FDA's Compliance Policy Guide on Marketed Unapproved Drugs

By Joshua Tropper

In 2006, the Food and Drug Administration (FDA) estimated that there could be several thousand drug products on the market in the United States without FDA approval. FDA published a Compliance Policy Guide on Marketed Unapproved Drugs in June 2006, in which FDA explained that it hoped to require them all to get approved or get off the shelf. In the meantime it would generally follow the enforcement priorities spelled out in the Guide. Manufacturers and marketers of unapproved drugs that were not at the top of the priority list were told, in essence, that they still might be able to enjoy many years of sales before having to worry.

Brand name unapproved drugs are typically marketed the same way as approved products: armies of sales representatives pitch their wares directly to physicians in the hope of persuading them to prescribe the products to patients. When patients fill their prescriptions, the pharmacists normally check a computerized database to verify that the particular patient's insurance covers the particular prescribed product. In most states, pharmacists also check for the availability of a generic substitute for the prescribed drug; in many states pharmacists are required by law to offer the least costly alternative available. The economic incentive to produce generic substitutes for highly profitable pharmaceutical products is, as a result, huge.

At this point, there is a world of difference between approved drugs and unapproved drugs. A company wishing to manufacture or market a generic substitute for an approved drug must not only obtain FDA approval for its own product, it must also obtain an FDA rating certifying it as therapeutically equivalent to the brand. Someone wishing to compete with an unapproved drug can get FDA approval, but cannot get an FDA equivalence rating relative to a drug that FDA has never approved in the first place.

Many states allow pharmacists to exercise their own professional judgment as to the appropriateness of a potential substitute. However, other states require the consent of both the patient and the prescribing physician to substitute a lower-cost alternative for a prescribed product unless the potential substitute is listed as therapeutically equivalent to the prescribed drug in FDA's compendium of Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book." At least in states requiring a rating in the Orange Book for substitution, this appears to allow producers of brand name unapproved drugs an effective monopoly that could not otherwise be achieved for approved products without a patent. The economic incentive for marketing brand name unapproved drugs is, therefore, quite substantial.

There is, of course, a fly in the ointment. The databases that pharmacists routinely consult to identify potential substitutes normally include information on FDA equivalence ratings, so it is possible to tell at a glance whether a lower-cost product is listed as therapeutically equivalent in the Orange Book. For one reason or another, products that are clearly shown as "not rated" in the major databases still get dispensed by pharmacies, even in Orange Book states. Physician consents and patient consents surely explain many sales of unapproved substitutes, but it is not at all clear that all such substitutions are fully consented.

Not surprisingly, the producers of the brand name products, thinking they had a legal monopoly in the Orange Book states, have not been amused. In their view of the world and the applicable law, the mere fact that a less expensive product has been substituted for their own is enough to constitute unfair competition. In their view, the fact that such substitutions occur where they consider it to be illegal is proof enough that the producer of the competing product engaged in false advertising at some point.

At least in the Orange Book states, the view of brand name manufacturers seems reasonable enough. So, why is it that they have such a hard time winning false advertising lawsuits? Surprisingly enough, it seems to be precisely because of how obviously right they seem to be. Overconfident and impatient clients lead to a "shoot first and worry about proving it later" approach that simply does not go over well with more experienced judges.

Practical Tips:

1. File in the Right Place. If you represent a brand name manufacturer, sue in an Orange Book state. If you represent the competitor who is being threatened with suit, ask for a declaration of rights in a "pharmacists' discretion" state. Although most businesses, and most lawyers, have a natural preference for litigating in their own home court when possible, federal law permits filing suit in the judicial district "where any defendant resides [or] in which a substantial part of the events or omissions giving rise to the claim occurred." It would be a rare case in which suit could not be brought in any of the states in the preferred category.

2. Know Your Enemy. Get a sample of the offending product, and have it tested by a reliable independent laboratory. The chances are fairly good that the manufacturer–knowing that its product and processes were not being closely scrutinized by FDA–cut a corner somewhere along the way. Develop proof that the substitute is not what it claims to be, and you no longer need to depend on how obvious your case is. Do be sure that the test itself is done right,. Courts do not tend to look kindly on those who base their claims on tests that appear rigged.

3. Know Yourself. Make sure your own product is what it claims to be. For the same reasons that a test of your adversary's wares is worthwhile, send a sample of your own off for an independent examination. Do not depend on your own people, or on a contract manufacturer, to have done everything perfectly when FDA's eyes were not on them. A manufacturer claiming that a competitive product is falsely claiming to be "the same as" a product that is itself falsely described is likely to find the court decreeing a plague on both parties.

4. Find Out What "Advertising" Was Involved. Analyze the product label, the package insert, everything that was sent to the databases and everything that was sent to customers. Very few people are perfect, and salespeople are believed to be inclined toward exaggeration. Find out exactly what your adversary said that was not completely accurate and drive it home. Reliance on suspicions and reasonable expectations of what sort of things they probably said, merely implies that what they really said would not create liability.

5. Talk to Local Physicians and Pharmacists (If They Will Talk to You!). Find out whether any physician was ever asked to consent to the substitution–and what she answered. Find out under what circumstances a pharmacist would substitute an unrated product. Then, get a survey to show the ones you talked with are typical (or not). Again, you may think it easy enough to guess at what happened, but judges and juries pay much closer attention to evidence of what actually occurred.

Mr. Tropper is an Intellectual Property attorney in Baker Donelson's Atlanta office.