Patterson Belknap Webb & Tyler LLP

Products Liability Alert December 2018

FDA Withdraws Proposed Rule Abolishing Generic Preemption; Recognizes "Downsides" Of Expanded Tort Liability

On December 13, 2018, the FDA withdrew a proposed rule that would have authorized manufacturers of generic drugs to use the Changes Being Effected (CBE) procedure to add new safety information to their labeling—something that name-brand manufacturers have long been able to do. The proposed rule would have abolished so-called *Mensing* preemption for generic drug manufacturers, exposing them to tort liability on the same terms as name-brand manufacturers.

Promulgated in 2013 by the Obama administration, the proposed rule was a direct response to the Supreme Court's 2011 decision in *Pliva, Inc. v. Mensing*, which held that generic manufacturers are immune from failure-to-warn claims—the most common form of product-liability litigation. The Court's rationale was that, while name-brand manufacturers are permitted to use the CBE procedure to adopt new warnings unilaterally, generic manufacturers are barred from using that procedure, and must instead seek prior approval from the FDA to add new warnings. Because it was impossible for generic manufacturers to comply with their purported state-law duty to warn without the intercession of a federal agency, that state-law duty was preempted by federal law. By opening the CBE procedure to generic manufacturers, the proposed rule would have undermined the basis for *Mensing*'s preemption holding and left generic manufacturers once again subject to failure-to-warn claims.

After the 2016 election, the proposed rule was widely considered moribund, and in that sense, the FDA's action is unsurprising. However, the FDA's stated rationales for the withdrawal are significant for *both* generic *and* name-brand manufacturers. In their public statement, FDA Commissioner Scott Gottlieb and Center for Drug Evaluation and Research (CDER) Director Janet Woodcock explained that the proposed rule could have "compromise[d] public health" by bringing about several "unintended consequences." One of these was the "confusion" caused by label warnings that could differ between a generic drug and its name-brand analogue, or between different generic versions of the same name-brand drug. Others flowed directly from the increased litigation exposure that the rule would have created. For example, fear of liability could have led generic manufacturers to "crowd[]" their labels with "redundant" and "superfluous" safety information, to the detriment of consumers. And the added litigation expense "would have imposed significant burdens on the generic drug industry," potentially "le[ading] to an increase in the cost of generic drugs or the market exit of certain products and manufacturers, exacerbating the risk of drug shortages and resulting in a less competitive marketplace." The agency's formal withdrawal notice published in the Federal Register also "acknowledge[d] … [these] significant potential downsides."

Notably, these arguments about the negative "unintended consequences" of expanded tort liability are not unique to *generic* drug manufacturers. *Name-brand* manufacturers, too, have long argued that expansive liability results in over-warning, increased medicine costs, decreased innovation, and premature exit from the market—all to the detriment of consumers and the public health. These arguments have played a central role in the ongoing battle over the "innovator liability" doctrine, which would shift liability for injuries caused by generic drugs to the "innovator" manufacturer who sells the name-brand analogue. For example, earlier this year (in a case litigated by Patterson Belknap), the West Virginia Supreme Court rejected innovator liability, finding that the "significant litigation costs" that the doctrine would impose on name-brand manufacturers could increase the price of medicines and reduce innovation, which would entail "negative health consequences for society." Now, these same "unintended consequences" arguments—or, at least, very similar ones—have the imprimatur of the FDA itself, and courts should have even more reason to reject innovator liability for name-brand manufacturers.

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