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The report chronicles the way Pfizer provided information to the FDA from 1979—when the convexo-concave valve first won approval—to 1986, when the company withdrew it from the market. Appearing at the hearing, Acting FDA Commissioner James Benson testified that the report "dug deeply into the issues we faced. ... We found a few errors, but, in general, I thought the report was good." Dr. Richard Chiacchierini, director of the Division of Biometrics at the FDA's Center for Devices and Radiological Health, told *Barron's* that, to the FDA's knowledge, there were no errors regarding what Pfizer knew, and what it disclosed and failed to disclose to the FDA.

Shiley Inc. developed the convexo-convcave heart valve, in collaboration with Dr. Viking Bjork, in 1976. The invention was meant to be an improvement over Shiley's radio-opaque-spherical valve, the so-called RS standard valve, which had become the Chevy of heart valves. All told, 119,000 RS valves had been embedded in human hearts, and Shiley had captured an estimated two-thirds share of a $100 million international market. But Bjork and Shiley believed that the new convexo-concave valve would reduce thrombus (blood clotting problems at the site of the valve), a side effect that plagued most mechanical heart valves. They didn't expect fractures—that was not a common problem for most mechanical valves. Indeed, of the 119,000 RS valves implanted, only one had ever broken.

But, from the start, the new convexo-concave valve would be betrayed by a weak link—the delicate juncture where one fine piece of metal was welded to another (see drawing). As the congressional staff report describes it: "The valve consists of a disc located inside a metal ring. ... The disc is held in place by two metal holders, called inflow and outflow struts." One of the metal holders, the inflow strut, is an integral part of the ring, but the outflow strut is welded to the ring. In every case in which the valve has fractured, it has done so at or near the point where the outflow strut is welded to the ring, and the result, the report observes, is "an uncontrolled blood flow through the heart. Death has resulted in an estimated two out of three incidences of strut fracture."

The first outflow strut fracture appeared during clinical trials in 1978. Six months later, in February of 1979, Bruce Fettel, then one of the chief design engineers on the valve, and subsequently Shiley's president, appeared before the FDA Circulatory Systems Device Panel. In closed session, Fettel told the panel: "There has been no change in the welding or the fabrication technique or the specifications in the convexo-concave model over the standard (RS) model. We feel that it is an isolated failure ... we can't really explain that one case." Apparently persuaded that the fracture was a freak event, the FDA approved Shiley's new invention for marketing in April 1979.

It was then that Pfizer entered the picture. The New York-based drug company purchased Shiley in 1979, just one month before the convexo-concave valve received the FDA's imprimatur. And, according to the congressional staff report, that same year, a large number of experienced welders left Shiley—as the new valve was moving into full production. "We don't know why they left, and are still trying to ascertain if that assertion is true," says Vodra, the Pfizer attorney from Arnold & Porter. "So far, we haven't been able to prove it or disprove it."

From then on, the number of fractures began to mount. One occurred on July 15, 1979, another on Oct. 20, 1979, still others on May 23, 1980; Sept. 3, 1980; Sept. 22, 1980; Jan. 1, 1981. In each case, the patient died. And, the subcommittee staff report notes, Shiley appeared reluctant to let word of the fatal flaw spread.

Not only did the company caution Bjork not to publish his data about fractures at the end of 1980; it also failed to report the earliest fractures to the FDA in a timely fashion. As a result, the FDA believed that the one fracture that occurred during clinical trials was, indeed, an anomaly. The Dingell subcommitee staff related the chronology of events: "Records provided by Shiley to the subcommittee staff show that the second known strut fracture occurred on July 15, 1979, ten months after the clinical trial fracture. Shiley notified the FDA by phone on March 7, 1980." The seven-month delay was not unique. "While a substantial number of fractures were reported within 10 days as required in conditions attached to the premarket approval, some delays in reporting did occur. Delays ranged from three weeks to as long as 24 months," according to the report.

"The premarket approval only required that the company report 'unexpected' events, events not seen in clinical trials," notes attorney Vodra. But the one fracture in clinical trials, according to Fettel, Shiley's design engineer, was an "isolated event."

Shiley appeared fearful of creating anxiety in the medical community. "For example," the subcommittee staff report says, "in a Feb. 5, 1980, 'Dear Doctor' letter, Shiley told cardiovascular surgeons that it had recently been informed of one strut fracture similar to one that had occurred during clinical trials. In reality, Shiley was aware of at least two strut fractures occurring after clinical trials—July 15, 1979, and Oct. 20, 1979."

Meanwhile, production soared from 5,715 valves in 1979 to 17,529 in 1980 to 25,647 in 1981. During these years the company continually tried new manufacturing procedures and quality controls, and even recalled specific lots of valves, followed by letters to doctors that indicated the problem may well have been isolated. To illustrate, on Sept. 1, 1982, Shiley wrote: "Since February 1982, all sizes of valves have been subjected to the new Quality Control test. We are pleased to inform you that to date, there have been no strut fractures reported among the more than 16,000 Bjork-Shiley Convexo-Concave Valves distributed with the new Quality Control test. We will continue to provide you with updated results with regard to valves from this group."

But in each case, Shiley's reassurances proved premature. The Dingell subcommittee staff report notes: "Fractures occurred after each of these changes. Shiley clearly did not allow enough time to pass before assuring the medical community that the problem had been identified and solved."

Roger Sachs, vice president and medical director of Shiley, disagrees: "The company was not assuring the medical community, it was informing."

In retrospect, Richard Martin, Shiley's engineering product manager from 1981 to 1984, testified in a 1987 deposition that it would have been a "terrific idea" for the company to have simply halted production, and focused on solving the problem rather than continuing to sell faulty valves. Instead, Shiley tried out various manufacturing changes on a trial-and-error basis, while continuing full-scale production—a strategy that the subcommittee staff report characterizes as "earn while you learn."

Testifying before the Dingell subcommittee last February, Bruce Fettel, the design engineer who became Shiley's president, explained why Shiley didn't halt production. Rep. Ron Wyden of Orgeon put the question: "Did you ever, during your tenure at Shiley, Mr. Fettel, put forth or entertain the idea that it might be a good idea to cease the operations until a solution to the strut fracture was found?"

Responded Fettel: "Every day and every night, almost. I mean, I lived with this problem for years and we were constantly evaluating the risk and the benefit, but at the same time, I was directing a company that was manufacturing many other products, not just this one ... and the other divisions within the company under my responsibility seemed to be going well every place else except for when there was a strut fracture, everybody pointed their fingers at all the things we were doing wrong."

When asked why the company sent that Christmas telex urging Bjork not to publish data informing the medical community about fractures, Fettel replied: "We were concerned that Bjork was going to publish only his strut fractures. ... We were trying to face it down and see if, in fact, they were real, and make sure that when Bjork published, that he would include all of the data and all of the information we knew about at the present time and not just represent it as being a small problem."

Fettel insists that when the company told Bjork not to publish, it was, in fact, telling him *to* publish: "So, although it reads like we were trying to keep him from publishing, in fact, we were trying to get him to publish the entire story."

Later, Fettel testified that the company didn't want to pull the product because "in the years '80 to '82, we were supplying—I would guess, more than half of the heart valves in the world. To cease production ... we felt there would probably be a supply void. ... Shiley is and was a caring company. We cared for the patients with valvular heart disease."

Bruce Finzen, the attorney representing Khan, notes that there were other products on the market to fill the void: "Their own RS standard valve, the valve that the convexo-concave valve was meant to replace, was still in the market—and some doctors, who didn't want to switch, continued using it through the mid-'Eighties. Their competitors also had mechanical valves on the market. The real problem is that Pfizer feared losing market share."

Dr. Robert Frater, a professor of cardio-thoracic surgery at Albert Einstein College of Medicine Hospital in New York who has been testing heart valves, including Pfizer's valves, since 1960, comments: "Their own RS standard valve had worked well. Was it perfect? No. It had a small disadvantage, a small tendency to thrombus [a blood clot causing the valve to stick]. They tried to correct that disadvantage, they shifted the axis, and somehow they missed the change in stress. I don't really think they tested the convexo-concave valve properly. If they had, they would have known there was a problem. That first RS valve was a good one. It fractured only once. There are thousands and thousands of patients doing all right with it."

ATTN: DONALD SHILEY, CHIEF OF BOARD OF DIRECTORS
BRUCE FETTEL, PRESIDENT
BOB ELLIOTT, VICE PRESIDENT
PAUL MORRIS, CHIEF PRODUCT ENGINEER

HAVE YOU NOT YET REALIZED THAT STRUT FRACTURE IS ONE QUESTION BROUGHT UP WHEREVER I APPEAR.

SHOULD THEY ALL BE RE-OPERATED??

WHAT ARE THE RISKS??

YOU HAVE PROVIDED ME WITH ABSOLUTELY NO FA
WORTHY DATA FOR THE FUTURE.

YOUR REPUTATION IS DEPENDING ON SOME RADIC
ACTION IN CHANGING YOUR MANAGEMENT.

I AM TRYING TO HELP

VIKING O BJORK
PRESIDENT OF THE EUROPEAN CARDIOVASCULAR

Dr. Viking Bjork

Frater himself has been using and testing a variety of mechanical valves since 1960, when, he recalls, "I made the second successful mitral valve replacement—on my kitchen table in a Quonset hut at the Mayo Clinic." Today, he says, his hospital uses two or three different mechanical valves, depending on the patient's needs.

But Frater is not able to use what he calls "undoubtedly, a superb valve," a valve that Shiley now sells in Europe, but that hasn't won FDA approval for sale in the U.S. The reason that it hasn't, Frater believes, is that Shiley poisoned the well with the FDA.

"Bruce Fettel behaved like a jerk," Dr. Frater says. "He tried to stonewall the FDA. If Bruce had had any sense he would have said, 'We're going to stop production, take a six-month hit, and get a new valve ready.'

"They were already developing a new monostrut valve, which they began selling in Europe in 1983. First, they had the RS valve, then they invented the convexo-concave valve, and then they introduced the monostrut valve. It isn't welded, it's made in a single piece, and it doesn't break. I've read the reports from colleagues using it in Europe, and those reports tell me that it's a very good valve.

But now, the FDA will never approve it. The FDA was burned by Bruce, and they're not going to approve the monostrut for marketing here." (The FDA says it is still considering the monostrut, but is awaiting further clinical evidence before reaching a decision.)

But in 1980, Shiley didn't have the monostrut ready for market. And, according to Frater, it didn't want to undermine its own credibility by telling doctors to switch back to its RS standard valve. So, the Pfizer subsidiary kept trying to mend the convexo-concave valve.

Indeed, in 1980, the company came up with a new, improved version of the convexo-concave valve, a valve with a wider, 70-degree opening. Shiley soon began turning out 70-degree convexo-concave valves, and beginning in 1980, sold them abroad, while continuing to manfacture the original 60-degree variety for sale in the U.S. The hope was that the 70 degree convexo-concave valve would prove more durable, and in time would win FDA approval, replacing the 60-degree original.

Later study showed "the 70-degree valve was more deadly," alleges the Dingell report. "Over 4,000 people would be implanted and the fracture rate for 70-degree convexo-concave valves would be found to be seven times that of the 60-degree convexo-concave valves. Also, Shiley was in such a hurry to introduce the 70-degree convexo-concave valve that early production was achieved by converting existing 60-degree convexo-concave valves to 70-degree valves through remilling. ... As of June 30, 1989, 94 fractures have been experienced with 70-degree valves and 70 people have died."

"The remilling didn't effect the outlet strut, the strut that broke. We were remilling the inlet strut," contends Dr. Sachs, Shiley's medical director. "But in the light of understanding gained some years later," he concedes that "the remilling might have contributed to fractures by adding to the stress on the valve when it closed."

The FDA never approved the 70-degree version for marketing in the U.S., but it did give export approval. Working at his clinic in Sweden, Dr. Bjork, Shiley's lead investigator, was among the first to realize that the 70-degree convexo-concave valve was a lemon, and he tried to sound the alarm.

On March 14, 1982, Bjork sent a lengthy telex to Bruce Fettel, Shiley's president, and Paul Morris, chief product engineer:

LAST NIGHT A 60-YEAR-OLD MAN WITH A DOUBLE VALVE REPLACEMENT PERFORMED AUGUST 24, 1981, WITH 70 DEGREE VALVES HAD RUPTURE OF THE SMALLER STRUT AND PULMONARY EDEMA.

DURING THE NIGHT, I REOPERATED THE BROKEN MITRAL VALVE AND THE LOST STRUT WAS LOCALIZED IN THE PULMONARY VEIN. THE PATIENT HAS NOW AWOKEN, BUT HAS NEUROLOGICAL SEQUELE. IT IS EVIDENT BY NOW THAT THE MANUFACTURE OF THE VALVE IS NOT ACCEPTABLE. THE SMALL STRUT MUST BE MADE IN ONE PIECE AND MUCH MORE EFFORT AND PRIORITY MUST BE PUT ON THIS THAN HAS BEEN DONE SO FAR.

YOUR PROGRAMMED CONFERENCES IN ATLANTA AND CALIFORNIA IN THE END OF AUGUST ARE EXTREMELY ILL TIMED BEFORE AN ACCEPTABLE PRODUCTION CAN BE ACHIEVED.

DEAR FRIENDS, I AM SERIOUS.

On March 29, Dr. Bjork sent a second, longer warning:

GENTLEMEN,

HAVE YOU NOT YET REALIZED THAT STRUT FRACTURE IS ONE QUESTION BROUGHT UP WHEREVER I APPEAR?

... G. CARLSSON OPERATED ON 14 OCTOBER 1981 HAD A STRUT FRACTURE MARCH 27, 1982, AND DIED AFTER REOPERATION.

THE SAME DAY ANOTHER PATIENT WITH MITRAL VALVE DIED AFTER REOPERATION FOR STRUT FRACTURE....

AN INTEGRAL MONOSTRUT MAY BE THE ONLY ANSWER.

YOUR CIRCLING AROUND WITH OTHER SOLUTIONS IS PROBABLY A WASTE OF TIME. AT THIS STAGE WELDING WILL NOT BE ACCEPTABLE ANY MORE.

OTHER FIRMS DO ONE PIECE METAL HOUSING, FOR INSTANCE. OMNISCIENCE.

YOUR STATEMENT RE STRUT FRACTURE THAT I JUST RECEIVED ONLY TELLS ME THAT YOUR MANUFACTURING PROCEDURE IS NOT ACCEPTABLE. YOU HAVE PROVIDED ME WITH ABSOLUTELY NO FACTS AND TRUTHWORTHY DATA FOR THE FUTURE.

YOU MUST FINALLY BRING THE ART AND TECHNIQUE OF MANUFACTURE UNDER YOUR OWN SUPERVISION.

IF VALVE RING WITH MONOSTRUT CAN BE DONE AS YOU HAVE STATED, WHY DON'T YOU TAKE THE TROUBLE OF DOING IT? SOMETIME YOU HAVE TO MAKE A SINCERE EFFORT TO START AND TO PUT ALL YOUR RESOURCES INTO THAT ADVENTURE.

YOUR REPUTATION IS DEPENDING ON SOME RADICAL AND QUICK ACTION IN CHANGING YOUR MANAGEMENT.

IN MY EARLIER DISCUSSION WITH LAUERBACK, HE PROMISED TO PROVIDE YOU WITH THE NECESSARY MONEY TO BUY NEW MACHINERY, INVENTORY AND KNOW-HOW. I WILL CONTACT THEM AGAIN.

I AM TRYING TO HELP.

VIKING BJORK
PRESIDENT OF THE EUROPEAN CARDIOVASCULAR SOCIETY

Questioned about the telexes during the subcommittee hearings, Fettel explained that Bjork was "frustrated" because he wanted to move ahead on the one-piece monostrut. It was then March 1982, and fractures at that vulnerable welding point were mounting. By the end of that year, 41 of the 60-degree convexo-concave valves had broken, and eight 70-degree valves had failed, raising the death toll to 42.

Meanwhile, only when the Australian Embassy sent notice of two fractures to Washington did the FDA discover that the 70-degree convexo-concave valves being marketed abroad were fracturing. Following that warning, in November 1982, FDA inspectors visited the Shiley plant and requested information on the total number of fractures.

"Shiley refused to provide them with that information because it contended that since the 70-degree convexo-concave valve was not used in the United States, it was outside the jurisdiction of FDA and Shiley was not obligated to provide that information," the subcommittee staff report says. "At the time, Shiley had been notified of a total of seven 70-degree strut fractures. It was only

after FDA officials in Washington, D.C., threatened to withdraw export approval of the valve that Shiley provided information."

Meanwhile, Shiley applied for Investigational Device Amendments to begin clinical trials for the 70-degree convexo-concave valves in this country. The company acknowledges that it informed the FDA of only one of three 70-degree fractures that occurred while the FDA was reviewing its application. When *Barron's* asked about the omission, Pfizer explained that the fractures took place two days following submission of the application and were not reported because the company felt it was going to be turned down, anyway. And indeed, the FDA rejected the application on other grounds.

Finally, on Jan. 11, 1983, the FDA suspended permission for Shiley to export any more 70-degree convexo-concave valves. But the FDA could not stop Shiley from marketing the 70-degree valves that had already been shipped.

On Jan. 25, 1983, two weeks after the export pass was suspended, Larry Wettlaufer, director of sales at Shiley, telexed distributors in 17 countries:

THE BRUSSELS OFFICE HAS A COMPLETE LISTING BY SIZE ... OF THE APPROXIMATELY 1,500 70-DEGREE VALVES NOW IN INVENTORY IN VARIOUS PARTS OF EUROPE. YOU SHOULD CONTACT THE BRUSSELS OFFICE IN ORDER TO MAKE USE OF THE VALVES BEFORE ORDERING THE 60-DEGREE CONVEXO-CONCAVE OR SPHERICAL (RS) DESIGN FOR SHILEY.

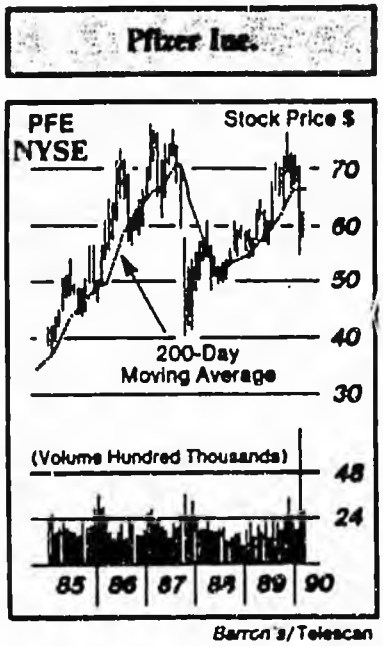
Pfizer attorney William Vodra says that "Wettlaufer thought it was a temporary suspension; Shiley was applying for reinstatement of the export permit and hoped to get it."

The telex was sent early in 1983. Over the next year, another 20 of the 70-degree valves would fracture, accounting for 17 additional deaths. In 1984, 15 fractures, 12 deaths. In 1985, 10 fractures, eight deaths. By January 1990, three fatal fractures brought the total to 94 fractures and 70 deaths among some 4,000 individuals wearing the 70-degree convexo-concave valve. Meanwhile, the company continued producing the 60-degree convexo-concave valves, sold in the U.S. from 1979 to 1986. By January 1990, the 60-degree version had experienced 295 fractures causing 178 deaths. All told, the two valves had suffered 389 fractures, and caused 248 deaths.

According to recent medical literature, it now appears that some 500 especially large 70-degree valves are considered so fragile that doctors who implanted these valves are advised to consider putting the patient back on the operating table, and replacing the valve.

"We're concerned about the option of elective replacement because it carries a high risk of mortality," says Pfizer's Dr. Sachs. "In general, we are advised that it's not appropriate, though with this one group of valves, some doctors feel it is indicated on a patient-by-patient basis."

The year that Pfizer stopped shipping the 70-degree valves, 1983, was also the year that one Shiley employee, George Sherry, launched a campaign to inform top management of what he saw as sloppy manufacturing practices at the plant. When he felt his warnings were falling on



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deaf ears, the tool design engineer quit his job.

"I didn't particularly want the job working on that valve—I knew they had problems," Sherry recalls. "When I was transferred down there, in September of 1982, I saw the drawings were a mess. I requested a meeting with Jack Coggan, senior manufacturing manager, and Frank Haskins, vice president of manufacturing. I have all my handwritten notes from that meeting. I explained that the parts did not fit the drawings. I said, 'I know this is sensitive, you set the tone as to how it should be handled. But something has to be done.'

"They looked at me, like, 'Who is this dip-s———?' Jack Coggan, who was senior manufacturing manager, said, 'I'll tell management what I want them to know.'" Pfizer's attorney says that Coggan is not available for comment.

"As I got into the manufacturing process," Sherry continues, "I discovered what condition the tools were in, how they were keeping them. It was all a horror story, the welding was a half-hearted effort, at best."

Sherry alleges that Shiley's welding effort was slipshod, in part because the company hoped to soon switch over to the monostrut, the one-piece valve that requires no welding. "People told me, 'Hey, we're not going to be making these much longer anyway; soon we'll be making the monostrut.'" (Shiley began manufacturing the monostrut for sale abroad within a year, but hadn't received FDA approval to sell the device in the U.S.)

After four or five months, Sherry says, "I realized that they didn't want this problem solved. They wanted it hidden. At the end, they were harassing me. My supervisor, a young guy, started writing out hour-by-hour assignments of what I should do. Finally, I walked out." Today, Sherry is a senior engineer at a major aerospace corporation in Southern California.

But even though he quit, Sherry continued to try to warn management. This time, he went to the top—to Pfizer—phoning both Edmund Pratt Jr., chairman and CEO of Pfizer, and Ed Bessey, CEO of the Howmedica division, which oversaw Shiley. Bessey returned his call.

"The day I quit, I called Ed Bessey, and the first time, I talked to Bessey for half an hour or 45 minutes," Sherry says. "He kept saying, 'What do you want out of this?' I think he thought I wanted money, or to have someone fired. I told him, 'I don't want a damn thing. I just want you to take the product off the market and fix it.'"

Vodra. Pfizer's attorney, says that Bessey is not available for comment on this or any other matters relating to the heart valve. He adds that the company has no comment on Sherry's story.

Sherry claims that he had at least four conversations with Bessey, and was also visited in his home by Richard Myerson, director of research and development for Pfizer's Howmedica division, and Phil Kearns, vice president of personnel.

An internal Pfizer memo confirms the home visits. It begins by describing Sherry: "Sherry is from Pennsylvania coal country. He has no formal engineering training. Nonetheless, he appears to be bright. . . . He produced very detailed layouts of the 29mm convexo-concave valve in 20:1 and 10:1 scales. He also produced a cardboard cutout of the disc. He claims the valve cannot be built to the specifications. . . ."

The memo goes on to list Sherry's complaints:

- "The wire used for the strut is not good enough quality for a product as critical as a heart valve."
- "The tools in use did not conform with the tool drawings."
- "He felt the disc fitters work the valves too many times."
- "He was critical of the reweld process and claimed it can't be done after polishing."
- "He was critical that welders are not certified."

The list continues for four pages.

At the end, the memo returns to the executives' impression of Sherry:

"Sherry's home is pleasant, and is decorated with family portraits and an end table book on the Bible.

"Sherry admits to being a 'nit-picker.' Sherry appears to be a very intense man. He appears to be genuinely concerned for the safety of patients and that concern seems to be his sole motivation.

"Sherry offered drinks but there was no indication that he is a heavy drinker. For example, though the group had two drinks during the interview, Sherry only sipped his. . . .

"Sherry is a very concerned individual with no ulterior motives. . . . After being ignored by Shiley, Sherry now 'needs' some attention from Howmedica Management. If not, he will look for attention and vindication elsewhere."

And in 1984 Sherry contacted the Public Citizen's Health Research Group, a Nader health organization based in Washington, D.C.

