Chantix Anti-Smoking Pill: How Significant Is The Heart Risk; Should Chantix Be Recalled

Canadian Medical Journal Article Suggests That The June 2011 Label Change By FDA And Pfizer Is Not Sufficient Measure

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 5, 2011; see http://bit.ly/jnyora)

As some may recall, in mid-June 2011 the FDA issued these two items:

- Chantix (varenicline): Label Change - Risk of Certain Cardiovascular Adverse Events; and,
- FDA Drug Safety Communication: Chantix (varenicline) may increase the risk of certain cardiovascular adverse events in patients with cardiovascular disease.

A few weeks later the *Canadian Medical Association Journal* (*CMAJ*) published an article, "Risk of serious adverse cardiovascular events associated with varenicline: a systematic review and meta-analysis", which raised two "new" concerns about this popular anti-smoking drug Chantix: (1) whether the June 2011 cardiovascular, or heart, side effects risk warning label change is sufficient; and, (2) whether Chantix should be recalled by Pfizer and the FDA.

For an overview of this emerging drug-safety issue concerning Chantix (varenicline), we look to this July 4, 2011 *Bloomberg* news report, "Pfizer Addiction Pill Weighed by FDA After 72% Added Heart Risk":

> Pfizer Inc. (PFE)'s anti-smoking pill Chantix may receive new warnings from U.S. regulators after a study released today found the drug increased the risk of hospitalizations for heart problems by 72 percent.
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> The report, led by researchers at Johns Hopkins University, analyzed 14 Pfizer-sponsored drug trials with 8,216 patients and found about one new heart attack or similar disorder for every 400 patients taking Chantix. The U.S. Food and Drug Administration is examining the study and may consider new warnings, Curtis Rosenbraugh, director of the agency's office of drug evaluation, said in an interview....
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> An FDA staff review from 2006 shows the agency was aware of a potential link between Chantix and serious heart complications. At the time, two researchers were asked to independently review each reported heart problem to rule out cases that were incorrectly reported or not related to the drug. On closer inspection, one reviewer said there was a 16 percent added risk of heart problems with Chantix, while the second reviewer found an 8 percent decreased risk, according to the staff documents.
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> "We saw a swing going anywhere from favorable to unfavorable," said the FDA's Rosenbraugh. "When you get results like that it's hard to draw a definitive conclusion. It's not something we would label.
>
> **Label Uncertain**

> "Dr. Singh has added to what we have seen and is helping to define the picture better," Rosenbraugh said. "I'm not sure until we can further evaluate the study whether it's going to change the label or not, but I can assure you this is something we're very concerned about and are taking very seriously."

The senior author of this new Chantix medical journal article, Dr. Curt D. Furberg, a Wake Forest medical professor, was quoted in a July 4 *New York Times* article, "Study Links Smoking Drug to Cardiovascular Problems", as calling for a Chantix recall: "I don't see how the F.D.A. can leave Chantix on the market."

Of course, we will continue to monitor this Chantix - heart risk safety issue and report significant developments, here.

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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