MEMORANDUM

TO: Interested Parties

FROM: Frederick A. Stearns (Partner)
Alisa Karlsons (Associate)

RE: Wyeth v. Levine – U.S. Supreme Court Rejects FDA Preemption in Pharmaceutical Cases

April 15, 2009

On March 4, 2009, the Supreme Court issued its long-awaited decision in Wyeth v. Levine, the controversial case addressing whether the Food and Drug Administration’s (FDA) approved labeling of prescription drugs shields drug manufacturers from state tort suits.\(^1\) In a 6-3 opinion, the Court held that FDA’s approval of a prescription drug label did not preempt state-law failure to warn claims given the facts of this case, although it left open the door open for a finding of preemption under different circumstances. As a result of this decision, pharmaceutical companies should thoroughly document their interactions with FDA with respect to product labeling decisions and work to obtain clear FDA responses on whether proposed labeling changes are, or are not, acceptable.

The Wyeth decision is part of a trilogy of FDA preemption cases taken up by the Supreme Court in the last year and signals a move towards limited availability of the implied preemption defense in the context of FDA regulated drugs. The case has also sparked speculation that the Court’s decision may potentially be applied in other contexts of agency regulation, impacting consumers who are suing for injuries caused by motor vehicles, chemicals, pesticides, and household products, etc.\(^2\) As stakeholders begin to assess the impact of the decision, reviewing the issues raised in Wyeth and other recent FDA preemption cases, as well as possible future congressional action, may provide important clues for what is to come regarding FDA’s regulation of the safety of products covered by the Federal Food, Drug, and Cosmetic Act (FDCA).

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\(^2\) Thomas N. Tiedt, “Pharmaceutical Safety is Not Served by Federal Supremacy,” The Food and Drug Law Institute Update (September/October 2008) at 47; see also Adam Liptak, “No Legal Shield in Drug Labeling, Justices Rule” NY Times (March 4, 2009); see also High Court Hears Arguments on Limiting Drug Company Lawsuits,” The Online NewsHour with Jim Lehrer (November 3, 2008).
I. An Overview of Wyeth v. Levine

This case involved Vermont guitarist, Diana Levine, who lost an arm due to gangrene caused by an improperly administered drug. In April of 2000, Levine suffered from nausea caused by a migraine headache and visited a health clinic for medical treatment. She was given two injections of Phenergan, an anti-nausea drug manufactured by Wyeth. The first dose was given via intramuscular injection, the preferred method of administration identified by Phenergan’s labeling. When Levine’s nausea continued, she was given a second injection by “IV push,” a method through which the medication is administered directly into a vein in order to promote faster relief. Unfortunately, the drug was accidentally injected into an artery, rather than a vein. As a result, the drug caused irreversible gangrene and led to the amputation of Levine’s right hand and forearm.

Having settled with the health clinic, Levine sued Wyeth on claims of negligence and strict liability alleging that Phenergan’s label failed to sufficiently warn about the grave risks associated with the IV push method. Although the label repeatedly emphasized the risk of gangrene arising from inadvertent intra-arterial injection, the label did not specifically address the term “IV push,” nor prohibit its use. Levine argued that Wyeth should have modified the Phenergan labeling using FDA’s “Changes Being Effected” (CBE) regulations, which allow drug manufacturers, in limited circumstances, to add new safety information to a label without FDA approval while the agency reviews the change.\(^3\)

Wyeth countered that based on FDA’s extensive review and approval of Phenergan’s label,\(^4\) Levine’s common law claims relating to the adequacy of the label are preempted. Specifically, Wyeth argued that Phenergan has been an approved drug since the 1950s and FDA had evaluated the risk of IV push administration many times, each time concluding the labeling was adequate, even when Wyeth proposed stronger language to FDA.

