

FDA ties newer birth control drugs to blood clots

October 27 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- Safety concerns with the popular birth control pill Yaz increased Thursday as federal health scientists reported that the Bayer drug and other newer birth control treatments appear to increase the risk of dangerous blood clots more than older medications.

A new study released by the Food and Drug Administration reviewed the medical history of more than 800,000 U.S. women taking different forms of birth control between 2001 and 2007. On average, woman taking Yaz had a 75 percent greater chance of experiencing a blood clot than women taking older birth control drugs.

Yaz contains estrogen along with a next-generation synthetic hormone called drospirenone, which is known to increase potassium levels in the blood. FDA compared medical records of women taking the drug with those taking the older drug levonorgestrel.

Yaz, Yasmin and related drospirenone-containing pills were Bayer's second-best-selling franchise last year at \$1.6 billion in global sales.

In 2009, the FDA took the unusual step of ordering Bayer to run corrective TV advertisements on Yaz, saying the drugmaker's marketing campaign overstated the drugs' ability to prevent acne and premenstrual syndrome.

Bayer Healthcare, a division of the German conglomerate, said it "is currently evaluating this publication and cannot comment at this point in

time."

The agency also reported higher complications in women using the Ortho Evra patch from Johnson & Johnson and the Nuvaring vaginal ring from Merck & Co. Inc. Those drugs combine estrogen, which is present in all birth control pills, with two other synthetic hormones launched in the last decade.

The FDA said it hasn't reached a final conclusion on the drugs' safety but will hold a meeting with scientific advisers Dec. 8.

Consumer safety advocates have criticized the agency for approving newer, more expensive birth control drugs when cheaper, generic drugs with established safety records are widely available.

"At a certain point we have to ask why the FDA continues to approve drugs that are less safe and have no benefit compared to drugs already on the market," said Dr. Diana Zuckerman, president of the National Center for Women and Families, a consumer group for women's health issues. "With all these different birth control options, why take the most expensive one that can also kill you?"

Recent studies have reached differing conclusions on the risks of newer birth control pills.

A study published earlier this week involving more than 1 million Danish women found that women taking Yaz and other newer medications had twice the risk of blood clots as women taking the older hormone levonorgestrel. The findings appeared Tuesday in the British Medical Journal.

However, two studies published in 2007, conducted as part of the postmarketing requirements of the FDA or European regulators, did not

find any difference in blood clotting between the two comparable groups.

Birth-control pills that contain drospirenone include Bayer's Yaz, Yasmin, Beyaz, Safyral; Sandoz's Syeda and Loryna; as well as Barr Laboratories' Ocella, Watson Pharmaceuticals' Zarah and Teva Pharmaceuticals' Loryna.

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