BNA

Product Safety & Liability Reporter™

PREEMPTION

PRODUCT LIABILITY

The U.S. Supreme Court's recent ruling in *Pliva Inc. v. Mensing* clearly illustrates the doctrinal fault lines that have lain just below the surface in the court's recent preemption jurisprudence, says attorney Lisa M. Baird in this BNA Insight. *Mensing* offers pharmaceutical and medical device lawyers important guidance about the preemptive impact of federal regulations on state tort law duties to warn when applied to prescription generic drugs, the author says. This article also ponders the implications of the ruling on other product liability cases against food and drug manufacturers.

PLIVA Inc. v. Mensing: The U.S. Supreme Court Muddles Through Another One

By Lisa M. Baird

As pharmaceutical and medical device product liability lawyers well know, the doctrine of federal preemption can produce seemingly inconsistent results. For example, whether a state-law tort lawsuit alleging defects with the design, warning label, or manufacturing process for a medical device can proceed or will be dismissed as preempted by federal law will usually turn on whether that device was cleared by the FDA through its ''substantial equivalence'' (or ''510(k)'') process, or whether it was approved by the FDA through its Premarket Approval process. *Compare Medtronic v. Lohr*, 518 U.S. 470 (1996) (''*Lohr*'') (tort claims involving medical device cleared through the substantial equivalence process not preempted) *with Riegel v. Medtronic Inc.*, 552 U.S. 312 (2008) (''*Riegel*'') (tort claims involving medical device approved through Premarket Approval process preempted).

 ISSN 0092-7732

The Supreme Court's latest preemption decision, *PLIVA Inc. v. Mensing*, __ U.S. ___, 131 S. Ct. 2567 (2011) *petition for rehearing filed* 2011 WL 2874547 (U.S. July 18, 2011) (''*Mensing*''), fits squarely within this tradition of inconsistency. Where *Mensing* held that state-law failure to warn claims are preempted when the medical product in question is a prescription generic drug, in 2009 the Supreme Court held that state-law failure to warn claims are not preempted when the medical product in question was a brand-name prescription drug. *Compare Mensing*, 131 S. Ct. at 2572 (failure to warn claim against manufacturer of prescription generic drug preempted) *with Wyeth v. Levine*, 555 U.S. ___, 129 S. Ct. 1187 (2009) (''*Levine*'') (failure to warn claim against manufacturer of prescription brand-name drug preempted).

But the Supreme Court has not singled out the pharmaceutical and medical device industry for uniquely inconsistent treatment. On the whole, ''[m]odern preemption jurisprudence is a muddle.'' Caleb Nelson, Preemption, 86 *Va. L. Rev.* 225, 232 (2000).

At least *Mensing* can be said to have clearly laid bare the doctrinal fault lines that have been just below the surface in the Court's recent preemption jurisprudence—and perhaps that alone should provide hope to litigants and lower courts alike that someday soon, a clean majority of the Court will announce clear rules for preemption—ones that will stick.

And even if the Supreme Court has yet to ultimately decide the correct analytical approach to preemption questions, at least it definitively answered the particular preemption question posed in *Mensing*. Seemingly consistent with prior preemption precedent or not, pharmaceutical and medical device lawyers now have the answer *Mensing* provides about the preemptive impact of federal regulations on state tort law duties to warn when applied to prescription generic drugs and can proceed accordingly.

The Preemption Doctrine

The preemption doctrine is grounded in the Supremacy Clause of the Constitution, which ''establishes that federal law 'shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the contrary notwithstanding.' '' *Mensing*, 131 S. Ct. at 2577 (quoting *U.S. Const., Art VI, cl. 2*). Simply stated, when state law and federal law are ''to the contrary,'' federal law prevails. In practice, deciding whether state and federal law are ''to the contrary'' can be quite difficult, yet given the breadth of state and government regulation, overlap and the resulting preemption questions are inevitable.

Congress, of course, may anticipate that federal and state law will or could be ''to the contrary,'' and then speak directly to the issue of what should occur if both the federal government and a state legislate or regulate a particular area. Congress does so by enacting an express preemption provision (one that expressly declares that state law is superseded by federal law to some extent), a savings clause (one that declares that state law and federal law can co-exist, and to what extent), or both. When Congress has spoken directly to the issue, the primary task of courts in resolving whether state law can apply despite the federal law is one of statutory interpretation: What did Congress say in its express preemption provision or its savings clause, and what does the statutory language mean?

