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Retroactivity In The Medical Device Safety Act

Law360, New York (April 21, 2009) -- Legislation introduced in the House and Senate on March 5, 2009, would overturn the Supreme Court's 2008 decision in Riegel v. Medtronic Inc., 128 S. Ct. 999 (2008), which held that the express preemption clause of the Medical Device Amendments of 1976 preempts state law tort claims challenging the safety of medical devices "that received premarket approval" from the FDA.

The bills were introduced the day after the Supreme Court's decision in Wyeth v. Levine, 129 S. Ct. 1187 (2009), which held that Federal drug laws do not ordinarily preempt state law failure to warn claims.

The legislation, entitled the "Medical Device Safety Act of 2009," was introduced in identical form in the House and Senate as H.R. 1346 and S. 540. The principal House sponsors of the bill are Frank Pallone Jr., D-N.J., and Henry Waxman, D-Calif. The principal Senate sponsor is Edward Kennedy, D-Mass. Hearings have not yet been announced.

The legislation would amend Section 521 of the Food, Drug and Cosmetic Act ("FDCA") (21 U.S.C. § 360k), which specifies that no state or local government may "establish or continue in effect ... any requirement" which is different from or in addition to any requirement applicable under the FDCA and which "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device [under the FDCA]."

The amendment would add a new section, stating that "[n]othing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State." Congressman Pallone has said he intends to move the legislation through his subcommittee "quickly."

Retroactivity Provisions

While the legislation will not affect final, non-appealable judgments, it does provide that the amendments will apply “to any civil action pending or filed on or after the date of enactment” of the amendments.

Significantly, the amendments will take effect “as if included in the enactment of the Medical Device Amendments of 1976,” which would allow plaintiffs in pending or future actions to challenge conduct that would have been lawful under Riegel when it occurred.

The retroactivity provisions are certain to be controversial, but it is clear that the sponsors see the provisions as a core element of the bill. On introducing the bill, Sen. Tom Harkin, D-Iowa, an original co-sponsor, said that the amendment is “consistent with Congress’s intent when it passed [the MDA] over 30 years ago.”

“Practically,” added Sen. Harkin, “that means that it applies to cases pending on the date of enactment of this legislation or claims for injuries sustained prior to enactment.”

Sen. Patrick Leahy, D-Vt., another original co-sponsor and the chairman of the Judiciary Committee, argued that “the preemption clause in the medical device amendments ... does not, and never was intended to preempt the common law claims of consumers injured by a federally approved medical device.”

If the retroactivity provisions of the Medical Device Safety Act are enacted, companies may have grounds to challenge retroactive application in certain cases.

“Retroactive legislation presents problems of unfairness that are more serious than those posed by prospective legislation, because it can deprive citizens of legitimate expectations and upset settled transactions.” GMC v. Romein, 503 U.S. 181, 191 (1992).

While Congress “has the power to amend a statute that it believes [courts] have misconstrued” and may “make such a change retroactive and thereby undo what it perceives to be the undesirable past consequences of a misinterpretation of its work product,” it must work “within broad constitutional bounds.” Rivers v. Roadway Express Inc., 511 U.S. 298, 313 (1994).

The Constitution expresses concern with retroactive legislation through several of its provisions, including the Due Process Clause (protecting the interests in fair notice and repose), the Ex Post Facto Clause (prohibiting retroactive application of penal legislation), and the Fifth Amendment’s Takings Clause (prohibiting legislatures from depriving private persons of vested property rights except for a “public use” and upon payment of “just compensation”).

Retroactivity and Punitive Damages Claims

There are strong ex post facto and due process arguments against retroactive application of the Medical Device Safety Act where plaintiffs claim entitlement to punitive damages based on pre-enactment conduct that, under Riegel, would have been lawful at the time.

The Supreme Court has recognized that "[r]etroactive imposition of punitive damages would raise a serious constitutional question." Landgraf v. USI Film Products, 511 U.S. 244, 281 (1994).

While the Ex Post Facto Clause has been interpreted to apply only to penal statutes, "[t]he very labels given 'punitive' or 'exemplary' damages, as well as the rationales that support them, demonstrate that they share key characteristics of criminal sanctions." Id. (citing Louis Vuitton S.A. v. Spencer Handbags Corp., 765 F.2d 966, 972 (2d Cir. 1985)) (retroactive application of punitive treble damages provisions of Trademark Counterfeiting Act of 1984 "would present a potential ex post facto problem").

Another case supporting an argument against retroactive imposition of punitive damages is BMW v. Gore, 517 U.S. 559 (1996). While BMW is not a retroactivity case per se, it holds that "[e]lementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice ... of the conduct that will subject him to punishment." Id. at 574.

