NOTE

KNOWLEDGE IS POWER: THE FEDERAL GOVERNMENT MUST REQUIRE COMPANIES TO TELL MENSTRUATORS THE INGREDIENTS IN PERIOD PRODUCTS

I. INTRODUCTION

Imagine being a twelve-year-old girl experiencing her period for the first time.[1] Like most women[2] in the United States,[3] you begin using feminine hygiene products[4] ("menstrual products" or "period products").[5] Four years later, at age sixteen, you begin experiencing longer,

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1. *See* Steven M. Weissberg & Melvin G. Dodson, *Recurrent Vaginal and Cervical Ulcers Associated with Tampon Use*, 250 J. AM. MED. ASS'N 1430, 1431 (1983).

2. In order to reflect the relevant literature, this Note will primarily use the term "women" to refer to people who use menstrual products. *See* ALEXANDRA SCRANTON, CHEM FATALE: POTENTIAL HEALTH EFFECTS OF TOXIC CHEMICALS IN FEMININE CARE PRODUCTS 9 (2013), https://womensvoices.org/wp-content/uploads/2013/11/Chem-Fatale-Report.pdf (reporting the health risks period products create for women). However, it is important to note that women are not the only group of people that menstruate and use period products. *See* S.E. Frank & Jac Dellaria, *Navigating the Binary: A Visual Narrative of Trans and Genderqueer Menstruation*, *in* THE PALGRAVE HANDBOOK OF CRITICAL MENSTRUATION STUDIES 75 (Chris Bobel et al. eds., 2020). Therefore, the term "menstruator" will also be used to identify people who menstruate. *See* Anureet, *Menstruators: A Gender Neutral & Inclusive Term for All Our Period Conversations*, SHE THE PEOPLE (Aug. 17, 2020), https://www.shethepeople.tv/home-top-video/menstruators-a-gender-neutral-inclusive-term-for-all-our-period-conversations ("Menstruators, evidently means, people who menstruate/have periods. This is a much more inclusive term used by informed health care providers, because it includes transgender men and non-binary people as well."). See Sarah E. Frank, *Queering Menstruation: Trans and Non-Binary Identity and Body Politics*, 90 SOCIO. INQUIRY 371, 376-77 (2020), for an inclusive discussion of experiences from people who menstruate and do not identify as female.

3. *See The Ultimate Guide to Feminine Hygiene*, DUQ. UNIV. SCH. NURSING, https://onlinenursing.duq.edu/master-science-nursing/the-ultimate-guide-to-feminine-hygiene/#:~:text=About%2020%20to%2050%20percent,to%20Women's%20Voices%20for%20Earth (last visited Aug. 1, 2021) (discussing the percentage of women using period products in the United States).

4. *See* Weissberg & Dodson, *supra* note 1, at 1431.

5. *See* Elizabeth Licorish, *Stop Calling Them "Feminine Hygiene Products,"* BUSTLE (Jan. 11, 2017), https://www.bustle.com/articles/194989-why-we-need-to-ditch-the-term-feminine-hygiene-products. Historically in the United States, the industry standard for products used during menstruation, like tampons and sanitary pads, have been referred to as "feminine hygiene products."

painful periods and seek the medical advice of a doctor.[6] After an examination and a few tests, your doctor discovers that you have a vaginal ulcer and recommends that you stop using tampons for the time being.[7] After discontinuing the use of tampons, your ulcer clears up one month later.[8] Fourteen months later, you start using tampons again, and the doctor discovers another ulcer on your right lateral vaginal wall.[9] Once again, your doctor recommends that you discontinue the use of tampons, and your ulcer goes away one month later.[10] Since that time, you have not experienced another vaginal ulcer.[11] It is not uncommon for menstruators in the United States to experience health problems, like vaginal ulcers, as a result of using popular period products like tampons.[12]

The average woman experiences approximately 456 periods throughout her lifetime.[13] This means a woman uses around 16,000 tampons[14] and spends over $26,000 on period products during her lifetime.[15] In the United States, only two states require manufacturers to

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See id. However, the term feminine hygiene product is restrictive and does not acknowledge the audience that uses these products. *See id.* Therefore, this Note will refer to these products as menstrual products or period products to recognize the shift toward gender identity inclusivity in sexual health. *See* Kells McPhillips, *Why We Need Genderless 'Feminine Hygiene Products'*, WELL + GOOD (Oct. 24, 2019), https://www.wellandgood.com/feminine-hygiene-products. See Claire McCormack, *Products for People with Vaginas: The Shift Toward Gender Identity Exclusivity in Sexual Health and Period Care*, BEAUTY INDEP. (May 23, 2019), https://www.beautyindependent.com/products-people-vaginas-gender-identity-inclusivity-sexual-health-period-care, for further discussion of gender identity inclusivity in sexual health.

6. *See* Weissberg & Dodson, *supra* note 1.

7. *See id.*

8. *See id.*

9. *See id.*

10. *See id.*

11. *See id.*

12. *See id.*; Tampon Safety and Research Act of 1997, H.R. 2900, 105th Cong. (1997); SCRANTON, *supra* note 2, at 20 (analyzing the health problems many women experience in the United States as a result of using period products).

13. Jessica Kane, *Here's How Much a Woman's Period Will Cost Her Over a Lifetime*, HUFFPOST (Dec. 6, 2017), https://www.huffpost.com/entry/period-cost-lifetime_n_7258780.

14. Jane Sheffer, *New Tampon Testing Confirms Need for Ingredient Disclosure!*, WOMEN'S VOICES FOR THE EARTH (June 5, 2018), https://www.womensvoices.org/2018/06/05/new-tampon-testing-confirms-need-for-ingredient-disclosure (reporting the results of a new study observing tampon usage). This number does not include the other period products women use during their lifetime. *See id.*; Robin Danielson Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. § 2(2) (2017) (describing a 2017 congressional study that found women use around 16,800 tampons during their lifetime).

15. *See* Rachel Moss, *Women Spend More Than €18,000 on Having Periods in Their Lifetime, Study Reveals*, HUFFPOST (Sept. 3, 2015), https://www.huffingtonpost.co.uk/2015/09/03/women-spend-thousands-on-periods-tampon-tax_n_8082526.html.

disclose the ingredients in menstrual products.[16] Pursuant to the Federal Food, Drug, and Cosmetic Act,[17] the Food and Drug Administration ("FDA") does not require companies to label menstrual products with their ingredients because menstrual products are classified as medical devices.[18] Therefore, under current federal law, menstruators do not know the ingredients in their period products.[19]

Multiple studies that tested the ingredients in menstrual products revealed that they contain toxins and other chemicals that are dangerous to menstruators' health.[20] These ingredients have been linked to cancer, as well as many other adverse health effects.[21] Yet, menstruators continue to use these products in the most absorbent part of their body without knowing their dangerous ingredients.[22]

This Note will argue that the Federal Food, Drug, and Cosmetic Act must be amended to require companies to label menstrual products with their ingredients and associated health risks and impose a penalty on companies that do not comply with the requirements.[23] This will ensure that menstruators know the ingredients in their period products and the associated health risks, which will allow them to choose products that are less likely to put their health in danger.[24] In Part II, this Note will

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16. Estrella Jaramillo, *Cuomo Signs Bill Making New York the First State to Mandate Ingredient List for Tampons*, FORBES (Oct. 11, 2019, 3:44 PM), https://www.forbes.com/sites/estrellajaramillo/2019/10/11/cuomo-signs-bill-new-york-first-state-to-mandate-ingredient-list-for-tampons/#7f96ef5c2b77 (stating that New York was the first state in the country to pass a law requiring companies to disclose the ingredients in menstrual products).

17. 21 U.S.C. § 301 et seq. (2018).

18. SCRANTON, *supra* note 2, at 8; Joan Raymond, *How Safe Is Your Tampon?*, TODAY, https://www.today.com/health/how-safe-your-tampon-t112885 (Aug. 14, 2018, 2:49 PM) (explaining that menstrual product companies do not have to label the products with their ingredients because the Food and Drug Administration ("FDA") classifies them as medical devices).

19. *See* Rachel Polansky, *Do You Know What's in Your Tampon?*, WOMEN'S VOICES FOR THE EARTH (Feb. 6, 2019), https://www.womensvoices.org/2019/02/06/do-you-know-whats-in-your-tampon/#:~:text=The%20answer%20is%20likely%20no,both%20sides%20of%20the%20issue.&text=Women's%20Voices%20For%20The%20Earth%20is%20a%20non%2Dprofit%20that,makers%20to%20be%20more%20transparent (explaining that women do not know the ingredients in their tampons because the federal government does not require companies to disclose the ingredients).

20. SCRANTON, *supra* note 2, at 20; Tampon Safety and Research Act of 1997, H.R. 2900, 105th Cong. (1997); *What's in Your Tampon? 2018 Tampon Testing Results*, WOMEN'S VOICES FOR THE EARTH (2018), https://www.womensvoices.org/menstrual-care-products/whats-in-your-tampon (explaining the findings of studies that tested the ingredients in menstrual products and revealed toxic chemicals).

21. SCRANTON, *supra* note 2, at 20; H.R. 2900 (discussing the health risks menstrual products create for the women who use them).

22. *See* SCRANTON, *supra* note 2, at 3-4.

23. *See infra* Part IV.

24. *See On Day of the Girl, Governor Cuomo Signs Legislation to Make New York the First State in the Nation to Require Disclosure of Ingredients in Menstrual Products*, N.Y. ST. (Oct. 11, 2019), https://www.governor.ny.gov/news/day-girl-governor-cuomo-signs-legislation-make-new-

discuss types of menstrual products and the reason they are used.[25] Furthermore, Part II will discuss the ingredients found in menstrual products, how these ingredients create a dangerous risk to menstruators' health, and the unique structure of the vagina.[26] Subsequently, Part III of this Note will discuss the Federal Food, Drug, and Cosmetic Act that regulates the current labeling and disclosure requirements for menstrual products, as well as the FDA's authority regarding ingredient disclosure requirements.[27] This Part also separately assesses the New York and California Menstrual Products Right to Know Acts, as well as a proposed federal bill, that requires menstrual product manufacturers to disclose the ingredients in their products.[28] Part IV will propose a federal approach, amending the Federal Food, Drug, and Cosmetic Act to require companies to disclose the ingredients in menstrual products, include a warning of the associated health risks, and impose a monetary penalty on companies that do not comply with the requirements.[29] Finally, Part V of this Note will conclude and reiterate the importance of bringing awareness to the health risks that menstrual products create for menstruators under current federal law because companies are not required to disclose the ingredients in menstrual products.[30]

II. MENSTRUAL PRODUCTS IN THE UNITED STATES

Part II of this Note discusses menstrual products in the United States.[31] Subpart A defines and discusses types of menstrual products and how they are classified under current federal law.[32] Subpart B identifies the undisclosed, dangerous ingredients in period products and discusses the risks those ingredients create for menstruators' health.[33] Subpart C discusses the unique structure of the vagina and how it relates to the chemicals found in period products.[34] In order to understand the importance of disclosing the ingredients in period products, it is critical

york-first-state-nation-require-disclosure ("Requiring the disclosure of ingredients in menstrual products will allow women and girls to make more informed decisions about the products they use.") [hereinafter *On Day of the Girl*].

25. *See infra* Part II.
26. *See infra* Part II.
27. *See infra* Part III.
28. *See infra* Part III.C.
29. *See infra* Part IV.
30. *See infra* Part V.
31. *See infra* Part II.
32. *See infra* Part II.A.
33. *See infra* Part II.B.
34. *See infra* Part II.C.

to know the health risks menstruators face from using these products containing undisclosed ingredients.[35]

A. What Are Menstrual Products?

Menstrual products are products that are used by menstruators once a month during menstruation.[36] These products generally include tampons, menstrual pads, menstrual cups, menstrual discs, and period panties.[37] Additionally, there is a separate category of hygiene products branded toward women to allegedly help maintain vaginal cleanliness.[38] These products include feminine washes,[39] feminine wipes,[40] feminine deodorants,[41] and vaginal douches.[42]

These two categories of products are regulated differently under current federal law.[43] Under the Federal Food, Drug, and Cosmetic Act, the former category of products are regulated as medical devices, and the latter category of products are regulated as cosmetics.[44] However, both

35. *See On Day of the Girl*, *supra* note 24.

36. *The Ultimate Guide to Feminine Hygiene*, *supra* note 3.

37. *Period Products: The Good, the Bad, and the Ugly*, UT HEALTH AUSTIN, https://uthealthaustin.org/blog/period-products (last visited Aug. 1, 2021).

