What Is in Your Tampon? Increasing Transparency in Menstrual Products

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CONTENTS

INTRODUCTION

The average person who menstruates will bleed for an average of five days, every twenty-four to thirty-eight days, over several decades and could use thousands of disposable menstrual products[1] in their lifetime.[2] Menstrual products line retail shelves. They can be found in homes, bags, and bodies—but until 2021,[3] manufacturers were not required to disclose the ingredients used to make these products to consumers at all. In fact, they still are not federally required to disclose menstrual product ingredients on product packaging.[4] Instead, in recent years, changes to menstrual product labels have largely been the result of state legislation. In 2019, New York State passed the first Menstrual Right to Know Act, which gave manufacturers eighteen months to begin disclosing menstrual product ingredients on boxes sold within the state.[5] California passed its own disclosure law in 2020.[6]

In addition to increasing transparency through ingredient disclosures, states are legislating to end menstrual product taxes and to increase access.[7] Amid these efforts to increase menstrual equity,[8] it is important to evaluate whether changes to state laws are the appropriate route for a product historically regulated by the FDA. It is also important to consider whether these laws might be more effective if taken a step further. This Note argues that menstrual products deserve increased scrutiny and that legislation can support important changes to further the health of

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1. Kristen Upson, Jenni A. Shearston & Marianthi-Anna Kioumourtzoglou, *Menstrual Products as a Source of Environmental Chemical Exposure: A Review from the Epidemiologic Perspective*, 9 CURRENT ENV'T HEALTH REP. 38, 38 (Mar. 17, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9876534/ [https://perma.cc/RYY9-DBVG].

2. This number could be lower if the menstruator regularly relies on reusable products like period underwear or menstrual cups.

3. New York's menstrual product act went into effect eighteen months after it was signed into law in late 2019. *See* Estrella Jaramillo, *Cuomo Signs Bill Making New York the First State to Mandate Ingredient List for Tampons*, FORBES (Oct. 11, 2019), https://www.forbes.com/sites/estrellajaramillo/2019/10/11/cuomo-signs-bill-new-york-first-state-to-mandate-ingredient-list-for-tampons/.

4. The Food and Drug Administration (FDA), which does require some specifics in terms of labeling on some menstrual product packages, does not require ingredient disclosure. *See* 21 C.F.R. § 801.430 (2024).

5. *See* Jaramillo, *supra* note 3.

6. CAL. HEALTH & SAFETY CODE § 111822.2 (West 2021).

7. *See* PERIOD EQUITY, AM. CIV. LIBERTIES UNION, THE UNEQUAL PRICE OF PERIODS: MENSTRUAL EQUITY IN THE UNITED STATES, https://www.aclu.org/wp-content/uploads/legal-documents/111219-sj-periodequity.pdf [https://perma.cc/CBM9-EY36] (last visited Aug. 18, 2024).

8. *Id.* (explaining that Jennifer Weiss-Wolf coined the term "Menstrual Equity," which refers to the idea that without laws and policies that ensure menstrual products are safe and accessible, we cannot have a fully equitable and participatory society).

menstruators in the United States. In delving into the history of the tampon and the Toxic Shock Syndrome Crisis of the 1980s, this Note also aims to highlight the importance of product safety and regulation, particularly as new products enter the market. Parts I and II provide an overview of the menstrual product market, including the history of FDA regulation and more recent research efforts. Part III evaluates efforts to increase menstrual product transparency through state and federal legislation. Part IV proposes additional regulations to increase transparency and consumer safety, focusing on eco-labeling, fixing absorbency charts, and legislating at the federal level. California and New York's laws are an important step toward increasing consumer awareness and autonomy, but they are just a start. Significant changes are needed to combat existing menstrual stigma, achieve future equity, and ensure product safety.

DISCLAIMERS

This Note intentionally uses non-gendered language as a way to subvert harmful societal norms that ignore menstruating individuals who do not identify as "women." However, this Note will necessarily rely on less inclusive sources; many of the cited sources will refer to menstruating individuals as "women."

Additionally, this Note does not address menstrual product accessibility, even though access to period products remains a barrier for menstruating individuals around the world.[9] A significant amount of scholarly work has been devoted to increasing accessibility as a means of reducing menstrual injustice.[10] However, it is possible to acknowledge a gap in accessibility and still demand increased safety and transparency in menstrual products.

I. WHAT ARE MENSTRUAL PRODUCTS AND HOW ARE THEY REGULATED?

It is difficult to understand period product regulation without understanding the products themselves. In the United States, stores generally offer the following products for use during menstruation: tampons, pads, pantyliners, period underwear, and menstrual cups.

9. *See id.*
10. *Id.*

A. Types of Menstrual Products

"Regular" tampons are a popular option for menstruators in the United States.[11] A tampon is a small wad of material[12] inserted into the vagina digitally or with a plastic/cardboard applicator.[13] Once inserted, the tampon absorbs menstrual blood.[14] It has a string attached to one end for the menstruator to pull for removal.[15] Tampons are sold with absorbency ratings that range from "light" to "super plus" or "ultra."[16] These ratings are regulated by the FDA.[17]

Disposable sanitary napkins, also known as pads, are also an extremely popular option in the United States.[18] A pad is a piece of absorbent material that attaches or sticks to underwear.[19] Disposable pads have a "layered design: a fluid permeable surface (topsheet), an absorbent core, and impermeable backing with adhesive (backsheet)."[20] Many pads also have "wings," which are strips of material lined with adhesive that wrap around the sides of underwear to secure the pad in place.[21] Similar to tampons, pads also display absorbency ratings, though the ratings are generally specific to each brand because uniform absorbency labeling is not federally required.[22] The rating might refer to the duration for which the menstruator might wear the pad, i.e., "overnight."[23] Or, it might refer to the rate of flow, such as "heavy."[24] Included in this category are "panty liners," which are thinner and less absorbent pads that have an adhesive

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11. Apple Women's Health Study, *Menstrual Hygiene Products: Pads and Tampons Are the Go-to Choice*, HARV. T.H. CHAN SCH. OF PUB. HEALTH (May 2023), https://www.hsph.harvard.edu/applewomenshealthstudy/updates/menstrualhygieneproducts/ [https://perma.cc/G6CV-4W7G].

12. Zia Sherrell, *What to Know About Using Tampons as a Beginner*, MEDICAL NEWS TODAY (Mar. 29, 2023) https://www.medicalnewstoday.com/articles/how-to-put-in-a-tampon-for-beginners-tampon-types-and-more [https://perma.cc/9G7F-YN3D].

13. *The Facts on Tampons—and How to Use Them Safely*, U.S. FOOD & DRUG ADMIN. (Sept. 30, 2020), https://www.fda.gov/consumers/consumer-updates/facts-tampons-and-how-use-them-safely [https://perma.cc/AU89-N3FQ].

14. *Id.*

15. *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 [https://perma.cc/4TEF-VHU9] (last visited Aug. 16, 2024).

16. 21 C.F.R. § 801.430(e)(1) (2024).

17. *Id.*

18. Apple Women's Health Study, *supra* note 11.

19. PLANNED PARENTHOOD, *supra* note 15.

20. Kara E. Woeller & Anne E. Hochwalt, *Safety Assessment of Sanitary Pads with a Polymeric Foam Absorbent Core*, 73 REGUL. TOXICOLOGY & PHARMACOLOGY 419, 420 (2015).

21. *See* PLANNED PARENTHOOD, *supra* note 15.

