tassium fluoride (a precursor of nerve gas) to Iraq. The shipment attracted attention because Iraq had requested that it be air freighted, immediately.

The Commerce Department is preparing a list of chemicals to be banned from export to Iraq and Iran. The first five are potassium fluoride, dimethyl methylphosphonate, methylphosphonyl difluoride, phosphorus oxychloride, and thioglycol. The action was triggered by the unexpected volume of these chemicals ordered by Iraq within recent weeks. All may be used in the production of chemical weapons, although they have other legitimate uses as well. This interdiction of supplies is a temporary measure. A long-term remedy will require the cooperation of all the industrial nations, something not easily won.

—ELIOT MARSHALL

Lawyers Flush Out Toxic Shock Data

Battle over researcher's findings raises questions about access to sensitive scientific information in legal disputes

In 1979, Tammy Lynn Wallace, a young music teacher from Fort Worth, Texas, was one of hundreds of women who fell victim to toxic shock syndrome. Wallace, who was lucky enough to survive sued Procter & Gamble, the manufacturer of a tampon that she had used, and recently won a large sum of money in an out-of-court settlement. An important factor in her success was the unveiling during the trial of provocative research data developed by a University of Wisconsin researcher. The findings were said to demonstrate for the first time that Procter & Gamble's Rely tampon, in laboratory experiments, was linked to the toxin associated with toxic shock. These data could similarly play an important role in the hundreds of lawsuits still pending against Procter & Gamble.

Attorneys for toxic shock victims have had a tough time obtaining first hand the test data introduced in the Texas trial. For 2 years, Procter & Gamble and microbiologist Merlin S. Bergdoll, who conducted the experiments with money from Procter & Gamble and other tampon manufacturers, have strenuously tried to block access to the information by legal means. Bergdoll, a professor at the university's Food Research Institute at Madison and one of the leading researchers in the toxic shock field, has repeatedly refused to release the data, arguing they are preliminary and inconclusive. He has, however, discussed his findings with Procter & Gamble.

The company, which withdrew Rely from the market on 22 September 1980, has won numerous court rulings that bar outsiders from examining company records, including Bergdoll's data. Even though his findings were revealed in the Texas trial, Procter & Gamble persuaded the presiding judge to prohibit the victim's attorneys from disseminating the data sheets. These events have raised questions about whether the information has been unfairly withheld from scientific scrutiny or whether, as Bergdoll maintains, his findings have been misinterpreted and misused in court.

Since 1979, when toxic shock syndrome was identified, scientists have been searching for its cause. Researchers in the field now believe that a toxin produced by *Staphylococcus aureus* is the most likely culprit. But it is not clear whether tampons contribute to toxin production and, if so, how this happens. Research demonstrating a link would fill an important gap in information about the syndrome, which still occurs. In fact, in 1982, a National Academy of Sciences panel, formed to evaluate the research needs related to toxic shock syndrome, reported that "characteristics of tampons that may be related to [toxic shock] should be studied. Such characteristics could include tampon ability to affect growth and toxin production by microorganisms *in vitro* and in the vagina." At the time, Bergdoll had already undertaken the research to address these questions.

Since 1980, he has conducted a variety of experiments supported solely by industry. Bergdoll and other researchers have had to depend on industry money because the federal government has not taken much interest in supporting grants for toxic shock research. For 4 years, Bergdoll's laboratory has received about $150,000 a year from four tampon manufacturers. Of this amount, Procter & Gamble contributed roughly $50,000 annually, Bergdoll told *Science*.

Although he has not yet submitted any of his test results for publication, a transcript of the Texas trial, held in U.S. District Court in Fort Worth, provides a substantial amount of information about his experiments. Even though Bergdoll refused to testify, his data were revealed through testimony by Bruce Hanna, a microbiologist at New York University Hospital who was brought in by Wallace's attorneys as an expert witness. Hanna is also conducting research on the toxic shock toxin. Under court order, he was allowed to read company records that described in general terms Bergdoll's methodology and listed his specific test results.