But federal and state law may be ''to the contrary'' regardless of whether Congress has expressly spoken to the issue. As explained further below, this ''implied preemption'' sometimes is discussed as an inquiry into the preemptive intent implicit in federal law and sometimes as an inquiry into whether federal and state law can co-exist or directly conflict.

The Court's deep divisions about preemption stem from disagreement about the interpretive principles that should guide courts when deciding federal-state law conflicts.

In many, but not all, preemption cases, the Supreme Court traditionally has started from the premise that congressional intent is the ''ultimate touchstone'' for any preemption analysis. *See Cipollone v. Liggett Group Inc.*, 505 U.S. 504, 516 (1992).

In other preemption cases, but not all, the Supreme Court has employed a ''presumption against preemption.'' Sometimes the Court describes it as a rule of construction for express preemption clauses, particularly those enacted in areas historically within the purview of the states (health, safety and welfare), one which results in the Court assuming that Congress intends to preserve as much state law as possible. *See*, *e.g.*, *Lohr*, 518 U.S. at 485. On occasion, the Court has gone further and described the presumption against preemption as applicable regardless of whether the issue is one of express or implied preemption. *See*, *e.g.*, *Levine*, 129 S. Ct. 1195 n. 3.

In deciding whether state and federal law are ''to the contrary'' in the absence of an express preemption provision, in the past the Court has found implied preemption in two circumstances: First, when state and federal law impose directly conflicting obligations, and second, when state law ''stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'' *See*, *e.g.*, *Frieghtliner Corp. v. Myrick*, 514 U.S. 280 (1995). But the Court is not always in agreement about what gives rise to a direct conflict, and whether the standard is a demanding or less rigorous one. And it also is not always in agreement about how the ''purposes and objectives'' of Congress should be determined and what it takes for state law to amount to an obstacle to them—or even whether this type of preemption is appropriate at all.

Finally, even when Congress has spoken directly to the issue of preemption through an express preemption provision, implied preemption questions still lurk. As the Court has put it, ''neither an express pre-emption provision nor a savings clause 'bar[s] the ordinary working of conflict preemption principles.' '' *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (''*Buckman*'') (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000)).

Although these background principles may or may not make an appearance in any given preemption decision issued by the Supreme Court in recent years, most members have signed on to majority opinions at one time or another endorsing them. In recent years, however, Justice Thomas has begun to articulate a dramatically different approach to preemption, one rooted in Professor Caleb Nelson's interpretation of the Supremacy Clause as a *non obstante* provision. *See* Nelson, Preemption, 86 *Va. L. Rev.* 225.

According to Professor Nelson, legal drafters at the time of the Constitution frequently employed phrasing similar to the Supremacy Clause's ''any Thing in the

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Constitution or Laws of any State to the Contrary notwithstanding'' phrase. Such *non obstante* provisions were included in recognition that a statute might contradict other laws, and as an instruction that courts should ***not*** employ any presumption or rule of construction against finding an implied repeal. *Id.* at 232.

Reading the Supremacy Clause as containing a *non obstante* provision results in guiding preemption principles quite different from those traditionally, if inconsistently, used by the Court in its modern preemption decisions. Once the operating premise of the Supremacy Clause is that federal law always ''impliedly repeal[s] conflicting state law'' [*Mensing*, 131 S. Ct. at 2580], the relevant inquiry becomes one more of statutory interpretation: what does the federal law mean, what does the state law mean, and do they conflict?

Whether Congress ***intends*** a preemptive effect in passing a particular piece of legislation becomes irrelevant, or far less relevant, even when an express preemption clause exists, because the Constitution tells us the answer is that preemption always is intended whenever when state and federal law are ''to the contrary.'' In other words, congressional intent is demoted from its place as the ''ultimate touchstone'' of preemption to obsolescence, and a ''presumption ***against*** preemption'' in any form is in some respects the reverse of what the court actually should presume.

Examining pharmaceutical and medical device preemption cases does not alone provide a full picture of the Supreme Court's divisions over preemption. But because the Court has decided five such cases over the last 15 years, this universe provides good insight into the evolving dispute about the role of congressional intent, the presumption against preemption, and how quick the Court should be to find state law barred by federal law.

On a practical level as well, the Court's holdings in each of these cases continue to control the issues decided, and any understanding of whether *Mensing* has broader implications must take these prior decisions into account.