38. SCRANTON, *supra* note 2, at 8. The products in this category are not necessary for women to use in order to maintain vaginal hygiene and cleanliness. *Id.* Many women use these products because they do not understand that the vagina is self-cleaning and "normal secretions are a natural self-cleaning process of the vaginal area." Barbra Hansen Cottrell, *Vaginal Douching*, 32 J. OBSTETRIC, GYNECOLOGIC, & NEONATAL NURSING 12, 17 (2003). See Amanda Jenkins & Kieran O'Doherty, *The Clean Vagina, the Healthy Vagina, and the Dirty Vagina: Exploring Women's Portrayals in Relation to Vaginal Cleansing Product Use*, FEMINISM & PSYCH., Aug. 25, 2020, at 2-5, for further discussion about the reason women choose to use these hygiene products although they are not necessary to maintain vaginal cleanliness.

39. SCRANTON, *supra* note 2, at 14. Products like these are not recommended to maintain routine vaginal hygiene. Cottrell, *supra* note 38, at 16.

40. SCRANTON, *supra* note 2, at 12. Vaginal wipes are not recommended to be used on the vagina but, if they are, they should be unscented. Cottrell, *supra* note 38, at 16 (explaining that unscented wet wipes, if used, should be used once and then immediately discarded).

41. SCRANTON, *supra* note 2, at 16. Feminine deodorants include sprays, powders, and suppositories. *Id.* These products are well known for their associated health risks. *Id.*

42. *Id.* at 15. Although regulated as cosmetics, vaginal douches have created health problems for women. Cottrell, *supra* note 38, at 12-13. Some of these health complications include bacterial vaginosis, increased risk of HIV and chlamydia, pelvic inflammatory disease, reduced fertility, and ectopic pregnancy. *Id.* at 13.

43. SCRANTON, *supra* note 2, at 8.

44. *Id.* Under federal law, cosmetics must be "free of poisonous or deleterious substances that might harm users under conditions of normal use." *Id.* Regarding safety testing for cosmetics, the FDA determined:

> Companies and individuals who manufacture or market cosmetics have a legal responsibility to ensure the safety of their products. Neither the law nor FDA regulations require specific tests to demonstrate the safety of individual products or ingredients. The law also does not require cosmetic companies to share their safety information with the FDA.

categories of products pose dangerous risks to women's health.[45] This Note addresses the former category of menstrual products that are regulated as medical devices.[46]

1. Tampons and Menstrual Pads

The most commonly used and well-known period products are tampons[47] and menstrual pads.[48] Tampons are inserted directly into the vagina to absorb menstrual blood and prevent leakage.[49] The FDA recommends that tampons should be changed every four to eight hours to reduce the risks associated with tampon use.[50] Under federal law, tampons are broken down into two categories: unscented menstrual tampons,[51] and scented or scented deodorized menstrual tampons.[52] Unscented tampons and scented or scented deodorized tampons are classified as Class II medical devices.[53] This classification is significant because it determines how the FDA regulates the safety testing and disclosure of ingredients in period products.[54]

Id. As a result, in 2019, the United States House of Representatives ("U.S. House") proposed a bill to amend the Federal Food, Drug, and Cosmetic Act to make the regulation of cosmetics safer. *See* Safe Cosmetics and Personal Care Products Act of 2019, H.R. 4296, 116th Cong. (2019).

45. *See* SCRANTON, *supra* note 2, at 20.

46. *See infra* Part II.A.1–2.

47. *See* SCRANTON, *supra* note 2, at 6 (analyzing a study that found between fifty to eighty percent of women use tampons).

48. *See id.* (finding between sixty-two and seventy-three percent of women use menstrual pads during their period).

49. *How Do I Use Tampons, Pads, Period Underwear, and Menstrual Cups?*, PLANNED PARENTHOOD, https://www.plannedparenthood.org/learn/health-and-wellness/menstruation/how-do-i-use-tampons-pads-and-menstrual-cups (last visited Aug. 1, 2021) ("[T]ampons are little plugs made of cotton that fit inside your vagina and soak up menstrual blood.").

50. *See The Facts on Tampons—and How to Use Them Safely*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/consumers/consumer-updates/facts-tampons-and-how-use-them-safely (last visited Aug. 1, 2021).

51. 21 C.F.R. § 884.5470 (2020). Unscented tampons are defined as a medical device that is "a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. This generic type of device does not include menstrual tampons treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs." *Id.*

52. *Id.* § 884.5460. Scented or scented deodorized menstrual tampons are defined as "a device that is a plug made of cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual tampon) or for deodorizing purposes (scented deodorized menstrual tampon)." *Id.*

53. *Id.*; *id.* § 884.5470.

54. *See* SCRANTON, *supra* note 2, at 8. For a further discussion of the importance of medical device classification see *infra* Part III.A.1.

Separately, menstrual pads are often made of absorbent fibers that have an adhesive to stick to underwear to absorb a menstruator's flow.[55] Similar to tampons, under federal law, pads are broken down into two categories: unscented menstrual pads[56] and scented or scented deodorized menstrual pads.[57] Pursuant to federal law, unscented pads are Class I medical devices.[58] On the other hand, depending on the material out of which the pad is made, scented or scented deodorized menstrual pads are classified as a Class I or Class II medical device.[59]

2. Menstrual Cups, Menstrual Discs, and Period Panties

Recently, in response to concerns associated with traditional period products, like tampons and menstrual pads,[60] new period products have emerged with growing popularity.[61] These products include menstrual cups,[62] menstrual discs,[63] and period panties.[64] Unlike other period

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55. *See Period Products: The Good, the Bad, and the Ugly*, *supra* note 37.

56. 21 C.F.R. § 884.5435 (2020). Unscented menstrual pads are defined as:

> [A] device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. This generic type of device includes sterile unscented menstrual pads used for medically indicated conditions but does not include menstrual pads treated with scent (i.e., fragrance materials) or those with added antimicrobial agents or other drugs.

Id.

57. *Id.* § 884.5425. Scented or scented deodorized menstrual pads are defined as "a device that is a pad made of cellulosic or synthetic material which is used to absorb menstrual or other vaginal discharge. It has scent (i.e., fragrance materials) added for aesthetic purposes (scented menstrual pad) or for deodorizing purposes (scented deodorized menstrual pad)." *Id.*

58. *Id.* § 884.5435.

59. *See id.* § 884.5425. Menstrual pads made of "common cellulosic and synthetic material with an established safety profile" are classified as Class I medical devices. *Id.* Scented or scented deodorized menstrual pads not made of these materials are classified as Class II medical devices. *Id.* Unscented pads are classified as Class I medical devices. *Id.* § 884.5435.

60. *Period Products: The Good, the Bad, and the Ugly*, *supra* note 37. There are health and environmental concerns associated with traditional period products. *See id.* See Alejandra Borunda, *How Tampons and Pads Became So Unsustainable*, NAT'L GEOGRAPHIC (Sept. 16, 2019), https://www.nationalgeographic.com/environment/2019/09/how-tampons-pads-became-unsustainable-story-of-plastic, for a further discussion of the impact of period products on the environment.

61. *See* Melissa Kang, *Menstrual Cups vs Tampons – Here's How They Compare*, THE CONVERSATION (July 22, 2019, 3:59 PM), https://theconversation.com/menstrual-cups-vs-tampons-heres-how-they-compare-120499.

62. *Period Products: The Good, the Bad, and the Ugly*, *supra* note 37.

63. *Id.* Menstrual discs are similar to menstrual cups because they are inserted into the vagina to collect menstrual fluid. *Menstrual Discs vs. Period Cups*, THE FORNIX (Jan. 27, 2020), https://flexfits.com/blogs/thefixx/menstrual-discs-vs-menstrual-cups-what-s-the-difference. However, unlike menstrual cups, menstrual discs are single use, sit in the vaginal fornix, and can be worn during sexual intercourse. *See id.*

64. Rose Eveleth, *The Science Behind Period Underwear*, RACKED (Jan. 5, 2016, 10:00 AM), https://www.racked.com/2016/1/5/10708976/period-underwear-technology. Period panties are

products, menstrual discs and period panties are not currently addressed under federal law.[65]

However, the Federal Food, Drug, and Cosmetic Act recognizes menstrual cups as a category of period products.[66] Under federal law, menstrual cups are defined as "a receptacle placed in the vagina to collect menstrual flow."[67] Menstrual cups are typically made out of "medical-grade silicone, rubber, latex, or elastomer and can last up to [ten] years."[68] Federal law classifies menstrual cups as a Class II medical device.[69]

B. Why Are Period Products Dangerous to Menstruators' Health?

Generally, the FDA has deemed menstrual products safe for women to use.[70] According to one of the leading studies on the ingredients in period products, "[n]either the Food and Drug Administration (FDA) nor the Environmental Protection Agency (EPA) has direct authority to monitor or require safety testing for feminine care products."[71] This means, in the United States, toxic ingredients in period products are completely unregulated by the government.[72]

Research regarding the effect of menstrual products on reproductive health did not begin in the United States until the 1990s.[73] In 1997, the United States House of Representatives ("U.S. House") first conducted an investigation into the undisclosed ingredients found in period

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underwear that can be worn during a woman's period to absorb menstrual fluid. *See Underwear That Absorbs Your Period*, THINX, https://www.shethinx.com/pages/thinx-it-works (last visited Aug. 1, 2021). Period panties have been around since World War I. Carina Hsieh, *The 10 Best Period Panties*, COSMOPOLITAN (May 5, 2020), https://www.cosmopolitan.com/sex-love/a20964907/period-panties. Yet, despite their growth in popularity, there is not much information readily available concerning the kind of material out of which the underwear is made. *See* Eveleth, *supra* (stating that there is a lack of information on the materials used to make period panties).

65. *See* 21 C.F.R. § 884.5400 (2020); 21 C.F.R. § 884.5425 (2020); 21 C.F.R. § 884.5435 (2020); 21 C.F.R. § 884.5460 (2020); 21 C.F.R. § 884.5470 (2020) (failing to recognize menstrual discs and period panties).

66. *See* 21 C.F.R. § 884.5400 (2020).

67. *Id.*

68. Anna Maria van Eijk et al., *Menstrual Cup Use, Leakage, Acceptability, Safety and Availability: A Systematic Review and Meta-Analysis*, 4 LANCET PUB. HEALTH e376, e377 (2019). Single-use menstrual cups also exist, but they are less common. *See id.*

69. 21 C.F.R. § 884.5400.

70. Raymond, *supra* note 18 (discussing the procedures the FDA followed to test the safety of tampons).

71. SCRANTON, *supra* note 2, at 8.

72. *See id.*

73. *See* Nicole Wendee, *A Question in Women's Health: Chemicals in Feminine Hygiene Products and Personal Lubricants*, 122 ENV'T HEALTH PERSP. A70, A71 (2014) (stating that the National Institutes of Health did not start a program for vaginal research until 1992).

products.[74] Since then, the U.S. House has updated its research, and independent medical studies have further investigated the undisclosed dangerous ingredients in period products.[75] Yet, there is still inadequate information about the effects of undisclosed ingredients, and risks, of period products.[76]

1. Studies Reveal the Ingredients in Menstrual Products

Medical studies have exposed the toxic ingredients in menstrual products.[77] These studies found alarming chemicals in tampons and menstrual pads.[78] However, despite these studies, the extent of the dangerous, undisclosed ingredients in period products is still an under-researched topic.[79]

Tampons are primarily composed of cotton and rayon,[80] that go through a chlorine-bleaching process.[81] The toxic chemicals found in tampons likely stem from the bleaching process, which leaves behind traces of dioxin.[82] Cotton and rayon "can be contaminated with highly toxic dioxins when bleached with chlorine compounds, as well as pesticides from non-organic cotton."[83]

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74. *See* Tampon Safety and Research Act of 1997, H.R. 2900, 105th Cong. (1997).

75. *See* SCRANTON, *supra* note 2, at 20; Wendee, *supra* note 73, at A72.

76. Robin Danielson Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. (2017); SCRANTON, *supra* note 2, at 5.

77. SCRANTON, *supra* note 2, at 9-10; H.R. 2900; *What's in Your Tampon? 2018 Tampon Testing Results*, *supra* note 20 (analyzing studies that revealed the ingredients in menstrual products). Although all people that use period products are susceptible to the health risks associated with these products, Hispanic and Black women have experienced more health issues from using period products. *See* Wendee, *supra* note 73, at A72. See SCRANTON, *supra* note 2, at 7, for a further discussion of the relationship between race and reproductive health issues.

78. *See* SCRANTON, *supra* note 2, at 9-11.

79. *See, e.g.*, *id.* at 3.

80. *See So, What's Really in Tampax Tampons?*, TAMPAX, https://tampax.com/en-us/tampon-truths/what-tampons-are-made-of (last visited Aug. 1, 2021); SCRANTON, *supra* note 2, at 9. Rayon is a synthetic fiber that can "cause the production of large quantities of toxins absorbed by the vaginal mucosa." Wendee, *supra* note 73, at A73. *But see The Facts on Tampons – and How to Use Them Safely*, *supra* note 50 ("The absorbent fibers used in FDA-cleared tampons sold today are made with a bleaching process that is free from elemental chlorine, which also prevents products from having dangerous levels of dioxin.").

