RECKLESS REGULATION: THE FRIGHTENING TRUTH BEHIND FEMININE HYGIENE PRODUCTS

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Titanium dioxide should be handled as a CARCINOGEN–WITH EXTREME CAUTION.[1]

Depending on manufacturing processes, PEGs may be contaminated with measurable amounts of ethylene oxide and 1,4-dioxane.[2] *The International Agency for Research on Cancer classifies ethylene oxide as a known human carcinogen and 1,4-dioxane as a possible human carcinogen.*[3] *Ethylene oxide can also harm the nervous system and the California Environmental Protection Agency has classified it as a developmental toxicant based on evidence that it may interfere with human development.*[4]

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[1] *Right to Know Hazardous Substance Fact Sheet*, N.J. DEP'T OF HEALTH 1 (May 2016), https://nj.gov/health/eoh/rtkweb/documents/fs/1861.pdf.

[2] *The Dirty Dozen: PEG Compounds and Their Contaminants*, DAVID SUZUKI FOUND., https://davidsuzuki.org/living-green/dirty-dozen-peg-compounds-contaminants/ (last visited Dec. 18, 2023).

[3] Melissa J. Vincent et al., *Ethylene Oxide: Cancer Evidence Integration and Dose-Response Implications*, DOSE-RESPONSE (Oct.–Nov. 2019), https://journals.sagepub.com/doi/10.1177/1559325819888317; Sharon Wilbur et al., *Toxicological Profile for 1,4-Dioxane*, AGENCY FOR TOXIC SUBSTANCES & DISEASE REGISTRY 4 (Apr. 2012), https://www.atsdr.cdc.gov/toxprofiles/tp187.pdf.

[4] *The Dirty Dozen: PEG Compounds and Their Contaminants, supra* note 2.

I. INTRODUCTION

Titanium dioxide and polyethylene glycols (PEGs) have one thing in common: both are chemical ingredients found in the #1 U.S. gynecologist-

recommended tampon.[5] These ingredients, alongside many others found in popular tampon brands, could pose a substantial health risk, even in trace levels, due to the chronic exposure to tampon users over the course of their lives.[6]

To understand the impact of chemicals found in tampons, it is essential to consider the magnitude of the issue. These chemicals present an alarming threat to the health of approximately forty-three million women in the United States who use tampons, alongside other tampon users that are not self-identified.[7] Most tampon users in the United States experience their periods for the first time between the ages of 10 to 15 years old;[8] the average age of first-time menstruation in the United States is 12.16 years old for African American women, and 12.18 years old for white women.[9] An overwhelming majority use tampons, with *Women's Voices for the Earth* finding up to 70% of women in the United States use tampons.[10] Although an important issue, informational statistics regarding tampon usage by nonbinary, transmen, and other identities that possess the ability to menstruate, are scarce.[11] This paper will focus on the available statistics affecting women, finding this issue affects an even larger pool of users that do not identify as women but still choose to use these products.

Furthermore, it is estimated women use twenty tampons per menstrual cycle.[12] Period length varies widely across users; however, the typical

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[5] *So, What's Really in Tampax Tampons*?, TAMPAX, https://tampax.com/en-us/about/ingredients/what-tampons-are-made-of/(last visited Dec. 18, 2023).

[6] *Menstrual Care Products and Toxic Chemicals*, CAMPAIGN FOR SAFE COSMS., https://www.safecosmetics.org/resources/health-science/menstrual-care-products/ (last visited Dec. 18, 2023).

[7] *Id.*

[8] Robyn R. Miller, *Talking to Your Child About Periods*, NEMOURS KIDSHEALTH (Oct. 2018), https://kidshealth.org/en/parents/talk-about-menstruation.html.

[9] Karen Sarpolis, *First Menstruation: Average Age and Physical Signs*, CONTEMPORARY OB/GYN (Nov. 18, 2011), https://www.contemporaryobgyn.net/view/first-menstruation-average-age-and-physical-signs.

[10] *Menstrual Care Products & Toxic Chemicals*, WOMEN'S VOICES FOR THE EARTH, https://womensvoices.org/menstrual-care-products/ (last visited Dec. 18, 2023).

[11] Sarah E. Frank, *Queering Menstruation: Trans and Non-Binary Identity and Body Politics*, 90 SOCIO. INQUIRY 371, 376 (Feb. 5, 2020), https://onlinelibrary.wiley.com/doi/full/10.1111/soin.12355.

[12] *The Ultimate Guide to Feminine Hygiene*, DUQUESNE UNIV. SCH. OF NURSING, https://onlinenursing.duq.edu/master-science-nursing/the-ultimate-guide-to-feminine-hygiene/ (last visited Dec. 18, 2023).

length is three to five days, although some can last upwards of a week.[13] Women experience roughly 456 period cycles in their lives.[14] At this rate, women will use around 9,000 tampons in their lifetime.[15] The Food & Drug Administration (FDA) recommends changing tampons every four to eight hours.[16] If tampons are used consistently over the period cycle, the exposure to tampons is 24 hours a day for approximately three to five days, calculating to a minimum of 72 hours every cycle, or 32,832 hours in a lifetime being exposed to the potentially dangerous chemical ingredients. If a period were to last a full seven days, as is the case for some, exposure for chronic users is at a minimum of 168 hours in a cycle of toxic exposure, and therefore 76,608 hours in a lifetime. In sum, this is not a small-scale issue, but rather a large-scale concern exposing millions of users to the absorption of harmful ingredients linked to severe health conditions.[17]

The United States FDA regulates tampons, pads, and menstrual cups,[18] collectively referred to as "feminine hygiene products" (FHPs) for the remainder of the article; however, the regulatory procedure is far from satisfactory. Analysis of the current health concerns regarding the FDA's lack of regulation on FHPs begins with the history of the FHP industry and its regulation in the United States, followed by a description of the FDA's current regulation of FHPs, a comparison of international FHP regulation, a critique of the current regulations, and concludes with a proposal to regulate these FHPs as Class III medical devices more effectively within the FDA's current regulatory structure.

The primary concern of these FHPs remaining deregulated is not the known harms, but rather the unknown, potential harms that remain undiscovered because of a lack of testing. The current regulation of FHPs is inadequate because it does not require stringent safety testing for these products whose chemical additives are harmful in other contexts;

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[13] Zia Sherrell, *What to Know About Using Tampons as a Beginner*, MEDICALNEWSTODAY, https://www.medicalnewstoday.com/articles/how-to-put-in-a-tampon-for-beginners-tampon-types-and-more (Mar. 29, 2023).

[14] *The Ultimate Guide to Feminine Hygiene*, *supra* note 12.

[15] *Id.*

[16] *The Facts on Tampons—and How to Use Them Safely*, U.S. FOOD & DRUG ADMIN. (Sept. 30, 2020), https://www.fda.gov/consumers/consumer-updates/facts-tampons-and-how-use-them-safely.

[17] *See* Erica Zurek, *Period products can contain hazardous ingredients. Some states are requiring more transparent labeling*, PBS NEWS HOUR (May 4, 2023, 1:21 PM), https://www.pbs.org/newshour/health/period-products-can-contain-hazardous-ingredients-some-states-are-requiring-more-transparent-labeling.

[18] 21 C.F.R. § 801.430 (2023); 21 C.F.R. § 884.5400 (2023); 21 C.F.R. § 884.5425 (2023).

therefore, these products should be regulated as Class III medical devices requiring rigorous Pre-Market Approval (PMA) testing.

II. A HISTORY OF THE FEMININE HYGIENE PRODUCTS INDUSTRY: TAMPONS, PADS, AND MENSTRUAL CUPS

A. Tampons

Tampons are described by the FDA as "one method of absorbing menstrual flow during your period. Tampons are designed to be inserted into the vagina with or without an applicator."[19] These apparatuses are typically made of mostly cotton and rayon for absorption, with a string at the bottom for easy removal, oftentimes accompanied by a plunging applicator for easy insertion.[20] Although tampons have an efficient structure today, they have looked vastly different throughout history.[21] The first documented use of tampons is believed to be by the Egyptians, made of papyrus in 1400 B.C.[22] Since then, several other forms of make-shift tampons were created cross-culturally, such as ferns in Hawaii and rolled grass in Africa.[23] These products were used to absorb what is now known as menstruation.[24]

Menstruation is "the monthly shedding of the lining of [the] uterus."[25] Menstrual blood is the product of blood and uterus tissue expelled from the body through the vagina which tampons are designed to absorb.[26] The tampon is placed into the internal vaginal canal and absorbs the menstrual bleeding before it exits the body, to be removed once full, or every four to eight hours.[27] The structure of the modern tampon was not commercially recognized until 1931, when Dr. Earl Haas patented the cotton and string design.[28] The tampon, as it is currently known, did not enter the

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[19] *The Facts on Tampons—and How to Use Them Safely*, *supra* note 16.

[20] Sherrell, *supra* note 13.

[21] *The History of Tampons*, BARNHARDT PURIFIED COTTON (Feb. 5, 2020), https://barnhardtcotton.net/blog/the-history-of-tampons/.

[22] *Id.*

[23] *Id.*

[24] *See id.*

[25] *Menstrual Cycle*, CLEVELAND CLINIC, https://my.clevelandclinic.org/health/articles/10132-menstrual-cycle (Dec. 9, 2022).

[26] *Id.*

[27] *Period Products: The Good, the Bad, and the Ugly*, UNIV. OF TEX. HEALTH AUSTIN (Mar. 20, 2019), https://uthealthaustin.org/blog/period-products.

[28] Mary Bellis, *A Brief History of the Tampon*, THOUGHTCO. (June 21, 2019), https://www.thoughtco.com/history-of-the-tampon-4018968.

United States market until 1936.[29] The prototype invented by Dr. Haas became trademarked under the brand "Tampax" but was soon competing with another design, known as the "o.b. Tampon."[30] This new design favored natural human application in lieu of an additional applicator.[31] The company behind o.b. Tampons was later sold to fan-favorite pharmaceutical company, Johnson & Johnson.[32]

Today's tampons have retained much of this initial structure, only becoming more discrete, absorbent, and diverse in size to accommodate different flow volumes.[33] They are still composed of cotton blend fabric, compressed into a cylindrical shape, and accompanied by both an applicator and exterior string for easy removal.[34] Sizes of tampons range in flow from light, regular, heavy, super, super plus, and ultra.[35] These flow types can vary widely among tampon users and are not always consistent per person, or even per cycle.[36] There are several other forms of FHPs utilized, including sanitary napkins and menstrual cups to help during menstruation.[37]

B. Sanitary Napkins or "Pads"

Sanitary napkins, otherwise known as "pads"[38] are defined as "feminine hygiene products fabricated to absorb and retain menstrual fluid at all times."[39] Sanitary napkins are usually made up of several layers, likely to promote leakproof protection, adhere to undergarments, and provide comfortability of wear.[40] However, pads, just like tampons, come from an

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[29] *The History of Tampons*, *supra* note 21.

