HBW INSIGHT
CITELINE COMMERCIAL

24 Aug 2022 | **Analysis**

Age-Restriction Labeling, Behind-The-Counter Sales Likely In HRA's US OTC Contraceptive NDA

by Malcolm Spicer

> "I think the issue is whether it is going to have age restricted labeling, which would be a political issue rather than a medical issue," says Susan Lavine Coleman, long-time OTC switch consultant.

The sponsor of a proposal in the US for an OTC daily oral contraceptive can look to the approval of an emergency contraceptive formulation both for guidance on gaining approval and on enduring political pressures against it.

HRA Pharma's new drug application submitted to the Food and Drug Administration in July for OTC sales of 0.075-mg norgestrel hasn't been made available.

No details about the formulation or the proposal are known other than the *Perrigo Company PLC* business submitted the NDA it prepared in collaboration with women's health and reproductive rights advocacy group Ibis Reproductive Health. (Also see "*US FDA Has 10 Months To Provide Answer On Perrigo/HRA OTC Oral Contraceptive Application*" - HBW Insight, 11 Jul, 2022.)

Labeling including restricting sales to consumers 18 and older likely was considered or included in HRA's NDA, says Susan Lavine Coleman, a long-time consultant to pharma firms about OTC switches.

Political Winds, Like Previous Storms

"I think the issue rather, is whether it is going to have age restricted labeling, which would be a political issue rather than a medical issue," said Coleman, formerly president of NCI Consulting LLC

HBW INSIGHT
CITELINE COMMERCIAL

in Moorestown, NJ.

"We saw the multiple phases of litigation that finally freed emergency contraceptives from those age restrictions," she added.

In discussions with the FDA while preparing its NDA, HRA could've asked whether it should include age-restriction labeling, or the agency could've suggested it.

"As you think about who the potential market is, one could imagine that this could be of interest to younger women, and for people who would want parental approval, that age restriction is one of those political things that we might see in the labeling," Coleman said.

A representative for HRA declined to provide additional information about the NDA and about any response from the FDA.

No Behind-The-Counter Status

The sponsor of the OTC switch proposal for the original Plan B (levonorgestrel / 2 x 0.75 mg) added an age restriction to its proposed labeling after the FDA in 2003, counter to an advisory panel's near-unanimous recommendation, initially rejected its NDA. The agency in 2006 approved OTC Plan B with sales limited to consumers 18 and older, a restriction enforced by requiring behind-the-counter sales at pharmacies. (Also see "*Plan B Ruling: Little Commercial Impact, Big Policy Implications*" - Pink Sheet, 30 Mar, 2009.)

An age restriction could be included in an NDA submitted to the FDA, but not the enforcement piece.

"They didn't ask for behind the counter. What they asked for, when they ran into the opposition, was an age restriction. In order to have the age restriction, you have go through the pharmacist or you had to go through some intermediary in order to impose that age restriction," Coleman

Over US FDA Decisions, Stir Around OTC Contraceptive Proposal

By Malcolm Spicer

24 Aug 2022
Experts spoke with HBW Insight about potential impact on US contraceptive market from Supreme Court's decision in Dobbs v. Jackson overturning its 1973 ruling in Roe v. Wade, which was upheld in 1992 ruling in Planned Parenthood v. Casey, stating a woman has a constitutional right to reproductive health services.

Read the full article here

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

said.

“Maybe it's just semantics, but it wasn't an official behind-the-counter status, just like cigarettes are behind the counter, because of an age restriction. That is how they worked out how you would ensure that people under 18 didn't have access to the product.”

As reproductive rights advocates continued litigation to force allowing OTC Plan B sales to all consumers, the agency in 2011 moved to lift age restrictions but was overruled by the Health and Human Services Department secretary. However, Plan B and generic equivalents as well as formulations with one 1.5-mg levonorgestrel tablet became available OTC in 2013 when a federal judge, in one of multiple rulings in years-long litigation, ordered OTC sales for Plan B without age restrictions. (Also see "*Court Ruling Compels Emergency Contraceptives Over The Counter*" - Pink Sheet, 8 Apr, 2013.)

“In terms of politics, my hunch is that you're more likely to see the potential stumbling blocks might be around access for minors. Similar to what happened with Plan B, there might be stumbling blocks related to, if only from a political perspective, whether our 12-year-olds can go in and purchase that’,” said Emily Leongini, a partner at ArentFox Schiff LLP in Los Angeles.

“I wouldn't be surprised to see those types of issues come up during the approval process. Maybe not at FDA when they're discussing it as part of the advisory committees, or by the scientific review, but at the higher levels of clearance and within HHS similar to Plan B,” Leongini added.

‘Maintain FDA’s Sole Authority’

Democrats in Congress have indicated they anticipate political influences could sway FDA decisions on reproductive health product proposals.

By Malcolm Spicer

23 Aug 2022

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.

Read the full article here

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

By Malcolm Spicer

23 Aug 2022

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

They re-introduced the Affordability is Access Act earlier in 2022 in the House and Sente to require private insurance companies to cover comprehensive preventive health services and expand coverage to include full access to OTC daily oral contraception. (Also see "*Likely Limits On Reproductive Rights Drive Democrats' Urgency For OTC Oral Contraceptive*" - HBW Insight, 10 Jun, 2022.)

The bills, S.4347 and H.R.7394, which track with bills introduced in previous sessions of Congress by some of the same sponsors, also target limiting the influence courts and state legislators have on the FDA's decisions about the drugs.

Before the Supreme Court published its Dobbs v. Jackson (Mississippi) Women's Health Group ruling but after an unauthorized leak of a draft of the decision in May, sponsors in both chambers amplified the FDA's regulatory role in a release saying the bills intend to "maintain the FDA's sole authority to determine the safety and efficacy of drugs and make them available over-the-counter without a prescription."

In this article and the related articles linked above, HBW Insight reports 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 ruling in Dobbs v. Jackson (Mississippi) Women's Health Group.