

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MINNESOTA

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4 In Re: St. Jude Medical, Inc. 01-MD-1396 JRT/FLN
5 Silzone Heart Valves Products
6 Liability Litigation.

7 Minneapolis, Minnesota
8 October 2, 2002
9 10:08 a.m.
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11 TRANSCRIPT OF PROCEEDINGS
12 (Plaintiffs' Motion for Class Certification)

13 BEFORE THE HONORABLE JOHN R. TUNHEIM,
14 UNITED STATES DISTRICT COURT JUDGE.

15 APPEARANCES:

16 On behalf of plaintiffs: James T. Capretz
17 Tony Jensen
18 Steven E. Angstreich
19 Carolyn Lindheim
20 Michael Coren
21 J. Gordon Rudd, Jr.
22 David Cialkowski
23 Joe D. Jacobson
24 Patrick J. Murphy

On behalf of defendant: James C. Martin
Steven M. Kohn
David E. Stanley
Tracy J. Van Steenburgh
Liz Porter

Court Reporter: Karen J. Grufman
U.S. Courthouse, Suite 1005

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1 THE COURT: On the Court's civil calendar today is
2 case number 01-1396. It involves the Multidistrict Litigation
3 In Re: St. Jude Medical Silzone Heart Valves Products
4 Liability Litigation.

5 Counsel, let's note appearances for the record today.
6 For the plaintiffs.

7 MR. CAPRETZ: James Capretz for the class.

8 MR. ANGSTREICH: Steven Angstreich for the class.

9 MR. RUDD: Gordon Rudd for the class.

10 MR. JACOBSON: Joe Jacobson for the class.

11 MR. COREN: Michael Coren for the class.

12 MR. MURPHY: Pat Murphy, plaintiff state liaison
13 counsel.

14 MS. LINDHEIM: Carolyn Lindheim for the class.

15 MR. SILVA: Mario Silva for the class.

16 MR. CIALKOWSKI: David Cialkowski for the class.

17 THE COURT: The defendant.

18 MR. KOHN: Good morning, Your Honor. Steven Kohn
19 for St. Jude Medical.

20 MR. MARTIN: James Martin, Your Honor, for St. Jude
21 Medical.

22 MR. STANLEY: David Stanley for St. Jude Medical.

23 MS. VAN STEENBURGH: Tracy Van Steenburgh for St.

24 Jude Medical.

25 MS. PORTER: Liz Porter, in-house counsel for St.

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1 Jude Medical.

2 MR. ROSE: Mitchell Rose, TIG Insurance Company.

3 THE COURT: Good morning to all of you.

4 We have the motion this morning, the motion for class

5 certification that the plaintiffs have made.

6 As I understand it, Mr. Capretz, you're going to go

7 first?

8 MR. CAPRETZ: Yes, Your Honor.

9 THE COURT: Good morning. You made it off the

10 train.

11 MR. CAPRETZ: Before we go with the strict time

12 constraints, I ask the Court's indulgence to first explain, I

13 apologize for missing that conference call. I was on the

14 Eurostar, and they used to have telephones on that train, but

15 I guess now cellphones are more popular, because they were

16 ringing constantly. I didn't have one that worked in Europe.

17 They took them off. So I was somewhere going across the

18 channel and could not make it.

19 THE COURT: That's all right.

20 MR. CAPRETZ: And one other housekeeping matter,

21 Your Honor, just to clarify. It's my understanding that it
22 was agreed that each side would have approximately one hour
23 for their presentation.

24 But we had talked earlier -- and if I missed this during
25 the September 24 telephonic conference I apologize -- of a

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1 short rebuttal period by the class. And I don't know if we
2 set any parameters or established any rules for that.

3 THE COURT: Well, I'll make sure that you have some
4 rebuttal. I think we assumed that would all be part of the
5 one-hour period. But let's proceed and see how this goes.

6 MR. CAPRETZ: Very well.

7 Good morning once again, Your Honor. Today we are here
8 concerning --

9 THE COURT: Just one moment, Mr. Capretz. I've got
10 the proposed times from each of those of you who will be
11 arguing. The system incorporates a warning. A one-minute
12 warning okay, or a two-minute?

13 MR. CAPRETZ: We established a protocol from our
14 side. Although I threatened Steve with taking one of those
15 kid's hammers and smashing it. But we established something
16 with Lou Jean.

17 MR. ANGSTREICH: Your Honor, my understanding was
18 with respect to the 20-minute presentations, the yellow would
19 go on with five minutes to go, the red would go on with one

20 minute to go.

21 MR. CAPRETZ: That's internal for our side, as

22 opposed to our --

23 THE COURT: That's right. Yellow at five and red at

24 one. Okay.

25 Actually, the way the system works is that the red, I can

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1 put it on at, to go on at one minute. But I can't adjust when
2 the red stops. Because the red is normally the end, and then
3 it stays on for a little period of time.

4 So it probably would be best if we just stuck to a
5 particular time limit for the yellow. And then if you look on
6 that little monitor that is on the podium, it does have the
7 actual times on there. So that you can always tell exactly
8 how much time is left.

9 So I'll give you a five-minute yellow, and then the red
10 will come on when the time is up, so then that just means you
11 should wrap up.

12 MR. COREN: Thank you, Your Honor.

13 MR. CAPRETZ: Okay. Thank you.

14 Today, Your Honor, we are here concerning a major public
15 health issue involving thousands of heart valves patients,
16 approximately 36,000 of the St. Jude Silzone valves implanted
17 worldwide. Of course, our concentration is on the United
18 States class. But this gives the Court an impression of the

19 size of the class -- excuse me, of the patients wearing these
20 valves.

21 The Class I representatives that we have are a lady by
22 the name of Beatrice Bailey, who had her valve and surgery
23 implanted in January of '99. Lester Grovatt -- these are the
24 Class I representatives -- had his implanted in February of
25 '99. And Levy Redden, a Louisiana resident, who had his

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1 implanted in July of 1999. All of these patients are still
2 wearing the Silzone valve.

3 The Class II representatives, and if the Court recalls,
4 Mr. Jacobson is the lead counsel for the Class II claimants,
5 is Bonnie Sliger. Ms. Sliger had her Silzone valve explanted.
6 She received it in August of '99. It was explanted in August
7 of 2000.

8 And Mr. Joe W. Sanchez, a gentleman who lives in Denver,
9 Colorado, who has paravalvular leakage with complications, he
10 had his Silzone valve implanted in March of '99.

11 THE COURT: And it's still in?

12 MR. CAPRETZ: I'm sorry? It's still in. Yes, sir.

13 The U.S. Silzone product line, basically what is showing
14 on the slide, Your Honor, we had the St. Jude Silzone coated
15 heart valve on the sewing cuff. We had the St. Jude Tailor
16 annuloplasty rings with Silzone coating. And the St. Jude
17 Master Series Seguin annuloplasty rings with Silzone coating.

18 Then there were two other products produced, the so-called
19 Regent valve, heart valve, and the Epic heart valve. The
20 Court will see research concerning those in its review of the
21 various files and briefs.

22 Our job today, however, is to highlight for class
23 certification under Federal Rule 23 for Classes I and II, and
24 answer any questions the Court may have.

25 It is not deciding the ultimate merits of the class

1 claims that St. Jude tries to do in its multiple briefs,
2 declarations and objections.

3 In order to avoid the inevitable legal conclusions that
4 the plaintiffs can demonstrate this class action should be
5 certified under the federal rules, St. Jude has continuously
6 tried to complexify this class. To be sure, there are complex
7 issues in the litigation, but nothing that can't be understood
8 and managed by the Court.

9 The facts are the claims can achieve medical benefits,
10 and a monitoring program can be designed and implemented
11 efficiently and promptly.

12 A one-minute manager snapshot of the problem is as
13 follows:

14 From its corporate headquarters in Minnesota, St. Jude
15 Medical has long produced and marketed a prosthetic mechanical
16 heart valve known as the Master Series.

17 In between 1997 through 2000, it impregnated, through a
18 process created by the Spire Corporation, some of the sewing
19 cuffs in the Master Series valves with a silver coating
20 trademark as Silzone in order to reduce the disease called
21 endocarditis.

22 It was a timely marketing concept, since heart valve
23 surgeons were easily sold on the concept of a product that
24 might reduce this disease occasionally associated with
25 artificial heart valve implants. And a premium could be

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1 charged for the enhancement.

2 Considering the market share St. Jude Medical enjoyed, a
3 \$300 plus premium on each Master Series valve sold would
4 result in a significant profit increase.

5 The problem with the valve was that this valve was rushed
6 to market. There was no adequate study or testing done, nor
7 actually of the safety or efficacy of the Silzone valve, as we
8 will demonstrate to the Court.

9 The problems that arose, the injuries, were first of all,
10 a clinically significant increase in paravalvular leakage,
11 known as PVL; inadequate excessive pannus growth; and
12 thromboembolic complications. And that includes a stroke as
13 we all know it; and a TIA, transient ischemic attack; and
14 myocardial infarction.

15 We also find that in research as demonstrated that there

16 was a danger of sarcomas from this valve. We'll get into that
17 as we move on.

18 Some patients have died. Others have undergone painful
19 and risky surgery. And still others are suffering from the
20 anxiety of not knowing if their untested Silzone heart valve
21 is a time bomb that may require further surgery. There is
22 compelling evidence that the Silzone valve presents a clear
23 and present danger to those who have it implanted in their
24 hearts.

25 What does the class claim? St. Jude is a resourceful

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1 company that has produced and is producing many useful and
2 life-enhancing medical products. In the case of Silzone
3 valves, however, a major worldwide public health problem was
4 needlessly created in a rush to increase sales and profits and
5 raise stock values. Regrettably, this otherwise successful
6 company used human beings as experiments, and placed them in
7 positions of peril or worse.

8 The time has come for the company to recognize the human
9 suffering it has caused, and provide a means for Silzone
10 patients to be properly tested without concern about payment
11 for the procedure, and to create a scientific research fund to
12 further evaluate the risks attendant to the thousands of
13 Americans still wearing a valve, and to pay damages to those
14 who have been diagnosed with clinical injuries.

15 The order of argument today will be myself presenting the
16 background and factual circumstances, Your Honor. Mr.
17 Angstreich will walk through the legal elements of the Federal
18 Rules of Civil Procedure 23(a) and 23(b). Mr. Rudd will
19 address the Minnesota UDAP claim, and a choice of law issue
20 recently asserted by St. Jude. And Mr. Jacobson will present
21 the personal injury aspects of the claim.

22 The time line, as the Court can perceive, goes back to
23 1997, when St. Jude, the leading supplier of mechanical heart
24 valves, approximately 80 percent of the market, approximately
25 30 year old -- less than a 30 year old company, marketed its

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1 Master Series valves since the early '80s. Approximately one
2 million, or over one million of these valves have been sold,
3 and it's considered the gold standard through today.

4 Perhaps thinking it was time for a marketing boost and a
5 competitive edge, St. Jude embraced the idea developed by the
6 Spire Corporation of affixing a coating of elemental silver on
7 the sewing cuff of its standard heart valve, on the theory but
8 without adequate evidence that the toxic properties of silver
9 might inhibit bacterial growth on the cuff.

10 St. Jude licensed the process for affixing the silver
11 coating for the sewing cuff from the Spire Corporation. It is
12 interesting to note that Spire had previously tried to license
13 the process to a competitor medical device company, Sulzer

14 Carbomedics out of Texas, but Sulzer rejected the idea as
15 controversial and unproven.

16 St. Jude called the experimental silver coating Silzone.
17 Rudimentary animal testing did not bear out the efficacy of
18 the Silzone coating in preventing bacterial growth. Safety
19 was also a question. St. Jude basically relied on what Spire
20 Corporation sold them, as well as two limited sheep studies.

21 In 1996, in October, at a design review meeting of St.
22 Jude Medical, we can see that the company concluded, "We'll
23 never know how blood reacts to the Silzone until we implant it
24 in humans."

25 "A clinical trial is not required for this device.

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1 Therefore, a limited release where we monitor the initial
2 patients is the next logical step in the verification of the
3 design."

