IS THE USE OF ARTIFICIAL INTELLIGENCE IN THE FEMTECH INDUSTRY FEMINIST? THE BIOETHICAL AND LEGAL DILEMMAS IN THE FEMTECH INDUSTRY FROM A FEMINIST PERSPECTIVE

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ABSTRACT

This article offers another 'take' on the lively and current discussions being held on the outline of bioethical principles and legal regulation of artificial intelligence technologies, in the areas of medicine and health. It examines to what extent women's interests and feminist agendas are taken into account in these discussions. For this purpose, the article focuses on the FemTech industry. It is specifically interested in AI-based technologies in the area of medicine and health that targets women and is focused on female issues. By doing so, the article studies the crossroads between AI-based technologies' regulation, devices in favor of medicine and health, and technologies targeted for women.

Based on empirical illustrations, and in light of the current positive law, the article explores the bioethical and legal dilemmas in the FemTech Industry from a feminist perspective. It specifically asks whether the use of AI in the FemTech industry can be considered feminist. In other words, it explores whether the technologies that aim to treat women's health, address new challenges facing feminist ethics or social philosophy, or if they simply raise old bioethical questions in relation to new technologies. The article looks at the advantages, alongside the challenges, of AI-based FemTech devices from a feminist perspective. Additionally, it sets the grounds for a feminist regulatory and ethical policy, with respect to AI-based medical devices.

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I. INTRODUCTION

> *I'm increasingly inclined to think that there should be some regulatory oversight, maybe at the national and international level, just to make sure that we don't do something very foolish. [I mean] with artificial intelligence we're summoning the demon.*[1]
>
> [- Elon Musk -]

> *The real question is, when will we draft an artificial intelligence bill of rights? What will that consist of? And who will get to decide that?*[2]
>
> [- Gray Scott -]

As can be evidenced in Elon Musk's comment and Gray Scott's question, the topic of artificial intelligence-based technologies' regulation and its connection to human rights protection have been, for quite a long time, a matter of interest for governments, industries, and scholars.[3] This article focuses on a narrow aspect of the topic of artificial intelligence (AI) regulation and its protection of human rights – that is the protection of women's interests and the preservation of feminist principles – in the course of regulation of AI. As

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1. Samuel Gibbs, *Elon Musk: Artificial Intelligence is Our Biggest Existential Threat*, THE GUARDIAN (Oct. 27, 2014) (emphasis added), https://www.theguardian.com/technology/2014/oct/27/elon-musk-artificial-intelligence-ai-biggest-existential-threat[https://perma.cc/Y8KB-22C9].

2. Gray Scott, *Gray Scott Quotes*, BRAINYQUOTE, https://www.brainyquote.com/quotes/gray_scott_776538 [https://perma.cc/4KLE-HHQ9] (last visited Oct. 20, 2024).

3. *See, e.g.*, Scott J. Shackelford, et al., *Should We Trust a Black Box to Safeguard Human Rights? A Comparative Analysis of AI Governance*, 26 UCLA J. INT'L L. & FOREIGN AFFS. 35, 37–39 (2022); Kimberly A. Houser, *Symposium: Artificial Rights? Artificial Intelligence and the Struggle Between Good and Evil*, 60 WASHBURN L.J. 475, 475–76 (2021); David S. Rubenstein, *Acquiring Ethical AI*, 73 FLA. L. REV. 747. 747, 749–57 (2021).

Melinda Gates stated: "If we don't get women […] at the table – real technologies doing the real work – we will bias systems. Trying to reverse that a decade or two from now will be so much more difficult, if not close to impossible."[4] This article is specifically interested in AI-based technologies in the area of medicine that targets women and focuses on female issues.

The crossroads between regulation of AI-based technologies, medical and health devices, and technologies that target women, have rarely been studied.[5] While there is a digital revolution happening in the field of medical devices, medical devices have historically been less regulated than their drug and biologic counterparts.[6] The FDA proposed a new framework for review of the ongoing artificial intelligence algorithm changes for device software.[7] Moreover, cutting-edge literature is preoccupied with the question: What should a robust regulatory regime for medical devices look like in the coming years?[8] This question has yet to be studied with respect to technological solutions and innovations addressing women's issues.

Based on empirical illustrations, and in light of the current positive law, I offer an initial discussion on the bioethical and legal dilemmas in the FemTech Industry from a feminist perspective. I specifically ask whether the use of AI in the FemTech industry can be considered feminist. In other words, I explore whether the technologies that aim to take care of women's health, address new challenges facing feminist ethics or social philosophy. Another option is that these technologies simply raise old bioethical questions in relation to new technologies.

This article explores the advantages, alongside the challenges, of AI-based FemTech devices from a feminist perspective. I set the grounds for a feminist

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4. *See* Jessi Hempel, *Melinda Gates and Fei-Fei Li Want to Liberate AI from "Guys With Hoodies"*, WIRED-BACKCHANNEL (May 4, 2017), https://www.wired.com/2017/05/melinda-gates-and-fei-fei-li-want-to-liberate-ai-from-guys-with-hoodies/ [https://perma.cc/6ERA-MWR3].

5. On the regulation outlines of AI-based technologies in the medical and health arena, *see generally* Nicolas Terry, *Of Regulating Healthcare AI and Robots*, 18 YALE J. HEALTH POL'Y L. & ETHICS 133 (2019); SARA GERKE, ET AL., *Ethical and Legal Challenges of Artificial Intelligence-Driven Healthcare*, *in* ARTIFICIAL INTELLIGENCE IN HEALTHCARE 295 (Adam Bohr & Kaveh Memarzadeh eds., 2020); Jessa Boubker, *When Medical Devices Have a Mind of Their Own: The Challenges of Regulating Artificial Intelligence*, 47 AM. J.L. & MED. 427 (2021); Catherine M. Sharkey & Kevin M.K. Fodouop, *AI and the Regulatory Paradigm Shift at the FDA*, 72 DUKE L.J. ONLINE 86 (2022). For exceptional writing on the ethical challenges relating to technologies that target women, *see* Bethany A. Corbin, *Digital Micro-Aggressions and Discrimination: Femtech and the "Othering" of Women*, 44 NOVA L. REV. 337 (2020); Leah R. Fowler & Michael R. Ulrich, *Femtechnodystopia*, 75 STAN. L. REV. 1233 (2023); MICHELE E. GILMAN, *Feminism, Privacy and Law in Cyberspace*, *in* THE OXFORD HANDBOOK OF FEMINISM AND LAW IN THE UNITED STATES 552 (Deborah Brake et al eds., 2023).

6. Wendy Netter Epstein, *Disrupting the Market for Ineffective Medical Devices*, *in* THE FUTURE OF MEDICAL DEVICE REGULATION: INNOVATION AND PROTECTION 179 (I. Glenn Cohen et al. eds., 2022).

7. *Id.* at 179–80.

8. *Id*.

regulatory and ethical policy, with respect to AI-based medical devices. The next second section of this article introduces the entrance of AI-based technologies to the FemTech industry. The third section discusses and exemplifies the main areas of interest of the FemTech industry. The forth section presents the topic of raising funds for the FemTech industry, and its challenges. The fifth section introduces the research questions, approach, and method. The sixth section studies the opportunities and challenges of applying AI-based technologies in the FemTech industry from a feminist perspective. The seventh section sets an initial normative horizon for feminist regulation of AI-based medical technologies. The eighth section offers some concluding remarks.

II. ARTIFICIAL INTELLIGENCE & THE FEMTECH INDUSTRY

The term "FemTech" was first coined in 2016 by entrepreneur Ida Tin.[9] FemTech is described as any digital technology in the female health sector.[10] The industry includes, inter alia, wearable AI, mobile applications, diagnostic tools, or monitoring software for managing women's health. The issues to be considered in women's health include, among others, fertility, reproduction, menstruation, diseases typically recognized as women's diseases (e.g., breast or cervical cancer), mental health, and sexuality.

Ever since the term FemTech was coined, its global market has grown to become a sector of its own right. In 2022, the global MedTech market reached 646.7 billion US dollars.[11] FemTech companies accounted for 28 billion US dollars in 2024.[12] The sector has over 1800 companies and is still growing.[13] However, it is not receiving the recognition it should, considering the fact that women make up over fifty percent of the general population.[14] Nevertheless, it seems that the FemTech sector is rapidly increasing, and it has been estimated that it will reach 766.7 billion US dollars by 2025.[15]

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9. *See* Marija Butkovic, *Top 100 Women in FemTech and Health Tech*, MEDIUM (Apr. 13, 2019), https://medium.com/women-of-wearables/top-100-women-in-fem-tech-and-health-tech-34eccf021053 [https://perma.cc/W43S-5N2R].

10. Corbin, *supra* note 5, at 338–39.

11. *See 2023 – A Maintenance Phase of the Pandemic, unless Covid Rears its Ugly Head Again*, MED. BUYER (Dec. 27, 2022), https://www.medicalbuyer.co.in/2023-a-maintenance-phase-of-the-pandemic-unless-covid-rears-its-ugly-head-again/ [https://perma.cc/X8EJ-92WR].

12. *See Femtech: What is Femtech?*, DEALROOM.CO, https://dealroom.co/guides/femtech#:~:text=Femtech%20companies %20are%20now%20worth%20%2428%20billion%20in%202023 [https://perma.cc/XD5M-A8H9] (last visited Oct. 20, 2024).

13. *See* Ariela Karmel, *Israel is Poised to Lead the Way in FemTech, but Challenges Remain in Realizing Full Potential*, CTECH BY CALCALIST (June 7, 2023), https://www.calcalistech.com/ctechnews/article/hjggw0ti2 [https://perma.cc/M6JD-4JK8].

14. *See* Corbin, *supra* note 5, at 342–47.

15. MEDICAL BUYER, *supra* note 11.

In recent years the idiomatic phrase, "artificial intelligence," has described machines, or computers, whose work is perceived as smart, sophisticated, or human.[16]

The various trials to define "artificial intelligence" can be divided into two major definitions – technological definitions and functional definitions.

The technological definitions usually focus on the basic abilities of the AI-based tools, and they are mostly identified with the areas of data science and machine learning. While data science focuses on producing information and deriving insights from existing databases, machine learning emphasizes the ability of machines to learn and improve the implementation of activity based on data, examples and acquired experience. Both data science and machine learning are interested in the technological essence of collecting and producing data, in order to fulfill a given algorithmic task.

