Managing a Low-Incidence Risk: The Example of Toxic Shock Syndrome

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This article demonstrates a methodology that allows individuals to reach a personal decision on the use of products which carry very small risks to health and life but also offer considerable benefits. A combination of the principles of dominance, extended dominance, and various methods of direct risk–benefit tradeoffs are shown to reduce the number of possible decisions regarding product use to the one optimal for the value structure of a particular individual. An historical examination of toxic-shock syndrome identifies tampons as a product with risks too small to warrant public intervention but too sizeable to be ignored. The methodology described here can be applied for all such products.

KEY WORDS: Toxic-shock syndrome; small-incidence risk; risk–benefit analysis; personal value trade-offs.

1. INTRODUCTION

In the summer of 1980 North American women found themselves confronted with yet another, unexpected, threat to their lives. Strong evidence was reported that toxic shock syndrome (TSS), a rare but extremely visible and sometimes fatal disease, was associated with the use of tampons in general and with the use of Proctor & Gamble's "Rely" brand in particular. The symptoms of TSS (sudden high fever, sunburn-like rash, diarrhea, vomiting, and desquamation of the skin on palms and feet) are the result of blood poisoning and resultant drop in blood pressure which occur when a certain bacterium (Staphylococcus aureus) secretes its toxin into the bloodstream. Early diagnosis is important since a special antibiotic, resistant to an enzyme also secreted by the culprit bacteria, is required for treatment.

Tampon use dropped almost immediately by 20% and while the recall of the Proctor & Gamble tampon in September 1980 seemed to lead to a decrease in the incidence of TSS, public apprehension remained high until well into 1981. In the second half of 1980 the New York Times alone published 25 articles on the subject.

TSS achieved this quick notoriety because it killed clearly identifiable young women (63 reported deaths by November of 1980). These deaths could be attributed to a product used on a more or less regular basis by some 50 million women in the U.S. which previously had been considered perfectly safe. Results in the psychology of risk perception (acceptable level of risk being inversely related to the number of participants, society favoring the saving a known life to saving a statistical life, perceived riskiness increasing with the immediacy of consequences, and people overvaluing outcomes considered certain relative to outcomes that are merely probable) make the magnitude of public concern understandable.

Public opinion and sentiment undoubtedly play a role in risk policy decisions. Such considerations should, however, be preceded by an assessment of the objective risk of TSS (e.g., incidence and mortality rates). The next section of the paper will review these statistics, the evidence linking TSS to tampon use,
and the status of some hypotheses that have been proposed as causal mechanisms behind the TSS—tampon use association. There are different methods of detecting and managing societal risk. We will consider whether the TSS case was handled correctly, focusing in turn on the roles played by the catamenial industry, government, and the public.

The second part of the paper describes a methodology which allows individuals to reach a personal decision regarding tampon use. Applying this methodology to the question of tampon use will serve to demonstrate how individuals can weigh risks and benefits of products with risks that do not warrant public intervention but are too large for them to ignore.

2. STATISTICS AND HYPOTHESIS

Table 1 provides a chronology of the most important actions and events regarding tampon safety and TSS. Even though cases of TSS were first reported in 1978, the report of an increase in the incidence of the disease by the Center for Disease Control (CDC)\(^{(10)}\) coincided with the nationwide distribution of the new Proctor & Gamble tampon “Rely.” An estimated 80% of American households received a free sample of “Rely” at that time.\(^{(11)}\) By November of 1980 the CDC had received a total of 652 reports of TSS, including 63 deaths. By May of 1982, the total of reported cases had reached 1660, including 88 deaths. There are currently between 30 and 50 new reports of TSS every month, 3.3% of which are fatal.\(^{(12)}\) Even though there have been reported cases of TSS in other countries, the incidence there is negligible. For example, by Oct. 31, 1981, 53 cases of TSS were reported in Canada, six in the United Kingdom, and eleven in Australia, as opposed to 1470 in the U.S.\(^{(13)}\)

TSS seems to be primarily a tampon-related problem. The toxin producing bacterium, Staphylococcus aureus, thrives in the vagina of menstruating women who wear tampons. It has also been found in wounds and abscesses, but of the 1660 TSS cases reported to the CDC by May of 1982, only 55 occurred in men and only 154 in nonmenstruating women.

