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The History of the Regulation of Menstrual Tampons

Introduction

Tampons are used by up to 70 percent of menstruating women in the United States today, and the average woman may use as many as 16,800 tampons in her lifetime.[1] For this reason, the safety and effectiveness of tampons is a health issue of vital importance for all women. Manufacturers, consumers and the federal government each have played a critical role in creating the law that regulates tampons in the United States today.

This paper examines the regulation of menstrual tampons in the United States from their introduction to the market some twenty five years ago to the standards that govern them in the twenty first century. After a brief replay of the introduction of the tampon into the US, this paper discusses the background regulatory scheme for such a medical device. Next, this paper traces the development of the federal rules regulating tampons and tampon packaging, as well as the battles fought in courts of law to accomplish this goal. Finally, topics related to tampon regulation are explored, including the debate over tampon ingredient labeling and the preemption of state law by the federal regulation of tampons.

[1] *See* HR 2900 IH, November 7, 1997 *in* `http://thomas.loc.gov/cgi-bin/query/z?c105:H.R.2900`; 2001 H.R. 360; 107 H.R. 360 (January 31, 2001).

The Development of Tampons by Manufacturers

While menstrual tampons had been marketed throughout Western Europe since the late 1930s, they were not introduced to the United States until decades later. [2] In 1974, o.b. tampons were imported into the United States and test-marketed in various regions of the country, and in that same year, Procter & Gamble Manufacturing Company began test-marketing its own brand known as the Rely tampon.[3] Tampons were well received in the United States, to say the least. By the end of 1979, Rely tampons were marketed nationally, and over half a billion Rely tampons were sold.

As early as 1975, however, anecdotal evidence started to come in to manufacturers about the suspected link between TSS and tampon use. Despite this, manufacturers conducted no research for five years.[4] In subsequent litigation years later, it became apparent that the manufacturers were aware of the connection between unnecessary absorption capacity of tampons and increased rates of TSS.[5] This fact would come back to haunt the manufacturers, leaving them liable for millions in damages to women injured by tampon use.

[2]When Tampax tampons were introduced in Europe in 1936, U.S. priests objected to them. *See* Emily Nelson & Miriam Jordan, "Firm Fights Hard to Win Foreign Acceptance of Tampons," The Houston Chronicle, Dec. 10, 2000, at 3. In the 1940s, the Carl Hahn Company, a German firm owned by Johnson & Johnson, marketed o.b. tampons abroad. *See* West v. Johnson & Johnson Products, Inc., 174 Cal. App.3d 831, 844.

[3]*See* Kehm v. Procter & Gamble Mfg. Co. (8^{th} Cir.1983) 724 F.2d 613, 616-617.

[4]Marcia Angell, Keeping Women in the Dark: Lessons Not Learned and the Real Sins of the Breast Implant Manufacturers: Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case (London: W.W. Norton & Co., 1996).

[5]*See* Thomas Koenig & Michael Rustad, "His and Her Tort Reform: Gender Injustices in Disguise," 70 Wash. L. Rev. 1, 41-42 (1995).

The Federal Food, Drug, and Cosmetic Act and The Medical Device Amendments of 1976

The Federal Food, Drug, and Cosmetic Act ("FDCA")[6] gives the Food and Drug Association ("FDA") broad authority to regulate medical devices for human use.[7] For instance, the FDA prohibits the adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.[8] §502(a) of the FDCA provides that a device is misbranded if its labeling is false or misleading in any particular.[9]

Congress responded to public concerns about the danger of medical devices by passing the Medical Device Amendments ("MDA") to the FDCA in 1976.[10] Congress said it intended to assure "that Americans are not put at risk from the use of unsafe and ineffective medical devices."[11] The drafters of the MDA were concerned that "interstate commerce would be unduly burdened" if states imposed "a substantial number of differing requirements" for medical devices.[12]

[6]21 USCS §§ 301 et seq. The FDCA became effective on June 25, 1938, and replaced the Federal Food and Drugs Act of June 30, 1906.

[7]21 USCS § 301(h) defines "device" for purposes of the act:

The term device (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c) means an 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.

[8]21 USCS § 331(b). § 352 of the FDCA denotes misbranded devices when "If its labeling is false or misleading in any particular." As medical devices, tampons are also subject to the general labeling provisions, which require that labels "in package form shall specify conspicuously the name and place of business of the manufacturer, packer, or distributor." 21 C.F.R. § 801.1.

[9]§ 201(n) of the FDCA declares that in determining whether labeling is misleading:

there shall be taken into account... not only representations make or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling... fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the [medical device].

[10]21 U.S.C. § 521, *amended by* 21 U.S.C. § 360(k) Congress was moved to action largely by the scandal over the A.H. Robins Company's Dalkon Shield. Despite being verdicts holding A.H. Robbins responsible for the harms caused by the intrauterine contraceptive device known as the Dalkon Shield," the company did not recall the product or warn of its dangers. "Instead, Robins responded with the same position it had taken for the last decade – that the Dalkon Shield was safe and effective. . . ."Robins did not recall the product; it did not warn users of the Dalkon Shield's dangers; it did not warn physicians. . . . it reacted to the modest punitive damages award in Deemer by promptly attempting to destroy all evidence of its knowledge of the Dalkon Shield's dangers, consigning hundreds of documents to the draft furnace." Tetuan, v. A.H. Robins Co., 241 Kan. 441, 493 (1987).

[11]S. Rep. No. 33, 94^{th} Cong., 2d Sess. 2 (1976), *reprinted in* 1976 U.S. Code Cong. & Admin. News 1070, 1071.

[12]H.R. Rep. No. 853, 94^{th} Cong. 2d Sess. 45 (1976).

The MDA gave the FDA jurisdiction over medical devices and preempted state "requirements" regarding medical devices.[13] Under the MDA, manufacturers of medical devices are required to secure pre-market approval from the FDA for their products and the products' labeling.[14] The manufacturer must submit to the FDA a pre-market approval application ("PMA") and once approved,[15] must submit a PMA supplement for review and approval before making any change affecting the safety or effectiveness of the device.[16] 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."[17] 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.[18]

The MDA also regulates the development, marketing, and monitoring of medical devices. To this end, it requires the FDA to classify all medical devices into one of three categories, each of which is subject to a different level of regulation by the FDA. The MDA also created Classification Panels that determine which devices should be subject to the gender controls, performance standards, or pre-market approval, and notify the manufacturers and importers of such devices of such requirements.

Menstrual Tampons Are Class II Medical Devices

Chapter 9 of the FDCA establishes the classification of devices intended for human use. In 1980, menstrual

[13] Because the MDA does not include a private remedy to compensate the victims of dangerous devices, many victims have gone uncompensated when their state law claims were preempted by the MDA. *See infra.*

[14] 21 C.F.R. § 814.20.

[15] *Id.*

[16] 21 C.F.R. § 814.39. There are several exceptions to the requirement that manufacturers get FDA approval for changes, but the burden for determining whether a PMA supplement is required is on the PMA holder. *Id.*

[17] *Id.*

[18] *Id.*

tampons were classified as class II devices.[19] 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). This generic type of device does not include menstrual tampons treated with added antimicrobial agents or other drugs.[20]

Unscented 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. 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.[21]

Class II medical devices require more than the "general controls," which are sufficient for class I devices, in order to ensure their safety and effectiveness.[22] Devices classified as such, like menstrual tampons, require "special controls" to provide assurance.[23] If the FDA perceives a great enough risk, it may require/perform "the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines... recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance."[24]

The Government is Alerted of Toxic Shock Syndrome Associated with Tampon Use in 1980

While Dr. James K. Todd had identified toxic shock syndrome ("TSS") in children as early as 1978, the syndrome was not brought to the attention of the Center for Disease Control ("CDC") until 1980 when they

[19] 21 C.F.R. §§ 884.5460, 884.5470.
[22] 21 U.S.C. § 360(c)(a)(B).
[23] *Id.*
[24] 21 USCS § 360(c).

began receiving reports from health care practitioners and state health departments.[25] Approximately 97 percent of the cases reported involved menstruating women.[26] The potentially fatal disease causes women to experience fever, shock, low blood pressure, skin rashes and liver and kidney abnormalities.

The CDC created a task force to study the phenomenon, which began by drafting a restrictive definition of the new "disease." On May 23, 1980 they published a report, which indicated a strong correlation between the new "disease" and menstruation.[27] In a second bulletin published June 27, 1980, the CDC established a close association between incidents of TSS and tampon use.[28]

Somewhere in the middle of June, before its second bulletin on TSS was published, the CDC invited tampon manufacturers to Atlanta, GA to learn of its findings. The CDC asked manufacturers for information concerning tampon manufacturing and vaginal physiology and microbiology, but the manufacturers had no information to offer. Consequently, the CDC then undertook its own microbiological studies. Within a period of three to four weeks the CDC had established that the symptoms of TSS are caused by a particular type of toxin secreted by a particular strain of bacteria known as staphylococcus aureus.[29] In response, in the summer of 1980, it recommended that women who wish to avoid the risk of menstrually associated TSS stop using tampons. For women who wished to continue to use tampons, the CDC recommended that the tampons be used only part of the time during menstruation. The CDC also recommended to the FDA that warnings concerning the hazards of menstrually related TSS be placed on the outside of tampon packages.[30]

[25]Dr. Todd of the University of Colorado named the disease in an article in November 1978. *See* James K. Todd, "Toxic-Shock Syndrome Associated with Phasge-Group-I Sgtaphulococci, II," The Lancet 1116-8 (1978).