According to Hanna's subsequent testimony, in which he read the data sheets before the jury, Bergdoll conducted a series of 13 experiments to examine the growth of three strains of *S. aureus* under various conditions. Bergdoll tested the strains in several tampons and in the different material components of Rely. The three strains produce a variety of toxins but all of them produce *S. aureus* enterotoxin F or SEF, now considered the toxic shock toxin.

Despite changes in the experimental conditions, Rely tampons consistently produced more toxin than other brands, according to Hanna's interpretation of Bergdoll's data. For example, when one strain was grown in standard medium, Rely regular and Rely super tampons produced far more toxin than the other major brands. Two Rely super tampons tested yielded a total of 252 and 391 micrograms (μg) of SEF. A few other brands of super absorbent tampons produced up to 162 μg, but most tampons yielded less than about 50 μg. No toxin was detected in the controls. In another test, similar in design, Bergdoll added pig's blood to the growth medium and, according to Hanna, found that Rely again "produced more [SEF] than did the controls certainly and [than] did other tampons."

Bergdoll then experimented on two new materials that had been developed to increase absorbency in tampons. Unlike other tampons, Rely regular and super, Kotex super, and Tampax slender regular in 1980 contained a material called cross-linked carboxymethylcellu-

lose. The Rely regular and super tampons, however, had one ingredient that made them different from all the rest. This ingredient was polyester foam.

Bergdoll inoculated the carboxymethylcellulose and the foam with the three strains of *S. aureus*. The strains were then grown in medium with and without pig blood, with carbon dioxide—to simulate the anaerobic environment of the vagina—and without. In every test, Hanna reported, the foam yielded large amounts of SEF and in quantities far exceeding that produced in the carboxymethylcellulose or the controls. In one experiment, for example, in which one strain was grown in pig's blood in the presence of carbon dioxide, two samples of Rely foam produced 693 to 999 μg total of SEF. The carboxymethylcellulose yielded 72 to 81 μg; the controls, about 100 μg.

Some of these results were presented last year at a meeting of the American Society for Microbiology in New Orleans. The specific brands of tampons were not named, however. Bergdoll's colleagues at the University of Wisconsin, but not Bergdoll himself, were listed as the authors of the paper.

Bergdoll said in a telephone interview that Hanna "had no business interpreting my data" and defends his decision not to submit his work to a journal. Bergdoll still argues that "The data are so incomplete, we cannot draw adequate conclusions." The results "do not have the meaning that is being ascribed to them." Bergdoll questions, for instance, the reliability of his controls and contends that more experiments need to be performed before the data are meaningful.

Nevertheless, Bergdoll shared his data with Procter & Gamble in 1982. The company went so far as to duplicate the experiments and confirmed his results, according to previous testimony by one of its own scientists, James Widder. Procter & Gamble also has not publicly reported its test results.

How scientifically important are the data? Gail Bolan, an epidemiologist who studies toxic shock at the Centers for Disease Control, says the quality of any data can be judged by several standard criteria. Bolan, who has not seen Bergdoll's results, wants to know, for example, how many tampons Bergdoll tested and how the data were analyzed.

If reproducible results are regarded as a measure, then the findings seem significant in light of Procter & Gamble's own statements about its in-house findings. Furthermore, Hanna says that he and New York University colleague, Philip Tierno, Jr., have conducted experiments like Bergdoll's which have produced similar results. Hanna and Tierno, whose work is supported by income derived as consultants and expert witnesses in toxic shock litigation, have already submitted a paper for publication. Hanna points out, however, that until Bergdoll publishes, their own findings, if published, would stand alone and need confirmation. The importance of establishing a link between tampons and toxin production is heightened by the fact that researchers at the University of Hawaii and at New York State College have reported that baboons develop almost all the symptoms of toxic shock syndrome when injected with SEF.