Past Supreme Court Pharmaceutical and Medical Device Cases

Because Congress has enacted the federal Food, Drug and Cosmetic Act (''FDCA''), and authorized the federal Food and Drug Administration to heavily regulate medical products, pharmaceutical and medical device law is an area ripe with potential preemption questions. Taking Supreme Court decisions in this area chronologically, a review of these decisions reveals inconsistent results and variable application of the Court's traditional preemption principles—in other words, a muddle.

Lohr v. Medtronic

In 1996, the preemption issue facing the Supreme Court was one of express preemption, and whether a plaintiff's product liability lawsuit alleging harm from a defect in a pacemaker was preempted by federal law. *Lohr*, 518 U.S. at 474. *Lohr* is a fractured case. Justice Stevens' opinion in *Lohr* garnered a majority only on some issues, with opinions by Justice Breyer and Justice O'Connor combining to form a majority on at least one other issue.

When Congress granted the FDA regulatory authority over medical devices, it enacted a provision stating that '' 'no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement . . . which is different from, or in addition to, any requirement applicable . . . to the device.' '' *Id.* at 481 (quoting 21 U.S.C. § 360k(a)). Given the medical device express preemption provision, the Court's primary task was to interpret what the statutory language meant and how much state law it displaced. *Id*. at 484-85.

In doing so, however, a majority of the Court endorsed using two of the traditional preemption principles discussed above. *Id.* at 485. The first was that express preemption provisions are to be interpreted narrowly, because the Court presumes ''that Congress does not cavalierly pre-empt state-law causes of action.'' *Id.* The second is that congressional intent is the ''ultimate touchstone,'' and can be divined primarily by reference to the language of the statute and also by reference to the ''structure and purpose of the statute as a whole,'' and the Court's ''reasoned understanding'' of the problem Congress thought it was fixing and how it intended to do so (that is, legislative intent). *Id.* at 486 (internal quotations omitted); *see also id.* at 494 (declaring congressional intent behind the Medical Device Amendments).

Turning to the applicable federal medical device regulations, the Court recognized that different types of medical devices are subject to different types of regulatory review and control, with the strictest requirements reserved for the devices—called ''Class III'' devices—that carry the greatest risk or that are used to support or sustain human life or prevent impairment to human health. *Id.* at 476-77 (citing regulations).

It also recognized that even for Class III devices, what the federal government requires of manufacturers varies. For cutting-edge devices, federal law requires the manufacturer to provide the FDA with reasonable assurance of the device's safety and efficacy through the ''Premarket Approval'' process. *Id.* at 477.

For devices that are the substantial equivalent of other devices already being sold, federal law only requires the manufacturer to prove ''substantial equivalency'' between the two devices through the ''510(k) process.'' *Id.* at 478. However, even when the FDA clears a device for sale through this 510(k) process, it does not require the cleared device ''to take any particular form for any particular reason.'' *Id.* at 493-94.

Since the device in *Lohr* only had a 510(k) clearance, the FDA did not require any particular design, warnings, or manufacturing process for it, and thus the Supreme Court concluded that state law could—by imposing tort liability for product defects—require the manufacturer to change its design, warning label or manufacturing process for such devices. *See id.* at 494-95, 501. In addition, because the medical device express preemption provision only prohibited state requirements that were ''different from, or in addition to'' federal requirements in any event, the Court also concluded that states could ''provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.'' *Id.* at 495.

A majority of the Court also considered and decided a question about what constitutes ''state law,'' and held that common-law causes of action for negligence and strict liability are state law that impose state require-

ments or prohibitions, just as state legislation and state regulations do. *Id.* at 512 (O'Connor, J. joined by Chief Justice Rehnquist and Justices Scalia and Thomas); *id.* at 503-05 (Breyer, J.).

In sum, the outcome of *Lohr* was that state-law tort claims involving a 510(k) cleared medical device are not preempted, at least as a matter of medical device express preemption.

Buckman Co. v. Plaintiffs' Legal Committee

Five years after *Lohr*, the Supreme Court returned to preemption in another medical device case, *Buckman*, 531 U.S. 341. Like *Lohr*, *Buckman* involved a medical device cleared through the 510(k) process, but this time the issue was one of implied, not express, preemption. *Id.* at 347-48.