Functional definitions of artificial intelligence, on the other hand, focus on the comparison to human thinking or human concluding processes.[17] For the purposes of this article, the area of artificial intelligence will be identified as a general name for all technological developments that enable decision-making, produce forecasts, or any other activity by computers working at a high level of independence that imitate or substitute human intelligence.

III. THE FOCUS OF FEMTECH PRODUCTS: DISEASES, FERTILITY, AND SEXUALITY

Most AI-based products in the FemTech industry can be divided into three areas of expertise. The first is concerned with women's illness. This refers to all processes of detection, diagnosis, and treatment of diseases and conditions that affect women's health. The second is focused on fertility and reproduction – namely the ability to conceive children. The third area of FemTech products is

16. WORLD HEALTH ORGANIZATION GUIDANCE, ETHICS AND GOVERNANCE OF ARTIFICIAL INTELLIGENCE FOR HEALTH 4 (2021).

17. The OECD's definition of AI focuses on its functional abilities. According to this definition, an AI system is a machine-based system that can make predictions, recommendations, or decisions, for a given set of human-defined objectives that influence real or virtual environments. AI systems, thus, are designed to operate with varying levels of autonomy. *See* OECD COUNCIL, RECOMMENDATION OF THE COUNCIL ON ARTIFICIAL INTELLIGENCE 7 (2019), https://legalinstruments.oecd.org/en/instruments/oecd-legal-0449 [https://perma.cc/K82F-VB34].

A similar definition was included in the European Draft Act on Artificial Intelligence (AI) and the Canadian draft of AI legislation. *See* EUR. CONSULT. ASS., *Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence (Artificial Intelligence Act) And Amending Certain Union Legislative Acts*, Doc. No. 8115/21 (2024) [hereinafter *Proposal for European Council Regulation*]; HOUSE OF COMMONS OF CANADA, BILL C-27, AN ACT TO ENACT THE CONSUMER PRIVACY PROTECTION ACT, THE PERSONAL INFORMATION AND DATA PROTECTION TRIBUNAL ACT AND THE ARTIFICIAL INTELLIGENCE AND DATA ACT, IN ORDER TO MAKE CONSEQUENTIAL AND RELATED AMENDMENTS TO OTHER ACTS, 3 (2022) https://www.parl.ca/Content/Bills/441/Government/C-27/C-27_1/C-27_1.PDF [https://perma.cc/FBL2-HXN2].

connected to female sexuality. This endeavors to advance female sexual wellbeing and enables women to make positive choices about their own sexual lives. For purposes of illustration and later discussion, a few representative and non-exhaustive examples of products in the abovementioned areas of expertise will be provided here.

A. Diseases

AI technologies improve the detection, diagnostics, and treatment of female related illnesses. An example of a typical AI-based product, which endeavors to prevent and handle well-known female diseases, was developed by the Nevia start-up.[18] Nevia works at detecting female diseases, based on an AI analysis of vaginal discharge.[19] Due to the existence of various proteins in vaginal discharge, the changing rate of each protein is a good predictor of different kinds of diseases, starting from cervical and ovarian cancer, through ovulation problems, to endometriosis. The company developed smart pads, which are analyzed by an AI algorithm, in order to detect female diseases.[20] These smart pads are intended to be marketed as a shelf product, like home pregnancy detection tests. The company's algorithm is based on analysis of a unique Israeli bio-bank, the first of its kind.[21] Vaginal discharge samples have been deposited since 2019.[22]

In an innovative fashion, Nevia's AI algorithm takes into account vaginal discharge, as a source of medical knowledge. To date, medical research has barely treated vaginal discharge as a source of knowledge.[23] When Dr. Inbal Zafir-Lavie, one of Nevia's founders, was asked why the medical research had not previously treated vaginal discharge as a source of knowledge, she answered:

> When I stand in front of men and talk to them about vaginal discharge […] I frequently need to explain to them what I mean by vaginal discharge. They do not completely understand. I tell them that it is liquid, similar to tears. However, if one is not aware of a material, how can we expect them to study it? […] It is that simple. […] Men can study […] urine, […] blood, spittle, and sperm, but vaginal discharge is a red rag which they prefer to disregard.[24]

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18. On the Nevia start-up, *see The New Way for Early Detection*, NEVIA, https://www.nevia.bio/ [https://perma.cc/H7ZR-Z9QH] (last visited Sept. 22, 2024).

19. *Id.*

20. Roni Dori, *Vaginal Discharge is a Treasure of Information*, CALCALIST (Nov. 4, 2021), https://newmedia.calcalist.co.il/magazine-04-11-21/m01.html [https://perma.cc/6PVD-HH5Z].

21. *Id.*

22. *Id.*

23. *Id.*

24. *Id.*

Nevia's algorithm is designed, inter alia, to detect endometriosis.[25] Its symptoms include chronic pain, difficulties in getting pregnant and continuous bleeding during a woman's period.[26] Though one out of ten fertile women suffers from endometriosis, the reported average diagnosis time of this disease is ten years.[27] The accepted explanation for this unfortunate fact is physicians' ignorance.[28] Training Nevia's AI algorithm on a new source of medical knowledge – namely, vaginal discharge – aims to enable the detection of endometriosis, a disease from which women have traditionally suffered due to underdiagnosing and a lack of needed treatment.[29] Tulipon also developed an innovative tampon that monitors vaginal discharge and diagnoses diseases, based on biomarkers in the woman's menstruation.[30] Enthusiastically describing Tulipon's development, its founder, Hila Shaviv, stated:

> *I consider myself a female knight, fighting for gender parity by developing new technologies that address women's health and wellbeing.*[31] (emphasis added)

Another area of AI-based products in the FemTech industry focuses on fertility and women's reproduction. The following section is dedicated to illustrating this market niche.

B. Fertility

A rich variety of AI applications in the area of female fertility and reproduction are presently under development or marketing. These include, inter alia, the assessment of ovarian reserve parameters, the prediction of live-birth occurrence, improved matching of egg donors with receipts for third-party reproduction, enhanced pre-implantation genetic testing (PGT), etc.[32] An

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25. *See The New Way for Early Detection*, *supra* note 18.

26. Dori, *supra* note 20.

27. *Id.*

28. *Id.*

29. *Id.*

30. On the Tulipon start-up, *see Tulipon: Empowering Women with Home Period Diagnostics*, TULIPON, https://www.tulipon.com/ [https://perma.cc/F4A7-PQZY] (last visited Sept. 19, 2024). Similarly, Mobile ODT is an Israeli FemTech company that aims to create a revolution in the area of cervical cancer, which is the fourth-ranked cancer in the world. The company developed a smartphone-based technology using AI, in order to perform early detection of cervical cancer. *See High Technology for Women's Health*, MOBILEODT, https://www.mobileodt.com/ [https://perma.cc/HP3F-KJTB] (last visited Sept. 22, 2024).

31. *Interview with Eng. Hilla Shaviv, Inventor, Founder and CEO, Gals Bio Ltd.*, FEMTECH ANALYTICS (Jan. 18, 2022), https://www.femtech.health/post/interview-with-eng-hilla-shaviv-inventor-founder-and-ceo-gals-bio-ltd [https://perma.cc/DA3B-2MTD].

32. *See* Sivan Tamir, *Artificial Intelligence in Human Reproduction: Charting the Ethical Debate Over AI in IVF*, 3 AI & ETHICS 947, 948 (2023).

additional non-exhaustive example of the use of AI in gynecology is the potential integration of AI in IVF treatments.[33]

The start-up that claims to be the first one that initiated the introduction of AI into the IVF industry is AiVF.[34] AiVF offers a new technology that aims to simplify the IVF embryo selection process, by providing clinicians and embryologists with a fully automated AI-based decision support tool.[35] The company focuses on the embryo selection stage, in which the decision is made concerning which embryos have the best chances to develop into a full pregnancy.[36] As embryologist and AiVF CEO, Daniella Gilboa, puts it:

> The one million dollar question that all IVF units ask is 'which embryo has the best chance to turn into pregnancy.' You stand in front of the embryos and you need to pick 'the one'. The selection is made, based on years of experience of the embryologist and the physician. They see the embryos in the computer, diagnose them, look at their rate of division […] and try to grade each one of them. However, this grade is subjective and not based on data.[37]

AiVF designed its algorithm by studying millions of embryos, in order to be able to recommend which embryo is the best candidate for selection.[38]

An additional example of a product in the area of fertility and reproduction is the breakthrough for women's lives of self-scan ultrasound devices for AI-based and remote clinical diagnosis.[39] The home ultrasound system has real potential to provide doctors with better control of the prenatal path of care. For the patient, it could significantly reduce anxiety during pregnancy, thanks to the continuity of care between visits. The home ultrasound system gives the patients a better pregnancy experience and helps the non-pregnant partner to feel more involved.

Furthermore, AI-based devices for monitoring women's periods of fertility are recognized as FemTech products in the area of reproduction.[40] With the

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33. *Id*.

34. On the AiVF start-up, *see Next Generation IVF*, AIVF, https://aivf.co/ [https://perma.cc/A39C-X6XJ] (last visited Oct. 15, 2024).

35. *Id*.

36. *Id*.

37. Raz Smolsky & Tal Shahaf, *The Start-Up that Uses Artificial Intelligence in IVF Treatments Raises 25 Million Dollar*, TECH12 (June 22, 2022), https://www.tech12.co.il/index-startups/Article-1a0b6e5a03b8181027.htm [https://perma.cc/W7BW-SUPG].

38. *Id*.

39. An example of a self-scan ultrasound device, for AI-based and remote clinical diagnosis, was created and is produced by Pulsenmore. *See Bridging Healthcare Gaps with Home Ultrasound*, PULSENMORE, https://pulsenmore.com/ [https://perma.cc/B7RE-6M23] (last visited on Oct. 22, 2024).

40. Period-tracking applications are currently a "hot commodity," ranking as the fourth most popular application for adults in health care, and the second most popular among adolescents. *See* Corbin, *supra* note 5, at 344.

support of AI systems, these devices aspire to help women accurately identify their fertile window.[41] Integrating AI in IVF treatments, self-scan ultrasound devices for AI-based diagnosis, and AI-based devices for monitoring women's ovulation periods are all illustrations of AI breakthroughs in the market, concerning female fertility and reproduction.

