NOTE

Fertile Ground: Rethinking Regulatory Standards for Femtech

Alexandra M. Taylor[*]

TABLE OF CONTENTS

 J.D., 2021, University of California, Davis, School of Law; B.A., 2015, New York University. I would like to thank Professor Lisa Ikemoto for her invaluable input, supervision, and mentorship on this piece, and Sadie Grewe '20 for her feedback and advice on earlier drafts. I would also like to express gratitude to Johnathan Chai, Melissa Tribble, Sue Jones, and Members and Editors of the UC Davis Law Review for their superb production assistance.

INTRODUCTION

A woman awakens from sleep and reaches for the thermometer she keeps on her bedside table. This morning, just like every other, she takes her basal body temperature and opens the Natural Cycles app on her smartphone.[1] The screen emits a rosy glow as she logs in and inputs her data, then waits for the results.

Whether or not she knows it, the woman's reproductive fate is in the hands of an algorithm.[2] A red status circle will indicate that she is within her fertile window, and should use protection or abstain from sex if she wishes to avoid pregnancy; a green circle will indicate that she is not within her fertile window and does not need to utilize a backup contraceptive.[3] Natural Cycles purports to accurately calculate her fertility status based on a variety of health data points, including her temperature, menstrual cycle dates and symptoms, ovulation test results, and recent sexual activity.[4] In addition to assuring her that she can trust the app to help prevent a pregnancy,[5] Natural Cycles promises that the sensitive data she shares will not be compromised or sold to third parties.[6] Will these promises be kept?

The term "Femtech" was coined in 2016 by Ida Tin, founder of the period-tracking app Clue.[7] Femtech refers to a burgeoning category of software, diagnostics, services, and products that target female health needs using technology.[8] The industry encompasses reproductive health, pregnancy and nursing care, pelvic and uterine healthcare, and general female wellness.[9] Despite its relatively recent emergence,

---

[1] *See* CBSDFW, *Could an App Replace the Birth Control Pill?*, YOUTUBE (Nov. 16, 2017), https://www.youtube.com/watch?v=-TayGdz7UvM [https://perma.cc/4UWZ-FMK5].

[2] *See How Does the Birth Control App Work?*, NAT. CYCLES, https://www.naturalcycles.com/birthcontrol/how-does-natural-cycles-work (last visited Feb. 2, 2021) [https://perma.cc/H334-S4WM].

[3] *See id.*

[4] *See Add Data to Natural Cycles*, NAT. CYCLES, https://help.naturalcycles.com/hc/en-us/articles/360003352973-Add-data-to-Natural-Cycles (last visited Feb. 2, 2021) [https://perma.cc/3WVS-H4NF].

[5] *See id.*

[6] *See Privacy Policy*, NAT. CYCLES, https://www.naturalcycles.com/other/legal/#privacy (last visited Feb. 2, 2021) [https://perma.cc/K5VW-Y9GU].

[7] *See* Ida Tin, *The Rise of a New Category: Femtech*, CLUE (Sept. 14, 2016), https://helloclue.com/articles/culture/rise-new-category-femtech [https://perma.cc/QH8M-K5JG].

[8] *Id.*

[9] *Femtech — Time for a Digital Revolution in the Women's Health Market*, FROST & SULLIVAN (Jan. 31, 2018), https://ww2.frost.com/frost-perspectives/femtechtime-digital-

Femtech has already proven to be a major disrupter in the global healthcare and technology markets. Investments into women's health tech startups totaled more than $300 million in 2018,[10] and Femtech is projected to reach a market share size of $50 billion by 2025.[11] Apps like Natural Cycles, which touts itself as a "fertility-awareness based" ("FAB") contraceptive, are becoming increasingly popular for women who want to track their menstrual cycles for contraceptive purposes.[12] A 2018 study published in mHealth indicated that over 75% of 1000 women surveyed intended to use fertility-tracking apps to prevent pregnancy in the future.[13]

Though Femtech is experiencing rapid growth, regulatory oversight of the sector may be lagging behind.[14] The U.S. Food and Drug Administration ("FDA") has taken a largely "hands-off" approach to regulating fertility-tracking apps[15] — with one major exception. In 2018, Nordic AB's Natural Cycles app became the first digital form of contraception approved for use in the United States.[16] The FDA approved the Swedish-made app as a Class II, or moderate risk, medical device through the de novo premarket review process.[17] The de novo premarket review process is a regulatory pathway for novel devices of low to moderate risk for which there are no predicate or preexisting

revolution-womens-health-market [https://perma.cc/Y88P-DMNR] [hereinafter *Time for a Digital Revolution*].

[10] Darius Tahir, *Fertility-Tracking Apps: Popular, Hyped — and Often Inaccurate*, POLITICO (July 10, 2019), https://www.politico.com/story/2019/0710/fertility-tracking-apps-popular-hyped-and-often-inaccurate-1563598 [https://perma.cc/FA8P-UZ5B].

[11] *Time for a Digital Revolution*, *supra* note 9.

[12] *See* Tahir, *supra* note 10.

[13] MARY SUMMER STARLING, ZOSHA KANDEL, LIYA HAILE & REBECCA G. SIMMONS, USER PROFILE AND PREFERENCES IN FERTILITY APPS FOR PREVENTING PREGNANCY: AN EXPLORATORY PILOT STUDY 4 (2018), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6043758/pdf/mh-04-2018.06.02.pdf [https://perma.cc/Q29Q-L2YZ].

[14] *See* Miranda Hall, *The Strange Sexism of Period Apps*, VICE (July 25, 2017, 6:00 AM), https://www.vice.com/en_us/article/qvp5yd/the-strange-sexism-of-period-apps [https://perma.cc/VPQ9-7MFF]; Tahir, *supra* note 10.

[15] Tahir, *supra* note 10.

[16] *FDA Allows Marketing of First Direct-to-Consumer App for Contraceptive Use to Prevent Pregnancy*, U.S. FOOD & DRUG ADMIN. (Aug. 10, 2018), https://www.fda.gov/news-events/press-announcements/fda-allows-marketing-first-direct-consumer-app-contraceptive-use-prevent-pregnancy [https://perma.cc/E5TR-J4CH] [hereinafter *FDA Allows Marketing*].

[17] *Id.*; *FDA Releases Final Classification for Natural Cycles, the First and Only Birth Control App in the U.S.*, NATURAL CYCLES (Mar. 7, 2019, 12:19 ET), https://www.prnewswire.com/news-releases/fda-releases-final-classification-for-natural-cycles-the-first-and-only-birth-control-app-in-the-us-300808657.html [https://perma.cc/F6S4-ZJR7].

legally marketed devices that can be used as points of comparison.[18] In approving the app, the FDA "inaugurated 'software application for contraception' as a new category of birth control under which similar products can now apply to be classified."[19] Many healthcare professionals were skeptical of the approval because the app was not tested with "nearly the same rigor as other FDA-approved contraceptives like the [intrauterine device] or the [birth control] pill, and therefore could be putting patients at risk for unwanted pregnancy and thus endangering their health."[20] The lack of supported efficacy data is especially concerning because the approval has major implications for the way that future fertility tracking apps will proceed through regulatory review. With Natural Cycles now able to serve as a predicate device for substantially similar apps, these apps will be able to route through a simpler approval process provided they meet the "special controls" that the FDA established when it approved Natural Cycles.[21] In the meantime, the FDA classifies apps that dispense fertility and pregnancy information as low-risk, meaning that they do not require agency approval, even if some women use them for contraceptive purposes.[22] These unregulated apps pose a serious public health problem when used as contraceptives because they render their

[18] *See Predicate Device*, GREENLIGHT GURU, https://www.greenlight.guru/glossary/predicate-device (last visited Feb. 4, 2021) [https://perma.cc/8EBT-X8HV] ("A predicate device is a medical device that may be legally marketed in the U.S. and used as a point of comparison for new medical devices seeking approval through FDA's 510(k) premarket clearance pathway. The new device must be proven to be substantially equivalent in safety and efficacy to the predicate device in order to receive clearance.").

[19] Anna Altman, *The Unlikely Politics of a Digital Contraceptive*, NEW YORKER (Oct. 2, 2018), https://www.newyorker.com/tech/annals-of-technology/the-unlikely-politics-of-a-digital-contraceptive [https://perma.cc/Q24X-WSK3].

[20] Hannah Harris Green, *It's Getting Easier to Get FDA Clearance — Just Ask Natural Cycles*, VERGE (Dec. 19, 2018, 8:50 AM EST), https://www.theverge.com/2018/12/19/18139681/natural-cycles-fda-approval-standards-de-novo-digital-health-devices [https://perma.cc/73GV-KBJV].

[21] Kate Sheridan, *FDA Clears Controversial Fertility App to Prevent Pregnancy*, STAT (Aug. 10, 2018), https://www.statnews.com/2018/08/10/fda-clears-natural-cycles-app [https://perma.cc/V83U-VFLS] [hereinafter *FDA Clears Controversial Fertility App*].

[22] *See* Lara Shemtob & Rebecca Littlewood, *Fertility Awareness Based Contraceptive Apps: A Case Study in the Digital Age*, BRIT. J. GEN. PRAC., https://bjgp.org/content/69/suppl_1/bjgp19X703169 (last visited Feb. 18, 2021) [https://perma.cc/X8Z2-ACUE] (finding that apps were being used for contraception even though they were not developed for this purpose); *FDA Allows Marketing*, *supra* note 16; *see also* Sheridan, *FDA Clears Controversial Fertility App*, *supra* note 21.

users vulnerable to unwanted pregnancies and, thus, serious health risks.[23]

Several policy issues have also emerged surrounding the use of unregulated fertility-tracking apps, such as Maya and MIA Fem.[24] Privacy International, an advocacy organization based in the UK, tested thirty-six period-tracking apps and found that 61% automatically transferred data to Facebook as soon as the user opened the app.[25] In some cases, this happened regardless of whether the user was logged into their Facebook account, or whether they had a Facebook account at all.[26] Privacy International also found that some period-tracking apps regularly share "incredibly detailed and sometimes sensitive personal data" with Facebook.[27] This represents a major policy concern for the millions of women worldwide who continue to input their intimate health data into period-tracking apps for personal purposes.[28] Additionally, the apps are designed in such a way that they fail to serve women with irregular periods, and also appear to cater towards a largely heterosexual user base.[29] These added policy concerns epitomize the problem of exclusionary health care writ large.

