Product Liability - USA

Goodbye to generic preemption? FDA publishes proposed rule

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The Food and Drug Administration (FDA) recently published a long-awaited proposed rule in the Federal Register in an effort to "create parity" between brand-name and generic manufacturers for their labelling obligations.(1)

Answering Supreme Court's call

The proposed rule directly responds to Justice Thomas's declaration, for the majority in *PLIVA v Mensing*, that the Supreme Court "will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the law and regulations if they so desire".(2)

In the time since that landmark decision, parties have attempted to avoid *Mensing* in creative ways. For example, plaintiffs have attempted to limit *Mensing*'s preemptive scope(3) or argued that brand-name manufacturers should be liable when plaintiffs took the generic.(4) In addition, in April 2012 Senator Patrick Leahy (D-VT) introduced a bill to eliminate disparity between brand-name and generic manufacturers with regard to labelling responsibilities – without success.(5)

Finally, in January 2013, the FDA quietly showed its intentions in a footnote to the solicitor general's brief in *Mutual Pharm Co v Bartlett*:(6)

> "*This office has been informed that FDA is considering a regulatory change that would allow generic manufacturers, like brand-name manufacturers, to change their labeling in appropriate circumstances. If such a regulatory change is adopted, it could eliminate preemption of failure-to-warn claims against generic-drug manufacturers*."

Ten months later, the proposed regulatory changes were introduced.

Proposed rule

Under the proposed rule, holders of abbreviated new drug applications (ANDAs) would be permitted to update product labelling with new safety information even if the revised labelling differs from the reference listed drug. The updated product labelling will be submitted as a 'changes being effected' (CBE) supplement, which permits the ANDA holder to distribute the revised label at the same time as it submits the changes to the FDA. In addition, the ANDA holder will be required to notify the new drug application holder, along with the information forming the basis for the revision. The proposed rule creates an exception to the existing regulatory scheme, under which approval for an ANDA may be withdrawn by the FDA if the labelling differs from the reference listed drug.

The proposed rule suggests that after receiving notification from an ANDA holder, the new drug application holder is "expected" to submit a revised label to the FDA and share its views as to whether the CBE supplement should be approved. The FDA will then evaluate the various proposed labels and determine which label should be approved. Once a label revision is approved, ANDA holders have only 30 days to update their labels electronically via the CBE process, followed by "timely distribution of drug product accompanied by an updated package insert as soon as feasible thereafter or at the time of next printing of the product labeling for packaging".

Increased liability and burden for all

Concerns over product liability exposure could turn the CBE revision process into a cacophony of competing and conflicting CBE revisions, as companies strive to stay ahead of failure-to-warn claims. If multiple labels are in effect at a given time, both generic and brand-name manufacturers would face increased exposure for failure-to-warn claims and be required not only to defend their own CBE submission, but also to explain why other submissions were not adopted or incorporated. The 30-day window in which ANDA holders must update their labels will also open the door to failure-to-update claims. Brand-name manufacturers' post-marketing surveillance burdens will increase, as they will be required to evaluate CBE submissions from all ANDA holders (which is not accounted for in the FDA's burden estimates).

Parity or chaos?

While the FDA has clearly made an effort to "create parity among application holders with respect to" certain labelling changes, implementation of the rule in its present form could quickly lead to confusion. Multiple companies would be permitted to submit different labelling changes based on different information, with the new drug application holder (if one still exists) responsible for evaluating the competing labels and submitting yet another proposal to the FDA.

Having laid the groundwork for confusion over what the most current label may be, the FDA proposes to address this confusion by dedicating a website to CBE label changes. Concerned members of the public, including healthcare providers, which might otherwise rely on their physicians' desk reference as a reliable, easy-to-access source for product information, can "subscribe to FDA's free email subscription service to receive an email message each time there is an update to this proposed FDA Web page". Healthcare providers might then be left to sort through numerous differing label changes to determine what the most current label actually is.

However, the FDA insists that:

> "*Concerns related to temporary differences in labeling between generic drugs and their RLDs [reference listed drugs] are outweighed by the benefit to the public health that would result from all application holders having the ability to independently update drug product labeling to reflect newly acquired information regarding important drug safety issues through CBE-0 [changes being effected] labeling supplements*."

Comment early

As with any proposed rule, the FDA welcomes comments. Implementation of this rule will significantly affect the entire pharmaceutical industry and, as a result, patient safety. All affected parties are urged to submit comments at www.regulations.gov, identified with Docket FDA-2013-N-0500. It is hoped that the proposed rule will undergo substantial revisions before the FDA publishes its final rule. However, the FDA will need intelligent guidance in order to achieve its goal of improving "communication of important safety information to prescribing health care providers and the public" without sowing confusion and chaos.

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Endnotes

(1) 78 Fed Reg 67985 (proposed November 13 2013).

(2) *PLIVA, Inc v Mensing*, 131 S Ct 2567, 2852 (2011).

(3) See "*Stengel* tangles medical device amendments pre-emption";
"Mind the gap: Sixth Circuit finds room for suit against generics after *Mensing*".

(4) See
"*Weeks* defies years of jurisprudence, allowing innovator liability for generic drugs".

(5) See
"Bill to Undo *Mensing* Decision and Allow Patients to Sue Generic Drug Makers for Failure to Warn".

(6) See "Driving on both sides of the road: Supreme Court hears *Bartlett* oral argument".

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