22. Pads do not have device-specific labeling requirements under the FDCA. *See* 21 C.F.R. § 801.430–.437 (2024).

23. *See* Korin Miller, *The 6 Best Pads for a Heavy Flow, According to Gynecologists*, WOMEN'S HEALTH (Mar. 31, 2021), https://www.womenshealthmag.com/health/a35913200/best-pads-for-heavy-flow/ [https://perma.cc/3SQW-9QXV].

24. *Id.*

backing, but usually do not have wings to secure them to underwear. Panty liners may be used as added protection for an individual's underwear when they are using another method of menstrual hygiene, such as a tampon.

Tampons and pads have cornered the period product market for decades. If you walk down the feminine hygiene aisle at any local supermarket, you will see evidence of their popularity by the sheer number of brands consumers can choose from. However, high costs per box and environmental concerns have opened the door to challenges from more sustainable products.[25] In recent years, the period underwear market has grown rapidly in North America.[26] Period underwear looks like a normal pair of women's briefs, but it is specifically designed to trap menstrual blood. Most brands use an absorbent material like microfiber polyester to prevent leakage.[27] Similar to the previous example, they have absorbency ratings as well; though, like pads, the ratings are brand-specific and are not required by the FDA.[28]

Menstrual cups have been around for a while, but they are a relatively new player in the sustainable menstrual product market.[29] A menstrual cup is a small foldable cup designed to be inserted into the vagina, generally made of "non-absorbent, medical grade silicon rubber or natural rubber material."[30] Once inserted, a menstrual cup forms a seal within the vagina to collect menstrual blood.[31] A user removes it by gently breaking the seal and using the stem to pull it out.[32] Once removed, a user empties the

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25. Olivia McCormack, *Curious about Sustainable Period Products? These People Were, Too.*, WASH. POST (Apr. 22, 2022), https://www.washingtonpost.com/lifestyle/2022/04/22/sustainable-menstrual-products/.

26. Market.us, *Period Panties Market Projected to Reach US $901.9 Mn by 2032 Due to Rising Convenience and Comfort*, GLOBE NEWSWIRE (Apr. 28, 2023), https://www.globenewswire.com/en/news-release/2023/04/28/2657583/0/en/Period-Panties-Market-Projected-to-Reach-US-901-9-Mn-by-2032-Due-to-Rising-Convenience-and-Comfort-Market-us.html [https://perma.cc/UYW8-F7V4].

27. *What Is Period Underwear and Does It Work?*, CLEVELAND CLINIC (Feb. 7, 2022), https://health.clevelandclinic.org/does-period-underwear-work [https://perma.cc/75AD-E4KY].

28. Unlike tampons, neither pads nor period underwear have device-specific labeling requirements. *See* 21 C.F.R. § 801.430–.437 (2024).

29. *See* Alison Grajkowski, *Menstrual Cups: Why the Recent Increase in Popularity?*, MAYO CLINIC HEALTH SYS. (July 7, 2022), https://www.mayoclinichealthsystem.org/hometown-health/speaking-of-health/menstrual-cups-vs-tampons-things-you-might-not-know-about-the-cup [https://perma.cc/KJC7-D5EQ]; Marion Renault, *Menstrual Cups Were Invented in 1867. What Took Them So Long to Gain Popularity?*, POPULAR SCI. (Aug. 23, 2019), https://www.popsci.com/menstrual-cups-history-period-care/ [https://perma.cc/D2DW-U2BU].

30. Anmiya Peter & Abhitha K., *Menstrual Cup: A Replacement to Sanitary Pads for a Plastic Free Period*, 47 MATERIALS TODAY: PROCEEDINGS 5199, 5201 (2021).

31. *Are Menstrual Cups Right for You?*, CLEVELAND CLINIC (Aug. 12, 2022), https://health.clevelandclinic.org/tired-of-tampons-here-are-pros-and-cons-of-menstrual-cups [https://perma.cc/NJ7T-G3LA].

32. *Id.*

menstrual blood and either cleans the cup with soap and water or boils the cup to sanitize it before re-inserting.[33]

Each of these products is regulated to some degree by the FDA, but none more than the tampon—likely due to the association of tampons and Toxic Shock Syndrome (TSS). To understand the FDA's regulation of menstrual products, it is important to acknowledge the somewhat complicated history of the FDA's role in relation to TSS in the 1980s.

B. Toxic Shock Syndrome and the History of Federal Tampon Regulation

The concept of a "tampon" has been around since the fifteenth century.[34] However, tampons were not particularly relevant in American culture until the 1930s, when a general practitioner obtained a patent for a product he coined "Tampax" based on the combination of the words "tampon" and "vaginal packs."[35] Tampax became wildly popular in the mid-1930s because of its innovative insertion method.[36] Tampax used a telescoping applicator for insertion, reducing the stigma around women having to touch themselves to insert the device.[37] The popularity of tampons grew throughout the following decades and they were particularly favored by women with "active" lifestyles.[38]

In 1974, Procter and Gamble (P&G) began test-marketing their own innovative tampon called "Rely."[39] P&G's advertising of the Rely tampon reflected their high hopes that the product would be a game changer: "Compared to traditional cotton and rayon tampons, everything about Rely is different—the shape, the material, the way it's made. Rely. It even absorbs worry."[40] What made Rely different from any other tampon on the market was its design.[41] It had a teabag-like sack that contained synthetic materials.[42] The sack would fill with menstrual fluid, trapping it inside.[43] The tampon could expand lengthwise and widthwise, meaning it would prevent bypass of menstrual fluid, something no other tampon on the

33. *Id.*

34. Alice S. Weissfeld, *The History of Tampons: From Ancient Times to an FDA-Regulated Medical Device*, 32 CLINICAL MICROBIOLOGY NEWSL. 73, 73 (2010).

35. Ashley Fetters, *The Tampon: A History*, ATLANTIC (June 1, 2015), https://www.theatlantic.com/health/archive/2015/06/history-of-the-tampon/394334/.

36. *Id.*

37. *Id.*

38. *Id.*

39. Sharra L. Vostral, *Rely and Toxic Shock Syndrome: A Technological Health Crisis*, 84 YALE J. BIOL. MED. 447, 449 (2011).

40. TOM RILEY, THE PRICE OF A LIFE: ONE WOMAN'S DEATH FROM TOXIC SHOCK 15 (1986).

41. *Id.* at 31.

42. *Id.*

43. *Id.*

market could promise; hence, the slogan.[44] Some of the same synthetic components that made Rely so revolutionary, also "acted like agar in a petri dish," encouraging the growth of bacteria.[45] In an article about the history of tampons for the *Atlantic*, Ashley Fetters noted, "It's startling, in hindsight, that Rely made it into consumers' hands, let alone their vaginas."[46]

As P&G worked to bring Rely to the market, Congress was in the process of passing laws that would change how the FDA classified tampons.[47] Prior to 1976, tampons were classified as cosmetics.[48] For years, the FDA had been operating pursuant to 21 U.S.C. Chapter 9, otherwise known as the Federal Food, Drug, and Cosmetic Act (FDCA).[49] The Act, signed into law by Franklin Delano Roosevelt in 1938, authorized the FDA to handle oversight and regulation of cosmetics and medical devices.[50] However, when it came to medical devices, the FDA's ability to impose pre-market regulatory controls was extremely limited until Congress passed the Medical Device Amendments of 1976 (MDA).[51] Through passage of the 1976 MDA, tampons were re-classified from cosmetics to medical devices.[52] This timing played a role in the tragedies related to Rely. Testing had begun before the enactment of the amendments, allowing Rely tampons to escape some requirements they may have become subject to under the new Act.[53]

Before the 1970's, TSS was not formally identified, let alone warned about through language on tampon packages. In November of 1978, Dr. James K. Todd of the University of Colorado published an article identifying TSS and listing its symptoms as "fever, vomiting, diarrhea, low blood pressure, rash, and subsequent skin peeling."[54] Reports of TSS increased rapidly, conspicuously timed with the release of Rely. Between October 1979 and May 1980, the Centers for Disease Control (CDC)

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44. *See id.*

45. Vostral, *supra* note 39, at 450.

46. Fetters, *supra* note 35.

47. Vostral, *supra* note 39, at 449.

48. *A History of Medical Device Regulation & Oversight in the United States*, U.S. FOOD & DRUG ADMIN. (Aug. 21, 2023), https://www.fda.gov/medical-devices/overview-device-regulation/history-medical-device-regulation-oversight-united-states [https://perma.cc/6JCW-9VZU].

