

## Bayer Affirms Safety Of YAZ / Yasmin And Refutes 2011 BMJ Articles About Risk Of Blood Clots

### Just As It Did In 2010 Label Change, Bayer Contends New Medical Studies Are Less Reliable Than Other VTE Evidence

(Posted by Tom Lamb at [www.DrugInjuryWatch.com](http://www.DrugInjuryWatch.com) on April 25, 2011; see <http://bit.ly/hwl4dB>)

Women who use Bayer's YAZ and Yasmin birth control pills -- or other oral contraceptives containing the progesterone, or progestin, drospirenone (DRSP), *e.g.*, Ocella, Gianvi, Zarah, Beyaz, and Safyral -- face a two-times to three-times higher risk for venous thromboembolism (VTE), or blood clots, than women using birth control products containing levonorgestrel, according to two case-control analyses published by *The British Medical Journal* (commonly called "*BMJ*") in April 2011.

As for Bayer's response to these two new *BMJ* articles about the safety of YAZ and Yasmin, it was more or less the same as the press release it issued back [in April 2010 when Bayer refuted the reliability of two earlier \*BMJ\* articles](#) which asserted that women using birth control pills with drospirenone, like YAZ and Yasmin, were at an increased risk of developing blood clot-related side effects such as pulmonary embolism (PE) or deep vein thrombosis (DVT).

The two *BMJ* articles in published in 2011 about DRSP birth control pills like YAZ and Yasmin are:

["Risk of venous thromboembolism in users of oral contraceptives containing drospirenone or levonorgestrel: nested case-control study based on UK General Practice Research Database";](#) and,

["Risk of non-fatal venous thromboembolism in women using oral contraceptives containing drospirenone compared with women using oral contraceptives containing levonorgestrel: case-control study using United States claims data".](#)

The earlier 2009 *BMJ* articles about two studies that Bayer characterizes as "unreliable" in its current package insert, or label, for YAZ and Yasmin (accessed 4/25/11) are:

["Hormonal contraception and risk of venous thromboembolism: national follow-up study";](#) and,

["The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study".](#)

The corresponding press releases issued by Bayer about these two sets of YAZ / Yasmin drug safety articles published by *BMJ*, which were issued almost exactly a year apart (but are virtually the same as far as their "tune" goes), are:

["Bayer Affirms Benefit-Risk Profile of Its Oral Contraceptives -- Established body of well grounded data show VTE risk comparable in combined oral contraceptives studied"](#) (April 22, 2011); and,

["BAYER UPDATES LABELS FOR YAZ and YASMIN -- Body of Evidence Affirms VTE Risk/Benefit Profile for YAZ and Yasmin Is Comparable to Other Combination Oral Contraceptives"](#) (April 9, 2010).

In fact, one wonders whether the March 2011 label change for YAZ which we wrote about here -- ["Another Rather "Odd" YAZ Label Change By Bayer: March 2011 -- Provides New Warnings About Certain Side Effects As Regards ALL Birth Control Pills \(Not Specific To YAZ\)"](#) -- was not made by Bayer in anticipation of more medical journal articles with findings about the increased blood clot risks, like those recently published by *BMJ*.

To summarize, several different medical researchers find a significant increased risk of developing blood clots when using YAZ or Yasmin and the medical journal *BMJ* accepts their articles for publication, but Bayer tells everyone to just ignore those findings because their safety evidence is better.

Hopefully the FDA will not follow Bayer's advice and, instead, take action based on these two sets of medical articles about the blood clot side effects linked to [YAZ and Yasmin, as well as Ocella, Gianvi, Zarah, Beyaz, and Safyral](#) -- all of which contain the fourth generation progestin drospirenone, or DRSP.

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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>