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APhA PERSPECTIVE ON "LANNETT"

When the so-called "Lannett decision" was handed down by the courts last fall, an acquaintance in the pharmaceutical industry commented to us, "Well, I guess this will make APhA happy, since you people think all generic drug products are equivalent and don't need to be tested or checked for their quality!"

He was surprised when I informed him that, "No, I can't say that we were happy about it; and, in fact, the decision appears to run contrary to official APhA policy."

This exchange seems to suggest that a brief review of the Association's position, in the context of the litigation situation, may be beneficial for all of our readers.

APhA has long and consistently held: (*a*) that judgment should enter into drug product selection; (*b*) that by training and experience, pharmacists are generally best equipped to fill the role of exercising drug product selection; and (*c*) that only quality pharmaceutical products should be dispensed in all situations—whether or not the pharmacist is selecting the source of the product.

The question then moves to: "What is a quality product?" and at this point the problem becomes much more sticky, if not downright difficult.

There is not sufficient space in this column to delineate all that the Association has offered by way of advice, suggestions, and information on this subject, but a few such examples include evaluating drug company recall records, physically examining the drug product itself, and reviewing information in APhA's *The Bioavailability of Drug Products.*

But beyond such suggestions, APhA has taken the position that—if three basic conditions prevail—drug products can generally be considered as being of acceptable quality and as being interchangeable irrespective of their source of manufacture. "Interchangeable" here is synonymous with therapeutically or clinically equivalent.

In APhA's view, the three requisite conditions are: (*a*) premarket approval of the product by the Food and Drug Administration; (*b*) manufacture of the product in a manufacturing facility that is in compliance with FDA's Good Manufacturing Practice regulations; and (*c*) the resultant product passes all applicable official compendium standards and specifications.

As long as these conditions prevail as the minimum hurdle for drug products to move legally into the marketplace, we could have a reasonable level of confidence in the quality of the drug supply.

This past fall, however, a court decision was handed down that significantly undercut the first of these three requisites. In the celebrated "Lannett decision," the court basically ruled against what FDA has chosen to define as constituting a "new drug."

The court decision goes on to lay out the crux of the case: The FDA "*maintains that for each specific drug product there must be general recognition of its safety and efficacy. This, the FDA contends, is especially true if applied to the bioavailability, the bioequivalence, and the quality control problems of specific drugs such as Lannett's.*" Hence, the FDA has required premarketing approval of each manufacturer's product in the form of a full or abbreviated new drug application.

Lannett, however, challenged this requirement, and the significance of the decision was that the court decided against FDA.

As noted above, this decision also appears to run contrary to the APhA policy position—a position that has contributed in great measure to the confidence that we feel regarding the general high quality of marketed drugs.

In November 1969, the APhA House of Delegates met in a special session, and one action taken during that meeting was to adopt an amended preamble statement on "Drug Product Quality," submitted by the APhA Academy of Pharmaceutical Sciences. That statement specified the need for every manufacturer to conduct appropriate and sufficient tests prior to the initial distribution of a drug product or modifications of an existing product in order to demonstrate its clinical safety and efficacy. This is the same policy that FDA has been following in its drug approval process, and which the Lannett decision would seem to overturn.

FDA has vowed to battle the Lannett decision, and in mid-January of this year an important court ruling was announced in the "Pharmadyne case." In this U.S. District Court decision, the judge denied Pharmadyne's suit to block FDA from seizing certain drug products that the company began to market without specific FDA preapproval. In handing down his ruling, the judge recognized that he was contradicting the Lannett decision.

It is apparent that the matter has not yet been fully settled, and appeals will be probably entered by several of the parties. But whatever the outcome, we wish to clarify that APhA continues to support a system that provides for appropriate premarket testing and approval as a basic requisite before the initial distribution of any manufacturer's drug products. On such a foundation, confidence in product quality is both logical and warranted.

—EGF