C. Sexuality

The third and last area of expertise to be illustrated concerns FemTech products that aim to foster healthy female sexuality in women's lives. Good examples for such products are AI-based applications that ease symptoms of menopause.[42] Femilog, for instance, is an application for documenting individual menopause symptoms, such as a sore and dry vagina or hot flashes.[43] Based on this documentation, the application offers personal-fitted recommendations.[44] Another company, Astinno, developed an automated tracking and cooling bracelet that is ready to detect and fend off hot flushes.[45] When hot flushes are detected, a cooling patch is activated on the woman's wrist, which reverses the effects of the flush.[46]

Obviously, the development of AI-based technologies in the areas of female diseases, fertility, and sexuality, could not have been fulfilled without significant capital. The following section discusses the unique challenges of funds raising in the FemTech industry.

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41. Take, for example, the product Tempdrop. The Tempdrop sensor is worn on the upper arm during sleep and continuously monitors the basal body temperature while the woman sleeps, in order to identify the fertile window. The sensor is synchronized with an application that analyzes the data with an AI-based algorithm. *See Monitor Your Fertility: The Smart Solution for Fertility Tracking*, TEMPDROP, https://www.tempdrop.com/en-il [https://perma.cc/DV6W-WAC5] (last visited Oct. 22, 2024).

42. The digital health company Lisa Health, for example, creates advanced technology solutions for menopause and healthy aging. It launched Midday, an application that leverages AI, sensor technology and digital therapeutics to support women during menopause. *See* Tia R. Ford, *Lisa Health Launces Midday, an App Leveraging AI to Personalize the Menopause Journey, in Collaboration with Mayo Clinic*, MAYO CLINIC NEWS NETWORK (July 19, 2022), https://newsnetwork.mayoclinic.org/discussion/lisa-health-launches-midday-an-app-leveraging-ai-to-personalize-the-menopause-journey-in-collaboration-with-mayo-clinic/[https://perma.cc/45Q9-3K38].

43. *See* Cate Lawrence, *Why Denmark is a Hotbed for Healthtech Startups and Innovation*, TECHEU-HEALTHTECH (Jan. 16, 2024), https://tech.eu/2024/01/16/why-denmark-is-a-hotbed-for-healthtech-startups-and-innovation/ [https://perma.cc/EJC7-WVFP].

44. *Id*.

45. *See* Natasha Lomas, *UK Femtech Startup Astinno, which is Working on a Wearable to Combat Hot Flushes, Picks up Grant Worth $450k*, TECHCRUNCH (May 13, 2020), https://techcrunch.com/2020/05/13/uk-femtech-startup-astinno-which-is-working-on-a-wearable-to-combat-hot-flushes-picks-up-grant-worth-450k/ [https://perma.cc/9629-9H22].

46. *Id.*

IV. RAISING FUNDS FOR THE FEMTECH INDUSTRY AND ITS CHALLENGES

Though women are half of the world's population, the women's health market has traditionally been considered negligible.[47] Until recently, investments in technologies related to women's health were a relatively small share of all investments in life sciences.[48] The negligible investment in the FemTech industry can be explained by the historic neglect of women's health.[49] As one of the founders of Aquafit Intimate, Rivka Sternberg, stated:

> We understood very quickly that the FemTech model does not fit local foundations . . . . These foundations invest in companies and do not mind losing a lot of money at first, but not in FemTech. In FemTech, economic feasibility is required from the very beginning. This economic standard is not realistic for most start-ups. I have been an entrepreneur for almost thirty years, and there is a . . . . double moral standard here. Male impotency is worth billions. It is only female sexual health that is forbidden to talk about. I sincerely do not understand why Viagra is a market, but a product for vaginal health is a risk.[50]

Only a small percentage of the investors are women, and men find it hard to understand women's needs.[51] Therefore, the chances of raising funding for a high-risk project in women's health are low.[52] Moreover, conservative social perceptions may be an economic obstacle for the FemTech industry. CEOs in this industry claim, for instance, that they need to invest much more money in marketing, since every mention of the word "vagina" is blocked on Facebook, due to suspicion of pornography.[53] Women are also known to be very unpredictable customers, who are not open to new technologies and to exploring new devices – a fact that may also make raising funds more difficult.[54]

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47. *See, e.g.*, Priya Joi, *Women's Health is Massively Underfunded and is One of the Biggest Missed Opportunities in Health*, VACCINESWORK (May 22, 2023), https://www.gavi.org/vaccineswork/womens-health-massively-underfunded-and-one-biggest-missed-opportunities-health [https://perma.cc/WJ8A-UMX7]; Karen Rubin & April Popescu, *Why Women's Health is a $500M Problem Worth Solving*, MEDIUM (Apr. 5, 2022), https://medium.com/@karenrubin/why-womens-health-is-a-500m-problem-worth-solving-d0f3696e1c6a [https://perma.cc/V6EB-TC4R].

48. *Id.*

49. *Id*.

50. *See* Roni Dori, *Perimenopause Age to Front Stage*, CALCALIST (May 4, 2022), https://newmedia.calcalist.co.il/magazine-04-05-22/m02.html [https://perma.cc/T66A-KXKY].

51. *Id*.

52. *Id*.

53. *Id.*

54. *Interview with Eng. Hilla Shaviv, Inventor, Founder and CEO Gals Bio Ltd*, *supra* note 31.

However, in recent years, FemTech developments are rapidly increasing.[55] According to the research company, Global Market Insights, the FemTech market is already estimated at twenty-two billion dollars, and it is expected that it will triple its value by 2027.[56] The economic potential embedded in the FemTech industry is recognized as one of the major catalysts for investing in this industry.[57] As one of Nevia's founders, Inbal Zafir-Lavie, states:

> I also had the chance to stand in front of a panel of investors, ten men wearing ties, and talk to them about vaginal discharge. At first, there is some kind of inconvenience, but it is over the moment they understand the economic potential. Male investors are very trained; they do not show how they think […], and the moment they understand we can bring them money and make them blockbusters – this is all they are interested in.[58]

She continues and argues that female investors have also fostered the rise of the FemTech industry:[59]

> *I think that the female sex understood that 'if not us – then who'. I don't have any claims against men, but at the end of the day, you take care of issues that concern you.*[60] (emphasis added)

As can be understood from the above, the difficulties of raising funds for the FemTech industry go hand by hand with the struggle for women's equality in the world. The historic neglect of women's health, the small number of female investors compared to male investors, and conservative social perceptions have turned the task of raising funds for the FemTech industry into a most challenging one. The recent increase in raising of capital for this market niche does not only serve women's needs, but also reflects a step toward a more equal allocation of funds.

V. RESEARCH QUESTIONS, APPROACH, AND METHOD

While most public attention is paid to the challenge of fundraising for FemTech developments,[61] the bioethical dilemmas raised by the FemTech

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55. *See* Dori, *supra* note 20.
56. *Id*.
57. *Id*.
58. *Id*.
59. *Id*.
60. *Id*.
61. *See* Melissa Houston, *The Challenges of Raising Capital for Business Owners in the FemTech Industry*, FORBES (Sept. 29, 2021), https://www.forbes.com/sites/melissahouston/2021/09/29/the-challenges-of-raising-capital-for-business-owners-in-the-femtech-industry/?sh=7797f75f7266 [https://perma.cc/NUL6-XYP3].

industry have received inadequate attention.[62] My research provides an account of these dilemmas, from a feminist's perspective. I explored how the FemTech revolution can affect women and asked: Do the technologies, which aim to improve women's health, address new challenges facing feminist ethics and social philosophy? Or, do they simply raise old bioethical questions, in relation to new technologies?

By adopting a sociological perspective toward bioethics, I offer an initial discussion on the opportunities, alongside the challenges, that the AI-based FemTech industry faces, from a feminist perspective. The discussion is based on representative and non-exhaustive examples of developments from the FemTech industry. Followed by a comparative normative analysis, the discussion aims at setting the basis for feminist regulation of AI-based medical devices.

VI. THE OPPORTUNITIES AND CHALLENGES OF AI-BASED FEMTECH PRODUCTS

Women's health is historically known as a neglected field.[63] The FemTech industry – which is partially based on AI – fosters gender equality by shedding light on a traditionally under-treated topic. Nevia's algorithm, for instance, is designed, inter alia, to detect endometriosis.[64] Nevia's algorithm, thus, is a good example of how AI in medicine can raise awareness of socio-medical problems. It offers a new source of data for bio-banks and detects illnesses that are rarely diagnosed or treated. Of course, the lack of available research and data concerning women's health seriously challenges the development of new technologies related to it.

In addition to fostering equality between men and women, the FemTech industry addresses the feminist slogan "my body, my choice" by strengthening women's autonomy over their bodies. FemTech products enable women to take responsibility for their bodies and health.[65] These products offer services and solutions that the doctor's office does not – be the direct access to professional testing and diagnosis from home, anonymity, and respect for busy schedules, which are all crucial for women. For women juggling domestic loads and work, there is little time to schedule in-person healthcare appointments. In addition to this obstacle, long waitlists, and healthcare bias and discrimination can make it even harder for women to be seen by medical staff and to receive appropriate care.[66]

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62. For an exceptional article discussing the bioethical dilemmas surrounding the FemTech industry, *see generally* Corbin, *supra* note 5.

63. *Id.* at 338.

64. *See The New Way for Early Detection*, *supra* note 18; *see also* Dori, *supra* note 20.

65. *See* Corbin, *supra* note 5, at 338.

66. *See, e.g.*, Vee Govender & Loveday Penn-Kekana, *Gender Biases and Discrimination: A Review of Health Care Interpersonal Interactions*, 3 GLOB. PUB. HEALTH 90, 93–94 (2008).

The FemTech industry provides accessibility to healthcare services for disadvantaged populations. We know, for example, that there are massive racial disparities in pregnancy-related deaths.[67] Statistics overwhelmingly show that black women are more likely to die during pregnancy than white women are.[68] Research has also found that black patients are more likely to wait longer for a primary doctor's appointment and are less likely to be offered pain relief than white patients.[69] Living in a rural area, distance, and transport issues can also dramatically affect access to healthcare and, of course, these challenges become even greater for disabled women and women who are caregivers.

FemTech products succeed in working directly with communities and reaching marginalized groups. They reduce health disparities and provide unbiased care. Supplying direct healthcare services and reaching marginalized communities enable the detection, diagnosing, and treating of the disease at early stages. Therefore, the FemTech industry can also save a great deal of money for the government.[70] FemTech products, therefore, not only provide solutions to women from marginalized communities, but due to frequent use of AI, the products can mitigate discrimination stemming from human biases and social structures.

