

## [Recent Report About Ortho Evra Safety Seems To Contradict Earlier Findings From Same Group](#)

### **Third Boston Collaborative Drug Surveillance Program Study Analysis Concerning Ortho Evra And Blood Clot Side Effect Risk Causes Confusion**

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on March 8, 2010; see <http://bit.ly/a6LFN6>)

Let us start with this relatively recent medical journal article, "[Postmarketing study of ORTHO EVRA and levonorgestrel oral contraceptives containing hormonal contraceptives with 30 mcg of ethinyl estradiol in relation to nonfatal venous thromboembolism](#)", published in the January 1, 2010 edition of *Contraception*, which reports the findings from a Boston Collaborative Drug Surveillance Program study about the Ortho Evra birth control patch.

From the [Abstract](#) for this January 2010 article:

**BACKGROUND:** Concern has been raised that the risk of venous thromboembolism (VTE) in users of the ORTHO EVRA patch is higher compared to users of oral contraceptives (OCs). **STUDY DESIGN:** We identified idiopathic cases of VTE and controls, matched on age and index date, from among women in the United States PharMetrics/IMS and MarketScan databases who were current users of the patch or levonorgestrel-containing OCs with 30 mcg of ethinyl estradiol.... **CONCLUSION:** These results provide evidence that the risk of idiopathic VTE in users of the patch is not materially different than that of users of levonorgestrel-containing OCs in women aged 39 years or younger. We cannot rule out some increase in the risk in women aged 40 years or older.

It seems that the findings presented in this January 2010 article come from a Phase IV Ortho Evra clinical trial known as "[Relative Risks for Non-Fatal Venous Thromboembolism, Ischemic Stroke and Myocardial Infarction in Users of ORTHO EVRA\(Norelgestromin and Ethinyl Estradiol Contraceptive Patch\) Compared to Levonorgestrel-Containing Oral Contraceptives.](#)"

From the [ClinicalTrials.gov record](#) for this Ortho Evra safety study (last processed on March 5, 2010 according to site; accessed March 8, 2010):

#### **Purpose**

This study uses the PharMetrics insurance claims database to estimate relative risks for non-fatal venous thromboembolism (including cerebral venous sinus thrombosis), ischemic stroke, and acute myocardial infarction (heart attack), in current users of ORTHO EVRA (norelgestromin and ethinyl estradiol contraceptive patch) compared to current users of oral levonorgestrel-containing oral contraceptives with 30 micrograms ethinyl estradiol, with special attention to duration of use....

#### **Contacts and Locations**

Please refer to this study by its ClinicalTrials.gov identifier: NCT00511784

#### **Sponsors and Collaborators**

Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Boston Collaborative Drug Surveillance Program

To recap, the bottom line from this January 2010 report about the latest study analysis done by Boston Collaborative Drug Surveillance Program (BCDSP) is that **Ortho Evra does not increase the risk of blood clot-related side effects, or venous thromboembolism**, any more than birth control pills that contain levonorgestrel and 30 micrograms ethinyl estradiol, with the possible exception of women over 40 years of age.

Now let us go back in time to see what J&J and BCDPS have said previously about a woman's risk of developing blood clot-related side effects such as pulmonary embolism (PE) and deep vein thrombosis (DVT) as well as heart attack and stroke while using the Ortho Evra patch.

In September 2006 J&J revised the Package Insert for Ortho Evra to include for the first time a warning about the increased risk of venous thromboembolism. This new label, however, included conflicting information about that risk by mentioning two different study results concerning clotting risk.

According to this new September 2006 label, 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.

The results from a later study that was done for J&J by the Boston Collaborative Drug Surveillance Program (BCDSP) regarding the safety of Ortho Evra -- the second such study done for J&J by BCDSP, to be precise -- became available in or about August 2007. In relevant part, this particular BCDSP study showed that **the odds of developing venous thromboembolism were, in fact, higher for women aged 15 – 44 who use the Ortho Evra patch than women using birth control pills**. [In January 2008 the FDA ordered J&J to put the results of this second BCDSP study on the Ortho Evra patch label.](#)

So does this January 2010 medical journal report about the latest Ortho Evra study done by BCDSP for J&J -- seemingly their third study -- serve to refute the key finding from the second study, namely that the odds of developing venous thromboembolism were higher for women who are 15 to 44 year old?

Any guidance or insight would be most appreciated.

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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.

<http://www.DrugInjuryWatch.com>