

**Federal preemption in the non-drug context after *Wyeth v. Levine***

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The Supreme Court's 6-3 decision in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), rejected implied conflict federal preemption in a state law failure to warn pharmaceutical lawsuit absent "clear evidence" the Food and Drug Administration (FDA) would not have permitted a stronger warning of the risk. The Court's reasoning in *Levine* in many respects seemed directly contrary to the rationale eight Justices signed onto only a year earlier in the Medical Device preemption case of *Riegel v. Medtronic*, 128 S.Ct. 999 (2008).

*Riegel* of course involved the Medical Device Amendments Act (MDA), which contains an express preemption provision, whereas the Food, Drug, and Cosmetic Act (FDCA) at issue in *Levine* contains no such express preemption provision. But by the express terms of the MDA preemption provision, preemption exists only when there is a conflict between ("different from, or in addition to") the federal and state regulatory schemes -- not terribly distant in concept from the background pre-*Levine* established implied conflict preemption principles.

Although much will be written on whether *Levine* fundamentally reshapes the legal landscape of implied conflict preemption, this short paper surveys the recent caselaw involving Medical Devices and Vaccines -- both of which involve express preemption statutory provisions -- to determine if the policy rationale articulated in the *Levine* majority (but

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thoroughly rejected by eight Justices in *Riegel*) has influenced courts to be more restrictive in the way they have applied preemption in those express preemption settings.

## I. OVERVIEW OF PREEMPTION PRINCIPLES

The federal preemption doctrine arises from the Supremacy Clause of the Constitution, U.S. const. art. VI, cl.2, and federal legislation may expressly or impliedly preempt state law. *See, e.g., Fidelity Fed. Sav. & Loan Ass'n v. De la Cuesta*, 458 U.S. 141, 152–53 (1982). Although the Court has been less than uniform in its application of core principles, the Court has said that the intent of Congress is the “ultimate touchstone” of the inquiry. *Medtronic Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 (1963)). At times, the Court has also applied a presumption against preemption where Congress has legislated in a field traditionally occupied by the states unless it was the “clear and manifest” purpose of Congress to preempt state law. *Id.* at 485 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

Express preemption exists where a congressional statute or federal agency regulation contains explicit language that it supersedes types of state law. *De la Cuesta*, 458 U.S. at 153. Even if the statute includes an express preemption provision, the scope and substance of the preemption still may be at issue. *Altria Group Inc. v. Good*, 129 S.Ct. 538, 543 (2008). Implied preemption sub-divides into conflict preemption and field preemption. *De la Cuesta*, 458 U.S. at 154. Conflict preemption further sub-divides into impossibility and obstacle preemption. For example, the Court in *Levine* held the federal statute at issue did not impliedly preempt state law because it was not impossible to comply with both federal and state law, nor was the state law an obstacle to the implementation of Congressional objectives. *Levine*, 129

S.Ct. at 1204. Field preemption exists where federal regulation is so pervasive that it occupies the entire field, leaving no room for state regulation. *Altria*, 129 U.S. at 543.

The implications of *Levine*, an implied preemption case, in the non-drug context are unclear and will be subject to much litigation in the coming years. This paper analyzes two major issues following *Levine* in the non-drug context: (i) first, the interplay between *Levine*, the express preemption provisions in the Medical Device Amendments Act of 1976 (MDA), 21 U.S.C. § 360c, *et seq.* and pending congressional bills; and (ii) second, the impact of *Levine* on the express preemption provisions in the National Childhood Vaccine Injury Act of 1986 (the Vaccine Act), 42 U.S.C. § 300aa-1 *et seq.*

## **II. MEDICAL DEVICES**

Unlike the FDCA at issue in *Levine*, the MDA expressly preempts state law claims for certain medical devices. The Supreme Court confirmed express, federal preemption of state law claims in *Riegel v. Medtronic*, 128 S.Ct. 999 (2008). Subsequently, Democratic members in both the Senate and the House of Representatives have introduced bills to legislatively reverse *Riegel* and the express preemption provisions of the MDA.

