

Contagious Trend or Isolated Outbreak?

By Sean W. Shirley  
and Jeremy W. Gregory

**An analysis of Vaccine Act preemption, U.S. Supreme Court preemption decisions, and the reasoning behind Georgia's high court's holding against preemption in design defect claims.**

# Manufacturers No Longer Immunized in Georgia

Federal preemption, particularly in the area of pharmaceuticals and medical devices, has become a hot button issue in recent years. The United States Supreme Court's most recent preemption decision held that federal law

preempted common law claims challenging the safety and effectiveness of a medical device. The Court is currently considering the scope of FDA preemption in the prescription drug context. *Wyeth v. Levine*, 128 S. Ct. 1118 (2008). Similarly, many state high courts have ruled that other federal laws preempt state common law claims in a variety of contexts. Several federal district and state courts have found that the National Childhood Vaccine Injury Compensation Act of 1986 (Vaccine Act) preempts state law defective design claims directed toward manufacturers, as discussed below. Recently, the Georgia Supreme Court deviated from this line of authority, holding that defective design claims are not preempted by the Vaccine Act, 42 U.S.C.S. §§300aa-1 *et seq.* *Ferrari v. American Home Products Corp.*, 2008 Ga. LEXIS 833, \*18 (October 6, 2008) (*Ferrari II*) (affirming *Ferrari v. American Homes Products Corp.*, 286 Ga. App. 305, 305, 650 S.E.2d 584, 586-587 (2007) (*Ferrari I*)).

This article provides (1) a brief overview of the Vaccine Act, (2) analysis of the case law dealing specifically with Vaccine Act preemption, (3) an analysis of recent United States Supreme Court preemption decisions in the context of product liability claims generally, and (4) analysis of the reasoning of the Georgia Supreme Court and the Georgia Court of Appeals in holding that the Vaccine Act does not preempt state defective design claims. The conclusion addresses arguments that a defendant can make to distinguish the Georgia Court's holding in *Ferrari II*.

## The Vaccine Act

The Vaccine Act establishes a no-fault compensation system for those injured by childhood vaccines. 42 U.S.C.S. §§300aa-11, 300aa-12. Claims must be filed in the Court of Federal Claims, and the petitioner does not have to prove either fault or causation. Instead, the petitioner is compensated



■ Sean W. Shirley is a partner in the Birmingham, Alabama, office of Balch & Bingham LLP. As a member of the firm's litigation section, Mr. Shirley's practice concentrates on casualty litigation, including toxic and environmental torts, product liability, personal injury and wrongful death. Jeremy W. Gregory is an associate in the Atlanta office of Balch & Bingham LLP and a member of the firm's litigation section. His trial and appellate practice includes business disputes, real estate and construction litigation, product liability and employment matters.

if (1) it can be shown that he or she received a vaccine covered by the Vaccine Act, (2) it can be shown that he or she suffered injuries associated with that vaccine, and (3) it cannot be shown by a preponderance of the evidence that the injuries were not caused by the vaccine. Awards are paid from a fund financed by a tax on vaccines. 42 U.S.C.S. §300aa-15; 26 U.S.C.S. §9510. In improper warning and manufacturing defect cases, the petitioner has the option of rejecting the Court of Federal Claims' award and pursuing tort damages in a state court action. 42 U.S.C.S. §300aa-21.

For preemption purposes, the Vaccine Act's provides, in pertinent part:

- (a) Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.
- (b)(1) No Vaccine manufacturer shall be liable in a civil action for damages arising from 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.  
...
- (c) Direct warnings. 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 the effective date of this part [effective Oct. 1, 1988] solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.  
...
- (e) Preemption. No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this subtitle.

42 U.S.C. §300aa-22.

The drafters of the Vaccine Act relied heavily on The Restatement (Second) of Torts, §402A, Comment K, which provides:

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. These are especially common in the field of drugs.... 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.