In *Buckman*, although the plaintiff claimed the device caused her physical harm, her cause of action was for fraud—namely that the defendant made fraudulent representations to the FDA during the 510(k) process, and that had it not done so, the FDA never would have approved the device and the injuries never would have occurred. *Id.* at 346-47.

A seven-member majority of the Court found this type of fraud claim, one which ''exist[s] solely by virtue of the FDCA's disclosure requirements,'' preempted by federal law. *Id.* at 353. The federal nature of the defendant's disclosure obligation was key to the decision. According to the Court, states have no place attempting to police ''the relationship between a federal agency and the entity it regulates.'' *Id.* at 347. Since the Medical Device Amendments themselves dictated what information was required through the 510(k) process, there was no concern or need to protect '' 'the historic primacy of state regulation of matters of health and safety' '' or to apply any presumption against preemption. *Id.* at 348 (quoting *Lohr*, 518 U.S. at 485).

Instead, the Court found a plain conflict between what federal law required—vesting the FDA with discretion in its decisions ''to punish and deter fraud against'' it—and what state law required—vesting state court juries with authority to punish and deter fraud against the FDA without regard for the FDA's discretionary decisions. *Id.* at 348. The Court's conflict inquiry, however, did not turn on any determination that it was impossible for the defendant to comply with both federal and state law—the Court did not discuss that issue. Instead, the conflict arose from the ''federal statutory scheme'' and the need to prevent state tort litigation from ''exert[ing] an extraneous pull'' on it. *Id.* at 348, 353.

In sum, the outcome of *Buckman* was that state-law ''fraud on the FDA'' claims are preempted as a matter of implied preemption.

Riegel v. Medtronic

In *Riegel*, the Supreme Court's next medical device preemption case, the Court returned to the medical device express preemption provision and an issue left open in *Lohr*: Does preemption result if the plaintiff's state-law tort claims involve a device approved through the Premarket Approval process, rather than cleared through the 510(k) process? *Riegel*, 552 U.S. at 315.

This time, a clear majority of the Court found the claims preempted. Central to the Court's holding was its recognition that unlike the 510(k) clearance process, the Premarket Approval process results in ''design specifications, manufacturing processes, labeling,'' and other attributes of the device that, as a matter of federal law, cannot be changed without FDA approval. *Id.* at 319. Because federal law did in fact mandate that premarket-approved devices take ''a particular form,'' any state law requirement—including those imposed as a matter of duty for purposes of tort liability—that would differ from, or add to the federal requirement is preempted. *Id.* at 330.

That said, ''State requirements are pre-empted under the MDA only to the extent they are 'different from, or in addition to' the requirements imposed by federal law.'' *Id.* Medical device express preemption ''does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations, the state duties in such a case 'parallel,' rather than add to, federal requirements.'' *Id.*

The majority also dispelled any ambiguity left over from *Lohr* about whether state-law tort claims are requirements subject to medical device express preemption in the same manner as state legislation or state regulations. *Id.* at 323. As the Court explained, ''Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments. Absent 'other indications,' reference to a State's 'requirements' includes its common-law duties.'' *Id.* at 324. In analyzing whether the medical device express preemption provision contains any such ''other indications,'' the Court concluded it did not. In fact, the ''federal scheme'' would be disrupted by ''State tort law that requires a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved.'' *Id.* at 325.

A majority in *Riegel* also dismissed the dissent's suggestion the preemption of tort law remedies should require a particularly clear statement of congressional intent, concluding that ''[t]he operation of a law enacted by Congress need not be seconded by a committee report on pain of judicial nullification.'' *Id.* at 326.

In fact, the Court went further, declaring that ''[i]t is not our job to speculate upon congressional motives. If we were to do so, the only indication available—the text of the statute—suggests that the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.'' *Id.*

In sum, the outcome of *Riegel* was that state-law tort claims involving a premarket-approved medical device are preempted as a matter of medical device express preemption.

Wyeth v. Levine

The year following *Riegel*, the Supreme Court turned from medical devices and the express preemption clause of the Medical Device Amendments to prescription drugs. Because no express preemption provision applies to prescription drugs, the issue for the Court in *Levine* was one of implied preemption, and whether it was impossible for the manufacturer to comply with the state-law duty to enhance the warnings without violating federal law, or whether permitting state-law tort liability would stand as an obstacle to the ''purposes and objectives'' of the federal law by substituting a lay jury's opinion about labeling in place of the FDA's expert judgment. *Levine*, 129 S. Ct. at 1193-94.

