Client Alert.

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Bill to Undo *Mensing* Decision and Allow Patients to Sue Generic Drug Makers for Failure to Warn

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Senator Patrick Leahy (D-Vt.) introduced legislation yesterday to counter the effect of the Supreme Court's June 2011 decision in *Pliva v. Mensing*, 131 S. Ct. 2567 (2011). *Mensing* held that patients who claim injury from generic drugs cannot sue the manufacturer for failure to warn, even though patients who take the same drug, but the brand name, can. Senator Leahy's bill is intended to undo this perceived inequality. If it succeeds, the bill would not only place a heavy burden on generic manufacturers contrary to the intent of the Hatch-Waxman Act, but it would also ignore the reality of how prescription drugs are used in the healthcare system.

WYETH V. LEVINE: BRAND NAME MANUFACTURERS CAN BE LIABLE

In 2009, the Supreme Court decided the landmark case of *Wyeth v. Levine*, 555 US 555 (2009). Diana Levine, a guitarist, was given the drug Phenergan, developed gangrene, and had to have her arm amputated. She sued Wyeth, the manufacturer of the drug, claiming that its warning was inadequate.

Wyeth argued that Levine's claims were preempted because FDA approval of the warning in question immunized Wyeth from liability. The Supreme Court disagreed, finding that Wyeth could have strengthened its warning without prior FDA approval using the "Changes Being Effected" ("CBE") supplement. Central to the Court's decision was the notion that a drug manufacturer must maintain responsibility for the content of its labels.

MURKY WATERS: *LEVINE* MEETS HATCH-WAXMAN

The Supreme Court made clear that its ruling in *Levine* applied only to brand name drugs. The ruling left open the question of whether generic manufacturers could be held liable in similar fashion in light of certain restrictions placed on generics by the Hatch-Waxman Amendments of 1984 ("Hatch-Waxman").

Hatch-Waxman was intended to bring generic drugs to the market quickly and inexpensively. In exchange for this expedited approval process, generic drug manufacturers were required to ensure that their products were *identical to* the Reference Listed Drug ("RLD"), or brand name drug, in certain respects. In particular, Hatch-Waxman required that generics maintain labeling identical to that of the RLD.

Courts and litigants alike had already been divided on the relationship between the CBE and sameness requirements. Some courts read the sameness requirement to prohibit generic manufacturers from submitting CBEs. Other courts stuck to traditional notions of manufacturer responsibility, holding that generics were held to the *Levine* standard and, therefore, could use CBEs to strengthen warnings. The latter position necessarily allowed a generic label to deviate from the RLD, despite statutory language to the contrary. The case law provided no conflicting guidance to the generic pharmaceutical industry.

SUPREME COURT REJECTS "SIMILAR PRE-EMPTION ACROSS A DISSIMILAR STATUTORY SCHEME"

In 2011, the *Mensing* decision resolved this tension. Citing Hatch-Waxman and regulations enacted by FDA, the Supreme Court held that generic manufacturers' labels could not deviate from the RLD label, and therefore could not be held liable for failure to warn.

Yet the core of this solution presented an inherent "inequality." The *Mensing* decision delineated two categories of plaintiffs: those who took brand name drugs, and those who took generics. Despite Hatch-Waxman's emphasis on "sameness," brand name drugs now carried the right to sue, while generics did not. Although the Court recognized this unfairness it refused to "distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme." Instead, the policy question was left to Congress and the FDA.

LEAHY'S BILL ALLOWS GENERIC LABELS TO DEVIATE

In response to several consumer advocacy groups, yesterday on the Senate floor Senator Leahy introduced S. 2295, 112th Cong. (2d. Sess. 2012) titled "Patient Safety and Generic Labeling Improvement Act." Senators Al Franken (D-Minn.), Jeff Bingaman (D-N.M.), Sherrod Brown (D-Ohio), Sheldon Whitehouse (D-R.I.), Chris Coons (D-Del.), and Richard Blumenthal (D-Conn.) co-sponsored the bill. A parallel bill was introduced in the House by Congressmen Chris Van Hollen (D-Md.) and Bruce Braley (D-Iowa).

The bill would permit generic drug manufacturers to change their labels "in the same manner" as brand name drug manufacturers. In essence, the proposed legislation permits generic manufacturers to submit CBE labeling changes. In addition, the bill would allow the FDA to order all other generics and the RLD holder to conform to the changes made by the generic drug manufacturer.

Senator Leahy noted that the legislation was introduced to directly address the perceived inequality created by the Supreme Court's decision. He cited an editorial published by *The New York Times* in March, as well as letters of support from the AARP, Alliance of Justice, and Public Citizen. He concluded that the legislation "will promote accountability and ensure that all drug makers can take appropriate steps to enhance warnings given to doctors and consumers."

DOING AWAY WITH "SAMENESS" COMPLICATES THE SYSTEM

What Senator Leahy failed to address, however, is the chaos and disarray that would result from the proposed amendment, and the realities of modern healthcare. Under this amendment, it is feasible that multiple labels for the same drug, each containing a different set of warnings. Healthcare practitioners and patients are already over-saturated with warnings. If a physician reads one label, he or she is unlikely to read any additional labels. Accordingly, the proposed legislation would only increase confusion without any demonstrated potential to increase patient safety.

Empowering, but not obligating, the FDA to order conformity does little to mitigate this problem. The nature of regulatory approval is that it can take months for the FDA to evaluate and approve modified warnings. Currently, CBE warning changes are implemented unilaterally by the RLD holder; only after the FDA approves the CBE submission are generics then permitted to change their labels accordingly. Under this new system there could be long periods of time where multiple warnings and labels are on the market.

LEGISLATIVE AMENDMENTS SHOULD TRY TO PRESERVE SAMENESS

Ultimately, given the Republican majority in the House of Representatives, this legislation is unlikely to pass both the House and the Senate in its current form. However, it is equally unlikely to be the last word from the legislature in

response to the Supreme Court's suggestion that legislative change could address the inequality created by *Mensing*. Other alternatives may surface, such as obligating generics to inform FDA if they believe a label change is called for, but leaving it to FDA to use that information to mandate a uniform label across all versions of a drug, generic or branded.

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