49. *Id.*

50. *Part II: 1938, Food, Drug, Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (Nov. 27, 2018), https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-ii-1938-food-drug-cosmetic-act [https://perma.cc/LW79-SRKT].

51. *See* James O'Reilly, *"Left to Our Own Devices, What Did We Get Wrong?" the Medical Device Amendments of 1976 as Seen from the Insider's View*, 74 FOOD & DRUG L.J. 110, 113–15 (2019).

52. Vostral, *supra* note 39, at 449.

53. *Id.*

54. Kehm v. Procter & Gamble Mfg. Co., 724 F.2d 613, 616–17 (8th Cir. 1983).

received fifty-five reports of TSS.[55] Seven of them were fatal.[56] By the end of 1980, however, that number had climbed to 812 menstruation-related TSS cases, with thirty-eight of them ultimately becoming fatal.[57] The FDA met with P&G on September 16, 1980, to discuss CDC reports of TSS, and ten days later, P&G entered into a consent agreement for the notification and retrieval/refund of Rely tampons.[58] Notably, many manufacturers would be sued for product liability in subsequent years, but P&G would face more than 1,100 lawsuits related to their Rely tampon.[59]

Even though TSS is often linked to tampons, tampons themselves do not *cause* TSS.[60] TSS is a bacterial illness caused by a strain of Staphylococcus aureus (S. aureus).[61] Rely tampons, and other tampons made with synthetic material, were merely a particularly good breeding ground for the toxigenic bacterium that caused TSS.[62] The toxin from S. aureus "crossed the vaginal epithelium, entered systemic circulation, and produced a range of serious symptoms in individuals, including hypotensive shock and even death."[63] While TSS is most commonly associated with menstruating individuals assigned female at birth, cases of TSS have been reported in infants and men.[64]

With what seemed like a mounting TSS crisis, calls for regulation quickly intensified.[65] Some of the calls concerned labeling.[66] As a result, the FDA undertook two important changes to its federal labeling

55. Fetters, *supra* note 35.

56. *Id.*

57. *Id.*

58. Wolf by Wolf v. Procter & Gamble Co., 555 F. Supp. 613, 623 (D.N.J. 1982).

59. SHARRA L. VOSTRAL, UNDER WRAPS: A HISTORY OF MENSTRUAL HYGIENE TECHNOLOGY 158 (2010).

60. Vostral, *supra* note 39, at 448.

61. *Id.*

62. *Id.* at 450. Rely used "foam cubes and the gelling agent carboxymethylcellulose encased in a polyester pouch. The gelled carboxymethylcellulose in essence acted like agar in a petri dish, providing a viscous medium on which the bacteria could grow. Along with this, the foam cubes offered increased surface area for proliferation." *Id.* Researchers also hypothesized that other factors, unrelated to Rely's synthetic materials, promoted S. aureus to present as TSS including the menstruator's age, vaginal pH, and a tampon's introduction of "carbon dioxide and oxygen into the usually anaerobic vagina." *Id.*

63. Jenni A. Shearston, Kristen Upson, Milo Gordon, Vivian Do, Olgica Balac, Khue Nguyen, Beizhan Yan, Marianthi-Anna Kioumourtzoglou & Kathrin Schilling, *Tampons as a Source of Exposure to Metal(Loid)s*, 190 ENV'T INT'L 1, 2 (2024).

64. Patrick M. Schlievert & Catherine C. Davis, *Device-Associated Menstrual Toxic Shock Syndrome*, 33 CLINICAL MICROBIOLOGY REV. 17, 9 (2020).

65. Nancy King Reame, *Toxic Shock Syndrome and Tampons: The Birth of a Movement and a Research 'Vagenda'*, *in* THE PALGRAVE HANDBOOK OF CRITICAL MENSTRUATION STUDIES 687, 689 (2020).

66. *Id.*

requirements for tampon packaging: a TSS warning label and an absorbency chart.[67]

1. FDA Implements TSS Warning Labels

Relying on its powers to prevent false or misleading labeling of medical devices under Section 502(a) and Section 201(n) of the FDCA, the FDA sought to force manufacturers to include labeling on their tampon packaging that warned of the risk of TSS.[68] The FDA issued a proposed rule with suggested language in October of 1980, allowing comments until November 20, 1980.[69] The FDA received additional studies after the close of the comment period, prompting the agency to reopen the comments and delay issuance of the final rule.[70] Much of the discussion around formally adopting the rule centered on connecting TSS to tampons other than Rely.[71] Finally, in 1982, the FDA issued its final rule, giving manufacturers 180 days to add TSS warning labels to tampon packaging.[72] The final rule required a more detailed warning than initially proposed, adding the incidence of TSS, additional symptoms of TSS, and absorption/flow requirements.[73] Notably, the FDA declined to require "the labeling of tampons to include a complete listing of all fibers or ingredients used in the product," because of insufficient "data to establish an association between the occurrence of TSS and a particular tampon fiber, ingredient, or combination of ingredients."[74] Thus, in at least one context, ingredient labeling was considered and rejected as early as 1982.[75]

2. FDA Implements Standardized Absorbency Chart

The FDA undertook at least one other important labeling change in the early 1980s. At the time, there was no industry standard for absorbency ratings, and the FDA did not require tampon packaging to offer consumers

67. *See* 21 C.F.R. § 801.430(d)–(e) (2024).

68. Menstrual Tampons; User Labeling, 45 Fed. Reg. 69840 (proposed Oct. 21, 1980) (codified at 21 C.F.R. pt. 801).

69. *Id.* The FDA originally proposed the following language: "WARNING: Tampons have been associated with Toxic Shock Syndrome, a rare disease that can be fatal. You can almost entirely avoid the risk of getting this disease by not using tampons. You can reduce the risk by using tampons on and off during your period. If you have a fever of 102° or more, and vomit or get diarrhea during your period, remove the tampon at once and see a doctor right away." *Id.*

70. Menstrual Tampons; User Labeling; Reopening of Comment Period, 46 Fed. Reg. 23766 (proposed Apr. 28, 1981) (codified at 21 C.F.R. pt. 801).