But in the meantime, Ed Bessey, CEO of Howmedica, the Pfizer division, did attempt to respond to Sherry's charges. In 1983, a Howmedica team went to the Shiley plant to observe manufacturing processes.

Internal memos reveal what various members of the team observed and heard at the plant. Some of their comments:

"Measurement techniques are poor."

"There are no real controls on the welding equipment."

"Shiley has had tremendous growth but their management systems have not matured with the company."

"Fettel appears to not want to make money and people available to solve the problems."

"Equipment and techniques don't appear to have been created for the product, but rather were adapted from the other products."

"Shiley relies on final product inspection only."

"The design concept appears poor in that the 29mm valve is probably underdesigned."

"Since the reorganization, Personnel finds that Quality Control staff individuals are not rated as highly as they were. . . . (Marano wonders if this is because they may be too quality-oriented rather than sharing the goal of moving production along.) [Marano was director of quality assurance for Pfizer's Hospital Product Group.]"

"Reportedly Quality Control operators were unhappy with their treatment. . ."

"There is concern by Quality Control inspectors that their work is not important, that they will be overruled if necessary to meet production goals."

By February 1984, Henry Andrews, a senior metallurgist at Howmedica, reviewed manufacturing of the convexo-concave valve and sent a handwritten memo to Richard Myerson, head of research and development at Pfizer's Howmedica.

Among other things, Andrews's memo observed that Shiley's welding practice was "out of control—not monitored," and that in a 1983 welding study, "Dr. Shim [a Shiley engineer] admitted that some of the dialogue was *massaged* because it was expected that the FDA would see the final report" (emphasis in original).

In the Dingell subcommittee hearings, Richard Myerson, the retired head of Howmedica's research and development who reviewed the memos, read a prepared statement, which concluded: "Anytime you ask someone to do an audit . . . they are going to find things to criticize. . . . Therefore, the comments and advice, in retrospect, are not a negative view of Shiley; they are a positive aspect of the vigor with which both the panel and Shiley conducted their investigation."

Testifying before the Dingell subcommittee, Pfizer executives explained that the Howmedica team was only trying to improve an already good process. The FDA disagreed. "I'm quoting from their reports, they used the phrase 'out of control,'" observed Daniel Chwirut, an FDA engineer. "That's not a phrase that I use when I'm talking about fine-tuning a good process."

"In my opinion, the problem was a quality control problem. It wasn't a design problem."

Chwirut was the engineer the FDA sent to inspect Shiley's plant in September and October 1984—shortly after George Sherry went public with his complaints.

As a result of his reviews, Chwirut testified to the committee, he concluded "that Shiley's processes were not the best," and "that they were definitely being less than fully honest with the agency in terms of submitting data that we had asked for in a timely manner."

When Rep. Wyden asked, "Do you feel that they were insincere in terms of their dealings with the FDA and their approach to solving these problems?" Chwirut replied, "Yes, I do."

In a written report following his September 1984 inspection, Chwirut cited 13 violations of good manufacturing practice. These included a "failure to ensure that all employees are trained in the proper performance of their jobs ... Specifically, an operator improperly performed the disc assembly operation on two consecutive monostrut heart valves by performing the final bend of the outlet strut in the 'down' direction. This is in direct conflict with the ... specification which requires final outlet strut bending in the 'up' direction. When pointed out to the operator, she commented that it is much easier to make the final bend in the down direction."

Chwirut testfied that "some of the violations were extremely significant relative to the strut fracture problem. ... Two that immediately come to mind would be in the area of rewelding, and the lacking of entry on the device history records as to the number of rewelds. ... The other one would speak to their quality control operations where they allow supervisors to unilaterally overrule a quality control inspector with no rationale."

According to Chwirut, the valve had been "marginally designed," leaving little room for error: "By 'marginal design,'" he said, "I mean that the valve would be very sensitive to minor variations. ... You would have to have almost perfect manufacturing operations in order to get a valve to function properly; if any little thing went wrong in the manufacture, it could lead to disaster."

The valve broke at the welding point, Chwirut said, partly because of welding problems, partly because "metallurgically, it's the weakest part of the device," and so any problems or variations in the manufacturing process could put added stress on that welded spot. Chwirut testified that, regardless of marginal design, "in my opinion, the problem with the strut fracture of this valve was a manufacturing quality control problem. It wasn't a design problem."

In April of 1985, Shiley responded to the charges of good-manufacturing-practice violations that followed from Chwirut's review by dismissing them as "technical critiques," and pointing out that it was already implementing several changes in its operating procedures.

In July 1985, the FDA asked its Los Angeles district office to follow up and determine if the changes were adequate to meet the violations Chwirut had cited.

Gregory Nelson, FDA compliance officer at the district office, replied with a long letter that said in part: "... What is to be gained by another inspection? When is enough enough?

"Shiley is producing a heart valve that demonstrates a nearly unique failure phenomenon—strut fracture. Well over 100 fractures have thus far been reported. No matter how euphemistically one wants to characterize the situation, a substantial number of human lives have been adversely affected by this large number of product failures. Whether the overall failure rate is statistically impressive or not, the problem has a major public health impact. We should seriously consider prohibiting the firm from further marketing of the valve, unless and until they can demonstrate conclusively that they have resolved their valve problems. ..."

But the FDA did not follow Nelson's recommendation. Instead, in September 1985, the agency, still attempting to assess Shiley's manufacturing and quality-assurance procedures, asked Shiley for studies in 15 areas of concern. Shiley responded on Sept. 30 by submitting 300 documents, which it took the FDA more than six months to analyze. Chwirut, the FDA engineer who analyzed this data, described Shiley's document submission in his report as a "data dump without analysis."

Dr. Sachs, Shiley's medical director, replies: "They said, 'We need everything you have in 15 days.' We gave them everything we had in about 16 days. We also gave them a 50-page summary. We believe we gave them what they asked for."

But in the Dingell hearing, Chwirut stood by his assessment: "My phrase was a data dump. They gave us all the documentation they had that could possibly relate to those things. The documentation was very poor. There was duplication, irrelevant documents. It made it very difficult to do our job of trying to analyze those data to formulate responses to the 15 questions that we had asked."

Rep. Wyden asked: "Would it be fair to say that if Shiley was deliberately trying to slow down the job of FDA in getting at this, this was a pretty good way to do it?"

Chwirut: "They did a good job."

Wyden: "What about the summary which accompanied the 300 documents?"

Chwirut: That was a very important and very useful summary. That report contained a lot of the information, for example, that should have been submitted in PMA supplements earlier, that we had never seen before. ... What it didn't do was show the relevance of all of the supporting documentation to answering the 15 specific questions we had asked."

More than a year later, in November 1986, Shiley withdrew the convexo-concave valve from the market—after learning that the FDA was about to convene an advisory panel to reconsider its approval. What prompted the FDA to act was not manufacturing violations,

out its conclusion that the convexo-concave valve had no unique attributes that outweighed the risk of fracture; that, in fact, when compared with Shiley's older model, the RS standard valve, it had no demonstrated advantage at all.

From the start, the company's premise was that the convexo-concave valve would reduce fatal blood clots, which were the basic drawback to Shiley's RS standard valve. The benefit of reduced blood clots supposedly would more than compensate for the greater risk of fracture posed by the convexo-concave valve. This risk/benefit analysis was Shiley's rationale for continuing production, even as the valves fractured.

"In July of 1984, Shiley gave us data comparing the convexo-concave valve to the RS valve over a period of time which showed a distinct advantage," says Dr. Richard Chiacchierini, director of the Division of Biometric Sciences at the FDA's Center for Devices and Radiological Health. "But then we asked for actuarial comparisons—comparing an RS valve that has been implanted for six months to a convexo-concave valve that was in for six months, an RS valve implanted for a year to a year-old convexo-concave valve; that data wasn't yet available." Chiacchierini grants that considerable time was necessary to generate such exact comparisons.

Over the next two years, the FDA continued to request various types of comparative data and, in September 1986, the company turned in the last of the benefit data. "Our evaluation indicated there was not a demonstrated advantage for the convexo-concave valve," Chiacchierini states, "and we began proceedings to convene a panel to discuss withdrawal of the valve."

Within weeks, citing adverse publicity that made the product no longer commercially viable, Pfizer took the convexo-concave valve off the market. Recently, the company has commissioned new studies to show the benefit of the convexo-concave valve, but after review, the FDA sees no reason to change its view that the device had "no statistically provable advantage."

Meanwhile, Pfizer argues that the negative publicity is hurting implant recipients. Last month, when the Public Citizen's Health Research Group announced it was suing to seek orders requiring that Shiley notify all recipients of convexo-concave heart valves of the risks, Pfizer replied: "All but a small fraction of one percent of these valves continue to function properly. Suits like the one brought by the Health Research Group frighten cardiac patients unnecessarily and ultimately do more harm than good." Pfizer added that its "Dear Doctor" letters to physicians had provided adequate notice of the "very small danger of fracture."

But the congressional subcommittee staff contends that the "Dear Doctor" letters sent before 1986 could lull doctors into a false sense of complacency. Moreover, critics complain, letters went only to doctors—and in many cases, not to the patient's cardiologist, but only to the surgeon who might well never see the patient again after he left the hospital.

Plaintiffs like Fred Barbee of Minong, Wis., insist that if patients were notified, lives could be saved. Appearing before the congressional hearing, Barbee testified how his wife, Carol, 50, died after a valve fracture. "The symptoms of the valve fracture are much like a heart attack, and because we had never been advised about any sort of valve failure whatsoever, I made an incorrect decision to take her to the closest, but limited, facility that could treat a heart attack, but not a broken valve."

Barbee related that he told the emergency room physician at that local facility that Carol Barbee was wearing a heart valve. But, Barbee testified, the doctor had never heard of the fracture problem with the convexo-concave valve. Assuming that Carol Barbee was having a heart attack, Barbee says, the doctor gave her a medication that would slow her heart rate, "exactly the opposite" of what should have been done. By the time Carol Barbee was transferred to a hospital that could perform open-heart surgery and remove the valve, she had slipped into "clinical death." She died two hours after the fracture.

Barbee testified that if he and his wife had had adequate information regarding the possibility of fracture in the valve, a visit to the local emergency room "would not even have entered my mind. I would have called the ambulance and had her transported directly to St. Mary's Hospital in Duluth, where heart and open surgery can be performed. I am convinced she would have survived had we known."

Pfizer argues further publicity will create anxiety for implant recipients still wearing the valve.

Significantly, Barbee is not suing the emergency room doctor, or his surgeon. In fact, there have been virtually no suits against doctors in the heart-valve cases because, according to plaintiffs' attorneys, the doctors were relying on the information released by the company.

Pfizer replies that the doctors didn't have to rely solely on the company—they could read the dozens of lengthy articles in the medical literature debating the merits of various heart valves, and draw their own conclusions.

Pfizer now endorses the idea of a patient registry so that valve manufacturers can provide patients' doctors with follow-up information over a long period.

So far, Pfizer has not allowed a single fracture suit to reach trial. In each case, the company has settled out of court and, as part of the settlement agreement, has required that plaintiffs sign nondisclosure agreements.

Two weeks ago, the Association of Trial Lawyers of America filed a friend-of-the-court brief in a Texas heart-valve case, asking that the court lift the confidentiality order on Pfizer documents.

"This is a case where an IBM engineer found out he needed a heart valve in late '81, researched heart valves, and

picked the Pfizer convexo-concave valve," says the association's Jeffrey White. "Now, he's suing on the grounds of fraud, and failure to disclose problems associated with the valve, and his attorney has made a motion to lift the secrecy order on Pfizer's documents. Up until now Pfizer has managed to get a court order so that when one case is settled, the plaintiffs can't disclose information in Pfizer documents to anyone—not to the FDA, not to other attorneys bringing similar suits."

Pfizer argues that further publicity will only create undue anxiety for some 56,000 implant recipients still wearing the valve. Certainly, publicity is likely to create more anxiety suits.

To date, all attempts to bring anxiety suits against Pfizer have failed. Courts have refused to award damages unless the valve has already broken. And legal experts point out that in California, where the Khan case is being tried, the state Supreme Court has become increasingly prone to limit corporate liability. But in the Khan suit, Finzen's firm will attempt to do what it did in the Dalkon Shield case—prove company misconduct. And this time, it hopes to sue, not for negligence under product liability laws, but for fraud.

If Khan succeeds in proving fraud, what is Pfizer's ultimate liability? Or, to put it another way, what is Pfizer's financial exposure if a substantial number of implant recipients decide to go to court?

Neither Pfizer nor Khan's lawyer cares to hazard a guess. Which is not surprising, since there's little precedent: If Khan wins she'll be making case law. Anxiety suits are very hard to win, but when won, the damages can be high. Rock Hudson's lover, for example, couldn't prove he had AIDS, but he was worried that he might have it. A California jury gave him $12 million.

There are 56,000 implant recipients, all of whom, presumably, might sue Pfizer if the company loses. Under the circumstances, Pfizer's potential liability seems enormous and if fraud is proved, its insurance coverage uncertain.

The Khan case won't come to trial until, at the earliest, late 1991. Which means that for the foreseeable future the company and its shareholders are likely to suffer considerable anxiety of their own. ■

Secrecy Rules Eased In Md. Cancer Lawsuits

By Benjamin Weiser
Washington Post Staff Writer

Lifting a veil of secrecy that has lasted nearly a decade, a federal magistrate in Baltimore has removed most confidentiality restrictions imposed by an earlier judge in lawsuits alleging that workers at a Western Maryland tire plant contracted cancer after improper exposure to toxic chemicals.

The previous confidentiality orders, which had covered thousands of Goodyear Tire & Rubber Co. documents and were agreed to by all parties in the case, were similar to the broad secrecy procedures that have become a routine practice in civil lawsuits around the country during the past 15 years.

Under court rules, secrecy orders are designed to protect a company's trade secrets. In practice, however, many overburdened judges have tended to impose blanket secrecy at the beginning of lawsuits and to allow that secrecy to continue after settlement of cases. As a result, documents that deal with significant questions of safety and health have been kept out of public files.

U.S. Magistrate Deborah K. Chasanow ruled April 20 that only those documents dealing with spacific manufacturing processes and chemical formulas at Goodyear's Kelly-Springfield plant in Cumberland, Md., could be kept secret. Attorneys for the workers publicly filed many of the documents June 29 in U.S. District Court in Baltimore.

Secrecy has been an issue in the Goodyear litigation since it began in 1980. Goodyear originally sought a protective order covering every document it provided to the workers, and Martin H. Freeman, attorney for the workers, says he consented because he felt it would expedite settlements. In 1986, Goodyear confidentially settled 34 cancer suits for between $10 million and $15 million, according to two sources. In settling, the company admitted no wrongdoing.

Freeman alleged in court papers that the documents show negligent behavior by company officials. He cited a document in which a company doctor overruled a plant supervisor who said the company had a legal responsibility to provide workers with more detailed information about certain toxic chemicals.

Freeman wrote, "A company operating within the bounds of moral, ethical and legal propriety would never trade off the health of its workers for dollars of profit. Goodyear has always done so."

Goodyear officials reject any link between the illnesses and exposure at the plant. They said epidemiological studies by the National Institute for Occupational Safety and Health and by Goodyear have found no excess cancers at the plant.

Goodyear officials attributed the illnesses to other factors, such as smoking and diet. They accused Freeman of drawing a distorted and misleading picture through selective use of the documents. They said the company frequently took corrective action in response to some of the memos cited by Freeman.

Company lawyers also said that the firm used court secrecy measures to protect trade secrets, not to avoid public scrutiny. "It just wouldn't make any sense to do that and I'm confident we have not done that," said Goodyear lawyer Jonathan Dean.

Peter Infante, director of the office of standards review for the Occupational Safety and Health Administration (OSHA) in the Department of Labor, said he is troubled generally by private settlements and court orders that restrict access to information that might aid government regulators in determining links between illness and chemical exposure in the workplace. "Shielding that information is not in the public interest, nor in the interest of safety or health," Infante said.

Louis Beliczky, director of industrial hygiene for the United Rubber Workers union in Akron, said he had been aware of the Goodyear litigation but had no access to the documents because of the confidentiality orders.

"It would have been helpful for us to have so it could be used in a preventive manner," Beliczky said.

By the early 1970s, Freeman says, Goodyear knew that many chemicals used in the tire-making process were toxic and in some cases carcinogenic, but did not reveal what it knew to workers.

In a Nov. 19, 1971, memo, a Kelly-Springfield official reported receiving a package of "special handling precautions" sheets from Goodyear's chief chemist, detailing the safe and proper handling of hundreds of toxic chemicals at the Cumberland plant.

"In the past the information contained in these reports has been treated as confidential," wrote W. L. Smelser, then manager for plant security and safety. "It is now my belief that under OSHA [regulations] we are committed to release such information to our employees . . . .

"I am well aware of the effect the release of this information may have and my remarks are my interpretations of the law as I read it," Smelser said. "By copy of this letter I am asking for a top management judgment and decision as to my proposals."

Goodyear officials later responded that the precaution sheets were for the "exclusive use of management personnel" and did not have to be "posted, distributed, or made available to employees."

Goodyear lawyers say plant officials always permitted employees to inspect individual precaution sheets but did not allow wholesale copying of the material because it could disclose trade secrets.

Other memos from 1972 deal with ventilation systems, which are critical to removing potentially dangerous fumes and particles from the air. One memo states that surveys of plant-wide air handling equipment "reveal a corporate wide inadequate performance record."

"No longer can we afford to treat this equipment on the basis of an 'out of sight, out of mind' philosophy," wrote E.R. Moats, then manager for mechanical engineering, on May 11, 1972.

Goodyear officials said chemical exposure levels at the plant have always been within mandated limits and that Moats's memo led to corrective steps.

Release of Sealed Records Ordered in Xerox Toxic-Chemical Case

By Benjamin Weiser
Washington Post Staff Writer

Citing the need to allay public fears, a New York State Supreme Court justice yesterday ordered the limited release of sealed court records in a $4.75 million settlement reached last year between Xerox Corp. and two New York families who alleged their children had contracted cancer and other serious illnesses from a toxic-chemical release.

Justice Joseph G. Fritsch, who had sealed the case at the request of all parties, ruled that county and state health authorities can have access to "anything under seal that may be helpful and beneficial for the protection of the public health."

The New York attorney general's office and local authorities had sought, along with Xerox, the opening of records after publicity about the confidential settlement sparked concern that important health and environmental data were unavailable to the public. Scientists say that court secrecy is making it more difficult to track the health effects of exposure to toxic chemicals.

Sen. Daniel Patrick Moynihan (D-N.Y.), who had called for the unsealing of the records at a hearing in Rochester, N.Y., last March, said yesterday that he welcomed the court's decision.

"Locking away vital health and environmental data serves no one, and throws up roadblocks to legitimate scientific inquiry into chemical contamination," Moynihan said.

In his decision, Fritsch criticized Xerox for its about-face in seeking release of the records. He said the request by Xerox, which had sought the secrecy in the first place, "lacks good faith and sincerity" and was "motivated by a self-serving purpose, and is a face-saving attempt to show good faith only after the print media disclosed [the secret settlement]."

However, Fritsch said he would act on his own inherent judicial power and in "the interest of justice" and "the interest of public welfare and good" to release the records.

Xerox officials declined to comment late yesterday, saying they had not had time to review the case. "We are aware of the opinion and received a copy of the ruling late this afternoon. We have yet to review it and aren't in a position to comment at this point," said Peter S. Hawes, a Xerox spokesman.

Attorneys for the families and the state could not be reached last night for comment. Monroe County, N.Y., Deputy County Attorney Mark C. Davison said, "We're happy with the decision."

William P. Polito, a Monroe County legislator who had criticized the settlement and filed a friend-of-the-court brief urging full disclosure of the records, said, "I think the judge made it very clear as to where the fault lay as to the facts not having gotten to the public or to governmental authorities. The New York State Department of Health has made it very clear that it needs the facts to protect the interests of the public."

In April 1988, Fritsch sealed records of the lawsuit and prohibited the parties from discussing the matter as part of a comprehensive settlement between Xerox and the two families. The families alleged that discharges into the groundwater and air from Xerox's Webster, N.Y., plant had damaged the health of their children.

The sealed lawsuit linked the illnesses to the industrial solvent trichlorethylene (TCE), a suspected carcinogen that Xerox in 1985 said had leaked into the groundwater over a period of years. The lawsuit also alleged that airborne emissions may have been a factor.

Medical specialists hired by lawyers for the families said they would testify that the chemical releases were a factor in several cases of neurological impairment and, in the case of one teenager, cancer of the lymph glands.

One specialist, John P. Morgan, who wrote a key report analyzing the health impact of the chemical exposures and drawing the connection between the discharges and the illnesses, last night expressed relief that his report might now be seen by appropriate health and environmental officials.

Morgan, chief of pharmacology at City University of New York medical school and an expert in clinical toxicology, said he had been troubled, as a scientist and a researcher, by the secrecy surrounding his findings.

"I have been frustrated in my inability to share my report, and provoke the needed discussion and feedback from others in the scientific community," Morgan said.

Xerox strongly disputed any causal link between the TCE spill and the illnesses and said that its air emissions are filtered and meet New York state standards. In settling the case, Xerox neither admitted nor denied fault.

Fritsch, in his ruling, appears to have tried to seek an accommodation between the privacy interests of the families and the public concerns.

At a recent hearing, after E. Gail Suchman, an assistant New York attorney general, argued that the confidentiality in the case was "contrary to public interest and perhaps contrary to state law," Fritsch told one of the family members that there would have to be a "balancing" of the issue.

Fritsch yesterday limited his order to epidemiological and environmental data, reports and tests, and did not authorize the release of the children's medical records. The New York State Health Department had sought the release of the children's records, telling Fritsch in court papers that "children may react differently than adults to environmental pollutants." It promised to review the material on a confidential basis.

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Secrecy in Toxic-Spill Case Assailed

Review of Xerox Settlement May Spur Legislation for Disclosure

By Benjamin Weiser
Washington Post Staff Writer

ROCHESTER, N.Y., March 21—Sen. Daniel Patrick Moynihan (D-N.Y.) and New York state health officials today sharply criticized a court-approved secret settlement involving a toxic spill at a Xerox manufacturing plant near here, citing the case as an example of how such legal secrecy can inhibit scientific and medical inquiry into questions of health and safety.

Moynihan, who chairs an Environment and Public Works subcommittee, suggested at a hearing here that legislation may be necessary to ensure that legal settlements in environmental lawsuits do not cut off the flow of information to communities and government agencies.

"There is something unseemly about public health information, environmental health information, not being available in any circumstances," Moynihan said.

As a result of the secret settlement, Xerox agreed to pay $4.75 million to two families who had alleged that discharges from Xerox's plant in Webster, N.Y., had damaged their health. Xerox also relocated the families and bought their houses, which are now vacant. The judge sealed all records in the case and prohibited the parties from discussing the matter.

At today's hearing, Xerox general counsel Richard S. Paul said the company will now support a motion to unseal the records if it is made by a health or government agency. Moynihan praised the company f r its willingness to open the records.

The settlement came after medical specialists, hired by lawyers for the two families, said they would testify that discharges from the plant were a factor in several serious illnesses in the families, including neurological impairment. A teen-ager was found to have cancer of the lymph glands.

The sealed lawsuit linked the illnesses to the industrial solvent trichloroethylene (TCE), a suspected carcinogen that Xerox in 1985 said had leaked into the ground water over a period of years. The lawsuit also alleged that airborne emissions may have been a factor. Xerox strongly disputed any causal link between the TCE spill and the illnesses and said that its air emissions are filtered and meet New York state standards. In settling the case, the company neither admitted nor denied fault.

> *"There is something unseemly about public health information ... not being available in any circumstances."*
>
> —Sen. Daniel Patrick Moynihan

Moynihan held the hearing to review the Xerox settlement, disclosed last week in The Washington Post, as well as a toxic contamination at a Kodak plant here. Both Xerox and Kodak officials assured Moynihan that they were cleaning up the contamination and stressed that they believe there have been no health problems.