4 So therein lies the problem. They didn't get to the
5 point of any human trials, although there was a limited human
6 clinical test in Europe, but nothing worthwhile or clinically
7 significant or useful. And as it's proven, it's not only
8 not -- it does not have efficacy as the FDA had announced it
9 didn't prove, but it clearly has been proven to be unsafe.

10 In May of '97, St. Jude submitted a formal premarket
11 approval application to the US government, the FDA. It
12 stalled its nominal introduction of Silzone not as a new

13 device or drug, but rather as a modification of its
14 longstanding mechanical Master Series Heart Valve. This
15 process is a quicker and easier way of getting FDA approval
16 for modification of existing Class III devices.

17 In the meantime, in 1997, St. Jude began marketing and
18 selling the valve in what St. Jude personnel later describes,
19 and the Court will get to see a memorandum known as the Guinea
20 Pig Continent of Europe.

21 In October of 1997, St. Jude also began marketing the
22 Silzone valve in Canada.

23 In March of '98, the FDA gave supplemental approval of
24 the PMA, and the company basically started selling the valve
25 immediately within the United States. However, the

1 restrictive approval prohibited St. Jude from representing
2 that the Silzone coating is actually effective at reducing
3 endocarditis.

4 St. Jude immediately marketed and continued to market
5 until approximately 10,535 of these were valves were
6 implanted. In July of '98, the AVERT study was commissioned
7 of human implantees of the Silzone valve at the University of
8 Pittsburgh. It was designed to include 4,400 human subjects.

9 In late '98, British surgeon Eric Butchart warned St.
10 Jude of a comparatively high number, approximately 25 percent,
11 of embolic events in patients implanted with the Silzone

12 valve.

13 Parenthetically, I'll note, Your Honor, that St. Jude
14 went to Mr. Butchart. He didn't ask for any moneys or so from
15 them. They asked that they test their valve along with other
16 valves that he was studying for TE events, and he found an
17 outrageous percentage.

18 He acted specifically indicating that the, noting that
19 the transthoracic echocardiogram, the nominal air monitoring,
20 would not be helpful in assessing the thermogeneity of the
21 Silzone coating.

22 Also, Doctor Jagdish Butany, a noted doctor at Toronto
23 General Hospital in Canada, who at that time was not a
24 consultant to St. Jude, reported a high incidence of adverse
25 events in the Canadian implantations. Over 25 percent.

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1 It is interesting and for the record to note that Doctor
2 Butany was subsequently retained by St. Jude as a consultant.
3 And Toronto General Hospital discontinued the use of the St.
4 Jude Silzone valve in early '99.

5 THE COURT: Mr. Capretz, do you know, when the
6 Silzone was first added to the valve product and sewing cuff,
7 was there any change at all made to the basic design of the
8 valve or the cuff when it was first introduced?

9 MR. CAPRETZ: I can speak absolutely about the valve
10 and say no, no change whatsoever.

11 The cuff, I don't think so. The only thing that I know
12 that was changed was it was impregnated by this process with
13 the silver ion coating.

14 In late '99, England's agency for regulating medical
15 devices, the MDA, issued a warning bulletin about the
16 thromboembolic complications associated with the St. Jude
17 Silzone heart valve. It recommended that implantees consider
18 transesophageal echocardiograms to monitor potentially
19 developing problems.

20 In December of '99, Australia and New Zealand bans
21 Silzone valves based on the English findings and the findings
22 of Doctor Butany, and a consultant to St. Jude by the name
23 of -- a heart surgeon, a prominent heart surgeon at Toronto by
24 the name of Doctor Tirone David. It's important to note that
25 a lot of the work, initial work and testing this valve was up

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1 in the Canadian Ontario province.

2 Despite the warnings and foreign recalls, St. Jude
3 continued to market and sell the valve in the U.S. And I can
4 say unequivocally, from speaking with heart valve surgeons in
5 the U.S., that even when they had all of these warnings, all
6 of these results, when the doctors called to ask about the
7 safety of the valve, St. Jude personnel assured them that it
8 was fine to do it. And in one instance, from Massachusetts,

9 the patient was undergoing a second implantation of a Silzone
10 valve. And St. Jude assured the surgeon that there was no
11 problem.

12 In January of 2000, someone took a snapshot of the data
13 coming in from their Web site. The results were striking.
14 The risk of paravalvular leak which required surgical
15 explantation of patients' heart valve was found to be 800
16 percent higher for Silzone implantees than for someone with a
17 Master Series artificial heart valve.

18 All of St. Jude's opposition brief notes in its motion
19 that the difference was small, and the AVERT study was
20 immediately halted. So they never did achieve the 4,000 plus
21 human subjects.

22 St. Jude recalled all of the Silzone coated heart valves
23 on January 21, 2000. The number stands, as we said, at 10,535
24 in the U.S. And that number has shrunk. We don't know what,
25 and we haven't commissioned any epidemiological studies as to

1 how many have died, or how many have had problems with the
2 valve and died.

3 St. Jude's "Dear Doctor" letters where it wrote telling
4 them about this valve and its problems, noted that there were
5 no individual differences in subjects receiving Silzone valves
6 to account for the much higher complication rate, and that it
7 was impossible to determine any more specific risk subgroups
8 of Silzone implantees.

9 Furthermore, Doctor Alan Flory, a veterinarian by
10 profession, and a Director of Clinical and Regulatory Affairs
11 of St. Jude's heart valve, has testified that St. Jude
12 postulated and looked at hundreds of variables to find other
13 possible causes of general heightened risk, but found none.

14 While maintaining that only customary patient monitoring
15 was all that was needed, St. Jude acknowledged that monitoring
16 may be appropriate, and instituted a token ineffective and
17 cumbersome program to pay for minimal additional monitoring of
18 Silzone valve implantees, known as MERP, a medical expense
19 reimbursement plan. It was scheduled to end this past spring,
20 but it is continuing, we understand, for one more year.

21 The March follow-up of 2000 follow-up study of AVERT
22 showed a 1600, not 800, 1600 percent increase of risk of
23 explants and need for explants for all Silzone valve
24 recipients in the study.

25 As the Court is aware, St. Jude currently paces in a ring

1 of lawsuits over the Silzone valve, including approximately 40
2 federal suits, and over 100 in state courts around the
3 country. Several suits have been already resolved by way of
4 settlement by St. Jude.

5 The statistical power of the AVERT study to reflect the
6 comparative danger of the St. Jude heart valve continues to
7 decline as subjects drop out of the analysis for various

8 reasons. The study was also designed and paid for by St. Jude
9 Medical. The issue of bias by the clinical investigators
10 cannot be dismissed by those seeking an objective review and
11 analysis of the subject.

12 What brings us here, Your Honor, is basically the valves
13 were recalled in January of 2001. Marketing in violation,
14 marketing we contend, the class contends, we will demonstrate
15 to this Court that marketing was in violation of FDA
16 conditional approval. And the studies commissioned by St.
17 Jude Medical showed a high incidence of injuries.

18 Accordingly, we are very concerned about the 10,500, or
19 whatever the point might be, the lesser amount might be,
20 Americans still at risk.

21 We'll run through the class, the Medical Monitoring class
22 23(b)(1)(A), 23(b)(2), 23(b)(3), and a bodily injury class
23 23(b)(3).

24 Medical monitoring, basically for medical monitoring is
25 anyone except those who have been medically diagnosed with a

1 failure, and have required repair or will require a repair, or
2 who have died as a result of having this valve, or who are
3 officers or employees of the defendant.

4 Class II is personal injury. Basically, it's everybody
5 else. Someone who has undergone a repair, or someone who has
6 died as a result of having the valve.

7 At this time, Your Honor, Mr. Angstreich will discuss the
8 legal requirements of Federal Rule 23(a) and 23(b)(1)(A),
9 (b)(2) and (b)(3) for class certification.

10 THE COURT: Thank you, Mr. Capretz.

11 MR. ANGSTREICH: Well, I see my time is up.

12 May it please the Court. Your Honor, we have supplied
13 the Court with enough trees setting forth the legal parameters
14 for class certification, that it would be inappropriate for me
15 to spend the 20 minutes to go over each and every one of them.

16 But suffice it to say that there are four requirements that
17 must be met with respect to Rule 23(a): numerosity,
18 typicality, common questions of law and fact, and adequacy of
19 representation.

20 Numerosity is not in dispute. We know that there are
21 more than 10,500 Americans that comprise both Class I and
22 Class II combined. We know that joining each and every one of
23 them in a lawsuit would be impractical. And we know that
24 these are identifiable people through the MERP program, the

25 serial numbers on the valves, the hospitals, and the doctors.

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1 So numerosity and the identification of our class is not
2 at issue.

3 I have not seen, in the several hundred pages of
4 opposition, any challenge to the adequacy of counsel. So I
5 won't address that at this point.

6 There is a challenge to the adequacy of the class
7 representatives. And it's unusual that there is a challenge
8 to adequacy where the class representatives have already
9 demonstrated a knowledge of the case, a willingness to
10 participate, actually participating in depositions.

11 Adequate doesn't mean perfect, it doesn't mean ideal, and
12 it doesn't mean the best. It just means what it is. That
13 there are adequate representatives. The test is whether or
14 not their claims are atypical of the claims, or there's a
15 conflict. There can be no conflict asserted.

16 Turning to typicality, the question arises as to whether
17 or not the claims come from the same event or same course of
18 conduct, or whether each class member has the same or similar
19 grievances.

20 Typicality and the challenge to adequacy, and the
21 challenge to common questions are really subsumed within one
22 concept that runs through St. Jude's opposition. It is a
23 repetitive theme: Individuals are individuals. No individual
24 is the same. It is the snowflake defense. It is the same

1 fraud cases, in antitrust cases, in each and every kind of
2 case where individual decision-making or individual personal
3 traits can apply.

4 Unfortunately, what has happened here is that the
5 defendant has equated and has confused the individual with a
6 test relating to same course of conduct from which the claims
7 arise, or the same grievance.

8 Class I all has the same grievance. Lester Grovatt, Levy
9 Redden, and Ms. Bailey all want a medical monitoring program
10 to determine whether or not the increased risk that they have
11 been placed in is in fact going to happen to them. They want
12 early detection, early warning, for early treatment.

13 In addition to which they want, as Lester Grovatt
14 testified, to have St. Jude do an epidemiological study.
15 That's the relief sought by Class I. Whether or not each of
16 the individuals is a different person is of no moment as it
17 relates to that claimed relief.

18 The course of conduct that we have is very simple. The
19 course of conduct is a single defendant designing,
20 manufacturing, developing, marketing, and selling a product,
21 the Silzone coated heart valve.

22 Your Honor asked Mr. Capretz whether or not there was any
23 difference between the two. The valve is the same. The
24 Dacron coating, the coated fabric, or the Dacron fabric is the

25 same, at least according to the testimony of St. Jude's

1 personnel. The difference is the fact that the fabric was
2 coated with titanium, palladium, and silver. Those other two
3 metals were used to make certain that the silver wouldn't
4 flake off. It would give a better bonded effect.

5 That's the issue.

6 We have heard from St. Jude's expert Doctor Rodricks and
7 others that there is a host of individual questions that
8 preclude these people being adequate, that precludes a finding
9 of typicality, that precludes a finding of predominance. And
10 as I said, that's the fact that there are all of these
11 possible other reasons.

12 What about their Coumadin? What about their physical
13 condition: How big they were. How tall they were. What was
14 their diet? You can list any number of possibles.

15 But as Doctor Flory testified, we looked at essentially
16 200 variables or more to try and figure out can we explain
17 this, and we couldn't. Doctor Flory conceded that the only
18 common thread was the Silzone coating on the fabric.

19 And when he was asked whether or not they were going to
20 continue to investigate it, he said they weren't. St. Jude
21 came to the conclusion that the cause of the problem was the
22 Silzone coating. Now, they went out and they got Doctor
23 Rodricks and others to say, oh, it's possible it's something
24 else.

1 inappropriate. What is the cause?

2 There's one other thing that's very important to
3 understand here. Doctor Butany, their consultant since
4 October of 2000, has in his possession explanted valves. Mr.
5 Butchart -- he's called a Mr. in the UK -- has in his
6 possession explanted valves. St. Jude has in its possession
7 over a hundred explanted valves.

