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The Supremacy Clause of the United States Constitution is the basis for the doctrine of preemption that renders void all state laws and causes of action that conflict with a federal law.\(^1\) Food and Drug Administration ("FDA") regulations dictate the form and content of all prescription drug labels including warnings of possible medical risks associated with the drug.\(^2\) In Levine v. Wyeth,\(^3\) the Vermont Supreme Court considered de novo whether FDA labeling requirements preempt an injured patient's state

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1 See U.S. CONST art. VI, cl. 2 (providing federal law is superior to state law and will override conflicting state laws). "This Constitution, and the laws of the United States which shall be made in pursuance thereof . . . shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding." Id. See also U.S. CONST. art. I, § 8, cl. 3 (granting Congress power to regulate interstate commerce); U.S. CONST. art I, § 8, cl. 18 (amplifying scope of the Commerce Clause). Congress has the power to enact laws "necessary and proper" to carry out its powers. U.S. CONST. art I, § 8, cl. 18. Congress may preempt state law by 1) explicitly stating intent to preempt, 2) indicating desire to occupy entire field of regulation, or 3) creating a law that directly conflicts with state law. See generally 72A C.J.S. Products Liability § 41 (2008). The Supremacy Clause allows Congress to preempt state laws. See generally 81A C.J.S. States § 46-49.


3 944 A.2d 179 (Vt. 2006).
law claim for failure-to-warn product liability. The United States Supreme Court has granted a writ of certiorari so the outcome of this case will have a determinative effect on product liability cases involving prescription medicines.

Northeast Washington County Community Health, Inc. ("Health Center") repeatedly treated Diana Levine ("Levine"), a professional musician, for debilitating migraine headaches. During one such treatment on April 7, 2000, a nurse administered an intramuscular injection of Demerol, a narcotic pain-killer, and Phenergan, a drug produced by Wyeth that counteracts the nausea associated with Demerol. On that occasion, the drug combination did not alleviate Levine's symptoms and she returned to the Health Center later that day. A physician's assistant ("PA") administered a second dose of the same Demerol/Phenergan combination using a "butterfly infusion set," also known as an "IV push," rather than the usual intramuscular injection. However, the PA inadvertently injected the Phenergan into an artery instead of the intended vein. The Phenergan caused necrosis and gangrene so extensive that it necessitated the eventual amputation of Levine's arm below the elbow.

Levine brought a state tort action against Phenergan's manufacturer, Wyeth, asserting that Wyeth's inadequate warning of the known dangers of direct intravenous injection of Phenergan caused Levine's injuries. The five-day trial revolved around

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4 Id. at 183, 184, 186, 193. (holding FDA regulations did not preempt Plaintiff's state law claim for failure to warn). The Vermont Supreme Court also rejected Wyeth's claims that the trial court was required to apportion negligence between the Health Center and Wyeth, and that the lower court was wrong not to issue a jury instruction to calculate the present value of Levine's non-economic damages. Id. at 194-197.


7 Levine, 2003 WL 25648135 at *1 (describing treatment Levine received). The nurse who administered the injection acted under the instructions of a physician assistant. Id.

8 Id. (describing results of treatment and subsequent return to Health Center).

9 Id. (describing PA's administration of second treatment)

10 Id. (detailing event causing injury).

11 Id. (indicating the nature of suit).

12 944 A.2d at 182. See generally Orr v. Shell Oil Co., 177 S.W.2d 608 (Mo. 1943) (explaining failure-to-warn cause of action). Orr states:
expert testimony on the adequacy of the drug's warning labels. At the time, the label for Phenergan cautioned against accidental intra-arterial injection and warned that repercussions included gangrene and amputation. In 1993, Wyeth proposed alterations to the FDA-approved label that made the intra-arterial injection warning stronger, but the FDA rejected these proposals in 1997.

The rule is now well settled that a duty is imposed upon the one who furnishes and article which he knows, or ought to know, to be peculiarly dangerous to give notice of its character or bear the nature consequences of his failure to do so. This rule originated as an exception to the general rule of non-liability where no privity of contract exist, and was applied in cases involving injuries from poisonous drugs, chemicals... or articles inherently dangerous.

