STEROIDS AND SPINAL CORD INJURY: a questionnaire

The Joint Section on Disorders of Spine and Peripheral Nerve Disorders of the AANS/CNS is interested in your treatment of patients with spinal cord injuries. Current neurosurgical care of these patients, particularly with respect to steroid administration, has been the subject of much debate. While guidelines committees are working towards an analysis of the available data, the value of the cumulative clinical experience and attitudes of surgeons around the country is important to consider.

The Spine Section has designed a simple one-minute electronic questionnaire to survey attitudes towards the use of steroids in the acutely injured spinal cord injured patient. Regardless of your present participation in managing these patients, your point of view on this topic is important to us. We would like your input to see how you are dealing with this contentious issue.

Please submit your response on-line at http://thinker.neurosurgery.org/scisurvey

1. **Are you a**
   a) Neurosurgeon
   b) Orthopedic Surgeon
   c) Research Scientist
   d) Resident / fellow in training
   e) None of the above

2. **Do you manage spinal cord injured patients?**
   a) Yes
   b) No

3. **How many acute SCI do you manage a year?**
   a) < 10
   b) 10 – 40
   c) > 40

4. **Do you currently follow**
   a) NASCIS I guidelines
   b) NASCIS II guidelines
   c) NASCIS III guidelines
   d) A Generic steroid protocol
   e) I do not give my acute SCI patient steroids

5. **Should methylprednisolone be considered**
   a) A Standard of care for all non-penetrating SCIs
   b) A Recommended treatment
   c) A Treatment option
   d) An Experimental therapy
   e) Not recommended in the treatment of acute SCI

PEDICLE SCREW LITIGATION: a behind the scenes look

The following story is reprinted with permission from The Philadelphia Inquirer, Aug. 27, 2000

THE BONE SCREW FILES

THE DEFENDANT FACED DOWN A DEULGE OF LAWSUITS BECAUSE HE BELIEVED IN HIS PRODUCT. AND HE WON. AT A COST OF $75 MILLION AND COUNTING.

BY L. STUART DITZEN

On the evening of Dec. 17, 1993, the employees of a small company in Memphis, Tenn., were sipping drinks and chatting at their annual Christmas party when a handful of executives slipped away to watch television. The magazine show 20/20 was on, and one of its segments was a critical report on a small medical device called a bone screw - the main product made by the company, Sofamor Danek Group Inc.

Hosts Hugh Downs and Barbara Walters announced they had uncovered "shocking facts" about bone screws: They were potentially dangerous devices being used by spine surgeons all over the country. The screws had not been approved by the Food and Drug Administration for such uses. They were being used experimentally during spine surgery and causing terrible harm. Lives were being ruined.

The TV report was based on a handful of lawsuits in which back pain patients claimed bone screws had broken, bent or come loose after being surgically implanted in their spines. The lawsuits targeted a Cleveland manufacturer, AcroMed Inc. - not Sofamor Danek. But the 20/20 report strongly suggested - incorrectly - that there was a problem with all screws used in spine surgery, technically known as pedicle bone screws.

As Downs and Walters signed off, the executives at Sofamor Danek were troubled, but they had no idea of the storm that was about to descend.

An American phenomenon called a mass litigation was about to swarm their company with the biblical fury of a plague of locusts. Thousands of lawsuits, whipped up by lawyers around the country in the slipstream of the 20/20 report, would be filed against Sofamor Danek, AcroMed and other bone screw makers. Waves upon waves of complaints would accuse them of selling bone screws illegally and blame them for causing severe injury.

How this story was put together:

Information was gathered from court pleadings, transcripts, judicial rulings, texts of news articles and broadcasts, and interviews. Lawyers John J. Cummings 3d and Michael Fishbein declined to be interviewed. Their comments are taken from court proceedings.

The crushing pressure of mammoth litigation attacks has evolved into a form of legal terrorism in the last 25 years. Corporations targeted in mass litigation - as the makers of diet drugs, cigarettes, birth control devices and other products can attest - often find the legal defense costs and other pressures overwhelming. The cost of hiring lawyers to answer several thousand lawsuits can, by itself, drive a company to bankruptcy.

Typically, the only escape for a corporation under siege is to pay a huge sum in a "global settlement" to end the litigation. Some companies are willing to pay billions - as was Dow Corning Corp. in litigation over silicone breast implants - even if there is no clear evidence they did anything wrong.

Sofamor Danek's president, Ron Pickard, had no experience with mass litigation, but he believed the attack on his company was unjust.

The way he responded was, for an American corporate executive, most unusual.

Ron Pickard, a major manufacturer of spinal bone screws: "Sofamor Danek is not intimidated." Much of the legal war was fought and won in a Philadelphia courtroom.

