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Toxic Shock Syndrome, Tampon Absorbency, and Feminist Science

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Abstract

In 1980, the Centers for Disease Control recommended that women limit their use of superabsorbent tampons since the risk for Toxic Shock Syndrome increased with greater levels of absorption. However, women had no way of following this advice because products did not have consistent absorbency labels. The Tampon Task Force, comprised of manufacturers and consumer advocates, convened to set standards for absorptive capacity as well as nomenclature for all commercial tampon brands. Esther Rome from the Boston Women's Health Book Collective participated as a feminist health activist and recruited scientist Nancy Reame to help generate data on their behalf. Importantly, Reame rejected the use of blue saline as a menstrual fluid replacement in the syngyna—the synthetic vagina lab instrument—to test tampon absorbency, and insisted upon heparinized blood instead. In the process, the advocates developed a feminist science: they challenged the process by which a standard is established, the method by which variables are controlled, and the erasure of menstrual fluid from tests about tampon

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absorbency. The feminist science yielded both usable and valid outcomes, with results that challenged the design of the experiment upon which industry-wide standards were to be based.

Introduction

On September 6, 1980, twenty-five-year-old Patricia Kehm died from complications due to Toxic Shock Syndrome (TSS). Her death, along with seventy-three women and two thousand others sickened between 1970 and 1980 after using superabsorbent tampons, precipitated action ("Toxic Shock Syndrome—United States, 1970–1980," 1981). In the short term, the Food and Drug Administration (FDA) pressured Procter & Gamble to recall Rely—the superabsorbent tampon with the highest rate of TSS—and the company removed the tampons from store shelves (though other superabsorbent tampons, including those from Playtex, Tambrands, and Kimberly-Clark remained on the market). Product liability lawsuits, including that of Kehm's family against Procter & Gamble, garnered meager payouts to compensate for injuries and deaths. A less obvious but long-lasting result was the establishment of the Tampon Task Force in 1982. The task force, composed of manufacturers, consumer groups, and feminist health advocates, sought to set uniform standards concerning tampon absorption capabilities and deliver labeling recommendations to the FDA. The importance of this was that higher absorptions were linked to higher rates of TSS, but women did not have an accurate way of knowing which tampons were more or less absorbent. This essay examines how feminist science influenced the proceedings of the Tampon Task Force and how feminist health advocates initiated the approach.

On the task force was Esther Rome, one of the founders of the Boston Women's Health Book Collective (BWHBC) and co-authors of *Our Bodies, Ourselves* (OBOS). Her inclusion marked an important departure from regulation-as-usual with men and corporate representatives setting the policy standards. Rome brought to the Tampon Task Force the same tactics she deployed in writing *Our Bodies, Ourselves*. From the

BWHBC's beginning, the founders set out to obtain and distribute medical knowledge about women's health that had been the exclusive purview of mostly male physicians, who were often "condescending, paternalistic, judgmental and noninformative" (Boston Women's Health Book Collective, 1973). What these doctors would not provide, the women set out to learn, discover, and take for their own to share with other women. The scene would repeat itself on the Tampon Task Force.

When manufacturers would not share data, were not forthcoming, and were not even using menstrual blood for absorption tests, Rome solicited feminist scientist Nancy Reame, a nursing professor at the University of Michigan, to generate data on the consumer advocates' behalf. Together with other Tampon Task Force members, they insisted upon sharing data amongst all the scientists and the FDA regulators, enacting an ethic of feminist science. Reame used heparinized blood (blood treated with heparin so it does not coagulate quickly) instead of saline to test tampon absorption rates. It was a watershed moment for consumer groups, feminist health advocates, and women scientists, with feminist science producing data and networks of knowledge based upon the biological materiality of menstruating bodies. Thus, at this historical moment when feminists challenged the universality and androcentrism of medicine, the inclusion of a reified "woman" and an understanding of essentialized "women's bodies" was a radical departure.¹ Feminist ideas privileging women's knowledge and the materiality of women's bodies were critical in shaping science during the 1980s in the face of the unknowns related to Toxic Shock Syndrome.

In this case, feminist methods relied upon a universal biological female as the basis for which to establish lab practices and tampon absorbency standards. We now understand this essentialized reading of the female body as conflating gender, sexed bodies, and experiences of menstruation. It makes sense to think of people who have periods—as a category—simply as "menstruators" (Bobel, 2010), rather than using gender as a proxy. Menstruators might yield different ways of knowing about periods, their management, and related health outcomes

associated with tampon use.

At the time, however, insistence that menstrual blood mattered informed feminist science, which valued not only female bodies but also common-sense research practices that incorporated real-life applicability to menstruators. This approach challenged the privileged position of "fastidious" science as described by epidemiologist Alvan Feinstein, a shortcoming of which is to eliminate so many variables that context—in this case, that of menstruating bodies—is erased. Through feminist science, advocates challenged the process by which a standard was established, the method by which variables were controlled, and the disappearance of menstrual fluid from tests about tampon absorbency. Feminist science yielded both usable and valid outcomes, with results that disputed the design of the experiment upon which standards were to be based.

