

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: St. Jude Medical, Inc. File No. 01-MD-1396
Silzone Heart Valves (JRT/FLN)
Products Liability Litigation

Minneapolis, Minnesota
October 14, 2003
1:45 P.M.

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

(PLAINTIFFS' MOTION REGARDING PROPOSED SUBCLASSES & STATUS
CONFERENCE)

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1 (In open court.)

2 THE COURT: You may be seated everyone. Good
3 afternoon. On the Court's civil calendar today is case
4 number 01-1396, In Re: St. Jude Medical, Incorporated,
5 Silzone Heart Valves, Products Liability Litigation.

6 Counsel, note your appearances, please.

7 MR. CAPRETZ: James Capretz for the plaintiff.

8 MR. ANGSTREICH: Steven Angstreich for Class I.

9 MR. JACOBSON: Joe Jacobson for Class II.

10 MR. RUDD: Gordon Rudd for plaintiffs.

11 MR. SILVA: Mario Silva for Bonnie Sliger.

12 MR. MURPHY: Pat Murphy for plaintiffs' state
13 liaison counsel.

14 THE COURT: Good afternoon, all of you.

15 MR. NILAN: Michael Nilan for St. Jude, Your
16 Honor.

17 THE COURT: Mr. Nilan.

18 MR. KOHN: Steven Kohn for St. Jude, Your Honor.

19 MR. MARTIN: James Martin also for St. Jude.

20 MR. STANLEY: David Stanley for St. Jude, Your
21 Honor.

22 MS. VAN STEENBURGH: Tracy Van Steenburgh for
23 St. Jude Medical.

24 MS. PORTER: Liz Porter for St. Jude Medical.

25 MR. BORANIAN: Steven Boranian for St. Jude

1 Medical.

2 THE COURT: Good afternoon to all of you. We
3 have arguments this afternoon on the motion regarding
4 proposed subclasses, and I suggest we go through that
5 first, and then we will move on at that point to our status
6 conference scheduled for the afternoon.

7 Mr. Angstreich?

8 MR. ANGSTREICH: Yes, Your Honor. Thank you.
9 Your Honor, before I address the subclass issue, I just
10 wanted to make a point. Despite a statement made by
11 Mr. Kohn at one of our last hearings that St. Jude's
12 position with respect to the subclass briefing would not be
13 an attempt at a reconsideration of class recertification,
14 we have before the Court appendices, the overwhelming
15 majority of which were the very same appendices supplied
16 during class certification argument.

17 We have challenges to typicality, common issues
18 and superiority of the class which are not the issues that
19 we understood were issues to be addressed at this time.
20 Rather, the issue to be addressed at this time was the
21 manageability of this case based upon subclasses.

22 The criteria for Rule 23 determination was
23 argued, I believe, over a year ago. This is not the time
24 to do it. I think Your Honor's opinion at pages 6, 7 and 9
25 make it clear that you focused in on typicality. You

1 focused in on common questions. You focused in on the
2 superiority of the class action. You found that all of
3 those criteria were met, and you asked us then to address
4 subclasses and manageability.

5 Local Rule 7(g) has not been complied with, and I
6 would ask that any attempt by St. Jude during their
7 presentation to reargue the issue of the fact that each
8 plaintiff is different and all of the other efforts at
9 attempting to litigate whether or not this is an
10 appropriate class action should not be permitted.

11 Turning to the issue at hand, Your Honor
12 recognized in the conditional certification order that we
13 should focus in on the differences to the extent that there
14 are differences of a substantial and significant nature,
15 and that's what we did when we addressed each of the
16 different causes of action.

17 We agree that no plaintiff in this case is the
18 same. We agree that no state law is identical. That's not
19 the issue and it's not the test. If that were the test,
20 then Telectronics could never have gone forward with the
21 subclasses that Judge Spiegel found.

22 The reality and the issue is, how can we try this
23 case, how can we present this case based upon the legal
24 theories that are before the Court in a manageable fashion
25 affording due process to both the plaintiffs and the

1 defendants, and what we attempted to do, Your Honor, in our
2 submission was to look at those significant differences and
3 say, how do you deal with it? Is it an issue of proof as
4 opposed to a semantical issue of, giving an example,
5 whether you call something terminated or something
6 cancelled or something ended.

