Client Alert

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FDA Proposed Rule in Flux?

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On Tuesday, the U.S. Food and Drug Administration (FDA) announced that it has reopened the comment period for its proposed rule on generic drug labeling. It has also scheduled a day-long public meeting to hear comments and discuss alternatives to the much-criticized rule, which would allow generic drug manufacturers to unilaterally update their warning labels. Comments and suggestions related to the rule will now be accepted through April 27, 2015, and the meeting will take place on March 27, 2015.

PROPOSED RULE

The FDA proposed the rule in response to the Supreme Court's opinion in *PLIVA v. Mensing*. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011). *Mensing* held that generic drug manufacturers could not unilaterally change or strengthen their warnings. The end result was that most failure-to-warn claims were preempted as to generic manufacturers, though the corresponding claims against branded manufacturers survived. Justice Thomas memorably noted 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." *Id*. at 2852.

The proposed rule was no doubt a direct response to Justice Thomas' plea. Under the proposal, holders of abbreviated new drug applications (ANDAs) would be allowed to update product labeling to reflect newly acquired safety information even if the updates differ from the reference listed drug (RLD). ANDA holders would be permitted to distribute a revised label to the market without prior FDA guidance or approval, while concurrently submitting the proposed label changes to the FDA. Additionally, ANDA holders would have an affirmative duty to notify the new drug application (NDA) holder about the supplemental revisions and pass along information forming the basis for the revision.

The proposed rule further suggests that, upon receiving notification from an ANDA holder, the NDA holder is "expected" to submit its own revised label to the FDA along with its views as to whether the ANDA holder's proposed supplement should be approved. The FDA would then evaluate the proposed labels and decide which should be approved. Upon approval, ANDA holders would have only 30 days to update their labels through an electronic process. The proposal then requires "timely distribution" of the product label "accompanied by an updated package insert as soon as feasible thereafter or at the time of next printing of the product labeling for packaging."

RESISTANCE TO PROPOSED RULE

As we've previously highlighted, the proposed rule has drawn ire from industry insiders and lawmakers who have voiced concerns over multiple potential issues, including excessive costs, uncertain potential liabilities, and

decreased generic drug availability.[1] Given the proposal's potential impact on the entire pharmaceutical industry, it is no surprise that the Generic Pharmaceutical Association (GPhA) has already threatened to sue the FDA if the agency adopts the proposed rule.[2]

Although the FDA has insisted the proposed rule's benefit to public health outweighs "concerns related to temporary differences in labeling," the reopening of the comment period belies the strength of its position.

NEW COMMENT PERIOD

The FDA's proposed rule, if adopted in its current form, would have a deleterious and widespread impact on the entire pharmaceutical industry. By reopening the comment period, the FDA has given the industry reason to believe that the rule could change significantly before final publication. This new comment period allows parties to submit guidance to the FDA as it attempts to achieve its goal of improving "communication of important safety information to prescribing health care providers and the public." The FDA welcomes guidance and is accepting comments until April 27, 2015. We strongly urge affected parties to submit comments at http://www.regulations.gov, identified with Docket No. FDA-2013-N-0500-0081. Those interested in attending the public meeting on March 27, 2015, in Silver Spring, Maryland, may register by emailing CBESupplements.PublicMeeting@fda.hhs.gov by March 20, 2015.

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[1] *See* "Goodbye to Generic Preemption? FDA Publishes Proposed Rule," Morrison & Foerster Client Alert (Nov. 13, 2013); "$4 Billion Price Tag for Pleasing Plaintiffs' Bar? New Study Estimates Costs of FDA's Proposed Rule on Generic Drug Labeling," Morrison & Foerster Client Alert (Feb. 26, 2014).

[2] Alexander Gaffney, *Generic Drug Industry Threatens FDA With Lawsuit Over Drug Labeling Proposal*, Regulatory Affairs Professionals Society (Oct. 7, 2014).

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