The Rise of Toxic Shock Syndrome

By the 1970s, two separate but significant events converged. First, the new illness of Toxic Shock Syndrome was identified in 1978 (Todd, 1978). Second, synthetic materials had begun to displace cotton in tampon composition creating a category called "superabsorbent" (Tierno, 2001). Although TSS is not exclusive to people who menstruate, by September of 1980 the Centers for Disease Control (CDC) declared that TSS was associated with superabsorbent tampons ("Follow-up on Toxic-Shock Syndrome," 1980), thus the majority of cases affected them. Although many theories emerged to explain this new link, Mike Osterholm, an epidemiologist working for the state of Minnesota during the 1980s, determined that superabsorbent tampons captured and held air—specifically, oxygen (Osterholm, 1982). Tampons, especially superabsorbent ones, introduced enough oxygen into the usually anaerobic vaginal canal to change its ecology and promote the growth of *Staphylococcus aureus*, the bacterium responsible for tampon-related TSS, in those women who happened to carry this particular strain of

bacterium.

Pat Schlievert, a microbiologist, identified the co-factors of the tampon creating an aerobic vagina and the naturally occurring higher pH during menses as contributing to TSS. The conditions were ideal not only for reproduction of the *S. aureus* bacterium, but also the production of the toxin TSST-1 (Schlievert, 1981). When the toxin transferred into the bloodstream, and if the woman lacked the requisite antibodies and titers for it, it could precipitate organ failure and shock, thus the illness Toxic Shock Syndrome. The three elements of oxygen, bacterium, and lack of antibodies were required for TSS to foment. In general, more white women were affected since they were a larger part of the population, but the CDC reported cases of TSS across categories of race and ethnicity (MMWR, 1983). Toxic Shock Syndrome occurs in about 1 in 100,000 women, making it a rare occurrence, and cases are not necessarily terminal when treated early enough with antibiotics (Hajjeh, 1990). However, for a small segment of women, the risk is quite real.

All of this, though, has taken years to understand and was science-in-the-making during the early 1980s. Scientists scrambled to understand the most rudimentary elements of the illness and its transmission. By the fall of 1980, it was clear was that something potentially deadly was going on with tampons. Procter & Gamble removed its successful tampon Rely from production and sales, and the CDC and the FDA recommended that women use the least absorbent tampon possible (CDC, 1980; Vostral, 2011). The FDA did not want to suggest banning tampons, due in part to their long safety record since the 1930s. However, without accurate information and labeling, there was no way for women to determine which tampon to purchase with the lowest absorbency. They could not follow guidelines to avoid tampon-related TSS, short of abandoning tampons altogether.

Feminist Interventions in TSS

Women needed accurate information about tampons, and quickly. The

FDA held responsibility for safety and labeling, and reached out to ASTM for assistance. Currently known just by its initials, ASTM (American Society for Testing and Materials) is a professional organization that develops voluntary consensus standards concerning materials, engineering, and testing practices. Everything from steel gauge to screw threads requires agreed-upon standards, and as a technology, tampons were now the focus of negotiation. ASTM had a special committee known as F-4 to develop standards for medical devices, and tampons fell under its purview. Standard setting usually included industry representatives, with ASTM helping to build consensus among stakeholders.

Important at this moment was the inclusion not only of producers but users and representatives of "general interest." ASTM partnered in a new cooperative program with the National Consumers League (NCL) to include layperson consumer input into the standard setting process. Becky LeBuhn (at the time Cohen), was the consumer representative from the NCL on the F-4 medical devices committee. She encouraged the F-4 committee to agree to the FDA's request to develop a tampon standard, but pointed out that with no other women on the committee, only she qualified as an actual user. A group purporting to represent consumers needed actual tampon users in the standards development effort; an all-male chorus was insufficient. Through the NCL, LeBuhn volunteered to "assemble a group of women, including representatives of women's health and advocacy organizations" to participate on the task force and make sure women's health and safety concerns were on the table (LeBuhn, 2017). In this case it was not just competing industries potentially vying to maintain the upper hand of a design or process but also consumer groups and feminist health advocates who had a stake in their personal safety and well-being.

The Tampon Task Force as it came to be known met in January of 1982, seven more times throughout that year, and for the next three years to develop "a tampon standard as expeditiously (sic) as possible" (Ellis, 1982). The following manufacturers, consumer groups, and women's health advocates composed the group: Johnson & Johnson, Kimberly-

Clark Corporation, Tambrands, Inc., Playtex International, BWHBC, Coalition for the Medical Rights for Women, Empire State Consumer Association, National Consumers League, National Women's Health Network, and Woman Health International. Though the advocacy groups had a unified front, this essay focuses upon the involvement of the BWHBC through its papers archived at the Arthur & Elizabeth Schlesinger Library at Harvard University.

Well known for its signature book *Our Bodies, Ourselves*, the BWHBC began in 1969 in Boston as a grassroots group of twelve women sharing frustrations about medical paternalism and the active withholding of information by physicians. The collective grew into a nonprofit, and shaped the women's health movement during the 1970s. BWHBC goals included providing health and medical information in an accurate and understandable way so that women could make informed decisions about birth control, pregnancy, and sexual health, for instance, and thus become their own health experts. Within the history of women's rights, this is characterized as the "difference" approach; that is, placing the female body at the center of politics, knowledge, and power as opposed to the "equality" approach that deemphasizes female biology, in part due to the legacy of discrimination based upon it (Kline, 2010). Embracing difference, BWHBC advocated for the normalcy of women's life events, from birthing to aging, and challenged frameworks that unnecessarily pathologized their bodies.

The relationship of tampons to TSS and women's health was therefore a serious concern for BWHBC. Esther Rome² had already published a menstruation brochure written in red ink, and was very concerned about the link between menstruation, tampons, and TSS. Rome was a well-informed feminist activist, and an important voice to include on the Tampon Task Force. Her colleague and co-author of the 1984 edition of OBOS, Jill Wolhandler, participated intermittently as well. The BWHBC was a significant advocacy group; with its heft representing women, calling upon them for letter writing campaigns, and publishing and distributing *Our Bodies, Ourselves*, the FDA and manufacturers could

not easily dismiss their concerns.

