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WYETH v. LEVINE: A DETAILED ANALYSIS OF THE SUPREME COURT'S REJECTION OF FDA PREEMPTION IN PHARMACEUTICAL CASES

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On March 4, 2009, the United States Supreme Court handed down its decision in *Wyeth v. Levine*, holding that the U.S. Food and Drug Administration's ("FDA's") approval of drug labeling for Phenergan (promethazine HCl) did not preempt Diana Levine's state law tort suit. 555 U.S. __ (2009) (No. 06-1249). The Court's 6-3[1] ruling is fact-specific, making its finding of no preemption narrower than it could have been. The reasoning behind the ruling, however, may have larger consequences for the preemption doctrine and the pharmaceutical industry in general. Importantly, the opinion also provides instruction on how a company may be able to avoid a similar result to *Wyeth*.

In navigating the complex legal requirements imposed on drug companies, an understanding of relevant state and federal law, and how those two bodies of law interact, is critical to minimizing a company's exposure to enforcement activities by state and federal governments, and in lawsuits by private litigants. Preemption of state law by federal law can simplify a company's overall compliance obligations. Simply put, if federal law preempts state law, then compliance with federal law is sufficient and a company need not worry about complying with a myriad of state and local laws.

Wyeth v. Levine is the most recent of several Supreme Court decisions addressing preemption in connection with FDA regulated products. The Court in *Wyeth* ruled that, based on the facts of that case, the Federal Food, Drug, and Cosmetic Act (the "FDC Act") does not preempt state law. The immediate effect was to let stand the state law tort judgment against Wyeth, but the effects of the case are almost certainly not going to be so limited.

In fact, *Wyeth v. Levine* is likely to remain an important Supreme Court preemption case for the drug industry for the foreseeable future. Most of the recent Supreme Court preemption analysis concerning FDA-regulated products has focused on medical devices. *Riegel v. Medtronic*, 552 U.S. ___, 128 S. Ct. 999 (2008), found that the FDC Act does preempt state laws for medical devices subject to premarket approval. *Riegel* was a preemption "win" for the device industry twelve years after *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which found no preemption for devices not subject to premarket approval. Even *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), which has generally been understood to be a "fraud on the FDA" case with implications for both the drug and device industry, was a device case. As we now know from the

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[1] Justice Stevens delivered the majority opinion, in which Justices Kennedy, Souter, and Ginsburg joined. Justice Breyer filed a concurring opinion, while Justice Thomas filed an opinion concurring in the judgment. Justice Alito filed a dissenting opinion, in which Chief Justice Roberts and Justice Scalia joined.

Wyeth decision, there is no *Riegel*-like preemption for drugs approved by FDA. Rather, the Court rejected a broad-brush preemption argument in a decision that ***could make the availability of a preemption defense turn on a company's regulatory interactions with FDA***.

Background and Procedural History

In April 2000, Levine sought treatment for a migraine headache at her local clinic. 555 U.S. at ___ (slip op. at 2). As part of her treatment, she received an intramuscular injection of Demerol for her headache and Phenergan, manufactured by Wyeth, for her nausea. *Id.* She later returned to the clinic for another round of both drugs. *Id.* This time, a physician assistant administered Phenergan through an IV-push injection, whereby the drug is injected directly into a vein. *Id.* Due to the physician assistant's error, however, the drug entered Levine's artery, which ultimately led to gangrene and the amputation of Levine's forearm. *Id.* Levine first sued the clinic and the clinician, who settled; she then sued Wyeth.

Despite the warning in Phenergan's labeling about the "danger of gangrene and amputation following inadvertent intra-arterial injection," Levine alleged that the warning was inadequate. *Id.* She argued that the labeling failed to warn health care providers to use an IV-drip method to administer the drug, instead of the IV-push method, because of the risk of intra-arterial injection.[2] *Id.* at 2-3. At trial, Levine showed evidence that the risk of intra-arterial injection can be mostly eliminated using the IV-drip method of administration. *Id.* 4-5.

The jury found Wyeth negligent and Phenergan's label defective due to its inadequate warnings and instructions for use. *Id.* at 5. The jury awarded Levine $7,400,000, which the court later reduced to account for the settlement from the suit against the health care center and clinician.[3] In addition, the court rejected Wyeth's post-trial arguments that a direct conflict existed between FDA

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[2] In his dissent, Justice Alito noted that the Phenergan's labeling had "at least six separate warnings" about using the IV-push method, making it difficult to understand how a "stronger" or additional warning would have remedied the alleged defect. 555 U.S. at ___ (Alito, J. dissenting at 1).

