# Asthma Drug Xolair Is Being Investigated By FDA For Possible Cardiac Problems

## Serious Side Effects Include Heart Attacks, Abnormal Heart Rhythms, Heart Failure, And Various Conditions Caused By Blood Clots

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 22, 2009; see http://bit.ly/9pE1R)

By means of a July 16, 2009 MedWatch Email Alert we first learned about an ongoing FDA investigation of Xolair (omalizumab):

> FDA is evaluating interim safety findings from an ongoing study of Xolair (omalizumab) titled Evaluating the Clinical Effectiveness and Long-Term Safety in Patients with Moderate to Severe Asthma (EXCELS) that suggests a disproportionate increase in ischemic heart disease, arrhythmias, cardiomyopathy and cardiac failure, pulmonary hypertension, cerebrovascular disorders, and embolic, thrombotic and thrombophlebitic events in patients treated with Xolair compared to the control group of patients not given the drug. Xolair is approved for use by adults and adolescents (12 years of age and above) with moderate to severe persistent asthma who test positive for reactivity to a perennial airborne allergen, and whose symptoms are inadequately controlled with inhaled corticosteroids.

In its "Early Communication about an Ongoing Safety Review of Omalizumab (marketed as Xolair)" the FDA informs us that the EXCELS study is ongoing and final results are not expected until 2012.

Health Canada has followed the lead of the FDA, according to an August 13, 2009 report from *CBC News*, "Asthma drug probed for links to cardiac problems":

> The safety of the asthma drug Xolair is under review to investigate a potential link to cardiovascular problems, Health Canada said Thursday.
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> The probe was triggered by interim findings in an ongoing U.S. study into the long-term safety of Xolair, known generically as omalizumab.
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> The early data point to a disproportionate increase in cardiovascular problems among people treated with Xolair compared with those who did not take the drug. The reported problems include heart attacks, abnormal heart rhythms, heart failure, fainting, mini-strokes and blood clots.

Xolair, which is made by Genentech and co-marketed by Novartis, was approved by the FDA in 2003.

From a July 17, 2009 report from *CNN*, "FDA scrutinizing safety of asthma drug Xolair"", we get a comment and some context regarding this safety study of Xolair:

> "We're not getting into numbers at this point because we're still in that evaluation stage," said Genentech spokeswoman Tara Cooper. "It's premature to really get into the details at this point."
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> The drug is used by 30,000 to 35,000 patients, representing less than one half of 1 percent of the eligible patient population, Cooper said. It is administered by injection every other week in a doctor's office. The estimated annual cost of the drug to the doctor -- before it gets marked up for the patient -- is about $19,000, Cooper said.

We will continue to monitor developments concerning the safety of Xolair, and we welcome any comments or information that you would like to submit concerning this issue.

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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.
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