

▶ PRODUCT LIABILITY

Drug Preemption v. Medical Device Preemption: A Study in Contrast

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Suppose the Food and Drug Administration (“FDA”) approves a label for a drug or a medical device and that product is subsequently the subject of a personal injury lawsuit. The plaintiff claims that the label for the product did not provide an adequate warning notwithstanding that it was approved by the FDA. Is the plaintiff’s state-law tort action preempted by federal law? According to two U.S. Supreme Court cases, one decided last February and one decided this March, the answer may be very different depending upon whether the product is a drug or a Class III medical device.

Three Ways State Law Can Be Preempted By Federal Law

The Supreme Court, in *English v. Gen. Elec. Co.*,¹ explained that state law is preempted under the Supremacy Clause of Article VI, cl. 2, of the U.S. Constitution in the following three circumstances.

- 1. Express Statutory Preemption:** Congress can define explicitly the extent to which its enactments preempt state law.
- 2. Implied Field Preemption:** State law is preempted when the federal regulatory scheme is so pervasive as to make reasonable the inference that Congress left no room for the states to supplement it or where the federal interest is so dominant that the federal system will be assumed to preclude enforcement of

state laws on the same subject.

3. Implied Conflict Preemption: State law is preempted to the extent that it actually conflicts with federal law so that it is impossible to comply with both state and federal requirements, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Wyeth—Prescription Drug Labels Approved By the FDA

In *Wyeth v. Levine*,² the Supreme Court held that an FDA-approved drug label does not necessarily shield the manufacturer from liability for a state-law failure-to-warn tort claim if the circumstances indicate that the manufacturer should have put stronger warnings on the label. The drug involved was Phenergan, used to treat nausea.

The plaintiff, Diana Levine, a professional musician, suffered from migraine headaches and on April 7, 2000, as she had on previous occasions, went to her local clinic for an intramuscular injection of Demerol for her headache and Phenergan for her nausea. The treatment did not provide relief on this occasion, and she returned later on the same day for a second injection of both drugs. This time, however, the drugs were administered by a physician assistant, not intramuscularly but by directly injecting the Phenergan into Ms. Levine’s vein—called the “IV push” method.

The drug inadvertently entered

Ms. Levine's artery, as opposed to the intended vein, either because the needle penetrated an artery directly or because the drug escaped from the vein into the surrounding tissue where it came into contact with arterial blood. As a result, Ms. Levine developed gangrene. Ultimately, her entire right forearm had to be amputated.

The trial court record contained evidence that the physician assistant administered a greater dose than the label prescribed and that she continued to inject the Phenergan even after Ms. Levine complained of pain, notwithstanding that the label warned that an intravenous injection of Phenergan should be stopped immediately if the patient complains of pain so that an evaluation of whether the Phenergan has inadvertently been injected into an artery can be undertaken.

Phenergan's FDA-approved labeling warned of the danger of gangrene and amputation should the drug be inadvertently injected into an artery. The warning for "Inadvertent Intra-arterial Injection" stated:

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 [i.e., escape of the drug into surrounding tissue] or inadvertent intra-arterial injection.** Reports compatible with inadvertent intra-arterial injection of Phenergan Injection, 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.** ...Aspiration of dark blood does not preclude intra-arterial needle placement, because blood is discolored upon contact with

Phenergan Injection. Use of syringes with rigid plungers or of small bore needles might obscure typical arterial backflow if this is relied upon alone. **When used intravenously, Phenergan Injection should be given in a concentration no greater than 25 mg per mL and at a rate not to exceed 25 mg per minute.** When administering any irritant drug intravenously, it is usually preferable to inject it through the tubing of an intravenous infusion set that is known to be functioning satisfactorily. **In the event that a patient complains of pain during intended intravenous injection of Phenergan Injection, the injection should be stopped immediately to provide for evaluation of possible arterial placement or perivascular extravasation.**³ (Emphasis added.)

