

# **FEDERAL PREEMPTION OF STATE LAW REMEDIES**

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**Alabama Association for Justice**

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Counting seashells and untangling fishing lines would be less tedious and mind-numbing than studying federal preemption so I am doing the conference attendees the favor of putting the citations and legal discussion in this paper, freeing us to have more interesting and exciting discussions during the time devoted to this subject. The first three sections of this paper outline the rules and bases of federal preemption. The last two sections discuss two specific cases: defective medical devices and railroad grade crossing accidents. Special attention is devoted to these areas to suggest ways to defeat federal preemption.

Finally, there is a case pending before the United States Supreme Court slated for oral argument this fall, on the issue of implied preemption in a pharmaceutical case. The specific issue presented by the Petitioner, Wyeth, is whether “the prescription drug labeling judgments imposed on manufacturers by the FDA pursuant to the Food Drug and Cosmetics Act preempt state law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use.” Wyeth v. Levine, Supreme Court No.: 06-1249.

## **I. THE TRADITIONAL AND LEGAL BASIS OF PREEMPTION**

Article IV of the United States Constitution provides the legal basis for federal preemption.

This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of Any State to the Contrary notwithstanding.

Not only is the Supremacy Clause the legal basis, it is the only basis for holding that state laws in conflict with federal law shall be “without effect.” McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 427, 4 L. Ed. 579 (1819).

## **THE TYPES OF FEDERAL PREEMPTION: EXPRESS AND IMPLIED PREEMPTION**

### **II. EXPRESS PREEMPTION**

Congress may specify in its legislation that the particular federal law will preempt state laws and requirements. Express preemption clauses are still subject to debate whether Congress intended that the federal act preempt only positive state law (state statutes or administrative regulations), or whether it also preempts judge and jury determinations made in common law tort actions.

#### **A. Application of express preemption at its worst...**

Recently, the Supreme Court held that the express preemption provision of the Medical Device Amendments to the Food Drug and Cosmetic Act (FDCA), 21 U.S.C. § 360k(a) expressly preempted positive state laws and regulations, as well as common law tort remedies. Riegel v. Medtronic, Inc., \_\_\_ U.S. \_\_\_, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008). The FDCA provision involved says:

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 matter included in a requirement applicable to the device under this chapter.

AAJ is working to put legislation before Congress to restrict the application of the preemption clause, and thus, to preserve some common law tort remedies for compensation when citizens are harmed by defective Class III medical devices.

**B. And at its best...**

The Flammable Fabrics Act, 15 U.S.C. § 1203(a) contains an express preemption clause that states:

Except as provided in subsections (b) and (c) of this section, whenever a flammability standard or other regulation for a fabric, related material, or product is in effect under this chapter, no State or political subdivision of a State may establish or continue in effect a flammability standard or other regulation for such fabric, related material, or product if the standard or other regulation is designed to protect against the same risk of occurrence of fire with respect to which the standard or other regulation under this chapter is in effect unless the State or political subdivision standard or other regulation is identical to the Federal standard or other regulation.

The First Circuit, in Wilson v. Bradlees of New England, Inc., 96 F. 3d 552 (1<sup>st</sup> Cir. 1996), held that this express preemption provision preempted positive state laws and regulations, but did not have the effect of preempting common law claims of design defect and failure to warn.

**C. And in between...**

The courts sometimes hold that the express preemption clauses are not intended to preempt anything other than conflicting positive state laws and regulations, such as in the Wilson decision above. However, the analysis frequently does not end there, because the courts may proceed to use the clauses to divine congressional intent, and rely on them as support for the decision that although Congress did not expressly preempt common law, it impliedly preempted common law and the tort actions based thereon, as well as expressly preempting positive state laws and rules.

For example, read Geier v. American Honda Motor Co., Inc., 529 U.S. 861, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000), known as the “airbag case,” which examined the express preemption provision contained in the

National Traffic and Motor Vehicle Safety Act of 1966, 15 U.S.C. § 1392(d):

Whenever a Federal motor vehicle safety standard established under this subchapter is in effect, no State or political subdivision of a State or political subdivision of a State shall have any authority either to establish, or to continue in effect, with respect to any motor vehicle or item of motor vehicle equipment, any safety standard applicable to the same aspect of performance of such vehicle or item of equipment which is not identical to the Federal standard.

The Supreme Court in Geier held that this provision of the Safety Act did not *expressly* preempt a tort claim that the vehicle was defective without airbags. The Court, however, did hold that the common law claims of the lawsuit were *impliedly* preempted because they conflicted with the requirements of the Safety Act.

