HBW Insight
Informa Pharma Intelligence

Will Influences Behind US FDA's Delayed Approval For OTC Plan B Also Shadow 'Plan A' Switch?

By Malcolm Spicer

July 12, 2022

Executive Summary

FDA history with emergency contraceptives and opioid overdose antidote naloxone doesn't assure Jeffrey Singer, Valley Surgical Clinics founder and advocate for making more drugs available OTC, the agency will approve HRA Pharma's NDA for OTC 0.075-mg norgestrel.

An Arizona surgeon and advocate for making more pharmaceutical products available OTC isn't sure the Food and Drug Administration is ready to approve the change for a drug he's singled out as a prime candidate, daily oral contraceptives.

The FDA's history with emergency contraceptives and with opioid overdose antidote naloxone doesn't assure Jeffrey Singer, president emeritus and founder of Valley Surgical Clinics Ltd., that the agency will approve a new drug application which Perrigo Company PLC business HRA Pharma submitted for OTC sales of 0.075-mg norgestrel.

"Even though the FDA has now been asked, there's a lot of politics involved. It's been very frustrating," said Singer, also a senior fellow at the Cato Institute's Health Policy Studies with more than 35 years in private practice as a general surgeon.

Similar influences likely are reaching the FDA around making naloxone available OTC *(see related story)*.

He pointed out a potential sign of the agency's response to HRA's NDA could be the FDA's 2003 decision, counter to an advisory panel's near-unanimous recommendation, against allowing OTC sales of the original Plan B (levonorgestrel / 2 0.75 mg) emergency contraceptive.

The FDA in 2006 approved nonprescription sales after the initial marketer of Plan B changed its NDA to require behind-the-counter sales at pharmacies and limit purchases to consumers 18 and older. (Also see "Plan B Ruling: Little Commercial Impact, Big Policy Implications" - Pink Sheet, 30 Mar, 2009.)

"It's perfectly safe for young girls to take and, finally the FDA actually recommended … that it be available over the counter for all ages," Singer told HBW Insight.

However, the then-Health and Human Services Department secretary overruled the FDA's decision, saying the Obama administration was concerned about young girls' access, before a federal judge in 2013, 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.)

"Here you have the irony where anybody can get Plan B, but they can't get 'Plan A' over the counter. The morning after pill is OTC, but not the night-before pill," Singer said.

Political Influences And 'Regulatory Capture'

That irony might be lost on FDA and other federal officials who could have some influence on whether a daily oral contraceptive is approved for OTC sales.

"It'll be interesting to see if the same pressures come up that led to the delay of the making Plan B over the counter. It was the resistance that if you can have the morning after pill, you're encouraged to sexual promiscuity," Singer said.

“It's the same attitude that may slow down the FDA,” he added.

The problem driving the attitude, he says, is “you have a government organization we'd like to think is completely devoid of politics and there's no such thing as ‘regulatory capture’.”

Singer noted a white paper he and Cato Institute colleague Michael Cannon published in 2020 discussing barriers to making more drugs available OTC in the US and suggesting that regulatory capture – an expectation that regulatory agencies are influenced by the industries subject to their oversight and act to benefit them rather than the public interest – is a factor.

“We know, number one, there is regulatory capture, and number two, there's no such thing as a government monopoly agency not being subject to politics. It could be that political pressures will cause the FDA to drag its feet on this. I don't know, I hope not. But that could happen,” he said.

Meanwhile, some states are allowing pharmacists to distribute oral contraceptives to customers without prescriptions *(see related story)*.

Doctors Support OTC Sales

Safety and efficacy for OTC use aren’t a barrier for an oral contraceptive switch, Singer added.

“The doctors have been saying for 20 years, you don't need me to write you a prescription, you should be able to get this over the counter. And doctors are basically foregoing an opportunity to make money here … so we can't blame them.”

Most daily oral contraceptives currently available in the US contain both progestin and estrogen compounds, with progestin-only, such as the norgestrel formulation HRA is proposing for OTC sales, accounting for 4% of the total.

However, progestin-only has a better safety profile as it has fewer contraindications and the ingredient is the only one approved in the US for use in OTC emergency contraceptives, researchers have reported.

Singer noted objections to OTC sales have included contending that women need annual pelvic and Pap tests. “I'm not a gynecologist. I'm a general surgeon, but the bulk of the OB/GYN literature suggests that actually unless you're in a high-risk category, you don't need that.”

“Even the Cancer Society says that. So, what's been holding it up?” he said.

The American Medical Association recently for the first time encouraged the FDA to make daily oral contraceptives available OTC after previously targeting its suggestion to manufacturers. The recommendation was adopted from a proposal submitted by the American College of Obstetricians and Gynecologists. (Also see "AMA Shares OTC Birth Control Diagnosis With FDA" - HBW Insight, 16 Jun, 2022.)

The ACOG’s recommendation, Singer noted, is based on what’s best for OB/GYNs’ patients, not for their practices.

“They’re a group that benefits from it being prescription-only because of insurance payments for office visits. Family physicians have saying this for at least a decade, and the AMA is joining the chorus,” he said.

‘Easy As Possible To Avoid Unwanted Pregnancies’

Another factor that may influence the FDA’s thinking is heightened attention to access to birth control, including allowing OTC sales of oral contraceptives, following the Supreme Court’s June ruling allowing states to ban access to abortion services. (Also see "‘Storm Of Change’ Could Propel Industry On Making Daily Oral Contraceptive Available OTC In US" - HBW Insight, 6 Jul, 2022.)

“Regardless of where anyone stands on the abortion issue, I would like to think that everyone agrees that we like to see fewer unwanted pregnancies and we'd like to make it as easy as possible for women to avoid unwanted pregnancies so that the abortion issue doesn't have to come up,” Singer said.

“That should be something that should be non-controversial.”

However, some states already have banned abortion services since the ruling and more will make the change. Conversely, those states are opposed to expanding access to birth control by allowing pharmacists to dispense the products to customers without prescriptions.

“What's been holding things up is there are groups of people, for whatever reason, don't like the idea of making it too easy for people to engage in sexual intercourse out of wedlock,” Singer said.

“I can't guarantee that those same pressures that are being brought to bear on state levels will be brought to bear on the national level. The president has declared a public health emergency and he's instructing agencies to do what they can, I understand all that. But, we'll see what happens when the rubber hits the road.”