This Note argues that the FDA should implement more robust safeguards to regulate fertility-tracking apps that meet the definition of Software Applications for Contraception ("SACs"), and should hold SACs to the same regulatory standards in place for certain other contraceptives, such as intrauterine devices ("IUDs") and multiple-use female condoms ("MUFCs").[30] Part I explores the modern landscape of fertility-tracking apps, and provides background information on FDA

---

[23] *See* Green, *supra* note 20.

[24] *See No Body's Business but Mine: How Menstruation Apps Are Sharing Your Data*, PRIVACY INT'L (Sept. 9, 2019), https://www.privacyinternational.org/long-read/3196/no-bodys-business-mine-how-menstruation-apps-are-sharing-your-data [https://perma.cc/27MQ-H4QU] [hereinafter *No Body's Business but Mine*].

[25] *Id.*

[26] *Id.*

[27] *Id.*

[28] *See* LAURA SYMUL, KATARZYNA WAC, PAULA HILLARD & MARCEL SALATHÉ, ASSESSMENT OF MENSTRUAL HEALTH STATUS AND EVOLUTION THROUGH MOBILE APPS FOR FERTILITY AWARENESS 2 (2019), https://www.nature.com/articles/s41746-019-0139-4.pdf [https://perma.cc/LAQ3-HN8B] (discussing the accumulation of self-tracked menstrual data, including record of sexual intercourse); Kaitlyn Tiffany, *Period-Tracking Apps Are Not for Women*, VOX (Nov. 16, 2018, 12:36 PM), https://www.vox.com/the-goods/2018/11/13/18079458/menstrual-tracking-surveillance-glow-clue-apple-health [https://perma.cc/SSB5-2VBE].

[29] *See* Hall, *supra* note 14; *see also* SYMUL ET AL., *supra* note 28, at 2.

[30] *See generally* FDA Obstetrical and Gynecological Devices, 21 C.F.R. § 884 (2020) (noting FDA requirements for obstetrical and gynecological devices).

approval processes and existing regulatory controls for medical devices.[31] Part I also introduces the 21st Century Cures Act[32] ("Cures Act") and the Digital Health Innovation Action Plan,[33] which have both helped pave the way for the Natural Cycles approval.[34] Part II argues that currently unregulated fertility-tracking apps, including those that claim to facilitate natural family planning or only warn against such use in fine print, meet the definition of SACs and should be regulated as such.[35] These Parts explore the Natural Cycles approval in greater depth, and frame it as a cautionary tale for the future approval of similar apps.

Part III explores the current regulatory controls in place for certain other types of contraceptives, such as IUDs and MUFCs, and argues that SACs should be subject to the same special controls as those devices.[36] Part IV examines policy concerns around unregulated fertility-tracking apps from a privacy perspective as well as an exclusionary perspective.[37] Part V suggests regulatory and legislative solutions to address the privacy concerns articulated in Part IV.[38] This Note concludes by reflecting on the future of the Femtech industry and its impact on female reproductive health.

I. BACKGROUND

A. Fertility-Tracking Apps: A Modern Landscape

Upon first glance, the most popular fertility-tracking apps on the market share an unmistakable commonality: their names. Quippy,

[31] *See infra* Part I.

[32] *See generally* 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016) (discussing the expectations and requirements of the Cures Act).

[33] *See generally* U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN 1 (2017), https://www.fda.gov/media/106331/download [https://perma.cc/2CTN-GQGG] [hereinafter DIGITAL HEALTH INNOVATION ACTION PLAN] (providing the Digital Health Innovation Action Plan).

[34] *See* Tahir, *supra* note 10; *infra* Part I.

[35] *See infra* Part II.

[36] *See FDA Allows Marketing*, *supra* note 16; *infra* Part III.

[37] *See infra* Part IV.

[38] *See infra* Part V.

feminine monikers like "Glow,"[39] "MIA,"[40] "Eve,"[41] and "Flo"[42] grace the smartphone screens of women across the globe searching for alternatives to hormonal contraception, or wanting to learn more about their bodies.[43] The monosyllabic names and pink-laden designs make them seem trustworthy, as if users are sharing their private information with a friend instead of an algorithm.[44] Indeed, a since-deleted 2019 Instagram post from Glow asked, "BBT or BFF?",[45] while Flo assures users that they can "safely discuss intimate topics."[46] The apps' marketing reduces complex fertility science to a series of decorative animations, suggesting that the information they provide, despite its medical implications, is actually not all that serious.[47] In addition, products like Natural Cycles are primarily marketed on Instagram through endorsements from trendsetting influencers who vouch for the apps' dependability.[48] This advertising technique, along with the apps' aesthetically-pleasing interfaces, make them especially appealing to

[39] GLOW, https://glowing.com (last visited Feb. 5, 2021) [https://perma.cc/U86B-BPLA] (noting the purpose of the "Glow" app and how it works).

[40] *Mia Fem Period Tracker*, APPLE APP STORE, https://apps.apple.com/us/app/mia-fem-period-tracker/id1451972357 (last visited Feb. 5, 2021) [https://perma.cc/9Q3H-C4W7] (noting the purpose of the "MIA" app and its many uses).

[41] *Period Tracker – Eve*, APPLE APP STORE, https://apps.apple.com/us/app/id1002275138 (last visited Feb. 5, 2021) [https://perma.cc/H4SQ-Q6Y3] (noting the functionality of the "Eve" app).

[42] FLO, https://flo.health (last visited Feb. 5, 2021) [https://perma.cc/YY8W-9Z7R] (noting the features of the "Flo" app).

[43] *See* Altman, *supra* note 19.

[44] *See* Tiffany, *supra* note 28; *see also* Kate Sheridan, *A Fertility App Bills Itself as Contraception, Raising Questions About Marketing and Efficacy*, STAT (Mar. 18, 2019), https://www.statnews.com/2019/03/18/fertility-app-dot-bills-itself-as-contraception [https://perma.cc/L29D-Y8SM] [hereinafter *A Fertility App Bills Itself as Contraception*] ("'Extensive analysis and scientific research indicates Dot is accurate and effective. All you need is Dot the app!' the [Dot] app says in a Q&A entry.").

[45] *See* Tiffany, *supra* note 28. BBT here refers to a user's basal body temperature. BFF is an initialism of the phrase "best friends forever."

[46] *Flo My Health & Period Tracker*, APPLE APP STORE, https://apps.apple.com/US/app/id1038369065 (last visited Feb. 6, 2021) [https://perma.cc/28DS-FXZS].

[47] *See* Tiffany, *supra* note 28.

[48] Chavie Lieber, *The FDA Just Approved a "Digital Birth Control" App for the First Time: The Controversy, Explained*, VOX (Aug. 14, 2018, 8:40 PM), https://www.vox.com/2018/8/14/17684392/natural-cycles-birth-control-app-fda [https://perma.cc/8ABA-VEBE] ("Natural Cycles' sponsored content posts on Instagram don't always include important details, like that users should be okay with the fact that they could get pregnant, or that they absolutely need to have a regular routine of taking their temperature."); Tiffany, *supra* note 28 ("[Fifty] percent of [Natural Cycles'] subscriber growth came from these ads . . . .").

young women looking for a "chic, tech-savvy solution for monitoring their [bodies]."[49]

While tracking one's menstrual cycle and basal body temperature to predict fertility is not a medical novelty, using an app as a means of contraception is relatively new.[50] Some unregulated apps claim to offer "natural family planning," while others merely warn against such use in fine print.[51] Regardless, many women appear to trust that the apps will meet their contraceptive needs.[52] Out of 1000 women who had downloaded a fertility app to use as contraception, "about a quarter . . . were 'very confident' that the app they used would help them avoid pregnancy . . . [whereas] 46.3% were somewhat confident."[53] This sense of confidence is especially staggering in light of the tens of millions of users who frequent any of the nearly one hundred fertility-tracking apps on the market today.[54] According to Dr. Nathaniel DeNicola, co-chair of telehealth at the American College of Obstetricians and Gynecologists, "fertility-tracking apps are second in popularity only to fitness apps when it comes to mobile health."[55] While they have the potential to benefit some women, as Dr. DeNicola points out, "an app that miscalculates users' fertility windows has more serious consequences than one that miscalculates the number of steps they took in a day."[56]

---

[49] *See* Molly McHugh, *Does Femtech Give Users Control of Their Health or Take It Away?*, RINGER (Mar. 18, 2019, 6:30 AM EDT), https://www.theringer.com/tech/2019/3/18/18267094/femtech-female-health-apps-menstruation-fertility-trackers-clue-glow-ava [https://perma.cc/5YW6-HNQY]; *see also* Arielle Pardes, *In Contraceptive Tech, the App's Guess Is as Good as Yours*, WIRED (Jan. 19, 2018, 7:00 AM), https://www.wired.com/story/natural-cycles-contraceptive-apps [https://perma.cc/LU6A-PH34].

[50] *See* Tahir, *supra* note 10.

[51] *Id.*

[52] *See* STARLING ET AL., *supra* note 13, at 4.

