagrined by the fact that the lay public will view technical subjects in a simplistic manner. For example, it is often said that the lay-person rarely understands or comprehends the fact that no drug is completely and absolutely "safe." In other words, the concept of benefit-to-risk, which ultimately applies in the case of every drug, appears to be a bit beyond general public comprehension.

However, those trained in the pharmaceutical and medical sciences—whether they be scientists or practitioners—should have sufficient knowledge and sophistication that they can be expected to recognize and understand such distinctions. Unfortunately, for some reason this is not always the case.

Specifically, over the years, APhA and Association officials have frequently pointed out that drug products must be formulated with care, that principles of good manufacturing practice must be followed, that specifications and standards must be adopted, and that drug marketing and distribution must be controlled and monitored. Moreover, APhA has taken the position that the absence of any of these vital components would give rise to serious questions about the suitability of the resultant drug products.

Subsequently, these APhA statements at times have been cited by various outside sources to support their claim or conclusion that the drug supply is of uncertain quality and that there is ample reason to be concerned about the safety and effectiveness of a very substantial portion of drugs on the market.

In turn, APhA has been surprised by such faulty reasoning and has been annoyed when efforts of this type are made to misconstrue the Association's position. Indeed, people who certainly should know better have alleged that, when APhA states that problems of therapeutic equivalence are of a very limited magnitude, the Association is "changing its position" or "reversing itself." These people appear to believe that the statements concerning *(a)* the potential for drug quality problems, the need for care in drug manufacturing, and the surveillance of products entering the market, and *(b)* the general low level of therapeutic inequivalence somehow are mutually contradictory positions. But such is not the case.

Simply stated, APhA has clearly recognized that drug products must be produced with appropriate care if they are to perform at the level of potency, safety, and uniformity expected of them; but at the same time, it is APhA's assessment that the comprehensive system of laws, regulations, programs, and other elements in the drug production, marketing, and surveillance network results in a very high level of drug quality experience. The net effect of this is that problems in general, and of therapeutic equivalency in particular, are rarely encountered.

But APhA also recognizes that our generally favorable experience to date is directly based upon the effective functioning of the overall drug regulatory system. And future success will be dependent upon continued functioning at the same level at least. For this reason, the Association maintains a close watch on the system itself, as well as on proposals to change or modify it. If it is felt that any such proposed change could have the effect of weakening this system, the Association has not hesitated to voice its concern.

On this basis—and again at some risk of being misunderstood or misinterpreted—APhA presented its concern most recently before the HEW Review Panel on New Drug Regulation this past May. In particular, the Association's comments were intended to ensure that no gap would be permitted to develop between the time that the abbreviated NDA system might be relaxed and the time that the so-called "old drug monograph" system is instituted and becomes effective. In short, APhA believes our present drug supply is of good quality, and we intend to do all that we can to see that it stays that way!

Edward G. Feldmann