Bergdoll's data came to light as the consequence of persistent and skillful probing by lawyers and a stroke of luck, according to a recent article in the *National Law Journal*. After Rely was withdrawn from the market, Procter & Gamble set aside $75 million in a legal defense fund, organized an in-house team to tackle research related to toxic shock, and issued research grants to 24 university scientists. So far the company has spent $3 million for academic research.

For 2 years, Procter & Gamble and a Wisconsin scientist it supported have tried to block the release of data they call preliminary.

Many attorneys representing toxic shock patients have tried without success to obtain from Procter & Gamble the information generated by this research. Each time, the company has contended in pretrial proceedings that any internal records on toxic shock research collected after Rely was taken off the market are part of its preparation for litigation and therefore confidential.

But the first breach in Procter & Gamble's line of defense came during litigation in Kansas in 1983. This eventually led to the introduction of Bergdoll's data in the Texas trial. Kansas attorney Victor Bergman, representing the family of a toxic shock victim, successfully persuaded the trial judge that the company's records should be made available by arguing that even if the research was conducted to prepare for litigation, the circumstances of the toxic shock case were exceptional because his client did not have the resources to obtain the same scientific facts as Procter & Gamble. Furthermore, Bergman contended that the company's stated reasons for conducting the research had been inconsistent. He cited public statements by company officials who had said that the purpose of the research was to benefit former Rely users as well as the company's stockholders.

With the right of access in hand, Bergman and colleagues began sifting through thousands of records at the company's Cincinnati headquarters. One of Bergman's associates spotted a chart describing some of Bergdoll's results. "I had no idea what the acronyms meant. I didn't know how to decipher the chart," said Mark Johnson. He was, however, struck by the comparison of Rely tampons and other brands and the "incredibly disparate figures." Johnson tossed the document into the pile of records to take back to Kansas. Several months later, when reexamining the records, Bergman and Johnson realized they had uncovered findings that would be significant to their case and others. Procter & Gamble, however, persuaded the judge to bar Bergman from releasing the documents to anyone else.

But Bergman got around this barrier. Lawyers representing toxic shock victims exchange information through formal and informal networks to beef up their arsenal of evidence against Procter & Gamble. Bergman collaborated with lawyer Mike Liles of Texas who was at the time preparing for trial on behalf of Tammy Lynn Wallace. In August, 1983, the two men simultaneously took the deposition of company scientist Widder who had examined Bergdoll's data. As Bergman questioned Widder on the data, Liles learned the details about Bergdoll's results.

Liles then convinced his judge that the data should be admitted into evidence and Bergdoll's data eventually were publicly revealed for the first time in his case. (Bergman's case went to trial later.) Liles said in an interview that Bergdoll's data were "very important" to his case. Again, Procter & Gamble succeeded in securing a similar court ban on dissemination of their documents. But Liles and others say that the cat is out of the bag. Liles says, for example, that Hanna's reading of the data results, as recorded in the transcript, could be considered admissible evidence in other cases.

Bergdoll himself still maintains that his experiments are inadequate. He says, for instance, that the in vitro test results cannot be translated to humans and that,

in retrospect, his controls were unreliable. Such criticism could undercut the impact of the results in court.

Attorney Mark Johnson points out that knowledge of Bergdoll's data probably gave Procter & Gamble an unfair advantage in earlier litigation. Until recently, lawyers arguing against the company were citing the wrong scientific theories to buttress their arguments. "By knowing your opponent is on a false lead, it's easy to encourage it . . . and win," he said. "I think it was an incredible advantage [to Procter & Gamble]."

Procter & Gamble says that it is entirely up to Bergdoll to decide to publish or not. "The idea that we suppressed his data is preposterous," says company spokeswoman Sydney L. McHugh. Are Bergdoll's data preliminary? "We're not about to second guess Dr. Bergdoll," McHugh said.