The unassuming 51-year-old executive had grown up on a cotton farm, missed out on college, found work in Memphis as a janitor, and worked his way to the presidency of his corporation. Pickard took tremendous pride in Sofamor Danek and its products. To him, the accusation that bone screws were experimental gizmos that crippled people was preposterous. "We would shut this company down in a moment," he says, "if we thought our products were jeopardizing anybody."

But it was quickly clear to him that his company and the jobs of its 300 workers were in grave danger.

When the blizzard of lawsuits began, Pickard declared publicly that Sofamor Danek was being subjected to extortion. He refused to negotiate with the lawyers orchestrating the attack. He chose to fight back.

That decision produced fascinating results. For one thing, his company lost only one case at trial - one injury claim out of 3,200 lawsuits filed against it. Cases were dismissed or abandoned in droves. It turned out that the majority of people who sued Sofamor Danek had no injury clearly attributable to bone screws. In huge numbers, lawyers who filed suits were unable to produce evidence that the screws had malfunctioned.

Pickard's crusade also unveiled something else: a graphic picture of mass litigation lawyers as they ply their trade.

Among the revelations: A national advertising campaign was pumped up to bring in clients. False information was submitted to the courts on behalf of more than 200 plaintiffs. Tainted experts' reports were proffered as evidence. And lawsuits were filed in the names of people who had no idea they were suing anybody.

The lead lawyers in the litigation conjured a succession of imaginative legal theories. They made charges in their lawsuits of fraud, conspiracy, corruption and black market dealings. Bone screw makers and their top executives were depicted in and out of court as corporate villains of the first rank - outright criminals. They were accused of engineering a sweeping conspiracy to market bone screws in defiance of federal law and the Food and Drug Administration. The leaders of the litigation dragged in doctors, medical associations - even the federal government - as defendants.

Pickard employed a small army of defense lawyers to fight off the charges, at staggering costs. The litigation went on for six years.

In the end, Pickard won. The son of a Tennessee sharecropper beat back an onslaught by some of the most canny and aggressive lawyers in the country.

Pickard had a strong ally: Right, it seems, was on his side.

That, however, is a point some of the lawyers who promoted the litigation will dispute to the end of time. Philadelphia lawyer Arnold Levin, one of the key players, insists Sofamor Danek and other manufacturers engaged in appalling chicanery. Levin says he can't understand why more people aren't upset about it.

THE ONSLAUGHT

By New Year's 1994, lawsuits were starting to trickle in to Sofamor Danek's headquarters. Soon they were coming by the hundreds, and then by the thousands.

Lawyers around the country had launched a screaming advertising campaign. Newspaper ads showed up in Atlanta, Boston, Buffalo, Dallas, Minneapolis, New Orleans, Richmond, Rochester, Washington and other cities.

"Do you have screws in your back?"

"The use of pedicle screws in back surgery has not been approved by the FDA!"

"The manufacturers of these products could owe you a large sum of money."

Thousands of back pain sufferers responded.

One thing never in dispute was this: Everyone with screws in their spines had serious back problems. Most had had terrible, disabling back pain, which is why they had spine surgery in the first place.

The pedicle screws had been developed to foster healing in spinal fusion patients. When inserted in the tips of the vertebrae, or pedicles, the screws hold delicate metal braces in place. The braces stabilize the area where two vertebrae have been joined. Bone screws were - and still are - widely in use by spine surgeons around the country.

For the most part, the bone screw suits were filed by people who continued to suffer pain after surgery.

About 300 lawyers filed suits against Sofamor Danek.

Two consortiums of lawyers, working in cooperation, ran the litigation. Some of the kings of class action and mass tort led these consortiums, men who had made huge fortunes securing giant settlements from embattled corporations. Among them was a New Orleans land baron and casino operative named John J. Cummings 3d. He, in concert with Arnold Levin, a deft and amiable veteran of mass litigation, would lead a consortium handling the bone screw cases in the federal courts.

A second group, based in Louisiana, would press huge numbers of claims in state court in Memphis.

For the defense, Pickard hired the Philadelphia law firm of Pepper Hamilton, which is nationally known for guiding big corporate clients through treacherous legal waters. A partner there named Stephen S. Phillips became Pickard's field marshal in the bone screw wars. The Pepper firm recruited more than 40 law firms around the country.

"Our strategy was simple," said Pickard in an interview. "We were going to fight and we were going to win. I couldn't conceive of doing anything else."