8 If in fact the cause of the need for explanation was the
9 result of any of this parade of horrible possibilities, they
10 certainly could have had their experts come into court to show
11 us that the reason that Mrs. Jones's valve was explanted had
12 nothing to do with Silzone, it had to do with the fact that
13 her Coumadin level was too high or too low. Or that she took
14 other medications.

15 They haven't done that. All they've done is come in here
16 to suggest that a human being is different from another human
17 being. And that's a given. We can't dispute that.

18 But what we do know, and what they have acknowledged, and
19 what they have not gone forward to try to disprove, is the
20 fact that the common thread here is the Silzone coating.

21 That's why there's typicality. That's why the
22 representatives are adequate.

23 Common questions clearly exist. Common factual questions
24 and common legal questions.

1 Honor, there are always individual claims. Is the
2 investigator sophisticated or not sophisticated? Did he find
3 out about the stock from his broker? Or from his friend? Or
4 did he do his own investigation? Those kind of individual
5 questions, similar to what are being posed here, do not
6 militate against a finding of class certification.

7 We have been told, well, this case is the same as PPA.
8 It's the same as Propulsid. It's the same as Rezulin. But
9 it's not.

10 The reason that it's not is that we have, unlike PPA, one
11 product, one manufacturer, one kind of injury. The other
12 important aspect to those three compared to this, and that
13 goes to the issue of medical monitoring.

14 And I probably messed up all of the slides and the order
15 of the slides. But I knew I was going to do that, because
16 that's my nature.

17 We have a situation where in those three cases, it was
18 the plaintiffs' experts who came forward and said there's a
19 need for medical monitoring. The defendant's expert said oh,
20 no, there's no need for medical monitoring.

21 Now, the two significant questions relating to Class I
22 is, is there a need for medical monitoring? And would an
23 epidemiological program be appropriate and necessary under
24 these circumstances?

Now, that's as to Class I. There are a myriad of common

1 issues of fact and law relating to Class II. Those common
2 issues relate to whether or not there's a higher incidence of
3 paravalvular leakage compared to nonSilzone valves. And I'll
4 touch on that in a moment as to why we submit there is.
5 Whether or not there's an increased risk of thromboembolic
6 events between Silzone valves and the regular valves, which
7 has been documented.

8 Now, it's an interesting phenomenon here. There is both
9 excessive and inadequate pannus. That's the growth over the
10 cuff to seat the valve. We find that there's situations where
11 it's inadequate, or it's excessive, all of which still come
12 about because of the Silzone coating. That's another common
13 factual issue.

14 We have the issues of whether or not St. Jude reported
15 their test results accurately. Whether they completed their
16 forms to the FDA honestly and completely. It does not fall
17 into the fraud on the FDA defense, but a requirement in order
18 to have the supplemental PMA properly acted upon.

19 There's a common issue of whether or not the warnings
20 that were given were appropriate in light of the information
21 then known to St. Jude.

22 We know that Doctor Butany and Mr. Butchart were telling
23 St. Jude long before the, quote, voluntary recall, closed
24 quote, came about that there was a significant problem.

1 FDA, contending that the AVERT study, the gold standard, was
2 showing no problem. We know that that gold standard showed a
3 problem. We know that that gold standard not only showed a
4 problem initially, but showed a problem in the next go-around,
5 as Mr. Capretz has stated.

6 We know that according to their now expert, Doctor Jones,
7 there's an absence of evidence of continuing risk. The
8 problem that exists with Doctor Jones is that her analysis is
9 dependent upon an under-powered study. It was supposed to be
10 4,000 people: 2,000 Silzone, 2,000 Master Series nonSilzone.
11 It never got to that level because of the higher incident.

12 And it has shrunk, and it has shrunk, and it has shrunk,
13 and it's down to 807: 400 Silzone, 400 nonSilzone.

14 One of the, the importance of the magnitude of the size
15 of a study is the power. Because merely because in a small
16 study there is no incidence of paravalvular leakage is not
17 proof that there's no risk of that problem in the larger
18 group.

19 On the other hand, as demonstrated by AVERT initially,
20 because they never reached the 4,000, it was a smaller study
21 than what statistically it should have been. But because
22 there was so much evidence of a problem with paravalvular
23 leakage, it was sufficient to establish the danger. In other
24 words, in an under-powered study, if there is a demonstrable

25 risk, that is proof of a risk. The converse is not true. And

1 our experts have taken Doctor Jones to task.

2 What is also very interesting is that AVERT was St.
3 Jude's commissioned study. I didn't see Doctor Schaff support
4 the conclusions of Doctor Jones. I didn't see any other
5 investigator from AVERT come in to support Doctor Jones.

6 But we get to the issue of medical monitoring and what we
7 must show, that there is a legitimate question concerning the
8 need of all Silzone patients who still have the Silzone valve
9 for special monitoring in a research program. And then makes
10 sense to address the question on a class-wide basis.

11 Now, one of the other differences with Rezulin and
12 Propulsid, aside from the fact that there was a dispute
13 between the plaintiff and defendant experts as to the need for
14 monitoring, you also had a much larger group who took the
15 drugs. And therefore, it was conceivable that you could
16 develop medical monitoring protocols within geographic areas,
17 as opposed to nationwide.

18 We have less than 10,500 people still with the valve.
19 You might find three or four in one geographic area. To try
20 and develop and create an epidemiological study doesn't make
21 sense for four people.

22 We also have a call for monitoring in this case that
23 doesn't exist in PPA, in Rezulin, or Propulsid.

24 We have Doctor Schaff from the AVERT study recommend a

1 serial Doppler echocardiograms.

2 We have an unpublished AVERT study that says further
3 monitoring is required to assess long-term clinical outcomes.
4 See, nobody has ever done a long-term study of the dangers of
5 silver in the body. That's a given.

6 In fact, the reports that were turned over by Spire to
7 St. Jude made it clear that even when they tested the silver
8 coated or the Spi-Argent coated catheters, that they have not
9 done it for long term analysis, and were being recommended for
10 that very purpose.

11 We also have the MDA, the Medical Device Agency, the UK
12 equivalent of the FDA, who are publicly recommending that
13 doctors consider transesophageal echocardiograms. Now, that's
14 a very important point. Because a TEE is not a routine part
15 of a yearly checkup for a valve patient.

16 Doctor Butany in his writings, their consultant,
17 concluded that continued surveillance of patients with this
18 valve is necessary. He further stated from a clinical
19 analysis of two patients that he believes that those with
20 mitral site prostheses appear to be -- to have potential for
21 damage by their paravalvular leak.

22 One of the important aspects of this, Your Honor, is that
23 you just don't have a paravalvular leak that immediately
24 requires explantation. It doesn't have to happen that way.

25 You can have a mild, a moderate, or a severe, requiring

1 explanation. That kind of monitoring is necessary.

2 So besides Doctor Butany, we also have Mr. Butchart in
3 1999 recommending close follow-ups with transesophageal echoes
4 to detect thrombus. He wrote a letter to St. Jude in 1998,
5 telling them that routine transthoracic echoes is not
6 sufficient to determine thrombogenicity of the silver coating.

7 We go on for the call to monitoring in the article
8 entitled, "Silver coated prosthetic heart valve: A
9 double-bladed weapon," where they say there's a need for
10 special surveillance.

11 And now, we find that there is at least one paper
12 published that there was a sarcoma found at the site of a
13 Silzone coated heart valve. And the authors say, "It is
14 necessary to eliminate whether there is a significant risk of
15 tumor formation in association with these valves. Follow-up
16 studies of large patient groups are necessary."

17 Well, we have a large patient group. We have 10,500.
18 And that's perfect for the epidemiological study. And the
19 finding of a solid tumor is critical in the early stages. And
20 that gives a perfect reason for a medical monitoring protocol.

21 We submit that under 23(a), we've met the four standards.
22 I'll get to predominance in a second. Under 23(b)(1)(A), as I
23 said earlier, it makes no sense with respect to Class I to
24 have separate cases for medical monitoring. Because in one

1 somebody may not.

2 St. Jude brought the valve to the market. Minnesota
3 recognizes this as an appropriate remedy.

4 And everybody who they implanted with this ticking time
5 bomb should have access to this medical monitoring study.

6 THE COURT: Are there a lot of cases out here that
7 have established medical monitoring classes with a scheme and
8 a plan for how to do the monitoring?

9 MR. CAPRETZ: Have there been a lot of cases in
10 Minnesota?

11 THE COURT: I mean around the country.

12 MR. CAPRETZ: A lot is a -- is a quantitative term.
13 I don't know that there are a lot.

14 I know that the most important one is Judge Bechtle's
15 decision in 1999 in Diet Drug. We've been chastised by the
16 defendant in their surreply at page ten that we're relying
17 upon the settlement class conclusions of Judge Bechtle. But
18 we weren't. We were relying upon Judge Bechtle's decision in
19 1999 in the Jeffers case, where he certified a medical
20 monitoring class, determining that it was appropriate to give
21 all of the people the relief that they seek. And it's
22 possible that they just didn't see the citation appropriately.

23 THE COURT: Because one of the problems here is that
24 essentially what experts are doing are assessing the level of

25 the risk. And the question then becomes, how big a risk

1 suggests that there is an injury in fact sufficient enough to
2 warrant the monitoring? And I guess that's a battle for the
3 experts, and that's how the other cases have developed.

4 MR. ANGSTREICH: Your Honor, we agree that at a
5 certain point, that is an appropriate inquiry.

6 It certainly can't be a balancing on the declarations of
7 the experts at this stage. Our experts have said there is a
8 need.

9 But beyond that, as demonstrated, unlike the other cases
10 where medical monitoring was rejected, there has been a call
11 for this monitoring from the others.

12 We have a situation in states that have recognized it.
13 In Pennsylvania, the Redland case recognized the need for
14 medical monitoring. We've had medical monitoring cases
15 certified, not on a nationwide basis, because they were
16 brought in state court.

17 But the question is whether or not this case should be
18 certified is not dependent upon whether or not Rezulin or
19 Propulsid should be, or was not certified. They're different
20 cases, as I've indicated.

21 The important thing also with respect to the equitable
22 relief and the remedy. This equitable relief is necessary
23 here, because what we have is a no monetary recovery for the
24 plaintiffs. In other words, the creation of the medical

25 monitoring program does not result in a check being given to

1 them, but in fact being able to obtain the program and having
2 their medical providers get reimbursed for that.

3 If Lester Grovatt brought his own case for medical
4 monitoring, by the time the case was over, he would have had
5 to advance all of the fees and all of the costs, and the
6 recovery would be that he would have a program to monitor
7 himself. And no one is going to undertake that on an
8 individualized basis.

9 So that the superiority for the equitable relief is
10 clear, we have a cohesive group, despite all of the arguments
11 to the contrary. We have a cohesive group, because the
12 equitable relief sought by the way of the epidemiological
13 study is clear. There is no difference in establishing the
14 proof of harm for the need of the epi study.

15 We've got the information from Mr. Butchart of the
16 thromboembolic events. You've got Doctor Butany's findings.
17 You've got Toby's findings. You've got AVERT's findings.

18 It is clear that there is a risk. That risk was a risk
19 created by St. Jude, and that's why the program is necessary.

20 We submit that the common questions of fact and law
21 predominate in this case. Not the individual issue of who the
22 person is, but the legal issues.

23 One more fast point, Your Honor --

24 THE COURT: That's fine.

MR. CAPRETZ: As we said, we have one product line,

1 one defendant. It is our mantra, it's been our mantra
2 throughout this case. We have a discrete population. We have
3 a product that was on the market from 1998 until 2000.
4 Although it was marketed before it was approved by way of
5 being posted on the Web site, the presentations at various
6 cardiology meetings, and the like, as Mr. Rudd will tell you,
7 that we believe Minnesota law applies.

8 And one of the other most incredible aspects here is that
9 one of the overarching defenses, that of the medical device at
10 preemption raised by St. Jude applies to each and every case,
11 whether it's done individually or collectively. Every case
12 will face that defense.