[30] Bellis, *supra* note 28.

[31] *Id.*

[32] *Id.*

[33] *The History of Tampons*, *supra* note 21.

[34] *The Facts About Cotton in Tampons*, COTTONWORKS (Feb. 21, 2023), https://www.cottonworks.com/en/news/the-facts-about-cotton-in-tampons/.

[35] Andrei Marhol, *Tampon Sizes: Which One to Pick?*, FLO (Jan. 14, 2021), https://flo.health/menstrual-cycle/health/period/tampon-sizes.

[36] *Id.*

[37] *Period Products: The Good, the Bad, and the Ugly*, *supra* note 27.

[38] Amy W. Anzilotti, *Tampons, Pads, and Other Period Supplies*, NEMOURS TEENSHEALTH, https://kidshealth.org/en/teens/supplies.html (last visited Dec. 18, 2023).

[39] Nikitha Narayanan, *Sanitary Napkins - The Potential Ill-Effects*, ICLINIQ (Mar. 23, 2023), https://www.icliniq.com/articles/womens-health/potential-ill-effects-of-sanitary-napkins.

[40] *Id.*

illustrious history before evolving into the modern pad known today.[41] The first iteration of pads were "homemade menstrual cloths" of flannel or woven fabric, going as far back as ancient Greece.[42] The use of these products to stem menstrual bleeding evolved until the technology became a patented consumer item between 1854–1915.[43] The first commercial cotton pad entered the U.S. in 1896.[44]

The technology was revolutionized during World War II, as the nurses discovered the absorptive property of cellulose bandages for bleeding wounds was far superior to the cloth material commonly used for managing menstruation.[45] Following this discovery, new forms of menstrual products were created in 1956, including the first pad with an adhesive,[46] and a more modern version of the menstrual cup.[47] Plastic became a much cheaper and accessible alternative, and "[s]uper Absorbent Polymers, Polyethylene, and other polymers" became common, while natural ingredients were phased out.[48]

As mentioned earlier, these modern pads are constructed with several layers consisting of:

> The Fluid Receiving Layer: It is a thin perforated layer that allows the menstrual fluid to pass through it to the absorbent layer. This helps prevent leakage and keeps the top surface dry. The propylene sheets are most commonly used as this top fluid-receiving layer.
>
> Distribution Component: The distribution component helps spread the fluid evenly, thereby increasing the possibility of retaining more fluid.
>
> Absorbent Layer: Absorbent layer helps absorb menstrual fluid and also retain it. This forms the significant bulk of the sanitary napkin. It primarily comprises superabsorbent polymers, cotton, wood pulp, and viscose.
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> Liquid Impervious Membrane: This layer acts as a barrier to prevent leakage. Polyethylene is generally used to fabricate this back cover.[49]

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[41] Jennifer Kotler, *A Short History of Modern Menstrual Products*, HELLOCLUE (Nov. 20, 2018), https://helloclue.com/articles/culture/a-short-history-of-modern-menstrual-products.

[42] Sabrina Rubli, *The History of the Sanitary Pad*, FEMME INT'L (June 24, 2013), https://femmeinternational.org/the-history-of-the-sanitary-pad; Kotler, *supra* note 41.

[43] Kotler, *supra* note 41.

[44] Narayanan, *supra* note 39.

[45] Kotler, *supra* note 41.

[46] *Id.*

[47] *Id.*

[48] Narayanan, *supra* note 39.

[49] *Id.*

During a study of the possible chemicals that could be transmitted to FHP users, one study described these layers as a "topsheet generally comprised of perforated, non-woven polypropylene/polyethylene fibers" designed for the fluid collection and "soft contact with the vulva,"[50] followed by "an absorbent polymeric core" for more fluid collection, and a "backsheet" that provides a leak shield with adhesive and sometimes added fragrance.[51] Just as with tampons, there are varying sizes of pads to accommodate different levels of menstrual flow,[52] such as overnight pads, or panty-liners, which are similar in composition with varying layers of leak protection.[53] Pads are recommended to be changed every three to four hours, regardless of the level of fluid, in order to prevent bacteria growth.[54]

C. Menstrual Cups

Menstrual cups are devices typically made of medical-grade silicon, rubber or latex, and are designed to "collect and hold menstrual fluid within the vagina."[55] They are used for 6-12 hours at a time and need to be removed and washed before being reused.[56] The structure of the cup is designed to simply collect, rather than absorb fluid, working as a removable barrier.[57] The cup has a small stem at the bottom of it, for easier removal access as well.[58] The cup works by being folded, inserted until it is fully contained, and the cup pops open with the stem inside but at the bottom.[59]

These cups are perhaps a more sustainable and inexpensive option given most versions of this medical device are reusable, but some are one-time disposables.[60] However, just like the other products, these cups have evolved in their technology, beginning in the later 17th century as

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[50] Kristen Upson et al., *Menstrual Products as a Source of Environmental Chemical Exposure: A Review from the Epidemiologic Perspective*, 9 CURRENT ENV'T HEALTH REPS. 38, 41–43 (Mar. 17, 2022), https://link.springer.com/article/10.1007/s40572-022-00331-1.

[51] *Id.*

[52] *Welcome to the Product Gallery*, GIRLS HELPING GIRLS PERIOD, https://girlshelpinggirlsperiod.org/menstrual-product-guide/ (last visited Dec. 18, 2023).

[53] *Id.*

[54] Anzilotti, *supra* note 38.

[55] Upson et al., *supra* note 50.

[56] Nicole Galan, *Menstrual Cups: Everything You Need to Know*, MEDICALNEWSTODAY (May 2, 2019), https://www.medicalnewstoday.com/articles/325093#_noHeaderPrefixedContent.

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] Upson et al., *supra* note 50.

aluminum or hard rubber apparatuses.[61] The first menstrual cups in the United States were known as "catamenial sacks" in the 1860s, but after World War II and a rubber shortage, production ceased for the wartime effort.[62] Later, these models were altered and after a series of failed marketing campaigns,[63] some models finally became successful, such as the "Keeper" with medical-grade silicone instead of latex.[64]

Today's medical-grade silicone cups are not susceptible to bacteria growth or chemical reactions; however, some are still made of "thermoplastic polymers."[65] One study found the presence of three siloxanes could not be determined as safe because there was "insufficient information about them."[66] These apparatuses are gaining popularity in recent years, and a study funded by Proctor & Gamble (P&G) stated although there were no obvious health effects from menstrual cup use. However, a "menstrual cup safety assessment scheme is currently lacking," and a "comprehensive assessment paradigm that covers all potentially relevant aspects of the safety assessment of intravaginal devices has not yet been published either in the scientific literature or in regulatory guidance."[67] This is troublesome because the intimate and chronic nature of these products warrants thorough safety research.

III. HISTORY OF REGULATIONS OF FEMININE HYGIENE PRODUCTS IN THE UNITED STATES

A. Tampons

Now that there is a clear understanding of these products and how they work, it is important to understand the current regulations

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[61] Kotler, *supra* note 41.

[62] *Short History of Menstrual Cups – When Were They Invented?*, LUNETTE, https://store.lunette.com/blogs/news/short-history-of-menstrual-cups (last visited Dec. 18, 2023).

[63] *Id.*

[64] *Id.*

[65] *Do Menstrual Products Contain Harmful Substances?*, WOMENA (June 14, 2019), https://womena.dk/do-menstrual-products-contain-harmful-substances/.

[66] *Chemicals in Feminine Hygiene Products*, EUR. CHEMS. AGENCY, https://chemicalsinourlife.echa.europa.eu/chemicals-in-feminine-hygiene-products (last visited Nov. 12, 2023).

[67] Vincent P. Sica et al., *Safety assessment scheme for menstrual cups and application for the evaluation of a menstrual cup comprised of medical grade silicone*, EBIOMEDICINE (Nov. 10, 2022), https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(22)00521-7/fulltext.

surrounding them. The FDA currently regulates tampons as "medical devices."[68] However, this regulation is relatively recent compared to their invention and was encouraged by litigation against tampon manufacturers.[69] The tampon, as we know it, was not used regularly in the United States until the 1970s.[70] In 1974, Proctor & Gamble (P&G) challenged this status quo by creating their tampon called Rely, although reports of Toxic Shock Syndrome (TSS) gathered in 1975.[71] According to Johns Hopkins Medicine, TSS is "a cluster of symptoms that involves many systems of the body. Certain bacterial infections release toxins into the bloodstream, which then spreads the toxins to body organs."[72] Further, Johns Hopkins found "TSS from *Staphylococcus* infections was identified in the late 1970s and early 1980s when highly absorbent tampons were widely used by menstruating women."[73] TSS can be fatal and "at its peak in 1980, there were approximately six cases of TSS per 100,000 women ages 19 to 44."[74] As of 2018, this rate had decreased from the above ratio of six cases to only one case.[75]

In response to a lack of oversight, the Medical Device Amendments (MDA) were passed in 1976[76] and elaborated on FDA regulation of tampons as medical devices, which had more stringent medical testing requirements than cosmetics under the Federal Food, Drug, and Cosmetic Act (FDCA).[77] Alongside this new regulation of tampons as medical devices was the accumulation of suggestive reports, finding Rely tampons responsible for increased occurrences of TSS.[78] The MDA also gave the FDA jurisdiction over medical devices and detailed the stricter process medical devices needed to undergo to be sold to the regular consumer market.[79]

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[68] *The Facts on Tampons—and How to Use Them Safely*, *supra* note 16.

[69] Jamie Kohen, *The History of the Regulation of Menstrual Tampons*, HARV. L. SCH. (Apr. 6, 2001), https://dash.harvard.edu/bitstream/handle/1/8852185/Kohen.html?sequence=2.

[70] *Id.*

[71] *Id.*

[72] *Toxic Shock Syndrome (TSS)*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/health/conditions-and-diseases/toxic-shock-syndrome-tss (last visited Dec. 18, 2023).

[73] *Id.*

[74] Kristen Domonell, *Toxic Shock Syndrome Is Rare. Here's What Tampon Users Should Know*, RIGHT AS RAIN, (Mar. 7, 2018), https://rightasrain.uwmedicine.org/well/health/toxic-shock-syndrome-rare-heres-what-tampon-users-should-know.

[75] *Id.*

[76] See Medical Devices Amendments of 1976, 21 U.S.C. §§ 351–360fff-8.

[77] Rainey Horwitz, *Menstrual Tampon*, EMBRYO PROJECT ENCYCLOPEDIA (May 25, 2020), https://embryo.asu.edu/pages/menstrual-tampon.

[78] Kohen, *supra* note 69.

