

## More Heat for Vytorin and Avandia

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Avandia and Vytorin are the subject of yet another government investigation. The Government Accountability Office (GAO) will look into whether the US Food and Drug Administration's (FDA) drug-review process cleared two popular medications without sufficient proof of their safety or effectiveness.

Senator Charles E. Grassley (Republican-Iowa) requested the GAO investigation after recent studies suggested that the diabetes pill Avandia increases the risk of cardiac problems in patients, and another study showed that the cholesterol drug Vytorin may not actually lower the risk of heart attack and artery-clogging plaque, as assumed by millions of patients and doctors. "There's enough of a pattern of problematic drugs to ask for an independent review of how the FDA follows up on the effects of medicines that it's approved," Grassley said. The question is whether the FDA should approve drugs based on biological measures, such as cholesterol and blood sugar, without evidence that they improve more meaningful measures, such as survival.

The makers of Vytorin have been named as defendants in a lawsuit filed by a New York man who took the defective drug based on the belief that it offered more protection from clogged arteries, heart attacks and strokes than other, less expensive statin drugs. Sigmond Tomaszewski, who began taking Vytorin in January 2007, alleges that Merck and Schering-Plough knew in April 2006 that Vytorin was ineffective at reducing artery clogging plaque, heart attacks and strokes, but purposely kept that information from the public and the medical community.

Lawsuits against GlaxoSmithKline over the diabetes drug Avandia are emerging and many more are expected. One man is suing GlaxoSmithKline in federal court, claiming Avandia caused him to undergo heart bypass surgery. Attorneys allege the drug maker should have known that Avandia—prescribed to improve blood sugar in type 2 diabetes patients—is linked to a significant and increased risk of heart failure, heart attack, and stroke.

The FDA refuses to withdraw Avandia from the market, but has asked Glaxo to conduct a long-term study comparing Avandia with other type 2 diabetes drugs. The trial will likely commence in a year; however, full results are not expected until 2014. Patient advocates and FDA critics consider the recent black box warning—the strongest warning for a drug—for Avandia a feeble response to Avandia's safety issues, and have requested it be pulled from the market. Meanwhile, the American Diabetes Association and the European Association for the Study of Diabetes released a revised consensus statement stating that emerging information suggests additional hazards associated with Avandia and may result in increased risk of myocardial infarctions. The US Department of Veterans Affairs announced it was dropping Avandia from its drug formulary because, in some, Avandia did not afford the same margin of safety as other diabetes drugs. A Congressional Committee Report found Glaxo executives intimidated a diabetes expert into keeping quiet about Avandia's safety problems.