The Vermont trial judge ruled in Levine’s favor, stating that FDA’s approval of Wyeth’s label did not prevent the manufacturer from adding to or strengthening warnings on the label. A jury awarded Levine millions in damages. The decision was affirmed by the Supreme Court of

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\(^3\) The supplement procedures described in 21 C.F.R. §§ 314.70(c), 814.39(d) and 601.12(f)(2) (2008) are commonly referred to as “Changes Being Effected” (CBE) supplements and provide that a holder of a FDA approved drug, medical device, or biological product may file a supplemental application to amend labeling when there is newly acquired drug risk or efficacy information. *See also* footnote 15, *infra.*

\(^4\) Since Congress passed the Federal Food and Drug Act of 1906, the FDA has controlled the standards for the labeling of prescription drugs and set extensive requirements in subsequent regulations. Before a drug manufacturer can market a drug, it must submit a New Drug Application (NDA), as part of which FDA will review the prescription drug label. The CBE regulations permit label changes without FDA approval only in limited circumstances where “new” risk or efficacy information is acquired. *See* footnote 3, *supra.*
Vermont and *certiorari* was granted by the Supreme Court to address whether FDA’s labeling judgments preempt Levine’s state-law tort claims.

**II. Understanding the Fundamentals of Preemption**

*Wyeth v. Levine* thus turns on the principle of preemption. The preemption defense is premised on the Supremacy Clause of the U.S. Constitution (Art. VI, clause 2) and provides that when federal and state laws conflict, the federal law takes precedence. Importantly, federal preemption of state action can occur in three ways. First, Congress may expressly preempt state action by language in the applicable legislation.\(^5\) Second, federal action may impliedly preempt state action where Congress’ intent in enacting a federal law is to occupy the regulated field exclusively. Congress’ intent to occupy the field may be inferred if the scheme of federal regulation is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.”\(^6\) Third, federal action may impliedly preempt state action when state and federal law actually conflict. Such “conflict preemption” may be found where it is impossible to comply with both state and federal law, or when the state law stands in the way of implementing Congress’ objectives.\(^7\)

In this case, Wyeth conceded that Congress has not expressly preempted state tort actions in the FDCA, nor did Congress intend for the FDCA to occupy the entire field of prescription drug regulation. Instead, Wyeth’s position, which was supported by FDA and the Bush Administration, was that the case involved the third type of preemption, implied conflict preemption.\(^8\)

In particular, Wyeth argued that it could not use the FDA-approved and required label and at the same time comply with the state common law duties that required stronger warnings about the IV push method.\(^9\) Second, by penalizing drug companies for using FDA-approved labeling, Wyeth argued that state tort claims like Levine’s would obstruct the purpose of the labeling regulations set forth by Congress in the FDCA by allowing juries to second-guess the expert risk determinations of FDA.\(^10\) Indeed, FDA’s decision of what to include on drug labels, as well as FDA’s approval of a drug or medical device generally, requires careful balancing to ensure that the benefits associated with the use of the product do not outweigh the risks. Of course, taking any FDA approved drug always involves some risks.

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\(^9\) Levine slip. op. at 11.

\(^10\) *Id.* at 17.
III. Public Health Implications of the Preemption Doctrine

When oral arguments in Wyeth concluded in November 2008, stakeholders on both sides of the issue raised valid arguments for how the Supreme Court’s ruling could dramatically impact public health. These policy viewpoints provide necessary context for understanding the potential impact of this case.

A. Arguments Opposing Preemption

Preemption opponents argued that preemption of pharmaceutical litigation would remove incentives for FDA and industry to improve product safety; in cases such as Levine’s, preemption would remove incentives to update product labels.\(^{11}\) Tort liability and trial discovery also disclose newly discovered dangers associated with certain drugs or instances of misrepresentation of drug safety risks.\(^{12}\) While frivolous lawsuits weaken this argument, FDA has historically acknowledged that private tort suits complement FDA regulatory action by providing a crucial back-end check on products once they have been approved.\(^{13}\) A decade ago, FDA stated that drug approvals set only minimal standards and states were free to provide additional protections.\(^{14}\) Under the Bush administration, FDA made a controversial about-face, indicating that the agency’s labeling requirements are not mere minimum safety standards, but also provide a ceiling.\(^{15}\)

Continuing reports that FDA falls dramatically short in its post-approval surveillance of drugs provide further support for the claim that safety will be compromised if preemption


\(^{12}\) Id. at 491-92.

\(^{13}\) Tiedt, supra footnote 2, at 47.