[79] *Id.*

In the latest efforts to improve tampon safety, campaigns began to stop the chlorine-bleaching process that creates dioxin, a known carcinogen, that tampon companies were using to achieve this sterile appearance.[80] The MDA also created three classes of medical devices for mandatory classification, and by 1980 tampons were considered a Class II medical device under the FDA regulation standards.[81] Tampons have stayed in this classification, despite further research, discussed more in the next section.[82]

B. Sanitary Pads

The history of the regulation of pads in this country is similar to that of the tampon, beginning with the addition of the Medical Device Amendments of 1976, giving FDA the discretion to regulate all feminine care products as medical devices.[83] After thorough research, it is uncertain when the sanitary pads became a Class I medical device, the lowest and most unregulated of the medical device categories;[84] however, it seems this has never changed and sanitary pads have consistently been a Class I medical device.[85] Unlike tampons, which experienced a tumultuous change of regulation and categorization as detailed above, pads have stayed consistent in this categorization assumably because of the lack of risk of TSS presented with tampons.[86] The sparse literature and historical discussions regarding how sanitary pads should be regulated only supports the notion that these devices are likely neglected from questions regarding their safety and efficacy.

C. Menstrual Cups

Menstrual cups, like pads, suffer from a lack of data and are insufficiently regulated. The menstrual cups as FHPs became under the control of the FDA during the Medical Device Amendments in 1976,[87] but having

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[80] *Id.*

[81] *Id.*

[82] *Id.*

[83] Chris Bobel, *From Convenience to Hazard: A Short History of the Emergence of the Menstrual Activism Movement, 1971–1992,* 29 HEALTH CARE FOR WOMEN INT'L 738, 743–46 (2008), https://www.tandfonline.com/doi/full/10.1080/07399330802188909.

[84] *FDA Medical Devices: Definition and Classifications*, IN2BEING, https://www.in2being.com/fda-medical-devices-definition-and-classifications/ (last visited Dec. 18, 2023).

[85] 21 C.F.R. § 884.5425 (2023).

[86] *See* Kohen, *supra* note 69.

[87] *See* Collin M. Pollard, *Menstrual Tampons and Vaginal Pessaries: Regulation of Intravaginal Medical Devices by the US FDA*, 5 FRONTIERS REPROD. HEALTH 1, 2 (Sept. 19, 2023), https://www.frontiersin.org/articles/10.3389/frph.2023.1224421/full.

preexisted in the United States, many of these products went without premarket evaluation from a regulatory entity.[88] The cups were categorized as a Class II medical device, and further research was prompted by a letter from Dr. Mark McClellan of the Associated Pharmacologists & Toxicologists of the United States who wrote to the FDA concerned over endometriosis possibly linked to the use of the menstrual cup.[89] Specifically, Dr. McClellan requested that the FDA:

> 'revoke the approval for the marketing of the devices categorized as menstrual cups because there is a high likelihood that the use of these devices as directed will endanger a woman's reproductive health by inducing endometriosis.' They asked for the ban to be upheld until the companies selling cups could submit animal and clinical data to support their safety claims, and warned that 'obstructions of the cervix and vagina are commonly recognized as important factors in inducing endometriosis.'[90]

Sadly, the FDA in 2019 exempted menstrual cups from the premarket notification usually required for Class II medical devices that would have included "full quality assurance, produce a declaration of conformity, affix certification marking, and prepare detailed technical documentation."[91] This decision was not well explained, citing "low health risks" and "redirect[ing] the resources that would be spent on reviewing such submissions to more significant public health issues."[92]

IV. THE CURRENT FDA REGULATORY STRUCTURE OF MEDICAL DEVICES AND CATEGORIZATION OF TAMPONS, PADS, AND MENSTRUAL CUPS

The FDA regulates food and drug products, as might be expected.[93] However, the FDA also regulates a multitude of other products, including dietary supplements, vaccines, medical products, blood products, medical devices, radiation-emitting products, veterinary products, cosmetics, pet

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[88] Barbara B. North & Michael J. Oldham, *Preclinical, Clinical, and Over-the-Counter Postmarketing Experience with a New Vaginal Cup: Menstrual Collection*, 20 J. WOMEN'S HEALTH 303, 304 (Feb. 13, 2011), https://www.liebertpub.com/doi/10.1089/jwh.2009.1929.

[89] Camilla Mørk Røstvik, *Safer, Greener Cheaper: The Mooncup and the Development of Menstrual Cup Technology in the Twentieth Century*, 26 INT'L COMM. FOR HIST. TECH. 81, 94 (2021).

[90] *Id.* at 94–95.

[91] *Id.* at 95.

[92] *Id.* at 95–96.

[93] *What Does FDA Regulate?,* U.S. FOOD & DRUG ADMIN. (Jan. 18, 2022), https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate.

food, tobacco, and bottled water, among other things. [94] Specifically, the FDA currently regulates medical devices under the authorization of the Medical Device Amendments passed in 1976, including all feminine hygiene products such as tampons, pads, and menstrual cups.[95] The FDA defines a medical device in section 201(h) of the Food, Drug, and Cosmetic Act of 1976 as:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
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> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
>
> (2) intended for use in the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
>
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.[96]

This definition of a medical device encompasses a wide range of apparatuses, ranging from replacement hips to pacemakers.[97]

Further, there are three detailed classifications of medical devices, first promulgated by the FDA after being directed to do so by the MDA in 1976.[98] The three categories each hold many types of medical devices, with exemptions allowed in each.[99] The FDA classifies medical devices in these three ways: 1) Class I General Controls, 2) Class II General Controls

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[94] *Id.*

[95] *See* Kohen, *supra* note 69; Røstvik, *supra* note 89.

[96] *Classification of Products as Drugs and Devices and Additional Product Classification Issues*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/regulatory-information/search-fda-guidance-documents/classification-products-drugs-and-devices-and-additional-product-classification-issues#device (July 12, 2018).

[97] *See generally List of Medical Devices, by Product Code, that FDA Classifies as Implantable, Life-Saving, and Life-Sustaining Devices for purposes of Section 614 of FDASIA amending Section 519(f) of the FDC Act*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/87739/download (Mar. 2015).

[98] *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, U.S. FOOD & DRUG ADMIN. 1–2 (July 28, 2014), https://www.fda.gov/media/82395/download.

[99] *Classify Your Medical Device*, U.S. FOOD & DRUG ADMIN. (Feb. 7, 2020), https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device.

and Special Controls, and 3) Class III General Controls and Premarket Approval (PMA).[100] The FDA describes the prominent processing difference of the classifications as "the [c]lass to which your device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market."[101] These classifications allow manufacturers and consumers to be confident the FDA is ensuring products undergo testing as needed to ensure safety and efficacy before they are used by the public.[102]

The differences between the first two categories are nuanced, but there are variations in production, marketing, labeling, and testing requirements, especially once classified even further as a Class III medical device.[103] The FDA uses several distinctions to categorize devices, and considers: 1) the intended use of the product, 2) the indications for use, and 3) the risk of the product in use.[104] First, the intended use of the product is defined as "the objective of the persons legally responsible for the labeling of devices."[105] Second, the indication for use continues to distinguish the particular uses for this device beyond the general purpose (e.g., lowering blood pressure) but also lists specifically "the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended."[106] Finally, the risk of the product is determined by "weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use."[107]

Class I devices are regulated by general controls, and these controls are also imposed on the two remaining classes.[108] The general controls are authorized by several sections of the FDCA, including §§ 501, 502, 510, 516, 518, 519, and 520.[109] The general controls standard, in summary,

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[100] *Id.*

[101] *Id.*

[102] *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, *supra* note 98, at 3–4, 6.

[103] *See Classify Your Medical Device*, *supra* note 99.

[104] *Id.*

[105] Catherine Milford, *The Difference Between Intended Use, Indications For Use, And Instructions For Use*, EMMA INT'L (Dec. 9, 2020), https://emmainternational.com/the-difference-between-intended-use-indications-for-use-and-instructions-for-use/.

[106] *Id.*

[107] 21 U.S.C. § 360c(a)(2)(C) (2022).

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

[109] See *id.; see also* 21 U.S.C. §§ 501, 502, 510, 516, 518, 519, 520.

ensures devices are not adulterated or misbranded, they are registered with a premarket notification, records are kept, remedies are available to anyone harmed by these products including an adverse event reporting system, and good and safe manufacturing is maintained.[110] Class I medical devices are defined in the Code of Federal Regulations based on the following considerations:

> (1) General controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or
>
> (2) There is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining, or for a use which is of substantial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness or injury.[111]

Class I medical devices are those deemed safe having only undergone the basic general controls listed above.[112] The definition excludes lifesaving or life-sustaining devices, as well as those "of substantial importance in preventing impairment of human health" and ones that do not pose unreasonable health risks.[113] Class I devices include 47% of medical devices and things such as band-aids, electric toothbrushes, and gloves.[114]

Class II devices are subject to stricter controls known as specific controls.[115] A device is classified as a Class II if:

> . . . [G]eneral controls alone are insufficient. . . and there is sufficient information to establish special controls, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines . . . and other appropriate actions as the Commissioner deems necessary to provide such assurance. For a device that is purported or represented to be for use in supporting or sustaining human life, the Commissioner shall examine and identify the special controls, if any, which are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.[116]

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[110] *See Regulatory Controls*, *supra* note 108.

[111] 21 C.F.R. § 860.3 (2023).

[112] *Id.*

[113] *Id.*

[114] Carrie Britton, *What's the Difference Between a Class I and Class II Medical Device?*, STERLING MED. DEVICES (Apr. 8, 2021), https://sterlingmedicaldevices.com/medical-device-industry-news-trends/whats-the-difference-between-a-class-i-and-class-ii-medical-device/.

[115] *Regulatory Controls*, *supra* note 108.

[116] 21 C.F.R. § 860.3.

Class II devices are required to satisfy the listed general controls, as well as any of the specific controls listed above which the Commissioner deems appropriate to ensure the continued safety of using the product.[117] This standard can be presumed not as uniform as the first set of classifications because it relies on the discretion of the Commissioner to determine which further controls should be implemented.[118] This class of devices allows an unsettling amount of deference for safety testing over devices that spend a significant amount of time in close contact with some of the bodies' most vulnerable and absorbent mucosal linings,[119] like the tampon. For reference, other devices included in Class II are catheters and syringes.[120]

Finally, Class III medical devices are those that require all the controls listed above, as well as PMA.[121] These devices are the most regulated because the FDA defines them as devices under which general and specific controls cannot give safety assurances.[122] In addition, devices "which support or sustain human life, are of substantial importance in preventing the impairment of human health or present a potential unreasonable risk of injury or illness" are considered Class III medical devices.[123] PMA is only imposed upon the products that cannot be ensured as safe and effective with other measures and gives essentially a "private license granted to the applicant for marketing a particular medical device."[124]

PMA requires much more thorough and rigorous data gathering to ensure a full scientific review was established of the safety of the product.[125] Class III regulations require a thorough and tedious PMA application described below.[126] Although it is bulky, it provides an important visual and quantitative perspective to include the entire PMA here with all the rigorous testing and evaluation that could be used to ensure the safety

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[117] *Id.*

[118] *Id.*

[119] *See id.*; Britton, *supra* note 114.