7 The meaning is the same, so do you deal with the
8 language of the particular case law, or do you look at what
9 is the quantum of evidence? What do you have to prove? We
10 tried to address the issues in that fashion. Mr. Jacobson
11 is going to deal with the negligence count, negligence
12 claims, as well as one of the defendants' affirmative
13 defenses, which is contributory negligence and comparative
14 negligence. So I will not touch on those.

15 When you look at medical monitoring, and we
16 should start there. I apologize again. Let me step back.
17 We gave you subclasses. St. Jude gave you no subclasses.
18 St. Jude didn't say, these are the subclasses that should
19 be. What they effectively said to you was, you can't have
20 any subclasses because you really need 51 subclasses for
21 each of the different causes of action.

22 I came up with 306 subclasses. I probably
23 overstated their position by some factor, maybe three or
24 four, but certainly a lot many more potential subclasses
25 are on their plate. They also suggested to you that you

1 should not even consider this motion or this issue because
2 we haven't come forward with named plaintiffs for each of
3 the proposed subclasses.

4 We submit that there is no requirement at this
5 time to do that. We don't even know which subclasses Your
6 Honor will certify or find appropriate. Certainly to the
7 extent that any named representative would not meet the
8 necessary criteria for the subclass, there are plaintiffs
9 that can be found and brought in, and the rules permit
10 substitution of class representatives. That can't be a
11 factor in deciding whether or not a subclass should go
12 forward.

13 Now, let me turn to medical monitoring. Contrary
14 to what St. Jude has said, no state that has confronted
15 medical monitoring has denied medical monitoring.
16 Basically what exists at this moment are those states that
17 have not addressed the issue, those states that have
18 addressed the issue and found it to be an appropriate cause
19 of action, and those states that have addressed the issue
20 and found it appropriate as a remedy.

21 But with respect to whether it's a cause of
22 action or a remedy, it really is of no moment. The
23 question in that context is whether or not you have to
24 prove an existing injury or you don't have to prove an
25 existing injury.

1 Obviously if the argument is, there is an injury,
2 every member of this class has been injured, as our experts
3 have presented to Your Honor during the class certification
4 presentation, there is some cellular damage caused by the
5 toxicity of the Silzone coating, and there is cell zone
6 damage. Everybody has been damaged. Effectively using the
7 criminal context, you have the lesser included crime being
8 subsumed within the greater crime.

9 Everybody has been injured and therefore whether
10 or not the test is, is there a need for an injury or not,
11 we will be able to establish, and we will prove that there
12 has been an injury. So what you have is two subclasses,
13 those subclasses, those people who are within a
14 jurisdiction that say there is no need for an injury.
15 Whether or not it's a cause of action or remedy, you still
16 get the same result, those states that require the
17 existence of an injury.

18 Now, there is an argument that has been made by
19 St. Jude, well, there are a whole host of states that have
20 not confronted the issue, and therefore there is a due
21 process argument that you can't address those states, and
22 we submit under Phillips Petroleum versus Shutts that you
23 can.

24 Justice Steven's concurring opinion which we cite
25 at page 5 of our submission makes it clear that the only

1 time the forum state law should not be applied in
2 connection with the laws of another state is if it is in
3 conflict.

4 If another state has not addressed the subject,
5 if the highest court has not said to you there can't be
6 medical monitoring or alternatively you need an injury or
7 alternatively you don't need an injury, then this Court can
8 apply the law of Minnesota with respect to those states
9 that have not addressed the issue, and it's very clear from
10 the language of Justice Steven's concurring opinion in
11 Phillips Petroleum.

12 We have stated in our submission that at least at
13 this moment we are moving forward with the belief that
14 Minnesota requires an injury. We have not agreed that that
15 is in fact the standard in Minnesota, but again as I've
16 said before, it doesn't matter because when the time comes
17 to present the evidence in this case, we will present
18 evidence that there has been an injury. So we will meet
19 the highest threshold test with respect to medical
20 monitoring.