Id. at 612. Further, failure-to-warn has been extended to cover products that are inherently dangerous and to those that become dangerous by their use. Id. Error of a third party does not absolve a drug manufacturer from a claim of dangerous-product liability. Farley v. Edward E. Tower & Co., 171 N.E. 639 (Mass. 1930).

13 944 A.2d at 182 (restating Plaintiff’s expert’s assertion). Levine’s expert witness explained that Phenergan’s label should have warned against IV push as means of administration. Id. Defendant’s expert stated that Phenergan’s warnings against arterial injection were sufficient. Id.

14 Levine, 2003 WL 25648135 at 2 (noting FDA’s approval of original label). The warning, in relevant part states:

INADVERTENT INTRA-ARTERIAL INJECTION: Due to the close proximity of arteries and veins in the areas most commonly used for intravenous injection, extreme care should be exercised to avoid perivascular extravasation or inadvertent intra-arterial injection. Reports compatible with inadvertent intra-arterial injection of [Phenergan], usually in conjunction with other drugs intended for intravenous use, suggest that pain, severe chemical irritation, severe spasm of distal vessels, and resultant gangrene requiring amputation are likely under such circumstances. Intravenous injection was intended in all the cases reported but perivascular extravasation or arterial placement of the needle is now suspect. There is no proven successful management of this condition after it occurs.

944 A.2d at 183.


INADVERTENT INTRA-ARTERIAL INJECTION: There are reports of necrosis leading to gangrene, requiring amputation, following injection of [Phenergan], usually in conjunction with other drugs; the intravenous route was intended in these cases, but arterial or partial arterial placement of the
The trial judge denied Wyeth's motion for summary judgment in which Wyeth argued that federal law preempted Levine's claim. The jury found Wyeth liable for Levine's injuries and awarded her a total of $7,400,000. Wyeth appealed the verdict and maintained that the FDA's approval of Phenergan's warning label preempted state common law claims. The Vermont State Supreme Court, in a four to one decision, denied Wyeth's appeal and affirmed the lower court's decision. The Supreme Court granted Wyeth's request for a writ of certiorari and scheduled oral arguments for November 3, 2008.

The question of federal preemption of state laws stretches back to the Marshall Court. Gradually, and especially since the New Deal period, Congress's power to needle is now suspect. There is no established treatment other than prevention. Beware of the close proximity of arteries and veins at commonly used injection sites and consider the possibility of aberrant arteries . . . Injection through a properly running intravenous infusion may enhance the possibility of detecting arterial placement. In addition, this results in delivery of a lower concentration of any arteriolar irritant.

944 A.2d at 183.


17 944 A.2d at 182 (stating verdict). The jury awarded $2,400,000 in economic damages and $5,000,000 in other damages. Id. This was reduced by stipulation to a total of $6,774,000. Id.

18 Levine, 2004 WL 5456809 at 1 (denying timely filed motion for judgment following entry of judgment). The lower court denied summary judgment on the same grounds. 944 A.2d at 183. Wyeth also appealed alleging the court erred in failing to instruct the jury to reduce Levine's damages by the amount of fault attributable to the Health Center, and in failing to instruct the jury to calculate the present value of Levine's damages for future non-economic losses. Id. The Vermont Supreme Court affirmed the lower court's ruling as to these questions of law as well. Id. Wyeth conceded that Congress has not expressly preempted state tort actions through the Food, Drug and Cosmetic Act ("FDCA") but argued that a failure-to-warn claim brought under state common law actually conflicts with the federal law and should be preempted. Id. at 184.