In reporting the details of the secret Xerox settlement, The Post quoted environmental and public health officials as saying that the increased use of court secrecy is making it more difficult to collect information about the effects of human exposure to toxic chemicals.

Health officials for Monroe County, which includes Rochester and the town of Webster, told Moynihan that they had known nothing about the illnesses alleged in the Xerox lawsuit until The Post's article appeared.

Thomas F. Jorling, commissioner of the New York State Department of Environmental Conservation, said that secret settlements are "antithetical to the public right-to-know concept, which holds that the public is entitled to know the identity and the dangers associated with chemicals used by industry in their community."

"Shielding information from the public domain creates obstacles to scientists seeking to discover the true effect of exposures to toxics and to regulators like myself seeking to develop comprehensive regulatory and enforcement strategies," Jorling said.

Xerox officials suggested to Moynihan that The Post's article had mischaracterized the secrecy order. They said it applied only to the terms of the settlement and did not restrict family members from disclosing information.

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MARCH 22, 1989

The Washington Post

FRIDAY, SEPTEMBER 15, 1989 A31

Russ Herman

No More Dirty Little Secrets in The Courts

At long last, two court orders granting public access to vital public documents signal some headway in uncovering secrecy in our nation's courts. ["Secrecy Rules Eased in Maryland Cancer Lawsuits," Aug. 14; "Release of Sealed Records Ordered in Xerox Toxic-Chemical Case," Aug. 17.]

When a group of rubber workers sued their former employer because they had developed cancer by toiling, unwarned and unprotected, with toxic chemicals, U.S. Magistrate Deborah K. Chasanow in Baltimore refused to keep court records secret. In earlier cases, the employer had obtained a secrecy order for documents that dealt with ventilation and whether the company was obliged to disclose the hazards to its workers.

The secrecy orders had barred OSHA and union officials from using the facts—already documented and sitting in company files. These facts could not be used to prevent further injury, even after the original cases were settled out of court.

But now Chasanow has ruled that only documents that disclose actual chemical formulae and manufacturing processes may remain secret—*not* the essential facts, which the public deserves to know.

In another case, New York State Supreme Court Justice Joseph Fritsch ordered release of sealed court records involving settlements last year between Xerox Corporation and two New York families. The families alleged that their children had contracted cancer and other serious illnesses from a toxic-chemical release by the firm. Fritsch ruled that health authorities may have access to "anything under seal that may be helpful and beneficial for the protection of the public health."

So, at last, attorneys and public authorities committed to righting wrongs can obtain relief from secrecy orders. Wrongdoers who want to cover their tracks will have to think twice before labeling their negligence a "trade secret" or otherwise hiding vital facts from public view.

As The Post documented so well in a series of articles last fall ["Public Courts, Private Justice," Oct. 23-26, 1988], secrecy is rampant in court proceedings. Litigation documents—entire court files—are often hidden from public view, even though they may involve critical public health, safety and environmental concerns.

Litigators who have painstakingly uncovered crucial safety information about playground equipment, grain elevators, automobile fuel tanks, toxic wastes, defective heart valves, butane lighters and so many other products, have seen their work buried under judicial protective orders.

"Wrongdoers who want to cover their tracks will have to think twice before labeling their negligence a 'trade secret'..."

Such secrecy undermines the right to know of every American citizen. And it keeps secrets that can kill hidden from the public.

America's courts are *public* institutions. Court records and materials obtained during litigation are not generally kept secret.

But confidentiality restrictions and secrecy orders arbitrarily imposed on victims and their attorneys as a condition of settling a case can shut off public access to health, safety and environmental concerns. Injured persons are pressured into promising, in exchange for a satisfactory settlement, to keep mum about the matter in litigation.

Without Chasanow's reexamination, OSHA, union officials and other workers at the plant who have also developed cancer would need to try to uncover the same information again and again, at appreciable expense, as if the earlier cases never existed. Without Fritsch's ruling, the health consequences of toxic releases might have remained hidden from public view for all time.

The courts, and what goes on within them, are the province of the people. Private litigants must not be allowed to determine what the public will see. Judges must start with a presumption of public access. That presumption should not be waived except in very extraordinary circumstances and for very limited purposes.

Where secrecy in litigation is concerned, the path toward justice begins with a single step. The Association of Trial Lawyers of America recently took such a step. We passed a resolution urging attorneys to resist secrecy demands that are contrary to the public interest. We urge judges to refuse to enforce new secrecy orders that do not meet stringent standards to protect the public interest, and to reconsider past secrecy orders that are clearly no longer needed.

The actions of Chasanow and Fritsch help to safeguard public safety. All judges and lawyers should follow their lead.

The writer, a New Orleans attorney, is president of the Association of Trial Lawyers of America.

When courts keep secrets

USA Today
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INTERVIEW

Justice Lloyd Doggett says that when court records are closed, sometimes what you don't learn can hurt you.

Q: Courts often seal records of legal cases from view. Both parties like it. So how can it hurt the public?

A: A wide range of consumer products have a tendency to cause injury. Information that is hidden in one state may have consequences that literally result in people being killed and maimed in other states because you can't have accident avoidance and recognition of dangers if you never hear about the danger in the first place.

Q: That apparently happened recently with silicone gel breast implants. What other products are involved?

A: Motor vehicles — the recurring problems with certain kinds of deficiencies in motor vehicles. Toxic waste issues. It may not be an individual toxic waste problem, but recurring from dumps perhaps owned by the same company in different parts of the country.

Q: How extensive is secrecy of court records?

A: It has become quite commonplace to the extent that even when any benefit of secrecy is very minimal, secrecy has become so easy to get that litigants are encouraged to ask for it. The attitude becomes, why not get secrecy because there might be something in here someday that we would want to hide?

Q: Some defenders of court secrecy say it encourages settlements. Does that ease the docket for judges?

A: It's fair to say if a judge has presented to him or her an order that has been approved by both parties, the judge is likely to sign off on it. One party is told they could get the discovery [documents] they want if they'll agree not to share them with anyone else. Often, out of a desire to serve the individual client, the attorney may agree to the secrecy order, and the judge signs off.

Q: Do judges also consider public-safety concerns? Or is that not a factor?

A: Rarely is there ever any effort by the court to consider the public interest if both parties have signed off. In fact, the Third Circuit Court in the Cipollone tobacco case, now before the U.S. Supreme Court, suggested that the trial court would be in error under the federal rules if the judge in New Jersey had considered the public interest rather than just the interest advanced by the parties.

Q: You were instrumental in making it more difficult to seal records in Texas. And a bill calling for similar action is being considered this week in California.

A: We thought it was so important to put in this rule that the court does have to consider the public interest and not just what the litigants want.

Q: But are there reasons to keep records secret?

A: If someone comes forward and has a specific, substantial interest and he can show it — a legitimate trade secret he wants to protect from a competitor — it is likely to be the kind that would justify secrecy.

Q: What about companies that have their files sealed?

A: There are companies that, if they get a report of a problem with their product, may take steps to correct it. Then there may be companies that aren't sufficiently sensitive to public-health dangers and because of the tremendous economic benefit of continuing to sell a product that's been costly to market, they may not place a high priority on the first few reports that come through.

Q: Isn't there a way to punish companies that insist on making products they know will cause harm?

A: In debates I've had with opponents of openness, they insist we need to rely on our governmental agencies. The view espoused by those of us who believe in openness is a strong belief in individual rights rather than a continuing reliance on governmental action. The belief is people are informed from adequate access to information, they could make their own decision.

Q: Do you see a trend toward more people becoming more responsible about this?

A: The only way to alter it is by changing the rules and changing the laws to require specifically that judges do their job of balancing the interest between secrecy and the public's right to know. And it's definitely a balancing process. There's no guarantee that in every situation, including every breast-implant situation, the public has a right to know everything. But what's happening is the public is losing by default because judges aren't doing the job of balancing; they're just signing off on what the parties agree. And that's got to be changed.

Lloyd Doggett has been a justice of the Supreme Court of Texas since 1989. He was instrumental in the implementation of Texas Rule Procedure 76a, which discourages secrecy in the public interest and requires that most civil-court records be open to the public. He was interviewed by USA TODAY's ***Sharon Shahid.***

Doggett

How information stays hidden

USA TODAY 1/20/02

Protective orders

A judge can issue an order that allows lawyers to receive internal documents — generally from the defendant — on the condition that they not be shared with anyone else, including the press, safety regulators and attorneys for other clients.

Confidentiality settlements

Both sides agree to keep aspects of a lawsuit confidential, or companies offer a large settlement to keep sensitive documents from becoming public. That could include alleged defects in products, alleged causes of injury, defendants' names in medical malpractice suits or an amount paid in a settlement. Often, no admission of fault is part of settlement.

AP

SIOUX CITY CRASH: As part of a settlement two weeks ago with United over the July 1989 crash, lawyers for plaintiffs are barred from divulging details of the agreement.

Sealed court records

Judges may order all files of a lawsuit sealed from public view, which prevents access by the press, safety regulators, citizens interested in the case or other lawyers. Sometimes, even the names of parties in a suit can be dropped.

Some recent court cases involving secrecy:

Silicone breast implants: The Dow Corning Corp., maker of silicone gel breast implants, agreed last week to a request from the Food and Drug Administration to make public approximately 90 scientific studies and internal memorandums concerning implant safety. Those documents had been sealed in earlier settlements.

All-terrain vehicles: As part of $5.7 million award to a man who suffered brain damage from an accident in 1981 in Oregon, a protective order required defense attorneys to return documents to Honda and not reveal what the documents showed.

Jeep CJ-5: Several owners sued and won settlements for claims that the Jeep CJ-5 had a high center of gravity and narrow wheel base and as a result was unstable. But that apparent safety hazard was sealed from the public by the settlements.

AP

ZOMAX: Settlements sealed in cases on allergic reactions to pain reliever in which some died.

The Washington Post

SUNDAY, OCTOBER 23, 1988

PUBLIC COURTS, PRIVATE JUSTICE

First of Four Articles

Court Secrecy Masks Safety Issues

Key GM Fuel Tank Memos Kept Hidden in Auto Crash Suits

By Elsa Walsh and Benjamin Weiser
Washington Post Staff Writers

Over the last five years, in defending itself against scores of lawsuits filed by victims of fiery car crashes, General Motors Corp. has used court secrecy procedures throughout the nation to keep closely held and controversial documents about auto safety from becoming public.

GM's legal approach, which is becoming a favored way of preventing the disclosure of sensitive information in civil lawsuits, has helped avoid a public debate about whether the company placed financial considerations ahead of safety concerns in designing the fuel tanks used in most GM cars until the early 1980s. Fuel leaks are a key factor in starting fires, which can cause deaths in otherwise survivable accidents.

The documents that have been kept from public view show that company officials were told in 1970 that the gas tank was vulnerable to puncture during some high-speed crashes. In 1971, the company decided not to move the tank to a more protected location after top engineers concluded that the traditional design was adequate, and that the design change was too expensive and would reduce trunk space. GM's estimates for the cost of the change ranged from $8.59 a car to $11.59.

Two years later, when engineers were assigned to study the fuel tank location again, the question of cost arose once more, and a "Value Analysis" was prepared in a two-page memo dated June 29, 1973.

A GM engineer, Edward C. Ivey, assigned a $200,000 value to each human life and assumed that a maximum of 500 people died annually in GM cars "where the bodies were burnt."

Then, in a two-stage calculation relating to new GM cars, Ivey determined what level of expenditure could be justified to try to avoid the fiery deaths in the 5 million cars GM was producing annually. "This analysis indicates that for GM it would be worth approximately $2.20 per new model auto to prevent a fuel fed fire in all accidents."

Ivey cautioned, however, that "it is really impossible to put a value on human life."

These documents, which were made available to The Washington Post as part of a lengthy examination of the burgeoning use of court secrecy procedures, have remained confidential because of GM's legal strategy.

In case after case, GM has turned over documents to opposing lawyers only under court-imposed confidentiality orders that prohibit disclosure to anyone else. It has paid millions of dollars to settle cases before trial and, as part of those settle-

See COURTS, A22, Col. 1

COURTS, From A1

tion turned over to each other during the course of the case.

Such secrecy procedures—once used almost exclusively in cases involving business trade secrets, national security and personal privacy—are increasingly being used to prevent debate about critical problems of public safety and policy. Those who have sought to take advantage of secrecy procedures include corporations, hospitals, doctors, lawyers and law firms.

There is a striking lack of consistency and standards among the area's local and federal courts in the way they handle requests to seal cases. In an environment usually governed by formal rules, the process has become almost casual. Judges follow no set procedures, ask few probing questions, offer no notification to the public and often put nothing in the public court records to explain their reasoning in deciding to seal the files.

Judges here have approved secrecy orders in lawsuits involving allegations of misconduct by doctors and lawyers, safety hazards in public facilities and products, and race and sex discrimination. Considering themselves referees who monitor disputes between private parties, judges rarely reject a request to seal a case, according to lawyers and judges interviewed. If the two sides involved in a settlement want the file sealed from public access, most judges see no reason not to go along.

"There isn't any great objection to" it among the judges of the Montgomery County Circuit Court, said Chief Judge John J. Mitchell.

In Fairfax County Circuit Court, Chief Judge Lewis Griffith said, "Normally, the court honors the request."

This informal approach conflicts with the long-accepted American tradition that the public has a right to see basic records in a civil lawsuit, an expectation formally recognized by the U.S. Supreme Court. Although judges have broad discretion in handling cases, courts historically have adhered to the principle that records should be sealed in a selective way, and that open files should contain at least the original complaint, a list of the proceedings in the case and copies of any rulings made by the judge.

No local courthouse keeps a publicly available record of which lawsuits are sealed, and internal record-keeping is so haphazard that most of the courts could not provide reliable figures. At the request of The Washington Post, the clerk's office at D.C. Superior Court searched its records and initially came up with 43 cases. It declined to provide the names of those involved, listing only case numbers, the judge and the attorneys. Told of additional cases not on the list, the clerk's office provided a revised list of 53—which still did not include every sealed case found through other sources.

At the federal courthouse in the District, the clerk's office said it would be difficult to compile a list of all sealed cases; however, the court's files contain 23 references to sealed cases, including 12 referred to as "*Sealed v. Sealed*". At least some appeared to have been sealed when they were filed—the earliest possible time. In U.S. District Court in Alexandria, 31 cases are under seal, according to a clerk.

In Fairfax County, a review of a court clerk's handwritten list suggests there have been 13 sealings in the last two years. There is no record of sealings that occurred before then. In Montgomery County, there were 69 cases sealed before 1984; a change in record-keeping procedures since then makes it difficult to obtain an accurate count. In Prince George's County, the clerk's office said it had no figures. In Arlington County, the clerk's office also said it does not keep specific figures, but one clerk estimated "no more than one a year."

Some judges said in interviews that they did not realize that sealing a case meant the entire file would be removed from public access. When D.C. Superior Court Judge Eugene Hamilton was told that he is listed as sealing the records in five cases, including two medical malpractice matters, he said: "Is that right? The whole suit? Including the names of the plaintiffs and so forth?"

Hamilton said he assumed that his secrecy orders only applied to the amounts of money paid out as part of the settlements, but said it was "never too clear" to him what else would be covered.

Judge Leonard Braman, one of 32 Superior Court judges who have sealed cases, attributed the proliferation of secrecy to busy judges looking for a way to resolve cases. "It was done as a matter of practice and the judges were driven by the desire to keep their calendars churning," said Braman. "It just seems to me that it doesn't necessarily follow that the court has to be a mindless and conscienceless tool that serves the selfish . . . ends of a litigant."

But Judge Stanley Sporkin of the federal court here said courts have only a limited role in civil lawsuits before trial. "Criminal law is the public business. Private lawsuits are usually private business," he said. "The courts don't have much say."

Stephen R. Steinberg, a senior lawyer at a New York firm who heads a committee on trial practice for the American Bar Association, said sealing records is an extraordinary step and that judges should weigh carefully the "public right to know and the constitutional protection of an open court system" against the privacy of those involved in the lawsuit.

"Public interest should be paramount," Steinberg said.

Safety Issues Kept Secret

More than 75 sealed cases and 100 confidential settlements were reviewed for this article. Information about these cases was pieced together from court files, documents provided by sources, and interviews with lawyers, judges and parties in the lawsuits, some of whom did not want to be identified.

Those interviewed drew a distinction between a judge's direct involvement in lawsuits—such as sealing and confidentiality orders—and settlements in which two sides privately agree to resolve the issues, sign a

contract not to discuss the matter and then ask the court to dismiss the lawsuit.

Settlements, which usually involve no admission of fault, serve a variety of purposes. Many cases are resolved, lawyers said, to avoid costly trials.

In nearly all the cases reviewed for this series, settlements had the effect of keeping issues of public concern from surfacing. In the Howard University Hospital case, for example, no outside investigative body learned of the nurse's alleged falsification of records. The settlement included an order, agreed to by both sides, not to discuss the case.

According to pretrial statements, which are confidential, the nurse added entries to a patient's chart to make it appear that the nursing staff had conscientiously monitored the patient as she complained of breathing problems and had summoned McKenna, the on-duty physician, several times.

The patient's chart stated that McKenna had examined the woman three times that day, May 7, 1983, but McKenna said he did not. "I knew that it was a falsification of what had happened and that I had not been notified, and I wanted to get the record straight right then and there," McKenna said at his deposition.

Another patient who was sharing the woman's room said in an affidavit that she tried to alert the nursing staff to the woman's breathing difficulties. "[She] was having problems breathing and kept taking the oxygen mask off and would start to gasp and I would buzz for the nurses. They wouldn't respond," the other patient said.

The woman stopped breathing that night, lost consciousness and died six days later, medical records show. The cause of death was listed as a heart attack brought on by a blood clot in her lung. Breathing difficulties are often a symptom of such blood clots.

When Barry Nace, the attorney for the woman's family, learned of the alleged falsification, he used it as a bargaining chip, according to sources. Unless the hospital agreed to settle immediately, Nace told Howard's attorneys, he planned to alert the media.

The $1 million confidential settlement came a few weeks later.

The hospital's attorney, Francis Smith, declined to comment about the allegations or the settlement, except to say: "It is not the policy of the hospital ever to falsify records." Speaking generally, he said, "Sealing the record is an effort to protect people, from time to time, from illegitimate or . . . misleading implications."

Judge Webber said, "I believe it would be inappropriate for me to discuss the details of any sealed cases."

Nace defended the settlement. "Would I like to see confidentiality agreements prohibited and outlawed? Yes . . . but until that happens, our obligation is to our client and not to the rest of the world," he said.

Discovery of allegedly altered records also played a major role in the settlements of two other local medical malpractice cases, according to Ronald Karp, the attorney who brought the lawsuits.

Karp, who is prohibited from discussing the specific details of the two cases, said each was settled for a "six-figure" sum. One involved a surgeon who allegedly had forged an informed-consent form to show that he had told a patient of the risks of surgery, when no such discussion had taken place, Karp said. The patient later suffered major complications in the surgery.

In the other case, Karp said, a doctor allegedly had failed to diagnose symptoms of cancer in a patient and falsified the records to show that he had detected the disease.

Karp said he did not notify medical licensing authorities of the allegations raised in the cases. "I presumed that if I did, it would be discussing the case, and that would be a breach of the settlement terms," he said.

Under a 1986 D.C. law, it is illegal to falsify medical records.

Investigation Roadblocks

Allegations against local doctors or hospitals account for a sizable percentage of the confidential settlements and sealed cases. In D.C. Superior Court, for example, 14 sealed cases involve lawsuits against doctors or hospitals.

In a 1983 case in the D.C. federal court, Judge Thomas Jackson removed from the public file all records of a civil lawsuit that alleged a physician had sexually assaulted a female patient during a gynecological examination, according to sources.

In a deposition during the lawsuit, the doctor denied assaulting the woman, but acknowledged having sexual relations with her during an exam, saying the act was consensual, according to one source familiar with the case. Consensual sexual relationships between doctor and patient can be grounds for disciplinary action, according to medical codes of ethics.

The case was settled for $30,000, the source said. The doctor's partners severed their relationship with him, but the doctor—whose name could not be learned—remains in practice in this area, according to the source.

Even if a disciplinary body is told of possible misconduct, confidential settlements in a lawsuit can sometimes stymie an investigation. Eight years ago, D.C. medical authorities received a complaint alleging that Dr. Paul Weisberg, a prominent psychiatrist, had violated professional ethics by becoming sex-

ually involved with an emotionally-vulnerable female patient during therapy.

The woman had sued Weisberg and was engaged in negotiations to settle the case. A friend of the woman, Clarence Ditlow, said he wanted to alert authorities before the woman agreed to a confidential settlement that might keep her from discussing the matter in the future. Ditlow's fears proved true. When investigators sought to interview the woman, the woman's attorney told them that the terms of the settlement prohibited her client from cooperating, according to sources.

Weisberg, in a deposition taken during the lawsuit, said he began a friendship with the woman on the day that her therapy ended and that it later became a sexual relationship. Therefore, he said, it was not a violation of ethics.

Last year, when the ethics committee of the Washington Psychiatric Society received a complaint about Weisberg's practice, the eight-year-old settlement again caused problems. The ethics committee wanted to interview the woman and tried to negotiate a way around the confidentiality agreement. Before it could be worked out, the committee decided it had enough information to go to the American Psychiatric Association (APA), a committee member said. The committee subsequently had learned about a similar allegation from another patient.

The APA, which could revoke Weisberg's membership but has no authority over his license to practice, has made no decision yet. Weisberg, who has denied any misconduct with either patient, has closed his practice here and moved to California, according to his attorney, John Karr.

Some institutions routinely seek confidentiality agreements that include provisions barring opposing lawyers from discussing settled cases.

The general counsel for Children's Hospital, Lee Doty, said she viewed confidential settlements as agreements between private parties and, in the case of Children's, a way to protect the privacy of the children treated there. "It is the belief that it's nobody's business how we handle things out of court," she said.

She added, "Lawsuits are settled for reasons frequently that have absolutely nothing to do with whether we think [the hospital is] in error. Physicians' reputations may be on the line. The hospital's reputation may be on the line .... It may be really unfair to make it public."

Doty said she could not comment on the specifics of two settlements involving the hospital. In both cases, confidentiality agreements prohibit the attorneys and their clients from alerting anyone to the suits, even though there are some documents in the public file that raise questions about safety.

One of the cases, a 1983 suit, alleged that the hospital's decision to delay the purchase of additional infant heart/respiratory monitors had been a factor in causing severe brain damage to a 6-week-old baby, who later died. The baby, who was found in cardiac arrest and not breathing, was being monitored by less sophisticated equipment that measured only respiration, according to court records.

The hospital's top medical staff—including the chairman of neonatalogy, Dr. Gordon B. Avery—had been requesting three more monitors for some time. In one memo to hospital officials, they said the sophisticated monitors were "urgently needed," according to hospital records turned over during the suit and placed in the public court file.

One memo said, "Not uncommonly, a monitor must be taken off one baby to be put on another." Another called it an "unacceptable situation" and said "nor is it consistent with our hospital philosophy of providing safe patient care."

Citing budgetary restraints, the hospital put off the purchase, the records show. In responding to the suit's allegation, the hospital blamed a defect in the less sophisticated monitor. If it had been designed properly, the hospital said, the incident might never have occurred. The hospital denied that its delay in purchasing new monitors was a factor in the child's death.

The case was settled in 1985 for $1.9 million, with the hospital and the manufacturer of the monitor each contributing, court records show. A hospital spokesman, Lon Walls, said Children's since has built a state-of-the-art neonatal facility with "all the monitors needed."

The attorney who sued Children's, Jack Olender, said he could not comment on the case because of the confidentiality provisions in the settlement. Speaking generally, he said, "The public should know about poorly designed or defective medical equipment if we are ever to obtain improvements in the health care delivery system."