21 Now, we have offered therefore two subclasses,
22 those states that come within the at least agreed upon
23 Minnesota position right now of an injury and those states
24 that say no injury. We believe that those are manageable,
25 appropriate and take into consideration any and all

1 significant differences.

2 When you turn to strict liability, there are two
3 theories. There is the failure to warn and the design
4 defect. The problem that we face also with St. Jude's
5 response to our designations here is that they attempt to
6 play semantical games as it relates to the design defect.

7 They rely upon cases as we point out in our reply
8 brief that do not address -- that are incorrectly cited,
9 and they address their affirmative defenses, which I will
10 touch on in a minute because I think it's important not
11 just to look at what we presented to you, but the two
12 issues that they've raised with respect to affirmative
13 defenses and then what they say are other reasons why you
14 shouldn't even address the issue.

15 But with respect to failure to warn, there is
16 really again when everything is boiled down three different
17 tests: Whether the failure to warn rendered the product in
18 a defective condition, unreasonably dangerous. Whether you
19 have a defective product without regard to whether or not
20 it is unreasonably dangerous, and then whether or not it is
21 unreasonably dangerous and therefore there is no issue as
22 to whether or not it's defective.

23 So in effect you have three different standards,
24 defective product unreasonably dangerous, a defective
25 product regardless of whether it's unreasonably dangerous

1 or an unreasonably dangerous product and we'll assume it's
2 defective. Those are the three. They're easy to deal
3 with.

4 The proofs are easy to present. We'll get to the
5 question of how you do that in a moment, but clearly those
6 are the significant differences. Nothing that St. Jude has
7 offered you with respect to the failure to warn changes
8 that analysis.

9 With respect to the design defect, we have come
10 up with four subclasses. One of them really is two of the
11 subclasses combined, and the question also comes about with
12 respect to the proof, the quantum of proof, what are you
13 going to prove in the case with respect to a design defect?

14 You have a defective condition. There are states
15 that say if the product is in a defective condition, that
16 is a design defect, and you can get strict liability.
17 There are cases that require the application of the
18 consumer expectation test. There are states that require
19 that in order for there to be a design defect you have to
20 apply the risk utility test.

21 That is different from the consumer expectation
22 test. That is different from simply a design defect, and
23 the fourth one is a defective product unreasonably
24 dangerous irrespective of whether or not the risk utility
25 or the consumer expectation would apply. Those are the

1 four.

2 The proof, again, as we have set out in our brief
3 is simply that, application with a consumer expectation
4 test, the risk utility test, discrete significant
5 differences.

6 When you get into the breach of warranty, again
7 whether it is implied or express, you really fall into the
8 question of the need for privity or no privity. There has
9 been an argument that well, you should address reliance and
10 notice. St. Jude has offered that, but, again, reliance
11 and notice are red herrings in this case.

12 This is a recall case. This is a case in which
13 they got the doctors to buy into a defective product
14 without full disclosure to the doctors. The doctors were
15 relying upon them, and certainly it is not a real issue in
16 the case.

17 The real issue in the case is whether there is a
18 need for privity or no privity, but we submit to Your
19 Honor, as we have it both in our primary brief and in our
20 reply brief, that you could apply Minnesota's Uniform
21 Commercial Code to this case, both under Fetters versus
22 Taylor and Christiansen, which effectively say that there
23 is a specific UCC choice of law provision.

24 It's been recognized in other cases that the UCC
25 choice of law provision can result in a different law being

1 applied than would normally be applied using the standard
2 state choice of law provision. We have a defendant housed
3 in Minnesota, and we have plaintiffs from all over the
4 country, similar to Fetters. There would be nothing wrong
5 with applying Minnesota's UCC requirement, UCC case law, to
6 this case and thereby resulting in one class.

7 THE COURT: Even in Louisiana?

8 MR. ANGSTREICH: Well, Your Honor, to the extent
9 that a state does not follow, whether it's the UCC, for
10 example, and I'm sure Mr. Jacobson will talk about that in
11 the negligence context, Louisiana and New Jersey in product
12 liability don't recognize negligence.

13 Well, that cause of action can't apply with
14 respect to those people who were implanted in Louisiana or
15 New Jersey or for that matter under the UCC if there is a
16 significant difference or inapplicability of the UCC,
17 although it is our position, Your Honor, that Louisiana's
18 law is effectively the same.