19 Id. at 179 (rejecting claims of error and affirming lower court judgment).


21 See New York v. Miln, 36 U.S. 102, 161 (1837) (indicating health laws reserved to states generally). The Court stated, [T]he object of the people was to form a general national government, and to take from the states no powers not necessary for that object. Health laws, poor laws . . . are all necessary for the safety and security of the particular states, or of the inhabitants of those states; and they are in nowise necessary or proper
preempt state laws has increased greatly. Congress may either preempt a state law expressly by placing a preemption clause into a statute or legislating directly counter to an existing state law, or Congress may preempt a state law implicitly by demonstrating intent to "occupy the field" so comprehensively as to leave no room for any state regulation. Implied preemption also occurs when a state law actually conflicts with a federal law by making compliance with both the federal and the state regulations impossible or when the state law stands as an obstacle to Congress's objectives.

\[\text{Id. at 127-28. See also Gibbons v. Ogden, 22 U.S. 1, 130 (1824) (holding state law that directly conflicts with duly enacted federal law is void and without effect); McCulloch v. Maryland, 17 U.S. 316, 317-319 (1819) (holding state action may not impede valid constitutional exercises of power by federal government).}\]


\[\text{Fid. Fed. Sav. & Loan Ass'n v. De la Cuesta, 458 U.S. 141, 153 (1982) (holding Federal Home Loan Bank Board's regulations barred application of contrary state doctrine); Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 132 (1963) (holding California statute setting higher agricultural standards than federal regulations did not offend Supremacy Clause as it did not create actual conflict between schemes of regulations); Hines v. Davidowitz, 312 U.S. 52, 67 (1941) (declaring court is to determine in context if state law conflicts or stands as obstacle to federal law). Hines states that there cannot be a rigid formula or rule to determine the intent of}\]
However, because each state is a nominally independent sovereign in our federal system, courts assume a "presumption against preemption."26

The Food, Drug and Cosmetic Act ("FDCA"), signed into law by President Roosevelt on June 25, 1938, provided the statutory authority for the FDA and its subsequent regulations.27 Prior to the FDCA's enactment, common-law claims for

26 See Cipollone, 505 U.S. at 516 (explaining courts apply "clear and manifest" standard to determining if congress intended preemption) The court in Cipollone quoted Rice (331 U.S. at 230): "Consideration of issues arising under the Supremacy Clause start[s] with the assumption that this historic police power of the states [are] not to be suspended by... Federal Act unless that [is] the clear and manifest purpose of Congress." Id. See also Bates v. Dow Agrosciences, LLC., 544 U.S. 431, 449 (2005); Medtronic, Inc. v. Lohr, 518 U.S. 470, 504 (1996) (clarifying Supreme Court's duty to disfavor preemption); N.Y. State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995) (stating in areas of traditional state regulation Congress must make its intention "clear and manifest" for federal statute to supplant state law). In Medtronic, the court held that: "Because the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt [sic] state-law causes of action." 518 U.S. at 485. Bates states "The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption." 544 U.S. at 432. But see Colacicco v. Apotex Inc., 521 F.3d 253, 264 (3d Cir. 2008) (holding presumption against preemption was reduced by tension between presumption and implied conflict preemption). Colacicco reverses McNellis v. Pfizer, Inc., 2005 WL 3752269, at *5 (D.N.J. Dec. 29, 2005). Colacicco, 521 F.3d at 276. See McNellis, 2005 WL 3752269, at *5 (stating since 1965, FDA regulations have permitted manufacturer to strengthen label unilaterally).

27 See 21 U.S.C. § 301 (1938) (creating the FDA and providing its scope and powers). See generally JOHN P. SWANN, History of the FDA, THE HISTORICAL GUIDE TO AMERICAN GOVERNMENT (George Kurian ed., Oxford University Press 1998), available at http://www.fda.gov/oc/history/historyoffda/fulltext.html (detailing events that motivated Congress to enact FDCA). Several tragic events influenced Congress to enact the FDCA including the sale of an eyelash dye that caused blindness, a non-effective treatment for diabetes, and a tainted batch of sulfa drugs that resulted in the deaths of over 100 patients. Id. See also Chevron, U.S.A., Inc., v. Natural Res. Def. Council, Inc., 467 U.S. 837, 866 (1984) (holding that while courts are final authority on issues of statutory construction, they defer to any permissible construction of statute by agency). The Supreme Court stated in Chevron that a court should uphold an agency's interpretation of statute as long as it is a valid interpretation; it need not be the "best" interpretation but instead
negligence for the manufacture and sale of medicines were widely recognized. 28 Subsequently in 1965, the FDA promulgated 21 C.F.R. § 314.70, a law that mandated a specific procedure for drug manufacturers to change labels to strengthen the warning labels. 29 In 1976, Congress passed the Medical Device Amendments (“MDA”), extending the FDA’s scope to include medical devices, including an explicit preemption clause in the legislation. 30

