

## [Study About Using Glaxo's Avodart To Prevent Prostate Cancer Finds Possible Heart Risk](#)

### **Higher Rate Of Cardiac Failure In Men Taking Avodart (Dutasteride) – 0.7 Percent vs. 0.4 Percent For Those Taking The Placebo**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on April 1, 2010; see <http://bit.ly/aHspQ3>)

In the April 1, 2010 edition of the *New England Journal of Medicine (NEJM)* there is an article, "[Effect of Dutasteride on the Risk of Prostate Cancer](#)" ([free Abstract](#)), which may spell trouble for the efforts of GlaxoSmithKline to get FDA approval for the use of Avodart (dutasteride) to prevent prostate cancer.

From [the full-text of this April 2010 NEJM article about Avodart \(subscription required\)](#), we get this information about its apparent cardiac side effects:

There was an unexpected imbalance in a composite event termed "cardiac failure," which included conditions such as congestive heart failure, cardiac failure, acute cardiac failure, ventricular failure, cardiopulmonary failure, and congestive cardiomyopathy. Although there was no significant difference between the two groups in the overall incidence of cardiovascular events or deaths from cardiovascular events, there was a higher incidence of the composite event of cardiac failure in the dutasteride group than in the placebo group (0.7% [30 of 4105 men] vs. 0.4% [16 of 4126 men],  $P=0.03$ ; relative risk estimate, 1.91; 95% CI, 1.04 to 3.50).

From an April 1, 2010 Associated Press (AP) article, "[Study finds possible heart risk with prostate drug](#)", by AP Medical Writer Marilyn Marchione, we get these background and contextual details:

Last year, a panel of health experts recommended that men consider Proscar [(finasteride) -- sold in generic form and as Proscar, made by Merck & Co. Inc.] or Avodart if they are regularly getting screened for prostate cancer. But the Avodart study was not available when the advice was developed.

The two drugs work in different ways and may not have the same safety profile, said Dr. Barnett Kramer, a National Institutes of Health scientist who led the expert panel and had no role in the study.

In the full Avodart results, "the important detail is there's a heart failure signal here that was unanticipated," Kramer said.

Dr. Otis Brawley, who helped run the study before becoming the American Cancer Society's chief medical officer in 2007, said the heart failure risk may be a fluke, but men would need to be watched for it. If it develops, "it's reason to stop the drug," he said.

One presumes there will further studies about whether this finding of cardiac failure in men taking Avodart is truly a signal of an emerging drug-safety issue or a fluke, as mentioned by Dr. Brawley, above.

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.  
<http://www.DrugInjuryWatch.com>