

FDA panel backs birth control patch despite risks

December 10 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- A panel of federal health advisers said Friday that a birth control patch from Johnson & Johnson probably carries a higher risk of blood clots than older drugs, but should remain available as an option for women who have trouble taking a daily pill.

The Food and Drug Administration's panel of reproductive health experts voted 19-5 that the benefits of the Ortho Evra patch outweigh its risks, specifically a potentially higher risk of dangerous blood clots in the legs and lungs. Panelists said the patch can be especially useful for younger women who have difficulty sticking to a daily pill regimen.

"I have many teenagers and it's the only method they'll use - for them it's the perfect method," said Dr. Melissa Gilliam of the University of Chicago. The FDA sought the experts' advice as it reviews the safety of newer hormone-based contraceptives launched in the past decade. The agency is not required to follow their advice, though it often does.

Johnson & Johnson's weekly Ortho Evra patch was approved in 2001 and has been marketed for its convenience as an "option for busy women who are looking to simplify life." The drug works about as well as other contraceptive medications, allowing about one unplanned pregnancy per year for every 100 women.

Studies assessing Ortho Evra's blood clot risk have reached differing conclusions over the years. At least two studies found that patch users have twice the risk of clots as women taking birth control pills. Even a

slightly higher risk can be critical because blood clots can trigger heart attacks, strokes and blockages in lungs or blood vessels, which in rare cases have been fatal, even among young women.

The most recent study by the FDA found that women using the patch have a 50 percent higher risk of clots than women taking various oral contraceptives. However, agency scientists said the data was not definitive.

Panelists voted 20-3 with one abstention that the drug's current label is inadequate and should be updated with the latest information about the potentially higher risk. In discussion, a majority of panelists said Ortho Evra probably carries a higher risk than older birth control pills, though the risk is less clear when compared with newer birth control pills launched in the last decade.

Despite the safety concerns, the experts stressed that Ortho Evra fills a unique niche among birth control products.

"There is no alternative in this range for women who desire hormonal contraception but can't take the pill, so I think it is important to maintain that option," said Dr. Michele Orza of the George Washington University.

Prescriptions for Ortho Evra have declined steadily over the last five years, from 5 million in 2006 to about 1.3 million last year.

The decline has followed repeated updates by J&J of New Brunswick, N.J., to the product's labeling, including language indicating that patients absorb up to 60 percent more estrogen via the patch than with the pill.

"The company will continue to collaborate with the FDA on a product label that adequately reflects the known risks and benefits of the

product, including new information," said Jeff Christensen, communications manager with J&J's Janssen unit.

Ortho Evra is part of a new generation of contraceptives that use recently-developed, laboratory-made forms of the female hormone progesterone. In the past decade the medications have overtaken older medications, though studies have reached conflicting conclusions on whether the drugs carry a higher risk of [blood clots](#). On Thursday, the same panel recommended clearer risk labeling on Yaz, Yasmin and similar [birth control](#) pills marketed by Bayer and Teva Pharmaceuticals. As with Ortho Evra, the panel affirmed their overall benefit of the pills for women.

Ortho Evra sales last year totaled \$124 million, trailing Merck & Co. Inc.'s NuvaRing, which posted sales of \$437 million, according to health care data firm IMS Health. NuvaRing is the most widely used, non-pill contraceptive drug.

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