   ISSN 0092-7732

In *Levine*, the plaintiff had secured a jury verdict premised on the theory that the defendant manufacturer failed to adequately warn of the ''catastrophic consequences'' that can result when the prescription drug in question, a brand-name drug called Phenergan, was administered using a particularly risky method. *Levine*, 129 S. Ct. at 1190-91.

The FDA had approved the drug's warnings when it approved the New Drug Application (''NDA'') for Phenergan in 1955, and over the years had considered several changes to the label with regard to its methods of administration and the risks that entailed. *Id.* at 1191. Nevertheless, the majority interpreted a federal drug labeling regulation (the ''changes being effected'' or ''CBE'' regulation) to allow manufacturers to add or strengthen warnings or contraindications without first seeking the FDA's approval. *Id.* at 1196.

According to the majority, ''the jury verdict established only that Phenergan's warning was insufficient,'' and then turned to the question of whether the CBE regulation gave manufacturers a way to strengthen its warning label as state law required without giving rise to a federal law violation. *Id.* at 1194. The Court thus did not address ''whether a state rule proscribing intravenous administration would be preempted,'' but only whether a state-law claim that the warning was inadequate was preempted. *Id.*

Informing the majority's analysis were what it termed the ''two cornerstones of our pre-emption jurisprudence''—namely, that Congress's purposes are the ultimate touchstone, and the presumption against preemption, which the Court stated has particular application in areas like health and safety that the states traditionally have occupied. *Id.*at 1194-95.

The Court first turned to the issue of whether federal and state law are in such direct conflict that it was impossible for a manufacturer to comply with both, which it called ''a demanding defense.'' *Id.* at 1199. The majority explained that the FDA's CBE regulation allowed the manufacturer to add or strengthen warnings or contraindications even before receiving the FDA's approval, and thus concluded that the manufacturer could have complied with both state and federal law. *Id.* at 1196.

At the same time, the Court acknowledged that the FDA retained the authority to reject label changes made pursuant to the CBE regulation, and held out the possibility that conflict preemption would result if there were ''clear evidence that the FDA would not have approved a change to the [drug] label.'' *Id.* at 1198.

As to ''purposes and objectives'' preemption, the majority dismissed that argument quickly, stating that ''[i]f Congress though state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point'' applicable to prescription drugs. *Id.* at 1200.

Justice Thomas concurred in the judgment in *Levine* because he agreed that the CBE regulations made it possible for the manufacturer to label Phenergan as federal law required while still providing additional warnings beyond what the FDA first approved as state law required. But, foreshadowing his majority opinion in *Mensing*, he wrote separately to explain how his preemption analysis differs.

Starting with the Supremacy Clause, Justice Thomas first emphasized that federal laws have preemptive effect only when they are constitutional: a valid exercise of an enumerated power, enacted or promulgated according to valid procedures. *Id.* at 1206-07 (Thomas, J., *concurring in the judgment*). Assuming a valid federal statute or regulation, the next question for Justice Thomas is whether federal and state law are in conflict; and Justice Thomas argues that so long as a ''direct conflict'' exists, it can be found on a showing of something less than ''physical impossibility.'' *See id.* at 1209 (Thomas, J., concurring in the judgment). The Court's entire body of ''purposes and objectives'' preemption, however, is ''inherently flawed.'' *Id.* at 1211, 1213-15 (Thomas, J., *concurring in the judgment*).

Although in *Mensing* Justices Alito and Scalia and Chief Justice Roberts would join Justice Thomas, in *Levine* they signed Justice Alito's dissenting opinion. Justice Alito gave a nod to congressional intent as the ultimate preemption touchstone, and found that intent to be plain from the fact that Congress authorized ''the FDA—not state tort juries—to determine when and under what circumstances a drug is 'safe.' '' *Id.* at 1219. The dissenters would have found state law preempted, because ''[w]here the FDA determines, in accordance with its statutory mandate, that a drug is on balance 'safe,' our conflict pre-emption cases prohibit any State from countermanding that determination.'' *Id.* at 1220. They also would have rejected the presumption against preemption, and declared that it has no role in determining whether an actual conflict exists between state and federal law. *Id.* at 1228-29.

In sum, the outcome of *Mensing* was that a state-law failure to warn claim involving a brand-name prescription drug is not preempted, as a matter of either conflict preemption or ''purposes and obstacles'' preemption.