[26]*See West,* 174 Cal. App.3d, at 843.

[27]This report was published in the official federal government publication of the CDC, the Morbidity and Mortality Weekly Report ("MMWR").

[28]The MMWR continued to publish the CDC's findings regarding the connection between menstruation and TSS. Such reports were published on September 19, 1980, October 3, 1989, October 17, 1980, January 30, 1981, April 30, 1982 and August 5, 1983.

[29]For at least 65 years, it has been known that Staphylococcus aureus commonly occur in the vaginas of a small percentage of women. *See West,*174 Cal. App.3d 831, 844.

[30]In the coming months and years, experts would disagree over whether changing tampons, or alternating tampon and pad use, could significantly reduce the risk of contracting TSS. *See* Davis, et al., "Toxic Shock Syndrome in Menstruating Women," 303 New England J. of Med., December 18, 1980, at 1429-1435 (reporting that changing tampons more frequently or avoiding a super-absorbent tampon does not reduce the risk of TSS, but a tampon-free interval appears to decrease the risk of TSS); Richard Severo, "Physician Says Changing Tampons Does Not Reduce Risk of Toxic Shock," The New York Times, Dec.

Proctor & Gamble voluntarily withdrew Rely tampons from the market shortly after learning of the results of studies, which indicated a higher statistical association of TSS with Rely than with any other brand of tampon. On September 16, 1980, the FDA met with representatives from Proctor & Gamble in order to discuss the CDC statistics on the Rely tampons' association with TSS. Before the FDA made any threats of legal action, P&G, on its own initiative, announced it was withdrawing Rely from the market....[31] On September 26, 1980, Proctor & Gamble entered into a Consent Agreement with the FDA providing for a program for notification to consumers and retrieval of the product from the market.

The TSS Studies and the FDA Proposal For Tampon Warning Labels

Two epidemiological research studies conducted in 1980 were enormously influential in developing the regulation of menstrual tampons. The Federal Center for Disease Control in Atlanta ("CDC") undertook one study and the other, the Tri-State Study, was conducted by reputable and highly recognized public health officials and epidemiologists from Minnesota, Wisconsin and Iowa.

The FDA had asked manufacturers to voluntarily adopt a warning on their packaging on September 26, 1980,[32] and many manufacturers complied by adding a warning on to their products. When the preliminary findings of the studies were published,[33] however, the FDA decided to exercise its authority to prevent false and misleading labeling by promulgating regulations.[34] Relying on the data from the CDC and the

18, 1980, at A16. This advice contradicted that given several months before by the American College of Obstetricians and Gynecologists.

[31]Wolf v. Proctor & Gamble, 555 F. Supp. 613, 623 (1982).

[32]The Acting Director of the Bureau of Medical Devices sent a telegram to manufacturers.

[33]Wisconsin data was reported in the MMWR for June 27, 1980 and the FDA recorded some of Minnesota's findings in October 1980. *See* 45 Fed. Reg. 69,840-42 (Oct. 21, 1980).

[34]The ability of the FDA to require label warnings and other affirmative disclosures has been upheld by the courts. *See, e.g.,* Cosmetic, Toiletry and Fragrance Ass'n v. Schmidt, 409 F. Supp. 57 (D.D.C. 1976), *aff'd without opinion,* Civil No. 75-1715 (D.C. Cir. Aug. 19, 1977).

Tri-State studies, FDA proposed a regulation requiring TSS warning labels.[35] FDA believed that to fail to warn consumers about the risk of TSS in the labeling of tampons constituted an omission of a material fact about the products, and would render the products "misbranded."[36]

The FDA broadly requested information including regarding on what warning should be required, what information about TSS in particular and tampon use in general should be mandated, whether package inserts, brochures, or pamphlets should be created to disseminate the information, and what criteria the FDA should use to grant an exception.[37] Interested persons were given only 30 days for notice and comment.[38]

After the comment period for the FDA's proposed rule on tampon warning labeling had expired, two influential articles were published in December 1980. These articles, one of which was a compilation of all the data from the Tri-State and the CDC studies, added credibility to the studies.[39] In January 1981, the findings of the Tri-State Toxic Shock Syndrome Study were announced to the FDA.[40] The research confirmed that users of tampons had a greater risk of contracting TSS than non-tampon users. [41] Further, the findings alerted that high-absorbency tampons carried an increased risk for TSS.[42]

[35] 45 Fed. Reg. 69,840 (Oct. 21, 1980). Commentators criticized the FDA's use of data from the CDC and Utah studies that were "gathered in different locations using somewhat different survey techniques." Because both studies had the same hypothesis and both sets of data, when analyzed separately, showed the same results, the FDA felt comfortable relying on their statistical models. Further, when the agency compared the groups of subjects in terms of income, race, education and marital status, they found no important differences. *See id.*

[36] *Id.*

[37] *See* i*d.*

[38] *See id.*

[39] *See* Davis, et al., "Toxic Shock Syndrome in Menstruating Women," 303 New England J. of Med., Dec. 18, 1980, at 1429-1435; Kathryn N. Shands, M.D., "Toxic Shock Syndrome in Menstruating Women," 303 New England J. of Med., Dec. 18, 1980, at 1436.

[40] News Release from the Minnesota Department of Health, January 13, 1981. The findings of the Tri-State Study were published in 1982. Osterholm, M.T., et. al., "Tri-State Toxic-Shock Syndrome Study. I. Epidemiologic Findings," 145 J. of Infectious Diseases 431-440 (April 1982).

[41] *See id.*

[42] The Tri-State finding of the relationship between absorbency and TSS was based on a subset of patients who used exclusively one tampon style of one brand. The relationship of the absorbency of the tampons (measured in mean fluid capacity in grams) to relative risk of TSS was calculated for four groups of patients:

Absorbency	Relative risk
19.11	8.84
16.09	6.26
12.91	4.36
10.30	3.24

Id.

In response to the new information that had become available, the FDA in April 1981 published another notice reopening the comment period on the proposed regulation until June 29, 1981. [43] In this proposal, the FDA tentatively accepted the studies' findings, stating: "users of high-absorbency tampons have a greater risk of contracting TSS than users of low-absorbency tampons." [44] More than 300 comments were received—all favored some form of labeling.

Manufacturers attempted to distinguish their products from the ones, like Rely, which had been found to cause TSS.[45] Some argued that there was "no evidence of an association between the use of a recently introduced cotton tampon with no super-absorbent materials and the occurrence of TSS. Another manufacturer said that the incidence of TSS among users of its product is less than would be expected when compared to the percentage of controls in the studies using its product and its general market share."[46] The FDA declined to make any exceptions for these manufacturers, noting that once the "FDA justifies the need for a warning affecting a general category of products, [ ] the burden shifts to a manufacturer to show that an individual product should be excluded from the general warning requirement."[47]

The FDA Promulgates TSS Warning Label Regulations in 1982

[43] 46 Fed. Reg. 23,766 (April 28, 1981). FDA took this action "because of new information concerning TSS and in response to two requests to extend the comment period." *Id.* The Davis Shands articles, *see surpa* note 39, were published on December 18, 1980. The next month the CDC issued a *Morbidity and Mortality Weekly Report* summarizing the incidence of TSS through December 1980. *See* "Epidemiologic Notes and Reports: Follow-up on Toxic-Shock Syndrome, Internation Notes, Toxic-Shock Syndrome-Canada," Morbidity and Mortality Weekly Report, Vol. 30 No. 3, Centers for Disease Control, January 30, 1981. It reported that 98 per cent of the 941 cases of TSS that had been confirmed to CDC began during a menstrual period while the woman was using tampons.

[44] 46 Fed. Reg. 23,766.

[45] Rely tampons were taken off the market in 1980, after it was found to be associated with a higher incidence of TSS. *See supra* note 31. Rely tampons were made of polyester foam and carboxymethylcellulose, whereas other tampons are made of cotton and rayon. After the discovery that users of the Rely brand tampons had a higher risk of getting TSS than users of other brands, the data of the Rely brand users was excluded from the analyses of the studies. For instance, when the FDA analyzed data from the CDC2 and the Utah studies, it excluded the Rely data. *See* BMD Combined Utah and CDC 2 Data Analysis, February 3, 1981.

[46] 46 Fed. Reg. 23,766.