[53] *Id.*

[54] *See* Alexandra Sifferlin, *Can an App Prevent Pregnancy?*, TIME (Aug. 15, 2018, 12:03 PM EDT), https://time.com/5365564/fertility-apps-contraception [https://perma.cc/8PJL-XGMM]. For example, take Glow and Clue, two of the most popular period-tracking apps on the market today. As of February 2019, Clue had approximately ten million users, while Glow had approximately fifteen million. *Does Digital Health Technology Know Women?*, MED. FUTURIST (Feb. 21, 2019), https://medicalfuturist.com/femtech-womens-health [https://perma.cc/HK7M-U9ZE].

[55] Green, *supra* note 20.

[56] *Id.*

Some experts contend that apps like Natural Cycles, which advertise themselves as FAB contraceptives,[57] are really promulgating a glorified version of the old-fashioned rhythm method. The rhythm method is a natural family planning method that uses a calendar-based approach to predict ovulation.[58] In discussing the efficacy of these apps, Mary Jane Minkin, a gynecologist and reproductive clinician at the Yale University School of Medicine, referenced an old adage: "What do you call women who use the rhythm method? Mothers."[59] Critics disagree with the conflation of FAB contraceptives to the rhythm method, pointing to the fact that many apps combine factors like basal body temperature and vaginal mucus levels with fertility-awareness. "Pair all that with an inviting design and a tab that cites research studies, and you've got something that looks more like science and less like folklore," Minkin counters.[60]

At least 600 women in Sweden can personally attest to the efficacy of FAB contraceptives like Natural Cycles.[61] In January 2018, a single clinic in Stockholm reported that thirty-seven women within a four-month period sought abortions after becoming pregnant while using the Natural Cycles app as their primary contraceptive.[62] The Swedish Medical Products Agency conducted an investigation, and found that the app had a "typical use failure rate" of 6.9%.[63] During the Agency's investigation, an additional 676 Natural Cycles users in Sweden reported unintended pregnancies.[64] This number is likely an underestimate, as it only represents users who self-reported directly to

[57] *See* E. Berglund Scherwitzl, O. Lundberg, H. Kopp Kallner, K. Gemzell Danielsson, J. Trussel & R. Scherwitzl, *Perfect-Use and Typical-Use Pearl Index of a Contraceptive Mobile App*, 96 CONTRACEPTION 420, 420-21 (2017).

[58] *See* Michelle Andrews, *Biorhythms and Birth Control: FDA Stirs Debate by Approving 'Natural' App*, KAISER HEALTH NEWS (Aug. 21, 2018), https://khn.org/news/biorhythms-and-birth-control-fda-stirs-debate-by-approving-natural-app [https://perma.cc/V579-BJCK]; Sifferlin, *supra* note 54 ("[The rhythm method is] the basis of many of the fertility apps on the market.").

[59] Pardes, *supra* note 49.

[60] *Id.*

[61] *See* Altman, *supra* note 19.

[62] *See id.* All thirty-seven women filed lawsuits against Natural Cycles. *Id.* Natural Cycles since has responded that the resulting pregnancies were proportional to the registered number of Swedish users and "in line with [their] expectations." Olivia Sudjic, *'I Felt Colossally Naive': The Backlash Against the Birth Control App*, GUARDIAN (July 21, 2018, 3:00 PM), https://www.theguardian.com/society/2018/jul/21/colossally-naive-backlash-birth-control-app [https://perma.cc/6RV3-S7NM] (discussing anecdotes about unintended pregnancies that severely impacted women's lives).

[63] *Id.*

[64] *Id.*

Natural Cycles.[65] Indeed, one October 2018 article estimated that "'typical use' would result in more than 62,000 unintended pregnancies" if all those registered with the company were to use it as their primary contraceptive.[66]

B. Regulatory Controls for Medical Devices and Fertility-Tracking Apps

The FDA's responsibility to protect public health underlies its overall approach to testing and regulating medical devices, including SACs. In addition to "ensuring that . . . drugs . . . and medical devices intended for human use are safe and effective,"[67] the FDA is also responsible for "advancing the public health by helping to speed product innovations."[68] Section 513 of the Federal Food, Drug, and Cosmetic ("FD&C") Act established a classification system for medical devices based on risk.[69] Devices are assigned to one of three regulatory classes depending on how much oversight is needed to ensure their safety and effectiveness.[70] As device class increases from Class I to Class III, so does the degree of regulatory control.[71] Class I covers low to moderate risk devices subject to the least regulatory control, Class II covers moderate to high risk devices subject to an intermediate level of regulatory control, and Class III covers the highest risk devices subject to the "most stringent" regulatory control.[72]

All classes are subject to general controls — regulatory requirements mandated by the FD&C Act that include registration of a device's producer, notifications, and device records and reports.[73] If a device is exempted from a general control, that exemption is stated in the device's regulation.[74] In addition to general controls, Class II devices are also subject to Special Controls, which are device-specific and include elements such as performance standards, postmarket surveillance, and

---

[65] *See id.*

[66] *Id.*

[67] *What Does FDA Do?*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/about-fda/fda-basics/what-does-fda-do (last updated Mar. 28, 2018) [https://perma.cc/Q7S7-82GC].

[68] *Id.*

[69] *Regulatory Controls*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls (last updated Mar. 27, 2018) [https://perma.cc/MG7U-RYBZ].

[70] *Id.*

[71] *Id.*

[72] *Id.*

[73] *Id.*

[74] *Id.*

premarket data requirements.[75] The FD&C Act defines Class III devices as those that "support[] or sustain[] human life or [are] of substantial importance in preventing impairment of human health or present[] a potential, unreasonable risk of illness or injury."[76] This class of devices requires an approved Premarket Approval Application ("PMA") in order to be licensed for market, and is also subject to both general and special controls.[77]

Title 21 of the Code of Federal Regulations ("CFR") lays out the classifications for Obstetrical and Gynecological Therapeutic Devices, which includes contraceptives like diaphragms, MUFCs, and IUDs, and also menstrual products such as pads and tampons.[78] IUDs and MUFCs are both designated Class III medical devices, meaning that they require PMAs in addition to having special controls.[79] By contrast, unscented menstrual pads are designated Class I devices, meaning that they are subject only to general controls.[80]

SACs emerged as an entirely new category of medical devices based on the FDA's approval of Natural Cycles.[81] The CFR describes SACs as "device[s] that provide[] user-specific fertility information for preventing a pregnancy."[82] SACs use "algorithm[s] that [analyze] patient-specific data (e.g., temperature, menstrual cycle dates) to distinguish between fertile and non-fertile days."[83] These devices then provide specific recommendations around contraception for each patient.[84] Since its approval in 2018, Natural Cycles remains the only FDA-approved SAC on the market.[85] However, the FDA's regulatory scheme for SACs means that many apps are in prime standing to follow in its footsteps.[86]

---

[75] *Id.*

[76] *PMA Approvals*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals (last updated Aug. 23, 2018) [https://perma.cc/H45B-SUEP].

[77] *Id.*

[78] 21 C.F.R. § 884 (2020).

[79] *Id.* §§ 884.5360, .5330 (2020).

[80] *Id.* § 884.5435 (2020).

[81] *See* Altman, *supra* note 19.

[82] 21 C.F.R. § 884.5370 (2020).

[83] *Id.*

[84] *See id.*

[85] NAT. CYCLES, https://www.naturalcycles.com (last visited Jan. 2, 2021) [https://perma.cc/VP2T-APTP]; *see* Nicole Wetsman, *Why You Should Not Trust Fertility Apps — Yet*, SLATE (Sept. 19, 2018, 9:00 AM), https://slate.com/technology/2018/09/fertility-apps-birth-control-evidence.html [https://perma.cc/A9DY-VX3H].

[86] *See* Wetsman, *supra* note 85.

SACs are designated as Class II devices and are subject to several special controls.[87] Section 884.5370(b)(1) states that the device must demonstrate clinical efficacy as a contraceptive in the intended population.[88] Section 884.5370(b)(2) mandates a performance evaluation to show that users can correctly identify themselves as part of the intended population, and that they can use the application correctly based on the directions.[89] Section 884.5370(b)(3) describes various software analyses that must be performed, including those related to cybersecurity and technical parameters.[90] Section 884.5370(b)(4)(i) outlines several labeling requirements for SACs, including four mandatory statements related to accuracy, efficacy, and intended use.[91] According to this section, labeling must include a warning that "no contraceptive method is 100% effective" and that "another form of contraception (or abstinence) must be used on days specified by the application."[92] Additionally, the labeling must include any factors that may impact the contraceptive information's accuracy, as well as a warning that use of the app does not protect against sexually transmitted infections.[93] Finally, the operating systems for these devices must include thorough instructions for use as well as data around clinical efficacy.[94]

There are various ways to obtain approval to market devices based on device classification.[95] One route is the de novo pathway, introduced by the FDA in 1997 as a response to an increase in new technology, including mobile medical apps.[96] The de novo classification program was instituted to streamline and expedite approval processes[97] for low to moderate risk medical devices "for which general controls alone, or

[87] 21 C.F.R. § 884.5370.

[88] *See id.*

[89] *See id.*

[90] *See id.*

[91] *Id.*

[92] *Id.*

[93] *Id.*

[94] *See id.* Specifically, operating systems must include "[i]nstructions identifying and explaining how to use the . . . application, including required user inputs and how to interpret the application outputs" and a "summary of the clinical validation study and results, including effectiveness of the application as a stand-alone contraceptive and how this effectiveness compares to other forms of legally marketed contraceptives." *Id.*

[95] Bruce Brown, *FDA Allows Fertility-Awareness Contraception App*, HEALTHTECH INSIDER (Aug. 28, 2018), https://healthtechinsider.com/2018/08/28/fda-allows-fertility-awareness-contraception-app-video [https://perma.cc/6ZBM-AUCC].