\(^{15}\) See Requirements on the Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (January 24, 2006) where FDA declared that it possessed preemptive power in the preamble to its new rules for drug labeling. The rules were updated on August 22, 2008 (Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603), providing broader preemption authority. In its amicus curiae brief in support of Wyeth, FDA stated that state-law claims that challenge labeling that FDA approved after being informed of the relevant risks are generally preempted as it threatens the agency’s authority and ability to regulate labels under the FDCA. See “Brief for the United States as Amicus Curiae Supporting Petitioner, Wyeth v. Levine,” No. 06-1249, available at: http://drugadvice.com/FDA%20Amicus%20Briefs/Levine%20SG-FDA%20brief%20on%20certiorari.pdf; see also Terry Carter, “The Preemption Prescription,” ABA Journal (November 2008), (discussing FDA’s change in position on preemption), available at: http://abanewswire.com/magazine/the_pre_emption_prescription/.
advocates prevail. The Government Accountability Office (GAO) reported that “FDA lacks clear and effective processes for making decisions about, and providing management oversight of, post-market safety issues.”\textsuperscript{16} Similar findings have been made by the Institute of Medicine in its report on the assessment of the U.S. drug safety system: “The [FDA] approval decision does not represent a singular moment of clarity about risks and benefits associated with a drug ....”\textsuperscript{17} Although not necessarily through fault of FDA, its approval of a new drug does not guarantee that a drug’s benefits outweigh the safety risks once the drug is widely used. In numerous instances, unforeseen risks or dangerous side effects are discovered once an approved drug hits the market.\textsuperscript{18} Thus, in the interest of public health, preemption opponents argued that FDA cannot provide the sole and final word on the safety and efficacy of a product as preemption could leave the agency “understaffed, underfunded and outgunned by the industries it regulates.”\textsuperscript{19}

B. Arguments in Favor of Preemption

Preemption proponents similarly argued that public health will be compromised if manufacturers are unable to rely on FDA’s approval of their products or labels. First, the ruling for Levine could cause FDA to be inundated with labeling revisions or labeling supplements through its CBE regulations.\textsuperscript{20} Such an influx of change requests could make it difficult for the already short-staffed agency to evaluate and respond to them appropriately.

Moreover, the credibility of drug warnings would be undermined if manufacturers are forced to over-warn about speculative risks in an effort to avoid liability. Exaggerated risks may cause individuals to forgo medical treatment they should be receiving. In their \textit{amicus curiae} brief in support of Wyeth, the Washington Legal Foundation and the American College of Emergency Physicians noted that controversial warnings regarding the dangers of vaccines led to increasing numbers of parents choosing to forgo vaccinating their children, resulting in a

\begin{footnotes}
\item[17] Tiedt, \textit{supra} footnote 2, at 48 (quoting “The Future of Drug Safety: Promoting and Protecting the Health of the Public,” Institute of Medicine, Committee on the Assessment of U.S. Drug Safety System (September 22, 2006)).
\item[19] Carter, \textit{see} footnote 15, \textit{supra}.
\end{footnotes}
dramatic increase of measles outbreaks.\textsuperscript{21} State level lawsuits could thus make beneficial drugs less available to consumers and threaten FDA’s prescribed role as the expert body responsible for evaluating and regulating drugs. Wyeth argued, for example, that IV push was the most effective way to administer Phenergan for some patients.\textsuperscript{22} Allowing juries, rather than FDA, to determine the adequacy of a drug label will not necessarily promote drug safety. Preemption proponents explain that juries too often see only those consumers hurt by a drug, and not those who receive its benefits.\textsuperscript{23}

IV. A Review of the 2008 Supreme Court FDA Preemption Cases and the Decision in \textit{Wyeth v. Levine}

\textit{Wyeth v. Levine} was the third Supreme Court case in the last year to address preemption in the context of FDA regulated products, indicating that the Court recognized the urgent need to define the scope of the FDA preemption defense. In addition, the Supreme Court had indicated an interest in two other FDA preemption cases in 2008 in which petitioners had applied for \textit{certiorari}.\textsuperscript{24}

A. Preemption Upheld in \textit{Riegel v. Medtronic}

In February 2008, the Court ruled in \textit{Riegel v. Medtronic} that an express preemption clause in the 1976 Medical Device Amendments (MDA) to the FDCA preempts state actions challenging the safety and effectiveness of medical devices that have FDA approval.\textsuperscript{25} In this


\textsuperscript{22} Brief of Petitioner at 44.


