

REVIEW

Rely and Toxic Shock Syndrome: A Technological Health Crisis

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This essay examines factors leading to the identification of Toxic Shock Syndrome with the bacteria *Staphylococcus aureus* in 1978 and the specific role of Rely tampons in generating a technologically rooted health crisis. The concept *biologically incompatible technology* is offered to explain the relationship between constituent bacteria, women's menstrual cycles, and a reactive technology that converged to create the ideal environment for the *S. aureus* bacteria to live and flourish in some women. The complicated and reactive relationship of the Rely tampon to emergent disease, corporate interests, public health, and injury law reveals the dangers of naturalizing technologies.

INTRODUCTION

Since the early 1980s, health advocates, marketers, scientists, and physicians have taught menstruating women that the use of a tampon may cause Toxic Shock Syndrome (TSS†). For the most part, we have a general understanding that tampons are to blame for TSS. One college student

said that in her microbiology class, she learned “if you leave a tampon in too long, you can get Toxic Shock Syndrome.” This message has been so well distributed and internalized that this misleading statement is understood as scientific fact. However, despite the good intentions to protect women's health, the message about the

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†Abbreviations: CDC, Centers for Disease Control; FDA, Food and Drug Administration; TSS, Toxic Shock Syndrome; TSST-1, Toxic Shock Syndrome Toxin-1; FDCA, Food, Drug and Cosmetic Act; MDA, Medical Device Amendments; MRSA, methicillin-resistant *Staphylococcus aureus*; EIS, Epidemic Intelligence Service.

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dangers of tampons perpetuates a crucial misunderstanding. Tampons alone do not cause TSS. Specifically, the bacterium *Staphylococcus aureus* (*S. aureus*) is responsible for TSS, and its role and complicated relationship to the tampon have vanished from the message.

In an effort to simplify warnings, protect women's lives, and stem a potential epidemic at one moment during the early 1980s, the irrefutable link between tampon use and possible death served a necessary purpose. Yet, the simplification not only overlooks facts, it has perpetuated misinformation, instilled unnecessary fear in women, and placed the responsibility upon women to police their bodies to prevent TSS. The historical memory about the production of synthetic (rather than cotton) tampons and the identification of a disease has been reduced to warning labels and informational pamphlets, making tampons culpable for a deadly bacterial infection while simultaneously universalizing all women to be at risk.

This essay examines factors leading to the identification of Toxic Shock Syndrome with the bacteria *Staphylococcus aureus* in 1978 and the specific role of Rely tampons in generating a technologically rooted health crisis. I develop the concept of *biologically incompatible technology* to explain the relationship between constituent bacteria, women's menstrual cycles, and a reactive technology that converged to create the ideal environment for the *S. aureus* bacteria to live and flourish in some women. Identifying and naming the condition associated with the symptoms presented by these women proved to be one underlying challenge. Linking these symptoms not only to a bacterium but also to a new technology — the Rely tampon produced by Proctor & Gamble — created a second problem. Lastly, warning women about the danger of using tampons constituted a third element of this health crisis. Each phase utilized science in a different way to manipulate action. How the science was used and by whom is also an underlying theme in this story of the technologically rooted health crisis of TSS and tampons.

BACKGROUND: TOXIC SHOCK SYNDROME

In order to better understand the historical origins of tampon-related TSS, it is useful to begin with the currently accepted clinical case definition of TSS put forth in February 1980 and established by the Centers for Disease Control (CDC). According to the CDC, the clinical case of Toxic Shock Syndrome included a fever of 102 degrees or more, rash, desquamation (flaking, peeling skin), and hypotension (drop in blood pressure, dizziness). It also included the broad category of "multisystem involvement," which encompasses three or more of the following: gastrointestinal (vomiting, diarrhea), muscular pain (creatine phosphokinase levels twice that of normal), mucous membranes (enlarged blood vessels of the eye, throat, or vagina), renal dysfunction (blood urea nitrogen or creatinine twice that of normal without the presence of a urinary tract infection), liver dysfunction (serums twice that of normal), blood abnormalities (platelets less than 100,000/mm³), and central nervous system issues (disorientation). Lastly, negative results ruling out diseases such as measles and Rocky Mountain spotted fever and negative throat, blood, and cerebrospinal fluid cultures eliminated diseases with similar symptoms. The CDC also indicated that a TSS diagnosis of "probable" included five of the six categories, while "confirmed" included six of the six categories [1].

