

the net effect of weight loss in the management of incontinence.

Zekeriya Ulger, M.D.

Mustafa Cankurtaran, M.D.

Servet Arýogul, M.D.

Hacettepe University
06100 Ankara, Turkey
zulger@hacettepe.edu.tr

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THE AUTHORS REPLY: Kelly and Vichayavilas suggest that changes in sodium intake rather than weight loss may mediate the effect of the Program to Reduce Incontinence by Diet and Exercise (PRIDE) weight loss intervention on frequency of urinary incontinence. To test this hypothesis, we added weight loss and changes in sodium intake to the generalized estimating equation negative binomial model we used to assess the effect of treatment on the frequency of urinary incontinence. We assessed the relative difference between the overall effect of treatment, as estimated in the unadjusted model, and its direct effect through other pathways, as estimated in models controlling for post-randomization changes in weight and sodium intake. Sodium intake was quantified using the Block Food Frequency Questionnaire, a 110-item self-administered questionnaire validated to estimate the intake of nutrients and foods in the various food groups.¹ Completed questionnaires were sent to Berkeley Nutrition Services (Berkeley, CA) for a complete nutrient analysis including macronutrients and micronutrients.²

The overall effect of assignment to the weight-loss intervention was an estimated 21.7% reduction in the frequency of urinary incontinence over 6 months. This overall estimate is based on a complete case analysis and cannot be computed from the within-group percent reductions in frequency that are based on multiple imputation and shown in Table 2 of our article.

Analyses adjusting for change in weight only indicated that change in weight explained 74% of the overall effect of treatment. In contrast, adjustment for change in sodium intake explained, at most, 9% of the treatment effect. Thus, change in weight appears to be a much more important mediator than change in sodium intake in the present study.

Ulger et al. suggest that we should have matched the two study groups with respect to medication use to avoid the confounding of an effect of weight loss. Drugs proposed to have an effect on urinary incontinence include α_1 -adrenoceptor antagonists, antipsychotic agents, benzodiazepines, diuretics, and antidepressants, as well as hormone-replacement therapy in postmenopausal women. Because this was a randomized study, the use of these medications is expected to be balanced at baseline. To verify the balance, we examined medication logs collected for each woman and found that among all medications reported at baseline, there was no difference in medication use among the noted drug categories (12.9% in the weight-loss group and 12.8% in the control group). However, there is no way for us to control the potential influence of study group on post-randomization changes in use.

Leslee L. Subak, M.D.

University of California, San Francisco
San Francisco, CA 64115
subakl@obgyn.ucsf.edu

Rena Wing, Ph.D.

Warren Alpert Medical School at Brown University
Providence, RI 02912

Eric Vittinghoff, Ph.D.

University of California, San Francisco
San Francisco, CA 64115

for the PRIDE Investigators

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Preemption and Malpractice Liability

TO THE EDITOR: In their Perspective article about the Supreme Court, preemption, and malpractice liability (Feb. 5 issue),¹ Kesselheim and Studdert

suggest that preemption will not result in more malpractice claims against physicians for failure to warn, which they say are uncommon and finan-

cially unattractive to plaintiff's attorneys. I hope they are correct but have yet to find a plaintiff's attorney who agrees with them.

In 2008, the U.S. Supreme Court ruled in *Riegel v. Medtronic*² that a product-liability lawsuit brought against Medtronic in a state court was preempted because the device (an angioplasty catheter) had received marketing approval from the Food and Drug Administration (FDA). Recently, a federal judge in Minnesota, citing that ruling, dismissed scores of patients' lawsuits involving the Medtronic's Sprint Fidelis lead, which the manufacturer had recalled because it was fracturing in patients. Thus, FDA approval now immunizes medical-device manufacturers from state tort liability. As a result, plaintiffs will target physicians, hospitals, and health care systems.

Plaintiffs will assert, not unreasonably, that physicians who are qualified to use medical devices should be able to assess the quality and completeness of the data supporting a product's safety and efficacy. A defense based on the fact of FDA approval may be insufficient if other practitioners would not use the product because of inadequate safety or efficacy data. Hence, preemption should make physicians wary of devices approved on the basis of limited or short-term studies.

Congress must consider the long-term implications of preemption. Rather than spurring innovation, preemption may create an environment in which, for fear of liability, physicians and hospitals decline to use promising new therapies, to the detriment of patients. If Congress decides that medical-device companies are to be immunized through preemption, then physicians and hospitals should be similarly protected from tort lawsuits when using products according to FDA-approved labeling or guidelines.

Preemption underscores the need for the FDA to become a rigorous scientific organization whose primary objective is patients' safety. To achieve this goal, the agency must be led by distinguished scientists empowered to apply scientific methods to regulation. Some FDA officials may say the agency is already strictly applying such methods, but its record of miscues suggests otherwise.

Congress should pass tort-reform legislation preserving a patient's right to legal redress while excluding claims that lack merit. Liability offers a strong incentive for companies to develop and

manufacture safe drugs and devices. If companies are not accountable for their products, the public loses a safeguard that has motivated quality improvements in the health care industry for the past half-century.

Robert G. Hauser, M.D.

Minneapolis Heart Institute
Minneapolis, MN 55407
rhauser747@aol.com

Dr. Hauser reports holding stock in Atritech and Sonosite. No other potential conflict of interest relevant to this letter was reported.

1. Kesselheim AS, Studdert DM. The Supreme Court, preemption, and malpractice liability. *N Engl J Med* 2009;360:559-61.
2. *Riegel v. Medtronic*, 128 S.Ct. 999 (2008).

THE AUTHORS REPLY: Our analysis of how preemption of product-liability litigation may affect physicians' malpractice risks focused on pharmaceuticals, the issue before the Supreme Court in *Wyeth v. Levine*, not medical devices, the subject of Hauser's letter. Since the publication of our article, the Court has issued its decision: approval of warning labels on pharmaceuticals by the FDA does not preempt state product-liability claims against the manufacturer.

We applaud this outcome. However, *Levine* now puts the preemption status of pharmaceuticals and devices somewhat at odds, as Justice Samuel Alito's dissenting opinion in *Levine* points out. In *Riegel v. Medtronic*, the Court found that a federal statutory provision barred state claims against device manufacturers when the device in question had FDA approval. This decision may well have increased the scrutiny of the role of physicians with regard to the use of devices.

An important policy argument against the type of preemption Wyeth sought in *Levine* is that the FDA has a limited capacity to oversee the vast array of drugs on the market. The same is surely true for devices. Consequently, we agree with Hauser that preemption of device claims is problematic and support the passage of legislation currently before Congress that would reverse the effect of *Riegel*.

Aaron S. Kesselheim, M.D., J.D.

Brigham and Women's Hospital
Boston, MA 02115
akesselheim@partners.org

David M. Studdert, LL.B., Sc.D.

University of Melbourne
Melbourne, VIC 3010, Australia