71. *Id.*

72. Menstrual Tampons; User Labeling, 47 Fed. Reg. 26982 (June 22, 1982) (codified at 21 C.F.R. pt. 801).

73. *Id.*

74. *Id.*

75. *Id.*

standardized ratings for tampon absorption. What some brands considered "regular" absorbency was equivalent to what others considered "super."[76] Without standardization, menstruating individuals could not determine the absorbency of a tampon, making it difficult to determine how long to leave a tampon in.[77]

In 1982, the FDA asked the American Society for Testing of Materials to convene a task force to create a set of federal tampon absorbency ratings.[78] The task force was made up of representatives from each tampon company, consumer organizations, and women's health advocacy groups.[79] To test tampon absorbency, the task force used the "Syngina method," which is still "considered the gold standard" in the tampon industry today.[80] The Syngina method uses an apparatus that "simulate[s] body temperature, vaginal pressure, and flow rates."[81] Once the tampon is placed within the structure, the apparatus "introduces defined amounts of test fluid ([a] blue saline solution) until the tampon leaks."[82] To calculate how many grams of fluid were absorbed, researchers would take the weight of the tampon before and after the test.[83]

The Syngina method had issues from the outset. For instance, the method relied on blue saline instead of blood to test tampon absorbency.[84] In 1982, a nonindustry researcher and task force member, Nancy King Reame, proposed using outdated, heparinized blood from hospital blood banks to better simulate menstrual blood in the apparatus.[85] Blood differs from saline in its chemical and physical properties.[86] As Reame recalls, "Industry members of the Task Force emphatically refused this suggestion based on the presumption that the blood would be too viscous and would clog up the machine."[87] Despite this, Reame went ahead to perform Syngina tests using both the saline solution and venous blood.[88] Reame concluded that "in all cases the absorbency of the surrogate menstrual fluid

76. Reame, *supra* note 65, at 690.

77. *Id.* at 689; A recent study out of France suggests the eight-hour maximum rule for tampons should really be closer to six hours. *See generally* Amaury Billon, Marie-Paule Gustin, Anne Tristan, Thomas Bénet, Julien Berthiller, Claude Alexandre Gustave, Philippe Vanhems & Gerard Lina, *Association of Characteristics of Tampon Use with Menstrual Toxic Shock Syndrome in France*, ECLINICALMEDICINE, April 2020, at 5.

78. Reame, *supra* note 65, at 689.

79. *Id.*

80. *Id.* See 21 C.F.R. § 801.430(f)(2) (2024) for further description of the Syngina method.

81. Reame, *supra* note 65, at 689.

82. *Id.*

83. *Id.*

84. *Id.*

85. *Id.* at 690.

86. *Id.* at 689.

87. *Id.* at 690.

88. *Id.* at 690–91.

exceeded that of the blood-free test fluid, especially for the superabsorbent brands."[89] Despite Reame's study and findings, blue saline is still the industry standard.[90]

Recent research further calls into question the decision to test and rate tampon absorbency using saline solution. In 2023, researchers at Oregon Health & Science University tested tampon absorbency with both saline and expired blood.[91] When tested using expired blood, some menstrual products had a higher or lower capacity than as-advertised using saline fluid tests.[92] As a result, the FDA's mandated absorbency chart may be inaccurate in some instances. Accuracy is important, particularly because tampons may be used in diagnosing heavy bleeding among menstruators.[93] Due to the difficulty of measuring menstrual blood loss, doctors may rely on self-reported menstrual product use to diagnose heavy bleeding.[94] A menstruator complaining of heavy bleeding might describe their bleeding in terms of how many tampons or pads they use each day. For example, if an individual tells a doctor that they use five "regular" tampons per day, and those tampons are supposed to hold a small amount of menstrual blood, the doctor may not diagnose the individual with heavy bleeding. However, if those five tampons absorb far more blood than the physician is aware of, they may be failing to properly diagnose the individual.

In addition to concerns raised over the diagnosis of heavy bleeding, the absorbency study raises questions about methods the FDA uses to evaluate menstrual products. Today, most menstrual products are considered

89. *Id.* at 691.

90. The path to a federally standardized absorbency chart was arduous. It took years and a lawsuit to get the FDA to issue its current rule. *See* Pub. Citizen Health Rsch. Grp. v. Comm'r, Food & Drug Admin., 724 F. Supp. 1013 (D.D.C. 1989). Simply getting the FDA to mandate standardization of absorbency was likely considered a win for activists due to the vast absorbency disparities between different brands of tampons rated "regular." Therefore, it is unsurprising that a more effective testing method has not been adopted in subsequent years.

91. Emma DeLoughery, Alyssa C. Colwill, Alison Edelman & Bethany Samuelson Bannow, *Red Blood Cell Capacity of Modern Menstrual Products: Considerations for Assessing Heavy Menstrual Bleeding*, 50 BMJ SEXUAL & REPROD. HEALTH 21, 22 (2023).

92. *Id.* at 25.

93. Joanna Thompson, *No One Studied Menstrual Product Absorbency Realistically Until Now*, SCI. AM. (Aug. 22, 2023), https://www.scientificamerican.com/article/no-one-studied-menstrual-product-absorbency-realistically-until-now/ [https://perma.cc/M5SJ-677H].

94. *Id.*

Class I or Class II medical devices,[95] and Class II devices are reviewed through a premarket notification process.[96]

C. FDA Regulation Today

The FDA has not dramatically changed its regulation of menstrual products since the 1990s, with its largest overhaul occurring after the passage of the Medical Device Amendments (MDA) in 1976. Under the MDA, the FDA classifies all medical devices using a three-tier risk-based system.[97] Each "tier" or "classification level" contains a set of controls.[98] It is important to note that the FDA does not *approve* Class I or Class II medical devices. "Premarket Approval" is reserved for Class III medical devices.[99] Instead, medical devices that are Class I or Class II undergo a premarket *notification* process.[100] Under the premarket notification process, if the FDA finds that the device is substantially equivalent to an existing device, the device can be marketed in the United States[101] Essentially, a finding of substantial equivalence "clears" the device for commercial distribution, rather than "approves" it. The FDA, seemingly acknowledging this lower level of scrutiny, calls advertising that boasts FDA approval for products that have only undergone a pre-market notification process "misleading."[102]

Class I contains general controls that apply to all devices regulated by the FDA, and most Class I devices are exempt from 501(k) premarket notification.[103] If the FDA determines that a device should be subject to special controls to ensure its safety, the device will be subject to Class II controls.[104] Class II controls are usually device-specific.[105] The highest

95. U.S. FOOD & DRUG ADMIN., MENSTRUAL TAMPONS AND PADS: INFORMATION FOR PREMARKET NOTIFICATION SUBMISSIONS (510(K)S): GUIDANCE FOR INDUSTRY AND FDA STAFF (2005) [hereinafter FDA GUIDANCE], https://www.fda.gov/regulatory-information/search-fda-guidance-documents/menstrual-tampons-and-pads-information-premarket-notification-submissions-510ks-guidance-industry#2.

96. *Premarket Notification 510(k)*, U.S. FOOD & DRUG ADMIN. (Oct. 10, 2020) [hereinafter *FDA Premarket*], https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k#who.

97. Colin M. Pollard, *Menstrual Tampons and Vaginal Pessaries: Regulation of Intravaginal Medical Devices by the US FDA*, FRONTIERS REPROD. HEALTH, Sept. 19, 2023, at 1, 1–2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10546303/ [https://perma.cc/XM3F-647D].

98. *Id.* at 2.

99. *Id.*

100. *FDA Premarket*, *supra* note 96.

101. *Id.*

102. 21 C.F.R. § 807.97 (2024) ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding.").

