

AMERICAN MEDICAL ASSOCIATION WOMEN PHYSICIANS SECTION

Resolution XXX
(I-24)

Introduced by: Madeline Penn, Rohini Guin, Sara Kazyak, Adrienne Nguyen, Sharon Zeldin, Priya Gupta, Eva Yarsky, Rutgers New Jersey School of Medicine; Aaron Kiel, Christian Tallo, Jessica MacIntyre,

Subject: Regulation and Transparency of Contaminants in Menstrual Hygiene Products

Referred to: Reference Committee (Assigned by HOD)

1 Whereas, menstrual hygiene products (MHP), such as tampons, menstrual cups, menstrual
2 discs, flex-cups, or menstrual sponges, are currently classified as a medical device regulated by
3 the Food and Drug Administration (FDA) in the US;¹ and
4

5 Whereas, tampons are currently Class II medical devices and have to adhere to Good
6 Manufacturing Practices (GMPs) and Quality System Regulations (QSR), which include general
7 requirements to ensure product safety and quality, such as controlling contamination, which can
8 encompass testing for various contaminants, including heavy metals and per and polyfluoroalkyl
9 (PFAS), depending on the “risk assessment” and product specifications;² and
10

11 Whereas, the FDA currently recommends that tampons be free of 2,3,7,8- tetrachlorodibenzo-p-
12 dioxin (TCDD)/2,3,7,8-tetrachlorofuran dioxin (TCDF) and any pesticide and herbicide residues,
13 which does not represent a sufficient range of potentially harmful contaminants;³ and
14

15 Whereas, new research found that tampons in the US contained the presence of 16 metals
16 contaminants, including arsenic, lead, and cadmium, and reported that no previous studies have
17 measured levels of metals in tampons;⁴ and
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19 Whereas, tampons purchased in the US were found to have statistically significantly higher
20 levels of lead, cobalt, and cadmium than those purchased in the UK and EU;⁴ and
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22 Whereas, research has found that menstrual products contain PFAS, phthalates, and volatile
23 organic compounds (VOC), such as terpenes and aromatic compounds like benzenes (in
24 scented products), 1,4-dichlorobenzene, and naphthalene, which are known or suspected
25 carcinogens;^{5,6} and
26

27 Whereas, chemicals known to be allergens, preservatives, and potential carcinogens have also
28 been found in numerous different brands of vaginal wipes;^{7,8} and
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30 Whereas, the vaginal canal is highly absorbent and has direct access to the bloodstream due to
31 its dense network of blood vessels, allowing substances that are absorbed to bypass the
32 digestive system and first-pass metabolism;⁹ and
33

34 Whereas, though there is limited research assessing the bioavailability for vaginal absorption in
35 tampons of contaminants specifically, vaginal vasculature has been well established as an
36 effective and efficient method of drug absorption, leading to higher drug concentration due to
37 steady state absorption and lack of gastrointestinal limitations;¹⁰ and
38

Whereas, arsenic is a known carcinogen and is associated with cardiovascular, and respiratory and neurological disease, and in vivo research has shown vaginal arsenic exposure disrupts oxidative mechanisms in the uterus and ovaries;¹¹

Whereas, the U.S. Environmental Protection Agency (EPA) has said there is no safe level of exposure to lead in water,¹² and even low-level exposure to lead negatively impacts cognitive function; and lead accumulates in bones, substituting for calcium, and can remain in the body for decades, contributing to long-term health issues;¹³ and

Whereas, cadmium is known to be a cause of kidney and cardiovascular disease;¹⁴ and

Whereas, the FDA currently provides levels of acceptable limits of heavy metals in other drug products that have direct contact with vasculature and are made primarily of cotton, such as nonresorbable gauze (lead <10 ppm, mercury <0.5 ppm, and arsenic <1.5 ppm);¹⁵ and

Whereas, PFAS can have half-lives of up to 8.5 years and undergo rapid hematogenous dissemination to the brain, liver, lungs, bones, and kidney and have been associated with reproductive toxicities, developmental delays in children, thyroid cancer, delayed onset of puberty in girls, and liver disease,⁵ and