The second lawsuit alleged that one of the hospital's surgeons had connected the wrong blood vessel to a 9-month-old baby's heart, causing neurological damage before the mistake was corrected. In a statement filed with the court, the hospital acknowledged the surgeon's mistake and said the child had received treatment that was "not acceptable," but pointed out that the operation was technically difficult because of the child's size. The hospital questioned whether the mistake was solely the reason for the child's condition.

This case was settled in 1986 for $2 million, according to one source.

Secrecy Is Bargaining Chip

In the back and forth of settlement negotiations, secrecy has become leverage.

For example, in a Montgomery County case filed last November, a Maryland physician agreed to settle a claim of sexual misconduct if the lawsuit was filed under seal so that his name would never appear on the public record, according to the attorney who brought the suit on behalf of a female patient. Under terms of the deal, the doctor paid an undisclosed sum to the woman and agreed to enter a rehabilitation program, the attorney said.

In a 1982 case, a judge's willingness to seal the case file became a critical element in the settlement. A group of local dentists sued Chesapeake & Potomac Telephone Co., complaining that the company was refusing to correct a phone number in an advertisement set to appear in 670,000 copies of the new D.C. Yellow Pages.

C&P said it was too late and too expensive to fix the error. D.C. Superior Court Judge David Norman temporarily blocked distribution of the books, which were about to be bound. The case was settled when C&P agreed to correct the phone number—which it called an unprecedented move and not legally required—as long as Norman agreed to seal the case.

C&P did not want other advertisers to know such a remedy was available, Ken Pitt, a C&P spokesman, said. "If every time we had a complaint we had to stop the presses, it would be an impossible situation," Pitt said. "We would never get the books out."

The Washington Post has asked judges in some business cases to impose protective orders on internal company documents relating to individual personnel records and marketing information, but has not sought sealing orders on information filed in court, according to newspaper vice president and counsel Boisfeuillet Jones Jr.

In libel cases, Jones said, The Post seeks to protect the identity of confidential sources, but otherwise turns over records detailing the editorial process without any protective order precluding public access.

Lawyers also have learned to use secrecy when they are sued personally. In D.C. Superior Court, nearly a fourth of the 53 sealed cases involve allegations of legal malpractice or disputes between lawyers. "It's judges and lawyers saying, 'We'll take care of our own,' " said lawyer John Karr.

In Prince George's County, Chief Judge Ernest A. Loveless said he sealed the records of a lawsuit filed in June against a Maryland lawyer because—in Loveless' words—he did not want "nosy" clerks to have access to the file. "You've got people handling that [court] jacket all day long who would know him," Loveless said.

In one case in D.C. Superior Court, attorneys agreed between themselves to seal certain records in a case against Howard University Hospital, only to run into stiff opposition from Judge Gladys Kessler—one of the few instances in which a judge refused to go along with such a request.

The hospital had agreed to pay $275,000 to the family of a 36-year-old Washington man who died after the hospital staff allegedly misdiagnosed his pneumonia as malaria, an allegation that the hospital denied. When they presented the deal at a July 24, 1986, hearing, Kessler said, "Across the board, I believe that court documents are public documents, and the world has a right to look at them," according to a transcript of the hearing.

The case later was settled for the same amount, and the file remained open.

Kessler was surprised when she was reminded during an interview that she, too,

See COURTS, A21, Col. 4

COURTS, From A1

appeared on the list of Superior Court judges who have sealed cases. Told that the case involved a lawyer and a bank, she said she could not discuss her reasons for sealing it but acknowledged her action was "inconsistent" with her stated philosophy.

"It really is a good example of my feeling that sealing is often done on an arbitrary or ad hoc basis," she said. "Sealing is often granted to people who are economically and socially advantaged and are therefore able to hire lawyers who know how to ask for that remedy. I suspect that you will rarely see a case involving poor people which has been sealed."

But defense lawyers say secrecy is just another tool in the vigorous representation of a client. "I will have clients I know are guilty of some wrongdoing civilly and it's still my obligation to go in and defend them as best I can," said Joseph Montedonico, whose D.C. firm has obtained five sealing orders in Superior Court civil lawsuits.

Montedonico, whose firm represented Howard University Hospital in the case that Judge Webber sealed, said lawyers have no ethical responsibility to decide if a confidentiality order is contrary to the public interest. "I don't make the ultimate decision. That's up to the judge," he said.

In another twist on the kind of leverage that secrecy can offer, lawyer Jean D. O'Malley said one of her clients was offered a "substantial increase" in a settlement in return for agreeing to the other side's request to seal a case in D.C. Superior Court.

According to documents apparently left by mistake in the open file, the suit alleged that a 6-month-old child died after a D.C. doctor failed to diagnose and treat diarrhea, a charge the doctor denied.

O'Malley declined to comment on the case, citing the seal. She said she felt ambivalent about closing the records in the case because it involved questions about a doctor's performance. At the same time, she said, her client did not object to the secrecy as long as it meant a higher settlement.

As a general rule, O'Malley said, "secrecy is worth money. No seal, no bucks."

The doctor's attorney said he made no such offer and does not engage in such tactics. "The amount of the settlement was not affected at all by the agreement to seal," he said.

'Top Dollar' for Privacy

Some settlement negotiations have nearly collapsed over the issue of confidentiality. In 1984, Judge James C. Cacheris in Alexandria federal court sent attorneys back to the negotiating table when it was clear there was a difference of opinion over the effect of a proposed confidentiality agreement.

The suit alleged that a Falls Church resident, Michael A. Webber, had suffered a near-fatal rupture of the stomach after taking Arm & Hammer Baking Soda for indigestion, a usage suggested on the package. The baking soda manufacturer, Church & Dwight Co., disputed in court papers that its product had caused Webber's illness.

At a settlement conference with the judge, Church & Dwight Co.'s attorney, Richard H. Lewis, complained that a Washington Post reporter had inquired about the case. Lewis said the company would not go forward unless Webber and his attorneys agreed not to talk about the matter, according to a transcript of the July 25, 1984, hearing.

The company was paying "top dollar" to settle, Lewis said, "but part of that reasoning was . . . no one would discuss this matter with the press or anybody else, not only the dollars and cents, but the facts [of the case]."

Webber's attorneys were reluctant to go along. After a short recess, however, they gave in to the company's demand. Back in court, Cacheris asked Webber, his wife and one of his attorneys, Kenneth Trombly, whether they understood the secrecy provision, repeating his questions several times to make sure. Satisfied, he dismissed the case, saying, "I'm glad you all resolved it."

The strategy worked. No news article appeared about the case.

Staff researcher Melissa Mathis contributed to this report.

NEXT: One company's strategy

Court Confidentiality Stymies Disciplinary Probes

Judges have sealed case files in at least 200 lawsuits in the District of Columbia and its suburbs. Hundreds of other cases have been settled with confidential contracts in which judges are not involved. Such settlements generally bar either side from discussing the suits.

CONFIDENTIAL
PROTECTED BY COURT-IMPOSED
PROTECTIVE ORDER

Secrecy procedures are increasingly being used to prevent debate about critical problems of public safety and policy. Those who have sought to take advantage of secrecy procedures include corporations, hospitals, doctors and other professionals.

Party Name	Case Number	Party Type	Date Filed	Case Title / True Party Name
				ASSOCS., ET AL
SEA[illegible]			[illegible]/77	SEA[illegible]
SEALE, WILL[illegible]	[illegible]-00346	D	02/01/84	KAHN, ET AL V PHILLIPS, ET AL
SEALED	1:82-cv-00856	D	03/26/82	SEALED
SEALED	1:82-cv-00856	P	03/26/82	SEALED
SEALED	1:83-cv-01401	D	05/16/83	SEALED
SEALED	1:83-cv-01401	P	05/16/83	SEALED
SEALED	1:83-cv-03591	D	12/01/83	NAT.STABIL.,ETC.ETL V COMMERCL.SHT.METAL
SEALED	1:83-cv-03591	P	12/01/83	NAT.STABIL.,ETC.ETL V COMMERCL.SHT.METAL
SEALED	1:83-x -00200	U	06/22/83	USA V TREADWELL
SEALED	1:84-cv-00050	D	01/06/84	SEALED
SEALED	1:84-cv-00050	P	01/06/84	SEALED
SEALED	1:84-cv-01582	D	05/21/84	SEALED
SEALED	1:84-cv-01582	P	05/21/84	SEALED
SEALED	1:84-cv-02103	D	07/13/84	SEALED
SEALED	1:84-cv-02103	P	07/13/84	SEALED
SEALED	1:85-cv-01094	D	04/05/85	SEALED
SEALED	1:85-cv-01094	P	04/05/85	SEALED
SEALED	1:86-cv-02091	pla	07/30/86	SEALED v. SEALED, et al
SEALED	1:86-cv-02091	dft	07/30/86	SEALED v. SEALED, et al
SEALED	1:86-cv-02091	dft	07/30/86	SEALED v. SEALED, et al
SEALED	1:86-cv-02091	dft	07/30/86	SEALED v. SEALED, et al
SEALED	1:86-cv-02091	dft	07/30/86	SEALED v. SEALED, et al
SEALED	1:86-cv-02091	dft	07/30/86	SEALED v. SEALED, et al
SEALED	1:86-cv-02091	dft	07/30/86	SEALED v. SEALED, et al
SEALED	1:86-cv-02091	dft	07/30/86	SEALED v. SEALED, et al
SEALED	1:87-cv-00669	pla	03/12/87	HARD ROCK CAFE, et al v. JOHN DOES
SEALED	1:87-cv-00669	dft	03/12/87	HARD ROCK CAFE, et al v. JOHN DOES
SEALED	1:87-cv-00945	pla	04/06/87	SEALED v. SEALED
SEALED	1:87-cv-00945	dft	04/06/87	SEALED v. SEALED
SEALED	1:87-cv-01175	pla	04/29/87	SEALED v. SEALED
SEALED	1:87-cv-01175	dft	04/29/87	SEALED v. SEALED
SEALED	1:87-cv-01197	pla	05/01/87	SEALED v. SEALED
SEALED	1:87-cv-01197	dft	05/01/87	SEALED v. SEALED
SEALED	1:87-cv-01251	pla	05/08/87	SEALED v. SEALED
SEALED	1:87-cv-01251	dft	05/08/87	SEALED v. SEALED
SEALED	1:87-cv-01547	pla	06/08/87	SEALED v. SEALED
SEALED	1:87-cv-01547	dft	06/08/87	SEALED v. SEALED
SEALED	1:87-cv-02081	pla	07/28/87	NIKE, INC., et al v. JOE'S SPOT, INC., et al
SEALED	1:87-cv-02081	dft	07/28/87	NIKE, INC., et al v. JOE'S SPOT, INC., et al
SEALED	1:87-cv-02372	pla	08/27/87	LOUIS VUITTON, S.A., et al v. LIMSCO, INC., e
SEALED	1:87-cv-02372	dft	08/27/87	LOUIS VUITTON, S.A., et al v. LIMSCO, INC., e
SEALED	1:87-cv-03124	pla	11/18/87	SEALED v. SEALED
SEALED	1:87-cv-03124	dft	11/18/87	SEALED v. SEALED
SEALED	1:87-cv-03434	pla	12/17/87	SEALED v. SEALED
SEALED	1:87-cv-03434	dft	12/17/87	SEALED v. SEALED
SEALED	1:88-cv-00578	pla	03/03/88	SEALED v. SEALED
SEALED	1:88-cv-00578	dft	03/03/88	SEALED v. SEALED
SEALED	1:88-cv-00579	pla	03/03/88	SEALED v. SEALED
SEALED	1:88-cv-00579	dft	03/03/88	SEALED v. SEALED
SEALED	1:88-cv-01426	pla	05/25/88	SEALED v. SEALED
SEALED	1:88-cv-01426	dft	05/25/88	SEALED v. SEALED
SEALED	1:88-cv-01458	pla	05/27/88	SEALED v. SEALED
SEALED	1:88-cv-01458	dft	05/27/88	SEALED v. SEALED
SEALED AIR CORPORATION	1:81-cv-00797	P	04/03/81	SEALED AIR CORP V. ALDERGER, [illegible]
SEALES, DEBORAH	1:85-cv-03335	pla	10/18/85	WELLS [illegible]
[illegible]RAH	1:85-cv-03325	R	[illegible]	[illegible]

THE WASHINGTON POST

A list of files in D.C.'s federal courthouse. "*Sealed v. Sealed*" may mean that even the names involved were shielded at the outset.

Secrecy Boosts Settlements

VIEWPOINTS

KESSLER

"Criminal law is the public business. Private lawsuits are usually private business. The courts don't have much say."

—Stanley Sporkin, a federal court judge who believes that courts have only a limited role in civil lawsuits before trial

". . . I believe that court documents are public documents, and the world has a right to look at them."

—Gladys Kessler, a D.C. Superior Court judge who has ordered one case sealed but who believes that such actions are often done on an arbitrary or ad hoc basis

SPORKIN

MONTEDONICO

"I don't make the ultimate decision [to seal a lawsuit case file]. That's up to the judge."

—Joseph Montedonico, a D.C. lawyer whose firm has obtained five sealing orders in Superior Court civil lawsuits

As a general rule, "secrecy is worth money. No seal, no bucks."

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O'MALLEY

TUESDAY, OCTOBER 25, 1988

PUBLIC COURTS, PRIVATE JUSTICE

Third of Four Articles

Drug Firm's Strategy: Avoid Trial, Ask Secrecy

Records Reveal Story of Zomax Recall

By Benjamin Weiser
and Elsa Walsh
Washington Post Staff Writers

In mid-January 1985, an important memorandum began circulating to top officials at McNeil Pharmaceutical, a major subsidiary of the Johnson & Johnson company, the maker of Band-Aids and Tylenol.

The memo was both a warning and a reminder of a difficult period in McNeil's history. Nearly two years earlier, on March 4, 1983, McNeil had withdrawn its prescription painkiller Zomax after only 28 months on the market. The decision came after reports of hundreds of severe allergic reactions to the drug, a top seller. After the recall, the company faced nearly 600 lawsuits, many alleging that McNeil had failed to adequately warn the medical community about Zomax's risks—an allegation the company has strongly disputed in court.

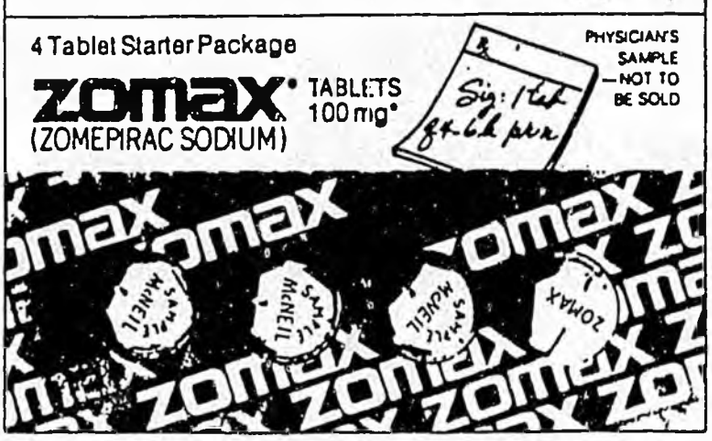
The Jan. 14, 1985, memo, written by McNeil legal aide Herman Lutz, listed 18 lawsuits that "presented McNeil with the most exposure or had sensitive problems." Many of the cases involved patients who had taken Zomax during periods when the company had decided to issue stronger warnings, but had not yet done so. The memo, sent to company President Jack O'Brien, also noted other factors, including the potential testimony of several witnesses that might prove worrisome.

To defend itself against these lawsuits and dozens of others that McNeil's lawyers regarded as serious, the company adopted a strategy that it has pursued vigorously during five years of Zomax litigation in 43 states.

It has used court secrecy procedures—called protective orders—to prevent the disclosure of information that McNeil turned over during the course of the lawsuits. It has taken only three cases to trial, choosing instead to settle cases outside the courtroom without admitting any liability. As part of these settlements, it has obtained confidentiality agreements that prohibit opposing lawyers and their clients from revealing what they have learned about Zomax.

What McNeil's attorneys consistently have managed to keep out of the courtroom are documents and testimony that might have provoked a public debate about whether McNeil withheld information from the medical community about the risks of Zomax. The U.S. Food and Drug Administration concluded in 1985 that the drug was probably a factor in 14 deaths and 403 life-threatening allergic reactions. The material also did not reach congressional investigators who, a month after the recall, held two days of hearings

See COURTS, A12, Col. 1



COURTS, From A1

that centered on the FDA's role in regulating Zomax, and not the company's internal procedures.

McNeil officials, pointing out that drugs are inherently unsafe, said in interviews that they promptly alerted doctors or the FDA whenever they had solid data about Zomax's risks. They sought broad secrecy orders, they said, to prevent disclosure of trade secrets that would be valuable to competitors and because some documents might be misinterpreted. "McNeil's only protection is secrecy," the company has said in court papers.

The Washington Post, as part of a lengthy examination of secrecy in the civil courts, has reviewed much of this still-confidential material. It provides an inside look at how McNeil tested and marketed Zomax, then struggled to understand why the drug—which was being taken safely by millions of people—also was causing unpredicted and life-threatening reactions in some patients.

According to the documents, there were indications during premarketing testing that Zomax might cause a severe allergic reaction known as anaphylaxis, which can lead to seizures and respiratory failure. McNeil said the results were not conclusive enough to include in Zomax's package insert—the primary way that a company warns prescribing doctors of harmful side effects.

A warning about anaphylaxis was first included nine months after the drug went on the market, following several reports of anaphylactic reactions, but one internal memorandum to McNeil's president criticized the company for not acting sooner. "We resisted too much and waited too long," wrote Patrick Seay, McNeil's longtime head of regulatory affairs in a Sept. 8, 1984, critique of the company's overall performance in marketing drugs.

Another internal document is a Feb. 26, 1982, memo sent to the company's sales force immediately after a case of anaphylactic shock was reported in the Journal of the American Medical Association. The memo said, "This information is being sent to you so you will be fully prepared to respond to a physician or pharmacist who initiates discussion on the article. You should not bring up the subject."

Six weeks later, other documents show, the company launched a high-pressure sales campaign shortly after McNeil had sent out a special warning letter to 200,000 physicians. As the letter was being drafted, a McNeil researcher gathered data that suggested Zomax might be riskier for some patients than previously believed.

Concerns within McNeil climaxed in a series of tense weekend meetings on Feb. 5 and 6, 1983, at the firm's headquarters in Spring House, Pa. Three of the company's four top doctors told McNeil's president they no longer had confidence in the drug's safety, according to one of the doctors, James A. Dale. The company considered various options, including a recall, before deciding instead to strengthen its package warning.

As the new warning was being prepared, two people died of anaphylactic reactions allegedly related to Zomax use, and the company took the drug off the market. "They were avoidable deaths," Dale, then McNeil's associate medical director and now in private practice, said in an interview. "They were avoidable side effects .... I felt guilty .... We met and had the opportunity to take action .... We could have done something sooner."

Dale has never testified in any Zomax lawsuit. In several instances where his testimony has been sought, McNeil has settled before he could appear for a deposition, sworn pretrial testimony that is taken outside the courtroom. Information about the Feb. 5 and 6 meetings has never become public.

McNeil also moved quickly to settle two cases in which opposing lawyers had unexpectedly referred to sensitive McNeil documents in publicly filed legal briefs in Miami and Seattle. As part of those settlements, judges in both cases ordered that the entire file be sealed from public view.

During four hours of interviews and in 22 pages of written responses to questions submitted in advance, officials at McNeil and its parent company, Johnson & Johnson, strongly defended both their legal strategy and their handling of Zomax.

"The strategy was to dispose of the Zomax cases as expeditiously and as cheaply as possible," said Roger Fine, associate general counsel of Johnson & Johnson, which handles the legal work for all the company's subsidiaries.

According to Fine, secrecy orders were necessary to guard the company's chemical formulas and marketing methods, as well as to prevent others from using documents to suggest unfairly that McNeil did not care about the safety of its products. The company settled cases, he said, for a variety of reasons, not just concern over documents and testimony.

James E. Burke, chairman of Johnson & Johnson, said in an interview that he was proud of the company's handling of Zomax and rejected any suggestion that the company should have withdrawn the drug immediately after the Feb. 5 and 6 meetings. Once the company decided to recall the drug, he said, "I think we did a good thing—I don't see how you could do it any faster."

Dr. Patricia Stewart, McNeil's head of medical research, said her staff carefully monitored adverse reactions to Zomax for the entire time that it was on the market. McNeil officials said the company's decision to issue a stronger warning after the Feb. 6 meeting was a prudent course of action given what was known at the time.

Lawrence G. Foster, Johnson & Johnson's vice president for public relations, said, "As we demonstrated in response to the Tylenol poisonings and again in the way we managed Zomax, our first responsibility under our credo is to our customers. Anybody who manages a business for the long term, as we do, knows that putting the customer first is the only way to increase sales."

Foster said that nearly 15 million patients used Zomax without incident, and that the recall of Zomax was not an admission that the drug was unsafe for everyone. "Decisions regarding Zomax labeling had to be made based on fragmentary information about possible adverse reactions experienced by a small number of patients out of the millions who actually used the medication," he said. "This is hardly an exact science .... And warning of every conjectural side effect, no matter how thin the evidence, results in a label so expansive and indiscriminate that it in effect warns of nothing ...."

The company revised its warning labels whenever it had enough information to war-

rant it, he said. "This is the simple truth—and no amount of second-guessing of McNeil's and FDA's judgments . . . can negate it."

Responding to Seay's criticism that McNeil had not issued a warning about anaphylaxis soon enough, Foster said the company's decision was reasonable at the time.

The adequacy of McNeil's warnings is the central issue in the Zomax lawsuits. The courts have long recognized that prescription drugs are inherently unsafe, that what is enormously beneficial for some people may not be for others. Federal law has resolved that medical dilemma by requiring drug companies to assess a drug's risks, as well as its benefits, and issue full and accurate warnings about possible adverse side effects. If a company complies, the courts have ruled, it usually cannot be held liable for an adverse reaction.

Seay, in his 22-page internal critique written 18 months after Zomax was recalled, voiced his belief that the company had failed, at times, to meet its own high standards. "We can do little about the past," he wrote, "but we should perform now strictly according to the letter and spirit of the regulations and to ethical principles to preserve the good name of J&J [Johnson & Johnson]."

Conflicting Interests

The information in this article is drawn from internal McNeil records made available by sources, and from interviews with present and former McNeil employees, lawyers who have sued McNeil and officials at McNeil and Johnson & Johnson.

McNeil's attorneys agreed to discuss some aspects of their legal strategy and to comment on internal documents that The Post had obtained elsewhere. They declined to disclose settlement amounts or to release internal records.

A handful of plaintiffs' attorneys agreed to a limited discussion of their impressions of McNeil's legal strategy. A few other lawyers consented to interviews on the condition that they not be identified by name. Most plaintiffs' attorneys, however, declined to make any comment, saying they feared it might be construed as a violation of court-imposed protective orders or a breach of the confidentiality agreements they have signed with McNeil.

Some of the plaintiffs' attorneys, while acknowledging that they agreed to McNeil's requests for secrecy, took issue with the company's statements about its need for confidentiality.

Allan Kanner, a lawyer in Philadelphia who has represented several clients in Zomax settlements, said, "What they are trying to do is not be accountable to the vast majority of the public for what they've done . . . . They paid my clients a ton of money for me to shut up."

Maryland lawyer Steven Nemeroff, who settled a Zomax lawsuit in Baltimore, said generally of lawsuits involving drugs, "The problem is that they have a gun to your head. The client is concerned about being compensated in full. The lawyer must abide by the concerns and wishes of his client . . . not the fact that [information will remain secret or] other victims may be injured."

For some of Zomax's alleged victims and their families, the legal process left them ambivalent. They agreed to financial settlements—in which the company admitted no fault—and found themselves with important unanswered questions.

Carol Sawyer, whose lawsuit alleged that her 42-year-old husband Michael died of anaphylaxis after taking Zomax, said she settled the case without knowing of the Feb. 6 meeting at which Dale said he and two other McNeil doctors had declared their lack of confidence in Zomax's safety.