Ms. Levine alleged that the foregoing labeling was defective because it failed to instruct clinicians to use the "IV drip" method of intravenous administration rather than the higher risk IV push method. With the IV drip method, the drug is introduced into a saline solution in a hanging intravenous bag and allowed to drip slowly through a catheter inserted into a patient's vein.

The Court found that the evidence presented at trial demonstrated that the risk of in intra-arterial injection or perivascular extravasation [i.e., escape of the drug into surrounding tissue] can be almost entirely eliminated through the use of the IV drip method of administration and also found that even a careful and experienced clinician using the IV push method will occasionally expose an artery to Phenergan. The trial court record also contained evidence of at least 20 incidents prior to Ms. Levine's injury in which a Phenergan injection resulted in gangrene and an amputation.

When the FDA approved the labeling for Phenergan, it instructed Wyeth that Phenergan's final printed label "must be identical" to the approved package insert.⁴ While this package insert contained the warnings quoted above regarding intravenous administration, it did not specifically warn about the risks

of IV push administration. The narrow question decided by the Supreme Court in *Wyeth* "is whether federal law pre-empts Levine's claim that Phenergan's label did not contain an adequate warning about using the IV-push method of administration."⁵ The Court was guided by two cornerstones of preemption jurisprudence:

First, "the purpose of Congress is the ultimate touchstone in every pre-emption case." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (internal quotation marks omitted); see *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103, 84 S.Ct. 219, 11 L.Ed.2d 179 (1963). Second, "[i]n all pre-emption cases, and particularly in those in which Congress has 'legislated ... in a field which the States have traditionally occupied,'... we 'start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Lohr*, 518 U.S., at 485, 116 S.Ct. 2240 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230, 67 S.Ct. 1146, 91 L.Ed. 1447 (1947)).⁶

The "Changes Being Effected" Regulations

In identifying the purposes of Congress, the Court noted that the Federal Food, Drug, and Cosmetic Act (FDCA),⁷ enacted in the 1930s, provided for the premarket approval of new drugs. It required every manufacturer to submit a new drug application, including reports of investigations and specimens of proposed labeling, to the FDA for review. Before 1962, the agency had to prove harm to keep a drug out of the market. In 1962, Congress amended the FDCA and shifted the burden of proof from the FDA to the manufacturer, requiring the manufacturer to demonstrate that its drug was "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling"

before it could distribute the drug.⁸ In addition, the amendments required the manufacturer to prove the drug's effectiveness by introducing "substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling."⁹

While manufacturers must generally use the exact labeling approved by the FDA, absent FDA approval of a supplemental application to change that labeling, there is an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval.¹⁰

When a Manufacturer is Obligated to Update Its Labeling

In 2008 amendments to the CBE regulations, the FDA, in a notice of the final rule, explained that a manufacturer has an obligation to add to or strengthen its warnings, not only when it acquires new data about its drug but also when there is a basis for a new analysis of previously submitted data:

The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments: "[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement

for 'newly acquired information.'"¹¹

The first amputation in connection with Phenergan occurred in 1967. The Court found that as amputations continued to occur in later years, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug. The Court referenced evidence that a similar anti-nausea drug manufactured by Pfizer had been withdrawn from the market as a result of gangrene and amputations. Although Wyeth argued that if it had unilaterally added warnings to Phenergan's label it would have violated federal law governing unauthorized distribution and misbranding, the Court found that "the very idea that the FDA would bring an enforcement action against a manufacturer for strengthening a warning pursuant to the CBE regulation is difficult to accept—neither Wyeth nor the United States has identified a case in which the FDA has done so."¹²

Thus, the Court concluded that when the risk of gangrene from IV-push injection of Phenergan became apparent, Wyeth had a duty to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval. While the FDA retains the ultimate authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications, the Court concluded that absent clear evidence that the FDA would not have approved a change to Phenergan's label, it was not impossible for Wyeth to comply with both the federal FDA labeling requirements and with a state-imposed duty to strengthen Phenergan's label regarding IV-push administration.¹³

When Preemption Might Apply to a Drug Label

The Court indicated that if Wyeth had offered evidence that it attempted to give the warning required by Ms. Levine

but the FDA prohibited it from doing so, Wyeth may have been able to establish the "demanding defense" of the impossibility of complying with both federal and state requirements.¹⁴ Given the variables that accompany labeling—in terms of exact wording, prominence, size, and color—even if the FDA were to prohibit a warning previously proposed by a manufacturing defendant, a plaintiff may be able to distinguish the prohibited warning from the one it argues should have been given.