For lawyers who specialize in mass litigation, the fundamental strategy is to bedevil the targeted corporation with an endless litany of claims, spreading them all over the country in class actions and individual lawsuits, in state and federal courts, creating such an oppressive weight that the company buckles. A relatively small corps of skilled plaintiffs' lawyers has shaped this activity into a fully developed industry, one that can instantly churn into action when a drug, a medical device or a consumer product is labeled defective or dangerous by the government or is targeted by an investigative news report. The raw materials of this industry are lawsuits. Its end product is a settlement. Its profits are fees, drawn in one-quarter or one-third measure from the tenderloin of every settlement fund.

The courts have struggled without much success to devise effective ways to tame mass litigation, beginning with the deluge of asbestos cases a quarter century ago.

In what has become the typical procedure, all the bone screw cases in federal courts were consolidated for pretrial proceedings in 1994 and assigned to U.S. District Judge Louis C. Bechtle in Philadelphia. The snowy-haired 72-year-old judge is nationally recognized for his ability to organize and resolve mass cases. He has wrestled several of them to resolution over the years, most recently the sprawling litigation over the diet drug fen-phen. One of Bechtle's techniques is to drive the litigation toward trial on a brutally strict timetable. That pressure can be the catalyst that brings on a settlement.

THE CONSPIRACY THEORY

As an organizational step in the bone screw litigation, Bechtle appointed nine lawyers to a panel called the Plaintiffs' Legal Committee, or PLC. It is one of the techniques he has devised to make mass litigations manageable. This committee, headed by Cummings and Levin, would run the litigation.

Early in the going, the PLC came up with an elaborate theory: Almost everyone connected with bone screws, including surgeons and medical associations, was a crook.

As framed by the PLC lawyers, there was a huge conspiracy that worked, roughly, like this: Bone screws were dangerous, untested and probably useless devices for spinal applications, and everybody who made and installed them knew it. But there was a huge population of back pain sufferers. If bone screws could be marketed as healing devices, there was a bundle of money to be made. The average cost of a set of screws and rods was $2,500. Multiplied by a few hundred thousand surgeries, the dollars were huge. The FDA had not approved expanding the use of bone screws to the spine, but surgeons all over America were using spinal screws anyway. Under the PLC's construction, bone screws were being twisted into the spines of patients, causing pain and injury, solely for the purpose of making doctors and corporate bigwigs rich.

Hundreds of lawsuits were filed making those charges.

The suits accused Sofamor Danek and other companies of making an end run around the FDA to get bone screws to market. The core of the conspiracy was this: The manufacturers had paid "bribes" and "kickbacks" to prominent orthopedic surgeons to induce them to hawk bone screws to fellow surgeons on the "black market." The black market operated through professional medical associations such as the American Academy of Orthopedic Surgeons and the American Association of Neurological Surgeons. The bone screw makers had paid off the associations to underwrite seminars at which corrupt surgeons hyped bone screws to colleagues.

The conspiracy charge sent shock waves into the medical profession.

Historically, manufacturers of surgical devices have routinely worked with surgeons and hospitals to develop and refine products, with doctors being compensated for their participation. The heart-lung machine, which keeps patients alive during heart surgery, was developed through this kind of relationship. When a device begins to evolve into general use, professional associations often sponsor educational forums to inform and instruct members.

All of those things had occurred in the development of bone screws. About 30 physicians had worked with Sofamor Danek in the development of its screws. They had received consulting fees and in some instances stock options. Medical associations had held seminars on the use of pedicle screws.

Now suddenly, the surgeons and professional associations found their relationships with manufacturers depicted in lawsuits in utterly nefarious terms.

"We were concerned that they were challenging our basic right to educate our members on new surgical procedures," said William W. Tipton Jr., executive vice president of the Academy of Orthopedic Surgeons. "It was a challenge to our whole educational mission. We were very concerned."

As the litigation slowly unfolded, it became apparent that most leading orthopedic surgeons in the country used pedicle bone screws and many considered them the best stabilizing method available.

"The patients are out of bed quicker, they get home quicker, their pain relief is better, their rehabilitation is shorter," testified a New York surgeon, William Capicotto, in one case. ". . . I don't think there's a question of whether or not it should be used. My bias is that it works."

The FDA was conducting a meticulous review of the use of pedicle screws before clearing them for market. But despite the lack of FDA clearance, it was legal for surgeons to use them. Doctors are permitted to use their own judgment on what drugs and devices to use in the treatment of patients. If the treatment is not expressly approved by the FDA, it is called an "off-label" use.

