Preemption: The Pendulum Swings Yet Again

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All litigation has its hurdles. In product liability cases, preemption is by far the biggest obstacle to success. Because the federal government regulates, to some extent, most if not all products sold in the US, the question will inevitably be to what extent federal regulatory action serves to bar common law claims regarding a given product. Under the doctrine of federal preemption arising from the Supremacy Clause, federal may expressly or impliedly preempt state laws and products liability claims founded on state law. Congress *can* definitively determine when its product regulations displace state common law; however, more commonly it leaves the extent to which the regulation is intended to occupy the field open for interpretation, and courts are then required to work it out. Unfortunately, this means that there is little consistency in the preemptive effect of product regulation, unless and until the Supreme Court weighs in – and even then, the rule often changes with the wind. As one commentator put it, "preemption is multidimensional, involving layers of legal and policy issues--from the determination of the optimal regulatory sphere (national or state), to federalism issues, to the level of deference accorded agency determinations."[1]

Products liability is an area where Congress often takes an all or nothing approach, meaning it will expressly proclaim the preemptive affect of the legislation, or it will mention it not at all. However, it often also includes broad "savings clauses" that would seem to preserve some of the very actions it has supposedly expressly preempted. Again, this leaves much up for interpretation in any given case.

Federal law may preempt state products liability law in any of three ways: (1) Congress, in enacting a federal statute, may explicitly define the extent to which it intends to preempt state law by express wording in the statute or in its legislative history. (2) Implied preemption may be found where Congress has indicated its intent to occupy an entire field of regulation, in which case the states must leave all regulatory activity in that area to the federal government. (3) Even if Congress has not displaced state regulation entirely, it may preempt state law to the extent that the state law actually conflicts with federal law, as when compliance with both state and federal law is impossible or when the state law stands as an obstacle to the accomplishment of the full objectives of Congress.

To complicate matters, the preemptive effect can be complete or partial, depending on the types of claims asserted. For example, the duty that manufacturers of dangerous products have to warn individuals as to the product's dangers falls within the state's traditional role of protecting the health and safety of its citizens, and therefore an

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[1] Catherine M. Sharkey, "Products Liability Preemption: An Institutional Approach," 76 Geo. Wash. L. Rev. 449 (2008).

anti-preemption presumption may apply absent clear evidence of an intent on the part of Congress to impliedly preempt state products liability claims. On the other hand, where federal law exclusively establishes standards of care in a field, such as with aviation safety, a state-law failure to warn claim will be preempted.

For a number of years, the courts were increasingly interpreting regulatory action to have a broad preemptive effect. It was starting to look like products claims were going to regulated into extinction. Certainly, the decisions have been seen as pro-business and against the interests of consumers. Recently, however, the Supreme Court has taken head of the assumption that the historic police powers of the States are not to be superseded by a federal act unless that was the clear and manifest intent of Congress. Nowhere has the change been more apparent than in the pharmaceutical arena – particularly with regard to medical devices.

I. U.S. Supreme Court Jurisprudence

An interesting dichotomy occurs in the Court's preemption decisions. The more conservative the Court, the more likely to find that federal law trumps state common law tort claims. The irony is that conservatives tend to advocate for a reduced role for the federal government; yet it is these "conservative" Justices who have consistently found preemption.[2] For example, in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), a 5-4 decision, the Court found that federal law preempted a state law regulating the location of cigarette advertisements, which were part of the state's efforts to reduce underage smoking. The Justices in the majority were the same five who in other decisions limited Congress's commerce power and emphasized the importance of states' rights. [3]

The trend toward broader preemption began in the Rehnquist era. For example, in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), the Court held that federal law preempted a routine state products liability lawsuit against an auto manufacturer. The issue in the case was whether the failure to install airbags, arguably the state-of-the-art safety technology at the time, could be the basis for liability. In passing the National Traffic and Motor Vehicle Safety Act of 1966 ("MVSA"), Congress stated a clear intent to regulate the field of automotive safety, while at the same time adding a "savings clause" that assured that nothing would alter the customary operation of tort law. In reaching its implied preemption conclusion foreclosing state tort liability, the majority referred to a verdict in a common-law tort suit as a "jury-imposed safety standard," which was in conflict with the federal regulatory scheme. *Id*. at 871. In a sharply worded dissent, Justice Stevens challenged the majority's understanding of the role of the tort system and its overly broad interpretation of the term "safety standard" used in the regulation

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[2] In contrast to the other conservative Justices, Justice Thomas tends to reject preemption arguments, taking a more traditionally federalist view. *See, e.g.,* Justice Steven's dissent in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), to which Justice Thomas joined, as well as Justice Thomas's concurrence in *Wyeth v. Levine*, 2009 WL 529172 (U.S. Vt. 2009)

[3] *See, e.g., United States v. Morrison*, 529 U.S. 598 (2000); *New York v. United States*, 5505 U.S. 144 (1992).

to effectively ignore the manufacturer's duties imposed by tort law. *Id.* at 896.

