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Legislating Screening for Atherosclerosis Reply

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iatric Surgery (LABS) study funded by the National Institutes of Health does not include a nonoperated control group.⁵ These 2 large, carefully conducted US studies currently running in parallel could provide a valuable comparison between patients with diabetes in the LABS study matched with participants from each arm of the Look AHEAD study.¹ We would encourage discussion of this synergy. Surgery is not “set and forget” and should always be complemented with comprehensive and ongoing lifestyle modification and monitoring.

We agree that comprehensive weight management programs should be available for obese patients with type 2 diabetes with nonsurgical options attempted first. But if these approaches fail, without unnecessary delay the next step should be to consider a proven, safe surgical treatment. There is evidence from a number of observational bariatric surgical series that treating persons with diabetes sooner rather than later following diagnosis is more likely to achieve remission of diabetes, presumably due to preservation of β -cell function.⁶ If patients with diabetes can achieve and maintain the weight loss required to obtain excellent glycemic control in this time frame without surgery, that is optimal. For those who cannot accomplish this, obesity surgery provides a realistic opportunity to achieve remission.

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Legislating Screening for Atherosclerosis

To the Editor: In his Commentary, Mr Jacobson¹ called on national medical societies to oppose proposed Texas legislation that would mandate that health insurers provide reimbursement for screening to detect atherosclerosis, indicating that it is based on a flawed concept and should be rejected because it lacks endorsement from the American Heart Association (AHA), the American College of Cardiology (ACC), or the European Society of Cardiology. The concept was introduced by the Society for Heart Attack Prevention and Education (SHAPE).² We believe that this Commentary contains several misunderstandings.

First, most initial myocardial infarctions occur in asymptomatic individuals with unrecognized atherosclerosis who are classified by the Framingham Risk Score as low or intermediate risk.³ Thus, when screening is based on risk factors alone, most individuals destined for a near-term myocardial infarction are not identified and, consequently, not offered adequate preventive treatment.

Second, the potential outcome benefits of global cardiovascular risk assessment based on risk factors alone, including the Framingham Risk Score and the European Systematic Coronary Risk Evaluation, have never been tested in a randomized controlled trial.

Third, coronary artery calcium score predicts risk better than the Framingham Risk Score.⁴ The proposed legislation mandates insurance coverage up to \$200 every 5 years for coronary artery calcium score or carotid intima-media thickness by ultrasound in men aged 45 to 75 years and women aged 55 to 75 years with diabetes mellitus or intermediate or higher Framingham Risk Score.⁵ This is in line with the recent ACC/AHA expert consensus document on coronary artery calcium score in global cardiovascular risk assessment, which acknowledges that coronary artery calcium score can be used to identify high-risk individuals in the intermediate risk category who need more aggressive treatment.⁴

Fourth, the proposed Texas legislation incorporates what we consider to be the most accepted part of the SHAPE guidelines: the usefulness of coronary artery calcium score in individuals with intermediate Framingham Risk Score.⁴

Fifth, all potential conflicts of interest for SHAPE members as of July 2006 were disclosed in the print edition of the journal supplement containing the SHAPE guidelines² and are posted on the SHAPE Web site (<http://www.shapesociety.org>).

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Financial Disclosures: Dr Naghavi is chair of the Society for Heart Attack Prevention and Eradication (SHAPE), and Drs Falk and Shah are members of the board of directors of SHAPE; they reported receiving no compensation for these roles. Dr Naghavi reported being a shareholder of Volcano Corporation and Endothelix and president of American Heart Technologies. Dr Falk reported being a shareholder of Endothelix and a scientific advisor to BG Medicine and Boston Scientific. Dr Shah reported being a scientific advisor to Roche, BG Medicine, Kowa Pharmaceuticals, Resverlogix, Cardiovox, and Bioinvent.

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In Reply: In response to Dr Falk and colleagues, as a non-specialist I cannot comment on the merits of any particular screening mechanism or the coronary artery calcium score vs the Framingham Risk Score as a better predictor of coronary artery disease. However, I take issue with their statement that “the proposed Texas legislation incorporates what we consider to be the most accepted part of the SHAPE guidelines.” Accepted by whom and under what circumstances? Are they conceding that the guidelines as a whole have not been accepted as professional consensus through the peer-review process? Most importantly, should legislators determine which aspects of guidelines should be mandated and which should not?

What is missing from their letter is a compelling reason why the legislature should be involved. For example, is there evidence that insurers are refusing to cover the specific tests the SHAPE guidelines are designed to encourage?¹ Is there evidence that professional societies are illegitimately blocking the potential scientific advances of the coronary artery calcium score? Nothing in their letter suggests the need for legislative intervention.

Where I think my Commentary is most vulnerable is in its acquiescence to medical consensus as the sine qua non of clinical practice guidelines. For instance, there are many instances where cascades have led to inappropriate scientific consensus that can be difficult to overcome.² Falk et al are correct in implying that an unwavering reliance on professional consensus could impede innovative clinical strat-

egies. The possibility that the professional consensus is wrong is exactly why individual physicians must have the discretion to exercise their best clinical judgment.

In relying on professional consensus, perhaps I am too mindful of the debacle of high-dose chemotherapy with autologous bone-marrow transplantation, in which premature diffusion of the technology had such adverse consequences.³ Nonetheless, there is no better alternative to professional consensus for most clinical interventions.

Finally, the issue of conflict of interest has been a major consideration in the SHAPE guidelines.⁴ The potential conflicts for SHAPE members may be posted on its Web site. But in a case like this, in which the physicians involved in drafting the guidelines have multiple potential financial conflicts of interest,⁵ one mechanism to attenuate the influence of these investments is to demonstrate that there is a broad professional consensus independent of potential financial conflicts.

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Nomenclature in Translational Research

To the Editor: In his Commentary, Dr Woolf¹ identified a critical problem in the field of translational research—lack of clarity in nomenclature. Vague language conflates very different types of research and fosters definitional creep as researchers struggle to ensure that their own work falls under this umbrella. We agree that the terms *T1* and *T2* lack inherent meaning and should be replaced with ones that are more descriptive.

We suggest that *T1* be replaced with the term *preclinical research*. We define this as research designed to yield a tool or an intervention related to screening, risk assessment, prevention, diagnosis, treatment, or rehabilitation that will be suitable for clinical evaluation within 10 years. *Long-term preclinical translational research* would have a time frame of 5 to 10 years. *Short-term preclinical translational research* would be less than 5 years. Basic research that has an anticipated time frame beyond 10 years would not be considered preclinical translational research.