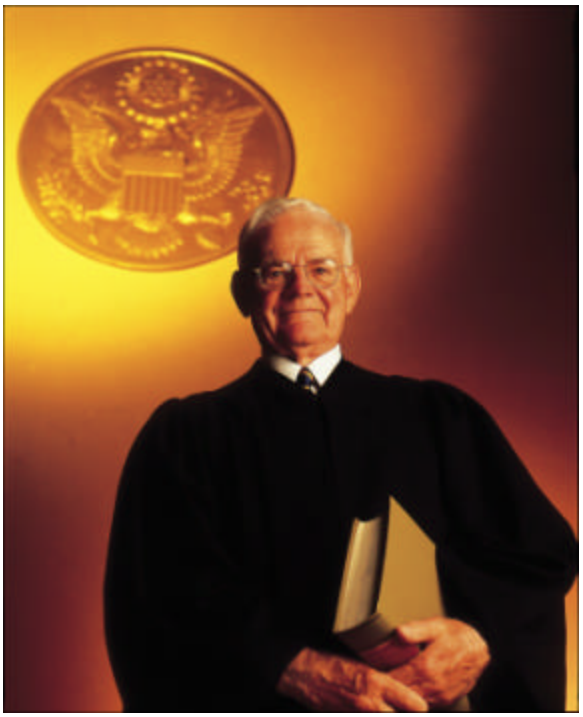
The conspiracy claims ultimately were rejected by the courts.

But it took three years.

It cost the Academy of Orthopedic Surgeons $2 million in legal bills.

Looking back, Tipton laughed - sourly. "What a ridiculous thing this all was," he said. "Bone screws aren't new. Bone screws have been used for years. They have provided dependable fixation for years."

In fact, bone screws have been around since the 19th century. In an array of forms, they are used by surgeons to repair injuries from head to toe. Screws,



U.S. District Judge Louis C. Bechtle of Philadelphia overwa much of the litigation

pins, rods, plates and other hardware are used in as many as five million surgeries a year in this country.

THE DUBIOUS EXPERTS

While the conspiracy theory buzzed about, thousands of product liability claims - the foot soldiers of the bone screw litigation - slogged forward.

The lawyers pushing them didn't get far before they bogged down at a major obstacle.

Since most respected orthopedic surgeons favored bone screws, the lawyers weren't able to find credible experts to back their accusations.

An expert was essential to every claim - to say bone screws caused pain. What were the lawyers handling individual lawsuits to do?

Many of them turned to John S. Ferguson of Sherman, Texas. Ferguson was a former dermatologist who had lost his medical license after being convicted and sent to prison in the 1980s for illegal distribution of prescription drugs. After his release, Ferguson had gone into the business of recruiting medical experts in various specialties for lawyers.

After Ferguson attended an organizational meeting with plaintiffs' lawyers in Philadelphia, about 20 lawyers with bone screw cases enlisted his services.

The expert Ferguson found was Merrill W. Reuter, an orthopedic surgeon in West Palm Beach, Fla. Reuter agreed to supply opinions on bone screw cases for $200 each.

He cranked out about 550 of them.

He did not examine the surgery patients. He did not speak with them. He did not talk to their doctors. He testified in depositions that he formed his opinions from medical records sent to him by Ferguson.

Invariably, Reuter concluded, with scant explanation, that bone screws caused injury.

Reuter's automated production line was humming along nicely until Cynthia Adams, a woman who worked in his office, discovered a collection of tape recordings in the fall of 1997.

Adams listened to the tapes and heard a man's voice dictating bone screw reports.

The voice did not belong to Reuter. It was the voice of John Ferguson.

Adams, who handled all the mail between the two men, telephoned Ferguson to ask about the tapes.

She testified in a deposition that Ferguson replied: "Oh, my Lord, destroy those MF'ing tapes. If anyone gets ahold of those tapes, that's going to be the end of this. . . ."

Adams testified that soon afterward Reuter made sure she did destroy the tapes, giving her instructions to erase them, unfurl them, break the cartridges and throw them away.

Shortly after Adams gave that account to Pepper Hamilton lawyers, Reuter withdrew as an expert in the bone screw cases. When questioned later in a deposition, he took the Fifth Amendment.

Ferguson offered an explanation: Yes, he had dictated the medical reports. But only, he testified, after Reuter had given him the information for each report - by telephone.

Judge Bechtle barred all 550 of the Reuter-Ferguson opinions from the bone screw litigation.

Under less egregious circumstances, many other expert reports also were rejected by the courts.

The phantom plaintiffs

Down in Memphis, on Sofamor Danek's home turf, the Louisiana consortium was fighting another phase of the bone screw wars. About 1,600 bone screw injury claims had been filed in Shelby County Circuit Court.

But some of the people named in those suits didn't even know they were participants. And some emphatically did not want to be involved.

The unwitting litigants' existence came to light after more than 600 bone screw claims were dismissed by Memphis Judge John R. McCarroll Jr. in January 1998. The plaintiffs, it seemed, had abandoned their lawsuits.

Lawyers for Sofamor Danek decided to find out why. Pepper Hamilton's investigators interviewed and took written statements from 60.

