

## Femtech and the law (or a tale of how Eve fights to overturn Adam and take control over her body)

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**ABSTRACT:** “Femtech” is a fancy word that refers to digital products and services aimed to cope with women’s health concerns and other issues that specifically regard women. Originally, femtech was created with the clear purpose of giving women a voice in the digital market, as they have traditionally been a silent audience assisting tech developments. However, along the line femtech became exactly the opposite: a mechanism for law enforcement authorities to build legal cases against women and for other public entities and private invade women’s privacy. More radical criticism goes as far as arguing that femtech is a tool of oppression. This paper will analyse the potential legal/social hazards of femtech, its legal framework within EU law and the possible remedies to make femtech come back to its roots as a mechanism of women empowerment.

**KEYWORDS:** European law; femtech; medical device; privacy; women’s rights

**SUMMARY:** 1. Introduction: contextualization of femtech – 2. From women’s control to control over women – 3. Controlling women by using femtech data – 3.1. Control by public entities – 3.2. Control by private bodies – 4. Controlling women by using femtech stereotypes – 4.1. The criticisms of femtech as a mechanism of oppression – 4.2. The criticism of the criticism – 5. The legal framework of femtech within European law – 6. What about the future?

### 1. Introduction: contextualization of femtech

The term femtech was coined by Ida Tin, back in 2016, to describe the set of products and services aimed to cope with women’s health issues, or other matters specifically concerning women.<sup>1</sup> Today, this kind of products are extremely popular<sup>2</sup> (for instance, they occupy a leading role in the app market)<sup>3</sup> which might be a result of a basic premise of our times: women are the largest consumer group.

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<sup>1</sup> B. KIEFER, *The Femtech Revolution*, Adweek, August 2022, 8.

<sup>2</sup> E.A. BROWN, *The Femtech Paradox: how workplace monitoring threatens women’s equity*, in *Jurimetrics: The Journal of Law, Science & Technology*, 61, 3, 2021, 2.

<sup>3</sup> M.D. MANHART, M.A. DUANE, *A comparison of app-defined fertile days from two fertility tracking apps using identical cycle data*, in *Contraception.*, 115, 2022, 12-16. There are, however, criticism, even from the perspec-

Femtech<sup>4</sup> embraces a large spectrum of technologies, aiming to empower women about their health, and enhance their autonomy. Many femtech solutions are already available on the market. Examples of these solutions are bracelets to combat hot flashes associated with menopause, fertility-tracking mobile apps, apps for pre- and post-partum care, digital blood tests for pregnancy detection, apps for pregnancy and maternity educational purposes, and apps aimed at controlling anxiety (more common in women than on men).<sup>5</sup> Issues related to pregnancy – or the avoidance of it – play a significant role in femtech<sup>6</sup> (even though not all are based on scientific evidence).<sup>7</sup> Fertility plays a major role in femtech. Femtech apps are employed to notify women that the menstrual cycle is overdue, that it is time to take their contraceptive pill or when it is the best period to have sexual intercourse considering a future pregnancy. As for their format, femtech comes in the form of stand-alone apps, wearable or even insertable technology that sends data to a paired smartphone app.

Because of the “innocent” and helpful function of these apps, users are willing to input personal information, which might range from simple facts, like name and age, to more complex and private matters, like occasions of intimacy.<sup>8</sup> Besides data actively input by the app user, femtech apps are also fed with data collected from the woman’s body, by using, for instance, biosensors that measure body temperature, analyse saliva samples and/or measure the heartbeat.<sup>9</sup>

Femtech enthusiasts claim that these solutions can help both to destigmatise female-specific conversations and to nurture and improve knowledge of typically female conditions on which there is still little research.<sup>10</sup> Furthermore, through the collection of health data, femtech empower women, supporting them in knowing and understating their bodies. Femtech also has the potential to improve healthcare accessibility: women living in remote and underserved areas may find a valuable first digital response to their health concerns in femtech solutions. Overall, these technologies can improve women’s wellbeing in general and their maternal experience through a personalized healthcare experience.

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tive of women’s rights. An overview of the main remarks in T. HENDL, B. JANSKY, *Tales of self-empowerment through digital health technologies: a closer look at “Femtech”*, in *Review of Social Economy*, 80, 1, 2022, 30.

<sup>4</sup> In general about FemTech from a legal standpoint see C. MCMILLAN, *Monitoring Female Fertility Through “Femtech”: The Need for a Whole-System Approach to Regulation*, in *Medical Law Review*, 30, 3, 2022, 410-433; E.A. BROWN, op. cit., 1; P. MISHRA, Y. SURESH, *Datafied body projects in India: Femtech and the rise of reproductive surveillance in the digital era*, in *Asian Journal of Women’s Studies*, 27, 4, 2021, 597-606.

<sup>5</sup> R. VACH, “Femtech” Seeks A Movement Toward Holistic Women’s Health’, in *Chiropractic Economics*, 2021, 64-68.

<sup>6</sup> M. DUANE, A. CONTRERAS, E.T. JENSEN, A. WHITE, *The performance of fertility awareness-based method apps marketed to avoid pregnancy*, in *J Am Board Fam Med*, 4, 2016, 508-11.