[3] The trial court also found that the inadequate Phenergan labeling was the but-for and proximate cause of Levine's injury despite the physician assistant's conduct, which included giving Levine a larger dose than the label prescribed, evidence that she may have injected the drug into the artery and that she continued the injection despite complaints of pain (a warning sign that the drug may have entered an artery, as indicated on the Phenergan label). *Id.* at 7, 7 n.2.

regulations and Levine's tort claims. *Id.* at 5. The court reasoned that FDA's "changes being effected" ("CBE") regulations at 21 C.F.R. § 314.70(c) allow warnings to be strengthened without FDA approval. Furthermore, because FDA had received reports of 20 amputations since the 1960s, the trial court found that a strengthened warning would have been appropriate.

The Vermont Supreme Court affirmed. *Id.* at 6. In so doing, the court explained that the jury verdict did not conflict with FDA labeling requirements because FDA regulations allowed Wyeth to strengthen Phenergan's warning against IV-push administration without FDA's prior approval. Furthermore, the court concluded that FDA's regulations regarding labeling "create a floor, not a ceiling, for state regulation." *Id.* at 6 (quoting __ Vt. __, __ 944 A.2d. 179, 184 (2006)).

Wyeth's Preemption Arguments in the U.S. Supreme Court

Wyeth appealed to the U.S. Supreme Court with two preemption-based arguments: (1) that it was impossible for Wyeth to comply with the state-law duty to modify Phenergan's labeling without violating federal law; and (2) that the state tort action obstructed Congressional intent by allowing a jury's decision on drug labeling to trump FDA's expert judgment. *Id.* at 6-7.

The Supreme Court's Analytical Framework: Congressional Purpose and Presumption Against Preemption

As noted above and explained more fully below, the Court rejected Wyeth's preemption arguments. Also, as is often the case in an opinion, the Court's analytical framework foreshadowed its holding. To address Wyeth's arguments, the Court looked to "two cornerstones of [] pre-emption jurisprudence": (1) Congressional purpose; and (2) the presumption against pre-emption when Congress legislates in areas of law that the states have traditionally occupied. *Id.* at 8. To identify the purpose of Congress, the Court recounted the history of federal regulation of drug labeling. According to the Court, the history suggested that Congress intended to preserve state law authority for drug labeling. This conclusion was supported by the absence of Congressional action to insert an explicit preemption provision for drugs as it did for medical devices in 1976. *Id.* at 10. Furthermore, the Court noted that, in 2007, Congress changed the FDC Act such that FDA could require safety labeling changes, but it excluded a proposed requirement that FDA pre-approve all labeling changes. *Id.* at 11. Responsibility to update labeling, the Court concluded, remains with the manufacturer. *Id.* Consequently, the door remained open for state tort litigants to argue the merits of federal drug labeling.

Argument No. 1: Preemption Due to Impossibility

Wyeth first argued that it was impossible to comply with both the state-law duties and federal FDA labeling requirements. *Id.* Wyeth pointed to the CBE regulation, which FDA amended in 2008 to require "newly acquired information" to change a label without prior FDA approval. *Id.* at 11-12. Wyeth argued it did not have such evidence and that Levine did not present new risks about IV-push administration. *Id.* at 12.

Although the Court admitted that the record on the issue was limited, it concluded that Wyeth could have analyzed the accumulated data of similar incidents of gangrene and amputation and added a stronger warning about the IV-push method through the CBE regulatory process. *Id.* at 13. Similarly, the Court rejected Wyeth's argument that such a "unilateral" move would have rendered Phenergan misbranded.[4] *Id.* at 13, 16.

The Court stated that, as evidenced by the legislative history of the FDC Act, the manufacturer "bears primary responsibility for drug labeling." *Id.* at 14. Wyeth argued that it had proposed changes to the warning in Phenergan's labeling about intra-arterial injection in 1988, but that when FDA responded in 1998, it instructed Wyeth to retain the original warning. *Id.* at 15 n.5. The Court concluded that the proposed warning recalled by FDA was different, but not stronger than, the earlier FDA-approved labeling.

The Court further reasoned that FDA's approval of labeling without a strengthened warning did not mean that the agency would have prohibited Wyeth from making the labeling change. *Id.* at 16. Because Wyeth failed to present "clear evidence" that FDA would not have approved the change in Phenergan's label, the Court refused to conclude that it was impossible for Wyeth to comply with federal and state labeling requirements.