[47] *Id.*

In June 1982, the FDA produced a final rule responding to the concerns of the consumers, manufacturers, health departments, consumer organizations, and industry organizations that had commented to the proposed rule. [48] Citing the requirement that remedial statutes like the FDCA "demand to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable,"[49] the FDA stated that it would not further delay the promulgation of standards awaiting further proof of the association of tampon use and TSS. The final rule required "that menstrual tampon packages contain a brief statement alerting consumers to the dangers of TSS and advising them to read and save the package insert which provides additional information."[50] The FDA assured that it would continue to disseminate information and to utilize press releases, and professional, consumer and industry education programs.[51]

To address the issue of misbranding under the FDCA, the rules required packages to say that a woman can almost entirely avoid the risk of getting tampon-associated TSS by not using tampons. While commentators argued that this was not a material fact with respect to the consequences of the use of tampons, the FDA disagreed, noting that the failure to inform consumers about the disease constitutes omission of material facts about the products.[52]

The regulation took effect on December 20, 1982. The regulations required certain consumer information to appear "prominently and legibly" in a package insert or on the package in terms understandable by the layperson: [53]

[48] 47 Fed. Reg. 26,982 (June 22, 1982). The rule was codified at 21 C.F.R. § 801.430 (1982).
[49] Ethyl Corp. v. EPA, 541 F.2d 1, 25 (D.C. Cir.1976), *cert. denied,* 426 U.S. 941 (1976).
[50] 47 Fed. Reg. 26,982.
[51] *See id.*
[52] *See id.*
[53] Today, this provision reads "in such terms as to render the information likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 C.F.R. § 801.430(d).

> (1)(i) Warning signs of TSS, e.g., sudden fever (usually 102 deg. or more) and vomiting, diarrhea, fainting or near fainting when standing up, dizziness, or a rash that looks like a sunburn;
> (ii) What to do if these or other signs of TSS appear, including the need to remove the tampon at once and seek medical attention immediately;
> (2) The risk of TSS to all women using tampons during their menstrual period, especially the reported higher risks to women under 30 years of age and teenage girls, the estimated incidence of TSS of 6 to 17 per 100,000 menstruating women and girls per year, and the risk of death from contracting TSS;
> (3) The advisability of using tampons with the minimum absorbency needed to control menstrual flow;
> (4) Avoiding the risk of getting tampon-associated TSS by not using tampons, and possibly reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods; and
> (5) The need to seek medical attention before again using tampons if TSS warning signs have occurred in the past, or if women have any questions about TSS or tampon use. [54]

If the above information is provided in a package insert, then the package must also contain an "alert statement" printed "prominently and legibly" which reads: "ATTENTION: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and save the enclosed information."[55] The manufacturers were permitted to vary the wording of the warning, subject to FDA's approval.[56] The FDA also declined to regulate where the alert statement appears on the box, thus providing flexibility to the manufacturers.[57]

Reports supporting the relationship between tampon use and TSS continued to be published throughout 1982; importantly, one was published by the Institute of Medicine.[58] This report advanced several important recommendations to women regarding tampon use: women who have had TSS should not use tampons; postpartum women should be informed that tampon usage is likely to increase the risk for TSS; and adolescent

[55] *Id.* Any menstrual tampon intended to be dispensed by a vending machine is exempt from the labeling requirements. 21 C.F.R. § 801.430(g). While the proposed regulation would have required that any tampon sold through a vending machine be labeled with the warning, the FDA, in its final rule, decided that this was not necessary: "Women tend to purchase tampons from vending machines only infrequently. They will be made aware of the association between TSS and tampons from information provided with packages obtained from other retail sources." 47 Fed. Reg. 26,982.

[56] *Id.*

[57] The FDA said it believed that the statement can be placed on all sizes of tampon boxes, and there was not a need to specify a required size or location. *Id,*

[58] Institute of Medicine, National Academy of Sciences, "Toxic Shock Syndrome: Assessment of Current Information and Future Research Needs" (Washington D.C.: National Academy Press, 1982).

women, especially, should be advised to minimize the use of high absorbency tampons.[59]

While the regulation was revolutionary in its regulation of the packaging for tampons, it had one major weakness: it failed to require manufacturers to use standardized terminology for absorbencies of different styles of tampons.[60] The FDA was aware of the call for absorbency standards, and recognized that there was no voluntary standard, industry agreement, or other common understanding of the meaning of "super," "regular," or any other words used to describe tampons' absorbencies.[61] But the FDA claimed that the relationship between TSS and tampon "absorbency" was uncertain, and "determined that absorbency is not a basis upon which to exclude any style or brand of tampon from the requirements of the final rule."[62] Thus, the required labeling did not provide a way for women to intelligently choose among tampon brands or styles for the one that would minimize their risk of TSS. While they were told to choose the tampon with the minimum absorbency they needed, they were left without an adequate means to compare the absorbencies of tampons.

[59] *Id.* at 85-86. While the relationship of tampon use and TSS was questioned and the findings accused of being produced by biases in the studies, see Harvey, M. et al., "Toxic Shock and Tampons, Evaluation of the Epidemiologic Evidence, " 248 J. Amer. Med. Assoc., Aug. 20, 1982, at 840-846, the medical community (and the FDA) accepted the findings because "the great amount of careful surveillance actually done at the time of the Tri-State Study" belies concerns that there were great errors committed. Hulka, B.S., "Tampons and Toxic Shock Syndrome (editorial)," 248 J. Amer. Med. Assoc., Aug. 20, 1982, at 872-874.

[60] 21 C.F.R. § 801.430.

[61] 47 Fed. Reg. 26,982.

[62] *Id.*

The Fight for Absorbency Standards

As early as July 1981, the FDA had initiated a call to develop a task force to develop standards for tampons, including absorbency standards.[63] In January 1982, a task force comprised of representatives of industry, the FDA and consumer organizations was formally established and first met. Their goal was to develop a standard for tampons that addressed concerns regarding absorbency and to provide for appropriate labeling. On June 29, 1982 the Public Citizen Health Research Group ("Public Citizen")[64] filed a Citizens Petition calling for FDA to issue standards that would prescribe standards and justifiable test methods for determining tampon absorbency and require the industry to label their products with standardized absorbency terms.[65] On September 22, 1982, the FDA issued a tentative response agreeing "in substance" with the Citizen Petition, but stating that it preferred to work with the task force to establish voluntary standards. The FDA believed that the voluntary standards process was the most efficient and economical method available for developing uniform tampon absorbency testing and labeling.[66] On November 2, 1982, the Public Citizen supplemented and clarified its petition, claiming that tampons were misbranded within the meaning of the FDCA.[67]

On April 22, 1983, nine months after Public Citizen had filed its petition, the FDA issued a final response. The FDA denied the petition, despite that it continued to agree with its objectives and specifically noted that absorbency terms were not standardized. The FDA promised it would reevaluate the need to take regulatory

[63]On July 31, 1981, the FDA via F. Alan Andersen had asked Patrick G. Laing, the chairperson of the American Society for Testing and Materials Committee on Medical and Surgical Materials and Devices to form a task force to develop standards for tampons. In November 1981 the Committee met with representatives from consumer groups, industry and FDA and agreed to set up the task force. *See* 53 Fed. Reg. 37,250 (Sept. 23, 1988).

[64]The Public Citizen Health Research Group is a nonprofit organization, lead by Ralph Nader, which engaged in research and consumer advocacy on public health and safety issues. *See* Public Citizen Health Research Group v. FDA, 724 F. Supp. 1013 (D.D.C. 1989).

[65]The PCHG wanted to require tampon manufacturers to determine the absorbency of each of their styles of tampons using the test method adapted by the task force (the Syngyna simulated vagina test). *Id.*

[66]*Id.* (*citing* letter from Mark Novitch to Sidney M. Wolfe and Allen Greenberg, Sept. 22, 1982).

[67]*See supra* notes 8 and 9.

action in the event that the task force did not propose a satisfactory standard in a timely fashion. In June 1983, the FDA did take some action in response to the petition's accusations regarding tampon absorbency labeling– though not that which the PCHG desired. The FDA's Center for Devices and Radiological Health sent a letter to all manufacturers of tampons regarding the recent "advertising and promotional materials that stressed absorbency" on tampon packaging.[68] The FDA requested that the manufacturers advise consumers to use the minimum absorbency needed on their packaging.

* * *

Years passed as the task force continued to meet frequently. Articles proliferated detailing toxic shock and raising awareness of the condition in an effort to increase diagnosis of menstruating women.[69] The task force ultimately was unable to reach consensus on an approach to tampon absorbency labeling.[70] Despite that a subcommittee of the task force gained consensus on an absorbency test, the consumer members of the group told the FDA in April 1984 that they believed that neither the task force nor the manufacturers on their own was able to agree upon a disclosure standard. On May 2, 1984 the task force unanimously passed a resolution tabling any further discussion of absorbency labeling.[71]

In response to the failure of the task force to resolve the issue, on May 7, 1984 Public Citizen sent another letter to the FDA urging it to reconsider April 22, 1983 response to their earlier petition. The FDA reviewed

[68] 53 Fed. Reg. 37,250 (*citing* Letter from John C. Villforth to "Tampon Manufacturers," June 1983). All manufacturers voluntarily complied with this request.

[69] *See, e.g.,* Jill Whettam, "Update on Toxic Shock: How to Spot it and Treat it," RN, Vol. 47. at 55 (February 1984).

