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Blood-Clot Warning On Ortho-Evra Birth Control Patch Increased, Again, In January 2008

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POSTED: Saturday, January 19, 2008

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

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Label For "The Patch" No Longer Has Conflicting Information About Its Increased Risk Of Blood Clots

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

A January 18, 2008 *WebMD* article, "[Stronger Warning for Birth Control Patch](#)", provided a concise summary of the latest news about the Ortho Evra Contraceptive Transdermal (Skin) Patch manufactured by Ortho-McNeil Pharmaceuticals, a division of Johnson & Johnson (JNJ):

The FDA today strengthened its warning on the risk of serious blood clots in women using the Ortho Evra birth control skin patch.

The warning about venous thromboembolism -- clots in veins that may be life-threatening if they travel to the lungs and cause pulmonary embolism -- isn't new. It's been on the Ortho Evra patch label since September 2006.

What's new is that now, the patch's label no longer notes conflicting information about that risk.

Previously, the Ortho Evra patch's label mentioned mixed results from two studies on clotting risk. One study showed that patch users were twice as likely as birth control pill users to develop venous thromboembolism. The other study showed that patch users and pill users were equally likely to develop venous thromboembolism.

Now, results from a third observational study are in, and that study shows that the odds of developing venous thromboembolism are higher for women who use the Ortho Evra patch than for women using birth control pills.

Today, the FDA ordered the results of that new study to go on the Ortho Evra patch label.

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In [February 2007 the *Obstetrics and Gynecology* medical journal published a study report](#) which concluded that women who used the Ortho Evra birth control patch seemed to be at double the risk of developing a dangerous blood clot in their veins as were women who used oral contraceptives.

As background, in [November 2005 the FDA announced a label change for Ortho Evra](#) to warn that the use of this contraceptive patch exposes women to higher levels of estrogen than a typical birth control pill and, in turn, women using Ortho Evra for birth control are at an increased risk of developing blood clots.

Blood clots -- sometimes called venous thromboembolisms (VTEs) -- can lead to deep vein thrombosis (DVT) and pulmonary embolisms (PE), which can be fatal.

Results from two studies that were preliminarily released in February 2006 prompted [another label change for Ortho Evra in September 2006](#).

A January 18 *FDA News* item, "[FDA Approves Update to Label on Birth Control Patch](#)", explains the connection between studies involved in the September 2006 label change and this new warning about blood clots related to Ortho Evra:

The [January 2008] label changes are based on a study conducted by the Boston Collaborative Drug Surveillance Program (BCDSP) on behalf of Johnson and Johnson. The patch was studied in women aged 15-44. These recent findings support an earlier study that also said women in this group were at higher risk for VTE....

In September 2006, FDA revised the label for Ortho Evra to warn women of the risk of VTE based on two epidemiology studies. One study, conducted by i3 Ingenix, showed that some women using the patch were at a two-fold greater risk of developing VTE. The other study, conducted by BCDSP, showed they were not at increased risk compared to women using birth control pills containing 30-35 micrograms of estrogen and the progestin norgestimate.

Ortho Evra, sometimes simply called "The Patch" by women, was approved by the FDA in 2001.

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