### **A. Overview of the Medical Device Amendments Act**

Congress enacted the MDA to impose federal oversight over a haphazard state supervision process. Prior to the MDA, each state supervised medical devices as it saw fit; the MDA introduced uniformity into this process by classifying devices according to their risk. *See Riegel*, 128 S.Ct. at 1003–04. Under the MDA, medical devices are subject to three classifications and regulated accordingly. Class I devices require the least and most general oversight. 21 U.S.C. § 360c(a)(1)(A). Class II devices are reviewed according to more stringent “special controls,” such as performance standards. *Id.* § 360c(a)(1)(B). Finally, Class III

devices receive the most oversight and require rigorous premarket review and approval. *Id.* § 360c(a)(1)(C)(ii). Once a device obtains premarket approval, the manufacturer cannot make changes in design specifications, manufacturing processes, labeling, or any other feature that would affect safety or effectiveness without prior FDA approval. *Id.* § 360e(d)(6)(A)(i).

In response to the thousands of tort claims over medical devices that arose in the 1970s and 1980s, and in recognition of the exacting pre-approval process, Congress included an express preemption provision in the MDA for Class III devices. *Id.* § 360(k)(a). The provision preempts state or local requirements “different from, or in addition to, any requirement applicable . . . to the device” under federal law and “which relate[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device . . . .” *Id.*<sup>†</sup>

## **B. *Riegel* and Its Progeny**

The Supreme Court applied the MDA preemption provision in *Riegel v. Medtronic*, holding that federal law preempted a state law claim alleging the device was designed, labeled, and manufactured in violation of New York common law. *Riegel*, 128 S.Ct. at 1010. In an 8-1 decision, the Court confirmed that the MDA preemption means what it says: premarket approval imposes federal requirements on medical device manufacturers, and federal law preempts state laws or actions that seek to impose requirements different from or in addition to those requirements. *Id.* at 1006–07, 1010. The overarching questions for subsequent cases therefore are whether: (1) the FDA has established federal requirements that apply to the device

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<sup>†</sup> The full text of § 360(k)(a) reads:

(a) General Rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

(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.

in question, and (2) the asserted claims are based on state requirements “that are different from, or in addition to the federal ones, and that relate to safety and effectiveness.” *Id.* (internal quotations omitted). Although *Riegel* left openings for medical device plaintiffs, courts generally have been reluctant to entertain state law claims in light of the MDA’s express preemption provision unless the manufacturer violated federal regulations.

### **1. Parallel Requirements**

First, the premarket approval process leaves open the “parallel requirements” loophole. The opinion in *Riegel* noted that a state may provide a damages “remedy for claims premised on a violation of FDA regulations [because] state duties in such a case ‘parallel,’ rather than add to, federal requirements.” *Riegel*, 128 S.Ct at 1011. To satisfy a parallel requirements claim, the state affirmatively must provide a damages remedy for recovery under state law if the plaintiff can prove violation of a federal requirement caused an injury. *See, e.g., Bausch v. Stryker Corp.*, No. 08-C-4248, 2008 WL 5157940, at \*5–6 (N.D. Ill. Dec. 9, 2008) (holding that common law negligence claims cannot escape preemption simply by including allegations that FDCA regulations were violated). Thus, the plaintiff first must prove the manufacturer violated a specific federal regulation. *See, e.g., Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301–02 (D. Colo. 2008) (granting motion to dismiss because plaintiff failed to plead particularized facts regarding violations). In some instances, a violation may never be found if the federal regulation is too general to violate. *See In re Medtronic*, 592 F. Supp. 2d 1147, 1157–58 (D. Minn. 2009) (granting motion to dismiss because the plaintiff did not allege specific violations of FDA regulation, and plaintiffs *could not* allege specific violations given the generality of regulations). Second, the plaintiff must prove the specific violation in fact caused the injury. *See, e.g., Heisner v. Genzyme Corp.*, No. 08-C-593, 2009 WL 1210633, at \*2 (N.D. Ill. Apr. 30, 2009)

