Client Advisory

KELLEY DRYE

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# Supreme Court Upholds Medical Device Amendment Preemption

## Introduction

On February 20, 2008, in a landmark 8 to 1 decision, the United States Supreme Court put new limits on lawsuits against medical device manufacturers and distributors. In *Riegel v. Medtronic*, the Court ruled that a provision of the Medical Device Amendments (MDA) to the Food Drug and Cosmetic Act, which provided federal safety oversight for medical devices, bars state-law claims challenging the safety or effectiveness of devices that have been given premarket approval by the Food and Drug Administration.

## The Facts of *Riegel*

The *Riegel* case involved a New York man who was injured during a coronary angioplasty procedure. His doctor was attempting to treat a blockage in his right coronary artery by inflating a balloon catheter to compress the arterial plaque. After multiple inflation attempts, the balloon burst, necessitating emergency coronary artery bypass graft surgery. The device at issue was an Evergreen Balloon Catheter manufactured by Medtronic. The catheter was a Class III device that received premarket approval from the FDA in 1994. Changes made to the labeling were approved pursuant to supplemental applications submitted in 1995 and 1996.

Mr. and Mrs. Riegel sued Medtronic in New York federal court. Their suit claimed that the catheter had been designed, labeled and manufactured in a way that violated New York common law and that Medtronic, the maker of the device, should be held responsible for injuries suffered by Mr. and Mrs. Riegel. The federal court in Albany dismissed several of the plaintiffs' claims holding that the MDA pre-empted claims of strict liability, breach of implied warranty, and negligence in design, testing, inspection and distribution. The court left standing claims of breach of express warranty and negligent manufacturing based on failure to follow federal standards, but later granted Medtronic's motion for summary judgment on these claims. [1] The U.S. Court of Appeals for the Second Circuit affirmed.

## Justice Scalia's Majority Opinion

Justice Antonin Scalia, writing for the majority, defined the issue as follows:

> Since the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law, §360(k)(a)(1), we

[1] Summary judgment was later granted because the plaintiff could not establish a genuine issue of material fact that negligent manufacture caused the balloon to burst and Medtronic showed that its labeling disclaimed express warranties.

> must determine whether the Federal Government has established requirements applicable to Medtronic's catheter. If so, we must then determine whether the Riegels' common-law claims are based upon New York requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness.

In addressing the first question of whether there were federal device-specific requirements, Justice Scalia contrasted the scope of FDA review under premarket approval with that under §510(k). In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the first Supreme Court case to consider the scope of pre-emption under the MDA, the court held there was no pre-emption for a device marketed under the substantial equivalence standard of §510(k). A showing of substantial equivalence qualified as an "exemption" rather than a requirement under the MDA. Premarket approval, on the other hand, is in no sense an exemption from FDA safety review, "it is federal safety review," according to Justice Scalia. In contrast to the §510(k) focus on equivalence rather than safety, premarket approval is only granted after the FDA determines that standards of safety and efficacy have been met. Accordingly, premarket approval imposes requirements under the MDA that are device-specific.[2]

The second question in the analysis is whether the common law claims of the Riegels impose requirements that are "different from or in addition to" the federal requirements imposed under premarket approval. Justice Scalia noted that although the *Lohr* majority did not find pre-emption in that case, a majority of the Lohr Court nonetheless held that common law claims for strict liability and negligence constituted "requirements" under the MDA and would be pre-empted given device-specific federal requirements. This was consistent with the holding of the Court in other federal pre-emption cases. *See*, *e.g.*, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) (common law duties are requirements under the Federal Insecticide, Fungicide and Rodenticide Act). State tort law that requires a product to be safer, but possibly less effective than the model approved by the FDA "disrupts the federal scheme."[3]

Justice Scalia concluded his majority opinion by addressing the issue of state requirements that are not "different from or in addition to" federal requirements. §360(k)(a) does not pre-empt state tort duties premised on violations of FDA regulations. These are said to "parallel" the federal requirements. In *Riegel*, the district court recognized this limit on the pre-emptive scope of the statute in denying Medtronic's pre-emption motion for sum-

[2] The majority opinion notes that the premarket approval process involves 1,200 hours of agency review on average, during which the FDA weighs the risks and benefits of the device. This review includes all clinical studies, device design, manufacture, and labeling. Outside experts may be relied upon to scrutinize the data, specifications, etc. and make recommendations to the agency. Post approval, no changes to design, manufacture, labeling or any other aspect of the device may be made without application to the FDA. Agency review under premarket approval is far more rigorous, far more demanding and invasive than that applied under §510(k).

[3] The plaintiff argued that general tort duties were not "requirements" and relied on a regulation, 21 CFR § 808.1(d)(1), which seemed to carve out of the pre-emption statute state and local requirements of "general applicability." Justice Scalia noted that the FDA itself did not agree with this position, and, furthermore, this regulation did not unambiguously stand for the proposition advanced by plaintiff.

mary judgment on the counts of negligent manufacture and breach of express warranty.