A condition named in 1978 and further defined in 1980, Toxic Shock Syndrome had been identified across the population, including both adult men and children. However, its etiology took a unique course with the overwhelming majority of cases at the time linked to tampon-using women. The particular strain of *Staphylococcus aureus* responsible for tampon-related Toxic Shock Syndrome is more specifically referred to as Toxic Shock Syndrome Toxin-1 (TSST-1). Though TSS seemed to come out of nowhere, the bacterium *Staphylococcus aureus* is not new. Named in 1884 for its yellow-hued clusters, *S. aureus* produces a variety of ailments from rashes, pimples,

and boils to more serious bouts of food poisoning [2]. It is responsible for a variety of diseases, and about 20 percent of the general population carries *S. aureus* on the skin and many more carry it in the nose. *S. aureus* has different relatives, some of whom produce enterotoxins, harmful and toxic proteins specific to cells in the intestine and responsible for food poisoning. Others create exotoxins, toxic materials secreted and released by the bacteria that may travel throughout a person's body. More recently, methicillin-resistant *Staphylococcus aureus* (MRSA), currently known as the "super bug" contracted in hospital-like settings, has gained notoriety.

AN EMERGENT TAMPON TECHNOLOGY: RELY

The link between TSS and tampons was not intuitive. Tampons had become a trusted and normalized technology in upwards of 70 percent of women's hygiene routines [3]. What had changed were the materials, whose composition shifted from cotton to synthetic materials [4]. Companies often sought cheaper ingredients, and rayon — derived from wood pulp and combined with cotton — served to be a cost-effective and efficient absorptive material in some tampons. As new polymer technology emerged during the 1960s, companies began to add more synthetic materials, such as polyacrylates, to tampons. Most major brands utilized synthetics to varying degree, including Playtax, Tampax, and Kotex. Though the components changed, tampon shape and design did not alter substantially [5].

A newcomer to the tampon market, Proctor & Gamble needed a radically superior product to lure consumers from traditional brands. It aimed to revolutionize the market when it introduced Rely, named presumably because it was more "reliable" than other products. According to the packaging, women could also rely on it to manage mental strife because "it even absorbs the worry" [6]. Researchers there championed a tampon composed of

polyester foam cubes and chips of carboxymethylcellulose, an edible thickening agent used in puddings and ice cream and known as "grass" — recognized as safe because it passes through the body without decomposing [7]. Encapsulated within a polyester teabag-like pouch, the tampon was unlike any other. According to Martin Cannon, Associate Director of Product Development at Proctor & Gamble, the biggest problem that the researchers identified with available tampons was the issue of "bypass," the tendency for menstrual fluid to flow past the tampon, which resulted in leaks. This was due, in part, to the shape of the tampon that usually expanded lengthwise, without conforming to the contours of the vaginal cavity [8]. Thus, the design intention of the new tampon was good because it worked with vaginal physiology by expanding widthwise as well.

During the design process, corporate scientists followed generally accepted standards of product safety, which in retrospect proved to be shortsighted. This was in part due to changes in regulations, which at the time seemed to be fortuitous for Proctor & Gamble. In May 1976, new regulatory policies emerged in the Food & Drug Administration (FDA) to ensure the safety of medical devices, known as the Federal Food, Drug and Cosmetic Act (FDCA). The act regulated labeling and branding, with an eye toward protecting consumers from misleading claims. In addition, the Medical Device Amendments (MDA) set further protections by requiring that companies seek "pre-market approval" for new devices from the FDA [9]. Re-categorized, tampons and sanitary napkins were now no longer cosmetics but medical devices, just like toothbrushes and pacemakers. The Rely tampon, however, was first test-marketed in Fort Wayne, Indiana, in 1974, predating the new 1976 FDA regulations that spared it from testing [10]. As such, Proctor & Gamble was not bound by federal law to produce scientific evidence concerning Rely's safety because it was "grandfathered" in.

Marketers blitzed mailboxes as early as 1975 with sample packets of Rely, and the tactic proved wildly successful. Rely was officially introduced for sale across the country in August 1978, with marketing efforts escalating each year. The number of packets — with four tampons per box — distributed through the mail was impressive and aggressive: 45 million samples distributed, with the April 1980 campaign alone numbering 16.8 million samples [11]. In an interview with Lisa, she recalled receiving these samples and saving them for a special occasion. As she explained: “It was 1980, and Styx was playing at the Cow Palace in Oakland. We took the BART from San Jose (or rather Fremont, near where we lived) and anticipated little bathroom access” at the arena so the tampons offered a big “convenience” to her instead of waiting in the predictably long lines at the women’s restroom. It was the first time she had used Rely, and the tampon worked amazingly well. But, she said, “I remember removing that Rely tampon after getting home late at night and wondering whether I had lost my virginity, that thing had gotten so huge. I stopped using them after that because of being too grossed out.”

