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IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

United States of America,

Plaintiff,

v.

Smart Women's Choice, Inc., a corporation; and Jennifer A. Richard, an individual,

Defendants.

No. _____

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and this Court's inherent equitable authority, to permanently enjoin and restrain Smart Women's Choice, Inc., an Arizona corporation, and Jennifer A. Richard, an individual (collectively, "Defendants"),

from violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce a new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(b) or (j) nor exempt from approval.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant Smart Women's Choice, Inc. ("the company") is incorporated under the laws of the state of Arizona, within the jurisdiction of this Court. Prior to being incorporated in Arizona on or about October 13, 2021, the company was incorporated in California from approximately 2014 until 2019, and the company continued to do business in California after 2019.

5. Defendant Jennifer A. Richard is the Chief Executive Officer ("CEO") of Smart Women's Choice, Inc. She is the most responsible person at the company.

6. On or about October 13, 2021, Defendant Jennifer Richard acquired ownership and control of the company and its assets from its founder and former CEO, and Richard has overseen the company's operations since that time.

7. Defendants sell and distribute a product called Smart Women's Choice (the "SWC product"), a cream that Defendants market as a vaginal contraceptive. According to the SWC product's labeling, it contains: water, glycerin, potassium palmate, potassium olivate, potassium castorate, potassium citrate, and mono- and diglycerides.

8. Defendants conduct business in El Mirage, Arizona, within the jurisdiction of this Court. On or about July 28, 2022, Defendants shipped the SWC product from Arizona to Maryland. The shipping package bore a return address of 12805 W. Bloomfield Rd., El Mirage, Arizona 85335.

9. As of July 11, 2023, Defendants maintained the website

www.smartwomenschoice.com ("Defendants' website"), which Defendants used to sell and receive orders for the SWC product. Defendants' website identified 12425 W. Bell Rd., Suite 107, Surprise, Arizona 85378 as the company's address, which is within the jurisdiction of this Court. Additionally, as of July 11, 2023, Defendants maintained Facebook and Instagram pages ("Defendants' social media pages"), which contained links to Defendants' website and from which customers were able to obtain information about the SWC product.

DEFENDANTS' SWC PRODUCT IS A DRUG UNDER THE ACT

10. The Act defines "drug," in relevant part, as "articles (other than food) intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C).

11. The intended use of a product refers to the objective intent of the persons legally responsible for the labeling of the product and may be determined from claims in the product's labeling. 21 C.F.R. § 201.128.

12. The Act defines "label," in relevant part, as "a display of written, printed, or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). The Act defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The labeling of a product includes any written, printed, or graphic matter that supplements or explains the product's use, regardless of whether it is physically attached to the product itself. *See Kordel v. United States*, 335 U.S. 345, 349–50 (1948).

13. The SWC product is a drug within the meaning of the Act because its labeling contains claims that it impedes sperm mobility by interacting with seminal fluid in the vagina, thereby working as a contraceptive, including but not limited to the following:

A. On the company's website (www.smartwomenschoice.com) (as of July 11, 2023):

I. "Smart Women's Choice[:] A revolutionary birth control cream that

you and your partner can rely on to prevent unintended pregnancy."

II. "Our patented, hormone-free and spermicide-free vaginal cream can be relied upon to prevent pregnancy. Smart Women's Choice is used right before each act of intercourse. No need for daily tracking, no barrier between you and your partner, and no effect on your hormones."

III. Under the heading "What Our Customers Say": "I needed an effective birth control method that didn't give me yeast infections like condoms had. I no longer dread trying to keep from getting pregnant. SWC is 10/10 for me!"

IV. Under the heading "How to Use Smart Women's Choice": "01 Squeeze approximately one inch of Smart Women's Choice cream onto your finger. 02 Insert into the vagina immediately before having intercourse. This takes only a moment. 03 Enjoy yourself. 04 Follow your normal hygiene routine."

V. Under the heading "Using Smart Women's Choice with other birth control methods": "SWC was formulated to be used as a stand-alone contraceptive product."