[120] Sumatha Kondabolu, *The 3 FDA Medical Device Classes: Differences and Examples Explained*, QUALIO (Jan. 25, 2023), https://www.qualio.com/blog/fda-medical-device-classes-differences#what-is-class-2-device.

[121] 21 C.F.R. § 860.3.

[122] *Id.*

[123] *Premarket Approval for Medical Devices*, UNIV. LAB PARTNERS (Jan. 18, 2022), https://www.universitylabpartners.org/blog/premarket-approval-for-medical-devices.

[124] *PMA Approvals*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/pma-approvals (Nov. 6, 2023).

[125] *See* 21 C.F.R. § 814.20(b).

[126] *See id.*

of these products, versus what is currently required of these companies as shown above describing the Class I and II device requirements. The notable takeaways of this application in contrast to Class I and Class II devices are highlighted in the summary following the application:

> (1) The name and address of the applicant.
>
> (2) A table of contents that specifies the volume and page number for each item referred to in the table. A PMA shall include separate sections on nonclinical laboratory studies and on clinical investigations involving human subjects. A PMA shall be submitted as a single version. The applicant shall include information that it believes to be trade secret or confidential commercial or financial information in the PMA and identify the information that it believes to be trade secret or confidential commercial or financial information.
>
> (3) A summary in sufficient detail that the reader may gain a general understanding of the data and information in the application. The summary shall contain the following information:
>
> (i) *Indications for use.* A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.
>
> (ii) *Device description.* An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device. The generic name of the device as well as any proprietary name or trade name should be included.
>
> (iii) *Alternative practices and procedures.* A description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.
>
> (iv) *Marketing history.* A brief description of the foreign and U.S. marketing history, if any, of the device, including a list of all countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device. The description shall include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person.
>
> (v) *Summary of studies.* An abstract of any information or report described in the PMA under paragraph (b)(8)(ii) of this section and a summary of the results of technical data submitted under paragraph (b)(6) of this section. Such summary shall include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section shall include the following:
>
> (A) A summary of the nonclinical laboratory studies submitted in the application;
>
> (B) A summary of the clinical investigations involving human subjects submitted in the application including a discussion of subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation,

patient complaints, device failures and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate (any investigation conducted under an IDE shall be identified as such).

(vi) *Conclusions drawn from the studies.* A discussion demonstrating that the data and information in the application constitute valid scientific evidence within the meaning of § 860.7 and provide reasonable assurance that the device is safe and effective for its intended use. A concluding discussion shall present benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA.

(4) A complete description of:

(i) The device, including pictorial representations;

(ii) Each of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition;

(iv) The principles of operation of the device; and

(v) The methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device.

(5) Reference to any performance standard under section 514 of the Federal Food, Drug, and Cosmetic Act or under section 534 of Subchapter C - Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968) in effect or proposed at the time of the submission and to any voluntary standard that is relevant to any aspect of the safety or effectiveness of the device and that is known to or that should reasonably be known to the applicant. The applicant shall -

(i) Provide adequate information to demonstrate how the device meets, or justify any deviation from, any performance standard established under section 514 of the Federal Food, Drug, and Cosmetic Act or under section 534 of Subchapter C - Electronic Product Radiation Control of the Federal Food, Drug, and Cosmetic Act (formerly the Radiation Control for Health and Safety Act of 1968); and

(ii) Explain any deviation from a voluntary standard.

(6) The following technical sections which shall contain data and information in sufficient detail to permit FDA to determine whether to approve or deny approval of the application:

(i) A section containing results of the nonclinical laboratory studies with the device including microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests as appropriate. Information on nonclinical laboratory studies shall include a statement that each such study was conducted in compliance with part

58, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(ii) A section containing results of the clinical investigations involving human subjects with the device including clinical protocols, number of investigators and subjects per investigator, subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the clinical investigations, device failures and replacements, contraindications and precautions for use of the device, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE shall be identified as such. Information on clinical investigations involving human subjects shall include the following:

(A) For clinical investigations conducted in the United States, a statement with respect to each investigation that it either was conducted in compliance with the institutional review board regulations in part 56 of this chapter, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in part 50 of this chapter; or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(B) For clinical investigations conducted in the United States, a statement that each investigation was conducted in compliance with part 812 of this chapter concerning sponsors of clinical investigations and clinical investigators, or if the investigation was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(C) For clinical investigations conducted outside the United States that are intended to support the PMA, the requirements under § 812.28 of this chapter apply. If any such investigation was not conducted in accordance with good clinical practice (GCP) as described in § 812.28(a), include either a waiver request in accordance with § 812.28(c) or a brief statement of the reason for not conducting the investigation in accordance with GCP and a description of steps taken to ensure that the data and results are credible and accurate and that the rights, safety, and well-being of subjects have been adequately protected. Failure or inability to comply with these requirements does not justify failure to provide information on a relevant clinical investigation.

(7) For a PMA supported solely by data from one investigation, a justification showing that data and other information from a single investigator are sufficient to demonstrate the safety and effectiveness of the device and to ensure reproducibility of test results.

(8)(i) A bibliography of all published reports not submitted under paragraph (b)(6) of this section, whether adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the device.

(ii) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness

> of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience.
>
> (iii) Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the applicant if an FDA advisory committee or FDA requests.
>
> (9) One or more samples of the device and its components, if requested by FDA. If it is impractical to submit a requested sample of the device, the applicant shall name the location at which FDA may examine and test one or more devices.
>
> (10) Copies of all proposed labeling for the device. Such labeling may include, e.g., instructions for installation and any information, literature, or advertising that constitutes labeling under section 201(m) of the Federal Food, Drug, and Cosmetic Act.
>
> (11) An environmental assessment under § 25.20(n) prepared in the applicable format in § 25.40, unless the action qualifies for exclusion under § 25.30 or § 25.34. If the applicant believes that the action qualifies for exclusion, the PMA shall under § 25.15(a) and (d) provide information that establishes to FDA's satisfaction that the action requested is included within the excluded category and meets the criteria for the applicable exclusion.
>
> (12) A financial certification or disclosure statement or both as required by part 54 of this chapter.[127]

This is clearly a much larger set of requirements than those of Class I and Class II devices. In particular, the most distinctive changes of the Class III regulations require a summary of all studies, their methods, their results, and mandatory additional testing such as "microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests as appropriate."[128] In addition, the PMA requires human clinical investigations with "safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures, and replacements . . . results of statistical analyses of the clinical investigations, device failures, and replacements, contraindications and precautions for use of the device."[129]

These clinical studies must be accompanied by statements of compliance with required clinical investigation standards.[130] The last requirement of note is the applicant must share a "bibliography of all published reports . . . whether adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the

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[127] *Id.* § 814.20(b)(1)–(12).

[128] *Id.* § 814.20(b)(3)(v), (b)(6)(i).

[129] *Id.* § 814.20(b)(3)(v)(B), (b)(6)(ii).

[130] *Id.* § 814.20(b)(6)(i), (b)(6)(ii)(A)–(B).

device."[131] Common Class III medical devices include breast implants, pacemakers, cochlear implants, and female condoms.[132] Only 10% of all medical devices are classified as Class III.[133]

All these disclosures will help ensure the product is supported by reliable and compliant research and is indeed safe for consumer use. The PMA required for Class III medical devices should be applied to any medical device used with long-term, intimate contact with the body. It is clear that Class I and Class II medical devices enjoy much more freedom from regulation and testing than Class III devices, and the next section discusses deeper why this is a problem when it comes to tampons, pads, and menstrual cups. For example, FHPs are not Class III, despite being "used on highly permeable and sensitive vaginal and vulvar tissues that have high uptake rates and sensitivity to chemicals and irritants."[134] The next section critiques the problematic Class I and Class II classification of tampons, pads, and menstrual cups and explains why all should be regulated as Class III devices.

V. A COMPARISON OF AVAILABLE INTERNATIONAL REGULATIONS OF FHPS

There is not a wealth of literature regarding the international regulation of these FHPs; however, a few entities seem to have clearer and more accessible policies regarding these products.[135] The international policies found will provide a comparison with other potentially effective regulations to consider. These governments include the European Union, South Korea, India, Australia, and Low-Middle Income Countries (LMIC) generally.[136]

A. European Union and the United Kingdom

The foremost developed governmental regulation of these FHPs outside of the United States appears to be the European Union.[137] The European Union regulates menstrual products as "hygiene" or "general"

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[131] *Id.* § 814.20(b)(6)(i), (b)(6)(ii)(A)–(B).

[132] Kondabolu, *supra* note 120.

[133] *Id.*

[134] Nan Lin et al., *Volatile organic compounds in feminine hygiene products sold in the US market: A survey of products and health risks*, ENV'T INT'L (Aug. 28, 2020), https://www.sciencedirect.com/science/article/pii/S0160412020303494?via%3Dihub.

[135] *See* discussion *infra* Sections V.A–D.

[136] *See* discussion *infra* Sections V.A–E.

[137] *See* Council Directive 2001/95, 2002 O.J. (L 011) 4-17 (EC).

products.[138] Because this categorization lacks any medical designation and is treated as a general consumer product, there is no requirement for listing ingredients or for testing to produce satisfactory results.[139] This categorization then puts these FHPs under the control of the General Product Safety Directive (2001/95/EC)[1].[140] This directive states in relevant part:

> Producers shall be obliged to place only safe products on the market . . . A product shall be deemed safe . . . when, in the absence of specific Community provisions governing the safety of the product in question, it conforms to the specific rules of national law of the Member State in whose territory the product is marketed . . . [a] product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards . . . producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks . . . . Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements.
>
> Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, keeping and providing the documentation necessary for tracing the origin of products, and cooperating in the action taken by producers and competent authorities to avoid the risks . . . [w]here producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities.[141]

The European Union system appears to apply similar regulations as the United States. These regulations are unsatisfactory, requiring minimal testing and reporting, and lack any explanation for what is considered "risk to the consumer incompatible with the general safety requirement."[142] This implies there is no specific safety standard for a product; thus, unless a member state provides further regulation, "codes of good practice" are used to determine if the product is safe or not.[143]

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[138] *Do Menstrual Products Contain Harmful Substances?*, *supra* note 65.

[139] *Id.*

[140] *See id.*; *see also Answer Given by Ms. Jourová on Behalf of the Commission*, *Parliamentary Question*, EUR. PARLIAMENT (May 13, 2016), https://www.europarl.europa.eu/doceo/document/E-8-2015-013116-ASW_EN.html [hereinafter *Answer Given by Ms. Jourová*].

