What Does the Future Hold for Generic Pharmaceutical Manufacturers?

Implied Conflict Preemption Defense

By Stephanie M. Rippee and Ceejaye S. Peters

It would be surprising if the plaintiffs' bar did not experiment with some novel theories of recovery to fill the gap left by the Supreme Court's recent decision.

Under the Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §301 *et seq.*, a manufacturer cannot sell a new drug in interstate commerce before obtaining the FDA's approval of that drug. Approval requires submitting the precise language that the manufacturer proposes to use in the drug's labeling. 21 U.S.C. §355(a); 21 U.S.C. §355(b)(1)(F); 21 U.S.C. §355(j)(2)(A)(v); 21 C.F.R. §314.50(e)(2)(ii); 21 C.F.R. §314.94(a)(8)(ii). Much of state tort law product liability litigation for drugs centers on allegations that the approved labeling was somehow inadequate. These "failure-to-warn" claims set the stage for the implied conflict preemption debate.

Legal Basis for Implied Conflict Preemption

The doctrine of preemption originates from the supremacy clause of the United States Constitution: the "Constitution, and the laws of the United States which shall be made in Pursuance thereof… shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. The supremacy clause invalidates state laws that "interfere with, or are contrary to, federal law." *Hillsborough Cnty v. Automated Med. Labs.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 22 U.S. 1 (1824)). Under the doctrine of implied conflict preemption, although Congress has not expressly displaced all state law, "state law is nullified to the extent that it actually conflicts with federal law." *Colacicco v. Apotex, Inc.*, 521 F.3d 253, 261 (3d Cir. 2008) (quoting *Hillsborough*, 471 U.S. at 713); *see also English v. Gen. Elec. Co.*, 496 U.S. 72, 78–79 (1990). A court can find that Congress, by implication, preempted certain state law claims by "conflict" if (1) complying with both federal and state law is impossible, or (2) the state law claims stand as an obstacle to the accomplishment of Congress's objectives. *Fid. Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 522 (1992); *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871–72 (2000).

Drug manufacturers have long argued that state law tort claims that different or

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additional language should have been used in a drug's FDA-approved labeling necessarily conflict with the FDA's regulatory approval scheme. That conflict makes it impossible to comply with both federal and state law because under federal law you cannot say "more" in your warning, and under state law, you must to avoid liability. They further argue that these state law claims are an obstacle to Congress's dual objectives that the FDCA both protect and promote public health by ensuring that safe and effective drugs are made available to the public. Thus, according to manufacturers, these state law tort claims are preempted by implication and must yield to federal law.

Generic drug manufacturers have argued that they *cannot* change warning labels as state tort allegations would demand because federal law requires a generic drug label to be "the same as" the innovator drug label.

Supreme Court Scrutiny for Branded Drug Manufacturers

In 2009, the United States Supreme Court analyzed the implied conflict preemption defense in a branded drug product liability case and greatly limited branded drug manufacturers' ability to successfully assert this defense. *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 183 L. Ed. 2d 51 (2009). The Court refused to find that federal law preempted the plaintiff's state law tort claim that Phenergan contained inadequate warnings about the risk of administering the drug through an IV-push injection. *Levine*, 129 S. Ct. at 1196–99.

First, the Court rejected Wyeth's "impossibility" argument, which was premised on the notion that under federal law and regulations, Wyeth could not change the drug's label without first receiving FDA approval. The Court reasoned that Wyeth, immediately upon recognizing a warning deficiency, could have strengthened its warning without securing FDA approval first by using the "CBE" or "changes being effected" regulation, 21 C. F. R. §314.70(c)(6)(iii), and then subsequently sought approval of the change. *Id.* at 1199. Without clear evidence in the regulatory record that the FDA did or would reject a different warning about the specific risk at issue, the Court rejected Wyeth's claim that Wyeth could not have made the labeling change alleged necessary under state law and also complied with federal law. *Id.*

Second, the Court ruled that state law failure-to-warn claims do not stand as obstacles to Congress's objectives for the FDCA. According to the Court, Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness. *Id.* at 1201–02. The Court found this evidenced by the historic coexistence of state tort law and federal law and regulations, as well as by Congress's failure to include an express preemption provision in the FDCA. *Id.* at 1200.