103. Pollard, *supra* note 97, at 2.

104. *Id.*

105. *Id.*

risk classification is Class III, and devices are assigned to this group of controls when Class I and Class II controls are insufficient to ensure the safety and effectiveness of a device.[106]

Unscented menstrual pads are generally Class I devices.[107] Tampons and menstrual cups are Class II devices and are required to submit for 501(k) premarket notification.[108] In this submission, the FDA expects the following: a description of the menstrual tampon; potential risks to health; performance characteristics; tampon absorbency; chemical residues; physical testing of string strength, fiber shredding, and tampon integrity; material safety (results from preclinical toxicological testing); and risk of TSS and preclinical microbiological testing.[109] Manufacturers conduct tests to meet these expectations, but not all of the testing manufacturers conduct is explicitly required by the FDA. Some testing is simply industry practice to ensure the safety of any new period product before it hits the market.[110]

Final labeling is not required for 510(k) clearance, but proposed labeling is required and should include sufficient detail to satisfy 21 C.F.R. 807.87(e), which asks for language "sufficient to describe the device, its intended use, and the directions for its use."[111] However, final labeling must comply with the general labeling requirements under 21 C.F.R. Part 801 (i.e., name, place of manufacture, etc.) before a product can be marketed and sold.[112] The FDA's labeling requirements and recommendations mostly focus on safety rather than the contents of the device.[113] For example, the FDA recommends tampon and pad manufacturers include instructions with their products that "familiarize users with the features of the device and how to use it in a safe and effective manner and include a description of the product and the materials it contains."[114] However, it does not require those instructions. Instead, it imposes a few device-specific labeling requirements. As previously mentioned, tampons have to comply with 21 C.F.R. 801.430(d) and 21 C.F.R. 801.430(e), which require an

106. *Id.*

107. FDA GUIDANCE, *supra* note 95.

108. *Id.*

109. Pollard, *supra* note 97.

110. For instance, a recent article, funded by P&G and authored by current or former P&G scientists, outlines a four-part safety assessment for tampons which evaluates "biocompatibility and chemical safety of the product components; physical impacts to the vaginal mucosa; impact to vaginal microbiota; and risk for Toxic Shock Syndrome (TSS)." Anne E. Hochwalt, Joan M. Abbinante-Nissen, Lisa C. Bohman, Anne M. Hattersley, Ping Hu, Jan L. Streicher-Scott, Amber G. Teufel & Kara E. Woeller, *The Safety Assessment of Tampons: Illustration of a Comprehensive Approach for Four Different Products*, FRONTIERS REPROD. HEALTH, June 19, 2023, at 1–2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10319135/# [https://perma.cc/FU4U-K6T5].

111. FDA GUIDANCE, *supra* note 95.

112. *Id.*

113. *See generally id.*

114. *Id.*

absorbency chart and information regarding TSS.[115] Additionally, the FDA *recommends* but does not *require* that manufacturers include instructions related to the selection of tampon size and absorbency, tampon insertion, how a tampon should be worn, wear-time, and tampon removal/disposal.[116]

II. THE STATE OF MENSTRUAL PRODUCT RESEARCH

Although menstruation is a monthly reality for a significant portion of the United States population, "[m]enstrual bleeding and its importance for environmental health has long been overlooked in environmental epidemiologic research."[117] Studies reviewed for this Note emphasized the need for additional research into how menstrual products interact with the human body.[118] Conflicting and inconsistent results warrant further study. For example, out of nearly two dozen studies that measured environmental contaminants in menstrual products, all of them "detected environmental chemicals but had discrepant conclusions on exposure risks."[119]

One epidemiological study from 2022, identified only three other studies (the earliest conducted in 2015) that investigated the link between menstrual product use and subsequent concentrations of environmental chemicals measured in women.[120] The first investigated the presence of phthalates—industrial chemicals that may affect human health—in tampons, pads, vaginal douche, vulvar spray, powder, wipes/towelettes, and

115. *See supra* Part I.B.

116. *Id.*

117. Upson, Shearston & Kioumourtzoglou, *supra* note 1, at 11.

118. *Id.* ("Given the detection of environmental chemicals in menstrual products, challenges in exposure assessment due to the lack of data on transmucosal absorption of environmental chemicals, the scarcity of human studies of menstrual product use and environmental chemical exposure, and the exceedingly common event of [menstruation], . . . further research is warranted."); Francesca Branch, Tracey J. Woodruff, Susanna D. Mitro & Ami R. Zota, *Vaginal Douching and Racial/Ethnic Disparities in Phthalates Exposures Among Reproductive-Aged Women: National Health and Nutrition Examination Survey 2001–2004*, ENV'T HEALTH, Jul. 15, 2015, at 1, 7 ("Further research is needed on the adverse reproductive health consequences of chemical exposures originating from feminine hygiene products that are used in and around the vaginal area."); Ning Ding, Stuart Batterman & Sung Kyun Park, *Exposure to Volatile Organic Compounds and Use of Feminine Hygiene Products Among Reproductive-Aged Women in the United States*, 29 J. WOMEN'S HEALTH 65, 65 (2020) ("Our findings suggest that differences in whole blood [volatile organic compound] concentrations might be explained by feminine hygiene practices. The presence of environmental chemicals in [feminine hygiene products] warrants further examination."); Jessica Singh, Sunni L. Mumford, Anna Z. Pollack, Enrique F. Schisterman, Marc G. Weisskopf, Ana Navas-Acien & Marianthi-Anna Kioumourtzoglou, *Tampon Use, Environmental Chemicals and Oxidative Stress in the BioCycle Study*, ENV'T HEALTH, Feb. 11, 2019, at 1, 8 ("Tampon use is a potentially important, yet understudied, source of chemical exposure that could be associated with adverse health. This potentially important public health issue requires additional research efforts, including the chemical assessment of tampons and the conduction of larger and sufficiently-powered biomarker studies of tampon users.").

119. Upson, Shearston & Kioumourtzoglou, *supra* note 1, at 11.

120. *Id.*

other products.[121] The study determined there was a connection between vaginal douching and exposure to diethyl phthalate (DEP), but found no similar link in tampons and pads.[122] The second study investigated a similar group of products for volatile organic compounds (VOCs).[123] It similarly found a possible association between the use of vaginal douching or vulvar powders and whole blood VOC concentrations.[124] Of particular note, the final of these three studies evaluated the association between tampon use and whole blood concentrations of the toxic metals cadmium, lead, and mercury.[125] Most tampons are made out of cotton or rayon, derived from "cotton plants and wood pulp, which can bioaccumulate metals present in soil and water from industrial processes or metal-containing fertilizers."[126] The study found that tampon use "was associated with a 25% higher geometric mean mercury concentration," but found no associations with cadmium and lead concentrations.[127] Researchers noted that they did not consider the results to be statistically significant, but that their observed suggestive associations between tampon use and elevated levels of mercury and oxidative stress biomarkers preliminarily indicated that tampons *could* be a source of exposure to metals and chemicals that have been largely ignored.[128]

In 2024, a different study sought to evaluate tampons as a potential source of exposure to metals.[129] Researchers tested a "selection of widely available tampons" and "confirmed the presence of several toxic metals, including [lead] Pb, [cadmium] Cd, and [arsenic] As" in the tampon materials.[130] Researchers explained that additional research was needed to determine "whether metals can leach out of tampons and cross the vaginal epithelium into systemic circulation."[131] Notably, this study, and growing concerns from lawmakers, recently prompted the FDA to commission two

121. Branch, Woodruff, Mitro & Zota, *supra* note 118.

122. *Id.*

123. Ding, Batterman & Park, *supra* note 118, at 65.

124. *Id.* at 71.

125. Singh, Mumford, Pollack, Schisterman, Weisskopf, Navas-Acien & Kioumourtzoglou, *supra* note 118.

126. Upson, Shearston & Kioumourtzoglou, *supra* note 1, at 9.

127. *Id.*

128. Singh, Mumford, Pollack, Schisterman, Weisskopf, Navas-Acien & Kioumourtzoglou, *supra* note 118.

129. Shearston, Upson, Gordon, Do, Balac, Nguyen, Yan, Kioumourtzoglou & Schilling, *supra* note 63, at 1.

130. *Id.* at 5.