As it turned out, there was more to fear than a perpetually expanding tampon. The unique components, instead of being inert as Proctor & Gamble scientists assumed, possessed what I call reactive traits that set into motion a complex chain of events that few understand well to this day. Philip Tierno, a politically active microbiologist, contends in his 2004 book *The Secret Life of Germs* that there were three major factors promoting *S. aureus* to present as TSS. First were the synthetic components of Rely, consisting of foam cubes and the gelling agent carboxymethylcellulose encased in a polyester pouch. The gelled carboxymethylcellulose in essence acted like agar in a petri dish, providing a viscous

medium on which the bacteria could grow. Along with this, the foam cubes offered increased surface area for proliferation. Second was the changing pH of the vagina during menstruation, to about 7.4. The optimal pH for *S. aureus* to trigger TSS is 7, or neutral. The relatively acidic, non-menstrual vagina measures a pH of about 4.2, which keeps *S. aureus* well in check. Tierno also hypothesized that a tampon introduces both carbon dioxide and oxygen into the usually anaerobic vagina, thus the gases offered an abundant food source to *S. aureus*. Finally, the pyrogenic toxins produced by *S. aureus* induced fever in humans. This fever of about 102 degrees proved to be the perfect temperature for *S. aureus* to reproduce and thus create further deadly toxins [12]. An additional factor was a woman’s age; many adult and older women had built up immunity to some forms of *S. aureus*, while young women and teenagers were more susceptible without a developed immune response to the pathogen. In some cases, TSS presented as mild, flu-like symptoms, while in others the toxins released literally sent the person into shock.

Though Tierno’s work is readily accessible to lay audiences, many other scientists and research groups have examined TSS and TSS-1 and published results in various academic journals that detail conflicting results and no definitive answers.¹ These multiple variables intensified the health crisis. There was no scientifically agreed upon understanding of how tampons specifically triggered TSS; the bodies of only some and not all women harbored *S. aureus* that then ramped into overproduction. *S. aureus* might be part of the normal ecology of a woman’s body, be a passing germ, or successfully eliminated from her body by her immune system. Not all of these variables were recognized at the time, and even as some characteristics emerged, they were difficult to translate into a health warning. And, though other tampons also triggered TSS, Rely

¹It is not the goal of this essay to list all the scientists who have researched *S. aureus* or TSS and adjudicate their scientific accuracy, but to shed light on how scientific thinking influenced policy decisions that ultimately affected women’s perceptions about their bodies and how each should manage her own period.

shouldered the brunt of the responsibility for the outbreak.

CONCEPTUALIZING BODIES, BACTERIA, AND INJURY

At root, the tampon, once a culturally risky technology, had been embraced by a majority of women and many manufacturers by the late 20th century. So ubiquitous was the technology that catastrophic dysfunction seemed improbable. In part, this was also due to a prevailing notion of the body as an independent agent. As historian Linda Nash has pointed out, the modern conception of the body relies upon a bacteriological notion of disease as existing outside an otherwise healthful person. She calls for reclaiming the ecological body, one more porous and situated with and within a landscape and environment, often polluted with industrial toxins also now found in human bodies [13]. I am suggesting an even broader framework of bodily ecology to look inward to include an ecology complete with bacterial constituents. I argue that this model must take into account the internal ecologies, for though the body is also subject to its external environment, it is situated among conditions created by not only bacterium, but viruses, fungi, and the like. Some also refer to this ecosystem as a personal microbiome, and the NIH has embarked on a project to characterize these communities with the Human Microbiome Project (HMP).

This means looking to bacterium with a different perspective and using different language to explain its behavior and activity. We have come to understand bacteria as having some generalizable traits. There is “symbiosis,” when organisms often live and interact together [14]. More specifically, this relationship may be mutual (benefiting both organisms), commensal (benefiting one but not harming the other), and parasitic (living at the expense of the other) [15]. Heather

Paxon refers to political debates about bacteria, and particularly food pasteurization, as micropolitics [16]. Extending her discussion of politics, I suggest that claiming bacteria as constituents eliminates the need to evaluate them as good or bad. Some bacteria are simply part and parcel of being human, and considering them constituents affords them a bit of recognition in the larger body politic. Labeling bacteria as constituent also avoids the problematic constructions of the “host” body, in which a universal male bears the burden of feeding the greedy pests. Never mind that the body is not a gendered female hostess; the body simply becomes the site for unwelcome, ungrateful, and usually harmful guests. Constituents also demand a degree of representation, unlike the bacteria that form “colonies” that rebel against the master body and take on the pejorative role of an invader [17]. According to this model, the body is not a holistic ecosystem, but a primary empire exerting dominance, power, and control.