[70] The subcommittee on test methods did reach agreement on the use of the Syngyna test to measure absorbent capacity. 53 Fed. Reg. 37,250. But ultimately, the tampon manufacturers were unable to agree to provide, on a voluntary basis, absorbency information that would facilitate interbrand comparisons of products.

[71] Subsequently, on April 18, 1985 the task force recommended that it become inactive because it could not resolve its differences.

the scientific data again and advised that the agency planned to promulgate a rule that would include a standardized absorbency test and absorbency labeling requirements. On June 29, 1984, the FDA released a Talk Paper,[72] which announced proposals for absorbency standards. Three reasons were offered for the decision: 1) disclosure of such information would promote public health; 2) a standard proposal from the voluntary task force appeared impossible; and 3) the task force "develop[ed] and prov[ed] the feasibility of a test method for measuring tampon absorbency. Thus a consistent means [existed] for manufacturers to establish the absorbency of their products." [73] Several days later on July 9, 1984, the FDA also responded to HRG's letter of May 7, 1984, stating that: "labeling regulation is necessary to assure that consumers can make meaningful interbrand comparisons with respect to absorbency.... We intend to specify in the regulation the absorbency test to be used, with the result to be expressed as a numerical... factor, somewhat analogous to the sun protection factor used in sunscreens."[74]

The CDC Study of 1987

The link of tampon use and TSS again caught center stage in the public's eye when in August 1987, the CDC published an epidemiological study entitled "Relationship of Tampon Characteristics to Menstrual Toxic Shock Syndrome,"[75] confirming the association between increased absorbency and enhanced risk of TSS.[76] Based on an analysis of 215 tampon users who disclosed the absorbency of the tampon they used, the

[72]Talk Papers are prepared by the FDA Press Office to guide FDA personnel in responding consistently and accurately to questions from the public on topics of current interest. Talk Papers are subject to change as more information becomes available and are not intended for general distribution outside of the FDA. All information included in them, however, is public.

[73]*Public Citizen Health,* 724 F. Supp. at 1017.

[74]*Id.*

[75]Berkley, S.F., et al., 258 J. of Amer. Med. Assoc., Aug. 21, 1987, at 917.

[76]The study included cases of TSS with onset between January 1, 1983 and December 31, 1984 and compared the data of 285 tampon-associated cases of TSS where the woman reported using single brand of tampon, to age- and year-matched controls from a national survey of tampon usage. *See* 53 Fed. Reg. 37,250. Other studies published since the association between TSS and tampon use was first discovered sought to demonstrate the bias that may have influenced the data exemplifying a tampon/TSS association. For instance, a 1984 study tested how physician's diagnostic judgments were influenced by knowledge

CDC also found that the 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.[77] Further, the study debunked popular belief that it was the materials constituting the tampon that affected the risk of TSS, rather than increases in absorbency.[78] The testing revealed a major problem: the industry had no standard tampon absorbency test and there were great absorbency differences between brands. Coupled with the finding that there is a greater risk of contracting TSS the greater the absorbency of the tampon used, this was a dilemma the FDA needed to address promptly.[79] Frustrated, Public Citizen filed a second Citizen Petition on August 20, 1987 concerning absorbency labeling of tampons,[80] but the FDA did not respond for eight months.

The FDA's 1988 Proposed Rule (and 1989 Reproposed Rule) to Add Absorbency Labeling

On September 23, 1988, the FDA finally issued a proposed rule for absorbency label requirements.[81] FDA proposed to amend the regulations to require manufacturers of menstrual tampons add to each tampon pack-

of a patient's gender, menstrual history, or menstrual product use and concluded that there was a bias toward diagnosing TSS in tampon users. Harvey, M., et al., "Diagnostic Bias and Toxic Shock Syndrome," 76 Amer. J. of Med. 351-360 (March 1984).

[77] *See* Berkley, "The Relationship of Tampon Characteristics to Menstrual Toxic Shock Syndrome," 258 J. of Amer. Med. Assoc., Aug. 21, 1987, at 917; *see also* Memorandum from Chief, Meningitis and Special Pathogens Branch, Division of Bacterial Diseases, Center for Infectious Diseases to Director, Office of Program Planning and Evaluation, Centers for Disease Control, October 19, 1987.

[78] "Tampon Absorbency, Not Material, Increases TSS Risk," FDA Consumer Vol. 21, No. 9 at 2 (Nov. 1987). News article from years before warned consumers to check the ingredients of the tampons they were buying and to try to use as natural a product as possible, rather than synthetics or polyacrulates. *See e.g.,* Karen Friefeld, "Know Your Tampon," Health, Vol. 16 at 71 (October 1984).

[79] The media began to revisit the problem of TSS in menstruating women after the results of the CDC study were revealed. *See, e.g.,* Leanne Kleinmann, "Toxic Shock Revisited," Health, Vol. 20, No. 4, at 8 (April 1988). Women were again warned that every additional gram of fluid absorbency increases their risk of TSS, thus they should use the least absorbent products possible.

[80] Sidney Wolfe, M.D., a consumer advocate and director of the Pubic Citizen Health Research Group, complained that one manufacturer's "super" may be another's "regular." *See* "Tampon Absorbency, Not Material," *supra* note 78. In 54 Fed. Reg. 25,076 (June 12, 1989), *see infra* note 88, the FDA's reproposed rule, they addressed the petition, and noted that any other provisions that were not discussed were tentatively denied.

[81] It was entitled "Medical Devices; Labeling; User Labeling for Menstrual Tampons; Proposed Ranges of Absorbency for Menstrual Tampons." 53 Fed. Reg. 37,250 (Sept. 22, 1982).

age label a letter designation of the range of absorbency of the tampons.[82] This would enable consumers to compare the absorbency of brands and styles of tampons.[83] Further, the FDA proposed using the Syngna test to determine tampon absorbency.[84]

In the proposed rule, the FDA noted that the incidence of TSS remained unknown, but that thirty-nine deaths from TSS had been reported to FDA's medical device reporting system during the period from December 1984 through May 1987. The FDA also discussed alternatives to the letter designation scheme which it was proposing, including absorbency represented by a single number rather than by a range;[85] a single number with a plus or minus variation shown; allowing manufacturers to market an unlimited number of ranges;[86] or using the terms commonly used by manufacturers at the time of the proposal, for instance, "super" or "regular."[87]

In this proposed rule, the FDA also announced the Citizen Petition submitted by the PHRG concerning absorbency labeling for tampons and requested comments on such. Comments on the proposed rule were set to be due on December 22, 1988 and the final rule would commence 6 months after its date of publication in the Federal Register, for packages of tampons initially introduced or initially delivered for introduction into commerce.

[82]Manufacturers would be required to put one of the six letter designations (each of which correspond to a range of absorbency in grams) on the packages prominently and legibly: A: 6 and under; B: 6-9 grams; C: 9-12 grams; D: 12-15 grams; E: 15-18 grams; F: above 18. *See id.* Manufacturers would be required to put an explanation of the absorbency designation on the package and also could use one of the current terms (i.e., "super") on the labeling, as long as it was placed in close proximity to the letter designation used.

[83]While tampon manufacturers had been using common terms to describe tampon absorbency on their packages' labels, there was great variation in what the terms meant across brands. "For example, one manufacturer's tampon labeled as "regular" was found to absorb between 12 and 13 grams of fluid, while another manufacturer's "super" tampon absorbed only 9 grams." *Id.*

[84]The FDA conducted lot-to-lot and run-to-run tests of the homogeneity of tampons' absorbency. They found that while there were variations which would be expected due to differences in raw materials (e.g., cotton or rayon) or in production conditions (e.g., degree of humidity), the test was feasible for manufacturers. If a manufacturer wanted to use another test method that yielded similar results, they could submit a citizen petition in accordance with 21 C.F.R. §10.30. *See id.*

[85]While this option satisfied the requirement that labeling be easy for consumers to understand, the FDA did not believe available technology at the time allowed for absorbency to be accurately represented by a single number, because there would be great variation from tampon to tampon and box to box. *See id.*

[86]This approach was criticized because it could result in product lines with overlapping absorbencies, which would be confusing to consumers. *See id.*

[87]*See id.* (*citing* Berkley, S.F., et al., "The Relationship of Tampon Characteristics to Menstrual Toxic Shock Syndrome," 258 J. Amer. Med. Ass'n, Aug. 21, 1987, at 917-920).

After receiving more than 270 comments on its proposed rule of September 23, 1988 from tampon manufacturers, consumer groups, individual consumers, health-care professionals and researchers, on June 12, 1989, the FDA issued a reproposed rule.[88] Interestingly, the FDA wrote in its reproposed rule that it believed that it could justify publishing the amendments as a final rule without further opportunity for public participation, but it feared subjecting itself to litigation challenging the rule on procedural grounds which would delay promulgation of a final tampon absorbency label regulation.[89] Regarding the incidence of TSS, utilizing new data collected from studies of reported incidence of TSS, the FDA revised its estimate of the prevalence to "between 1 and 17 per 10,000 menstruating women and girls per year."[90]

After analyzing the comments, the FDA concluded that the absorbency test methodology and sampling procedures in the proposed rule were appropriate.[91] The FDA had received more than 250 comments arguing that the existing absorbency terms should be standardized.[92] However, the FDA determined that while there remained a question as to the appropriateness of the use of a system of letters to represent absorbency ranges, it was not going to propose standardizing currently used terms of absorbency (i.e., regular, super, and super plus).[93] Thus, the reproposed rule would require that manufacturers of menstrual tampons express

[88] 54 Fed. Reg. 25,076.