In addition to the consumer representatives, lawyers for the different parties attended meetings as well. David Swankin was general counsel for the National Consumers League, and Becky LeBuhn recruited him to the task force. He attended all the meetings and corresponded with the FDA and manufacturers and represented their interests. Swankin was the first executive director of the White House Office of Consumer Affairs under Lyndon Johnson, and later worked at the US Department of Labor. Swankin emphasized the dramatic divide between the consumers and manufacturers: "I cannot overstate the cultural gap that governed this entire thing. So there were legal considerations because of what was going on with Toxic Shock, [and] the cultural thing that just was overwhelming, *overwhelming* [emphasis in original]" (Swankin, 2016).

This "cultural thing" was not just the emergence of an active consumer rights contingent but feminism-in-action. The feminist advocates challenged assumptions, questioned language, and embodied a new approach. Together, they required the men to acknowledge and bear witness to the materiality and biological functioning of their bodies. Swankin recalled that an FDA representative came to one of the first meetings and said "you know, everything is a balance in medicine, even an aspirin can kill you." This approach was not well received by the advocates or Rome herself. Swankin remembered Rome arguing:

"excuse me," she says "I think that is probably true, but this is not medicine. It [menstruation] is a normal everyday process that half the world goes through and to treat it like an illness and therefore to say what you have is a risk/benefit, it is a risk you have to take into account, there is no benefit." And they did not like that.

Justifying risk to treat an infection or illness with medicine was one thing; a healthy person assuming the risk of death by wearing a superabsorbent tampon was quite another. Thus, the standpoints of the manufacturers, the FDA, and consumer advocates were quite stark. Characterizing their competing positions, Swankin compared them to entrenched international adversaries. "So right away it was like dealing with the North

Koreans to try to settle the problem. You couldn't do it because it was from such different perceptions" (Swankin, 2016).

Rome had a dynamic personality, and was not shy about getting her larger points across. Swankin recalled that at one of the first meetings, "Esther, comes in in a white dress...She was nursing her baby, and she was nursing [him] at the meeting. It was not enough to cover her breast; we're doing natural things here. You should have seen these guys [lawyers in the three-piece suits]. They were gulping, gulping, gulping," their discomfort palpable about the perceived impropriety. Swankin continued with his recollection of the scene, with Rome saying, "[you] know. We don't have to actually do anything. We can bleed all over our dresses; they do in many, many places. I don't know if you appreciate that, but it wouldn't bother me if we couldn't do something here. Maybe that's the alternative." Here, a veiled threat of abandoning tampons for an "alternative" approach reminded the corporate representatives of the collective influence millions of tampon wearers had on their future profits.

Rome, in a way, was living evidence of the political power of reproductive processes. With her behavior Rome challenged multiple norms: do not bring a baby to a business meeting, do not expose a breast in public, do not breastfeed in public, do not "free bleed" on a white dress. With her very body she offered evidence that had been excluded from the realm of common knowledge amongst these male corporate representatives and she demanded that they understand women's bodies differently. She also requested that payment for a babysitter of her choice be included in her travel expenses, although it was not deemed a legitimate cost of the trip to Philadelphia for the meetings. Her ability to push these boundaries was crucial because corporate representatives had not been confronted by menstrual realities in this visceral way. Though they had significant familiarity with their companies, marketing strategies, and the tampon as an object of manufacturing, they had little grasp of consumer expectations, preferences, and actual experience using tampons, and no embodied understanding of how well the tampons functioned (or not). This was

exactly why Becky LeBuhn knew that women needed to be the major voice on the Tampon Task Force. Simply by inhabiting their gendered male bodies, the corporate representatives did not have to participate in the social norms required to hide menstrual fluid. They were exonerated from the disproportionate cost of possible illness and death borne upon their bodies due to tampon-associated TSS.

Swankin recalled that the manufacturers really did not understand—or chose not to understand—the feminist advocates and consumer stakeholders, and their usual mode of business thinking did not help. The corporate representatives fell into de facto salesmanship, which pandered to the women rather than engaging their legitimate concerns. As Swankin put it:

[o]ne time they brought in Stephan–wife [Stepford-wife] types to the meeting, and the discussion that time was deodorants [in tampons]...The women that they brought were all dressed up, absolute straight out of New York ad agencies, and they had prepared expensive sample kits to pass out, of all the different things, and everybody threw in what they wanted to give them, in this little goody basket (Swankin, 2016).

The "freebie" baskets were ironically filled with the very deodorant tampons and products for which the women sought safety regulations and also had no intention of ever using. LeBuhn, who continued to serve as the convener and secretariat for the advocacy groups, felt that it was very condescending, as if the companies were trying to influence the consumer representatives with token gifts (LeBuhn, 2017). Swankin concurred, noting that the advocates "refused to take them. But that's another example, of obviously, they [the corporate reps] thought that by...taking a Madison Avenue approach that they [the consumer groups] were going to say 'Ah, I see what you are trying to do.'" And that was to get them to agree with the manufacturers that the products were perfectly fine as they were. Swankin concluded that the corporate representatives "just had zero connection in their minds to what people wrote [*Our Bodies, Ourselves*] and their allies," as he put it, which

included not only all the consumer advocates at the meeting but the strong grass-roots network that each organization cultivated.