131. *Id.* at 8.

new studies regarding the presence of metals like lead and arsenic in tampons.[132]

Additionally, in at least one study, participants using tampons reported a higher incidence of urinary tract infections than participants who used pads.[133] The founder of at least one brand of menstrual products cited her experience with continuous bacterial vaginosis[134] as the inspiration behind her brand of menstrual products.[135] Whether or not these studies and anecdotal experiences have a direct bearing on the safety and effectiveness of menstrual products is unclear. That is the issue. The preliminary nature of these studies being conducted for nearly 100-year-old products indicates just how much research remains to be done. The first step toward encouraging more independent studies is to create consumer awareness of the ingredients and their sourcing used in menstrual products.

III. RECENT EFFORTS TO INCREASE TRANSPARENCY

Alone, labeling will not decrease any potential harm caused by the ingredients in menstrual products. However, it is an important first step. Some see raising consumer consciousness as a means of increasing brand accountability.[136]

A. States Pass Menstrual Right to Know Acts

Menstrual right to know acts are legislation aimed at changing how manufacturers label menstrual products.[137] So far, two states have passed this type of legislation.

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132. Rachel Treisman, *The FDA Is Probing Tampon Safety After a Study Found Toxic Metals in Popular Brands*, NPR (Sept. 11, 2024), https://www.npr.org/2024/09/05/nx-s1-5100168/tampon-metals-fda-congress-democratic-womens-caucus [https://perma.cc/4PH2-Y4R6].

133. *See generally*, H.A. Omar, S. Aggarwal & K.C. Perkins, *Tampon Use in Young Women*, 11 J. PEDIATRIC & ADOLESCENT GYNECOLOGY 143 (1998).

134. "Bacterial vaginosis (BV) is a condition that happens when there is too much of certain bacteria in the vagina, causing an imbalance." *Bacterial Vaginosis (BV)*, U.S. CTRS. FOR DISEASE CONTROL & PREVENTION (Dec. 11, 2023) https://www.cdc.gov/bacterial-vaginosis/about/index.html [https://perma.cc/L3ZF-5PZ4].

135. *Our Story*, THE HONEY POT CO., https://thehoneypot.co/pages/our-story [https://perma.cc/3XFP-2XB8] (last visited Aug. 16, 2024).

136. After the passage of New York's Menstrual Right to Know Act, New York State Assemblymember Linda Rosenthal told Forbes, "Menstrual product ingredient disclosure is a vital consumer empowerment tool, and will hold menstrual product manufacturers to the highest level of accountability." Jaramillo, *supra* note 3; *see also* Press Release, Congresswoman Grace Meng, Meng and Lesko Introduce Bipartisan Legislation Requiring Ingredient Labeling for Menstrual Products (Sept. 16, 2022) [hereinafter Press Release], https://meng.house.gov/media-center/press-releases/meng-and-lesko-introduce-bipartisan-legislation-requiring-ingredient [https://perma.cc/S7RK-N3KB].

137. Press Release, *supra* note 136.

In late 2019, New York became the first state to pass a law requiring menstrual product brands to disclose ingredients on their packages.[138] Under the New York Menstrual Products Right To Know Act, "each package or box containing menstrual products sold in [New York] 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."[139] "Ingredient" refers to "an intentionally added substance present in the menstrual product."[140] The definition of "menstrual product" is broad, capturing any product used to catch menstrual or vaginal discharge.[141]

California soon followed suit with its version of a menstrual right-to-know act. Signed into law almost a year later, Assembly Bill 1989 is more extensive, even if solely measured by the sheer length of the statute.[142] The bill requires packages containing menstrual products manufactured on or after January 1, 2023, to have a plain and conspicuous list of all ingredients in the products by weight.[143] It also prohibits the sale of menstrual products in the state unless the product complies with the law.[144]

California's law, Assembly Bill 1989, does a few things differently from New York's law. First, Assembly Bill 1989 includes far more detail. Codified under California Health and Safety Code Section 111822.2(b), a manufacturer may protect "confidential business information" by listing an ingredient by its "common name."[145] However, a manufacturer cannot use this confidential business information exception if the ingredient is part of a "designated list" that includes at least twenty-two different groups of chemicals and toxins.[146] The California law also requires manufacturers to update labels within eighteen months of a change in ingredients.[147] While the New York law imposes "a civil penalty of one percent of the manufacturer's total annual in-state sales not to exceed one thousand dollars per package" on the manufacturer,[148] the California law makes violation of its code a misdemeanor, punishable by a set fine.[149] Depending on

138. *Id.*
139. N.Y. GEN. BUS. LAW § 399-AAAA (McKinney 2020).
140. *Id.*
141. *Id.*
142. Assem. Bill 1989, 2019–2020 Reg. Sess. (Cal. 2011).
143. *Id.*
144. *Id.*
145. CAL. HEALTH & SAFETY CODE § 111822.2(b) (West 2022).
146. CAL. HEALTH & SAFETY CODE § 111822 (West 2022).
147. CAL. HEALTH & SAFETY CODE § 111822.4(b) (West 2022).
148. N.Y. GEN. BUS. LAW § 399-AAAA (McKinney 2020).
149. Assem. Bill 1989, 2019–2020 Reg. Sess. (Cal. 2011); CAL. HEALTH & SAFETY CODE § 11374 (West 2023).

the percentage of the manufacturer's total income, the New York law's penalty could be higher than the set fine in California.

B. Federal Counterparts Stall

Passage of state Right to Know Acts spurred the introduction of a federal bill. In late 2022, House Representatives Grace Meng (D-NY) and Debbie Lesko (R-AZ) introduced the Menstrual Products Right to Know Act of 2022 (H.R. 8829).[150] The Act proposed an amendment to Section 502 of the FDCA to require additional labeling for menstrual products.[151] According to the text of the proposed bill, the goal was to enable the FDA to "treat certain menstrual products as misbranded if their labeling does not list each component of the product."[152] The proposed federal bill likely drew inspiration from the California and New York laws.[153] Like the state versions, this federal law would require disclosure of any "component" of the finished product, including any fragrance ingredients.[154] Unlike the California law, the proposed federal regulation leaves much to be desired with its implicit allowance of unintended components. The bill was introduced and referred to the House Committee on Energy and Commerce in September 2022.[155] C-SPAN reports it as "stalled" as of January 2, 2023.[156]

C. Potential Limitations for Menstrual Right to Know Acts

State legislation is already changing the content of menstrual product labels around the United States However, it is important to consider how the laws may be impacted by existing and future federal legislation, as well as whether they are the best approach to increasing transparency.

1. Federal Preemption

The FDA already regulates some elements of tampon labeling such as absorbency charts.[157] If the MDA federally preempted additional state regulation of tampon labeling, the California and New York laws would be an ineffective way of increasing transparency.

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150. *See* Menstrual Products Right to Know Act of 2022, H.R. 8829, 117th Cong. (2022); Press Release, *supra* note 136.

151. Menstrual Products Right to Know Act of 2022, H.R. 8829, 117th Cong. (2022)

152. *Id.*

153. Press Release, *supra* note 136.

154. Menstrual Products Right to Know Act of 2022, H.R. 8829, 117th Cong. (2022).

155. *Bills in the 117th Congress H.R. 8829*, C-SPAN, https://www.c-span.org/congress/bills/bill/?117/hr8829 [https://perma.cc/296P-AMBN] (last visited Feb. 14, 2024).