<sup>7</sup> M.D. MANHART, M.A. DUANE, op. cit., 1.

<sup>8</sup> See D. LUPTON, *Quantified Sex: A Critical Analysis of Sexual and Reproductive Self-Tracking Using Apps*, in *Cult Health Sex*, 17, 4, 2015, 440-53.

<sup>9</sup> R.E. MADRID, F. ASHUR RAMALLO, D.E. BARRAZA, R.E CHAILE, *Smartphone-Based Biosensor Devices for Healthcare: Technologies, Trends, and Adoption by End-Users*, in *Bioengineering*, 9, 2022, 101; T. BEDUK, D. BEDUK, M.R. HASSAN, E. GULER CELIK, J. KOSEL, J. NARANG, K.N. SALAMA, S. TIMUR, *Smartphone-Based Multiplexed Biosensing Tools for Health Monitoring*, in *Biosensors*, 12, 2022, 583.

<sup>10</sup><http://bit.ly/3EkxWP> (last visited 8/02/2023); <http://bit.ly/3Kiszq6> (last visited 8/02/2023); <http://bit.ly/3KfBtEZ> (last visited 8/02/2023); <https://www.entrepreneur.com/en-in/technology/femtech-in-a-guest-for-better-female-health/442597> (last visited 8/02/2023).

However, alongside those who perceive femtech positively, many have a pessimistic or even nefarious vision of these technologies. These two perspectives are, in a sense, a mirror of what is happening with femtech: on one hand, it is a flourishing market, nourishing promises of increased knowledge and control over one's own body; on the other hand, a darker backdrop of the broader ever-present risk of control and stigmatisation of women's bodies within society.<sup>11</sup>

This negative perception of femtech is further aggravated by recent events in the United States regarding the right to abortion, in the aftermath of the reversion of *Roe v. Wade*,<sup>12</sup> and policies which also in Europe are moving towards a reduction of women's autonomy about their reproductive choices.<sup>13</sup>

These events increase the perception of multi-layered, institutionalised attacks on autonomy that women have to face when it comes to their health and well-being. Examples of these are the politicisation and criminalization of women's bodies and reproductive decisions, the use of captivating layout to prompt "optimal" and subliminal decision-making during pregnancy,<sup>14</sup> the parallel stigmas surrounding (in)fertility and menstruation,<sup>15</sup> and the absence of women's issues from clinical trials.<sup>16</sup> Furthermore, the leakage of women's health data from major femtech companies increases the fear that technologies such as femtech may fuel stigmatisation and ultimately jeopardize women's rights. The growing pessimism and dystopia around the above-mentioned events generate the need to clarify the European regulatory framework applicable to femtech and understand whether the fears are well-founded. Against this backdrop of potential promise and feared pitfalls, this paper describes some of the main concerns related to the misuse of femtech and its growing presence in the market. Secondly, the paper gives an insight into the regulations applicable to femtech within the European Union (EU).

## 2. From women's control to control over women

Thanks to femtech, women's issues and health-related questions are no longer spoken in a whisper to become objects of open conversation between femtech's CEOs. By bringing women's issues to the

<sup>11</sup> See L. GURRIERI, J. PREVITE, J. BRACE-GOVAN, *Women's Bodies as Sites of Control: Inadvertent Stigma and Exclusion in Social Marketing*, in *J Macromarketing*, 3, 2013, 128.

<sup>12</sup>We refer to the discussion raised after *Dobbs v. Jackson Women's Health Organization*, No. 19-1392, 597 U.S. (2022). In this landmarking decision of the U.S. Supreme Court, the court held that the Constitution of the United States does not confer a right to abortion. The court's decision overruled both *Roe v. Wade* (1973) and *Planned Parenthood v. Casey* (1992), giving each state the full power to regulate any aspect of abortion not protected by federal law. See also, as a commentary, A. KOBAYASHI, M. THOMAS, *How will the reversal of Roe v. Wade affect American women?*, in *Economic Observatory*, 2022, <https://www.economicsobservatory.com/how-will-the-reversal-of-roe-v-wade-affect-american-women/>.

<sup>13</sup> Thinking one for all, to the example of Poland. See, *inter alia*, <https://www.euractiv.com/section/politics/news/eu-parliament-to-look-into-polands-deadly-abortion-laws/>.

<sup>14</sup> See WHO, *Global Alcohol Action Plan 2022-2030 to Strengthen Implementation of the Global Strategy to Reduce the Harmful Use of Alcohol* (WHO, June 2021).

<sup>15</sup> M. SHILDRICK, *Leaky bodies and Boundaries: Feminism, Postmodernism and (Bio) Ethics*, 2015, Routledge.

<sup>16</sup> I. MALHAME, R. D'SOUZA, M.P CHENG, *The Moral Imperative to Include Pregnant Women in Clinical Trials of Interventions for COVID-19*, in *Ann Intern Med*, 173, 2020, 836.

private area,<sup>17</sup> femtech managed to put the spotlight on traditional taboos, such as menstruation, women's sexual appetite, menopause, and infertility. Reproduction and fertility used to be private issues restricted to the house and close family members. Femtech managed to bring it to the public sphere, opening the discussion and directing science and medicine toward topics always perceived as marginal.