13 And that is therefore a common legal issue in this case
14 which predominates over any individual legal issue.

15 And Your Honor, as far as superiority is concerned, we
16 believe that it makes no sense to try these cases over and
17 over again. We really have, as I said before, a negative
18 value claim for medical monitoring.

19 And Mr. Rudd will discuss the issues of choice of law and
20 the UDAP plan.

21 THE COURT: One more question for you, Mr.
22 Angstreich.

23 I notice that throughout your briefs there was a
24 reference to the device, the heart valve, and its accompanying

1 MR. ANGSTREICH: Yes.

2 THE COURT: And I just wanted to clarify that.

3 We have considered this to be a medical device all along.

4 It seems to me that that was the nature of the review that was
5 given the product by the FDA.

6 Are we really dealing with something that can be, from a
7 legal standpoint, considered a combination device?

8 MR. ANGSTREICH: Absolutely, Your Honor.

9 And the reason it can be determined to be a combination
10 device is the fact that St. Jude advertised and marketed this
11 product as being both bacteriocidal and bacteriostatic. Those
12 are important terms. In terms that Spire ran into when it
13 went after a Spi-Argent cuff under a 510(k) submission, where
14 they tried to get their Spi-Argent coating on a Dacron cuff
15 approved by the FDA, and the FDA came back and told them that
16 they needed a new drug application because the product was
17 both bacteriocidal and bacteriostatic. The difference is
18 bacteriostatic means that the coating on the cuff prevents
19 colonization on the cuff; however, bacteriocidal means it
20 sloughs off.

21 One of the points that St. Jude made was that it was
22 intended to slough off. And the silver ions would combat the
23 bacteria away from the cuff, which is bacteriocidal.

24 Therefore, it's our position that we can establish, and

25 we will establish at the time of the preemption argument that

1 this was a combination product; and therefore, there is no
2 preemption under the MDA.

3 That's an issue. And it's clear from the documents that
4 we have been finding that St. Jude understood that.

5 And in fact, my recollection is that in one of the
6 submissions to one of the agencies outside the United States,
7 the MDA, the MDA said, no, this is a combination. You need a
8 new drug application. And recognized it as to what it is.

9 The issue of whether or not the knowledge of what
10 happened to Spire with their Spi-Argent cuff was used by St.
11 Jude to downplay to the FDA the bacteriocidal effect of the
12 silver while it was up-playing the bacteriocidal effect in the
13 marketplace to fight off endocarditis, is an issue that is
14 within Your Honor's jurisdiction to determine, and whether or
15 not the FDA should have viewed this as a combination product.

16 That's part of the issue, common issues as to whether or
17 not they supplied all of the information, completed all of the
18 forms, which does not get to, quote, the fraud on the FDA, per
19 se, but gets to the question of whether or not the
20 supplemental PMA application was sufficient to give it the MDA
21 protection.

22 THE COURT: Thank you.

23 MR. ANGSTREICH: You're welcome, Your Honor. Thank
24 you.

1 MR. RUDD: Good morning, Your Honor. May it please
2 the Court. I'm going to address, as Mr. Capretz and Mr.
3 Angstreich stated, the issues of the choice of law in the
4 consumer fraud statutes in Minnesota. And I'm going to do so
5 briefly.

6 THE COURT: You've got five minutes.

7 MR. RUDD: My yellow light has just come on. I see
8 my time is running short.

9 (Laughter.)

10 THE COURT: I'll give you a yellow light at one
11 minute. How does that sound?

12 MR. RUDD: That's very kind of you. It's nice to
13 see the green light.

14 Very quickly, Your Honor, on the choice of law issue,
15 this is actually a very simple issue for the Court to address.
16 Number one, because we have the benefit of Judge Magnuson's
17 decision in the Lutheran Brotherhood MDL; and also, based upon
18 actual statements St. Jude has made in motions to transfer
19 other cases that were pending in New Jersey and Missouri
20 before the before the MDL was created.

21 But essentially, the issue, first of all, is what choice
22 of law rules apply. Is it Minnesota's choice of law, or some
23 other state's choice of law rules?

24 It's our position that the operative complaint here under

25 which the plaintiffs move for certification is the complaint

1 under which the Court would determine what the forum is, and
2 what choice of law rules apply. That's clearly Minnesota.
3 There's a consolidated complaint pending here.

4 And in addition, the Bailey case, which is one of the
5 first cases filed, was filed here in Minnesota. Ms. Bailey
6 is, of course, one of the class representatives. So clearly,
7 the forum state for consideration of choice of law would be
8 Minnesota.

9 So we look then to Minnesota's choice of law rules, which
10 are a significant contact, significant interest test. And in
11 fact, every one of the transfer of courts in this MDL applies
12 significant contact, significant interest analysis. So there
13 aren't any variations on the choice of law rules.

14 The other type of analysis that can be done in other
15 states, such as Indiana where, in the Firestone case, and in
16 Propulsid before Judge Fallon, is the place of injury test.
17 You look to the interest of the state where the place of
18 injury occurred. That is not the test here.

19 And, of course, every state has some interest in events
20 that occurred in the state. But the issue for this Court is
21 really which state has the most significant contacts, leading
22 to the most significant governmental interest. And that
23 clearly points to Minnesota, Your Honor.

24 And I would just like to take you through a couple of

1 contacts, so that Minnesota law can be applied on a nationwide
2 basis. And again, this is according to St. Jude. I would
3 refer the Court to the motion to transfer venue that was filed
4 in the Grovatt matter. Grovatt was a case that was filed in
5 New Jersey, and St. Jude moved to transfer that case to
6 Minnesota prior to the MDL.

7 The statements that St. Jude made were that there were
8 significant contacts to this state warranting transfer of the
9 case from New Jersey to Minnesota. St. Jude said, of course,
10 it's a Minnesota corporation. Minnesota is, quote, the
11 location of the critical operative facts. These Silzone
12 valves were designed in Minnesota. They were researched in
13 Minnesota. They were developed in Minnesota, engineered in
14 Minnesota, and tested in Minnesota. In fact, even a St. Jude
15 Medical subsidiary, which is a marketing arm, was involved in
16 selling the heart valves in all other states.

17 This is St. Jude's words, not the plaintiffs', Your
18 Honor.

19 In addition, the carbon components for the valves were
20 made in Minnesota. And all oversight of labeling, creation of
21 warnings and instructions drafted here in Minnesota. Quality
22 assurance occurred here in Minnesota.

23 And last of all, marketing, which is a central issue with
24 regard to the consumer fraud claims. The marketing and

25 distribution efforts were based, quote, in Minnesota. And

1 that again is from the Grovatt motion to transfer.

2 With regard to Mr. Grovatt's connection to New Jersey,
3 St. Jude's position was that the operative facts of this case
4 have little connection to the home forum of New Jersey. The
5 only connection is that Mr. Grovatt happened to be from New
6 Jersey.

7 And in fact, he is a Medical Monitoring plaintiff. And
8 so according to St. Jude, they believe he hasn't even suffered
9 an injury for the place of injury to occur.

10 We believe, Your Honor, based upon those statements, as
11 well as the interests of this state, in assuring that a
12 company that is governed by the laws of Minnesota does what is
13 necessary to not harm patients and individuals and consumers,
14 that the significant contacts clearly lead to application of
15 Minnesota law.

16 And, of course, that is exactly what Judge Magnuson
17 determined in the MDL for him involving Lutheran Brotherhood.

18 So we believe clearly that that law applies to the state
19 of Minnesota.

20 Briefly, Your Honor, I would like to address the
21 statutory consumer claims. This is set forth in extensive
22 detail in our briefing. But there are really two issues.

23 One: You have the Medical Monitoring class which seeks
24 injunctive relief. And clearly, the Minnesota consumer

1 Deceptive Trade Practices Act, do not require any individual
2 reliance, which is an issue that the defendants have raised in
3 the injunctive case. It's just not an issue.

4 Look at Judge Magnuson's decision in Lutheran
5 Brotherhood, the Group Health decision, where the Minnesota
6 Supreme Court set forth the standard. There are no individual
7 issues there. The state statutes themselves make that clear.
8 They don't require any actual confusion proven by the
9 individual.

10 The other issue then would be in the damages claim,
11 whether or not individual reliance needs to be proven. That
12 issue was addressed in the Group Health case. It was applied
13 by Judge Magnuson in the Lutheran Brotherhood case.

14 And it's clear that individual reliance is not necessary.
15 That this is a remedial statute. We have remedial statutes
16 which have a broad effect. And all that is required is a
17 causal nexus between the conduct and the injury. That can be
18 proven by circumstantial evidence. But there is no need for
19 direct testimony from an individual plaintiff.

20 That's really the two issues that are before the Court.
21 I think our briefing goes into much greater detail, but
22 supports everything I said. And I would again refer the Court
23 to Judge Magnuson's decision in Lutheran Brotherhood.

24 THE COURT: Thank you, Mr. Rudd.

1 THE COURT: Okay, Mr. Jacobson.

2 MR. JACOBSON: Good morning, Your Honor.

3 To just amplify on a couple items Mr. Rudd stated. The
4 type of representations that he described were also made by
5 St. Jude in their motion to transfer the Sliger case from
6 Missouri to Minnesota. Again, suggesting that Minnesota was
7 the only place that was appropriate.

8 And looking at it from the perspective of the defendant,
9 there certainly isn't any sort of a due process violation.

10 There's no right of the defendant St. Jude that would be
11 violated by having Minnesota law apply to their conduct, no
12 matter where the harm may have taken place. They are a
13 Minnesota company. They are based here. And they are
14 certainly subject to laws of this state.

15 Under Rule 23(b)(3), which is the provision in which the
16 injury class is seeking to be certified, the Court looks to
17 two primary issues:

18 The first is whether the common questions predominate or
19 individual questions. And the second is whether the class
20 action is superior to the other available methods for fair and
21 efficient adjudication.

22 In their papers, the defendant suggests, actually, as I
23 see it, two main reasons why they believe that these cases,
24 injury cases, should be treated as individual cases as opposed

25 to as a class action.

1 The first is a suggestion that with an injury case,
2 you're talking about big dollars. And each plaintiff has a
3 strong incentive to pursue their own case individually, and
4 has the likely financial outcome to make that something that's
5 feasible.

6 I would suggest that there are cases here, injury cases,
7 which are going to be substantial dollar cases, where the
8 likely awards are going to be in the millions of dollars.
9 There are also going to be injury cases in which the likely
10 award, because the injuries are less severe, are going to be
11 in the hundreds of thousands, or even less.

12 But in trying to determine whether that is enough, you
13 don't look just at the recovery amount. I think you also need
14 to look at the expense of getting there.

15 And these are a very expensive case for an individual
16 plaintiff to pursue on their own. The discovery in this case
17 to date, which has just been primarily the document discovery,
18 a few depositions, it's as large as any discovery you've seen.
19 We get documents on CD-ROMS. We're in the 70's now. And the
20 number of documents you can put on CD-ROM is immense.

21 The experts that we have involved in this case are real
22 experts who are involved in research, in medical care. They
23 don't have time or the willingness to traipse from court to
24 court to testify. And they're very expensive.

Plaintiffs have put a lot of money into this case. And I

1 would anticipate that it would be easily \$500,000 to get this
2 case prepared.

3 Now, for the MDL process, a lot of the work that's done
4 can be shared with individual plaintiffs. But there's still a
5 tremendous amount of expense that each individual plaintiff
6 would face in taking their individual case to court.

7 In determining whether to certify a class, there is a lot
8 of discretion on the part of the Court. The Court has the
9 discretion in most circumstances to determine whether, in its
10 view, it's capable of handling a case on a class basis or not.
11 And we believe that it's reasonable in this case to exercise
12 the discretion in favor of class certification.

13 So the one idea that plaintiffs have a strong incentive
14 and ability to go it alone, I don't think really holds up.

15 But I'll address that a little more.

16 The second is what Mr. Angstreich referred to as the
17 snowflake theory. The idea that everybody is individual.

18 And they talk about -- in their surreply materials, they
19 talk about a couple of factors. They say, well, maybe these
20 factors have some relationship to why some people have a
21 problem. And we have to study that.

