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## Natural Cycles: When an Algorithm Digitally Mandates Your Sexual Health

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# Natural Cycles: When an Algorithm Digitally Mandates Your Sexual Health

*Jacqueline Tran\**

## I. INTRODUCTION

Contraception has been materialized in a variety of forms—pills, t-shaped plastic, and even nothing at all—so, in this technology-driven world, is it really a surprise that contraception would be delivered through our phones? Apparently not. In 2017, a Swedish start-up introduced the world to Natural Cycles, the first mobile application to be CE-marked<sup>1</sup> in Europe as a Class IIb medical device to be used as a method of contraception.<sup>2</sup> This past August, the U.S. Food and Drug Administration (FDA) classified Natural Cycles as a Class II medical device and cleared the mobile application for marketing in the United States as a method of contraception.<sup>3</sup> By embodying a fertility-awareness-based (FAB) method of contraception, Natural Cycles advertises itself as a hormone-free, noninvasive option for women intending to prevent or plan a pregnancy.<sup>4</sup> Despite the array of existing mobile applications that assist women who choose this method of contraception, Natural Cycles is the only mobile application to break through the convoluted market as a medical device that attempts to navigate consumers through the not-so-simple journey of fertility awareness.<sup>5</sup>

Fertility awareness, and using FAB methods of contraception, revolves around the basic principle of women monitoring their ovulation cycles to determine their highest chances of conception in order to either plan or pre-

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1. A certification mark that indicates conformity with health, safety, and environmental protection standards.
2. *Quality Assured & Recognised*, NAT. CYCLES, <https://www.naturalcycles.com/en/science/certifications/> (last visited Aug. 26, 2019).
3. *See id.*; *see also* Press Release, U.S. Food & Drug Admin. (Aug. 10, 2018) (on file with author).
4. *See* E. Berglund Scherwitzl et al., *Perfect-Use and Typical-Use Pearl Index of a Contraceptive Mobile App*, 96 *CONTRACEPTION* 420, 420–21 (2017); *see also* *Is Natural Cycles the Birth Control Method for Me?*, NAT. CYCLES, <https://www.naturalcycles.com/birthcontrol/is-natural-cycles-for-me> (last visited Aug. 26, 2019).
5. *See* Nicole Wetsman, *Why You Should Not Trust Fertility Apps—Yet*, SLATE (Sept. 19, 2018), <https://slate.com/technology/2018/09/fertility-apps-birth-control-evidence.html>.

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vent pregnancy.<sup>6</sup> When monitored diligently and accurately, traditional FAB methods can be an effective way to replace hormonal intake. However, these methods may not transfer as well into a digital form, although many mobile applications have tried.<sup>7</sup> Natural Cycles joins the likes of Daysy, an existing FAB mobile application, in the way they both track fertility, yet Natural Cycles differs drastically by being able to advertise itself as an actual method of contraception.<sup>8</sup> After paying an annual or monthly fee,<sup>9</sup> a Natural Cycles customer receives a basal thermometer, used every morning to directly measure the woman's temperature and indirectly measure the woman's hormone levels to provide data that is entered into the mobile application.<sup>10</sup> The mobile application then utilizes an algorithm to analyze the thermometer readings and the woman's manual input of her period data to determine whether the woman is likely to be fertile.<sup>11</sup> From there, the application emits a red or green display to indicate the likelihood of ovulation, giving the woman guidance on how to proceed with her sexual activity for the day.<sup>12</sup> Due to the sensitive nature of these readings, Natural Cycles notes that the "Instructions for Use" must be adhered to carefully in order to reach the desired results of perfect use and also notes examples of factors that could affect a woman's basal body temperature and potentially fluctuate the application's output.<sup>13</sup> Critics have found this point to be unsettling because this FAB method of contraception conveyed through this digitalized medium seems to simplify the hard work and patience that is traditionally invested by women who choose to engage in the complexities of fertility awareness.<sup>14</sup>