Full Purposes and Objectives of Congress

Wyeth also argued that requiring it to comply with a state-law duty to provide a stronger warning about IV-push administration would obstruct the purposes and objectives of federal drug-labeling regulations—in other words, that Ms. Levine's tort claims were preempted because they interfered with Congress' purpose to entrust an expert agency to make drug-labeling decisions that strike a balance between competing objectives. The Court found that the evidence of Congress' purpose was to the contrary in that Senate hearings indicated that Congress contemplated that common-law claims under state law would continue to be available to protect injured consumers and that therefore it was not necessary to establish a federal remedy for consumers harmed by unsafe or ineffective drugs in the FDCA. Further, the Court stated:

If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, *see* § 521, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)), Congress has not enacted such a provision for prescription drugs. *See Riegel*, 552 U.S., at ---, 128 S.Ct., at 1009 ("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”).¹⁵

The Court did not accord any weight to the FDA’s position—stated in the preamble to a 2006 regulation governing the content and format of prescription drug labels—that FDA approval of labeling preempts conflicting or contrary state law. While the court noted that agencies do have a unique understanding of the statutes they administer and that their views have in the past been given some weight, the Court did not find the FDA’s position to be thorough, consistent, or persuasive in this case:

The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the post-marketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.¹⁶

When the Drug Manufacturer is a Generic Manufacturer

In a post-*Wyeth* case, *Stacel v. Teva Pharmaceuticals, USA*,¹⁷ the court considered the labeling preemption issue in the context of a generic drug. Plaintiff Melanie Stacel alleged that she was afflicted with drug-induced lupus as a result of consuming the drug Minocycline, which is a generic of the brand-name, FDA reference-listed drug Minocin. Ms. Stacel alleged, among other things, negligent failure to warn. Defendant Teva, the manufacturer of Minocycline, argued that the entire complaint was preempted by the labeling requirements of the FDCA and pointed to the FDA’s position, expressed in a proposed new rule in the Federal Register published on January 18, 2008, that generic manufacturers are *prohibited* from utilizing the CBE regulations and are required to conform to the approved labeling for the listed drug.

Once again, the FDA’s position was not afforded deference. Instead, the

court found that the regulations affecting generic drug applications state explicitly that the CBE provisions apply to generic drug manufacturers just as they do to name-brand manufacturers.¹⁸ The only qualification to the court’s opinion was that it thought it likely that a generic manufacturer would be spared any risk of negligence liability *during the application process* for the generic drug, since the generic drug application must be identical to the reference-listed drug.¹⁹

President’s Statement on Preemption

On May 20th of this year, the President weighed in on department/agency pronouncements on preemption. The White House Press Office released a Memorandum for the Heads of Executive Departments and Agencies regarding Preemption, which directed that:

1. Heads of departments and agencies should not include in regulatory preambles statements that the department or agency intends to preempt State law through the regulation except where preemption provisions are also included in the codified regulation.
2. Heads of departments and agencies should not include preemption provisions in codified regulations except where such provisions would be justified under legal principles governing preemption, including the principles outlined in Executive Order 13132.
3. Heads of departments and agencies should review regulations issued within the past 10 years that contain statements in regulatory preambles or codified provisions intended by the department or agency to preempt State law, in order to decide whether such statements or provisions are justified under applicable legal principles governing preemption. Where the head of a department or agency determines that a regulatory statement of

preemption or codified regulatory provision cannot be so justified, the head of that department or agency should initiate appropriate action, which may include amendment of the relevant regulation.²⁰