VI. Under the heading "How is SWC different from other contraceptives?": "SWC is unique; it works by immobilizing the sperm in the vagina. Immobilized sperm cannot make the journey into the Fallopian tubes, the only place where an egg can get fertilized. Without fertilization, it is impossible to get pregnant. SWC does not

impact a woman's hormonal system. It simply coagulates the sperm and prevents it from meeting the egg."

VII. Under the heading "How effective is SWC?": "Smart Women's Choice is 99.8% effective. Out of every 1000 containers sold, 2 women report becoming pregnant while using SWC."

B. On the company's Instagram page (as of July 11, 2023):

I. In the biography section: "All natural, hormone-free, on-demand birth control."

II. In a post containing the heading "customer testimonial": "Been using it for 5 years now. Love the freedom and effectiveness! ~ M.J."

C. In the SWC product's package insert (collected August 2022):

I. "INSTRUCTIONS FOR PROPER USE: SWC works entirely differently from other contraceptives: it immobilizes the sperm (video #2 on website) on contact, in the vagina, where it is deposited during intercourse. Being immobilized, it cannot travel into the fallopian tubes, where fertilization occurs (video #1). NO FERTILIZATION = NO PREGNANCY."

II. "One application protects you completely . . . ."

14. Based on the claims listed in Paragraph 13, and many others found on Defendants' website, Defendants' social media pages, and the labeling within and upon the SWC product's packaging (e.g., its package insert), Defendants' SWC product is a drug

under the Act because it is an article other than food intended to affect the structure or function of the human body.

DEFENDANTS' SWC PRODUCT IS AN UNAPPROVED NEW DRUG

15. It is a violation of the Act to introduce or deliver for introduction, or cause to be introduced or delivered for introduction, into interstate commerce a "new drug" that is neither approved by FDA nor exempt from approval. *See* 21 U.S.C. § 331(d). Specifically, a "new drug" cannot be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from the approval requirement. *See* 21 U.S.C. §§ 331(d), 355(a), (b), (j).

16. The Act defines "new drug," in relevant part, as "[a]ny drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and expertise to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

17. For a drug to be "generally recognized as safe and effective" ("GRASE") within the meaning of 21 U.S.C. § 321(p)(1), three criteria must be met. First, the specific drug must have been the subject of adequate and well-controlled clinical investigations establishing that the drug is safe and effective for its intended use. *See* 21 U.S.C. § 355(d); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 629 (1973). Second, these clinical investigations must be published in the scientific or medical literature so that they are generally available to qualified experts. *See Weinberger v. Bentex Pharms., Inc.*, 412 U.S. 645, 652 (1973). Third, there must be consensus among qualified experts, based on the published investigations, that the drug is safe and effective for its intended use. *Id.*; *United States v. Western Serum Co.*, 498 F. Supp. 863, 866 (D. Ariz. 1980). Failure to meet any one of these three criteria establishes that a drug is not GRASE and therefore a "new drug" as a matter of law. *See United States v. Innovative BioDefense, Inc.*, 2019 WL 7195332, at *4–5 (C.D. Cal. Nov. 15, 2019).

18. FDA has conducted a comprehensive search of the publicly-available scientific and medical literature for Defendants' SWC product and determined there are no published adequate and well-controlled clinical investigations or any other scientific literature demonstrating that Defendants' SWC product is GRASE for its intended use as a contraceptive. As such, qualified experts cannot come to a consensus that Defendants' drug is safe and effective for its intended use. Therefore, Defendants' SWC product is not GRASE and is a new drug under 21 U.S.C. § 321(p).

19. FDA has conducted a search of its records for NDA and ANDA submissions and found no approved NDAs or ANDAs for the SWC product. Additionally, FDA has confirmed that Defendants' SWC product does not qualify for an exemption from the new drug approval requirement pursuant to an investigational new drug application under 21 U.S.C. § 355(i) and 21 C.F.R. part 312. Accordingly, Defendants' SWC product is an unapproved new drug within the meaning of 21 U.S.C. § 355(a).

DEFENDANTS ENGAGE IN INTERSTATE COMMERCE

20. The Act defines "interstate commerce" as commerce between any State and any place outside of it. 21 U.S.C. § 321(b)(1).