As noted, it is not uncommon to find mobile applications that assist women in their efforts to participate in fertility awareness, yet Natural Cycles differentiated itself through the successful obtainment of a CE-mark in Europe and FDA clearance for marketing in the United States.<sup>15</sup> Natural Cycles was able to accomplish this by closing the existing gap, a lack of scientific research and backing in nearly all FAB applications, through its own pro-

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6. *See id.*

7. *See id.*

8. *See Technology*, DAYSY, <https://usa.daysy.me/technology/> (last visited Aug. 26, 2019); *How it Works*, NAT. CYCLES, <https://www.naturalcycles.com/en/contraception/howitworks/> (last visited Aug. 26, 2019).

9. *Sign Up*, NAT. CYCLES, <https://www.naturalcycles.com/en/signup> (last visited Aug. 26, 2019).

10. *How it Works*, *supra* note 8.

11. *See id.*

12. *See id.*

13. *Frequently Asked Questions*, NAT. CYCLES, <https://www.naturalcycles.com/faqs> (last visited Aug. 26, 2019).

14. *See Wetsman*, *supra* note 5.

15. *See Quality Assured & Recognised*, *supra* note 2.

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spective study.<sup>16</sup> This study served as the basis that propelled Natural Cycles forward as a mobile application that could be legitimately considered by the FDA, especially during a time when the FDA's efforts have been concentrated on digital health innovations.<sup>17</sup> However, from this standpoint, the FDA's approval process seems rather basic, and critics are skeptical of the standards used to evaluate Natural Cycles' study in light of the FDA's goals for digital health.<sup>18</sup> Additionally, it is unclear whether or not consumers are aware of the varying classifications of medical devices and the processes used to classify each device. Because Natural Cycles was tagged as a novel device with low-to-moderate risk, it was given automatic classification as a class III medical device with subsequent classification into class II after a de novo classification request and review.<sup>19</sup> This classification and approval process for Natural Cycles has acted as a jumping-off point from which the FDA aims to build off of and develop a new regulatory classification, "software application for contraception," for similar devices to more swiftly go through the 510(k) process.<sup>20</sup> As noted in the FDA's Digital Health Innovation Action Plan, a relaxed 510(k) process is one of the several initiatives the FDA seeks to accomplish in order to decrease submission content and produce faster reviews of marketing submissions for certain digital health products.<sup>21</sup> Although efficiency is almost always seen as a positive in today's world of immediate gratification, a rapid evaluation of devices similar to Natural Cycles may not be the appropriate way to test this newer, lenient process. The FDA's approval process for this type of medical device may negatively impact consumers who have not been properly educated on the variety of approval levels and those who do not understand the implications of an "FDA approved" or "FDA cleared" device beyond what is conveyed to them through their phone screen.<sup>22</sup>

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16. See Scherwitzl et al., *supra* note 4, at 420; see also Wetsman, *supra* note 5.
17. See *Digital Health Innovation Action Plan 1*, U.S. FOOD & DRUG ADMIN. (2017) <https://www.fda.gov/MedicalDevices/DigitalHealth/>.
18. Katie Brigham, *Fertility Apps are Increasingly Being Used as Contraception and One Has Even Gained FDA Approval*, CNBC (Oct. 13, 2018), <https://www.cnbc.com/2018/10/13/fertility-apps-are-one-the-rise-and-natural-cycles-is-now-fda-approved.html>.
19. See Letter from Angela C. Krueger, Deputy Dir., Ctr. for Devices & Radiological Health, to Sheila Hemeon-Heyer, President & Founder, Heyer Regulatory Sols. (Aug. 10, 2018) (on file with the author); see also Press Release, *supra* note 3.
20. See Letter from Angela C. Krueger, *supra* note 19.
21. See *Digital Health Innovation Action Plan 1*, *supra* note 17, at 2, 4–5.
22. David McNamee, *How Does the FDA 'Approve' Medical Products?*, MED. NEWS TODAY (Feb. 20, 2014), <https://www.medicalnewstoday.com/articles/272986.php>.

