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Physician Group Support Boosts OTC Contraception Chances

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Recent physician association support for increased OTC availability of hormonal contraception appears to reflect increased receptivity to potential Rx-to-OTC switches in the category.

Though stakeholders say the support of medical professional groups is crucial to the success of contraception switches, finding pharmaceutical companies willing to take the risk of sponsoring a new drug application to FDA remains the primary challenge.

The American College of Obstetricians and Gynecologists in a Nov. 20 committee opinion on over-the-counter access to oral contraceptives concluded that the drugs' safety issues were outweighed by the individual risks and public health costs of unintended pregnancy. And the American Academy of Pediatrics recently announced support for increased nonprescription access to emergency contraception for teenagers regardless of age and improved insurance coverage.

While OB/GYN physicians in the past argued that making oral contraceptives available OTC would lead women to forgo screenings for cervical cancer and sexually transmitted infection, ACOG now says such preventive services are “not required” for initiating contraceptive use and “should not be used as barriers to access” (“*Benefits, Pitfalls Of OTC Birth Control Apparent In Cross-Border Study*” – “*The Tan Sheet*,” Feb. 28, 2011).

The committee opinion acknowledges the increased risk of venous thromboembolism with oral contraceptive use, but notes that even when elevated, the risk remains “extremely low.” Additionally, ACOG points out that studies show women can self-screen for contraindications using checklists and more likely will adhere to a regimen when they have access to multiple pill packs at a time.

Ibis Reproductive Health VP for Research Daniel Grossman, whose research helped shape the opinion, said ACOG's stance “will be a critical step to help motivate a company to move forward with” the switch process. Ibis' Oral Contraceptives Over-the-Counter Working Group seeks a manufac-

turer willing to sponsor a switch application (“*Advocates For Switching Birth Control Pill Face Social, Risk Obstacles*” – “*The Tan Sheet*,” Jul. 26, 2010).

Grossman says some potential sponsors in the pharmaceutical industry have expressed interest to Ibis, but he is not aware of any movement forward with research in support of an oral contraceptive switch.

Companies with oral contraceptive products in the U.S. or Europe include **Bayer AG, Merck & Co. Inc., Johnson & Johnson, Teva Pharmaceutical Industries Ltd.** and **Watson Pharmaceuticals Inc.**

A spokesman for J&J, which offers birth control drugs through its **Janssen Pharmaceuticals Inc.** subsidiary, said FDA should consider the perspective of family planning organizations, women's health groups and physicians “when determining whether the over-the-counter availability of oral contraceptive products is in the best interest of public health.” He declined to comment on whether the firm has switch plans of its own.

Susan Coleman, president of NCI Consulting in Moorestown, N.J., notes her pharmaceutical consultancy performed its first analysis of an oral contraceptive switch more than two decades ago and over the years has worked with at least four companies to evaluate the switch possibility. Despite the passage of time, the road to a switch has not necessarily eased.

“It's been so frustrating to see companies get close, and several times it's been the CEO that has pulled the plug on it - and probably for the right reasons,” Coleman said. “With the political polarization in America today, it's a tricky category.”

Plan B Outcome In Limbo

The political complications surrounding OTC reproductive health drugs are apparent in the long quest for universal OTC availability of emergency contraception.

While *Plan B One-Step* (levonorgestrel 1.5 mg) and equivalents are sold nonprescription from behind the pharmacy counter to consumers 17 years and older, the American Academy of Pediatrics recommends in a Nov. 26 policy statement that physicians provide adolescent girls younger than 17 with prescriptions for emergency contraceptives in advance of actual need.

"I think there's been a sense in the pharmaceutical industry that emergency contraception had to [switch] first, and then confidence would get built that might help oral contraceptives down the road."
- Susan Coleman, NCI Consulting

Additionally, the academy calls on pediatricians to "advocate for increased nonprescription access to emergency contraception for teenagers regardless of age and for insurance coverage of emergency contraception to reduce cost barriers."

The safety of levonorgestrel in adolescents is established and recognized by FDA ("*FDA Analysis Finds Plan B Safe For Children*" – "*The Tan Sheet*," Jan. 30, 2012). But the agency's approval of Teva's application to switch Plan B One-Step for consumers of all ages was overruled by Health and Human Services Secretary Kathleen Sebelius in late 2011, likely for political reasons.

