



CORRESPONDENCE

[◀ Previous](#)

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[Next ▶](#)

Modernizing Device Regulation

To the Editor: The Perspective article by Garber (April 1 issue)¹ overstates the impact of the Supreme Court's 2008 decision upholding federal preemption for medical-device companies. The 8-to-1 decision did not bestow immunity on medical devices approved by the Food and Drug Administration (FDA), as the article asserts, but merely confirmed long-standing legal precedent.

Patients have always been able to sue a manufacturer if a device is not manufactured or marketed according to FDA specifications, guidelines, or regulations. It is also important to note that preemption applies only to a narrow class of devices that account for only about 2% of devices approved annually.

Abolishing preemption will eliminate the FDA's primacy as the sole arbiter of the safety and effectiveness of medical devices and instead allow state courts and lay juries to make those important determinations. This could result in a patchwork of regulations in the 50 different states, and access to new treatment options could be limited, depending on where a patient lives. Replacing the judgment of FDA scientists with those of untrained juries would not be good for American patients.

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Mr. Samp reports having filed an amicus brief in the U.S. Supreme Court case *Riegel v. Medtronic* on behalf of the [Washington Legal Foundation](#). No other potential conflict of interest relevant to this letter was reported.

References

1. Garber AM. Modernizing device regulation. *N Engl J Med* 2010;[362:1161-1163](#). [[Free Full Text](#)]

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