

The Toxic Shock Crisis of 1980

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Introduction

By the hot summer months of 1980, a feeling of panic had slowly crept into the homes of American women. The cause of all this concern was an apparently new disease called toxic shock syndrome, commonly referred to as TSS. Never recognized as a national health issue until that year, in 1980 there were an unprecedented 890 reported cases of toxic shock, which ultimately resulted in the deaths of 35 women.¹ Earlier that spring, hospitals around the country began admitting increasing numbers of female patients with a strikingly similar battery of symptoms. Their symptoms pointed to some type of toxic shock, the source of which was seemingly unknown and unidentifiable to doctors at the time. Doctors at the Center for Disease Control and Prevention (hereafter, CDC) in Atlanta, Georgia first suspected a connection between toxic shock syndrome and tampons in June of 1980, weeks before the major swell of cases.² Following the announcement of the findings, scientists working independently and for the CDC began working feverishly to come up with a concrete link between the disease and tampons, though it would take years for its final discovery.³ The CDC, functioning in conjunction with the Food and Drug Administration (hereafter, FDA), would eventually act as a clearinghouse for all information regarding TSS by collecting individual reports from state health departments and in turn, making the media and the public aware of any new developments.

The news media in turn would eventually play an important role during and after the 1980 crisis, though initially, it essentially ignored or was not aware of the existence of toxic shock. Little by little, reports of the mysterious illness were picked up by reporters

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and stories about toxic shock syndrome made their way into the headlines of widely circulated magazines and newspapers. Reporting of the disease reached its full impact when a popular brand of tampon, Rely, was implicated as a primary culprit in the development of toxic shock in menstruating women. Following this revelation, the American public was virtually saturated with daily information containing new developments, medical breakthroughs, illness totals, and death tolls. The media frenzy coincided with the great swell in cases that was experienced during the months of July, August and September.⁴ This phenomenon prompted many to question the effects of the intense media scrutiny on the number of reported TSS cases. Did the daily inundation of TSS news result in increased reporting of cases by doctors or in women developing fictitious toxic shock-like symptoms?

Studies would later show that the media effects, while seemingly significant, did not account for the increased number of cases during the summer of 1980. Rather, they pointed to an entirely different cause – Rely tampons.⁵ Though CDC studies revealed a direct causal connection between using Rely tampons and the onset of TSS, Procter & Gamble, manufacturer of Rely, vigorously denied the accusations. Following the Rely recall, the company even went so far as to fund its own studies in an attempt to establish the safety of its product and exonerate the Rely brand. The Procter & Gamble studies, however, proved to be irrelevant at best as most were undertaken using flawed methodology. As a result, Procter & Gamble was never able to effectively establish Rely's innocence.

At the time of the toxic shock crisis, there was heated debate over whether Procter & Gamble or the United States Government (the FDA) bore primary responsibility for the 1980 outbreak of TSS. Never before that year had tampons and the tampon industry undergone such intense scrutiny by the media, the public or the government. However, it was not simply because of a problem within the tampon industry that toxic shock entered the lives of so many American women in 1980. Prior to that year, government regulation of the tampon industry had amounted to little more than occasional inspections of tampon manufacturing plants. The laws did not allow the FDA the right to view any information the manufacturing company considered to be a trade secret, ask for tampon ingredients or require

pre-market product safety testing.⁶ There is evidence pointing to Rely's guilt as well, indicating that the company was aware of some of the potential dangers of its product, and that it deliberately misled consumers and the medical community by denying evidence pointing to its hazards. Thus, both parties were at fault for allowing, whether knowingly or by inaction, a flawed and unsafe product to be marketed to hundreds of thousands of women across the country.

Despite the media circus and public anxiety that invaded so many lives during 1980, later figures eventually proved that the actual threat of toxic shock was only minor; only about five percent of the total adult population, male and female, is actually at risk of contracting the disease.⁷ Most adults (about ninety five percent)⁸ naturally harbor TSS-causing bacteria, *Staphylococcus aureus*, commonly located in the vagina as well as in nasal and throat passages. Thus, the majority of the population have natural antibodies that prevent them from contracting toxic shock, but the remaining five percent lack the protective antibodies and are therefore, susceptible to the deadly disease either through the use of tampons or as a result of postpartum or postoperative infections.⁹ Although the risk for menstruating women was higher before the FDA required Procter & Gamble, to remove its Rely tampon from the market in September of 1980, it is currently estimated that only between .005 percent and .02 percent of all menstruating women will contract TSS each year.¹⁰ Regardless of this fact, at the time of the 1980 scare, TSS seemed to most American women to be an unstoppable epidemic sweeping across the country. Luckily for the women at risk the severity of the situation, as well as the panic, lasted for only a short while as the alarmingly high number of TSS cases experienced during the summer of 1980 began to reach a more moderate level.¹¹

Todd's Discovery

The first person to identify toxic shock syndrome did not at first associate the disease with either women or tampon usage. Dr. James Todd of the Department of Pediatrics at Children's Hospital of Denver and the University of Colorado School of Medicine is credited with officially identifying toxic shock syndrome as a new disease in 1978.¹² His findings, published in the British journal, *The Lancet*,

outlined the study he conducted on the case histories of seven children who were all seen between June, 1975 and November, 1977. The patients, ranging in age between 8 and 17, presented with symptoms indicative of staphylococcal-toxin-related diseases: persistent high fever, headache, confusion, watery diarrhea, and rash.¹³ This link prompted Todd to pursue further investigation.

The study focused on five of the seven children on whom a bacteriological and serological survey was conducted. Tests were administered to eliminate other diseases commonly associated with children, such as streptococcal scarlet fever, leptospirosis, Kawasaki's disease, and Rocky Mountain spotted fever.¹⁴ The elimination of these possibilities led Todd to the conclusion that he had discovered a new disease caused by the toxins produced by staphylococcal phage-group I organisms. At the time Todd's report was published he believed the disease to be one affecting only older children who contracted toxic shock through cuts or minor wounds.¹⁵ Future events and research would prove that Todd's disease, which he subsequently named toxic shock syndrome, was not merely a children's disease. Rather, it was one that primarily targeted a different demographic, namely, menstruating women.¹⁶

What is Toxic Shock?

Although toxic shock syndrome can strike every segment of the population, it is a disease that primarily occurs in menstruating women. After the dramatic rise in cases in 1980, a menstruating woman's probability of contracting the disease is only about three in 100,000. Although TSS is generally associated with menstruation, about fifteen percent of all cases occur as postoperative infections or postpartum. The disease is caused by the exotoxins produced by some strains of phage-group one *S. aureus* that are released into the body.¹⁷

According to *The Merck Manual of Diagnosis and Therapy*, the symptoms that characterize the disease are a sudden and sustained high fever, severe headache, sore throat, nonpurulent conjunctivitis (non-pus producing inflammation of the inner eyelids), lethargy, confusion, vomiting, watery diarrhea, hypotension (abnormally low blood pressure) and peeling of the skin, especially on the hands and feet (erythroderma).¹⁸ In July of 1980, Dr. Julius B. Richmond,

Assistant Secretary for Health and Surgeon General of the United States, wrote an article in the FDA *Drug Bulletin* entitled “Advisory on Toxic-Shock Syndrome” in which he outlined five criteria for defining TSS in a patient. They are as follows:

1. Fever equal to or greater than 102 degrees F.
2. Erythematous macular rash with subsequent desquamation. (Sunburn-type rash with peeling and scaling settling particularly on the palms and soles.)
3. Systolic blood pressure 90mmHg for an adult.¹⁹
4. Involvement of at least four organ systems.
5. Reasonable evidence for absence of meningococemia, Rocky Mountain spotted fever, or bacteremia.²⁰

The severity of the disease is evident in its capability of inflicting multi-system injury.²¹ In the same article, Dr. Richmond listed the body systems that are most commonly involved in TSS. In decreasing order they are gastrointestinal, muscular mucous membrane, renal, hematologic (blood), hepatic (liver), central nervous, and cardiopulmonary.²² Possible effects of toxic shock syndrome include elevated white blood cell count, low red blood cell count (anemia), increased bleeding and decreased clotting, liquefaction of muscular tissue, cardiopulmonary involvement, and renal dysfunction.²³

Recurrence is a common attribute of the disease, especially in women who do not discontinue their use of tampons in the four months following an attack of TSS. The most effective treatments during the most severe stages of sickness include the administration of antibiotics and fluid and electrolyte replacement to treat or prevent shock. About eight to fifteen percent of all serious cases of toxic shock syndrome result in fatalities.²⁴ Although medical knowledge of toxic shock is now common, unraveling the mystery proved to be a long and complicated process.

Early Explanations of TSS

Even before the onset of the TSS outbreak in the summer of 1980, doctors at the CDC suspected a link between the new disease and tampons. In June of that year, the CDC announced the results of

three studies that were conducted in Wisconsin and Utah that prompted them to associate TSS with tampon usage. Although the studies provided the official link between toxic shock syndrome and tampons, no particular brand of tampon was implicated. The studies, which were conducted on 93 women who had toxic shock syndrome, identified the tampon-TSS association based on the fact that only one of the female subjects was not a regular tampon user. While the discovery of the connection between TSS and tampons was significant, doctors knew that tampons alone could not be the only factor leading to TSS, because so many women had used them without any occurrence of the disease.²⁵ What the researchers were not sure of, however, was what, exactly, was the connection between the rare disease and tampons, and more specifically, what were the biological causes of toxic shock syndrome.²⁶

The widespread public concern over toxic shock led many doctors to try to understand the disease and come up with a plausible explanation that could eventually lead to a cure or vaccine. The theories ranged from the highly implausible – the notion that TSS was seasonal – to the realistic and possible.²⁷ However good the doctors' intentions were, it would take many years and many incorrect theories before scientists would discover the actual link between tampons and TSS – that certain tampon fibers deplete the magnesium that prevents TSS-causing toxins from entering the bloodstream.²⁸

One of the early theories came on October 10, 1980 in the form of a letter written to *The New England Journal of Medicine* by four doctors from Massachusetts General Hospital in Boston.²⁹ In the letter, the doctors suggested that toxic shock syndrome was caused by the blockage of the vaginal canal by tampons. Their theory, presented without proof, suggested that tampons force menstrual blood that contains toxins, from the vaginal canal through the fallopian tubes, and into the peritoneal cavity where it collects, forming a stagnant pool.³⁰ This warm, moist environment provides a more than adequate breeding ground for the absorption of the toxin into the bloodstream.³¹

Another plausible theory, developed the following year by Dr. Patricia Garrett of the Harvard Medical School, was published in the *New York Times*. Garrett concluded that the type of insertion devices used by various tampon brands might cause tiny tears in the vaginal

tissue allowing the toxins that cause TSS an easy entranceway into the bloodstream.³² If her theory had proven correct, the suggestion made by the CDC and FDA that women should change their tampons frequently would have actually increased the likelihood that women would contract TSS, because more abrasions would have resulted from increased frequency of tampon changing.

A third theory was presented by researchers at the University of Minnesota and a group of Dutch scientists. The theory held that staphylococci increase their production of their deadly toxin in oxygen-rich environments. When a tampon is inserted into the vagina, normally an oxygen-poor environment, it brings in a sufficient amount of oxygen the bacteria needs to produce the toxin that causes TSS.³³ The heated debate over the validity of these early TSS theories took place not just behind the closed doors of hospitals or CDC and FDA laboratories, but also and perhaps more importantly, in the bright glare of the media spotlight.

Media Frenzy

The media played a crucial role in the development of the TSS story in America. Charting the course of media coverage of toxic shock syndrome by looking at *The New York Times*, one can see three major phases: discovery, panic and aftermath. The initial phase begins with the June 27, 1980 CDC announcement of the study linking toxic shock syndrome and tampons.³⁴ Between June 27 and September 22, coverage of TSS was relegated to the Style, Living or Home sections of newspapers such as the *New York Times*, where infrequent articles about the disease were placed next to recipes and fashion tips. For example, the first article on TSS appearing in the *Times* in June of 1980 was entitled, "Tampons are Linked to a Rare Disease." From the title, it is evident that the article announced important new information for women, yet it was printed on page seventeen of the newspaper in the Style section.³⁵ In September of the same year, the *Times* again relegated TSS to second-rate news. An article reporting the CDC announcement that women should reduce their use of tampons was placed next to a recipe for marinara sauce in the Living section of the paper.³⁶ The so-called "women's disease" was seemingly not considered to be much of a threat to the general population and it

was treated accordingly.

The panic phase of media coverage began with the September 22 recall of the Rely tampon. By September of 1980, it appeared as if the media had suddenly decided that TSS was deserving of their time and attention. But the decision may not have been made entirely on their own. The FDA had begun releasing massive amounts of information regarding toxic shock and especially its connection to Rely tampons. This targeted media campaign was initiated as a deliberate attempt to saturate the airwaves with the Rely recall information in order to maximize its impact on the public. There is no doubt that the constant influx and availability of information from such a reliable source prompted the media to probe further into this new disease and its daily developments.³⁷

A dramatic increase in media reporting of toxic shock syndrome began on the day following the announcement of the Rely recall. It was on this date that TSS finally became front-page news; it would remain so throughout 1980. After the recall, hardly a day went by when the *Times* did not include an article updating the public on the TSS cases, deaths, new studies, CDC announcements, and new discoveries. Papers began assigning reporters strictly to cover TSS, one of whom, Nan Robertson of the *Times*, herself a TSS survivor, won a Pulitzer Prize for her work on the subject.³⁸

The steady stream of articles continued through the rest of 1980 and into 1981 as well, slowly quieting down during the latter part of that year. When the crisis seemed to be over, media coverage of toxic shock syndrome became more and more infrequent. The aftermath stage began roughly around 1982 and ended in 1990. From 1982 through 1984 most of the few newspaper articles concerning TSS dealt with the lawsuits filed against tampon manufacturers by TSS victims or their families. Virtually nothing was written in the general news concerning TSS from 1984 to 1987, and for the next two years only a few articles appeared covering the FDA's debates over tampon absorbency ratings. The steady decline continued through the remainder of the decade.