22 Doctor Flory, and you saw earlier the excerpt from his
23 deposition, testified that he tested over 200 factors. And I
24 suggest to you that if these "maybe" factors that the

25 defendants are raising, if these "maybe" factors were part of

1 these 200 factors, we don't know what the 200 factors were,
2 Your Honor. And if they were part, then they were not part of
3 the fact. Because St. Jude's own research determined that
4 those factors did not have a part to play in the injury.

5 If they were not part of the 200, then I would suggest
6 that that's a pretty eloquent statement, that these are not
7 factors that affect them. If the company that's doing the
8 work, that has been studying this, they come up with 200
9 factors, so there's going to be things that are so trivial, if
10 it was something that important, it would have been on that
11 list. So the fact that they've done that and found nothing
12 other than Silzone I think eliminates the snowflakes.

13 In their argument, they suggest in part that by doing a
14 class, we're interfering with the individual plaintiff's
15 ability to pursue individual cases because they have an
16 incentive. Well, I would suggest, Your Honor, this is not a
17 mandatory class that we're seeking. There's going to be an
18 opt out. If individual plaintiffs feel that they want to
19 pursue their case individually, they have the ability to
20 simply opt out of this and to continue to do so.

21 But to follow defendant's theory is to have a mandatory
22 opt out in effect for all potential plaintiffs. And it
23 doesn't take into account the fact that many of these people,
24 the people that get the heart valves are typically elderly, or

25 at least older, typically ill. If the heart valve is failing

1 and not pumping blood to circulate properly in their body,
2 they're in not shape to really be pursuing interests.

3 We have people here who are sick, whose rights may expire
4 because of statute of limitations, because they're even
5 unaware of the potential claim, or lack the wherewithal or the
6 physical strength to pursue it at this time. A class action
7 protects the rights of these absent people.

8 And the Court, it's the Court that is the fiduciary for
9 the absent class members. Not the defendants. For the
10 defendants to come in and suggest, you know, this plaintiff
11 who is not here might want to pursue it separately, or this
12 plaintiff who is not here might want to have a different law
13 apply, well that's fine. They're entitled to make whatever
14 arguments they want. But really, it comes down to the Court
15 is the fiduciary for the potential class. And these
16 individuals' rights to pursue things individually are
17 protected through the opt out process.

18 Also, I would note that if a large number of class
19 members choose to opt out, and the Court determines that a
20 class in the future is not practical, is not a superior way,
21 the Court always retains the discretion to say circumstances
22 have changed. I'm de-certifying the class. You don't have
23 the option down the road if you don't certify now to certify
24 in the future.

1 plaintiffs, to make sure that they have a chance to have their
2 rights protected, and to receive recovery for their injuries,
3 a class certification I believe is the way to go.

4 We've cited in the briefs an immense number of cases.

5 And unless you have a question about particular law or
6 particular issues, I'm not going to go into that. I just
7 don't think it's necessary.

8 I think Mr. Angstreich covered, and Mr. Rudd covered so
9 many of the points I was going to do. I'm not going to take
10 more time. Unless there's a question, I will sit down.

11 But I would say that this is a suitable case for class
12 certification. The Court has the discretion to do so, and it
13 is reasonable to do so in this case.

14 THE COURT: Thank you, Mr. Jacobson.

15 MR. ANGSTREICH: Your Honor, based upon everything
16 that we've presented, we respectfully submit that the Court
17 should certify this case on behalf of Class I and Class II.
18 Thank you.

19 THE COURT: Thank you.

20 Before we turn to the defendants, let's take about a
21 five-minute break.

22 (A short recess was taken.)

23 THE COURT: Mr. Martin, are you going to proceed
24 first?

MR. MARTIN: Yes, Your Honor, I am.

1 THE COURT: Welcome.

2 MR. MARTIN: I'm happy to be here.

3 Our responsive argument, with the Court's permission,
4 will be divided into three parts. The first will be a short
5 overview by me, setting the stage for the issues that we are
6 going to examine and deal with. Then Tracy will present a
7 factual overview that is directly relevant to the
8 prerequisites of Rule 23. And then finally, I will come back
9 on the specific elements of Rule 23, and provide the Court
10 with a legal analysis of the issues relevant to certification.

11 Preliminarily, Your Honor, there was a portion of the
12 discussion this morning devoted to the merits of this dispute
13 on the development of the valve and other things, and a
14 preemption argument that crept in. I don't plan on addressing
15 any of that directly here. We've done it in our briefs, and
16 preemption is for a later day.

17 There are, however, a couple of things that I think need
18 to be kept in mind in view of the plaintiffs' arguments as an
19 overview.

20 The first is that these claims and the request for
21 certification is for a class-wide trial. That is the backdrop
22 against which the request for certification, whether it's for
23 injury or medical monitoring, has to be evaluated.

24 The other point is that Rule 23, Your Honor, is not an

25 end in itself. It's not a principle of substantive law. And

1 it's not something that's supposed to be invoked. Because
2 there are judicial economies or needs, or there is some level
3 of discretion that the Court can exercise because you can
4 envision a class-wide trial. It is only used when the
5 specific factors in the rule are met, and then and only then.

6 Plaintiffs' arguments for certification really fit two
7 paradigms:

8 One is that the one defendant, one product, one injury
9 cases readily lend themselves to class certification. And the
10 other paradigm is that any claimed health risk creates the
11 need for medical monitoring, and that creates a need for class
12 and for epidemiological studies and testing.

13 They principally cite four cases in support of their
14 paradigm: Telectronics, Boggs, Inter-Op, Diet Drug, cases
15 that are distinguishable and that we have undertaken to
16 distinguish.

17 But the basic problem with both paradigms is that they
18 don't hold up in this case against the discrete facts of each
19 case; the elements of the causes of action that are invoked
20 under the statutes; and finally, the specific inquiries
21 required by Rule 23.

22 As to the specific facts -- Tracy will emphasize this a
23 little bit more -- the record before this Court establishes
24 that there will be a principled, factual debate on whether the

25 Silzone valve is defective, and in whom. There will be

1 debates on whether the valve can cause injury, and in whom,
2 and why.

3 And these debates will be extended causes of action by
4 cause of action, theory by theory, plaintiff by plaintiff.

5 And it doesn't matter, Your Honor, for purposes of this
6 hearing today, who wins this debate. What matters is that the
7 debate exists.

8 It's going to be joined further on issues of law. And in
9 the second part of my argument, I will get specifically to the
10 conflict of law issues. But these nationwide cases in
11 particular do trigger a conflict of law analysis. The Court
12 has to undertake it state by state. And when the laws of
13 multiple jurisdictions are shown to apply, as they will be
14 here, the courts have described this as a morass, and rightly
15 so.

16 So the case law has taken a very different approach to
17 cases like these, where no one set of operative facts
18 establishes the right to recover, where the laws of myriad
19 states are implicated, where no one by proving their own case
20 proves someone else's. The cases send a singular message:
21 Class certification for injury or medical monitoring is
22 inappropriate.

23 Now, this isn't a surprising conclusion. And it's not
24 borne of some hostility to class certification. It's borne

25 from a rigorous analysis of the factors under Rule 23, the

1 spirit of the rule, and the letter of the rule.

2 The drafters of Rule 23 in fact recognized many, many
3 years ago that these sorts of cases were not suitable for
4 resolution in a class action. It's a specific comment in the
5 drafter's notes.

6 The Supreme Court of the United States, the first time it
7 got asked to resolve the issue, said very much the same thing,
8 and demonstrated why as a matter of predominance, adequacy of
9 representation and the like, these cases were not suitable for
10 class treatment.

11 The Third, Fifth, Sixth, Seventh, and Ninth Circuits have
12 all weighed in and said the same thing, as have district
13 courts across the country, from New York, to Louisiana, to
14 California, to Kansas. And here in Minnesota, in the Raye
15 case, and in the -- as well.

16 Now, plaintiffs quarrel with the applicability of this
17 law, Your Honor. And we've undertaken in our briefs and
18 exhibits to show why this unmistakable message translates to
19 these cases, too.

20 But the principal issue is that the fundamental inquiry
21 into the elements of the causes of action, and the facts
22 applied the elements of the causes of action is what defeats
23 predominance, it is what defeats manageability, it is what
24 defeats superiority, and it is what defeats medical

1 And whether the cases have multiple defendants, or
2 multiple products, or multiple injuries, when you see that
3 kind of factual diversity combined with the 50-state choice of
4 law analysis, then you can't certify a class.

5 And in the cases that the plaintiffs rely on, Your Honor,
6 these key factors and these major disputes were either
7 minimized, or they didn't exist. Defect was conceded. The
8 defect produced a readily identifiable injury. The cases were
9 settled, so there was no question of how they were going to be
10 tried. Predominance inquiries were not undertaken. Even the
11 conflict of law analysis was not done.

12 And those sorts of expediencies aren't present in these
13 cases or in this request for certification. Now, these
14 difficulties can't be glossed over. Again, they go to the
15 heart of what the rule is about.

16 The purpose of the inquiry here today is to determine
17 whether there's a genuine case in controversy presented by the
18 class plaintiffs, and how it will be presented.

19 And to amplify on that, Tracy is going to cover the
20 factual aspects of this case that show this uniqueness.

21 THE COURT: Very well.

22 MS. VAN STEENBURGH: Good morning, Your Honor.

23 THE COURT: Good morning.

24 MS. VAN STEENBURGH: Well, I would be remiss if I

25 did not raise the issue of baseball before we start.

1 THE COURT: Appropriate time of the year.

2 MS. VAN STEENBURGH: Yes. Especially with my
3 compatriots from Oakland sitting here. And as you see, Mr.
4 Kohn gets to run the bar code reader while I am up here.

5 Now, I'm not sure if I lost the bet or won the bet in
6 terms of who was going to win last night. But I'm glad the
7 Twins won, and they are on to victory, I'm sure, all the way
8 around.

9 MR. KOHN: No comment does not mean that I agree
10 with that.

11 (Laughter.)

12 MS. VAN STEENBURGH: But baseball is not an inept --

13 THE COURT: I should just add that Mr. Kohn isn't
14 going to win that one in this Court.

15 (Laughter.)

16 MS. VAN STEENBURGH: Well, baseball is not an inept
17 reference today, actually. Because it's funny, a couple days
18 ago, I heard Frank Viola interviewed. And he talked about the
19 days of Tom Kelly, and how Tom Kelly emphasized the
20 fundamentals. And it occurred that the fundamentals are what
21 we're talking about here.

22 The reason a nationwide product action alleging personal
23 injury and medical monitoring is not appropriate for a class
24 action is the fundamental. And what is the fundamental that

25 we have that we are faced with here? The elements of proof.

1 What are the elements of proof for the plaintiffs? What are
2 St. Jude Medical's affirmative defenses?

3 You know, on the medical monitoring claim, there has to
4 be some kind of proof on risk. But there are unique factual
5 inquiries that have to be made on that.

6 I listened to Mr. Angstreich very carefully, and wrote
7 down what he said. He asked the Court here to skip the
8 inquiry on risk. He said all the plaintiffs want is medical
9 monitoring because of the increased risk that they've been put
10 into. That the common thread is that St. Jude admits that it
11 was caused by Silzone.

12 As Mr. Martin indicated, those are all issues that are
13 going to have to be reviewed in every single case. You can't
14 make the assumption at this stage that risk is inherent merely
15 because someone has a Silzone valve.

16 Same with the product action. Whether there's a defect,
17 whether there is causation, all require factual inquiries.
18 And proof as to one plaintiff is not going to be proof as to
19 all.

20 The likelihood of risk, of complications by any one
21 patient really depends on the patient's medical history,
22 disease process, physical condition, anatomy. And there are
23 some genuine disputes as to whether some of these patients
24 really are at a heightened risk. Whether that risk is related

25 to the valve at all. Whether there was a defect. Whether

1 there is causation.

2 Proving any of those elements requires an individualized
3 inquiry.

4 Now, we have submitted affidavits I'm sure the Court has
5 seen by Doctor Riordan, Doctor Cheitlin, others. What we have
6 done is put together a sample of some of those individual
7 patient factors that truly demonstrate why this is an
8 unsuitable mechanism for class treatment.