It took awhile for the manufacturers to realize that the feminist health advocates and consumer groups would not easily be swayed and that they had multiple concerns. There were other tampon-related problems besides just a lack of absorbency standards: tensile strength of string so it would not break, particulates sloughing and fraying from the tampon's "pledget" wadding, applicators that cut vaginal skin, allergic reactions to embedded perfumes and deodorants, undisclosed leachable chemicals, and overall general "biocompatibility" (Kobren, 1981). Since none of this was tested for or regulated, it was an opportunity for sweeping policy recommendations. In this regard, a significant point of contention for the health advocates was the lack of available scientific data about any of these issues. The consumer groups had the burden of proof on their side since CDC scientists as well as state epidemiologists had reported a significant association with superabsorbent tampons and an increased risk of TSS (Osterholm, 1982). Additionally, manufacturers still could not prove definitively that tampons were uninvolved. Manufacturers were not forthcoming with all their data, calling it "proprietary," though Swankin felt results could have been easily squelched if they did not serve corporate needs. Furthermore, corporate lawyers were well aware of product liability lawsuits filed against all the manufacturers related to both bodily harm and deaths resulting from tampon-related TSS, the most well publicized and successful being *Kehm v. Procter & Gamble* (1982), concerning Patricia Kehm's death resulting from the use of Rely tampons (Riley, 1986).

The issue of data sharing and the integrity of the corporate-sponsored research was a serious concern. At the outset, the consumer advocates were at a disadvantage without their own scientific research lab to double-check data and results. The manufacturers possessed a depth of scientific know-how with engineers, biologists, animal labs, and money to run any number of tests. The consumer groups had no such resources or facilities. Furthermore, Swankin reflected, "[t]he

manufacturers, nobody believed them...it was going to be bought research." He added, "[t]here were all these allegations [about proprietary studies], that if the study was legitimate, and it came out and it didn't say what they wanted it to hear they'd kill it, so we'd never see it anyway." Due to the lack of open sharing, and fears of proprietary secrets being revealed not only to corporate rivals but the broader public, the data collected was not made available to the advocates to examine. Furthermore, ASTM would not pay for tests at the behest of the consumer groups. Within the negotiating structure, they were at the mercy of manufacturers and data produced by in-house scientists who chose whether or not to share. The consumer groups had no way to evaluate the validity of scientific presentations without their own lab to corroborate or challenge the methods and data. This was about to change.

Fighting Fire with Fire

If absorbency was the key factor to convey in warning labels, it was important to have data on it. The Tampon Task force was charged with creating a standard for measuring absorbency and a standard for intra-laboratory results. The consumer groups and health advocates wanted one that was not solely in service of the manufacturers, and at the same time through their presence they did not want to give tacit approval for a hollow standard (Memo, 1983). The consumer groups recognized that they needed a sympathetic scientist with access to a lab to help them translate their feminist intents through the language of science to the other manufacturers at the negotiating table. They found this in Nancy Reame.

Reame met Rome in the late 1970s at a small conference sponsored by the Society for Menstrual Cycle Research (SMCR). She held a Master of Science in Nursing and was just finishing her PhD in Physiology, focusing on reproductive sciences. She had always been interested in women's reproductive health, including the endocrinology of

menstruation, and was headed toward a tenure-track position in the School of Nursing at the University of Michigan. Later in her career, Reame was named to the Institute of Medicine and became a fellow with the American Association for the Advancement of Science. Her work on endocrinology and menstrual health brought her to the SMCR meeting. There, Reame learned about the problematic politics of tampons.

First, she got a crash course in tampon testing from a newly hired researcher at Kimberly-Clark Corporation, the manufacturer of Kotex sanitary napkins and tampons, whom she met at the conference. This researcher, referred to here as "Karen," confided in Reame about the overall lack of understanding the corporate scientists had about all things vaginal and menstrual. Reame summarized the essence of their conversation.

[Karen] said "[y]ou would be amazed how tampons are tested by the industry...They hired me because I'm the first reproductive physiologist they have in the feminine care division. It's all paper chemists. It's all men. They don't use menstrual fluid. They don't use blood of any kind. They use blue dyed saline water. It's pretty clear it's repugnant to talk about menstrual blood much less work with it in the lab." And she [Karen] said, "[w]hat's worse, they don't even understand the functioning of the female human vagina." And she said "[t]hey hired me, [and] as part of the interview when I sat down, they said could I please draw a human vagina, just the anatomy?"

Reame commented,

[a]nd that was pretty much the extent of her interview...They knew enough to go after a physiologist, but two other male candidates were vying for the job: one a primate specialist, one a guinea pig physiologist, and she herself was a basic scientist in reproductive physiology. [Karen] said, "I was working with guinea pigs, but I have a vagina, and I knew enough about basic anatomy that I drew the right relationship of the vagina and uterus from my anatomy class," and she said, "and I got the job." And she said "[t]hat just

shows the level of ignorance in the feminine care industry; no wonder something serious was going to happen" (Reame, 2016). The conversation left an impression upon Reame about the systematic misunderstanding of women's bodies in relation to menstruation and tampon development. Following this meeting, Karen invited Reame to Neenah, Wisconsin and the headquarters of Kimberly-Clark Corporation to present her dissertation work on the biology of menstruation. The seminar resulted in a one-year, \$25,000 contract to conduct viscosity studies of menstrual fluid. This late-1970s interaction was the last of Reame's connection to the company.

The second important result of attending the SMCR conference was that Reame met Esther Rome. Rome had not forgotten her. After the first two meetings of the Tampon Task Force, it was clear that the health advocates needed scientific help, and Rome reached out to Reame. Reame remembered Rome, saying to her 'you're not going to believe this! They expect us to just buy into their data! We aren't going to do that. We need somebody who can do this!' (Reame, 2016). Rome further explained to Reame why it was so important to get her on board. Reame recalled her saying,

"[y]ou are the only person in the country that's ever worked with menstrual blood! We don't want an epidemiologist, we don't want someone who can crunch the numbers, we want someone who's actually done some clinical research." I said of course! I love it!