Since the creation of the FDA in the 1930s, courts have found drug manufacturers liable in state common-law tort claims. 31 Recently, in litigation across

need only be a reasonable interpretation. Id. 28 See, e.g., Boyd v. Coca Cola Bottling Works, 177 S.W. 80, 81 (Tenn. 1915) (holding drug manufacturers owe duty to consumers). “[A] tort is committed, a legal right invaded, by practices which prejudice another's health.” Id. See also Thomas v. Winchester, 6 N.Y. 397 (1852) (holding drug manufacturer liable for injury). 29 21 C.F.R. § 314.70(c) (2000) (allowing companies to add or strengthen instructions intended to increase safe use of product). The regulation promulgated by the FDA states that pharmaceutical companies may make limited changes to an already approved drug including: “(iii) Changes in the labeling . . . to accomplish any of the following: (A) To add or strengthen an contraindication, warning, precaution, or adverse reaction . . . . (C) To add or strengthen an instruction about the dosage and administration that is intended to increase the safe use of the drug product[.]” Id. In 2006, the FDA propounded new rules which claim that state failure-to-warn causes of action are preempted by FDA regulations and the drug approval process § 314.70 notwithstanding. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-36 (Jan. 24, 2006). However, these new rules did not take effect until 2006 and are thus moot for the purposes of Wyeth v. Levine. 944 A.2d at 191. 30 21 U.S.C. § 360(c) (2000) et seq. (dictating states may not establish or continue any requirement relating to medical devices). The preemption statute states in relevant part:

Except [for any state or local requirement specifically exempted by the FDA]. . . . . . . no state . . . . . . may establish or continue in effect with respect to a device intended for human use any requirement-

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.


The Supreme Court has ruled that this express preemption clause does preempt all state tort claims, common-law or otherwise. See Riegel v. Medtronic, Inc., 128 S. Ct. 999, 1011 (2008) (holding Congress made its intent to preempt state law manifest in explicit preemption clause).

several jurisdictions relating to the anti-depressant Zoloft, courts have established that
21 C.F.R. § 314.70 only sets a minimum labeling requirement and does not dictate the
ultimate label, and that the regulation permits state law to augment the label
requirements to promote greater safety. However, since the Vermont Supreme Court
ruled on Levine, the Supreme Court and the United States Court of Appeals for the
Third Circuit weakened the presumption against preemption and gave greater deference
to the FDA in two recent cases.

In Levine v. Wyeth, the Vermont Supreme Court reviewed de novo the lower
court's decision regarding whether FDA regulations preempt Vermont's common-law
failure-to-warn cause of action as a matter of law, and determined that Congress did
not demonstrate a clear intent to preempt state causes of action when it passed the
FDCA. The court also evaluated the language of 21 C.F.R. § 314.70 to determine if
the regulation created a conflict with Vermont common-law failure-to-warn actions thus
preempting the state action by implication, and held that, because 21 C.F.R. § 314.70
allowed a drug maker to unilaterally strengthen warnings, the FDA-approved label was
only a minimum standard, and that room existed for the state to compel companies to
strengthen warning labels in the interest of public safety. The court determined that