[96] *See id.*

[97] *Id.*

general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device."[98] Devices approved via the de novo pathway (as Class I or Class II) are permitted to serve as predicates for subsequent 510(k) submissions to approve new products.[99] A 510(k) submission for a new product must establish that the new device is "at least as safe and effective, that is, substantially equivalent"[100] to an existing, legally marketed predicate.[101] For example, Natural Cycles, an existing, legally marketed Class II device, can serve as a predicate device for future 510(k) submissions, which will allow other "substantially equivalent" SACs to seek market approval.[102] In order to demonstrate substantial equivalence in their 510(k) submissions, these SACs will only need to establish that they share the same intended use and technological characteristics as the predicate device.[103]

C. Setting the Stage for Femtech: FDA Guidance and the 21st Century Cures Act

As part of its overall obligation to public health, the FDA must oversee "the safety and effectiveness of medical devices, including mobile medical apps ("MMAs").[104] MMAs are "medical devices that are mobile apps, meet the definition of a medical device, and are an accessory to a regulated medical device or transform a mobile platform into a regulated medical device."[105] FDA guidance around MMAs, as well as the Cures Act and the 2017 Digital Health Innovation Action Plan, symbolize a push in recent years to lessen regulatory burdens for

98 *De Novo Classification Request*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/premarket-submissions/de-novo-classification-request (last updated Sept. 6, 2019) [https://perma.cc/54T2-GQ8H].

99 *Id.*

100 *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (Sept. 27, 2018), https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k [https://perma.cc/UK2J-XY7J].

101 *See id.*

102 *See id.*

103 *See id.*

104 *Device Software Functions Including Mobile Medical Applications*, U.S. FOOD & DRUG ADMIN. (Sept. 26, 2019), https://www.fda.gov/medical-devices/digital-health/device-software-functions-including-mobile-medical-applications [https://perma.cc/9ZPV-YK6G].

105 *Id.*

innovative devices in an effort to bring them to market more quickly.[106] Together, these efforts have helped set the stage for Femtech's debut.

As noted in an MMA guidance document first issued in 2013,[107] the FDA regulates apps that "transform mobile device[s] into medical device[s]"[108] and can expose users to health risks if they function improperly.[109] Other apps may meet the definition of a medical device under the FD&C Act,[110] but are deemed low to moderate risk in that they mainly "offer patient education or serve as reference aids."[111] The MMA Guidance notes that the FDA only exercises "enforcement discretion" over these types of apps rather than full regulatory enforcement because they pose lower risk to the public.[112]

The Cures Act of 2016 was designed to foster the innovation of new medical products and bring them to market more quickly for patients in need.[113] Much of the impetus for the bill came from advocacy groups who lobbied for a program that would facilitate further research and expedited approval for innovative medical products.[114] Section 3060(a) of the Cures Act explicitly addresses MMA regulation; specifically, it amended the FD&C Act by limiting the definition of a device to certain software functions,[115] such as those merely intended "for maintaining or encouraging a healthy lifestyle."[116] In 2019, the FDA updated the MMA Guidance to be consistent with this amended definition of a device.[117] Despite its ultimate success in Congress, the Cures Act has drawn criticism around its aim to relax regulatory standards in the name

106 *See id.*; *see also 21st Century Cures Act*, U.S. FOOD & DRUG ADMIN. (Mar. 31, 2018), https://www.fda.gov/regulatory-information/selected-amendments-fdc-act/21st-century-cures-act [https://perma.cc/3S76-LMUC].

107 *Device Software Functions Including Mobile Medical Applications*, *supra* note 104.

108 Brown, *supra* note 95.

109 *See* U.S. FOOD & DRUG ADMIN., POLICY FOR DEVICE SOFTWARE FUNCTIONS AND MOBILE MEDICAL APPLICATIONS: GUIDANCE FOR INDUSTRY AND FOOD AND DRUG ADMINISTRATION STAFF 2 (2019), https://www.fda.gov/media/80958/download [https://perma.cc/EJS2-P3RB] [hereinafter MMA GUIDANCE]. This Guidance also states that these types of apps "meet [] the definition of a [medical] device under section 201(h) of the FD&C Act." *Id.* at 4-5.

110 *Id.*

111 Brown, *supra* note 95.

112 U.S. FOOD & DRUG ADMIN., MMA GUIDANCE, *supra* note 109, at 12, 23.

113 *21st Century Cures Act*, *supra* note 106.

114 *See* Curetoday, *Rep. Frank Pallone Jr. on the Impetus for the 21st Century Cures Act*, YOUTUBE (June 10, 2015), https://www.youtube.com/watch?time_continue=124&v=pHNu4M5n8gA&feature=emb_logo [https://perma.cc/HLJ9-9777].

115 U.S. FOOD & DRUG ADMIN., MMA GUIDANCE, *supra* note 109, at 2.

116 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033, 1130 (2016).

117 *Device Software Functions Including Mobile Medical Applications*, *supra* note 104.

of efficiency.[118] It specifically lowered the standards for medical device evaluations, allowing for "the consideration of 'real world evidence,' which includes 'sources other than randomized clinical trials'" and could involve established biases.[119] Opponents are concerned that the overall strategy of the Cures Act may not actually be beneficial to patients.[120] One article went so far as to suggest that the Act would transform the phrase "FDA approved," typically seen as a "mark of trustworthy stewardship" for healthcare providers and patients alike, into "a shadow of its former self."[121]

Lastly, in 2017, the FDA released the "Digital Health Innovation Action Plan," which "lays out the [FDA's] vision for fostering digital health innovation while continuing to protect and promote the public health."[122] The Action Plan expands on the FDA's approach to digital health technology as it was outlined in the Digital Health Program of 2012.[123] The Program "[balances] the benefits and risks to patients" through the types of products on which it chooses to focus its oversight.[124] For example, the Plan states that the FDA Digital Health Program enforces compliance only for high-risk MMAs and declines to regulate "products that only promote general wellness."[125] On the other hand, the FDA's Plan also acknowledges the degree of public reliance on the digital health technology industry: "Because [digital health products] impact the health of millions of Americans, the U.S. public should be able to trust that these products are high-quality and do what they are supposed to do."[126]

The Digital Health Innovation Action Plan and the Cures Act together reflect the fundamental tension between the FDA's core responsibilities. The agency must balance the need for innovation and efficiency in the approval process with the need to provide patients with treatment

---

[118] *See* Robert M. Kaplan, *Is the 21st Century Cures Act a Solution or a Problem?*, REG. REV. (May 7, 2019), https://www.theregreview.org/2019/05/07/kaplan-21st-century-cures-act [https://perma.cc/3KXV-JCR].

[119] *Id.*

[120] *Id.*

[121] Reshma Ramachandran & Zackary Berger, *21st Century Cures Act Will Distort the Meaning of 'FDA Approved*,' STAT (Dec. 1, 2016), https://www.statnews.com/2016/12/01/21st-century-cures-act-fda-approval [https://perma.cc/PWG7-LJNU].

[122] U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN, *supra* note 33, at 1.

[123] *See id.* at 2.

[124] *Id.*

[125] *Id.*

[126] *Id.* at 1-2.

options that are backed by proven safety and efficacy data.[127] The FDA approved fifty-nine new drugs in 2018, breaking all previous records.[128] Natural Cycles was one of the first innovations to benefit from the relaxed regulations when it sought agency approval in the first full year after the passage of the Cures Act, and would not be the last.[129]

II. UNREGULATED FERTILITY-TRACKING APPS SHOULD BE SUBJECT TO THE REGULATORY CONTROLS IN PLACE FOR SACS

Unregulated apps like Flo, Dynamic Optimal Timing ("DOT"), and Ovia should be regulated as SACs because they use algorithms to provide "user-specific fertility information" for preventing pregnancy, and therefore meet the CFR's basic definition for SACs.[130] These apps tout themselves as contraceptives without having gone through the FDA clearance process intended to evaluate and authorize such claims.[131] They share in common the type of data they collect from users, including "period flow, menstrual products used, sex, pain, moods, cervical fluid, and PMS symptoms."[132] Flo, in particular, allows users to "monitor basal temperature, test results, and see the tracker's estimate of [their] most fertile days."[133] This echoes the CFR's definition of a SAC — particularly the language around using patient data to distinguish between fertile and non-fertile days.[134] At the very least, the option to input a user's basal body temperature suggests that Flo is meant to be used similarly to Natural Cycles. Likewise, DOT uses "data sets to calculate [a user's] conception risk, or chances for each day of [a user's] cycle, using period start dates," while Ovia "uses its estimation of [a user's] cycle to give [a user] a daily 'fertility score,' or how likely [a user is] to get pregnant that day."[135] The descriptions of these apps appear to be a near-perfect match to the regulatory definition of a SAC,

---

[127] *See* Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA CONSUMER MAG. (Jan.–Feb. 2006), https://www.fda.gov/media/110482/download [https://perma.cc/UR7S-HVXS].

[128] Kaplan, *supra* note 118.

[129] *See* Green, *supra* note 20.

[130] 21 C.F.R. § 884.5370 (2020).

[131] Sheridan, *A Fertility App Bills Itself as Contraception*, *supra* note 44.

[132] Carina Hsieh, *9 Period Tracking Apps That'll Never Make You Wonder if Your Period's Starting or if It's Just Discharge*, COSMOPOLITAN (Apr. 21, 2020), https://www.cosmopolitan.com/sex-love/a18210028/best-period-tracker-fertility-app [https://perma.cc/6Y4X-52VL].

[133] *Id.*

[134] *See* § 884.5370; Hsieh, *supra* note 132.