Whereas, some states have mandated transparency in disclosing ingredients, such as in New York,^{16,17} but there remain loopholes that allow companies to protect trade secrets and omit information regarding ingredients, such as the use of certain fragrances in tampons which contain phthalates, a group of chemicals that are known estrogen disruptors;^{18,19} therefore be it

RESOLVED, that our AMA support more comprehensive research on contaminants in menstrual hygiene products (MHP), including but not limited to tampons, other MHPs, and vaginal wipes, and the absorption of toxins into systemic circulation in an effort to better understand their effects on health; and be it further

RESOLVED, that our AMA support regulations and legislation that mandate transparency, disclosure, and accurate labeling of contaminants in menstrual hygiene products.

Fiscal Note: Assigned by HOD

Date Received: XX/XX/2024

REFERENCES

1. Jin Il Kwak, Sun-Hwa Nam, Dasom Kim, Youn-Joo An, "Comparative study of feminine hygiene product regulations in Korea, the European Union, and the United States" Regulatory Toxicology and Pharmacology, Volume 107, 2019, 104397, ISSN 0273-2300.
2. Quality System (QS) Regulation/Medical Device Current Good Manufacturing Practices (CGMP). <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp>
3. Menstrual Tampons and Pads: Information for Premarket Notification Submissions (510(k)s) - Guidance for Industry and FDA Staff. fda.gov. Accessed August 15, 2024. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/menstrual-tampons-and-pads-information-premarket-notification-submissions-510ks-guidance-industry#ft9>
4. Jenni A. Shearston, Kristen Upson, Milo Gordon, Vivian Do, Olgica Balac, Khue Nguyen, Beizhan Yan, Marianthi-Anna Kioumourtoglou, Kathrin Schilling, Tampons as a source of exposure to metal(loid)s, Environment International, Volume 190, 2024,108849, ISSN 0160-4120.
5. Zhou Y, Lin X, Xing Y, Zhang X, Lee HK, Huang Z. Per- and Polyfluoroalkyl Substances in Personal Hygiene Products: The Implications for Human Exposure and Emission to the Environment. Environ Sci Technol. 2023 Jun 13;57(23):8484-8495. doi: 10.1021/acs.est.2c08912. Epub 2023 Jun 1. Erratum in: Environ Sci Technol. 2023 Jul 18;57(28):10489. doi: 10.1021/acs.est.3c04640. Erratum in: Environ Sci Technol. 2024 Feb 6;58(5):2584-2585.
6. Lin N, Ding N, Meza-Wilson E, Manuradha Devasurendra A, Godwin C, Kyun Park S, Batterman S. Volatile organic compounds in feminine hygiene products sold in the US market: A survey of products and health risks. Environ Int. 2020 Nov;144:105740. doi: 10.1016/j.envint.2020.105740. Epub 2020 Aug 28.