(granting motion to dismiss because events for a per se negligence claim post-dated, and therefore could not have caused, plaintiff's injury); *Horowitz v. Stryker Corp.*, No. CV-07-1572(DGT), 2009 WL 436406, at \*6, \*8 (E.D.N.Y. Feb. 20, 2009) (granting motion to dismiss because plaintiff failed to plead how a particular violation caused an injury). Overall, courts have been extremely reluctant to entertain parallel requirements claims. *See, e.g., Mattingly v. Urologix Inc.*, No. 07CI12014, 2008 WL 3895381 (Ky. Cir. Ct. July 7, 2008) (holding federal preemption because plaintiff failed to prove any parallel violation claims); *Troutman v. Curtis*, 185 P.3d 930, 935 (Kan. 2008) (holding that lower court did not abuse its discretion by denying plaintiffs more time and granting motion to dismiss even though plaintiffs complaint was minimally adequate to sustain a non-preempted claim); *cf. Walker v. Medtronic, Inc.*, No. 2:07-00317, 2008 WL 4186854, at \*3 (S.D. W. Va. Sept. 9, 2008) (holding that complaint did not sufficiently plead parallel violation claims, but allowing amended complaint).

## **2. Manufacturing Defects**

Courts have been more willing to allow claims based on allegations that a manufacturer deviated from a federally-approved manufacturing process. *See, e.g., Kavalir v. Medtronic, Inc.*, No. 07-CV-0835, 2008 WL 4087950, at \*4 (N.D. Ill. Aug. 27, 2008) (allowing manufacturing defect claim because defendants did not establish conclusively that products had premarket approval). This violation may serve as the basis for a parallel requirements claim. *See, e.g., Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 836–37 (S.D. Ind. 2009) (allowing parallel requirement claim that alleges defendant failed to comply with federal manufacturing requirements); *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790, 799 (W.D. La. 2008) (same).

Importantly, however, the mere fact of product recall following premarket approval does not revoke the manufacturer's prior compliance with premarket approval. Therefore, a claim based on subsequent recall does not escape preemption. *See, e.g., In re Medtronic*, 593 F. Supp. 2d at 1155 (noting distinction between a device recall and complete revocation of premarket approval). Similarly, supplemental approval does not diminish the preemptive effect of the initial approval and also is entitled to preemptive effect. *See, e.g., Riegel*, 128 S.Ct. at 1005 (holding preemption where device received premarket approval and two supplemental approvals); *Blunt v. Medtronic*, 760 N.W.2d 396, 407 (Wis. 2009) (affirming preemption and holding supplemental approvals deserved equal preemptive effect).

### **3. Fraud on the FDA**

Plaintiffs often claim that the manufacturer misled the FDA during the premarket approval process, though courts have nearly uniformly rejected these types of claims. In *Buckman v. Plaintiffs Legal Commission*, 531 U.S. 341 (2001), the Court held that federal law preempts fraud-on-the-FDA claims. The Court reasoned that only the FDA may enforce obligations owed by a manufacturer to the FDA; private plaintiffs cannot interfere in this relationship. Following this reasoning, courts have held that federal law preempts claims where a plaintiff alleges the manufacturer was not truthful to the FDA. *See, e.g., McCutcheon v. Zimmer Holdings Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008) (finding preemption under *Buckman* where plaintiff alleged manufacturer did not honestly disclose all risks to the FDA); *Johnson v. Endovascular Tech. Inc.*, No. 1-05-CV-037784, 2008 WL 3139424 (Cal. App. Dep't Super. Ct. May 19, 2008) (finding preemption under *Buckman* where plaintiff alleged manufacturer did not adequately test and warn of risks prior to FDA approval); *McGuan v.*

*Endovascular Tech. Inc.*, No. 1-04-CV-025603, 2008 WL 3139418 (Cal. App. Dep't Super. Ct. May 19, 2008) (same).

### C. Congressional Response to *Riegel*: The Medical Device Safety Act

The *Levine* Court places near talismanic reliance on the fact that the FDCA regulating pharmaceuticals contains no preemption provision, while the MDA regulating medical devices does. *See Levine*, 129 S.Ct. at 1196 (“And when Congress enacted an express preemption provision for medical devices in 1976 . . . it declined to enact such a provision for prescription drugs.”). Some Democratic members of Congress now have sought to revoke the express preemption provision in the MDA, effectively overruling *Riegel*, in the Medical Device and Safety Act, S. 540, 111th Cong. (2009); H.R. 1346 111th Cong. (2009). Specifically, the Act would eliminate § 360(k) preemption for suits seeking damages for injuries by plaintiffs.