This naturalized understanding of the body as empire falls far short in conceptualizing how multiple life forms interact with technologies in and of the body. It may be that there are technologies that are fundamentally compatible with muscle tissue, but not the indigenous bacteria living quite well on the skin. I suggest the category *biologically incompatible technology* to help interrogate those innovations that are not primarily deadly or harmful to humans but have potential to produce other biological harm through their use.² With this analytical move, I suggest that it is not enough for scientists and designers to consider just the human body, but a core question in the design of medical and bodily technologies must also be “how will this object interact with bacterial constituents?” Furthermore, we should ask how emergent nanotechnology will interact with bacterial constituents. A premise of my analysis is to consider the

²In the appendix to “Biotechnology in the Twentieth Century,” Robert Bud lists evolving terms for biotechnology, in which Craig & Boelter introduced biologically compatible technology in 1947. I, therefore, am suggesting the opposite of this, which must be understood in terms of multiple life forms and biologies including bacterium. See Bud, Robert, “Biotechnology in the Twentieth Century.” *Social Studies of Science* 21.3 (August 1991): 415-457.

two non-human entities of tampon and bacteria as necessary and vital cofactors of a medical and technological drama [18,19,20]. In the case of TSS, this powerful relationship between technology and bacterium was not just overlooked (since this would imply willful disregard) but worse, unimagined as a possibility.³

As a technology capable of inducing TSS, Rely tampons did not fit the mold for usual measures of product injury. It differed because it possessed the potential to precipitate a reactive consequence, but not necessarily direct injury from the object per se. The uneven injuries were difficult to track medically and from a legal, compensatory model as well. This is not a surprise. The likes of lead poisoning, asbestosis and mesothelioma, and other environmental pollutants are constant reminders of damage caused by human-created products [21,22,23]. Sarah Lochlann Jain has theorized about the social and economic consequences of human wounding resulting from manufactured goods. She argues that injury is not merely an unfortunate accident, but integral and assumed within consumption and, therefore, capitalism itself. She suggests “injury law demonstrates the recursive way in which design issues also materialize and naturalize sets of injuries as visible and compensable or invisible and non-compensable” [24]. Jain looks at examples such as the Ford Pinto, cigarettes, and keyboards, to name a few. In these types of cases, the relationship of technology to injury can be interpreted as causal.

The resulting injury brought about by Rely, however, was complicated because the causal model did not fully account for relational injury. In and of itself, Rely was not

defective. It was not composed of toxic materials causing direct harm or triggering cancerous growths. As a medical device, it seemed inert, and Rely did not directly cause TSS. The injury incurred is better understood, I argue, through a reactive model. Once moistened and lodged in a vaginal canal, Rely held the strong potential to interact with bacterium that may be present as constituent communities within some women’s bodies. Since makers presumed it to be inert, the leap to the reactivity of the technology seemed far-fetched.⁴ Yet, the live bacteria and synthetic tampon energetically interacted and were co-factors in producing illness. As Jain points out, design flaws may materialize as visible requiring compensation or remain invisible and go unrecognized. It is exactly the invisibility of a reactive gendered technology in the form of a tampon and injury manifesting in women’s bodies identified as Toxic Shock Syndrome that contributed to this health crisis.

RESEARCH AND TESTING

How this injury played out varied considerably. Much of my research is based upon *Kehm v. Proctor & Gamble*, the 1982 liability case that took place in the federal courthouse in Cedar Rapids, Iowa, in which the family of Patricia Kehm sued Proctor & Gamble upon her death from TSS linked to the use of Rely tampons. It was the first successful case to sue Proctor & Gamble and win a favorable judgment concerning a wrongful death, made particularly troubling since she died on September 6, 1980, just days before the products were pulled from market shelves on September 22. Proctor & Gamble was ordered to pay \$300,000 in

³James Todd adds, “It should have been obvious that the group of young women with ‘vaginitis’ were of menstruating age and, in fact, three of our original patients, in retrospect, were menstruating at the onset of their illness, but we missed completely the possibility of any connection with tampon use.” See James K. Todd, “Toxic Shock Syndrome—Scientific Uncertainty and the Public Media.” *Pediatrics* 67.6 (June 1981): 921-923. p. 922.