Justice Stevens' position prevailed in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002). In *Sprietsma*, the survivor of a boat passenger who died after falling from boat and being struck by propeller blades of outboard engine filed action against engine designer, alleging that engine should have been equipped with propeller guard. The trial court dismissed the action, on the grounds that the Federal Boat Safety Act preempted the plaintiff's claims and both Illinois appellate courts affirmed. The United States Supreme Court reversed finding a lack of both express and implied preemption. First, the Court found that the FBSA did not expressly pre-empt petitioner's common-law tort claims because the express pre-emption clause, which applies to "a [state or local] law or regulation"-is most naturally read as not encompassing common-law claims. The Court determined that the Coast Guard's decision not to regulate propeller guards also did not pre-empt petitioner's claims. Second, there was no implied preemption because The Act did not require the Coast Guard to promulgate comprehensive regulations covering every aspect of recreational boat safety and design; nor must the Coast Guard certify the acceptability of every recreational boat subject to its jurisdiction. The Court found no clear and manifest intent to completely occupy the field so as to foreclose state common-law remedies

The medical device litigation quagmire essentially began in 1996 with the case of *Medronic, Inc. v. Lohr*, 518 U.S. 470 (1996). *Lohr* involved fairly typical negligence and strict liability claims by a plaintiff who was injured by an allegedly defectively designed pacemaker that had been granted premarket notification approval by the FDA. The plurality attempted to diverge from the idea that tort law standards of care ought to be preempted under express preemption clauses because they are "requirements" every bit as regulatory as an administrative regulation or statute. Instead, the Court relied on Silkwood v. Kerr-McGee Corp., 464 U.S. 238 (1984), a case in which the Court held that a plaintiff could collect damages on a common-law strict liability cause of action notwithstanding the fact that the United States Nuclear Regulatory Commission had "exclusive authority to regulate safety matters." In considering whether the MDA had preemptive effect in the case, the Court concluded that Act's manufacturing and labeling requirements did not preempt the common law claims because they were not requirements specific to the device in question, but were only "generic." Justice Stevens wrote for the majority in *Lohr*, with Justices O'Connor, Rehnquist, Thomas and Scalia, dissenting. Justice Stevens suggested that preemption of state remedies would have the "perverse effect" of immunizing an industry that "in the judgment of Congress, needed more stringent regulation." *Id*. at 487. Justice O'Connor, however, did not agree that the term "requirement" could be read in any way other than to encompass state common-law causes of action. The view of the dissent in *Lohr* ultimately won out.

Last year, in *Riegel v. Medtronic, Inc,* 128 S.Ct. 999 (2008), the Supreme Court held that the preemption provision in the Medical Device Amendments of 1976 (MDA) preempted state common law claims brought after a medical device subject to the most stringent level of federal regulation caused injury. In *Riegel*, the plaintiff developed a heart blockage after his doctor unsuccessfully attempted to dilate his partially blocked

coronary artery with a medical device called a balloon catheter. The device had been approved by the FDA after a lengthy approval process. Although the label warned against inflating the catheter beyond a pressure of 8 atmospheres, the doctor inflated it to 10, and the balloon exploded. The suit alleged negligence a strict liability in the design, testing, inspection, distribution, labeling, marketing and sale of the device.

The Court held that the claims came within the meaning of the word "requirement" in the statute's express preemption clause. In a complete turn about from the *Lohr* analysis, the Court noted that "absent other indication, reference to a state's 'requirements' includes its common law duties." *Id*. at 1008. Because the approval process requires that a product be "made with almost no deviations from the specifications in its approval application," state law cannot require a safer, but perhaps less effective product, than the FDA approved model. *Id*. The majority specifically acknowledged and adopted the view of the minority in *Lohr*, which concluded that common-law causes of action for negligence and strict liability impose "requirements" that would be preempted by specific federal requirements for a medical device.[4] Even Justice Stevens concurred as he believed the text of the federal regulation covered all such "requirements." Justice Ginsberg was the lone dissenter, finding that the history of the legislation and principal purpose of the preemption provision did not mandate a finding of preemption of the state law claims.