[89] *Id.* ("Under these circumstances, FDA believes that publication of a reproposal, rather than a final rule, is the more prudent, and ultimately the more expeditious, course of action."). In light of the subsequent litigation which arose because the FDA did not promulgate regulations fast enough, this statement seems ironic. *See infra* note 104 and accompanying text.

[90] In March, 1989 it was reported that those who have one episode of menstrual-related TSS have a 30 percent risk of recurrence. To date, all recurrences had been associated with menstruation; most occurred one to two months after the initial episode. "In most cases of multiple recurrences, each successive episode becomes less severe and shorter in duration, until the episodes resolve entirely." Charles L. Bryner, Jr., "Recurrent Toxic Shock Syndrome," American Family Physician, Vol. 39, No. 3, at 157 (March 1989).

[91] 54 Fed. Reg. 25,076. The test method specified was the syngyna test that uses a saline solution to stimulate menstrual fluid. The tampon is placed inside a condom on the test apparatus, pressure is applied and fluid is pumped into the tampon. After the tampon is saturated, it is removed and weighed to the nearest 0.01 gram. Any manufacturer that wishes to use a different test method that produces substantially similar results may file a citizen petition for FDA approval. *Id.*

[92] Many comments were received regarding the proposed system of lettered absorbency labeling. Comments criticized the proposed letter system because it would force consumers to learn two systems of absorbency labeling (the letters and the corresponding numerical ranges) and consumers would not know whether "A" was high or low. Most commentators favored the use of nonoverlapping ranges, and agreed with FDA's conclusion that variations in tampon production and absorbency testing make the use of ranges necessary. The FDA continued to believe that current technology did not make feasible use of a single number representing the average absorbency of any sample of tampons. *See id.*

[93] The FDA declined to standardize currently used terms for two reasons: there are six ranges for which terms are needed and only three or four widely used terms; and FDA believed an effective labeling scheme could be established which would allow manufacturers to continue to use the familiar terms without compromising the intent of the rule. *See id.*

absorbency on tampon labeling by using one of six specified absorbency terms.[94] Instead of using the letters A-F, the rule would establish a new set of standardized terms of absorbency, each of which corresponded to a range of absorbency specified in grams: low absorbency (less than or equal to 6 grams); medium absorbency (6-9 grams); medium-high absorbency (9-12 grams); high absorbency (12-15 grams); very high absorbency (15-18 grams); and highest absorbency (above 18 grams).[95] These terms would be required to be more prominent than, and separate from, any other information on the principle display panel except the corresponding numerical range of absorbency.[96]

The reproposed rule also suggested other changes to the labeling requirements including removing the word "possibly" from the warning "possibly reducing the risk of getting TSS by alternating tampon use with sanitary napkin use during menstrual periods."[97] Further, since the absorbency test methodology was challenged as not techonolgically feasible, the FDA reproposed its rule to require a lower tolerance interval (that the probability be 90 percent that 90 percent) of the absorbencies of the individual tampons within a package be within the range of absorbency stated on the package label.[98] FDA written comments were due on August 11, 1989 and the rule was to take effect on December 12, 1989.[99]

Public Citizen Goes to Court to Hasten the FDA's Promulgation of Tampon Absorbency

[94]Since tampon manufacturers were already to provide labeling on tampon packages, the FDA did not believe that these minor labeling changes would constitute an additional burden. *Id.*

[95]The rule would not proscribe the use of currently used or other terms of absorbency so long as they did not make the label misbranded under 21 U.S.C. § 352. The rule would also require that the label include an explanation of the range of absorbency and its corresponding term. *See id.*

[96]*Id.*

[97]*Id.* Since the original proposed rule, another study had been published which was presented at the November 1987 Sientific Conference on TSS. The study confirmed that tampon use is a risk factor for developing TSS during menstruation, and that the risk increases with tampon absorbency. The study also confirmed an earlier finding (*see* 47 Fed. Reg. 26,982, *supra* note 48) by the CDC that continuous use of tampons throughout the menstrual cycle increases the risk of TSS, and that each day of continuous tampon use increases the risk of TSS. The FDA also proposed to amend the introductory text to refer to "labeling," instead of referring to packages and package inserts. *Id.*

[98]The FDA concluded that there was no substantial difference in the public health consequences between the tolerance level 95/95 (as was previously proposed), 95/90 or 90/90. *Id.*

[99]*Id.*

Labeling in 1989

Public Citizen then decided to bring their case to court, bringing suit against the FDA by charging several federal officials with unreasonable delay in failing to promulgate long-needed regulations requiring tampon manufacturers to display standardized absorbency labels on the packaging of tampons.[100] The Group sought immediate promulgation of regulations requiring absorbency labeling and unambiguous notices of the risks and dangers associated with continuous tampon use.

Concerned about TSS and fed up with FDA delays, on August 28, 1989 a district court for the District of Columbia issued an opinion granting Public Citizen immediate injunctive and declaratory relief. The order required the FDA to issue a final rule amending the 1982 tampon labeling regulation in two months– by October 30, 1989– and that it take effect when it was issued.[101] The FDA was heavily criticized in the press for its lagging on creating regulation regarding this important women's health issue. [102] The FDA "has been lethargic in responding to and carrying out its legal obligation and thus failed to adequately inform and protect the public on this important health issue," the district court judge, Barrington D. Parker, said August 29, 1989.[103]

On September 29, 1989 the court rejected the FDA's request for more time to comply with the court order, holding that it had not shown that six months was the shortest amount of time necessary for compliance with the regulation, nor did it otherwise justify its delay in issuing a regulation requiring tampon absorbency labeling.[104] Since the record demonstrated that four months was adequate for compliance, the court modified the order to indicate that compliance would be required four months after October 30, 1989, the date by

[100] *Public Citizen Health,* 724 F. Supp. 1013.
[101] Dixie Farley, "Preventing TSS: New Tampon Labeling Lets Women Compare Absorbencies," FDA Consumer, vol. 24, No. 1, at 6 (February, 1990).
[102] *See, e.g.,* "Judge Orders U.S. to Require Tampon Absorbency Labels," The New York Times, Aug. 31, 1989, at B13.
[103] *Id.*
[104] *Public Citizen Health,* 724 F. Supp., at 1026.

which publication of the regulation must occur.

The FDA's Final Rule on Absorbency Labeling

The June 12, 1989 reproposed rule garnered 39 comments overwhelmingly disapproving using terms and corresponding absorbency ranges.[105] The industry preferred to use the existing terms, and consumers agreed that the dual system would be confusing. Finally, the FDA agreed that standardizing the existing terms would create the least confusion, would be easily understood by consumers, and was the simplest scheme to implement.

On October 26, 1989, the FDA published the final rule for "Ranges of Absorbency Labeling" for menstrual tampons.[106] The FDA recited and responded to the comments received regarding the absorbency labeling proposals, noting that it could not reduce the number of ranges because the only way to do so would be to create ranges that are unnecessarily broad. Since most of the consumers, and all of the manufacturers preferred the non-overlapping range scheme, the FDA retained this characteristic of its requirement.[107]

Regarding the use of terms, many comments strongly objected to the reproposal's dual system, and while some stated that the new terms would be acceptable, many of those thought that confusion would be eliminated only if the use of existing terms was proscribed.[108] The FDA concluded that the dual system retaining the existing terms would have little impact on reinforcing absorbency information and would not achieve its stated public health purposes. Thus, the 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

[105] Dixie Farley, *supra* note 101.
[106] 54 Fed. Reg. 43,766 (Oct. 26, 1989).
[107] *Id.* The FDA noted, however, that if technology improved so as to allow for accurate average absorbency measurements, the FDA would consider proposing amendments to the rule.
[108] *Id.* The FDA rejected the suggestion to proscribe the existing terms because it would not take advantage of consumer familiarity with existing terms, and it would be a more restrictive rule than is necessary.

changed. The packages also required an explanation of the ranges of absorbency (mandated as follows): junior: less than 6; regular: 6 to 9; super: 9 to 12; super plus: 12 to 15. The 15- 18 and over 18 grams absorbency ranges were not termed. In fact, there were no tampons marketed at the time which had an absorbency of 18 or greater, and only one which was in the 15-18 gram range. This product, labeled "super plus" would have to alter its absorbency to comply with the rule.[109]

Manufacturers also complained about the proposed six month implementation date, claiming that they required more time to design effective packaging, and that the changes would affect manufacturing, including machinery and testing protocols.[110] The FDA rejected this assertion, holding that the manufacturers' existing quality assurance programs merely need to be modified, not replaced, and that any time beyond six months is "neither necessary nor appropriate."[111] The FDA then noted, that in fact, because of the court order,[112] the rule would go into effect on March 1, 1990.[113] In the rule, the FDA also said that it would consider new data submitted in support of development for a "standard for tampon performance to include parameters such as biocompatibility, leachability of materials, anchor string strength, and smoothness and mechanical operation of the tampon inserter."[114] On April 26, 1990, the FDA issued an amendment authorizing a change in the test apparatus for absorbency measurement.[115] Other minor changes were made to the rule in the following decade. In January 2000, the FDA issued amendments to certain references in the regulations to reflect current American Society for Testing and Material Citations.[116]

[109]The rule set up a procedure by which manufacturers that wanted to market tampons with absorbencies above 15 grams could apply for premarket approval.
[110]*See id.*
[111]*Id.*
[112]*Public Citizen Health,* 724 F. Supp. 1013
[113]In order to cushion this harsh requirement, the FDA provided that manufacturers for up to 12 months after the effective date, could include the information "formerly Brand X super" in the product labeling. *Id.*
[114]*Id.*
[115]55 Fed. Reg. 17,599.
[116]65 Fed. Reg. 3584, *codified at* 21 C.F.R. § 801. 65 Fed. Reg. 44, 435, published July 18, 2000, confirmed (in relevant part) the proposed changes. 65 Fed. Reg. 51, 532, published August 24, 2000, amended the July report by correcting a page number.