With this jump into the spotlight, femtech also had the chance to bust women's autonomy. The idea behind fertility apps was to empower women and enhance their freedom to make conscious choices about their health (leading to its qualification as a "feminist issue").<sup>18</sup> By knowing more about their bodies (basically, knowing the respective data),<sup>19</sup> they would gain control over them and their reproductive function, ultimately deciding if and when to have kids.

"Empowerment is, thus, framed as a result of a woman acquiring data-driven knowledge about her body and its processes to step up in charge of her body and exercise individual autonomy and choice in her menstrual, sexual and reproductive health and life more broadly".<sup>20</sup> Ultimately, the aim was to grant women the control over their bodies they have been lacking for years. Though the 70's emancipation revolutions were a major step in that regard, the fact is that some of the acquired rights and liberties were not accompanied by technological advanced suited to materialize those rights and liberties. Tech companies have traditionally focused on men's issues and only recently has the aim to satisfy women's needs gained the spotlight.<sup>21</sup> However, this empowerment could be overturned against women, as it has become a way for external entities to control women's bodies. In the following lines, we explore the darker side of the femtech industry that lurks in the shadows, calling in to question the beneficial nature of these devices.<sup>22</sup>

### 3. Controlling women by using femtech data

#### 3.1. Control by public entities

Privacy intrusion from public entities, namely law enforcement agencies, were fuelled by recent event surrounding abortion laws. In the US, some State governments tried (and managed) to seek access to data collected by femtech devices and other digital tools to initiate or advance legal proceedings against women,<sup>23</sup> regarding abortion, drug use, or prostitution.<sup>24</sup> The Iranian situation pro-

<sup>17</sup> P. MISHRA, Y. SURESH, *op. cit.*, 1.

<sup>18</sup> C. McMILLAN, *op. cit.*, 1.

<sup>19</sup> P. MISHRA, Y. SURESH, *op. cit.*, 4.

<sup>20</sup> T. HENDL, B. JANSKY, *op. cit.*, 1.

<sup>21</sup> L. WILSON, *Femtech Companies Closing the Gender Health Gap*, June 2022, <https://www.beaurost.com/blog/uk-femtech-startups/>.

<sup>22</sup> C. CODINHA, *What Is Femtech, and Is It the New Pink Tax?*, in *Allure: wellness*, April 2019, <http://www.allure.com/story/what-is-femtech>.

<sup>23</sup> A woman's search history on the internet was used as evidence to show intention to carry out an abortion. Cf. A. GEOFFREY, *Fowler and Tatum Hunter, "For people seeking abortions, digital privacy is suddenly critical"*, in *The Washington Post*, Published May 4, 2022, Updated June 24, 2022, <https://www.washingtonpost.com/technology/2022/05/04/abortion-digital-privacy/>.

vides another example of the use of femtech data by public entities. Following the criminalization of abortion and other practices hindering reproductive capacity, the government has imposed a “tracking” of Iranian women’s pregnancies (e.g., centralizing the results of every pregnancy test in a unique governmental system) to prevent abortive practices.<sup>25</sup>

Not much imagination is required to speculate about a future in which some governments may use these technologies to reinforce discriminatory and borderline eugenic policies. An example could be tracking the menstrual cycles of migrant girls through fertility apps, with an agenda in line with a policy of birth control within these ethnic minority groups.<sup>26</sup>

These dystopian scenarios seem far from coming true on this side of the Atlantic. In the majority of European countries, abortion laws remain more based on women’s self-determination and the use of femtech in abortion criminal proceedings is not a foreseeable issue. However, in some countries, such as the UK, data taken from devices (femtech included) are being used in other criminal proceedings. For instance, victims of rape, and sexual or domestic violence are being asked to deliver their devices to get data regarding their communications, web searches, and downloaded materials. The British Information Commissioner’s Office (the competent data protection authority in the UK) has already issued a report on this question, alerting police forces to the need to comply with the 2018 Data Protection Act (the UK’s implementation of the GDPR).<sup>27</sup>

Besides police forces, femtech data can be of particular interest to other public authorities, for instance, to organize and manage health services. This option could also be a force for good, making the provision of health services more inclusive for women. Still, there are no guarantees as to the real implication of such data access, which in theory could make healthcare more women-tailored. On the contrary, what we have witnessed in terms of sharing these specific data on women’s health have been attempts to gain a new kind of control over women’s bodies.<sup>28</sup>

### 3.2. Control by private bodies

Data intrusions might also come from private companies, eager to use the data generated by femtech for business-related purposes, making women’s bodies (again) a source of profit. This time, not because of services provided with their bodies, but because of the data collected from them. After all, behind the golden armour of an altruistic purpose femtech apps and products are created for profit in the same way as other consumer products.<sup>29</sup>

The problem lies in the fact that, although most users know that femtech apps collect information in exchange for the service offered, they are not aware of the specificities of these business models or

<sup>24</sup> Cf. B. CORBIN, N. GWILT LAW, *The Shifting Data Privacy Landscape For Femtech & Beyond*, in *MedDevice online*, June 29, 2022, <https://www.meddeviceonline.com/doc/the-shifting-data-privacy-landscape-for-femtech-beyond-0001>.

