A Reversal of Medtronic v. Riegel? A Legislative Update on Liability Against Medical Device Companies

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On March 5, 2009, both the House and the Senate proposed legislation amending the Federal Food, Drug, and Cosmetic Act to reverse the 2008 Supreme Court decision in *Medtronic v. Riegel* H.R. 1346; S. 540. The law, if passed, would permit plaintiffs to bring state law liability suits against medical device companies with respect to devices approved by the federal Food and Drug Administration ("the FDA") under the premarket approval ("PMA") process, a longer, more complicated evaluation process undertaken by the FDA in approving a device.

In the *Riegel* decision, the Supreme Court held that state liability lawsuits are preempted for devices granted PMA approval from the FDA. In particular, *Riegel* held that plaintiffs could not proceed with common law tort claims, such as strict liability, breach of implied warranty, or negligence, that would impose requirements relating to the safety or effectiveness of a PMA-approved device that were different from the FDA's own requirements.

Both the House and Senate bill propose to amend Section 521 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 360k) in two ways: first, by adding a provision that the federal law has no effect on state tort law. Entitled "No Effect On Liability Under State Law," the new provision, as proposed, states, "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."

Second, the bills propose to make the legislation retroactive, stating that the amendment is to take effect as if it had been included in the enactment of the original legislation back in 1976 and explicitly saying that the change applies "to any civil action pending or filed on or after the date of enactment of this Act."

This explicit language is likely necessary if the legislation is to have retroactive effect and apply to cases already pending in the courts. Generally, there is a presumption against applying statutes that affect substantive rights or liabilities to conduct that arose before the statute was enacted.

The courts have made clear that an express Congressional command needs to be very explicit and very clear. Statutes are not to be construed as retroactive unless their language "requires" that they be so and allows of no other interpretation. The language in the proposed Medical Device Safety Act appears to have been drafted with this in mind. If the bills are enacted, what this means for companies engaged in suits now is that they will lose any relief they might have had under *Riegel* and common law tort claims that might have been barred will be permitted to proceed.

There are not many limits on Congressional authority to make a statute retroactive. While the Due Process clause of the Constitution does protect fair notice interests that could be compromised by retroactive legislation, courts have recognized that Due Process restrictions on retroactive civil legislation are "modest." (In the criminal arena, the analysis is different.) To pass muster, civil retroactivity provisions must have a "rational basis," meaning that there is a legitimate legislative purpose served by making the statute retroactive. Legitimate legislative purposes are defined broadly, and courts have found that merely correcting the results of an unexpected judicial opinion can qualify as a legitimate interest sufficient to justify a statute's retroactivity.

Because most medical devices are not approved through the PMA process, it is not clear how broad-reaching an effect either the *Riegel* decision or its legislative "fix" will have. As an example, the Supreme Court in *Riegel* noted that in 2005, a total of 3,148 devices were approved under the alternative "substantial equivalence" test, while only 32 new devices were approved through the PMA process. At the same time, the inclusion of supplemental PMA's, which can involve the most intensive, high value items, would significantly increase that figure.