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[4] The Court dismissed this argument in part because the FDC Act "contemplates that federal juries will resolve most misbranding claims" and that "FDA's belief that a drug is misbranded is not conclusive." *Id.* at 13 (citations omitted). This statement, though technically true, belies the reality of the pharmaceutical industry. For a variety of reasons, including but not limited to the risks associated with administrative, civil and criminal penalties that may flow from an FDC Act violation and the desire to have a good working relationship with the agency, drug companies frequently accept FDA's conclusions about misbranding as expressed in Warning Letters or other non-final agency actions without objection. As a result, FDA's position on misbranding does not necessarily progress to court and into the hands of a jury.

Interestingly, however, the Court hinted that it would consider evidence of what FDA "***would***" have done. *Id.* at 15 (emphasis added). Specifically, the Court stated that "absent clear evidence that the FDA would not have approved a change to [the] label, we will not conclude that it was impossible [] to comply with both federal and state requirements." *Id.* The use of the conditional *would* suggests that even if no evidence existed of what the company or FDA *actually* did, a company could still establish preemption if it could show that ***if*** the company had done X, FDA would (or would not) have done Y.

Traditionally, FDA, like other parts of the federal government, has strenuously resisted attempts by private party litigants to compel discovery from the agency. *See, e.g., Connaught Labs., Inc. v. SmithKline Beecham PLC*, 7 F. Supp. 2d 477 (D. Del. 1998) (granting motion to compel and denying FDA motion to quash subpoenas arising out of patent litigation). The Court's language, however, may prompt increased efforts by private parties to elicit testimony from FDA on what it *would* have done with a particular labeling or warning issue. Specifically, one could imagine subpoenas to FDA seeking an agency designee to testify on a particular issue. Of course, pursuing such discovery may be a risky proposition given the uncertainty of the testimony FDA might give.

Argument No. 2: Preemption Due to Obstruction with Objectives of Congress

The Court also rejected Wyeth's argument that the FDC Act creates both a "floor and a ceiling for drug regulation" such that a state-law duty requiring a strong warning about IV-push administration would "obstruct the purposes and objectives" of federal drug labeling. 555 U.S. at ___ (slip op. at 17). As the Court explained, if Congress thought state-lawsuits would interfere with FDA's objectives regarding drug labeling, it would have inserted an express preemption clause into the FDC Act. *Id.* at 18. The fact that Congress did so for medical devices but not prescription drugs reinforces the conclusion that Congress did not intend to preempt state-law suits. *Id.*

Wyeth, however, pointed to a statement by FDA in 2006 in a preamble to a final rule in which FDA stated that the FDC Act establishes a "'floor' and a 'ceiling'" such that FDA approved labeling trumps "conflicting [] State law." *Id.* at 19 (citing 71 Fed. Reg. 3,934-3,935 (Jan. 24, 2006)). The Court acknowledged that some federal regulations can preempt conflicting state law; however, it considered this statement by FDA to be a "mere assertion" of the agency's opinion on the impact of state law on federal labeling requirements. 555 U.S. at ___ (slip op. at 19-20). The weight given to the statement, therefore, depended on the

"thoroughness, consistency, and persuasiveness" of the FDA's explanation. *Id.* at 20.

First, the Court noted that FDA's statement was "inherently suspect" because it was not included in the proposed regulation – only the final rule – and, hence, bypassed the public notice and comment process. *Id.* at 21.

Second, the Court found the statement constituted a "dramatic change" in the agency's position, *id.* at 23, which had long been that federal labeling standards constituted a "floor" only. *Id.* at 21. The Court pointed to a preamble to a final rule issued in 1998 in which FDA stated that it did not believe that labeling standards developed by state tort law would interfere with FDA regulations. *Id.* (citing 63 Fed. Reg. 66,378, 66,384 (Dec. 1, 1998)). Similarly, the Court found the United States' *amicus* brief to be "undeserving of deference" in part because the "Government's explanation of federal drug regulation departed markedly from the FDA's understanding at all times relevant to this case" *Id.* at 24 n.13. This out-of-hand dismissal of a United States *amicus* brief is unusual given the typical respect the Court shows the Office of the Solicitor General. Moreover, the Court implies that an agency's interpretation of a law it administers does not deserve deference. This arguably conflicts with well-established case law on the matter. *See, e.g., Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837 (1984) (holding that an agency's interpretation of a statute it administers deserves deference if the statute is silent or ambiguous and the agency's interpretation is reasonable).