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## II. LEGAL BACKGROUND

Concerns, and the need to address them, are arising in response to the positive movement forward by the FDA in regulating digital health technology.<sup>23</sup> The FDA's Digital Health Innovation Action Plan, released in 2017, recognized the need for a restructuring to better address the health technology that was developing in our nation.<sup>24</sup> Part of this plan was an acknowledgement of what has been in the works, as well as an effort to build off of those accomplishments to bring forth more policies into fruition.<sup>25</sup> One of the needs the FDA has been working to meet is one of digital health oversight, which was originally addressed through the creation of a "Digital Health Program."<sup>26</sup> This program has been streamlining oversight of mobile medical applications that present a higher risk to patients and continues to impose more lenient compliance for the ones deemed a lower risk.<sup>27</sup> To do so, the FDA relies on a 510(k) premarket notification process that approves Class I, II, or III devices for marketing without requiring a Premarket Approval (PMA).<sup>28</sup> Although the FDA may meet its goal of delivering more health technology to consumers at a faster rate through this streamlined process, it may be doing so at the risk of conducting insufficient testing and releasing unsafe or ineffective products into the market.<sup>29</sup>

The level of scrutiny drops when evaluating Class III down to Class II devices and is reflected in the processes in place for evaluating these devices for clearance or approval.<sup>30</sup> There are two heavily used forms of FDA premarket submissions: the 510(k) premarket notification and the PMA.<sup>31</sup> The PMA process is specific to evaluating only Class III medical devices for approval and adheres to the most stringent evaluation, including a submission of clinical trials, due to the higher risk levels of these types of devices.<sup>32</sup> In contrast, a 510(k) is submitted for any device class that is intended for human use, and these devices only need to convince the FDA of their substantial equivalence to an existing legally marketed device before being cleared for

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23. *See id.*

24. *See Digital Health Innovation Action Plan 1, supra* note 17, at 1–2.

25. *See id.* at 2–3.

26. *Id.* at 2.

27. *See id.*

28. *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k> (last visited Aug. 26, 2019).

29. McNamee, *supra* note 22.

30. *See id.*

31. *FDA Submissions*, KEN BLOCK CONSULTING, <https://kenblockconsulting.com/fda-submissions> (last visited Aug. 26, 2019).

32. *See id.*

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marketing.<sup>33</sup> If the FDA determines that a device is not substantially equivalent, the device may be submitted for a de novo review—the clearance pathway that was taken by Natural Cycles.<sup>34</sup> This de novo pathway is a “risk-based classification process” that the FDA undertakes in evaluating the safety and efficacy of a novel device, making a determination of the general or special controls that need to be in place before the specific device can be given clearance.<sup>35</sup> From there, the devices that have been cleared through the de novo pathway act as predicates for future, similar devices that are submitted through a 510(k) premarket notification process.<sup>36</sup>

The differences between PMA and 510(k) go beyond the device review process undertaken by the FDA.<sup>37</sup> Though the review process is significant on a regulatory level, the language used thereafter in addressing and marketing the product impacts consumers in their most integral choices.<sup>38</sup> On the most basic level, when a device receives PMA, that product is then entitled to the label nearly all consumers are familiar with: “FDA approved.”<sup>39</sup> In contrast, when a device receives 510(k) clearance, it can be referred to as “FDA cleared,” “FDA listed,” or even “FDA registered.” These are not the same as “FDA approved.”<sup>40</sup> Labeling in this manner may not *seem* significant to consumers, because most are under the impression that it all amounts to the same result: that the FDA reviewed a product and found it to be safe and effective. Unfortunately, this is not the case. The differences between the PMA and 510(k) processes are drastic enough that there is language in § 807.97 of the Code of Federal Regulations to note the severe issue of misbranding.<sup>41</sup> Section 807.97 explicitly notes that “submission of a premarket notification . . . does not in any way denote official approval of the device.”<sup>42</sup> The language of the statute offers a jarring look at the contrast that exists between the literal text of the regulation and consumers’ perception of what approval from the FDA really means. The FDA’s new regulatory classification will put a host of devices at odds with § 807.97 and may present an issue to manufacturers when determining the language to utilize when marketing to consumers. Even if manufacturers were to abide by the basic language stan-

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33. *Id.*

34. *See* Letter from Angela C. Krueger, *supra* note 19.