It is clear that the media played an important role in the history of toxic shock syndrome. But what, exactly, were the effects of the intense media reporting on the population as a whole? A study was

conducted by two doctors at the University of California School of Medicine in San Francisco between November 1980 and January 1981 to determine just that. Dr. Charles E. Irwin, Jr. and Susan Millstein set out to discover the effects of the media coverage of TSS on tampon use in adolescent females. The primary purpose of the study was to determine whether adolescents decreased their tampon use as a result of the heavy reporting of TSS.³⁹ Participants in the study were asked to report information regarding their tampon usage during the summer of 1980, the time period when the toxic shock scare reached its peak. Out of the 714 subjects studied, a twenty percent decrease in tampon usage was noted following the news coverage of TSS. Scattered TSS reports began circulating in June of 1980, which may have caused a decrease in tampon usage even before the period about which respondents were asked to provide information. Because of this, the twenty percent figure is very likely a conservative figure.⁴⁰

In addition to an overall decrease in tampon usage, the researchers observed another significant phenomenon. Prior to the toxic shock scare, American women were moving more toward using tampons in place of sanitary napkins as their primary menstrual control device. But after the summer of 1980, this shift decreased about nineteen percent, and a move was made in the opposite direction. More than thirty percent of the regular tampon users began switching to napkins after the major impact of TSS coverage, delivering a powerful blow to a booming industry with a long history behind it.⁴¹

History of Tampons

Tampons and the tampon industry were at the forefront of the toxic shock debate in the 1980's. Although the general public believes tampons to be a relatively new phenomenon in the realm of menstrual protection, their history is actually quite long. There is evidence dating all the way back to 1550 BC that women have used tampons as a method of contraception. The presence of Egyptian, Greek and Hebrew inscriptions describing the use of tampons, or pessaries as they were originally called, for contraception and the administration of medicine indicates the strong probability that tampons were also used to control menstruation.⁴² Women from different cultures used equally distinct materials such as papyrus, wool, and paper as well as

various types of grasses, mosses and ferns to fashion tampons, a practice that continued throughout the Middle Ages and into the modern period.⁴³

In the United States, however, the use of tampons did not become widespread until the 1930's.⁴⁴ Prior to that decade, some women, mostly athletes, actresses, models and prostitutes, made their own tampons at home using surgical cotton or natural sea sponges.⁴⁵ The first commercial tampons were marketed to more mainstream female members of society and were made of a gauze-like cotton material; absorbency agents were not added until the 1970's.⁴⁶ The Fax tampon was possibly the first tampon on the market in the U.S. although the exact year of its introduction is not known.⁴⁷ None of the tampons manufactured in the U.S. during the 1920's and 1930's contained applicators, and some did not even have strings.

In 1933, Dr. Earle C. Haas of Denver, Colorado revolutionized the tampon industry by patenting the first tampon with an applicator.⁴⁸ The tampon was made using compressed surgical cotton strips surrounded by a two-piece cardboard applicator.⁴⁹ Haas soon sold the patent and trademark to Gertrude Tenderich, a German immigrant and savvy businesswoman, who used Haas's design as the cornerstone of her new company, Tampax Incorporated, which was chartered on January 2, 1934.⁵⁰ The first Tampax tampons were made by Tenderich at her home using her sewing machine.⁵¹ The tampon industry has come a long way since then, booming into a multi-million dollar industry that services over fifty million American women.⁵²

The Rely Difference

One particular brand of tampon, Rely, was at the heart of the TSS controversy in the early 1980's. In 1962, Procter & Gamble, a multi-billion dollar corporation, began developing its own line of tampons in order to stake its claim on a share of the profits from the already booming feminine hygiene market. Procter & Gamble named its new product Rely, and conceived for it a catchy slogan, "It even absorbs the worry."⁵³

The design of the Rely tampon was different from that of any of the four major brands on the market at the time. Tampax and Kotex tampons shared a similar design structure known as the "wick."

In this design a rectangular strip of rayon-cotton vleece is stitched together surrounding a string. Playtex tampons favored the “tulip” design, which uses two strips of rayon-cotton vleece, which are layered and pulled in the center by an attached string; o.b. tampons used the same rectangular rayon-cotton strip, which was rolled up surrounding a string. Playtex, Tampax, Kotex, and o.b. tampons, while structurally different from one another, were all composed of the same primary ingredients, rayon and cotton, though in different combinations.⁵⁴

The design of the Rely tampon was not the only thing that set Rely apart from the other brands: its absorpsion agents were radically different as well. Abandoning the traditional cotton-rayon composition used by other brands, Procter & Gamble constructed the Rely tampon using all synthetic ingredients.⁵⁵ Carboxymethyl cellulose chips and polyester foam sponges were packed into a permeable nonwoven polyester bag, a design called the “teabag.” This design gave the Rely tampon the capacity to absorb almost twenty times its weight in fluid and enabled it to expand to three times its original volume when soaked with liquid.⁵⁶ The new product appealed to women because more absorpsion gave women greater flexibility with their time, in that women would have to change their tampons less frequently. Rely vigorously marketed its new product in magazine ads and television commercials concentrated in the evening hours when working women would be home.⁵⁷ Evidence pointing to the effectiveness of this strategy was that the relatively new Rely held a fifty percent share of the super absorbent tampon market by the time the toxic shock crisis reached its peak.⁵⁸

The Rely Question

There seems to be little question now whether Rely tampons had anything to do with the sudden rise in cases of toxic shock syndrome in 1980. Evidence from numerous studies points to the fact that women using Rely tampons during that time period were at higher risk of getting TSS than users of other brands. Although this is a well documented fact today, between 1980 and 1983 there was heated debate between Rely manufacturers and the CDC over the actual causes of TSS and whether or not Rely was a leading factor that caused the illness of hundreds of women in the United States.

The question of whether users of Rely brand tampons were at higher risk than users of other tampons was answered by the CDC on September 17, 1980. Until that date, the CDC had refrained from declaring an association between any one brand of tampon and the incidence of toxic shock. The September 17 report concluded that the absorbency agent used in Rely tampons could promote the growth of the harmful bacteria that causes TSS. The study further reported that seventy percent of the women in the sample were using Rely tampons at the time they contracted toxic shock syndrome.⁵⁹

Despite the CDC's evidence indicating that Rely users faced a risk of getting toxic shock that was three times higher than the risk faced by users of other tampon brands, Procter & Gamble, the manufacturer of Rely tampons, refused to admit that their product was defective, or that it could in any way lead to the disease.⁶⁰ In an article appearing in the *San Diego Union* on September 19, 1980, a Procter & Gamble spokesman encouraged women to continue using Rely tampons because, "There is no evidence to make them change."⁶¹ The company would not accept the CDC's findings, vehemently asserting that the tests had no validity because they did not use a large or diverse enough sample.⁶² It is interesting to point out that little more than two weeks prior to the recall, Procter & Gamble was relying exclusively on the judgment of the CDC as its basis for not including a warning label on its product or restricting its sale.⁶³ The company's attitude seemed to change, however, when the CDC produced information unfavorable to Procter & Gamble's reputation.