In light of all the opportunities that AI-based FemTech products invite, can we state that the FemTech revolution advances equality between sexes and is committed to the feminist ethos? Alongside its significant advantages for women's lives, it appears that the use of AI technology in the health sector also raises serious legal and bioethical challenges from a feminist perspective. Three of these challenges will be discussed now.

A. The Problem of Bias

I argued before that AI-based technology has the potential to mitigate human biases and discriminations grounded in social structures, by using an

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67. *See* Roni Caryn Rabin, *Huge Racial Disparities Found in Deaths Linked to Pregnancy*, N.Y. TIMES (May 7, 2019), https://www.nytimes.com/2019/05/07/health/pregnancy-deaths-.html [https://perma.cc/CF5J-GE9K].

68. *Id*.

69. *See* Janna M. Wisniewski & Brigham Walker, *Association of Simulated Patient Race/Ethnicity with Scheduling of Primary Care Appointments*, 3 JAMA NETWORK OPEN 1, 1 (Jan. 29, 2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6991290/ [https://perma.cc/JFD7-SRKP]; Antoinette Schoenthaler & Natasha Williams, *Looking Beneath the Surface: Racial Bias in the Treatment and Management of Pain*, 5 JAMA NETWORK OPEN 1, 1 (June 9, 2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793179 [https://perma.cc/4YYE-XZEF].

70. Based on a study from 2012, one of Nevia's founders claimed that the economic burden of endometriosis is the same as that of type-2 diabetes, and is estimated to cost the U.S. economy $50 billion. *See* Dori, *supra* note 20. She asserted: "When a woman comes to the emergency room, is hospitalized, and later told to go home, since 'it's just menstrual cramps', but then returns a few hours later with paralyzing pain that could cause her to lose her fertility […] that's a problem. This doesn't only just harm women, but it is a burden on the entire health care system and on society." *Id.*

objective and neutral algorithm. However, AI-based technology may also foster unwanted discrimination. This discrimination does not have to be necessarily intentional (i.e., a biased algorithm is deliberately designed in order to prioritize one group over another). The discrimination can also unintentionally stem from the feature selection or data that serve the decision-making model. When AI-based technology trains on data that either reflect an existing bias in society or is not representative, the innovative technology will duplicate and continue discrimination.[71] Medical studies are a good example for this kind of discrimination.[72] These studies have been historically conducted on males and, therefore, the amount of data concerning men is significantly larger than the amount of data concerning women.[73] Hence, AI-based medical diagnosis tools may be biased, less effective and discriminatory toward women.

A diversity in data used for training and features for selection are required, in order to deal with the bias problem embedded in AI-based medical tools. How can such a diversity be achieved? Moreover, do diverse features for selection maintain the goal of an AI algorithm, from the very beginning? Take, for example, the AiVF algorithm, mentioned above. Do diverse features for selection of the best embryos for fertilization maintain the goal of identifying the one formula for selecting the embryos that have the best chance to turn into pregnancy?

Among the advantages of AiVF algorithm are that the algorithm shortens the one-cycle treatment time, diminishes the number of treatment cycles, and eases the physical and mental suffering of the women.[74] Embryo selection by humans is highly subjective and changes between embryologists and laboratories. In contrast, an AI algorithm used for selecting embryos is perceived as more objective, neutral, and consistent.

Responsible AI selection of embryos requires integrating the work of human beings and machines.[75] The algorithm dictates who is allowed to join the human community and who is not, and which lives are worth living and which lives are not. The AiVF algorithm advances the race for the perfect child, fosters discrimination of people with disabilities, and may lead to human enhancement, and even eugenics. Above all, I would like to offer that using AI in IVF treatments may endanger human evolution itself. Human mutations are required in order to ensure evolution and, therefore, nothing fails like a successful AI

71. A technological solution for such a problem is to periodically cleanse the data used for training. However, if a social bias is deeply rooted in culture, it will take time until the cleansing mechanism's affects are visible.

72. Corbin, *supra* note 5, at 342.

73. *Id.*

74. The AiVF algorithm raises the tension between women's interests and the rights of people with disabilities. On the one hand, this technology helps ease the often difficult experiences of IVF treatments for women. On the other hand, the practice of choosing flawless embryos for transplantation itself sends a message that there are lives which are not worth living. Tamir, *supra* note 32 for information and discussion of this tension.

75. On the ethical debate over AI in IVF, *see generally* Tamir, *supra* note 32.

algorithm.[76] We could argue that using AI in IVF treatments simply mimics the embryo selection that already exists in nature. An additional argument, from a different direction, can be that there is nothing new under the sun of AI. There has been embryo selection for several decades, with the Pre-Implantation Diagnosis technique (PGD) as only one example of it. However, the change that might occur, as we move away from the traditional embryo selection process to an AI world, is that the process will become consistent, uniform and, above all, less diverse. Human embryologists or laboratories might succeed, more or less. Nonetheless, they offer us a much more random, arbitrary, incidental, and, therefore, diverse, process of embryo selection.

In order to achieve social fairness and an unbiased algorithm, the principle of inclusiveness has been adopted by regulatory regimes for AI.[77] How can we understand the principle of inclusiveness and the race for diversity with respect to AI in medicine? The medical anthropologist, Sandra Soo-Jin Lee, attributes a dual meaning to diversity: (1) it is a solution to the technical problem of capturing genetic variation, and (2) it fulfills the ethical imperative to include marginalized social groups in medical research.[78] Indeed, more and more medical sociologists are studying the ways in which the categories of identities are organized in bio-banks.[79] Inter alia, they examine the extent to which epigenetic parameters should be taken into account.[80] They warn that AI's endeavor to harmonize variables and blur differences in life experiences can affect the health of the technology's consumers.[81] According to these medical sociologists, common disease etiology should be studied with a growing

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76. A good example of this argument can be taken from another technological procedure of gene editing, CRISPR-Cas9 technology. The CRISPR-Cas9 gene editing technology is used, inter alia, for the purpose of repairing the mutation in the hemoglobin gene responsible for sickle cell anemia. *See* Christian E. Ogaugwu, Stanley O. Agbo & Modinat A. Adekoya, *CRISPR in Sub-Saharan Africa: Applications and Education*, 37 TRENDS BIOTECHNOLOGY 234, 235 (2019). However, while this technology has demonstrated highly satisfactory results, by curing people diagnosed with sickle cell diseases, it has been found to be problematic for people most in need of it. *Id.* Eighty percent of the people suffering from sickle cell anemia live in Africa. *Id.* at 236. While CRISPR-Cas9 technology could cure their disease, it was found that it simultaneously harms their immunity to malaria, a much more life-threatening disease in Africa. *Id.* at 234. In order to minimize the risk of such catastrophes for evolution, scientists have decided to use the gene editing technology only in order to cure the individual patient, and never to edit the germ cells, which can also affect future generations. *Id.* at 236. I wonder what the parallel decision for the use of AI in IVF treatments should be.

77. *See* WORLD HEALTH ORGANIZATION GUIDANCE, *supra* note 16.

78. *See* The Israel Academy of Sciences & Humanities, *2050: Bioethical Issues, The Ethics of Diversity, Inclusion and Global Data Harmonization in the Age of Precision – Sandra Soo-Jin Lee*, YOUTUBE (Oct. 25, 2023), https://www.youtube.com/watch?v=SnkoYKwcMMY [https://perma.cc/9C9X-Z2QH].

79. *See, e.g.*, Sandra Soo-Jin Lee et al., *The Ethics of Characterizing Difference: Guiding Principles on Using Racial Categories in Human Genetics*, 9 GENOME BIOLOGY 404–06 (2008).

80. *See* Sara L. Ackerman et al., *The Ethics of Translational Science: Imagining Public Benefit in Gene-Environment Interaction Research*, 3 ENGAGING SCI. TECHNOL. SOC. 351, 362–63 (2017).

81. *Id.* at 352–53.

understanding of, and explicit attempts to, study the many ways that bodies and environments are inextricably linked.[82] As one scientist puts it: "genes . . . are really important in physiologic functioning, and . . . almost all genetic effects are contingent on some environment."[83] It should be noted that the sociologist's imperative to take into account epigenetic parameters and life experiences are in line with feminist ethos. The feminist movement (mainly, its second wave) has emphasized the importance of taking into account the lived phenomenological experience of women.[84]

In order to include epigenetic parameters and life experiences in data, which will be the basis for organization in bio-banks' categories, a collaboration across disciplines is required. Biologists and behavioral and environmental scientists need to work together in the process of building categories in bio-banks. In this spirit, critics have argued that the welcome collaboration between biologists and social/behavioral or environmental scientists may lead to greater attention to how particular social and material environments are embodied in biological processes.[85]

In order to include epigenetic parameters in bio-banks, biologists and social scientists, working together, should make an effort to reconstruct an individual's geographic ancestry, so that we will have results that reflect the broader context of an individual's ancestry. An individual's 'geographic ancestry' or 'biogeographical ancestry' is understood in the literature as all the geographic locations inhabited by an individual's biological ancestors.[86] The idea is that genetic data reflect only a small subset of all ancestors. Furthermore, an individual's self-definition can be different from their biogeographic ancestry, due to varied historical, cultural, or sociopolitical factors. Therefore, a collaboration between biologists and social scientists is required in order to build biogeographical and cultural ancestry. In order to ensure the establishment of an interdisciplinary ancestry, and to refrain from using stereotypical and stigmatized categories, medical anthropologists encourage all researchers, who use identity categories in bio-banks to do a number of things. They encourage researchers to describe how individual samples are assigned category labels, to explain why samples with such labels were included in the study, and to state whether the identity categories are research variables.[87] The editorial boards of

82. *Id.* at 363–65.

83. *Id.* at 359.

84. *See generally, e.g.*, FEMINIST PHENOMENOLOGY (Linda Fisher & Lester Embree eds., 2000); LOUISE LEVESQUE-LOPMAN, CLAIMING REALITY: PHENOMENOLOGY AND WOMEN'S EXPERIENCE (1988); FEMINIST INTERPRETATIONS OF MAURICE MERLEAU-PONTY (Dorothea Olkowski & Gail Weiss eds., 2006); SANDRA LEE BARTKY, FEMINIST AND DOMINATION: STUDIES IN THE PHENOMENOLOGY OF OPPRESSION (1990).

