

## US reviews birth control pill safety over clot risk

## May 31 2011

The US Food and Drug Administration said Tuesday it is reviewing recently published studies which have pointed to an increased blood clot risk associated with a certain type of birth control pill.

The studies involve pills that contain drospirenone, as opposed to another type of progestin known as <u>levonorgestrel</u>. Some brand names include Yaz, Yasmin, Beyaz, Ocella, Loryna, Gianvi, Safyral, Syeda and Zarah.

"The FDA is currently evaluating the conflicting results from these studies and will look at all currently available information to fully assess the risks and benefits of drospirenone-containing birth control pills," it said in a statement.

"FDA will continue to communicate any new safety information to the public as it becomes available."

The European Medicines Agency concluded on May 27 that such birth control pills carry a higher risk of venous thromboembolism and that <u>warning labels</u> should be updated accordingly.

However it noted the overall risk of blood clot from any birth control method remains small and stopped short of advising women to stop taking pills containing drospirenone.

The pills have been the focus of numerous lawsuits, including one lodged earlier this month on behalf of a teenager who died from a blood clot



allegedly linked to the German chemical and pharmaceutical company Bayer's Yaz contraceptive.

Michelle Pfleger, an 18-year-old college student in North Carolina, died of cardiac arrest last September after taking YAZ, also known as Yasmin or Ocella, to treat acne, according to the complaint.

Last month, two studies in the <u>British Medical Journal</u> found that drugs like Yaz and Yasmin increase the risk of serious blood clots three-fold or two-fold compared to earlier-generation <u>oral contraceptives</u>.

Bayer criticized the results of the studies at the time, insisting that side effects were rare.

The official Yaz website says the drug is associated with "increased risks of several serious side effects, including blood clots, stroke, and heart attack."

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