[135] Hsieh, *supra* note 132.

which the FDA defines as devices that use data such as temperature and menstrual cycle dates to predict fertility.[136] Their descriptions also suggest that these apps are de facto contraceptives.[137]

Furthermore, the advertising around unregulated period-tracking apps strongly supports the contention that they can be used as contraceptives, regardless of whether the apps themselves warn against such use when users create their accounts. Natural Cycles itself came under fire from the United Kingdom's Advertising Standards Agency ("ASA") when the Agency received several complaints about the app's paid advertising on Facebook.[138] One advertisement, which was eventually banned, "[described] the app as highly accurate contraception that [had] been clinically tested."[139] At the conclusion of the ASA's investigation, it found that Natural Cycles' statements were misleading because they conflated "perfect-use" failure rates with "typical-use" failure rates.[140] Referring to these rates interchangeably is problematic because the chance of pregnancy increases with typical-use of a contraceptive, which accounts for some incorrect or inconsistent uses.[141] Typical-use of a SAC reflects how an average person uses the app, while perfect-use requires correct and consistent use throughout the menstrual cycle.[142] Additionally, many users likely cannot or will not immediately understand the difference between perfect- and

136 *See* § 884.5370; Hsieh, *supra* note 132.

137 *See* § 884.5370.

138 Maev Kennedy, *Natural Cycles: ASA Investigates Marketing for Contraception App*, GUARDIAN (July 29, 2018), https://www.theguardian.com/technology/2018/jul/29/natural-cycles-asa-investigates-marketing-for-contraception-app [https://perma.cc/VA32-6DHZ].

139 *Id.*

140 *ASA Ruling on NaturalCycles Nordic AB Sweden t/a Natural Cycles*, ADVERT. STANDARDS AUTHORITY (Aug. 29, 2019), https://www.asa.org.uk/rulings/naturalcycles-nordic-ab-sweden-a17-393896.html [https://perma.cc/YNY6-V99E] ("Given the very low level of perfect-use by users of the app and the significant difference between the effectiveness of the app when in perfect- and in typical-use, we considered that it would be misleading to base an accuracy claim on the perfect-use results and that the relevant data was the level of effectiveness seen in typical-use. . . . Whilst we considered the evidence demonstrated the app could be effective as a method of birth control, we considered that it was misleading to describe it as 'highly accurate.'").

141 *See Fertility Awareness-Based Methods of Family Planning*, AM. C. OBSTETRICIANS & GYNECOLOGISTS (Jan. 2019), https://www.acog.org/Patients/FAQs/Fertility-Awareness-Based-Methods-of-Family-Planning [https://perma.cc/ADS8-Q8Y2] ("When fertility awareness is used to prevent pregnancy, fewer than 1–5 women out of 100 will become pregnant during the first year of perfect use. . . . In the first year of typical use, 12–24 women out of 100 will become pregnant.").

142 *Id.*

typical-use rates.[143] Two weeks after the ASA finished its audit, the Swedish Medical Products Agency conducted its own investigation, and cleared the app because it found Natural Cycles' nearly 7% failure rate to be consistent with typical-use.[144]

Flo, which calls itself a "go-to digital fertility predictor for women," promotes on its website that one of its key features is precise ovulation prediction.[145] The website also publishes heavily about fertility, pregnancy, nursing, and post-partum care, suggesting that the app is meant to support users before, during, and after conception.[146] DOT and Ovia are no different: Ovia's "Fertility and Cycle Tracker" allows users to "receive accurate predictions for period[s] and ovulation";[147] DOT unambiguously states that it can "help [a user] plan or prevent pregnancy and predict future periods simply by entering start dates of [a user's] period."[148] In the Frequently Asked Questions section of the app, DOT explicitly states that "[it] can be used as birth control."[149] DOT's manufacturers claim that they plan to apply for agency approval in the future, and are already making a substantial effort to comply with FDA standards.[150] In the meantime, the unregulated app remains available for download for both Android and Apple device-users.[151]

The fact that currently unregulated apps also allow women to browse articles about "fertility facts and health tips,"[152] or to merely "track [their] period[s], symptoms, moods, and more" does not obviate their fertility prediction features, and thus, their unequivocal status as SACs.[153] While these apps do have "low risk" features that serve to educate women about their menstrual cycles or allow them to monitor their personal health data, they are undeniably marketed and meant to

143 *See id.*

144 Kimberly Leonard, *Swedish Authorities Clear "Natural Cycles" Birth Control App*, WASH. EXAMINER (Sept. 13, 2018), https://www.washingtonexaminer.com/policy/healthcare/swedish-authorities-clear-natural-cycles-birth-control-app [https://perma.cc/FB6B-WUS6].

145 FLO, *supra* note 42.

146 *Id.*

147 OVIA HEALTH, https://www.oviahealth.com/apps (last visited Dec. 20, 2020) [https://perma.cc/RS8F-XBGT].

148 *Frequently Asked Questions*, DOT, https://www.dottheapp.com/faqs (last visited Dec. 20, 2020) [https://perma.cc/XM4D-CPM5].

149 Sheridan, *A Fertility App Bills Itself as Contraception*, *supra* note 44.

150 *See id.*

151 *See id.*

152 OVIA HEALTH, *supra* note 147.

153 *Id.*

be used as contraceptives just like Natural Cycles.[154] Even Clue's founder has acknowledged that some women use her unregulated app for contraceptive purposes, though she claims Clue is not meant to be used in that way.[155] The FDA has confirmed that "software apps intended to prevent pregnancy are considered Class II devices that are required to undergo FDA premarket review before being marketed."[156] Unregulated apps that can be used to prevent pregnancy should be subject to the same general and special regulatory controls required for SACs. This is especially critical as more apps begin to seek FDA approval, because the average user may not be able to distinguish between regulated and unregulated apps. Unsuspecting users may assume that all apps on the market are FDA-approved just as Natural Cycles is, particularly if these apps all purport to provide the same services.

While giving women the tools to educate themselves about their menstrual cycles is an obvious public health benefit, the FDA has an obligation to respond and regulate these apps accordingly.[157] Currently unregulated apps such as Ovia, DOT, and Flo that clearly call themselves fertility-trackers, with algorithms aimed at preventing pregnancy, meet the CFR definition for SACs and should be regulated to protect patients and consumers who use MMAs to manage their health needs.

III. THE FDA SHOULD CLASSIFY AND REGULATE SACS AS CLASS III MEDICAL DEVICES

The FDA should reclassify SACs as Class III devices and mandate that fertility-tracking apps obtain pre-market approval because of their similarity to existing contraceptive devices, their reliance on user input, and the demonstrated need for more robust clinical efficacy standards for this type of contraception.

---

154 *See* Shemtob & Littlewood, *supra* note 22, at 326.

155 Tahir, *supra* note 10.

156 Sheridan, *A Fertility App Bills Itself as Contraception*, *supra* note 44.

157 *See* U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN, *supra* note 33, at 1-2 ("Because [digital health products] can impact the health of millions of Americans, the U.S. public should be able to trust that these products are high-quality and do what they are supposed to do.").

A. Similarity to Existing Contraceptive Devices

MUFCs, IUDs, and SACs are similar devices in that they are all intended to help users prevent pregnancy.[158] The FDA regulates both non-hormonal IUDs and MUFCs as Class III medical devices, meaning they "support[] or sustain[] human life or [are] of substantial importance in preventing impairment of human health or present[] a potential, unreasonable risk of illness or injury."[159] These devices are designated as high risk and require an approved PMA in order to be legally marketed.[160] The PMA process is the "most stringent of the device marketing applications" due to the higher level of risk associated with Class III devices.[161] PMAs require both non-clinical laboratory studies and clinical investigations to ensure that these devices are effective and safe for human use.[162]

This level of regulatory scrutiny is fitting for Class III devices that are critical to preventing detriment to human health — including impairment resulting from pregnancy.[163] Indeed, pregnancy poses certain inherent health risks.[164] One researcher estimated in 2017 that "in the United States, being pregnant is about twenty times more likely to result in death than is a skydive."[165] Some of the most common pregnancy complications include infections, hypertension, diabetes, and preeclampsia, a condition that causes problems with the kidneys and other organs.[166] While complications during pregnancy range in severity, they have the potential to be life-threatening for both the mother and fetus.[167] Furthermore, the Centers for Disease Control and Prevention estimate that more than 50,000 women per year in the United States experience the most severe complications, collectively

158 21 C.F.R. §§ 884.5330, .5360, .5370 (2020).

159 *PMA Approvals*, *supra* note 76.

160 *See id.*

161 *FDA Submissions*, KEN BLOCK CONSULTING, https://kenblockconsulting.com/fda-submissions (last visited Jan. 3, 2021) [https://perma.cc/EZ7Q-53VA].

162 *Id.*

163 *See PMA Approvals*, *supra* note 76.

164 *See* CORDELIA FINE, TESTOSTERONE REX: MYTHS OF SEX, SCIENCE, AND SOCIETY 116 (2017).

165 *Id.*

166 *See Pregnancy Complications*, OFF. ON WOMEN'S HEALTH, https://www.womenshealth.gov/pregnancy/youre-pregnant-now-what/pregnancy-complications (last updated Apr. 19, 2019) [https://perma.cc/SK54-FXMK].