This sounds like such an adventure! (Reame, 2016).

Reame joined forces (receiving \$2,500 for the lab studies) and attended the meetings alongside Rome, Swankin, and the others, thus legitimizing their position. Swankin explained, "Nancy was the connection to the science; she could explain deep science" and had a fluid way of doing so, and she "played that role of connecting science to activists." In addition, Reame had "a very important function; they [the corporate representatives and lawyers] respected her, you couldn't laugh at her, you couldn't make believe she wasn't there" (Swankin, 2016). With Reame on board, the consumer groups and feminist advocates could

participate in a more robust manner, matching science with science.

Setting a Test Method: The Syngyna

The syngyna—a synthetic-vagina test apparatus—was a device designed to measure tampon absorbency. It was developed in 1958 by G. W. Rapp, a professor of biochemistry and physiology at Loyola University Chicago for the Campana Corporation, which manufactured Pursettes tampons (Rapp, n.d). As his lab report explains, Rapp first devised some basic methods to measure absorbency, such as dripping a measured amount of fluid on a tampon or dunking a tampon in a flask filled with fluid until it reached full capacity, but neither seemed to replicate body temperature, muscular pressure, or angle and positioning of a vaginally-worn tampon. He tried developing an "in vivo" test using women as test subjects but rejected this approach because they presented too many uncontrollable variables. As a result, he devised a glass vacuum tube with a hydrostatic head, and inside the tube a condom pulled taut served as the vaginal orifice. It was surrounded by a warm water bath to simulate body temperature (Figure 1 and Figure 2). The hydrostatic head controlled the flow rate of the liquid entering the syngyna chamber. (To see a modern version in use go to "Tampons—Syngyna Test by SGS" on YouTube, <https://youtu.be/KYXUQDzSg4o>.)

The absorption testing methodology called for either a saline solution or a viscous material called "blue goo"—composed of cellulose gum, glycerol, sodium chloride, sodium bicarbonate and water—to be used as the control (Rapp, n.d.). To make this a "known" in an experiment, it made sense to produce a fluid with consistent elements that any decent lab technician could create. This helped to eliminate variables and focus upon the unknown properties of the tampons, each with their various sizes, shapes, and absorbencies. The syngyna apparatus and test method circulated throughout the industry as a means of determining tampon absorbencies, but it had not been scrutinized in terms of its efficacy to set a federal standard. This was one of the goals

of the Tampon Task Force. Thus, the Bureau of Medical Devices, a division of the FDA, and the manufacturers began using the syngyna test to assess its accuracy across brands, but the consumer groups and feminist health advocates were left out until Nancy Reame joined them. The task force accepted Reame as a peer scientist, and one of the manufacturers sent her the specialized syngyna lab apparatus to begin. She said that when it arrived, there were plenty of jokes about it in her all-female lab, including speculations about "vagina envy." They named theirs Sally (Reame, 2017).

The very basis of the standardizing process was questionable to Reame and the health advocates. The syngyna was a poor representation of the dynamic vagina, and its methodology excluded real menstrual fluid. The feminists questioned whether or not the saline was a sufficient stand-in for menses, which was complex during any given menstrual cycle, containing proteins, mucus, and cellular debris as well as blood. This lab-made representation of menstrual blood was decidedly synthetic, and not in any way a natural product of a woman's body. What kind of effect would a simulated product rather than menstrual fluid have upon absorbency? The consumer advocates did not know, and even if the industry scientists had any inkling, they certainly were not going to say, for fear of revealing anything they perceived as proprietary or legally incriminating.

The convenient de-gendered and dehumanized syngyna erased all forms of difference, from the size of the vaginal canal, with its shape, angle, elasticity, length, and circumference, to the fluids coming from it, eliminating vagaries of menstrual fluid from watery to clotted and its rates as well as volume, which women would never conceptualize and measure in grams anyhow. Perturbed, Reame recalled that even the canal itself was represented by a condom, "Sheik" unlubricated #9, loaded with racialized and ethnic overtones (Reame, 2017).

The reduction of vaginal canals to one form and shape had a long history with tampon developers. Earle Cleveland Haas, a doctor of osteopathy and the inventor of the Tampax tampon in the 1930s, held a

similarly dismissive attitude. When asked if he measured any part of the vagina or cervix during the development of Tampax, Haas remarked, "I have seen so damn many of them I had an idea. Some are short and some are longer, of course, but that didn't make any difference" (*Kehm v. Procter & Gamble*, p. 1179). Reame wondered aloud what kind of testing device women might devise, for surely it would not involve a condom. Reame challenged this entrenched legacy of reducing menstruation to a simplistic mechanical process disconnected from the materiality of bodies and launched a research program to alter the science.

By 1983, Reame's lab at the University of Michigan became one of the eight (she estimates) to test the differences in absorbency amongst the pooled tampon samples across a range of categories (Regular, Super, and Super-Plus) provided to her by the other manufacturers. Her lab was on par with the industry labs, which was critical in terms of legitimacy, especially since she was the sole investigator to test tampon absorption of blood. In her prior studies for Kimberly-Clark, she tapped into her OB/GYN nursing network and asked the labor and delivery nurses to collect their own menstrual fluid in a menstrual cup called a Tassaway. For the syngyna experiments, she dropped by the hospital blood bank to gather outdated donated blood, which the technicians were more than happy to offload. (These were the days before HIV and there were no IRB protocols, so this grassroots approach was a creative and pragmatic solution.) Early on in planning the design of the studies, Reame had proposed to the task force using heparinized blood as a comparative test fluid against saliva at all eight study sites, but was told by several industry scientists that such an approach would simply not be realistic under laboratory conditions (although no data were ever presented she pointed out). Deciding to proceed anyway with testing both saline and blood, she was pleasantly surprised when the donated blood performed as well as a reproducible test fluid (Reame, 2016).