<sup>25</sup> Iran death penalty threat for abortion unlawful: UN rights experts. United Nations (2021). <https://news.un.org/en/story/2021/11/1105922>.

<sup>26</sup> In a horrifying history of forced sterilizations, some fear the US is beginning a new chapter. <https://edition.cnn.com/2020/09/16/us/icehysterectomy-forced-sterilization-history/index.html>.

<sup>27</sup> R v Carl Bater-James and Sultan Mohammed [2020]EWCA Crim 790.

<sup>28</sup> B. CORBIN, op. cit., 5.

<sup>29</sup> C. McMILLAN, op. cit., 1.

the privacy policies that govern them. Companies tend to comply with the General Data Protection Regulation (GDPR)<sup>30</sup> obligations that require consent for data sharing (otherwise they will be sanctioned for a violation of the GDPR), however, users are not always completely aware of how their information is used (which might also equate to a GDPR violation).<sup>31</sup>

A 2020 study by the Norwegian Consumer Council examined some of the most popular femtech apps, including Clue<sup>32</sup> and Flo,<sup>33</sup> and concluded that data collected by them were far and wide.<sup>34</sup> The study found that these apps collectively transferred personal data to at least 135 third-party companies, or “data brokers”, who collect, aggregate and combine personal information about the user from different sources to create a digital profile. The breadth of uses that can be made is as manifold as the information collected is vast and inclusive. Data ranging from a user’s location to information on his/her personal health and sexual orientation are sold to data brokers for various functions, such as marketing and targeted advertising campaign, ascertaining the price of health insurance premiums, developing novel women’s products, or even deepening scientific knowledge. Overall, data-sharing practices, frequently with money involved,<sup>35</sup> created a parallel business.

There are also other common “private purposes” which relate to the labour environment. Femtech apps are being used by employers to manage the workplace and control their personnel. Indeed, it is a growing and laudable trend for employers to pay attention to the general well-being of their employees. However, when that is done by having access to their personal health details – e.g., using wearable health apps, very often provided by the company itself – a legal problem arises. Moreover, this genuine interest towards employees often comes hand in hand with the interest to save money on employees’ health insurance or adopt targeted management policies. The expansion of this trend to more intimate details – such as fertility and menstrual cycle data – is inevitable and thus threats to privacy and data protection are on the rise.

For instance, the gaming company Activision Blizzard encourages its female workers to use the app Ovia<sup>36</sup> and subsequently transmit to the company the respective aggregated data, allegedly for the

<sup>30</sup> *EU General Data Protection Regulation (GDPR)*: Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation), OJ 2016 L 119/1.

<sup>31</sup> The GDPR applies to the treatment of personal data as defined by Article 4 and Recital 26. According to Article 2(1) of the GDPR, the situations here described involving the processing of health data through femtech app, fall in the material scope of the regulation.

<sup>32</sup> Clue (<https://play.google.com/store/apps/details?id=com.clue.android&hl=en&gl=US>) is a very popular fertility tracking app that claims to merely use the data for scientific research: “When you track in Clue, you contribute to an unprecedented data set that is forwarding the understanding of female health” (Amanda Shea, Scientific research at Clue, Clue, June 20 2022, <https://helloclue.com/articles/about-clue/scientific-research-at-clue>).

<sup>33</sup> Likewise, Flo (<http://bit.ly/3Z00JDI>) is a very popular menstrual and period tracker, that some consider the number one female OB-GYN (<https://www.news-medical.net/news/20220322/Flo3b-Much-more-than-a-period-tracker.aspx>).

<sup>34</sup> See <https://bit.ly/3YHhQJj>.

<sup>35</sup> Data brokers (i.e., companies that sell personal data) are selling abortion related data for merely \$160 (B. CORBIN, op. cit., 5).

<sup>36</sup> Ovia is a fertility, pregnancy tracking, and parenting app; (<https://play.google.com/store/apps/details?id=com.ovuline.fertility&hl=en&gl=US>).

company to better manage their costs with health insurance plans.<sup>37</sup> However, it is fair to assume that some more business-related concerns were the base of such requests to access data, namely, to identify how many employees were planning to have children (and thus will be unavailable to work). Data retrieved from femtech solutions could also trigger strong discrimination by health insurers based on the “fertility status” or other health issues related to women. This may be the case, for example, if a private insurance company comes into possession of data symptomatic of an infertility condition or concerning the presence of breast cancer or other pathologies that would require specific medical treatment.<sup>38</sup> The breach of strictly private information such as this not only leads to privacy violations, as it also can carry detrimental consequences for the ones involved because once it gets into the hands of insurance companies, the latter might consider not covering that individual or doing it at much higher rates.<sup>39</sup>

