<u>A Theory Of How Yasmin Or YAZ Might Cause Pulmonary Embolism</u> (PE) And Other Blood Clot Related Side Effects

Combination Of Ethinylestradiol And Drospirenone Increases Serum Copper, A Situation That Could Be Associated With Increased Cardiovascular Risk

(Posted by Tom Lamb at www.DrugInjuryWatch.com on August 13, 2009; see http://bit.ly/XgTF5)

In the August 1, 2009 edition of the medical journal *Contraception* there was an article which offers one possible explanation about why Yasmin and YAZ might cause an increased risk of developing serious side effects involving blood clots, such as pulmonary embolism (PE), deep vein thrombosis (DVT), stroke or cerebrovascular accident (CVA), and heart attack or myocardial infarction (MI) -- any of which can cause death if not detected and treated promptly.

From the Abstract for this August 2009 article, <u>"Effects of oral contraception with ethinylestradiol and drospirenone on oxidative stress in women 18-35 years old."</u>:

- BACKGROUND: Oral contraceptives (OCs) with estrogens and progestins may affect oxidative stress (OS) status.
- STUDY DESIGN: A group of 32 women using oral contraceptives (OCU) containing 0.03 mg ethinylestradiol and 3 mg drospirenone [i.e., Yasmin and its generic equivalent Ocella] have been compared to a matched control group of 30 noncontraception users (NCU).
- CONCLUSIONS: The recently introduced combination of ethinylestradiol and drospirenone induced the heightening of lipid peroxidation correlated with high levels of copper, a situation that could be associated with increased cardiovascular risk.

This possible "causation" theory actually pre-dates Yasmin and YAZ -- which were approved by the FDA in 2001 and 2006, respectively -- as can be seen from this 1998 medical journal article, <u>"Effect of oral</u> contraceptive progestins on serum copper concentration.", which was published in the *European Journal of Clinical Nutrition*. From the Abstract for that article:

- OBJECTIVES: Recent epidemiologic studies have shown an increased mortality from cardiovascular diseases in people with higher serum copper levels. Even though higher serum copper concentration in women using oral contraceptives is well known, there is still uncertainty about the influence of newer progestin compounds in oral contraceptives on serum copper concentration. This issue is of particular interest in the light of recent findings of an increased risk of venous thromboembolism in users of oral contraceptives containing newer progestins like desogestrel compared to users of other oral contraceptives.
- CONCLUSION: While elevated serum copper concentration was found in users of all types of oral contraceptives, elevation was more pronounced among women taking oral contraceptives with antiandrogen effective progestins like antiandrogens or third generation oral contraceptives containing desogestrel. Further investigation is required to shed light on the possible role of high serum copper concentration in increasing cardiovascular or thrombotic risk of women using oral contraceptives.

An example of a so-called "third generation" birth control method is the vaginal ring NuvaRing, which contains etonogestrel, a biologically active metabolite of desogestrel. <u>NuvaRing -- sometimes simply called</u> <u>"the Ring" -- has been associated with an increased risk of serious blood clot side effects like pulmonary</u> <u>embolism (PE), stroke, and even death</u>.

Yasmin and YAZ are regarded as "fourth generation" birth control pills for the reasons explained by this part of a 2005 article, <u>"Oral Contraceptives: Mode of Action & Dermatologic Applications: Antiandrogenic Effect</u> of Oral Contraceptives", published online by *Medscape* (FREE registration required):

New progestins have been synthesized in the past decade with no intrinsic androgenic effects but potent antiandrogenic activity, including cyproterone acetate, chlormadinone acetate, and dienogest....

Another progestin is drospirenone [(DRSP)], derived from 17-α-spirolactone and pharmacologically resembling endogenous progesterone. It has both antiandrogenic and antimineralocorticoid activities. It is antiandrogenic by inhibiting ovarian androgen production like other progestins, and it also blocks androgen receptors in the skin.

http://www.jdsupra.com/post/documentViewer.aspx?fid=7b414c2c-7156-405a-b8f1-dfaea9a1f327 Estrogen stimulates angiotensin synthesis and enhances aldosterone-mediated water and sodium retention, making it responsible for such unpleasant symptoms as bloating, breast tenderness, and weight gain.

Drospirenone [(DRSP)] counters estrogen effect by blocking the aldosterone receptor, thus being antimineralocorticoid. This unique progestin attenuates the aforementioned bothersome estrogenic effects that some women report with the use of OC. It is also reported to improve androgen-related skin disorders, including acne, hirsutism, and seborrhea. [footnote omitted]

Returning to the Conclusion from that 1998 medical journal article -- *"Further investigation is required to shed light on the possible role of high serum copper concentration in increasing cardiovascular or thrombotic risk of women using oral contraceptives." -- in fact, there is an ongoing FDA-mandated safety study about YAZ which is intended to compare this fourth generation birth control pill containing drospirenone (DRSP) to other established oral contraceptives for the incidence of deep vein thrombosis (DVT), pulmonary embolism (PE), heart attack (MI), and stroke (CVA).*

In addition, we will likely learn more about the blood clot side effects risks of Yasmin and YAZ -- as well as what their maker, Bayer, knew about those risks, and when -- during the course of the increasing number of <u>Yasmin, Ocella, and YAZ lawsuits being filed on behalf of women injured and the families of women killed</u> while using these birth control pills.

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. <u>http://www.DrugInjuryWatch.com</u>