⁴Recognition of indirect harm is gaining traction. Recently, the EPA announced that it will set limits on perchlorate in drinking water. According to physician and CNN chief medical correspondent Sanjay Gupta, “it’s the first time we’ve ever regulated a chemical not because of what it does directly to you, but because it has an impact on iodine uptake that might affect your child down the road.” CNN Health [Internet]. “EPA to set limit on chemicals in drinking water.” (accessed Feb 2, 2011). Available from: <http://www.cnn.com/2011/HEALTH/02/02/epa.water.chemical/index.html>.

compensatory damages, and the lawyer for the case, Tom Riley, said it was “the highest verdict in Iowa’s history for the death of a housewife” [25].

The court exhibits and trial transcript offer insight about the product development of Rely, how the company managed the phone calls of concerned women who thought they must be experiencing an allergic reaction to tampons, and the drama scientists felt in identifying an unnamed epidemic. The trial revealed that indeed Proctor & Gamble had spent a good deal of time and effort testing the tampon, though researchers missed the greater picture of bacterial interactions with technology.

In fact, according to Martin Cannon in product development at Proctor & Gamble, scientists conducted more than enough testing, and furthermore, the company had garnered its solid reputation through meticulous research protocol [26,27]. The individual components comprising Rely were each scrutinized to ensure the sanitary nature of the product itself. By 1979, new requirements concerning protocol and data collection were required by the FDA, and Proctor & Gamble moved forward by meeting criteria in advance of these laws. Specifically, Proctor & Gamble conducted clinical trials in which 1,332 women participated in various studies, which in scientific parlance amounted to “730 woman years of experience with Rely tampons,” according to the company [28]. Minor ulcerations comparable to that of Tampax were reported to the FDA, and the results of both acute and long-term toxicity tests — based upon 1 full week of use and another spanning more than 2 years — in animals proved negative [29]. Scientists determined carcinogenic and teratogenic potential of the new product by fashioning pledgets — tiny tampons — for mice to wear [30]. Of course, mice do not menstruate, so there can be no valid results related to interactions with menstrual fluids. Nonetheless, the results yielded data that convinced corporate leaders as well as the FDA that the products were not cancerous.

Scientists also assayed changes in microflora of the vagina, a process that proved

more difficult. As Cannon described it: “What we find is that the microflora of the vagina . . . it just changes, changes for an individual woman, and it changes in spite of what product habits that, you know, we were able to observe.” His is not an unusual reaction to the vagina as a vexing site for control. The history of medicine and gynecology is rife with examples to subdue women’s reproductive health, including pregnancy, fertility, and menstruation. In this case, women’s bodies were unable to conform to the dictates of the lab to remain fixed; for the scientists, there were just too many variables related to the fluctuating, permanent, and transient microorganisms to isolate. Thus, lab conditions were different than environmental conditions, and the scientists were not required by any regulating body, whether internal or external, to conduct such tests [31].

However, not all was rosy. By July 1980, one of the junior engineers, referred to by only his last name, Dzialo, in memos, wrote to R.L. Stone at Proctor & Gamble, expressing some frustrations about the research process. Apparently, around 1978, during the so-called “absorbency wars” triggered by competitors’ offerings, work had begun on “Rely N,” the next generation of Rely tampons. As Dzialo put it: “With all major brands offering comparable product performance, Rely’s marketing objective of category leadership is seriously jeopardized.” One reason for this, he felt, was a poor understanding of the vagina and its fluids. “[I]t is clear that an inadequate understanding of menstrual fluid characteristics and of the functional anatomy of the vagina has complicated an already difficult task. An improved understanding of both areas would significantly reduce the need for a trial by error mode of operation” [32]. Here, Dzialo voices what Harry Collins and Trevor Pinch describe as “experimenter’s regress;” that is, the difficulty for “a test to have an unambiguous outcome because one can never be sure whether the test has been properly conducted until one knows what the correct outcome ought to be” [33]. In many ways, the scientific testing had no way to measure the

outcome of TSS, precisely because it was unknowable at that time.