Proponents of the Act argue that it would align drug and medical device manufacturer liability because, under the current system, drug makers can be sued in state courts under *Levine* whereas medical device makers cannot under *Riegel*. *See, e.g., The Medical Device Safety Act of 2009: Hearings on H.R. 1346 Before the H. Subcomm. on Health*, 111th Cong. 23–24 (2009) (testimony of David C. Vladeck, Professor of Law, Georgetown University Law Center). As a practical matter, however, only about one percent of medical devices are subject to Class III premarket approval and therefore preemptive protection. *See U.S. Gen. Accounting Office, Medical Devices: FDA Should Take Steps to Ensure that High-Risk Device Types Are Approved through the Most Stringent Premarket Review Process* 8–9, (Jan. 2009). Tort litigation is still open to the vast number of medical device litigants who seek redress through the courts; thus, liability is aligned in the vast majority of medical device and drug cases.

*See The Medical Device Safety Act of 2009: Hearings on H.R. 1346 Before the H. Subcomm. on Health*, 111th Cong. 8 (2009) (testimony of Richard M. Cooper, former Chief Counsel, FDA).

Supporters of the Act also contend that the Supreme Court decided *Riegel* on a point of statutory law rather than in the interests of public health. *See* Gregory D. Curfman et al., *The Medical Device Safety Act of 2009*, 360 N.E. J. Med. 1550 (2009). Congress, however, enacted the MDA in the interests of public health to prevent and avoid unpredictable safety requirements and open-ended liability. Congress determined the FDA is in a better position to balance the costs and benefits of life-saving medical devices than the courts of fifty states. *See generally The Supreme Court 2007 Term —Leading Cases*, 122 Harv. L. Rev. 405, 410–15 (2008). If regulations are too stringent and too few devices are allowed on the market, then patients who would have benefited from the device bear the cost. If regulations are too lax, then patients who suffer from unsafe devices bear the cost. The jury only hears the latter story, whereas the FDA hears both. *See Riegel*, 128 S.Ct. at 1008.

The bills currently remain in the Senate Committee on Health, Education, Labor and Pensions and the House Subcommittee on Health. Similar legislation failed to pass in the last session, though the prospects for both bills have improved with the Democrats' gains in the recent election. *E.g.*, Jonathan D. Rockoff, *Dems Move to End Pre-Emption of Medical-Device Lawsuits*, Wall St. J., Mar. 5, 2009.

### **III. VACCINES**

Like the MDA, the Vaccine Act contains an express preemption provision. The vast majority of courts have held that this provision expressly preempts state law claims for vaccine-related injuries. In a recent controversial decision, however, the Georgia Supreme Court ruled that such claims can avoid preemption under the Act.

## **A. Overview of the Vaccine Act**

Congress enacted the Vaccine Act to promote use of vaccines and prevent infectious diseases while compensating individuals who suffer adverse reactions to a vaccine. Legislators sought to achieve this goal in a two-pronged strategy. First, the Vaccine Act created the National Vaccine Injury Compensation Program (NVICP) to compensate individuals for vaccine-related injuries and deaths. 42 U.S.C. § 300aa-11–21. Second, Congress included an express federal preemption provision in § 300aa-22(b)<sup>‡</sup> to maintain a healthy and immunized population. Prior to the Vaccine Act, the rapid increase in tort claims against vaccine manufacturers increased the cost of vaccines, reduced the number of manufacturers in the market, and resulted in an overall decrease in the rate of immunization. H.R. Rep. No. 99-108, at 4–5 (1986). As a result of the federal NVICP remedy and congressional intent against state tort suits, courts generally interpret § 300aa-22(b) to preempt all product liability claims against manufacturers of FDA-approved vaccines.

## **B. Majority Approach**

State and federal courts have nearly uniformly found federal preemption under the Vaccine Act. *See, e.g., Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289, 300–03 (E.D. Pa. 2007) (holding that Vaccine Act expressly preempts strict liability and negligent design defect claims);

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<sup>‡</sup> § 300aa-22(b) reads:

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 *et seq.*] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa-23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