*Id.*

This article focuses on the jurisdictional split regarding the preemptive power of the Vaccine Act and the meaning of "unavoidable" as used in (b)(1). For different reasons, both *Ferrari I* and *Ferrari II* held that the question of whether a vaccine was unavoidably unsafe must be determined by a jury on a case-by-case basis. *Ferrari II*, 2008 Ga. LEXIS 833 (2008); *Ferrari I*, 286 Ga. App. 305. Every other court to address this issue, however, held that vaccine-related tort claims are preempted by the Vaccine Act, and state courts were unauthorized to make such a case-by-case determination.

### Vaccine Act Jurisprudence before *Ferrari*

Before the Georgia Supreme Court's holding in *Ferrari II*, federal district and state courts in Pennsylvania, Texas, and New York found the Vaccine Act provides blanket preemption of any defective design claims under state law. See *Bruesewitz v. Wyeth, Inc.*, 508 F. Supp. 2d 430 (E.D. PA 2007) (residual seizure and developmental delay allegedly caused by thimerosal in TRI-IMMUNOL® vaccine); *Sykes v. Glaxo-SmithKline*, 484 F. Supp. 2d 289 (E.D. PA 2007) (neurological and neurodevelopmental injuries allegedly caused

by thimerosal in ante-partum injections of HypRho-D and direct vaccinations of ACEL-IMUNE®, HibTITER®, TETRAMUNE®, Engerix-B®); *Blackmon v. American Home Products Corp.*, 328 F. Supp. 2d 659 (S.D. TX 2004) (developmental injuries allegedly caused by thimerosal in various unlisted vaccines); *Miltrano v. Lederle Laboratories*, 769 N.Y.S.2d 839 (2003) (allergic

## Every other court to

address this issue, however, held that vaccine-related tort claims are preempted by the Vaccine Act.

reaction allegedly caused by diphtheria, tetanus, pertussis, and haemophilus b conjugate vaccination).

*Bruesewitz*, *Sykes*, *Blackmon*, and *Miltrano* expressly considered, and rejected, the case-by-case analysis now applied in Georgia. *Bruesewitz*, 508 F. Supp. 2d ("allowing case-by-case inquiries into whether a particular vaccine is unavoidably unsafe would do nothing to protect vaccine manufacturers from suit from design defects, since such an inquiry would require a finder of fact to consider the manufacturer's design against a purported safer alternative"); *Sykes*, 484 F. Supp. 2d at 301 ("the purposes of the Vaccine Act would not be served if defective design claims could be tried before juries"); *Blackmon*, 328 F. Supp. 2d at 665. ("to permit juries in each state to pass judgment on the design of childhood vaccines could interfere with the federal government's efforts to establish a uniform national standard for childhood vaccines"); *Miltrano*, 769 N.Y.S.2d at 845 ("Congress did not intend that the national vaccine policy be determined by the vagaries of a jury's determination on a case-by-case basis").

In reaching this conclusion, *Bruesewitz*, *Sykes*, *Blackmon*, and *Miltrano* relied on the legislative history of the Vaccine Act, each finding the following language determinative:

Vaccine-injured persons will now have an appealing alternative to the tort system. Accordingly, if they cannot demonstrate under applicable law either that a vaccine was improperly prepared or that it was accompanied by improper directions or inadequate warnings [they] should pursue recompense in the compensation system, not the tort system.

■ ■ ■ ■ ■  
**Although the Court's**  
two most recent  
preemption cases have  
divergent outcomes, the  
determinative factor is  
the statutory language.

Report of the Committee on Energy and Commerce, H.R. Rep. No. 99-908 at 26, reprinted in 1986 U.S. C.C.A.N. at 6367; *Brusewitz*, 508 F. Supp. 2d at 442; *Sykes*, 484 F. Supp. 2d at 302; *Blackmon*, 328 F. Supp. 2d at 664-665; *Miltrano*, 769 N.Y.S.2d at 845. The *Ferrari II* decision rejected this reasoning, and relied on different legislative history not expressly discussed by the other Vaccine Act cases.