As a result of all the hubbub, Bergdoll now says he plans to submit a manuscript to a journal within the next month. He bases his change of heart on the fact that the *National Law Journal* printed a chart of his test results and that the results are being misinterpreted. The meaning of the results "has been blown way out of proportion," he said.

Sharing data with a sponsor "is normal procedure," Bergdoll said. Asked whether his disclosure of data to Procter & Gamble alone could have given the company unfair advantage in litigation, Bergdoll replied, "I don't know about that. I'm not involved in the legal aspects. ". . I don't know why the big fuss about this data."

None of the lawyers questions a researcher's right to prevent disclosure of his or her test results if they are regarded as preliminary. But attorney Bergman points out that Bergdoll reported his data to Procter & Gamble, that some of the results were presented at a scientific meeting and that Procter & Gamble says it confirmed Bergdoll's results. Johnson put it this way: "How long is 'preliminary' preliminary?"—**MARJORIE SUN**

Universities Gag on Research Controls

The presidents of three major research universities have sent a letter to Under Secretary of Defense Richard DeLauer protesting the latest Defense Department proposals for controlling the release of unclassified but militarily sensitive information. They are particularly upset by a provision that would give the department control over the publication of individual research papers in some fields.

The letter is the latest salvo in a long battle over the Reagan Administration's attempts to curb the release of unclassified information that it deems militarily sensitive. The Defense Department's proposal goes well beyond what the universities have been willing to accept in the past and is viewed as a violation of a researcher's right to decide what to publish.

An internal Defense Department committee approved the proposal several weeks ago and it was brought up at a meeting between defense officials and university representatives on 22 March. The university people said in no uncertain terms that it was unacceptable and that message has now been strongly reinforced by the letter to DeLauer. The letter, which was signed by the presidents of Stanford, Massachusetts Institute of Technology, and California Institute of Technology, has not been made public.

The department is proposing three different levels of control over the publication of papers from research it supports. The restrictions would be spelled out in advance in individual contracts so that universities would know what is required of them before they agree to do the research.

- In areas that are not deemed to be sensitive, papers would have to be sent to the department at the same time as they are submitted to a journal for publication. They would be submitted to the department solely for its information.
- In sensitive areas of basic research, a researcher would be required to send papers to the department 60 days before submission for publication. The department's review would be purely advisory, and the final decision on publication would be left to the researcher.
- The third area is the one that is causing most of the problems. The department wants to see papers derived from grants and contracts in sensitive areas of exploratory development 90 days before submission for publication, and it wants the right to insist on changes or withhold publication.

A Defense Department official also told *Science* that, in addition to these prepublication controls, the department may require that foreign nationals be barred from participation in some sensitive research projects, particularly those involving exploratory development.

When these proposals were aired at the 22 March meeting of an advisory panel on Defense-university relationships, representatives from Stanford and Caltech said they would not accept Defense Department contracts that take away the university's control over publication. Edith Martin, deputy under secretary of defense for research and advanced technology, then provoked a sharp exchange by asking just how much money the universities were willing to give up for their principles. She also suggested that if some universities will not take Defense contracts on these terms, others will.

Gerald Lieberman, vice president for academic affairs at Stanford, pointed out that Stanford's own policies, which were laid down in the 1960's, prohibit the acceptance of any research grant or contract which requires approval by an outside body before the results can be published. David Wilson, executive assistant to the president of the University of California, told Martin that many of the universities with which the department would want to work would refuse to participate in the sensitive areas. The University of California, he said later, "would not yield to any sponsor authority over final approval for publication."

The amount of Defense money going to the universities in the category that would be most tightly controlled is relatively small. Lieberman says, however, that some work that Stanford is now doing would probably fall into this area, but "there is no way of telling."

Although the department's proposal has not yet formally been issued in a policy directive, one Defense official said that it has already been accepted as de facto policy. Nevertheless, an informal group including Wilson and Martin has agreed to meet to try to work out something more palatable to the universities.—**COLIN NORMAN**