167 *Pregnancy Complications*, CENTERS FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pregnancy-complications.html (last updated Aug. 13, 2020) [https://perma.cc/JN9P-M354].

referred to as "severe maternal morbidity."[168] The health risks also stem from the stress of added financial burdens; researchers estimate that in the UK, "mothers earn almost a third less per hour than equally qualified fathers" by the time a child turns twenty years old.[169] The implications of an unintended pregnancy can be catastrophic for a woman's health and livelihood, which is why the availability of safe and effective contraceptive options like IUDs and MUFCs is so critical.[170] It makes sense that these Class III devices are subject to the most stringent regulatory controls because of the severity of the risks associated with their failure, though the FDA does not appear to take this into account in its risk-based classification system.[171] Even so, it follows that SACs should also be Class III devices, and therefore subject to the most stringent regulatory controls, because the failure of this type of contraceptive ultimately leads to the same set of health risks as a failed IUD or MUFC.[172]

Furthermore, IUDs and SACs involve a similar set of processes for patients and users. In both circumstances, the patient (or user) provides intimate information to their healthcare provider (or app), and in both cases that information is then used to deliver a recommendation.[173] In the IUD scenario, the healthcare provider recommends whether or not the patient should utilize an IUD as a form of contraception, and the patient chooses whether to follow that recommendation and have an IUD inserted.[174] In the SAC scenario, the app recommends whether or not the user should abstain from sex or utilize a backup contraceptive, and the user chooses whether to follow that recommendation and use

---

168 *Id.*

169 Caroline Criado Perez, Opinion, *Pregnancy is Riskier than Skydiving – Birth Control Should Be Harder to Market*, CNN (Sept. 20, 2018), https://www.cnn.com/2018/09/20/opinions/natural-cycles-pregnancy-skydiving-caroline-opinion-intl/index.html [https://perma.cc/CJ7Y-P98P].

170 *See generally, e.g.*, Christine Dehlendorf, Maria Isabel Rodriguez, Kira Levy, Sonya Borrero & Jody Steinauer, *Disparities in Family Planning*, 202 AM. J. OBSTETRICS & GYNECOLOGY 214, 214 (2010) (discussing how access to contraceptives can improve the circumstances of disadvantaged demographics); *see* Sudjic, *supra* note 62.

171 *FDA Submissions*, *supra* note 161.

172 *See* Sudjic, *supra* note 62.

173 *See* Elea Carey, *Choosing the Right IUD: Mirena vs. ParaGard vs. Skyla*, HEALTHLINE, https://www.healthline.com/health/birth-control/mirena-paragard-skyla (last updated Nov. 5, 2019) [https://perma.cc/KBZ2-7D4Q]; *How Does the Birth Control App Work?*, *supra* note 2.

174 *See IUD Fact Sheet*, REPROD. HEALTH ACCESS PROJECT (Mar. 1, 2017), https://www.reproductiveaccess.org/wp-content/uploads/2014/06/IUD_facts.pdf [https://perma.cc/3V39YLFL].

an alternate form of contraception.[175] The app, like an IUD, enables users to make medically significant decisions about their own bodies. As the ultimate consequence of an erroneous or unheeded recommendation — an unintended pregnancy — is the same, the fact that SACs are not physically invasive in the same way as IUDs should not exempt them from having to proceed through the same approval process. In fact, as discussed further in Part IV,[176] the quality and quantity of intimate data that SACs collect render them similarly invasive to IUDs and MUFCs even though they are not physically inserted into the body. Since IUDs, MUFCs, and SACs all share the fundamental purpose of preventing pregnancy, and are similar in terms of general invasiveness, the FDA should reclassify SACs as Class III devices and mandate that fertility-tracking apps obtain approved PMAs before legally marketing themselves as contraceptives.

B. Reliance on User Input

SACs also merit the highest level of scrutiny as Class III devices because they arguably involve a higher degree of risk than IUDs or MUFCs, in that they require a greater degree of user oversight.[177] This is a crucial distinction, because contraceptives necessarily become less effective to the extent that they that rely on user input.[178] To the extent that an app depends on user-collected and user-input data in order to accurately predict a user's fertile window, the potential for human error rises exponentially.[179]

Natural Cycles requires users to actively and diligently participate in their contraception in a way that IUDs and MUFCs do not.[180] For example, users must record their temperatures every morning at the same time, and also must input data around their menstrual periods and

---

[175] *See How Does the Birth Control App Work?*, *supra* note 2.

[176] *See infra* Part IV.

[177] *See* Perez, *supra* note 169.

[178] *Id.*; *see* McHugh, *supra* note 49 ("As with all health apps, period trackers' efficacy depends on how much information a user is willing to feed it: 'The more data you enter, the more accurate your predictions,' as Glow puts it. 'Finally understand your body,' promises Ava."); Pardes, *supra* note 49.

[179] *See* Marguerite Duane, Alison Contreras, Elizabeth T. Jensen & Amina White, *The Performance of Fertility Awareness-Based Method Apps Marketed to Avoid Pregnancy*, 29 J. AM. BOARD FAM. MED. 508, 511 (2016); Pardes, *supra* note 49; *Frequently Asked Questions*, NAT. CYCLES, https://www.naturalcycles.com/faqs (last visited Dec. 20, 2020) [https://perma.cc/Z7V4-CK6Z].

[180] *See* Perez, *supra* note 169.

sexual activities.[181] To increase the accuracy of fertility predictions, users can even measure how much "luteinizing [or ovulation stimulating] hormone[s]" are in their urine at various times of the month.[182] Furthermore, a whole host of factors can affect a user's basal body temperature reading, including lack of sleep, stress, illness, and alcohol.[183] As long as women are relying on these apps as their sole source of contraception, the credibility of SAC-issued fertility guidance is rendered even more critical.[184] If IUDs and MUFCs require no user input in order to function accurately, and yet warrant the highest level of regulatory oversight, surely SACs deserve the same treatment.[185]

C. Demonstrated Need for More Robust Clinical Efficacy Standards

Natural Cycles' approval as a Class II device sets a dangerous precedent for future fertility-tracking apps seeking the agency's official go-ahead to market themselves as contraceptives. While "[o]nly a handful of individual apps have published data on their models and efficacy," this does not necessarily mean that the data that *is* available has been well-received.[186] For example, the study that Natural Cycles used to obtain FDA approval reported around 93% efficacy with "typical" use,[187] but the study has been widely criticized in the scientific community for its poor design.[188] In the *European Journal of Contraception & Reproductive Health Care*, one clinician wrote that the study incorrectly calculated its "perfect use" rate, and that the "available data (based on basal body temperature) are insufficient to establish

---

181 *Id.*

182 *Id.*

183 *Id.*

184 *See* Duane et al., *supra* note 179, at 508; McHugh, *supra* note 49 ("Using femtech apps without inputting detailed information not only decreases their efficacy, but those flawed outcomes can lead to incorrect predictions that become data points informing the larger health market. It matters whether what the apps are concluding is wrong.").

185 *See* Perez, *supra* note 169.

186 Wetsman, *supra* note 85; *see* Perez, *supra* note 169 (discussing Natural Cycles' use of social media to make their app appear "authentic" despite a lack of research).

187 Scherwitzl et al., *supra* note 57, at 420; *see* CTRS. FOR DISEASE CONTROL & PREVENTION, EFFECTIVENESS OF FAMILY PLANNING METHODS (2011), https://www.cdc.gov/reproductivehealth/unintendedpregnancy/pdf/contraceptive_methods_508.pdf [https://perma.cc/V7F2-NFGZ] (comparing the effectiveness of various contraceptives, including FAB methods, female condoms, and IUDs).

188 *See* Petra Frank-Herrmann, Joseph B. Stanford & Günter Freundl, *Fertility Awareness-Based Mobile Application*, 22 EUR. J. CONTRACEPTION & REPROD. HEALTH CARE 396-97 (2017).

precision and accuracy of the Natural Cycles proprietary algorithm."[189] Moreover, the study was funded by Natural Cycles itself, and two out of the six authors were Natural Cycles co-founders.[190] Ultimately, the research was strong enough for an FDA approval because the app was classified as a Class II, moderate risk device for which an approved PMA was not necessary.[191] More stringent regulatory controls may have prevented this app from being prematurely approved, or at the very least established a precedent for greater controls to ensure the collection of proper efficacy data in the future.

As it currently stands, with SACs regulated as Class II devices, future fertility-tracking apps seeking agency approval will merely have to proceed through the FDA's 510(k) process.[192] Devices undergoing the 510(k) process need only demonstrate substantial equivalence to an existing device in order to be approved.[193] In other words, if apps like DOT, Ovia, or Flo can show that they are substantially equivalent in efficacy to Natural Cycles, they will be able to route through this more efficient review pathway and avoid undergoing the rigorous investigation of a Class III device. Furthermore, as Class II devices, SACs merely need to disclose that "no contraceptive method is 100% effective," among other nebulous warnings.[194] This could mislead users into thinking that the apps are comparable in risk to other forms of contraception. However, "[b]irth control methods like the pill or the [IUD] have been tested numerous times, over decades, in independent trials,"[195] making this a perilous inference. Reclassifying SACs as Class III devices will deter other apps from following in Natural Cycles' footsteps, and help to ensure that they undergo a more robust regulatory investigation prior to entering the marketplace.

189 *See id.*

190 *See* Scherwitzl et al., *supra* note 57, at 420.

191 *See* Wetsman, *supra* note 85.

192 *FDA Allows Marketing*, *supra* note 16.

193 *FDA Submissions*, *supra* note 161; *Premarket Notification 510(k)*, *supra* note 100.

194 *See* 21 C.F.R. § 884.5370 (2020). Additional labeling requirements, such as the inclusion of "[a] statement that another form of contraception (or abstinence) must be used on days specified by the application," do not adequately reflect the higher degree of risk inherent in SACs because of their greater reliance on user input. *Id.*; *see also* McHugh, *supra* note 49; Duane et al., *supra* note 179, at 508.

