

Riegel v Medtronic: A Victory for Patients and Device Manufacturers in the US

Kenneth Geller and David Gossett discuss the Supreme Court's decision and why, by protecting the FDA's review process from second-guessing by juries, that decision will benefit countless patients.

In December 2007 the US Supreme Court heard oral argument in *Riegel v Medtronic, Inc*, to determine whether, if a Class III medical device has been approved for sale by the Food and Drug Administration via its premarket approval process, that approval precludes patients from bringing lawsuits against the manufacturer based on claims that the device was not safe and effective despite complying with the FDA's conditions of approval¹.

On 20 February, the court released its decision², and held by an 8-1 margin that the express pre-emption provision in the Medical Device Amendments pre-empts state common law causes of action – whether premised on negligence, strict liability, implied warranty, or otherwise – to the extent such claims would impose liability on the manufacturer for a device that complied with the FDA's conditions of approval. The court held that the PMA process imposes federal “requirements” on device manufacturers, that state common-law causes of action challenging the design or labelling of a compliant device would impose contrary state-law requirements on the manufacturers and that such state-law claims are barred.

In so ruling, the court merely affirmed the result reached by the vast majority of the federal courts of appeals over the years³. Thus, we expect that the decision will have only a minor effect on the approach the device industry will take towards the FDA's regulatory process. The only obvious effect is that the decision may somewhat increase the attractiveness of the PMA process over the 510(k) substantial-equivalence process to manufacturers, because the latter approval process does not lead to protection from state common-law litigation under the pre-emption provision.

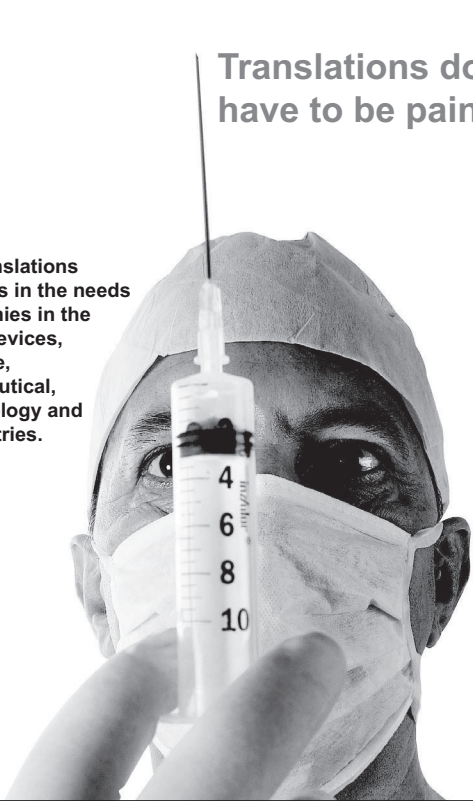
Benefits to patients

The more important effect of the decision, to our minds, is the way in which it will benefit the thousands of individuals whose lives will be saved and health improved by Class III medical devices in the future. As the court explained in *Riegel*, subjecting device manufacturers to the whims of juries could have had devastating effects not just on those manufacturers but also on patients. As the court noted, in approving devices FDA experts “apply cost:benefit analysis” to determine, among other things, “[h]ow many more lives will be saved by a device which, along with its greater effectiveness, brings a greater risk of harm”⁴. “A jury, on the other hand, sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.” Had the court ruled against Medtronic in *Riegel*, the resultant common-law litigation may well have caused device manufacturers not to market devices that, while helping countless patients, could nonetheless have caused some harm to a few patients.

Thus, the true victors in the *Riegel* case are not device manufacturers but the general public. Protected by the knowledge that, if the scientific experts at the FDA agree that a cutting-edge medical device should appropriately be marketed to the public without fear of catastrophic liability through the common-law tort system, manufacturers are now free to innovate and design devices that will continue to save lives for generations to come.

References

1. *The Regulatory Affairs Journal – Devices*, 2008, 16(1), 56-57
2. *Riegel v Medtronic, Inc*, US Supreme Court No 06-179, 20 February 2008, www.supremecourt.us/opinions/07pdf/06-179.pdf
3. See, eg, *Riegel v Medtronic, Inc*, 451 F 3d 104 (2d Cir 2006), *McMullen v Medtronic, Inc*, 421 F 3d 482, 487–488 (7th Cir 2005); *Cupek v Medtronic, Inc*, 405 F 3d 421, 424 (6th Cir 2005); *Horn v Thoratec Corp*, 376 F 3d 163, 171–173 (3d Cir 2004); *Brooks v Howmedica, Inc*, 273 F 3d 785, 799 (8th Cir 2001) (en banc); *Martin v Medtronic, Inc*, 254 F 3d 573, 585 (5th Cir 2001); *Kemp v Medtronic, Inc*, 231 F 3d 216, 226–227 (6th Cir 2000); *Mitchell v Collagen Corp*, 126 F 3d 902, 911 (7th Cir 1997)
4. See Reference 2



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