Most of the 60 said they had been prompted by newspaper ads to call lawyers. Twenty-eight said they didn't know their names had been used in lawsuits. Several of those individuals were interviewed for this story and confirmed that they did not know they were named as plaintiffs. Here are excerpts from some of their statements:

Phyllis Gaske of Sunnyvale, Calif., said she and her husband had seen a newspaper ad and called to get more information. "We never spoke with an attorney on the phone or in person," Gaske said. "They pursued us. . . . We wrote a letter back informing them we were not interested. . . . We have never sued anyone. . . . We didn't intend to pursue a lawsuit because I was doing well and it would have seemed fraudulent. We wouldn't do that."

"I never had a face-to-face meeting with any attorneys," said Mary K. Halverson of Coon Rapids, Minn., whose chronic back pain had led to four surgeries. "There was no difference between when the screws were in and when they were out, no difference whatsoever. So the screws weren't the problem. The screws saved me from being in a body cast for six months. . . . I was surprised to learn I had been part of a lawsuit. . . ."

Deborah Scheers of McDonald, Pa., said she responded to a newspaper ad and filled out some papers mailed to her. "I also included a statement saying that I didn't want to be a part of a lawsuit. I told them the screws worked for me and I was very happy with them. They gave me my life back. . . ."

There were no consequences for the lawyers who filed those suits.

THE QUESTIONABLE QUESTIONNAIRES

Back in Philadelphia, two lawyers in the Louisiana consortium got caught trying to float bogus evidence.

All plaintiffs with cases in Bechtle's court were required to complete lengthy questionnaires detailing their medical histories and their alleged bone screw injuries. The judge relied on the questionnaires as a way of streamlining the litigation.

In the spring of 1997 lawyers for Sofamor Danek discovered a pattern of irregularities in hundreds of questionnaires submitted by the two Louisiana lawyers, Roy E. Amedee Jr. and Andrea S. Lestelle. There were no questionnaires at all, or unverified ones, for more than 400 people. On behalf of 225 others, the lawyers had presented documents that contained false answers and glaring omissions.

For example, one question was, Do you smoke? The answer entered on numerous questionnaires was no, though for many claimants, evidence would show, the answer should have been yes.

Why was that important? Because people who smoke face a significantly higher risk of failure in spinal fusion surgery.

Philip H. Lebowitz, a Pepper Hamilton lawyer, asked Bechtle to impose sanctions on Amedee and Lestelle, saying they had committed a fraud on the court.

The two lawyers did not deny the shortcomings in their questionnaires. They blamed a faulty computer program, saying it had inserted the word "no" by default in blank spaces in the questionnaires.

Rising to their defense at a hearing in July 1997 was John Cummings. One of the consummate insiders in the practice of mass litigation, Cummings, 63, is a strategist and organizer who enjoys Bechtle's confidence and who, with a graying beard, rounded belly and Deep South lilt to his speech, has the aspect of a sage. During proceedings, Cummings often ambles the courtroom with the casual air of a proprietor.

Speaking to the judge, Cummings declared the fiasco of the bad questionnaires a regrettable mistake, but merely a computer glitch. "There is no evidence . . . ," he said, "that even comes close to fraud."

Unpersuaded, Bechtle imposed $126,500 in sanctions on Amedee and Lestelle. "I think it's unprofessional," Bechtle said, "and I think it could violate the professional code of ethics."

LIFE UNDER SIEGE

In 1996 Sofamor Danek reported a $50 million write-off to its stockholders - money spent to fund the bone screw wars. And the costs continued.

While legal costs shot up, the company's stock fell. At least in the beginning. In the first year of the litigation Sofamor Danek's stock dropped from $33 a share to $11. Pickard convinced his board of directors to stand firm. He told Wall Street financial analysts that the company and its products were sound. He sent letters to his customer base of 6,000 surgeons, promising not to buckle under pressure of "unfounded" lawsuits.

All that seemed to have an effect. Through the years of litigation Sofamor Danek's bone screw sales rose steadily. Revenues doubled from $161 million in 1994 to $312 million in 1997. Sofamor Danek expanded its headquarters in Memphis. It hired more employees. Its stock soared to $121. In late 1998 Sofamor Danek was acquired by Medtronic Inc., a medical technology giant in Minneapolis, for $3.6 billion. Pickard remained in charge of the division now called Medtronic Sofamor Danek, headquartered in Memphis.

Through all that, the litigation continued.

By 1998 about 600 federal cases were en route from Bechtle's court back to courts of origin for trial.

