

**Client Alert:**  
**Product Liability Victory for Generic  
Pharmaceutical Manufacturers —**  
*Pliva, Inc. v. Mensing*

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In one of its last opinions of this Term, on June 23, 2011, the Supreme Court decided that the Hatch-Waxman Act, which provides statutory authorization for FDA approval of generic drugs, pre-empts some state product liability law. In a rare majority opinion authored by Justice Thomas, in which Justices Scalia, Roberts, Alito and, in significant part, Justice Kennedy joined, the Court reversed decisions by the Fifth and Eighth Circuit Courts of Appeal and held that the Constitution's Supremacy Clause precludes actions under state common law for alleged breach of duty to provide adequate warnings of risks of harm on their product labels.

At issue in *Pliva, Inc. v. Mensing*, No. 09-993 (S.Ct., June 23, 2011), and related cases decided simultaneously, were common-law actions brought under tort laws of Minnesota and Louisiana, that "require a drug manufacturer that is or should be aware of its product's danger to label that product in a way that renders it reasonably safe."<sup>1</sup> None of the cases before the Court directly presented issues about other potential theories of liability, such as simple negligence, resulting from a failure of a manufacturer to exercise reasonable care in the production, design or assembly of the manufacturer's product, or strict liability, allegations of which may arise from the manufacture and sale of defective and unreasonably dangerous products. Some elements of the Court's decision in *Pliva* may impact such causes of action as well, and will likely be the source of further litigation.

*Pliva* concerned the labeling of generic bioequivalents of Reglan, a drug (metoclopramide) administered to speed the movement of food through the digestive system, that was first approved by the FDA in 1980. Evidence "accumulated that long-term metoclopramide use can cause tardive dyskinesia, a severe neurological disorder," and "warning labels for the drug [were] strengthened and clarified several times."<sup>2</sup> In 2009, "the FDA ordered a black box warning—its strongest—which states: "Treatment with metoclopramide can cause

tardive dyskinesia, a serious movement disorder that is often irreversible. . . . Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases.”<sup>3</sup>

Under the Hatch-Waxman Act, an Abbreviated New Drug Application “must also “show that the [safety and efficacy] labeling proposed . . . is the *same* as the labeling approved for the [brand-name] drug.”<sup>4</sup> Hence, the Court said,

[B]rand-name and generic drug manufacturers have different federal drug labeling duties. A brandname manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. See, *e.g.*, 21 U. S. C. §§355(b)(1), (d); *Wyeth, supra*, at 570–571. A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name’s. See, *e.g.*, §355(j)(2)(A)(v); §355(j)(4)(G); 21 CFR §§314.94(a)(8), 314.127(a)(7).

What was in dispute in *Pliva* was “whether, and to what extent, generic manufacturers may change their labels *after* initial FDA approval.”<sup>5</sup> The plaintiffs, who developed tardive dyskinesia after use of generic metoclopramide for several years, asserted that federal law provided several avenues through which the generic defendants could have attempted to alter their labels, to provide still stronger warnings against long-term use of metoclopramide, in time to prevent the injuries that the plaintiffs claimed. The FDA interpreted “its regulations to require that the warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of ‘sameness.’”<sup>6</sup> These interpretations of the FDA’s own regulations, the Court said, “are ‘controlling unless plainly erroneous or inconsistent with the regulation[s]’ or there is any other reason to doubt that they reflect the FDA’s fair and considered judgment.”<sup>7</sup>

In particular, the plaintiffs in *Pliva* contended the FDA's "'changes being effected' (CBE) process allowed the [generic] manufacturers to change their labels when necessary."<sup>8</sup> This assertion was denied by the FDA, which interpreted the CBE regulation "to allow changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions."<sup>9</sup> Finding no inconsistency or plain error, the majority deferred to the FDA's interpretation of its CBE and generic labeling regulations and concluded "that the CBE process was not open to [generic manufacturers] for the sort of change required by state law."<sup>10</sup> Similarly, because the FDA construes "Dear Doctor" letters as "labeling," that the FDA said "must be 'consistent with and not contrary to [the drug's] approved . . . labeling.'" 21 CFR §201.100(d)(1)," the Court also rejected the plaintiffs' contention that additional warnings could have been issued through such letters.<sup>11</sup>

Based on these findings, Justice Thomas wrote for the Court that under the Supremacy Clause, "state and federal law conflict where it is "impossible for a private party to comply with both state and federal requirements."<sup>12</sup> Finding that "[i]t was not lawful under federal law for the [generic manufacturers] to do what state law required of them," and that "even if they had fulfilled their federal duty to ask for FDA assistance, they would not have satisfied the requirements of state law," the majority found "impossibility" within the meaning of prior Supremacy Clause jurisprudence, and held the challenged state common law product liability laws relating to labeling and adequate warning to be pre-empted by the Hatch-Waxman Act's statutory requirement of generic labeling "sameness" with brand name sponsor labeling.