19 But the point is that there are cases where class
20 members who think they are class members, who are class
21 members, punitive class members, during the case at the
22 time that they go back to their many hearings, their proofs
23 of claim in front of a master, their home state, whatever
24 it is, find out that either their statute is gone or their
25 cause of action doesn't exist with respect to them, or

1 there is some unique defense as to that particular
2 plaintiff, and they can't recover.

3 There is nothing wrong with saying that the
4 subclass consists of all members of states that have a
5 Uniform Commercial Code provision or who recognize the
6 Uniform Commercial Code as providing a cause of action for
7 express or implied warranty, but still applying Minnesota's
8 case law with respect to that and having one class.

9 Now, if you happen to be in a state that doesn't
10 recognize express, breach of an express or implied warranty
11 under the Uniform Commercial Code, obviously you can't
12 recover. That can be carved out. You wouldn't create a
13 subclass of people who can't recover. They would just not
14 be within the class of people who can recover.

15 Now, I think it's important to focus in on the
16 six affirmative defenses that somehow create a problem with
17 the subclasses, one of which Mr. Jacobson will talk about.
18 The unavoidably unsafe product, the application of Comment
19 k, and therefore somehow there is a defense that this
20 product was unavoidably unsafe. The problem with that
21 defense is multiple.

22 The first is that Comment k requires that there
23 be a warning, an adequate warning of the danger. There was
24 no warning of the danger. There can't be an alternative
25 available, otherwise there is no reason to have an

1 unavoidably unsafe product out in the marketplace.

2 But we know that the Masters Series was, the
3 conventional Masters Series was in fact in the marketplace
4 and was available, and we know that the product has never
5 been proven to be efficacious.

6 So how anybody could argue for an unavoidably
7 unsafe product defense from our standpoint is just
8 ludicrous, and therefore what has happened with respect to
9 that defense is an attempt to create a picture of, look at
10 all these defenses that we may have available. Some states
11 recognize them. Some states don't, but the reality is,
12 they can't advance it here.

13 State of the art? Well, they were the state of
14 the art. Their conventional valve was the state of the
15 art, and they created the new state of the art knowing of
16 the dangers, knowing that it was untested, knowing that it
17 was not allowed to be marketed for allegedly the very
18 purpose for which it was created.

19 Again, we submit that for St. Jude Medical to
20 come before this Court and argue state of the art defense
21 is just incredible. It just doesn't make any sense that
22 that will happen. Alternative design? Again, we know that
23 there was an alternative design, and it's very interesting.

24 In their statement, they say, It is by no means a
25 foregone conclusion that using a conventional Masters

1 Series valve would have reduced or avoided the risk of
2 harm. What an incredible statement for this company to
3 make.

4 What they're saying is, their original Masters
5 Series valve, the, quote, "gold standard in the industry,"
6 was just as unsafe, just as defective as the Silzone valve?
7 I don't think they're going to make that argument in front
8 of the jury or before Your Honor.

9 I think that when they have testified, as
10 Dr. Flory did, as their experts have, that they've searched
11 high and low for an explanation as to why there was an
12 increased incidence of paravalvular leak with the Silzone
13 valve as compared to the gold standard, and they couldn't
14 come up with anything other than the Silzone itself, the
15 coating itself, we find it hard to believe that they could
16 satisfy the alternative design defense, and it will not be
17 advanced.

18 The learned intermediary defense, no doctor has
19 been brought in as a third-party defendant. No argument
20 has been made that these doctors somehow insulate St. Jude.
21 There can't possibly be an argument that these doctors
22 implanted a knowingly defective valve. They took the risk.

23 Every time you find the learned intermediary,
24 there is a warning. There is a disclosure, and the doctor
25 has made a reasoned choice because of the exigencies of his

1 patient. There was no opportunity to do that here. There
2 was no disclosure, and that's a total red herring.

3 The FDA approval argument is similar to the
4 preemption argument. As far as we're concerned, it just
5 doesn't exist, but more importantly under Section 4 of the
6 restatement third of product liability, in order for that
7 presumption to exist, they must have had full and complete
8 disclosure of all material information to the FDA.

