

# Top-selling prescription drug mismarketed to women

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Lipitor has been the top-selling drug in the world and has accounted for over \$12 billion in annual sales. It has been prescribed to both men and women to lower cholesterol and reduce the risk of heart attack and stroke in patients with common risk factors for heart disease. However, a new study appearing in the *Journal of Empirical Legal Studies* was unable to find high quality clinical evidence documenting reduced heart attack risk for women in a primary prevention context. Furthermore, advertising omits label information relevant to women.

Theodore Eisenberg of Cornell Law School and Martin T. Wells of Cornell University assembled studies for a meta analysis of drugs' effects on cardiovascular risk, taking into account all relevant studies reporting risks for both men and women.

Not one of the studies that included women with a mixture of risk factors for heart attacks provided statistically significant support for prescribing Lipitor or other statins to protect against cardiovascular problems. Pfizer's claims of clinical proof that Lipitor reduces risk of heart attack in patients with multiple risk factors for heart disease does not appear to be scientifically supported for large segments of the female population.

In addition, Lipitor's advertising repeatedly fails to report that clinical trials were statistically significant for men but not for women. Unqualified advertising claims of protection against heart attacks may therefore be misleading. Pfizer's advertising also does not disclose

critical portions of the Lipitor FDA-approved label, which acknowledges the absence of evidence with respect to women.

"Our findings indicate that each year, reasonably healthy women spend billions of dollars on drugs in the hope of preventing heart attacks but that scientific evidence supporting their hope does not exist," the authors conclude.

Source: Wiley

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