Five days after the September 17 announcement and only four days after a Procter & Gamble spokesman urged women not to discontinue use of Rely, the company voluntarily removed Rely from the market amidst company protests against the CDC study.⁶⁴ However, this "voluntary" recall was announced only after the FDA initiated a meeting with Procter & Gamble officials on September 16 and threatened to recall the product unless Procter & Gamble could produce compelling evidence that keeping Rely on the market was safe. The recall was, in fact, Rely's only option considering that its petition to place warning labels on its packages instead of removing them from the shelves was rejected at that same meeting.⁶⁵ Protesting and delaying a voluntary recall could have led to a mandatory federal

recall, which would have severely compromised the company's image and threatened its position in any potential lawsuits. Rather than face a very uncertain, and most likely detrimental, outcome, Procter & Gamble made the preemptive move to avoid further scandal.⁶⁶

Rely was further compelled by the FDA to sign an agreement to undertake a major ad campaign warning women about the possible consequences of using Rely tampons.⁶⁷ The "Stop Using Rely" ads aired on 600 television stations and 350 radio stations, and were printed in 1,200 newspapers around the country.⁶⁸ These moves were made amidst Procter & Gamble's insistence that there were no known flaws or dangers associated with its product which, it claimed, had undergone extensive research before it was introduced in 1974.⁶⁹

Regardless of the validity of Procter & Gamble's statements concerning pre-market research, because of laws that exempted certain products from government approval, the Rely tampon was not required to demonstrate its safety to the FDA before it hit the market.⁷⁰ Therefore, at the time, the only government-sponsored study conducted concerning the safety of Rely tampons had essentially come out strongly against the brand. But Procter & Gamble would soon launch a multi-million dollar research campaign of its own to disprove the government's findings and attempt to exonerate the Rely brand.⁷¹

Flawed Procter & Gamble Studies

Procter & Gamble's decision to fund TSS research created the appearance of impropriety and immediately forced the company to fend off accusations of bias. The August 1981 edition of *The Progressive* raised the important question, "Can a corporation with millions of dollars at stake refrain from influencing research on its product?"⁷² Though Procter & Gamble officials asserted that they would have no control over the scientific findings of the studies they funded, the company could hardly avoid exercising some influence in order to save its reputation and bottom line.⁷³ Because Procter & Gamble was providing the lucrative research grants, the grant recipients had a financial incentive to conduct studies in the areas that the company requested. This often led scientists away from studying the link between TSS and tampons. Instead, their primary focus was on TSS in general and on other areas that were not likely to have detrimental

effects on the future of Procter & Gamble and Rely.⁷⁴ Stipulations of the grant agreements between Procter & Gamble and research scientists reveal the extent to which the company desired the researchers to submit findings consistent with Procter & Gamble's position. Scientists were required to allow the company to review any research report twenty-one days prior to submitting it for journal publication. Thus, it was the Procter & Gamble's prerogative to suppress or delay any findings that would further implicate Rely or the tampon industry in general.⁷⁵

The motivation behind Procter & Gamble's move to fund toxic shock research was threefold. First, by providing a substantial amount of money to scientists to study the disease, Procter & Gamble could portray itself as a philanthropic company working for the good of mankind in order to find a cure for TSS. Second, the company would fund targeted research that could be manipulated to give the appearance of exonerating the Rely brand, thus erasing Rely's image as the culprit behind the TSS crisis. Third, and perhaps most importantly, if Procter & Gamble could clear its name, it would be spared from the threat of numerous lawsuits (at the time Procter & Gamble established its research grant program, more than 200 lawsuits had been filed against the company).⁷⁶ With potential damages totaling over \$100 million, \$3 million spent on research grants seemed a small price for the company to pay.⁷⁷

Adding further support for the argument that the Procter & Gamble research was not undertaken for altruistic motives is the fact that the grant money came from the Rely defense project.⁷⁸ The fund was established by Procter & Gamble to pay attorneys and other expenses dealing with ongoing TSS litigation. By implication, it would seem that Procter & Gamble viewed its research grant endeavor as primarily a legal matter and a ploy to avoid the expense of settling the claims of TSS victims. Though Procter & Gamble's motives were questionable, some argued that the studies funded by Procter & Gamble opened the door to new and important discoveries concerning TSS.⁷⁹ However in reality, most, if not all of the studies funded by Procter & Gamble were flawed in their methodology and later proved to be irrelevant in unraveling the toxic shock mystery.

Soon after the Rely recall, the incidents of toxic shock in the

United States fell drastically, a fact supported by CDC studies that Procter & Gamble quickly sought to refute.⁸⁰ The company eagerly attempted to find fault with the revelation in terms that did not associate the decline in TSS cases after September, 1980 with the removal of Rely from the market. Procter & Gamble asserted that the rise in cases during the summer of 1980 was due to the widespread attention the new disease received in the media. The reasoning behind this claim, according to the company, was that the media coverage prompted more cases to be reported to the CDC than ordinarily would have been had news of toxic shock stayed out of the headlines.⁸¹

Procter & Gamble based its assertion that the incidents of TSS remained relatively constant on information gathered from two studies funded by the company, that were based on active surveillance of TSS cases following the Rely recall. The studies claimed that there was not a decrease in cases after the removal of the tampon, as the CDC had asserted. Active surveillance is the process of seeking out cases rather than waiting (as is the standard process) for them to be reported.⁸² Prior to the recall, the CDC had reported numbers based only on passive surveillance. Active surveillance would naturally be expected to find more cases of the disease after the recall. Despite the flawed information gathering techniques of the researchers, their apparent findings were used by Procter & Gamble to cast doubt on the CDC studies.⁸³ In order to further bolster its argument that there was no real decline in TSS cases, Procter & Gamble pointed to the proven fact that after September, tampon usage in the United States dropped from seventy percent of menstruating women to only fifty-five percent, a significant decline that effectively decreased the number of women at risk of getting TSS.⁸⁴ The company cited the possibility that women were using tampons differently and more carefully after the initial TSS scare which, Procter & Gamble said, would have contributed to the decline in the number of toxic shock cases that the CDC studies had shown.⁸⁵

The CDC responded to Procter & Gamble's claims almost immediately. They rejected the study based on a number of factors that were later backed up by another CDC study conducted in September of 1980 and a follow-up study conducted in 1981, both published in August of 1982. The combined studies asserted two

important findings: first, that the failure of the initial June, 1980 CDC study to link any single tampon brand with the occurrence of TSS was based on flawed data; and second, that regardless of media effects, there was a clear association between Rely tampons and TSS.⁸⁶

The September 1980 study reported that in the earlier June study, participants were asked to give the name of the brand of tampon they used from the late 1970's until the time they contracted TSS. The problem with the data obtained from this question, however, was that some brands of tampons were not introduced into the market until the late 1970's and therefore were not available to study participants. Most importantly, although Rely was introduced by Procter & Gamble in 1974 in the West and Mid-West, it was not nationally distributed until early 1980.⁸⁷ Thus, because of the length of the time period reported, the frequency of Rely being named as a tampon of use would have been much lower than it actually was during only the time period when the number of TSS cases spiked in August 1980.⁸⁸

The February 1981 follow-up study effectively associated Rely tampons with as much as a 7.7 times greater risk of its users contracting toxic shock syndrome than users of other brands. Contrary to Procter & Gamble's claims, no other tampon brand was associated with any increased risk. As for Procter & Gamble's insistence that the increase in TSS cases was due to intense media coverage of the disease, and especially coverage somehow implicating Rely, the February study proved otherwise. It was designed specifically to reduce errors and biases dealing with media coverage. Data from participants living in California, Oregon and Washington, areas where local TSS cases associated with Rely were widely publicized, were eliminated from the data analysis. With all this data excluded, the risk factor for Rely tampon users was actually greater than the reported 7.7. Additionally, the data from this particular study was collected prior to the CDC's release of the September 17, 1980 study associating Rely with TSS. With all these factors taken into consideration, it is clear that there was indeed, a statistical association between TSS and Rely tampons although the exact biological cause of the increased risk was still not yet known.⁸⁹