The fate of One-Step now lies in the hands of a federal district court in New York, where the Center for Reproductive Rights sued FDA and Sebelius in an attempt to force a levonorgestrel switch. The court held a hearing in April and is weighing several motions - CRR's motions for preliminary injunction and partial summary judgment, and the government's motion for summary judgment - according to CRR ("*Judge Likely To Order Lower Age Restriction For Emergency Contraceptives*" – "*The Tan Sheet*," May 7, 2012).

Coleman says oral contraceptives are highly unlikely to move over the counter while One-Step and other emergency contraceptives remain in limbo. For one thing, oral contraceptives' continuous use indication would make them unusual in the OTC space.

"I think there's been a sense in the pharmaceutical industry that emergency contraception had to go first, and then confidence would get built that might help oral contraceptives down the road," she said.

CRR would consider filing a citizen petition with FDA to force a switch decision regarding oral contraceptives, said Janet Crepps, senior counsel in the center's U.S. legal program. However, given the agency's delayed response and ultimate denial of CRR's 2001 petition to switch Plan B, this strategy would seem an unlikely means of compelling oral contraceptives to move over the counter.



Image courtesy of Johnson & Johnson

Janssen Pharmaceuticals' Ortho Tri-Cyclen Lo oral contraceptive

Cost Concerns Crucial

Kirsten Moore, CEO of the Reproductive Health Technologies Project, voiced support for ACOG's opinion as a means to break "unwarranted barriers that are harmful to women" and hinder access to birth control.

However, she added in a Nov. 20 statement that OTC oral contraception also must be affordable, which speaks to concerns that insurance plans would force women to pay out of pocket for hormonal drugs sold without a prescription.

FDA-approved contraception methods are covered fully by insurance under the Patient Protection and Affordable Care Act, though HHS officials have said OTCs such as One-Step and generic equivalents must be obtained via prescription for cost-sharing to be waived ("*Contraceptives Covered Without Cost-Sharing In HHS Prevention Rule*" – "*The Pink Sheet*" DAILY, Aug. 1, 2011).

Crepps says HHS needs to clarify through rulemaking exactly how OTC oral contraception, should it come to pass, would be covered by insurance. She noted that some states allow women to present a Medicaid card to the pharmacy to obtain an emergency contraceptive without a prescription and without an out-of-pocket expense.

Grossman adds that insurance companies also vary in how they handle One-Step and equivalents, with some covering the drugs when obtained with a prescription and others not at all. He noted that an Institute of Medicine report on which HHS based its Guidelines for Women's Preventive Services suggests all FDA-approved contraception, Rx and OTC, should be covered without cost-sharing.

The ultimate coverage question still is "a little unclear at this point," he said in an email. "But if the spirit of the IOM report is upheld, OTC contraceptives should be covered."

Grossman says his research has shown women are willing to pay a maximum of about \$20 out of pocket per month for oral

contraceptives, with interest and adherence tending to drop off above that point.

Kiosks May Be Key

Oral contraception eventually may be a candidate for nonprescription availability under FDA's proposed "new paradigm" for conditions of safe use.

At the agency's public hearing in March, Grossman noted that automated kiosks could play a role in screening women for oral contraceptive contraindications, including checking blood pressure, and then could either print a voucher for the product or dispense oral contraceptive pills directly ("*Birth Control Primed For Switch*" – "*The Tan Sheet*," Apr. 2, 2012).

Another presenter at the FDA hearing, Eleanor Bimla Schwarz of the University of Pittsburgh, described research on a computerized emergency contraception screening program deployed in a clinic setting, which seemed to increase understanding

of contraceptive methods and reduce unintended pregnancy among the women who used it.

"This kiosk worked," said Schwarz, director of Pitt's Women's Health Services Research Unit, at the hearing. "It increased the number of women at high risk of unintended pregnancy who received a contraceptive prescription the day they visited the clinic."

Coleman highlighted the potential benefits of kiosks and other technology for improving understanding of all forms of contraception, especially among low-literacy consumers, which could facilitate expanded access.

"You read the label of these oral contraceptive products, and they're scary. But what ACOG has said is that the risks of the status quo are even greater than the risks of use of these products," she said.

"So technology or other approaches that can expand understanding of the label ... could potentially help a lot in building confidence that this is the right move." 

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