[141] Council Directive 2001/95, 2002 O.J. (L 011) 4-17 (EC).

[142] *Id.* art. 5.3.

[143] *Answer Given by Ms. Jourová, supra* note 140.

In the United Kingdom, tampons and other FHPs are regulated by the General Product Safety Regulations 2005, which echoes much of the EU regulatory scheme and are almost entirely reactive to later found risks with no premarket requirement.[144] Because this scheme is not tailored for the use of FHPs, it does not include a standard requiring all menstrual cups to be composed of "medical-grade materials," only that the product is "safe," which is ill-defined at best within the regulations.[145] Lastly, a common concern in these FHPs as will be discussed later are phthalates;[146] the European Union limits phthalates to a "maximum content of 0.1% by weight of the plasticized material in the article,"[147] which is one small step in the right direction in preventing these dangerous chemicals from permeating from plastic-containing FHP, which truthfully should be banned altogether.

B. South Korea

As recently as 2017, South Korea experienced several issues of "harmful sanitary pads" being distributed, which sparked distrust in what regulatory protections the country has for evaluating the safety of these products.[148] One study found the definition of FHPs is "similar for Korea, the EU, and the U.S.; however, they are categorized as quasi-drugs in Korea" specifically, "feminine hygiene products, comprising sanitary pads, sanitary tampons, and sanitary cups are categorized as quasi-drugs" regulated by the Pharmaceutical Affairs Act.[149] In the Act, "Quasi-drugs" include:

> (a) fibers, rubber products, or similar products used for the purpose of treating, alleviating, or preventing human or animal diseases;
>
> (b) non-appliance, non-machinery, or similar articles that have an insignificant influence or no direct impact on human bodies;

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[144] *Product Regulation and Guidance Documents*, ABSORBENT HYGIENE PROD. MFRS. ASS'N, https://www.ahpma.co.uk/product-regulation/ (last visited Dec. 18, 2023).

[145] *Answer Given by Mr. Vella on Behalf of the European Commission*, *Parliamentary Question,* EUR. PARLIAMENT (Aug. 2, 2019), https://www.europarl.europa.eu/doceo/document/E-8-2018-005725-ASW_EN.html.

[146] *See* discussion *infra* Section IV.A.5.

[147] Banjot Kaur, *'Popular Sanitary Pads Sold in India Have Harmful Chemicals, Cause Serious Health Issues': Report*, THE WIRE (Nov. 21, 2022), https://thewire.in/health/popular-sanitary-pads-sold-in-india-have-harmful-chemicals-cause-serious-health-issues-report.

[148] Jin Il Kwak et al., *Comparative Study of Feminine Hygiene Product Regulations in Korea, the European Union, and the United States*, 107 REGUL. TOXICOLOGY & PHARMACOLOGY 1, 1 (2019).

[149] *Id.*

> (c) preparations used for sterilization, insecticide, and similar uses for the purpose of preventing infectious diseases[.][150]

This regulation controls labeling, manufacturing practices, re-evaluation of products, and the approval, notification, and evaluation of new quasi-drugs.[151] This process looks eerily similar to that of the United States; although, the South Korean Ministry of Environment has been prompted to respond with further regulations after "over 200 VOCs, including benzene, styrene, and trichloroethylene, were found in ten types of sanitary napkins and panty liners sold in South Korea."[152] Additionally, South Korea has, unlike the European Union and the United States, fully banned phthalates and required full ingredient lists on the labels of FHPs.[153]

C. India

Regarding India, the regulations are even less stringent, and information on Indian FHPs is not as accessible.[154] Most sanitary pads are not tested for volatile compounds in India and are bleached to appear cleaner and whiter, a process which often creates the toxic byproduct dioxin.[155] This was further seen in a study performed by a nonprofit organization, Toxics Link, in which researchers found these sanitary pads often contained harmful chemicals, such as volatile organic compounds (VOCs) and phthalates.[156] This is likely due to the lack of concern over mitigating long-term users' exposure to harsh chemicals.[157]

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[150] *Id.* at 2; *see* Yaksabeop [Pharmaceutical Affairs Act] art. 2 para. 7 (S. Kor.).

[151] *Id.*

[152] Lin et al., *supra* note 134, at 2.

[153] Kaur, *supra* note 147; Kwak et al., *supra* note 148, at 2.

[154] Nikhil Ghadyalpatil, *Sanitary Pads Can Cause Cancer – Reasons and Prevention*, THE TIMES OF INDIA (Jan. 22, 2023, 4:47 PM), https://timesofindia.indiatimes.com/blogs/voices/sanitary-pads-can-cause-cancer-reasons-and-prevention/.

[155] *Id.* One researcher was quoted positing "one tampon is trace . . . but consider the menstrual lifetime of a woman. They use approximately 12,000 tampons in a lifetime. That means 12,000 exposures of dioxin ... That's a lot of dioxin absorbed directly into the blood," which resonates deeply with the questioning nature of this article. Nadia Kounang, *What's in Your Pad or Tampon?*, CNN HEALTH (Nov. 13, 2015, 11:19 AM), https://www.cnn.com/2015/11/13/health/whats-in-your-pad-or-tampon/index.html.

[156] Kaur, *supra* note 147.

[157] *Id.*

In one study, it was revealed that all tested products had concentrations of volatile compounds and phthalates, specifically the leading sanitary pads, which contained six phthalates.[158] Further, there are no laws limiting chemicals or requiring testing for toxic ingredients.[159] The Bureau of Indian Standards (BIS) includes only "very basic tests to determine absorbent fillers surface and pad texture."[160]

D. Australia

Australia represents a new, interesting quantification of FHPs;[161] however, they do not offer the ideal regulations being advocated for in this article. For example, Australia categorizes tampons as "therapeutic products."[162] Therapeutic products are a broad category, and therefore the regulations regarding tampons specifically are detailed in their own directive titled "AS 2869:2008 Tampons – Menstrual."[163] Briefly, the relevant portions of the Australian regulation are outlined as follows:

> 1) Tampons should be manufactured from cellulosic materials (such as cotton and viscose rayon), or synthetic textile polymers, either singly or in combination, provided that adequate testing does not demonstrate a hazard. Polyester foam shall not be used. Carboxymethylcellulose (CMC) shall not be added to tampons.
>
> 2) Tampons shall not contain ingredients in sufficient concentration to cause a toxic or irritant reaction when used as directed.
>
> 3) No foreign matter shall be evident when the material is visually inspected.[164]

There are also relevant portions of the requirements addressing the design of the string and applicator, as well as the packaging.[165] The labeling standards are entirely insufficient, with no ingredients listed, only the size and qualities of the tampons, manufacturer information, directions on how to use, and warnings about TSS.[166]

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158 *Id.*

159 *Id.*

160 *Id.*

161 *See Guidance on the Regulation of Tampons in Australia*, THERAPEUTIC GOODS ADMIN., https://www.tga.gov.au/resources/resource/guidance/guidance-regulation-tampons-australia (last visited Dec. 18, 2023).

162 *Id.*

163 *Id.*

164 *Id.*

165 *Id.*

166 *Id.*

Interestingly, Australia requires much more specific and consistent testing for tampon products than other observable international standards, including the United States.[167] Australia mandates testing from a certified lab on the "absorptive capacity," "withdrawal cord strength," "withdrawal cord water repellence," and "total aerobic microbial count."[168] Although the testing is not determinative,[169] it is a great start to regulate the quality of these intimate FHP products where little to no regulation was applied.

Australia also makes a distinction for menstrual cups and imposes different regulations for these products,[170] perhaps even more permissible than the vague regulation for tampons, unfortunately. Summarized, the regulation for menstrual products states:

> 1) Menstrual cups should be manufactured from material suitable for their intended purpose. None of the ingredients contained in the menstrual cup should appear in a sufficient concentration to cause an irritant or toxic reaction when the product is used as directed. The manufacturer/supplier should hold sufficient evidence to demonstrate that materials used for this purpose are in compliance with pharmacopoeia or other relevant standards.
>
> 2) Your menstrual cup should be smooth and designed to minimize trauma to the end consumer.
>
> 3) Packaging materials and processes such as assembly and sealing should be validated under the requirements of relevant standards.[171]

Additionally, Australia enforces permissive labelling requirements for menstrual cups, including manufacturer, batch number, and an information sheet containing instructions and a warning for TSS.[172] Postmarket requirements are also imposed, to "continue to meet all regulatory, safety and performance requirements and standards while it continues to be supplied within Australia" and to mandate reporting for adverse effects.[173] Australia did initially require these FHPs to be registered with the Australian Register of Therapeutic Goods (ARTG), however, this requirement

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[167] *Compare id.*, *with* 21 C.F.R. § 801.430 (2023).

[168] *Guidance on the Regulation of Tampons in Australia*, *supra* note 161.

[169] *Id.*

[170] *Compare id.*, *with Guidance on the Regulation of Menstrual Cups in Australia*, THERAPEUTIC GOODS ADMIN., https://www.tga.gov.au/resources/resource/guidance/guidance-regulation-menstrual-cups-australia (last visited Dec. 18, 2023).

[171] *Guidance on the Regulation of Menstrual Cups in Australia*, *supra* note 170.

[172] *Id.*

[173] *Id.*

was removed in 2018, and FHPs are now exempted from mandatory registration with the ARTG.[174]

E. Low-Middle Income Countries (LMIC)

Although the above-listed regulations represent a range of insufficient safety requirements, there are at least some attempts at regulating these products.[175] One publication researched the regulations in Low-to-Middle Income Countries (LMICs) in South Asia, Africa, and Latin America and found regulations were sparse, if not nonexistent entirely.[176] The report revealed several startling statistics showing disposable and reusable sanitary pads are regulated in only a few African countries.[177] The source also discovered there are currently no standards for menstrual cups in LMIC.[178] Worse still, Latin American countries currently have no standards for any menstrual products.[179]

The regulation of FHPs across the world is disappointing, with very few requirements to ensure the safety of these products in many of the major parts of the world.[180] It is imperative the United States recognizes the shortcomings of both their own regulatory scheme regarding FHPs, as well as the reductionist view of the potential harm held by other countries, in order to successfully close the information gap and promote safe FHPs everywhere.

VI. CRITIQUES OF THE CURRENT FDA REGULATION OF FHPS

The most troublesome aspect of the FDA's current regulation is the lack of testing required to prove the tampon's safety for prolonged usage.[181] The health risks for the ingredients in tampons have been linked

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[174] *Tampons & Menstrual Cups*, THERAPEUTIC GOODS ADMIN., https://www.tga.gov.au/resources/resource/guidance/tampons-menstrual-cups (last visited Dec. 18, 2023).

[175] *See id.; see also Guidance on the Regulation of Menstrual Cups in Australia*, *supra* note 170.

