

Riegel v. Medtronic, Inc.

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The Supreme Court of the United States recently ruled on February 20, 2008 that individuals injured by medical devices during the medical use of those devices are precluded from seeking recourse under either a State's common laws or statutory laws due to the preemptive effect of a federal law, the Medical Device Amendments of 1976 (MDA). Justice Scalia delivered the opinion supported by an overwhelming 7-2 majority of the Court.

The Court's decision in *Riegel v Medtronic*, affirming a Second Circuit decision, is further evidence of an increasingly determined trend by the Court in its pronouncements concerning Congressional statutes containing economic preemption language as that language relates to state laws. For example, on the same day as *Riegel*, the Court in a similar 7-2 ruling handed down *Rowe v. New Hampshire Motor Transport Assoc*, affirming a First Circuit decision dealing with essentially the same type of state law preemption. In *Rowe*, the Court held that the Federal Aviation Administration Authorization Act of 1994 (FAAAA), which preempts state law for regulations that related to the price, routes, and services of motor carriers of property, also preempted Maine's regulations that required companies delivering tobacco products to obtain the same age verification as traditional brick and mortar retailers. Although the Attorney General of Maine pointed to various federal laws, which require states to regulate the sale of tobacco products to minors, the Court found that the FAAAA did not contain a general "health and safety" exception sufficient to allow state laws regarding "sales" to apply to the home "delivery" of those same products.

Like *Rowe*, the *Riegel* decision relies on a federal statute that preempts state laws "requirements" regarding the development, marketing, sale, and use of medical devices characterized as "Class III" medical devices, which require pre-market approval by the Food and Drug Administration (FDA). The court asserted, relying in part on the foundation of its interpretation of the broad scope of "relates to" in the Employee Retirement Income Security Act of 1974 (ERISA) preemption from *Medtronic v. Lohr* and *Cipollone v. Liggett Group, Inc.* (cases cited in *Riegel* where the Court also partly dealt with the MDA), that "requirements" in the MDA's preemption under the ordinary meaning of the term engendered a similar type of broad preemption scope. The Court declared that the "requirements" preemption proscribed the application of state laws to manufacturers of medical devices approved by the FDA including such laws as common law tort claims like strict products liability, breach of warranty, loss of consortium, and negligence as well as statutory UCC warranty claims.

Riegel, *Rowe*, and the numerous cases that have come before them are justified by nebulous federal statutes such as the FAAAA, ERISA, and the MDA. It is upon these statutes that decisional authority and legal effectiveness is based, continuing to signal a trend towards the displacement of state consumer protection laws, both statutory and common law, in favor of federal schemes whose more important objectives are often

based on commerce regulation and market efficiency. When will an *individual's* health, safety, and welfare be restored as the objective of the law and not simply be the byproduct of a *company's* bottom-line profitability?

Sources:

Riegel v. Medtronic, Inc., 552 U.S. ___ (2008), *available at* 2008 WL 440744.

Medical Device Amendments of 1976, Pub. L. No. 94-295, §1(a), 90 Stat. 539 (1976), *relevant portions at* 21 U.S.C. §360 *et seq.* (2006)

Rowe v. New Hampshire Motor Transport Assoc., 552 U.S. ___ (2008), *available at* 2008 WL 440686.

Federal Aviation Administration Authorization Act of 1994, Pub. L. No. 103-305, 108 Stat. 1569 (1994), *codified at* 49 U.S.C. §14501 *et seq.* (2006)

Food and Drug Administration

Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (1974),