After the Court's ruling in *Riegel*, court-watchers anxiously awaited the Court's decision in another pharmaceutical case addressing the issue of preemption. Consumer advocates braced themselves for yet another narrowing of the rights of injured victims in product liability claims, fearing that the decision could relieve the drug industry of all accountability for drugs that have serious unrevealed side effects. The Court's decision in *Wyeth v. Levine*, 2009 WL 529172 (U.S. Vt. , March 4, 2009) came as a bit of a surprise. The Court held 6-3 that federal law does not preempt lawsuits against prescription drug manufactures for failing to warn of their drug's dangers.

The plaintiff, Diana Levine, was a professional guitarist who lost an arm after an injection of the anti-nausea drug Phenergan. Phenergan can be administered intravenously either through the "IV-push" method, meaning it is injected directly into a patient's vein, or the "IV-drip" method, in which it is introduced through the IV bag slowly through a catheter. The drug is known to be corrosive, and may cause gangrene if it enters an artery. In Ms. Levine's case, the IV-push method was utilized and the injection inadvertently hit an artery. As a result, she developed gangrene and her entire forearm was ultimately amputated.

The plaintiff presented evidence of other incidents in which a Phenergan injection resulted in similar injuries and a Vermont state court jury returned a verdict for Ms. Levine of $6.7 million. The jury found that Wyeth should have added a stronger

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[4] A majority of the Court in *Riegel* did, however, find that the claim based on the company's violation of FDA regulations was permissible, because there was no difference between the duty imposed by the federal government and that imposed by the common law.

warning about IV-push administration. On appeal, Wyeth argued that the claim was preempted because the warning label had been approved by the FDA and it could not have changed the drug's label without prior approval from the FDA. The Vermont Supreme Court disagreed, holding that the jury's verdict did not conflict with the FDA's labeling requirements because, under the Agency's "changes being effected" regulation, Wyeth could have added stronger warnings without FDA approval.

The Food Drug and Cosmetic Act does not have an express preemption clause; therefore, in the Supreme Court Wyeth argued that the plaintiff's claims were impliedly preempted because they conflicted with, or frustrated the purpose of the federal law. The majority rejected this view, holding that simply because the FDA approved the drug's label does not absolve the manufacturer of its responsibilities to adequately warn the public of the drug's risks. Significantly, the Court began by reasserting the presumption against preemption, something that it had backed away from consistently in other preemption decisions of late.

Wyeth argued that it couldn't comply with both state law duties and federal labeling requirements; however, the Court rejected this argument since the FDA's changes being effected regulations permits a manufacturer to make certain changes to its label before approval by the agency. The Court further rejected Wyeth's attempt to place on the federal government, rather than the manufacturer itself, the responsibility for creating a proper label, with adequate warnings. Because the Court found that Congress did not intend the regulation to be "both a floor and a ceiling for drug regulation," it rejected Wyeth's argument that the plaintiff's claims obstructed the purpose of the regulation. Finally, the Court emphasized the importance of damage suits in protecting the public, specifically noting that FDA cannot sufficiently monitor all of the drugs on the market; damage suits serve to level the playing field between manufacturers, who have superior access to information about drugs, by providing an incentive for injured people to come forward with information. In this way, failure to warn claims support, rather than conflict, with the purpose of the regulations.

Since almost all products liability actions against pharmaceutical manufacturers include a failure to warn claim, the *Wyeth* decision is a huge victory for consumers injured by dangerous drugs. *Wyeth* is not only important because it will help keep drug manufacturers honest, but it also demonstrates a trend toward limiting the scope of implied conflict preemption. In effect it rejected the *Geier v. American Honda Motor Co.* line of cases. Although *Wyeth* only addressed FDA requirements, the Court's opinion is broad enough to encompass all litigation involving defective products.