156. *Id.*

157. 21 C.F.R. § 801.430(e)(1) (2024).

In general, the concept of "federal preemption" is derived from the Supremacy Clause of the United States Constitution, which states that federal law is the "supreme" law of the land.[158] The Clause empowers the federal government to preempt an area of federal authority, depriving states of the ability to enact conflicting legislation.[159] There are two types of federal preemption: express and implied.[160] Express preemption arises when Congress enacts a law with language that disallows any state law governing the same subject matter.[161] Implied preemption arises when federal law completely occupies a field, when a state law conflicts with federal law, or when a state law is an obstacle to the accomplishment and execution of the federal law.[162]

Historically, federal preemption played a large role in litigation surrounding TSS in the 1980s. Litigators pursued "failure to warn" as an action, arguing that consumers were not adequately made aware of the potential risk of using tampons like Rely.[163] Most courts held that federal regulation controlling tampon labeling and warning preempted state tort law claims under that theory.[164] As a result, later cases assessed compliance with federal regulations. For instance, in *Rinehart v. International Playtex*, the Southern District of Indiana rejected a failure to warn argument because the tampon manufacturer had complied with all applicable federal labeling standards at the time.[165] The judge rejected the idea that a jury could hold manufacturers liable for failing to provide *additional* labeling regarding TSS, holding "the standard to be applied to the warning statements on defendants' tampon box and package insert is that set out in the federal regulations."[166]

Today, California and New York are imposing additional labeling requirements on manufacturers, once again raising the question of federal preemption. The MDA contains express preemption language that prohibits states from establishing "any requirement" that is "different from, or in addition to" requirements in the federal statute that relate "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the statute.[167] The MDA does not solely

158. U.S. CONST. art. IV.

159. Leonard H. Glantz & George J. Annas, *The FDA, Preemption, and the Supreme Court*, 358 NEW ENG. J. MED. 1883, 1884 (2008).

160. Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992) (plurality opinion).

161. *Id.*

162. *Id.; see* Hines v. Davidowitz, 312 U.S. 52, 67 (1941).

163. *See, e.g.*, Moore v. Kimberly-Clark Corp., 867 F.2d 243, 246 (5th Cir. 1989); Berger v. Pers. Products, Inc., 797 P.2d 1148, 1149–52 (Wash. 1990).

164. *See, e.g.*, *Moore*, 867 F.2d at 246; *Berger*, 797 P.2d at 1149–52.

165. Rinehart v. Int'l Playtex, Inc., 688 F. Supp. 475 (S.D. Ind. 1988).

166. *Id.* at 478.

167. 21 U.S.C. §360k(a).

prevent state laws from conflicting with it, but adopts language that even prevents state laws that impose additional regulations.[168] The FDA allows some exemptions of state and local requirements from preemption.[169] Regardless, in 2008, the United States Supreme Court ruled that the MDA's express preemption statute applies only to Class III devices with Premarket Approval.[170] Because menstrual products are classified as Class I or II medical devices,[171] they are not covered by the MDA's express preemption provision.[172] Therefore, the new state laws requiring labeling in addition to the FDA's labeling requirements are likely not expressly preempted by the MDA.

If adopted, H.R. 8829 would create a new avenue for express preemption. The federal bill contains language that would prevent the enactment of additional state laws, like those adopted in California and New York, but would grandfather in laws enacted prior to passage of the federal law.[173] However, without the passage of H.R. 8829, express preemption is likely not an issue for existing and future state laws.

2. The Problem with Allowing Piecemeal Legislation

The laws passed in California and New York have undoubtedly affected how manufacturers label their products nationwide. In Washington, many menstrual product boxes now list ingredients, despite the nonexistence of a parallel Washington Menstrual Right to Know Act.[174] It is likely that the cost of distributing boxes with different labeling to some states, and not others, is greater than simply changing labeling practices for boxes distributed in all states, particularly where a manufacturer can comply with both California and New York's laws.

However, there are a few potential issues with this piecemeal approach to legislating menstrual product labeling. First, enforcement of the labeling requirements will be limited to specific states. Currently, only New York and California will be able to require compliance with their laws. When limited to only two states, the cost for falling out of compliance may be so small that it would fail to achieve the stated goals of the respective laws. Second, the fact that the new laws have already

168. *See id.*

169. 21 U.S.C. §360k(b).

170. Riegel v. Medtronic, Inc., 552 U.S. 312, 322 (2008) (explaining that MDA preemption does not apply to devices that undergo substantial-equivalence review under § 510(k) but may apply to devices that undergo premarket approval).

171. FDA GUIDANCE, *supra* note 95 at 7.

172. *Riegel*, 552 U.S. at 322–23.

173. Menstrual Products Right to Know Act of 2022, H.R. 8829, 117th Cong. (2022).

174. I observed ingredients listed on boxes of Playtex Sport Regular/Super, Tampax Pearl Regular and Super, Honey Pot Regular, and Kroger Unscented Tampons Regular as of April 21, 2024.

encouraged industrywide changes to box labeling means that additional states will not be encouraged to pass their own menstrual right to know acts. Thus, there could be a scenario in which California and New York would not only police compliance with their own laws for the whole country but set nationwide standards for menstrual products.[175] Individuals from the other forty-eight states who would seek changes to requirements already set by California and New York may not have the ability to unless their own state were to pass similar legislation. Finally, a scenario could occur in which new legislation enacted in Washington, for example, contradicts legislation set forth in California and New York. If a manufacturer could not comply with differing labeling requirements in both states, they would likely turn to courts to resolve discrepancies. All of these potential issues could be solved by the passage of a bill similar to H.R. 8829, which would amend the MDA to require ingredient labels on menstrual products. California or New York should not have to step in to regulate labeling where *some* of a product's labeling is already mandated by the FDA. Amendment of the MDA would prevent piecemeal legislation and ensure that enforcing compliance does not fall heavily on some states, and not at all on others.

IV. ADDITIONAL REQUIREMENTS NEEDED TO INCREASE TRANSPARENCY

The laws passed in California and New York are a strong start to increasing transparency in menstrual products. However, additional changes to existing labeling could further that effort.

A. Create a Reporting and Testing Mechanism

As written, the New York and California laws do not require manufacturers to submit proof that their products include only the ingredients listed on labels.[176] Instead, the labeling laws essentially trust the reporting of these brands. The burden is on the attorney generals' offices to pursue fines if testing reveals inaccuracies in a brand's labeling. A stronger law could require manufacturers to submit evidence of labeling accuracy to the

175. If smaller states had passed similar legislation, the effects might not be the same. The economic prowess of California and New York likely impacted manufacturers' decisions to implement industry-wide packaging changes. Since 2017, California has had the fifth-largest economy in the world when ranked by gross domestic product (GDP). Press Release, Governor Gavin Newsom, California Remains the World's 5th Largest Economy (Apr. 16, 2024), https://www.gov.ca.gov/2024/04/16/california-remains-the-worlds-5th-largest-economy/ [https://perma.cc/64A4-H5NQ]. In 2018, "New York State's GDP was nearly $1.7 trillion, 8.2 percent of the U.S. total." THOMAS P. DINAPOLI, OFF. OF THE N.Y. STATE COMPTROLLER, STATE OF NEW YORK FINANCIAL CONDITION REPORT FOR FISCAL YEAR ENDED MARCH 31, 2019, 28 (2019), https://www.osc.ny.gov/files/reports/finance/pdf/2019-financial-condition-report.pdf [https://perma.cc/8RT2-3R32].