Femtech solutions could boost targeted – and perhaps politicized – advertising campaigns. Femtech apps frequently incorporate social media plugins and built-in features that link to forums focused on health issues. While users may view these forums as closed places, businesses and other parties frequently view this information as public.<sup>40</sup> The user may not always be aware of the group’s interests that are driving the apps. For instance, a 2019 Guardian investigation revealed that a period and fertility tracking app was backed by Catholic anti-abortion and anti-gay activists and that it was unclear how the app owners and these other entities were using the aggregated data sets.<sup>41</sup> Furthermore, there is a strong chance that misinformation will continue to circulate through these forums, a phenomenon that has been well-researched in relation to other healthcare-related topics, such as anti-vaccination movements.<sup>42</sup>

#### 4. Controlling women by using femtech stereotypes

##### 4.1. The criticisms of femtech as a mechanism of oppression

Besides the potential risks due to the misuse of these technologies by private and public actors, the marketing and use of femtech solutions might simultaneously enforce and impose various oppressive biases that have historically plagued women. It has been extensively argued that

<sup>37</sup> D. HARWELL, *Is your pregnancy app sharing your intimate data with your boss?*, in *The Washington Post*, April 2019, <https://www.washingtonpost.com/technology/2019/04/10/tracking-your-pregnancy-an-app-may-be-more-public-than-you-think/?noredirect=on>.

<sup>38</sup> M. CROSSLEY, *Discrimination against the unhealthy in health insurance*, in *Kansas Law Review*, 54, 2005, 73.

<sup>39</sup> M. MEHRNEZHAD, L. SHIPP, T. ALMEIDA, E. TOREINI, *Vision: Too Little too Late? Do the Risks of FemTech already Outweigh the Benefits?* In Proceedings of the 2022 European Symposium on Usable Security (EuroUSEC '22). Association for Computing Machinery, New York, NY, USA, 145-150.

<sup>40</sup> L. SHIPP, J. BLASCO, *How private is your period?: A systematic analysis of menstrual app privacy policies*, in *Proc. Priv. Enhancing Technol.*, 4, 2020, 491-510.

<sup>41</sup> J. GLENZA, *Revealed: women’s fertility app is funded by anti-abortion campaigners*, in *The Guardian*, <https://www.theguardian.com/world/2019/may/30/revealed-womens-fertility-app-is-funded-by-anti-abortion-campaigners>.

<sup>42</sup> G. PENNYCOOK ET AL., *Shifting attention to accuracy can reduce misinformation online*, in *Nature*, 592, 2021, 590-595.

femtech presumes compliance with the stereotypical role of the woman.<sup>43</sup> Through the use of predefined settings and design assumptions, such as choice of specific layouts and features,<sup>44</sup> it is said that femtech developers have created products that categorize women, imposing a range of values that are considered “normal”. In consequence, it arguably ostracizes women whose personal and unique biology is not within the range of artificial normal values,<sup>45</sup> requiring women to flatten to cultural standards. These perspectives argue that numerous subsets of women, including transgender women, are excluded, stigmatized and devalued in their most intimate experiences.

Some authors have envisaged even more obscure outcomes related to the oppression and the stereotyping of women. Elisabeth Brown gives the following example: suppose that the data collected from a menstruation tracking app reveal that women’s brains operate differently during the different stages of the fertility cycle. In the “wrong hands” this information might be used to exclude competent women from top leading positions, by synchronizing (or desynchronizing) their agenda in such a way that important tasks are scheduled for those less auspicious days, leading to women’s dismissal for poor performance.<sup>46</sup> At the same time, this information could be used as a scientific basis to relegate women to a role of semi-incapacity, once again subjecting them to male power. The outcome is particularly gloomy if we look into a futuristic scenario where instead of apps femtech embraces mandatory wearable devices or even mandatory implantable chips.<sup>47</sup> However, there is no sound ground for such an apocalyptic feminist scenario.

#### 4.2. The criticism of the criticism

It is a fact that conception or fertility-related technologies may work with the presumption that users adhere to specific social, sexual, and physical standards.<sup>48</sup> It could not be in any other way. Data-driven products are developed based on given standards, which refer to the source of the data used and on a population-based statistical model. However, it should be recognised that in the specific case of femtech products the standard relates to gender-based norms and “gender-based reprisals” (prejudice, discrimination) that women often face. Digital products tend to tell women what their biological characteristics should be (e.g. a thirty-day cycle), what reproductive goals they should aim for (e.g. through the apposition of a smiley face on a menstruation monitoring app when a woman does not have her period, which means her goal should be pregnancy), and what their sexual activi-

<sup>43</sup> M.E. GILMAN, *Periods for Profit and the Rise of Menstrual Surveillance*, in *Columbia Journal of Gender and Law*, 41, 1, 2021, 100-13.

<sup>44</sup> Often presented in pastel colours and “feminine” motifs (e.g., hearts and flowers).

<sup>45</sup> J. MCGRATH, *With Period-Tracking Apps, the Fate of Your Fertility Is Far from Clear*, in *Digital trends*, September 2019, <http://www.digitaltrends.com/mobile/the-problems-and-promises-of-periodtracking-apps/>; M. MCHUGH, *Does Femtech Give Users Control of Their Health or Take It Away?*, in *Ringer Tech*, <http://bit.ly/3ICY3q0> (explaining that “many health apps try to shove users and their bodies into strict categories”).