But there were very few trials. In a monolithic consensus, more than 80 judges around the country threw out the cases on summary judgment, finding the claims so lacking in merit as to make trials unnecessary. More than 170 rulings of this type were made in federal and state courts in Pennsylvania, New Jersey, Texas, Florida, Ohio, Tennessee, Louisiana, Minnesota, Georgia, Wisconsin, Kentucky and other states. In many of those cases, there was no evidence that the screws had malfunctioned.

In Memphis, Judge McCarroll considered the merits of a sampling of the hundreds of bone screw cases before him and dismissed them on summary judgment. His decision was upheld in March of this year by the Tennessee Court of Appeals.

Of the thousands of cases filed, Sofamor Danek lost only one: A jury in Texas awarded $418,000 to a plaintiff. That case is on appeal.

It was not that the bone screw cases lacked sympathetic plaintiffs. They lacked evidence.

The case of Jason Leigh is typical. Leigh, 52, of Cleburne, Texas, was severely injured in 1984 when a scaffold collapsed and he fell 73 feet. Leigh, an aerospace worker, had three spinal fusion surgeries. By the third, in 1992, he was ready, as he put it in a deposition, for "a bullet through the brain."

His surgeon used bone screws to secure metal bracing around the fused vertebrae. But Leigh remained in agonizing pain. In 1995 he filed suit, blaming the screws.

In December 1998 U.S. District Judge John McBryde of Fort Worth dismissed the case. The judge said he could find no evidence of any kind to support Leigh's claim. The spinal fusion had healed properly. The bone screws had functioned properly. There was no identifiable link between Leigh's pain and the bone screws.

As such rulings piled up in 1998 and 1999, the plaintiffs' lawyers did not relent. When rulings went against them, they filed appeals.

Steve Phillips, Sofamor Danek's lead lawyer, was exasperated. He had come to admire Pickard so much that he had left Pepper Hamilton to be the manufacturer's general counsel.

Sofamor Danek was winning the war, but there was no end in sight. Every case, potentially, could to be dragged out to its own conclusion - at huge expense. "You would go home at night and say how can this be happening?" Phillips says. "There is no social benefit here."

Sofamor Danek's main competitor, AcroMed, had gotten out early.

In late 1996 AcroMed agreed to pay $100 million to end all claims against it, while admitting no liability. The company said it could not afford to defend itself against a crush of 5,000 lawsuits.

Ron Pickard was so angry at AcroMed's decision to settle - or, in his view, surrender - that he fired off a letter to surgeons around the country.

"Sofamor Danek is not intimidated and will not be coerced," Pickard vowed in this amazingly unCEO-like missive on Dec. 6, 1996. ". . . We hope you will join with us as we continue to fight against extortion and for the advance of medical science and the care of patients."

The PLC lawyers were offended - particularly by the word extortion. Levin and Cummings protested to Bechtle.

Cummings declared at a hearing: "This communication accuses me personally, the PLC and every plaintiff of extortion. It is a charge that I will not take lightly. . . ."

Bechtle didn't like the letter either.

"I don't want anymore letters like this," he warned Phillips. "This to me is insulting to the system in which your client is a party. . . ."

If all else fails, sue the government

With the conspiracy theory in flames and the product liability claims being killed off, the Plaintiffs' Legal Committee went after a new target in 1998 - the Food and Drug Administration.

The lawyers already had made a couple of thrusts in the FDA's direction. First, the PLC contended that the bone screw makers, when applying for FDA approval, misrepresented how pedicle bone screws would be used. That didn't fly. Later, when the FDA granted preliminary approval, the PLC launched several hundred lawsuits charging the agency itself with inflicting injury on spinal surgery patients. All those suits were dismissed.

But in July 1998 the FDA did something the plaintiffs' lawyers considered an outrage.

It ruled bone screws "safe and effective" for spinal surgery and officially cleared them for market. The FDA's action punched a colossal hole in the already tattered bone screw offense.

In a moment of euphoria, Steve Phillips told the Memphis Business Journal: "The litigation has just been declared over by the federal government."

But he spoke too soon.

Within a month of the FDA's action, the Plaintiffs' Legal Committee filed a 62-page complaint asking the courts to block the bone screw approval. The suit accused the FDA - which had spent years reviewing the pros and cons of spinal bone screws - of acting in an "arbitrary and capricious" manner and without proper scientific evidence.

In a creative twist, the PLC named itself a plaintiff. The lawyers were calling themselves injured parties.

Their injury? The FDA, in its ruling, had weakened their litigation position. It had "altered the legal regime." Though couched in the language of a legal complaint, the message was shrill: With bone screws cleared for market, the task of extracting money from manufacturers for the lawyers and their clients now would be harder, and probably impossible.

That extraordinarily revealing lawsuit soon drifted into suspension as the thumping drumbeat of dismissals and summary judgments rolled back on the bone screw lawyers.