81. *See* RUNE LEITHE, WHY THE TOXIC TAMPON ISSUE ISN'T GOING AWAY 3 (2018), https://www.environmentalpaper.org/wp-content/uploads/2018/03/RL_7mars_2018-1.pdf.

82. *Id.*; Tampon Safety and Research Act of 1999, H.R. 890, 106th Cong. § 2(4) (1999).

83. SCRANTON, *supra* note 2. The FDA reported that menstrual product manufacturers no longer use chlorine when bleaching tampons. *The Facts on Tampons – and How to Use Them Safely*, *supra* note 50. However, dioxins are still found in tampons. *See* Robin Danielson, Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. § 2(3) (2017).

Furthermore, furans and pesticide residues have also been found in tampons.[84] Similar to dioxin, furans are a chemical that comes from the process of bleaching tampons.[85] Moreover, pesticide residues result from traditionally grown cotton.[86] The dioxins, furans, and pesticides found in tampons are undisclosed by period product manufacturers.[87]

Similar to tampons, the material in menstrual pads go through a bleaching process which leaves behind traces of dioxins and furans.[88] Studies found traces of pesticides in cotton menstrual pads as well.[89] Like tampons, these chemicals found in menstrual pads are unregulated by the FDA and remain undisclosed to the consumer.[90]

Additionally, period products with fragrances create a higher risk of containing undisclosed, dangerous chemicals.[91] Scented tampons have added fragrances, and it is unclear what ingredients are in these fragrances.[92] Similarly, while testing menstrual pads that were not labeled as scented, a study found traces of fragrances that pose health risks to women which were undisclosed to the consumer.[93] Due to the lack of transparency of ingredients in period products, experts suggest that women use 100% organic cotton tampons.[94]

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84. SCRANTON, *supra* note 2, at 20.

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.* at 11.

89. *Id.*

90. *Id.*

91. *Id.* at 10-11 ("Unfortunately, a 'fragrance' is a mixture of ingredients that can include any of over 3,000 different chemicals; and the components of any one fragrance are usually kept secret by manufacturers. According to a master list of fragrance chemicals made available by the International Fragrance Association, fragrances can include chemicals which are carcinogens, irritants, allergens, and potential endocrine disruptors.").

92. *See id.* Beginning in Spring 2021, Tampax no longer manufactures tampons with fragrance. *See id.*

93. *See* SCRANTON, *supra* note 2, at 11.

94. *See* Wendee, *supra* note 73, at A73. Recently, recognizing the risks associated with popular tampon brands, new companies have emerged that offer 100% cotton tampons. *See* Andrea Yip, *Rise of the 100% Organic Tampon*, RED DOT PROJECT (Sept. 8, 2019), https://www.reddotprojecttoronto.org/single-post/2019/08/26/Rise-of-the-100-Organic-Tampon. *But see* Caroline Praderio, *Organic Tampons Aren't Worth Your Money – Here's Why*, INSIDER (Oct. 2, 2017, 2:00 PM), https://www.insider.com/are-organic-tampons-safer-better-2017-9 (explaining that organic cotton tampons carry the same risk of toxic shock syndrome ("TSS") as other tampons and, therefore, are not always safer).

2. Health Risks from Menstrual Products

The chemicals discovered in menstrual products create many health risks for the people who use them.[95] Numerous studies revealed dioxin as a dangerous chemical commonly found in period products.[96] Dioxin is a "probable human carcinogen."[97] However, the FDA is not concerned with dioxin levels in period products because they consider the levels of dioxin safe.[98] The FDA makes recommendations about the dioxin levels in menstrual products, but these recommendations are not mandatory for menstrual product manufacturers to follow.[99]

Moreover, the U.S. House reported that "[i]nternal documents of the Food and Drug Administration suggest the agency has not adequately investigated the danger of dioxin in tampons."[100] In assessing the safety of dioxin levels, the FDA relied on data from "paper mill officials" rather than studies that directly test the effect of dioxins in period products on the unique composition of the vagina.[101] Additionally, the FDA leaves period product companies to regulate the level of dioxins in their own products.[102] These levels are not made available to the public.[103]

Despite the FDA's assessment of dioxins, private studies, as well as government research, revealed that dioxins can have an adverse effect on reproductive health in the aggregate.[104] The U.S. House reported, "[t]he effects of dioxin from various sources are cumulative and can be meas-

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95. *See id.* at 20; Tampon Safety and Research Act of 1997, H.R. 2900, 105th Cong. § 486C(a)(1)(A) (1997) (revealing the negative health effects that women experience from using menstrual products with hazardous ingredients).

96. *See* SCRANTON, *supra* note 2, at 20; Michael J. DeVito & Arnold Schecter, *Exposure Assessment to Dioxins from the Use of Tampons and Diapers*, 110 ENV'T HEALTH PERSP. 23, 27 (2002); Robin Danielson Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. § 2(3) (2017).

97. H.R. 2379 § 2(3).

98. Wendee, *supra* note 73, at A73 ("[T]he U.S. Food and Drug Administration (FDA) describes the risk of adverse effects from dioxins in tampons as 'negligible.'").

99. SCRANTON, *supra* note 2 ("FDA guidance for the marketing of tampons recommends that tampons be . . . 'free of 2,3,7,8-tetrachlorodibenzo-p-dioxin(TCDD)/2,3,7,8-tetrachlorofuran (TCDF) and any pesticide and herbicide residues.'").

100. Tampon Safety and Research Act of 1999, H.R. 890, 106th Cong. § 2(6) (1999).

101. *See* JAMIE M. KOHEN, THE HISTORY OF THE REGULATION OF MENSTRUAL TAMPONS 28 (2001), https://dash.harvard.edu/bitstream/handle/1/8852185/Kohen.pdf?sequence=1&isAllowed=y. See Marc Smolonsky & Phillip J. Wakelyn, *Dioxin in Single-Use Diapers and Tampons*, 67 MOTHERING 44 (1993), for a further discussion of the role paper companies play in dioxin testing.

102. H.R. 890 § 2(7).

103. Robin Danielson Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. § 2(5) (2017).

104. *See* Wendee, *supra* note 73, at A73; Tampon Safety and Research Act of 1997, H.R. 2900, 105th Cong. § 2(3) (1997).

ured twenty to thirty years after exposure."[105] A woman's reproductive life lasts approximately sixty years, meaning dioxin levels are cumulating throughout the many years a woman is using period products.[106]

Due to the undisclosed chemicals, period products have caused a multitude of health issues for menstruators.[107] Dioxins and furans have been linked to cancer, endocrine disruption,[108] and reproductive toxicity.[109] Similarly, pesticide residues have been linked to cancer, endocrine disruptions, and acute toxicity.[110] Moreover, the chemicals found in period products can interfere with "estrogen signaling."[111] Tampons are also known to cause vaginal ulcers.[112]

Similarly, menstrual pads cause health problems for menstruators.[113] One common problem menstruators experience from using menstrual pads is contact dermatitis.[114] Menstrual pads can also cause irritation, itching, burning, and allergic rashes on the vulva.[115]

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105. H.R. 2900 § 2(3).

106. H.R. 890 § 2(5).

107. *See, e.g.*, SCRANTON, *supra* note 2, at 20.

108. *Id.* Endocrine disruption can interfere with reproduction, increase the risk of cancer, and affect the immune and nervous system function. *Endocrine Disruption*, ENV'T PROT. AGENCY (Feb. 22, 2017), https://www.epa.gov/endocrine-disruption/what-endocrine-disruption.

109. SCRANTON, *supra* note 2, at 20. Reproductive toxicity is "any effect of chemicals that would interfere with reproductive ability or capability, with subsequent effects on lactation and the development of offspring . . . ." Efstathios Nikolaidis, *Relevance of Animal Testing Sensitivity of End Points in Reproductive and Developmental Toxicity*, *in* REPRODUCTIVE AND DEVELOPMENTAL TOXICOLOGY 111 (Ramesh C. Gupta ed., 2011).

110. SCRANTON, *supra* note 2, at 20.

111. Wendee, *supra* note 73, at A72. Estrogen signaling "refers to all proteins of estrogen function and related regulatory proteins." *Estrogen Signaling Pathway*, CREATIVE DIAGNOSTICS, https://www.creative-diagnostics.com/estrogen-signaling-pathway.htm#:~:text=The%20estrogen%20signaling%20pathway%20refers,function%20and%20related%20regulatory%20proteins.&text=Estrogen%20works%20mainly%20by%20binding,cytoplasm%20to%20play%20its%20role (last visited Aug. 1, 2021). Estrogen signaling is important because it can "regulate function" in cancers including breast cancer and leukemia. *See* Simon P. Langdon, *Estrogen Receptor Signaling in Cancer*, MDPI (Sept. 24, 2020), https://www.mdpi.com/2072-6694/12/10/2744/htm.

112. Weissberg & Dodson, *supra* note 1, at 1431. *But see Scientist Sees a Connection Between Endometriosis and Tampon Use, Orgasm*, YALE MED., Autumn 2002, at 15 (discussing one study that found that using tampons can protect women against endometriosis).

113. *See* SCRANTON, *supra* note 2, at 11; Wendee, *supra* note 73, at A73.

114. Wendee, *supra* note 73, at A73; Letter from Women's Voices for the Earth et al. to Members of Congress (Aug. 5, 2020) (on file with author) ("Acrylates and methacrylates are also commonly included in menstrual pads. The disclosure of specific acrylates and methacrylates used in pads is lacking, but there are several published case studies of patients with diagnosed contact dermatitis from exposure to acrylates from the use of menstrual products and incontinence pads.").

115. SCRANTON, *supra* note 2, at 11.

Additionally, period products have been linked to vaginal yeast infections and bacterial vaginosis.[116] As a result, many women seek over-the-counter treatment to deal with the irritation they experience.[117] However, the ingredients in the over-the-counter treatments, which are often undisclosed under federal law, can exacerbate the problems women experience.[118]

In 2018, a study tested tampons from popular brands to investigate whether they contained undisclosed chemicals.[119] This study revealed that "there may be ingredients . . . in tampons leading to exposure to chemicals of concern."[120] Although period products contain undisclosed chemicals, due to the lack of research regarding the effects of chemicals on the vagina, the severity of this concern is unclear.[121] Nevertheless, it is clear from medical studies that period products contain undisclosed chemicals and other toxic ingredients that pose serious risks to the health of people who use period products.[122]

C. The Uniqueness of the Vagina and Why It Matters

The toxic ingredients in menstrual products create a magnified health risk because of the area of the body in which these products are used.[123] Therefore, it is vitally important to consider the structure and uniqueness of the vagina when discussing the impact of period products on menstruators' health.[124] Some period products, like tampons, menstrual cups, and menstrual discs, are inserted directly into the vagina.[125] Other products, like menstrual pads and period panties, make direct contact with the vulvar skin.[126]

Both vaginal and vulvar tissue are "structurally different than the skin of the rest of the body" and, therefore, are more sensitive to the

116. Wendee, *supra* note 73, at A73.

117. *Id.*

118. *Id.* (explaining that over-the-counter treatments can create "overgrowth of azole-resistant yeast species" and anogenital dermatitis).

119. *What's in Your Tampon? 2018 Tampon Testing Results*, *supra* note 20.

120. *Id.*

121. *Id.* Moreover, due to the lack of research, it is unclear whether menstrual cups, menstrual discs, and period panties create medical concerns for menstruators' health. *See How Do I Use Tampons, Pads, Period Underwear, and Menstrual Cups?*, *supra* note 49.

122. *See supra* Part II.B.1–2.

123. *See* SCRANTON, *supra* note 2, at 4.

124. Wendee, *supra* note 73, at A72 (discussing research which showed that the structure of the vagina affects the rate at which toxic chemicals from menstrual products are absorbed into the body).

125. *See* Kang, *supra* note 61 (explaining that both tampons and menstrual cups are used by inserting them into the vagina).