The current FDA estimate of the incidence of TSS which appears on the information inserts of tampon packages ranges between 6 and 17 cases per 100,000 menstruating women per year. The FDA arrived at this estimate by making the following assumptions\(^{(14)}\): (1) Based on past experience with

### Table 1. Chronology of events

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1936</td>
<td>Tampons introduced by Tampax, Inc.; classified as “medical devices” by FDA</td>
</tr>
<tr>
<td>1973</td>
<td>FDA sets up Device-Experience Network (computer databank for complaints from physicians and users); by mid 1980, 49 reports of tampon-related problems: difficulty of removal (4), infection (12), lacerations (12), ulcerations (7), tampon disintegration (6)</td>
</tr>
<tr>
<td>1976</td>
<td>Medical Devices Amendment to FDA charter; more power for regulation to FDA; grandfather clause; tampons classified as “nonsignificant risk medical devices” (class II)</td>
</tr>
<tr>
<td>1978</td>
<td>TSS first reported by Denver physician (1 boy and 6 teenage girls)</td>
</tr>
<tr>
<td>May 1980</td>
<td>Center for Disease Control (CDC) reports increase in incidence of TSS: 55 cases, with 95% occurring among menstruating women; coincides with national distribution of Proctor &amp; Gamble’s new tampon “Rely.”</td>
</tr>
<tr>
<td>June 1980</td>
<td>CDC case-control study (CDC-1) shows statistically significant association between TSS and tampon use</td>
</tr>
<tr>
<td>Sept 17, 1980</td>
<td>CDC-2 study establishes association between TSS and P&amp;G tampon brand “Rely.”</td>
</tr>
<tr>
<td>Sept 18, 1980</td>
<td>P&amp;G halts production of “Rely.”</td>
</tr>
<tr>
<td>Sept 22, 1980</td>
<td>P&amp;G recalls “Rely.”</td>
</tr>
<tr>
<td>Sept 29, 1980</td>
<td>FDA asks for warning on all tampon packages</td>
</tr>
<tr>
<td>Oct 20, 1980</td>
<td>FDA proposes mandatory package label; manufacturers (except Tampax) agree to voluntary label; (Johnson &amp; Johnson subsequently refuse package label, use insert instead, argue that Tampax is at competitive advantage)</td>
</tr>
<tr>
<td>Nov 21, 1980</td>
<td>CDC reports 653 cases of TSS, including 63 death</td>
</tr>
<tr>
<td>April 1981</td>
<td>FDA reports a decline in incidence of TSS</td>
</tr>
<tr>
<td>May 1982</td>
<td>CDC reports a total of 1660 cases of TSS, including 88 death</td>
</tr>
<tr>
<td>June 22, 1982</td>
<td>FDA passes Tampon Label Regulation: mandatory label and TSS information insert; into effect after 180 days, Dec 22, 1982</td>
</tr>
<tr>
<td>July 16, 1982</td>
<td>FDA denies petition for reconsideration of labeling by Playtex, Inc.</td>
</tr>
</tbody>
</table>
epidemiological reporting, only 15% of severe cases of TSS get reported to the CDC; (2) There is an equal number of non-reported, less severe, cases; (3) 50 million women in the U.S. use tampons. With 600 reported cases per year, the estimate of the actual number of cases per year is 8,000 in 50 million, or 16 in 100,000. This figure includes 4,000 severe cases per year for which the mortality rate estimate is 3.3%. This means that TSS is responsible for approximately 130 deaths each year (equivalent to 2.5 deaths in 1 million users). This estimate is high since I used the upper extreme of the 30 to 50 incidences-per-month range in my calculation.

The statistical evidence linking TSS and tampon use comes from case-control studies. An animal model of TSS which would allow causal attribution of responsibility does not seem to be feasible. Few animals have a menstrual cycle similar to that of women and those that do (primarily the great apes) do not take to wearing tampons. While technically, case-control studies are ineffective in establishing causal relationships, the evidence linking TSS and tampon use clearly satisfies the criteria (consistency, strength, and specificity of association) that were suggested by the U.S. Surgeon General’s Advisory Committee on Smoking and Health(15) as a basis for inferring causality. Attacks on the methodology of TSS studies claim that results from these studies are not valid because of the possibility of diagnostic and reporting biases favoring the detection of TSS in tampon-wearing menstruating women.(16) Yet, even if such biases existed (which was not the case for at least the CDC-1 study, they would not be sufficient to account for the results. Seven investigations, most of which were conducted between May and October of 1980, examined the association between TSS and a number of potential contributory factors including sexual habits, methods of contraception, and cata menial habits. In the two national CDC studies (CDC-1(18,19) ; CDC-2), the four statewide studies (Wisconsin(22, 23); Utah(24, 25, 26); Minnesota(27); Oregon(28) and the Tri-State study(29, 30) no factors other than the fact that women used tampons and “Rely” in particular showed a statistically significant association with the occurrence of TSS. The correlation between TSS and tampon use was significant in six of the seven studies, with a median correlation coefficient of .25. The correlation between TSS and use of “Rely” tampons was significant in only four of the seven studies, but had a median value of .27. The sample sizes in these studies varied between 18 and 80 cases and between 36 and 160 controls.