In response to the absorbency labeling rule, as well as changes in absorbency and the fact that women began to use tampons intermittently, the incidence of TSS declined.[117] For instance, statistics from the CDC indicated that there were 61 reports of TSS in 1989, down from 86 in 1988, and 890 in 1980. Of the 1989 cases, 74 percent were menstrually-related, compared with 55 percent in 1988 and 91 percent in 1980.[118] However, in the mid 1990s articles began to surface warning that while the public concern regarding TSS may have waned, the incidence of the disease had not.[119] The cause of TSS and health conditions associated with the staphylococcus aureus infection continued to be researched. Although most early cases of TSS were associated with vaginal tampon use, only 55% of cases being reported in 1998 were associated with menses.[120]

[117] Jennifer Newman, "With Tampons, Less is More; Now Consumers Know What They're Buying," American Health, Vol. 9, No. 2, at 16 (March 1990); *see also* "Toxic Shock Toll Plummets," New York Times, July 5, 1990, at B7; "Reduced Incidence of Menstrual Toxic-Shock Syndrome," Morbidity and Mortality Weekly Report, Vol. 39, No. 25, June 29, 1990, at 421.

[118] "Reports of TSS Wane," FDA Consumer, Vol. 24, No. 8, at 4 (October 1990).

[119] See e.g., "Personal Health; Toxic Shock: Out of Mind, But Still a Serious Disease," The New York Times, Aug. 24, 1994, at C8.

[120] Other risk factors include use of contraceptive diaphragms or vaginal contraceptive sponges and infections following childbirth or abortion. *See* Neil Barg, et al., "Common and Potentially Fatal Staph Infections," Patient Care, Vol. 6, No. 32 at 26 (March 30, 1998)

The Debate Over Tampon Ingredient Labeling

As early as 1982, the FDA was asked to require ingredient labeling for tampons because of consumer concerns about the safety of some ingredients, but it declined to do so.[121] Because the FDA did not have data demonstrating an association between any particular ingredient and any risk of health, including allergic reaction, sensitivity, and irritation, it did not have enough information to require ingredient labeling. The FDA noted, however, that it was reviewing the problem of adverse reactions that might be associated with tampons to determine if it should supplement current voluntary standards with regulation.[122]

This refusal to require such labeling displayed a policy consideration by the FDA that inundating consumers with too much information could result in their not processing any of it, or especially, not being able to appreciate which safety information is the most meaningful or important. "Routinely, the agency has avoided requests for nonmaterial information or warning-like statements for ingredients that cause only mild or idiosyncratic responses."[123]

On August 20, 1985, after the task force tampon safety had dissolved,[124] the FDA's Obstetrics-Gynecology Devices Panel discussed the safety of tampons. The Panel recommended the FDA consider including "content" labeling in the tampon absorbency labeling regulation, perhaps by regulating scented tampons as cosmetics.[125] The FDA declined to take up this suggestion to regulate tampons as cosmetics, since doing so would not induce ingredient labeling anyway. Under 21 C.F.R. § 701.3, which governs the labeling of ingredients in cosmetics, a fragrance may be listed on the label as "fragrance" without any further information

[121] *See* 47 Fed. Reg. 26,982, published on June 22, 1982. In fact, a citizen petition also was received, suggesting that because of TSS and other adverse effects, such as allergic reactions, FDA should require labeling to include a complete listing of fibers and ingredients. *See id.*

[122] *See id.*

[123] Fred H. Degan, "Biotechnology and the Food Label: A Legal Perspective," 55 Food Drug L.J. 301, 306 (2000).

[124] *See supra* notes and accompanying text.

[125] The need for ingredient labeling arose during discussions concerning scented tampons when a consumer group suggested that scented menstrual tampons be regulated as cosmetics so that they would be required to list their ingredients on their packages.

supplementing.[126]

However, concerns over tampon ingredients, particularly regarding dioxin, continued to surface in the 1980s. In 1987, an 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. The capacity to measure such levels exists within FDA. Extraction data for dioxin from these products... would improve the accuracy of any risk assessment."[127] In its Proposed Rule for absorbency labeling of September 23, 1988, the FDA invited comment on the need for ingredient labeling of scented or other tampons.

In its June 12, 1989 reproposed rule for absorbency labeling,[128] the FDA reported that many consumer groups and individual consumers had commented on the need for ingredient labeling. Some argued that all materials, additives, and fragrances should be listed on the product label so that consumers may choose products on the basis of which ingredients are known to be or suspected to be hazardous, as well as which have the potential for an allergic reaction. Other comments argued against requiring ingredient labeling, maintaining that there were no data suggesting the need for ingredient labeling, or that it simply was not as important as absorbency labeling and as such might not be used by consumers. Additionally, comments noted that manufacturers had voluntarily implemented an ingredient labeling system for tampons so no required system was necessary.[129]

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,

[126] At the time of the Panel's recommendation to the FDA, the only manufacturer of scented tampons already listed "fragrance" on its packaging as an ingredient.
[127] Don Galloway, "Background Information on Dioxin and Medical Devices," Oct. 8, 1987.
[128] 54 Fed. Reg. 25,076.
[129] *See id.*

sensitivity, or irritation, and FDA is unaware of any such data."[130] Without information indicating that such labeling is necessary for the safe and effective use of tampons, FDA is without legal authority to require such labeling.

In its final rule for absorbency labeling, the FDA again responded to consumers' and consumer groups' requests for ingredient labeling. Once again, the 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.[131]

* * *

The debate over whether the dioxin content in tampons is harmful to women continued through the 1990s. In 1990, the FDA, EPA and the Consumer Product Safety Commission, authored a study of risks related to products containing materials derived from wood pulp bleached with chlorine (including tampons), and concluded that these produces did not contain enough dioxin to cause harm.[132] While the FDA and the paper industry claim that the exposure to dioxin is not harmful, others question their conclusion.[133] One commentator claims that the "sale of dioxin-contaminated products is allowed because of a highly successful campaign waged by such industry giants as the American Paper Institute and the Chlorine Institute. Call it spin control, call it whitewashing, call it media manipulation."[134] In fact, the FDA does not independently

[130] *Id.*
[131] 54 Fed. Reg. 43,766.
[132] US Environmental Protection Agency, "Background Document to the Integrated Risk Assessment for Dioxins and Furans from Chlorine Bleaching in Pulp and Paper Mills," (July 1990).
[133] *See e.g.,* Marc Smolonsky and Phillip J. Wakelyn, "Dioxin in Single-Use Diapers and Tampons," Mothering, No. 67, June 22, 1993, at 44.
[134] *Id.*

test the amount of dioxin in tampons, but instead relies on the information of paper mills officials.

House of Representatives Representative Carolyn B. Maloney introduced a bill on November 7, 1997 proposing an act entitled "The Tampon Safety and Research Act of 1997."[135] The act provided for research to determine the extent to which the presence of dioxin, synthetic fibers, and other additives in menstrual tampons pose any risks to the health of women.[136] Dioxin is a toxic by-product of a chlorine-bleaching process used in the manufacture of paper products. Since dioxin is stored in fatty tissue, the effects of dioxin from various sources are cumulative and can be measured 20 to 30 years after exposure. The 1994 Environmental Protection Agency report stating that dioxins are a probable human carcinogen (cancer-causing agent) ought to be a great cause of concern.

Internal documents of the FDA suggest the agency has not adequately investigated the danger of dioxin in tampons, according to a 1992 staff report of a subcommittee of the Committee on Government Operations, House of Representatives. The FDA does require tampon manufacturers to monitor dioxin levels in their finished products, but the information is not readily available to the public. Further, the FDA relies solely on data provided by feminine hygiene manufacturers in determining product safety.[137] The bill for The Tampon Safety and Research Act of 1997 was referred to the House Committee on Commerce, and the next week referred to the Subcommittee on Health and Environment, but ultimately was never passed.