9 Now, as Your Honor will recall during the
10 preemption argument that we had before you, there was a
11 whole host of information withheld, half disclosed or
12 misstated to the FDA. We submit that that's a defense that
13 just cannot be presented.

14 Now, they've also argued, and this is the last
15 points I want to touch on, five other reasons why you
16 shouldn't consider this case going forward as a class
17 action. It has nothing to do with subclasses, really.
18 It's an attack on class actions, and it's an attack on the
19 certification by Your Honor, and it's an attack really on
20 the jury system.

21 The notice will be too complicated, the too
22 complicated defense to certification. There are many more
23 complicated cases than this. How difficult is it to define
24 who is in the class and what the classes are? It happens
25 all the time.

1 I'm certain with the meet and confer process and
2 then with Your Honor's assistance if there is an issue, we
3 can craft a notice that will not be too confusing or too
4 complicated for people to understand, but certainly that is
5 not the basis to throw up your hands and say you can't
6 certify this. Let's give up. Let's not even try to focus
7 in on what appropriate subclasses should be.

8 There is an issue over the introduction of
9 evidence. We're going to present facts as you do in every
10 case. Those facts will have to be presented slightly
11 differently. There will be more facts that may have to be
12 added because of the subclasses on a particular theory.

13 For example, if the only issue in the case in
14 medical monitoring, if the only class were a class of
15 people where injury was not an issue, then obviously we
16 wouldn't need expert witnesses to testify about the
17 subclinical injury, but here we will put on evidence about
18 injury so that the jury will hear that.

19 And I am certain that the instructions from Your
20 Honor will easily be, if you find an injury, you can then
21 find in favor of the plaintiffs for medical monitoring,
22 and/or do you find that there was no injury.

23 Now, if the jury finds no injury, that's not the
24 end of the case. Those people within the jurisdictions
25 that permit medical monitoring without the existence of an

1 injury would then be able to recover. The others will not.

2 It happens all the time.

3 The jury instructions will be conflicting, long
4 and confusing. Well, I guess a patent infringement case
5 should never have a jury trial because I can't think of
6 anything more confusing or more conflicting or more
7 difficult for lay people to understand than a patent
8 dispute and the nuances of engineering and scientific
9 designs. So we might as well not have juries if that's
10 going to be the test.

11 I think that the standard instructions from each
12 of the jurisdictions on each of the theories can be read.
13 Yes, there may be a conflicting statement where the jury
14 will be told that a failure to warn is this, it's this and
15 it's this, and then the jury interrogatory will be, do you
16 find that the product was defective or that there was a
17 failure to warn and that the product was defective?

18 Do you find that there was a failure to warn and
19 that the product was unreasonably dangerous? Do you find
20 that the -- that there was a failure to warn and the
21 product was -- I forget what the third one was, but the
22 gist of it is, that's how they would do it.

23 There would be an instruction with respect to
24 each of those. There are alternative theories presented to
25 juries all the time. That doesn't preclude the jury from

1 considering them.

2 The verdict form will be unintelligible. I guess
3 that's really an indictment of counsel and not of the jury
4 because I guess we will not be able to provide to the jury
5 a jury sheet that they could answer in an appropriate
6 fashion. Again, that's like throwing out the baby with the
7 bath water. It doesn't address the issue of subclasses.

8 And the final one, which I really found very
9 insightful was, the jury deliberation will be confused and
10 prejudicial. They have an insight into the jury system
11 that we certainly don't have. They know who the jury will
12 be. They know that they will be confused, that they won't
13 understand the question. That is truly an indictment of
14 the entire jury system.

15 You shouldn't have a complex case because how
16 could this jury understand? How could this jury in a long,
17 drawn out case ever render a verdict? I guess I tried a
18 case for 72 days in federal court in Pennsylvania in front
19 of a jury. I guess the argument could have been made, how
20 would this jury ever remember what happened on day one and
21 who said what?

22 Part of the problem was solved with the jury
23 being allowed to take notes, but that's what the jury
24 system has been all about. Sometimes they don't remember.
25 Sometimes they hear what they want to hear. Sometimes

1 juries find wrong. Sometimes miraculously they find in the
2 right way, but as long as this is our system, this is the
3 way we have to proceed.

