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## Reports Of Anti-Smoking Pill Chantix Causing Depression And Suicidal Ideation Made To FDA powered by BlogBurst

POSTED: Monday, January 21, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

The following blog post is from an independent writer and is not connected with Reuters News. The opinions and views expressed herein are those of the author and are not endorsed by Reuters.com.

### Pfizer Increases Warning About Abnormal Behavior Of Patients Using Its Smoking Cessation Medication In January 2008

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

On November 20, 2007 the FDA issued an "Early Communication About an Ongoing Safety Review Varenicline (marketed as Chantix)" to inform healthcare providers about reports the agency had received of people exhibiting various types of abnormal behaviors while using Chantix. These reports included new-onset of depressed mood and suicidal ideation, as well as other unusual changes in emotion and behavior within days to weeks of initiating Chantix treatment.

In that November 2007 Early Communication item regarding Pfizer Inc.'s anti-smoking pill Chantix, the FDA recommended the following measures:

- Healthcare professionals should monitor patients taking Chantix for behavior and mood changes.
- Patients taking Chantix should contact their doctors if they experience behavior or mood changes.
- Patients should use caution when driving or operating machinery until they know how quitting smoking with Chantix may affect them.

And in the closing part of that Early Communication: "FDA is considering, but has not reached a conclusion about whether this information warrants any regulatory action."

Only two months later it was announced that the package insert, or label, for Chantix was getting a stronger warning about such abnormal behavior in people taking this smoking cessation drug.

From a January 18, 2008 *Bloomberg* report, "[Pfizer's Chantix Gets Warning Over Suicidal Thoughts \(Update1\)](#)", we get these details about the announcement concerning the increased Chantix warning:

A possible link between the drug and reports of agitation, depressed

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mood and suicidal thoughts among some patients taking it can't be ruled out, Pfizer said today in a statement. The behavior could be worse in people with a pre-existing mental illness, the New York-based company said....

"A causal relationship between Chantix and these reported symptoms has not been established," Pfizer said in the statement. "In some reports, however, an association could not be excluded."...

An advisory about the symptoms was already included in the drug's prescribing information under the "post-marketing experience" section. The enhanced warning will make the advisory more prominent to doctors and advise them to monitor for unusual behavior in their patients, Pfizer said. The drug was approved in the U.S. in 2006.

For those interested, we have provided links so that you can [see how this new warning appears in the January 2008 Chantix package insert](#) -- in the new WARNINGS section -- and [compare it to the November 2007 version of the Chantix](#).

[Read more from this blogger at Drug Injury Watch](#) | [Let us know what you think of this feature](#)

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