### Justice Stevens' Concurrence

Justice Stevens concurred in the judgment, but wrote separately to note his conclusion that while the language of the statute was clear, it went beyond the scope Congress intended, given the history of the MDA and what constitutes a "requirement" under the Act. The facts leading up to the adoption of the MDA did not suggest that Congress intended to pre-empt state tort suits. Rather, the purpose of the legislation was to provide additional protection for consumers by pre-empting existing state device regulations enacted in the wake of certain high-profile product failures.[4] Clearly, however, in Justice Stevens' view, common-law rules administered by judges impose legal obligations and qualify as "requirements."

### Justice Ginsburg's Dissent

Justice Ruth Bader Ginsburg was the lone dissenter in the *Riegel* case. She is alone among the justices in her view that §360(k)(a) should not be interpreted according to its plain language, but rather in the context of its historical underpinnings. The legislation was intended to protect the consumer against harm from faulty medical devices and restrain state premarket approval systems. It arose at a time of noteworthy product failures, such as the Dalkon Shield intrauterine device. Nothing in the history of the statute indicated that Congress intended to restrict consumers' resort to common law remedies. Such a construction would have the "perverse effect" of granting broad immunity to an industry that Congress was attempting to subject to greater regulation. Device pre-emption in this fashion was also inconsistent with the manner in which Congress had historically legislated with regard to drugs and foods. This historical backdrop created for Justice Ginsburg an uncertainty about the pre-emptive scope of the statute. In such instances, the statute should be given a reading that disfavors pre-emption.

### What *Riegel* Means For Medical Device Companies

The scope of the holding in Riegel is arguably narrow. It is clear that strict liability, including implied warranty, and most negligence claims are pre-empted in the case of Class III medical devices given premarket approval. This includes claims for defective design and failure to warn. Negligent manufacturing claims premised on failure to follow federal standards are not pre-empted. Nor would express warranty claims appear to be expressly pre-empted by §360(k)(a). Devices not given premarket approval by the FDA would appear to remain subject to state product liability claims, unless there is another argument for dismissal aside from express pre-emption under §360(k)(a).

Prior to *Riegel*, some courts had held that common law claims against device makers could be impliedly pre-empted. In *Buckman Co. v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001), the Supreme Court held that fraud against the FDA claims were impliedly pre-empted. Implied preemption was extended by some other courts beyond fraud claims. *See*, *e.g. Webster v. Pacesetter, Inc.*, 259 F. Supp, 2d 27 (D.D.C. 2003) (holding that failure to warn and fraud claims were impliedly pre-empted where plaintiff alleged defendant had failed to comply with FDA requirements

[4] California, for example, in the wake of the Dalkon Shield product failures enacted its own regulatory scheme requiring premarket approval of medical devices.

regarding labeling, design, and adverse event reporting). Riegel does not appear to have any immediate impact in these cases.

Another question concerns product liability claims associated with devices used pursuant to an Investigational Device Exemption. A few cases have held such claims to be expressly pre-empted under the MDA. *See*, *e.g.*, *Martin v. Telectronics Pacing Systems Inc.*, 105 F.3d 1090 (6th Cir. 1997). The logic of these holdings is that FDA review and regulation of these devices is much more comprehensive than §510(k) clearance and closer to the type of review associated with premarket approval. The holdings of these cases would not appear to be in question in light of *Riegel*.

## Looking Ahead

Notwithstanding the holding of *Riegel*, plaintiffs will endeavor to find arguments to support defective design and warning claims against makers of premarket approved devices. For example, plaintiffs have and will likely continue to argue that in the event of a product recall, pre-emption based on FDA premarket approval should not apply. Plaintiffs may also seek to distinguish between devices approved under premarket approval, and premarket approval supplements, arguing that supplement review is streamlined and more akin to §510(k) review.

The *Riegel* ruling is hardly the last word on pre-emption of claims against medical device or drug companies. The Supreme Court is preparing to decide two more pre-emption cases, *Warner-Lambert Co. v. Kent* and *Wyeth v. Levine*. The genesis for *Kent* is a Michigan law barring suits against drug companies except in the case of fraud. The question presented is whether all fraud suits are pre-empted as the Supreme Court held in *Buckman* (leaving plaintiffs in Michigan possibly without a legal remedy), or whether they can be maintained in some manner. Next term, the Supreme Court will hear argument in *Levine*, where it will consider the broader question of whether federal law displaces products liability claims against drug companies.

It is, of course, difficult to predict how the Court will decide those cases based on a reading of the *Riegel* opinion. Only Justice Ginsburg, in her dissent, addressed these upcoming pre-emption cases, noting that the Court will soon consider the issue of whether FDA approved drug labeling pre-empts state law products liability claims premised on failure to warn. Early reports from the oral argument in *Kent* suggest that some key Justices, notably Breyer and Kennedy, appear to favor the industry view of the argument.[5]

## For More Information

Attorneys in Kelley Drye's Litigation Group have substantial experience assisting clients in defending drug and device products liability claims. If you have questions about this Client Advisory, please contact:

**Stephen A. Wood**

(312) 857-2311

swood@kelleydrye.com

[5] Christopher S. Rugaber, *Justices wrestle with Michigan lawsuits against Pfizer*, (http://www.law.com/jsp/nlj/) (accessed Feb. 26, 2008).