

Preemption and the Distinction between Drugs and Devices

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On March 4, 2009, the Supreme Court issued their decision on Wyeth v. Levine, one of the most important court cases in recent history for the pharmaceutical industry. The central issue in the case presented to the Supreme Court is preemption – the idea that federal law trumps state law in cases where the two potentially conflict.

The Supreme Court ruled that Federal Drug Agency (FDA) approval of the warnings on pharmaceutical product labels does not preempt state court decisions in civil suits claiming that those warnings are inadequate. Interestingly, a year earlier, in the case of Riegel v. Medtronic decided on February 20, 2008, the Supreme Court ruled that premarket approval from the FDA preempted common-law claims challenging the safety or effectiveness of a medical device.

Why did the Supreme Court rule that FDA approval preempts state law for medical devices but not for pharmaceutical products? As the NY Times explained, “the discrepancy reflects the different legal issues in the two cases.” While this is true that each of these cases brought different issues before the Supreme Court, the differences can be attributed to the fact that some of the decades-old regulations underlying the medical device industry differ from those underlying the pharmaceutical industry. The 1976 Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act explicitly bar state and local governments from imposing requirements on medical devices that differ from the requirements established by the FDA. No pharmaceutical equivalent to this preemption provision exists.

In the wake of the Supreme Court’s decision in Wyeth v. Levine, the Medical Device Safety Act of 2009 (H.R. 1346) was introduced in the House of Representatives by Rep. Frank Pallone [D-NJ]. If passed, this bill would, “prohibit specified provisions preempting state and local requirements for medical devices intended for human use from being construed to modify or otherwise affect any action for damages or the liability of any person under state law.”

In short, this bill would reverse the Supreme Court's decision in *Riegel v. Medtronic* and, "place medical devices and drugs on a level playing field with respect to patient lawsuits," according to an [editorial](#) in the [New England Journal of Medicine](#). This change would not only apply to future claims – it would also be applied retrospectively. The language of the Medical Safety Act of 2009 states that it would:

(1) take effect as if included in the enactment of the Medical Device Amendments of 1976 (Public Law 94-295) and

(2) apply to any civil action pending or filed on or after the date of enactment of this Act.

In practice, this bill would give standing to pending medical device cases that probably would have been dismissed in the wake of *Riegel v. Medtronic*. The retroactive removal of preemption protection in these cases would obviously have enormous ramifications for the medical device industry. Bizarrely, the actions set into motion by the Supreme Court decision in *Wyeth v. Levine* may have a larger impact on the medical device industry than the pharmaceutical industry.

Whether the Medical Device Safety Act of 2009 passes or not, its introduction is part of a trend to reduce the regulatory differences between the pharmaceutical industry and the medical device industry. Companies in the pharmaceutical and medical device industries should note this trend and adjust their corporate compliance programs accordingly.