195 Perez, *supra* note 169.

D. In the Context of Femtech, Is the FDA's Digital Health Innovation Action Plan Performing as Intended?

The Digital Health Innovation Action Plan ("Action Plan") was put in place to help patients by spurring innovation and efficiency in the digital health technology space, but may not accomplish this goal when applied to Femtech.[196] Proponents of Natural Cycles claim that in approving the app, the FDA made progress on the Action Plan's objective to reduce regulatory barriers for lower-risk digital health products.[197] In fact, "[t]he link between the . . . [Digital Health Innovation Action Plan] and Natural Cycles has even been made by the FDA itself."[198] In its press release announcing Natural Cycles' approval, the FDA stated that the Action Plan was created to "provide clarity and find efficiency in how the agency regulates digital health technologies like the Natural Cycles app."[199]

However, part of the Action Plan's push for efficiency means that future FAB digital contraceptives like Natural Cycles will be able to proceed through the 510(k) process when seeking FDA approval. As noted in the Action Plan, the 510(k) approval process increases efficiency by reducing the amount of content necessary for a submission and allowing for a faster review.[200] Although this expedited pathway may help the FDA accomplish its goal of bringing innovative products to patients sooner, it may be doing so at the expense of human health. The FDA requests clinical data in around 10% of 510(k) submissions; however, as the majority of submissions do not require clinical data, "one concern over the 510(k) system is that testing is insufficient and so products that are either unsafe or ineffective could be released to market."[201] Nonetheless, advocates of fertility-tracking apps maintain that even flawed efficacy studies represent a "positive step forward"

---

196 *See* U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN, *supra* note 33, at 1-2 (noting the FDA's Action Plan is based on the premise that "[t]raditional implementation of the premarket requirements may impede or delay patient access to critical evolutions of software technology, particularly those presenting lower risk to patients").

197 *See id.* at 2.

198 Green, *supra* note 20.

199 *FDA Allows Marketing*, *supra* note 16.

200 *See* U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN, *supra* note 33, at 5.

201 David McNamee, *How Does the FDA 'Approve' Medical Products?*, MED. NEWS TODAY (Feb. 20, 2014), https://www.medicalnewstoday.com/articles/272986.php [https://perma.cc/6DBV-KTMK].

because they allow the FDA to engage in the conversation around these devices.[202]

While the Action Plan may be intended to help patients by fostering digital innovation, it does not accomplish this goal when applied to fertility-tracking apps that are not backed by science and yet have enormous implications for users. As Rebecca Simmons, a researcher and fertility awareness specialist at the University of Utah, noted, "[t]he quality of the evidence around [these] apps is a particular concern because most [users] probably don't have prior exposure to the science around fertility awareness methods or realize what they actually need to do in order to use them properly."[203] The digital revolution in Femtech is an inevitable reality, but the FDA should address the lack of evidence around efficacy by requiring SACs to proceed through the Class III PMA approval process. Compelling participation in clinical studies to ensure efficacy would have the effect of forcing developers to design SACs in consultation with the scientific community.[204] Ultimately, this would aid the FDA in responsibly balancing efficiency and innovation with its obligation to protect consumer and patient health.[205]

IV. SIGNIFICANT POLICY ISSUES FOR FERTILITY-TRACKING APPS MOVING FORWARD

A. Privacy Infringement in the Femtech Space

For many users, the decision to begin using a digital contraceptive is not made lightly. The data that users must share in order for a fertility-tracking app to perform optimally is extremely sensitive and personal in nature, as it requires more than just daily temperature-taking.[206]

---

202 Wetsman, *supra* note 85.

203 *Id.*

204 *See id.* ("[M]ost of the fertility apps available weren't developed in consultation with the scientific community. 'What you get is a lot of products without a lot of scientific backing. It's not necessarily the fault of the tech industry or the fault of science, but there's not been a lot of cross communication and there needs to be more,' [Simmons] says.").

205 *See* U.S. FOOD & DRUG ADMIN., DIGITAL HEALTH INNOVATION ACTION PLAN, *supra* note 33, at 1-2; Green, *supra* note 20.

206 *See* Drew Harwell, *Is Your Pregnancy App Sharing Your Intimate Data with Your Boss?*, WASH. POST (Apr. 10, 2019), https://www.washingtonpost.com/technology/2019/04/10/tracking-your-pregnancy-an-app-may-be-more-public-than-you-think [https://perma.cc/564K-MCMD]; McHugh, *supra* note 49 ("Trackers . . . work by asking users to input data like when their periods start and end, how heavy their cycles are, and related factors like

Users trust fertility apps with information about their menstrual cycles, moods, medications, and sexual activities, all of which are quintessentially intimate.[207] It is difficult to imagine what a breach of this trust might feel like, but some Ovia users are all too familiar.[208]

A 2019 report in the *Washington Post* revealed that by paying Ovia's developer, Ovia Health, employers could offer a "special version of the app[] that relays their [employees'] health data — in a 'de-identified,' aggregated form — to an internal employer website accessible by human resources personnel."[209] Participating employers often offer this version of the app alongside other health benefits and provide incentives for workers to input as much health data as possible, citing reduced healthcare spending as a key rationale.[210] In reality, this type of monitoring amounts to what many now refer to as "menstrual surveillance."[211] Menstrual surveillance is the extensive monitoring, and subsequent monetization, of women's intimate health data by employers and other corporate entities.[212] One company in the *Washington Post* report had access to "aggregate data on how many workers using [Ovia] . . . had faced high-risk pregnancies or gave birth prematurely; the top medical questions they had researched; and how soon the new moms planned to return to work."[213]

Companies pay to access the data under the guise of "corporate wellness," but experts point out that this practice invites malfeasance, even if the data is presented in an aggregate form.[214] For instance, this information could be used to justify increasing the cost or decreasing the coverage of health benefits, or it could be exposed in a data breach.[215] At best, corporations might use this data to assess how

mood, sexual activity, physical pain, body temperature, and pulse. Some fertility-oriented apps even ask users to log their sexual positions.").

207 *See* Harwell, *supra* note 206.

208 *See id.*

209 *Id.*

210 *See id.*

211 *Id.*

212 *See* Arwa Mahdawi, *There's a Dark Side to Women's Health Apps: 'Menstrual Surveillance,'* GUARDIAN (Apr. 13, 2019, 8:00 AM EDT), https://www.theguardian.com/world/2019/apr/13/theres-a-dark-side-to-womens-health-apps-menstrual-surveillance [https://perma.cc/F5DN-CDVJ] ("There are positive aspects to [the explosion of Femtech], but there's also a dark side, including the rise of what has been called 'menstrual surveillance.' Corporations are increasingly aware that female bodies are temples of lucrative information, and are exploiting this data in new and ever-more-dystopian ways.").

213 Harwell, *supra* note 206.

214 *Id.*

215 *Id.*

employees' collective health has changed over time.[216] At worst, they could use it to identify and retaliate against women "based on information relayed in confidence, particularly in workplaces where few women are pregnant at any given time."[217]

Ovia's CEO acknowledges the sensitivity of the information shared with employers, but has said the company is in compliance with privacy laws like the Health Insurance Portability and Accountability Act.[218] Ovia has also claimed that it does not sell aggregate data to third parties for advertising purposes, but the contract language that greets users upon downloading the app suggests otherwise.[219] Users must consent to the app's "6,000-word 'terms of use' which [as of April 2019] grant the company a 'royalty-free, perpetual, and irrevocable license, throughout the universe' to 'utilize and exploit' their de-identified personal information for scientific research and 'external and internal marketing purposes.'"[220] The terms also state that Ovia has the right to "sell, lease or lend aggregated Personal Information to third parties."[221] For participating companies, Ovia data can be viewed by the company itself and its insurers, and, for self-insured companies, the third parties who process employee medical claims.[222] While women ostensibly consent to this when they sign up for the app, it is clear that the data they share with Ovia is not solely their own. SACs claim to help women gain control over their own bodies, but, as one article asks, "what if they're instead new methods of giving it up?"[223]

Other fertility and pregnancy tracking apps are not immune to similar privacy concerns. In 2016, Consumer Reports discovered that using only a Glow user's email address, anyone could access all of her private information, including whether she'd had an abortion and the last time she'd had sex.[224] Earlier this year, the *Wall Street Journal* found that Flo

---

216 *See id.*

217 *Id.*

218 *See id.*

219 *See id.*

220 *Id.* Ovia appears to have amended its Terms of Use in May 2019 to include less binding language. *See Ovia Health Privacy Policy*, OVIA HEALTH, https://www.ovuline.com/dynamic-terms (last updated May 15, 2019) [https://perma.cc/DR2S-ACX9].

221 Harwell, *supra* note 206.

222 *Id.*

223 McHugh, *supra* note 49.

224 Harwell, *supra* note 206; *see* Jerry Beilinson, *Glow Pregnancy App Exposed Women to Privacy Threats, Consumer Reports Finds*, CONSUMER REP. (July 28, 2016), https://www.consumerreports.org/mobile-security-software/glow-pregnancy-app-exposed-women-to-privacy-threats [https://perma.cc/AT9S-PPGQ] (concluding that "it would be

was selling data related to user menstrual cycle dates and conception goals to Facebook for advertising purposes.[225] The aforementioned Privacy International report uncovered that Maya and MIA Fem also shared information with Facebook every time a user logged in.[226] According to the report, Maya shared data such as when a user last had sex, and if she used protection.[227] This exchange apparently occurred before users even agreed to the app's privacy policy.[228]

B. Exclusionary Concerns Raised by Fertility-Tracking Apps

Proponents of digital contraceptives are quick to point out that SACs can serve as an affordable, convenient option for women in countries where birth control is not accessible.[229] In a time when access to abortion is also restricted in the U.S., more contraceptive options allow women to exhibit more agency over their bodies and health outcomes.[230] Echoing this point, a Natural Cycles spokesperson said that the app's goal is to "provide greater contraceptive choice to women who wouldn't otherwise be using contraception at all."[231] Women certainly benefit from a greater variety of contraceptive options, especially those that are non-hormonal and less physically intrusive than some alternatives. Moreover, these technological innovations have given many women access to information about their reproductive

easy for stalkers, online bullies, or identity thieves to use the information they gathered to harm Glow's users").