<sup>46</sup> E.A. BROWN, *op. cit.*, 1.

<sup>47</sup> About mandatory wearable devices, see V.R. RAPOSO, *Big Brother Knows that you are infected: wearable devices to track potential COVID-19 infections*, in *Law, Innovation and Technology*, 13, 2, 2021, 422-438;

<sup>48</sup> D LUPTON, “Mastering Your Fertility” *The Digitised Reproductive Citizen*, in A. MCCOSKER, S. VIVIENNE, A. JOHNS (eds), *Negotiating Digital Citizenship: Control, Contest and Culture*, 2016, 81-87.

ties and preferences should be (with images on the apps strongly focusing on male genitalia).<sup>49</sup> The way in which fertility (and its importance) is socially and culturally constructed has a direct impact on the well-being of women and thus these arbitrary standards reinforce the notion of otherness for women who do not – and often cannot – conform.<sup>50</sup>

However, against these criticisms, it seems appropriate to make two observations. Firstly, the generalised attack on femtech on several fronts would seem to lead to the unequivocal solution of giving up on this sector of medical innovation. A solution that is more drastic than sensible, renouncing innovation and the undeniable benefits of such applications, rather than building on them to improve femtech products. How is it better to fossilise innovation until the perfect balance of viewpoints is found, instead of advancing step by step towards a more comprehensive solution? Putting it even more simply, better no one than someone? Secondly, the criticism cannot be built in such a way that the desire of having kids, shared by many women, becomes the target. One thing is to argue that femtech apps shall be designed to embrace a more diversified range of users, especially considering transgenders and women who do not want/can have children; and that femtech could be featured less stereotypically, recognising that women, as well as women's tastes and desires, are not uniform. A different thing is to claim that femtech is a mechanism of female oppression and that we all will be shaped to think alike because of femtech. While the first observation is broadly agreeable, the second leads to the inevitable reversed discrimination against the "standardized women" represented in femtech. The claim that femtech and other technologies alike are oppressing women that do not want/can have kids might be reverted into an opposite criticism: would the ban of these technologies be an attack on women that do want to have kids?

## 5. The legal framework of femtech within European law

Within the EU, femtech manufacturers must untangle themselves in a waltz of old, renewed and desired regulations, which contribute in varying degrees to the regulation of these products. Regulation cannot solve all the problems raised by femtech. However, some of them, especially the ones related to safety and data, might benefit from a proper legal framework.

The first set of legal norms derives from the qualification of femtech as medical software. Some femtech apps and/or devices are considered medical devices in the EU under the Medical Devices Regulation (EU) 2017/745 (MDR)<sup>51</sup>, as software aimed for medical purposes. Medical devices in the EU should be certified following the demand requirements of the MDR and thus the manufacturer will have to satisfy growing safety requirements according to the risks related to the device.<sup>52</sup>

<sup>49</sup> C. McMILLAN, *op. cit.*, 1.

<sup>50</sup> MCHUGH, *op. cit.*, 7; J. TODRES, *Law, Otherness, and Human Trafficking*, in *Santa Clara Law Review*, 49, 2009, 605.

<sup>51</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) (OJ L 117 05.05.2017, 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

<sup>52</sup> See the classification system explained in S. PALMIERI, T. GOFFIN, *A blanket that leaves the feet cold: exploring the AI Act safety framework for medical AI*, in *European Journal of Health Law*, 1, 2023.

Femtech software frequently works based on artificial intelligence (AI) in its various forms (AI *stricto sensu*, machine learning).<sup>53</sup> The fact that it is constantly developing based on the “self-learning” components raises complex issues, as the current legal frameworks in Europe (and around the world) is not yet prepared to support AI models and applications. Regulators are debating how to guarantee the security, efficacy, and performance of AI-enabled medical devices, applications, and other digital technologies used in healthcare. Designing and establishing proportional legislation that permits a safety risk-based strategy to oversee AI-powered systems is a crucial problem in this regard. In this vein, the EU has made numerous efforts in recent years to curb the risks arising from big data and new technologies through robust regulatory proposals.

One of such set of norms, still in the draft stage, is the so-called AI Act.<sup>54</sup> AI-based medical devices – as it is the case of many femtech apps and related femtech technologies – are considered high-risk AI systems under the AI Draft Act,<sup>55</sup> and as such they must comply with various requirements before getting the CE marking of conformity and being allowed to go into the market.<sup>56</sup> One of such requirements relates to cybersecurity safeguards, which, in turn, might be useful to prevent undue access to information gathered by the device.

The harm caused by femtech devices is another concern. The Product Liability Directive, currently under reformulation,<sup>57</sup> provides a regime of strict liability for defective products, and it will soon be complemented by the AI Liability Directive.<sup>58</sup> The Product Liability Directive is targeted at safety issues pertaining to the use of such devices, while the AI Liability Directive relates to other malfunctions. Undue access or undue use of data are not among the issues included in the Directives, even though the revised Product Liability Directive will cover “material losses due to the loss, destruction or corruption of data”,<sup>59</sup> as confirmed by Article 6(4)(c) of the draft, that lists the “loss or corruption of data that is not used exclusively for professional purposes” as one of the damages to be covered by this Directive.