Third, the Court – at least implicitly – rejected the preemptive effect of the preamble statement because the Court viewed it as an "assertion" of preemption. In fact, FDA carefully explained its position in the 2006 preamble to the final drug labeling rule. 71 Fed. Reg. at 3,934-3,936. It is more likely that the Court reacted to FDA's refusal to admit its change in position in that preamble. A review of FDA's litigating position on preemption clearly shows that FDA has switched positions with different administrations, as it is fully authorized to do. Rather than admitting to such a switch, FDA attempted to argue consistency. In fact, FDA and the government's *amicus* brief asserted that preemption has been FDA's "long standing view[]." Brief for the United States as Amicus Curiae Supporting Petitioner at 26, *Wyeth v. Levine*, 555 U.S. __ (2009) (No. 06-1249) (quoting the 2006 preamble), http://www.usdoj.gov/osg/briefs/2007/3mer/1ami/2006-1249.mer.ami.html. The *amicus* brief attempted to dismiss as misleading any contrary "snippets" used by the plaintiff to suggest a switch in position by FDA. This strategy did not work for the agency.

The majority's analysis of FDA's position did not address the assertion, set forth in the government's *amicus* brief, that "If a state regulatory agency directed

manufacturers not to use FDA-approved labeling, but instead to provide different or additional warnings, the conflict with federal law would be manifest." Brief for the United States as Amicus Curiae Supporting Petitioner at 19. Interestingly, if the Court has occasion to consider such an asserted "conflict" in the near term, the FDA may, yet again, have changed its opinion. While the above-cited statement reflects the position of the prior administration, the generally accepted wisdom is that the current administration has a different position on preemption.[5]

Finally, the Court rejected Wyeth's argument that its case resembled *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). In *Geier*, the Court held that the state-law tort claim, which alleged that the Honda's cars were defectively designed because they did not have airbags, conflicted with a federal regulation that did not require airbags for all cars. The *Geier* Court found that if the plaintiff had succeeded in her suit, it would have created an obstacle for FDA to achieve the regulation's purpose to allow several restraint devices. 555 U.S. at ___ (slip op. at 23). In distinguishing *Geier*, the Court noted that, unlike the present case, a "specific agency regulation bearing the force of law" existed that allowed car manufacturers the option to install a variety of passive restraint devices, including airbags. *Id.* at 23-24. Given these reasons, the Court concluded that the FDA's "newfound opinion" included in the 2006 preamble merited no deference. *Id.* at 20, 24; *but see* Alito, J. dissenting at 20 ("[I]t is irrelevant that the FDA's preamble does not 'bear the force of law' because the FDA's labeling decisions surely do….[M]oreover, it cannot be said that *Geier*'s outcome hinged on the agency's choice to promulgate a rule.").

The Implications of *Wyeth v. Levine*

Is the Preemption Doctrine Still Viable for Drug Labeling?

Yes. Despite the Court's ruling, the preemption window remains open for future FDA labeling cases. The holding in *Wyeth* is largely fact-specific: that FDA's approval of drug labeling for Phenergan did not preempt Levine's state tort suit alleging the labeling was defective for a failure to adequately warn about the IV-push administration of the drug. The record indicated that Wyeth did not pursue a labeling change despite incidences of gangrene and amputation similar to Levine's and despite the ability to do so through FDA's CBE regulations. Also, in claiming preemption, Wyeth could only heavily rely on a statement by FDA, included in a preamble to a final rule that did not undergo the notice and public comment process, that federal labeling standards preempted state lawsuits.

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[5] As the present administration considers changing earlier policies, it will be interesting to see whether the Court's unstated message in *Wyeth* affects how the administration explains those policy switches.

If the facts had indicated that Wyeth had pursued labeling changes through the CBE process, and that FDA rejected those changes, or that FDA required specific labeling changes that a manufacturer could not change, the impossibility preemption argument would have carried more weight. This latter avenue for preemption exists in the new safety labeling authority granted to FDA under the Food and Drug Administration Amendments Act of 2007 ("FDAAA"). Under FDAAA, which amended the FDC Act, FDA can require a New Drug Application ("NDA") holder to make changes to its labeling "to address the new safety information." FDC Act § 505(o)(4)(E). If FDA were to issue such an order, one could imagine that, notwithstanding *Wyeth*, a Court could find preemption based on: (1) conflict/impossibility; or (2) frustration of Congressional purpose if the state law failure to warn claim was based upon an assertion that the label should have gone beyond the language that FDA required be inserted into labeling under FDC Act section 505(o)(4)(E).

