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IDENTIFYING "THE BAD CHARACTERS"

The so-called "Lannett decision" threw into question the authority of the Food and Drug Administration to require its approval of a duplicative drug product before that product is placed in distribution on the open market. At this writing, the effect of the court decision is still in question for various reasons including FDA appeals and differing decisions by courts in other judicial districts.

In the meantime, however, certain manufacturers have proceeded to market products without submitting them for FDA review and approval. The FDA has been seizing many of these products—particularly in those judicial districts where decisions have not been handed down that are adverse to its claim that federal law gives it the authority to require premarketing drug approval.

Nevertheless, at least a few unapproved products have gotten into general distribution. Moreover, according to the FDA, several of these products have been poorly formulated in a manner to make them less than satisfactory for their intended clinical uses, and the problem presented by these defective products has been widely publicized.

In an effort to avoid creating therapeutic problems for patients, pharmacists have been strongly advised to avoid purchasing and dispensing any products lacking FDA's approval. Indeed, pharmacists have been warned that they expose themselves to potential legal liability and to possible malpractice suits by using such products—particularly if patient injury were to result.

This well-intended advice has been offered from a variety of sources. In addition to a veritable bombarding of mailings from certain major pharmaceutical companies, pharmacists have gotten such cautions from state boards of pharmacy, from editors in the pharmaceutical press, from various professional associations, from attorney-pharmacists at conferences and symposia, and so on.

Indeed, a report in the drug press even quoted FDA Commissioner Jere E. Goyan as telling his Bureau of Drugs staff in mid-February that the situation concerning "unapproved generics"—the problem that some manufacturers may be marketing drugs illegally—is one that calls for an information campaign directed at the pharmacist. According to the Commissioner, "We have to go very heavily to pharmacy and say, 'Look, you're taking a terrible risk.' "

We do not quarrel in the least with the Commissioner's assessment that dispensing unapproved drugs constitutes a very serious risk to both the pharmacist and the patient. But what we do wonder is whether the Commissioner, and all the other well-meaning dispensors of "Dutch-uncle advice" noted above, recognize or appreciate the pharmacist's real problem.

We are personally convinced that virtually all pharmacists would shun such unapproved drug products *if*—and that's a very big "if"—they could immediately identify which products are approved or which are not. Fully 99% of the nation's pharmacists have the integrity and intelligence to avoid dealing with products of such questionable quality; and most of the other 1% are at least wise enough to do so, even if they are not motivated out of professional integrity.

Imagine for a moment the confusion that would reign if the millions and millions of automobiles in this country were all being driven around without license plates. The vehicles themselves still might be properly registered with the respective state vehicle departments, but there would be no outward evidence of such registration, or verification of registration, or means of identification, or the like, displayed on each automobile for all to see. To say that this would be a chaotic situation is a gross understatement.

And yet, when it comes to marketed drug products, we have no reliable system—short of telephoning the FDA offices in Washington concerning each individual drug product—for identifying those that have been so approved. Hence, there is no ready means of being able to distinguish them from products that may be on the market without having gone through the FDA's new drug application (NDA) or abbreviated new drug application (ANDA) approval process.

In mid-December, APhA President William S. Apple and this writer met with FDA officials and made a strong pitch for the agency to permit (or to require) drug manufacturers to carry the NDA or ANDA approval number in the labeling of those drug products that do, in fact, have such approval. In the past, and continuing at least to the time of this writing, FDA has prohibited the inclusion of such information as part of the product labeling on grounds that it constituted a form of inappropriate advertising; that is, the FDA was concerned that the approval number would be interpreted by consumers as an FDA endorsement of the product or that the product had a "seal of approval" from the federal government.

However justified this prohibition may have been in the past, present circumstances have drastically changed. In our opinion, if pharmacists are going to be able to exercise due care in product selection and dispensing, and if the health and welfare of patients are to be duly guarded, then it is essential that the FDA rescind its restriction and permit approved products to be appropriately identified for the benefit of all pertinent parties. —EGF