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A Pivotal Medical-Device Case

TO THE EDITOR: Three cheers for the *Journal* for recognizing the importance of the Supreme Court's upcoming rulings on "FDA [Food and Drug Administration] preemption" cases: whether the fact that a drug or medical device is in compliance with FDA regulations ought to shield its manufacturer from product-liability claims. In your editorial on this topic (Jan. 3 issue),¹ you rightfully describe these cases as having "major, even momentous, implications" for patients' rights and manufacturers' accountability.

There is one point in the editorial that needs clarification. *Warner-Lambert v. Kent* — which concerns drugs rather than devices — turns on a Michigan law that allows liability claims if plaintiffs can show that the FDA was defrauded. Defendants argue that only the FDA can find fraud against itself, not state courts, and thus Michigan's "fraud exception" is preempted.

The *Kent* case explicitly does not address the wider issue of FDA preemption in the drug arena. However, that latter question — the big one — is the heart of another case the Supreme Court recently accepted, *Wyeth v. Levine*. Stay tuned.

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TO THE EDITOR: The editorial concerning the Medtronic medical-device case now before the Supreme Court concludes, "Ultimately, we believe that the pivotal question for the justices in *Riegel v. Medtronic* resides in what is in the best interest of American society." This is a commonly made er-

ror. The pivotal question for the justices is actually to decide whether FDA approval preempts liability claims in the state courts. It is the justices' job to decide on this issue based on their understanding of the law in question and the Constitution, not on what they perceive to be the best interest of American society. They are supposed to be interpreting the laws as written, not advocating for any individual vision of what they conclude is best for protecting patients.

If the American people deem that the justices' conclusions are not in their best interest, then they have the privilege of changing the law through Congress.

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TO THE EDITOR: In the case of *Riegel v. Medtronic*, it would seem logical to state that premarketing approval by the FDA addresses solely the functional and medical adequacy of the device and that faultless quality of the marketed devices is assumed to be inherent. It would seem unreasonable to maintain that FDA approval would protect the manufacturer of an approved device against litigation based on faulty product quality (i.e., the defective balloon in *Riegel v. Medtronic*).

The approval process and subsequent approval do not and cannot ensure product quality or provide surveillance of manufacturing processes and quality control. The *Lohr* case proves this point.

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Central Venous Catheterization — Subclavian Vein

TO THE EDITOR: In their video and accompanying article, Braner et al. (Dec. 13 issue)¹ omit an important and common complication of subclavian

central-venous-catheter placement — misplacement of the catheter tip in the internal jugular vein. This occurs in approximately 5% of patients,