The Distinction Between Innovator and Generic Drug Approval

In *Levine*, 555 U.S. 555, 129 S. Ct. 1187, (2009), however, the Court did not discuss implied preemption in a case involving a generic drug. The differences in the regulatory approval schemes for the two types of drugs, branded and generic, create arguments that the *Levine* rulings do not extend to generic drugs.

A company seeking approval of a branded or innovator drug must submit a new drug application (NDA) that demonstrates—after significant, costly studies and tests—that the drug is safe and effective. 21 U.S.C. §355(b)(1)(A). In contrast, as specified in the 1984 Hatch-Waxman Amendments to the FDCA, generic drugs are subject to an abbreviated approval scheme that facilitates cheaper and quicker approval. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (Hatch-Waxman Amendments). Generic drug manufacturers need only submit an "abbreviated new drug application" (ANDA) demonstrating that the generic drug is bioequivalent to a drug that has already been found safe and effective. 21 U.S.C. §355(j)(2)(A)(iv).

As part of the ANDA approval process, a generic drug manufacturer must show, in a side-by-side comparison format, that the proposed labeling for the generic drug is "the same as" the approved labeling for the branded drug. 21 U.S.C. §355(j)(2)(A)(v); 21 C.F.R. §314.94(a)(8)(i) through (iv). Based on this requirement, generic drug manufacturers have made an "impossibility" preemption argument that differs from the arguments rejected by the Supreme Court in *Levine*. Generic drug manufacturers have argued that they *cannot* change warning labels as state tort allegations would demand because federal law requires a generic drug label to be "the same as" the innovator drug label. Thus, finding a generic drug manufacturer liable under state law for failing to change a branded drug's label used on a generic "equivalent," creates a direct conflict with federal law—federal law that does not permit them to deviate from the branded drug label.

Generic drug manufacturers have also argued that if they must propose or initiate labeling changes, rather than simply adopting branded drug labeling verbatim, they would need to engage in the time-consuming, expensive testing of their drugs for safety and efficacy, which the Hatch-Waxman Amendments were specifically designed to avoid. Requiring generic drug manufactures to undertake that testing, they argue, would create an obstacle to Congress's objective of bringing low-cost generic drugs to market quickly.

Before and after *Levine*, generic drug manufacturers made these generic-drug-specific implied conflict preemption arguments with mixed success among the trial courts. At the appellate level however, they did not achieve success. The Eighth Circuit, and subsequently the Fifth Circuit, rejected the implied conflict preemption defense in decisions that cast doubt on its continued viability for generic drug manufacturers as well. Although at the appellate level, the courts had not split, late in 2010, the Supreme Court agreed to address the issue.

The Eighth Circuit *Mensing* Decision

In November 2009, the Eighth Circuit

Court of Appeals became the first federal appellate court to address the application of the implied conflict preemption defense in a failure-to-warn case against a generic drug manufacturer. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). Mensing filed state law failure-to-warn claims against the manufacturer of the innovator drug Reglan and multiple generic metoclopramide manufacturers. The U.S. District Court of the District of Minnesota dismissed Mensing's claims against the generic manufacturers holding that to require generic metoclopramide manufacturers to deviate from the approved language of the Reglan label created an impermissible conflict with federal law. *Mensing v. Wyeth, Inc.*, 562 F. Supp. 2d 1056 (D. Minn. 2008).

