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# Marketer Of Glycerin, Oleate OTC Contraceptive Cream Consents To Ending Production, Sales

by [Malcolm Spicer](#)

Smart Women's Choice agrees to consent decree requiring it to halt production and sales of namesake brand product promoted as being hormone-free and with claims including "immobilizing sperm" and "preventing fertilization." Related company with similar name, product and claims continues sales.

An Arizona company agreed to stop making and marketing a topical labeled as a vaginal cream after previously saying its commitment to continue selling the product as a contraceptive was "unalterable."

The US Department of Justice, litigating a complaint for the Food and Drug Administration, on 15 November announced that Smart Women's Choice Inc. agreed to a consent decree requiring the firm to halt production and sales of its namesake brand product promoted as being hormone-free and with claims including "immobilizing sperm" and "preventing fertilization."

A company with a history linked to Smart Women's Choice and also warned by the FDA, however, continues to offer its own contraceptive cream with a similar formulation and claims (see box below).

Smart Women's Choice, which was launched in 2014 in California before being acquired in 2021 and moved to El Mirage, AZ, by current owner Jennifer Richard, agreed to requirements including hiring a consultant to guide remediation to reach complete regulatory compliance should it intend to resume making and selling its product formulated with water, glycerin, potassium oleate, palmate, castorate, citrate and mono- and di-glycerides.

Should the company resume operations, audit inspections by an expert confirmed by the FDA would be required at least once every six months for five years.

Compliance with FDA labeling regulations, supervised by a “labeling expert,” to prevent the firm’s formulations from being deemed unapproved drugs is prominent in the remediation requirements detailed in [the decree](#) entered on 14 November in US District Court for Arizona and approved by Chief Judge Murray Snow.

“The FDA remains fully committed to taking enforcement action against companies and executives responsible for marketing unapproved drugs in violation of federal law,” said Jill Furman, compliance director in the FDA’s Center for Drug Evaluation and Research, in the DoJ announcement.

The settlement also states that in the event Smart Women’s Choice fails to comply with any requirement stated in the decree or in FDA regulations, it must pay \$1,000 in damages for each day a violation continues, an additional \$1,000 for each product or act in violation and “further additional sum equal to the retail value of drugs that have been manufactured, prepared, processed, packed, repacked, received, labeled, held, and/or distributed in violation.”

The document states that Richard and the firm “understand and agree that the liquidated damages specified ... are not punitive in nature and their imposition

## ***‘If It Can’t Swim’***

Wise Women’s Choice LLC has a history linked to Smart Women’s Choice and continues to offer its own contraceptive cream with a similar formulation and claims although it also warned by the FDA.

The FDA in July 2021 submitted a warning to Wise Women’s Choice, at an address in San Antonio, TX, stating that its namesake brand creams are unapproved drugs. (Also see [“Glycerin, Oleate Cream Marketed Under Different Brand Still Not Approved As OTC Contraceptive”](#) - HBW Insight, 26 Jul, 2023.)

Wise Women’s Choice’s website was active and offering sales of its products on 15 November. Information on the website includes statements that Wise Women’s Choice previously operated as Smart Women’s Choice and that the company is located in Costa Rica.

The formulation “works by simply immobilizing the sperm, if it can’t swim it can’t get to the egg,” an image on the site states.

The site also offers a history of the idea for the formulation of both firms’ products.

Inventor Françoise Farron studied at the University of California-Berkeley and obtained a biochemistry Ph.D. from New York University Medical School before studying control mechanisms of cell growth at Harvard

does not in any way limit the ability of the United States to seek, or the Court to impose, civil or criminal penalties ... or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant.”

Additionally, if the DoJ seeks and gains a contempt order to enforce the terms, Richard and the firm “shall, in addition to other remedies, reimburse the United States for its attorneys’ fees (including overhead), investigational and analytical expenses, expert witness fees, and any other court costs or fees.”

[The complaint](#) filed in October stated that as of mid-July, the firm maintained Facebook and Instagram pages featuring links to its website and where customers could obtain information about its product.

Smart Women’s Choice’s website remained live but showed no content on 15 November; the phone number listed with the company’s Arizona business registration has been disconnected.

## ‘Market Tested’ Isn’t GRASE

The company responded in May 2021 to an FDA warning letter, submitted the same month to the firm’s former California address, disputing that the Smart Women’s Choice is a “drug” under FDA regulations and stating that the “product is market tested” and has been sold “for over seven years to many thousands of couples,” according to the complaint. (Also see "[Ruining The Mood, US FDA Says Glycerin, Oleate Cream Not Approved As OTC Contraceptive](#)" - HBW Insight, 25 May, 2021.)

