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## Birth Control Primed For Switch

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Women's health advocates push for FDA to make oral hormonal contraceptives available nonprescription under a potential new paradigm for drug approvals, but they note progesterone-only pills likely could be switched under the traditional system because they have low risk.

“There is a considerable amount of evidence suggesting that prescription requirement is an important obstacle to obtaining hormonal contraception,” Dan Grossman, senior associate and assistant clinical professor at the University of California, San Francisco, said March 23 at an FDA public hearing.

He explained that a 2004 national survey found a third of contraceptive users experienced a gap in coverage during the prior year and that 25% of women who currently or want to use prescription contraceptives complained about the long wait time to see a physician, the inconvenience of taking time off work or school to visit a provider or dislike of pelvic exams as barriers to continual use.

“Removing the prescription barrier to hormonal contraceptives could possibly improve access to contraception and increase contraception uptake, improve continuation, reduce unintended pregnancies and reduce disparities in contraceptive use,” said Grossman, also with the advocacy group Ibis Reproductive Health.

Looking at oral contraceptives through traditional nonprescription criteria, the drug is safe in that it has no significant toxicity in overdose, is not addictive and is for a self-diagnosable condition. However, birth control medicines diverge from the traditional OTC profile on whether women can self-select without a physician's screening given that some contraindications - hypertension and migraines - might not be apparent.

Grossman said a new paradigm for nonprescription approvals could address this by having pharmacists counsel and screen women prior to their obtaining hormonal contraception methods or by having women use a kiosk to work through a predetermined algorithm that would help them appropriately self-select the best contraceptive method for them (“*Glaxo Demos Cholesterol Self-Diagnosis Algorithm*” – “*The Tan Sheet*,” Mar. 26, 2012).

To support the idea that pharmacists could play a pivotal role in self-selection, Grossman pointed to a collaborative drug therapy protocol in Washington state from 2003 to 2005 that empowered pharmacists to help women select hormonal contraceptive methods.

“The model was safe, the screening protocol worked well and while almost everyone had a learning curve initially, it appeared to be effective,” he said.

Lack of reimbursement for pharmacist services ultimately caused the program to end and is something FDA should consider when developing the new paradigm, Grossman said.

Cost for the patients is another factor to consider, because if the contraceptives are too expensive as nonprescription drugs then women will not use them. He suggested a price point equivalent to the average price of patients' current copays for the medicine.

Grossman is part of a working group trying to switch oral hormonal contraceptives to OTC status, but as of last summer the group still needed a drug sponsor to switch their product (“*Advocates For Switching Birth Control Pill Face Social, Risk Obstacles*” – “*The Tan Sheet*,” Jul. 26, 2010). 

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