Riegel— Medical Device Labels Approved By the FDA

In *Riegel v. Medtronic*,²¹ the Supreme Court clarified the scope of FDA preemption with respect to a Class III medical device approved through the FDA’s “premarket approval,” or “PMA” process, in accordance with the Medical Device Amendments of 1976 (“MDA”), to the FDCA.²²

The MDA created a scheme of federal safety oversight for medical devices that varies with the type of device at issue. The most extensive oversight is reserved for Class III devices that undergo the PMA process. These devices may enter the market only if the FDA reviews their design, labeling, and manufacturing specifications and determines that those specifications provide a reasonable assurance of safety and effectiveness.

In contrast to the CBE regulations applicable to prescription drug manufacturers, medical device manufacturers may not make changes, including labeling changes, that would affect safety or effectiveness of a medical device that has been approved through the PMA process, unless they first seek and obtain permission from the FDA. Also in contrast to the FDCA provisions relating to prescription drugs, the MDA expressly preempts the states from establishing safety and effectiveness requirements that are “different from, or in addition to,” the FDA requirements governing medical devices.²³

The plaintiffs in *Riegel*, cardiac patient Charles Riegel and his wife, sued Medtronic, the manufacturer of a coronary balloon catheter used in Mr. Riegel’s angioplasty, asserting New York state-law claims for strict liability; breach of implied warranty; and negligent design, testing, inspection, distribution, labeling, marketing, sale,

and manufacture of the medical device. The catheter, which ruptured during the procedure, was contraindicated for someone with diffuse or calcified stenosis, such as Mr. Riegel, and was also inflated beyond the maximum pressure indicated on the labeling for the device. The U.S. District Court granted summary judgment to Medtronic both as to claims that it held were preempted by the MDA and, later, as to the Riegels' remaining claims that were not preempted. These dismissals were affirmed by the U.S. Court of Appeals, and the Riegels petitioned the U.S. Supreme Court for certiorari as to their preempted claims only.²⁴

The issue before the U.S. Supreme Court was whether the MDA preemption clause barred common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the FDA. The preemption clause provides:

[N]o 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 [Act] 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 [Act].²⁵ (Emphasis added.)

Interpreting FDA regulations for the preemption clause state, in relevant part:

State or local requirements are preempted only when the Food and Drug Administration has established **specific counterpart requirements** or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific FDA requirements.²⁶ (Emphasis added.)

The *Riegel* Court came to two conclusions with respect to the application of the foregoing statute and regulation.

First, the Court held that the FDA's approval of a medical device pursuant to the PMA process, standing alone, imposes specific federal requirements applicable to that particular device and, therefore, has preemptive effect under section 360k(a) of the MDA.²⁷ In arriving at this conclusion, the Court noted that the PMA process for approval of a new Class III medical device is rigorous, typically includes a multivolume application, may involve referral by the FDA to a panel of outside experts, may involve a request by the FDA for additional data from the manufacturer, includes review of the device's proposed labeling, and that on average the FDA spends 1,200 hours reviewing such applications.²⁸

The Court further noted that “[o]nce a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.”²⁹

Second, the Court held that the Riegels' New York common-law causes of action for negligence, strict-liability, and implied-warranty imposed safety and effectiveness requirements on the coronary balloon catheter that would be different from or in addition to specific federal requirements and, therefore, were preempted under the MDA.³⁰ In arriving at this conclusion, the Court stated that “excluding common-law duties from the scope of preemption would make little sense. State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.”³¹

The Court also pointed to the language of 21 C.F.R. § 808.1(b) that states that the MDA sets forth a general rule preempting state duties “having the force and effect of law (whether established by statute, ordinance, regulation, or court decision)...”³² (Emphasis added.)