The Eighth Circuit, relying heavily on the reasoning from *Levine*, disagreed, reversing the lower court decision and allowing the inadequate warnings claims to stand. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009). The Eighth Circuit stated that the key considerations in applying the implied conflict preemption defense were congressional intent and the presumption against preemption. *Id.* at 607. The court pointed out that Congress could have included an express preemption provision in the Hatch-Waxman Amendments if it had intended to insulate generic drug manufacturers from liability for inadequate labeling, but it did not. The court, focusing on the regulatory framework of the FDCA, found that it was not impossible for a generic drug manufacturer to comply simultaneously with the federal law and state tort law. *Id.* at 608. The court relied heavily on *Levine*'s central premise that the content of a drug label is the responsibility of the manufacturer at all times, both before and after approval, and it held that the regulatory requirements for changing drug labeling, or at least bringing needed labeling changes to the FDA's attention, apply to manufacturers of generic drugs as well as to innovator drug manufacturers. *Id.* at 608–09.

The generic drug manufacturers argued that they each were prohibited from unilaterally implementing label changes without first receiving FDA approval through the CBE procedure. The Eighth Circuit, however, found it unnecessary to decide whether generic drug manufacturers could use the CBE procedure. *Id.* at 608. Instead, the Eighth Circuit noted that the generic drug manufacturers had a duty to ensure that their drugs had adequate labeling and could have fulfilled their duty by merely proposing a label change for consideration by the FDA through the FDA "prior approval process" used for most labeling changes. *Id.* The court emphasized that "[t]he regulatory framework makes clear that a generic manufacturer must take steps to warn its customers when it learns it may be marketing an unsafe drug." *Id.* at 608. The court held that generic drug manufacturers cannot simply ensure that their labels are identical to the corresponding brand name drugs' labels. *Id.* at 609 ("§201.57(e) does not permit generic manufacturers passively to accept the inadequacy of their drug's label as they market and profit from it.").

The Eighth Circuit noted that commentary by the FDA published contemporaneously with the Hatch-Waxman Amendments "supports the requirement that at a minimum a generic manufacturer should alert the agency to any new safety hazard associated with its products." *Id.* at 609. Specifically, the FDA stated that "'[a]fter approval of an ANDA, if an ANDA holder [a generic manufacturer] believes that new safety information should be added, *it should provide adequate supporting information to FDA*, and FDA will determine whether the labeling for the generic and listed drugs should be revised.'" *Id.* (citing 57 Fed. Reg. 17,950, 17,961 cmt. 40 (Apr. 28, 1992) (emphasis supplied)). Additionally, the court reasoned that 21 C.F.R. §314.98 requires that generic drug manufacturers follow the same post-marketing record keeping and reporting of adverse drug experiences as brand-name drug manufacturers, presumably with the expectation that generic drug manufacturers will initiate label changes and not merely make changes to match those initiated by the branded drug manufacturers. *Id.* at 609. The court also pointed out that, instead of proposing labeling changes, generic drug manufacturers could suggest that the FDA send warning letters to health care professionals. *Id.* at 610.

The Eighth Circuit cited *Levine* for the proposition that uncertainty about whether the FDA would accept or reject a proposed labeling change makes preemption, in general, less likely. *Id.* at 610. In other words, to support implied conflict preemption by "impossibility," the generic drug manufacturers needed to demonstrate that the FDA likely would have rejected a stronger or different proposed warning. *Id.* at 610–11. The court did not find evidence to that effect in the record, and quite the opposite: the FDA had mandated that the brand-name drug manufacturer enhance the specific warning at issue. *Id.* at 611.

Finally, the Eighth Circuit rejected the generic drug manufacturers' argument that state law failure-to-warn claims obstruct the goal of the Hatch-Waxman Amendments of bringing low-cost generic drugs to market quickly. *Id.* at 611–12. The court held that the "scientific substantiation" needed to support a proposed labeling change need not consist of additional, expensive studies. Rather, the Eighth Circuit pointed out that the substantiation could take the form of adverse drug experiences, which FDA regulations already required generic drug manufacturers to collect. *Id.* The court noted that the FDA, in fact, had mandated an enhanced warning for the drug at issue based on studies published elsewhere rather than on clinical studies that the FDA had conducted. *Id.* at 611.