126. *See* SCRANTON, *supra* note 2, at 11.

toxic chemicals found in period products.[127] Vaginal and vulvar tissue are covered in mucous membranes.[128] Unlike the skin, "[d]rugs absorbed from the vagina does [sic] not undergo first-pass metabolism because blood leaving the vagina enters the peripheral circulation via a rich venous plexus, which empties primarily into the internal iliac veins."[129]

Moreover, the vagina and the vulva are "capable of secreting and absorbing fluids at a higher rate than skin."[130] The large number of blood vessels in the vagina allow absorption to occur more quickly than regular skin.[131] These blood vessels allow for "direct transfer of chemicals in to the circulatory system."[132] Therefore, the chemicals discovered in period products are absorbed at a higher rate than if they came into contact with the skin.[133] Yet, the FDA considers the chemicals in period products safe based only on data from products tested on skin, which is less absorbent than the mucous membrane.[134]

III. THE UNREGULATED REGULATION OF THE INGREDIENTS IN MENSTRUAL PRODUCTS

This Part discusses the inadequate legislation governing the disclosure and labeling requirements for menstrual product ingredients in the United States.[135] Subpart A will discuss the Federal Food, Drug, and Cosmetic Act and the Medical Device Amendments that set forth the disclosure requirements for the ingredients in menstrual products.[136] Subsequently, Subpart B will discuss the FDA's authority over requiring manufacturers to make disclosures for menstrual products.[137] Subpart C will discuss state action taken to require period product manufacturers to disclose the ingredients in the period products sold in their states.[138] This Subpart entails the New York and California Menstrual Products Right to Know Acts, which set forth the period product ingredient disclosure

127. *Id.* at 4.
128. *Id.*
129. Alamdar Hussain & Fakhrul Ahsan, *The Vagina as a Route for Systemic Drug Delivery*, 103 J. CONTROLLED RELEASE 301, 302 (2005).
130. Wendee, *supra* note 73, at A72.
131. *See id.* Due to its high absorption rate, medical studies have tested administering drugs through the vagina rather than orally or on the skin to get the drugs into the bloodstream faster. Hussain & Ahsan, *supra* note 129, at 302.
132. SCRANTON, *supra* note 2, at 4.
133. *See* Wendee, *supra* note 73, at A72.
134. *See id.*; SCRANTON, *supra* note 2, at 5.
135. *See infra* Part III.
136. *See infra* Part III.A.
137. *See infra* Part III.B.
138. *See infra* Part III.C.

requirements in New York and California.[139] Finally, Subpart D will discuss the proposed bill in the U.S. House attempting to amend the Federal Food, Drug, and Cosmetic Act.[140] This Subpart also explains why the proposed bill, also known as the Menstrual Products Right to Know Act, is inadequate in ensuring all people who menstruate know the ingredients in period products.[141]

A. The Federal Food, Drug, and Cosmetic Act

The FDA regulates menstrual products through the Federal Food, Drug, and Cosmetic Act.[142] The Federal Food, Drug, and Cosmetic Act was originally passed in 1938 to allow consumers to know important information about the products they use, including the ingredients in products.[143] More importantly, this law gave the FDA the "authority to regulate medical devices and cosmetics, and to establish standards for foods."[144] The three main categories regulated under this federal legislation include food,[145] drugs and devices,[146] and cosmetics.[147]

Over time, with developments in research and ongoing discoveries, the Federal Food, Drug, and Cosmetic Act has been amended multiple times.[148] Most significantly, in 1976, the Medical Device Amend-

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139. *See infra* Part III.C.

140. *See infra* Part III.D.

141. *See infra* Part III.D.

142. 21 U.S.C. § 301 et seq. (2018). The Federal Food, Drug, and Cosmetic Act was enacted in the early twentieth century. *See 80 Years of the Federal Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (July 11, 2018), https://www.fda.gov/about-fda/virtual-exhibits-fda-history/80-years-federal-food-drug-and-cosmetic-act.

143. *See 80 Years of the Federal Food, Drug, and Cosmetic Act*, *supra* note 142.

144. *Id.* ("Drugs and devices were required to provide adequate directions for use; falsely labeled uses were misbranded; and there was no longer a need to establish intent to defraud to prove misbranding. In addition, it became illegal to market drugs or devices that inherently endangered health, and all new drugs had to be proven safe for their labeled use before they could be marketed."). The Federal Food, Drug, and Cosmetic Act was largely a consumer protection law. *See id.*

145. *See* 21 U.S.C. §§ 341–350 (2018). The Federal Food, Drug, and Cosmetic Act regulates, *inter alia*, adulterated food, misbranded food, nutrition labeling, dietary supplements, food additives, bottled drinking water, and infant formulas. *Id.* §§ 342-350.

146. *See id.* §§ 351–360 (2018). The drugs and devices section of the Federal Food, Drug, and Cosmetic Act covers a wide range of drugs and devices. *See id.* The regulated areas include adulterated drugs and devices, misbranded drugs and devices, new drugs, clinical trials, animal drugs, medical gases, as well as many others. *Id.*

147. *See id.* §§ 361–364 (2018). The relevant sections of the Federal Food, Drug, and Cosmetic Act regulate adulterated cosmetics, misbranded cosmetics, and other cosmetic regulations. *See id.*

148. *See e.g.*, Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 1(a), 104 Stat. 2353 (2018) (codified as amended at 21 U.S.C. §§ 337, 343, 343(i), 345, 371(e)); Food Quality Protection Act of 1966, Pub. L. No. 104-170, § 401, 110 Stat. 1513 (2018) (codified as amended at 7 U.S.C. § 321 et seq.); Securing Opioids and Unused Narcotics with Deliberate Disposal and

ments[149] were adopted to amend the Federal Food, Drug, and Cosmetic Act.[150] In 1980, the Medical Device Amendments were further amended to include menstrual products as medical devices.[151] Therefore, under current federal regulations, period products are classified as medical devices.[152] As a result of this classification, companies are not required to disclose the dangerous ingredients in menstrual products that create serious health risks.[153]

1. Medical Device Amendments

The Medical Device Amendments of the Federal Food, Drug, and Cosmetic Act[154] govern the current disclosure requirements of the ingredients in menstrual products.[155] Period products are classified as medical devices because they "are intended to affect the function of the body."[156] Medical devices are broken down into three classes depending on the risk the device carries.[157] These classifications include Class I

Packaging Act of 2018, Pub. L. No. 115-271, § 3031, 132 Stat. 3940 (2018) (codified as amended 21 U.S.C. § 355 et seq.).

149. 21 U.S.C. § 360 et seq. (2018).

150. *See* INST. OF MED. OF THE NAT'L ACADS., PUBLIC HEALTH EFFECTIVENESS OF THE FDA 510(K) CLEARANCE PROCESS 3 (Theresa Wizemann ed., 2011).

151. *See* Tina Beaudoin, *Are Your Tampons a Medical Device?*, EMERSON ECOLOGICS, https://edu.emersonecologics.com/2017/04/11/are-your-tampons-a-medical-device/#:~:text=Yes%2C%20your%20tampons%20are%20considered,government%20and%20FDA%20since%201980 (last visited Aug. 1, 2021).

152. SCRANTON, *supra* note 2, at 8.

153. *See* KOHEN, *supra* note 101, at 25.

154. 21 U.S.C. § 360 et seq. (2018).

155. *See* KOHEN, *supra* note 101, at 3. Medical devices are defined 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—
>
> (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 in 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.

21 U.S.C. § 321(h) (2018).

156. Andrea Donsky, *Why Are Tampons Classified as Medical Devices?*, NATURALLY SAVVY, https://naturallysavvy.com/care/why-are-tampons-classified-as-medical-devices (last visited Aug. 1, 2021).

157. *See What's the Difference Between the FDA Medical Device Classes?*, BMP MED., https://www.bmpmedical.com/blog/whats-difference-fda-medical-device-classes-

Medical Devices,[158] Class II Medical Devices,[159] and Class III Medical Devices.[160]

Under current federal law, unscented menstrual pads are Class I medical devices[161] because the FDA considers these menstrual pads "low risk medical devices."[162] Moreover, all tampons and menstrual cups are Class II medical devices[163] because they are higher risk medical devices than unscented menstrual pads.[164] On the other hand, depending on the risk of the material they are composed of, scented or scented deodorized menstrual pads are classified as either Class I or Class II medical devices.[165]

Under this classification, period product manufacturers are "required to submit to [sic] FDA a detailed risk assessment of the device components, the design, and the test results."[166] The submissions made

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2/#:~:text=A%20Class%20I%20medical%20device%20are%20those%20devices%20that%20have, exempt%20from%20the%20regulatory%20process (last visited Aug. 1, 2021).

158. *See id.* ("Class I medical device[s] are those devices that have a low to moderate risk to the patient and/or user. Today, [forty-seven percent] of medical devices fall under this category and 95% of these are exempt from the regulatory process. If a device falls into a generic category of exempted Class I devices, a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, the manufacturer is required to register their establishment and list their generic product with FDA. Examples include enema kits, elastic bandages, manual stethoscopes, and bedpans.").

159. *See id.* ("Class II medical devices are those devices that have a moderate to high risk to the patient and/or user. 43% of medical devices fall under this category. Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits.").

160. *See id.* ("Class III medical devices are those devices that have a high risk to the patient and/or user. These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. They represent 10% of medical devices regulated by the FDA. Examples of Class III devices include implantable pacemakers and breast implants.").

161. *See supra* Part II.A.1.

162. Donsky, *supra* note 156.

163. *See supra* Part II.A.1–2.

164. *See What's the Difference Between the FDA Medical Device Classes?*, *supra* note 157.

165. *See supra* Part II.A.1.

166. *FDA Regulation of Tampons and Pads*, FEMCARE ANSWERS, https://www.femcareanswers.com/safety/regulation (last visited Aug. 1, 2021) (describing the FDA submission process to include a "[d]etailed description of the products including its composition;" "[d]etailed risk assessments;" "[a]ssessments of human safety, such as irritation and allergy, in accordance with internationally-recognized consensus standards;" "[c]onfirmation [sic] the microbiological safety of tampons;" and "[e]valuation of the intended labeling to assure women have access to the proper usage and safety information"). Under the Medical Device Amendments, manufacturers must "submit to the FDA a pre-market approval ("PMA") application . . . before making any change affecting the safety or effectiveness of the device." KOHEN, *supra* note 101, at 4 ("Some of the changes which require a PMA supplement include: '1) new indication for use of the device; 2) labeling changes; 3) the use of a different facility or establishment to manufacture, process, or package the device; 4) changes in sterilization procedures; 5) changes in packaging.' If a change 'does not affect the device's safety or effectiveness and the change is reported to FDA,' the change does not require submission of a PMA supplement.").

to the FDA are not available to the public.[167] Moreover, the labeling requirements for medical devices under the Federal Food, Drug, and Cosmetic Act require that "the device labeling bear adequate warnings against dangerous uses to health, or information necessary for the protection of users."[168] Notably, there is no requirement that medical devices be labeled with their ingredients.[169]

As Class I and Class II medical devices, period products are currently governed by the same requirements regulating a multitude of products including, among other things, carbon monoxide gas analyzers,[170] ureteral stents,[171] dental preformed crowns,[172] and audiometers.[173] These types of medical devices, some of which are used externally on the body, are significantly different from period products.[174] Period products are used in a unique, sensitive part of the body[175] and, therefore, should not be regulated the same as other medical devices that pose a lesser health risk.[176]

B. The Current Disclosure Requirements Under Federal Law Are Insufficient

Under current federal law, the FDA requires a multitude of product manufacturers to disclose and label the ingredients found in their products.[177] In order for the FDA to have the authority to require

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167. *See* Robin Danielson Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. § 2(5) (2017).

168. U.S. FOOD & DRUG ADMIN., LABELING: REGULATORY REQUIREMENTS FOR MEDICAL DEVICES 1 (1997), https://www.fda.gov/files/medical%20devices/published/Labeling---Regulatory-Requirements-for-Medical-Devices-(FDA-89-4203).pdf.

169. *See* KOHEN, *supra* note 101, at 25.

170. *See* 21 C.F.R. § 868.1430 (2020) ("A carbon monoxide gas analyzer is a device intended to measure the concentration of carbon monoxide in a gas mixture to aid in determining the patient's ventilatory status.").

171. *See id.* § 876.4620 (defining a ureteral stent as a "tube-like implant device inserted into the ureter to . . . allow the passage of urine").

172. *See id.* § 872.3330. A preformed crown is a temporary device "affixed temporarily to a tooth after removal of, or breakage of, the natural crown." *Id.*

173. *See id.* § 874.1050. An audiometer is a device used to conduct diagnostic hearing tests. *Id.*

174. *See e.g.*, 21 C.F.R. § 892.1000 (2020) (describing a magnetic resonance diagnostic device as a Class II medical device); *id.* § 888.5960 (stating that an orthopedic cast removal instrument is a Class I medical device).

175. *See supra* Part II.C.

176. *See* KOHEN, *supra* note 101, at 25.

177. *See On Day of the Girl*, *supra* note 24; Laura E. Derr, *When Food Is Poison: The History, Consequences, and Limitations of the Food Allergen Labeling and Consumer Protection Act of 2004*, 61 FOOD & DRUG L.J. 65, 66 (2006) (explaining that ingredients are required to be disclosed in food products); U.S. FOOD & DRUG ADMIN., COSMETIC LABELING GUIDE 5 (2020),

manufacturers to label menstrual products with their ingredients, they must have information "indicating that such labeling is necessary for the safe and effective use of [the products]."[178] The FDA has not yet exercised this authority over the ingredients in period products.[179]

The FDA first exercised this authority by requiring menstrual product manufacturers to label tampons with a warning for toxic shock syndrome ("TSS").[180] Despite the fact that tampons have existed since the early twentieth century,[181] TSS was not discovered until 1980.[182] TSS is a life-threatening illness, and one of its main causes is tampon use.[183] After recognizing the seriousness of TSS,[184] the FDA required companies to label tampons with a warning regarding the risk of TSS.[185] The FDA wanted consumers to be informed of the possible risks associated with tampon use and exercised their authority to require tampons to be labeled with a TSS warning.[186]

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https://www.fda.gov/media/88234/download (describing the labeling requirements for the ingredients in cosmetics).