NAMING A NEW SYNDROME

The case of TSS was not easily identified in tampon-using women because researchers had not thought to look for it. All-cotton tampons had not posed such a threat, and no one had ever heard of TSS. Thus, there were two unknown variables needing identification: the role of the synthetic tampon and the labeling of a new disease. While Proctor & Gamble made preparations in Cincinnati for distribution of this new product, a physician in Denver began tracing the similarities of symptoms in some of his patients. It was only in 1978 that “the toxic shock syndrome” was named by pediatricians James Todd and Mark Fishaut working in the Department of Pediatrics at the Children’s Hospital of Denver and University School of Medicine with their colleagues Frank Kapral in the Department of Medical Microbiology at Ohio State University and Thomas Welsh in the Department of Pediatrics, Herkimer Memorial Hospital in New York [34]. As historian of medicine Charles Rosenberg argues, it is only after a set of symptoms is named as a disease or ailment that social constructions of behaviors, treatments, and expectations of patients and clinicians can be associated with it [35]. Thus, according to Todd and the other researchers, children were constructed as the patients. As described in *The Lancet*, symptoms included high fever, rash, headache, vomiting, acute renal failure, and even severe shock in seven boys and girls between the ages of 8 and 17 between 1975 and 1977. The link that Todd, the principle investigator, was able to make between the children was that the infection derived from phage-group-I *Staphylococcus aureus*. He referred to this as “a unique new syndrome” affecting older children, different from scarlet fever or Rocky Mountain spotted fever that share some similar traits [34]. It was also framed within the category of new diseases such as Kawasaki’s disease or Reye’s syndrome that affect children. Such a small

sampling was nowhere near an epidemic, more like a blip in infectious diseases seen in children.

Yet, Todd’s article in *The Lancet* became the authoritative academic work on TSS because this was the only published piece to outline specific symptoms and name this *Staph*-related infection as a syndrome. How this health crisis in children could be linked to tampon use was not obvious, and it is the very origins of these initial cases that caused many to dismiss any sort of association with Rely. What could be the possible relation between young children, and even men, with the number of women who were exhibiting scarlet fever-like symptoms? Luckily, Jeffrey Davis, the new State Epidemiologist and Chief of the Section of Acute and Communicable Disease Epidemiology at the Wisconsin Division of Health, became familiar with TSS in 1978 while completing a pediatrics residency and pediatric infectious diseases fellowship at Duke University, before the publication of Todd’s article. When colleagues at the University of Wisconsin School of Medicine contacted him in late 1979 with questions about three patients exhibiting unusual symptoms, Davis suggested that the cases might be TSS [36]. He began investigating commonalities among the women by asking questions about grocery purchases that might have linked them through food-borne illness; travel and locale pointing toward regional infections; and sex partners suggesting sexually transmitted infections. In addition, Davis remembered from his medical training that often “menstrual history is overlooked” [37]. He believed that it was “more than a coincidence” that each contracted her illness at the onset of the menstrual period.

By early 1980, his surveillance of four other Madison hospitals revealed four more cases. Upon learning of these new cases, Davis took the proactive step of mailing a report on January 31, 1980, to “3,500 internists, pediatricians and family practice physician licenses in Wisconsin” concerning the state of TSS, outlining surveillance procedures for the disease, and importantly, es-

tablishing protocol for specimen collection. In essence, Davis positioned physicians in Wisconsin to be on the forefront of intervention concerning TSS outbreaks, wherever and however they might occur. This proved to be a critical act. Davis, well-connected to other university physicians and departments of health, began receiving calls of self-reported cases of TSS, questions from practitioners, and requests for collaboration with the Centers for Disease Control (CDC). At the CDC, Kathy Shands, an Epidemic Intelligence Service (EIS) officer in the Special Pathogens Branch, requested input from researchers and public health officials, including Davis, to define the criteria of TSS. Though the medical team outlined physical symptoms and manifestations, the circumscribed definition carried political consequences because numerous infected women fell outside the strict boundaries. Many argued, and continue to do so, that the less severe presentation of symptoms should be included within the terms of the definition, since it results in illness from TSS [38].

With such a specific set of criteria in mind, researchers in different hubs began to track outbreaks and define patterns of infection. To summarize, there were a few prominent studies linked to state-level departments of health corroborating evidence, sharing results, and exchanging information. These included the Wisconsin Study, a case control study emerging from interest in Davis's original mailing, during the winter and early spring of 1980, the results of which were formally published in the *New England Journal of Medicine*. During the summer of 1980, the CDC also conducted CDC-1 and later CDC-2. This small study matched 52 cases with 52 controls, with all of the cases using tampons at the onset of menstruation. CDC-2, conducted during the fall of that year, examined methodology of "recall accuracy" and the size of the tampons used, as well as the brand. It was CDC-2 that implicated Rely, citing its prevalence in relation to TSS and women's menstrual hygiene practices. So impressed with the results, the research team published preliminary findings in the Septem-

ber 19, 1980, edition of the CDC's *Morbidity Mortality Weekly Report (MMWR)*.

