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Riegel v. Medtronic: Better Off Without It?

Law 360, New York (August 1, 2008) — The Supreme Court's recent decision in Riegel v. Medtronic Inc. concluded that the law on medical device preemption should remain the same as it ever was: medical devices approved by the FDA's Pre-Market Approval process are expressly preempted from design defect and inadequate warning claims.

Hysteria ensued among the plaintiffs bar and some of the news media, with proclamations that the sky was falling on patients' safety.

In fact, Riegel merely echoed the conclusions of the vast majority of Circuit Courts. Nonetheless, members of Congress have vowed to reverse the decision through legislation, spurred by the illusion that Riegel had dramatically altered the legal landscape.

In so doing, they threaten to do more harm to patients by discouraging innovation and increasing health care costs.

The Riegel Opinion

At the heart of the Riegel decision was the issue of whether the plaintiff's lawsuit, brought under state law tort theories, was preempted by the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. 360c, et seq. The MDA includes an express preemption provision (21 U.S.C. 360k(a)) that states:

> "[N]o 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."

The device at issue in Riegel went through the Pre-Market Approval process, requiring significant testing and development, and a multi-volume application to the FDA.

While a 510(k)[1] device may be approved by showing that it is substantially equivalent to a predicate device, a PMA application may only be approved if the FDA finds a "reasonable assurance" of the device's "safety and effectiveness."

This distinction made all the difference in the preemption analysis, as both the District Court for the District of New York and the Second Circuit held that Riegel's claims were expressly preempted.

In affirming the Second Circuit, eight of the justices held that premarket approval did, in fact, impose device-specific requirements pertaining to safety and effectiveness: "Premarket approval is specific to individual devices . . . it is federal safety review."

Justice Ginsburg's dissent focused primarily on the history behind the MDA, noting that prior to the FDA's regulation of medical devices, individual states had attempted to do so on their own creating an uneven and unpredictable landscape of requirements for device manufacturers to follow.

The Medical Device Amendments brought uniformity to medical device regulation, and were meant to prevent haphazard and inconsistent requirements from being imposed by the individual states.

Thus, Ginsburg reasoned, "state premarket regulation of medical devices, not any design to suppress tort suits, accounts for Congress' inclusion of a preemption clause in the MDA."

Meeting Ginsburg's appeal to policy, Scalia's majority opinion argued that the regulation of medical devices by jury is "less deserving of preservation" than any other.

Regulation by state legislature "could at least be expected to apply cost-benefit analysis similar to that applied by the experts at the FDA."

A jury, on the other hand, would examine only the cost of improving the safety of a particular design, and often the cost of improving the safety to prevent the single, particular injury suffered by the suing plaintiff.

Such a jury "is not concerned with [the device's] benefits; the patients who reaped those benefits are not represented in court."

Ultimately, the Supreme Court decided that the plaintiff's product liability claims would, if successful, impose requirements on Medtronic's catheter that would be different from, or in addition to, the FDA's requirements as imposed through the PMA process.

The express preemption provision therefore preempted Riegel's claims.

Justice Stevens' concurrence noted that Justice Ginsburg was likely correct in her explanation of the intended purpose of the preemption provision, but acknowledged that its plain meaning compelled a decision in Medtronic's favor.

Presciently, he suggested that if Congress was unhappy with the decision, it could simply pass legislation making its intentions clear.

Same As It Ever Was

Contrary to the ensuing panic, Riegel did not signal that the sky had fallen on medical device cases.

The devices affected by this ruling comprise a very small percentage of the total number of medical devices on the market.

Further, the Riegel decision merely affirmed what the majority of circuit courts had already concluded,

causing only a couple ripples of change in the Eleventh Circuit and the D.C. circuit, along with a single district in California, as demonstrated below:

First Circuit, King v. Collagen Corp., 983 F.2d 1130 (1993). Claims preempted.

Second Circuit, Riegel v. Medtronic Inc., 451 F.3d 104 (2006). Claims preempted. Affirmed by Supreme Court.

Third Circuit, Horn v. Thoratec Corp., 376 F.3d 163 (2004). Claims preempted.

Fourth Circuit, Rattay v. Medtronic Inc., 482 F. Supp. 2d 746 (2007). Claims preempted. "Of the circuit courts that have addressed the issue, all save one have concluded that the PMA process does indeed create device-specific requirements."

Fifth Circuit, Martin v. Medtronic, Inc., 254 F. 3d 573 (2001). Claims preempted.

Sixth Circuit, Kemp v. Medtronic Inc., 231 F. 3d 216 (2000). Claims preempted. The anti-Goodlin (below).

Despite "nearly indistinguishable facts," the Sixth Circuit "respectfully disagree[d] with the conclusions drawn by the panel of the Eleventh Circuit in Goodlin."

Seventh Circuit, Mitchell v. Collagen Corp., 126 F. 3d 902 (1997). Claims preempted. "We agree that the PMA process . . . can constitute the sort of specific federal regulation of a product that can have a preemptive effect."

Eighth Circuit, Brooks v. Howmedica Inc., 273 F. 3d 785 (2001). Claims preempted.

Ninth Circuit, Northern Notmeyer v. Stryker, 502 F. Supp. 2d PMA 1051 (2007). No preemption. Persuaded by Goodlin that District Corp., process does not impose specific requirements. Carson v. Depuy Spine, U.S. Dist. (June 25, 2007). Claims preempted. Noted that Goodlin "stands alone amongst the Circuits that have considered the scope of preemption."