The CBE regulation, however, somewhat tempers the possible preemption effect of FDAAA-required safety labeling. For example, the CBE regulation lays some responsibility at the feet of manufacturers to update drug labeling. This is true despite the new FDAAA requirements. *See* 73 Fed. Reg. 49,603, 49,605 (Aug. 22, 2008) (FDA explained that section 505(o)(4) "does not take away a sponsor's obligation to maintain its labeling under Federal law…."); 555 U.S. at ___ (slip op. at 11) (noting that despite FDAAA, Congress "adopted a rule of construction to make it clear that manufacturers remain responsible for updating their labels"). In other words, FDA safety labeling changes required under FDAAA may not insulate an entity from state-law tort claims for defective labels. It does, however, provide better protection in certain factual situations. If an injured party alleges, for example, that a safety labeling change required by FDA under FDAAA was defective, a court could find that party's claim preempted.

Also, as the Court noted, *Wyeth* involved no "specific agency regulation bearing the force of law," unlike the case in *Geier*. *Id.* at 24*; but see* Alito, J dissenting at 20 (*supra* p. 7). If such a regulation regarding preemption makes its way into Title 21 of the Code of Federal Regulations, the Court may find that it has a preemptive effect. *See* 555 U.S. at ___ (Breyer, J. concurring at 1-2) (noting that "specific regulations describing…when labeling requirements serve as a ceiling as well as a floor…[could] have pre-emptive effect").

Can Industry and FDA Continue to Rely on Preamble Language?

After the dismissive treatment of FDA's preamble, the answer is a qualified yes. The reality of administrative law is that an agency offers an explanation for its regulations in the preamble to its rules. The rules themselves state what must

be done, and the preambles explain why. FDA generally gives statements in a preamble the same or even more weight as a guidance document or an advisory opinion. Industry, as a result, uses preamble language as a guideline in complying with FDA law and regulations.

As noted above, the Court dismissed FDA's "newfound opinion" that FDA-approved labeling preempted state-law tort claims, which was included in the preamble to a 2006 final rule about drug labeling changes. 555 U.S. at ___ (slip op. at 24). The Court did so after finding that the statement lacked the "thoroughness, consistency, and persuasiveness" necessary to give it due deference. *Id.* at 20.

Admittedly, the preamble statement relied upon in *Wyeth* is something of an outlier. Although not discussed in the opinion, the language was controversial at the time it was asserted. In fact, there is some indication that FDA purposely avoided including it in the preamble to the proposed rule in order to avoid debate. As a result, some viewed the statement as an attempt by FDA to create a legal position without undergoing the prerequisite notice and comment rulemaking procedure.[6] Additionally, as noted above, the Court may have been irked at the government's seemingly disingenuous attempt to pretend that it had not changed positions on the preemption issue.

Moreover, as the Court noted, several other factors affected the weight (or lack thereof) that it afforded FDA's position. First, the Court noted an inconsistency between the proposed and final rules. The preamble to the proposed rule stated that FDA would not preempt state law, but the final rule purported to do just that "without offering States or other interested parties notice or opportunity for comment." *Id.* at 21. Similarly, the Court concluded that FDA's position in favor of preemption contradicted other earlier statements by the agency on the subject. *Id.* at 21, 23. In other words, only preamble language that is consistent with previous agency statements and action could meet the Court's standard of "thoroughness, consistency, and persuasiveness" to garner (some) deference. *Id.* at 20.

It is also worth noting that the Court did not foreclose the possibility that court might give FDA preamble statements deference in preemption cases. Notably, the Court recognized the unique position an agency holds in

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[6] Notably, Justice Alito points out that, in *Geier*, the Court rejected the argument that "conflict pre-emption is appropriate only where the agency expresses its preemptive intent through notice-and-comment rulemaking." 555 U.S. at ___ (Alito, J. dissenting at 19). This aspect of *Geier* seemingly conflicts with the majority's reasoning in *Wyeth*.

understanding the federal statues that it is required to implement and how state requirements can thwart that implementation. *Id.* As a result, the Court admitted to giving in prior cases "'some weight' to an agency's views about the impact of tort law on federal objectives when the 'subject matter is technical[] and the relevant history and background are complex and extensive." *Id.* (citation omitted). Importantly, the Court added that it had not deferred to "an agency's *conclusion* that state law is preempted…" *Id.*

What Should Industry Do in a Post-*Wyeth* World?