Parallel State-Law Claims Are Not Preempted By *Riegel*

Since the MDA expressly preempts only state requirements “different from” or “in addition to” any federal law requirements applicable to the device, a state-law cause of action has the potential to survive preemption if it is premised on the contention that the PMA-approved Class III medical device was manufactured, designed, or labeled in a manner that was in violation of the model that received PMA approval from the FDA:

State requirements are pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.³³

In *Medtronic, Inc. v. Lohr*,³⁴ Justice O’Conner explained that “[s]ection 360k does not preclude States from imposing different or additional remedies, but only different or additional requirements.” (Emphasis in original.)

However, as the U.S. Supreme Court pointed out in *Buckman Co. v. Plaintiffs’ Legal Comm.*,³⁵ not every violation of the FDCA will support a state-law claim. According to the *Buckman* Court, 21 U.S.C. § 337(a), which provides that all proceedings for the enforcement or to restrain violations of the FDCA “shall be by and in the name of the United States,” leaves no doubt that “it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.”³⁶ Applying ordinary conflict preemption principles, the *Buckman* Court held that plaintiffs’ fraud-on-the-FDA claims were impliedly preempted by the federal law:

The conflict stems from the fact that the federal statutory scheme amply

empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law.³⁷

Legislative Efforts to Overturn *Riegel*. H.R. 1346: Medical Device Safety Act of 2009

On May 12, 2009, the Subcommittee on Health, of the Committee on Energy and Commerce, House of Representatives, held a hearing on H.R. 1346, the “Medical Device Safety Act of 2009.” If passed, the legislation would overturn *Riegel*. Proponents of the bill argued that the FDA does not have the resources to identify and take action on defective products. The bill’s detractors argued that decisions concerning the safety and efficacy of medical devices are best left to the FDA and its experts rather than to juries, and that innovation would be hampered if medical device manufacturers could not rely upon preemption.

As currently drafted, the legislation would add a section to the express preemption language of 21 U.S.C. § 360k stating that nothing in the section “shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State” and would apply to any civil action pending or filed on or after the date of enactment.

Conclusion

Whether, and to what extent, legislation will ultimately reconcile the differences between the law governing preemption in prescription drug cases and Class III medical device cases remains

to be seen. Currently, however, the law governing the two is markedly different in ways that may seem counterintuitive to the unwary. The prudent practitioner, therefore, whether for the plaintiff or the defense, should evaluate preemption issues early and carefully in such cases. ▲

Endnotes

- 1 110 S. Ct. 2270, 2275 (1990)
- 2 129 S. Ct. 1187 (2009)
- 3 *Id.* at 1192 n.10
- 4 *Id.* at 1192
- 5 *Id.* at 1194
- 6 *Id.* at 1194-1195
- 7 21 U.S.C. § 301 et seq.
- 8 *Wyeth*, 129 S. Ct. at 1195
- 9 *Id.*
- 10 *Id.* at 1196
- 11 *Id.* at 1197
- 12 *Id.* at 1197
- 13 *Id.* at 1198
- 14 *Id.* at 1199
- 15 *Id.* at 1200
- 16 *Id.* at 1202
- 17 No. 08 C1143, 2009 WL 703274 (N.D. Ill. March 16, 2009)
- 18 *Id.* at *5
- 19 [^] at *7
- 20 http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption
- 21 128 S. Ct. 999 (2007)
- 22 21 U.S.C. § 360c et. seq.
- 23 21 U.S.C. § 360k(a); 21 C.F.R. § 808.1(d)
- 24 *Riegel*, 128 S. Ct. at 1005-1006, n.2
- 25 21 U.S.C. § 360k(a)
- 26 21 C.F.R. § 808.1(d)
- 27 *Riegel*, 128 S. Ct. at 1007
- 28 *Id.* at 1004
- 29 *Id.* at 1005
- 30 *Id.* at 1007
- 31 *Id.* at 1008
- 32 *Id.* at 1010
- 33 *Id.* at 1011
- 34 518 U.S. 470, 513 (1996)
- 35 531 U.S. 341, 353 (2001)
- 36 *Id.* at 349 n.4
- 37 *Id.* at 348



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