35. *FDA Evaluation of Automatic Class III Designation (De Novo)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/medical-devices/premarket-submissions/evaluation-automatic-class-iii-designation-de-novo> (last visited Aug. 26, 2019).

36. *See id.*

37. *Id.*

38. *Id.*

39. McNamee, *supra* note 22.

40. *Id.*

41. 21 C.F.R. § 807.97 (2019).

42. *Id.*

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dards and correctly label a 510(k) cleared device as “FDA cleared,” it continues to pose a risk to consumers because of the perceptions the labels hold.<sup>43</sup> Because perceptions may be difficult to alter, it is useful to review the underlying need for the burden to shift onto the FDA to do something instead.

### III. DEVELOPMENTS AND PROBLEMS

#### A. International Ramifications and Basis of Approval

First, the level of scrutiny administered by the FDA when reviewing a mobile application for clearance must be considered in the context of its scientific backing and how that may impact consumers based on their perceptions of traditional marketing language of these types of mobile applications. The recent stir of Natural Cycles is derived not only from the innovative aspect of the mobile application and being cleared by the FDA, but also, as critics will point out, the international scrutiny that has been clouding its name for months prior to the FDA’s press release in August 2018.<sup>44</sup> After being CE-marked in Europe in 2017, Natural Cycles came under fire when a Swedish Hospital reported thirty-seven unwanted pregnancies resulting from patients’ relying on the mobile application to prevent pregnancy.<sup>45</sup> Additionally, a formal investigation regarding Natural Cycles and its marketing was launched by the United Kingdom’s Advertising Standards Authority (ASA) after they received complaints about a misleading July 2017 paid-for-post advertisement on Facebook.<sup>46</sup> Although Sweden’s Medical Products Agency recently cleared Natural Cycles for use, the United Kingdom’s ASA concluded that the language used in Natural Cycles’ Facebook advertisement was misleading.<sup>47</sup> Despite the international activity surrounding Natural Cy-

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43. See McNamee, *supra* note 22; see also Anna Altman, *The Unlikely Politics of a Digital Contraceptive*, THE NEW YORKER (Oct. 2, 2018), <https://www.newyorker.com/tech/annals-of-technology/the-unlikely-politics-of-a-digital-contraceptive>.

44. Kate Sheridan, *Controversial Contraception App Approved in U.S. Drawing Scrutiny Overseas*, STAT (Sept. 11, 2018), <https://www.statnews.com/2018/09/11/contraception-app-natural-cycles-scrutiny-sweden/>.

45. See Dave Muoio, *Another Regulatory Investigation Launched Against Natural Cycles Contraceptive App*, MOBI HEALTH NEWS (Aug. 2, 2018), <https://www.mobihealthnews.com/content/another-regulatory-investigation-launched-against-natural-cycles-contraceptive-app>.

46. Maev Kennedy, *Natural Cycles: ASA Investigates Marketing for Contraception App*, THE GUARDIAN (July 29, 2018), <https://www.theguardian.com/technology/2018/jul/29/natural-cycles-asa-investigates-marketing-for-contraception-app>.