32 See e.g., McNellis, 2005 WL 3752269 at *4 (stating failure-to-warn not in conflict with FDCA
because of leeway provided by 21 C.F.R. § 314.70(c)). Contra Colacisco, 521 F.3d at 265 (holding
presumption against preemption was reduced by tension between presumption and implied
conflict preemption). Colacisco reverses McNellis. Id. at 276. However, Colacisco was not decided
until after Levine. Colacisco, 521 F.3d at 253.
33 See Riegel, 128 S. Ct. at 1001 (holding MDA explicitly preempted state tort claims to extent that
they are different from or in addition to federal requirements); Colacisco, 521 F.3d at 265.
34 944 A.2d at 183-184 (following procedural precedent that questions of law are reviewed de
of law are reviewed de novo).
35 944 A.2d at 184.
36 Id. (noting defendant conceded that Congress had not expressly preempted state tort actions
through FDCA). There was no evidence of express preemption under the Cipollone definition.
See supra note 25 and accompanying text. The court also chose to follow Lohr's assertion that
there is a presumption against preemption absent manifest congressional intent. 944 A.2d at 184.
The court analyzed the FDCA and focused on Section 314.70(c) which allows manufacturers to
unilaterally strengthen warnings. Id. at 186.
37 Id. at 186 (stating § 314.70(c) encourages manufacturers to strengthen warnings insufficient to
protect consumers). The court states: "Section 314.70(c) allows, and arguably encourages,
manufacturers to add and strengthen warnings that, despite FDA approval, are insufficient to
protect consumers. State tort claims simply give these manufacturers a concrete incentive to take
this action as quickly as possible." Id. In its decision, the court relied heavily on McNellis. Id. at
because there is no conflict between the state common-law causes of action and the FDA regulations there is no preemption.\textsuperscript{38} Additionally, the Vermont Supreme Court reviewed how other jurisdictions treated the matter and noted that the majority of jurisdictions held that state claims were not preempted.\textsuperscript{39} The court affirmed the lower court's ruling for Levine and asserted that state failure-to-warn claims do not offend the Supremacy Clause of the Constitution and, therefore, are not preempted by FDA regulations.\textsuperscript{40}

The Levine court's sound decision rested upon a foundation of legislative history, case law, and traditional principles of federalism despite newly promulgated FDA rules and the reversal of a case heavily relied upon by Levine majority.\textsuperscript{41} The court handily dismissed Wyeth's claims that the FDCA and subsequent FDA regulations either expressly preempted state laws or preempted them implicitly by "occupying the field."\textsuperscript{42} While in both its 2006 regulations and its amicus curiae briefs, the FDA declares that its drug approval process preempts state claims,\textsuperscript{43} the court properly dismissed the

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185, 186 (referencing McNellis claim that § 314.70(c) allows drug manufacturers to comply with both federal and state regulations). The Vermont Supreme Court in Levine, citing McNellis, states: "While specific common-law duties might otherwise leave drug manufacturers with conflicting obligations, § 314.70(c) allows manufacturers to avoid state failure-to-warn claims without violating federal law." \textit{Id.} See also McNellis, 2005 WL 3752269 at *5. McNellis has since been reversed by Colacicco. See supra note 26 and accompanying text.

\textsuperscript{38} 944 A.2d at 186 (declaring no conflict between federal leveling requirements and state failure-to-warn claims).


\textsuperscript{40} 944 A.2d at 196 (affirming lower court decisions).

\textsuperscript{41} See supra notes 26 and 37 and accompanying text (explaining Colacicco's overturning of McNellis).

\textsuperscript{42} See supra notes 23 and 24 and accompanying text (describing field preemption). While Wyeth did not argue that there was express preemption, had it done so, this would have been easily dismissed by applying rules of basic statutory construction; while Congress included an express preemption clause in the MDA it failed to do so in the FDCA. See supra note 30 and accompanying text. Additionally, the requirement for express preemption under Cipollone is the manifest intent of Congress. See supra note 26 and accompanying text.

\textsuperscript{43} Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3933-36 (asserting FDA regulations preempt state common-law claims).
FDA's assertions on two grounds: 1) the *Chevron* doctrine gives deference to an agency's interpretation but does not bind the judiciary, and 2) the FDA's assertion does not alter the language of the regulation but instead usurps the courts' role in interpreting statutory construction. Finally, Congress's silence in the face of at least a dozen states allowing tort claims against drugs with FDA-approved labels over the last seven decades indicates that Congress did not intend the FDCA to "occupy the entire field;" *Qui tacet consentit.*

Whether compliance with state common-law makes it impossible to comply with FDA regulations is the much more difficult question that the court addressed. The issue is complicated by 21 C.F.R. § 314.70(c), which allows the drug manufacturer to strengthen warnings. The FDA now declares that its approved label is not, as held by several courts, a minimum safety standard but is instead both "a 'floor' and a 'ceiling' such that additional disclosures of risk information can expose a manufacturer to liability under the act." Despite this contention, 21 C.F.R. § 314.70(c) is clear on its

In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act. A manufacturer may, under FDA regulations, strengthen a labeling warning, but in practice manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree (and that therefore might subject the manufacturer to enforcement action).