[176] *Menstrual Product Standards*, REPROD. HEALTH SUPPLIES COAL., https://www.rhsupplies.org/uploads/tx_rhscpublications/Menstrual_product_standards_%E2%80%93_a_pathway_to_quality_product_access.pdf (last visited Dec. 18, 2023).

[177] *Id.*

[178] *Id.*

[179] *Id.*

[180] *Id.*

[181] Jasmine Wang, *The Mystery of Tampon Regulation*, THE REGUL. REV. (Sept. 2, 2021), https://www.theregreview.org/2021/09/02/wang-mystery-tampon-regulation/.

to endocrine disruption, cancer, neurological dysfunction, and infertility.[182] For example, Tampax Pearl tampons' ingredient list includes titanium dioxide.[183] Recall the lawsuits filed earlier against P&G in the 1970s and 1980s for tampons linked to causing TSS in women; this is the same company that creates Tampax Pearl today.[184]

Although TSS may not be a looming concern anymore, a 2014 study was performed on four *Always* pads manufactured by none other than Proctor & Gamble (P&G); the results of this study confirmed these pads "emit toxic chemicals, including chemicals identified by the U.S. Department of Health and Human Services National Toxicology Program, the Agency for Toxic Substances and Disease Registry, and the State of California Environmental Protection Agency as carcinogens, and reproductive and developmental toxins."[185] Of course, the chemicals that were identified as carcinogens, reproductive toxicants, and neurotoxins were not disclosed with the product to unsuspecting FHP consumers.[186] As indicated by the results of this study, there is still a large need to regulate these companies and the toxic chemicals added to these products.

The FDA's current regulation is insufficient due to the risk of harm from toxic ingredients, and the below analysis establishes why additional testing requirements are needed to ensure the safety of these various FHPs. All FHPs should be regulated as Class III medical devices, requiring a PMA application before consumer usage. The first section addresses the presence of toxic chemicals and their potential for harm going unregulated, followed by a second section analyzing similar devices categorized as Class III medical devices to explain why FHPs should also be regulated as Class III medical devices.

A. Toxic Ingredients

The main ingredients primarily found in tampons that raise serious health concerns and the need for additional premarket testing and

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[182] *Menstrual Care Products and Toxic Chemicals, supra* note 6.

[183] *So, What's Really in Tampax Tampons?*, *supra* note 5.

[184] *The History of Tampax*, TAMPAX, https://tampax.com/en-us/about/our-story/history-of-tampax/ (last visited Nov. 12, 2023); Kohen, *supra* note 69.

[185] *Always Pads Testing Results*, WOMEN'S VOICE FOR THE EARTH, https://womensvoices.org/menstrual-care-products/detox-the-box/always-pads-testing-results/#:~:text=The%20Always%20menstrual%20pads%20were,Chloroethane%3A%20carcinogen (last visited Nov. 12, 2023).

[186] *Id.*

approval are cotton, PEG-100 stearate, and titanium dioxide.[187] In sanitary pads several more chemicals should be tested for and prohibited due to increased potential health risks, including plastic compounds known as per-and polyfluoroalkyl substances or "PFAS," phthalates, Volatile Organic Compounds (VOCs),[188] and thermoplastic polymers, usually referenced as the PFAS above, in menstrual cups.[189] This section is designed to provide a critique to the current regulation by detailing the dangerous chemicals that pose a potential health risk to chronic users of FHPs. The risks of these chemicals cannot be alleviated without more stringent regulation as a Class III medical device requiring sufficient long-term safety studies to affirm these products are in fact safe for long-term use.

1. Cotton

Although an organic plant, cotton is treated with pesticides just like any other crop.[190] Surprisingly, there is no current FDA-sanctioned data regarding whether or not there are remnants of pesticides used in tampon products.[191] Aside from pesticides, cotton plants can absorb heavy metals, fertilizers, sewage, and other irritants from treated agricultural soil.[192] Studies have also noted it is difficult to determine the specific chemical composition of tampons due to the lack of labeling requirements for tampons because they are a medical Class II device.[193]

Other studies have found that "non-organic cotton in regular tampons may contain trace amounts of the pesticide glyphosate, an herbicide used to kill weeds and rumored to be carcinogenic," even though the EPA dismissed it as "not likely carcinogenic."[194] A 2019 study found "people who are highly exposed to the popular herbicide [glyphosate] have a 41

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[187] *So, What's Really in Tampax Tampons?*, *supra* note 5.

[188] Jeffrey Kluger, *PFAS 'Forever Chemicals' Are Turning Up in Menstrual Products. Here's What You Need to Know*, TIME (Feb. 9, 2023, 12:09 PM), https://time.com/6254060/pfas-period-chemicals-underwear-tampons/; Lin et al., *supra* note 134.

[189] *Womena Faqs: Do Menstrual Products Contain Harmful Substances?*, WOMENA 1, https://womena.dk/wp-content/uploads/2019/06/WOMENA-FAQ-DO-MENSTRUAL-PRODUCTS-CONTAIN-HARMFUL-SUBSTANCES.pdf (last visited Dec. 18, 2023).

[190] *Menstrual Care Products and Toxic Chemicals*, *supra* note 6.

[191] *Id.*

[192] Jessica Singh et al., *Tampon Use, Environmental Chemicals and Oxidative Stress in the BioCycle Study*, ENV'T HEALTH (Feb. 11, 2019), https://ehjournal.biomedcentral.com/articles/10.1186/s12940-019-0452-z.

[193] *Id.*

[194] Madison McGuire, *The Feminine Cotton Controversy*, UNIV. OF TEX. AUSTIN (Feb. 21, 2020), https://sites.utexas.edu/think-twice/2020/02/21/the-feminine-cotton-controversy.

percent increased risk of developing non-Hodgkin lymphoma."[195] This finding is further supported by the conclusion of the International Agency for Research on Cancer (IACR) that "glyphosate is probably carcinogenic to humans."[196] This conclusion was based on approximately 1,000 studies of human and animal interactions with the popular pesticide.[197] Sadly, although the FDA recommends tampon materials are free of pesticide residue, there is no mandatory testing for compliance, and studies show this residue is still found in tampons.[198] Because the FDA does not require further testing for trace amounts of these chemicals, the safety of the cotton used in tampons is uncertain.[199]

2. PEG-100 Stearate

Next, the chemical PEG-100 stearate is also found in popular tampon brands,[200] and although seemingly safe, potentially is not. PEGs are made by ethoxylation, a process used to "create surfactants, which are compounds that reduce the surface tension of liquids."[201] Tampax states this chemical serves to help "fibers wick fluid."[202] The process of ethoxylation often produces 1, 4 dioxane ("dioxane") as a byproduct and traces of ethylene oxide mixed with water to create this reaction lingers.[203] Dioxane is a known animal carcinogen and is recognized as an impurity found in PEGs by the cosmetic industry.[204] The other chemical used in this

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[195] Lorraine Chow, *Glyphosate Exposure Increases Cancer Risk by Up to 41%, Study Finds*, EARTH ISLAND J. (Feb. 14, 2019), https://www.earthisland.org/journal/index.php/articles/entry/glyphosate-exposure-cancer-roundup/?utm_source=google&utm_medium=paid&utm_campaign=tfd_dsa&gclid=Cj0KCQjw7PCjBhDwARIsANo7CgnLp7GNbM5ObM-VrTHR_YlfpO7zu1EzRwX7LVG7g9fq1XXhKwiLhG0aAtwYEALw_wcB.

[196] *Id.*

[197] *IARC Monograph on Glyphosate*, INT'L AGENCY FOR RSCH. ON CANCER, https://www.iarc.who.int/featured-news/media-centre-iarc-news-glyphosate/ (last visited Dec. 18, 2023).

[198] Alexandra Scranton, *Chem Fatale*, WOMEN'S VOICES FOR THE EARTH 9 (Nov. 2013), https://womensvoices.org/wp-content/uploads/2013/11/Chem-Fatale-Report.pdf.

[199] *See id.*

[200] *So, What's Really in Tampax Tampons?*, *supra* note 5

[201] E.A. Sanker, *What Is Ethoxylation?*, ALL THE SCI., https://www.allthescience.org/what-is-ethoxylation.htm (Nov. 9, 2023).

[202] *So, What's Really in Tampax Tampons?*, *supra* note 5.

[203] Christina L. Burnett et al., *Safety Assessment of PEGylated Oils as Used in Cosmetics*, 33 INT'L J. OF TOXICOLOGY 13S, 15S (2014), https://journals.sagepub.com/doi/pdf/10.1177/1091581814546337.

[204] *Id.*

reaction, ethylene oxide, has also been linked to infertility in laboratory animal studies.[205]

The dioxane produced concurrently with the PEGs used in tampons is recognized by the IARC and the state of California as a possible human carcinogen.[206] These products are known to remain in traces with the PEGs they create, and this necessitates further purification and testing requirements to ensure products such as tampons that contain PEG-100 do not also contain these very harmful chemicals.[207] Although some studies have found the levels of dioxane are *de minimis* in tampons, even trace amounts can be cancerous.[208]

3. Titanium dioxide

Titanium dioxide is a chemical found in tampons used for "making the thread look whiter."[209] This chemical is linked—even in trace amounts—to cancer and reproductive disruption.[210] It was found that "many scientists believe there is no safe level of exposure to a carcinogen. Such substances may also have the potential for causing reproductive damage in humans."[211] Inhalation of titanium dioxide can cause lung cancer in animals and could also cause this in humans.[212] This would likely leave a reasonable person to question the safety of the presence of titanium dioxide particles in anything consumable or potentially absorbable into the body. The concern regarding titanium dioxide is well stated in an article for *Well + Good*, which states:

> There is no published research available currently that has examined the impacts of vaginal or vulvar exposure to titanium dioxide, . . . But while no study has positively linked titanium dioxide exposure to ovarian cancer, miscarriages, or UTIs, we also don't have the science to assure us that this kind of exposure is perfectly safe either.[213]

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[205] *Ethoxylated Ingredients*, CAMPAIGN FOR SAFE COSMS., https://www.safecosmetics.org/chemicals/ethoxylated-ingredients/ (last visited Dec. 18, 2023).

[206] *Id.*

[207] *See* Burnett et al., *supra* note 203.

[208] *Ethoxylated Ingredients*, *supra* note 205.

[209] *So, What's Really in Tampax Tampons*?, *supra* note 5.

[210] *Right to Know Hazardous Substance Fact Sheet*, *supra* note 1, at 2.

[211] *Id.*

[212] Alex Scranton, *Questions About Titanium Dioxide in Tampons and Pads?,* WOMEN'S VOICES FOR THE EARTH (Aug. 2, 2022), https://womensvoices.org/2022/08/02/questions-about-titanium-dioxide-in-tampons-and-pads/.