176. CAL. HEALTH & SAFETY CODE § 111822 (West 2022); N.Y. GEN. BUS. LAW § 399-AAAA (McKinney 2020).

attorney general's office or the Department of Health before the product is marketed to the public. Ironically, this is another reason why an amendment to the FDA's labeling requirements would make more sense than allowing states to independently police menstrual product labeling. The FDA already requires disclosure of much of the information states would need to ensure menstrual products are properly labeled. Adding a reporting mechanism to these state laws—to ensure enforcement of the laws—would essentially require manufacturers to double-report ingredients to multiple agencies, both to the state agencies and the FDA. Double reporting could be avoided by federal passage of a Menstrual Right to Know Act.

B. Develop Eco-Labeling Guidance

Menstrual right to know acts require transparency. However, it is important to question just how transparent the resulting labels are for consumers. A typical menstrual product label might include words like "polyester," "polyethylene," "polypropylene," "polysorbate 20," "paraffin," and "rayon." Proper understanding of these terms requires research, not just to define the terms themselves, but to ascertain their safety in menstrual products. As a result, menstrual right to know acts essentially shift the burden to consumers to educate themselves on what materials and chemicals are safe.

Similarly, California and New York's labeling acts do little to combat the eco-labeling problems associated with menstrual products as consumers seek out more sustainable brands. The success of newer products like reusable period underwear and reusable menstrual cups demonstrates consumer interest in products that are economically and environmentally friendly. Simply requiring ingredient labels on these menstrual products does not signal to consumers whether or not the brands fulfill the sustainability promises they make. A brand may claim that its cotton is grown in a particular way, but there is little that a consumer can do to verify those claims. In light of concerns over the potential bioaccumulation of metals in plants like cotton,[177] it is important for consumers to have a means of vetting agricultural claims.

One way to decrease the burden on consumers of having to research menstrual product ingredients and ensure sustainability promises are fulfilled is to develop a mark or stamp of approval for products that do not contain problematic chemicals and do contain organic materials. If administered by the FDA or a state agency, the mark could support ingredient transparency while relieving consumer burden. The European Union

177. *See supra* Part II.

(E.U.) recently announced Eco-label criteria for menstrual hygiene products.[178] Essentially, the label establishes a set of criteria for brands to meet in order to receive the stamp of approval.[179] Generally, the E.U. Eco-label is geared towards ensuring that its products and their packaging meet certain recyclability and durability requirements, but it also requires that products do not include certain additives.[180] A United States version of the E.U. Eco-label could be adopted federally or through a state like California or New York. The label would be desirable for manufacturers as well as consumers because it would be a simple way to signal sustainability and safety.

Some may argue that this labeling is unnecessary because concerned consumers in the United States vet sustainability and safety marketing through lawsuits. For example, in January of 2023, a period underwear brand, Thinx, settled a misrepresentation lawsuit.[181] The class action suit alleged that third-party testing had identified perfluoroalkyl and polyfluoroalkyl substances (PFAS)[182] in Thinx's period underwear.[183] In the settlement, the brand denied the third-party results and admitted no wrongdoing.[184] An issue with relying on third-party testing and consumer lawsuits is the damage that a class-action lawsuit can do, such as reducing consumers' faith in the safety of a class of products. Thinx is not the only period underwear brand, but a class action suit against it may have impacted consumer faith in other period underwear brands. Thinx lost consumer trust and likely lost sales as a result.[185] Purely anecdotally, I

178. Commission Decision 2023/1809 of Sept. 14, 2023, Establishing the EU Ecolabel Criteria for Absorbent Hygiene Products and for Reusable Menstrual Cups, 2023 O.J. (L 234), https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32023D1809 [https://perma.cc/EHL7-DAES].

179. *Id.*

180. *Id.* at Annex I.

181. Rachel Treisman, *Thinx Settled a Lawsuit Over Chemicals in Its Period Underwear. Here's What to Know*, NPR (Jan. 19, 2023), https://www.npr.org/2023/01/19/1150023002/thinx-period-underwear-lawsuit-settlement [https://perma.cc/36XA-923H].

182. *See* Lisa Friedman, *E.P.A. Says 'Forever Chemicals' Must Be Removed From Tap Water*, N.Y. TIMES (Apr. 10, 2024), https://www.nytimes.com/2024/04/10/climate/epa-pfas-drinking-water.html (explaining that PFAS are "synthetic chemicals" that have been linked to "cancer and other health problems"); *See also* Katherine E. Pelch, Anna Reade, Taylor A.M. Wolffe & Carol F. Kwiatkowski, *PFAS Health Effects Database: Protocol for a Systematic Evidence Map*, 130 ENV'T INT'L (2019); Ning Ding, Siobán D Harlow, John F Randolph Jr, Rita Loch-Caruso & Sung Kyun Park, *Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS) and Their Effects on the Ovary*, 26 HUM. REPROD. UPDATE 724 (2020).

183. Class Action Complaint at 10, Dickens v. Thinx, Inc., No. 1:22-cv-4286 (S.D.N.Y. May 25, 2022).

184. Treisman, *supra* note 181.

185. Lila MacLellan, *How Thinx, the Buzzy Underwear Company Once Worth $230 Million, Lost Its Way*, FORTUNE (May 28, 2024), https://fortune.com/2024/05/28/thinx-period-underwear-kimberly-clark-layoffs/ [https://perma.cc/888P-DHCP].

observed a decrease in available period underwear options for sale at a local Target store after January 2023. Enabling Eco-labeling certifications would limit subsequent damage to brands that do live up to their promises. It would also give brands that fail to live up to their marketing a means of re-establishing consumer trust.

C. Fix the FDA's Tampon Absorbency Chart

As previously explained, the FDA's absorbency chart does not accurately represent the blood absorbency of menstrual products.[186] An updated chart is necessary to ensure that doctors can accurately diagnose heavy bleeding. Additionally, for the same reason, the FDA should require uniform absorbency testing and labeling for period underwear and pads. Any task force convened to re-evaluate absorbency should also evaluate the current "eight-hour" recommendation for replacing one's tampon, as recent research has called that number into question.[187]

Updates to the FDA's existing absorbency chart likely cannot be achieved through the passage of state legislation because state-mandated charts may conflict with the FDA's chart, creating federal preemption. Therefore, the FDA should convene a new task force to re-assess the Syngina method and develop a means of testing menstrual product absorbency with some form of blood.

CONCLUSION

Despite their ubiquity in American culture, menstrual products are *not* FDA-approved medical devices, and new research indicates just how much research still needs to be done to properly understand these products' long-term impact on a menstruator's body. The Toxic Shock Crisis of the 1980s offers a sharp example of how important it is to understand the role that menstrual products play in an individual's health. It should not have taken passage of state laws in California and New York to increase transparency regarding products that have been marketed to menstruators in the United States for decades. Nor should tampon manufacturers have to comply with both state and federal labeling requirements, particularly when research suggests at least one federal labeling requirement, the absorbency chart on a tampon box, is inaccurate. Law has a significant role to play in supporting both transparency and safety. States should consider enacting additional reporting mechanisms as part of their labeling laws. Federally, the FDA should prioritize updating its tampon absorbency chart and enacting additional regulations to standardize absorbency rates across

186. *See generally* DeLoughery, Colwill, Edelman & Samuelson Bannow, *supra* note 91.

187. Billon, Gustin, Tristan, Bénet, Berthiller, Gustave, Vanhems & Lina, *supra* note 77.

different brands of pads, period underwear, and menstrual cups. States and the federal government should work to develop eco-labeling guidance, which would aid both consumers and manufacturers.