In a telling conclusion that perhaps reveals a significant underlying motivation for the case's outcome, the Eighth Circuit stated, "We decline to assume that Congress intended to shield from tort liability the manufacturers of the majority of the prescription drugs consumed in this country and leave injured parties like Mensing no legal remedy." *Id.* at 612.

The Fifth Circuit *Demahy* Decision

Demahy also sued both the manufacturer of Reglan, a brand-name drug, and Actavis, a manufacturer of a generic metoclopramide. The U.S. District Court of the Eastern District of Louisiana denied Actavis' motion to dismiss the state law failure-to-warn claims as preempted, and in January 2010, the Fifth Circuit affirmed the district court's denial. *Demahy v. Wyeth, Inc.*, 586 F. Supp. 2d 642 (E.D. La. 2008), *aff'd*, *Demahy v. Actavis, Inc.*, 593 F.3d 428 (5th Cir. 2010).

Similar to the Eighth Circuit, the Fifth Circuit focused on congressional intent as

well as the presumption against preemption. *Id.* at 433–34. The court noted that when, as in Demahy's case, federal law did not provide a substitute remedy, courts have demonstrated an even greater reluctance to find that federal law preempted state law claims. *Id.* at 435. Also the court emphasized Congress's awareness of the operation of state tort law in this area and yet failed to act on expressly mandating preemption, which differed from its approach to medical devices. *Id.*

The court held that the FDA's power to withdraw approval of a generic drug if its manufacturer fails to maintain labeling consistent with that of the innovator drug was meant as a sword and not as a shield.

In response to Actavis' "impossibility" arguments, the Fifth Circuit, in some contrast to the Eighth Circuit, focused on the distinction between what the FDCA and the related regulations say about the "sameness" of the content of the generic drug and innovator drug labeling at the *approval* stage as opposed to *after* approval, the stage at which Demahy alleged labeling had become inadequate. *Id.* at 436. The court pointed out that although the FDCA and the regulations require that a generic drug's labeling conform to the innovator's label *at* the time that the drug is being approved, the statutory scheme and regulations do not say anything about whether labeling needs to *remain* the same *after* the FDA grants an ANDA. *Id.* In looking at other parts of the FDCA and the applicable regulations, however, the court noted that the regulatory scheme clearly requires that generic drug manufacturers—as with innovator manufacturers—ensure that drug labeling post-approval accurately reflects evidence of the risks associated with drugs and that they alert the FDA as new risks emerge. *Id.* at 437. Similar to the Eighth Circuit, the Fifth Circuit focused on the FDA commentary that accompanied the Hatch-Waxman Amendments as supporting a generic drug manufacturer's duty to alert the FDA to new safety hazards. *Id.* at 437–38.

The court held that the FDA's power to withdraw approval of a generic drug if its manufacturer fails to maintain labeling consistent with that of the innovator drug was meant as a sword and not as a shield. That is, it was not meant to relieve a generic drug manufacturer from the obligation to attempt to strengthen its label or to prohibit it from doing so. It was instead implemented to give the FDA a weapon to ensure that generic drug manufacturers update their labels to mirror changes proposed and made by drug innovators. *Id.* at 438–39.

The court also recognized that while a generic drug manufacturer is not free to simply change its drug labeling however it sees "fit," a generic drug manufacturer has at least three mechanisms that it can use to disseminate new or updated warning information, the CBE process, the "prior approval" process, and "dear doctor" letters, and to demonstrate that it was truly impossible to comply with both federal and state law, a generic drug manufacturer would have to demonstrate that it could not use those mechanisms. *Id.* at 439. The court, through a lengthy and detailed analysis, concluded that generic drug manufacturers likely could use the CBE process. *Id.* at 439–44. But even if that were, at best, an open question, the court concluded that nothing barred generic drug manufacturers from using the remaining two mechanisms, which defeated the impossibility argument. *Id.* at 444–45.