178. *See* KOHEN, *supra* note 101, at 27.

179. *See* SCRANTON, *supra* note 2, at 8. This is likely due to the fact that the FDA "has avoided requests for nonmaterial information or, warning-like statements for ingredients that cause only mild or idiosyncratic responses." *See* Fred H. Degnan, *Biotechnology and the Food Label: A Legal Perspective*, 55 FOOD & DRUG L.J. 301, 306 (2000). *But see* SCRANTON, *supra* note 2, at 8 (discussing the serious health risks created by the undisclosed ingredients in menstrual products).

180. *See* KOHEN, *supra* note 101, at 10. In fact, when the Center for Disease Control and Prevention ("CDC") first discovered that tampons caused TSS, they suggested that women stop using tampons altogether to avoid the risk of TSS. *See id.* at 6 (explaining the CDC "recommended that women who wish to avoid the risk of menstrually associated TSS stop using tampons").

181. *See id.* at 2.

182. *See* Thomas Koenig & Michael Rustad, *His and Her Tort Reform: Gender Injustices in Disguise*, 70 WASH. L. REV. 1, 41 (1995) ("Toxic shock syndrome (TSS) was first identified in 1980 as an infection which largely affects menstruating women.").

183. *See* Amanda L. Wilkins et al., *Toxic Shock Syndrome – the Seven Rs of Management and Treatment*, 74 J. INFECTION S147, S147-48 (2017). The symptoms of TSS include, *inter alia*, decreased kidney functions, liver impairment, and difficulty breathing. *Toxic Shock Syndrome (TSS)*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/health/conditions-and-diseases/toxic-shock-syndrome-tss#:~:text=Toxic%20shock%20syndrome%20(TSS)%20is,cause%20severe%20damage%20and%20illness (last visited Aug. 1, 2021).

184. *See* KOHEN, *supra* note 101, at 10. When it was first discovered that TSS was linked to tampon use, the FDA was not quick to address this problem. *See id.* at 5-12. After multiple studies and pushback from tampon manufacturers, the FDA finally adopted a requirement for tampons to be labeled with TSS warnings. *See id.*

185. *See* 21 C.F.R. § 801.430 (2020). This requirement applies to unscented and scented or scented deodorized tampons. *See id.* Furthermore, if companies choose to include the warning in an insert inside of the tampon box, the company must also label the outside of the box with an alert. *See id.* However, the FDA does not mandate where on the box the warning must be displayed. *See* KOHEN, *supra* note 101, at 11.

186. *See* KOHEN, *supra* note 101, at 8.

One of the main causes of TSS from tampon use is attributed to the previously undisclosed absorbency levels of tampons.[187] The higher the absorbency level of the tampon, the more likely the tampon is to cause TSS.[188] As a result, the FDA recognized the risk consumers faced by not knowing the absorbency level of tampons and required manufacturers to label them with their absorbency level.[189] Furthermore, the FDA set forth testing methods that tampon manufacturers must follow when they measure the absorbency levels of tampons.[190] Regarding TSS and tampon absorbency levels, the FDA uncovered sufficient evidence to require tampon manufacturers to label their products.[191]

The FDA has not exercised this authority to require menstrual product manufacturers to disclose the ingredients in period products despite knowing the risks associated with the ingredients in these products.[192] When the FDA first investigated the health risks associated with period products, there was a lack of research revealing the numerous health risks associated with menstrual products beyond the use of tampons and their link to TSS.[193] Therefore, the FDA only

187. *See id.* at 16 ("[T]he relative risk of TSS generally increases as the absorbency of the tampon increases and that without regard to the chemical composition of the tampon, for each gram increase in absorbency, there is a significant increase in the risk of illness.").

188. *See* David Samadi, *Toxic Shock Syndrome Is Most Common with Use of Super-Absorbent Tampons; Here Are the Best Ways to Prevent It*, N.Y. DAILY NEWS (June 24, 2015, 6:30 AM), https://www.nydailynews.com/life-style/health/doctor-minimize-risk-toxic-shock-syndrome-article-1.2268476 ("Toxic shock syndrome has most commonly been associated with the use of super-absorbent tampons, which can instigate bacterial growth due to prolonged use.").

189. *See* 21 C.F.R. § 801.430. The absorbency categories include light absorbency, regular absorbency, super absorbency, super plus absorbency, and ultra absorbency. *Id*. These categories of absorbency are measured in grams. *See id.* Similar to the approval process of a TSS warning, when the FDA first discovered that higher absorbency tampons are more likely to cause TSS, they were not quick to require absorbency disclosure. *See* KOHEN, *supra* note 101, at 13 (stating that at the start, "[t]he FDA believed that the voluntary standards process was the most efficient and economical method available for developing uniform absorbency testing and labeling"). Ultimately, the FDA recognized the need for uniform absorbency level labeling standards. *See id.* at 13-24 ("[T]he FDA decided to standardize the current terms, and to require that the word 'absorbency' accompany the terms to alert consumers that the packaging has been changed.").

190. *See* 21 C.F.R. § 801.430(f). The FDA also provides an exception to the absorbency level testing methods set forth. *See id*. Tampons that are dispensed from a vending machine are exempt from the TSS and absorbency labeling requirements. *See id.* See *id.* § 801.430, for the current complete user labeling requirements for tampons.

191. *See* KOHEN, *supra* note 101, at 16.

192. *See id.* at 27 ("[T]he FDA responded that in the absence of data showing an association between any ingredient and any risk to health, nor any legal theory under which the FDA could reside, the FDA lacked the authority to mandate ingredient labeling.").

193. *See id.* at 26-27 ("Ultimately, the FDA felt it did not have the authority to adopt ingredient labeling requirements. 'None of the comments favoring ingredient labeling cited, discussed, or submitted any data showing an association between any ingredient in any currently marketed tampon and any risk to health, including allergic reaction, sensitivity, or irritation, and FDA is unaware of any such data.'").

required companies to label tampons with a TSS warning and the absorbency level.[194]

However, in addition to TSS, studies have exposed other health risks associated with menstrual products.[195] Beginning in the 1990s, research developed and revealed that there is a myriad of health risks associated with multiple period products.[196] Yet, the FDA has not changed the labeling requirements for menstrual products to reflect this new research.[197]

Although the FDA does not require manufacturers to disclose the ingredients in menstrual products, federal law allows companies to make ingredient disclosures on a voluntary basis.[198] Today, some of the most popular menstrual product brands are Tampax, U by Kotex, and Playtex,[199] and only one of these brands discloses the ingredients in their products.[200] Albeit, the voluntary list of ingredients disclosed only includes a limited list of generalized ingredients.[201] As a result of the need for ingredient disclosure, new companies have emerged that market their brand on ingredient transparency.[202] However, these ingredient

194. *See id.* at 11.

195. *See supra* Part II.B; SCRANTON, *supra* note 2, at 20 (stating that menstrual products are linked to cancer, endocrine disruption, and reproductive toxicity).

196. *See* SCRANTON, *supra* note 2, at 20; Robin Danielson Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. (2017); Tampon Safety and Research Act of 1999, H.R. 890, 106th Cong. (1999); Tampon Safety and Research Act of 1997, H.R. 2900, 105th Cong. (1997).

197. *See* SCRANTON, *supra* note 2, at 8 (stating that as medical devices, menstrual products "lack any government requirement to disclose ingredients to the consumer").

198. *See id.*

199. *See* Syden Abrenica, *Periods Are Uncomfortable (We Know) but These 10 Tampons Are Not*, BYRDIE (Oct. 21, 2019), https://www.byrdie.com/best-tampons-4766540. All of these brands were tested in a study conducted by the Women's Voices for the Earth, which found volatile organic compounds in their tampons. *What's in Your Tampon? 2018 Tampon Testing Results*, *supra* note 20.

200. *See Everything You Need to Know About Periods*, U BY KOTEX, https://www.ubykotex.com/en-us/periods (last visited Aug. 1, 2021) (omitting the ingredients in their products); *Period 101*, PLAYTEX, https://www.playtexplayon.com/period-faq/period-101 (last visited Aug. 1, 2021) (stating no ingredients in their products).

201. *See So, What's Really in Tampax Tampons?*, *supra* note 80 (describing tampons as containing "rayon, cotton, polypropylene, polyethylene, polyester, glycerin, paraffin, ethoxylated fatty acid esters, PEG-100 Stearate, [and] titanium dioxide").

202. *See, e.g.*, Alexander Abraham, *How Organic Tampons Compare to Non-Organic*, THE HONEY POT, https://thehoneypot.co/blogs/latest/how-organic-tampons-compare-to-non-organic (last visited Aug. 1, 2020). Regarding ingredient disclosure, this company stated:

> We want to eliminate the infections, irritation, cramps, and more issues that can stem from toxins in tampons. Our natural organic tampons are created with organic cotton, grown without any pesticides or chemicals. All of our natural organic tampons are also fragrance-free and are wrapped in a BPA-free plastic applicator. We also proudly list all ingredients on the box. We believe everyone should have a healthy period and know what they are putting in their body.

Id.

disclosures are only voluntary because federal law does not require menstrual product companies to disclose the ingredients in their products.[203]

In the past, the FDA recognized the risk people faced because tampons were not labeled with a warning for TSS or absorbency levels and required period product manufacturers to make these disclosures.[204] The undisclosed ingredients in all menstrual products create a risk for menstruators' health of equal gravity.[205] The current FDA regulations only address some of the health risks that are created by tampons.[206] However, unscented and scented or scented deodorized tampons are not the only period products that pose a risk to menstruators' health.[207] Moreover, TSS is not the only health risk created by unscented and scented or scented deodorized tampons.[208]

Today, studies revealed sufficient evidence that proves that the undisclosed ingredients in menstrual products pose more than "mild or idiosyncratic"[209] health risks for menstruators.[210] Therefore, the FDA has the necessary information indicating that such labeling is necessary for the safe and effective use of menstrual products.[211] In order to ensure that menstruators are aware of the health risks they face when using period products with undisclosed ingredients, federal law must require menstrual product companies to disclose the ingredients in their products.[212]

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203. *See* SCRANTON, *supra* note 2, at 8. As early as the 1980s, the FDA has been aware that the undisclosed ingredients in menstrual products create health risks for women. *See* KOHEN, *supra* note 101, at 26 ("[A]n FDA scientist warned, 'It is critical to an adequate risk assessment that the level of dioxins in tampons, sanitary pads, diapers, and other medical devices be measured.'").

204. *See* KOHEN, *supra* note 101, at 5-24 (canvassing this history).

205. *See* SCRANTON, *supra* note 2, at 20.

206. *See* 21 C.F.R. § 801.430 (2020).

207. *See* SCRANTON, *supra* note 2, at 20 (stating that the undisclosed ingredients in tampons and menstrual pads create health risks for women).

208. *See id.* (discussing the multitude of health risks women face from using period products with undisclosed ingredients).

209. Degnan, *supra* note 179, at 306.

210. *See* SCRANTON, *supra* note 2, at 20; Robin Danielson Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. (2017); Tampon Safety and Research Act of 1999, H.R. 890, 106th Cong. (1999); Tampon Safety and Research Act of 1997, H.R. 2900, 105th Cong. (1997).

211. *See* KOHEN, *supra* note 101, at 29.

212. *See, e.g.*, *On Day of the Girl*, *supra* note 24; Lauren Valenti, *Why New York's Period Product Labeling Act Is So Important*, VOGUE (Oct. 14, 2019), https://www.vogue.com/article/new-york-menstrual-period-product-labeling-act ("Women are thinking more critically and making more informed decisions about menstruation.").

C. State Menstrual Products Right to Know Acts

Due to the lack of action from the federal government regarding the disclosure of ingredients in menstrual products, states have begun passing legislation to require manufacturers to disclose the ingredients in period products.[213] New York and California became the first two states in the United States to pass legislation requiring period product manufacturers to disclose the ingredients in their products.[214] In both states, the legislatures passed the laws in order to protect the health of people who experience periods.[215]

1. New York

In 2019, recognizing the danger women face from not knowing the ingredients in their period products under current federal law,[216] New York became the first state in the United States to require companies to disclose the ingredients in their menstrual products.[217] On the International Day of the Girl, Governor Andrew Cuomo signed the New York Menstrual Products Right to Know Act.[218] Governor Cuomo expressed the importance of requiring companies to disclose the ingredients in menstrual products and stated, "[p]ractically every product on the market today is required to list its ingredients, yet these items have inexplicably evaded this basic consumer protection."[219]

The New York State Assembly first recognized the danger the undisclosed ingredients in period products create for women[220] and

213. *See* N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020); Assemb. 1989, 2020 State Assemb., Reg. Sess. (Cal. 2020).