[225] Harwell, *supra* note 206; *see* Sam Schechner & Mark Secada, *You Give Apps Sensitive Personal Information. Then They Tell Facebook.*, WALL ST. J. (Feb. 22, 2019), https://www.wsj.com/articles/you-give-apps-sensitive-personal-information-then-they-tell-facebook-11550851636 [https://perma.cc/PP64-AENP] ("Flo Health Inc.'s Flo Period & Ovulation Tracker, which claims 25 million active users, told Facebook when a user was having her period or informed the app of an intention to get pregnant, the tests showed."). Flo also allows users to input a range of data related to their sex and sex drive, including options to select "high sex drive" and "masturbation." *Flo My Health & Period Tracker*, *supra* note 46.

[226] Ryan Ayers, *The Rise of "Menstrual Surveillance" and the Fight for Data Privacy in Women's Health*, DATACONOMY (Sept. 26, 2019), https://dataconomy.com/2019/09/the-rise-of-menstrual-surveillance-and-the-fight-for-data-privacy-in-womens-health [https://perma.cc/SBE8-N2S]; *see No Body's Business but Mine*, *supra* note 24.

[227] Ayers, *supra* note 226.

[228] *Id.*

[229] *See* Nichi Hodgson, *Natural Cycles May Be Flawed, but Contraception Apps Are Still the Future*, GUARDIAN (Aug. 31, 2018, 7:44 AM EDT), https://www.theguardian.com/commentisfree/2018/aug/31/natural-cycles-tech-contraception-condoms-coil-pill-birth-control [https://perma.cc/JD4L-EE8P].

[230] McHugh, *supra* note 49.

[231] Pardes, *supra* note 49.

health that they might not have had otherwise. One professor at the University of British Columbia noted, "[t]here is good evidence that women who track their cycles in almost any way have a greater sense of autonomy which often goes with improved self-worth."[232]

However, while the apps can help meet the needs of women looking for alternative contraceptive options, experts note that women should use them in consultation with their doctors or supplement SACs with education about the FAB method.[233] This seems feasible in theory, but in practice, access to a healthcare provider or fertility education is out of reach for many women, especially women of color and those from economically disadvantaged backgrounds.[234] These users instead must rely wholly on the efficacy claims made by Natural Cycles, or similar unapproved apps that promise to provide accurate fertility predictions based on the same kinds of algorithms. Considering that women in these populations are disproportionally impacted by unintended pregnancies,[235] they are especially vulnerable to the ramifications of unsupported efficacy data.

Fertility-tracking apps are exclusionary in other ways, too. Their algorithms are designed around a "regular" menstrual cycle of twenty-eight days, even though cycles can range from twenty-one to thirty-five days in length.[236] These discrepancies matter, since the American Academy of Family Physicians estimates that between 9% and 14% of women have irregular periods.[237] According to Dr. Ann Peters, a

---

[232] Beilinson, *supra* note 224.

[233] *See* Jenny McGrath, *With Period-Tracking Apps, the Fate of Your Fertility Is Far from Clear*, DIGITAL TRENDS (Sept. 2, 2019), https://www.digitaltrends.com/mobile/the-problems-and-promises-of-period-tracking-apps [https://perma.cc/8PN6-BX26]; Wetsman, *supra* note 85.

[234] *See* Dehlendorf et al., *supra* note 170.

[235] *See id.* Buried deep in Natural Cycles' website on an informational page reserved for healthcare providers, "there's a diagram showing doctors who the ideal app user is; the company says that patients who would be 'devastated' by pregnancy shouldn't be recommended the app. Still, the app is currently marketing itself on the iTunes app store page as a catchall 'digital birth control.'" Lieber, *supra* note 48.

[236] *See* Lieber, *supra* note 48; Emma Lundin, *Could an Algorithm Replace the Pill?*, GUARDIAN (Nov. 7, 2016, 9:55 AM EST), https://www.theguardian.com/lifeandstyle/2016/nov/07/natural-cycles-fertility-app-algorithm-replace-pill-contraception [https://perma.cc/3T3D-Y2M5] ("[Natural Cycles'] Gemzell Danielsson points out that it's not a good option for women who absolutely want to avoid a pregnancy. Nor does she recommend it for anyone who has what she describes as 'an irregular lifestyle,' irregular menstrual cycles or lacks the motivation to stay on top of their cycles."); McGrath, *supra* note 233; Tiffany, *supra* note 28.

[237] *Irregular Periods: Why Is My Period Late?*, PENN MED. (Nov. 2, 2020), https://www.pennmedicine.org/updates/blogs/womens-health/2015/april/when-should-you-see-a-doctor-for-irregular-periods [https://perma.cc/X7YQ-2VTC].

gynecological surgeon, SACs are "unfortunately completely not helpful for those patient populations."[238] Many apps also make unwarranted assumptions about users' gender identities and sexual orientations.[239] Even their interfaces reflect these biases, with design elements like "floating clouds, superfluous flowers, and strange faux-empowering language where straightforward medical terminology would more than suffice."[240] Eve prompts users to input their intercourse data using heteronormative emojis,[241] and greets users with the phrase, "Get it, girl."[242] The availability of more contraceptive options may be a step in the right direction, but in the case of fertility-tracking apps, it turns out that only some women can reap the benefit.[243]

V. POTENTIAL LEGISLATIVE AND REGULATORY SOLUTIONS

Greater FDA regulatory oversight around efficacy, advertising, and privacy would greatly benefit Femtech as the industry grows and reaches more users. In terms of efficacy, the FDA should first put into place a measure that subjects currently unregulated fertility-tracking apps to the regulatory controls in place for SACs, because they meet the regulatory definition of these devices and clearly tout themselves as contraceptives.[244] For apps already on the market that elect not to comply with the regulations, Congress could pass legislation requiring these trackers to display stronger efficacy disclaimers and clearer warnings that unregulated apps should not be used for contraceptive purposes. This legislation could include an advertising component to enumerate restrictions on the language that unregulated apps can use to market themselves to users. For instance, Congress could make it

238 McGrath, *supra* note 233.

239 *See* Tiffany, *supra* note 28.

240 *Id.* For instance, if Eve users choose to input data around their libidos, they can select from the following options: "DO ME NOW," "I'm down," or "MIA." *Period Tracker – Eve*, *supra* note 41; *see also* Hall, *supra* note 14 ("[A]pps like Glow and Eve offer to explain 'What's Up Down There' so we can 'MASTER' our private parts and 'DEMYSTIFY' Aunty Flo.").

241 *See* Tiffany, *supra* note 28. The Eve app allows users to input a range of sexual activities, from a "makeout sesh" (depicted using two strawberry emojis) to "sex without a condom" (a banana emoji) to "banana free" (two peach emojis). *Period Tracker – Eve*, *supra* note 41.

242 *See* Tiffany, *supra* note 28.

243 *See* Hall, *supra* note 14 ("No fertility apps on the market have adequately addressed the reality that non-binary or trans folks may also benefit from tracking their period.").

244 *See supra* Part II.

illegal for unregulated fertility-tracking apps to call themselves out as "highly accurate" or say that they have been "clinically tested."[245]

Additionally, the FDA should classify and regulate SACs as Class III medical devices because of their similarity to existing contraceptive devices, reliance on user-generated input, and the demonstrated need for more robust clinical efficacy standards. Currently, the FDA classifies Class III devices based on its evaluation of their risk to human life. The FDA should also consider failure rates and the impact that these devices could have if they do not operate as intended. Congress could also implement legislation to mandate that future SACs seeking agency approval to market themselves as contraceptives be regulated as Class III devices.

In terms of privacy, laws such as the 2018 California Consumer Privacy Act[246] could help give users more control over their personal information. This legislation requires businesses to tell their consumers the information they collect, what they do with it, and who will ultimately have access to it.[247] In the context of Femtech, this could be especially helpful for companies that provide special versions of fertility-tracking apps to their employees, giving them insider access to personal information. At the very least, there should be legislation in place to prevent apps from sharing intimate data with third parties for advertising purposes. Apps could also implement a way to "lock" certain data points that may be more sensitive than others, and agree to reserve them for the user's eyes only.

CONCLUSION

If Femtech was once an idea of the future, today, that future has arrived. The BBC estimated in 2016 that as many as 200 million women worldwide had downloaded a fertility-tracking app.[248] In 2018, Natural Cycles reported half a million subscribers across 160 countries.[249] Ovia, Glow, Clue, and Flo together count tens of millions of users every month,[250] and Ovia alone has amassed "billions of data points into what

[245] Kennedy, *supra* note 138.

[246] California Consumer Privacy Act of 2018, CAL. CIV. CODE § 1798.100 (2020) (effective Jan. 1, 2020).

[247] Ayers, *supra* note 226.

[248] Jane Dreaper, *Women Warned About Booming Market in Period Tracker Apps*, BBC (Aug. 11, 2016), https://www.bbc.com/news/health-37013217 [https://perma.cc/9W78-EG63].

[249] Pardes, *supra* note 49.

[250] Harwell, *supra* note 206.

it calls 'one of the largest data sets on women's health in the world.'"[251] This is all somewhat unsettling in the context of the intimate information these apps possess, but women's willingness to use them even despite their shortcomings lends valuable insight into the potential of contraceptive technology.[252] In an age where so much of our health information can be already managed from our personal devices, fertility-tracking apps are a natural progression of this trend. However, as the industry expands and evolves, so too should the FDA's regulatory oversight. Otherwise, Femtech will remain a "wild west"[253] wherein users will continue to bear the burden of verifying efficacy and privacy claims on their own time, using their own bodies as the ultimate tests.[254]

[251] *Id.*

[252] *See* Hodgson, *supra* note 229.

[253] McHugh, *supra* note 49.

[254] *See* Hall, *supra* note 14 ("As regulatory frameworks fail to keep up with the pace of technological innovation, it is down to the users to hold apps to high standards.").