85. *See* sources cited *supra* note 84.

86. *See* Soo-Jin Lee et al., *supra* note 79, at 405.

87. *Id.*

several flagship scientific journals have issued publication guidelines to their authors on the use of 'race', for example, in reporting research findings.[88]

Indeed, the pursuit of diversity raises serious questions in relation to how to describe, define, measure, compare, and explain inferred similarities and differences among individuals and groups. Social parameters, such as self-definition, or perception of the other, may justify the differentiation or unification of categories. For example, studies have shown that American adults, who do not self-identify as white, report better mental and physical health if they think others perceive them as white.[89]

As in epigenetic parameters and lived experiences, the social parameter of self-identification is also in line with feminist ethos. From its very early stages, the feminist movement encouraged women to have an independent point of view, to be able to have self-identification, and not to blindly adopt the "universal" (namely, the male) perspective.[90]

Bio-bank categories and their organization have also had reciprocal effects on society and its ideologies. Sandra Soo-Jin Lee identified an "infrastructure of racialization" in bio-banks that incorporated racialized labels for groups whose DNA samples they store.[91] In so doing, according to Lee, they privileged the human body as the grounds in and from which racial difference can be read, and genomics as the official language for reading race.[92] Furthermore, Duana Fullwiley found much the same in her ethnography of two medical genetics laboratories in the United States. She showed how the comparison between the allegedly pure "Old World" reference populations to "New World" admixed populations led scientists to read race in DNA and revive race as biogenetically valid.[93]

Nevertheless, the turn to classification as a problem may obscure other ways of understanding how difference matters. Abolishing "racist categories" through careful language and more precise genetic distinctions both sidesteps the issue and distracts from the recognition that racial categorization is embedded within institutions and processes that sustain configurations of power and reproduce racial inequalities in health. It appears that the immediate and direct response to the bias problem, related to AI-based medical technology, is the fulfillment of the inclusiveness principle through including diverse data. Diverse data can be achieved by including non-representative populations, such as women in the data. Moreover, modifying data to suit new target audiences when medical

88. *Id.*

89. Sandra Soo-Jin Lee et al., *Ethics of Inclusion: Cultivate Trust in Precision Medicine*, 364 SCI. 941, 942 (2019).

90. *See* Tony Lawson, *Feminism, Realism, and Universalism*, 5 FEMINIST ECON. 25, 44, 49 (1999).

91. Janet K. Shim et al., *Race and Ancestry in the Age of Inclusion: Technique and Meaning in Post-Genomic Science*, 55.4 J. HEALTH SOC. BEHAV. 504, 506 (2014).

92. *Id.*

93. *Id.*

devices are applied in contexts different from their original intended use can promote the principle of inclusiveness.[94]

However, I have argued that diverse data will also be enabled by engaging in new methods of data collection, such as the inclusion of epigenetic parameters and the individuals' self-identification, which are in line with the feminist ethos. The classification problem in bio-banks raises the well-known issue of politics of identities and positions that questions who is considered "black," what it means to be a "woman," etc. These questions, so I claimed, should be answered by bio-ethicists and social scientists working together. I additionally think that empirical research is required in order to understand how to conceptualize diversity in bio-banks and which goals of inclusion are implemented. Building categories in bio-banks is not only a matter of population recruitment and its classification. It should also be a matter of population involvement, starting from data collection, their measurement, and their interpretation.

Up until here, I described and appraised the bias problem currently facing AI-based medical devices. Nonetheless, the danger of discrimination stemming from AI-based medical devices may relate also to the future. The use of AI algorithms in FemTech products is potentially dangerous, since, due to their predictive abilities, they can create perceptions of normalcy and support discriminatory stereotypes in society. If an AI algorithm can predict the chances of developing a certain disease, social discrimination based on this potential future disease is not hard to imagine. Think of an AI algorithm that predicts the chances of a woman being diagnosed with ALS. The predicted future possibility of becoming disabled may cause discrimination in the job market, for instance, against candidates, who are defined as having risk factors, according to AI predictions.[95]

How does a possibility of future prediction-based social discrimination affect the design of an AI regulatory regime? To what extent are AI medical predictions different from other traditional medical records?[96] These are some of the questions facing future regulation of AI-based medical devices.

In conclusion of this section, alongside the potential of AI-based FemTech products to mitigate biases toward women, they can also foster discrimination (whether it be deliberate, unintentional, or consequential). I argued that the principle of inclusiveness should be advanced, in order to achieve social fairness. The development of the techniques need to also take into account

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94. *See generally* Boris Babic et al., *Algorithms on Regulatory Lockdown in Medicine*: *Prioritize Risk Monitoring to Address the "Update Problem"*, 366 SCI. 1202 (2019).

95. On the risk of being discriminated against in the job market, due to predicted future possibilities of becoming disabled, *see generally*, *e.g.*, Sharona Hoffman, *Big Data's New Discrimination Threats: Amending the Americans with Disabilities Act to Cover Discrimination Based on Data-Driven Predictions of Future Disease*, *in* BIG DATA, HEALTH LAW, AND BIOETHICS 85 (Glenn Cohen et al. eds., 2018).

96. Of course, the potential of discriminatory future effects of AI-based technologies is not unique to FemTech products. However, due to the fact that women are a vulnerable population in the job market, AI discriminatory future effects are more devastating.

epigenetic parameters and individuals' self-definitions that are in line with feminist ethos. In order to fulfill this ambition, a collaboration across disciplines is required.

B. Constructing Stereotypical Social Perceptions about Women

As in all other technologies, AI-based medical devices can also construct social perceptions. Nevia's algorithm, mentioned above, is a good example of how FemTech can raise awareness of socio-medical problems. It offers a new source of data for bio-banks and detects illnesses that are rarely diagnosed and treated. Detecting rarely diagnosed and treated illnesses is enabled due to the development of smart pads that are available to all women. However, FemTech products may also advance unwelcome and reactionary social perceptions. They may be based on incorrect assumptions of female needs and desires that not only stereotype women, but also serve to define the default female body.

Take, for example, an application that tracks periods. By sending a notice to the woman's smartphone, the application can inform a woman in welcoming letters and a positive tone that they are late for their period. The woman may have to continue seeing the notice, even if they are preparing for an abortion, since the application's designers clearly misunderstood that pregnancy is not always a welcome occurrence.[97] Moreover, when an abortion or miscarriage happens, some applications prevent women from logging this data, a fact that sends them a message that their experience falls outside normal data calculations.[98]

While the world embraces the ongoing AI revolution, the example of a period-tracking application shows us that new technological developments can have devastating consequences, as they impose social perceptions of normalcy on women. In light of this understanding, the socio-legal question to be asked is: How do we advance FemTech products that do not support stereotypes of women? In other words, how do we guarantee regulatory regimes that encourage the development of welcome awareness of existing social problems? And, how do we discourage the design of unwelcome narrow-minded social perceptions? Is it only a problem of diversity? Will diverse representation within the company ensure that all social viewpoints are acknowledged and considered? Or, will AI-based technologies subvert some of the most crucial feminist achievements – that is taking into account women's needs and worlds of content.

C. Challenging Privacy

Due to the fact that AI technology frequently uses large amounts of data for the purpose of its development, training, and operation, it raises serious

97. *See* Corbin, *supra* note 5, at 349.
98. *Id.*

challenges to privacy.[99] Firstly, it should be examined whether consent was given for the use of the person's data that includes personal information. The collection and use of personal data should be limited to purposes stated in the law. Thus, during data collection, the individual should know (at least in theory) why their data is being collected, for which they gave their consent in advance.

However, AI technology frequently uses data for purposes that differ from the original reason for the collection. Transforming the target of data collection by AI technology also raises an ethically controversial question concerning this technology: Do we use AI technology in order to cure the people from whom we collected data, or do we use certain people in order to cure others? Furthermore, the difficulty of explaining how the technology works may also make it more difficult to receive consent. AI-based medical technologies challenge individuals' privacy in too many and complex ways to be seriously handled in this article. My goal in this section is much more modest. Here, I aim to shed light on why the threat to women's privacy is so important that this issue needs to be more urgently handled.

When it comes to women, the use of data derived from their bodies, without gaining their informed consent, is even more problematic. For years, the feminist movement has been working to ensure that women will gain autonomy over their bodies, so that they can make decisions concerning their bodies.[100] This perception has been expressed by the slogan "My Body, My Choice."[101]

An additional challenge to privacy protection, related to AI technology, comes from cyber attacks.[102] These attacks may specifically threaten women's autonomy over their bodies and undermine some of the most important feminist achievements, such as abortion rights. Information stored on period trackers, for example, can be used by governments banning abortions, in order to determine if a woman has had an illegal abortion. Therefore, significant restrictions on how FemTech companies collect, use, store, or disclose health data should be regulated in order to preserve women's autonomy over their bodies.[103]

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99. *See, e.g.*, Effy Vayena, *Protecting Health Privacy in the World of Big Data*, *in* BIG DATA, HEALTH LAW, AND BIOETHICS 157 (Glenn Cohen et al. eds., 2018); Karl Manheim & Lyric Kaplan, *Artificial Intelligence: Risk to Privacy and Democracy*, 21 YALE J.L. & TECH. 106, 116–31 (2019).

100. *See, e.g.*, Diana Tietjens Meyers, *The Feminist Debate over Values in Autonomy Theory*, *in* AUTONOMY, OPPRESSION, AND GENDER 114 (Andrea Veltman & Mark Piper eds., 2014); MOIRA GATENS, IMAGINARY BODIES: ETHICS, POWER, AND CORPOREALITY 1, 49 (1996).

101. On the controversial use of this slogan, *see generally* ABDUL RASHEED SAJID, MY BODY MY CHOICE: HISTORY OF THIS CULTURE 1 (2021).

102. On potential dangers of digital surveillance of women and their bodies, *see* Cynthia Conti-Cook, *Surveilling the Digital Abortion Diary*, 50 U. BALT. L. REV. 1, 3–74 (2020).

103. On how femtech products can address gaps created by U.S. states and stakeholders seeking to restrict birth control and abortion access while increasing pregnancy surveillance, as well as potential solutions, *see* Fowler & Ulrich, *supra* note 5. On the oppression women suffer through a loss of privacy in the digital age, *see* Gilman, *supra* note 5.

