

November 18, 2019

The Honorable Joseph J. Simons, Chairman
Federal Trade Commission
600 Pennsylvania Avenue, NW
Washington, DC 20580

Dear Chairman Simons:

This letter provides the Federal Trade Commission (FTC) with the troubling findings of our investigation into dietary supplements that explicitly or implicitly claim to treat female infertility.¹ We urge the FTC to take enforcement action against the 39 products we identified as making unsubstantiated claims in violation of the FTC Act by issuing warning letters to the offending manufacturers and prohibiting the sale of these products.²

Each of these 39 supplements, in addition to making unsubstantiated advertising claims, has labeling bearing disease claims in violation of the Federal Food, Drug, and Cosmetic Act. For this reason, we also are sending a letter to the Food and Drug Administration (FDA) urging them to act alongside FTC in taking enforcement action against these companies.

FTC rules state that advertisers must have a “reasonable basis for advertising claims before they are disseminated.”³ In deciding whether a claim is appropriately substantiated, FTC considers a variety of factors, including the type of product, the type of claim, and the “consequences of a false claim.”⁴ Health-related claims, such as a claim that a product will treat or cure a health condition, must be supported by reliable scientific evidence.⁵ It is unlawful to advertise with health claims, directly or indirectly, that lack reliable scientific evidence, or to exaggerate the health benefits of products.⁶

An enforcement effort by the FTC is more than justified by the vulnerability of the population targeted by these supplements. The emotional and physical struggle of being unable to get pregnant is a challenge that many women face and will go to great lengths to overcome. In the U.S., approximately 12 couples in 100 have trouble becoming pregnant, and about ten in 100 (6.1 million) women of childbearing age face difficulties becoming or staying pregnant, according to the Centers for Disease Control and Prevention.⁷ Women may be under time pressure to conceive, and relying on ineffective supplements, rather than seeking effective, proven treatments, may waste precious time. Many women are willing to go to great lengths to overcome the emotional and physical struggle of being unable to get pregnant, and these purported fertility aids seek to profit from the vulnerability created by this sense of urgency.

I. *Identification of Products that Make Unsubstantiated Claims*

We conducted a market scan and compiled a list of dietary supplements for women that claimed, directly or by implication, to help with infertility. We searched each manufacturer's website or Amazon product page for valid scientific studies to support their claims. When none were found, we reached out to the company to ask for scientific substantiation. Transcripts of those interactions are included in the Appendix.

We identified 39 women's fertility supplements containing a total of 94 ingredients manufactured by 27 companies that were unable to substantiate their products' claims.⁸ These findings show that health fraud and unapproved drug claims are rampant in the female fertility supplement marketplace.⁹

As detailed in the attached chart, the manufacturers of these female fertility supplements claim that their products treat infertility, targeting women who have had difficulties conceiving or who have underlying health conditions that put them at risk of infertility, such as Polycystic Ovary Syndrome (PCOS), obesity, or diabetes. Their claims include such statements as:

- “Recommended for all trying-to-conceive women, and particularly women trying to conceive later in life & women with PCOS.” (Ovaboost)
- “Especially recommended for: Women with PCOS and/or obesity, Women with infertility” (Conflam-Forte)
- “[T]reatment of choice for many fertility-related issues. D-Chiro-Inositol helps to lower elevated blood insulin levels, which more and more research is showing to be the cause of PCOS.” (D-Chiro Inositol)
- “More than 800 customers shared their experience with us in a self-reported, opt-in internet survey... **1 in Every 3** Survey Participants Diagnosed with Unexplained Infertility Became Pregnant While Using FertilAid for Women” (FertilAid for Women) (*Emphasis in original.*)
- “[F]ormulated for women who may be having difficulty conceiving” (Pregnitude)
- “Proxeed Women is recommended for women of reproductive age who: are experiencing fertility problems [...] are preparing for IVF and want to ensure the best possible quality of egg (ovum) and an optimum environment for implantation”
- “[T]he ingredients in our herbal blend have been used for centuries in TCM and Ayurvedic Medicine to overcome fertility issues.” (Women's Fertility Boost)

Some manufacturers make further unsubstantiated claims that could deter patients from seeking effective, FDA-approved drugs by indicating that the supplements are effective alternatives to conventional care:

- “[A] perfect natural alternative to fertility drugs or invasive treatments.” (FertilHerb for Women)
- “PHYSICIAN FORMULATED: At Doctor MK's we know that PCOS can be stressful. Our goal is to help women overcome infertility and increase pregnancy rates without the unwanted side effects of prescription medications.” (doctorMK’s Natural Myo-inositol)
- “[R]ecognized as a viable non-prescription option for women who may be having difficulty conceiving.” (Pregnitude)
- “If you are tired of fertility drugs and their lame promises, we have news for you!” (Conceive Plus Women’s Fertility Support)
- “I’ve been taking it for 8 days now and i’m [*sic*] getting amazing readings on my ovacue monitor. This is better than when I took clomid!” (FertileDetox testimonial)
- “No need to fuss with making a tea or having to pay thousands for drugs and other treatment methods that can cause side effects” (Ready. Set. Go!)