Reame reflected on the results and commented, "the overall findings were pretty close to what I showed in my lab, which makes me think they were all pretty on target," but "I couldn't get a handle of how

similar my data were with everybody else's, although they all...had to contribute and show data, but nobody wanted to say [what they had]. That just made me mad. That's just not the way [we do things]. We're used to sharing." Here, her understanding of both good science and feminist science came to the fore. There was not an open practice of sharing data, and Swankin felt that the industry folks were always hedging for the next lawsuit, worrying about every possible implication of the data in terms of liability. This was not entirely unwarranted since Procter & Gamble had been successfully sued for product liability due to injuries and deaths related to Rely tampons, and there were at least one thousand cases in the works against them alone (Gruber, 1989; Vostral, 2011). Swankin also recalled that the litigation lawyers were a different crew than the task force lawyers, indicating an extensive legal department to look out for each of the manufacturers interests, yet another challenge for the resource-deprived consumer groups.

The report that Reame submitted to the Tampon Task Force titled "Comparison of Syngyna Fluid and Venous Blood Using the Syngyna Absorbancy (sic) Test" drew attention to some important differences in findings between saline and heparinized blood (Reame, 1983). Esther Rome and Jill Wolhandler also chimed in with Reame in the "Letters" section of *JAMA*, the *Journal of the American Medical Association*, bringing feminist science to established and mainstream medicine. As they saw it, there were "questions about the statistical validity of the analysis of test data presented to the task force" in which the results using saline and heparinized blood were different. "Although the relative ranking of the product does not change," they stated, "the differences in absolute absorbency seem significantly different at the higher absorbencies, with much more blood being absorbed" (Rome, Wolhandler, & Reame, 1988, p. 686). This raised the concern that some tampons might be miscategorized as less absorbent than they actually were; when presented with menstrual fluid they would absorb more than they did with saline. This had potential health ramifications if women thought that they were using a less-absorbing tampon due to the way it

was potentially mislabeled. Here, the very basis of the standard could be inherently flawed due to the use of a less-than-ideal synthetic fluid in the lab protocol.

For the consumer groups and feminist advocates, the goals of the study were to establish absorbency ranges measured in grams of fluid, which then correlated with an agreed-upon nomenclature such as Regular, Super, and Super-Plus. The manufacturers argued on both fronts. They wanted decent margins within a category due to the fact that not every tampon, even from the same lot number, is exactly the same. For example, a box of Regulars could contain tampons that absorbed more or less, and the manufacturers wanted these allowances likely because the machinery was not calibrated for this kind of precision (Swankin, 2016). The other hurdle was nomenclature, since the terms used were generated by marketing departments. Both Tampax and Playtex produced Super tampons, but Playtex absorbed far more. Regularizing the Super designation would force material changes for one or both. As these companies were fierce business competitors, the stakes were high concerning the implications of the standards for market share and costs.

The naming of the sizes remained a problem. Several ideas were floated. One was to do nothing and just list the grams of absorption. This allowed advertisers to use any words they wanted to describe the product, which would prolong the misunderstandings. Another was to create a scale similar to sunscreen, with higher numbers correlating with higher absorption, also conveyed numerically in grams. This, Rome insisted, was equally confusing and misleading (Rome & Wolhandler, 1985). Steve Fellman, the lawyer representing Tambrands, Inc., described how manufacturers suggested offering "small, medium, large, and extra large" as possible terminology, but this was not well received (Fellman, 2016). The implication was that this system correlated to vaginal size rather than tampon absorbency, which had no relationship to one another.

The task force as a whole, however, never came to any

agreements and disbanded by 1985. Rome and Wolhandler wrote a letter to the Living Section of *The New York Times* indicating "[o]ne thing we learned from the Tampon Task Force is that the materials used in tampons have not been tested adequately. Most have never been studied in the vaginal environment" (Rome & Wolhandler, 1985). Furthermore, Rome wrote that the manufacturers ultimately agreed "on an industry standard for the Syngyna test that is similar to the test proposed by the American Society of Testing and Materials and that continues to have the same flaws" (Rome, Wolhandler, & Reame, 1988). Fellman may have had influence behind the scenes with manufacturers, however, breaking the stalemate amongst them. Whether it was his personality, the fact that Tambrands had not succumbed to the "absorbency wars" (as they were referred to in-house), or that the company simply had less to lose, he likely helped convince some manufacturers to agree to absorbency ranges and terminology. But this still included the flaw mentioned by Rome: the use of saline rather than blood or menstrual fluid in the syngyna test.