214. *See* GEN. BUS. § 399-aaaa; Cal. Assemb. 1989.

215. *See Menstrual Products Right to Know Act Signed by Governor*, CAL. ST. ASSEMB. DEMOCRATIC CAUCUS (Sept. 30, 2020), https://asmdc.org/press-releases/menstrual-products-right-know-act-signed-governor; *On Day of the Girl*, *supra* note 24.

216. N.Y. St. Assemb., Assemb. 2019-164B, Reg. Sess. (N.Y. 2019).

217. Jaramillo, *supra* note 16.

218. *Id.*

219. *On Day of the Girl*, *supra* note 24.

220. Assemb. 2019-164B. The New York State Assembly stated:

> Tampons are marketed and sold with little or no data assuring the ingredients they contain are safe. These products are intended for use on or in the extremely permeable membranes of the vaginal area of a woman's body. Toxic and allergenic chemicals may be contained in tampons, raising significant health concerns. Labeling of tampon packages would serve to protect the public and allow consumers to make informed decisions regarding the purchase of tampons.

Id. Assembly Member Linda B. Rosenthal spearheaded the law and stated, "[m]enstrual product ingredient disclosure is a vital consumer empowerment tool, and will hold menstrual product manufacturers to the highest level of accountability." *On Day of the Girl*, *supra* note 24.

proposed the New York Menstrual Products Right to Know Act.[221] The New York Menstrual Products Right to Know Act[222] requires "each package or box containing menstrual products sold in this state to contain a plain and conspicuous printed list of all ingredients which shall be listed in order of predominance."[223] The purpose of the law was to "empower women to make decisions about what goes into their bodies."[224]

Regarding the ingredients in period products, the New York Menstrual Products Right to Know Act requires menstrual product companies to disclose the added ingredients in their products.[225] Moreover, the law imposes a penalty on companies that do not comply with the requirement.[226] The pertinent portion of the statute states:

> 1. For purposes of this section:
> (a) "ingredient" shall mean an intentionally added substance present in the menstrual product;
> (b) "menstrual product" shall mean products used for the purpose of catching menstruation and vaginal discharge, including but not limited to tampons, pads, and menstrual cups. These products may be either disposable or reusable.
> 2. No later than eighteen months after this section shall have become a law, each package or box containing menstrual products sold in this state shall contain a plain and conspicuous printed list of all ingredients which shall be listed in order of predominance. Such list shall either be printed on the package or affixed thereto.
> 3. The requirements of this section shall apply in addition to any other labeling requirements established pursuant to any other provision of law.
> 4. Whenever a violation of this section has occurred, a civil penalty of one percent of the manufacturer's total annual in-state sales not to exceed one thousand dollars per package or box shall be imposed on the manufacturer.[227]

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221. N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020).

222. *Id.*

223. *Id.*; *New York Requires Disclosure of Ingredients in Menstrual Products*, THE NAT'L L. REV. (Oct. 16, 2019), https://www.natlawreview.com/article/new-york-requires-disclosure-ingredients-menstrual-products.

224. *On Day of the Girl*, *supra* note 24 ("[E]very single New Yorker who uses tampons and pads will know exactly what's in the products they use in and on some of the most sensitive parts of their bodies for 24 hours a day, seven days a week, one week out of the [sic] for as many as 40 years.").

225. *See* GEN. BUS. § 399-aaaa.

226. *See id.*

227. *Id.*

The New York law is regarded as the current industry standard for ingredient disclosures.[228]

Although the New York law requires menstrual product manufacturers to disclose ingredients in menstrual products, the law leaves the requirements open for interpretation.[229] Unlike the labeling requirements for TSS and absorbency levels,[230] there is no standard form period product manufacturers must follow when labeling menstrual products with ingredients.[231] Furthermore, it is unclear from the definition of "ingredient" whether menstrual product manufacturers have to test their products in order to discover all of the ingredients in their products, like dioxins or pesticides.[232] Therefore, although the New York Menstrual Products Right to Know Act requires menstrual companies to disclose the ingredients in their products,[233] the broad language of the law creates the risk that some ingredients may continue to remain undisclosed.[234]

2. California

More recently, California adopted a similar law requiring period product manufacturers to disclose the ingredients in their products.[235] On September 29, 2020, California Governor Gavin Newsom signed the Menstrual Products Right to Know Act of 2020.[236] Similar to New York, California recognized the danger women face for not knowing the

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228. *See* Erin Bunch, *California Is About to Become the Second State Requiring Ingredient Transparency in Period Products*, WELL + GOOD (Sept. 8, 2020), https://www.wellandgood.com/period-product-transparency.

229. *See New York Requires Disclosure of Ingredients in Menstrual Products*, *supra* note 223 ("The law itself is exceedingly short, leaving open questions, including but not limited to, determining those entities responsible for product labeling and confirming whether ingredient identities can be protected as confidential.").

230. *See* 21 C.F.R. § 801.430 (2020) (stating the labeling requirements for TSS and absorbency levels on tampon boxes).

231. *See New York Requires Disclosure of Ingredients in Menstrual Products*, *supra* note 223.

232. *See id.* ("[T]he requirement to disclose only intentionally added substances seemingly limits the ingredient disclosure requirement.").

233. *See* N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020).

234. *See New York Requires Disclosure of Ingredients in Menstrual Products*, *supra* note 223 ("[T]erms such as 'plain and conspicuous' and 'listed in order of predominance' are amenable to interpretation and require guidance and stakeholder engagement to effectuate legislative intent.").

235. *See* Assemb. 1989, 2020 State Assemb., Reg. Sess. (Cal. 2020).

236. *See id.* Assembly member Cristina Garcia was a main advocate for the legislation. *See Menstrual Products Right to Know Act Signed by Governor*, *supra* note 215 ('"Consumers in California have a right to know what is in the products they will be using for over 40 years of their life, in order to protect their health.' Garcia continued, 'My goal with this law is to increase the awareness of the toxic chemicals currently in our menstrual products. It was troubling at best to learn that products people rely on contain Phthalates, Bisphenols, Parabens, and PFAS/PFOA, which all have been found to be harmful to human health. Periods are not a luxury and people should have the knowledge to make safer choices.'").

ingredients in their period products and passed this legislation to allow women to make safer, more informed choices when choosing their period products.[237]

The California law requires menstrual product manufacturers to label "a package or box containing menstrual products" with "all of the ingredients in the product."[238] Under the California law, the definition of ingredients is broader than the New York Menstrual Products Right to Know Act.[239] Critics argue that the California definition of ingredients falls below the industry standard.[240] The California law does not require manufacturers to disclose certain dangerous added fragrances.[241] Notably, under the California Menstrual Products Right to Know Act, manufacturers are not required to disclose two "problematic allergens known to cause genital contact dermatitis."[242] The law also allows ingredients that are classified as "confidential business information" to remain undisclosed to the consumer.[243] There is no guarantee that the ingredients excluded under the disclosure exceptions will not create health risks for menstruators.[244] Therefore, even though the California law on its face requires manufacturers to disclose all of the ingredients in

237. *See Menstrual Products Right to Know Act Signed by Governor*, *supra* note 215.

238. Cal. Assemb. 1989 § 111822.2(a).

239. *See id.* § 111822(d) ("'Ingredient' means a fragrance ingredient or other intentionally added substance or combination of substances present in the menstrual product, unless the intentionally added substance or combination of substances is confidential business information, in which case the manufacturer may identify the ingredient by its common name to protect its confidential identity. . . .").

240. *See* Bunch, *supra* note 228.

241. *See id.* ("[T]he bill allows for added fragrance which falls under a certain threshold to be left off of ingredients lists, so California consumers will remain unaware of their inclusion in products. 'This is concerning because these are products that are coming into contact with sensitive, absorptive tissue, and even fragrance ingredients below 100 parts per million could pose some health concerns.'"); *Press Statement: Women's Voices for the Earth's Statement on the Passing of California's AB 1989, Period Product Ingredient Disclosure Bill*, WOMEN'S VOICES FOR THE EARTH (Sept. 30, 2020), https://www.womensvoices.org/2020/09/30/statement-passing-of-ab1989-period-product-ingredient-disclosure-bill [hereinafter *Press Statement*] ("AB 1989 also puts alarming restrictions on fragrance disclosure by only requiring disclosure above a 100ppm threshold. Fragrance can contain toxic ingredients, and considering the use of these products in the vagina and on sensitive vulvar tissue, this is information people who menstruate have a right to know, no matter the level.").

242. *Press Statement*, *supra* note 241 ("Methylisothiazolinone (MI) and the combination of Methylchloroisothiazolinone/methylisothiazolinone (MCI)—do not need to be disclosed under AB 1989. Studies show that these allergens are commonly used as preservatives in adhesives like the kinds used on menstrual pads. This is the type of information that should require disclosure, instead AB 1989 will allow corporations to continue to withhold this information from the public.").

243. *See id.*; Cal. Assemb. 1989 § 111822(c)(1)(A) ("'Confidential business information' means an intentionally added ingredient or combination of ingredients for which a claim has been approved by the federal Environmental Protection Agency for inclusion on the Toxic Substances Control Act (TSCA).").

244. *See Press Statement*, *supra* note 241.

period products, the law includes significant exceptions to the disclosure requirements that pose health risks for the consumers who use the products.[245]

Furthermore, similar to the New York law,[246] the California law requires manufacturers to label period products with a conspicuous list of all ingredients in order of predominance by weight.[247] In addition to a label on the physical period product container, the California law also requires manufacturers to provide a list of ingredients on their website.[248] This allows the manufacturers' disclosures to be more readily available to the public.[249] Moreover, the California law provides guidance for period product manufacturers to follow when there is a change to the ingredients in their products.[250]

The most significant difference between the California and New York Menstrual Products Right to Know Acts is that the California law does not have a separate penalty for manufacturers that do not comply with the law.[251] Unlike the industry standard, period product manufacturers that do not comply with the disclosure requirements of the California law will not be uniformly sanctioned.[252] Ultimately, the disclosure requirements under the California Menstrual Products Right to Know Act are less comprehensive than the industry standard set forth in the New York Menstrual Products Right to Know Act.[253]

245. *See id.*; Cal. Assemb. 1989 § 111822(c)(1)(A).

246. *See* N.Y. GEN. BUS. LAW § 399-aaaa (2) (McKinney 2020).

247. Cal. Assemb. 1989 §§ 111822.2(a)–(b) ("A package or box containing menstrual products that was manufactured on or after January 1, 2023, for sale or distribution in this state shall have printed on the label a plain and conspicuous list of all ingredients in the product. The ingredients shall be listed in order of predominance by weight in the menstrual product, except ingredients present at a weight below one percent may be listed in any order following the other ingredients. Ingredients shall be identified using a standardized nomenclature."). Unlike the California law, the New York Menstrual Products Right to Know Act does not contain a nomenclature requirement for manufacturers to follow when disclosing ingredients. *See California Passes Menstrual Products Right to Know Act*, BUREAU VERITAS (Oct. 1, 2020), https://www.cps.bureauveritas.com/newsroom/california-passes-menstrual-products-right-know-act.

248. Cal. Assemb. 1989 § 111822.2(c).

249. *See* Bunch, *supra* note 228.

250. Cal. Assemb. 1989 §§ 111822.4(a)–(b).

251. *See* Cal. Assemb. 1989.

252. *See id.*; N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020).

253. *See* GEN. BUS. § 399-aaaa; Cal. Assemb. 1989. The downfalls of the California Menstrual Products Right to Know Act have been attributed to the corporate influence over the legislature's decision making. *Press Statement*, *supra* note 241.

D. The U.S. House Proposed Federal Menstrual Products Right to Know Act

In 2019, the U.S. House introduced a bill that would require companies to disclose and label menstrual products with all of their ingredients.[254] This was not the first time the U.S. House attempted to introduce such a bill.[255] In the past, the U.S. House has shown concern for the risks of the undisclosed ingredients in period products.[256] Consequently, the U.S. House proposed to enable multiple programs researching the presence and effects of dangerous toxins in period products.[257] Yet, none of the proposed bills have made it out of a U.S. House Committee or Subcommittee.[258]

Recognizing the dangers period products create for people who menstruate, the U.S. House proposed a bill titled the Menstrual Products Right to Know Act of 2019 to amend section 502 of the Federal Food, Drug, and Cosmetic Act.[259] Section 502 concerns misbranded drugs and devices.[260] Therefore, under the proposed legislation, if a period product manufacturer does not label the ingredients in their products, the violation is treated as a misbranded product.[261] The relevant portion of the statute states:

> [A drug or device shall be deemed to be misbranded] [i]f it is a menstrual product, such as a menstrual cup, a scented, scented deodorized, or unscented menstrual pad or tampon, a therapeutic vaginal douche apparatus, or an obstetrical and gynecological device described in . . . [the] Code of Federal Regulations (or any successor regulation), unless its label or labeling lists the name of each ingredient or component of the product in order of

254. Menstrual Products Right to Know Act of 2019, H.R. 2268, 116th Cong. (2019).

255. *See* Menstrual Products Right to Know Act of 2017, H.R. 2416, 115th Cong. (2017). The bill was introduced in the U.S. House on May 12, 2017. *Id.* The bill was then referred to the U.S. House Committee on Energy and Commerce and then referred to the U.S. House Subcommittee on Health. *Id.* The bill never made it out of the U.S. House Subcommittee. *See id.*

256. *See* Robin Danielson Feminine Hygiene Product Safety Act of 2017, H.R. 2379, 115th Cong. (2017); Tampon Safety and Research Act of 1999, H.R. 890, 106th Cong. (1999); Tampon Safety and Research Act of 1997, H.R. 2900, 105th Cong. (1997).