Using the benchmark date of September 19, the Tri-State TSS study coming out of Minnesota, Iowa, and Wisconsin carefully examined cases, brands, and absorbency as related to TSS. The researchers found that the absorbency of the tampon or the wearing of Rely "were the only variables that significantly increased the relative risk of TSS." Furthermore, the study directly implicated Rely, stating that "the rise associated with Rely was greater than that predicted by absorbency alone, suggesting that chemical composition of tampons was an important factor" [39]. To offer a broader comparative historical perspective concerning the extent of the problem, microbiologist Philip Tierno surmised that "of the more than 2,200 cases reported to the CDC though June 1983, 90 percent were associated with women who were menstruating at the time they became ill. Most of these women were young, and 99 percent were using tampons" [40].

POLICY MAKING: DECISIONS AND INCONCLUSIVE SCIENCE

Problems concerning synthetic tampons, especially Rely, moved from the realm of speculation to public health fact during the spring and summer of 1980. Discontent from consumers grew from whispers to more angry complaints directed at Proctor & Gamble. As far as Proctor & Gamble was concerned, its scientists had conducted sound research, and there was no reason to question the integrity of the new product. In a memo from Gordon Hassing, a director of product safety, to Peter Morris in research and development on June 24, 1980, Hassing assured him, "[t]hus far, there is no direct evidence for the causal involvement of tampons in TSS. The etiology of TSS is unknown but is likely to involve an infectious agent." In many ways, he was correct. It was not a causal relationship, as understood in usual risk and injury cases. However, it was a cofactor in that it caused a reactive encounter with *S. aureus*, precipitating illness in some women. Though he believed Rely

was not an issue, he predicted that disfavor might come from the media. He continued by saying that “the potential for adverse publicity for tampons as a product category remains high, particularly if the CDC data are made public irresponsibly. Strategically, we can only help to keep any publicity from being irresponsible.” By positioning Rely as “part of the pack,” Hassing aimed to address the TSS-tampon link as just that: associated with a category as a whole and not a particular brand [41]. This tactic contradicted earlier marketing with its focus on the difference between Rely and other tampons. The connection was crucial for the sale of the tampon, and Hassing noted: “Keep this problem only theoretically associated with the category. This is extremely important because of the unique construction of Rely and its very high marketing profile.” As a follow-up to this deflection strategy just a few days later on June 27, 1980, interdepartmental correspondence from area managers flatly ordered representatives to control their comments by stating: “You should not initiate discussion of this subject” [42].

Managers at Proctor & Gamble grew more concerned. The CDC had been keeping all the affected companies apprised of data and results coming from its studies. Proctor & Gamble, however, wanted to conduct its own research to verify the findings of the CDC. At first, researchers at the company requested to see the interviews and raw data sets from the CDC, but it refused, citing patient confidentiality. This would become a contentious issue; in defense cases after the product was discontinued, Proctor & Gamble later accused the CDC of bad science because it sought out sick individuals and not a broad sampling [43]. Lawyers also sought to subpoena records from the CDC in order to obtain the names of women interviewed during the CDC’s investigations, purportedly to exonerate tampons as the culprit of TSS [44]. The CDC countered that it was in the business of epidemic prevention, thus chasing disease was a crucial matter of public health policy. Proctor & Gamble interpreted this as a political solution and not a scientific one, especially since policy de-

isions were being based upon self-reported cases to the CDC [45].

In order to bypass this disciplinary and ethical squabble, researchers at Proctor & Gamble exercised a new tactic: Track down women who called the company complaining of sickness but later recovered, and talk to them more specifically about their health with an eye toward gaining access to their medical records, which presumably would more accurately reflect a diagnosis of TSS by a credentialed physician. According to Roscoe Owen Carter, the PhD chemist in charge of paper products development and, therefore, Rely, the self-reporting of TSS to doctors and the CDC was sketchy at best, with cases not meeting all of the criteria for the clinical definition. He believed “the only way that you could make a decision as to whether this might have been toxic shock syndrome was to get to the physician, talk with him, and then actually see the medical records, go through these medical records” [46].

Company officials used this aggressive approach with Karen Swartzentruber and her daughter from Washington, Indiana, who purchased Rely tampons from the local Kmart. Swartzentruber complained to the company on July 25, 1980, that her teenage daughter was hospitalized with a *Staph* infection and her doctor believed the cause of it was Rely. By July 31, Carter called her physician, Dr. Calder, who was quite forthcoming about the teen’s symptoms, ranging from high fever and muscle pain to diarrhea. However, Calder withheld her name from Proctor & Gamble. This was of no concern to Proctor & Gamble, because members from Carter’s division spoke to the Kmart store manager, who previously divulged the identity of both Calder and Swartzentruber. Under the guise of collecting medical evidence, strategists at Proctor & Gamble flagrantly violated patient confidentiality, abetted no less by the family physician and Kmart store manager [47]. Strategists and managers at Proctor & Gamble seemed to want it both ways: to invoke the need for proper procedures by the CDC but violate customary patient/doctor confidentiality when it favored the company.