21. As of July 11, 2023, Defendants' website contained an e-commerce page where customers could purchase Defendants' SWC product for shipment throughout the United States.

22. FDA purchased twelve units of the SWC product from Defendants' website on September 15, 2021. On or about September 20, 2021, Defendants shipped six units of their SWC product from California to Maryland. FDA received this shipment on September 27, 2021.

23. On or about October 1, 2021, Defendants shipped six additional units of their SWC product from California to Maryland. FDA received this shipment on October 13, 2021.

24. FDA purchased two units of the SWC product from Defendants' website on July 26, 2022. On or about July 28, 2022, Defendants shipped two units of their SWC

product from Arizona to Maryland. FDA received this shipment on August 2, 2022.

25. Defendants' shipments from California and Arizona to Maryland constituted distribution in "interstate commerce" within the meaning of 21 U.S.C. § 321(b)(1). Therefore, Defendants violated 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce unapproved new drugs within the meaning of the Act.

FDA WARNED DEFENDANTS THAT THEIR CONDUCT IS UNLAWFUL

26. Defendants are well aware that their conduct violates the Act and that continued violations could lead to enforcement action.

27. On May 19, 2021, FDA issued a Warning Letter to the company based on a review of the company's website. Among other things, FDA's Warning Letter informed the company that the claims on its website establish that the SWC product is a drug under the Act, 21 U.S.C. § 321(g)(1), because it is an article other than food intended to affect the structure or function of the human body. The Warning Letter also informed the company that the SWC product is an unapproved new drug under the Act, 21 U.S.C. §§ 321(p) and 355(a), and that its introduction or delivery for introduction into interstate commerce of the SWC product was prohibited under the Act, 21 U.S.C. § 331(d). The Warning Letter cautioned the company that its failure to promptly correct its violations and to prevent future ones could lead to an enforcement action, including an injunction. This Warning Letter has been posted on FDA's public website since shortly after its issuance.

28. On May 25, 2021, the company responded to FDA's Warning Letter by email, disputing that the SWC product is a "drug" under the Act, and stating that the "product is market tested" and has been sold "for over seven years to many thousands of couples."

29. On June 25, 2021, FDA responded by email to the company, explaining that "immobilizing sperm," "preventing fertilization," and other claims on the company's website and social media pages regarding the use of the SWC product as a contraceptive rendered the SWC product a "drug" under the Act. Additionally, FDA explained that the

Agency approves new drugs on the basis of scientific data and information demonstrating that the drug is safe and effective for its intended uses, and that the company's claims regarding consumer testing does not demonstrate safety and efficacy. FDA again advised the company "to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your product as safe and effective for the prevention of pregnancy, a use for which your product has not been approved by FDA."

30. That same day, the company replied by email, indicating that it intended to continue selling the SWC product without FDA approval.

31. On November 30, 2021, after Defendant Jennifer Richard identified herself as the CEO of Smart Women's Choice, Inc. with the Arizona Corporation Commission, FDA contacted the company at the email addresses that were listed on its website to request a meeting to discuss their continued violations.

32. On December 8, 2021, the company responded by email by refusing to meet with FDA, stating that the company's position was "unalterable."

33. Thus, despite FDA's repeated notifications, Defendants have demonstrated their unwillingness to comply with the Act. Unless restrained by order of this Court, Defendants will continue to violate the Act in the manner set forth above.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Pursuant to 21 U.S.C. § 332(a) and the Court's inherent equitable authority, permanently restrain and enjoin Defendants, and each of all of their directors, officers, agents, employees, representatives, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from violating 21 U.S.C. § 331(d), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce any new drug within the meaning of 21 U.S.C. § 321(p) that is neither approved under 21 U.S.C. § 355(b) or (j) nor exempt from approval; and

II. Order that FDA be authorized pursuant to this injunction to inspect Defendants' places of business and all records relating to the manufacturing, preparing, processing, packing, receiving, labeling, holding, and distributing of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

III. Order that Plaintiff be awarded costs and such other equitable relief as the Court deems just and proper.

Respectfully submitted this 12th day of October 2023,

FOR THE UNITED STATES OF AMERICA

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