The majority recognized that, if a generic manufacturer learned, through adverse event reporting or otherwise, a label change was necessary, that manufacturer could have

suggested to the FDA that “‘labeling [should] be revised to include a warning [because] there is reasonable evidence of an association of a serious hazard with a drug.’ 21 CFR §201.57(e).”<sup>13</sup> Without resolving whether a duty exists, the Court noted the FDA’s contention that its rules require generic drug manufacturers “that become aware of safety problems” to “ask the agency to work toward strengthening the label that applies to both the generic and brand name equivalent drug.”<sup>14</sup> The plaintiffs contended that “that if the [generic manufacturers had asked the FDA for help in changing the corresponding brand-name label, they might eventually have been able to accomplish under federal law what state law requires.”<sup>15</sup> The Court responded:

... That is true enough. The [generic manufacturers] “freely concede” that they could have asked the FDA for help. ... If they had done so, and if the FDA decided there was sufficient supporting information, and if the FDA undertook negotiations with the brand-name manufacturer, and if adequate label changes were decided on and implemented, then the [generic manufacturers] would have started a Mouse Trap game that eventually led to a better label on generic metoclopramide.

This raises the novel question whether conflict preemption should take into account these possible actions by the FDA and the brand-name manufacturer. Here, what federal law permitted the [generic manufacturers] to do could have changed, even absent a change in the law itself, depending on the actions of the FDA and the brand-name manufacturer. Federal law does not dictate the text of each generic drug’s label, but rather ties those labels to their brand-name counterparts. Thus, federal law would permit the [generic manufacturers] to comply with the state labeling requirements *if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so.*<sup>16</sup>

Rejecting the plaintiffs' contentions, the Court continued:

... Accepting [the plaintiffs'] argument would render conflict pre-emption largely meaningless because it would make most conflicts between state and federal law illusory. We can often imagine that a third party or the Federal Government *might* do something that makes it lawful for a private party to accomplish under federal law what state law requires of it.

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If these conjectures suffice to prevent federal and state law from conflicting for Supremacy Clause purposes, it is unclear when, outside of express preemption, the Supremacy Clause would have any force. We do not read the Supremacy Clause to permit an approach to preemption that renders conflict pre-emption all but meaningless. The Supremacy Clause, on its face, makes federal law "the supreme Law of the Land" even absent an express statement by Congress. U. S. Const., Art. VI, cl. 2.

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Here, state law imposed a duty on the Manufacturers to take a certain action, and federal law barred them from taking that action. The only action the [generic manufacturers] could independently take—asking for the FDA's help—is not a matter of state-law concern. [The plaintiffs'] tort claims are pre-empted.<sup>17</sup>

In March 2009, Justice Thomas, the author of the majority opinion in *Pliva*, concurred in the judgment rendered in *Wyeth v. Levine*. In *Wyeth*, the Supreme Court held that the Supremacy Clause did *not* pre-empt state common law, product liability cases against brand name manufacturers that alleged failure to provide adequate warnings of risk of harm

resulting from the administration of Phenergan (promethazine), an old anti-emetic. The decision in *Wyeth*, authored by Justice Stevens, in which Justices Kennedy, Souter, Ginsberg and Breyer joined, considered many of the statutory and regulatory provisions at issue in *Pliva*, as well as similar Vermont state product liability doctrines and allegations. A different result was reached because, in the case of brand name manufacturers, "Congress has repeatedly declined to preempt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight."<sup>18</sup>

Striking, perhaps, is the composition of the majorities in both *Wyeth* and *Pliva*. In both cases, Justices Scalia, Alito and Roberts joined in opinions that pre-empted (or would have pre-empted) state common laws, precluding actions for failure to warn against pharmaceutical manufacturers. In both cases, Justices Breyer, Stevens, Ginsberg and, at least in significant part, Justice Kennedy, joined in opinions that would have reached the opposite result. The jurisprudential division arose over construction and application of the Supremacy Clause, in the face of the two principles of pre-emption;

First, "the purpose of Congress is the ultimate touchstone in every preemption case." ... [and] Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,' ... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'"<sup>19</sup>

Given prior decisions, one might have expected the positions of the majority and minorities in both cases to have been different, if not reversed. Justice Thomas resolved the dispute in both cases.