Michael Sawyer was one of two people to die of anaphylactic reactions allegedly caused by Zomax in the four-week period between that meeting and Zomax's recall. "That's very upsetting to know, that [his death] might have been prevented," she said. "I just can't believe [McNeil] would take a chance and wait and see."

Devra L. Davis, a Washington toxicologist who settled with McNeil after suffering a near-fatal anaphylactic reaction, said she believes court secrecy impairs "free scientific inquiry and the right of the public to know specific information about drugs it consumes."

If independent scientists could make a thorough study of what happened with Zomax, Davis said, they might be able to learn lessons that would help others in the future.

McNeil's attorneys dispute these characterizations, saying that the civil courts are primarily intended to be a place to resolve private disputes—and, therefore, not the proper forum for a public debate on McNeil's performance. "We don't really have anything to hide in this thing," said David F. Dobbins, of Patterson, Belknap, Webb & Tyler, the New York law firm that has represented McNeil in court throughout the Zomax litigation.

Code Name: Operation 111

In large part, the information contained in McNeil's internal records and in still-confidential depositions shows a side of the drug industry that the public rarely sees: the inevitable tension between the medical staff and the marketing division, the sometimes flawed relationship between a drug company and its regulators at the FDA, and the high-pressure sales tactics used to promote a drug to doctors and hospitals.

When Zomax was approved for sale in October 1980, McNeil called the painkiller a breakthrough, as strong as a narcotic but not addictive. The drug was an immediate success, capturing 11 percent of the new prescription analgesic market within four months, according to McNeil records.

Zomax's initial package insert cautioned that doctors should not prescribe the drug for patients with allergies to aspirin or similar medication, but it made no mention of anaphylactic reactions.

The first reports of anaphylactic reactions—none of which had resulted in death—surfaced soon after Zomax was launched. In July 1981, the company revised its package insert to include a statement that "anaphylactoid reactions have been reported."

Seay, in his internal critique, suggested that the package insert should have been revised sooner. He faulted the company for allowing its marketing division to gain "a greater role in the content and changes of the package insert," an area traditionally left to the medical side.

Pointing out that several severe allergic reactions occurred in 1978 during the premarketing testing of Zomax, Seay said an argument could be made that the company should have interpreted them as anaphylactic—an argument the company rejects. Seay also cited reports of anaphylatic reactions to another McNeil drug, Tolectin. "We knew the

chemical relationship of Zomax to Tolectin and we knew that Tolectin produced anaphylactoid/anaphylactic reactions," he wrote.

McNeil's Foster said, "With hindsight, one can debate whether the label should have been changed a month or two earlier," but not earlier than that.

Another memo shows McNeil's growing concern as anaphylactic reactions escalated through 1981 and into 1982. "Zomax allergic reactions are continuing to be reported at a relatively high rate and need close surveillance," wrote Dr. Stewart, McNeil's medical research chief, on Feb. 18, 1982.

A month later, the company learned of the first fatal anaphylactic reaction in a patient who had taken Zomax. Because the patient was allergic to aspirin and should not have been given a prescription for Zomax, the company decided to issue a special "Dear Doctor" letter to the medical community to call attention to the aspirin warning already in the package insert.

As the Dear Doctor letter was being drafted with the aid of FDA officials, the company undertook a study of the 178 allergic and anaphylactic reactions that had been recorded since Zomax was introduced. The results surprised some members of McNeil's medical staff.

According to a March 31, 1982, internal memo from researcher Thomas Teal to McNeil president O'Brien, the study found a pattern of anaphylactic reactions in patients who took Zomax intermittently—starting, stopping, starting again. It made no conclusions about these statistics.

Intermittent users were Zomax's largest market, about 75 percent. They took Zomax like aspirin, whenever necessary. If they were at risk, that might require a broad warning.

A few days after Teal presented his study to McNeil management, documents show, an explicit paragraph-long warning was drafted for the proposed Dear Doctor letter, specifically citing risks for intermittent users who had no previous problems with Zomax. In the final draft, however, the word "intermittent" was dropped and the warning shortened to a single sentence: "Hypersensitivity upon re-exposure or extended use cannot be ruled out."

In recent interviews, McNeil and Johnson & Johnson officials stood by the letter's final wording. They said the Teal study, while worthy of consideration, was based on fragmentary information. At that point, they said, intermittent use was still an "unproven risk factor."

On April 9, the less explicit version was mailed to 200,000 prescribing doctors.

Seven days later, internal documents show, McNeil instructed its sales force to undertake a major new marketing campaign. An April 16 Mailgram said, "We're calling it 'Operation One-Eleven.' Now, if that sounds like war, well, in our world of selling that's what it is."

It was being called Operation 111, the Mailgram said, because McNeil hoped to garner $111 million in annual sales for Zomax and its sister drug, Tolectin. To do so, the Mailgram instructed the sales force to concentrate exclusively for 10 weeks on those two drugs.

During the duration of the sales campaign, McNeil sent memo after memo to its sales force, all written in mock military language and styled as if they were military intelligence reports. At the top of each was the Operation 111 insignia: crossed rifles. The sales reps received new stationery,

See COURTS, A13, Col. 1

Staff Doctors Voice Concern At Tense Weekend Meetings

COURTS, From A12

adorned with pictures of a tank, a cannon and a fighter plane.

An April 22 memo to the sales force, titled "Operation 111 War Bulletin," warned of a competing drug firm's plans to introduce its own painkiller. It began:

"Situation: Be advised, the invading forces of Pfizer are currently amassing on our borders. Intelligence reports that no aggressive actions have taken place thus far. Each day Pfizer delays gives us more time to make preemptive strikes.

"Mission: We will not only hold our ground but continue to increase our strength by aggressive pursuit of current competitors.

"Strategy: Immediate deployment to all territory representatives and hospital representatives for strengthing the Zomax . . . flanks has begun . . . .

"Tactical support: Our factories have been converted to increase production of samples, direct mail, literature, and journal ads."

Halfway through Operation 111, a memo went out reminding the sales force that "high volume prescribers" of Zomax should be called a minimum of four times before the campaign was over. Each sales representative had been sent a list of these physicians in their area.

At McNeil headquarters, some medical staffers were upset about the sales campaign, believing that it had probably increased sales to intermittent users, according to Dale.

McNeil officials said Operation 111 was a typical sales campaign that had been conceived to respond to the introduction of Pfizer's new drug. They stressed that the sales force also had been sent copies of the Dear Doctor letter, which in their view contained the best warning statements that could be written at that time.

The Demise of Zomax

The internal documents also contain revealing insights into McNeil's dealings with the FDA and provide new details about the company's decision to recall the drug.

By law, drug companies are required to forward all reports of adverse reactions to the FDA. In 1982, documents show, Seay informed the FDA that McNeil had inaccurately reported the seriousness of several adverse reactions to Zomax. According to an April 21, 1982, internal memo by Seay, who was the company's liaison with the FDA, several cases described simply as allergic reactions "should have been designated" as the more serious anaphylactic.

It is clear from Seay's 1984 critique that he considered accurate reporting to the FDA to be of paramount importance. Not naming any specific drugs, he recounted one McNeil official's complaint that the company was "reporting too many adverse reactions on our drugs." Responded Seay, "We must report every adverse drug reaction that is received by us . . . . The requirements are clear."

Seay's critique also criticized other McNeil officials who paid visits to the FDA commissioner's office, which Seay said were seen by the FDA "as a form of pressure" to win favorable decisions. "We are having some difficulty in maintaining credible relations with FDA," he wrote.

Another internal memo criticized Dr. John Harter, the FDA official in charge of regulating Zomax. Robert Z. Gussin, McNeil's vice president for scientific af-

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fairs, described Harter as someone who "seems to have a different cause celebre every week, and we would go out-of-our-minds if we seriously followed up every one," according to his Jan. 25, 1982, memo to a McNeil colleague.

McNeil officials told The Post that Gussin's "colorful choice of words" does not reflect McNeil policies. They said the company took all FDA requests seriously.

By early 1983, with Johnson & Johnson still reeling from the highly publicized Tylenol poisonings in the fall of 1982, a task force was appointed at McNeil to study the deaths associated with Zomax use. At a meeting of McNeil officials, "It was pointed out . . . that this is a sensitive issue which can become the focus of immediate attention," according to minutes of the Jan. 21, 1983, meeting.

The issue came to a head at the Feb. 5 and 6 weekend meetings. At a Sunday session, McNeil president O'Brien heard for the first time that three of his four highest-ranking medical staffers were sufficiently concerned that they would not prescribe the drug for a patient, according to Dale, one of those who participated. His account was confirmed by another McNeil employee who attended the meeting with O'Brien.

McNeil officials differ over what happened next. Dale said there was a consensus that the company should recall the drug and immediately publicize its concerns. Foster, of Johnson & Johnson, said, "The possibility of voluntarily withdrawing the drug from the market was considered, but it is incorrect to state that the medical personnel concluded that a recall should take place."

The company decided to strengthen its package insert again. As it was being prepared, McNeil learned of three cases in which patients with no known allergy to aspirin had died of anaphylactic shock. Then, on March 3, a Syracuse, N.Y., television station carried a report of several nonfatal anaphylactic reactions in that city, the first time the issue had surfaced in the general media.

The next day, Johnson & Johnson announced the nationwide recall.

Troubling Witnesses

From the filing of the first lawsuits, after the wide publicity about the recall, McNeil's lawyers divided the cases into two categories. Many cases were considered frivolous or involved mild reactions that caused no long-term injuries. These were typically settled for less than $20,000, according to McNeil, and involved no extensive exchange of documents or secrecy orders.

The second category were cases deemed more difficult to defend for a variety of reasons, including the severity and timing of the injury, as well as the company's desire to prevent sensitive documents from emerging or certain witnesses from testifying.

One such witness was Jody Perez, a former McNeil sales representative in Texas who had resigned in 1982 because he believed the sales campaign downplayed Zomax's risks. Perez is listed as one factor in some cases on the list of 18 sensitive cases that circulated inside McNeil in January 1985.

McNeil's lawyers said Perez was only one factor in their decision to settle, and never the most important one. "We looked at the cases in the total spectrum . . . the injuries involved, the jurisdiction, all the things which go into evaluating a case, and attempted to negotiate a settlement," said Roger Christiansen, another Johnson & Johnson attorney.

McNeil was more concerned about anonymous notes that began mysteriously arriving in 1986 at the offices of attorneys suing McNeil. The notes urged that they "not be deflected" from taking depositions of three McNeil employees—Dale, Seay and Edward Lemanowicz, one of Seay's deputies.

The depositions never took place.

One note went to lawyer W. Thomas Smith. He was the attorney for Carol Sawyer and the children of Michael Sawyer, whose death had occurred in the four-week interval between the Feb. 6 meeting and the recall. The Sawyer lawsuit, filed in Boston federal court, was on McNeil's list of 18 sensitive cases.

Another note went to Florida attorney James Gray, who was representing Higinio Acosta, a 41-year-old construction worker who had a severe reaction on the same day as Sawyer.

Both cases were settled soon after Smith and Gray sought to take the depositions. Under the terms of the settlements, the attorneys said they could not discuss the cases. In the Acosta case, the entire file in the Miami federal court has been sealed "in accordance with certain confidential agreements," according to an Oct. 2, 1986, order by Judge Thomas E. Scott.

McNeil's attorneys said they settled these two cases for a variety of reasons and not because they feared the testimony of potential witnesses.

Referring to the three men, Fine said, "They were not the best spokespeople for the company. It was as simple as that."

Staff researcher Melissa Mathis contributed to this report.

NEXT: A sealed dispute

Settlements Kept Former Drug Salesman's Story Under Wraps

Jody Perez, a former sales representative for McNeil Pharmaceutical, went to his garage in June 1984, retrieved some documents stored there and took them to a law office in downtown Lubbock, Tex.

He was an important witness in several lawsuits against McNeil, which had been filed by alleged victims of Zomax, a prescription painkiller that McNeil pulled off the market in March 1983. Perez, 34, had quit the company in frustration and disgust in 1982, believing that the sales force had participated in a campaign that minimized Zomax's risks.

His audience at the law office was limited: attorneys suing McNeil, attorneys representing McNeil and a stenographer making a record of Perez's words. No judge or jury was present. This was a sworn deposition, pretrial questioning intended to help the lawyers prepare their case, the first of two depositions that Perez gave.

In all, the Perez transcripts total more than 900 pages. But no one, other than that small group of attorneys and their clients, has read them. Before Perez could tell his story in open court, the lawsuits were settled. As part of the settlements, the lawyers are prohibited from discussing the cases.

McNeil's attorneys said the company had many reasons for settling cases in which Perez was deposed, and that Perez was only a small factor. "What he had to say was not something that we were concerned about. We knew what he had said. We had taken his deposition and it wasn't anything extraordinary," said Steven Charen, a lawyer with the New York firm that has represented McNeil in Zomax cases.

McNeil officials, both in court and in recent interviews, rejected any suggestion that the company sales campaign had played down Zomax's risks. Safety concerns, they said, were the company's first consideration in its marketing of drugs, including Zomax. The drug was taken safely by millions and the company issued warnings about its risks whenever necessary, they said.

Perez's testimony and his documents were a casualty in the five-year legal battle over Zomax. In defending against the Zomax lawsuits, McNeil used an array of court-approved secrecy procedures to control the disclosure of documents and testimony.

The attorneys suing McNeil saw witnesses such as Perez as extra leverage. They knew how some juries might react to his testimony, and they used it in bargaining with McNeil.

Perez had no pharmaceutical background when he was hired at McNeil in June 1981 at an annual salary of $19,500. A former teacher and football coach at Lubbock High School, he went through a weeklong orientation devoted in part to Zomax, which had gone on the market eight months before.

Perez spent much of his time on the road in western Texas, visting doctors' offices and hospitals. The trunk of his company car was filled with boxes of Zomax samples, along with Zomax-imprinted golf tees, prescription pads and pens that he handed out on sales calls.

Hospital personnel welcomed his visits—and his gifts. "The staff was hungry for some good down-home conversation and service," Perez wrote in a weekly report one week after visiting hospitals in eastern New Mexico. At Guadalupe Hospital in Carlsbad, he noted, "McNeil is the only company where reps bring them donuts, notepads or anything. Very appreciative. They usually have to pry notepads from Lilly rep."

He treated doctors to college football games and boxing matches, delivered pizzas to their offices and took doughnuts to their surgical suites. He gave samples to medical students and medical residents for their headaches, hangovers and menstrual cramps. He flattered nurses and receptionists to gain access to their office supply closets, which he then filled with Zomax samples.

Before Halloween, he carried pumpkins filled with candy and Zomax samples into doctors' offices, announcing, "Doctor, medicine is very serious business and you don't want to trick your patients, so treat your patients [with] Zomax," according to his Oct. 30, 1981, field report.

By early 1982, Zomax had become a phenomenal success, ranking second among McNeil's prescription products behind Tylenol with Codeine. "No other company has ever come close to this record of productivity for a new product launch," according to a Dec. 17, 1981, memo to Perez and McNeil's national sales force. "Let's make the McNeil sales force and Zomax the 'talk of the industry' for the second year in a row."

That same month, Perez learned of four severe anaphylactic reactions associated with Zomax use at local hospitals. At Methodist Hospital, an emergency notice was posted and the staff was told not to prescribe Zomax pending further investigation.

Word quickly spread to doctors throughout Lubbock. Perez's weekly reports took on a worried tone.

Jan. 29: "They want to know the details about what is going on. But the big question is whether they will keep writing for Zomax???"

Feb. 12: "I got kicked out of Dr. Patrick Pappass's office. I just mentioned Zomax and he said, 'Get out if you don't want me to quit writing your other products.' "

Feb. 19: "I won some battles this week concerning Zomax, but I do not believe that the war will be easily won . . . . The overall movement of Zomax in Lubbock is slowing down immensely."

Soon, six of the seven Lubbock hospitals stopped using Zomax. Pharmacists questioned doctors who prescribed the drug, according to one of Perez's reports. For Perez, months of hard work had come undone.

In early March, McNeil's head of medical research, Dr. Patricia Stewart, flew to Texas to investigate the reactions. She met with doctors and one of the people who had an anaphylactic reaction. On her return to McNeil headquarters in Spring House, Pa., she wrote a memo to her superiors, citing Perez for his "outstanding" performance in helping to reassure the Lubbock medical community. "Without his stabilizing influence the situation there would be much more problematic," she wrote.

In early April, Perez and the other sales people received a copy of a letter that McNeil was sending nationwide, reminding doctors that Zomax should not be prescribed for patients with sensitivity to aspirin and noting that "hypersensitivity" was a possible side effect for occasional users. "The attached letter need not be the focus of a Zomax presentation," an April 8 memo said. "However, the issues it raises should be communicated as part of a balanced presentation to physicians and pharmacists . . . . Zomax business is excellent. We are ahead of our sales forecast to date. Keep up the good work!"

A few days later, the company sent another announcement to its sales force, launching a major 10-week sales campaign for Zomax dubbed Operation 111. "Your role is vital" to Operation 111, said a Mailgram signed by Thomas Odiorne, then sales vice president and now McNeil's president. "Use your samples abundantly . . . . Remember, business belongs to those who ask for it."

McNeil officials said in recent interviews that their sales tactics, including Operation 111, are typical of the industry. "The communications to the sales force that are designated 'Operation 111' represent nothing but an unexceptional effort to compete in the marketplace with a resourceful competitor," said Lawrence G. Foster, vice president for public relations at Johnson & Johnson.

As Perez made his rounds to carry out Operation 111,he found strong resistance. One doctor told him that McNeil had, in his view, lost "all credibility" because of Zomax, Perez noted in one report. Perez, too, began to have doubts. At home, he threw away the samples he kept in the medicine cabinet.

At work, he kept his feelings to himself. McNeil was pleased with his efforts to promote the drug. "The Lubbock Zomax situation creates a big challenge," J.W. Davis, one of Perez's supervisors, wrote in Perez's March 1982 performance evaluation. "The goal is to sell as much Zomax as possible . . . . From all I see, you are the man for the challenge."

On May 21, Perez heard from his immediate supervisor, Chuck Marshall, McNeil's regional sales manager. "Wanted to express my appreciation for the outstanding way that you have handled the Zomax . . . situation in Lubbock," Marshall wrote. " . . . Suggest that you do not spend selling time initiating discussion on the Zomax side effects."

He recommended Perez concentrate his efforts on "other products" but then mentioned that he might want to continue offering Zomax samples to those doctors who "have expressed a desire to continue to prescribe the product." Marshall's note concluded: "Jody, most coaches never give up . . . . Most coaches, when their team is down, fight even harder and I know that you are this type of person."

On June 16, Perez heard of another severe reaction, according to one of his reports. Two days later, another Operation 111 memo arrived. "Keep the momentum going," the memo said. "It's looks like we're winning the battle, but the war is far from over . . . ."

A short time later, over breakfast, Perez said he voiced his growing concern with Marshall. "I said, 'What are we doing here? We're passing out stuff that's hurting people. People are dropping . . . . People are near death.' I said, 'Pull the drug off the market.' "

According to Perez, Marshall replied that that couldn't be done, citing competition and "business reasons . . . money reasons."

Asked about Perez's account of his conversation with Marshall, McNeil officials said they spoke with Marshall and he said he had not made those comments. The officials also said the company has never placed financial considerations ahead of public safety.

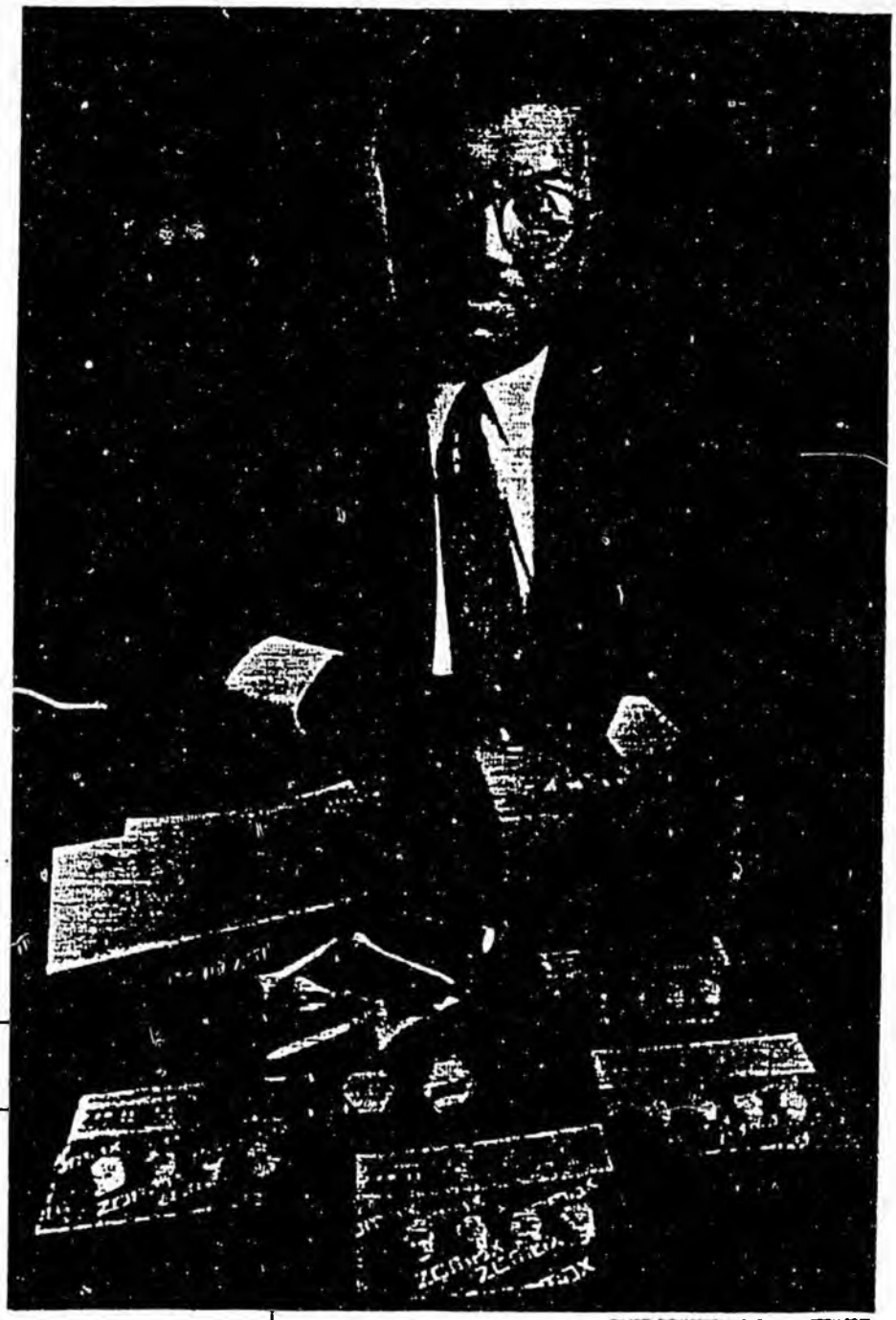
On July 1, McNeil gave Perez a $33-a-week raise, thanking him in a note for his help in "containing the Lubbock situation."

Eight days later, Perez quit.

Asked about Perez's account, McNeil said the cluster of Zomax reactions in Lubbock was an "isolated situation" and "aberrational." The company's attorneys said Perez had allowed his emotions to color his perspective about the highly competitive drug industry. "How drugs are marketed is common knowledge," said David Dobbins, another attorney who represents McNeil. "Jody Perez may think this is bad."