The agency the following month further explained its policy in an email to the company. FDA officials said “immobilizing sperm,” “preventing fertilization” and other claims on the company’s website and social media pages rendered its product a drug under FDA regulations codified in [21 USC Sec. 321\(k\)](#).

Medical School as part of a larger research program on the phenomenon of interrupted differentiation and uncontrolled growth in cancer cells.

Through personal experience and research, Farron determined a vaginal cleaning agent could coagulate sperm. After a friend’s daughter died when blood clots that formed due to her use of a hormone-containing birth control device,

She shared her discovery with other women as an alternative contraceptive after a friend’s daughter died when blood clots formed due to her use of a hormone-containing birth control device.

Farron began selling her contraceptive worldwide in 2016 and in 2018 received a patent for her invention.

Emails to the firm asking for comment weren't answered.

The officials also explained that the company's claims regarding consumer testing does not demonstrate safety and efficacy because the agency, under [21 USC Sec. 331\(d\)](#) and [Sec. 355\(a\)\(b\) and \(j\)](#), approves new drugs on the basis of scientific data and information demonstrating a drug is safe and effective for its intended uses.

However, Smart Women's Choice replied the same day saying it intended to continue selling the product without FDA approval, according to the complaint.

And when the FDA in November 2021 requested a meeting to discuss the continued violations, Smart Women's Choice company responded a month later by refusing to meet with the agency, "stating that the company's position was 'unalterable'."

"FDA has conducted a comprehensive search of the publicly-available scientific and medical literature for [the Smart Women's Choice] product and determined there are no published adequate and well-controlled clinical investigations or any other scientific literature demonstrating [the product is generally regarded as safe and effective] for its intended use as a contraceptive," DoJ's Consumer Protection Branch attorneys wrote in the complaint.

They added that "qualified experts cannot come to a consensus [the product] is safe and effective for its intended use.

The attorneys, working with the FDA Office of General Counsel, also wrote in the complaint that "despite FDA's repeated notifications, Defendants have demonstrated their unwillingness to comply with" FDA regulations and would continue "unless restrained by order of this Court."

## OTC Contraceptive Approved Since Smart Women's Warning

Although the FDA regularly warns firms that dietary supplement products, and less often food

### Moisturizer, Emulsifiers Among Ingredients

Glycerin, one of the ingredients in Smart Women's Choice cream, is commonly available in the US in wound and burn treatments and as a moisturizer to treat or prevent dry, rough, scaly, itchy skin and minor skin irritation.

The other ingredients are common in cosmetics and personal care lotions or foods: potassium oleate is a fatty acid with soap properties; castorate has cleansing, emulsifying, dispersing, solubilizing, lubricating and foaming qualities; mono- and di-glycerides are fatty acid chains that act as surfactants and are commonly used as emulsifiers to stop water and oil from separating.

Palmate commonly is defined as a natural leaf. Smart Women's Choice didn't explain the ingredient's role in its products.

and topical products, are unapproved drugs because they're marketed with claims for preventing or treating diseases and other health conditions, a lotion available OTC and marketed with claims as a contraceptive was a rare find for the FDA.

No daily oral contraceptive had been approved for OTC sales in the US when the FDA warned Smart Women's Choice. Since then, the agency approved [Perrigo Company PLC](#) business HRA Pharma's supplemental new drug application for a full Rx-to-OTC switch of 0.075-mg norgestrel branded Opill and for sales without age restrictions. (Also see "[First OTC Birth Control Pill Approved In US Will Launch With Three-Year Market Exclusivity](#)" - HBW Insight, 13 Jul, 2023.)

The approval in July 2023 came 60 years after Rx birth control's initial approval in the US and one year after both HRA submitted the sNDA and the Supreme Court decided in *Dobbs v. Jackson (Mississippi) Women's Health Organization* to allow states to regulate access to abortion services. (Also see "[Allowing States To Ban Abortion Services Increases Calls For Making Birth Control Available OTC](#)" - HBW Insight, 24 Jun, 2022.)

Additionally, President Biden weeks earlier had issued an executive order on expanding access to birth control in the US including OTC access to oral contraceptives. The executive order was the Biden administration's third on reproductive health care access since the Supreme Court's *Dobbs* decision. (Also see "[Biden Calls For Expanding Access To Reproductive Health Care, Including OTC Oral Contraceptives](#)" - HBW Insight, 23 Jun, 2023.)

Perrigo plans to launch Opill sales in the 2024 first quarter.