The FTC has stated that “[i]f an advertiser asserts that it has a certain level of support for an advertised claim, it must be able to demonstrate that the assertion is accurate.”¹⁰ Therefore, if an advertisement claims that “scientists agree” that a product is effective, or that an ingredient has been the “subject of U.S. government-sponsored research,” the company must have proof that such statements are true.¹¹ The companies in the appended chart, as we demonstrate, instead make claims with only faulty substantiation (*e.g.*, they furnish citations to unrelated studies), or in most of the cases, lack any substantiation for the claims.

Action Requested

We respectfully urge FTC to issue warning letters to the offending companies requiring the cessation of sales, and to allow inspectors to seize the products. We appreciate that the FDA and FTC recently issued joint letters focusing on what the two agencies consider to be illegal and deceptive claims in advertising and labeling for dietary supplements intended to treat serious diseases, such as Alzheimer’s disease and cancer.¹² We ask that the FDA and FTC continue in such joint efforts to bring companies making such claims to account.

We would welcome the opportunity to speak with you at your convenience regarding our urgent and mutual interest in eliminating false and deceptive advertisements for harmful dietary supplements. We seek to ensure that Americans' access to truly effective treatments is not hampered by the misleading marketing of supplements, including those for female fertility.

Sincerely,

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Executive Director and President
Center for Science in the Public Interest

Laura MacCleery
Policy Director
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Notes

¹ Fertility is defined as “being able to become pregnant (conceive)” (U.S. Department of Health and Human Services. *Female Infertility: Quick Facts*. 2019. <https://www.hhs.gov/opa/reproductive-health/fact-sheets/female-infertility/index.html>. Accessed August 27, 2019).

² Section 5 of the FTC Act (15 USCS § 45) prohibits unfair or deceptive acts or practices in or affecting commerce, and FTC has stated that such acts include failure to rely upon a “reasonable basis for objective claims.”

³ <https://www.ftc.gov/public-statements/1983/03/ftc-policy-statement-regarding-advertising-substantiation>

⁴ <https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf>

⁵ U.S. Federal Trade Commission. *Dietary Supplements: An Advertising Guide for Industry*. 2001. <https://www.ftc.gov/tips-advice/business-center/guidance/dietary-supplements-advertising-guide-industry>. Accessed July 25, 2019.

⁶ See *Daniel Chapter One*, FTC Dkt. No. 9239, 2009 WL 516000 at *17-19 (F.T.C. Dec. 24, 2009), *aff'd*, 405 Fed. Appx. 505 (D.C. Cir. 2010).

⁷ Fertility is defined as “being able to become pregnant (conceive)” (U.S. Department of Health and Human Services. *Female Infertility: Quick Facts*. 2019. <https://www.hhs.gov/opa/reproductive-health/fact-sheets/female-infertility/index.html>. Accessed August 27, 2019).

⁸ These products were still available on Amazon as of August 2019.

⁹ Previous CSPI reports have documented similar unapproved drug claims for products purported to treat opioid addiction (CSPI. Crackdown Urged on Supplements Marketed as Opioid Withdrawal Aids. December 8, 2017.) and to aid in tobacco use cessation (CSPI. FDA Urged to Take Enforcement Action against Manufacturers of Dietary Supplements that Promise to Help Smokers Quit. April 23, 2019).

¹⁰ <https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf>

¹¹ *Id.*

¹² U.S. Federal Trade Commission. *FTC and FDA Send Warning Letters to Companies Selling Dietary Supplements Claiming to Treat Alzheimer’s Disease and Remediate or cure Other Serious Illnesses Such as Parkinson’s, Heart Disease, and Cancer*. February 11, 2019. <https://www.ftc.gov/news-events/press-releases/2019/02/ftc-fda-send-warning-letters-companies-selling-dietary>. Accessed July 25, 2019.