Uncovering the Truth — Scientists Explain TSS

An important step in uncovering the link between toxic shock and Rely officially came on October 20, 1983 when Dr. Richard P. Novick, director of the Public Health Research Institute of the City of New York introduced the finding that he had located the gene for the toxin that causes toxic shock syndrome.⁹⁰ By that time, doctors had already discovered that the presence of *S. aureus*, the TSS-causing bacteria, in nasal and throat passages, the vagina, and on the skin was common in the majority of Americans.⁹¹ Most people, about ninety-five percent of the population, have natural antibodies that would prevent them from contracting TSS. The remaining five percent lack the protective antibodies and are therefore, susceptible to contracting the disease. An even smaller category of people within that five percent not only lack the necessary antibodies but are for some reason, unable to develop a resistance to the disease after their first contraction of it, leaving them susceptible to getting toxic shock over and over again. Dr. Novick's finding would be especially important for those people whose bodies are unable to produce the TSS antibody. His successful location of the gene within *S. aureus* that produces the deadly TSS toxin was particularly important, not because it pointed to the exact cause of TSS – that was still a question – but because it could lead to the development of a test to identify those who are most susceptible to TSS and possibly to the future formulation of a vaccine.⁹²

Two years later, a research team lead by Dr. Edward Kass and working at the Harvard Medical School and Brigham and Women's Hospital, finally placed the last piece in the complex puzzle of toxic shock syndrome. The researchers' experiments pointed to evidence linking two tampon fibers, polyester foam and polyacrylate rayon, with toxic shock.⁹³ The results showed that these fibers have the ability to attract, absorb and retain large amounts of magnesium, an element that is generally present in vaginal tissue and fluid. As soon as the magnesium-soaked tampon is removed from the environment in which the *S. aureus* bacteria is located (the vagina) it begins producing large amounts of the toxin that causes TSS.⁹⁴ In short, the presence of magnesium in the vagina is necessary to prevent the production of the toxin that causes toxic shock. This could explain why toxic shock usually appears on the fourth day of a woman's period, when the flow

is not as heavy as the first three days. In the early days of menstruation, because of the heavy volume of blood present in the vaginal canal, even after the removal of a tampon there is probably enough excess blood, and thus unabsorbed magnesium, remaining to prevent the bacteria *S. aureus* from producing its deadly toxin.⁹⁵

The Super-absorbency Question is Answered

Kass's discovery was additionally important as it led to the resolution of other trends and events that occurred during the 1980 scare that could not have otherwise been explained. Throughout the toxic shock crisis, many in the media and the medical community raised the question: does greater tampon absorbency increase a woman's risk of contracting TSS? Kass's findings succeeded in answering this question, and provide a viable explanation for the rash of cases that occurred in 1980, around the same time that tampon manufacturers began using polyester foam and polyacrylate rayon as ingredients in their tampons, making them super absorbent.⁹⁶

Kass's tests revealed that tampons made of cotton fibers, cotton and viscose rayon, or carboxymethyl cellulose (CMC) did not affect the production of the toxin causing TSS unlike tampons made of polyester foam. Tampons containing polyacrylate rayon fiber were also found to increase the production of the toxin, although the increase was limited.⁹⁷ In 1980, Rely was the only brand on the market that contained the dangerous polyester foam, but the manufacturers of both Playtex and Tampax brand tampons used polyacrylate fiber as an absorbing agent in their products.⁹⁸ This information accounts for the fact that women using tampon brands other than Rely were diagnosed with toxic shock syndrome in 1980. (In April of 1985, tampon manufacturers stopped using polyacrylate fibers in tampons.)⁹⁹

For years, Procter & Gamble and others had speculated that the existence of widespread TSS beginning in 1980 was a direct result of the increased use of all brands of super absorbent tampons, rather than Rely in particular. Some scientists speculated that the increased risk of TSS associated with Rely could be attributed to the fact that at the time of the toxic shock crisis, Rely had a fifty percent share of the super absorbent tampon market.¹⁰⁰ This point of view was supported by a study conducted in January 1981 that determined that users of

high absorbency tampons had a greater risk of developing TSS than users of lower absorbency tampons.¹⁰¹ Subscribers to this perspective argued that the decreased percentage of tampon users after 1980 explained the drop in TSS cases following the removal of Rely. But the fact that the percentage of women using high absorbency tampons remained the same during and after the TSS scare refutes that possibility.¹⁰²

Absorbency clearly played an important role in the TSS crisis but only in that the new super absorbent tampons relied on hazardous fibers for their improved effectiveness. Thus, there is some basis for arguing that the onset of TSS is a direct result of the emergence of super absorbent tampons into the market. Kass's research, while indicating the factors responsible for the onset of the 1980 crisis, had more significant effects in that it provided conclusive proof of the case against Rely tampons. Though other tampons were found to contain fibers that posed minor danger, Rely was the only brand of tampons on the market that contained the potentially deadly polyester foam that is an ideal breeding ground for TSS.¹⁰³

The Battle over Blame

The years following 1980 saw a bitter debate over the question of responsibility for the toxic shock crisis. One perspective suggests that the United States government was at fault because of its seemingly lax regulations on tampons. Supporters of this opinion claimed that the CDC and FDA pursued the case against Rely in order to divert blame from themselves. Those who held the government primarily responsible for the outbreak of TSS argued that implementing stricter guidelines for tampon manufacturers would avert future crises. The other side responded that the Rely recall was, indeed, a necessary step taken by the FDA to protect the lives of American women. Additionally, those who supported with the recall cited evidence that Rely had previous knowledge of its product's flaws yet made no changes in its ingredients and did nothing to warn the public or the medical community of the dangers involved in using Rely tampons.¹⁰⁴

The evidence indicates, however, that neither of these positions is correct in itself. The government bore primary responsibility for allowing Rely tampons, with their new composition and toxic materials,

to reach the public as a result of the lenient tampon regulations that existed in 1980. Rely, on the other hand, was negligent in that they misled consumers and the medical community and ignored evidence pointing to their product's potential hazards.¹⁰⁵ Thus, both parties were culpable in the chain of events that led to the TSS crisis of 1980.

The history of governmental regulation of tampons began in 1938 with the Food, Drug and Cosmetic Act. Under the legislation, tampons were classified as cosmetics, a categorization that allowed the FDA only limited authority to regulate the product. The FDA could inspect plants occasionally in order to ensure that companies were following good manufacturing practices, but they could not conduct tests, require that they be allowed to view information that the manufacturing company considered to be a trade secret, or require that companies list product ingredients on packaging.¹⁰⁶

In 1968, tampons were reclassified as medical devices, along with everything from thermometers to bandages and at-home pregnancy tests, but this did not affect the level of scrutiny the FDA was permitted to exercise.¹⁰⁷ In 1976, Congress passed the Medical Device Amendments, which required that every medical product be classified into one of three categories. Finally, in 1979, the classification of menstrual products was completed and it was announced that tampons were to be under the heading of Class II devices, which would allow the FDA to implement product performance standards. However, the law, which went into effect in February of 1980, still did not permit the FDA to require ingredient lists on packaging or conduct pre-market tests.¹⁰⁸

Aside from the limited control the FDA was permitted to exercise, there were additional flaws in the Medical Device Amendments that rendered the legislation ineffective as it related to tampons. A loophole in the 1976 law required that only new products demonstrate their safety to the FDA. Known as a "grandfather clause," the section read, "A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent."¹⁰⁹ Products that had already been on the market, like most brands of tampons including

Rely, were not subject to government safety testing. It was this section of the law that allowed Rely to market a tampon containing fibers that could cause TSS.¹¹⁰