\textsuperscript{24} See Colacicco v. Apotex, Inc., 521 F.3d 253 (3d Cir. 2008), petition No. 08-437, finding FDA preemption of state-based failure to warn claims for the risk of suicide on labels for antidepressants Paxil and Zoloft. On March 9, 2009, the Supreme Court granted cert., vacated the appellate decision, and remanded for reconsideration in light of \textit{Wyeth v. Levine}; \textit{See also Albertson’s v. Kanter (Farm-Raised Salmon Cases), 42 Cal. 4th 1077, 175 P.3d 1170 (2008)}, petition No. 07-1327, finding no FDA preemption of California state-law claims addressing the failure to disclose the use of artificial coloring agents in farm-raised salmon. The Supreme Court denied \textit{cert.} to the \textit{Farm-Raised Salmon Cases} in January 2009, heightening the anticipation of the decision in \textit{Wyeth v. Levine}.

\textsuperscript{25} 128 S. Ct. 999 (2008). In particular, the express preemption provision provides that “no State . . . may establish or continue in effect with respect to a device . . . any requirement— (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates (continued …)
case, Charles Riegel and his wife sued Medtronic after he was severely injured by a balloon catheter that burst during an angioplasty procedure. Writing for the 8-1 majority, \textsuperscript{26} Justice Scalia denied his claims, focusing on the rigorous nature of the medical device pre-market approval process, in which FDA reviews safety and efficacy of the device while balancing the potential risks and benefits. Key to the Court’s interpretation of the preemption clause was its finding that state negligence and strict liability tort claims impose requirements that are different from or in addition to federal requirements. The Court also found that a state law that required a safer, but therefore less effective, device than the model approved by FDA would disrupt the federal regulatory scheme established by Congress.

Because FDA had approved Phenergan’s label and similarly balanced the known risks and benefits associated with the drug’s label, \textit{Riegel} initially appears instructive on the issue of preemption in \textit{Wyeth}. Indeed, both medical devices and drugs undergo similar FDA balancing processes prior to their approval. The holding in \textit{Riegel}, however, is limited as it only addresses preemption in the context of an express preemption clause in the medical device law. \textsuperscript{27} Unlike the law governing medical devices, the FDCA contains no such express preemption clause for drug products. Whether state tort litigation is impliedly preempted in \textit{Wyeth}, therefore, is less straightforward than in \textit{Riegel}.

\textbf{B. Court Split in \textit{Warner-Lambert Co. v. Kent}}

Next the Court took on the preemption prescription drug case of \textit{Warner-Lambert Co. v. Kent}.\textsuperscript{28} In this case, Michigan residents sued Warner-Lambert for personal injuries arising from its FDA-approved diabetes drug, Rezulin. Under Michigan law, prescription drug manufacturers have immunity from personal injury lawsuits if the drug was approved by FDA.\textsuperscript{29} The plaintiffs claimed that this defense did not apply, however, because the statute provided an exception to immunity if FDA approval was based on material misrepresentations or withholding of information by the drug manufacturer. Warner-Lambert, now owned by Pfizer Inc. (Pfizer),

\textsuperscript{26} Justice Ginsburg was the only Justice to dissent in \textit{Riegel v. Medtronic}, stating that given the traditional primacy of state regulation of matters of health and safety, Congress did not intend for the MDA to radically curtail state common-law suits seeking compensation for injuries caused by defectively designed or labeled medical devices.

\textsuperscript{27} In addition, the ruling was further limited to Class III medical devices that had undergone rigorous pre-market approval (PMA) with the FDA. In \textit{Medtronic, Inc. v. Lohr}, 518 U. S. 470 (1996), a fractured Court held that medical devices cleared under the less-rigorous Section 510(k) premarket notification process were not covered by the express preemption provision.

\textsuperscript{28} 128 S. Ct. 1168 (2008)

\textsuperscript{29} See Mich. Comp. Laws § 600.2946(5).
argued that such state based “fraud-on-the-FDA” suits are impliedly preempted by federal law because they conflict with the agency’s functions by permitting state courts to second-guess FDA’s product approval and fraud-detection processes.\(^{30}\)

The Second Circuit held, however, that the implied preemption doctrine does not bar the fraud-on-the-FDA exception set forth in a Michigan statute.\(^{31}\) This ruling contrasted with the Sixth Circuit case of Garcia v. Wyeth-Ayerst Laboratories, which reached the opposite result when it interpreted the same Michigan statute.\(^{32}\) Yet in March 2008, the Supreme Court failed to provide clarity on the Circuit split. With Chief Justice Roberts having to recuse himself because of his ownership of Pfizer stock, the divided Court affirmed the Second Circuit 4-4 and provided no accompanying opinion. The equally divided ruling has no precedential value and with no opinion, it left stakeholders guessing as to which Justices favored FDA preemption and which did not. The 4-4 decision did indicate, however, that unlike the nearly unanimous decision in Riegel, the Court is far less inclined to rule in favor of preemption when there has been no express preemption mandate by Congress.