[213] Kells McPhillips, *What You Need to Know About Titanium Dioxide in Pads and Tampons*, WELL+GOOD (Aug. 6, 2022), https://www.wellandgood.com/titanium-dioxide-in-tampons-pads/.

We don't know what we don't know, and we don't know about the safety of these chemicals because they are not subject to Class III medical device testing standards.[214] These chemicals in tampons could be causing irreversible damage, but without a more stringent classification requiring more clinical tests and analysis, there is no way to guarantee safety to the millions of tampon users in the United States.

4. Per- and polyfluoroalkyl substances (PFAS)

PFAS are found in many products used daily; however in several recent studies 48% of pads were found to contain these chemicals.[215] These chemicals are referred to as "forever chemicals" because of their extended half-life, which is the scientific term for how long it takes a compound to reduce by half, allowing them to stay in the body for years.[216] PFAS have been linked to several harmful effects, such as "decreased fertility, high blood pressure in pregnant people, increased risk of certain cancers, developmental delays and low birthweight in children, hormonal disruption, high cholesterol, reduced effectiveness of the immune system."[217]

Further, researchers have documented it is "biologically plausible that environmental contaminants in contact with vaginal and vulvar epithelium can be absorbed and pass into systemic circulation," because the "vagina is well-vascularized and chemicals absorbed by the vagina bypass first-pass metabolism by the liver and directly enter systemic circulation."[218] Even acknowledging the potential for hazardous chemicals infiltrating and wreaking havoc on users' bodies, this same study also acknowledges there is no epidemiological study specifically determining the "association between menstrual product use and the concentration of dioxins in menstruating individuals."[219] Traditional sanitary pads were composed of potentially up to 90% plastic.[220] The main issue, once again, is the lack of testing inquiring how much of these chemicals that are found to be present in the sanitary napkins are actually being absorbed. [221]Until there is research verifying the intake rate of these various known harmful

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[214] Scranton, *supra* note 198, at 8–9.

[215] Kluger, *supra* note 188.

[216] *Id.*

[217] *Id.*

[218] Upson et al., *supra* note 50.

[219] *Id.*

[220] Heidi Ringshaw, *Plastic Periods: Menstrual Products and Plastic Pollution*, FRIENDS OF THE EARTH (Oct. 15, 2018), https://friendsoftheearth.uk/sustainable-living/plastic-periods-menstrual-products-and-plastic-pollution.

[221] Upson et al., *supra* note 50.

chemicals over long-term chronic exposure, there is no guarantee these products are safe.

5. Phthalates and Volatile Organic Compounds (VOCs)

VOC is a designation that includes various harmful chemicals, including reproductive toxin carbon disulfide.[222] Carbon disulfide was found in several rayon tampons, in addition to other carcinogens and toxins like toluene, xylene, and methylene chloride, the latter being used for paint stripping.[223] These compounds were not listed in the products, just the material these chemicals are found in, the basic ingredient "rayon."[224]

In another study, all of the tested FHPs contained "toxic VOCs," and the researchers concluded the article suggesting the "risks of using some products should be addressed," discussing specifically the effects of VOCs, such as skin irritation, respiratory, liver, and kidney damage, and "reproductive effects."[225] The researchers further advocated for "the elimination of toxic ingredients and the disclosure of all chemicals used in these products."[226] Surprisingly, out of all FHPs tested (including sprays and powders), sanitary pads had the highest concentration of n-heptane, a VOC affecting the skin, respiration, and the central nervous system.[227]

Other research from sanitary pads shows VOCs, benzene, toluene, acetone, and chloroform in pads, as well as an increased "risk of impaired neurocognitive development, asthma, cancers, and reproductive illness."[228] P&G continues to make headlines, with their sanitary pads containing styrene (a carcinogen), chloroform, and chloroethane, a neurotoxic chemical even in short-term exposure.[229] These chemicals were also found

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[222] *New Tampon Testing Reveals Undisclosed Carcinogens And Reproductive Toxins*, WEN, https://www.wen.org.uk/2018/06/07/new-tampon-testing-reveals-undisclosed-carcinogens-and-reproductive-toxins/ (last visited Dec. 18, 2023); *see also What are Volatile Organic Compounds (VOCs)?*, EPA (Mar. 15, 2023), https://www.epa.gov/indoor-air-quality-iaq/what-are-volatile-organic-compounds-vocs.

[223] *New Tampon Testing Reveals Undisclosed Carcinogens And Reproductive Toxins*, *supra* note 222.

[224] *See id.*

[225] Lin et al., *supra* note 134.

[226] *Id.*

[227] *See* i*d.*

[228] Narayanan, *supra* note 39.

[229] Kounang, *supra* note 155; *see, e.g.*, Marisa Sarnoff, *Tampax 'Pure Cotton' Tampons Contain Dangerous 'Forever Chemicals': Lawsuit*, L. & CRIME (Feb. 27, 2023, 3:02 PM), https://lawandcrime.com/lawsuit/tampax-pure-cotton-tampons-contain-dangerous-forever-chemicals-lawsuit/.

alongside phthalates, chemicals used "as [a] plasticizer of polymers," all of which are associated with conditions like endometriosis and infertility.[230]

B. Analogizing Similarly Functioning Medical Devices

For the purposes of this analysis, the best analogous device is the female condom, which is currently regulated as a Class III medical device.[231] On the other hand, male condoms are regulated in the same class as tampons as a Class II medical device, even given the significant dissimilarities found between the two devices.[232] This section will be devoted to comparing these devices to FHPs, exhibiting why FHPs are currently in the wrong classification and should be Class III medical devices.

1. Internal "Female" Condom

The internal condom is defined in the Code of Federal Regulations as "a sheath-like device that lines the vaginal wall and is inserted into the vagina before the initiation of coitus. At the conclusion of coitus, the device can be reused. It is indicated for contraception and prophylactic purposes (for preventing the transmission of sexually transmitted infections)."[233] As stated above, these devices are classified as Class III medical devices, requiring PMA.[234] These devices function much like tampons, being inserted vaginally and remaining there for up to eight hours if desired, similar to the length of time a tampon is inserted.[235]

Tampons are likely used more often than internal condoms, as internal condoms have never been popular in the United States,[236] and a tampon user needs a new tampon inserted every 8 hours for the three to five days of their menstrual cycle.[237] This exposure to absorbent mucosal

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[230] *Do Menstrual Products Contain Harmful Substances?*, *supra* note 65.

[231] 21 C.F.R. § 884.5330 (2023).

[232] *See id.* §§ 884.5300, 884.5460, 884.5470.

[233] *Id.* § 884.5330.

[234] *Id.*

[235] *See* Suzy Davenport & Jenna Fletcher, *Female (Internal) Condom: Review and Where to Buy*, MEDICALNEWSTODAY (Feb. 1, 2022), https://www.medicalnewstoday.com/articles/female-internal-condom#_noHeaderPrefixedContent; *see also The Facts on Tampons—and How to Use Them Safely*, U.S. FOOD & DRUG ADMIN. (Sept. 30, 2020), https://www.fda.gov/consumers/consumer-updates/facts-tampons-and-how-use-them-safely.

[236] *See* Nick Paul Taylor, *FDA Reclassifies Female Condoms to Reduce Regulatory Burden*, MEDTECH DIVE (Sept. 27, 2018), https://www.medtechdive.com/news/fda-reclassifies-female-condoms-to-reduce-regulatory-burden/533364/.

[237] *See All of Your Tampon Questions Answered*, CLEVELAND CLINIC (Nov. 9, 2022), https://health.clevelandclinic.org/tampons/; *see also Menstrual Cycle: What's Normal, What's*

linings of the vagina[238] is the same for the female condoms as with tampons, for even longer exposure, presumably. Therefore, it does not seem like a far stretch to suggest these two devices would be regulated similarly, as they pose similar health risks to the product being in physical contact with the body for a prolonged period. The similarity in placement, as well as the time exposure to the chemicals from the products, makes a compelling argument that if internal condoms must pass PMA testing, then tampons should similarly have to comply.

However, a distinctive difference in the safety of these products is timing, as the FDA began regulating female condoms in 1993 as a Class III medical device.[239] Internal condoms had stringent quality safety standards to meet and therefore have established the safety and efficacy of their product. so much so that organizations are now advocating for the reduction of these products to a Class II medical device in order to make them faster to distribute and more easily accessible.[240] The lack of safety concerns around internal condoms here once again proves the point that these standards under a Class III medical device do work by requiring testing to ensure a product's safety.

2. "Male" Condoms

"Male" condoms are used for the prevention of pregnancy and sexually transmitted diseases and are defined in the Code of Federal Regulations as "a sheath which completely covers the penis with a closely fitting membrane."[241] Unlike the female or internal condoms mentioned above, these devices are not worn by the person with the uterus but are transiently placed into the vagina when worn on a penis.[242] This reduced amount of contact with the skin, therefore reducing the risk of irritants or harmful chemical exposure, presumably explains why this is regarded as a Class II medical device.

Not, MAYO CLINIC (Apr. 22, 2023), https://www.mayoclinic.org/healthy-lifestyle/womens-health/in-depth/menstrual-cycle/art-20047186.

[238] Raphaela Regina de Araújo Pereira & Marcos Luciano Bruschi, *Vaginal Mucoadhesive Drug Delivery Systems*, 38 DRUG DEV. & INDUS. PHARMACY 643, 643–45 (2012).

[239] *See* Beatrice A. Chen et al., *Acceptability of the Woman's Condom in a Phase III Multicenter Open-label Study*, 99 CONTRACEPTION 357, 357–58 (Mar. 6, 2019), https://www.contraceptionjournal.org/article/S0010-7824(19)30040-X/fulltext.

[240] *Create the Future of Female Condoms*, THE WELL PROJECT (July 2015), https://www.thewellproject.org/groups/call-action/create-future-female-condoms.

[241] 21 C.F.R. § 884.5300(a) (2023).

[242] *See id.*

Tampons and condoms are fundamentally different yet are classified the same under the FDA's current regulation.[243] This is likely because the regulations fail to consider the exposure time to the toxic chemicals in these devices. Harmful compounds, like dioxane, have acceptable limits in cosmetic products, being labeled contaminants of manufacturing;[244] however, this lengthened exposure of tampons and absorbency of mucosal linings[245] is cause for concern. This risk is presumably much lower with "male" condoms due to the shorter length of contact time, and therefore tampons deserve a stricter classification than "male" condoms. The difference in materials is stark between "male" condoms and FHPs, with condoms usually consisting of polyurethane, latex, and "natural membranes," with a few brands that add spermicide or flavorings.[246] These ingredients do not pose a similar health risk as those cited above found in FHPs, primarily only posing risks of allergic reactions or irritation.[247] This explains why FHPs should not be regulated as a similar classification.

