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OTC Daily Oral Contraceptive Proposal In US Packs Promise Of Access, But Peril Of Single Option

by Malcolm Spicer

Discussion of whether progestin-only formulation will be approved for OTC sales and succeed in the US nonprescription market perhaps has been overshadowed by expectations of political pressures affecting FDA's evaluation and decision after HRA submitted its NDA.

Discussion emerged soon after a proposal for the first OTC daily oral contraceptive in the US was announced on whether approval would swing on influences other than the drug's safety and efficacy for use without the intervention of a medical professional.

Prevalent in the discussion are mentions of HRA Pharma's new drug application for OTC 0.075-mg norgestrel emerging soon after a US Supreme Court decision on restricting access to abortion services could somehow also affect states' decisions on allowing sales of birth control drugs.

Perhaps less expected after HRA Pharma announced submitting its NDA to the Food and Drug Administration, and at the same time overshadowed by expectations for political pressures affecting the FDA's decision, is discussion of whether the progestin-only formulation will be approved for OTC sales and succeed in the nonprescription market.

A reproductive health service business founder and an OTC switch consultant spoke with HBW Insight recently about

US OTC Birth Control NDA Could Debut 'Additional Conditions for Nonprescription Use' Labeling

By Malcolm Spicer

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HRA didn't have time to incorporate into its switch NDA instructions stated in proposed ACNU rule published in June, but the firm,

the chances for approval of the NDA submitted in July by HRA, a *Perrigo Company PLC* business.

They also discussed the FDA's evaluation of HRA's proposal within the agency's "additional conditions for nonprescription use" considerations for labeling *(see related story)*.

which worked with Ibis Reproductive Health on proposal, had time to plumb a draft guidance FDA published in 2018 on novel switches.

Read the full article here

'Not One Size Fits All'

HRA can't be faulted for using norgestrel for its OTC NDA, say Elizabeth Ruzzo, founder and CEO of Adyn Inc., which provides advice and a test to help women avoid prevent birth control side effects, and Susan Lavine Coleman, who consulted pharma firms on OTC switches before leaving the field in 2018.

ADYN CEO ELIZABETH RUZZO: "BIRTH CONTROL IS MEDICINE ... ONE OF THE MAIN MEDICINES USED TO TREAT REPRODUCTIVE DISORDERS, FROM ENDOMETRIOSIS TO PCOS."
Source: Source: Adyn

Norgestrel has a lower potential blood clot risk for some women than combined-ingredient oral contraceptives. But the ingredient, currently available Rx in the US only in progestin-estrogen combination formulations, isn't the correct oral contraceptive drug for all women.

"I think in general, this is good news for accessibility of birth control. But the thing to remember is that it's not one size fits all," Ruzzo said.

"I think the argument that the drug company is making here is, 'Look, this is very safe. There are even more dangerous drugs that are already over the counter. By that standard, we should be over the counter'."

Ruzzo references her experience founding Adyn, after struggling with side effects from the "wrong birth control" before finding the formulation right for her, in her concerns about approving OTC access for one oral contraceptive drug.

"My biggest critique of it is that there are nearly 200 highly effective methods of contraception on the market in the US. And birth control is not one size fits all. To think that you could offer one and only one over the counter and help everyone is just not reflective of the reality that most birth control users try three or more methods primarily in an attempt to avoid unwanted side

effects," she said.

"The vast majority of those 200 options are combined oral contraceptive, which are estrogen and progestin. I think the reason that those are very common is because of their additional potential health benefits when it makes sense for your individual biology," Ruzzo added.

Although HRA gained approval in 2021 in the UK for nonprescription sales of 10-mg desogetrel as a daily oral contraceptive, duplicating that approval in the US would have been more complicated than proposing a norgestrel switch. (Also see "*HRA Pharma And Maxwellia To Launch The UK's First OTC Daily Contraceptives*" - HBW Insight, 9 Jul, 2021.)

Paris-based HRA, acquired by Perrigo in a deal that closed earlier in 2022, could use information from norgestrel's approval as a single-ingredient Rx drug to help guide preparing its OTC NDA for the ingredient. (Also see "*OTC Oral Contraceptive In US Would Bring Market Uncertainties Along With Public Health Benefits*" - HBW Insight, 10 Sep, 2021.)