— **Benjamin Weiser and Elsa Walsh**

Settlements Kept Former Drug Salesman's Story Under Wraps



BY JOEL RICHARDSON—THE WASHINGTON POST

McNEIL PHARMACEUTICAL

May 21, 1982

TO: Jody M. Perez

FROM: C. D. Marshall

SUBJECT: Field Work Session

Dear Jody:

Wanted to express my appreciation for the outstanding way that you have handled the ZOMAX® zomepirac sodium situation in Lubbock. You have been the right person for us to have in that location at the right time. Dr. Stewart, Jack Vaughan, Dick Jackson, J. W. Davis, and myself all know that no one could have done a better job. You have kept us informed of the situation, known exactly who should be contacted, and have established the necessary rapport and understanding with your customers to accurately report the facts. We realize you are not responsible for this situation and are concerned over how sales figures in this particular product category may effect your outlook and opinion of McNeil. Let me assure you that you will not be held responsible for this situation.

Suggest that you do not spend selling time initiating discussion on the ZOMAX side effects. We have a lot of other products to sell and I feel that you should be concentrating your efforts on this other items. I really wonder, however, if the physicians shouldn't be offered ZOMAX samples if they have expressed a desire to continue to prescribe the product.

Six weeks before he quit his sales job at McNeil, Jody Perez, above, received a letter from his immediate supervisor praising his handling of the Zomax "situation" in Lubbock, Tex., where there had been several reports of adverse reactions to the drug. The supervisor also suggested Perez not spend "selling time" by bringing up Zomax's side effects.

VIEWPOINTS

SAWYER

"That's very upsetting to know, that [her husband's death] might have been prevented."

— Carol Sawyer, who sued McNeil after her husband, Michael, 42, died of anaphylaxis after taking Zomax

Court secrecy impairs "free scientific inquiry and the right of the public to know specific information about drugs it consumes."

— Devra L. Davis, a Washington toxicologist who settled with McNeil after suffering a near-fatal anaphylactic reaction

DAVIS

KANNER

"What they are trying to do is not be accountable to the vast majority of the public for what they've done . . . they paid my clients a ton of money for me to shut up."

— Allan Kanner, a Philadelphia lawyer who has been involved in a number of Zomax settlements

"The strategy was to dispose of the Zomax cases as expeditiously and as cheaply as possible."

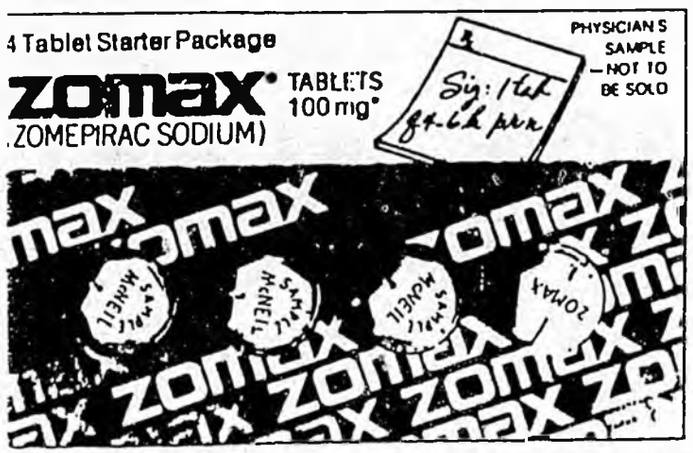
— Roger Fine, Johnson & Johnson associate counsel, who believes secrecy orders are needed to guard company formulas and marketing methods

FINE

Drug Label Warnings at Issue in Suits

October 25, 1988

HE CORPORATE PHILOSOPHY



physician's sample of Zomax, developed
McNeil Pharmaceutical

"I think we did a good thing —I don't see how you could do it any faster."

— James E. Burke, chairman of Johnson & Johnson, rejecting any suggestion that the company should have withdrawn Zomax sooner

OPERATION ONE-ELEVEN

III

Operation III
ZOMAX® Tactical Maneuvers 22 April

Battle Strategy: ZOMAX, "the after aspirin analgesic," should be promoted to capture the following strongholds beyond the range of aspirin:

Osteoarthritis	Painful Injuries
Musculoskeletal Pain	Post-Acute Fractures Pain
Post-Acute Surgical Pain	Painful Arthritis

Directives: These positions are currently held by Motrin and Darvocet-N 100. Focusing on Feldene won't help us meet our objective and may in fact help Pfizer reach theirs.

Tactical Supports:

Samples

An airlift operation is underway to provide additional samples by May 1. A second airlift will occur by June 1.

Literature

Two shipments are en route. By May 15 additional file cards and the New York Symposium Highlights Brochure will be available to support your attack.

Mail

Several squadrons will drop mailings to universe and concentrator physicians around the clock to support sampling and promotional efforts.

Journal Advertising

Destroyers are currently in key strategic offshore locations. They will continue to bombard the physician universe reinforcing the ZOMAX "after aspirin" position.

CONFIDENTIAL
PROTECTED BY COURT-IMPOSED PROTECTIVE ORDER

AUTHORIZED
McNEIL PHARMACEUTICAL

McNeil marketing strategy memo, left, has a military motif. The paper, sealed as part of a lawsuit, bears a "confidential" stamp.

"... Our first responsibility under our credo is to our customers."

—Lawrence G. Foster, Johnson & Johnson vice president for public relations, who said that nearly 15 million patients used Zomax without incident

A portion of the corporate philosophy of Johnson & Johnson's founder, below

Johnson & Johnson

"The evidence on this point is clear . . . institutions, both public and private, exist because the people want them, believe in them, or at least are willing to tolerate them. The day has passed when business was a private matter — if it ever really was. In a business society, every act of business has social consequences and may arouse public interest. Every time business hires, builds, sells, or buys, it is acting for the . . . people as well as for itself, and it must be prepared to accept full responsibility for its acts . . ."

Excerpt from "Or Forfeit Freedom" by General Robert Wood Johnson, 1947

WEDNESDAY, OCTOBER 26, 1988

PUBLIC COURTS, PRIVATE JUSTICE
Last of Four Articles

Secret Filing, Settlement Hide Surgeon's Record

Questions Raised Over Patients' Deaths

By Benjamin Weiser
and Elsa Walsh
Washington Post Staff Writers

On Aug. 25, 1982, heart surgeon Richard N. Scott sued Washington Hospital Center, alleging that the hospital's internal review of the deaths of three of Scott's patients was unfair and improper. He said he learned of the confidential review only when the hospital suspended him from performing open heart surgery pending further inquiry.

Usually, such lawsuits are filed publicly. But Scott's attorneys asked a D.C. Superior Court judge to seal the suit, arguing that a public proceeding would damage Scott's reputation when he may be a victim of the hospital's procedures.

The hospital agreed to the sealing and Judge Frank Schwelb ordered the records closed to the public. To this day, the only available record of the case is a file number in Superior Court.

Scott's suspension came after hospital reviews concluded that his performance had been a factor in two of the three deaths, and criticized his technical skill in the third case, according to hospital records made available to The Washington Post. A year earlier, another review had concluded that his performance had been a factor in two other deaths. Scott denied fault in the five cases; the hospital defended its review process as fair.

Three months after Scott filed suit and before the hospital proceedings were resolved, the two sides reached a confidential settlement. Scott agreed to give up his surgical privileges at the hospital and drop his lawsuit; the hospital agreed to remove selected documents from Scott's personnel file and not to release details of Scott's suspension.

Schwelb's order to seal the court records and the subsequent settling of the case allowed Scott and the hospital to avoid the normal consequence of going to court—that a private dispute becomes public and may result in debate, controversy and

See COURTS, A16, Col. 1

■ *Church pays secret six-figure out-of-court settlement.* *Page B1*

COURTS, From A1

detailed examination of the issues involved.

Today, Scott, 47, runs his own cardiovascular clinic in the District and has privileges at Montgomery General Hospital in Olney, where he has performed vascular surgery since March 1978. Open heart surgery is not performed at Montgomery General.

When Montgomery General conducted a routine review of Scott's credentials in 1983 and asked Washington Hospital Center about Scott, it was told that Scott had been suspended and had resigned for "personal reasons." It was not given access to the review committees' files.

The internal documents, reviewed by The Post as part of a lengthy examination of court secrecy in civil lawsuits, provide a revealing glimpse into the peer-review system that hospitals use to police themselves and their doctors, a process that is confidential.

Peer reviews often address highly technical and sophisticated medical judgments, about which the doctors involved may disagree. Committees look at medical records, and may seek independent opinions or interview those who handled the case. The committees act as fact-finders and report their conclusions to hospital authorities, who then make final decisions.

The internal records show Scott's colleagues candidly debated and assessed Scott's performance. "Entire case was mismanaged by surgeons," one committee reported in 1981 after reviewing a case in which a 69-year-old patient died after Scott's surgical team allegedly failed to maintain an adequate blood supply to the patient during a heart bypass. Scott has denied mismanaging any cases.

That case was examined as part of a routine audit of all heart surgery deaths at the hospital during a six-month period in 1980. The Feb. 12, 1981, audit report concluded that 12 of 26 deaths occurred because of surgeons' alleged mistakes, including judgmental and technical errors, or failure to maintain appropriate life support systems. Scott was singled out for criticism in two cases.

Later, a committee concluded in a Sept. 14, 1982, memorandum to the head of the medical staff: "Dr. Scott's pattern of practice does not comply with the guidelines for open heart surgery of the Washington Hospital Center. His practice of cardio-vascular surgery has shown at times questionable performance and judgment."

Scott and his attorneys declined to be interviewed for this article. After his privileges were suspended in August 1982, he appeared before two committees asked to investigate the matter. He submitted a 24-page statement, in which he offered a rebuttal to the conclusions that led to his suspension and strongly objected to the review process.

Scott criticized the hospital for not examining the performance of other medical staff members, saying their mistakes had contributed to the death of one of his patients. Responding to questions about why he decided to operate in some of the cases, he agreed that the surgery was risky but said he felt the patients would benefit and that the risks were known to the patients and their families.

He alleged that the hospital's investigation violated his rights as well as hospital procedures. He said he had no choice but to file suit, "a regrettable and distasteful process . . . nonetheless the only available alternative."

Scott also outlined his views briefly during a 1984 deposition in an unrelated court case. Asked to explain why his privileges had been suspended, he said, "The reason was due to a difference of opinion on the management of two cardiac cases, and during the hearing that resulted from that suspension it was apparent to me that the medical reasons were not valid for the suspension and that the hearings had escalated to a personal level, and during the hearings I voluntarily resigned my privileges."

Dr. Harold H. Hawfield, vice president for medical affairs at Washington Hospital Center, declined to comment specifically on the hospital's proceedings, citing the confidential settlement with Scott and the court's sealing order.

Referring to Scott's allegations about the fairness of the process, he said Scott "had ample opportunity to respond, ample notice of the meetings and of his rights in the matter" during the investigation that followed the suspension in August 1982.

Hawfield said some doctors who had reviewed Scott's performance were unhappy with the settlement because it "allowed him to leave the hospital" without stronger corrective action, enabling him to continue practicing elsewhere.

Edward J. Krill, Washington Hospital Center's legal counsel, said of the secrecy involved in both the court and the hospital's review, "There's been a balancing of the public's right to know . . . and the privacy of the process . . . . The benefit that is seen is that physicians will come forward, and forthrightly and confidentially evaluate each other in a very vigorous way."

Dr. John J. Lynch, a former president of the D.C. Medical Society and a current member of the D.C. Board of Medicine, which licenses doctors, said he was troubled by the concept of sealing court cases that raise questions about a doctor's performance. "I would worry," said Lynch, who is on the staff at Washington Hospital Center. "What is the gravity of a case that is sealed? Is it something that ought to be looked at in renewing somebody's license? . . . . There's no way of knowing, if it's sealed."

'Profound Concern' Surfaces

The dispute between Scott and the hospital has its origins in the February 1981 audit of 26 heart surgery deaths at the hospital, the first time the records show that questions were raised about Scott's performance. The study, conducted by three departments at the hospital, concluded that doctors' errors were "a predominating factor" in 12 deaths and recommended that the hospital more closely monitor the mortality rates of patients under treatment by its heart surgeons.

Two of the 12 cases were Scott's and involved questions about whether the patients had received an adequate flow of blood during heart bypass surgery. The report cited "profound concern" about Scott's handling of the cases.

One patient was Helen Taliaferro, 69, who died Aug. 20, 1980. "Dr. Scott was informed of the situation during entire case," the report said. "Entire case was mismanaged by surgeons."

The second patient was Willard Jackson, 78, who died Aug. 26, 1980. In this case, a major artery near the heart was punctured during a bypass. "Bleeding was not adequately stopped," the report concluded. Scott was assisted in this operation by another doctor. "Between the two of them, case was very mismanaged," the report said.

The records do not reflect Scott's specific response to the allegations against him in these two cases.

Then, in May 1981, came complaints from medical staff members that Scott had prepared a patient for surgery, ordered her placed under anesthesia, then had her awakened 45 minutes later without operating so that he could perform emergency surgery on another patient. Other doctors were available to handle the emergency, according to minutes of a June 18, 1981, meeting of an ad hoc committee reviewing the incident.

Anesthesia contains life-threatening risks for a patient that are separate from the surgery itself. One doctor at the meeting commented that "in all of his years of practice he had never seen a surgeon leave a patient during anesthesia, and he brought up the question of possible abandonment of the patient," according to the minutes. Had such abandonment occurred, it would have been a violation of medical ethics.

Scott appeared before the committee on June 24. He said he did not order the anesthesia and discovered it had been administered only when he came to the operating room to check on the patient. He said the emergency patient was in more critical condition and that he had saved the man's life.

On July 17, Scott was reprimanded about this case by Dr. William J. Fouty, the head of the department of surgergy. Adopting the language of the committee's recommendation, Fouty wrote Scott of "the profound concern of the Department of General Surgery with regard to the serious nature of errors in professional judgment and infractions of prevailing standards of medical practice and operating room policy."

Then, in 1982, came the reviews that eventually led to Scott's suspension of privileges in open heart surgery and his lawsuit. The reviews were conducted without Scott's knowledge, which is the hospital's

The first review began in April, when Fouty asked the chief of cardiac surgery, Dr. Jorge Garcia, to investigate the deaths of two of Scott's patients after heart operations.

Garcia convened a five-member committee. It first looked into the April 7 death of Charles Kidd, 64. Committee members debated whether the operation should have been done, given Kidd's severe heart disease and a six-month life expectancy. A routine pathology report said Kidd died from bleeding in a major artery, which apparently began after the surgery.

Scott's technique also became a subject of the committee's deliberations. Scott used an artificial heart valve that was too large and then implanted it "at a strikingly abnormal angle," according to the pathology report by Dr. William C. Roberts, a top pathologist at the National Heart, Lung and Blood Institute, one of the National Institutes of Health in Bethesda.

Scott, in his 24-page statement, said the bleeding that caused Kidd's death was the result of mistakes by other medical staff members. He said he implanted the correct heart valve and had positioned it properly. He described the operation as "extremely high risk" because of Kidd's deteriorating heart condition, but said Kidd and his family were fully aware of the risks.

On April 22, Richard Fortkiewicz, 60, died of complications after Scott performed a bypass operatio... Garcia's committee concluded on May 20 that Fortkiewicz was a good candidate for surgery but that the operation had taken too long. The committee also questioned why Scott had completed only two of the three grafts needed to bypass blockages. The report said, "In all probability the death was related to the procedure."

Scott, in his statement, suggested that other surgical staff members were at fault in the death for their inept handling of a catheter, causing complications during surgery. He also cited their "inappropriate" use of certain drugs and "belated" resuscitative efforts.

As Garcia's committee was reviewing these two cases, a third patient of Scott's died after surgery. Fouty asked the head of vascular surgery, Dr. Nicholas P.D. Smyth, to examine the matter.

Smyth reported that Walter H. Fields, 77, died of a stroke after Scott conducted two operations to improve the blood flow in Fields' partially obstructed carotid arteries, the major vessels that supply blood to the brain.

Fields had cancer, and Smyth questioned whether the surgery was necessary or safe, suggesting that the stroke may have been caused by the operations. A surgical resident, Dr. Frederick Finelli, had objected to the surgery and had refused to "scrub" for the first operation, according to Smyth's report.

When the stroke occurred, another doctor telephoned Scott and urged him to operate immediately to reverse the stroke's effects. Scott, who was outside the hospital, said such an operation was ill-advised so soon after the stroke. He did not come to the hospital to examine the patient. Fields went into a coma and died three days later.

Smyth said in his report that he believed Fields' treatment was "inadequate" from the outset, including "the pre-operative work-up, the indications for the surgery, the timing of the surgery, and the management of the post-operative complications."

Scott said in his statement that the operations were necessary and that the stroke was caused by other factors. The patient knew the risks of the surgery and had agreed, Scott said.

Members of three of the five patients' families, contacted recently, said they were not told of the 1981 audit or the subsequent reviews, which are normally conducted in confidence.

On Aug. 18, 1982, the hospital notified Scott that it was suspending his privileges to perform open heart surgery. A letter to Scott said the decision was based on a "preliminary review" of the Fields, Kidd and Fortkiewicz cases. The next day, the hospital appointed a fact-finding committee of the Department of Surgery to conduct a full-scale investigation.

Acting to Ensure Privacy

On Aug. 25, Scott went to Superior Court in hopes of stopping the investigation. One of Scott's attorneys, Jacob Stein, met with the hospital's attorney at the time, George Hart, and Hart said the two sides agreed to ask for the case to be sealed. "Obviously both parties agreed that they were both well served by having it under seal," said Hart, who now lives in Buffalo.

At a closed hearing, Judge Schwelb rejected Scott's request for immediate action on the hospital's review, ruling that the investigation could continue while the lawsuit was progressing, Hart said.

Schwelb did agree, however, to seal the records in the case. "He listened very carefully and posed a number of questions," Hart said. "He was concerned about the public's right to know."

Schwelb, who is now on the D.C. Court of Appeals, declined to comment. It could not be learned how much Schwelb knew about the dispute between Scott and the hospital when he sealed the records.

Two weeks later, the ad hoc committee interviewed Scott and his partner in several of the operations and received the 24-page statement, which rebuked the hospital for failing to notify Scott of the reviews of the Kidd, Fields and Fortkiewicz cases before suspending him.

On Sept. 14, the committee reported that it had examined the records in the three deaths—as well as the Taliaferro and Jackson cases—and had looked at the mortality rate of Scott's 49 open-heart surgery patients from 1980 to 1982. Six of Scott's patients had died, or a rate of 12 percent. Hospital guidelines called for open-heart surgeons to have a rate of less than 7 percent.

The committee criticized Scott's judgment and performance in a letter to Dr. Nelville K. Connolly, head of the medical and dental staffs. The matter was then referred to one of the hospital's highest-ranking committees, the Standards of Professional Conduct Committee, headed by Dr. David Morowitz.

On Oct. 25, after another interview with Scott, the committee said Scott, while technically capable, was "not equipped to make preoperative and intraoperative decisions relative to performing" heart surgery without "the strictest" supervision.

After the hospital took the matter to its highest committee, the Appellate Review Board, Scott's attorneys and the hospital's attorneys reached a confidential settlement of the pending lawsuit and the hospital's investigation. On Nov. 12, 1982, the two sides asked the court to dismiss the case. In a routine action, Judge Frederick Weisberg signed the order. The seal remained intact.

In 1983, when Montgomery General Hospital began a routine review of Scott's privileges to conduct vascular surgery there, it sent a letter to Washington Hospital Center.

"It has come to [our] attention that there was some question regarding Dr. Richard N. Scott at your institution," said the April 11, 1983, letter. "It would be most helpful in our deliberations if you could shed some light on this issue."

Hawfield replied in a two-paragraph letter that Scott had been reprimanded in a July 1981 case and that his privileges had been suspended in August 1982. His April 19 letter also said, "During the hearing procedures [that followed the] suspension, Dr. Scott resigned from the Medical and Dental Staff of the Washington Hospital Center for personal reasons."

Montgomery General was told that it could not have access to the records of the review committees, according to Dr. John N. Delahay, Montgomery General's chairman of surgery. "All I know is [we] were told that only some material would be available for review. All matters would not be," Delahay said. After obtaining Scott's permission, Delahay said, several doctors from Montgomery General examined medical charts of some of Scott's patients.

Based on this limited review, Montgomery General renewed Scott's privileges.

Staff writer Susan Okie and staff researcher Melissa Mathis contributed to this report.

PUBLIC COURTS, PRIVATE JUSTICE

Case Number Only Trace of Suit Involving Surgeon's Performance

THE DISPUTE OVER DR. SCOTT

LYNCH

"What is the gravity of a case that is sealed? . . . There's no way of knowing, if it's sealed."

— Dr. John J. Lynch, a member of the D.C. Board of Medicine that licenses doctors, who says he is troubled by the concept of sealing court cases that raise questions about a doctor's performance

Scott "had ample opportunity to respond, ample notice of . . . his rights in the matter . . ."

— Dr. Harold H. Hawfield, vice president for medical affairs, Washington Hospital Center, referring to Scott's allegations about fairness of the disciplinary process

HAWFIELD

Helen Taliaferro, 69, died in 1980 after heart bypass surgery. A hospital report cited "profound concern" about Scott's performance and said that the "entire case was mismanaged by surgeons." Records do not reflect Scott's specific response to the allegations, but he has denied mismanaging any cases.

Willard Jackson, 78, also died after bypass surgery in 1980. A hospital report called the case "very mismanaged." The records do not reflect Scott's specific response to the allegations in this case either, but in a 24-page statement, he objected strongly to the conclusions of hospital review committees.

Walter H. Fields, 77, died of a stroke after Scott conducted two operations to improve blood flow in arteries that supply the brain. Questions were raised as to whether the surgery was necessary or safe. Scott's statement said the operations were necessary and the risks of the surgery were known to the patients and their families.

About This Series

On Sunday, The Washington Post began a series of articles examining the burgeoning use of court secrecy in civil lawsuits; the first article reported how General Motors Corp. has used these procedures and avoided a public debate about the safety of its automobile fuel tanks.

Monday's article looked at secrecy procedures in Washington area courts and how judges often ask few questions in sealing cases. More than 200 lawsuits have been sealed from public view, many of which deal with questions of public policy or safety. Hundreds of other lawsuits have been settled with confidential agreements that prevent discussion of what was learned in the case.

Yesterday's story examined how McNeil Pharmaceutical, a major subsidiary of Johnson & Johnson, used court secrecy and avoided a public debate about whether the company withheld critical information from the medical community before it recalled its pain-killing drug Zomax.

HB

172

Alaska Court System
State of Alaska
OFFICE OF ADMINISTRATIVE DIRECTOR

CHARLES S. CHRISTENSEN III
Staff Counsel

303 K Street
Anchorage, AK 99501
(907) 264-8228

HB 172

February 12, 1991

The Honorable Dave Donley
Chairman, House Judiciary Committee
P.O. Box V
Juneau, Alaska 99811

Dear Representative Donley:

Attached you will find a bill draft relating to the preparation of the jury list. We respectfully request that the Judiciary Committee introduce this legislation on behalf of the court system.

At the present time, the administrative director of the court system is charged by AS 09.20.050 with preparing a list of persons qualified for jury service. This list must be prepared by March 15 of each year. It is compiled from a list of applicants for the permanent fund dividend, which must be submitted by the Department of Revenue to the court system by the preceding January 15.

It has been determined that jury service could be administered more efficiently if the jury year corresponded to the calendar year. Accordingly, the bill draft requires the administrative director to prepare a jury list by November 30 of each year, from a list submitted by the Department of Revenue by September 30. This will enable a new jury list to be used beginning on January 1 of each year. The bill has no fiscal impact, and the Department of Revenue has advised me that the dividend applicant list is available by September 30.

Thank you for your courtesy. Please feel free to contact me if you have any questions or comments.

Very truly yours,

C. S. Christensen III
Staff Counsel

CSC:bh

Attachment

SENATE BILL NO.

IN THE LEGISLATURE OF THE STATE OF ALASKA

SEVENTEENTH LEGISLATURE - FIRST SESSION

A BILL

FOR AN ACT ENTITLED

"An Act relating to the preparation of the jury list."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* SECTION 1. AS 09.20.050(a) is amended to read:

(a) At such time as need may require, but not later than November 30 [MARCH 15] of each year, the administrative director of courts shall prepare for each judicial district a list of the names of the residents of the district who are qualified by law for jury service. If the superior court is located in different cities in the same judicial district, the administrative director shall prepare for each location of the court a list of the names of the qualified residents of that portion of the district considered to be appropriate.

