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On Drugs and Therapeutics

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IN BRIEF

FDA Warning about Drospirenone in Oral Contraceptives

The FDA has announced that combination hormonal contraceptives (CHCs) containing the synthetic progestin drospirenone (*Yaz*, *Yasmin*, *Beyaz*, *Safyral*, and others) may be associated with a higher risk of thromboembolism than CHCs containing other progestins.¹

The new warning was based partly on an unpublished, FDA-funded, retrospective study that found a 1.7-times higher risk of venous thromboembolism among US women who used a CHC that contained drospirenone than among women whose CHC contained levonorgestrel, norgestimate or norethindrone as the progestin component.² As with all retrospective studies, unknowable confounding factors, such as why doctors prescribed one progestin over the other, could have distorted the results.

All CHCs increase the risk of venous thromboembolism; whether the progestin component affects the risk has been controversial. The Medical Letter and several other reviews and consensus statements have found no convincing evidence of an increased risk with drospirenone.³⁻⁵

1. FDA Drug Safety Communication: Updated information about the risk of blood clots in women taking birth control pills containing drospirenone. Available at www.fda.gov/Drugs/DrugSafety/ucm299305.htm. Accessed April 23, 2012.
2. FDA. Combined hormonal contraceptives (CHCs) and the risk of cardiovascular disease endpoints. Available at www.fda.gov/downloads/Drugs/DrugSafety/ucm277384. Accessed April 23, 2012.
3. Combination oral contraceptives and the risk of venous thromboembolism. *Med Lett Drugs Ther* 2010; 52:23.
4. RL Reid. Oral contraceptives and venous thromboembolism: pill scares and public health. *J Obstet Gynaecol Can* 2011; 33:1150.
5. L Manzoli et al. Oral contraceptives and venous thromboembolism: a systematic review and meta-analysis. *Drug Saf* 2012; 35: 191.

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