"Desogestrel has no history as a single ingredient in the United States as it has only been available in combination products. HRA would have needed probably a whole new NDA and it would have been a more complicated approval pathway," said Coleman.

Coleman, formerly president of NCI Consulting LLC in Moorestown, NJ, anticipates a good chance for approval of

A Proposal About More Than Birth Control

Both Ruzzo and Coleman also made more over-arching observations about proposing OTC access to daily oral contraceptives.

"One thing to remember is that birth control is medicine. It's one of the main reproductive medicines used to treat reproductive disorders, from endometriosis to [polycystic ovary syndrome]," she said.

"Improving that access is really important, as well as preventing unintended pregnancy, which has broad economic impacts as well."

And nonprescription sales for an oral contraceptive isn't a proposal many pharmas would make, Coleman said.

"It really takes a brave company to go into this. I think Perrigo is well-positioned to do right by it and HRA is a great partner and has tremendous experience with all kinds, both with emergency contraception and oral contraceptives," she said.

Firms with one or more Rx oral contraceptives in their portfolios likely haven't found sufficient incentive to propose making one available OTC. Not only are Rx product sales' strong, and currently without OTC competition, but offering nonprescription sales of a birth control pill likely will come

HRA's NDA, but also for some questions emerging from the target market after its launch.

"I assume there's going to be a lot of hoopla and excitement when it initially gets approved. They'll see at least among whatever the target audience is, they'll see sort of a lot of people coming to try the product," she said.

"But after that initial excitement, you get the question of product satisfaction. There's a reason the progesterone-only pill is really not even a factor in the Rx market."

with potential marketplace unrest.

"The main reason, at least initially, was the companies that actually had access to oral contraceptives didn't see enough incremental benefit to having it OTC and saw it potentially be actually damaging to their businesses for a whole lot of different reasons," Coleman said.

"These companies that have big portfolios, especially portfolios of RX drugs, but even the big OTC companies, don't want to start a firestorm that's going cause your product or your entire product line to be boycotted."

A progestin-only contraceptive could cause irregular menstruation and breakthrough bleeding, or breast tenderness acne.

While available as a prescription drug for 30 years at the same strength and formulation as the proposed OTC switch, a product containing only 0.075-mg norgestrel hasn't been marketed in the US since 2005. And among all oral contraceptives, its efficacy is most sensitive to being taken at the same time daily.

Costs For OTC, Not Rx

In addition to customer satisfaction with the formulation, another potential impediment to sales of an OTC oral contraceptive would be costs.

Health insurance plans pay for birth control prescriptions, although employers are allowed to opt out of including the coverage in their plans under the Supreme Court's Hobby Lobby Stores v. Sebelius decision in 2014.

"People should be able to have access to contraception without paying if they have insurance. Then the question is, is the market here only for the uninsured? Or is it the uninsured plus young people who don't want to tell their parents or people seeking convenience?" Coleman said.

"It's not clear to me what, or who the sweet spot of this market is."

Another concern about costs is that paying for the potential OTC switch likely won't end with

the first purchase. Labeling for the product, as it is for oral contraceptives already available Rx in the US, would instruct for ongoing use of the product.

"You need to pay out of pocket on an ongoing basis because you're not going to just use this for one month, you're going to use it every single month, or at least that's the way it ought to be used," Coleman said.

The package size potentially approved for OTC sales under HRA's NDA would affect the retail price and have effect on the market's response to the product.

SUSAN LAVINE COLEMAN: "IT'S NOT CLEAR TO ME WHAT, OR WHO THE SWEET SPOT OF THIS MARKET IS." *Source: NCI Consulting*

"Will you use it one month and then remember to buy again? Or do you get a 90-day supply to try to build the habit of using it. If they use it continuously does that price then discourage regular, ongoing use?" Coleman said.

"Is it going to be for people who have options? Is it going to be worth it? For people who don't have options? Will it be worth it?"

In a third article from interviews with Coleman and Ruzzo and with attorneys Emily Leongini and Shoshana Golden from ArentFox Schiff LLP, HBW Insight will report on 24 August on the potential for political influences on FDA's decision on allowing OTC birth control pill sales and for changes in access to birth control products in the US, or in states, following the Supreme Court's decision in Dobbs vs. Jackson (Mississippi) Women's Health Group.