Even though the Tampon Task Force did not achieve its goals, letter-writing campaigns to the FDA spearheaded by BWHBC and a lawsuit brought against the FDA by the Public Citizen Health Research Group pressured the agency to act on the issue of labeling, which was still unresolved (Public Citizen, 1988). The judge ruled in the consumers' favor that the FDA must publish a final regulation by October 31, 1989. The final categories for absorption by grams as well as nomenclature came that year, with standardized labeling for tampons effective in March of 1990 (CDC, 1990; Farley, 1991). The final standards were defined in terms of ranges, while keeping the same language of the marketers, though regularizing the meaning: 6 g or less (junior absorbency), greater than 6 g up to and including 9 g (regular absorbency), greater than 9 g up to and including 12 g (super absorbency) or greater than 12 g up to and including 15 g (super plus absorbency) (Federal Register). That information about absorptive ranges and their correlating definition was finally encoded into federal policy was a success. These ranges and

descriptive terms were non-negotiable elements for the consumer groups and health advocates from the very beginning. Their influence upon the Tampon Task Force is printed upon every box of tampons by its display of absorbency ranges, so that women can have accurate information about their tampons in an effort to best match their menstrual flow.

The Elusive Pursuit of Standards

Despite the success of labeling in terms of grams and nomenclature, the feminist advocates felt shortchanged. They had far greater ambitions for tampon safety and wanted to address chemical residue in deodorant tampons and their perfumes, string breakage, plastic applicator lacerations, and overall material safety. They wanted standards for these things, but in the end they all got dropped. In part, early conversations by the task force about these agenda items helped the manufacturers delay discussions about the real issue of absorbency, and detracted from the greater goal at hand. At a certain point, the consumer groups and health advocates realized they needed to distill their efforts to focus on one issue rather than diluting things with lots of demands, though they were legitimate. They were unable to get all the industry scientists on board to use any form of blood, which ironically would seem to offer more accuracy in terms of replicating real life conditions. It may also be that there was not a critical mass of feminist scientists in the room to overcome the prevailing norm for saline. Even Sydney Wolfe of the Public Citizen Health Research Group, who supported labeling and helped to sue the FDA, sided against feminist science in support of saline. He argued that because blood came from different sources, it was simply impossible to reproduce lab conditions and standardize tests, thus saline was the best test fluid upon which to base absorbency standards (Wolfe, 1987).

The results for both saline and blood did yield the same rank order of tampons, so using blood was not necessarily required, though the protest about the higher absorbency of blood was never resolved and tampon users remain in the dark about this important piece of

information. Yet, the very act of offering an alternative means of envisioning the methodology and providing data challenged dominantly held views about the insignificance of menstrual fluid. The women's health advocates, and especially the influence of Esther Rome, was felt beyond the standard setting process. Some of the men were personally affected by their involvement with the task force. Swankin acknowledged he got "a real education" from the women on the task force, and he appreciated the way Rome raised her points. Steven Fellman, the lawyer who represented Tampax, Inc. took a copy of *Our Bodies, Ourselves* home to his wife due to meeting Rome, something he would not have done otherwise (Fellman, 2016).

Conclusion

The process to agree upon an absorbency standard suffered on multiple fronts during the 1980s: President Ronald Reagan's administration was unsupportive of new federal regulations, industries resisted changes to tampon packaging and product design since they threatened profitability, and there was no critical mass of feminist scientists on board with the proposed methodology. Though the task force disbanded without agreement in 1985, the process of bringing consumer groups, health advocates, and corporate representatives together marked an important precedent in standard setting. Furthermore, some of the goals of the feminist health advocates were included in federal labeling guidelines appearing five years after the last official meeting of the Tampon Task Force.

The need for more precise labeling and testing remains. Categorized as Class II medical devices, tampon contents are considered "trade secrets" and not publicly disclosed, so there is still no way to know what materials or chemicals they may contain, even when a new product is introduced, or how they might relate to TSS. Carolyn Maloney (D-NY) introduced the Tampon Safety and Research Act in 1997, renamed the Robin Danielson Act regarding tampon safety, in recognition of Danielson's death due to TSS in 1998. For nearly twenty years Maloney

has pursued this legislation, to no avail. It would require independent research upon tampons and sanitary napkins to gauge their health impact, and content labeling similar to clothing or food (H.R. 1708, 2015). This basic information is long overdue, and the threat of a House bill along with grassroots protests have compelled some manufacturers such as Kimberly-Clark (Kotex) and Procter & Gamble (Tampax, Always) to list ingredients (Kounang, 2015).

This historical case study points to the significant implications of consumer groups and feminist advocates using tactics learned while writing *Our Bodies, Ourselves* and deploying them in the federal regulation process by producing their own scientific data. It also highlights the importance of feminist ideas privileging women's understandings of their own bodies to shape science during the 1980s, in the face of the unknowns related to Toxic Shock Syndrome. Though the overall lab methods employed may seem conventional, the testing of actual blood when it was purposely excluded demonstrates resistance to status quo scientific practice. Importantly it asserts the primacy of bodily experiences to menstruation and Esther Rome's insistence upon flesh, vaginal orifices, and menstrual blood being inseparable from the tampon as a technology—women's bodies were the requisite context.

The syngyna summarily detached menstruation and tampons from women's embodied experiences by instrumentalizing them for lab purposes. Women and their bodies were invisibilized and simulated by technoscientific apparatus, with differences erased and then standardized into glass, tubing, and latex condoms (which, incidentally, come in various sizes to accommodate differently shaped penises). All difference between women was extricated; the resulting data from the syngyna test were more "real" than could be gathered from a flesh-and-blood person. Yet, the quality of the data drawn upon to set policy recommendations was absolutely crucial to absorption standardization. Feminist science both questioned assumed lab practices as well as devised new methods, insisting upon the biological materiality of menstruating bodies in an effort to accurately label tampon boxes and

therefore stem the rates of tampon-related TSS.