*Blackmon v. Am. Home Prod. Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004) (granting motion for summary judgment on design defect and failure-to-warn claims because § 300aa-22(b) “shows Congress’s intent to foreclose all design defect claims against vaccine manufacturers”); *Militrano v. Lederle Labs*, 810 N.Y.S.2d 606 (N.Y. App. Div. 2006) (holding that Vaccine Act expressly preempted state law design defect claim). For instance, in *Wright v. Aventis Pasteur, Inc.* No. 3861, 2008 WL 4144386 (Pa. Com. Pl. Aug. 27, 2008), the court affirmed summary judgment and held that the Vaccine Act preempted defect and failure-to-warn claims. In support of its motion, the defendants relied on FDA approvals and licenses and FDA-approved labeling. Plaintiffs argued that the defendants must show the injuries were an unavoidable result of the vaccine before preemption would be available because of the general presumption against preemption. The court squarely rejected this case-by-case determination, and instead held the plaintiffs bore the burden of demonstrating (1) the defendants “engaged in fraud or intentional and wrongful withholding of information from the FDA while seeking approval of the vaccine,” (2) the defendants engaged in “intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval,” or (3) by “clear and convincing evidence” show that the defendants failed to exercise “due care notwithstanding its compliance with the applicable federal laws and regulations.”

Even after *Levine*, the Third Circuit held § 300aa-22(b) expressly preempts state law claims against vaccine manufacturers for vaccine-related injuries. *Bruesewitz v. Wyeth*, 561 F.3d 233 (3d. Cir. 2009). The court first held the plain language of the statute “conveys a clear intent to override state law civil action claims.” *Bruesewitz*, 561 F.3d at 243. The court then relied on congressional purpose as the “ultimate touchstone” to resolve the ambiguous scope of the preemption. *Id.* (quoting *Lorillard Tobacco Co.*, 533 U.S. 525, 541 (2001)). The scope of

preemption hinged on the meaning of “if the injury or death resulted from side effects that were unavoidable . . . .” *Id.* at 245 (quoting § 300aa-22(b)).

The court focused on a House Committee on Energy and Commerce Report (Commerce Report) because that committee had jurisdiction over the Vaccine Act and guided its passage through Congress. The Commerce Report revealed the Committee acknowledged there was “no ‘perfect’ or reaction-free childhood vaccine on the market”; thus, it sought to compensate individuals harmed by the vaccines but simultaneously stressed reducing the cost of such claims to encourage the development and availability of such helpful vaccines. *Id.* at 247 (quoting H.R. Rep. No. 99-108, at 7 (1986)). In short, the Committee sought to balance the competing interests of general public health and individual harm. Moreover, the Commerce Report was aware the Vaccine Act would “change most State laws,” but determined that result would be acceptable to keep manufacturers in the marketplace, and by extension, ensure a well-immunized population. Finally, the Commerce Report relied on the principle of the Restatement (Second) of Torts, § 402A comment k,<sup>§</sup> which states that manufacturers, including of vaccines, should not be subject to strict liability when it is not possible to make their products entirely safe.

In light of the legislative history, the “ultimate touchstone” of the preemption inquiry, and the clear legislative language, both state and district courts across the country have

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<sup>§</sup> Restatement (Second) of Torts § 402A comment k (1966) reads:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. . . . An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to both serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

found the Vaccine Act expressly preempts state law claims against vaccine manufacturers for vaccine-related injuries.

## **2. Georgia Supreme Court Decision**

In contrast to *Bruesewitz* and *Wright*, the Georgia Supreme Court held last year in *American Home Products Corp. v. Ferrari*, 668 S.E.2d 236 (Ga. 2008) that the “Vaccine Act does not preempt all design defect claims, but instead provides that a vaccine manufacturer cannot be held liable for defective design if it is determined, *on a case-by-case basis*, that the injurious side effects of the particular vaccine were *unavoidable*.” *Ferrari*, 668 S.E.2d at 237–38 (emphasis added). Although the court recognized § 300aa-22 provided for express preemption, the court read the Act to require (1) a demonstration that the vaccine’s side effects were “unavoidable,” and (2) that preemption is *disfavored* where a different statutory interpretation may exist. *Id.* at 242.

In its post-*Levine* decision, the Third Circuit in *Bruesewitz* squarely rejected this approach because each of the legislative objectives of the Vaccine Act would be undermined if such claims were permitted to survive under state law. A case-by-case determination would undermine a manufacturer’s ability to predict and estimate costs. Vaccine manufacturers also would be forced to pursue every potential alternative for safer vaccines, regardless of cost. The problems that would result from this case-by-case interpretation are precisely the types of problems that Congress sought to correct and prevent with the Vaccine Act. *Bruesewitz*, 561 F.3d at 249.