Some within the FDA argued that at the time, regulations were not necessary because Rely had a history of safe usage. But had the government required mandatory testing, they almost certainly would have discovered that Rely's super absorbent fibers provided at the very least, an ideal breeding ground for bacteria. A study conducted in 1979, around the same time Rely began introducing super absorbent tampons, revealed that carboxymethyl cellulose, or CMC, worked as a filter for bacterial toxins. A simple analysis of the ingredients in Rely's new tampons would have revealed the presence of this fiber to the FDA. Though it is now known that CMC was not the ingredient that caused TSS, had the FDA then required that more research be conducted on the Rely tampon before it entered the market, they might have identified a problem with Rely's polyester foam, which may have spared many lives.¹¹¹

From the beginning, there were problems with the Rely tampon. When Rely was test-marketed in Rochester, New York in 1975, the Empire State Consumer Association voiced their concern over one of Rely's original ingredients, polyurethane, which had been proven to cause cancer when implanted in animals.¹¹² There is evidence to suggest that the FDA was aware of these early problems with the Rely tampon, yet did not prevent its entry into the market or require further testing. When Procter & Gamble decided to discontinue the use of polyurethane in its tampons, they submitted voluntary product modification notices to the FDA describing the proposed changes in Rely's absorbent materials. Though the proposed modifications were to the tampon's main absorption ingredients, the FDA still viewed the new Rely tampon as "substantially equivalent" to the original, and therefore did not require that it prove its safety.¹¹³

Even before the government began speculating about the safety of Rely, the company repeatedly asserted that they had tested the product themselves, effectively proving its safety.¹¹⁴ Procter & Gamble continuously affirmed its innocence and claimed to have had no prior knowledge indicating that their product was in any way dangerous. But evidence shows that Procter & Gamble executives knew of the

product's potential risks but did nothing to warn the public.

Procter & Gamble, along with other tampon manufacturers, had early knowledge of the association between tampons and toxic shock. The company obtained the information in June of 1980, before the media picked up the TSS story, yet it did not make any effort to warn their consumers about the potential dangers of its product. Other manufacturers ignored their responsibility to the public as well. Later evidence would show, however, that Rely knew much more than their competitors about the specific risks of its product.

Following the toxic shock outbreak in 1980, investigators discovered that Procter & Gamble had a special file containing numerous complaint letters from consumers. The volume of letters from the time period surrounding the outbreak of TSS in early 1980 averaged about ten to fifteen a month. Although most of the complaints were not related to anything resembling TSS, several were written by women who had suffered from illnesses bearing strong resemblance to the disease. Even with this awareness, Procter & Gamble made no move to inform Rely consumers.¹¹⁵

In fact, Procter & Gamble did exactly the opposite by lying and misleading the public. On more than one occasion women wrote to the company asking to know the ingredients of Rely tampons. Most were interested because they had become sick after using the product and were hoping to identify the source of their sickness, possibly a substance that they were allergic to. In most cases, Rely employees told questioning consumers that the tampons were made of rayon and cotton, which was untrue. On other occasions consumers were told that the super absorbent fibers were composed of natural cellulose, which was again, not true. Rely tampons did contain cellulose, but it was synthetic cellulose that had been chemically treated with carboxymethyl.¹¹⁶

The secrecy and misleading statements indicate that Procter & Gamble was aware of the potential dangers of some of its ingredients. Not only did the company fail to inform the public, it deliberately misled women in an effort to conceal its own guilt, and continued marketing its product as if it was made up of basically the same traditional, safe ingredients. A further indictment of Procter & Gamble came with the revelation that from the time the company first learned

of the association between tampons and TSS until they were forced by the FDA to submit to the “Stop Using Rely” ad campaign, Procter & Gamble gave their employees specific instructions not to bring up TSS when speaking to doctors. Had doctors been aware of the existence of TSS – most of them were not – many more would have been able to identify the disease in their patients and treat it accordingly.¹¹⁷

Economic Ramifications

The emergence of toxic shock syndrome had such a devastating effect on the tampon market that it took a full six years for the industry to recover from the scare that began in the summer of 1980.¹¹⁸ Prior to the vast public awareness of TSS that resulted from extensive media coverage, the tampon industry boasted a forty-six percent share of revenues from the menstrual product market, or \$460 million of the one billion dollar industry.¹¹⁹ In early 1980, approximately seventy percent, or forty-nine million of the seventy million American women of menstruating age reportedly used tampons at any time during their menstrual period, with thirty-seven percent of those women using tampons exclusively and thirty-three percent alternating between using tampons and sanitary napkins.¹²⁰

Almost immediately after TSS headlines began appearing on the front page of national newspapers and magazines, tampon sales dropped twenty percent.¹²¹ By May of 1981, about nine months after the major scare, the number of women using tampons had dwindled from forty-nine million to thirty-five million.¹²² By the end of 1980, tampon sales only amounted to a thirty-five percent share of the menstrual protection market, resulting in a revenue loss for that year totaling \$110 million.¹²³ It was clear that many women abandoned using tampons due to the fear of TSS and its unknown causes. But while the tampon industry suffered, the sanitary napkin market flourished as thousands of women chose safety over convenience and switched to using sanitary napkins exclusively. Between July and December 1980, the sanitary napkin market experienced a sales boom amounting to a twelve percent increase in its share of the menstrual product market.¹²⁴

Most of the major tampon manufacturers in the United States

suffered heavy losses during the time period during and after the widespread coverage of TSS. However, with the elimination of Rely, the Tampax corporation, Rely's closest competitor, experienced a seemingly unexpected sales inflation that year, making it the only tampon manufacturer to actually benefit from the toxic shock crisis.¹²⁵ In the first month after Rely was withdrawn from the market in September 1980, Tampax's share of total tampon sales in the U.S. soared thirteen percent, giving the company control of fifty-six percent of the tampon market.¹²⁶ The explanation behind this phenomenon is twofold. First, Tampax decided to reinvent its product line, bringing back the Original Regular 100 percent cotton tampon that had been discontinued three years earlier because of decreasing popularity for lower absorbency tampons. This inevitably proved to be an effective marketing tool, given the stigma associated with super absorbent tampons in 1980.¹²⁷

The second explanation for Tampax's success lies in their prominent, yet risky advertising campaign.¹²⁸ At a time when tampon manufacturers were exercising caution as a result of the unknown origins of TSS, Tampax embarked on a boldly different strategy. Rather than keep a low profile in the face of a potential catastrophe, Tampax was determined to increase its visibility. While other tampon companies reduced their advertising budgets or even halted ads altogether, Tampax stepped up its ad campaign and continued heavily promoting its tampons throughout 1980. Tampax embraced the mood of uncertainty that was present at the time and used the opportunity to cement, or more accurately invent, a reputation for being the safe tampon choice. It did this by refusing to place optional warning labels on the outside of tampon boxes. Tampax chose instead to include the information as an enclosure on the inside of the box, thus giving the impression that users of Tampax tampons were not in any danger of contracting TSS as were users of other brands (every other tampon brand placed warning labels on the outside of boxes.)¹²⁹ Had scientists discovered any information linking TSS to materials or manufacturing practices common to all brands of tampons, Tampax would have faced a situation not unlike Rely's. Luckily for Tampax, its marketing tactics, though risky and somewhat unethical, proved effective. No further information was released to endanger the brand and force Tampax to be held

accountable for marketing a potentially dangerous product to an unwitting public.