VII. PROPOSAL FOR FHPS TO BE REGULATED AS A CLASS III MEDICAL DEVICES

FHPs should be regulated as Class III medical devices under the FDA's regulatory scheme of medical devices. As stated throughout this note, FHPs have been underregulated since the 1970s and have only been subject to regulation as a medical device at all starting in the 1980s.[248] This lack of regulation led to ingredients in FHPs that are at the very least, untested in the safety vaginal use.[249]

The current regulation of these FHPs is unnecessarily confusing and lacks cohesion or explanation. Unscented sanitary pads are Class I, scented or unscented tampons and menstrual cups are Class II medical devices.[250] The FDA uses an advisory committee, specializing in medical devices,

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[243] *See id.; see also* Wang, *supra* note 181.

[244] *1,4-Dioxane in Cosmetics: A Manufacturing Byproduct*, U.S. FOOD & DRUG ADMIN. (Mar. 3, 2022), https://www.fda.gov/cosmetics/potential-contaminants-cosmetics/14-dioxane-cosmetics-manufacturing-byproduct.

[245] Wendee Nicole, *A Question for Women's Health: Chemicals in Feminine Hygiene Products and Personal Lubricants*, 122 ENV'T HEALTH PERSPS. A70, A72 (Mar. 1, 2014), https://ehp.niehs.nih.gov/doi/full/10.1289/ehp.122-A70.

[246] Heba Mahdy et al., *Condoms*, STATPEARLS, https://www.statpearls.com/point-of-care/19830 (Apr. 17, 2023, 4:33 PM).

[247] *Id.*

[248] Kohen, *supra* note 69.

[249] *See* McPhillips, *supra* note 213.

[250] 21 C.F.R. §§ 884.5400, 884.5425 (2023).

which "reviews and evaluates data concerning the safety and effectiveness of marketed and investigational devices for use in obstetrics and gynecology, making appropriate recommendations to the Commissioner of Food and Drugs."[251] This system is outdated and does not give effect to the power of these scientific studies and the actions that should be taken to acknowledge the gap in safety research for these chemicals found in FHPs.

Some of these toxic ingredients include PEG-100 stearate, titanium dioxide, cotton, VOCs, phthalates, and PFAS.[252] The regulation as a Class II medical device is not preventing these ingredients from being used in these products.[253] This glaring problem in the current regulatory structure was highlighted when the FDA spokesperson confirmed she was "unaware of any well-conducted peer-reviewed research on absorption of pesticides from tampons that would serve as the basis for regulatory decision-making."[254] A lack of research stating these products are safe for their proper use is a testament that these products are not known to be safe for the use they currently provide.

Similarly, loose regulation allows avoidance of any testing on the risk or rate of absorption of these chemicals. To determine the safety of these ingredients for prolonged internal exposure, FHPs should be regulated as Class III medical devices and therefore pass PMA tests. If regulated as Class III medical devices, companies will be legally obligated to fulfill these safety trials, not historically performed, ensuring these products are safe to use.[255]

There are several arguable weaknesses to this argument, although none hold up against the health and safety of the many tampon users across the nation. The counterarguments to the proposal are three-fold: 1) testing takes more time to get products to market, 2) testing is expensive, and 3) there are viable alternatives.[256]

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[251] *Obstetrics and Gynecology Devices Panel*, U.S. FOOD & DRUG ADMIN. (Nov. 18, 2021), https://www.fda.gov/advisory-committees/medical-devices-advisory-committee/obstetrics-and-gynecology-devices-panel.

[252] *So, What's Really in Tampax Tampons?*, *supra* note 5; *Always Pads Testing Results*, *supra* note 185.

[253] *See Always Pads Testing Results*, *supra* note 185.

[254] Nicole, *supra* note 245 (paraphrasing FDA spokeswoman Morgan Liscinsky).

[255] 21 C.F.R. § 814.20 (2023).

[256] *See generally* Joanne S. Eglovitch, *Pharma, Device Groups Oppose FDA's Planned Drug to Device Transition*, REGUL. FOCUS (Dec. 10, 2021), https://www.raps.org/news-and-articles/news-articles/2021/12/pharmaceutical-and-medical-device-groups-oppose-fd (discussing opposition to the FDA's reclassification of certain drugs to devices by pharmaceutical companies).

However, the answer is simple: many products undergo lengthy safety trials, and this is just the cost of doing business as usual for any product that is "of substantial importance in preventing the impairment of human health or present a potential unreasonable risk of injury or illness."[257] FHPs do present a "potential[ly] unreasonable risk of injury or illness,"[258] and a loose regulatory application until now does not excuse the need for important safety testing required of similar devices, such as the internal condom as a Class III device.[259]

Another likely response to this proposal is the insinuation there are other alternatives to these products. Unsurprisingly, the "alternatives" to these products pose a similar possible health risk.[260] For example, in one study testing FHPs for PFAS, thirteen of the twenty-two samples that tested positive were labelled as "'organic,' 'natural,' 'non-toxic,' 'sustainable,' or using 'no harmful chemicals.'"[261] Companies have also marketed absorptive underwear as an alternative free of chemicals.[262] Sadly, multiple companies were sued for these misleading claims, after studies alleged the material did in fact contain PFAS, with the scientists commenting that these levels were even "high enough to suggest they were intentionally manufactured with PFAS."[263]

The strengths of this proposal lie in the lack of data gathered so far on this subject. The fact is there are very few scientific studies performed on the detrimental, or even possibly detrimental, effect of toxic chemicals found in tampons on the human body.[264] The fact these ingredients are exposed to such an intimate part of the body for at least 72,000 hours for regular tampon users with zero safety tests[265] is truly disturbing. The little data gathered suggests there could be detrimental effects caused by these chemicals, simply from reviewing their other interactions with the body.[266]

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[257] *General Controls for Medical Devices*, U.S. FOOD & DRUG ADMIN. (Mar. 22, 2018), https://www.fda.gov/medical-devices/regulatory-controls/general-controls-medical-devices.

[258] 21 C.F.R. § 860.3.

[259] 21 C.F.R. § 884.5330(b).

[260] Kluger, *supra* note 188.

[261] *Id.*

[262] Ketura Persellin, *New Lawsuit Contends Period Products Contain 'Forever Chemicals,'* ENV'T WORKING GRP. (Apr. 26, 2022), https://www.ewg.org/news-insights/news/2022/04/new-lawsuit-contends-period-products-contain-forever-chemicals.

[263] *Id.*

[264] *See Menstrual Care Products and Toxic Chemicals*, *supra* note 6.

[265] McPhillips, *supra* note 214; *Menstrual Care Products & Toxic Chemicals*, *supra* note 10.

[266] *Right to Know Hazardous Substance Fact Sheet*, *supra* note 1, at 2; *Menstrual Care Products and Toxic Chemicals*, *supra* note 6.

Clearly, without any studies definitively establishing the safety of these products, there is serious potential the effects of these toxic chemicals could pose a potentially unreasonable risk for illness or injury, as many of them are linked to cancer or infertility when found in other products.[267]

The current regulation of FHPs as Class I or Class II medical devices lacks any of the clinical testing or PMA procedures that similar intimate medical devices, such as implants or pacemakers, undergo.[268] Once assigned as Class III, FHPs will have to undergo these safety trials[269] and will undoubtedly be made safer because of it. As seen in the beginning of this article, Class III medical devices face a slew of required safety testing, disclosures, and investigative procedures that the lesser classes do not require.[270] The proposal to upgrade FHPs to a Class III medical device is not a conclusive solution; there is much work to be done in the area of menstrual products. However, this is one important step towards a safer market for the forty-three million women and countless other tampon users who have the right to feel safe when using tampons.[271]

VIII. CONCLUSION

The regulation of FHPs by the FDA is underwhelming, to say the least. Classifying tampons and menstrual cups as a Class II medical devices and pads as Class I devices not only poses health concerns to millions of users over almost the entirety of their life but also degrades users' access to safe and effective healthcare as well. These users deserve to be comfortable using their products, knowing the product internally inserted for thousands of hours throughout their lives are not causing chronic health problems.

The problem, when distilled from the complex scientific studies and chemical names is quite simple: a product used for extended periods of time consistently over an entire lifetime cannot be claimed "safe" if testing has not been done that declared this product safe for long-term use. As of March of 2022, no research had been performed to determine if there was in fact "any association between menstrual product use and the concentration of dioxins in menstruating individuals" exposed to the chemicals and metals from FHPs.[272]

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[267] *Menstrual Care Products and Toxic Chemicals*, *supra* note 6.

[268] Kondabolu, *supra* note 120.

[269] 21 C.F.R. §§ 814.20(b)(6)–(9), 814.20(e) (2023).

[270] *Id.*; Kondabolu, *supra* note 120.

[271] *Menstrual Care Products and Toxic Chemicals*, *supra* note 6.

[272] Upson et al., *supra* note 50.

Furthermore, the analysis in this article does not even account for users who may use multiple products at the same time to guarantee leak-proof protection. The combination of these products does increase the exposure to materials proven to have harmful chemicals,[273] so it may be possible that the greater this exposure, the more likely the chemicals have a harmful effect on the body; however, there is no way to support this finding, because the classification lacks premarket testing[274] to ensure the wearing of one, let alone two, FHPs simultaneously is safe. To place this concern in quantitative terms of what risk this may pose, one survey determined "a third of tampon users frequently add a pad for additional protection. Nearly half of tampon users in Italy (51%) and the U.S. (47%) indicate they add a pad when wearing a tampon."[275]

Although not conclusive, there are many unanswered questions about the safety of these FHPs. The current regulation in the United States of these products is outdated, and FHP users deserve updated regulations reflecting current data. In particular, FHP users deserve regulation that acknowledges scientific results implying these products need to be reevaluated after significant safety concerns over hazardous chemicals were raised. By upgrading tampons, sanitary pads, and menstrual cups to Class III medical devices, the FDA will be reacting appropriately to evolving science and taking reasonable actions not to stop distribution or access to FHPs, but rather to protect the United States consumer.

By not addressing this public health concern, the FDA is telling millions of users their health is a secondary consideration that comes after the profits of menstrual product manufacturers. FHPs should not be treated as a Class I or Class II medical device, as the FDA currently has them classified. There is ample scientific evidence these devices "present a *potential* unreasonable risk of injury or illness"[276] and therefore could be regulated as a Class III medical device under the current regulatory scheme of the FDA. FHPs should be regulated as Class III medical devices to ensure all FHPs are safe and users can rest assured knowing these products are only helping, not harming them.

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[273] *See id.*

[274] 21 C.F.R. § 860.3 (2023).

[275] *An Assessment of the Global Feminine Care Market*, NONWOVENS INDUS. (Nov. 7, 2016), https://www.nonwovens-industry.com/issues/2016-11-01/view_features/an-assessment-of-the-global-feminine-care-market/.

[276] § 860.3.