VII. TOWARD FEMINIST REGULATION OF AI-BASED MEDICAL DEVICES: BIOETHICAL PRINCIPLES, REGULATORY REGIME & LEGAL ACCOUNTABILITY

In light of these challenges facing AI-based FemTech products, I now examine how to set a legal and regulatory basis for feminist AI. I am specifically interested in the bioethical principles that should be taken into account when advancing feminist regulation of AI technologies.

The bioethical principles, in relation to AI-based FemTech products, should combine three sets of principles. *The first* is the long-standing principles of bioethics, which advance the patient-centric approach relating to personal and societal aspects of implementing the medical device.[104] *The second* is the currently evolving AI ethics, which foster the human-centric AI ethics, with respect to the technological architecture of medical devices (i.e., the design of AI in a way that keeps humankind interests protected against AI's capabilities).[105] *The third* is feminist ethics, which places women's perspectives on caring and moral issues of private life and family responsibilities on 'center stage'.[106] This principle gives more weight to cultural female traits, such as: connection, community, sharing, emotion, and absence of hierarchy.[107] If we want to outline feminist bioethical principles relating to AI-based medical devices, then a woman-centric logics should be adopted.

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104. WORLD HEALTH ORGANIZATION GUIDANCE, *supra* note 16; *Principles of Artificial Intelligence Ethics for the Intelligence Community*, OFF. OF DIR. OF NAT'L INTEL. (2020), https://www.dni.gov/files/ODNI/documents/Principles_of_AI_Ethics_for_the_Intelligence_Community.pdf [https://perma.cc/KMK9-Y9P9].

105. *See* sources cited *supra* note 104. AI ethics principles are currently being developed mainly by international organizations, governments, civil society organizations, and by voluntary self-regulation of the technology industry. *See, e.g.*, *AI Principles Overview*, OECD, https://oecd.ai/en/ai-principles [https://perma.cc/9GP8-W7QW] (last visited Oct. 31, 2024); *High-level Expert Group on Artificial Intelligence: Ethics Guidelines for Trustworthy AI*, EUR. COMM'N, (Apr. 8, 2019), https://op.europa.eu/en/publication-detail/-/publication/d3988569-0434-11ea-8c1f-01aa75ed71a1[https://perma.cc/V3MQ-274B]; UNESCO, FINAL REPORT ON THE DRAFT TEXT OF THE RECOMMENDATION ON THE ETHICS OF ARTIFICIAL INTELLIGENCE 1–10 (Mar. 31, 2021), https://unesdoc.unesco.org/ark:/48223/pf0000376712 [https://perma.cc/2NMJ-E87T]; OFF. OF MGMT. & BUDGET, EXEC. OFF. OF THE PRESIDENT, MEMORANDUM, GUIDANCE FOR REGULATION OF ARTIFICIAL INTELLIGENCE APPLICATIONS (2020); *Asilomar AI Principles*, FUTURE OF LIFE INST. (Aug. 11, 2017), https://futureoflife.org/open-letter/ai-principles/ [https://perma.cc/4KJX-6VYZ]; *Artificial Intelligence at Google: Our Principles*, GOOGLE, https://ai.google/static/documents/EN-AI-Principles.pdf [https://perma.cc/UF26-ULDS] (last visited Oct. 31, 2024); *Responsible AI Transparency Report*, MICROSOFT (May 2024), https://query.prod.cms.rt.microsoft.com/cms/api/am/binary/RW1l5BO [https://perma.cc/2W5A-ESB2].

106. For literature on Feminist ethics, *see, e.g.*, MAURICE HAMINGTON, EMBODIED CARE: JANE ADDAMS, MAURICE MERLEAU-PONTY, AND FEMINIST ETHICS (2004); FIONA ROBINSON, THE ETHICS OF CARE: A FEMINIST APPROACH TO HUMAN SECURITY (2011); CRISTINA H. TRAINA, FEMINIST AND NATURAL LAW: THE END OF ANATHEMA (1999).

107. *See* sources cited *supra* note 106.

A global landscape analysis from 2019 identified global convergence around five ethical principles relating to AI technology.[108] These five ethical principles are justice and fairness, transparency, non-maleficence, responsibility, and privacy.[109] Healthcare-specific AI ethics principles are also being gradually formed, though these are at an even more initial stage of development, with very few examples. In 2018 and 2019, the American Medical Association's (AMA) outlined its policy on Augmented Intelligence in Health Care.[110] The WHO also outlined its policy on Ethics and Governance of Artificial Intelligence for Health.[111] This framework identified the following key ethical principles for the use of AI for health: ensuring inclusiveness and equity; protecting human autonomy; ensuring transparency, explainability, and intelligibility; promoting human well-being and safety, and the public interest; fostering responsibility and accountability; and promoting AI that is responsive and sustainable.[112] As for feminist-specific AI ethics, to date, I have not found any such published frameworks.

Given the initial stage of AI-based technologies, and due to the yet to be studied AI's potential benefits, alongside its harmful potentialities, I do not intend to offer an exhaustive feminist theory for AI-based medical devices for women. Instead, I take a principle-based approach and apply relevant bioethical principles and feminist considerations to the novel technology of AI. The following discussion examines how to apply bioethics and AI ethics principles in the FemTech Industry.

A. Social Justice and Fairness

Social justice and fairness are, in fact, cited by the European Commission's High-Level Expert Group on AI as one of four ethical imperatives necessary for trustworthy AI.[113] What could be considered as "fair" and "just" in the context of AI-based medical tools for women? The problem of biased algorithms and the pursuit of diversity data, concerning AI-based medical devices, are often-

108. Anna Jobin et. al., *The Global Landscape of AI Ethics Guidelines*, 1 NATURE MACHINE INTEL. 389, 389 (2019).

109. *Id.*

110. *Augmented Intelligence in Health Care H-480.940*, AM. MED. ASS'N, https://policysearch.ama-assn.org/policyfinder/detail/augmented%20intelligence?uri=%2FAMADoc%2FHOD.xml-H-480.940.xml [https://perma.cc/W487-4E8N] (last visited Jan. 12, 2025); *Augmented Intelligence in Health Care H-480.939*, AM. MED. ASS'N (2019), https://policysearch.ama-assn.org/policyfinder/detail/AI?uri=%2FAMADoc%2FHOD.xml-H-480.939.xml [https://perma.cc/WEP6-8WX5] (last visited Jan. 12, 2025).

111. WORLD HEALTH ORGANIZATION GUIDANCE, *supra* note 16.

112. *Id.*

113. *High-level Expert Group on Artificial Intelligence: Ethics Guidelines for Trustworthy AI*, *supra* note 105.

debated topics in the bioethical analysis of AI.[114] In terms of biology, an AI-based medical device that uses non-diverse data is highly problematic and may produce unsatisfactory results. By adopting a sociological perspective toward bioethics, I suggest that in order to understand the AI-related diversity principle, we must approach it not only as a biological necessity, but also as a social imperative.[115]

The ways in which the categories of identities are organized in bio-banks illustrates the social imperative regarding the diversity principle. I propose that epigenetic parameters, for instance, will be taken into account, for the purpose of organizing identity categories in bio-banks.[116] Moreover, the self-definition of individuals, whose data have been collected, should be regarded. Taking into account epigenetic parameters and self-definitions is also supported by feminist ethics that fosters female traits, such as community, sharing, and emotion.[117] In general, the very categories, techniques, and objects of scientific practice should also be studied from a social point of view, in order to fulfill the principle of diversity. Furthermore, we should think of how to generate principles to guide the use of identity categories in bio-banks. The fear is that, under certain conditions, genetic data might transform social understanding of identity categories that can enhance misogynist ideology.

B. Autonomy, Transparency, and Explainability

The phrase "striking a balance between the decision-making power we retain for ourselves and that which we delegate to artificial agents" is defined as an AI ethics' sense of autonomy in light of the human-centered approach.[118] In order to guarantee this kind of balance, according to the 2019 Ethics guidelines

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114. *See, e.g.*, Sarah E. Malanga, et. al., *Who's Left Out of Big Data?: How Big Data Collection, Analysis, and Use Neglect Populations Most in Need of Medical and Public Health Research and Interventions*, *in* BIG DATA, HEALTH LAW, AND BIOETHICS 98–99 (Glenn Cohen et al. eds., 2018).

115. Steven Epstein argues that we are now fully in an age of inclusion, in which the regulatory mandate to include underrepresented populations has become both scientific and social common sense. *See generally* STEVEN EPSTEIN, INCLUSION: THE POLITICS OF DIFFERENCE IN MEDICAL (2007). On the requirement for diversity as social common sense, *see also* Shim et al., *supra* note 91, at 505.

116. A number of publications, many of them authored by prominent leaders from the U.S. National Institutes of Health, calls for research exploring the mutual and synergistic interactions of genetic and environmental determinants on human health. *See, e.g.*, Francis S. Collins, et. al., *A Vision for the Future of Genomics Research: A Blueprint for the Genomic Era*, 422 NATURE 835 (2003); Teri Manolio et. al., *Genes, Environment and the Value of Prospective Cohort Studies*, 7 NATURE REV. GENETICS 812 (2006). A new "sociogenomic" paradigm, in Bliss' terms, that combines both social and biological inquiry with respect to AI-based medical devices, is now required. *See* CATHERINE BLISS, RACE DECODED: THE GENOMIC FIGHT FOR SOCIAL JUSTICE 70–100 (2012).

117. *See* sources cited in the literature on Feminist ethics *supra* note 106.

118. Luciano Floridi & Josh Cowls, *A Unified Framework of Five Principles for AI in Society*, 1 HARV. DATA SCI. REV. 1, 6 (2019).

for trustworthy AI that was developed by the European Commission's High-Level Expert Group on AI, "humans need to be aware that they interacting with an AI system, and must be informed of the system's capabilities and limitation."[119] Of course, the demand for transparency does not mean that complete technical transparency should be achieved. This is because technical specifications tend to be too complicated for laypeople to understand. According to AI ethics, appropriate informed consent requires that the patient be informed about the use of an AI tool, the role of AI in the process, and the potential risks and limitations of this use.[120] Concerning AI-driven health technologies, the council of Europe's 2020 recommendation is that they do "not replace human judgment completely and that thus enabled decisions in professional healthcare are always validated by adequately trained health professionals."[121]

AI ethics' sense of autonomy and transparency, related to medical devices, could become highly important, especially for women, due to their unique characteristics and phenomenological existence in this world. Take, for example, the often-debated principle of human interference relating to AI-based medical devices discussed above. Prima facie, AI-based devices are autonomous. However, human involvement in the AI systems' activity (such as general human supervision) can improve the decision-making procedure of the AI systems, reduce their mistakes, strengthen the accountability toward these systems, increase their legitimation, and diminish the violation of the patient's dignity.[122] With respect to women, it is highly important to preserve their sense of autonomy over their bodies, both by disclosing to them that they are interacting with an AI system and by not completely forgoing human judgment. When women are the target audience, who historically have been deprived of autonomy over their bodies, it might be more important to be aware of the use of AI systems and to have human involvement in the operation of medical devices.[123] The sense of being forced to obey autonomous AI devices may be

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119. *High-level Expert Group on Artificial Intelligence: Ethics Guidelines for Trustworthy AI*, *supra* note 105.