While Tampax reaped the benefits of the toxic shock situation, Procter & Gamble sustained seemingly heavy losses. Faced with the threat of a mandatory recall, Procter & Gamble voluntarily removed Rely from supermarket shelves in September 1980, a move that cost Procter & Gamble \$75 million, or ninety-one cents per outstanding stock share, which it took as an after-tax write off.¹³⁰ Though this one-time loss may seem large, Rely constituted less than one percent of Procter & Gamble's total consolidated revenues of \$10.8 billion and represented only one of the company's roughly 100 national brands.¹³¹ Following the Rely withdrawal, Procter & Gamble chairman-CEO, Edward Harness insisted that the suspension of Rely, "did not mean the end of P&G in the tampon business."¹³² Though the company saved 898,000 Rely packages in hopes that the brand might be brought back, it never was.¹³³ James A. Lack, a market analyst with the Mayflower Management Company, reasoned that it would be nearly impossible for Procter & Gamble to ever attempt a Rely reentry into the market due to a negative product association.¹³⁴ But in 1997, Procter & Gamble found its way back into the feminine hygiene market by different means – purchasing Tambrands, the makers of Tampax tampons, once again giving Procter & Gamble a leading place in the tampon industry.¹³⁵

Toxic Shock, Rely and the Courts

Following the toxic shock crisis of 1980, every major tampon manufacturer faced at least one lawsuit from a TSS victim or the family of a victim.¹³⁶ In some cases, the FDA was even named as a codefendant on the grounds that the government agency did not monitor the tampon industry closely enough.¹³⁷ Legally, the party hit the hardest by toxic shock litigation was Procter & Gamble. In all, TSS victims and their families filed over 200 lawsuits against the manufacturing giant for damages totaling more than \$4 billion.¹³⁸

The first individual to bring a case against Rely did so in August, six weeks prior to the publishing of the CDC study officially linking Rely to TSS. Linda Imboden of Redding, California filed suit for \$5 million on August 6, 1980, declaring that she "lost parts of her fingers

and toes as a result of getting TSS from using Rely tampons.”¹³⁹ The first federal class-action suit to be filed against a tampon manufacturer for damages suffered as a result of TSS was brought against Procter & Gamble on the day following the Rely withdrawal. The suit, which did not specify a monetary amount of damages sought, challenged that, “Rely is unsafe and that all women who use it face lacerations and toxic reactions.”¹⁴⁰

In order to combat the accusations, Procter & Gamble designed a multifaceted strategy to deal with the lawsuits in such a way as to cause the least possible amount of damage to the company, both its finances and reputation. The company’s legal strategy was closely intertwined with its sponsoring of TSS related scientific studies. Procter & Gamble’s success in TSS legal proceedings depended on its ability to corner the market on TSS research. After it had successfully funded or employed the vast majority of scientists in the field of toxic shock research, Procter & Gamble was able to effectively control the flow of information entering both the scientific and mainstream press.¹⁴¹

Procter & Gamble’s complicated legal strategy can be looked at in two distinct phases. The first phase, or delay stage, was under way even before any TSS cases actually went to trial.¹⁴² Contracts between Procter & Gamble and research grant recipients stipulated that Procter & Gamble be allowed immediate access to all scientific findings prior to their publication.¹⁴³ By exercising such intense scrutiny over TSS research projects, Procter & Gamble wielded the immense power to suppress or delay damaging information long enough for the statute of limitations, determined by state law, to expire. In most states, claims filed after October 1, 1982, approximately two years after the Rely recall, would be refused. Any cases filed before that date would have already entered into settlement negotiations or been tried without the plaintiffs’ attorneys having had the benefit of new scientific evidence discovered by research grant recipients that would have strengthened their cases against Procter & Gamble.¹⁴⁴

In many states, negligence did not need to be proven in order to hold a company responsible for damages caused by one of its products. In other words, attorneys were not required to establish that Procter & Gamble had prior knowledge of its product’s defects. They only had to prove that a defect did indeed exist and that it was

“causally” related to the injury.¹⁴⁵ This rule would make it much easier for TSS victims to establish grounds for suit because at the time, the magnesium connection had not been established and therefore, the exact cause of the relationship between tampons, specifically Rely, and toxic shock had not yet been specifically identified. Procter & Gamble was aware of the potential problems it could face as a result of the rule, and embarked on the second phase of its legal strategy, protecting information, in order to deter the deluge of cases that were to inevitably follow.¹⁴⁶

In order to prevent the sharing of information between attorneys embarking on separate lawsuits against Procter & Gamble, the company applied for a protective order. Under such a restriction, lawyers for TSS victims would be denied the ability to view information uncovered in similar lawsuits, thus preventing any cooperative efforts to benefit the cases of TSS victims in court. Any document Procter & Gamble deemed confidential could only be viewed by an attorney who had signed an agreement stating that the documents would be shown only to witnesses in that particular case. In turn, each witness who viewed the documents was required to sign a similar agreement. Procter & Gamble’s divide and conquer strategy worked – the company was granted the protective order. With this order in place, damaging company documents, such as those that revealed Procter & Gamble’s prior knowledge of Rely complaints, could be declared “proprietary information” and thus, would never be openly released to the public or to other TSS victims’ attorneys.¹⁴⁷

In the end, Procter & Gamble’s strategy proved to be effective. In 1987, the company revealed that there had been only three trial verdicts involving Rely, none of which resulted in any punitive damages being awarded. The company did not reveal the number of cases it settled. However, in only one case, a jury found Rely to be responsible for the death of a TSS victim and awarded \$300,000 in compensatory damages to the victim’s family.¹⁴⁸ Procter & Gamble appealed the decision and lost. By the time the family received a check from the company, the total judgment amounted to \$404,000 with accumulated interest.¹⁴⁹ It is likely that the full amount was covered by Procter & Gamble’s product liability insurance.¹⁵⁰ Though Procter & Gamble was victorious in most of the Rely-related lawsuits, in the end, the

Rely brand never recovered as the company had originally hoped. Fortunately, America did.

TSS after 1980: Stricter Government Regulations

Following the 1980 toxic shock crisis in America, the number of reported TSS cases from around the country declined steadily. Doctors currently estimate that only three cases for every 100,000 menstruating women are likely to occur in the United States each year. The declining incidence of TSS in America is partially attributable to the widespread knowledge about the disease and the government's stricter regulation of the tampon industry prompted by the events that occurred in 1980.¹⁵¹ Those stricter regulations include uniform absorbency labels for tampons and mandatory warnings on package labels.¹⁵²

Faced with criticism over their handling of the TSS situation in 1980, the United States government finally began taking a proactive approach to tampon regulation. The first evidence of this tightening of control came in 1982, when the FDA established a task force to begin the process of standardizing tampon absorbency. During this meeting, officials at the FDA declared that tampon manufacturers be required to lower the maximum tampon absorbency from 20 grams of liquid to 15 grams.¹⁵³ This marked a big change in absorbency as many brands of tampons marketed in 1980 and 1981 as "super" or "super plus" generally held 18.5 grams of fluid or more.¹⁵⁴

In addition to reducing the maximum allowed absorbency of tampons, the task force faced the difficult job of determining the most effective method of standardizing tampon absorbency. But this end was not accomplished without much debate. There was turmoil both within the FDA and the tampon industry over whether standardized terms or a standardized numerical system based on the number of grams of fluid a tampon could absorb should be used to describe absorbency.¹⁵⁵ The final decision made by the task force was to use standardized terms. Thus, a box bearing the label "junior" would contain a tampon that could absorb between four and six grams of fluid, from six to nine grams for "regular" tampons, nine to twelve grams for "super," and twelve to sixteen for "super plus."¹⁵⁶

In October of 1982, the FDA held hearings to discuss the

issue of toxic shock syndrome prevention. During the meeting, officials at the organization proposed mandatory warning labels on tampon packages to make women aware of the possible risks of tampon use. The exact wording of the proposed warning was as follows:

Warning: Tampons have been associated with toxic shock syndrome, a rare disease that can be fatal. You can almost entirely avoid the risk of getting this disease by not using tampons. You can reduce the risk by using tampons on and off during your period. If you have a fever of 102 degrees or more, and vomit or get diarrhea during your period, remove the tampon at once and see a doctor right away.¹⁵⁷

A final FDA warning, however, was not approved until June 21, 1982. The approved version of the warning label was much shorter than the original though it conveyed the same message. The 1982 warning contained the same language used on tampon boxes today, “Attention: Tampons are associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease. It may cause death. Read and save the enclosed information.”¹⁵⁸ Prior to 1980 only a handful of people even knew of the existence of a disease called toxic shock syndrome. Information was not easily accessible to doctors, let alone the general public. Now, over twenty years after the TSS scare, every American woman who buys a box of tampons can learn about the potentially deadly disease.

