

May 2008

FEDERAL PREEMPTION

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According to many legal scholars, the United States Supreme Court is a body of policy rather than law. Its history has proven that to be true.

From its decision in 1857 in Dred Scott v Sanford to its 2000 decision in Bush v. Gore, 531 U.S. 98 (2000), the Court seems driven more by prevailing political views than consistent legal principles.

In the former case, the Court held that African Americans, whether slaves or not, could never be U.S. Citizens, could not sue in Court and were private property and when owned as a slave, could not be taken without due process.

In Bush v. Gore, a 5-4 majority held that no method could be established as a matter of law to count Florida ballots within the time limit imposed by Florida's Republican Legislature even though the count was nearly concluded by the time the opinion was published. This gave George W. Bush Florida's twenty-five electoral votes, providing him with one more than was needed to take the presidency.

President Bush has, in his eight years in office, left his pro corporate mark on the Court for a lifetime. The recent decision of Riegel v. Medtronic, Inc., 128 S. Ct. 999, 76 USLW 4087 (2008) reflects that concern for corporate insulation.

That decision holds that a state court action for damages as a result of an allegedly defective medical device can be preempted by The Federal Food, Drug and Cosmetic Act 52, Stat. 1040 as amended 21 U.S.C. §301, et seq. and in

particular the Medical Device Amendment of 1976 (MDA) 21 U.S.C. §360(c), et seq.

That Act provides:

“Except as provided in subsection (b) of this section, 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. §360k(a).”

The issue before the Court was whether a complaint based on State common law was “different from or in addition to” FDA requirements.

The Supreme Court had previously held in Medtronic, Inc. v Lohr, 518 U.S. 470 (1996) that State Court cases were not preempted under a section of the same act which dealt with a truncated FDA approval of medical devices which were approved as substantially equivalent to a previously manufactured device. Interestingly, in that case, the Court gave deference to the FDA’s position during the Clinton administration that State common law claims were not preempted but in Riegel the Court asked for, and received from the FDA another opinion which reversed itself and asked the Court to hold §360 devices preempted.

Since the Act in question provides no recourse for death or personal injury from an approved defective product, preemption means there is no remedy for those damages. For an act that was designed to improve the safety and efficacy of potentially dangerous devices, such a result seems incongruous. The majority dismissed that concern as follows:

“The dissent would narrow the pre-emptive scope of the term ‘requirement’ on the grounds that it is ‘difficult to believe that Congress would, without comment, remove all means of judicial recourse’ for consumers injured by FDA-approved devices. *Post*, at 5 (opinion of GINSBERG, J.) (internal quotation marks omitted). But, as we have explained, this is exactly what a pre-emption clause for medical devices does by its terms. The operation of a law enacted by Congress need not be seconded by a committee report on pain of judicial nullification. *See, e.g., Connecticut Nat. Bank v. Germain*, 503 U.S. 249, 253-254 (1992). It is not our job to speculate upon congressional motives. If we were to do so, however, the only indication available – the text of the statute – suggests that the solicitude for those injured by FDA-approved devices, which the dissent finds controlling, was overcome in Congress’s estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States to all innovations.”

Ever since the opinion in Lohr, supra, the Circuits have been divided on the question of whether its holding precluded preemption in products approved under the more stringent requirements of §360. Even in those Circuits holding that preemption applied, State Court cases have been held not to be preempted where allegations are made that the product or its marketing by the manufacturer

violated the terms of FDA approval. Those claims are considered to “parallel” rather than be “in addition to” the Federal requirements. In Riegel, the Court agreed at 17:

“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. *Lohr*, 518 U.S., at 495; see also *id.*, at 513 (O’Connor, J., concurring in part and dissenting in part). The District Court in this case recognized that parallel claims would not be pre-empted, see App. to Pet. for Cert. 70a-71a, but it interpreted the claims here to assert that Medtronic’s device violated state tort law notwithstanding compliance with the relevant federal requirements, see *id.*, at 68a.”

Thus it is apparent that only when a State Court suit for damages alleges a defect which has been specifically approved by the FDA in a product covered by this Act is such a suit subject to dismissal based upon preemption. Where a manufacturer markets a product “off label,” which is specifically prohibited by the FDA, there is a strong argument against preemption. Logic would dictate that when a manufacturer misleads the FDA or omits contrary information to obtain premarket approval that a defect hidden from the FDA would preclude preemption.

The Court has accepted for decision no less than five preemption cases during this term and the next. While this case dealt only with medical devices, pending cases run the gamut from drugs to tobacco.

It is sad, indeed, that the backdrop of this decision and those soon to come is an FDA which the press and the scientific community almost daily labels under funded and inept. In November, 2007, the subcommittee on Science and Technology of the FDA issued a report that stated, because of underfunding, the FDA's scientific base, its scientific organizational structure, its scientific work force and its technology infrastructure were overworked and inadequate so that the FDA could not possibly fulfill its mission. Worse still are the revelations revealed in discovery that pharmaceutical companies are more than willing to hide data from the FDA to get their products on the market even in the face of deadly consequences. Nevertheless, until Congress acts, medical device manufacturers are immune from suit based upon allegations concerning a defect which has been specifically approved by the FDA.

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