By early this year, it was clear: The litigation was a loser. The bone screw wars were over. Even the plaintiffs' lawyers acknowledged, bitterly, that they had been defeated.

NEVER SURRENDER

Arnold Levin and John Cummings still say they're all a bunch of criminals. The doctors. The medical associations. Most of all, the manufacturers. Most especially Sofamor Danek.

Says Levin: "Sofamor Danek got away with murder."

Says Cummings: Sofamor Danek should be indicted. "You have evidence to send people to jail."

At a hearing earlier this year, Michael Fishbein, Levin's partner, made a remarkable presentation to Judge Bechtle.

Fishbein, a bald, paunchy man with an exceptional legal mind, seemed angry. In the beginning, he said, the bone screw litigation had looked easy. But it had become "extraordinarily difficult." And this was why: America's most prominent spine surgeons had been bought off and "corrupted" by bone screw manufacturers. All doctors who knew the truth, who understood the evils of bone screws, had adopted a "code of silence." The nation's surgical community had been "tainted." There was no decent scientific data to show that bone screws were safe, but the FDA had gone ahead and approved them under heavy industry lobbying.

"We faced an enormous challenge here," Fishbein said. "We essentially had to take on an entire industry, that is the spinal manufacturer implant industry. We had to take on basically the entire organized orthopedic and neurosurgical community. We had to take on the United States government. . . ."

And they lost.

But losing on the merits does not mean that Michael Fishbein and his colleagues won't make money.

In fact, Fishbein's lamentation came at a "compensation hearing" in which he and other plaintiffs' lawyers sought millions in fees from the $100 million AcroMed settlement fund. As much as one-third of that money could be tapped by several hundred lawyers who filed claims against the fund.

In the end Sofamor Danek's expenses may end up nearly as high as AcroMed's settlement.

Ron Pickard estimates the total legal costs at $75 million. Having won the war, the company is now seeking to put lingering skirmishes behind it by working on a settlement to end about 500 cases. The price tag may run to $20 million, which Sofamor Danek's lawyers say would be less than the cost of litigating each one to a conclusion. When it is all over, the company's total costs to fight the bone screw wars could top $100 million.

Pickard thinks it is money well spent. He thinks more companies should stand up and fight.

But after six years, Pickard has a dim view of American civil justice.

Why did the litigation have to go on so long? Why didn't the courts crack down sooner and harder? Why are there no consequences for plaintiffs' lawyers who rush to start a mass litigation without proof of their claims?

"I find myself wondering, Does what I experienced happen often?" Pickard said. "You're guilty until proven innocent and it costs you millions. To me, the single thread throughout this litigation: It ain't right."

Mr. L. Stuart Ditzen graduated from George Washington University in 1968 with a degree in American Studies. He's been a newspaper reporter ever since. After a tour on a small daily newspaper, he worked for the Evening Bulletin in Philadelphia for 10 years. When the Bulletin folded in 1982, he joined the staff of The Inquirer. He enjoys investigative reporting, in-depth reporting on the courts and Sunday magazine stories on unusual court cases. For the past two years, he's published a number of articles on the growing phenomenon of mass litigation in America with a focus on abuses by plaintiffs' lawyers. The outgrowth of that work was this story on the Bone Screw Files.

Mr. Ditzen's e-mail address is sditzen@phillynews. com

HUMAN BONE ALLOGRAFT: the FDA's final word

The Food and Drug Administration has issued their final rule on Human Cells, Tissues and Cellular and Tissue-based Products; Establishment of Registration and Listing. It was the 1997 proposed Registration and Listing rule that first defined the terms "minimally manipulated" and "homologous" and then a subsequent September 1999 proposed Donor Suitability rule that sought to change the proposed definitions in a manner that was extremely detrimental to the manufacturing and processing of bone allograft tissue. This new final rule combines aspects of both the Registration and Listing and the Donor Suitability rule and deals definitively with the issue of bone allograft tissue. This new rule is final and takes effect on April 1, 2001.

The FDA clearly states that they wish to clarify any misunderstandings and to revise language that unintentionally appeared to place structural tissue at risk for further classification beyond a biological product. As outlined in the September 1999 rule four criteria must be met for human cells or tissue-based products be considered a biological and regulated under Section 361 of the Public Health Services Act: homologous use, minimally manipulated, have a non-systemic effect and not combined with a drug or device except for sterilizing, preserving or storing.