The *Mensing* Decision

Which brings us to the present day, and the Supreme Court's most recent preemption case involving a drug or medical device.

Mensing involves plaintiffs' state-law failure-to-warn claim about a prescription generic drug, metoclopramide, used for digestive problems. The plaintiffs alleged that the defendant drug manufacturers failed to strengthen their warnings about metoclopramide's risk of tardive dyskinesia upon learning new evidence about those risks. *Mensing*, 131 S. Ct. at 2572-73.

Starting with the Supremacy Clause, Justice Thomas, writing for the Court, noted that ''[w]here state and federal law 'directly conflict,' state law must give way.'' *Id.* at 2577. The majority agreed that the two are in conflict when it is impossible to comply with both state and federal requirements, and did not examine whether state and federal law could conflict short of impossibility. *Id.* at 2577 & n. 4. With direct conflict being the primary question, the majority began with the premise that ''[p]re-emption analysis requires us to compare federal and state law.'' *Id.*

As to federal law, the Court recognized that FDA regulations differ with respect to generic manufacturers and brand-name manufacturers. A brand-name manufacturer ''is responsible for the accuracy and adequacy of its label'' whereas a generic manufacturer ''is responsible for ensuring that its warning label is the same as the brand name's.'' *Id.* at 2574. The Court also recognized that federal law requires different things after approval as well. Whereas brand-name manufacturers can strengthen their warnings without prior FDA approval—as *Levine* concluded—the FDA ''interprets

its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same—thus generic manufacturers have an ongoing federal duty of 'sameness.' '' *Id.* at 2574-75. As a result, unlike brand-name manufacturers, generic manufacturers cannot employ the CBE regulation to strengthen their warnings prior to FDA approval or employ other methods (such as a ''Dear Doctor'' letter) to do so. *Id.* at 2575-76.

At most, federal regulations require generic manufacturers to propose stronger label warnings if they believe they are needed, although the FDA still must agree that the change is appropriate and implement a change to the label of the brand-name drug; only then would federal law require generic manufacturers to strengthen their warnings. *Id.* at 2576-77.

As to state law, the plaintiffs' allegations were that the manufacturers knew of the risk of generic metoclopramide labels and that their label warnings were inadequate, and these allegations—if proven—amounted to a state requirement that the manufacturer use a ''different, safer label.'' *Id.* at 2574.

Comparing the two, the Court concluded that ''[i]t was not lawful under federal law for the Manufacturers to do what state law required of them.'' *Id.* at 2577. Federal law (presumably) only required that the generic manufacturer propose a stronger label warning to the FDA, but this ''would not have satisfied the requirements of state law,'' which demanded a safer label, not a dialogue with the FDA about the possibility of a safer label. *Id.* at 2577-78.

On the other hand, had the generic manufacturers ''independently changed their labels to satisfy their state-law duty,'' they would have been in violation of their federal law obligation to keep their labels the same as the brand-name manufacturers' labels. *Id.* at 2578; *see also id.* at 2581. (''Here, state law imposed a duty on the Manufacturer to take a certain action, and federal law barred them from taking that action. The only action the Manufacturers could independently take—asking for the FDA's help—is not a matter of state law concern.'').

Having found preemption, the Court frankly acknowledged that from the plaintiffs' perspective the difference in the outcome over *Levine* ''makes little sense.'' *Id.* at 2581. But the majority agreed its job was not to decide whether the federal scheme was ''unusual or even bizarre,'' but to look to the particular federal statutes and regulations that apply and interpret them accordingly, even if different federal requirements give rise to different results in seemingly similar circumstances. *Id.* at 2582.

The majority concluded its opinion in *Mensing* by explaining that because its main preemption task is to compare federal and state law to determine if a direct conflict exists, the outcome of that analysis can change over time because, ''Congress and the FDA retain the authority to change the law and regulations if they so desire.'' *Id.*

In *Mensing*, a majority of the Court endorsed a good portion—although not all—of Justice Thomas's view of the Supremacy Clause and preemption, one that is concerned only with conflicts between federal and state law decided with reference only to the text of those laws and not to legislative intent or other indicators of congressional intent. In fact, four justices (Justices Thomas, Scalia, Alito and Chief Justice Roberts) were willing to go farther and endorse Professor Nelson's *non obstante* view of the Supremacy Clause, as well as its ''suggest[ion] that federal law should be understood to impliedly repeal conflicting state law,'' and ''that courts should not strain to find ways to reconcile federal law with seemingly conflicting state law.'' *Id.* at 2580.