* SEC. 2. AS 09.20.050(b) is amended to read:

(b) The jury list shall be based on a list prepared by the Department of Revenue of all persons who filed an

application for a distribution of Alaska permanent fund income under AS 43.23 during the current [PRECEDING] calendar year that show an Alaskan address, and of all persons who volunteer for jury duty under (d) of this section. If considered necessary by the administrative director of the Alaska Court System, the jury list shall incorporate a list prepared by the Department of Public Safety of all persons who hold a valid Alaska driver's license. The departments shall submit their respective lists to the Alaska Court System not later than September 30 [JANUARY 15] of each year. To the extent that it is available, the departments shall include on the lists they submit the following information for each person: first name, middle initial, and last name; mailing address, including the zip code; and birth date. The lists shall be recorded on magnetic tape compatible with Alaska Court System data processing equipment.

HOUSE COMMITTEE REPORT

(7)

Date Referred: February 27, 1991 FURTHER REFERRALS:

Date of Committee Action: 3-12-91

The JUDICIARY Committee considered: HB 172

HOUSE BILL NO. 172 PREPARATION OF JURY LIST

"An Act relating to the preparation of the jury list."

RECOMMENDATIONS: [ ] the same title
be replaced with _____ [ ] a new title

[ ] have attached amendments(s)
[X] do pass
[ ] do not pass
[ ] no recommendations
[ ] individual recommendations
[ ] additional referral to the _____ Committee

ADOPTS: _____ letter of Intent

ATTACHES NEW FISCAL NOTE(s): (Dept) APPROVES PREVIOUS: (Dept/Date)

[ ] fiscal impact _____ [ ] fiscal note(s) _____

2 [X] zero fiscal note Courts - Revenue [ ] zero fiscal note(s) _____

SIGNING DO PASS	DP	OTHER RECOMMENDATIONS	DNP	NR	AM
Mike Miller		Terry Martin		✓	
Mark Hanley					
[illegible]					
Steve Donley					
[illegible]					

Steve Donley
CHAIRMAN'S SIGNATURE

FISCAL NOTE

STATE OF ALASKA
1991 LEGISLATIVE SESSION

Bill No. HB 172

Revision Date:
Title: An Act relating to preparation of the jury list
Sponsor: Judiciary Committee by request
Requestor: Judiciary

Department Affected: Alaska Court System
BRU: Trial Courts
Components:
COMPONENT SERIAL NO.

EXPENDITURES/REVENUES: (Thousands of Dollars)

OPERATING	FY 92	FY 93	FY 94	FY 95	FY 96	FY 97
PERSONAL SERVICES						
TRAVEL						
CONTRACTUAL						
SUPPLIES						
EQUIPMENT						
LAND & STRUCTURES						
GRANTS & CLAIMS						
TOTAL OPERATING	0.0	0.0	0.0	0.0	0.0	0.0
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

GENERAL FUNDS	0.0	0.0	0.0	0.0	0.0	0.0
FEDERAL FUNDS						
OTHER						
TOTAL	0.0	0.0	0.0	0.0	0.0	0.0

POSITIONS:

FULL-TIME						
PART-TIME						
TEMPORARY						

Estimate of current year impact: None

ANALYSIS: (Attach a separate page if necessary)

No fiscal impact.

Prepared by: Chris Christensen, Staff Counsel
Phone: 264-8228
Division: Alaska Court System
Date: 03/06/91

Approved by: Arthur H. Snowden, II, Administrative Director
Agency: Alaska Court System
Date: 03/06/91

Distribution (by preparer): Legislative Finance, Legislative Sponsor, Requestor, OMB, & Impacted Agency(ies).

Rev 10/90

FISCAL NOTE

STATE OF ALASKA
1991 LEGISLATIVE SESSION

BILL NO. HB 172

Revision Date:
Title: An Act relating to the preparation of the jury list.
Sponsor: House Judiciary Committee
Requestor:

Agency Affected: Revenue
BRU: Permanent Fund Dividend Division
Components: Permanent Fund Dividend Division
COMPONENT SERIAL NO. 9 8 1

EXPENDITURES/REVENUES: (Thousands of Dollars)

	FY 92	FY 93	FY 94	FY 95	FY 96	FY 97
OPERATING						
PERSONAL SERVICES	-0-	-0-	-0-	-0-	-0-	-0-
TRAVEL	-0-	-0-	-0-	-0-	-0-	-0-
CONTRACTUAL	-0-	-0-	-0-	-0-	-0-	-0-
SUPPLIES	-0-	-0-	-0-	-0-	-0-	-0-
EQUIPMENT	-0-	-0-	-0-	-0-	-0-	-0-
LANDS & STRUCTURES	-0-	-0-	-0-	-0-	-0-	-0-
GRANTS, CLAIMS	-0-	-0-	-0-	-0-	-0-	-0-
MISCELLANEOUS	-0-	-0-	-0-	-0-	-0-	-0-
TOTAL OPERATING	-0-	-0-	-0-	-0-	-0-	-0-
CAPITAL	-0-	-0-	-0-	-0-	-0-	-0-
REVENUE	-0-	-0-	-0-	-0-	-0-	-0-

FUNDING: (Thousands of Dollars)

GENERAL FUND	-0-	-0-	-0-	-0-	-0-	-0-
FEDERAL FUNDS	-0-	-0-	-0-	-0-	-0-	-0-
OTHER	-0-	-0-	-0-	-0-	-0-	-0-
TOTAL	-0-	-0-	-0-	-0-	-0-	-0-

POSITIONS:

FULL-TIME	-0-	-0-	-0-	-0-	-0-	-0-
PART-TIME	-0-	-0-	-0-	-0-	-0-	-0-
TEMPORARY	-0-	-0-	-0-	-0-	-0-	-0-

Estimate of current year impact: None.

ANALYSIS: None required.

Prepared By: Thomas C. Williams
Division: Permanent Fund Dividend Division
Phone: 465-2323
Date: March 1, 1991

Approved by Commissioner:
Agency: Revenue
Date: 3-1-91

Distribution (by preparer): Legislative Finance, Legislative Sponsor, Requestor, OMB, & Impacted Agency(ies).

HB

174

DIVISION OF LEGAL SERVICES

LEGISLATIVE AFFAIRS AGENCY
STATE OF ALASKA

P.O. Box Y, Juneau, Alaska 99811
(907) 465-3867 or 465-2450
FAX (907) 465-2029

Deliveries to: 240 Main Street
Court Plaza, Room 500
Mail Stop 3101

MEMORANDUM February 22, 1991

SUBJECT: Alternative Incarceration Programs (W.O. 17LS-0787\A)

TO: Representative Niilo Koponen
Attn: Shari Paul

FROM: Jerry Luckhaupt JEL
Legislative Counsel

You have requested a sectional analysis of the above-referenced bill draft. Preliminarily, please note that a sectional analysis should not be considered an authoritative interpretation of a bill - the bill itself is the best statement of its contents. If you would like an interpretation of the bill as it relates to a particular set of circumstances, please advise.

Section 1 of the bill amends AS 11.56.340(a) to provide that a person while charged with or convicted of a felony and while sentenced or assigned to an alternative incarceration program leaves the place of alternative incarceration without permission is guilty of unlawful evasion in the first degree.

Section 2 of the bill amends AS 11.56.350(a) to provide that a person is guilty of unlawful evasion in the second degree if while charged with or convicted of a misdemeanor leaves a place of alternative incarceration without permission.

Section 3 of the bill provides a definition of alternative incarceration program for AS 11.56.

Section 4 of the bill amends AS 12.55.015(a) to provide a court with the authority to order a defendant to complete a term of alternative incarceration as the sentence or part of the sentence for the crime committed.

Section 5 of the bill amends AS 12.55.085(b) to provide that a court may revoke probation if the defendant fails to successfully complete a term of alternative incarceration.

Section 6 of the bill amends AS 12.55.100(a) to provide that as a condition of probation a court may order a defendant to successfully complete a term of alternative incarceration.

Section 7 of the bill amends AS 12.55.100 by providing that a suspended sentence may be revoked by a court upon the defendant's violation of a term or condition of an alternative incarceration program.

Section 8 amends AS 12.55.185 to provide a definition for alternative incarceration program in AS 12.55.

Section 9 amends AS 33.30.011 and requires the commissioner of corrections to establish alternative incarceration programs.

Section 10 amends AS 33.30.091 to provide that the commissioner may not assign a prisoner to an alternative incarceration program except as provided in new AS 33.30.096.

Section 11 creates a new section AS 33.30.096 that provides for the assignment of prisoners to an alternative incarceration program and other duties of the commissioner in relation to such a program.

Section 12 amends AS 33.30.901 to provide a definition of alternative incarceration program.

Section 13 provides for the establishment of a pilot alternative incarceration program in two judicial districts to get the program started and allow for evaluation.

Section 14 provides for reports by the commissioner of corrections concerning the pilot program to the legislature.

Section 15 repeals the pilot program.

Section 16 provides an immediate effective date for the bill.

GPL:pl
91-105.plm

Alaska State Legislature

Representative Niilo Koponen

House District 21

Pouch V
Juneau, Alaska 99811
(907) 465-4992

119 N. Cushman, Suite 207
Fairbanks, Alaska 99701
(907) 456-8172

M E M O R A N D U M

To: Representative Dave Donley

From: Representative Niilo Koponen

Re: CSHB 174 and HB 151 Relating to Corrections

Date: April 16, 1991

I would like to request the Judiciary Committee to hear both House Bill 174 and House Bill 151 relating to corrections at your earliest convenience.

Attached are position papers relating to these bills. If you have any questions, please feel free to contact me or my aide, Shari Paul. Thank you.

Alaska State Legislature

Representative Niilo Koponen

House District 21

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SPONSOR STATEMENT (ADDENDUM)

Since the Hammond Administration the Corrections operating budget has increased 272% the highest rate of increase of any department of the State government. The Corrections Budget actually exceeded the 272% increase due to the fact that facility leases are hidden in the Department of Administration budget, and lease purchases in excess of $20 million annually (principally the Spring Creek prison near Seward) occur in the "front end" of the annual operating budget.

Higher incarceration rates have not decreased crime rates in Alaska or elsewhere. In fact, prisons often appear to have operated as "crime schools" in some states. Crowded conditions have limited supervision of inmate activities leading to organization of groups such as the "Aryan Brotherhood", the "Mexican Mafia", the "Black Panthers," and other, lesser- known, networks, both vicious and benign. This does not appear to have occurred to any great extent in Alaska, but a facility such as Spring Creek does pose that possibility.

The Alaska Constitution allows incarceration for two reasons: protection of the public and rehabilitation of the offender. In reality, the two are one, as protection of the public is not served if the offender is not rehabilitated prior to final release from supervision by the courts and Corrections. Alaska has only a limited number of programs which contribute to rehabilitation, and they suffer from constraints imposed by statutes and underfunding. Successful sexual offender programs in other states (e.g. Vermont) rely on release from incarceration upon successful completion of the program, followed by community supervision and transitional counseling. Nationally, it has been found that continued incarceration after program completion without community transitional counseling, leads to <u>increased</u> recidivism.

HB 174 provides for the design and implementation of alternative sentencing plans under the control of the courts and the corrections system, appropriate to individual offenders and their offenses, designed to meet the constitutional requirements of rehabilitation of offenders, and public protection. This bill provides for pilot programs in at least two judicial districts, under direct control of the Department.

Alaska State Legislature

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House District 21

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Juneau, Alaska 99811
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POSITION PAPER

HB 174 "An Act relating to sentencing and the service of sentences; providing for alternative incarceration programs; providing for an alternative incarceration pilot program..."

In the last ten years, Alaska's prison population has increased at the fastest rate in the nation. Our oil wealth has allowed us to keep pace with this increase and we simply keep building new prison facilities. Unfortunately, the experience of other states shows that trying to match rising incarceration rates with new prison construction is a losing proposition. Building prisons cannot remain our only response to a growing population.

Clearly, offenders presenting serious threats to public safety should be in prison. However, AS 33.30.011 directs the Commissioner of the Department of Corrections to establish programs reasonably calculated to provide for the rehabilitation and reformation of prisoners, facilitating their reintegration into society. The success of alternatives to confinement to prison in other states presents promising courses of action, several of which are contained in this bill.

"Alternative incarceration program" means incarceration of a prisoner other than in a correctional facility and exclusive of assignment of the prisoner to a furlough or correctional restitution center; the term includes home arrest or detention enforced through electronic monitoring or phone checks with intensive supervision.

This bill allows judges to impose such detention upon offenders, with the added safeguard that an offender not meeting the terms of the sentence shall be re-arrested. Also, the commissioner may assign a prisoner committed to the commissioner's custody to an alternative incarceration program.

The commissioner must establish alternative incarceration pilot programs in at least two judicial districts in the state, and report regularly to the legislature concerning the progress and success of the programs.

The sponsor believes this measure provides an effective means of relieving prison overcrowding, while protecting the public.

STATE OF ALASKA
Department of Corrections
LEGISLATIVE POSITION PAPER

Lloyd Hamee, Commissioner

P.O. Box "T", Juneau, AK 99811-2000 (907) 465-3475 Carl Michel, Legislative Liaison

POSITION PAPER HB 174

The Department of Corrections supports House Bill 174 with certain modifications.

* The provision allowing the court to sentence offenders directly to electronic monitoring should be deleted.

Direct sentencing to electronic monitoring can easily bring about "net widening." Low risk offenders are placed on electronic monitoring who would routinely go to regular probation supervision. Probation supervision is less expensive than monitoring; to be cost effective, electronic monitoring has to impact offenders who are incarcerated.

* July 1, 1991 is too early to establish an electronic monitoring pilot program, as set in Section 13 of HB 174.

The RFP process, alone, would make this impossible. To best meet the needs of the program, it would be better to have a six month feasibility study to assure the Department develops the most effective program.

* The mandatory urinalysis section should be deleted.

This makes the assumption that all offenders being monitored have a substance abuse problem. This, in turn, puts a potentially excessive fiscal burden on this legislation and the Department.

* Allow the program to be introduced in only one Judicial District.

This allows the opportunity to establish a profile before the program is expanded.

Conceptually, electronic monitoring can be a viable intermediate sanction for corrections. It should, however, be cautioned that electronic monitoring does not necessarily mean great savings to the Department. In fact, it costs more than simple probation and conceivably more than furloughing offenders into halfway houses. Before electronic monitoring can save large sums of money, it must have a great enough impact on prison populations to enable reducing staffing and/or closing facilities. It could serve well, potential overcrowding and conceivably postpone construction.

A detailed analysis is attached which further discusses the Department's position, as well as elaborating on what could be accomplished with a pilot project.

FISCAL NOTE:
ZERO
ATTACHED ☑

APPROVED: _____
Commissioner

DATE: 4/2/91

DEPARTMENT OF CORRECTIONS

POSITION PAPER

The Department of Corrections recommends that House Bill 174 be modified to provide for a feasibility study prior to implementing electronic monitoring programs as defined in the bill.

The feasibility study would last approximately one year. This would include five to six months to solicit bids from various electronic monitoring equipment and service vendors.

Following the selection of a vendor, the equipment would be used by the Intensive Supervision Unit of adult probation in Anchorage. This unit is staffed by three specially trained probation officers who work flexible hours and receive on-call pay to provide around-the-clock coverage of a caseload of 25 parolees. This type of coverage would be needed to supervise an electronic monitoring program to ensure adequate staff response to curfew violations and tamper alarms reported by the computer monitoring service 24 hours per day.

There are approximately 25 parolees supervised by the ISP unit. The estimated cost per day for ISP supervision is $10.00, compared to $4.81 for regular community corrections supervision. With the addition of electronic monitoring equipment, this cost could almost double. However, it is possible that use of the equipment may decrease the staff time needed for surveillance, thus allowing the staff to supervise more offenders and mitigating the cost increase.

Use of the equipment by the ISP unit on their current caseload would not require any additional staff, vehicles, radios, beepers, or other security equipment since the unit is already set up for intensive supervision. No legislation would be required to use the equipment to enforce the curfews to which ISP participants are already subject. Electronic monitoring would have to be added as a condition of discretionary parole by the Parole Board for each participant.

ISP officers visit offenders' homes as often as five times per week currently. They conduct breathalyzer testing, and the parolees are subject to urinalysis performed by a contract agency.

Currently, although the offenders are subject to curfews, the ISP staff are not on active duty after 11:00 p.m., so there is no certainty that the curfews are enforced during late night hours. It is expected that if the equipment is reliable enough to improve curfew enforcement, it may enable the Parole Board to place more offenders on ISP supervision, thus reducing prison populations.

During the feasibility study, the Department would also survey all community custody offenders to determine how many could be reasonably supervised in an electronic monitoring program in lieu of community residential center placement. This would be broken down by geographical area to determine if there are enough candidates to make a program feasible in each area. The community custody offenders would be broken down into two risk categories: those whose violation of an electronic monitoring program condition or curfew could present an immediate risk to public safety and those whose violation(s) would not. The type of staffing for the first category would need to be similar to that of the ISP unit. Those in the second category might be able to participate in an electronic monitoring program that is staffed by a private contractor, and/or is not staffed 24 hours per day, since a curfew violation report would not necessarily require immediate staff response or home visit.

The cost of the feasibility study would include the lease of monitoring equipment for 25 offenders for 183 days, at $5.50 per day per offender. The cost of a contract to monitor the computer and report all violations and tamper alarms to an on-call officer would be $3.00 per day per offender. The lease of one drive-by unit at $8.50 per day would enable the officers to check on the location of the offender at work or any other place away from home by driving by the offender's reported location and receiving confirmation of his/her presence on the equipment in the officer's vehicle. These cost estimates are based on the most expensive vendor's prices and may be lower if another vendor can provide similar reliable equipment and/or monitoring services:

25 units	$25,254.00
Computer monitoring/reporting service	13,725.00
1 drive-by unit	1,556.00
	$40,535.00

The total cost of equipment per offender would be $9.00 per day if 100% utilized. The lease agreement would include provisions for returning any unused equipment, so that if only a portion of the 25 ISP offenders were placed on electronic monitoring, the cost of equipment would be lower.

At the end of the six month monitoring period, the Department would provide a written report within 90 days, addressing the feasibility of further use of electronic monitoring on ISP and other populations. The report would address:

- effectiveness and reliability of equipment and vendor service performance;

- staff time required to respond to violation/tamper alarms, broken down by times of day;

- frequency of false alarms requiring on-site visits by officers;

- offender reactions to equipment;

- numbers of violations, abscondments, and re-offenses, compared with the rates reported on ISP without electronic monitoring during the previous six months for the same number of offenders;

- estimates of the caseload which can be effectively supervised with electronic monitoring equipment compared to current ISP caseloads;

- estimates of the number of offenders who might be placed on ISP with electronic monitoring who would otherwise remain incarcerated, based on consultation with the Parole Board;

- estimates of the number of community custody offenders who could be placed on electronic monitoring in lieu of community residential center placement, or following a period of community residential center placement and recommendations for the type of staffing needed to supervise them in at least three geographical locations;

- proposed eligibility criteria and screening procedures for placing furloughees in an electronic monitoring program;

- proposed procedures for collecting fees from furloughees to help cover the costs of an electronic monitoring program and estimates of the amount to be collected based on records from community residential centers;

- training requirements for staff supervising offenders in an electronic monitoring program;

- procedures for data collection and recidivism figures on electronic monitoring participants;

- recommendations as to the feasibility of placing offenders directly in an electronic monitoring program following sentencing by the courts, based on studies in other jurisdictions.

FISCAL NOTE

STATE OF ALASKA
1991 LEGISLATIVE SESSION

BILL NO. H.B. 174

Revision Date: _____ Department Affected: Corrections

Title: "An Act relating to sentencing.. BRU: Statewide Operations

roviding for an alternative incar pilot program..." Component: Southcentral Probation. Northern Probation

Sponsor: Rep. Koponen

Requestor: _____ COMPONENT SERIAL NO. [ ][ ][ ][ ]

Expenditures/Revenues: (Thousands of Dollars)

OPERATING	FY 92	FY 93	FY 94	FY 95	FY 96	FY 97
PERSONAL SERVICES	285.0	285.0				
TRAVEL						
CONTRACTUAL	166.8	166.8				
SUPPLIES						
EQUIPMENT	5.0	5.0				
LAND & STRUCTURES						
GRANTS, CLAIMS						
MISCELLANEOUS						
TOTAL OPERATING	456.8	456.8				
CAPITAL						
REVENUE						

FUNDING: (Thousands of Dollars)

GENERAL FUND	456.8	456.8				
FEDERAL FUNDS						
OTHER						
TOTAL	456.8	456.8				

POSITIONS:

FULL-TIME	5.0	5.0				
PART-TIME						
TEMPORARY						

Estimate of current year impact: None

ANALYSIS: (Attach a separate page if necessary.)

See attached pages.

Prepared By: Tom Sutton, Director Phone: 465-3376

Division: Administrative Services Date: 04/01/91

Approved by Commissioner: _____

Agency: Department of Corrections Date: 04/01/91

Distribution (by preparer): Legislative Finance, Legislative Sponsor, Requestor, OMB, & Impacted Agency(ies).

Bill Analysis

The bill seeks to establish an alternative incarceration pilot program and to provide for an alternative sentencing options for offenders. The bill requires the Department to establish an alternative incarceration pilot program by July 1, 1991 in at least two judicial districts of the State. The program is to be designed to accommodate at least 20 inmates in each judicial district (Anchorage and Fairbanks would be the most likely locations). The law establishing the pilot program will be repealed June 30, 1993.

Estimated Costs

The following estimates are based upon quotes obtained from applicable venders and/or historical expenditure data for applicable costs:

	Anchorage	Fairbanks	Total
Leased Electronic Monitoring Equip	$40.2	$40.2	$80.4
Monitoring Services of Contractor	21.9	21.9	43.8
Drive-by Unit	3.1	3.1	6.2
Urinalysis	13.0	13.0	26.0
Probation Officers II	114.0	171.0	285.0
Leased Vehicle	5.2	5.2	10.4
Radios	2.5	2.5	5.0
Total Cost	$199.9	$256.9	$456.8
Costs Per Day (Divided by 20 offenders per location)	$27	$35	

Narrative Explanation of Costs

Although daily costs are lower if the equipment is purchased, it is recommended that the Department lease the equipment. By leasing, we will avoid purchasing equipment which becomes obsolete because of technological improvements. The cost of electronic monitoring equipment ranges from about $2.50 to $8.50 a day. Our best estimate is $5.50 a day. The annual rate for each location is $5.50 x 365 days x 20 offenders = $40,150.

Once the monitoring equipment is in place, an employee is required to moni or the equipment on a computer terminal. The monitoring of the equipment requires a 24-hour, post seven days a week. A contractor has expressed an interest in providing this services for an additional $3.00 a day per offender. The contractor would notify the probation officer whenever a violation occurs or the equipment tampered with. The cost of the vender's service on an annual basis is $3.00 a day x 365 days x 20 offenders = $21,900. The alternative would be even more expensive if a new State position was added to monitor the computer terminal.

To monitor offenders at work or other locations away from the home, a telephone a drive-by unit should be leased. The cost to lease this unit would be $8.50 a day x 365 days = $3,103.

The bill requires a weekly urinalysis of offenders. The cost of the weekly urinalysis is about $12.50 per test x 20 offenders x 52 weeks = $13,000 per year.

Department staff are required to respond to violations and the tampering with the equipment. If a violation is reported by the computer terminal, a failure to respond in a timely manner could create serious liability problems. The only staff currently available for 24 hour monitoring are correctional officers within the institutions. However, there isn't sufficient staff available to allow an officer to leave their post to respond to offender violations.