More recently, the Internet has created some interesting ado that has citizens wondering if the FDA's regulation is stringent, effective or a conspiracy. Email and Internet rumors tell that manufacturers add asbestos

[135] *See* 143 Cong. Rec. E. No. 156, at 2236, 105^{th} Congress, 1^{st} Session, Saturday, November 8, 1997. This wasn't the first time that a member of Congress had expressed concern about this issue. In 1992, Ted Weiss of New York brought up the issue on a subcommittee hearing of the Committee on Government Operations, after his staff had uncovered internal FDA documents suggesting that the agency had not adequately investigated the dangers of dioxin in tampons. Further, articles circulated about the dangers associated with dioxin in tampons as early as 1989. *See* Judith Finn, "The Tampon Debate: Have you Encountered the Alternatives?" East West, Vol. 21, No. 9, at 31 (November 1991).

[136] *Id.* Specifically, the research would examine risks relating to cervical cancer, endometriosis, infertility, ovarian cancer, breast cancer, immune system deficiencies, pelvic inflammatory disease, and toxic shock syndrome. The National Institute of Health would be responsible for the project, in accordance with an amendment to Part F of title IV of the Public Health Service Act (42 U.S.C. 287d et seq.).

[137] *Id.*

to tampons to encourage bleeding in order to sell more products; tampons cause lung cancer; and the tampon manufacturing process including bleaching adds dioxin to tampons.[138] While the asbestos claim has no scientific merit or data backing it up, the dioxin fear is perhaps less unwarranted. The July/August 1999 newsletter of the National Women's Health Institute reported that there is concern about dioxin, as well as rayon, which is used in some high-absorbency tampons.[139] The FDA's website says that while dioxin may be present, the level of exposure is "so small that any risk of adverse health effects is considered negligible."[140] While some sites advocate using all-cotton tampons, others point out that pesticides used in growing cotton could pose just as much a threat as dioxin.[141]

This year, Representative Carolyn Maloney again introduced a bill into the House to establish a program of research regarding the risks posed by the presence of dioxin, synthetic fibers, and other additives in feminine hygiene products.[142] The Act, which would be entitled the "Robin Danielson Act," would require the National Institute of Health to provide for the research or support of research. Additionally, the Act would mandate collection and analysis of data on TSS. In the bill, Congress finds that among women in the age group 12 to 44 who use tampons or barrier contraceptives, between one and two of every 100,000 will develop TSS each year.[143]

Preemption of State Tort Claims by Federal Tampon Regulations

[138] Ann Endo, "To Your Health: Toxic Rumor Syndrome," The Daily Yomiuri Dec. 16, 2000, at 9; *see also* Bob Condor, "Separating Fact from Quackery in Those Mass E-Mailings," The Chicago Tribune, June 12, 2000, at 1 (reporting about false email forwards which claim tampon manufacturers put asbestos in their products). Some websites are dedicated to debunking the myths that abound. *See* http://www.quackwatch.com; `http://www`.urbanmyths.com; `http://www.mum.org` (The Museum of Menstruation).

[139] Terris Shaw, "Don't Let Hoax Be On You; Verify E-mails on Health," The Plain Dealer, March 13, 2000, at 1F.

[140] *Id.*

[141] Terry Shaw, "E-Life; The Tale of the Killer Tampon; The Web is Full of Health Hoaxes. Here's How to Recognize Them," The Washington Post, Feb. 15, 2000, at Z08.

[142] 2001 H.R. 360; 107 H.R. 360 (Jan. 31, 2001). The bill, which would amend the Public Health Service Act, was referred to the House Committee on Energy and Commerce.

[143] *Id.*

While tampon manufacturers clearly may be liable for non-compliance with the FDA federal regulations, whether they could still be subject to suits under state law claims was less certain. In deciding whether a particular state law is preempted by the MDA, courts must first determine whether a corresponding federal requirement (such as an FDA regulation) applies to the device in question. Courts have found that the "presumption against preemption" is overcome by examining the perceived legislative intent behind the MDA, the FDA's interpretation of the MDA and the Supreme Court's decision in Cipollone v. Liggett Group.[144] The FDA did not intend to preempt all state and local regulations pertaining to tampons.[145] In 21 CFR § 801.1(d), the FDA elucidated that "state or local requirements are preempted only when the Food an Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act."

21 U.S.C. § 360(k) also contains special provisions dictating the regulation of devices by States and local entities. The rule establishes that no State or political subdivision may establish or continue any requirement with respect to a medical device intended for human use, any law which is different from, or in addition to, any requirement which relates to the safety or effectiveness of the device or to any other matter included under the act.[146] Nevertheless, some commentators have argued that courts should not read the MDA to preempt state law claims, particularly in cases in which the victims are then left without redress for their harm.[147]

In *O'Gilvie v. International Platex, Inc.*,[148] a suit under the Kansas law of strict liability in tort, Platex argued that its warning was adequate as a matter of law because it complied with FDA regulations.[149] The

[144] 505 U.S. 504 (1992) (holding petitioner's claims were only partially pre-empted and that federal law did not entirely insulate tobacco companies from all claims for liability); *see also "Kennedy v. Collagen Corp.*: Falling From the Medical Device Amendments' Federal Preemption Garden," 28 Ariz. St. L.J. 949 (1996).

[145] The regulations interpreting section 521(a) (*see supra* note 10) state that "court decisions" establishing state law requirements applicable to a device are preempted. 21 C.F.R. § 808.1(b).

[146] *See* 21 U.S.C. § 360(k)

[147] *See* "Falling from the Medical Device," at 949.

[148] 821 F.2d 1438 (10^{th} Cir. 1987).

[149] The district court had instructed the jury as a matter of law that the warning was in compliance with federal regulation and that "such compliance is not a defense if a reasonable and prudent manufacturer would have taken added precautions."

Tenth Circuit held that the state law claim was not preempted and that Playtex willfully and wantonly injured the plaintiff:

> [by] disregarding studies and medical reports linking high absorbency tampon fibers with increased risk of toxic shock at a time when other tampon manufacturers were responding to this information by modifying or withdrawing their high-absorbency products. Moreover, there is evidence that Playtex deliberately sought to profit from this situation by advertising the effectiveness of its high absorbency tampons when it know other manufacturers were reducing the absorbency of their products due to the evidence of a causal connection between high absorbency and toxic shock. This occurred in the face of Playtex' awareness that its product was far more absorbent than necessary for its intended effectiveness.[150]

Almost all cases around this time held that federal regulations preempted state requirements for warning labels.[151] Later suits assumed that state claims were preempted and addressed whether manufacturers were in compliance with federal labeling regulations. For instance, in *Sloman v. Tambrands, Inc.,* defendant Tampax placed its TSS alert statement on the back of its box, and the court summarily dismissed the claim that this violated 21 USCS § 352(c), because the FDA expressly declined to require that the alert statement appear on any particular panel of the box in 47 Fed. Reg. 26,987, "Menstrual Tampons; User Labeling."[152] In some cases the question became whether the court could deduce compliance from the FDA's premarket

According to Kansas law, mere compliance was not adequate under the circumstances, and the Court of Appeals therefore properly sent the issue to the jury. *Id.* at 1442.

[151] *See* Berger v. Johnson & Johnson Products, Inc., No. 86-2-01249-3 (Yakima County Superior Court, Washington Mar. 14, 1989); Remer v. Tampax, Inc., No. 578755 (San Diego County Superior Court, California May 10, 1989); Aase v. Tambrands, Inc., No. 68108 (Kootenai County District Court, Idaho, Aug. 24, 1989); LaVetter v. International Playtex, Inc., 706 F. Supp. 772 (D.Ariz. 1988); Edmondson v. International Playtex, Inc., 678 F. Supp. 1571 (N.D.Ga.1987); Rinehart v. International Playtex, Inc., 688 F.Supp 475 (S.D.Ind. 1988); Lindquist v. Tambrands, Inc., 721 F.Supp 1058 (D. Minn. 1989); Jones v. Tambrands, Inc. No. C0870102 (N.D.Iowa, Dec. 5, 1988); Stucker v. International Playtex, Inc., No. C-87-0440-L(B) (W.D.Ky. Feb. 26, 1988) (appeal dismissed for lack of appellate jurisdiction Jan. 24, 1989); Cornelision v. Tambrands, Inc., 701 F. Supp. 706 (D.Minn.1989); Needham v. International Playtex, Inc., No. 87-152 (E.D.Ky. Oct. 25, 1988); Briggs v. International Playtex, Inc., 1988 U.S. Dist. LEXIS 15573, No. 86-C-540-E (N.D.Ok. Apr. 7, 1988); Gilbert v. Kimberly-Clark Corp., No. 87-C-470-E (N.D.Ok. Nov. 4, 1988); Stewart v. International Playtex, Inc., 672 F. Supp. 907 (D.S.C. 1987); Craig v. Kimberly-Clark Corp., No. 86-2-14780-2 (Kings County Superior Court, Washington Sept. 15, 1988). The single court which held that federal labeling requirements do not preempt state law claims was also the first court to have confronted the question. Musatko v. International Playtex, Inc., No. 85-C-1540, slip op. (E.D.Wis. May 14, 1987).