4 And again, it isn't an offer to the Court of
5 another subclass. It's really a request that Your Honor
6 not even consider this case as a class action because of
7 that. We submit that that is totally inappropriate.

8 So when we go back and we examine what we have
9 presented, what we have offered to you, we have offered
10 realistic subclasses, fewer subclasses, Your Honor, than
11 Judge Spiegel approved in Telectronics, subclasses that
12 address and focus in on the significant issues in state
13 law, subclasses that can be provided to the jury by way of
14 appropriate jury interrogatories.

15 We gave the Court on page 29 of our reply the
16 specific example of the four jury questions. Do you find
17 from the evidence presented that the Silzone coated heart
18 valve was a defective product? Do you find from the
19 evidence that the Silzone coated heart valve was defective
20 because it failed to meet an ordinary consumer's
21 expectations?

22 Do you find from the evidence presented that the
23 Silzone coated heart valve was defective upon application
24 of the risk utility test? Do you find from the evidence
25 presented that the Silzone coated heart valve was

1 unreasonably dangerous?

2 Now, Your Honor will have given the jury
3 instructions on how to determine those questions, but it
4 will be the evidence that will be presented to establish
5 each of those four answers. That's our burden to present.
6 It's a burden of evidence. It's not a burden of nuances in
7 the case law.

8 This is the -- this is the thrust. This is the
9 theory for a defective product. The evidence either will
10 show that it is a defective product. The evidence will
11 either show that the consumer expectation test hasn't been
12 met or the risk utility test hasn't been met. We say that
13 that's really how we're going to try the case. It's very
14 simple.

15 The definitions are very clear, and when you're
16 presented with clear, concise and definitive subclasses as
17 opposed to no subclasses, in fact, not one specific
18 subclass has been offered to you by the defendants, only
19 argument that this state says this and that state says
20 this, but never attempting to deal with whether or not that
21 difference is significant.

22 We respectfully submit, Your Honor, that the
23 subclasses we've offered you should be approved by the
24 Court and the matter not conditionally but unconditionally
25 certified. Thank you.

1 THE COURT: Mr. Angstreich, just a question or
2 two perhaps.

3 MR. ANGSTREICH: Okay.

4 THE COURT: Would you, with respect to examining
5 your plan for subclasses, would you foresee bifurcation of
6 the case between all of the liability theories and damages
7 or not?

8 MR. ANGSTREICH: Your Honor, you can do that.
9 Obviously for medical monitoring, you wouldn't be doing
10 that. With respect to the other one, the personal injury
11 case, and Mr. Jacobson can deal with that, but my
12 expectation, Your Honor, is that fact of damage and amount
13 of damage are two different issues.

14 My expectation would be that the trial would be
15 fact of damage, has the plaintiff been damaged? Have the
16 members of Class II been damaged? I believe that there is
17 no difference between the Class II plaintiffs and the
18 amount of each individual's damage or the amount of each
19 stockholder's individual damage or the amount of each
20 plaintiff in an antitrust case or a consumer fraud case.

21 The amount of damage is left to a second trial,
22 and I think that what would happen, Your Honor, is that if
23 the plaintiffs in the MDL were to go forward with their
24 personal injury damage case before Your Honor, obviously
25 the jury could, the same jury could come back.

1 Now the argument has been made by St. Jude that,
2 well, if you're going to send these back to their home
3 states for another jury to determine the issue of amount,
4 it's very simple, Your Honor. It happens all the time.
5 It's standard practice in New Jersey. The jury -- because
6 when it is bifurcated, another jury comes in and addresses
7 damages.

8 It's very simple. You say to the jury, St. Jude
9 has been found liable under whatever the theories are.
10 Your job now is to determine the amount of damages suffered
11 by the plaintiff as a result of that conduct.

12 Now, to the extent that contributory or
13 comparative negligence is applicable, I'm going to leave
14 that to Mr. Jacobson to address, but that would be where
15 Your Honor's question would be going, and I think that it
16 becomes an individual issue and does not impact on the
17 class.