The Fifth Circuit clarified that the question in assessing preemption is not whether federal law imposes a duty on generic manufacturers to change their drug labels. Rather, the question is whether state law duties requiring labeling changes make simultaneous compliance with federal law impossible. *Id.* at 446.

Lastly, the Fifth Circuit rejected the idea that requiring generic drug manufacturers to bear liability for inadequacies in drug labeling obstructs the goals of the FDCA of making sure that drugs are indeed safe and effective, noting again that scientific substantiation to propose a labeling change need not require costly, time-consuming clinical trials. *Id.* at 446–47. Perhaps previewing one issue that the Supreme Court intends to clarify, the Fifth Circuit observed that to rule that the FDCA preempts state tort law claims against generic drug manufacturers "would leave us with the bizarre conclusion that Congress intended to implicitly deprive a plaintiff whose doctor prescribes a generic drug of *any* remedy, while under *Levine*, that same plaintiff would have a state-law claim had she only demanded a name brand drug instead." *Id.* at 449.

Supreme Court Scrutiny of Generic Drug Manufacturers

In February and June 2010, the generic manufacturers in *Mensing* and *Demahy* respectively petitioned the United States Supreme Court for writs of certiorari for review of the issue of whether state law tort claims for inadequate warnings asserted against generic drug manufacturers are impliedly preempted. In the context of the Eighth Circuit *Mensing* decision, the Court invited the solicitor general to express the views of the United States. *Actavis Elizabeth, LLC v. Mensing*, 130 S. Ct. 3349 (2010). He did so in an amicus brief that advocated denying certiorari to the petitioner because refusing to find that federal law preempted state law tort claims in that instance was essentially correct. The Generic Pharmaceutical Association (GPhA) submitted an amicus brief urging that the Court grant certiorari and urging it to reverse the holding of the appellate court. Even though the circuit courts had not split on this issue, the Supreme Court ultimately granted the petitions for certiorari in the cases and consolidated them for briefing. *Mensing v. Wyeth, Inc.*, 588 F.3d 603 (8th Cir. 2009), *cert. granted*, 131 S. Ct. 817 (Dec. 10, 2010) (No. 09-1039 and No. 09-993); *Demahy v. Actavis, Inc.*, 593 F. 3d 428 (5th Cir. 2010) *cert. granted*, 131 S. Ct. 817 (Dec. 10, 2010) (No. 09-1501).

Shortly after the Supreme Court granted certiorari to the petitioners in these cases, on January 24, 2011, the Ninth Circuit, agreeing with both the Fifth and Eighth Cir-

cuits, held that federal law did not preempt state law failure-to-warn claims against a generic ibuprofen manufacturer. *Gaeta v. Perrigo Pharmaceuticals Co.*, 630 F.3d 1225, 1227 (9th 2011). In line with the Fifth and Eight Circuits, the Ninth Circuit held that compliance was possible because generic drug manufacturers could discharge their state law duty to warn of additional risks associated with their products through the CBE process, the "prior approval" process, and "dear doctor" warning letters. *Id.* at 1231. The Ninth Circuit also concluded that there was no "clear evidence" that the FDA considered and rejected stronger warnings than those proposed by the plaintiffs. *Id.* at 1237. The court also found that state law did not pose obstacles to the purpose and objectives of the Hatch-Waxman Amendments. *Id.* at 1238. The Ninth Circuit held that Congress did not intend the Hatch-Waxman Amendments' goal of delivering low-cost generic drugs "to supplant the FDCA's overall goal of providing consumers with safe and effective drugs." *Id.* The court dismissed as speculative the notion that consumers will lose confidence in and refuse to purchase generic drugs if they contain warnings different from those of the corresponding branded drugs, noting that if generic manufacturers use the "prior approval" process, the FDA will impose labeling changes, once accepted, on both generic drug and the corresponding branded drug manufacturers. *Id.*