7. Intimate wipes: How a little wipe does more harm than good. womensvoices.org. Accessed August 15, 2024. <https://womensvoices.org/feminine-wipes-health-environment-concerns/>
8. Harmful Chemicals Found in Feminine Wipes. womensvoices.org. Accessed August 15, 2024. <https://womensvoices.org/harmful-chemicals-feminine-wipes/>
9. 23.3: Anatomy and Physiology of the Female Reproductive System. <https://med.libretexts.org>. Accessed August 15, 2024. https://med.libretexts.org/Courses/Skyline_College/BIOL_250%3A_Human_Anatomy/23%3A_The_Reproductive_System/23.03%3A_Anatomy_and_Physiology_of_the_Female_Reproductive_System
10. Alexander NJ, Baker E, Kaptein M, Karck U, Miller L, Zampaglione E. Why consider vaginal drug administration? *Fertil Steril*. 2004 Jul;82(1):1-12.
11. Innawati, R. Idroes, M. Akmal, E. Suhartono, A. Rusyana, I. Seriana. The effect and activity of free radical enzymes due to arsenic exposure through the vulva and vagina. *Macedonian Journal of Medical Sciences.*, 10 (B) (2022), pp. 2279-2285.
12. Basic Information about Lead in Drinking Water. <https://19january2017snapshot.epa.gov>. Accessed August 15, 2024. https://19january2017snapshot.epa.gov/ground-water-and-drinking-water/basic-information-about-lead-drinking-water_.html#:~:text=The%20MCLG%20for%20lead%20is,level%20of%20exposure%20to%20lead
13. United States Department of Health and Human Services Agency for Toxic Substances and Disease Registry. Toxicological Profile for Lead. US Department of Health and Human Services;2020.
14. United States Department of Health and Human Services Agency for Toxic Substances and Disease Registry. Toxicological Profile for Cadmium. September 2012.
15. 232 ELEMENTAL IMPURITIES—LIMITS. [usp.org](https://www.usp.org). Accessed August 15, 2024. <https://www.usp.org/sites/default/files/usp/document/our-work/chemical-medicines/key-issues/c232-usp-39.pdf>
16. Period products can contain hazardous ingredients. Some states are requiring more transparent labeling. [pbs.org](https://www.pbs.org). Accessed August 15, 2024. <https://www.pbs.org/newshour/health/period-products-can-contain-hazardous-ingredients-some-states-are-requiring-more-transparent-labeling#:~:text=Even%20though%20manufacturing%20of%20scented,can't%20copy%20the%20formulas>
17. Menstrual product labeling. 399-aaaa. New York State (2019-2020). <https://legislation.nysenate.gov/pdf/bills/2019/S2387B>
18. Wang Y, Qian H. Phthalates and Their Impacts on Human Health. *Healthcare (Basel)*. 2021 May 18;9(5):603. doi: 10.3390/healthcare9050603.
19. Perfluoroalkyl and Polyfluoroalkyl Substances (PFAS). [niehs.nih.gov](https://www.niehs.nih.gov). Accessed August 15, 2024. <https://www.niehs.nih.gov/health/topics/agents/pfc#:~:text=Although%20PFOS%20use%20has%20been,consistent%20evidence%20of%20liver%20damage>

RELEVANT **AMA POLICY**

Eliminating Lead, Mercury and Benzene from Common Household Products H-135.959

1. Our American Medical Association supports the development of standards to achieve non-hazardous levels of exposure to lead, mercury, or benzene arising from common household or workplace products.
 2. Our AMA encourages efforts to minimize or eliminate mercury use in hospitals and other health care facilities.
 3. Our AMA will work in coalitions with appropriate federal agencies and health care organizations to educate physicians and other healthcare professionals about suitable alternatives to the use of mercury and mercury-containing devices and the appropriate disposal of mercury and mercury-containing devices.
 4. Our AMA encourages efforts to minimize or eliminate lead in all commercial and household products.
- [Sub. Res. 418, I-92 Appended: Sub. Res. 410, A-00 Reaffirmation I-00 Reaffirmed A-03 Modified: CSAPH Rep. 7, A-10 Reaffirmed in lieu of Res. 522, A-12 Reaffirmed: CSAPH Rep. 1, A-22]

Increasing Access to Hygiene and Menstrual Products H-525.973

Our AMA: (1) recognizes the adverse physical and mental health consequences of limited access to menstrual products for school-aged individuals; (2) supports the inclusion of medically necessary hygiene products, including, but not limited to, menstrual hygiene products and diapers, within the benefits covered by appropriate public assistance programs; (3) will advocate for federal legislation and work with state medical societies to increase access to menstrual hygiene products, especially for recipients of public assistance; and (4) encourages public and private institutions as well as places of work and education to provide free, readily available menstrual care products to workers, patrons, and students.

[Res. 209, I-21]

Considering Feminine Hygiene Products as Medical Necessities H-525.974

Our AMA: (1) encourages the Internal Revenue Service to classify feminine hygiene products as medical necessities; (2) will work with federal, state, and specialty medical societies to advocate for the removal of barriers to feminine hygiene products in state and local prisons and correctional institutions to ensure incarcerated women be provided free of charge, the appropriate type and quantity of feminine hygiene products including tampons for their needs; and (3) encourages the American National Standards Institute, the Occupational Safety and Health Administration, and other relevant stakeholders to establish

and enforce a standard of practice for providing free, readily available menstrual care products to meet the needs of workers.

[Res. 218, A-18 Modified: Res. 209, I-21]