Several hypotheses were proposed to explain this association. Contamination of the new “Rely” tampon with Staphylococcus bacteria would have explained the puzzle of the sudden upsurge of TSS. However, tests of thousands of tampons of all brands never showed any evidence of bacterial contamination.(31) There is some tentative evidence that a new variant of Staphylococcus aureus may have been at least partially responsible for the suddenness of the TSS outbreak.(32) Strains of the bacterium taken from TSS patients produced toxins that were not produced by strains obtained from other sources. Some women also seem unable to develop the antibody to the TSS toxin found in the blood of many of non-TSS controls. This would explain why a full 30% of women who have had TSS once have a recurrence. While high absorbency of the tampon per se does not appear to be a risk factor,(33) there is some recent evidence that implicates the synthetic superabsorbent tampon material carboxymethylcellulose (which gets broken down into glucose by microorganisms present in the vagina) as a nutrient supporting the growth of Staphylococci.(34) Larger superabsorbent tampons may also be more likely to cause lacerations of the vaginal walls thus allowing easier passage of the TSS toxins into the bloodstream.(35)

3. RISK DETECTION AND MANAGEMENT

Premarket testing of a new product in a restricted and closely watched population is the most direct way of detecting problems associated with a product. Unfortunately, because of small sample sizes, problems or risks that will show up in premarket tests have to have a sizeable incidence rate. A rare risk like that of TSS (6 to 17 in 100,000) would almost certainly go undetected. The “Rely” tampon did in fact go through years of Proctor & Gamble’s own premarket testing(36) which showed no evidence of TSS.

This leaves epidemiological evidence, like that collected by the CDC, as the earliest warning signals for low-incidence risks. This mechanism leaves a time gap between the introduction of a potentially dangerous product on the market and the detection of its hazards, with even more time passing before action is taken to reduce the risk. While unfortunate for those “pioneers” that make up the epidemiological statistics, this time lag in the detection of low-probability risk seems unavoidable.

Risk perceptions often differ depending on one’s point of view. In the case of TSS, the public runs the
risk of contracting a potentially fatal disease by using tampons. Yet, from the point of view of the catamenial industry, there also is the risk of financial losses as the result of health warnings appearing on tampon packages. For particular companies, like Proctor & Gamble, there is also the risk of a loss of consumer confidence that might generalize to other of its products. Then there is the risk of competitors taking advantage of their present vulnerability. Regulatory agencies, like the FDA, run the risk of public indignation when their regulation is perceived as either insufficient or excessive.

These different and oftentimes opposing risks and interests underlie the dynamics of the risk resolution process. In the case of TSS, public interest groups took a position adversarial to both the tampon industry and the FDA, charging the industry with negligence for introducing unnecessary new and untested variants of tampons in their competitive struggle for market share. They attacked the FDA for its cavalier use of the grandfather clause allowing new products to be marketed without adequate testing. The tampon industry in turn accused the FDA of over reaction in the face of inconclusive evidence and managed to stall mandatory health risk labeling on tampon packages for over two years.

Both attacks on the FDA were probably unjustified. In almost 50 years of tampon use, there never had been any indication to doubt the safety of the product. This included the FDA monitoring of tampon-related complaints in the Device-Experience Network since 1973 (see Table 1). On the other hand, faced with the TSS crisis in the fall of 1980, the FDA first tried to appeal to the tampon industry for voluntary package labeling. Only after realizing that the competitiveness of the industry prevented companies from cooperating, did the FDA resort to regulatory legislation which eventually went into effect in December of 1982. The intent of the mandatory TSS warning and information was to allow potential tampon users to make an informed personal decision between tampons and risk-free, but less convenient, sanitary napkins.

This leaves the question of negligence on part of the tampon industry, and Proctor & Gamble in particular. Proctor & Gamble had done extensive pre-market testing of the “Rely” tampon and was cleared in both product-liability suits that were brought against the company to date. After some initial confusion about legal terminology the courts refused to award any punitive damages to the plaintiffs.

4. TAMPON USE AND TSS INFORMATION TODAY

Starting in December of 1982, the FDA required tampon manufacturers to include the following information with every tampon package: A statement describing the warning signs of TSS, as well as instructions on what to do when these signs occurred; an indirect warning about the risk of recurrence of TSS; advise on how to reduce the risk of TSS by alternating tampons with napkins, using tampons with the minimum absorbency needed, or not using tampons at all; and, lastly, the FDA incidence rate estimate (6 to 17 cases per 100,000 menstruating women and girls per year) together with a statement that TSS carries a risk of death.

There are at least three functions that the information insert should fulfill. The first two functions, namely, to foster increased awareness of TSS (with early diagnosis leading to smaller mortality rates) and to bring about habit changes that will reduce the risk of TSS without significantly taking away from the benefits of tampon use (e.g., using minimum absorbency brands or wearing napkins at night), seem to be met quite well by the insert in its present form.

