

Should women take statin drugs?

Here's a radical thought. Your doctor tells you to take Lipitor® or Zocor® or some other best-selling cholesterol drug, and you refuse. Not because of the oft-reported side effects—but because you're a woman.

Says who? Say two world-acclaimed mainstream women doctors.

We put the question to **Judith Walsh, MD, MPH**, associate clinical professor of medicine at the University of California, San Francisco—and **Beatrice A. Golomb, MD, PhD**, professor of medicine at the University of California, San Diego. Both mainstream doctors have nothing against prescription drugs—when they work. But **both say there's simply no evidence that statin drugs work for women.**

"BUT MY DOCTOR STILL INSISTS THAT I NEED ONE," YOU SAY...

Okay, we went for a third opinion. We interviewed a top medical statistician, **Dr. Theodore Eisenberg.**

He's a professor at Cornell Law School in Ithaca, New York. And he's just conducted an exhaustive meta-study of clinical trials for Lipitor. Same story. He found evidence that the drug did reduce heart attack risk for men... **but not for women.** His study was just published in the Journal of Empirical Legal Studies. Your doctor may not have read it because this is a legal journal, peer-reviewed by doctors of jurisprudence. You may want to tell him about it.

So, if statins don't save women's lives—and if the top statin won't even save us from heart attacks...

Just why are 12 million American women taking statins? Twelve million! Hmm, maybe they're not all being treated properly? Think that's possible? If this includes YOU or a woman you love, we think you deserve the un-prettified truth.

Abstract

This article presents: (1) meta-analyses of studies of cardioprotection of women and men by statins, including Lipitor (atorvastatin), and (2) a legal analysis of advertising promoting Lipitor as preventing heart attacks. The meta-analyses of primary prevention clinical trials show statistically significant benefits for men but not for women, and a statistically significant difference between men and women. The analyses do not support (1) statin use to reduce heart attacks in women based on extrapolation from men, or (2) approving or advertising statins as reducing heart attacks without qualification in a population that includes many women. The legal analysis raises the question of whether Lipitor's advertisements, which omit that Lipitor's clinical trial found slight increased risk for women, is consistent with the Food, Drug, and Cosmetics Act and related Food and Drug Administration (FDA) regulations. The analysis suggests that FDA regulation should not preempt state law actions challenging advertising that is not supported by FDA-approved labeling. Our findings suggesting inadequate regulation of the world's best-selling drug also counsel against courts accepting the FDA's claimed preemption of state law causes of action relating to warnings and safety. Courts evaluating preemption claims should consider actual agency performance as well as theoretical institutional competence. Billions of health-care dollars may be being wasted on statin use by women but the current regulatory regime does not create incentives to prevent such behavior.