<sup>53</sup> V. SUBBHURAAM, B.K. WIEDERHOLD, *Femtech: Digital Help for Women’s Health Care Across the Life Span*, in *Cyberpsychology, Behavior, and Social Networking*, 24, 11, 2021, 697-698; C. ROSAS, *The Future Is Femtech: Privacy and Data Security Issues Surrounding Femtech Applications*, in *Hastings Business Law Journal*, 15, 2, 2019, 319-341; L.M. BRAYBOY, A.M. QUAAS, *The DIY IVF cycle—harnessing the power of deeptech to bring ART to the masses*, in *J Assist Reprod Genet*, 2022.

<sup>54</sup> Proposal for a Regulation of the European Parliament and of the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union Legislative acts, COM/2021/206 final, meanwhile already updated. The last version – and all the ones in between – in <https://artificialintelligenceact.eu/developments/>.

<sup>55</sup> S. PALMIERI, P. WALRAET, T. GOFFIN, *Inevitable Influences: AI-Based Medical Devices at the Intersection of Medical Devices Regulation and the Proposal for AI Regulation*, in *European Journal of Health Law*, 28, 4, 2021, 341-358.

<sup>56</sup> V.L. RAPOSO, *Ex machina: preliminary critical assessment of the European Draft Act on artificial intelligence*, in *International Journal of Law and Information Technology*, 30, 1, 2022, 88-109;

<sup>57</sup> Proposal for a Directive of the European parliament and the Council on liability for defective products ([https://single-market-economy.ec.europa.eu/document/3193da9a-cecb-44ad-9a9c-7b6b23220bcd\\_en](https://single-market-economy.ec.europa.eu/document/3193da9a-cecb-44ad-9a9c-7b6b23220bcd_en)).

<sup>58</sup> Proposal for a Directive of the European parliament and the Council on adapting non-contractual civil liability rules to artificial intelligence (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0496>).

<sup>59</sup> Proposal for a Directive of the European parliament and the Council on liability for defective products – Explanatory Memorandum, 30.

Moreover, compliance with the data regulations norms is required: the GDPR for a start, and eventually the future Data Act,<sup>60</sup> Data Governance Act,<sup>61</sup> and European Health Data Space.<sup>62</sup> Presently, the GDPR is the law that best protects data subjects from undue and illegitimate access.<sup>63</sup> According to it, any data processing requires a proper legal ground,<sup>64</sup> to be found in Article 6(1) of the GDPR and, in case sensitive data are involved (as it is the case of health and genetic data), an additional one in Article 9(2) GDPR. Violations of the GDPR can lead to severe administrative penalties and allow the data subject that suffered moral or material harm to file a compensation request (chapter 8 of the GDPR).<sup>65</sup>

From all the potentially problematic issues raised by femtech, the possible discrimination and eventual oppression is the one we can most hardly trace back to a precise source of EU law, or, for what matters, in any law. Some of the norms of the Charter of Fundamental Rights<sup>66</sup> could be applicable, namely Articles 1 (Human dignity), 7 (Respect for private and family life), 8 (Protection of personal data), 10 (Freedom of thought, conscience and religion), 20 (Equality before the law), 21 (Non-discrimination), 22 (Cultural, religious and linguistic diversity) and 23 (Equality between women and men), 38 (Consumer protection), as well as others secondary regulations on non-discrimination.<sup>67</sup> However, the exact consequences of femtech in what regards women's oppression (or, at least, some women) is a matter open to debate and thus it is not evident how would these rights apply to a potential claim.<sup>68</sup>

<sup>60</sup> Proposal for a Regulation of the European Parliament and of the Council on harmonised rules on fair access to and use of data (Data Act), Brussels, 23.2.2022 COM(2022) 68 final 2022/0047 (COD), Strasbourg, 3.5.2022 COM(2022) 197 final 2022/0140 (COD).

<sup>61</sup> Proposal for a Regulation of the European Parliament and of the Council on European data governance (Data Governance Act) COM/2020/767 final.

<sup>62</sup> Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space.

<sup>63</sup> Compared to the protection offered to individual rights by other legal instruments dedicated to the protection of personal data, the GDPR adopts a more guarantee-based approach. See C.J. MCKINSTRY, *The HIPAA Privacy Rule: Flawed Privacy Exposed When Compared with the European Union's General Data Protection Regulation*, in *Journal of healthcare Finance*, 45, 1, 2018; see also the case Privacy Shield ECLI:EU:C:2020:559; More in general see: G. CHASSANG, *The impact of the EU general data protection regulation on scientific research*, in *Ecancermedicalscience*, 3, 11, 709, 2017; <http://bit.ly/3SaMmKe>.

<sup>64</sup> Principle of lawfulness of processing (Article 5(1)(a) GDPR).