Proctor & Gamble continued to behave as if Rely were safe, but evidence against Rely mounted by September 1980. In an interview, Nancy Buc, lawyer to the general counsel at the FDA, recalled that she informed the general counsel at Proctor & Gamble that if the company was unwilling to enter into a consent agreement and withdraw the product, she was prepared to bring it to court for violating the imminent hazard injunction under the Medical Device Amendments of the Federal Food, Drug and Cosmetic Act, and she would do it personally. According to Buc, it was clear that something was going on with Rely, but what exactly it was remained uncertain. She felt her job was to negotiate, as she put it, “sensible” terms to remove the product from shelves and have Proctor & Gamble comply with the demands of warning the public about this health threat. In this regard, Proctor & Gamble was lucky. Among discussions with chain-of-command leadership, Buc recalled that Secretary of Health & Human Services Patricia Harris, cabinet member to President Jimmy Carter, suggested implementing a total ban upon all tampons. This seemed extreme to Buc and reflected what *Washington Post* staff writer Victor Cohn characterized as a prevailing attitude among women, that they “have become accustomed to the convenience of tampons, and giving up familiar brands because of a slight chance of developing toxic shock syndrome seems almost as preposterous as walking to avoid the danger of car accidents” [3]. It was not Buc’s job to determine the origin of the problem, but to act to protect women and let them keep their tampons, too.

The health crisis of tampon-related TSS is inextricably linked to research and development practices at Proctor & Gamble, the science of epidemiology, the legal categorization of tampons as medical devices, and feminist notions of the right to a safe and hygienic menstrual period. In addition, the relationship of TSS to tampons reveals an important triad of a woman’s body to bacteria to technology to consider when designing and developing new biotechnologies. This case demonstrates the importance of

understanding the relationship of technologies to constituent bacterial communities in women’s bodies and thinking beyond a causal model to a reactive model. The complicated and reactive relationship of the Rely tampon to emergent disease, corporate interests, public health, and injury law reveals the dangers of naturalizing technologies. With growing reliance upon artificial joints and implanted medical devices, the study and framework of biologically incompatible technologies, as read through Toxic Shock Syndrome and tampons, offers a means to re-evaluate safety and injury in relation to all of our bodily ecologies.

CONCLUSION

Though Rely was the focus of this essay, all tampons were implicated, though those with synthetic components and higher absorbency seemed more amenable to *S. aureus*. Recommendations to use low-absorbency, cotton tampons seem sound, yet do not entirely prevent an infection. The only way to really prevent TSST-1 is to avoid *S. aureus* altogether. At the current moment, there is no standardized recommendation to run a bacterial culture to see if *S. aureus* is a permanent constituent vaginal bacterium for a particular woman. The shortcoming of this is that *S. aureus* may be permanent or transient and require follow-up testing to make such a determination. Though this is more commonly undertaken before surgery to manage MRSA, it is not currently a viable practice to test women’s vaginas. Regardless of the viability of such a procedure, for those women who permanently harbor *S. aureus*, the knowledge of this would be quite useful in making informed decisions about their menstrual hygiene choices. For those women with transient *S. aureus*, the recommendations are less clear. In this case, manufacturers rely upon informed women knowing the signs and symptoms of TSS, which are deceptively similar to the common cold and difficult to discern as life threatening. Researchers are also unsettled by the possibility of TSST-1 and MRSA exchanging

genes, which could create a very frightening prospect for tampon-using women [48].

This cultural and technological history of tampon-related TSS is complicated, and from this brief narrative presented here, it is clear that historians, researchers, and clinicians must provide a more nuanced interpretation of the disease and disease process. We all must be more knowledgeable about what TSS is and is not and have a better understanding of what it means to use technologies inside the body.

This is a story as much about technology as it is a bacterium and assumptions drawn based upon limited information to users and non-users of technology. Though pamphlets inserted into boxes are supposed to explain all this, they often seem more about liability instead of risk. It is exactly the type of risk that needs further explanation. TSS is rare, and more importantly, *S. aureus* has preferred conditions in which it is more likely to flourish, and this is with a synthetic, super absorbent tampon. Overall, the important message is to understand the multiple variables involved and that tampons and constituent bacteria are active agents within the human body.

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