47. 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> (finding that the thirty-seven unwanted pregnancies out of the 668 women

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cles prior to the FDA's press release, the FDA continued with its clearance of the mobile application for marketing, finding the clinical trials and prospective study sufficient to meet its standards.<sup>48</sup> When evaluating Natural Cycles' study, critics note how poorly it was conducted and express their concerns regarding the circumstances under which it was promulgated.<sup>49</sup> For example, not only was the research funded by the company, but also two out of the six authors of the study are also the co-founders of Natural Cycles.<sup>50</sup> Granted, though there may not be any hard-and-fast rules against co-authoring a study for a business you own, it does raise principled questions that critics use to scrutinize the FDA's decision to proceed without more inquiry. The skepticism around the scientific backing of Natural Cycles derives from the existing uncertainty of dealing with fertility awareness digitally, a notion that strays away from the more formalized methods that typically require more time and money.<sup>51</sup> A 2016 report that reviewed the various mobile applications available to track fertility exemplified the lack of reliable evidence proving a mobile application's ability to prevent pregnancy as well as the host of factors that may interfere with a basal body temperature reading, such as poor sleep, stress, alcohol, or even forgetfulness, which would ultimately affect the output given for the day.<sup>52</sup> Because there are many more factors that may play a part in the dictation of a Natural Cycles' reading, there is a

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who had abortions at that hospital was in line with the 7% unintended pregnancy rate claimed by Natural Cycles based on typical use.); *ASA Ruling on NaturalCycles Nordic AB Sweden t/a Natural Cycles*, ADVERT. STANDARDS AUTH. (Aug. 29, 2019), <https://www.asa.org.uk/rulings/naturalcycles-nordic-ab-sweden-a17-393896.html> (holding that the statement "Natural Cycles is a highly accurate, certified, contraceptive app that adapts to every woman's unique menstrual cycle. Sign up to get to know your body and prevent pregnancies naturally," in conjunction with "Natural Cycles officially offers a new, clinically tested alternative to birth control methods," is misleading because claims were based on the perfect-use results even though the relevant data of effectiveness should have been pulled from typical use).

48. See Altman, *supra* note 43.
49. See Wetsman, *supra* note 5 (noting Frank-Herrmann's comment in the European Journal of Contraception & Reproductive Health Care criticizing how the study calculated the "perfect use" rate inappropriately and how the "precision and accuracy of the algorithm . . . use[d] to identify the day of ovulation . . . has not been established").
50. See Scherwitzl et al., *supra* note 4, at 420.
51. See Wetsman, *supra* note 5.
52. See Marguerite Duane et al., *The Performance of Fertility Awareness-Based Method Apps Marketed to Avoid Pregnancy*, 29 J. AM. BD. FAM. MED. 508, 511 (2016); see Wetsman, *supra* note 5; see also *Starting Natural Cycles*, *supra* note 13.



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high risk of human error that could occur.<sup>53</sup> When a mobile application is a woman's sole source of pregnancy prevention, the guidance it provides is crucial because an erroneous reading may lead to an unwanted pregnancy, which is not a small incident for which to be at risk.<sup>54</sup> Unintended pregnancies bring with them health and financial risks that can negatively pervade a woman's life. Thus, critics are apprehensive about the ease with which Natural Cycles was cleared by the FDA since the extent of the required disclosures to the public are minimal.<sup>55</sup>

## B. FDA Review Processes

Because Natural Cycles is the most current and leading example of a Class II medical device that has gone through the 510(k) premarket notification process, it acts as the exemplary device for the FDA in dealing with future contraceptive medical devices in the form of a mobile application. Natural Cycles represents the future of contraception and, more generally, the digitalization of women's health to such a progressive extent so as to involve the FDA.<sup>56</sup> Although mobile applications such as Daysy have existed as fertility tracking devices for some time, none have successfully reached the point of obtaining FDA clearance.<sup>57</sup> This is the crux of the matter. While both fertility awareness as a natural method of contraception and mobile applications providing guidance for fertility awareness (even with the utilization of a thermometer) have existed, never before has a mobile application broken through the market as an FDA-recognized method of contraception.<sup>58</sup> This breakthrough is surely indicative of the future of health, and the FDA has exemplified its efforts in preparing for the transition, acknowledging the likelihood that the transition will not be gradual in any sense.<sup>59</sup> Although the Digital Health Innovation Plan was created and developed with the intention

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53. Caroline Criado Perez, *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>.

