The new engl and journal of medicine

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 error. 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.
Correspondence

Many health care professionals mistakenly believe that 18-gauge cannulas are adequate for rapid fluid resuscitation, despite international recommendations to use 14- or 16-gauge peripheral cannulas for this purpose. Flow rates for a green (18-gauge) cannula are significantly lower than those for a 16-gauge or larger cannula.\(^1\)

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To the Editor: We have some important concerns about the description of central venous catheterization of the subclavian vein in the video by Briner et al. We believe there are substantial discrepancies between the animation and the text regarding the anatomical landmarks. The course of the subclavian vein under the medial part of the clavicle is depicted as showing attachment through connective tissue to the clavicle, the subclavian muscle, the pretracheal fascia, and the first rib (Fig. 1).\(^2,3\) This explains why the vessel can never separate from the parietal pleura and why the vessel lumen is always open, even though its diameter is reduced when the shoulder is pulled downward, as would happen if a towel were placed between the shoulders.\(^2\) In addition, the video demonstrates a forward–backward movement of the guidewire through a cannula. This movement is associated with a high risk of damage to the wire and may result in fragmentation or even embolism.\(^4\) Therefore, one should refrain from retracting the catheter tip and repositioning.\(^3\)

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3. Naina HV, Harris S, Bharat A, Kuppachi S, Siddique S. Bedside maneuvers that may reduce the incidence of the guidewire rather than the straight end. Inserting the J wire such that it points caudad is an excellent way of directing the wire so that it goes downward toward the heart rather than upward into a neck vein.

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To the Editor: Briner et al. make the important point that when high-volume intravenous fluid resuscitation is required, short, large-bore peripheral cannulas are usually more rapidly inserted and more effective than central venous lines. However, the video shows an illustration of a green peripheral cannula that appears to be an 18-gauge cannula, not a large-bore cannula.

The New England Journal of Medicine
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Eosinophiluria and Acute Interstitial Nephritis

TO THE EDITOR: Over the past two decades, testing for eosinophiluria has gained widespread acceptance as a means of screening for acute interstitial nephritis. The frequent use of this test may be explained, in part, by the subtle clinical presentation of this condition (fever, rash, arthralgia, and renal failure), which mimics other entities, such as pyelonephritis and renal manifestation of varicella. Renal biopsy, although used infrequently to diagnose acute interstitial nephritis, continues to be the gold standard.

The data on urinary eosinophil testing are inconsistent. A report in the Journal in 1986 by Nolan et al.1 states that detection of eosinophils with Hansel’s stain “appears to be a sensitive marker for drug-induced acute interstitial nephritis.” Similar studies by Corwin et al.2,3 support this conclusion. All reports note a broad spectrum of diseases associated with eosinophiluria and urge caution in the interpretation of positive findings. Furthermore, a 1987 letter to the editor4 pointed out that in the report by Nolan et al., acute interstitial nephritis was not established on a histologic basis for the majority of patients. Seven years later, a study of 152 patients with pyuria and 51 patients with suspected acute interstitial nephritis5 showed that the sensitivity of eosinophiluria was 40% for the detection of acute interstitial nephritis and the positive predictive value was no greater than 38%.


The authors reply: We agree with Harris and Naina that malposition of a catheter in the internal jugular vein is an important complication. The constraints of video production do not permit the inclusion of all possible complications, and we agree that the articles by Ambesh et al. and Naina et al. describe this complication and potential solutions quite well. Evans notes a technique that can be used to avoid internal-jugular-vein placement; we have no experience with this technique.

Graham points out an important consideration: it is clear that higher-bore, shorter catheters result in more rapid fluid flow. Without doubt, use of a 14- or 16-gauge catheter would result in more rapid fluid administration than use of the 18-gauge catheter pictured in the video. However, it is important to keep in mind the length of the peripheral catheter. In some cases, smaller catheters that are also shorter may have higher infusion rates.

In response to the comments by Schummer and colleagues, many standard texts refer to placement of a towel underneath the spine. The intent is not to pull the shoulder caudad but to allow the shoulder to relax posteriorly to move the head of the humerus out of the working plane. It is one option in optimizing the position. As for the forward–backward movement of the wire, the potential for damage to the wire is not zero, but in the context described, in which advancement of the wire leads to dysrhythmia, we believe it is important to pull the wire back quickly. The operator should be sure that the wire always moves freely; it should never be tugged or require anything but minimal effort. If more than minimal effort is required, the wire and needle should be withdrawn together. We believe that the incidence of wire damage is low enough that the practice should not be avoided at all costs, but learners should keep in mind that when aberrancies from normal procedure occur, the procedure should be modified appropriately.

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