Pivotal to the majority's reasoning in *Wyeth* was the lower court's findings of a lack of evidence that Wyeth had "earnestly attempted" to strengthen its warning or that "FDA ha[d] 'specifically disallowed' stronger language." *Id.* at 3. A fair reading of the record could lead one to conclude that Wyeth was diligent while FDA was not, rendering the agency culpable as well. Regardless of the merits of that debate, when consumers are injured by an FDA-regulated product, they do not sue FDA, but rather the manufacturers and other related entities. Thus, if a company has a specific concern about whether its product's labeling is adequate, it should consider raising the issue with FDA and diligently pursuing a resolution. Effected companies should also closely read the new CBE regulations and its preamble to ensure they understand what kind of information can constitute "newly acquired information" to require a labeling supplement under 21 C.F.R. Part 314. *Wyeth* demonstrates that relying on FDA to tie up loose ends regarding labeling will not suffice. Similarly, if FDA resists efforts to change a drug's labeling, informally at the staff level or otherwise, that resistance – even if it does not rise to the level of specific disallowance – should be documented and preserved.

How Does *Wyeth* Affect the Preemption Doctrine?

The anti-preemption holding of *Wyeth* can be read to extend beyond tort lawsuits. In fact, the Court's ruling could open the door to increased enactments of positive state law by state legislatures or city councils, for example, creating the possibility that states (or even localities) would attempt to impose unique marketing or distribution requirements for drugs in their own states or cities. While such efforts would be subject to challenge under the Commerce Clause, *see, e.g.*, *PhRMA v. Walsh*, 538 U.S. 644 (2003), it appears as though preemption has been weakened as an obstacle to such state laws.[7]

[7] Justice Alito warns that the result of the majority opinion will be "whipsawing the medical community with 50 (or more) [ ] conflicting [voices]." 555 U.S. at ___ (Alito, J. dissenting at 24).

While the *Wyeth* decision indicates that preemption litigation is far from resolved, a mention of the various state preemption statutes seems warranted. First, Michigan, whose state statute was the subject of *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008), still has a broad state law preemption rule subject to two exceptions, including the "fraud on the FDA" exception, which was at issue in *Warner Lambert*. In that case, an evenly divided Supreme Court let stand a lower court ruling that the Michigan statute was not preempted, notwithstanding the general rule announced in *Buckman* that private-tort suits based on a fraud on FDA theory are barred.

Second, several states, including New Jersey and Utah, have codified a rebuttable presumption that FDA-approved labeling provides adequate warnings.

Third, several states (including some of the states in the second group above) have barred punitive damages for FDA-approved products, subject to certain exceptions. Utah, for example, has both a rebuttable presumption of adequate warning based upon compliance with government standards, and a bar on punitive damages for FDA approved (Premarket Approval ("PMA")) devices and drugs subject to a "fraud on the FDA" exception.

It is too early to tell whether *Wyeth* will provide momentum to efforts to strengthen (or weaken) these statutory provisions. At a minimum, it seems clear that, at least in the short term, the applicable state law in a failure to warn case will be more important than it would have been had *Wyeth* come out the other way.

Conclusion

The long-term ramifications of *Wyet*h for tort lawsuits may not be apparent for years, and because tort lawsuits in state and federal courts across the country will influence a developing body of post-*Wyeth* preemption and liability decisions, those ramifications may never be clear.[8] Importantly, the Supreme Court has already recently granted petitions for a writ of certiorari in two Third Circuit decisions, *Colacicco v. Apotex Inc.*, 521 F.3d 253 (3d Cir. 2008) and *Pennsylvania Employees Benefit Trust Fund v. Zeneca Inc*., 499 F.3d 239 (3d Cir. 2007), in

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[8] Justice Alito's dissent predicts a conflict between FDA and juries. He notes: "By their very nature juries are ill-equipped to perform the FDA's cost-benefit-balancing function . . . . [J]uries tend to focus on the risk of a particular product's design or warning label that arguably contributed to a particular plaintiff's injury, not on the overall benefits of the design or label . . . . In contrast, the FDA has the benefit of the long view." 555 U.S. at ___ (Alito, J. dissenting at 23).

which the Third Circuit had found preemption. The Supreme Court vacated the judgments and remanded the cases for further consideration in light of *Wyeth*.

Nevertheless, drug companies with pending labeling and drug safety issues, must make decisions now – well before the courts shape the full implications of *Wyeth* – that could affect preemption defenses and liability years in the future. Thus, quickly understanding the ***potential*** implications of *Wyeth* and other preemption decisions is critical to making informed regulatory decisions.