II. Georgia Law

Georgia courts have typically followed a similar path in preemption cases to that of their federal counterparts. Under Georgia law, a manufacturer's compliance with a federal safety standard is not conclusive of its liability, but is simply one factor the jury may consider in analyzing the risk utility balancing test. *Doyle v. Volkswagen*, 267 Ga. 574, 481 S.E.2d 518 (1997). The one exception is where liability is preempted by federal law.

Two appellate decisions resulted from a death claim against Volkswagen for the manufacturer's failure to have an adequate restraint system in its Rabbit vehicle. In *Gentry v. Volkswagen of America, Inc.*, 238 Ga. App. 785, 521 S.E.2d 13 (1999) ("*Gentry I")*, the plaintiffs appealed the grant of summary judgment on the ground that their state law claims were preempted by the National Traffic & Motor Vehicle Safety Act. The plaintiffs alleged that the Rabbit's passive restraint system was inadequate. Instead of a lap belt, the Rabbit was equipped with a ramped seat and a knee bolster to restrain the lower part of a passenger's body. This type of restraint system was an express option under the applicable federal regulations. The court held that the claim was preempted "to the extent that the Gentrys allege as a design defect a failure to include a lap belt." *Id.* at 788. Volkswagen argued that all of the claims were based on the absence of a lap belt, but the court founds this characterization "overly simplistic" and that the defective design claims amounted to more than that, which were not all preempted. *Id*. The court went on to state that "it would not conflict with congressional intent if Volkswagen were found liable in tort for failing to design a passive restraint system that exceeded federal standards." *Id*.

The case proceeded to trial and the jury returned a verdict for the plaintiffs. Thereafter, Volkswagen appealed, arguing that the plaintiffs should not have been permitted to discuss the issue of pelvic restraint, and the lack of a lap belt. *Volkswagen of America, Inc. v. Gentry*, 254 Ga. App. 888, 564 S.E.2d 733 (2002). The court again distinguished between a claim in which the sole issue is the lack of a lap belt, which would be preempted, and a broader claim for improper design, which would not be barred. Because the plaintiffs' "theory was that the particular design of the VWRA system was defective, particularly for someone of Lori Gentry's size, for a number of reasons including the placement and angle of the shoulder strap and the placement of the knee bolster relative to various positions of the car seat," the claim was not preempted. *Id*. at 889-890.

In *Duren v. Paccar, Inc.,* 249 Ga. App. 758, 549 S.E.2d 755 (2001), the spouse of motorist who was killed when tractor-trailer that lacked antilock brake system jackknifed and collided with motorist's vehicle brought defective design and manufacturing claims against manufacturer of truck. The trial court granted summary judgment on preemption grounds, but the Court of Appeals reversed. However, the basis for the ruling was one of timing. The court held that a federal standard that took effect March 1, 1997, which required that each truck tractor manufactured on or after that date be equipped with an antilock brake system, did not expressly or impliedly preempt the plaintiff's claims, which related to a truck tractor manufactured before standard's effective date. Having determined that the standards did not have a preemptive effect, the court found that a fact question existed as to whether manufacturer's failure to include antilock braking system, load-sensitive proportioning valve, or manual limiting valve rendered truck defective. Significantly, the court reiterated that under the risk-utility analysis, which applies to claims of design defects, compliance with federal standards or regulations is generally only one factor, among many, that the jury may consider in deciding whether product design was reasonable.

More recently, in *Parks v. Hyundai Motor America, Inc.,* 294 Ga. App. 112, 668 S.E.2d 554 (2008), the court again considered a product liability and wrongful death action against automobile manufacturer, alleging that automobile's lap-only center rear seat belt was the cause of their child's death in head-on collision. This time the court concluded that both the design-defect and failure-to-warn claims were preempted by Federal Motor Vehicle Safety Standard (FMVSS) under the National Traffic and Motor Vehicle Safety Act. The court specifically rejected the plaintiffs' claims that they were entitled under *Banks v. ICI Americas*, 264 Ga. 732, 450 S.E.2d 671 (1994) to produce evidence of alternative passenger restraint designs that Hyundai could have used instead of the lap-only seat belt to make the vehicle safer.

> The risk-utility analysis adopted in Banks for product liability design defect claims requires evidence of "the reasonableness of selecting from among alternative product designs and adopting the safest feasible one." Jones v. NordicTrack, Inc., 274 Ga. 115, 118, 550 S.E.2d 101 (2001). But the analysis adopted in Banks is not an exception to the Supremacy Clause and provides no basis for the Parkses to introduce evidence to advance claims preempted by FMVSS 208. Gentry, 238 Ga.App. at 786-788, 521 S.E.2d 13.