In *Pliva*, Justice Thomas noted that the decision in *Wyeth* is not to the contrary.<sup>20</sup> In one case, *Pliva*, it was “impossible” for the generic manufacturers to comply with both state and federal law, resulting in pre-emption of state law. In *Wyeth*, “the federal regulations applicable to Wyeth allowed the company, of its own volition, to strengthen its label in compliance with its state tort duty.” As a result, it was not “impossible” for the brand name manufacturer to comply with both state and federal law, and state law was *not* pre-empted, either under the “impossibility” doctrine or because of some obstruction of the purposes and objectives of Congress in enacting the Food and Drug Act, or regulations promulgated by the FDA under statutory authority conferred by Congress.<sup>21</sup>

Justice Thomas recognized, in *Pliva*, that from the perspective of the plaintiffs,

... finding pre-emption here but not in *Wyeth* makes little sense. Had [the plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors, *Wyeth* would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits. ... We acknowledge the unfortunate hand that federal drug regulation has dealt [the plaintiffs] and others similarly situated.

But “it is not this Court’s task to decide whether the statutory scheme established by Congress is unusual or even bizarre.”... We will not distort the Supremacy Clause in order to create similar preemption across a dissimilar statutory scheme. As always, Congress and the FDA retain the authority to change the law and regulations if they so desire.<sup>22</sup>

The decision in *Pliva* provides some solace for manufacturers of generic pharmaceuticals in cases of alleged product liability. The decision is nevertheless relatively narrow in scope, reaching only a portion of the state common law-theories that might be asserted in product

liability actions. It may yet provoke the kind of congressional response that Justice Thomas rightfully acknowledged may be exercised. For the moment, however, the decision in *Pliva* should afford generic pharmaceutical manufacturers armament in their efforts to defend against product liability claims, whether individual or asserted by a class.<sup>23</sup>

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<sup>1</sup> Slip Op. at 4.

<sup>2</sup> *Id.* at 6.

<sup>3</sup> *Id.* at 3.

<sup>4</sup> *Id.* at 6, citing 21 U.S.C. §355(j)(2)(A)(v); 21 U.S.C. §355(j)(4)(G); and D. Beers, *Generic and Innovator Drugs: A Guide to FDA Approval Requirements* §§3.01, 3.03[A] (7th ed. 2008).

<sup>5</sup> *Id.* at 10.

<sup>6</sup> *Id.*

<sup>7</sup> *Id.*

<sup>8</sup> *Id.* at 7, stating that “The CBE process permits drug manufacturers to “add or strengthen a contraindication, warning, [or] precaution,” 21 CFR §314.70(c)(6)(iii)(A) (2006), or to “add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,” §314.70(c)(6)(iii)(C). When making labeling changes using the CBE process, drug manufacturers need not wait for preapproval by the FDA, which ordinarily is necessary to change a label. *Wyeth, supra*, at 568. They need only simultaneously file a supplemental application with the FDA. 21 CFR §314.70(c)(6).”

<sup>9</sup> *Id.*

<sup>10</sup> *Id.* at 8.

<sup>11</sup> *Id.* at 8-9.

<sup>12</sup> *Id.* at 11, citing *Freightliner Corp. v. Myrick*, 514 U. S. 280, 287 (1995).

<sup>13</sup> *Id.* at 9.

<sup>14</sup> *Id.* at 10.

<sup>15</sup> *Id.* at 13.

<sup>16</sup> *Id.* at 13-14.

<sup>17</sup> *Id.* at 14, 17.

<sup>18</sup> *Wyeth v. Levine*, 555 U.S. 555, 129 S.Ct. 1187, 1204 (2009).

<sup>19</sup> *Id.* at 1194-95 (citations omitted).

<sup>20</sup> *Pliva*, Slip Op. at 18.

<sup>21</sup> *Id.* at 18 – 19.

<sup>22</sup> *Pliva*, Slip Op. at 18 – 20.

<sup>23</sup> See also *Walmart Stores, Inc. v. Dukes*, No. 10-277 (June 20, 2011)(class action requirements).

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