C. Preemption Denied in Wyeth v. Levine

Against this uncertain backdrop, in a 6-3 decision, the Supreme Court rejected Wyeth’s arguments that implied preemption should bar Levine’s state law failure to warn claims. As mentioned above, Wyeth first argued that it could not use the FDA required label and at the same time comply with the state common law duties that required stronger warnings about the IV push method of administration of Phenergan. Second, Wyeth argued that state tort claims like Levine’s would obstruct the purpose of the labeling regulations set forth by Congress in the FDCA by allowing juries to second-guess the expert risk determinations of FDA. Joined by Justices Kennedy, Souter, Ginsburg and Breyer,\(^{33}\) Justice Stevens wrote for the majority and

\(^{30}\) Specifically, Warner-Lambert relied on the 2000 Supreme Court case of Buckman Co. v. Plaintiffs’ Legal Committee, 531 U.S. 341 (2001) (holding that state law fraud-on-the-FDA claims are barred by implied conflict preemption if the state tort statute requires actual proof of fraud). A unanimous Supreme Court explained, “State law fraud-on-the-FDA claims inevitably conflict with the FDA’s responsibility to police fraud consistently with the Agency’s judgment and objectives.”

\(^{31}\) 467 F.3d 85 (2d Cir. 2006). Unlike Buckman, the Second Circuit determined that the Michigan statute did not require proof that FDA was actually defrauded; rather the claims were rooted in traditional state tort law. Accordingly, the statute did not establish a specific cause of action for fraud on the FDA and thus did not attempt to police cases of fraud against the FDA.

\(^{32}\) 385 F.3d 961 (6th Cir. 2004). The Sixth Circuit interpreted the Michigan statute differently as requiring proof of successful fraud on the FDA as a prerequisite to state tort liability and thus squarely preempted by Buckman.

\(^{33}\) Justice Breyer also filed a concurring opinion emphasizing that the majority’s decision does not consider the preemptive effect of an agency regulation bearing the force of law. In other words, as discussed in detail below, the Court ruled that the statement of FDA preemption that appeared in the preamble to the 2006 FDA regulation governing the content and format of prescription drug labeling (see (continued …))
rejected both arguments. Justice Thomas concurred in the judgment but wrote separately. Justice Alito wrote the dissent and was joined by Chief Justice Roberts and Justice Scalia.

In addressing Wyeth’s first argument, the Court held that it was not impossible for Wyeth to comply with both state and federal law obligations. While generally a manufacturer may only change a drug label after FDA approves a supplemental application, the Court emphasized that Wyeth had a duty to adequately describe the risk associated with IV push and that the CBE regulations permitted Wyeth to provide additional warnings before receiving FDA approval.

Wyeth had argued, however, that under the CBE regulations, as amended, a labeling change is not permitted unless a manufacturer has obtained “newly acquired information.” Wyeth argued that “newly acquired information” means data of a “different type or greater severity or frequency than previously included in submissions to FDA.” Since the risk of gangrene did not represent a change in the average frequency of this adverse event and FDA had already been aware of the risk of gangrene, Wyeth stated that there was no new information upon which to update the label. These arguments were echoed by Justice Alito in his dissent, where he emphasized that Phenergan’s label already warned about the risks of gangrene and that FDA had specifically considered and reconsidered the strength of warnings. He further wrote that the agency’s ultimate decision was to retain IV push as one means of administering the drug, albeit with stringent warnings. Unfortunately, the physician’s assistant who administered Phenergan ignored these and other warnings.

The Court majority referred to Wyeth’s arguments as a “cramped” reading of the CBE regulations, emphasizing that the regulations provide that a label may be updated based on “new...”

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footnote 15, supra) did not bear the force of law. However, because “state tort law will sometimes interfere with the FDA’s desire to create a drug label containing a specific set of cautions and instructions,” Breyer wrote that FDA may seek to preempt state laws by passing “lawful specific regulations” indicating that a labeling requirement serves as a ceiling as well as a floor.