9 First of all, we have the ages. We have 30 plaintiffs in
10 the MDL. Their ages range from 33 to 75. As Doctor Riordan
11 pointed out, age, unfortunately, as I have my glasses up here
12 with me, takes a toll on the eyes, but on the heart as well.
13 And your heart is a muscle, and the tissue changes over time.
14 And so age has to be a factor in considering any potential
15 outcome or complications.

16 Valve type. We have two kinds of valves: mitral and
17 aortic. I will not pretend to go through the differences in
18 those. But they are obviously in different places in the
19 anatomy. The difficulties in placing those valves. Sometimes
20 mitral valves are repaired, and then a mechanical valve is put
21 in. There are distinctions and differences that are important
22 because of the valve type.

23 The duration of the implant. The implant could be in as
24 short as a few hours, days, as long as up to four years for

25 some of the plaintiffs. With those for four years, what does

1 that say about risk, if any? For some of the shorter ones, as
2 Doctor Riordan has indicated, it may mean that there's a
3 surgical issue here, as opposed to anything having to do with
4 the implant itself.

5 Thus, issues of alternative causation arise with some of
6 these factors.

7 One of the most important factors, obviously, is the
8 cardiac history. These patients each come in with different
9 medical conditions, different histories. We have some who
10 have cardiomyopathy, which is a disease of the middle -- the
11 myocardium in the heart. We have others who have had
12 rheumatic fever, which is a condition that weakens the heart
13 over time.

14 A physician takes all of those things into consideration
15 in assessing whether there's a risk of complications from a
16 valve, or whether there is going to be a complication in the
17 future.

18 Another issue that shows the myriad of factors that have
19 to be considered are the implanting surgeons. That goes to
20 the issue of informed consent. What does the implanting
21 surgeon have to say about the risks that he was given in terms
22 of the warnings, what he understood, what he communicated to
23 the patients? Those are all relevant issues of liability, and
24 what that surgeon has to say about those cannot be just proved

25 up in one case and applied across the board.

1 Following cardiologists are also important, because it's
2 the cardiologist who determines the level of risk. It's a
3 medical decision based on all of those factors of history, of
4 complications, of whether the patient is taking their
5 medication that helps the cardiologist determine whether there
6 is an increased risk of complication, and what that monitoring
7 level should be.

8 The hospitals as well, there are a lot of hospital
9 related issues, lots of things can happen in hospitals.
10 Endocarditis, as we know, not just from this litigation, but
11 elsewhere, catching an infection in a hospital is a pretty
12 common occurrence. And so hospital-related issues are
13 relevant to any outcome that a patient might have, and it
14 would be important to inquire as part of discovery.

15 Two other ones: suture type and stitching methods.
16 Doctor Riordan has described how important those are.

17 The suture that's used, if it's thin, possibly could
18 break, which means there might be a paravalvular leak that has
19 nothing to do with the valve itself, but it could have been
20 the suture.

21 The same with suturing methods. The depth, the
22 anatomical design of the patient. All of those come into play
23 and must be considered.

24 The tissue implant also is a relevant inquiry, and may

25 differ from plaintiff to plaintiff.

1 And just because I want to use one of your toys, I'm
2 going to circle two of the important ones: calcification, and
3 then friable tissue.

4 Those are different kinds of conditions that a surgeon
5 may find when he goes into surgery. Calcification is the
6 hardening of the tissue because of calcium, and it has to be
7 debrided. But a little too little, a little too much can
8 affect whether the valve is going to function properly.

9 Friable tissue is breakable tissue. And again, that is
10 another consideration.

11 And finally, we have all of the intra and postoperative
12 complications that may or may not have anything to do with an
13 implant go to issues of alternative causation. Whether it be
14 someone who has a renal insufficiency, who has infection that
15 they picked up someplace else, who has all kinds of -- a
16 stroke that may not be related at all, but maybe in fact
17 because of medication.

18 So in sum, there are a variety of unique factors. And I
19 think to further illustrate this, what we have done is we've
20 taken a look real quickly at Ms. Bailey and one of the other
21 plaintiffs, Ms. Fox, and showed you where their differences
22 lie.

23 We have Ms. Bailey up on the screen at the moment. You
24 can see that she had a double valve implant. She had

25 congestive heart failure as a preexisting condition.

1 Fifty-one old at the time of implant. She had tissue, both
2 kinds, friable and calcified.

3 And most interesting, is a woman who had a urinary tract
4 infection after the valve was implanted, who ended up with
5 atrial fibrillation -- which is a rapid heartbeat -- and turns
6 out was diagnosed with a high cholesterol of 306 which, of
7 course, required monitoring that may not be at all related to
8 the implant. She missed dosages of her anticoagulation
9 medication, and was admitted to the hospital with a possible
10 stroke that may be related to that.

11 Ms. Fox, real quickly, was 72 at implant. Again, a
12 different age, a different heart condition. Mitral valve
13 only. She had rheumatic fever, and thus the condition of her
14 heart over a continuous period of time was affected by that.
15 She also had a heart -- a pacemaker, and had heart block, and
16 was admitted for pacemaker and lead changes.

17 Both of them still have their valves. And at last count,
18 the valves were functioning normally.

19 If you compare the two, which is our last slide, you can
20 see that there are a myriad of factors. And anything that
21 necessarily pertains to Ms. Bailey is not going to necessarily
22 apply directly to Ms. Fox.

23 In sum, Your Honor, the question here is, you know, what
24 are the things that we have to look at? What are the issues

25 that need to be examined? Those issues of risk. Those issues

1 of injury, of defect. Those all involve unique
2 characteristics, a unique factual inquiry. And there has to
3 be a case-by-case analysis in terms of whether it's a breach
4 of warranty, whether it's a product defect, and that a "one
5 size fits all" certainly will not apply.

6 Thank you.

7 THE COURT: Thank you, Ms. Van Steenburgh.

8 Mr. Martin.

9 MR. MARTIN: We know from the case law, Your Honor,
10 and it's not a matter of speculation, that this kind of
11 divergence that Tracy has identified translates directly to
12 Rule 23 requirements: typicality, commonality, predominance,
13 superiority, and manageability.

14 The point is that whether the valve has a defect, whether
15 it can cause injury, whether it requires follow-up treatment,
16 these are going to be disputed issues. And as I indicated, on
17 the elements of the cause of action, that requires jury
18 resolution.

19 These disputes, they don't go away because there's one
20 defendant, or one product, or because of paravalvular leak, or
21 thrombolism, or cancer. They are present in every case. The
22 patient's medical history, surgeries, experience with the
23 valve have to be investigated to even begin to determine
24 whether the valve played any role or, alternately, whether the

25 plaintiffs are even in the class, I or II.

1 Now, in this circumstance, when you see this kind of
2 diversity, the case law is unanimous. Rule 23's predominance
3 requirement is not met, and the cases aren't suited for
4 class-wide resolution. No other factors in this case override
5 that.

6 We have heard testimony about Mr. Flory and his supposed
7 identification of the cause as though that binds us to the
8 cause. Well, a full review of Mr. Flory's testimony would
9 reveal that he was encapsulating information that came from
10 the initial AVERT data. He wasn't talking about specific
11 causation in any person or individual.

12 And more importantly, the AVERT data that was available
13 at that point in time wasn't trying to determine the cause of
14 the injuries either. That is still a matter of contest and
15 debate.

16 Our product withdrawal, it's the same thing. That was
17 done for prudent reasons unique to St. Jude. It's no
18 admission of liability. We can contest liability. We can
19 contest damages. We can contest injury. And we're going to
20 do it, case by case, and claim by claim.

21 Now, preemption has been argued as though that's
22 overriding and somehow dispels this lack of predominance,
23 commonality, or typicality. But it's only one issue, Your
24 Honor.

And in the only case, Agent Orange, where that kind of

1 affirmative defense was deemed worthy of class certification,
2 it was the principal issue put to the court to resolve. And
3 the Agent Orange court, in the next breath, said: By the way,
4 if we had a personal injury product defect class or exposure
5 class that had individual inquiries on defect, cause, damage,
6 the need for further treatment, and the rest of it, we
7 wouldn't have certified this class. That's too amorphous, and
8 it's too unwieldy, and it won't work.

9 St. Jude's benefit program was described as a medical
10 monitoring program. We have not put any medical monitoring
11 program in place. What's done is the benefits are paid for
12 people who have claims. And none of that takes away from the
13 essential elements of this dispute.

14 Now, although plaintiffs disagree with it, the lack of
15 predominance is manifested in these cases in another very
16 fundamental way. And that is there is going to be a
17 nationwide dispute in these product defect cases about the
18 applicable law.

19 Now, at a minimum, plaintiffs again skipped one
20 fundamental here. And that is that at the outset, due process
21 requires the Court to consider this issue state by state and
22 plaintiff by plaintiff. We know that from the Shutts case.
23 We know that from all the published Federal Circuit Court
24 cases and district court cases that deal with it. You've got

25 to do that before you certify.

1 In fact, the plaintiffs are supposed to put in a trial
2 plan that would account for this, and show the Court how it
3 ought to be resolved. They haven't done that. That alone is
4 grounds to deny this motion.

5 But the choice of law inquiry does implicate all 50
6 states. Because Lutheran Brotherhood notwithstanding, where
7 you have personal injury and economic loss, and that requires
8 an examination of multiple states' jurisdictions. Because as
9 the courts have said, and they're unanimous on this, every
10 state has some interest in the compensation of its residents,
11 or whether they can recover for injuries that occurred in that
12 state from products that made their way to that state.

13 You can't discount that at the outset. Plaintiffs do it.

14 But again, the federal cases are unanimous, that the place of
15 residence, the place where the injuries occurred, or the place
16 where the product was bought all have an interest in the
17 dispute.

18 Now, once you get to Minnesota's conflict principles --
19 and I'll make it easy. I'll assume that Minnesota's conflict
20 principles apply -- although there could be some debate about
21 that -- they don't truncate this inquiry either.

22 First of all, they don't adopt this headquarters theory,
23 or place of manufacture theory as an absolute principle of
24 conflict of laws. And the plaintiffs' suggestion our MDL

25 pleadings which transferred the cases here have disposed of

1 this wrong place, wrong time, wrong issue, the point is that
2 the cases have rejected corporate headquarters as trumping
3 this nationwide inquiry. They've rejected the place of
4 manufacture and product defect and economic cases as trumping
5 the conflict. And these other interests still have to be
6 considered.

7 Now, let's just take the two cases cited by plaintiff
8 that illustrate Minnesota conflict principles. The Nodak
9 case, 604 N.W. 91; and the Neslidek case, 46 F.3d 1995. Both
10 those cases, using Minnesota conflict principles, applied the
11 law of a foreign state. That's the issue before the Court
12 with respect to the individual plaintiffs here. Both held
13 that consistent with Minnesota conflict principles, the law of
14 the foreign state at a minimum had to be considered and
15 examined. My point on the burden that the Court has to
16 undertake as a threshold matter.

17 And both courts note that the two states have an interest
18 when they have law on the issue. That's all it takes. And we
19 have put before the Court a 50-state survey to show that on
20 every claim in this case, there is law in some state for some
21 purpose.

22 Now, what do you have to do then? You have to look
23 outside. And that's what both those courts did as well. And
24 it matters.

1 from Nebraska, even though it was less favorable, and
2 prohibited a recovery. It found that interest to be
3 paramount.

4 There's also a risk here on this uniform application of
5 Minnesota law. The plaintiffs have assumed, for example, that
6 medical monitoring would be available. Well, the Werlein case
7 is skeptical about that. But at a minimum, it indicates that
8 an injury is required before medical monitoring recovery is
9 available.

10 And the point there would be that on that issue,
11 Minnesota law may well be less favorable. And to be sure, it
12 might advantage some plaintiffs, but it might disadvantage
13 others. And we don't just make that inquiry go away by
14 resorting to the place of manufacture or the corporate
15 headquarters of the defendant.

16 Now, to be sure, plaintiffs' request for Minnesota only
17 would make these cases easier to administer. But making them
18 easier to administer is an "ends justifies the means"
19 analysis. It's not part of class action analysis. It rejects
20 principles of due process that are well established. And in
21 fact, it violates basic principles of federalism, as the
22 Bridgestone case points out.