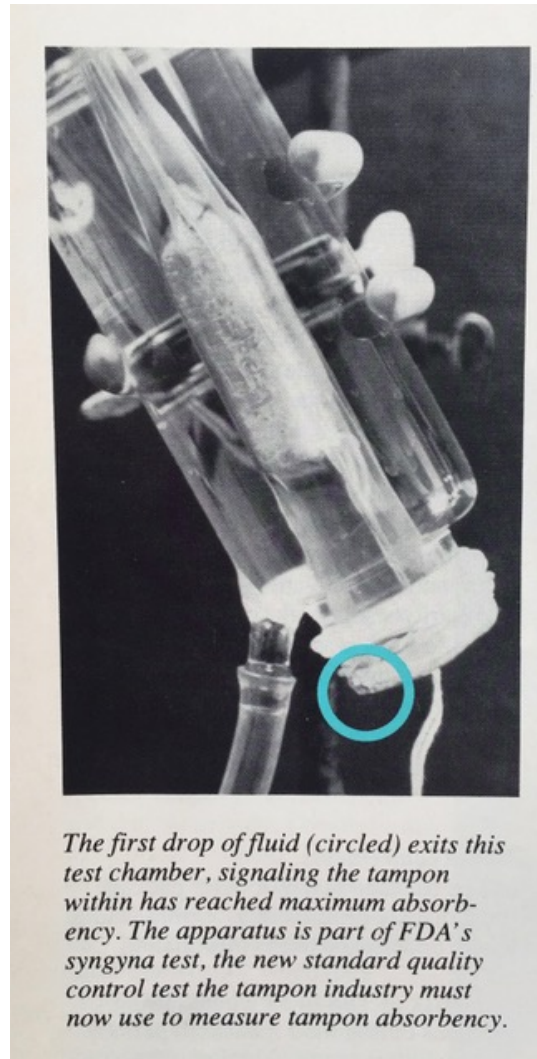


Figure 1. Image of the syngyna apparatus glass tubing with tampon. In Dixie Farley (1990, February), Preventing TSS: New tampon labeling lets women compare absorbencies, *FDA Consumer* 24(1), 8.

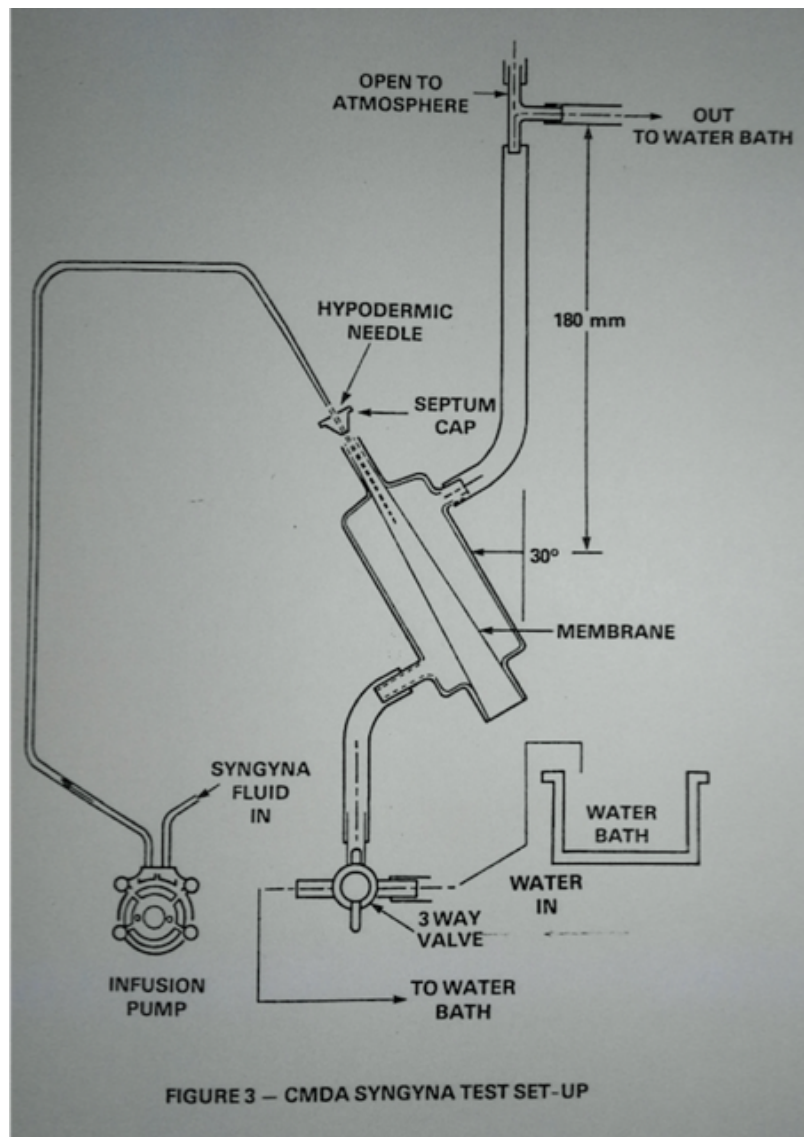


Figure 2. Line drawing of syngyna lab apparatus. In D. E. Marlowe, R. M. Weigle and R. S. Stauffenberg, (1981, May), "Measurement of Tampon Absorbency Test Method Evaluation," FDA, Bureau of Medical Devices, Report 81-013, Schlesinger Library, BWHBC, box 29, folder 2.

Notes

¹ The term "women" is used in its historical sense in this essay, since that was the common parlance of the moment.

² Esther Rome passed away in 1995, and her papers are part of the BWHBC records at the Arthur & Elizabeth Schlesinger Library on the History of Women in America.

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