

Advocates For Switching Birth Control Pill Face Social, Risk Obstacles

A women’s health advocacy group that hopes to meet with FDA within the next year to explore potentially switching oral contraceptives to OTC may be hard-pressed to find a pharmaceutical company interested in sponsoring such a venture.

The Oral Contraceptives Over-the-Counter Working Group, coordinated by Ibis Reproductive Health, is “interested in moving oral contraceptives over the counter as a way to increase access to” the drugs, “especially for women who now face barriers to access,” such as needing a prescription, said Daniel Grossman, leader of the working group and senior associate at Ibis.

“We are currently in the process of talking with a number of potential partners about what would be needed for a switch, and are hoping to meet with FDA in the next few months to discuss the regulatory pathway,” said Grossman, an obstetrician-gynecologist.

Those discussions could identify the types of studies, such as actual use and label comprehension studies, needed for a switch and what those would entail.

Grossman said while the group has been around since 2004, it is “just starting to look at this area,” and “explore potential regulatory strategy with the pharmaceutical industry.”

One aspect the group needs to explore is finding a drug firm as a partner to sponsor a potential switch application.

Grossman said the working group is not interested in sponsoring a switch application or filing a citizen petition to switch the category.

However, the group is interested in “playing a role in the regulatory process and representing the voices of the advocacy, research and clinician communities,” he added.

Finding A Partner Easier Said Than Done

“Historically, manufacturers haven’t wanted to switch [the pill] because they didn’t see a lot of financial upside from broader availability,” said Susan Lavine Coleman, president of NCI Consulting.

OTC drugs typically generate significantly less revenue than prescription drugs, largely because they sell at lower price points.

However, the increase in sales volume of switched drugs could offset partially the price drop, said Bill Howard, CEO of the Cough Company.

The working group notes a 2004 opinion survey found 68 percent of women said they likely would use hormonal contraception if it were available from a pharmacy and Latinas and blacks are even more likely to use OTC oral contraceptives than non-Hispanic whites.

That is a lot of women, and "a lot of money," especially considering women likely will take the pill long-term, Howard said.

However, he adds a lot of oral contraceptives are no longer patent-protected so they would face store brand competition that would eat into potential sales.

Switch Would Need To Overcome Baggage

Finances aside, other aspects of a switch could deter potential sponsors.

"Companies have done feasibility analysis [of switching oral contraceptives] and backed away," because a switch would be so difficult, Coleman said.

Progestin-only oral contraceptives, the type of pill the working group would consider switching first, meets most FDA criteria for a switch, the working group argues. The drug's benefits outweigh the risks, the potential for abuse or misuse is low, a consumer can easily self-diagnose the condition for which the pills are used and the directions are straightforward.

But the mini-pill has several factors working against it, which complicate a potential switch, Coleman said.

"Most notably, the chronicity of use," she said. Unlike emergency contraceptives already available OTC, women would use the pill on an ongoing, long-term basis. Most OTCs are for short or defined time periods of use.

In addition, Coleman noted, the serious side effects, including increased risk of strokes and heart attacks, may give the FDA pause when considering a switch.

Switching the pill also comes with a lot of baggage, including religious and moral opposition, similar to what Barr Laboratories dealt with when it switched *Plan B*, Howard said ("The Tan Sheet" April 6, 2010).

Coleman agreed that social issues may play a role in a possible switch. "The whole overlay of sexual politics" might discourage potential sponsors, she explained. "There are a lot of groups that are anti-contraception and there are concerns that if you make oral contraceptives available girls may become promiscuous."

Medical community concerns about a switch reducing consumers' use of primary care services and health care providers' revenues also could hinder a switch, Coleman said.

The medical community uses oral contraceptives "as a hook to get patients in the office for an annual pap smear even though that is not a fair way to look at it," she said.

"There is a fear that without that hook not only may you have loss in the continuity of routine care, but physicians may experience some revenue loss."

All of these factors, in addition to the scientific and safety requirements, make oral contraceptives "a hard switch," Coleman said, adding, "You have to be a masochist" to want to do this.

Working Group Could Abandon Switch

The working group acknowledges that it may decide against pursuing a switch.

"We are not necessarily interested in seeing an oral contraceptive switched to OTC if it doesn't achieve this broader goal of really trying to improve access," Grossman said.

For example, if the retail price of an OTC oral contraceptive drastically exceeds a consumer's prescription co-pay or fee, then a switch runs the risk of "replacing one barrier – the barrier of the prescription – with the barrier of an inaccessible price cost to women," he explained.

When Plan B switched it became more expensive. If that happened to the pill it could become unaffordable for women whose Medicaid covers the prescription but not OTC contraceptives, like condoms.

For this reason, the working group also is pushing to change Medicaid coverage to include all OTC contraceptives, and is reaching out to insurers to increase coverage, Grossman said.

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