54. See Olivia Sudjic, *'I Felt Colossally Naive': The Backlash Against the Birth Control App*, THE GUARDIAN (July 21, 2018), <https://www.theguardian.com/society/2018/jul/21/colossally-naive-backlash-birth-control-app>.

55. Criado Perez, *supra* note 53 (stating that the FDA's only specification for Natural Cycles was that their advertisements be clear about potential risks by including "a statement that no contraceptive method is 100% effective").

56. Nichi Hodgson, *Natural Cycles May Be Flawed, but Contraception Apps are Still the Future*, THE GUARDIAN (Aug. 31, 2018), <https://www.theguardian.com/commentisfree/2018/aug/31/natural-cycles-tech-contraception-condoms-coil-pill-birth-control>.

57. See Wetsman, *supra* note 5.

58. See generally *id.*

59. See Hodgson, *supra* note 56.

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of combatting the burdens to come from digitalizing health, it may not be as prepared for the realities of consumers intaking “birth control” through a mobile application.<sup>60</sup>

This digital age has given us the advantage of having readily accessible information at our fingertips and thus pushes consumers towards self-education on the existing resources for self-investment. Thus, it could be argued that the responsibility predominantly lies in the consumers to evaluate their options and make an informed decision.<sup>61</sup> However, in order for consumers to truly make an informed decision, they will continue to rely on the standards in place to guide them in the right direction, which is one of the purposes of the existence of our federal agencies. Consumers rely on the FDA and its processes to aid them in making those informed decisions about products, drugs, or devices they choose for their daily life.<sup>62</sup> To most consumers, the FDA imposes a presupposition of safety, efficacy, and security, and may be the reason why a consumer will choose one product over another.<sup>63</sup> Because so much weight may be put on the successful functionality of the FDA, it is important that consumers understand the approval process and the implications of the language used. However, the burden of education cannot be wholly placed on consumers. Thus, it may be necessary that stricter processes be put into place for certain devices, such as medical mobile applications.

Once a device has crossed the 510(k) threshold for FDA clearance, there are already preexisting issues of a consumer’s melded understanding of approval given by the PMA process versus clearance provided by a premarket notification of 510(k).<sup>64</sup> Unless a consumer is involved in, or particularly curious about, the practice industry, most consumers do not keep themselves apprised of the nuances within FDA regulations.<sup>65</sup> Rather, they have a generalized understanding and will likely infer a large degree of approval, safety, and efficacy from the marketing language used for these devices, despite the discrepancies in wording for these varying devices.<sup>66</sup> In this digital era, there is an over-reliance on mobile applications for their efficiency and functionality without a complete awareness about the motivation and discipline needed to achieve the “perfect use” that results in that 99% effective rate that is

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60. See *Digital Health Innovation Action Plan 1*, *supra* note 17.

61. See generally Hodgson, *supra* note 56.

62. See McNamee, *supra* note 22.

63. See *FDA Mission*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/aboutfda/whatwedo/> (last visited Aug. 27, 2019).

64. Amie C. O’Donoghue et al., *Consumers’ Understanding of FDA Approval Requirements and Composite Scores in Direct-to-Consumer Prescription Drug Print Ads.*, 21 J. HEALTH COMM’N 927, 934 (2016).

65. See *id.*

66. See *id.*

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comparable to substantiated contraception methods.<sup>67</sup> The mediums that are used to advertise mobile applications are under little to no regulation and pose issues in a consumer's journey to informed consent when the social interaction piece of obtaining a traditional form of contraception is removed from the Natural Cycles process. Without knowing the depths of the FDA's approval process, consumers may mistake marketing that includes basic FDA approval language as an all-encompassing "OK" to move forward. Consumers may operate under the assumption that anything that is marked "FDA Approved" has undergone the complete and necessary testing requirements that warrant a safe and minimally risky product.<sup>68</sup> With this kind of presumption going into making decisions regarding sexual health, women are at risk of making these crucial decisions on an incomplete knowledge base.