Anchorage currently has an intensive supervision unit. For the purposes of the pilot project, the Department could use a portion of existing staff to monitor the offenders. Therefore, only two probation officers are required in Anchorage to implement the program (two PO II's x $57,000 = $114,000). Fairbanks does not have a intensive supervision unit, so a staff of three is required to implement the program (three PO II's x $57,000 = $171,000).

A vehicle is needed to respond to violations and to conduct drive-by verifications of offenders at locations away from home. Yearly lease for a vehicle costs about $5,200 a year. To supply the vehicle with radio equipment costs approximately $2,500.

[redacted]USE COMMITTEE REPOR[redacted]

(7)

Date Referred: March 1, 1991

FURTHER REFERRALS: Judiciary
Finance

Date of Committee Action: 4/16/91

The HEALTH, EDUCATION AND SOCIAL SERVICES Committee considered HB 174

HOUSE BILL NO. 174 ALTERNATIVE INCARCERATION PROGRAM

"An Act related to sentencing and the service of sentences; providing for alternative incarceration programs; providing for an alternative incarceration pilot program; and providing for an effective date."

RECOMMENDATIONS:
be replaced with CS HB 174 (HES) [x] the same title
[ ] a new title

[ ] have attached amendments(s)
[x] do pass
[ ] do not pass
[ ] no recommendations
[x] individual recommendations
[ ] additional referral to the ______ Committee

ADOPTS: ______ letter of Intent

ATTACHES NEW FISCAL NOTE(s): (Dept)

[x] fiscal impact Dept. of Corr. 4/1/91

[ ] zero fiscal note ______

APPROVES PREVIOUS: (Dept/Date)

[ ] fiscal note(s) ______

[ ] zero fiscal note(s) ______

SIGNING DO PASS	DP	OTHER RECOMMENDATIONS	DNP	NR	AM
Cheri Davis	✓				
[illegible]	✓				
[illegible]	✓				
[illegible]	✓				
		Mark Hanley		X	

[illegible signature]
CHAIRMAN'S SIGNATURE

FISCAL NOTE

No. 1

STATE OF ALASKA
1991 LEGISLATIVE SESSION

Bill Version: CSHB 174(HES)
(H) Publish Date: 4/17/91

Revision Date: _____ Department Affected: Corrections

Title: "An Act relating to sentencing... providing for an alternative incar pilot program..." BRU: Statewide Operations

Component: Southcentral Probation, Northern Probation

Sponsor: Rep. Koponen

Requestor: _____ COMPONENT SERIAL NO. [ ][ ][ ][ ]

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TEMPORARY						

Estimate of current year impact: None

ANALYSIS: (Attach a separate page if necessary.)

See attached pages.

Prepared By: Tom Sutton, Director Phone: 465-3376

Division: Administrative Services Date: 04/01/91

Approved by Commissioner: [signature]

Agency: Department of Corrections Date: 04/01/91

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COMMITTEE COPY

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Penal administration shall be based on the principle of reformation and upon the need for protecting the public.[1]

Introduction

Under Alaska's constitution, the principles of reformation and the necessity of protecting the public constitute the touchstones of penal administration. The operation of the state penal system is dependent upon a properly staffed and functioning department which has, in addition to probation and parole functions, the responsibility for treatment, rehabilitation, and custody of incarcerated offenders.[2] The goals anticipated by these broad constitutional standards include

- rehabilitation of the offender into a noncriminal member of society
- isolation of the offender from society to prevent criminal conduct during the period of confinement
- deterrence of the offender after release from confinement or other treatment

The State Constitution and appellate court decisions do no implied that Penal administration of justice would be inexpensive. In fact, Alaska ranked second in the country, behind Washington, D.C., in the amount of state and local revenue consumed on justice systems.[3] There are, however, many factors which drive the cost of criminal justice. For corrections, serious consideration must be given to the consequences of understaffing, inadequate training and idle time for prisoners.

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1 Constitution of Alaska, Art. I, § 12

2 State v. Chaney, Sup. Ct. Op. No. 653, 477 P.2d 441 (1970)

3 Alaska Sentencing Commission, 1990 Annual Report to the Governor and the Alaska Legislature, December 1990, pg. 27.

Prisons: $100 million problem

The Alaska prison system is overflowing with prisoners. All prisons and jails are over capacity levels. Why? It seems to me the Department of Corrections is very reluctant to release any prisoners; and once free, why do so many violate their parole? I'm not talking about a few, but 85 percent of paroled prisoners end up back in jail. This is because DOC gets 100 million dollars a year, and wants even more. DOC is stealing your taxes and oil money. They have purposefully kept prisoners months past their due release date, by taking their good time for the slightest infraction, and leaving them behind bars to add to the congestion and ever crowding at chaotic levels.

Releasing prisoners on non-violent crimes, with six months or less to their release date, and putting a stop to the prisons taking a prisoner's good time would drop prison levels 20 percent and save the taxpayer and state millions of dollars in costly additions due to overcrowding.

Also, put a stop to parole officers who violate a parolee's rights about such things as missing AA meetings because of work, or buying a car without telling the parole officer. Violations like these small infractions are sick and unjust, when a person has a job and a place to live and a family to support. Why punish a man when he has solid goals and a new positive chance in life and has learned from his mistakes? Let prisoners out with less than six months, for a non-violent crime. Keeping them in jail and taking their good time just adds to this $100 million problem.

— *Robert Britton*

House arrest

Electronic gadget keeps track of man awaiting criminal trial

By SHEILA TOOMEY ANCH. DAILY NEWS 3/18/91
Daily News reporter

Life gets boring for Charlie Jenkins, having to stay home all the time except when he's at work. Or when one of his court-appointed custodians takes him somewhere — shopping, or to visit a friend.

But Jenkins is definitely not complaining. He'd rather be home and bored than in jail.

"Compared to being in jail, this is real good," he said.

Jenkins, a 35-year-old warehouse supervisor, is under house arrest in Spenard, tethered by an invisible cord to a monitor two miles away, on the 13th floor of the Denali Towers. He is one of three "prisoners" in Anchorage who are not occupying a pretrial cell thanks to a new electronic monitoring service being offered to the state as a way to save money and free up prison beds.

Jenkins is charged with drunken driving — his fifth such offense in seven years. He was arrested the morning after the Fur Rondy fireworks, although he says he doesn't remember the arrest itself. Bail was set at $5,000, cash only, an amount he couldn't come up with.

By all accounts, Jenkins isn't a danger to anyone except when he's drunk and behind the wheel of a car. But given his record, it looked like the only way to keep him out of cars was to keep him in jail at a cost of about $96 a day to the state.

For Jenkins, jail would have cost much more — his job, losing his rented home, finding someone to keep his dog, Bunker. If he had a family, it would mean loss of support for a wife and kids — maybe welfare.

Longtime Anchorage bail bondsman Fred Adkerson has a new business that offers an alternative. Jenkins has been fitted with a sealed, tamper-resistant "bracelet" that straps a beeper-size gray plastic gizmo to his ankle — not noticeable under Jenkins' white socks and work pants.

The gizmo transmits a signal to a receiver that looks like a cable box. The box is wired to a telephone in Jenkins' spare bedroom. It forwards the signal to Adkerson's office on Fireweed Lane, where a computer monitors the signal 24 hours a day, keeping relentless track of Charlie Jenkins.

The computer knows what time Jenkins leaves for work in the morning, accompanied by a court appointed guardian. It knows when he is due home in the evening,

ERIK HILL / Anchorage Daily News

After a fifth DWI charge, Charlie Jenkins is under house arrest. The monitor on his ankle records his movements.

when he goes to counseling sessions, when he is due to check in with his human monitor once a week.

When Jenkins gets more than 150 feet from the phone box, the computer printer back in Adkerson's office begins to chatter. If Jenkins' approved schedule doesn't include an absence at that time, the computer registers a violation and a computer voice pages John Hastie, a former police officer who runs the program for Adkerson.

"You're restricted virtually as much as in jail," Hastie said.

Please see Page E-2, HOUSE ARREST

HOUSE ARREST: Ankle strap makes him toe line

Continued from Page E-1

A judge lowered Jenkins' bail to $1,500 with the electronic monitoring, an amount Jenkins could afford. As long as he obeys his bail restrictions and pays Adkerson's $15-per-day fee, he can live at home and keep earning a salary. He can't leave his house alone for any reason. He is better monitored than most people out on bail and isn't costing the state any money or using up a jail bed.

"Being able to work is most important," Jenkins said. "They're going to hit you with the fines and all that. How are you going to pay for it?"

Jenkins speaks hesitantly, an ordinary working man with a personal problem that becomes a public safety issue when he gets behind the wheel of a car. Adkerson says he checked out Jenkins before signing him up to make sure he had no history of violence.

> *"Being able to work is most important. They're going to hit you with the fines and all that. How are you going to pay for it?"*
>
> — Charlie Jenkins

"This program is not designed for a person with a long criminal history," Adkerson said. "Non-violent, low risk, no threat to the community." Shoplifters, thieves, people like that. He thinks there are hundreds, maybe a thousand, prisoners in Alaska jails who could be freed on this system.

A spokeswoman for the Department of Corrections says that is most unlikely.

As of 1989, 37 states used such systems, with widely varying regulations and widely varying results. The Texas electronic monitoring program for early parolees has been successful to the extent that no serious crimes had been committed by the 322 people on the program as of 1988. Florida uses electronic monitoring as a solution to prison overcrowding, putting 10,000 convicts a year on the system. Four murders and a series of rapes in Broward County alone have been attributed to electronically monitored prisoners, according to the Fort Lauderdale Sun-Sentinel.

Jenkins did four months in jail on his last conviction and faces a longer sentence this time. If convicted, he hopes to do his time on house arrest also, which is most unlikely. Right now, the system is used in Alaska only for pretrial defendants, whose restrictions are determined by judges.

Once convicted, a defendant moves under the control of the Department of Corrections, which has just begun to examine a variety of electronic monitoring systems and their possible uses here.

Home Monitoring of Criminals Is Poised To Break Loose, Industry Analysts Say

Special to THE WALL STREET JOURNAL

NEW YORK -- As budget constraints mean less money to build and maintain prisons, states and cities are turning to companies that provide products for home monitoring of criminals and those awaiting trial.

"The absence of new prison facilities in the face of an ever-rising criminal population means alternative means of detention are becoming necessary," says David Leibowitz, an analyst at American Securities. Electronic monitoring of some criminals in their homes "is one approach to meeting that need."

Companies in this industry generally are still small. Market leader BI Inc. has annual revenue of about $11 million. And only those convicted for non-violent crimes tend to be considered for electronic monitoring. But many analysts say the industry is poised for big gains.

Jyoti Aggarwala, analyst at Ladenburg Thalmann & Co., says electronic monitoring of offenders has about tripled each year since the first quarter of 1987. Installed monitoring units stood at more than 12,000 by the first quarter of this year, she says. "Since this market still is in its initial growth phase, we expect the number of offenders on [electronic monitoring home arrest] to double each year through 1995," she adds.

A spokesman for the National Institute of Justice estimates it costs taxpayers on average $75,000 per bed to build a prison and $60 per inmate per day to operate it. Home-arrest equipment, Ms. Aggarwala says, costs about $4,500 per inmate and less than $10 per inmate per day to provide monitoring. She adds that some offenders pay for the privilege of electronic monitoring, rather than do jail time, and that those under such house arrest can continue to work, adding to the tax base of their communities.

Baton Rouge, La., is one community using electronic monitoring of criminals on a limited basis. Milton R. Skyring, court clerk-judicial administrator, says he is pleased with the program, which has been in effect there for just under two years.

Three different surveillance methods are used in Baton Rouge: television monitoring, a digital telephone monitor that alerts police when someone leaves home, and a wrist device that tracks offenders.

Mr. Skyring says electronic monitoring is typically used when unusual hardships would befall a family if an offender was sentenced to jail. He says the program has only had one failure--an offender who took all the television surveillance equipment "and kept on walking." A bench warrant for that person is outstanding.

Ms. Aggarwala says there are about 10 companies, private and public, that either make products or provide services in the electronically monitored home arrest industry.

She rates BI a "buy," calling it the "largest and best-seasoned player in the field." In the first quarter ended Sept. 30, net income rose to $497,000 on revenue of $3.7 million from $251,000 on revenue of $2.2 million a year earlier.

In October, the company sold one million common shares to the public at $9.75 each.

Ms. Aggarwala also recommends Digital Products Corp., which she calls "'an emerging participant with major turnaround potential."

Electronic Monitoring

The Missing Link For Successful House Arrest

by Mike Goss

The past seven years have seen a dramatic expansion in the use of electronic monitoring. Currently, there are approximately 7,500 offenders or pre-trial detainees, who would otherwise be in a cell, living in their own residences.

Most of these electronically monitored house arrestees are employed and *paying* taxes rather than consuming them. Those who have families are supporting them, rather than draining heavily burdened welfare rolls. These are offenders who could not otherwise have been legally released under the rules of criminal justice today.

Parole officer Tanya Murray puts an electronic monitor on a parolee, who has been placed under house arrest.

Without electronically monitored house arrest (or electronic home detention), these 7,500 offenders would need 10 prisons with 500 beds each to hold them. Otherwise, they would be turned loose with no method of determining whether they were observing their court-imposed curfews.

House arrest had previously been used effectively by the military, where carefully controlled conditions and a regimented milieu made it possible to enforce curfews and limited access to the community. However, outside military bases, home detention has always been both ineffectual and fraught with danger because no reasonable amount of added personnel could hope to determine whether an offender had left his/her residence.

With the added dimension of electronically monitoring curfews, it is now feasible to impose reasonable restrictions on the freedom of an individual and be certain those restrictions are being observed.

Suddenly, house arrest has the missing component that makes it effective. The offender's presence at home can be confirmed 24 hours a day, seven days a week. This provides credibility for a program that previously had to be run on trust with persons who had proved they could not be trusted.

One advantage of equipment that has

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been designed from day one as a high-security, large-volume system for use with high-risk offenders is that it can easily be selected for use in statewide systems that want to grow to very large numbers over a broad geographic area. Michigan, for example, uses electronic monitoring for 1,500 offenders, most of whom are being released from 3-7 year prison sentences and have residences all over the state, ranging from downtown Detroit to the rural areas of the Upper Peninsula.

Key Factors

It would be nice to say this all happened without a hitch, but that isn't true. There were many obstacles to overcome, both technical and programmatic. With the benefit of experience, it is possible to specify some of the common factors among the highly successful programs that are now operational:

1. The population to be addressed is defined and researched to determine if the number of eligible offenders justifies the size of the program.
2. Goals are defined and quantified so the program can later be evaluated.
3. Management and legislative support for funding and future operation are solicited and determined to be sufficient.
4. Sufficient officers to handle the caseload are budgeted and volunteers interested in an innovative approach are requested to apply as officers.
5. A risk assessment is done on the population being affected, and specifications for the equipment to be used are determined based on the features available and the hardware's ability to meet that risk level.
6. Personnel selected to supervise the offenders are brought on board well in advance, educated in the policies and procedures of the program, and trained in the operation of the equipment.
7. Equipment is placed on the officers for familiarization and several elected public officials such as sheriffs and judges are "strapped in" for publicity and public awareness. Media coverage is encouraged.
8. Fewer than 10 offenders are placed on the equipment for the first two weeks. Each transaction (message from the offender's residence) is scrutinized carefully to understand its implications in relation to the previous and subsequent transactions.
9. Equipment providers' personnel work hand-in-glove on a daily basis in the early days, providing hardware/software support and program guidance based on previous installations. All transactions are checked by the manufacturer from its office (by remote dial-in) until the implications of all apparent anomalies are understood by agency personnel.

It is now feasible to impose reasonable restrictions on the freedom of an individual and be certain those restrictions are being observed.

10. Curfew violations of even one minute are addressed with the offender so they know how tightly the system has absolute awareness of their schedule.
11. As much as possible, statistics are kept as the program progresses. Justification for subsequent funding is collected and comparisons are prepared to determine how well the program is meeting its intended goals.
12. The agency carefully tracks each monitor to record when and on whom it was used in order to build a history for future use in court if the data should be questioned.

Anyone who has implemented such a program could add several more items to this list. The three primary factors that seem to be present in every successful program are prior planning, prior planning, and prior planning. As many problems as possible are anticipated and addressed in the policies and procedures manual. The policies and procedures manual is assumed to be an evolutionary document that matures and grows as the program progresses.

All the effort involved in meeting these conditions is worth it. Most of the programs running today are effective and reliable. Agencies that had no place to go, with the offender population in rapid growth, are finding relief from those pressures. The law abiding citizen is still safe from the predations of the unscrupulous. The agencies' obligation to the community to punish and control proven offenders has been met. The agencies' mandate from the taxpayer to accomplish these tasks and keep costs under control has been met.

Agencies under court order to reduce their populations can ease the pressure and give themselves time and space to work on the problem instead of just throwing up more construction in a panic.

The evidence so far suggests that house arrest programs, under typical guidelines for intensive supervision probation, give the departments better interaction with the offenders than incarceration could accomplish. This happens because the supervisory personnel do not spend their time resolving the conflicts that occur when people who have shown themselves uncooperative in normal society are clustered in the close confines of an institution. Because most programs require the offender to be employed, and cost of supervision is charged to the participant, the offender is beginning to pick up part of the tab.

Certainly, supervising an offender in the community has its problems, but working on those problems helps to prepare the offender for eventual release to normal society instead of warping him or her from a normal track to an abnormal one.

Federal Parole Commissioner Vince Fechtel stated at a recent professional conference that a new probation or parole officer just starting on a career would be wise to "hitch his wagon to the rising star of electronic-monitored house arrest." The wave of the future in corrections is house arrest, he said, now that the missing link of verification of curfew compliance has been found. It shows promise of playing an increasingly important and valuable role in the profession.

Mike Goss is a private consultant for technology-oriented alternative sentencing programs.

U.S. Department of Justice
Office of Justice Programs

Electronic Monitoring in Intensive Probation and Parole Programs

Bureau of Justice Assistance

MONOGRAPH

U.S. Department of Justice
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Monograph

Bureau of Justice Assistance

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The Assistant Attorney General, Office of Justice Programs, coordinates the activities of the following program Offices and Bureaus: National Institute of Justice, Bureau of Justice Statistics, Bureau of Justice Assistance, Office of Juvenile Justice and Delinquency Prevention, and Office for Victims of Crime.

U.S. Department of Justice
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Few technical innovations in recent years have captured the imagination of corrections officials and criminal justice planners as much as electronic monitoring devices. The use of electronic monitoring for offenders as part of home detention has spread rapidly. However, the use of such devices should be carefully planned and be part of an overall supervision strategy.

Electronic monitoring devices have been used for a variety of criminal justice purposes. This monograph provides a suggested process for defining the objectives of electronic monitoring, developing policies, reviewing equipment bids and securing technical assistance. It is a supplemental document to the previous program brief, Intensive Supervision Probation and Parole (ISP). This document is not intended as a blanket endorsement of electronic monitoring as a component of all community supervision nor as a substitute for jail where appropriate, but as one innovation which can assist certain classes of higher risk offenders on probation or parole supervision.

The Bureau of Justice Assistance and the National Institute of Justice are continuing to evaluate the impact of electronic monitoring for various corrections populations. Over the next two years additional findings will assist probation, parole and other corrections agencies in the best use of electronic monitoring. In the meantime, this monograph should assist those jurisdictions considering the use of electronic monitoring as part of intensive supervision in the best ways to plan, purchase and use these aids. It also summarizes the legal basis for use of electronic monitoring as defined in court cases up to this time.

Sincerely,

Charles P. Smith
Director

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Introduction

Electronic signaling devices for monitoring criminal offenders are often seen as a "magic fence" which isolates offenders and protects the public at relatively little cost. Their use has spread rapidly and widely. First used in December 1984, by early 1987 electronic monitoring devices were being used in twenty states and by early 1988 in thirty-two states.

Electronic monitoring equipment is usually classified in terms of its signaling characteristics. One type, capable of programmed contact, is a receiver which requires the offender to respond on cue as directed; the other type has a miniaturized transmitter which emits a continuous signal. The availability of a telephone in the offender's home is implicit to the use of most monitoring technologies.

The programmed contact models operate from a central computer which is programmed to call offenders during times (randomly or specifically) required by the supervision plan. The types of equipment currently available include coded wristlets/anklets, voice verification, visual verification and pagers.

The continuously signaling devices consist of three parts. The first part is a small transmitter which is strapped to the offender. Coded radio signals are transmitted (generally six to ten times per minute) to a receiver/dialer in the offender's home. The devices have a receiving range of 100 to 200 feet. The second part, the receiver-dialer, receives the signal from the transmitter and dials the central computer when the transmitter first is within range or when the signal stops. The central computer compares data to the offender's schedule and reports on offender activities. Some systems alert supervision officers to violations; others simply record the violation, which is handled according to the program design.

Newly introduced "hybrid" systems have combined programmed contact and continuously signaling technology so that some of the limitations of each are reduced or eliminated by the strengths of the complementing system. These systems generally employ voice verification technology to support/verify a continuously signaling system's report of a violation.

2/1/91

AMERICA'S CORRECTIONAL CRISIS

A REPORT TO STATE AND LOCAL BAR ASSOCIATIONS

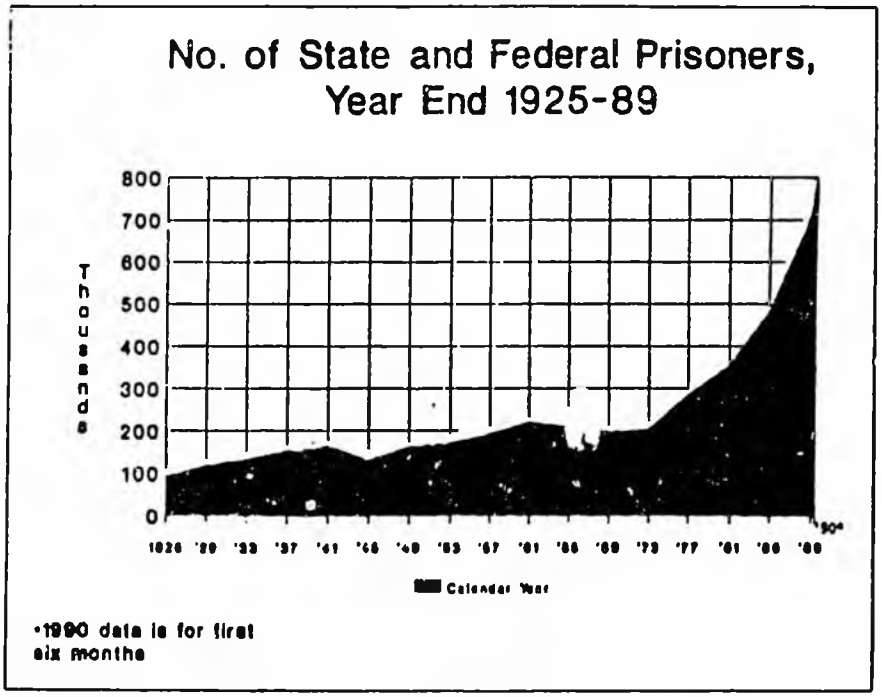
FROM

THE SECTION OF CRIMINAL JUSTICE

The growth of America's prison population is out of control. We need the help of the organized bar to bring reason to public debate on this issue.

What is happening?

Despite a basically static crime rate, we have almost quadrupled the number of persons in state and federal prisons since 1970. In 1970 we had roughly 197,000 persons behind bars.[1] In 1980 the number was 316,000.[2] As of June 30, 1990, it had jumped to 755,425.[3] Chart 1 presents the data from 1925 to mid-year 1990.



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[1] U.S. Department of Justice, Bureau of Justice Statistics, Bulletin: State and Federal Prisoners, 1925-85, at 2 (Washington, D.C., October 1986).

[2] Ibid.

[3] Department of Justice Press Release 90-54(H), at page 1 (October 7, 1990).