### The Georgia Decisions

The Ferraris asserted strict liability and negligence claims, alleging their son suffered neurological damage caused by multi-dose vials of vaccines that were manufactured by defendants containing the preservative thimerosal. *Ferrari I*, 286 Ga. App. at 305. The trial court granted partial summary judgment in favor of the defendants, finding the plaintiffs' design defect claims were preempted by the Vaccine Act. *Id.*

The plaintiffs appealed to the Georgia Court of Appeals, arguing (1) design defect cases are barred by the Vaccine Act only if side effects are determined to be unavoidable on a case-by-case basis, and (2) in this case, their son's injuries could have been prevented if the defendant had used mercury-free preservatives, or man-

ufactured single dose vials. *Ferrari I*, 286 Ga. App. at 208. The defendants argued that any vaccine-related injury should be deemed unavoidable under the Vaccine Act, so long as the vaccine was properly prepared and accompanied by proper warnings. *Id.* The Georgia Court of Appeals agreed with the plaintiffs and held that *Bates v. Dow Agrosciences*, 544 U.S. 431, 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005), required it to "accept a reading [of the Vaccine Act] that disfavors preemption." *Ferrari I*, 286 Ga. App. at 312.

The Supreme Court of Georgia granted certiorari and affirmed, but on different grounds. The Georgia Supreme Court held that based on the text of the statute and an analysis of congressional intent, the Vaccine Act "clearly does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, *on a case-by-case basis*, that a particular vaccine was unavoidably unsafe." *Ferrari II*, 2008 Ga. LEXIS 833, \*18 (emphasis added).

The Georgia Supreme Court found the following legislative history particularly instructive:

[T]he codification of Comment (k) of The Restatement (Second) of Torts is not intended to decide as a matter of law the circumstances in which a vaccine should be deemed unavoidably unsafe. *The Committee stresses that there should be no misunderstanding that the Act undertook to decide as a matter of law whether vaccines were unavoidably unsafe or not. This question is left to the courts to determine in accordance with the applicable law.*

*Ferrari II* at \*16 quoting H.R. Rep. 1003-391 (I), at 691 (1987), as reprinted in U.S.C.C.A.N. 2313-1, 2313-365 (emphasis added). The other cases analyzing the Vaccine Act's preemptive power do not discuss this legislative history.

### U.S. Supreme Court Preemption Decisions

"Preemption analysis starts with the assumption that the historic police powers of the States [a]re not to be superseded... unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S. Ct. 1146,

91 L. Ed. 1447 (1947). This presumption is heightened with health or safety issues, as these are traditionally fields governed by state law. *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655, 115 S. Ct. 1671, 131 L. Ed. 2d 695 (1995); *Riegel v. Medtronic*, 128 S. Ct. 999, 1004 (2008). Despite this presumption, "[t]he purpose of Congress is the ultimate touchstone of pre-emption analysis." *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992). Although the United States Supreme Court has not yet addressed the preemptive power of the Vaccine Act, it has recently addressed preemption in product liability claims twice, and come to different conclusions based on the language of the statute at issue.

### Bates v. Dow Agrosciences

In *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005), the Supreme Court examined the preemptive power of the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C.S. §136 *et seq.* (FIFRA). FIFRA generally provides for federal regulation of covered pesticides, including registration and labeling requirements. *Bates*, 544 U.S. at 438. FIFRA's express preemption provision states:

(a) In general

A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this subchapter.

(b) Uniformity

Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter.

*Bates*, 544 U.S. at 439 (citing 7 U.S.C.S. §136v).

In response to a declaratory judgment action by Dow Agrosciences, the manufacturer of a particular pesticide, the Fifth Circuit held that any state law claim resulting in a judgment against the manufacturer that would have "induced it to alter its product label" was preempted by FIFRA. The Supreme Court disagreed, holding that state common-law defective design,

defective manufacture, negligent testing, and breach of express warranty claims were neither expressly nor impliedly preempted. *Id.* at 448. In support of this finding, the Court noted, “[a] requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.” *Id.* at 445. In reaching this conclusion, the Court noted it:

[H]ad a duty to accept a reading that disfavors preemption.... [B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state law causes of action. In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention clear and manifest.