### **III. IMPLIED PREEMPTION**

In the absence of an express preemption provision in federal law, the defendant must rely on implied preemption. There are two types of implied preemption: conflict preemption and field preemption. In either case, the analysis is essentially identical.

#### **A. The touchstone of the implied preemption analysis is Congressional intent.**

The Supreme Court has “never assumed lightly that Congress has derogated state regulation, but instead ha[s] addressed claims of pre-emption with the starting presumption that Congress does not intend to supplant state law.” New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 654, 115 S. Ct. 1671, 1676, 131 L. Ed. 2d 695 (1995). “The ultimate touchstone of preemption analysis is the intent of Congress.” Medtronic v. Lohr, 518 U.S. 470, 485, 116 S. Ct. 2240, 2250, 135 L. Ed. 2d 700 (1996).

As with any statutory analysis, examine the language of the particular act, the legislative history and public policy. As an example of this three step analysis, see the case on the Flammability Act, cited above, Wilson v. Bradlees, 96 F. 3d 552.

**B. Congressional silence indicates that preemption of state law was not intended by Congress.**

For example, the Food Drug and Cosmetic Act (FDCA) contains the preemption clause relating to medical devices cited above, but does not have a parallel provision governing pharmaceuticals. Congressional silence on state laws related to pharmaceuticals, when Congress has addressed preemption of state laws on medical devices, is not without meaning. “Such reasoning is a variant of the familiar principle of *expressio unius est exclusio alterius*: Congress’ enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not preempted.” Cipollone v. Liggett Group, Inc., 505 U.S. 504, 517, 112 S. Ct. 2608, 2618, 120 L. Ed. 2d 407 (1992).

**C. It is settled that some matters are best left to the various states to regulate.**

It has long been recognized that it was left to the states to regulate matters of public health and safety. Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251, 104 S. Ct. 615, 78 L. Ed. 2d 443 (1984). The Supreme Court has instructed the federal courts that the various police powers of the states are not to be superceded by federal law, 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). There is a strong presumption against implied preemption with matters traditionally occupied by the states, “particularly those related to health and safety.” Abbot v. American Cyanamid Co., 844 F. 2d 1108, 1112 (4<sup>th</sup> Cir. 1988), citing Medtronic v. Lohr, 518 U.S. at 485, 116 S. Ct. at 2250.

**D. The courts should try to avoid preemption if it would rob plaintiffs of a state law tort remedy.**

“Historically, common law liability has formed the bedrock of state regulation, and common law tort claims have been described as ‘a critical component of the States’ traditional ability to protect the health and safety of their citizens’.” Desiano v. Warner-Lambert & Co., 467 F. 3d 85 (2d Cir. 2006), citing Cipollone v. Liggett Group, Inc., 505 U.S. 504, 544, 112 S. Ct. 2608, 120 L. Ed. 2d 407 (1992)(Blackmun, J., concurring in part and dissenting in part).

The presumption against implied preemption is even stronger when a decision imposing federal preemption would deprive a plaintiff of a remedy. Preemption should be less likely if the federal law leaves the plaintiff without any means of legal redress.

[T]he bar to a finding of preemption is raised even higher because the FDCA provides no remedy for an injured consumer. Thus, a finding of preemption here will foreclose a remedy that was traditionally available and for which federal law provides no substitute. Courts have (understandably) been particularly reluctant to find preemption in such cases without an unambiguous signal of Congressional intent. See Medtronic, Inc. v. Lohr, 518 U.S. 470, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996)(plurality opinion)(“It is, to say the least, ‘difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct’.”) (quoting Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251, 104 S. Ct. 615, 78 L. Ed. 2d 443 (1984)); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449, 125 S. Ct. 1788, 161 L. Ed. 2d 687 (2005)(“If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.”)

Perry v. Novartis Pharma. Corp., 456 F. Supp. 2d 678, 684 (E.D. Pa. 2006).

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Barnhill v. Teva Pharmaceuticals, Inc., 2007 U.S. Distr. LEXIS 44718 (S. D. Al. 2007).