120. *See generally* Daniel Schiff & Jason Borenstein, *How Should Clinicians Communicate With Patients About the Roles of Artificially Intelligent Team Members*, 21 AMA J. ETHICS 138 (2019).

121. Eur. Consult. Ass., *Artificial Intelligence in Health Care: Medical, Legal, and Ethical Challenges Ahead*, Rec. 2185, § 12.5 (2020).

122. It is accepted to differentiate between three types of human interference. The first type is entitled *human off the loop* and relates to occasions in which the decision is taken by a technological system, with no human engagement. The second type is entitled *human on the loop* and relates to occasions in which the technological system takes the decision by itself. However, the human factor is authorized to supervise and interfere when needed. The third and last type is entitled *human in the loop* and relates to occasions in which the human factor is part of the decision-making process. The person has independent discretion supported by the AI-based technology. *See*, *e.g.*, Rebecca Crootof et al., *Humans in the Loop*, 76 VAND. L. REV. 429, 441 (2023).

123. *See* Meyers, *supra* note 100; *see also* GATENS, *supra* note 100.

problematic for those whose autonomy over their bodies has often been discounted from the beginning of history.[124]

Another crucial tenet of autonomy, with respect to AI technologies, is explainability.[125] In order for the patient to be able to control their life, make informed choices according to their values and beliefs, and have the capacity for self-governance, the technological architecture should be explainable and understandable.[126] Scholars, in fact, identified this requirement as a good example of the new convergence of the classical bioethics principle of autonomy with the novel AI ethics principle of explainability.[127]

With respect to medical devices for women, the explainability principle becomes highly important. This principle states that for a system to be considered explainable, it should supply evidence, support, or reasoning related to an outcome from an AI process.[128] If an AI system is unexplainable and remains a "black box," it can violate the patient's dignity and interfere with their autonomy by allegedly exposing them to an arbitrary decision.[129] Since throughout history, women have not been their own masters, it is very important that they understand how AI-based decisions concerning their bodies are being made.[130]

C. Non-maleficence

Non-maleficence is a prominent AI ethics principle.[131] It requires that the benefits for the consumers of AI technology outweigh the risks.[132] In other words, it is required that a reasonable risk-benefit ratio exists. As can be

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124. Of course, human interference in the loop does not guarantee the making of effective or flawless decision-making. Firstly, because the person may be more (rather than less) biased than machines. And, secondly, because it is unclear whether, and under what circumstances, a human being would make a decision that contradicts the machine's decision.

125. Tamir, *supra* note 32, at 951.

126. Glenn Cohen argues that the pursuit of explainability cannot be fully accomplished and should be replaced with the pursuit of interpretability. *See* Boris Babic et al., *Beware of Explanations from AI in Health Care: The Benefits of Explainable Artificial Intelligence are Not What They Appear*, 373 SCI. 284, 285–86 (2021).

127. Tamir, *supra* note 32, at 952. A non-explainable/uninterpretable algorithm has legal implications. It may constrict the plaintiff's ability to bring a claim against agents involved in the implementation process of AI-based technologies. A minimal level of understanding of the technology's workings is required in order to effectively prove if the algorithm led to a faulty decision-making process.

128. *See* Babic et al., *supra* note 126, at 284.

129. It should be decided when an explanation about the technology's working should be given and how detailed it should be, dependent on the circumstance. Despite the explainability requirement's advantages, it might be difficult, and even impossible, to accomplish it in certain contexts.

130. *See* Meyers, *supra* note 100; *see also* GATENS, *supra* note 100.

131. Jobin et al., *supra* note 108, at 394.

132. *See generally, e.g.*, Luciano Floridi & Josh Cowls, *A Unified Framework of Five Principles for AI in Society*, 1 HARV. DATA SCI. REV. 2 (2019).

expected, the bioethical principle of non-maleficence is particularly relevant as a precautionary step for technologies that are in their research phase. In the context of FemTech products, there should be a guarantee that AI-based medical devices promise welfare for women and do not impose certain social perceptions on women, for example, that pregnancy is a welcomed occurrence.

D. Responsibility and Accountability

When harmful circumstances or outcomes appear, typically, the obligations of responsibility and accountability begin to be discussed. Due to the autonomous character of AI-based medical devices, and since they can imitate certain parts of human thought, these devices may undermine the legal design of accountability.

The classic legal design of accountability is based on the presumption of a human-centered focus. When human engagement in decision-making is limited, the question of legal liability becomes more arguable. Who is liable for harmful decisions made by AI-based devices: the developer, the operator, another human factor, or a separate legal entity? What kind of liability is relevant for the one considered liable? And, how can procedural difficulties involved in proving someone is liable be handled, when we tackle "black box" devices?

The FemTech industry pushes us to think about these questions related to legal design of accountability, in general, and, in specific, about women. In addition to the issue of whether or not the legal accountability regime should be universal, or designed specifically for women, we should also think how to implement feminist approaches toward torts and anti-discrimination law, concerning medical devices for women, based on AI. Having envisaged what may constitute a civil wrong or a wrongful bias in the context of FemTech products, the next question would be: Who can potentially make claims against such civil wrongs or wrongful biases? A complete framework of legal accountability should include the answer to the question: Who should be included in the moral circle?" as presented by Bredenoord.[133]

E. The Comparative Perspective

The regulation of artificial intelligence around the world is still in its first stages. On national, meta-national, international, and transnational levels, there have been attempts to establish principles for the initial regulation of artificial intelligence.[134] While, in some places, very general principles have been offered

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133. Annelien L. Bredenoord, *The Principles of Biomedical Ethics Revisited*, *in* ISLAMIC PERSPECTIVES ON THE PRINCIPLES OF BIOMEDICAL ETHICS 133, 135 (Mohammed Ghaly ed. 2016).

134. *See, e.g.*, *Recommendation of the Council on A.I.*, OECD (May 2, 2024), https://legalinstruments.oecd.org/en/instruments/oecd-legal-0449#mainText [https://perma.cc/U6K5-L96L]; *Proposal for European Council Regulation*, *supra* note 17; *Ad Hoc Committee on*

(e.g., Singapore), and at other levels, very detailed principles have already been outlined (e.g., the European Union's AI Act).[135]

In some countries, highly targeted legislation in the area of artificial intelligence is recommended, and in other countries, it is suggested to promote legislation based on the existing legal foundations. In the European Union, for instance, targeted legislation for artificial intelligence has been promoted.[136] However, at the same time, in the UK, governmental policy related to artificial intelligence has been based on highly general principles.[137] The differences between the two attitudes stem, inter alia, from the adopted regulatory perception and the characteristics of the technological markets. While the European Union, for instance, supports legal regulation of technological markets, the US aspires to minimize governmental interference and has advanced the approach that supports the dominance of the market powers.

Does the regulation process of artificial intelligence that has been initiated around the world on various levels take into account women's needs? How can feminist ethics be implemented in this regulation? These are the major questions of this section. Here, I critically appraise the ongoing regulation process of artificial intelligence from a feminist perspective and examine to what extent it can advance feminist ethos in relation to medical devices.

In 2019, the OECD confirmed a set of recommendations of the council on artificial intelligence.[138] This was the first document created by a leading international organization.[139] The first section of the document includes principles for responsible management of artificial intelligence. These principles aim to foster human-centered AI, in light of the impact of this technology on people. In human-centered AI, the development of artificial intelligence is meant to serve humankind, its liberty, autonomy, and welfare, to

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Artificial Intelligence (CAHAI), EUR. CONSULT. ASS. (Dec. 3, 2021), chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://rm.coe.int/cahai-2021-09rev-elements/1680a6d90d#:~:text=The%20CAHAI%20proposes%20to%20include,and%20the%20rule%20of%20law.; OFF. OF MGMT. & BUDGET, *supra* note 105; *Establishing a Pro-Innovation Approach to Regulating AI*, GOV.UK (July 20, 2022), https://www.gov.uk/government/publications/establishing-a-pro-innovation-approach-to-regulating-ai/establishing-a-pro-innovation-approach-to-regulating-ai-policy-statement [https://perma.cc/2658-ZUZA] (United Kingdom government paper establishing a pro-innovation approach to regulating AI).

135. *Proposal for European Council Regulation*, *supra* note 17.

136. *See id.*

137. *Establishing a Pro-Innovation Approach to Regulating AI*, *supra* note 134.

138. *Recommendation of the Council on A.I.*, *supra* note 134.

139. The OECD's recommendations were a source of inspiration for a similar document consolidated by the G20, an organization that includes the twenty biggest economies in the world (nineteen countries and the European Union). *See Science, Technology, and Innovation*, OECD, https://www.oecd.org/science/forty-two-countries-adopt-new-oecd-principles-on-artificial-intelligence.htm [https://perma.cc/KH8Z-J8TR] (last visited Oct. 31, 2024); *G20 Insights*, GLOB. SOL. INITIATIVE, https://www.global-solutions-initiative.org/g20-insights-homepage/ [https://perma.cc/KZT2-D2RN] (last visited Oct. 31, 2024).

prevent its damaging, and to defend its rights.[140] Adding the bioethical perspective to the idea of human-centered AI could transform it into patient-centered. Maintaining the commitment to feminist ethos could guarantee that it would be female patient-centered. The OECD's Council on Artificial Intelligence additionally recommended that AI-based technology foster fairness and social welfare, and be transparent, resistant, and safe.[141] It was also emphasized that accountability, in relation to AI-based technology's solutions, should be scrutinized.[142]

A recently published comprehensive US federal bill regarding the protection of privacy similarly set certain principles for using personal data-based algorithms.[143] It prohibits, for instance, discriminatory use of algorithms; thus, it is a bill that can also protect women.[144] The bill also allows the Federal Trade Commission (FTC) to supervise the use of algorithms in certain cases.[145] Moreover, the White House Office of Management and Budget's notice from 2020, following Presidential Act No. 13859, was targeted at fostering public trust in AI and participation of the public (e.g., industry, academy, and civil society) in its regulation.[146] It also aspired to ensure scientific trustworthiness, fairness, and anti-discriminatory results, transparency of the technology's nature, and safety regarding the ways in which data are collected and used.[147] In the spirit of the Office of Management and Budget's notice, technologies that have a high risk of harming women can be marked and obligated to undergo a preliminary test. It is worthwhile mentioning that the Biden administration has approached this topic with more caution, putting forth the "AI Bill of Rights" to strike a balance between life optimization and the protection of citizens against exacerbation of inequities.[148] However, this Bill of Rights is just a hortatory values statement. In other words, until there is more explicit AI oversight, AI

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140. *Recommendation of the Council on A.I.*, *supra* note 134. In Japan, the Integrated Innovation Strategy Promotion Council established the Social Principles of Human-Centric AI. *See Artificial Intelligence in Health Care: A Global Landscape*, 2023 WORLD ASS'N MED. L. 1, 2, https://wafml.wildapricot.org/resources/Documents/WAML_Newsletter_57_June_23.pdf.