34 Slip. op. at 25 (holding of the case).
35 Justice Thomas agreed with the majority that in light of the CBE regulation, FDA’s approval of Phenergan’s label did not preempt state law failure to warn claims. While he further agreed that Levine’s claims also did not obstruct the purposes and objectives of Congress, he disagreed with the majority’s approach to assessing claims of implied or conflict preemption by looking beyond the statutory text of federal statutes passed by Congress.
36 See §§ 314.70(c)(6)(iii)(A), (C).
37 73 Fed. Reg. at 49603. See also footnote 15, supra.
38 73 Fed. Reg. at 49604.
39 See slip. op. at 9 (Alito, J., dissenting). Phenergan’s label in part stated that “inadvertent intra-arterial injection can result in gangrene of the affected extremity.”
analysis of previously submitted data.” Thus, as amputations continued to occur, the Court stated that Wyeth could have analyzed accumulated data and added a stronger warning without first obtaining FDA approval. The opinion is silent on what sort of labeling language would have been appropriate, but emphasizes that manufacturers bear the responsibility for the content of their labels at all times. In addition, the Court viewed FDA’s review of the risks associated with IV push very differently than the dissent, stating that FDA “gave no more than a passing attention” to the dangers posed by IV push. Justice Stevens explained that “absent clear evidence that the FDA would have not have approved a change to Phenergan’s label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.”

The Court further found no merit in Wyeth’s second defense that Levine’s state law failure to warn claim would frustrate the purpose and objectives of the FDCA, which puts drug labeling decisions in the hands of FDA, an expert agency. The Court held that Wyeth’s argument was based on “an untenable interpretation of congressional intent and an overbroad view of an agency’s power to pre-empt state law.” In particular, the Court noted that unlike the express preemption clause that was controlling in Riegel, Congress had not enacted a similar express preemption provision during the 70 year-long history of the FDCA. While Wyeth and the dissent argued that juries are ill-equipped to perform FDA’s cost-benefit-balancing function, the Court reiterated many of the arguments that preemption opponents have made, namely that FDA has limited resources and that state law offers an important additional layer of consumer protection that complements, rather than conflicts with, FDA regulation.

Finally, the Court disregarded Wyeth’s and the dissent’s argument that FDA’s interpretation of its own labeling rules should be given deference. The Court was particularly critical of the preamble to the 2006 drug labeling rule where FDA articulated the FDCA’s preemptive effect. The Court found that the rule did not merit any deference because unlike an agency rule cited to by Wyeth and the dissent in Geier v. American Honda Motor Co. (529 U.S. 861 (2000)), FDA failed to provide notice and comment before finalizing the rule. In light of these procedural failures, the Court found “inherently suspect” both the preamble and FDA’s

40 73 Fed. Reg. at 49604.
41 Approximately 20 incidents of gangrene resulting in amputation were reported prior to Levine’s injury. See slip. op. at 13.
42 Id. at 15.
43 Id. at 17.
44 See footnote 15, supra.
45 In Geier, the Department of Transportation (DOT) had promulgated a rule through formal rulemaking that provided car manufacturers with a range of choices among passive restraint devices. The Court held that state tort claims premised on Honda’s failure to install airbags were impliedly preempted because they conflicted with the federal regulation that specifically did not require airbags for all cars.
views on preemption.\textsuperscript{46} In addition, the position contrasted with FDA’s traditional recognition of state law remedies. Thus, the Court concluded that FDA’s 2006 regulation did not bear the force of law and that although “some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case.”\textsuperscript{47}

Ultimately, the Wyeth decision makes clear that absent congressional intent to the contrary, the Court believes that state tort suits complement FDA regulation. Thus, the decision will likely limit the availability of the implied preemption defense in the context of FDA regulated drugs. The Court also indicated that there must be sufficient FDA oversight for an implied preemption argument to have prevailed. For example, if Wyeth had submitted a CBE supplemental application that had been denied by FDA, it appears that the Court may have found the state law claims to be preempted. Given its reading of the facts, however, the majority did not find that FDA had sufficiently considered and specifically rejected a stronger warning label for Phenergan. Thus, under the Court’s standard, manufacturers will have to increasingly provide “clear evidence”\textsuperscript{48} that FDA was fully informed about a drug’s risks and would have rejected a labeling change in order to succeed on implied preemption claims.