The FDA does not change these criteria or the definition of minimally manipulated from the 1999 proposed donor suitability rule. However, the FDA clearly states, "we consider examples of human cellular tissue-based products (HCT/P) that are included in the definition of minimally manipulated to be those that have been subjected to the following procedures: …cutting, grinding, soaking in antibiotic solution; sterilization by ethylene oxide treatment or irradiation..." They go on to say that the regulation of bone allograft as a medical device was not their intention and they consider cutting, shaping, grinding, threading and other machined procedures that create bone dowels, screws and pins to also be considered minimally manipulated. These clear-cut examples had been in the previous 1997 proposed rule but were not included in the 1999 rule. **By restating these examples, bone dowels and other machined bone products are again clearly considered minimally manipulated.**

Another concern raised in the 1999 Donor Suitability rule was the revised definition of homologous use. As proposed, any tissue that did not perform the same function in the same location of the recipient then that of where it was taken from the donor would have been considered non-homologous use. The FDA admits that that was a mistake and contrary to their actual intentions. The final new wording does not include the statement that for structural tissues, homologous use occurs "in a location where such structural function normally occurs." They use as an example the use of bone for repair, replacement or reconstruction anywhere in the skeleton of the recipient (including the vertebral column) to considered homologous use as long as it performs the same basic function. However, they add that the use of structural tissue in a location where it does not perform the same basic function as it did in the donor would not be homologous.

Another important activity that the FDA takes with this rule is to bring the regulation of hematopoietic stem cells into line with the regulation of other human cellular tissue-based products, including the regulation of such cells under this rule.

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AWARDS

RESEARCH FUNDING: The AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves has established two Research Grants: the ***Larson Award*** and the ***Sonntag Award***. They are intended to establish funding for clinical projects related to the spine and peripheral nerves, and to provide a means of peer review for clinical research projects to help improve the quality of the proposal and therefore, enhance competitiveness for National Institutes of Health (NIH) funding. The awards are also meant to provide continued funding on an annual basis to establish the AANS/CNS Spine Section as a known source for quality clinical research aimed at answering questions pertaining to the treatment of disorders of the spine and peripheral nerves.

The awards range from $15,000 - $30,000 and are intended for primary investigators of planned clinical studies requiring national level funding to support the preparation of grant proposals and external consultations and to assist in the development of the proposal, planning meetings, and the collection of pilot data. Work that can be completed without such support (such as literature review and preliminary protocol design) should be completed before applying for the Larson or the Sonntag Awards.

The format of the proposal should follow that of the NIH grant package. Specifically, applications should not exceed five single-spaced pages. The applicants should address their specific aims, pertinent literature review and previous studies review, include a brief summary of the proposed study, and a plan for utilization of the funds, as well as a detailed budget and budget justification. The budget should not include salary support for the primary investigator or co-investigators.

Application details for research grants are available from Michael G. Fehlings, MD, PhD, The Toronto Hospital, 399 Bathurst St., Suite 2-417, Toronto, Ontario M5T 2S8, Canada (tel. 416-603-5627), or check out our website at www.neurosurgery.org. The application deadline for grants to be awarded for 2002 is Dec. 1, 2001.

FELLOWSHIP FUNDING: The ***Cloward Fellowship Award*** is sponsored by Medtronic / Sofamore Danek and is awarded annually to one or two U.S. or Canadian trained neurosurgical residents to provide supplemental funds for advanced education and research in disorders of the

spine or peripheral nerves in the form of fellowship training. The amount of the award is $30,000.

Application information for the Cloward Fellowship Award can be acquired from Ziya Gokaslan MD, MD Anderson Cancer Center, 1515 Holcombe Blvd., Houston, Texas 77030-4095 (tel. 713-792-2400) or check out our website at www.neurosurgery.org. The application deadline for the 2002 Cloward Fellowship Award is Sept. 14, 2001.

RESIDENT AWARDS: The Mayfield Award is presented annually by the Joint Section on Disorders of the Spine and Peripheral Nerves to the neurosurgical resident who authors an outstanding research manuscript detailing a laboratory or clinical investigation in the area of spinal or peripheral nerve disorders. Two awards are available, one for clinical research and one for basic science research. Each award is valued at $500.00.

For further information and submission forms, please contact Keith R. Kuhlengel, MD, 1671 Crooked Oak Dr., P.O. Box 10247, Lancaster, PA 17605-4207, Phone (717) 569-5331, e-mail: kkuhleng@redrose.net, or check out our website at www.neurosurgery.org

DEADLINES

- September 14, 2001: Cloward Fellowship Award
- September 14, 2001: Mayfield Awards
- December 1, 2001: Sonntag and Larson Clinical Research Grants 2002

Comments, Submissions, or Suggestions for the Spine Section?

Please e-mail John Hurlbert at jhurlber@ucalgary.ca or contact through surface mail: Dr. R.J. Hurlbert, University of Calgary Spine Program, Foothills Hospital and Medical Centre, 1403-29th St. N.W., Calgary, AB Canada T2N 2T9