18 Your Honor said you may have had more than one
19 question?

20 THE COURT: That's fine. That's fine. I'll save
21 whatever else I have for Mr. Jacobson. Thanks.

22 MR. ANGSTREICH: Okay. Thank you, Your Honor.

23 THE COURT: Thank you, Mr. Angstreich.

24 MR. JACOBSON: Good afternoon, Your Honor. I
25 would like to start right in on the area that you were just

1 asking the question about. In our view when you have a
2 damage class, when you have a class of injured persons who
3 each are going to have an individualized damage amount
4 depending on the particular injury that they suffered, the
5 normal and customary practice is to initially have as a
6 class before the initial jury a determination of whether or
7 not the defendant had a duty, whether they breached that
8 duty, whether that duty resulted in an injury and was the
9 cause of the injury.

10 And then the individualized determinations of the
11 quantum of the damages is something that can be determined
12 on an individual basis, whether it's before the same hard
13 working jury that made the initial determination or whether
14 you go before a series of individual juries, whether in
15 this district or upon remand to the various originating
16 districts.

17 It's practical, and it's commonplace to do so,
18 and it does not raise a Seventh Amendment concern about
19 jury trials or a jury's decision being reconsidered, and
20 the reason is, for example, the comparative
21 fault/contributory fault issue.

22 I'm sort of getting to my negligence argument
23 from the backside of where I'm headed, but I think it
24 follows through with your question. That particular
25 question of whether a juror -- excuse me -- of whether a

1 patient, a plaintiff, contributed to their own fault, to
2 their own damages by, as I understand their brief, not
3 following doctor's directions, not doing a good job taking
4 their medication, not losing weight, doing the other things
5 which defendants suggest may contribute to their damages,
6 that's easily handled by the initial jury in the class
7 action simply making a finding of whether or not St. Jude
8 was at fault, but without attributing any percentage to the
9 fault.

10 Then upon the remands to the originating
11 district, the new jury who is doing the specific causation
12 and specific damage issue for each individual class member
13 will, one, determine the measure, dollar value, of the
14 damages suffered by the plaintiff and then the percentage,
15 if any, of that damage attributable to the plaintiff or to
16 some third party.

17 And as long as they don't assign a percentage of
18 fault to St. Jude of less than 1 percent, if they don't go
19 down to that zero percent fault for St. Jude, then they
20 have not in any way contradicted or replaced the decision
21 of the original class action jury.

22 So the comparative/contributory fault issues
23 which are one of the issues that St. Jude raises in
24 suggesting that there should be multiple subclasses on
25 negligence is actually an issue related to damages and

1 comes after the initial class action trial.

2 So it's not a basis for subclasses. It's an
3 individualized issue that goes to the damage relief, and as
4 the Court noted in its opinion conditionally certifying the
5 classes and following the long history of cases, damage,
6 individualized damage issues are not a basis for denying
7 class certification.

8 Now, let me move on to the front end of the
9 negligence question. We've demonstrated in our brief and I
10 think we've cited some cases that hold the same way that
11 we're talking, which is that every state, every
12 jurisdiction in the United States has the same four
13 elements for a negligence damage claim.

14 There is a duty, a breach, damages and causation,
15 and you have to prove all four elements. In the
16 Teletronics case, the Court held, as you did, that the
17 various warnings used by the courts in stating these four
18 elements are, quote, "A distinction without difference,"
19 close quote.

20 You can phrase it slightly differently.
21 Everybody has pride of authorship. Everybody writes their
22 opinions in a slightly different way, but the essence and
23 the substance is the same: Duty, breach, damages and
24 causation. And there is really no surprise, negligence
25 although not --

1 (Cell phone rings.)

2 MR. CAPRETZ: Excuse me, Your Honor.

3 MR. JACOBSON: While negligence may not have been
4 a cause of action in the very earliest days of the common
5 law, it was a recognized cause of action well before the
6 establishment of this country, and we all come from the
7 same common law for this common law cause of action. So
8 there is no surprise that this very fundamental cause of
9 action remains essentially the same in all jurisdictions.

10 Now, there are two jurisdictions in the United
11 States that either never did or no longer do recognize a
12 negligence cause of action in a products liability case,
13 and those are New Jersey and Louisiana, and Mr. Angstreich
14 already touched upon that.