Tenth Circuit, Oja v. Howmedica Inc., 111 F. 3d 782 (1997). While the Tenth Circuit had not yet addressed the issue, the Oja case offered the closest thing to such an analysis. While Oja involved a 510(k) device, the Court referred approvingly to prior case law holding that the express preemption provision should apply to Investigation Devices.

Eleventh Circuit, Goodlin v. Medtronic Inc., 167 F. 3d 1367 (1999). No preemption. PMA approval does not "provide any indication of what (if any) specific substantive requirement the FDA may have applied to reach that result.

D.C. Circuit, Webster v. Pacesetter Inc., 171 F. Supp. 2d 1 (2001). No preemption. Admits that PMA approval is "obviously device specific," but complains it is "otherwise too general to permit identification of any specific requirements."

Although Riegel merely mapped out what was already the law of most of the land, print media and the plaintiffs bar overreacted to Riegel as "a terrible and scathing opinion" that was sure to delight the "white shoe legal assassins" who represent medical device companies in teams "of 10 or 20 attorneys."[2]

The New York Times claimed that the decision was the "worst of both worlds: a government health agency that cannot protect them and rules that block them from winning compensation when injured."[3]

In fact, Riegel will not prevent lawsuits from being filed. While design and warning claims were foreclosed, manufacturing defect and "parallel" claims still survive under Riegel.

A "parallel claim" is a claim that alleges the manufacturer failed to follow FDA regulations, either through a manufacturing defect that deviated from the device's specifications, or in failing to report important information to the FDA.

PMA-approved devices are meant to sustain or save lives, and therefore are accompanied by a large jury award potential if they are alleged to have failed. As a result, the reward to plaintiffs and attorneys will be too great not to risk bringing a claim with the hope of proving up a parallel claim.

In nearly every case, a plaintiff may contend that he is unable to evaluate his chances of winning on such a claim unless he first filed suit and conducted discovery into whether, in fact, a parallel claim may exist.

Better Off Without It?

Both Senator Kennedy (D-Mass.) and Congressman Waxman (D-Calif.) promised to overrule Riegel through legislation, and complaining (inaccurately) that the decision "strips consumers of the rights they've had for decades"[4] and gives manufacturers "a green light for shoddy practices."[5]

On June 26, 2008, Congressman Frank Pallone (D-N.J.), along with Congressman Waxman and several others, submitted a bill titled the Medical Device Safety Act of 2008. The bill would amend the MDA by adding the following:

> "Nothing 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 stated that this act would reverse "an unfortunate Supreme Court decision that denied victims any legal recourse."[6]

The proposed language would expose manufacturers to liability for all medical devices, PMA or otherwise. Not only would this act reverse Riegel, it would reverse years of nearly unanimous decisions in most of the country's Circuit Courts.

More significantly, and perhaps not as apparent to Riegel's opponents in Congress, is the fact that this act would also reverse the fundamental principle and purpose of the Medical Device Amendments.

Manufacturers would again be subject to wildly varying requirements and standards in every state. These standards would be imposed by second-guessing juries with far less time, information and education than the FDA. FDA approval would be practically meaningless, and would offer, at best, evidentiary support of a device's safety.

Under the proposed legislation, manufacturers would be subject to suit all along the way of the PMA process, from early stage clinical trials through final FDA approval.

The only benefit of subjecting a manufacturer's device to a safety and effectiveness evaluation would be removed, and replaced instead with the imminent threat of crippling litigation.

Under this system, where innovation carries such great risk, many devices may simply never make it to the market.

Those devices on the market would also likely see a dramatic increase in cost to account for anticipated litigation expenses.

Not only do manufacturers stand to be harmed by the "Medical Device Safety Act," but patients would be better off without it, too.

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[1] Approval via 510(k) application accounts for the great majority of medical devices presently on the market. In order to receive approval, the applicant need only show that the subject device is "substantially equivalent" to a "grandfathered in" device that was in existence prior to the enactments of the Medical Device Amendments, or to a device that has received pre-market approval.

In 2005, more than 3000 devices were approved with 510(k) applications, while 32 devices entered the market after receiving Pre-Market Approval.

[2] Injury Law Blog, Riegel v. Medtronic – the anti-tort SC opinion and the federal preemption clause, (March 5, 2008), injurylaw.labovick.com/2008/03/articles/product-liability/riegel-v-medtronic-the-anti-tort-sc-opinion-and-the-federal-preemption-clause/.

[3] Gardiner Harris, Justices Add Legal Complications to Debate on FDA's Competence, (Feb. 21, 2008), www.nytimes.com/2008/02/21/washington/21fda.html?_r=2&scp=10&sq=supreme+court&st=nyt&oref=slogin&oref=slogin.

[4] Paul Halpern, Supreme Court Decision May Not Shield Medtronic Sprint Fidelis from Legal Action, (February 24, 2008), www.lawyersandsettlements.com/articles/10038/medtronic-decision.html.

[5] Jacqueline Bell, High Court Aims to Alter Product Liability Landscape, (February 26, 2008), www.productliability.law360.com/Secure/printview.aspx?id=48015.

[6] Medical Device Safety Act Would Restore Consumer Rights, NewsInferno.com, (June 27, 2008), www.newsinferno.com/archives/3357#more-3357.

