

Federal Preemption vs. The Plaintiff's Bar

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Recently, the plaintiffs' bar has renewed its clever efforts to increase theories of liability and recovery options related to Class III medical devices.

While the courts generally have used the doctrine of federal preemption to bar such claim if the Class III medical devices had received Premarket Approval from the FDA, there are some limited exceptions. The net effect of this protection on medical devices is a continued focus on health care providers as opposed to medical devices when things go wrong.

Our forefathers established that the laws of the federal government are "the supreme Law of the Land." Article VI, clause 2 of the United States Constitution, commonly referred to as the Supremacy Clause, provides that "any Thing in the Constitution or Laws of any State" that is contrary to or conflicts with any law of the United States is trumped, or preempted, by federal law. In o'ur overlapping system of state and federal government, one system must ultimately control, and that is the purpose of the Supremacy Clause.

Individual state laws can either be expressly or impliedly preempted under this provision. Federal preemption "is compelled whether Congress's command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." Metro. Life Ins. Co. v. Massachusetts (1985) 471 U.S. 724, 738. With respect to medical devices, Congress enacted an express federal preemption in

The Medical Device Amendments of 1976 (MDA) of the Food, Drug, and Cosmetic Act (FDCA). The scope of this preemption was to be decided by the courts.

On February 20, 2008, the United States Supreme Court issued a landmark 8-1 decision in Riegel v. Medtronic, Inc. (2008) 128 S.Ct. 999, declaring that state law product liability claims are preempted under the MDA where a Class III medical device received Premarket Approval from the FDA. Riegel held that the FDA established a defined premarket approval (PMA) process, and a company that successfully complies with the process before bringing the medical device to market will be protected from types of litigation. Put simply, a state common law claim cannot be upheld where the plaintiff's success would impose requirements that are different from or in addition to federal requirements. The Riegel Court held that state common law tort claims based on allegations of negligence, breach of warranty, or strict liability, challenging the design, testing, manufacture, safety, labeling, marketing and sale, of a device are all preempted by federal law. *Id.* at 1007.

The Supreme Court explained that individual state laws cannot supercede or even supplement the requirements established by Congress in the PMA. Consequently, a state law cannot create an additional obligation and/or duty on part of the manufacturer. However, a claim can still be premised on a state claim "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." *Id.* at 1011, emphasis added (citing Medtronic, Inc. v. Lohr (1996) 518 U.S. 470, 476). Consequently, a party suing on state law claims for product liability may attempt to avoid federal preemption by alleging that the medical device manufacturer failed to comply with federal requirements set forth by the FDA.

What the Riegel court meant by "parallel" requirements is extremely vague. While plaintiffs may consider this language an avenue around preemption, this so-called loophole appears relatively small when directly addressed by the court.

The plaintiffs' bar have attempted to evade federal preemption by alleging the defendants fraudulently misrepresented their devices to the FDA in order to obtain PMA approval. Parties attempting to make such an argument have alleged that "but for" the defendant's misrepresentations, the device would not have been approved by the FDA and, therefore, the plaintiffs would not have been injured. Buckman Co. v. Plaintiffs' Legal Comm. (2001) 531 U.S. 341, 343; Kemp v. Medtronic (6th Cir. 2000) 231 F.3d 216, 235.

That argument, while clever, has been rejected. The U.S. Supreme Court in Buckman Co. v. Plaintiffs' Legal Comm. (2001) 531 U.S. 341, 348 held that fraud-on-the-FDA claims "conflict with, and are therefore impliedly pre-empted by federal law." As the Court explained, "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency." *Id.* at 348.

As regulations upon which the plaintiff's claims in *Buckman* were premised were established by the FDA, the FDA has the exclusive authority to enforce them.

The United States Court of Appeals in *Kemp v. Medtronic* further held that a plaintiff could not maintain a state common law claim based on allegations that the defendant violated MDA amendments. *Id.* at 236. The plaintiffs in *Kemp* described their claim against the defendant as a "fraud against the FDA," alleging that the defendant "fraudulently obtained PMA Supplement approval from the FDA by failing to submit [] test results, by failing to perform [required] studies, and by failing to submit laboratory tests." *Id.* at 234. The *Kemp* Court declared, "States are not granted any authority to enforce compliance with the specific federal requirements established by the PMA process." Consequently, any claim premised on a defendant's failure to comply with FDA requirements is preempted under the *Kemp* and *Buckman* decisions.

Plaintiffs' only viable avenue around preemption at present stem from two Fifth Circuit cases. Those cases provide support for an argument that product liability claims are not preempted if the defendant failed to comply with FDA regulations. However, these rulings have very narrow application.

The Court in *Martin v. Medtronic* (5th Cir. 2001) 254 F.3d 573, 574, provided that the product liability claims were all preempted except those alleging that the device manufacturer failed to design, manufacture, warn or label the device pursuant to the FDA regulations that apply to the specific device. The Court in *Gomez v. St. Jude Medical Daig Division, Inc.* (5th Cir. 2006) 442 F.3d 919, held that a party's allegations that defendant's device deviated from FDA-approved manufacturing specifications were not preempted. *Id.* at 932.

These rulings did not provide an open door to parties attempting to argue general allegations that the device manufacturer did not comply with FDA regulations. Instead, juries would be permitted to determine only whether a particular device conformed to specific design, manufacture, or labeling requirements established and approved by the FDA, not whether PMA approval should have been granted or withdrawn. The Fifth Circuit cases did not authorize general allegations that a device manufacturer failed to comply with the FDA regulations. These cases do not apply when a party attempts to base a state common law tort claim on the defendant's failure to comply with PMA reporting requirements, testing requirements, research and analysis, or any other requirement that is considered

a part of the PMA application and supplement approval process. Such an allowance would create a private policing agency out of each individual litigant. This is exactly what Congress intended to avoid with the express preemption clause of the MDA.

The trend in Class III medical device litigation will likely continue to provide protection to manufacturers if they comply with the FDA approved design, manufacture, and labeling requirements, which they must do anyway. Because of that, plaintiffs' attorneys will remain focused on the health care providers involved in the surgery or decision to use the medical device, as opposed to seeking liability against the manufacturer itself. ■

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