Under this reasoning, punitive damages should not be allowed if the conduct was legal at the time it occurred. The court in BMW seemed less inclined than in Landgraf to consider an ex post facto challenge to retroactive imposition of punitive damages, noting that the "strict constitutional safeguards afforded to criminal defendants" by the Ex Post Facto Clause "are not applicable to civil cases." Id. at 574-75 n.22.

However, "the basic protection against 'judgments without notice' afforded by the Due Process Clause is implicated by civil penalties." Id.

Wholly apart from any constitutional argument, companies may argue that plaintiffs cannot meet state law legal standards for punitive damages — which usually require intentional or reckless misconduct — when the challenged conduct would have been construed as legal by the Supreme Court at the time it occurred.

Motions to dismiss punitive damages claims as a matter of law should be considered on this ground, as well as constitutional grounds. If a punitive damages claim survives dismissal, there may be an argument that companies should be entitled to introduce evidence of the legality of the conduct during the relevant time period.

Retroactivity and Compensatory Damages Claims

Challenges to retroactive legislation imposing non-punitive civil liability are more difficult to sustain. The most promising argument against retroactive application of the Medical

Device Safety Act to compensatory damages claims is that it would violate due process — the Ex Post Facto Clause does not pertain to purely civil liability.

Retroactive civil legislation passes due process scrutiny so long as Congress had "a legitimate legislative purpose [that it] furthered by rational means." Romein, 503 U.S. at 191. Despite this highly deferential standard of review, there are still some limits to retroactivity.

The potentially severe retroactive reach of the Medical Device Safety Act — 33 years — makes it vulnerable to a due process challenge in the right case.

"The distance into the past" that an act "reaches back to impose a liability" and "the magnitude of that liability" can "raise substantial questions of fairness." Eastern Enterprises v. Apfel, 524 U.S. 498, 534 (1998) (plurality opinion).

Although the plurality in Eastern Enterprises declined to address due process because it found that the act at issue violated the Takings Clause as applied to Eastern, it noted that the act's "severely retroactive impact" on Eastern implicated due process concerns. Id. at 537.

Justice Kennedy agreed that "the degree of retroactive effect is a significant determinant in the constitutionality of a statute" and would have held that "in creating liability for events which occurred 35 years ago the [act] has a retroactive effect of unprecedented scope" and "would violate the proper bounds of settled due process principles." Id. at 549-50 (Kennedy, J., concurring in the judgment and dissenting in part).

Other Supreme Court cases note that Congress generally establishes only a "modest period of retroactivity." U.S. v. Carlton, 512 U.S. 26, 32 (1994) (retroactive legislation met due process test with retroactive period slightly greater than one year).

The deferential rational basis standard of review has, however, led several courts to reject due process challenges to retroactive legislation, including a case where Congress retroactively stripped defendants of a preemption defense.

The Eighth Circuit recently upheld an amendment clarifying that § 20106 of the Federal Railroad Safety Act did not preempt state law claims. Lundeen v. Canadian Pacific Ry. Co., 532 F.3d 682, 688 (2008), petition for cert. filed, 77 U.S.L.W. 3432 (Jan. 8, 2009) (No. 08-871).

Prior to the amendment, several courts had interpreted § 20106 to preempt state law claims by people injured in railroad accidents.

The Eighth Circuit held that "[i]t was rational for Congress to 'clarify' this result was not an intended purpose of § 20106 prior to the amendment.

"Indeed, the very act of enacting a retroactive statute 'to correct the unexpected results of [a judicial] opinion' qualifies as a legitimate legislative purpose which survives scrutiny under the deferential rational basis standard of review." Id. at 690 (quoting Romein, 503 U.S. at 191) (upholding retroactive legislation against a due process challenge where purpose of legislation was to overturn Michigan Supreme Court opinion).

Challenges to retroactive application of the Medical Device Safety Act may be successful in the right case, particularly where retroactivity reaches back farther than the statutory amendment at issue in Lundeen, which was enacted in August 2007 and was retroactive only to January 2002.

This will be particularly important where plaintiffs allege a medical device caused latent injuries that manifested many years after implantation.

Moreover, one judge on the Lundeen panel dissented, leaving open the possibility that other Circuits or ultimately the Supreme Court will disagree with the Eighth Circuit panel majority's analysis.

See Lundeen v. Canadian Pacific Ry. Co., 550 F.3d 747, 754-55 (2008) (Beam, J.) (dissenting from denial of rehearing en banc: "the panel majority falls well short in its published rationale for its rejection of [defendant's] due process" challenge; "when jurisdiction stripping is coupled with dissipation of substantive rights, as, as for instance, when established preemption defenses are taken away from a railroad, due process protections demand a different outcome").

In short, if the Medical Device Safety Act is enacted, there may be strong constitutional and state law grounds to challenge the retroactive application of the act to punitive damages claims.

Challenges to compensatory damages claims will be more difficult to sustain, but there are legitimate bases to contest retroactivity, particularly in cases involving latent injuries from devices implanted many years ago.

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