See supra note 27 and accompanying text (explaining the "Chevron Doctrine").

See 944 A.2d at 193 (stating there is no change in regulation that prevents compliance with both state and federal regulations). See supra note 43 and accompanying text (stating only alteration to 21 C.F.R. § 314.70 is that changes to the newly added "Highlights" section of a drug label may not be made without prior FDA approval). See 71 Fed. Reg. 3922, 3934.

Commonly translated as: Silence implies consent, or, he who is silent seems to consent.

See 944 A.2d at 187 (dismissing Wyeth's contention that compliance with state common law duty to warn made compliance with FDA regulations impossible).

See supra note 29 and accompanying text.


face that strengthening the warning is contemplated and permissible, policy statements notwithstanding. Unless Congress or the FDA changes or deletes the provision, 21 C.F.R. § 314.70(c) allows drug manufacturers to strengthen warnings to comply with both FDA regulations and state laws. Indeed, as the FDA is largely dependent on drug manufacturers for information regarding side-effects and dangers, state tort actions actually bolster FDA regulations by publicizing potential dangers and providing an incentive to inform the FDA of new post-approval information.

By ruling that FDA regulations did not preempt state tort claims in Vermont, the Levine court created a controversy that has necessitated the intervention of the Supreme Court, which granted a petition for writ of certiorari and intends to hear this case.

51 See 21 C.F.R. § 314.70(c).
52 Only one case was cited by the FDA as an example of a state law complying with FDA regulations impossible. See Dowhal v. Smithkline Beecham Consumer Healthcare, 88 P.3d 1, 15 (2004) (holding state mandated warning conflicted with FDA regulations and was thus preempted). In this case, California passed a voter initiative which mandated a specific statutory warning be placed on any product that could cause birth defects. Id. However, the case dictated a specific warning which in the case of the specific drug at hand would have effectually been a weakening of the FDA approved label. Id. Thus, while this is a case where a state mandated warning conflicted with FDA regulations and was correctly preempted, it does not follow that all state mandated warnings will conflict with FDA regulations. Id. Nor does the case deal with common-law failure-to-warn causes of action. See Id. See also 21 C.F.R. § 314.70(c).
53 See generally Mary J. Davis, The Battle Over Implied Preemption: Products Liability and the FDA, 48 B.C. L. REV. 1089, 1153 (2007) (arguing state claims are necessary to ensure manufacturers provide correct information to FDA). In this article, Mary J. Davis, J.D., Stites & Harbison Professor of Law, University of Kentucky College of Law argues:

The FDA's final argument that its regulations provide optimal, not minimum, standards is inconsistent with the regulatory scheme it administers. The unilateral obligation of manufacturers to alter warnings when substantial risk information comes to them and the FDA's inability to require postmarketing trials to obtain risk information substantially undercut any argument that the labeling regulation was intended to provide a maximum standard of care. In the case of prescription drug labeling, there is unlikely ever to be full information of risk on which to base the conclusion that any labeling should be considered a maximum, or optimal, one, frozen for all time with only the regulated industry with an incentive to shed additional light.

Id.
54 See Sup. Ct. R. 10 (explaining grounds upon which the Court will grant certiorari and review case). Appeal to the Supreme Court is not a matter of right but of discretion to be granted only for compelling reasons including 1) a United States court of appeal has entered a decision in conflict with the decision of a state court of last resort or vice versa or 2) a court has decided an
case in November, 2008. While predicting how the individual Supreme Court Justices will rule is a highly risky proposition, recent cases indicate how the Supreme Court might treat the Levine decision. For example, in Riegel v. Medtronic, the majority of the Court was divided and ambiguous about the potential for preemption absent an explicit preemption provision. Affirming Levine will preserve the status quo and force drug manufacturers to order different warning labels for their products in different jurisdictions or unilaterally strengthen warnings to avoid common-law tort liability in all jurisdictions. Alternatively, reversing Levine will severely curtail an entire class of important question of federal law that has not been but should, in the opinion of at least four Supreme Court Justices, settled by the Court. Id. Since the 3rd Circuit Court of Appeals in Colaco has ruled on the same question of law in a way contrary to the Vermont Supreme Court's ruling in Levine, and there is disagreement among the states as to how this question should be answered, Rule One supra appears to be met. See supra note 25 and accompanying text. Additionally, the scope of the Supremacy Clause and the ability of federal agencies such as the FDA to preempt state claims may satisfy Rule Two supra and be considered “an important question of federal law.” See supra note 20 and accompanying text.