23 On superiority and manageability. When you take these
24 multiple factors of inquiry on the basic elements of the

25 claim, and you combine that with a 50-state law inquiry, the

1 courts are uniform that this is a nightmare, and it's not
2 capable of being tried in any fashion that makes a class
3 action superior. It's not possible to instruct the jury.
4 Going plaintiff by plaintiff is an exhausting exercise, but
5 you can't avoid it. And no case has attempted it. Not for
6 injury, and not for medical monitoring.

7 What it does do is superpose delay, prejudice, and
8 confusion, and result in an appeal. So the class members
9 really don't gain a whole lot by it.

10 What's the expedient alternative? Have the benefits of
11 combined discovery in this MDL, send the cases back to
12 individual adjudication in their jurisdictions under law that
13 can be applied there, and let the matter develop in that
14 fashion.

15 That is a better method for resolving the disputes. It
16 certainly demonstrates that the class action here is not a
17 superior method to resolve these disputes. It's (b)(3)'s
18 requirement, not mine.

19 There is no threat from this maneuver. The cases are
20 small in number nationwide, and they can be easily managed in
21 the respective jurisdictions.

22 Medical monitoring. A lot of emphasis has been put on
23 medical monitoring here. We have briefed it well.

24 But let me start with a couple of overview points there.

25 Your Honor asked the question of whether a lot of cases have

1 undertaken this. And the answer to that is no.

2 They haven't because it's considered to be a major step
3 to invade this kind of process, where treatment decisions are
4 concerned. It's considered to be a major concern because
5 these are nonopt-out classes that create problems of their
6 own.

7 And so the courts have been hesitant to do it. And I
8 dare say that no court has done it on facts like these.

9 Now, what are some of the reasons that the Court would
10 want to hesitate here before rushing head-long into this
11 medical monitoring approach?

12 The first is the debate on the risk.

13 We have a very strong argument here that there is no risk
14 from this product. The reliable scientific testimony, the
15 AVERT data establish it.

16 Plaintiffs don't analyze that data. They don't make an
17 attempt to interpret it. They criticize the AVERT study as
18 somehow being undernumbered. But the point is that our expert
19 affidavits demonstrate why it is indeed the gold standard as
20 applied by the FDA.

21 We can start with how they get around that by trying to
22 say that there are some risks. That all comes from anecdotal
23 studies that are not a reliable basis to determine a risk in
24 the first instance.

1 because the original AVERT study identified a potential risk
2 of paravalvular leak. I mentioned it earlier, and I want to
3 reinforce it. That AVERT study, and to this day, the AVERT
4 study is not attempting to establish causation. The authors
5 of that study would be surprised to learn that that was a
6 conclusion.

7 Furthermore, it was preliminary. Now that the AVERT
8 study is two years further down the line, and we have a case
9 controlled epidemiological pool, the plaintiffs are backing
10 away from this as though it doesn't matter.

11 But the point is, Your Honor, in terms of hesitancy,
12 there is going to be a debate on the risk.

13 There's no need. We've heard a lot about need. But only
14 a small number of people actually are affected here, under
15 anybody's analysis. Physicians are routinely following these
16 patients.

17 And the FDA has said that's enough. It hasn't said we
18 need a monitoring program. And it knows the risks, and it
19 knows the issue. It's been in front of the FDA.

20 And in fact, as Barbara Jones said, the AVERT data
21 fulfills this purpose. It is already collecting the
22 information that would be relevant.

23 So the plaintiffs will come back and debate this. But
24 consequentially here, you've got a question of need.

1 detect any of these conditions that the plaintiffs are talking
2 about. And let me make that clear. An echocardiogram doesn't
3 do it. A CT scan doesn't do it. It isn't the kind of
4 situation where you can just undertake the test and figure out
5 the risk.

6 Their proposal for medical monitoring here, one of our
7 experts said would provide nothing useful in terms of patient
8 treatment. Again, that is a concern. It should cause the
9 Court to hesitate.

10 Standards of practice. This calls for individual
11 physician decisions, including on whether echoes should be
12 used, or CT's, or any of these other tests. It need to be
13 customized to a plaintiff's current medical condition.

14 And this is not empty rhetoric, Your Honor. These are
15 physicians who treat these patients who say that this is the
16 appropriate way to proceed. Not by introducing a bunch of
17 tests that are not called for, or that a treating physician
18 doesn't want. And that is again something that should cause
19 the Court to hesitate.

20 In fact, the medical community says no to the protocol
21 that plaintiffs have provided. And that's not contradicted in
22 this record.

23 Difficulties of proof. Defect, causation, and injury,
24 those debates don't go away in a medical monitoring case.

25 There's no right to monitoring in the abstract. You've got to

1 find a cause of action. You've got to prove it. And you've
2 got to prove it under state law.

3 So all the problems that exist in terms of lack of
4 predominance, lack of superiority, lack of manageability
5 persist with medical monitoring. You've got to have proof of
6 enhanced risk tied to the product with the specific need for
7 it.

8 We put the elements of the claim in there. That is a
9 plaintiff-by-plaintiff inquiry of necessity here, to prove
10 that any plaintiff would be entitled to medical monitoring
11 over and above what they're already receiving. Much less
12 trying to link it to the product or any identified risk.

13 There's a due process issue out there, Your Honor. And
14 it's a fundamental one. The plaintiffs have slipped a
15 footnote into their opening brief at page 47, it's footnote
16 34, which says go ahead and do this medical monitoring, but
17 reserve out their later personal injury claims. Don't get
18 into that. Because these plaintiffs might have a claim later.

19 Now, the Thompson case from this district has already
20 identified the problem with that in a no opt-out situation.
21 And the Thompson case has cautioned that you shouldn't be able
22 to achieve class certification by tailoring your claims and
23 splitting a cause of action. That's a problem. And it will
24 be the problem for plaintiffs later who are faced with this

25 argument when they bring these subsequent suits.

1 It also creates a problem with the principal benefit of a
2 class certification. It's supposed to have res judicata
3 effect and some finality.

4 But what we're told is, even if you do this, we could
5 still face a host of other lawsuits. No judicial economy
6 would be achieved.

7 And you have to ask about the adequacy of representation
8 in these circumstances, where these plaintiffs potentially
9 being represented in this medical monitoring class are going
10 to be deprived perhaps of later lawsuits that the plaintiffs
11 indicate are going to be filed.

12 Now, if these cautions don't cause the Court to hesitate
13 and stop this before it starts, let's look quickly at the
14 specific requirements under the rule.

15 Rule 23(b)(2). It's an injunctive relief provision.
16 These claims for medical monitoring were not within the
17 historical perspective of 23(b)(2). It was intended to
18 redress civil rights violations under federal law that
19 occurred on class-wide bases.

20 That is not this case. Not even close to this case. And
21 that is not my characterization of the rule. That comes from
22 the drafters and the cases that have interpreted it.

23 Apart from not being within the historical purpose, the
24 idea that the money gets paid to the court by St. Jude, and

25 somehow making the court an intermediary establishes that this

1 is injunction relief has been rejected uniformly by the cases.

2 Where like here, the money is going to go to detection,

3 diagnosis, and treatment, the courts have said that fund

4 established under court auspices is damages. It's not

5 injunctive relief.

6 And treatment as damages will not come under 23(b)(2).

7 And this case is fungible with Zinser in its request and the

8 other cases that have rejected this.

9 Even if you got by that injunctive damage distinction,

10 there is no cohesion here in this class for the same reasons

11 it flunks under (b)(3). The individual issues to even

12 determine the right to monitoring or the need for it outstrip

13 any class-wide benefit. And that takes it away from the

14 appropriate 23(b)(2) requirements. The Rezulin case makes

15 this very clear.

16 23(b)(1)(A), Your Honor, gets the plaintiffs no farther.

17 It also is not this claim for medical monitoring within the

18 historical purposes of the rule. And I recognize that the law

19 can be adapted. But that's a good place to start for

20 determining whether we ought to let this get off the ground.

21 23(b)(1)(A) on inconsistent standards of conduct was

22 intended to protect the defendant. And it was intended to

23 help the defendant from being caught in the bind of having to

24 pay attention to different conduct as it related to shares of

25 stock, or the administration of a trust. Not because it might

1 be subject to different damage awards in different
2 jurisdictions.

3 In fact, the risk of separate damage awards doesn't meet
4 the requirements of the rule. The cases are uniform on that.
5 And the Zinser case makes it clear that that extends to
6 programs like the ones that the plaintiffs want to implement.

7 The fact that St. Jude might be subject in various
8 jurisdictions to claims for medical monitoring on an
9 individual basis doesn't create the kind of incompatibility
10 that the rule is talking about. This is not the Boggs case.
11 This is not the Teletronics case.

12 Both of those cases that the plaintiffs rely on, the
13 defendant's standard of conduct related to issues that didn't
14 involve these kinds of personal injury claims. In Boggs, it
15 had to do with the defendant's operation of the power plant.
16 And clearly, subjecting a defendant to inconsistent standards
17 of operation clearly failed within the rule.

18 In Teletronics, the defendant had an existing and active
19 medical monitoring program of its own that was overseen by the
20 FDA. And there was a risk there because of that ongoing
21 program that the defendant would be subject to inconsistent
22 standards, and the court undertook to fix that.

23 And finally, if the Court does conclude, as I think it
24 should under the controlling law, that this is in reality a

25 claim for damages made by personal injury claimants, you can't

1 have a nonopt-out class for damages. That's a matter of
2 constitutional law as set forth in the Shutts case and
3 reflected in the other authorities.

4 Very briefly, Your Honor, I want to walk through a couple
5 of the plaintiffs' principal cases to demonstrate some of the
6 significant differences that exist between this class and
7 these requests for class, whether it's medical monitoring or
8 injury, and what's going on elsewhere.

9 Diet Drugs was minimized as a settlement class, but that
10 is pivotal to the outcome in that case. No issues of
11 predominance or superiority for trial. The key dispute here
12 were before the court in that case.

13 No 50-state conflict of law analysis was undertaken or
14 required, because the parties were settling the case.

15 The FDA had issued a public health advisory in pursuit of
16 the defect alleged in the case. And there was a medical
17 consensus on injury, and the test, and the detection, with the
18 monitoring program having been initiated by independent
19 organizations.

20 None of those factors are present in this case.

21 Inter-Op, again a settlement class. No predominance or
22 superiority analysis undertaken for purposes of trial. A
23 single proximate cause. A defect was admitted by the
24 defendant. And there was a medical consensus that the defect

25 could cause injury.

1 All of those are disputed issues here. None of those
2 factors are present.

3 Teletronics. No dispute on defect again. A single
4 proximate cause. Medical consensus on the injury. FDA
5 advisory on the risk. The defendant had a medical monitoring
6 program in place. And there was no dispute based on FDA
7 oversight of the need for monitoring.

8 These cases are a far cry from this one. And they are
9 the hallmark of why the plaintiffs say the Court should act.

10 We submit there's another line of authority, Your Honor, that
11 indicates that the Court should not act.

12 And in closing, I would just make this point: The
13 plaintiffs have identified here, through anecdotal studies and
14 some expert testimony, a supposed need to act for a risk that
15 in its very essence is a matter of medical debate. It's a
16 matter of debate also whether any further care or treatment
17 ought to be implicated based on this. And it's also a matter
18 of debate whether this identified risk gives rise to any legal
19 liability.

20 That is the occasion for an individual lawsuit where
21 proof will be required. And if that's what the Court is going
22 to undertake, whether for the injury class or for medical
23 monitoring, class action shouldn't be used. It's not the
24 superior method for resolving the dispute. And there is no

25 compulsion to go forward with a class action simply because

1 somebody has asked for it.

2 What the Court has to examine in its exercise of
3 discretion is whether or not it's the appropriate way to
4 proceed. And if the benefits can be achieved in other
5 fashions, that's not only appropriate, it is consistent with
6 the purposes of the rule.

7 The rule is to be used only when it's demonstrated,
8 whether it's 23(b)(3), 23(b)(1)(A) or 23(b)(2), that it
9 applies, and convincingly applies.

10 Absent that, the cases should be left to coordinate a
11 discovery and individual resolution. And the plaintiffs can
12 have their day in court in that fashion whatever the outcome
13 of the case.