The insert fails in its attempt to provide a quantitative estimate of the risk of TSS. Population incidence rates per year have little meaning for a woman who wants to know how likely she is to get TSS and, more importantly, how likely she is to die from it. It would be more appropriate to provide estimates of the probability of contracting TSS and the probability of getting TSS and dying from it if tampons were used for the remaining years of menstruation. For example, with the assumption that the probability of getting TSS per year is .00017 and that the probability of dying from TSS per year is .00000264 (or 130 deaths in the approximately 50 million women using tampons in the U.S.), a teenager with an expected 30 years of tampon use would have a half percent (5 in 1000) chance on contracting TSS during this time period \( [1 - (1 - .00017)^{30}] \) and a 8 in 100,000 chance of dying from TSS during that same period \( [1 - (1 - .00000264)^{30}] \). Such figures could be provided for different age groups of tampon users, incorporating varying risk susceptibilities (higher for teenagers and for women over 30). Together with these probability estimates, products or activities that pose similar risks to one’s health or life could be listed. The probability of dying in childbirth, for example, is of the same order of magnitude as the
lifetime risk to a tampon-using teenager of dying from toxic shock.

While such extended-use statistics and comparison risks would help women to develop a more accurate intuition about the risks involved in tampon use, they still do not enable one to decide whether the benefits make taking these risks worthwhile. The fact that tampon use is up again from its 1980 drop\(^{51}\) could mean that women are willing to make the risk–benefit tradeoff. It could also mean that they have forgotten about TSS, that they believe the risk has gone away (i.e., that is was a "Rely" disease), or that they have chosen to ignore it.

5. RISK–BENEFIT ANALYSIS

To make an informed decision on whether to use tampons, an individual should weigh the associated risks against the subjective benefits. The probability of contracting TSS and dying from it is very small; on the other hand, the risk may be too sizeable to some women to simply ignore it. What should occur for low-probability risks like TSS is a personal risk–benefit analysis to resolve (at least for the time until any of one's values changes) the question of use.

Risk–benefit analysis shares the problem of all analyses that involve comparison or tradeoff between incommensurables. The challenge lies in bringing quantities like the possibility of death, the health and psychological effects of contracting TSS, the convenience of wearing tampons versus napkins, and the benefits of participation in social activities possible through tampon use on a common denominator. This is done in some implicit way whenever a decision about entering or not entering into a risky but beneficial situation is made. The ability of compensating wage differentials to attract workers into hazardous jobs, for example, indicates that workers implicitly weigh increases in risk against financial benefits. There is some controversy\(^{52}\) whether market mechanisms do, in fact, ensure equality of the advantages and disadvantages of different employments thus warranting the use of historical data in analyses of risk acceptance.\(^{53}\) Whatever the answer may be, the risk–benefit analysis suggested here has a more individual focus. The types of risk to which it applies are of a nature not warranting public intervention, while the benefits are of a highly personal nature that can only be assessed by the individual. Thus our concern is with a person's own assessment of costs and benefits to themselves that will help them decide whether or not the benefits are worth the risks associated with them. There is no guarantee that for such decisions implicit tradeoff methods lead to decisions that are optimal. People, for example, may lessen the conflict in their task by selectively focusing on the negative or the positive aspects of the situation. It would seems desirable to induce people to explicitly convert all risks and benefits into a common currency in which they can be compared. Yet, to find a currency in which concerns like health risks and personal or social benefits can be directly compared is not easy. While benefits may lend themselves to conversion into a monetary equivalent, for example, many people find it objectionable to put any sort of monetary tag on costs involving human life or suffering. Fortunately, many decisions can be made using methods which do not require such a conversion. The details of such an approach which could lead to the development of a self-administered and self-scored questionnaire are described below.

5.1. Reaching a Decision on Tampon Use

The approach of the personal risk–benefit analysis suggested here is that of reducing an originally intractable decision to several decisions for which people are better equipped and with which they have more experience. The first step in the analysis which follows Raiffa, Schwartz, and Weinstein’s recommendations\(^{54}\) is to produce an exhaustive list of all concerns and objectives which enter into the decision about tampon use. These objectives will most likely cluster into groups of advantages and disadvantages. The second step in the analysis consists of listing all reasonable decisions that might be made about tampon use, ranging all the way from never using tampons, through using minimum absorbency tampons but only during the day, to always using highly absorbent tampons. Table II is a cross tabulation of some possible decision alternatives (rows) and decision objectives (columns).

The ranking of mortality and morbidity in Table II reflects the fact that the risk of TSS in tampon users is increased by using tampons at night and by using highly absorbent tampons. Mortality and morbidity ranking is identical since the fatal cases of TSS (mortality risk) are a percentage of the incidences (morbidity risk). The rank orders of alternatives for the benefit objectives in Table II reflect the author’s perception. The benefit category includes the
Table II. Evaluation of Decision Objectives for all Decision Alternatives

<table>
<thead>
<tr>
<th>Decision alternatives</th>
<th>Objectives</th>
<th>Risks$^a$</th>
<th>Benefits$^b$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mortality</td>
<td>Morbidity</td>
<td>Physical</td>
</tr>
<tr>
<td>A: No tampons ever</td>
<td>7</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>B: Minimum absorbency</td>
<td>6</td>
<td>6</td>
<td>2</td>
</tr>
<tr>
<td>tampons only on special occasions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>C: Minimum absorbency</td>
<td>4</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>tampons during the day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(none at night)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>D: Minimum absorbency</td>
<td>3</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>tampons day and night</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>E: High absorbency</td>
<td>5</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>tampons only on special occasions (none otherwise)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>F: High absorbency</td>
<td>3</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>tampons during the day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(none at night)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>G: High absorbency</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>tampons during the day, minimum absorbency at night</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>H: High absorbency</td>
<td>1</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>tampons day and night</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$^a$Low ranks correspond to high risks.