Conclusion

The year 1980 brought a terrifying new disease to the forefront of American thought. By the end of that year, toxic shock had affected nearly 900 Americans with the majority of cases occurring in menstruating women. At first glance the toxic shock crisis appeared to be an event generated solely by a medical mystery. Upon closer examination, however, the origins of the TSS crisis of 1980 had more to do with governmental disregard and corporate misconduct than it ever did with the biological phenomenon of TSS.

The toxic shock crisis of 1980 involved a wide range of

participants, including both state and federal agencies, the news media, doctors and research teams at renowned universities, and multinational corporations. In the years following the crisis, questions were raised about the role of one participant, the media, and whether they were disseminating fear, rather than fact, at the time of the crisis. Analysis of numerous studies revealed strong evidence supporting the conclusion that the media's effects on the crisis were only minimal. Thus, the media played a part in the events of 1980 in that it spread the story of TSS to the public, but that was, in fact, the media's only role.

While the media was somewhat of a secondary character in the story of toxic shock, Procter & Gamble and Rely had leading roles. Even after numerous studies revealed that Rely was a defective and even dangerous product, company officials were still refusing to publicly admit that their product was in any way flawed or that they had prior knowledge of its potential hazards. Years after the removal of Rely from the market in September of 1980, the new president of Procter & Gamble, John E. Pepper, did not include Rely in a list of Procter & Gamble "problem brands." In an article that appeared in the August 20, 1987 edition of *Advertising Age*, Pepper was quoted as saying that Rely, "fulfilled all those things that we expect a brand to do to succeed. It was a better product; it was well advertised; it was a good value."¹⁵⁹ The fact that Rely was responsible for the death and sickness of hundreds of women was apparently not significant enough for the product to be considered a problem even seven years after the fact.

Following the same line of reasoning, Procter & Gamble officials began funding numerous TSS studies in an attempt to clear their name. Though it claimed to be acting on behalf of humanity, the company was instead, only looking out for its own self-interest. The priority Procter & Gamble's placed on protecting its profits and its image became even more apparent throughout the toxic shock litigation. The company continued to vigorously defend its position by employing less than scrupulous tactics rather than admit responsibility for a problem that was caused by its own negligence and disregard for the safety of Rely consumers.

Procter & Gamble was not the only party responsible for the events leading up to the TSS crisis; the United States government was

culpable as well. The events of 1980 revealed important information about previous regulation of the tampon industry by the FDA, which had for years proceeded with a policy of leniency toward tampon manufacturers that allowed new and potentially unsafe products to enter the market. It took a medical crisis and tragically, the loss of lives to finally compel the FDA to begin to put in place adequate regulations of the tampon industry.

The TSS crisis of 1980 had broad-reaching effects within the medical community, the United States government, the tampon industry and the homes of many American women and their families. Within the FDA, the events of 1980 gave rise to serious debates over pre-market safety testing of tampons, manufacturing site inspections, mandatory ingredient labeling, standardizing absorbency, and mandatory warning labels on tampon boxes. For six years following the crisis, the tampon industry paid the price for the outbreak of TSS economically, with a large decrease in sales and profits as many women discontinued their use of tampons and switched to other forms of menstrual protection. But this was a small price to pay compared to the avoidable deaths of thirty women who paid with their lives because of governmental indifference and corporate negligence. However, along with the obviously negative effects, the toxic shock crisis also led to some positive results that would affect the lives of millions of American women in the future, including new medical discoveries and much needed changes in governmental policy regarding the regulation of the tampon industry.

Time Line

1927	First documentation of case resembling TSS (Toxic Shock Syndrome)
1933	First commercial tampon introduced
1962	Procter & Gamble begins developing Rely tampon
1974	Rely brand tampon introduced to public
1975	Earliest known case of TSS
November 25, 1978	Todd publishes his findings on toxic shock and coins the term “toxic shock syndrome”

344 *Chrestomathy*: Volume 2, 2003

May 23, 1980	CDC's <i>Morbidity and Mortality Report</i> announces TSS as national health problem
June 27, 1980	CDC announces TSS link to tampons
September 17, 1980	CDC announces TSS link to Rely tampons
September 22, 1980	Rely voluntarily recalls its tampons
September 24, 1980	CDC urges reduced use of tampons
October 6, 1980	Procter & Gamble begins ad campaign warning consumers not to buy Rely
October 20, 1980	FDA begins debating mandatory warning labels for tampons
June 21, 1981	Government approves mandatory warning labels for tampons
June, 1985	The TSS-Magnesium connection is published in <i>The Journal of Infectious Diseases</i>
April, 1995	Tampons containing polyacrylate fiber are voluntarily recalled by their manufacturers
1997	Procter & Gamble purchases Tambrands

Notes

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² Harvey Sapolsky, *Consuming Fears* (Basic Books, Inc., 1986).

³ Richard Severo, "Sharp Decrease in U.S. Reported in Toxic Shock Syndrome Cases," *New York Times* (January 30, 1981), p. A1.

⁴ Walter F. Schlech, et. al., "Risk Factors for Development of Toxic Shock Syndrome," *Journal of the American Medical Association* 248, no. 7 (August 20, 1982), p. 835.

⁵ Schlech, pp. 836-839.

⁶ Nancy Friedman, *Everything You Must Know About Tampons* (Berkley Books, 1981).

⁷ Wallis, p. 77.

⁸ "U.S. Will Trace Toxic Shock," *New York Times* (December 2, 1985), p. B6.

⁹ Jane E. Brody, "Scientists Unraveling Mystery of Toxic Shock," *New York Times* (April 26, 1983), p. C1; and *The Merck Manual of Diagnosis*

and Therapy: Centennial Edition, <<http://www.merck.com/pubs/mmanual/selection13/chapter157/157a.htm>>, s.v. "Toxic Shock Syndrome," [accessed 28 October 2002].

¹⁰ Katrina Onstad, "Sanitary Sanity," *Chatelaine* (December 1997), p. 190.

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¹² "Disease Linked to Tampons Still Elusive," *New York Times* (August 30, 1980), S1 p. 14.

¹³ James Todd, "Toxic-Shock Syndrome Associated With Phage-Group-1 Staphylococci," *The Lancet* 2 (November 28, 1978), p. 1116.

¹⁴ Todd, p. 1116-1118.

¹⁵ Richard Severo, "Rely Tampon Recalled by Maker; Linked to Toxic Shock Syndrome," *New York Times* (September 23, 1980), p. A1.

¹⁶ Todd, p. 1117.

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