V. Possible Congressional Action and Expansion of the Wyeth Decision

The ruling against preemption in \textit{Wyeth v. Levine} may be further strengthened, and possibly expanded, to cover products regulated by other agencies, by new Congressional action. Aside from overturning regulations, there are two ways Congress may seek to overrule past and prevent future Supreme Court decisions upholding federal preemption, as well as FDA’s recent preemption policy.\textsuperscript{49} First, Congress could insert anti-preemption clauses into any future bills involving products regulated by FDA. Congress successfully added such clauses when it passed the Consumer Product Safety Improvement Act (CPSIA) in 2008. Preemption was addressed in several sections and the CPSIA specifically limits the ability of the Consumer Product Safety Commission (CPSC) to issue opinions on whether its rules preempt common law tort suits.\textsuperscript{50}

Second, stand-alone congressional measures prohibiting preemption of state tort suits in certain contexts have already been introduced. In the summer of 2008, Representatives Henry

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\item \textsuperscript{46} Slip. op. at 21.
\item \textsuperscript{47} \textit{Id.} at 24-25. In other words, had FDA’s 2006 preamble and regulation born the force of law like the rule promulgated \textit{Geier}, it appears the Court would have given greater deference to FDA and may have found Levine’s claims impliedly preempted.
\item \textsuperscript{48} Slip. op. at 15.
\item \textsuperscript{49} “Obama, Democratic Congress Could Change FDA Preemption Policy,” Inside Washington’s FDA Week (November 14, 2008).
\item \textsuperscript{50} “CPSC Reform Act Imposes New Requirements, including Limiting Phthalates in Children’s Products,” Keller and Heckman LLP (August 22, 2008), available at: \url{http://www.packaginglaw.com/index_news.cfm?ID=370}.
\end{itemize}
Waxman (D-CA) and Frank Pallone (D-NJ) introduced the Medical Device Safety Act of 2008 (HR 6381) to overrule Riegel.\textsuperscript{51} The legislation would have provided that existing federal law governing medical device approvals would not “modify or otherwise affect” lawsuits brought in state courts. When Senator Edward Kennedy (D-MA) and Senator Patrick Leahy (D-VT) introduced the Senate version of the bill, then-Senator Barrack Obama (D-ILL) served as a co-sponsor.\textsuperscript{52} Although the legislation stalled in both the House and Senate, the bill was recently reintroduced this year by Pallone and Waxman.\textsuperscript{53} As Waxman defeated Representative John Dingell (D-MI) in the race for House Energy and Commerce Committee Chair, he may be able to gather greater support for the bill as he now has broad power over health care and FDA legislation.\textsuperscript{54}

\section*{VI. The Bottom Line}

The \textit{Wyeth} decision makes clear that drug manufacturers, rather than FDA, bear the responsibility to monitor and update drug labeling when new risk information arises. The Court, however, provided little guidance on when newly acquired risk information triggers the burden to update product labeling. Thus, to protect themselves from liability, it may become increasingly imperative for manufacturers seeking FDA approval for their products, labels, or both, to create a comprehensive record of their application, demonstrating that FDA was informed of all known product risks and specifically evaluated all options prior to approval. Manufacturers will also have to pay closer attention to reported adverse drug events and accumulated risks, and when needed, unilaterally update drug labels while submitting supplemental applications to FDA under the CBE regulations.

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\item Full text of HR 6381, 110\textsuperscript{th} Cong. (2008) is available at: \url{http://www.house.gov/waxman/pdfs/bill_MDSA_2008.pdf}.
\item See “Health Leaders Introduce Legislation Reversing Supreme Court's Medical Device Decision” Committee on Energy and Commerce News Release (March 5, 2009).
\item The House Committee on Energy and Commerce has one of the broadest jurisdictions of any congressional committee. It maintains principal responsibility for legislative oversight relating to telecommunications, consumer protection, food and drug safety, public health, air quality and environmental health, the supply and delivery of energy, and interstate and foreign commerce in general. This jurisdiction extends over five Cabinet-level departments and seven independent agencies, including the Energy Department, Health and Human Services, the Transportation Department, the Federal Trade Commission, the FDA, and the Federal Communications Commission.
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