$^b$Low ranks correspond to small benefits.

physical comfort afforded by using tampons over napkins, the psychological comfort or ease of mind achieved by wearing tampons over napkins and especially highly absorbent tampons which do not have to be changed as frequently, and the social activities made possible or more comfortable by the use of tampons.

The principle of dominance allows us to eliminate an alternative if it is worse than another alternative on all or some of the objectives and of equal rank on the remaining objectives. The ranks in Table II were assigned such that low ranks indicate poor standing on both the risk and the benefit objective. Thus alternative $B$ dominates alternative $E$ by scoring better on the risks with equal benefits. Alternative $G$ dominates alternative $H$ for the same reason. For the remaining pairs of alternatives an advantage on one objective is always accompanied by a disadvantage on at least one other objective, so that strict dominance cannot be invoked. Some direct tradeoffs will have to be made to narrow the field of decision alternatives further.

To reduce the number of decision objectives, the mortality and morbidity risks of tampon use should be combined into a single risk index. Tradeoffs within categories are more easily made than tradeoffs between categories because the similarity of the objectives makes it possible to convert the value of one objective into that of the other by using marginal rates of substitution. How much of an increase in morbidity risk would I find acceptable if that would reduce the mortality risk by a fixed amount? It may be easier to answer this question if we conceptualize morbidity and mortality risks in terms of life-expectancy reduction. If my life expectancy without tampon use is one year or the equivalent of 31,536,000 seconds, the threat of death from TSS reduces it statistically by \(0.0000264 \times 31,536,000 \text{ secs} = 83 \text{ secs}\) per year. A similar time-loss figure can be computed for the risk of illness associated with tampon use this year: \(0.00017 \times 31,536,000 \text{ secs} = 5361 \text{ secs or 89 minutes of expected illness}.\) Say that I am virtually certain that I would tradeoff no less than 20 and no more than 500 seconds of illness for one second of life-expectancy loss. This would transform the morbidity risk into an increase in mortality risk between \(0.000085\) and \(0.0000034\), for a new total ranging from \(0.0000298\) to \(0.0001114\) with a mean of...
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.000000704. The upper and lower bounds on the estimate are applied in all subsequent computations to see whether this changes the decision. If so, we would have to develop methods of obtaining as precise an estimate as possible for this parameter. Fortunately, as we will see below, this is not necessary.

The new life and health risk index is based on the FDA estimates for mortality and morbidity discussed earlier, which were computed using the upper extreme of the incidences-per-month estimate. This, in addition to the fact that many women at the time these estimates were made had switched to highly absorbent tampons and were presumably wearing them day and night, will justify us in assigning the value of the new risk index computed above to the most dangerous decision alternative in terms of contracting TSS, namely alternative H. Avoiding night time use of tampons decreases the risk of TSS. A lower bound on the size of this risk reduction is the proportion of time that tampons are not used. Assuming that women sleep an average of 8 hours per night, the reduction factor would be 1/3. Yet other factors such as an increased blood flow in the vaginal walls at night might increase the TSS risk at night, thus leading to greater risk reduction by avoiding night time tampon use. If we assume that such factors may, on the outside, double the effect, we arrive at a range of 1/3 to 2/3 for the risk reduction factor due to avoiding night time use. While there is general agreement that highly absorbent tampons contribute significantly to the occurrence of TSS, there are no quantitative estimates of how much women can reduce their TSS risk by using only minimum-absorbency tampons. Because of this uncertainty, we will use a wide range of possible risk reduction factors (1/4 to 3/4).

Using the risk index of alternative H as a baseline, we can compute the risk for the other decision alternatives by applying the appropriate risk reduction factors. Table III shows the mean risk index estimate (using the average of both the mortality risk and of the risk reduction factor) and its upper and lower bound for each alternative. For alternative G, for example, risk is reduced by 1/4 to 3/4 for a third of the time (night time); thus total risk reduction ranges from 1/12 to 1/4. For alternative F (no night time use), risk reduction ranges from 1/3 to 2/3. For the other alternatives risk reduction can be similarly computed. The reduction for alternative B depends on the percentage of time that is classified as “special occasion” during which tampons are used. The values in Table III reflect a range of 5 to 20%. The risk estimate for alternative A is based on the proportion of non-menstrually related TSS incidences reported to the CDC by May of 1982 (approximately 200 out of a total of 1660 or 12.6%). This risk figure can serve as a base rate to which the additional risks associated with the different tampon use options can be compared. Also helpful in comparing risks and benefits may be a conversion of the risk probability