## **C. Impact of *Levine* on Vaccine Act Cases**

The court in *Bruesewitz* specifically distinguished *Levine* on two grounds. First, Congress included an express preemption provision in the Vaccine Act, whereas it did not in the

FDCA. *Bruesewitz*, 561 F.3d at 246 n.8. Second, a drug manufacturer may strengthen a drug label without pre-FDA approval, in contrast to more extensive control and oversight of a drug’s design and alteration. *Id.* Extensive control and oversight may provide the “clear evidence” needed to overcome *Levine*’s strict presumption against preemption.

Furthermore, the Vaccine Act provides a federal remedy, the NVICP, to compensate individuals for vaccine-related deaths and injuries, whereas the FDCA does not. Under the NVICP, the individual simply goes to “Vaccine Court” to prove that the vaccine caused the injury to receive compensation; there is no determination of fault or liability, so the process is faster and less costly than a traditional tort suit. *See Bruesewitz*, 562 F.3d at 235–36. Writing for the majority in *Levine*, Justice Stevens stressed that the FDCA was meant to bolster, not supersede, state consumer protection law because Congress did not provide a federal remedy for consumers who were harmed by unsafe drugs. *Levine*, 129 S.Ct. at 1199–200. The NVICP therefore is further evidence that Congress intended the Vaccine Act to preempt state claims.

The Supreme Court may resolve this issue shortly. The defendants in *Ferrari* recently submitted a petition for certiorari for the Court to resolve the conflict between the Georgia Supreme Court decision and other courts. Petition for Writ of Certiorari, *Am. Home. Prod. Corp. v. Ferrari*, No. 08-1120, 2009 WL 598046 (Mar. 5, 2009). The central conflict is whether the “unavoidable” injury language allows liability for design defect claims, or whether, as the majority of courts have held, the preemption clause preserves limited state remedies only if the vaccine was not made according to FDA-approved formulas or that does not provide proper warnings and directions for use.\*\* *Id.* at 11. Much like the opinion in *Bruesewitz*, the petitioners argue that the Georgia Supreme Court’s decision invites an onslaught of litigation of

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\*\* The Vaccine Act explicitly provides a presumption that FDA-approved warnings and directions for use are adequate. 42 U.S.C. § 300aa-22(b)(2).

the magnitude that compelled Congress to adopt the Vaccine Act. *Id.* at \*2. Moreover, the specter of liability threatens the supply of vaccine and development of new or improved vaccines. *Id.* at \*19-25.

At the time petitioners filed the writ of certiorari, the split remained between the Georgia Supreme Court and lower federal and state courts. *Id.* at \*28. Since then, the conflict has become even more pronounced and pressing—and the type the Court prefers to hear—because *Bruesewitz*, a federal court of appeals case, has joined the debate.

#### **IV. CONCLUSIONS**

On one level, Justice Stevens’s opinion in *Levine* seems to endorse the proposition that Congress’s “intent” to preempt only can be inferred by the inclusion of an express preemption provision. Surely, that extreme position cannot be the law, for it would eviscerate decades of jurisprudence on implied conflict preemption, something the Court did not purport to do. But the *Levine* Court’s decision to resurrect and reinvigorate the oft-ignored presumption against preemption makes it more likely that future preemption litigation will focus on statutory interpretation of express preemption provisions. The *Levine* Court demonstrably relies on the presumption against preemption as a way to bolster its outcome to avoid implied preemption, but the analytical weight the Court places on this presumption is remarkable and could do great damage to future preemption litigation. Although courts have been commendably resistant to creative tactics by Plaintiffs to avoid the strong express preemption provisions in the MDA and the Vaccine Act, an unrestrained “presumption against preemption” as a canon of statutory construction provides, as the Georgia Supreme Courts ruling in *Ferrari* shows, a powerful tool that an outcome-determinative court could leverage to emasculate otherwise duly-enacted and appropriate express preemption provisions. Hopefully, the Supreme Court will

correct this overreaching by the *Ferrari* court, signaling to future courts to resist this similar temptation.