### **E. Implied conflict preemption.**

State law that actually conflicts with federal law will be impliedly preempted. It is well accepted that implied conflict preemption occurs only when there is a direct and positive conflict between the federal and state laws. Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 713, 105 S. Ct. 2371, 2375, 85 L. Ed. 2d 714 (1985). For similar

language, see Nat'l Assn. of State Utility Consumer Advocates v. FCC 457 F. 3d 1238, 1252 (11<sup>th</sup> Cir. 2006)(there must be an “outright or actual conflict between federal and state law”); Irving v. Mazda Motor Corp., 136 F. 3d 764, 768 (11<sup>th</sup> Cir. 1998)(Conflict preemption will exist when state law “actually conflicts” with federal law.); Perry v. Novartis, 456 F. Supp. 2d 678, 682 (“what matters in the preemption analysis is not whether, in practice, manufacturers perceive a potential conflict between federal and state law, but whether there is an actual and direct conflict.”); Peters v. Astrazeneca, LP, 417 F. Supp. 2d 1051, 1056 (W.D. Wis. 2006)(finding that there will be implied conflict preemption only when state requirements are “actually conflicting with a standard implemented by the FDA”).

An “actual or direct conflict” can be proven by showing that “compliance with both federal and state regulations is a physical impossibility,” or by proving that “state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” Hillsborough v. Automated Medical, 471 U.S. at 713, 105 S. Ct. at 2375. Evidence that the state has “additional requirements above a federal minimum is unlikely to create a direct and positive conflict with federal law. Rather, a conflict is more likely to occur when a state...provides that compliance with a federal standard is not mandated, or when compliance with federal law actually results in a violation of local law.” Southern Blasting v. Wilkes County, 288 F. 3d 584, 592-3 (4<sup>th</sup> Cir. 2002).

#### **F. Implied field preemption.**

There may be preemption when federal law so thoroughly occupies a legislative field “as to make reasonable the inference that Congress left no room for the States to supplement it.” Fidelity Fed. Sav. & Loan Assn. v. De La Cuesta, 458 U.S. 141, 153, 102 S. Ct. 3014, 73 L. Ed. 2d 664 (1982), quoting Rice v. Santa Fe Elevator Corp., 331 U.S. at 230.

One of the clearest examples of field preemption are the decisions arising under the Federal Locomotive Inspection Act, 49 U.S.C. §§ 20701 – 20903. See eg. Napier v. Atlantic Coast Line R.R., 272 U.S. 605, 47 S. Ct. 207, 71 L. Ed. 432 (1926); General Motors Corp. v. Kilgore, 853 So. 2d 171 (Ala. 2002)(following Napier, which held “[o]ur concern is with delimiting areas of conduct which must be free from state regulation if national policy is to be left unhampered...Even the States’ salutary effort to redress private wrongs or grant compensation for past harm cannot be exerted to regulate

activities that are potentially subject to the exclusive federal regulatory scheme.”).

#### **IV. PREEMPTION OF MEDICAL DEVICE LAWSUITS AFTER RIEGEL**

**A. Medical Device Classifications.** There are three classes of medical devices.

**1. Class I:** Devices that are subject to minimal controls because they pose little or no risk of illness or injury, and are subject only to minimal regulation. 21 U.S.C. § 360c(a)(1)(A). Includes devices such as tongue depressors, elastic bandages and sterile examination gloves.

**2. Class II:** Devices that are potentially more harmful. Manufacturers must comply with federal performance standards or specific guidelines known as ‘special controls.’ 21 U.S.C. § 360c(a)(1)(B). Includes devices such as powered wheelchairs and tampons.

**3. Class III:** Devices that either “present a potential unreasonable risk of illness or injury,” or which are “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health.” 21 U.S.C. § 360c(a)(1)(C), Includes devices such as pacemakers, heart valves, prostheses, breast implants, and bone screws.

**B. Approval Process For Class III Devices.** Before a Class III medical device can be marketed, it must be approved by the FDA. The manufacturer must prove to the FDA that 1) the device has been manufactured soundly and, 2) the device is safe and effective. The primary route by which approval is obtained is the PMA or premarket approval. 21 U.S.C. § 360e(d)(2).

**1. Premarket Approval (PMA) Process** has been described by the Supreme Court as a “rigorous process, under which manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.” *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). The PMA process requires submission of clinical testing,

disclosure of specifications, intended use, manufacturing methods, and proposed labeling.

**2. 510(k) Process Is An Exception To The PMA Process.**

21 U.S.C. § 360k allows a manufacturer to sell a device that is “substantially equivalent” to a device that predates the MDA. The manufacturer must notify the FDA of its intent to market the medical device at least 90 days before its introduction to the market and to explain the device’s substantial equivalence to a pre-1976 device.

**C. FDCA Preemption Clause:**

**21 U.S.C. § 360k(a):**

“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.”

**Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996).**

This case involved a pacemaker wire, which is a Class III device approved on a 510k review. The Supreme Court held that state claims regarding the negligent design of the pacemaker wire were not expressly preempted by § 360k, because the 510k review process was not a review of the safety and efficacy of the device, and therefore, did not impose any “requirements” that would preempt state law. Central to this holding is the fact that the device was approved for marketing under the limited 510k review, not the more rigorous PMA process.

**Riegel v. Medtronic, Inc., \_\_\_ U.S. \_\_\_ (2008).**

This case involved a balloon catheter, which is a Class III device approved on a PMA. The Supreme Court held that state claims regarding the negligent design of the catheter were expressly preempted because the PMA expressly imposed requirements under the FDA Act. It did not overrule Medtronic v. Lohr.

**D. When Is There No Federal Preemption?**

1. **When the subject device is a Class I or II medical devices.**
2. **When the subject device is approved on a 510k application.**
3. **When the claim is for defective manufacturing of the device.** There is no preemption for defective manufacturing claims, regardless of whether the device is Class III, and whether it is approved on a 510K.
4. **When plaintiff alleges a violation of FDA regulations.** This is known as a “parallel claim” because the lawsuit is not pushing a state regulation that is in competition with, or different than the FDA regulations.
5. **When the harm arises from a breach of the PMA itself.** Eg., the defendant manufacturer modified the manufacturing process or label that had been part of the PMA approval. Pushing off-label use of the device would be a breach of the PMA.
6. **When the information about the defect first comes to light after the PMA is given.** This is addressed in the Ginsberg dissent. In this situation, the FDA never addressed the defect.
7. **When device has not gone through the rigorous PMA process.** Eg. the Sprint Fidelis lead wires, which were approved on a Supplement to the PMA, which did not require that clinical trials and research data be submitted to FDA scrutiny.
8. **When the claim is based on breach of implied warranty of merchantability.** See Horne v. Novartis Pharmaceuticals Corp., W.D. N.C. 3:06-cv-00368-MR-CH. This was a pharmaceutical case, in which implied preemption was recognized by the district court. However, the court refused to dismiss the breach of warranty claim, because it is not the same as a claim for failure to properly label and warn.

## **V. PREEMPTION OF RAILROAD GRADE CROSSING ACCIDENTS**

### **A. Amendment to the Federal Railroad Safety Act.**

On August 7, 2007 Congress passed an amendment to the Federal Railroad Safety Act, clarifying that not all state law causes of action are preempted by the Act. Subsection (a) of the provision remains essentially the same:

(a) National uniformity of regulation.

(1) Laws, regulations and orders related to railroad safety and laws, regulations and orders related to railroad security shall be nationally uniform to the extent practicable.

(2) A State may adopt or continue in force a law, regulation, or order related to railroad safety or security until the Secretary of Transportation (with respect to railroad safety matters),... prescribes a regulation or issues an order covering the subject matter of the State requirement. A State may adopt or continue in force an additional or more stringent law, regulation or order related to railroad safety or security when the law, regulation or order –

(A) is necessary to eliminate or reduce an essentially local safety or security hazard;

(B) is not incompatible with a law, regulation, or order of the United States Government; and

(C) does not unreasonably burden interstate commerce.

Subsection B is added, and specifically addresses situations under which a state law cause of action arising from a grade crossing accident would not be preempted. It is now possible to file a claim alleging that the railroad crew failed to follow regulations relating to blowing the whistle, speed, etc., when those regulations are written pursuant to railroad regulations or orders. Get a copy of the Book of Rules on which the engineers, brakemen and road foreman are tested, and tell me which of those rules were not written to comply with federal regulations!

(b) Clarification regarding State law causes of action.

(1) Nothing in this section shall be construed to preempt an action under State law seeking damages for personal injury, death, or property damage alleging that a party –

- (A) has failed to comply with the federal standard of care established by a regulation or order issued by the Secretary of Transportation (with respect to railroad safety matters)...,covering the subject matter as provided in subsection (a) of this section;
- (B) has failed to comply with its own plan, rule, or standard that it created pursuant to a regulation or order issued by either of the Secretaries...

The new section does not completely remove the specter of preemption from a grade crossing case, but it does provide a few means to avoid the wholesale dumping of the case on a motion to dismiss or early summary judgment. There are few cases so far, but some insight can be gained from Murrell v. Union Pacific, 2008 U.S. Dist. LEXIS 28886 (Ore. 4/4/08); and Van Buren v. Burlington Northern, 2008 U.S. Dist. LEXIS 28538 (Neb. 4/8/08).