294 Ga. App. 112, 114. The court distinguished the situation in *Parks* with that in *Gentry* on the grounds that in the manufacturer had "'opened the door' to or otherwise invited" the introduction of evidence concerning alternatives to installing a lap/shoulder belt, or comparing the operation of a lap-only belt to a lap/shoulder belt in the accident. *Id*. It is difficult to understand the distinction, other than to cynically suggest that the intended to result could be reached by finding preemption and this was the only way to get there in light of the *Gentry* precedent.

Georgia has not been immune from having to decide to what extent federal regulations protect manufacturers of pharmaceuticals from state common law suits. Fortunately, the Georgia Supreme Court has come down favorably on the issue, very recently deciding that the National Childhood Vaccine Injury Act does not preempt all design defect claims against vaccine manufacturers. *American Home Products Corp. v. Ferrari*, 284 Ga. 384, 668 S.E.2d 236 (2008).

In *Farrari*, the plaintiffs brought strict liability and negligence claims against several vaccine manufacturers alleging that their soon suffered neurological damage caused by vaccines made with the preservative thimerosal, which contains mercury. The trial court granted partial summary judgment, finding that the design defect claims were preempted by the Vaccine Act, 42 U.S.C. § 300aa-1 et seq. The Court of Appeals determined that there were two alternative ways to interpret the statute's preemptive effect: one is that the vaccine injuries are "'unavoidable' and subject to preemption if the vaccine was properly prepared and accompanied by proper directions and warnings." Or, design defect claims are preempted 'only if the side effects are determined to be unavoidable on a case-by-case basis." *Id*. at 386. The Court of Appeals held that it was constrained to read the Vaccine Act in a manner disfavoring preemption. The Supreme Court, while rejecting the Court of Appeal's analysis, nevertheless affirmed the decision.

Interestingly, the Court relied in large part on the Supreme Court's decision in *Medtronic v. Lohr*, for its analysis. Further, although the Court acknowledged that the only other courts to have considered whether the Vaccine Act preempts all claims that a vaccine was defectively designed held that all such claims are in fact preempted, the Georgia Court found those decisions to be faulty. In analyzing the language and intent of the preemption clause in the Statute, in the context of comment k of the Restatement of Torts, the Court found that it does not bar liability in all situations.

> Comment k, therefore suggests that the question of whether a particular vaccine is unavoidably unsafe and therefore subject to the immunity from suit posited by comment k – is a question of fact for a jury to determine. That is, the trier of fact must decide whether the challenged vaccine is the only design available, "in the present state of human knowledge."

Id. at 389 (quoting *Bruesewitz. V. Wyeth*, 508 F.Supp.2d 430, 445 (E.D. Pa. 2007)). With that backdrop, the Court held:

> As the statute is actually written, however, it is best understood as barring liability only for those side effects which were unavoidable by means other than proper manufacturing and packaging. Conversely, if such effects were avoidable by a feasible alternative design, liability is not completed barred. Accordingly, the last clause of subsection (b)(1) was necessary to ensure that its bar to liability would not apply to the manufacturing and packaging process, but only to side effects which were not avoidable by a safer design.

Id. at 390.

Because the Vaccine Act actually provides for a compensation scheme outside of the usual tort system. The Court had to consider whether injured persons are required to seek compensation solely through that fund. The Court found that the Act's no-fault compensation system is merely an "alternative" to the tort system. The Court was careful not to "'overstate the degree of uniformity and centralization that characterizes' the Vaccine Act," and found that a claim will be preempted only "if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably unsafe." *Id.* at 393.

Finally, it is notable that in finding that the Vaccine Act does not protect manufacturers from all design defect claims, the Court cited decisions which "emphasize that blanket immunity from tort liability would remove an incentive for developing safer designs." *Id*. Thus, the Court clearly recognized both the need to protect the manufacturer from claims that result from unavoidable injuries while still protecting the public by maintaining claims that will encourage the production of safer products.

III. Conclusion

Although preemption remains a significant issue in products liability claims, and in many instances may still serve to bar meritorious claims, the trend appears to be moving in the direction of finding a preemptive affect in a statue only when the intent is clear. Hopefully, we are reverting back to the days when the presumption was against, rather than in favor of preemption.