14 THE COURT: Thank you, Mr. Martin.

15 MR. ANGSTREICH: Your Honor, before we begin
16 rebuttal, Mr. Capretz wants to clarify something on the
17 record.

18 THE COURT: Very well.

19 MR. CAPRETZ: Actually, I don't think we need much
20 time to do the rebuttal aspect.

21 I want to mention, because I think there's some
22 misunderstanding of what the plaintiffs are seeking. And I
23 don't think it's clear at all, based on the comment of the
24 gentleman who just spoke, as well as Tracy. Just some tidbit

1 First, the small number of people affected. I have no
2 idea where they come up with the small number of people
3 affected, except that they're talking about the number of
4 lawsuits, approximately 150 or so filed. But we know there
5 are thousands of people that are impacted.

6 There's been overall discussion of the increased risk by
7 the various studies which they denigrate by saying these are
8 studies commissioned by themselves, they call them anecdotal.

9 So I think some of these things -- and then, most
10 interestingly, the comment is made we have failed to file a
11 trial plan. Most disingenuous, because they well know, Mr.
12 Stanley was approached by me on several occasions of setting
13 out a trial date and getting on with establishing a trial
14 plan. And it was always that it was premature to do until we
15 had this hearing.

16 So I would like, you know, to make sure the record clear.

17 And so the Court is aware, the risk is not a question of
18 whether or not four years the valve has been implanted, and
19 therefore there is no risk attendant, because a risk was
20 attendant to the valve that it would have presented itself by
21 this time.

22 The fact is, as Mr. Angstreich brought out, paravalvular
23 leakage goes in gradations. And it grows with many people
24 from a mild form, to a moderate form, to a severe form. When

25 it's in a mild form, very simple and conservative treatment is

1 all that is needed. But at four years, may well be the time
2 it took to get to a point where it's moderate to severe, and a
3 prophylactic explantation is in the cards.

4 The point I want to make about the medical monitoring, as
5 to what are we seeking, the medical monitoring that plaintiffs
6 are seeking, we're seeking first to locate and notify all
7 patients, number one.

8 Number two: To create a registry and baseline database
9 of class members.

10 Number three: To do research and assemble further
11 epidemiological data on the continuing danger.

12 Number four: Enhanced periodic monitoring and
13 assessment.

14 Now, the merits are not at issue, as I think the
15 gentleman has conceded. And as we brought out in our brief,
16 there has been repeated calls for some sort of monitoring.

17 There are specific recommendations for transesophageal
18 monitoring. Now, this is an invasive, expensive procedure
19 that many of these patients might not be otherwise be able to
20 afford.

21 We are not advocating interfering in the doctor/patient
22 relationship. The uniform Class I remedy in no way overrides
23 the judgment of patients' personal physicians, or prevents
24 them from attending to their individual health needs. That

25 will always be necessary.

1 This case provides an opportunity for an additional
2 health care option for these patients, and fulfills the health
3 need that all members of the class share as a common need.
4 And we talked about the increased risk that's prevalent.

5 So it's not a question of us creating some new device.
6 It's not a question of showing angular differences between two
7 of the class representatives. Of course, each individual is
8 unique. Each has its own DNA. We know that.

9 The common ground is that they have this valve, and this
10 valve has been shown to have an increased health risk
11 connected to it.

12 So it's quite elementary, that we're working from two
13 different pages.

14 We seek this Court's help and order to hold St. Jude
15 Medical accountable for its actions and omissions, and
16 responsible for certain research and health care costs of U.S.
17 Silzone patients. Quite simple.

18 The St. Jude company put Silzone patients in harm's way.
19 That's a reality. And it needs now to act as a good corporate
20 citizen, and stand accountable for what it has done. It is
21 disappointing that the company must be required by a judicial
22 system to do that which it should have done on its own.

23 Thank you, Your Honor.

24 THE COURT: Thank you, Mr. Capretz.

1 MR. ANGSTREICH: Thank you, Your Honor.

2 Your Honor, I'm certain that Mr. Martin didn't
3 intentionally misspeak relating to the Diet Drug case, and the
4 fact that we keep relying upon the settlement class. I
5 thought I took care of that in my opening presentation. We're
6 talking about the 1999 decision.

7 But what is more incredible is the fact that he
8 denigrates a judge's determination that a settlement class
9 should be approved. Because under the Supreme Court's
10 decisions in Amchem and Ortiz, the federal court is required
11 to more carefully scrutinize a settlement class. To make
12 certain that it is intended to benefit the class members, and
13 is not some other vehicle by which lawyers are to pad their
14 pockets.

15 So the Supreme Court made it very clear that a settlement
16 class is not given short shrift. In fact, it's to be given
17 greater scrutiny.

18 It's also incredible that he came and told you that
19 Doctor Flory didn't testify the way he did. I didn't see a
20 certification from Doctor Flory to tell us that he misspoke,
21 that he wasn't talking about St. Jude's efforts after the
22 recall. Because that's exactly what his deposition indicated.
23 But that's a factual dispute that goes to the merits.

24 What we do know is he said: We looked. He didn't say

25 AVERT looked. He said: We looked.

1 Now Mr. Martin would like you to assume that he spoke
2 about somebody else. The fact is, they looked at them.

3 But that gets into the disingenuousness of the entire
4 presentation by the defendant here. You don't assess risk on
5 an individual basis. You assess the risk class-wide.

6 That's why when the risk was evidence from AVERT, they
7 pulled it off the market. But they pulled it off the market
8 after three other jurisdictions banned it, not voluntarily.

9 Now, therefore, it has to be done across the board;
10 therefore, you must have an epidemiological study to assess
11 the real problems that these people face.

12 Now, I didn't see anything in the package inserts with
13 these valves that said that this valve is contraindicated
14 based upon age. It's contraindicated based upon how long
15 you're going to keep it in your heart. What your cardiac
16 history is. Whether your surgeon is competent or incompetent.
17 Whether he follows this suture type or that suture type. What
18 kind of stitching methods are going to be employed? What
19 hospital are you going to go to? You know, if you go to a
20 hospital that's just not clean, you could have problems.

21 I didn't see any of that in any of their warnings.

22 More importantly, you would think all of those factors
23 are the very factors that they looked at, and found none of it
24 attributed to any of those specifics.

1 this. There is no debate over the proximate cause of the
2 problem. They determined it to be Silzone. Now they would
3 like to get up here and say: Well, we're going to defend and
4 say that it wasn't Silzone. We're going to say it was
5 possibly something else.

6 Well, the Federal Rules of Evidence don't let an expert
7 get up and opine that it was possibly something else. It has
8 to be with a reasonable degree of probability in the field of
9 expertise. Not within a reasonable degree of possibility.

10 These are clearly red herrings. And they are clearly
11 within the 200 criteria that was looked at. And they clearly
12 would deal and assist us in an epidemiological study.

13 Also, Mr. Martin misspoke when he said that we can't be
14 held accountable, St. Jude, for what they put in their MDL
15 pleading. Well, Mr. Rudd didn't reference the MDL pleading.
16 He referenced the motion for transfer filed in Grovatt.

17 Also, the motion to transfer in Sliger, St. Jude said
18 this case should be transferred to Minnesota to further
19 interests of justice in having the court most familiar with
20 applicable law handle the case.

21 Applicable law. So when it suits their purpose to ask
22 courts to transfer the case from St. Louis, or from Camden,
23 New Jersey, to Minnesota, because Minnesota would be the most
24 one familiar with applicable law to handle the case, that was

25 okay. But now they come in here and they say, oh, no, you're

1 not the one.

2 Now, they also misquote Shutts. Because at page 30 of
3 our reply brief, we have the quote: A significant contact or
4 significant aggregation of contacts between the state and the
5 claims of class members, such that the choice of its law is
6 neither arbitrary nor fundamentally unfair, allows under a
7 constitutional analysis the choice of one state's law to be
8 applied against nonresidents. Further need not be said in
9 that regard.

10 The concept that the FDA hasn't told them to do a medical
11 monitoring program, that's not a statutory power that the FDA
12 has been given. They have no power to tell a company you must
13 do an epidemiological study or a medical monitoring study.

14 What they did tell them to do was you have to do a study
15 to see if it's efficacious before you can say that it fights
16 endocarditis, the study of the 4,000 people which never got
17 finished, and never proved the basis for which they were
18 entitled to put this thing out in the first place and sell
19 people on.

20 The fact that all of these issues are going to be debated
21 and disputed, it will be debated and disputed then in 10,000
22 cases instead of one case. That doesn't make sense. That
23 doesn't establish superiority by sending it off to other
24 places.

1 is going on. And damages is the tail. It is not entitled to
2 wag the dog. It just doesn't work that way.

3 Everybody knows in every class action that you may have
4 to have many trials on damages. But to assert that there are
5 other possible causes without one scintilla of evidence, and
6 then to say, oh, but remember, merits is not to be argued
7 today. But guess what? There are all of these other issues
8 we're going to raise.

9 Well, everybody raises all of these other issues. The
10 fact is that they did their analysis, they did their study,
11 and they never were able to prove it.

12 By the way, Your Honor, on pages 47 through 52 --
13 actually 51, of our original brief, we address the cases which
14 have applied medical monitoring as they exist right now.

15 And the fact that the drafters of Rule 23 in the '60s
16 didn't envision medical monitoring, that's no surprise. I
17 don't think 10 years ago, or 15 years ago we would have
18 envisioned medical monitoring as a remedy that's required
19 because of the rush to market all of the drugs and all of the
20 devices and all of the combination products that we face
21 today.

22 And if we were limited to what the drafters meant by
23 this, we wouldn't be standing here today, and the benefits of
24 class action litigation would not be available to all of the

25 people.

1 My final point, Your Honor, is simply because the
2 defendant may appeal an award of certification is not a basis
3 for not certifying this case. And I don't think that it was
4 intended to be a basis why Your Honor shouldn't reasonably
5 consider the certification of both of these classes.

6 And under all of the circumstances that we've raised --
7 and obviously, Your Honor, I can't and wouldn't spend the time
8 to go point by point. I think the briefs have done it. I
9 just wanted to highlight these. This case cries out for
10 certification for both classes. Thank you.

11 THE COURT: Thank you, Mr. Angstreich.

12 Anything else?

13 MR. MARTIN: No, Your Honor.

14 MS. VAN STEENBURGH: No, Your Honor.

15 THE COURT: Okay. Very well.

16 Mr. Capretz.

17 MR. CAPRETZ: There is one procedural point -- I'm
18 not arguing the particular merits. But as the Court may well
19 recall, the question was raised about the brief filed by the
20 defendants concerning the objections to the evidence. I
21 believe this Court instructed the class that it need not
22 respond unless the Court had certain questions or would pose
23 those questions.

24 I just want the record clear that we did not file a brief

25 on that because we had not heard from Your Honor.

1 THE COURT: And I don't think anything is necessary,

2 Mr. Capretz.

3 MR. CAPRETZ: Thank you.

4 THE COURT: Anything else for today?

5 MR. CAPRETZ: Yes, Your Honor, we do have a couple
6 housekeeping.

7 One is, I'm going to preempt my colleague, Mr. Kohn, in
8 the sense of the state court proceeding. We were just told
9 yesterday that the new judge, Judge Gearin, is holding a
10 status conference this afternoon. I was told yesterday.

11 Unfortunately, we won't be able to make that today.

12 But so that the Court is aware, you asked the Court to be
13 apprised of the state court action.

14 THE COURT: Okay.

15 MR. CAPRETZ: There was a telephonic motion heard by
16 the judge, I understand. I don't think anything else has
17 transpired. We hopefully will know more.

18 And we would like to ask the Court to set some date for
19 the next conference.

20 THE COURT: Okay, I think that Ms. Gleason will take
21 care of that with you. She's going to work out with you all a
22 status conference date. She'll talk to you next week to work
23 it out.

24 MR. ANGSTREICH: Very good.

1 motion under advisement, and will issue a written decision as
2 quickly as possible. I appreciate the arguments today.

3 The Court is in recess.

4 (Court recessed at 12:22 p.m.)

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20 CERTIFIED:

Karen J. Grufman
Official Court Reporter

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