[152] 841 F. Supp. 699, 702-03 (D. Md. 1993); *see, e.g.,* Papike v. Tampbrands, Inc., 107 F.3d 737 (9^{th} Cir. 1997), *cert. denied,* 522 U.S. 862 (1997) (warnings regarding toxic shock syndrome which tracked language of federal regulations almost verbatim, were sufficient under 21 USCS § 352 (c) to not be considered misbranded and to preclude liability); Beecher v. Tampbrands, Inc., 840 F. Supp. 86 (D. Minn. 1993) (claim summarily denied, where TSS alert statement was on the bottom of the box, the bulk of the warning was provided in the insert and the insert was folder so that consumer saw TSS alert first, because no genuine issue of material fact existed as to whether the manufacturer violated 21 USCS § 352(c) with its labeling.)

approval.[153] Other courts have held that state common law claims are preempted by federal regulatory law but then have distinguished the remedy issue and found that plaintiffs had an available remedy.[154]

Some courts held that compliance did not shield the manufacturers from all liability associated with the manufacturing of tampons, reasoning that despite compliance with federal regulations, if a reasonable manufacturer would have [done X] then the manufacturer can be held responsible. In *Rinehart v. International Playtex, Inc.,* a district court in Indiana held that plaintiff's claims for design defects based on negligence and strict liability were not preempted by federal law because there were no federal regulations concerning tampon design.[155] While claims concerning labeling and warning standards were preempted, state law claims regarding design defects did not conflict with any provision of federal law and were not preempted. Other courts followed this reasoning, and held that only warning and labeling claims were preempted. For instance, the Fifth Circuit in *Moore v. Kimberly-Clark Corp.,*[156] ruled that federal law[157] preempted only state law claims against manufacturers based on inadequate warning and labeling. In this case, the court reversed the district court's dismissal of claims regarding design, composition and construction of tampons.[158]

Thus, manufacturers may be subject to regulation at the state level in those area which are not specifically regulated by the Act and its regulations. It is likely that the state regulations in these areas will vary from state to state, and thus tampon manufacturer will be subject to differing standards of liability.

New Absorbency Ranges in the Twenty-First Century

[153]The Eight Circuit in *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.,* 38 F.3d 988 (8^{th} Cir. 1994), ruled that the FDA premarket approval requirements (the 501 (k) process) in the context of a class II device merely represent "permission to market." Thus, the main opinion reasons, claims under state tort law are not preempted since the FDA may grant permission to market without an express determination of compliance. As such, the question of whether the label complies with the FDA requirements could not be established as a matter of law and had to be left for the factfinder, and summary judgment was inappropriate. The concurrence, however, argues that since the FDA approved the 501(k), it in essence determined that the labels complied with § 801.430, and therefore the claims for inadequate labeling or failure to warn are preempted.

[154]For instance, see *Stewart v. International Playtex, Inc.,* 672 F. Supp. 907, 910 (D.S.C. 1987).

[155]688 F. Supp. 475 (S.D. Ind. 1988).

[156]867 F.2d 243 (1989).

[157]21 U.S.C. §360(k) and 21 C.F.R. § 801.1(b).

[158]*See also* "Selected Recent Court Decisions," 15 Am. J. L. and Med. 363, 372 (1989).

In January 1999, the FDA proposed to add the term "ultra" to describe tampons in the range of 15 to 18 grams absorbency.[159] Many comments rejected the proposal of the term "ultra" in favor of "extra" or "extra plus," but the FDA believed that "ultra" better conveys to consumers the absorbencies and is less confusing.[160] In October, 2000, the FDA officially amended the regulation of tampons by authorizing a new range of absorbency labeling, "ultra absorbency."[161] Effective January 16, 2001 the ranges of absorbency for the corresponding terms used on package labels were changed. The pre-2001 absorbency terms were:

Ranges of absorbency in grams	corresponding term of absorbency
6 and under	junior
6 to 9	regular
9 to 12	super
12 to 15	super plus
15 to 18	none
above 18	none

The current absorbency terms are:[162]

Ranges of absorbency in grams	corresponding term of absorbency
6 and under	junior
6 to 9	regular
9 to 12	super
12 to 15	super plus
15 to 18	ultra
above 18	no term

In the comments responding to the "ultra" proposal of January 1999, the FDA received suggestions that

[159] 64 Fed. Reg. 3,255 et seq (January 21, 1999). The comment period closed on April 21, 1999.

[160] 65 Fed. Reg. 62,282 et seq (October 18, 2000). Some manufacturers thought that "ultra" implied that the product was "more compact in size, more concentrated, more environmentally sounds, or possibly superior." *Id.*

[161] *Id.* The new rule became effective on January 16, 2001.

[162] 21 C.F.R. § 801.430(e)(2). The manufacturers must calculate the mean absorbency of a production run or batch by rounding to the nearest 0.1 gram. 21 C.F.R. § 801.430(f).

the absorbency term "junior" be changed to "light."[163] They suggested that the term junior implied such tampons were only for young teenagers. Subsequently, when promulgating the final rule on "ultra," the FDA sought comments on this change, and issued a proposed rule to change the term "junior" to "light."[164] The FDA agreed with manufacturers' reasoning that all women, regardless of their age or size (which the term "junior" might implicate) ought to use the least absorbent tampon possible, and that the proposed term change would help women decide which tampon to use.[165] Written comments on the proposed rule were due by January 16, 2001, and the final rule would become effective 90 days after the date of its publication.

Conclusion

While we patiently await the new administration's final rule on the term change from "junior" to "light," fairly confident that the proposal will be adopted, we can be thankful that today, tampons are considered safer than ever before. The incidence of TSS has steadily declined and today is drastically less than it was years ago.[166] "According to recently released statistics from the Centers for Disease Control and Prevention, only about one in 100,000 women will contract TSS from a tampon, down from 12 in 100,000 20 years ago. In 1997, only five confirmed TSS case related to menstruation were reported, compared with 814 in 1980."[167] As mentioned above, this trend is likely due to changes in the absorbency of tampons, and increases in women's awareness of TSS, and the warnings to use only the minimum absorbency necessary.

Conversely, perhaps many more cases of TSS could have been avoided if the FDA had acted more swiftly

[163] *Id.*

[164] 65 Fed. Reg. 62,317 (October 18, 2000).

[165] *Id.*

[166] Reviewing reports from 1979 to 1996, the CDC reported a marked drop in TSS cases in the early 1980s with a relatively flat, extremely low number of TSS reports since 1986. For instance, in 1996, there were five definite and four probable menstrual-related TSS cases reported to the CDC. See Hajjeh, R.A., et al., "Toxic Shock Syndrome in the United States: Surveillance Update, 1979-1996," Emerging Infectious Diseases, Vol. 5, No. 6, at 807-810 (November/December 1999).

[167] Laurie Green, M.D., "Toxic Shock Today," *WebMD Medical News,* June 12, 2000, *in* `www.webmd.com`, last visited March 3, 2000.

in its promulgation of tampon regulations. But is the FDA ultimately to blame? With its limited time and resources, and hundreds of comments being received in response to its proposals, perhaps it is no wonder that the creation of appropriate regulations for tampon absorbency labeling took so long. On the other hand, could the fact that this was strictly a *women's* health issue have designated the creation of regulations as less of an agency priority and somehow created even greater delays?

Of more immediate concern may be whether the FDA again will be blamed for injury to women's health in the coming decades, for not patrolling the ingredients of tampons. Congress ought to pass the "Robin Danielson Act" this year and fund research on the ingredient content of tampons. However, in light of the new administration's plans for government agency financing, it may be unlikely that such bill will be passed into law. Perhaps in the future, with advanced research into the causation behind cancer, we will witness mass tort law suits being brought against those who today could have monitored women's exposure to dioxin. Nevertheless, tampons continue to grow in popularity and are used by increasing numbers of women each year. However, while 70 percent of women in the United States, Canada and much of Western Europe use tampons, only 100 million of the world's 1.7 billion customers use the products today.[168] In many Catholic countries there are concerns that young girls who use them will lose their virginity, women are not comfortable with their bodies, and women aren't accustomed to spending money on disposable items for themselves.[169]

Tampons are also expanding beyond their traditional role as medical devices for menstruation, and being used in other ways, such as in the diagnosis of vaginal diseases.[170]This creates new hope that in the future, tampons will be associated positively with women's health— for example, as an aid to detection of disease—

[168] *See* Nelson, "Firm Fights Hard," *supra* note 2.

[169] *See id.* In Mexico, for instance, only two percent of the women use them. *Id.*

[170] *See, e.g.,* Dan Ferber, PhD, "Special Tampon Helps Diagnose STD; No Physical Exam Required," *WebMD Medical News,* Sept. 18, 2000, *in* http://www.webmd.com, last visited March 3, 2000 ("Specimens collected from specially designed tampons worked as well as a vaginal exam to diagnose vaginal trichomoniasis, a sexually transmitted disease. If the method holds up, it could lead to easier diagnosis as women test themselves and bring samples to the clinic instead of undergoing an invasive gynecological exam.").

instead of being associated with the harmful potential health problems of TSS.