257. *See* H.R. 2900; H.R. 890; H.R. 2379.

258. *See* H.R. 2900 (stating the last action was on November 14, 1997, when the bill was referred to the U.S. House Subcommittee on Health and Environment); H.R. 890 (describing the last action taken on the bill as the sponsor's introductory remarks on June 23, 1999); H.R. 2379 (explaining the last action on the bill occurred on May 5, 2017, when it was referred to the U.S. House Subcommittee on Health).

259. Menstrual Products Right to Know Act of 2019, H.R. 2268, 116th Cong. (2019).

260. *See* 21 U.S.C. § 352 (2018).

261. *See* H.R. 2268.

> the most predominant ingredient or component to the least predominant ingredient or component.[262]

Unlike the New York Menstrual Products Right to Know Act, the federal Menstrual Products Right to Know Act of 2019 does not include a separate provision that enforces the labeling requirements.[263] Rather, a violation of this bill follows the procedures of a misbranded medical device.[264] The FDA's enforcement against individuals for misbranded products varies depending on "the nature of the violation."[265] The sanctions vary in severity and can include a warning letter,[266] seizure,[267] injunction,[268] criminal prosecution,[269] and/or criminal fine.[270] Therefore, under the proposed federal law, the FDA will enforce violations on a case-by-case basis, and there is no uniform enforcement policy for manufacturers that violate the disclosure requirements.[271]

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262. *Id.*; 21 U.S.C. § 352.

263. *See* H.R. 2268; N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020).

264. *See* H.R. 2268.

265. *Types of FDA Enforcement Action*, U.S. FOOD & DRUG ADMIN. (Nov. 6, 2017), https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions.

266. *Id.* ("Warning Letters are sent to the individuals or firms, advising them of specific noted violations. These letters request a written response as to the steps which will be taken to correct the violation.").

267. *Id.* ("An action brought against an FDA-regulated product because it is adulterated and/or misbranded within the meaning of the Act. The purpose of such an action is to remove specific violative goods from commerce.").

268. *Id.* ("An order by a court that requires an individual or corporation to do or refrain from doing a specific act. FDA may seek injunctions against individuals and/or corporations to prevent them from violating or causing violations of the Act.").

269. *Id.* ("Criminal prosecution . . . may be recommended in appropriate cases for violation of [s]ection 301 of the Act; [m]isdemeanor convictions, which do not require proof of intent to violate the Act, can result in fines and/or imprisonment up to one year. Felony convictions, which apply in the case of a second violation or intent to defraud or mislead, can result in fines and/or imprisonment up to three years. The FDA field offices have primary responsibility for conducting inspections or investigations and collecting samples which may lead to recommendations for enforcement/regulatory action. The type of action recommended will depend upon the nature of the violation and the public health concern, Agency policy, previous history of violations by the firm, and other factors.").

270. *Id.* ("Misdemeanor fines under the Act may reach $500,000 under some circumstances. The Criminal Fine Enforcement Act of 1994 (Public Law 98-596) provides for fines for violations of Federal law. Although it is not part of the Act, the Criminal Fine Enforcement Act of 1994 applies to all fines levied under the Act, as well as other statutes that contain provisions enforced by FDA. The following fines are applicable for each offense: [u]p to $100,000 for a misdemeanor by an individual that does not result in death; [u]p to $200,000 for a misdemeanor by a corporation that does not result in death[; u]p to $250,000 for a misdemeanor by an individual that results in death, or a felony[; u]p to $500,000 for a misdemeanor by a corporation that results in death, or a felony. The maximum imprisonment for a misdemeanor under the Act remains a year for each offense.").

271. *See id.*

Another shortfall is that the bill does not include a definition of ingredients that period product manufacturers must disclose.[272] Both the New York and California laws include a section that defines the ingredients in period products that must be disclosed under the respective laws.[273] Therefore, the federal Menstrual Products Right to Know Act of 2019 is an inadequate bill to protect menstruators, because it does not have a definite enforcement mechanism, and the language is vague.[274] The U.S. House Menstrual Products Right to Know Act has yet to make it out of the House Energy and Commerce Subcommittee on Health.[275]

IV. A CHANGE TO EMPOWER MENSTRUATORS

Currently, under the Federal Food, Drug, and Cosmetic Act, people do not know the ingredients in their period products because they are classified as medical devices.[276] As a result, people continue to use menstrual products without knowing the associated health risks because companies are not required to disclose the information in the products.[277] This Note takes the position that a federal approach is necessary to ensure that all people who menstruate know every ingredient in their menstrual products.[278] The solution to this problem is to amend the Federal Food, Drug, and Cosmetic Act to require period product manufacturers to label all ingredients in their products, include a warning of the associated health risks, and impose a clear penalty on manufacturers who violate the disclosure requirements.[279]

Subpart A argues the necessity for a federal approach to the problem.[280] Subpart B sets forth the ingredient disclosure requirements menstrual product manufacturers must follow when labeling all menstrual products.[281] Unlike the current federal legislation proposed in the U.S. House, this solution will clearly define what manufacturers

272. *See* Menstrual Products Right to Know Act of 2019, H.R. 2268, 116th Cong. (2019).

273. *See* N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020); Assemb. 1989, 2020 State Assemb., Reg. Sess. (Cal. 2020). Albeit, the clarity of these definitions is criticized. *See Press Statement*, *supra* note 241; *New York Requires Disclosure of Ingredients in Menstrual Products*, *supra* note 223.

274. *See* H.R. 2268.

275. *See id.*

276. SCRANTON, *supra* note 2, at 8.

277. Wendee, *supra* note 73, at A74.

278. *See infra* Part IV.A–B.

279. *See infra* Part IV.A–B.

280. *See infra* Part IV.A.

281. *See infra* Part IV.B.

must disclose in order to comply with the proposed amendment.[282] Subsequently, Subpart C discusses the importance of labeling period products with a warning of the health risks associated with dangerous ingredients in the products.[283] Finally, Subpart D sets forth a clear, uniform penalty for manufacturers who violate the disclosure requirements.[284] In order to best protect people who menstruate from the serious risks of not knowing the ingredients in their menstrual products, it is important to have clear ingredient disclosure requirements with a label of their health risks and a uniform sanction for violations.[285]

A. A Federal Approach

Due to the severity of the issue,[286] a federal approach is necessary to ensure that all people who menstruate are able to choose products that are safe for their body.[287] This would not be the first time that the FDA required manufacturers to disclose ingredients in products.[288] Under the Federal Food, Drug, and Cosmetic Act, the FDA requires food and other products to be labeled with their ingredients.[289] These requirements have been implemented for consumer safety.[290] Thus, due to the health risks people who menstruate face from using menstrual products,[291] period product manufacturers must be required to disclose the ingredients in their products for consumer safety.[292]

Some critics argue that a federal approach is not necessary because once period product manufacturers change their labeling to conform with the New York Menstrual Products Right to Know Act, they will use the same packaging with the disclosed ingredients in every state.[293] This

282. *See infra* Part IV.B.

283. *See infra* Part IV.C.

284. *See infra* Part IV.D.

285. *See infra* Part IV.B–D.

286. *See supra* Part II.B.1–2.

287. *See* SCRANTON, *supra* note 2, at 18.

288. *See, e.g.*, U.S. FOOD & DRUG ADMIN., A FOOD LABELING GUIDE: GUIDANCE FOR INDUSTRY 5 (2013), https://www.fda.gov/files/food/published/Food-Labeling-Guide-%28PDF%29.pdf.

289. *See id.*; U.S. FOOD & DRUG ADMIN., *supra* note 177; Letter from Women's Voices for the Earth to Members of Congress, *supra* note 114 ("Ingredient listings are required for food, cosmetics, and over the counter drugs enabling the public to avoid ingredients they are concerned about, or that may cause allergic reactions like rashes, itchiness or burning.").

290. *See* U.S. FOOD & DRUG ADMIN., *supra* note 177.

291. *See supra* Part II.B.1–2.

292. *See infra* Part IV.B.

293. *See* Bunch, *supra* note 228 ("[I]t will be interesting to see what happens as the New York law goes into effect next year, as it's not exactly cost effective for companies to print different packaging for different states—meaning that hypothetically, New York's comprehensive law could be the tide that rises all boats by forcing transparent packaging into every market. For this reason,

is largely attributed to the fact that it could be costly to manufacture different packages depending on the state in which the product is sold.[294] Therefore, in theory, through the New York law, period product manufacturers could disclose ingredients on all of their products across the nation without a federal law mandating the disclosure.[295]

However, there is no guarantee that the cost of ingredient disclosure will be significant enough to encourage manufacturers to disclose all ingredients on menstrual product containers in every state, including states that do not have a law mandating the disclosure.[296] Moreover, the New York and California laws have different disclosure requirements.[297] In these states alone, period product manufacturers will have to make different disclosures on their products.[298] A federal approach would provide uniform disclosures and eliminate the need for manufacturers to make different ingredient disclosures depending on the state in which the product is sold.[299]

B. Companies Must Disclose All Ingredients in Menstrual Products

The Federal Food, Drug, and Cosmetic Act should be amended to adopt language requiring companies to disclose all ingredients in menstrual products and label the products with their ingredients.[300] Currently, under the Federal Food, Drug and Cosmetic Act, menstrual products are classified as medical devices and, therefore, companies are not required to label or disclose the ingredients in these products that create dangerous health risks for menstruators.[301] It is clear from medical studies that period products contain dangerous ingredients that pose serious risks to menstruators' health.[302] Therefore, for their safety, people who menstruate have a right to know the ingredients that are entering into their bodies.[303] For this solution to be effective, the

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she says, the industry may yet try to fight what's happening in New York and then do the same on the West Coast, too.").

294. *See id.*

295. *See id.*

296. *See id.*

297. *See id.*

298. *See id.*

299. *See* SCRANTON, *supra* note 2, at 18.

300. *See* Menstrual Products Right to Know Act of 2019, H.R. 2268, 116th Cong. (2019) (proposing an amendment to the Federal Food, Drug, and Cosmetic Act that would treat menstrual products as misbranded if they are not labeled with their ingredients).

301. *See supra* Part II.A.1–2.

302. *See supra* Part II.B.1–2.

303. *See Press Statement*, *supra* note 241.

amendment must provide clear guidance for the disclosure requirements under the law.[304]

The definition of "ingredient" is the most crucial piece of the amendment because it is important to ensure that all ingredients, including the most dangerous ones, are disclosed.[305] The U.S. House, New York, and California Menstrual Products Right to Know Acts are instructive in crafting an amendment to the Federal Food, Drug, and Cosmetic Act.[306] Regarding the definition of ingredients, under the proposed U.S. House Menstrual Products Right to Know Act of 2019, there is no definition of the ingredients that must be disclosed.[307] Moreover, the California Menstrual Products Right to Know Act's definition of "ingredients" is insufficient because it allows manufacturers to omit certain dangerous ingredients.[308] Finally, the New York Menstrual Products Right to Know Act is regarded as the current industry standard for disclosing ingredients in menstrual products, but the law still contains vague language.[309] In order for the amendment to serve its purpose in allowing people to know all ingredients in their period products, the definition of "ingredients" must include all ingredients without any exceptions.[310] Therefore, "ingredients" should be defined as, "something that enters into a compound or is a component part of any combination or mixture."[311]

Similar to the FDA requirement that tampon manufacturers must test the absorbency level of tampons, the amendment should require manufacturers to test the ingredients in their products.[312] Uniform testing procedures would ensure that all ingredients are disclosed.[313] Unlike the FDA testing requirements for absorbency levels, the ingredient test results should be made available to the public on the company's

304. *See id.*

305. *See supra* Part III.B–D.

306. *See supra* Part III.B–D.

307. *See supra* Part III.D.

308. *See supra* Part III.C.2.

309. *See supra* Part III.C.1.

310. *See New York Requires Disclosure of Ingredients in Menstrual Products*, *supra* note 223; *Press Statement*, *supra* note 241 ("New York's ground-breaking law, and—while flawed—AB 1989, are both clear examples that keeping ingredient secrets, especially in products that come into such intimate contact with the body, is simply not acceptable."). The California Menstrual Products Right to Know Act allows exceptions for confidential business information and certain added fragrances. *See* Assemb. 1989, 2020 State Assemb., Reg. Sess. (Cal. 2020). The New York Menstrual Products Right to Know Act only includes intentionally added substances, which allows certain ingredients to be excluded. *See* N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020).