Currently, the rate at which our nation is advancing technologically poses points of conflict for medical devices that are administered through mobile applications.<sup>69</sup> Accessibility is a double-edged sword. Not only is it key to moving our nation forward in digital health by reaching consumers in ways that were not possible fifteen years ago, but, by reaching consumers so quickly, the increased level of marketing may lead to consequences that we have not yet considered or for which we have not properly prepared.<sup>70</sup> With the introduction of social media outlets such as Facebook and Instagram, there has been a new wave of marketing through "influencers" who provide a type of advertising that takes the messaging of a product to a completely unforeseen level.<sup>71</sup> Specifically, the messaging of contraception through digital channels may invite more scrutiny than experienced in the past because of the pervasiveness of the internet. When an innovative method of contraception like Natural Cycles enters the market and targets a more modern marketing approach, it is perceived as the new and flashier product when compared to the tried and true "older" methods of contraception.<sup>72</sup> When companies utilize social media or "influencers" as a primary source for their marketing, they condense information about the device into easy-to-read snippets or thirty-second videos. It is therefore difficult to comprehend how enough accurate information can reach the consumer in those quick advertisements for her to make a fully informed decision. It seems as though there is a presumption on the part of the company that these consumers will complete their due diligence through further research of a device in which they are interested.<sup>73</sup> This is a weighty presumption to place onto consumers. As healthcare con-

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67. See Criado Perez, *supra* note 53.

68. Wetsman, *supra* note 5.

69. See Criado Perez, *supra* note 53.

70. See generally Hodgson, *supra* note 56; Wetsman, *supra* note 5.

71. Criado Perez, *supra* note 53.

72. See Criado Perez, *supra* note 53; see also Wetsman, *supra* note 5.

73. See generally Criado Perez, *supra* note 53.

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tinues to become commercialized,<sup>74</sup> the overarching goals of Natural Cycles as a company, and others that will mirror it in the years to come, will always be questioned as the struggle subsists between making money and helping others. But how much help are consumers really receiving from a mobile application like Natural Cycles that pushes all of the real work onto the user? Or, for that matter, from a federal agency that has the people's best interest at heart yet conducts the minimum evaluation for a Class II device that normally goes through a more rigorous review process?

Despite the flaws that critics find in the FDA's current review process for digital devices, the FDA has been able to track its objectives outlined in the Digital Health Innovation Plan by beginning to provide lighter review standards for innovative devices such as Natural Cycles.<sup>75</sup> Advocates for Natural Cycles find that innovation in this area is warranted as a step in the right direction for expanding women's right to make their own reproductive health choices. This expansion of reproductive choice is essential in keeping up with the technological advancements that are constantly occurring in this nation. By digitalizing reproductive health in this way, Natural Cycles has been able to increase efficiency, cut costs, and make contraception available to a wider range of women who would not otherwise have access to contraception at all.<sup>76</sup> Reproductive choice has been a longstanding conversation and therefore there may be constitutional issues shrouding the push for stricter FDA regulations in regard to the review and marketing of these digital devices.

### C. Constitutional Implications

Reasonable solutions, such as a reevaluation of the approval processes in place or more stringent marketing regulations, have been suggested to address the rising concerns of the implied risks connected with marketing for a mobile application like Natural Cycles.<sup>77</sup> These solutions bring in a sense of more federal involvement in the area of women's health and choice, which unearths sensitive issues of federal overreach in the constitutionally protected areas of privacy, a right that has been consistently discussed since the mid-1900s.<sup>78</sup> The Fourteenth Amendment acts as the basis for the constitutional implications that may arise if critics were to further advocate for more stringent rules around the clearance of these mobile applications as it pertains to contraception.<sup>79</sup> Although there does not exist an express constitutional right to birth control,<sup>80</sup> the right to reproductive choice is rooted in precedent, his-

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74. See Altman, *supra* note 43.