*Id.* at 449 (internal citations and punctuation omitted). Notably, the Court went on to state:

The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption. If Congress intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly. Moreover, this history emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items.

*Id.*

Despite the Court’s strong policy language against preemption, three years later in *Reigel v. Medtronic*, 128 S. Ct. 999 (2008), the Court held state common-law duties were expressly preempted by another federal regulatory scheme.

### **Riegel v. Medtronic**

In *Riegel*, the plaintiffs asserted defective design, manufacture, and labeling claims under state law against Medtronic, the manufacturer of an angioplasty catheter. *Riegel v. Medtronic*, 128 S. Ct. 999, 1004 (2008). Medtronic argued that the Medical Device Amendments of 1976, 21 U.S.C.S. §360c *et seq.* (MDA), preempted the plaintiffs’ claims. The MDA includes an express preemption provision that states:

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

*Id.* at §360k(a).

Interpreting this language, the Court noted that “[a]bsent other indication, reference to a State’s ‘requirements’ includes its common-law duties.” *Reigel*, 128 S. Ct. at 1008. Although the Court’s two most recent preemption cases have divergent outcomes, the determinative factor is the statutory language.

### **Conclusion**

The immediate implications of the *Ferrari II* decision are significant. Manufacturers of vaccines can be subjected to strict liability and negligence claims in Georgia despite the Vaccine Act. *Ferrari II*, 2008 Ga. LEXIS 833, \*21. The Georgia Supreme Court has indicated that whether an “injury or death resulted from side effects that are unavoidable” will be determined by a jury on a case-by-case basis. *Id.* at \*10. Although preemption is a legal question, in holding that the unavoidability of a side effect is a fact question, the *Ferrari II* opinion effectively puts the issue of preemption in the hands of Georgia juries.

It is too early to tell whether other states will follow Georgia’s example. Unless the United States Supreme Court provides a definitive answer, manufacturers are likely to see a deluge of vaccine-injury cases in Georgia. Moreover, defense attorneys nationwide will see citations to *Ferrari II* more frequently as persuasive authority. Of course, citing the cases contrary to *Ferrari II* discussed above is one way to counter any persuasive effect *Ferrari II* may hold.

Analogy to the Supreme Court’s analysis of the statute at issue in *Reigel*, in contrast to its analysis of the statute at issue in *Bates*, may also be effective. In *Bates*, the Court held that although state tort

law claims may *induce* a manufacturer to change its labels, no jury verdict *requires* a manufacturer to change its labels. *Bates*, 554 U.S. at 445. Since the federal statute at issue expressly prohibited a state only from requiring labels different from those required by federal law, state tort verdicts *inducing* but not *requiring* a label change were not preempted. *Id.* In contrast, the

## **The *Ferrari II* opinion**

effectively puts the  
issue of preemption  
in the hands of  
Georgia juries.

operative statute in *Reigel* prohibited states from establishing any requirement related to the safety or effectiveness of the regulated device, therefore, state law tort claims were preempted.

The Vaccine Act immunizes manufacturers from *liability* in any “civil action for damages arising from vaccine-related injury or death associated with the administration of a vaccine.” In *Bates*, the Court found that liability did not rise to the level of a “requirement,” but found in *Reigel* liability could rise to the level of a requirement. Careful analysis of the language of the Vaccine Act, however, reveals that *liability* itself is preempted; the act does not simply preempt any state law requirements. Certainly, a successful design defect claim would impose liability on the manufacturer, but liability against the manufacturer is expressly preempted by the Vaccine Act. Finally, careful analysis of the Vaccine Act’s language shows stronger preemption language than the MDA’s preemption language involved in *Reigel*. The Vaccine Act precludes *liability* itself, regardless of whether a design defect claim is a direct or indirect requirement. This total liability prohibition is arguably broader than the statute at issue in *Reigel*, and evidences Congressional intent much more effectively than any legislative history, at least with respect to design defect claims. 