<table>
<thead>
<tr>
<th>Decision alternativea</th>
<th>Mean risk estimate</th>
<th>Lower bound</th>
<th>Upper bound</th>
<th>Risk as multiple of baseline risk (alternative A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>.00000089 (28 secs)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>.00000089 (28 secs) .00000017 (5 secs)</td>
<td>.000000218 (70 secs)</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>.00000232 (74 secs) .00000053 (16 secs)</td>
<td>.00000552 (175 secs)</td>
<td>2.7</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>.00000348 (112 secs) .00000073 (23 secs)</td>
<td>.00000828 (263 secs)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>F</td>
<td>.00000348 (112 secs) .00000097 (31 secs)</td>
<td>.00000742 (234 secs)</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>.00000591 (187 secs) .00000220 (70 secs)</td>
<td>.00001022 (321 secs)</td>
<td>6.7</td>
<td></td>
</tr>
</tbody>
</table>

aThe letter code corresponds to the decision alternatives listed in Table II. Alternatives E and G do not appear because they were eliminated by dominance.
estimates which may be too small to be meaningful into seconds of life-expectancy reduction using the kind of computation outlined earlier. The risk value expressed as seconds of life-expectancy reduction are also shown in Table (III).

Having used all methods at our disposal to reduce the number of decision alternatives and decision objectives, it becomes unavoidable to make some direct tradeoffs between the risks and the benefits of the remaining decision alternatives. Because such tradeoffs are often highly personal and difficult to make, no single method that has been suggested to aid in making such tradeoffs has remained uncontroversial. One approach consists of converting both the risks and the benefits of an alternative into a common currency in which they can be easily compared. There are not many candidates for this “common currency”, that is, for a unit of measurement that can express both risks (costs) and benefits. The unit that has been most often suggested, $-equivalency, is also the most controversial. Many people find it morally objectionable to put a monetary tag on costs involving human life or suffering and would reject any decision methodology that would require them to do so. The method is presented below, but is preceded by an alternate analytic technique. Readers who find the $-equivalency approach objectionable can skip that section without any loss of continuity.

5.2. Using Extended Dominance

Extended dominance is defined as the transformation of a situation in which one alternative does not quite dominate another to a situation in which dominance can be invoked. This transformation is achieved by using incremental rates of substitution. The method can most easily be explained by an example. From Table II we know that alternative D (“Minimum absorbency tampons day and night”) carries a higher risk than alternative C (“Minimum absorbency tampons during the day only”), but that D on the other hand also scores higher on physical comfort. Dominance cannot be invoked. To transform the decision problem into one where dominance can apply, we have to know how much of an increase in risk I would accept to obtain the greater physical comfort offered by alternative D. Is it less or more than the risk increment of D over C which, according to Table III, is about 38 seconds?

To make such absolute decisions it may help to compare the risk increments under consideration to the risks of other actions or activities with which we are familiar and in which we voluntarily engage. Another baseline comparison risk can be the risk of TSS that is unrelated to tampon use (i.e., risk that cannot be eliminated by avoiding tampon use). The TSS risks of all tampon use decisions in Table III are expressed there as multiples of this baseline. To obtain an intuitive understanding of the size of this risk (8.9 in 10 million), we can compare it to other risks of equal size and equal quality. Travelling 250 miles by car, for example, carries (fatal accident) risks of the same magnitude. Drinking 25 12-ounce cans of diet soda or smoking 1 1/2 cigarettes also carries a fatal (cancer) risk of the same size. These risks may appear negligible, but in my evaluation the physical comfort advantage of night time tampon use is too small to even warrant an additional risk of this magnitude. As a result alternative C dominates alternative D which can thus be eliminated. Note that my judgment also eliminates alternative G (“High absorbency tampons during the day, minimum absorbency tampons as night”) which is now dominated by alternative F (“High absorbency tampons only during the day”). Alternative G offers greater physical comfort than F, an advantage of the same magnitude as that of D over C. The risk increment of G over F (in the neighbourhood of 75 seconds) is however twice that of D over C. If the advantage of D did not warrant its risk increment, it certainly will not warrant the risk increment of G. Thus G is dominated by F. This leaves alternatives B, C, and F as contenders. Alternatives F (“High absorbency tampons during the day”) and C (“Minimum absorbency tampons during the day”) score equal on physical comfort and social benefits, but F scores higher on psychological comfort because of the greater security afforded by highly absorbent tampons. Is this advantage sufficient to warrant the risk increment of approximately 38 seconds? In my evaluation the psychological comfort advantage of using highly absorbent tampons can be almost eliminated by developing appropriate habits (e.g., changing tampons more frequently), so that I would not accept the risk increment for its benefit. This eliminates alternative F. Alternative C (“Minimum absorbency tampons during the day”) ranks higher than alternative B (“Minimum absorbency tampons only on special occasions”) on all three benefit indices. These benefits
come for a risk increment of approximately 46 seconds or almost twice our baseline risk. Yet to me the benefits of C over B are substantial. Using tampons all day means that I do not have to anticipate "special occasions." Being ready for all social opportunities whenever and wherever they may arise, is an increase in psychological comfort that, by itself, would justify the risk increment for me. Thus alternative C dominates alternative B and is the only remaining decision alternative.