56 See Exxon Shipping Co. v. Baker, 128 S. Ct. 2605, 2609 (2008) (holding Clean Water Act's penalties for water pollution did not preempt maritime common law); Contra Riegel, 128 S. Ct. at 1001 (holding FDA preempted state common-law claims of negligence). As noted above, the MDA contains an express preemption provision. See supra note 30 and accompanying text. However, the FDCA contains no preemption clause, and thus the Court's interpretation of §360k(a) has no bearing on tort suits involving drugs and additives. Riegel, 128 S. Ct. at 1016.

57 See Riegel, 128 S. Ct. at 1001 (denying dissent's claim that it is established that no tort lawsuits are preempted by FDA approval). The relevant language in the decision is as follows:

The dissent also describes at great length the experience under the FDCA with respect to drugs and food and color additives. Post, at 1016 1018. Two points render the conclusion the dissent seeks to draw from that experience-that the pre-emption clause permits tort suits-unreliable. (1) It has not been established (as the dissent assumes) that no tort lawsuits are pre-empted by drug or additive approval under the FDCA. (2) If, as the dissent believes, the pre-emption clause permits tort lawsuits for medical devices just as they are (by hypothesis) permitted for drugs and additives; and if, as the dissent believes, Congress wanted the two regimes to be alike; Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices.

Id.

plaintiffs' right to recourse because their claims will be precluded as a matter of law and could impact other types of claims as well.\textsuperscript{59}

In \textit{Levine}, the Vermont Supreme Court decided that FDA labeling requirements do not preempt an injured patient's state law claim for failure-to-warn product liability. The court accurately resolved the issue in a manner consistent with judicial precedent, legislative history, and basic principles of federalism. Because there is no cause of action open to someone injured as the result of an inadequate but FDA-approved warning label and considering the fact that the FDA is still largely dependant on information provided to it by the manufacturer, preempting state common-law failure-to-warn claims would leave an entire class of plaintiff without recourse.\textsuperscript{60} This could lead to less safe drugs by removing a major incentive for drug companies to report potentially important information to either patients or the FDA.\textsuperscript{61} Finally, health and safety has traditionally been considered part of the states' police-powers since the founding of the Republic and the attempts of a federal agency to encroach on the traditional legal territory of the states should only occur with the manifest consent of the Congress which is clearly not indicated here.\textsuperscript{62} Therefore, the Vermont Supreme Court correctly decided that state failure-to-warn claims neither act as a substantial obstacle to the FDCA nor prohibit compliance with both the state common-law and FDA regulations.

\textsuperscript{59} See id. (predicting potential impact of \textit{Levine} on smoking/lung-cancer suits).
\textsuperscript{60} See supra notes 26-30 and accompanying text. See generally Catherine M. Sharkey \textit{Preemption by Preamble: Federal Agencies and the Federalization of Tort Law}, 56 DEPAUL L. REV. 227 (2007) (arguing preemption will lead to reduced individual rights and causes of action). Professor Sharkey, Professor of Law, Columbia Law School; Visiting Professor of Law, Harvard Law School (Spring 2007) argues:

Agency preemption preambles represent the latest manifestation of a broader trend of the increasing federalization of law governing products regulated in a national market. This inexorable momentum towards federalization raises a potentially troublesome asymmetry with respect to agency decisionmaking: courts appear to grant agencies expansive discretion to interpret or declare the preemptive scope of the regulations they promulgate, whereas agencies are not given corresponding latitude to infer private rights of action under those same regulations.

\textit{Id} at 258.

\textsuperscript{61} See supra note 53 and accompanying text.
\textsuperscript{62} See supra notes 20–22 and accompanying text.