The Ultimate Supreme Court Ruling

On June 23, 2011, the Supreme Court in a somewhat surprising, consolidated, 5 to 4 opinion rejected the reasoning of both the Eighth and Fifth Circuits and held that "impossibility" exists. It thus held that failure to warn claims against generic manufacturers are indeed categorically preempted, reversing the rulings in both cases. *Pliva, Inc., et al. v. Mensing*, ___ S. Ct. ___, 2011 WL 2472790 (U.S. June 23, 2011). The majority noted once again the undisputedly different labeling duties that exist at the time of drug approval that were not at issue and clarified that the issue was, instead, whether generic manufacturers had a *right* to change their labels post-approval, thus negating an assertion that it was impossible to comply with both state and federal law. *Id.* at *6.

In examining this right, or lack thereof, the majority relied in large part on the brief filed by the U.S. containing the views of the FDA. The majority deferred to the FDA's view that generic manufacturers cannot unilaterally change their labeling via the CBE regulation as branded manufacturers can. *Id.* (citing U.S. Brief at 15–16, n. 7 and 21 U.S.C. §355(j)(4)(G); 21 CFR §§314.94(a)(8)(iii), 314.150(b)(10)). The majority also deferred to the FDA's view that generic manufacturers cannot request the sending of a "dear doctor" letter that contains new warning information inconsistent with the drug's approved labeling. *Id.* at *7 (citing U.S. Brief at 18; 21 U.S.C. §321(m); 21 C.F.R. §202.1(*l*)(2)). But the majority also acknowledged and deferred to the FDA's assertion that generic manufacturers do indeed have a right to propose labeling changes though the customary prior approval process, as well as an actual duty to do so. *Id.* at *7 (citing U.S. Brief at 20; 57 Fed. Reg. 17961). Without resolving the issue of whether a duty exists which it deemed unnecessary to its opinion, the majority focused only on the right to change the label. Even with this right, however, the majority found that impossibility exists and preemption is justified. *Id.* at *8.

The majority's bottom line seemed to be that the "possibility" that a generic manufacturer could effectuate a labeling change, as both Mensing and Demahy had argued, is not enough to overcome the actual conflict that exists and justifies preemption. The majority noted that, as discussed above, to comply with federal law, a generic manufacturer could not unilaterally make a labeling change but rather, could only ask for one. *Id.* at *8–9. Asking however, the majority held, while complying with federal law, would *not* fulfill the company's duties under state law which demanded an actual change—not just a request for one. *Id.* at *9. Thus, it was impossible for the generic manufacturers to comply with both sets of laws. *Id.*

The majority was unwilling to consider the "possibilities" of what the manufacturers and/or FDA could have done (asked for/granted or denied a label change). *Id.* at *9–10. To do so, it held, would "render conflict preemption largely meaningless because it would make most conflicts between state and federal law illusory." *Id.* at *10. Such possibilities, the majority noted, are both speculative (the FDA could just as easily have denied a label change) and subject to change at any given time as laws and regulations change. *Id.* The majority held that such conjecture in the analysis would effectively render the Supremacy clause itself meaningless outside of express preemption scenarios. *Id.* The majority held that the wording of the Supremacy Clause itself suggests that implied preemption is contemplated and courts should not strain, by considering such conjecture, to reconcile conflicting federal and state laws but rather should look only to the ordinary meanings of the laws. *Id.* at *10–12.

Finally, the majority explained that its opinion was not contrary to *Levine*, as suggested by the dissent, because branded manufacturers can indeed unilaterally change their labels using the CBE process. Thus, they can comply with both state and federal law. *Id.* at *12. The majority recognized the "bad hand" dealt to Mensing and Demahy by the drug regulations since they would have had a remedy had they taken the branded product and they likely played no role in the decision to substitute the generic drug. *Id.* But the majority held it was not their place, but rather Congress's and the FDA's to fix that unfortunate result. *Id.*

The dissent sharply disagreed with the majority, noting that it had diluted the demanding impossibility standard by allowing preemption based on no more than the "possibility of impossibility." *Id.* at *13. The dissent acknowledged that impossibility might in some instances exist but opposed categorical preemption of failure to warn claims against generic manufacturers. *Id.* at *18.

