

A New Paradigm For Prescription Drug Labeling?

Law360, New York (November 30, 2015, 11:41 AM ET) -- The drug industry is anxiously awaiting new labeling regulations from the FDA that could dramatically alter drug labeling in the U.S. If these new regulations are enacted as proposed, both generic and brand name drug companies would be on the same playing field, with both being required to update labeling to reflect important new safety information. In an extended notice and comment period, all stakeholders have weighed in on the FDA's proposed changes and there is a sharp disagreement on what the FDA should do. This article will briefly explore the alternatives and suggest a compromise that would reconcile these differences and ensure that patient safety remains paramount.

Federal Preemption Prompts New Regulations

More than two years ago, the U.S. Food and Drug Administration announced its consideration of new drug labeling rules for both brand and generic drugs.[1] Generic drug labeling, for good reason, invariably has tracked the brand drug's or reference listed drug's (or RLD) labeling almost word-for-word. The Hatch-Waxman Act required this, as did FDA's regulations, mandating that generic drug labeling be "the same as" the generic drug's brand drug, or RLD, counterparts. Bioequivalency also precluded any material variations in the "design" of generic medicines. In 2011, and again in 2013, the U.S. Supreme Court reinforced these statutory and regulatory rules by barring under the Supremacy Clause of the United States Constitution products liability lawsuits against generics by patients claiming injuries caused by drugs with inadequate warnings or deficient design.[2]

The FDA's response to these rulings, under pressure from consumer lobbying groups and brand name drug manufacturers, was to propose new regulations released for public comment. Under these proposed regulations, brand and generic drug manufacturers would be equally obligated to strengthen product warnings on the basis of new information received about health risks. Because of the importance of the proposed rule changes and the interest they generated, the agency held a day-long public hearing in March of this year and the public comment period was extended into April. More than 150 individual comments were received by the FDA during the public comment period from a wide range of stakeholders: brand name and generic pharma, consumer groups, physicians and pharmacists, medical researchers, drug wholesalers and distributors, plaintiffs' law firms, state legislators, members of Congress and states' attorneys general, among others.

The agency's final regulations are anticipated to be finalized and published shortly.

What the New FDA Labeling Rules Would Do

Under the FDA's proposed regulations, brand and generic drug companies would be required to immediately strengthen or otherwise modify label warnings when they receive new safety-related information involving a marketed drug and in advance of FDA approval. To ensure the label change is communicated properly and promptly, the FDA would permit the company initiating the label change, whether a brand or a generic drug company, to distribute a "Dear Doctor/Health Care Provider" letter to physicians and would require the proposed label change to be submitted to the agency in a format permitting its public posting on the Internet. The FDA would then post the proposed label change on its own website for access by physicians, the public and other drug companies marketing the product. All involved drug companies would then have an opportunity to review and comment upon the proposed label change and the FDA would ultimately decide whether the label change is warranted by the supporting data. If so, the label changes must be made by the brand/RLD company and all other generics marketing the drug.

Consistent with current regulations, all drug manufacturers — brand and generic — would continue to monitor, collect and report adverse event drug experiences, but now both could propose and unilaterally implement revisions to product labeling based upon newly acquired safety information.

Criticisms of FDA's Proposed Regulations

With many drug companies frequently occupying the same marketplace for prescription drugs that are off patent, or for brand name drugs whose patents have been successfully challenged and deemed invalid,[3] commentators have noted the prospect for confusion among prescribing physicians as differing labels coexist for multisource drugs pending the FDA's decision on proposed label changes. The FDA itself has acknowledged these "concerns about temporary differences in safety-related labeling." [4] Whether these proposed rule changes, if adopted by the FDA, will promote or undercut prescription drug labeling uniformity, whether the expense to generics of compliance would increase the cost of drugs to consumers and whether generics may choose to abstain from producing certain medications altogether because of increased liability risks currently are unresolved questions.

A Labeling Approach That Makes Sense and Protects Patients

Although many stakeholders supported enactment of the FDA's proposed rules in their current form, another proposal submitted jointly by the Generic Pharmaceutical Association and Pharmaceuticals Research and Manufacturers Association, which represents brand name drug companies, may offer a better way of effecting necessary drug label changes while ensuring patient safety.

Under this proposal, which has garnered the support of consumer groups, physicians, pharmacists and others, label changes would proceed in a three-step process. First, the brand drug or generic sponsor/manufacturer would request an Expedited Agency Review of a proposed label change by the FDA, or the FDA could initiate a label change on its own. Second, the FDA would begin reviewing all available safety data and engage both new drug application and abbreviated new drug application holders in a discussion of the proposed change. Third, if the FDA determined that a label change is warranted, the agency would notify all manufacturers within 15 days, or longer if deemed necessary, and would instruct all to implement the change within 30 days via e-labeling.

This proposal would eliminate the necessity for unilateral label changes for multisource medicines, would avoid having differing labeling for the same drug in the marketplace at the same time and would enable the FDA to draw upon all of its resources and information — preclinical and clinical trial results, adverse event reports from all manufacturers of the drug and peer-reviewed medical and scientific literature. Also, the agency’s role in approving all label changes for multisource drugs would be similar to its current role in the Prior Approval Supplement process for label changes. The EAR approach would also reduce the risk of “overwarning” by drug sponsors and manufacturers by having the FDA do what it has always done in its watchdog role — carefully assess all of the clinical, medical and scientific evidence in evaluating proposed prescription drug labeling.

Conclusion

All eyes are on Washington as FDA determines what path to take in approaching new prescription drug labeling. What it does may certainly face a court challenge by those opposed to its actions, so the ultimate result and impact upon the drug industry of new regulations may not be known for some time.

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[1] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. 67,985 (Nov. 13, 2013).

[2] *Pliva Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Mutual Pharmacy Co. Inc. v. Bartlett*, 133 S. Ct. 2466 (2013).

[3] Generics account for about 84 percent of drug prescriptions currently dispensed in the U.S. In most instances, when generics enter the marketplace, they quickly capture upwards of 80 percent of the market for that drug, and about a third of all drugs dispensed in the U.S. have no branded drug equivalent in the marketplace. Comment of Public Citizen on Proposed Rule: Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, April 27, 2015, at p. 2.

[4] Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed. Reg. at 67, 989.

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