Justice Sotomayor's dissent (joined by Justices Ginsburg, Breyer and Kagan) took strong issue with the majority's approach in *Mensing*, and would have returned to the two cornerstones: that congressional intent is the ultimate touchstone, and there is a presumption against preemption, particularly in those areas that states have traditionally occupied. *Id.* at 2586 (Sotomayor, J., *dissenting*) (citing *Levine*, 129 S. Ct. at 1199). Even as to impossibility conflict preemption, the dissenters took issue with the majority's approach and prefer it to be a ''demanding standard.'' *Id.* at 2582 (Sotomayor, J., *dissenting*).

Despite the doctrinal differences that are so clear in the majority and dissenting opinions in *Mensing*, the Court still has resolved the issue before it: State-law failure to warn claims involving a prescription generic drug are preempted, as a matter of impossibility conflict preemption.

Mensing's Implications

Now that the Supreme Court has resolved *Mensing*, what comes next?

On the big picture question of what principles govern preemption analysis, the Court still has not supplied a definitive answer. Justice Thomas's *non obstante* view of the Supremacy Clause has not yet garnered the endorsement of a majority of the Court, and a majority of the Court took an approach to preemption principles in *Levine* in 2009 that is considerably different from the majority's approach in *Mensing*. For future drug or medical device preemption cases, what this portends is: Unless there is a change to the make-up of the Court, preemption decisions will continue to turn on relatively narrow questions about the particular federal and state law involved, rather than sweeping declarations of clear, broad preemption principles.

In the meantime, though, everyday product liability litigation continues. For litigators, these authorities suggest several points:

1. The basic first step in any drug or device product liability case is a detailed review of the federal regulations and statutes that apply to identify any applicable express preemption provisions or savings clauses, as well as the exact contours of the requirements of federal law. If the Court already has squarely resolved a case involving that type of medical product in *Mensing*, *Levine*, *Riegel*, *Buckman* or *Lohr*, at least there is clear guidance about the particular preemption issues already resolved (even if declarations about general preemption principles in the older cases must be continually reviewed with an eye toward whether they remain consistent with more recent statements garnering a majority vote). The Court has decided preemption cases involving vaccines as well. *See Bruesewitz v. Wyeth LLC*, 131 S. Ct. 1068 (2011) (preemption under the National Childhood Vaccine Injury Act of 1986).

2. Even if the Court has rejected preemption as a matter of express preemption, implied preemption avenues may well remain open and lead to success. The Supreme Court acknowledges that the existence of an

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express preemption provision does not alter the operation of conflict preemption, and Justice Thomas's increasingly important approach, in fact, makes conflict preemption the central inquiry.

3. As *Mensing* stated, Congress and regulatory agencies control the federal law side of the preemption coin. If they do not like the Court's conclusions about preemption in a particular case, they can amend the federal statute or regulation in an effort to eliminate (or heighten) any conflict with state law.

4. State law is the flip side of the preemption coin, but tort law does not by itself specify precisely what the defendant should have done or not done. The specifics of the state law requirements only are defined within the context of a particular case—and sometimes not well. On the facts of *Levine*, for example, state law only declared the manufacturer's label inadequate, it did not mandate the specific language that should have been used instead. To the extent that *Mensing* suggests analyzing conflicts between state and federal law will become increasingly important, defendants may be better positioned to use the preemption defense if they succeed in forcing the plaintiff to specifically articulate what actions state law required them to take, or prohibited them from taking.

5. Given *Mensing*, plaintiffs unable to sue generic manufacturers for failure to warn may increasingly sue brand-name manufacturers even when they have not ever taken the brand-name drug. Although most courts addressing such novel claims have rejected them on state-law grounds, not all have. See, *e.g.*, *Conte v. Wyeth*, 168 Cal. App. 4th 89 (2008).

6. Apart from the effect of decisions like *Mensing* and *Levine* on litigation, there may be a practical business effect as well. At risk of oversimplification, generic prescription drug manufacturers cannot be sued for failure to warn while brand-name prescription drug manufacturers can. This litigation risk may be enough to discourage manufacturers from investing in the development of new drugs, particularly as new drug development already involves considerable research and development costs well in excess of bringing another generic to market.

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