The dissent noted that, as recognized in *Levine*, manufacturers are in a better position than the FDA to monitor the post-approval safety of their drugs. Thus, as asserted by the FDA, both branded and generic manufacturers are required to do so through post-marketing surveillance activities such as investigating and reporting adverse events. *Id.* at *14–15. Just like the majority, the dissent also deemed it unnecessary to decide if generic manufacturers indeed have a duty to actually initiate proposed labeling changes, noting that even if they do not, it is undisputed that they may do so when they believe change

is needed. *Id.* at dissent *15. To the dissent, this ability itself negated categorical impossibility *Id.* at *18–19.

The dissent reiterated the underlying principles that are to guide preemption decisions in all cases: 1) the purpose of Congress; and 2) the presumption against preemption in a field traditionally occupied by the states. *Id.* at *16. Bearing these principles in mind, the dissent noted that Congress is certainly aware of state tort law suits but yet has declined to expressly preempt failure to warn claims as to drugs while at the same time expressly doing so as to medical devices. *Id.* Thus, the dissent posited, the standard for "impossibility" preemption is demanding and should not be met by the mere "possibility of impossibility" as was the case here. *Id.* at *17–18. Having not at least attempted to seek a labeling change, the dissent held that the manufacturers could not in this case meet the burden of showing actual, rather than hypothetical impossibility. *Id.*

With regard to the unilateral ability to change the label, the dissent pointed out that branded manufacturers cannot do so either. Even when employing the CBE process, the branded manufacturer must ultimately obtain FDA approval of the change it made. *Id.* at *17, 19. Thus, the dissent characterized the majority's categorical preemption of failure to warn claims against generic manufacturers as inconsistent with the *Levine* decision and advocated employing the *Levine* analysis, case by case, to both branded and generic manufacturers. *Id.* at dissent *19–21. That is, the dissent would require that either type of manufacturer demonstrate that it invoked the mechanism provided to it to try to change the label but, for whatever reason, was unsuccessful. Any other approach, the dissent held, would infringe upon the states' authority where Congress had expressed no intent to preempt. *Id.* at *18.

The dissent dismissed as nonsensical the majority's various rationales that its interpretation avoided conjecture and was necessary to preserve the viability of the doctrine of implied conflict preemption and instead viewed them as contrary to the longstanding presumption against preemption and to years of precedent. *Id.* at dissent *19–21. The dissent noted that the presumption against preemption should actually be even stronger where, as here, federal law provides the manufacturer with a mechanism to attempt to comply with its state law duties. *Id.* at *18.

Finally, the dissent outlined what it considered the absurd consequences dictated by the majority's holding. First, injured consumers of generic drugs, which make up 75 percent of current prescriptions, are left without a remedy even though Congress has never clearly expressed that intent. *Id.* at *22. In many instances the decision to use a generic drug is outside the control of the consumer and instead is dictated the applicable state substitution law leaving the consumer with no ability to preserve a remedy. *Id.* Second, the majority opinion compromises drug safety by removing state law incentives for generic manufacturers to monitor and disclose safety risks. *Id.* Third, the majority creates a distinction between branded and generic drugs that undermines Congressional intent that the drugs be "the same" so that consumers, doctors and legislators would accept and use them. *Id.* at *23. The dissent found no evidence that Congress intended any of these results. *Id.*

Conclusion

The Supreme Court opinion is somewhat surprising in that it does appear to leave the many users of generic drugs without the principal legal remedy pursued in cases of injury. Since the opinion was issued, generic manufacturers across the country have been filing dismissal motions that would appear difficult to deny in light of the categorical preemption espoused by the majority. It would be just as surprising, however, if the plaintiffs' bar did not experiment with some novel theories of recovery in order to fill this gap. While very good news for generic manufacturers, this opinion may be equally bad news for branded manufacturers who would appear to be likely targets for these novel theories.