5.3. Comparing Risks And Benefits In Terms Of $-Equivalencies.

Let us repeat the part of the analysis involving direct risk–benefit tradeoffs using a different methodology, which requires that we first compute $-equivalencies for the risks and benefits of decision alternatives. No matter how sophisticated the analysis, no analyst would claim that $-figures attached to costs and benefits reflect these quantities in any absolute sense. Fortunately all that is required to aid the decision making is an impression of the relative size of the two quantities (i.e., do the benefits outweigh the costs or vice versa). No other significance other than that for relative comparison should be attached to such figures.

5.4. $-Equivalent For Tampon-Use Risks

A currently popular method of assessing personal health and safety risks, the willingness-to-pay approach,(57) reasons that if people are willing to pay a certain sum of money to reduce their personal mortality or morbidity risk by some amount, this sum can serve as a functional $-equivalent for the costs (financial and otherwise) that people expect this additional risk will entail. The use of questionnaires asking people what they would pay for particular risk reductions has been advocated as such a method of estimation(58) but its validity and usefulness has been called in to question.(59–60) One source of problems lies in people's inability to discriminate between very small probabilities.(61) In the context of assessing willingness-to-pay, Schelling observed that, in consequence, people do not have pure preferences involving small risks of serious events. It is far from clear whether people can comprehend a reduction of risk by as much as a factor of 10 if it means a reduction of 1 in a million to 1 in 10 million. This difficulty may be circumvented if we make two assumptions about people's willingness-to-pay judgments. First, we assume that for very small probabilities of adverse consequences, the sum people would pay to eliminate that risk is equal to the sum they would demand to compensate them for assuming the risk. Such symmetry has been demanded by Schelling as at least a normative requirement for a valid estimate. Second, we assume that the sum people would demand to assume a certain additional risk is a linear function of the size of the risk, $p$, within a certain range (e.g., for $0 < p < .01$).

This second assumption is almost certainly not met by people's willingness-to-pay judgments.(62) Yet, this does not mean that it is not a useful working assumption. If not linear, the relationship between willingness-to-pay values and risk increments is most likely positively accelerated within our range of $p$. That means that, for risks between 0 and 1 in a 100, people are willing to spend increasingly larger sums for risk decrements of equal size at the larger probability levels. To the extent that the relationship deviates from linearity in this way, linear extrapolation of willingness-to-pay from higher to lower probability levels will be an overestimate of the actual value. Conservatism in evaluating the risks is generally considered a virtue in risk–benefit analyses.

Making these assumptions allows us to obtain willingness-to-pay estimates for very small risk reductions by extrapolation. Instead of questioning people about the small probability levels of risk that we are concerned with, we can employ probability levels that are more within people's range of imagination. Schelling(63) suggests to "bring the risk above some threshold where the size has some feel or familiarity, "... a feeling of the kind we associate with preferences and tastes." People are more likely to give reliable estimates of how much they would demand as compensation for assume an additional risk to their lives (their selling price) if the risk is 1 in 100 or 1 in 1000, rather than 2.81 in a million as that associated with tampon use. By assumption 2, the selling price for very small risk levels can be extrapolated from the answer for larger probability levels. By assumption 1, the amount people would pay for risk reduction (their buying price) is the same as their selling price at this level. It is not advisable to ask for
people's buying price at the larger probability levels because their financial assets put an upper bound on their willingness-to-pay for risk reduction. Buying price, as a result, is not a linear function of the size of risk reduction. Since equality of buying and selling price at small levels of risk seems intuitively plausible, and the idealization of linearity of selling price with risk level leads at worst to conservatism in our decision, the extrapolation of the buying price at risk levels like that of TSS from judgments of the selling price at risk levels imaginable to people seems to be a method well worth further consideration.

Let us take a quick pass through the risk analysis for tampon use. Assuming the hypothetical situation that I am offered a job next year identical to the job that I hold now except for an additional chance of death of 1 in 1000. How much additional remuneration would I demand so that I were indifferent between the new job and the old one? Say that I am almost certain that my answer would lie between $1,000 and $5,000. I can double check the adequacy of this answer by asking myself what my answer would be if the chance of death were, for example, 1 in 100. Would I be indifferent at values between $10,000 and $50,000? If not, I should rethink my answer to the first question. From my final answer we can extrapolate my selling price for a 2.81 in a million risk like that of TSS. In this case it would range between $1,000 \times 0.00000704 / 0.001 = $7.04 and $5,000 \times 0.00000704 / 0.001 = $35.20. By assumption 2, this is also the amount I should be willing to pay to reduce the risk of death by an amount equal to that posed by tampon use. If this sum seems reasonable to me, this lends some indirect support to the validity of assumptions 1 and 2. The option of buying my way out of risk of the magnitude of TSS is of course only hypothetical, but the $7.04 to $35.20 that I would be willing to pay for this option can be taken as a rough $-equivalent of the risks that I expect to be associated with TSS. Redoing these calculations using the upper and lower bounds on the risk probability estimate (.00000298 and .00001114, respectively) increases the range of $-equivalency values, for an new range from $2.98 to $55.70 per year.