75. See generally *Digital Health Innovation Action Plan 1*, *supra* note 17.

76. See generally Hodgson, *supra* note 56.

77. See McNamee, *supra* note 22.

78. See *Griswold v. Connecticut*, 381 U.S. 479, 494–99 (1965).

79. See generally U.S. CONST. amend. XIV.

80. See *id.*

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tory, and tradition.<sup>81</sup> Specifically, this right to reproductive choice can be derived from the fundamental, unenumerated right of privacy found in *Griswold v. Connecticut*.<sup>82</sup> It has not been a simple task to get to the point of open discussion and advocacy for these fundamental, unenumerated rights such as reproductive choice.<sup>83</sup> Those decisions by the United States Supreme Court paved the way for things such as “FemTech” to be seriously considered in today’s context. As a result, it is sensible that these persisting rights be protected from the scrutinization of any government agency. On these bases, advocates find that more stringent FDA regulations would only be taking a step back in the progressive accomplishments reached as well as a degrading of the existing freedom of reproductive choice, something that can still be considered freshly decided in our judicial history.<sup>84</sup>

#### IV. CONCLUSION

The first-ever FDA cleared mobile application to disrupt the existing market of contraception certainly causes critics and advocates alike to have an opinion about how this product should proceed and the implications in doing so. The international conversation revolving around Natural Cycles was an indicator of the rising concerns regarding the mobile application’s functionality and marketing scheme. In spite of the international skepticism, critics will note that the FDA cleared Natural Cycles for marketing in the United States.<sup>85</sup> In an effort to progress its objectives of effectively regulating digitalized health, the FDA adhered to its Digital Health Innovation Plan by relaxing its review processes for these new devices that they deem to be at a low-to-moderate risk level. In doing so, the FDA may be putting consumers at risk by allowing the manufactures of these new devices to have a freer rein on how they market. With a common understanding that consumers make certain assumptions about what it means to be FDA approved, or cleared, it can be alarming that in this new era of technological devices that review standards would be lowered rather than raised. Critics who recognize this issue are also aware of the complexities of the FDA processes and difficulties consumers must have with parsing out the differences between what it means to be “FDA Approved,” as governed by the PMA process, and “FDA Cleared,” through the 510(k) premarket notification process.<sup>86</sup> Thus, they find that though this is a crucial area of innovation, it is equally important that consumers are kept apprised of what these devices are and what they do beyond just how they are marketed.

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81. See *Griswold*, 381 U.S. at 494.

82. See *id.*

83. See *id.*

84. See generally Wetsman, *supra* note 5.

85. See Sheridan, *supra* note 44.

86. See McNamee, *supra* note 22.

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However, proponents of this quicker push for digital health and its promotion to consumers through streamlined means argue that a mobile application like Natural Cycles should be celebrated for providing greater reproductive choice to women. By advancing sexual health technologically, Natural Cycles is providing a “short-cut” for consumers and in that way cutting costs while also providing efficiency and accessibility. Advocates for maintaining this progression of digital health note the constitutional implications that shroud the efforts to cut back on clearing devices for public engagement. The Fourteenth Amendment recognizes a fundamental, unenumerated right to privacy which advocates have also found to be connected to the right of reproductive choice for women.<sup>87</sup> Persuasive arguments have been, and will continue to be, expressed for both sides regarding this topic of digital contraception, and the conversation of reproductive choice will nevertheless persist as it has through the years. But taking a look through the lense of the consumer, one can find the rather *unnatural* basis of these mobile applications that tout that their accessibility provides the get-away from hormones when, really, that accessibility is only providing more reliance on the man-made device of a mobile phone.

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87. See *Griswold*, 381 U.S. at 494.