<sup>65</sup> More details in C.J. HOOFNAGLE, B. VAN DER SLOOT, F. ZUIDERVEEN BORGESIU, *The European Union general data protection regulation: what it is and what it means*, in *Information & Communications Technology Law*, 28, 1, 2019, 65-98.

<sup>66</sup> Charter of Fundamental Rights of the European Union, [http://data.europa.eu/eli/treaty/char\\_2012/oj](http://data.europa.eu/eli/treaty/char_2012/oj).

<sup>67</sup> Directive 2000/43/EC against discrimination on grounds of race and ethnic origin; Directive 2000/78/EC against discrimination at work on grounds of religion or belief, disability, age or sexual orientation; Directive 2006/54/EC equal treatment for men and women in matters of employment and occupation; Directive 2004/113/EC equal treatment for men and women in the access to and supply of goods and services; Directive Proposal (COM(2008)462) against discrimination based on age, disability, sexual orientation and religion or belief beyond the workplace.

<sup>68</sup> More details on how the Charter protect women's rights in R. GUERRINA, *Gender, Mainstreaming and the EU Charter of Fundamental Rights*, in *Policy and Society*, 22, 1, 2003, 97-115.

## 6. What about the future?

Femtech was born as a mechanism of women's liberation and self-determination, but with recent legal changes in some jurisdictions, it risks becoming a mechanism of women's external control. The diffusion of femtech can certainly allow accessible and supportive healthcare, offering a sense of community, but also, as the discussion explored, a network of false or manipulative information, data gathering, and profiteering. It seems that women's issues reached the wrong side of the public area: instead of becoming a tool for emancipation, they became a mechanism for persecution and external control from governments, employers, and potentially any other entity (insurance companies, doctors). Some go even further and claim that femtech became a mechanism of women's oppression, though the substance of such radical accusations remains controversial.

As discussed earlier in the paper, some of the most popular fertility apps turned out to be sharing very intimate data of their user to advertisement companies. Fearing that poor data privacy and security practices could result in the disclosure of their reproductive data to law enforcement agencies, who could use it to investigate and prosecute women who have had illegal abortions, many women gave up on their femtech apps or swap for more privacy compliant apps.<sup>69</sup> If governments cannot have access to the information collected by the apps, access to their bodies is likewise barred.

As smart as this strategy is, it takes with it an evident downside: femtech, especially AI-driven femtech, needs data to improve and develop a better version of itself. However, if women up their fertility apps – and many women are doing that to avoid having their bodies controlled by public powers – the amount of collected data will substantially decrease, thus jeopardizing the future of femtech.<sup>70</sup> With fewer data, the accuracy of femtech apps will decrease.<sup>71</sup> Apps, especially AI-based apps, are only as good as the data they have been provided with. The lack of data and failures in their quality and quantity raise biases and lead to discriminatory and inexact results.<sup>72</sup>

In order to prevent these outcomes, femtech companies shall develop more robust privacy and cybersecurity measures and adopt FAIR data quality standards.<sup>73</sup> Such events led some femtech companies to consider adjustments and changes that are already taking place. Not long ago, the femtech app Flo announced that considering how data collected by femtech apps are being used to persecute women for illegal abortion they would include an “anonymous mode” to prevent the user's identifi-

<sup>69</sup> <https://bit.ly/4185Sep> (last visited 8/02/2023).

<sup>70</sup> B. CORBIN, *op. cit.*, 5.

<sup>71</sup> C. McMILLAN, *op.cit.*, 1.

<sup>72</sup> M. MEHRNEZHAD, T. ALEMIDA, *Caring for Intimate Data in Fertility Technologies*, CHI '21: Proceedings of the 2021 CHI Conference on Human Factors in Computing Systems, 409, 2021, 1-11.

<sup>73</sup> Research around the concept of data quality is a booming area. Today, there are numerous standards and systems for assessing data quality. Among many, by way of example and for assonance with the phrase referred to, we mention FAIR, which stands for findability, accessibility, interoperability, and reusability. See <https://www.go-fair.org/fair-principles/>. To date, there is no universally accepted data quality standard. However, there is a shared need, especially in the health sector, to find this standard to improve the quality of care, as expressed in the recent Porto Declaration (<https://www.i-hd.eu/health-data-forum-2022/ihd-porto-declaration-on-health-data-quality-2022/>).

cation.<sup>74</sup> These obvious cautions, however, will have little impact if the legal framework allows the state to gain access to such data for law enforcement purposes.

If femtech companies fail to protect their users, women will very likely abandon the use of these products, eventually converted into mechanisms of control. This outcome will jeopardize women's rights (reproductive rights, rights over the body, privacy rights) and sink what has been up until now a very profitable business.

Femtech should go back to what it was meant to be: a tool to empower women. Maybe for now it cannot satisfy all women, as we came in different "shapes and forms", but hopefully in the future femtech can develop to cover a wide range of the female public. If and when that happens femtech will become much more respectful of individual rights and liberties (and, by the way, much more profitable).

*Special issue*

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<sup>74</sup> <https://www.femtechworld.co.uk/news/period-tracker-app-flo-introduces-anonymous-mode-after-roe-outcome/>.