By the same logic used earlier, we can assign this risk estimate to decision alternative $H$ ("Using high absorbency tampons day and night"). Table IV shows the corresponding range of values for the other decision alternatives. These values are fractions of the range for alternative $H$ which correspond to the proportion of risk relative to $H$ entailed by the particular alternative.

<table>
<thead>
<tr>
<th>Decision alternative*</th>
<th>$-$Equivalent of Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lower bound</td>
</tr>
<tr>
<td>B</td>
<td>$0.35</td>
</tr>
<tr>
<td>C</td>
<td>$1.17</td>
</tr>
<tr>
<td>D</td>
<td>$2.34</td>
</tr>
<tr>
<td>F</td>
<td>$2.34</td>
</tr>
<tr>
<td>G</td>
<td>$5.28</td>
</tr>
</tbody>
</table>

*The letter code corresponds to the decision alternatives listed in Table II. Alternatives E and H have been eliminated by dominance. Alternative A is not listed because the risk of this alternative is not under our control.

5.5. $-$Equivalent For Tampon-Use Benefits

Summarizing the diverse benefits that come from using a particular product into a single number, usually a $-value, is something all of us do every day. It is perhaps because of this familiarity with benefit evaluation that most of the controversy about risk--benefit analysis evolves around the evaluation of risks. We frequently decide whether to buy a cheaper or more expensive brand of a given product, usually in a matter of seconds, without much conscious thought or effort. At the basis of such decisions lies a comparison between the benefits of the more expensive over the cheaper brand and the price differential between the two brands. To buy the more expensive brand means that to me its benefits are worth at least as much as the price differential. Thus the price differential can serve as a $-equivalent of the benefits. More specifically, we can obtain $-equivalents of benefits by probing people—either hypothetically in questionnaires or directly in market tests—as to just how much more they would be willing to pay for a product with some benefits over an otherwise equivalent product without.

The $-equivalency method for making direct tradeoffs also resorts to the extended dominance methodology, but differs from the earlier application of the principle in that both risks and benefits can be expressed in $-figures which makes comparison and substitution easier. The problem of not knowing how to decide how many seconds of life-expectancy reduction a particular benefit was “worth” does not arise,
because we are well trained in deciding how much we would pay for a particular benefit in dollars. For example, the physical comfort advantage that alternative \( D \) has over \( C \) carries a price tag ranging from $1.17 (the difference between the risk prices for alternatives \( C \) and \( D \), lower bound) to $10.56 (upper bound). How much more would I be willing to pay for a product that offered the additional physical comfort of alternative \( D \)? If my answer is less than $1.17 per year, or, 10 cents per month, alternative \( C \) dominates alternative \( D \). Following our earlier reasoning, this decision also causes alternative \( F \) to dominate alternative \( G \). A similar decision has to be made when comparing alternative \( F \) to alternative \( C \), and alternative \( C \) to alternative \( B \). In my personal evaluation, alternative \( C \) wins out again.

6. CONCLUSIONS

Among the many risks to life and health faced by members of our society today, there are some that do not warrant public intervention. Those risks are typically very small and are associated with the use of products or with activities that offer (or are at least perceived as doing so) certain benefits to individuals. The attempt to legislate such risks away would, aside from being an administrative nightmare, constitute some infringement of civil rights. What should happen instead is that individuals, faced with such decisions as whether to use tampons or to drink saccharin-sweetened softdrinks, should go through a personal risk-benefit analysis of this type suggested in this paper. The methodology described here was designed to show that the perceived benefits of a product may far outweigh the risks for one individual but not for another person with different values and priorities.

One perennial problem faced by the social scientists is their inability to "sell" its lessons and insights to the public who could profit from them. The decision methodology suggested in this paper faces similar obstacles. It can serve as a decision aid only to people who have been searching for an aid and agree with its premises. It has been my goal to develop a methodology that would make as few assumptions and value judgments as possible which might limit its usefulness by offending an individual in search of a decision aid. It is a different task altogether to convince people that their decisions can be improved by using systematic and analytic methodologies like the one described here. In the case of TSS this may be relatively easy, since there is little emotional involvement and no physical addiction associated with tampon use. In the case of substances that are physically or psychologically addictive, this task can be formidable. Once convinced of the utility of the approach, however, an individual could apply the same methodology to such decisions.

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