141. *Artificial Intelligence in Society*, OECD, https://www.oecd-ilibrary.org/sites/eedfee77-en/1/2/1/index.html?itemId=/content/publication/eedfee77-en&_csp_=5c39a73676a331d76fa56f36ff0d4aca&itemIGO=oecd&itemContentType=book [https://perma.cc/Z6JS-VPDM] (last visited Oct. 31, 2024).

142. *Id.*

143. Press Release, U.S. Senate Comm. on Com., Sci., & Transp., *House and Senate Leaders Release Bipartisan Discussion Draft of Comprehensive Data Privacy Bill*, U.S. SENATE (June 3, 2022), https://www.commerce.senate.gov/2022/6/house-and-senate-leaders-release-bipartisan-discussion-draft-of-comprehensive-data-privacy-bill [https://perma.cc/E6KR-UUXD].

144. *Id.*

145. *Id.*

146. *Id*.

147. *Id.*

148. Dr. Eric Lander & Dr. Alondra Nelson, *ICYMI: WIRED (Opinion): Americans Need a Bill of Rights for an AI-Powered World*, WHITE HOUSE (Oct. 22, 2021), https://www.whitehouse.gov/ostp/news-updates/2021/10/22/icymi-wired-opinion-americans-need-a-bill-of-rights-for-an-ai-powered-world/ [https://perma.cc/823H-4KZW].

for healthcare is being imperfectly retrofitted into existing regulatory frameworks.

Israel's Ministry of Justice also instructed AI-based technology industries to maintain fairness and an anti-discriminatory policy.[149] It recommended maintaining the requirement for diverse databases, the performance of preliminary and periodic tests, the implementation of a consequential test model, and human involvement for the prevention of discrimination.[150]

Another issue connected to regulation processes of AI, which appear relevant for AI-based medical devices for women, is whether to focus on creation and implementation of a broad and trans-sectional regulation, or to focus on narrow and sectional legislation. In other words, should regulation of AI-based technologies be broad and general, or should such regulation also be tailored to cover issues connected to medical devices for women?

In the European Union Artificial Intelligence Act, released in 2024, the European Union Commission confirmed a broad and trans-sectional model of AI regulation.[151] A broad process of regulation can monitor AI systems, according to their levels of risks to women. This approach can determine the required transparency of the technology, and what preliminary/consequential tests are necessary. A broad and trans-sectional model ensures a general, certain, and enforceable model of regulation. It ensures that different industrial sections will not adopt contradictory approaches to AI regulation, and it supports cooperation between governmental and private factors.

On the other hand, regulation, according to sector, can apply regulations that are relevant for each sector, including the relevant means of enforcement. Furthermore, such specific regulation enables stakeholders to become involved in the regulation process of AI-based technology: they can relate to detailed, specific aspects of the regulation of the sector with which they are familiar, ensuring flexible reactions of the regulator. In light of all these advantages of sectorial regulation, the UK government decided to employ an AI regulation approach that is very different from the EU Artificial Intelligence Act. In 2018, the British Parliament decided that there was no justification for the adoption of trans-sectional regulation, and decided to prioritize sectional regulation for AI technology.[152]

On March 29, 2023, the UK government unveiled its first White Paper on AI regulation.[153] The government's approach to an AI regulatory framework would be "proportionate and pro-innovation," and would focus on the context

149. *Israel's Policy on Artificial Intelligence Regulation and Ethics*, MINISTRY OF INNOVATION, SCI. & TECH. (Dec. 17, 2023), https://www.gov.il/en/pages/ai_2023 [https://perma.cc/8VDA-BQMG].

150. *Id.*

151. *Proposal for European Council Regulation*, *supra* note 17.

152. *National AI Strategy*, GOV.UK (Dec. 18, 2022), https://www.gov.uk/government/publications/national-ai-strategy/national-ai-strategy-html-version [https://perma.cc/4BKD-L6A7].

153. *Artificial Intelligence in Health Care: A Global Landscape*, *supra* note 140.

in which AI is deployed.[154] In the healthcare sector, a White Paper on AI in healthcare was published in 2020.[155] At the time, the document stated that any policy or regulatory framework should employ the AI lifecycle approach.[156] Israel has also vacillated between the adoption of trans-sectional or sectional regulation. The Ministry of Justice eventually decided to recommend trans-sectional regulation until the implications of the new technology would become clearer.[157]

In addition to implementing the bioethical principles in national and transnational regulation of AI-based medical devices for women, it is important to include them in international conventions. The Council of Europe, for instance, is drafting a Convention on Artificial Intelligence, Human Rights, Democracy and the Rule of Law.[158] This is the leading international convention on this topic. It aims to protect people's fundamental rights, in order to prevent the potential harms of Artificial Intelligence.[159] Moreover, it aims to become a global leading convention, as non-European states are also considering becoming signatories.

VIII. SUMMARY AND CONCLUSIONS

No AI-based system will replace a physician, but a physician working with AI will replace a physician working without AI.[160] This statement received the most attention and consensus among the participants in IBM's innovation conference.[161] In my opinion, like other technologies, AI technology will enter the medical world in three phases. Initially, it will analyze the same data as the physician and issue warnings if it detects medical errors. In the next phase, so I guess, it will assist the physician in making decisions. Eventually, I believe it will reach a point where it could fully replace the physician.

AI-based health technologies offer significant advantages, due to their ability to reduce resource shortages of health professionals. These advantages include, inter alia, extending access to healthcare, contributing to early disease detection and prevention, assisting diagnostics, disease surveillance and public health monitoring, and providing alternative healthcare delivery methods.[162] However, despite these potential benefits, rapidly developing technologies of this kind also pose a number of unique regulatory and governance challenges.

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154. *Id.*

155. *National AI Strategy*, *supra* note 152.

156. *Artificial Intelligence in Health Care: A Global Landscape*, *supra* note 140.

157. *Israel's Policy on Artificial Intelligence Regulation and Ethics*, *supra* note 149.

158. *Ad Hoc Committee on Artificial Intelligence (CAHAI)*, *supra* note 134.

159. *Id.*

160. Gali Weinreb, *Physicians are Having Difficulties Digesting Artificial Intelligence, but They Already Know They Do Not Have Any Other Choice*, GLOBES (Sept. 15, 2022), https://www.globes.co.il/news/article.aspx?did=1001424335.

161. *Id*.

162. *See supra* Part II.

Therefore, adequate ethical and legal safeguards need to be put in place to prevent infringements of patients' autonomy and malpractice. On the global level, there is an intense theoretical discourse on the ethical aspects of artificial intelligence.[163] This has given rise to hundreds of documents. As a result, there is a real concern about "ethics washing."[164] Scholars have begun to be concerned that the industry is encouraging theoretical discussions on the ethics of AI in order to postpone effective regulation.

This article focused on ethical discussions of artificial intelligence while adding a perspective that has yet to be addressed — the ethical dilemmas connected to the unique characteristics of AI-based medical devices for women that arise from a feminist perspective. The significant advantages of such devices for women are that they strive for gender equality, due to their automated processes of data processing and analyzing. Moreover, they advance women's autonomy over their bodies, address female medical problems that suffer from under-representation, are relevant for women's lifestyles, etc.[165] In light of the opportunities that AI-based FemTech products provide, I examined whether the FemTech revolution is indeed dedicated to the fulfillment of a feminist ethos. The article, thus, exposed the significant legal and bioethical challenges raised by AI from a feminist perspective: (1) the problem of bias; (2) stereotypical social perceptions about women; and (3) the challenges of maintaining privacy.[166] In order to deal with these challenges, I argued that a feminist regulatory and ethical policy should be promoted with respect to AI-based medical devices.[167] Regulatory policy additionally strengthens the financial certainty and trustworthiness, increases the public's faith in technology, and encourages its development.

This article proposed a basis for feminist regulation of AI-based medical devices. In the presentation of the normative horizon, some relevant bioethical principles were critically discussed, and a comparative legal perspective was examined. We still have a long way to go to achieve comprehensive and exhaustive regulation of AI-based medical devices. For that reason, this article offered a direction and an initial bioethical analysis of the principles that should serve as the basis of regulation for AI-based FemTech technologies, from a feminist perspective.

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163. *See generally*, *e.g.*, THE FRONTLINES OF ARTIFICIAL INTELLIGENCE ETHICS (Jeanine A. DeFalco & Andrew J. Hampton eds., 2022); THEMISTOKLIS TZIMAS, LEGAL AND ETHICAL CHALLENGES OF ARTIFICIAL INTELLIGENCE FROM AN INTERNATIONAL LAW PERSPECTIVE (2021); MACHINE LAW, ETHICS, AND MORALITY IN THE AGE OF ARTIFICIAL INTELLIGENCE (Steven John Thompson ed., 2021).

164. *See*, *e.g.*, Ravit Dotan, *AI Regulation: A Step Forward or Ethics Washing?*, SPICEWORKS (June 16, 2023), https://www.spiceworks.com/tech/artificial-intelligence/guest-article/ai-regulation-and-ethics/ [https://perma.cc/GK6C-TW7X].

165. *See supra* Part VI.

166. *Id.*

167. *See supra* Part VII.