311. *See Ingredient*, MERRIAM-WEBSTER, https://www.merriam-webster.com/dictionary/ingredient (last visited Aug. 1, 2021).

312. *See supra* Part III.B.

313. *See supra* Part III.B.

website.[314] In employing this definition and testing requirement, it will be difficult for period product manufacturers to hide the potentially dangerous ingredients that are not intentionally added that remain undisclosed under the current industry standard.[315]

In addition to defining "ingredients," other pieces of the amendment require definitions.[316] The state Menstrual Products Right to Know Acts are instructive in defining these key terms.[317] In conjunction with defining the ingredients that must be disclosed in menstrual products, the amended law should describe the nature of the language that manufacturers shall use.[318] In this respect, the California law is instructive.[319] Modeling the California Menstrual Products Right to Know Act, manufacturers must use standardized nomenclature to identify ingredients so that they are easy for the consumer to understand.[320]

Moreover, following the industry standard set forth in New York law, menstrual products should be defined as "products used for the purpose of catching menstruation and vaginal discharge, including but not limited to" tampons, pads, menstrual cups, menstrual discs, and period panties. "These products may be either disposable or reusable."[321] Finally, the amendment should include a procedure for manufacturers to follow when an ingredient changes in a period product.[322] This procedure should model the California law, which sets forth a procedure for both changes to the physical label of the menstrual product and to the manufacturer's website.[323] These definitions are important to ensure that

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314. *See supra* Part III.C.2.

315. *See supra* Part II.B.1.

316. *See* Assemb. 1989, 2020 State Assemb., Reg. Sess. (Cal. 2020); N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020).

317. *See* Cal. Assemb. 1989; GEN. BUS. § 399-aaaa.

318. *See* Cal. Assemb. 1989.

319. *See id.*

320. *Id.* § 111822.2(b) ("Ingredients shall be identified by using a standardized nomenclature, including, but not limited to, the International Nomenclature of Cosmetic Ingredients (INCI), the Household Commercial Products Association's Consumer Product Ingredient Dictionary (HCPA Dictionary), or common chemical name. If a standardized nomenclature does not otherwise exist for an ingredient, a name established by the Center for Baby and Adult Hygiene Products (BAHP) shall be used by all menstrual product manufacturers.").

321. *See* GEN. BUS. § 399-aaaa(b). This would also include period underwear and menstrual discs. *See supra* Part II.A.2.

322. *See* Cal. Assemb. 1989 §§ 111822.4 (a)–(b).

323. *See id.* This part of the amendment would read:

> (a) When a manufacturer is required to make a revision to information disclosed online due to a change in a designated list or a change in an ingredient or addition of a new ingredient, the manufacturer shall make the revision no later than six months after the change or addition of the ingredient, or after the adoption of the revised designated list

people who menstruate are aware of every ingredient, including potential hazardous ingredients, that are found in their period products.[324]

Another important aspect of the proposed amendment is to require uniform labeling standards.[325] Recognizing the health risks of tampons, the FDA already requires uniform labeling and disclosures for a TSS warning and absorbency levels on tampons.[326] Therefore, due to the potential health risks created by all period products, the federal law should require uniform labeling standards for ingredient disclosure.[327] Regarded as the current industry standard,[328] the language of the New York Menstrual Products Right to Know Act is instructive in crafting the labeling requirements.[329] The pertinent portion of the New York law states that "each package or box containing menstrual products sold . . . shall contain a plain and conspicuous printed list of all ingredients which shall be listed in order of predominance."[330] Similar to the California law, predominance should be defined as the weight of the ingredient.[331] In addition to labeling the products with their ingredients, for clarity, the manufacturers should also post the list of ingredients to their website.[332] Requiring ingredient disclosures to be labeled on the physical menstrual product packaging, as well as on the manufacturer's website, would enable people who menstruate to have greater knowledge about the ingredients in their menstrual products.[333]

C. A Warning Label to Explain the Health Risks

It is important to label menstrual products with their ingredients in order for people who menstruate to know the possible dangerous

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by its authoritative body, unless a later effective date for changes to a designated list is imposed by the relevant authoritative body.

(b) When a manufacturer is required to change the label on a menstrual product because of a change in a designated list or a change to an ingredient or addition of a new ingredient, the manufacturer shall make the change within 18 months of the change or addition of the ingredient, or after the adoption of the revised designated list by its authoritative body, unless a later effective date is imposed by the relevant authoritative body.

Id.

324. *See supra* Part II.B.1–2.
325. *See supra* Part III.B.
326. *See supra* Part III.B.
327. *See supra* Part III.B.
328. Bunch, *supra* note 228.
329. *See* N.Y. GEN. BUS. LAW § 399-aaaa (McKinney 2020).
330. *Id.*
331. *See* Assemb. 1989, 2020 State Assemb., Reg. Sess. (Cal. 2020).
332. *See id.* § 111822.2(c).
333. *See id.*

ingredients in these products.[334] However, from a label alone, people who use menstrual products may not know the health risks associated with these ingredients.[335] The health risks from these ingredients can be serious, and people who use these products have a right to be informed of their risks.[336] In order for people who use menstrual products to be aware of the health risks associated with the dangerous ingredients in these products, the amended federal law should require period product manufacturers to include a warning on all menstrual products that contain ingredients that are linked to negative health effects.[337]

This would not be the first warning label required for menstrual products.[338] Due to the severity of the health implications associated with TSS, the FDA requires tampon boxes to contain a warning with the health risks caused by TSS.[339] Certain dangerous ingredients in period products create risks to menstruators' health in equal severity to TSS.[340] For example, dioxins, furans, and pesticides found in menstrual products are all known to cause cancer in humans.[341] However, simply labeling period products with these ingredients does not convey to the average person the severity of the ingredients.[342] Therefore, in addition to labeling menstrual products with ingredients, the federal law must require period product manufacturers to label products with a warning explaining the health risks associated with the dangerous ingredients in the products.[343] A warning label will ensure that people know the health risks associated with the dangerous ingredients in period products.[344]

D. Penalty for Nondisclosure

In addition to clear disclosure requirements and a warning label, in order for the amended federal law to be effective, it must include a monetary penalty for companies that do not comply with these requirements.[345] Currently, under the New York law industry standard, companies who fail to comply with the requirements of the Menstrual Products Right to Know Act receive a "civil penalty of one percent of

334. *See supra* Part IV.B.
335. *See* KOHEN, *supra* note 101, at 8.
336. *See supra* Part II.B.2.
337. *See supra* Part II.B.2.
338. *See supra* Part III.B.
339. *See supra* Part III.B.
340. *See supra* Part III.B.
341. *See supra* Part II.B.2.
342. *See* KOHEN, *supra* note 101, at 8.
343. *See* 21 C.F.R. § 801.430 (2020).
344. *See* KOHEN, *supra* note 101, at 8.
345. *See* N.Y. GEN. BUS. LAW § 399-aaaa(4) (2020).

the manufacturer's total annual in-state sales not to exceed one thousand dollars per package or box."[346] Moreover, under the federal Menstrual Products Right to Know Act, there is no uniform penalty for violations of the disclosure requirements.[347] Rather, the FDA assesses punishment on a case-by-case basis.[348] Therefore, in order for there to be a clear penalty that is uniformly enforced, the amendment should be similar to the penalty in the New York Menstrual Products Right to Know Act.[349]

In the United States, the total sales for menstrual products in 2017 was $5.9 billion.[350] "In 2020, those numbers are expected to reach $6.2 billion" in the United States.[351] The size of the industry should be taken into consideration when crafting a penalty for the amended federal law to ensure that companies comply with the requirements.[352] Thus, using the New York law as guidance for developing a penalty for a violation of the amendment, there should be a monetary penalty of a set percentage of the manufacturer's total annual sales not to exceed one thousand dollars per package.[353] This percentage should be large enough to deter offenders from repeating a violation of the disclosure requirements.[354] Ultimately, a significant enough penalty will give period product manufacturers an incentive to comply with ingredient disclosure requirements of the amended federal law, thereby empowering people who menstruate to know all of the ingredients in period products.[355]

V. CONCLUSION

All people who menstruate have a right to know the ingredients in the products that come into direct contact with their bodies.[356] However, in the United States, people who menstruate do not currently have this right.[357] It is clear from medical research that some of the most popular menstrual products contain harmful ingredients that are dangerous to

346. *Id.*
347. *See* Menstrual Products Right to Know Act of 2019, H.R. 2268, 116th Cong. (2019).
348. *See supra* Part III.D.
349. *See* GEN. BUS. § 399-aaaa.
350. *The Ultimate Guide to Feminine Hygiene*, *supra* note 3.
351. *Id.*
352. *See* Kenneth Mann, *Punitive Civil Sanctions: The Middleground Between Criminal and Civil Law*, 101 YALE L.J. 1795, 1830 (1992).
353. *See* GEN. BUS. § 399-aaaa.
354. *See* Mann, *supra* note 352.
355. *See id.*
356. *See On Day of the Girl*, *supra* note 24.
357. *See supra* Part III.A.

menstruators' health.[358] These ingredients include dioxins, furans, and pesticides, which are known to cause serious health problems, among other things, cancer, infertility, reproductive toxicity, and endocrine disruption.[359] With the health risks associated with ingredients in menstrual products,[360] it is critical that people know the chemicals they are putting into their body.[361]

The solution to this problem is simple: require menstrual product manufacturers to disclose the ingredients in their products and provide a warning label stating the associated health risks.[362] This solution is not groundbreaking, in fact, the FDA has required similar disclosures for other products that have direct contact with the body.[363] Moreover, the FDA already requires tampon manufacturers to warn users about the health risks of TSS and the absorbency levels associated with tampon usage.[364] Therefore, requiring menstrual product manufacturers to disclose the ingredients in their products and provide a warning is well within the federal government's authority and would be another important consumer safety measure to protect menstruators.[365]

An amendment to the Federal Food, Drug, and Cosmetic Act will allow all people who menstruate to gain the right to know exactly what ingredients are in period products.[366] Under this amendment, period product manufacturers will be required to disclose all of the ingredients in their products, and provide a warning label with the associated health risks, thereby giving people who menstruate the power to choose products that are less likely to put their health at risk.[367] Moreover, manufacturers that do not comply with the disclosure requirements will receive a monetary penalty to incentivize them to comply with the regulations.[368]

The Federal Food, Drug, and Cosmetic Act was founded on consumer protection, and as research develops, the legislation should be amended to ensure the continued safety of all people who menstruate.[369]

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358. *See supra* Part II.B.1–2.
359. *See supra* Part II.B.1–2.
360. *See supra* Part II.B.2.
361. *See On Day of the Girl*, *supra* note 24.
362. *See supra* Part IV.
363. *See supra* Part IV.A.
364. *See supra* Part III.B.
365. *See supra* Part IV.A.
366. *See supra* Part IV.B–D.
367. *See supra* Part IV.B–D.
368. *See supra* Part IV.D.
369. *See supra* Part III.A.

With over twenty-six percent of the world being of reproductive age,[370] this amendment could prevent a loved one from one day experiencing cancer or some other serious health condition resulting from period product use.[371] In summation, it is left in the hands of the United States Congress to empower all people who menstruate with the knowledge of the ingredients they are putting in their bodies, so they can make educated, safer choices when choosing their period products.[372]

*Haley E. Clancy**

370. *See Fast Facts: Nine Things You Didn't Know About Menstruation*, UNICEF (May 25, 2018), https://www.unicef.org/press-releases/fast-facts-nine-things-you-didnt-know-about-menstruation#:~:text=Menstruation%20is%20stigmatized%20all%20over%20the%20world.&text=Roughly%20half%20of%20the%20female,about%20two%20to%20seven%20days. Although there are a vast number of individuals who menstruate, there is still a major problem with access to period products. *Id.* For a comprehensive discussion on the period product access crisis, see *The Ultimate Guide to Feminine Hygiene*, *supra* note 3.

371. *See supra* Part II.B.

372. *See supra* Part IV.

*J.D. Candidate, 2022, Maurice A. Deane School of Law at Hofstra University; B.A., *magna cum laude*, Political Science with a minor in Global Communications, 2019, Roger Williams University. I am deeply grateful to my parents, Diane and Michael Clancy; grandmother, Madeline Clancy; and sister, Steph Anderson, for their encouragement and unconditional love throughout my life and law school career. I would also like to thank my good friends, Aleena Abraham, Sarah Durning, Erica Meier, Haley Mock, and Nicole Newham for their unwavering support. Without all of you, I would not be where I am today. Thank you to my faculty advisor, Professor Janet Dolgin, and my Notes Editor, Ashley Ehman, for their invaluable guidance throughout the Note-writing process. Finally, I want to thank the entire membership of the *Hofstra Law Review* who made this publication possible.