15 It is our view that you don't set up a separate
16 subclass of class members who don't have a cause of action.
17 You simply say that they're not included in the overall
18 subclass, so our view is that there should be a single
19 subclass relationship to negligence cause of action, and it
20 should include all of the class members except those who
21 reside in New Jersey and Louisiana who have to rely on
22 other causes of action for relief in this case.

23 Now the causation standards, the defendants in
24 their brief and in their chart, now looking particularly at
25 tab 18 to their opposition, they set out a chart listing

1 the various states and suggesting how they might differ
2 from one another in connection with the negligence issues.

3 And the first difference that they show is
4 between those that use substantial factor causation and
5 those that use but for causation, and there is a difference
6 in those two standards, but those don't require any
7 particular difference in subclasses, and they are easily
8 managed, and the management of them is as follows.

9 And I think that this works throughout this case
10 for all the causes of action, but I'm focusing just on the
11 negligence because it's easy to talk about one, and that is
12 the use of special interrogatories. Special
13 interrogatories, which sometimes in Missouri where I'm from
14 are referred to as Texas instructions because Texas
15 apparently just uses special interrogatories and no verdict
16 forms like we use, are a series of questions that the jury
17 answers.

18 They answer particular questions about facts, and
19 then the judge, the trial judge, is the one who then
20 applies that and plugs it in to get the legal result, and
21 so for here, to deal with the causation standard, you could
22 have two questions, one after the other.

23 The first would be if you found that St. Jude
24 breached its duty to the plaintiffs and if plaintiffs were
25 thereby injured was the breach a substantial factor in

1 plaintiffs' injuries? That would deal with those who are
2 within those substantial factor cases.

3 Then you have a second question, very similar.
4 If you found that St. Jude breached its duty to the
5 plaintiffs and plaintiffs were thereby injured, would
6 plaintiffs have not suffered injury but for the breach of
7 duty? Now you've covered the but for cases.

8 The jury gets yes/no, yes/no, and you can do that
9 throughout all these causes of action. It's not going to
10 be a very difficult or complicated set of verdict forms,
11 and frankly, I don't think it's going to be a very
12 difficult and complicated set of instructions.

13 The Court will instruct on loss. The lawyers
14 will argue and explain the instructions and explain the law
15 through their argument and apply the facts to it, and it's
16 not that difficult. I think the manageability arguments
17 that have been raised have been tremendously blown over,
18 blown up beyond what they really are.

19 So let's see. The one last thing that I would
20 like to address, there was something Mr. Angstreich said
21 that I think he might have slightly misstated it, so I want
22 to have it clear. In discussing the state of the art
23 defense that was raised, the state of the art defense is
24 not applicable for a reason slightly different I think than
25 what Mr. Angstreich said.

1 It's not applicable because the Silzone valves
2 were not the state of the art. They were an innovation,
3 and innovations are not state of the art. They are beyond
4 the state of the art. The Masters Series, as
5 Mr. Angstreich said, was the state of the art.

6 The Silzone valves were innovations that were an
7 attempt to extend the state of the art but failed to do so,
8 and for that reason, state of the art would not be a
9 defense. If you have any questions about Class II or
10 subclasses of it, I would be happy to answer, otherwise
11 I'll sit down.

12 THE COURT: Thank you, Mr. Jacobson. Let's see.
13 Who is going to start first for the defense?

14 Mr. Martin?

15 MR. MARTIN: Thank you, Your Honor. Good
16 afternoon. James Martin for St. Jude Medical. As our
17 first slide shows with the Court's permission, we would
18 like to divide our argument time as follows: I'll give a
19 short overview on St. Jude's response to plaintiffs'
20 subclass proposal.

21 Mr. Nilan will then examine in greater detail the
22 substance of plaintiffs' subclass proposal and the
23 material, legal issues implicated in a class wide trial of
24 the claims and defenses.

25 Mr. Kohn will pick up after that and focus more

1 closely on the individualized issues that necessarily will
2 affect the proof in any subclass trial and the effect that
3 will have in turn on the complexity of such a trial. And
4 finally, I will close, Your Honor, with some brief comments
5 on the superiority and manageability issues created by the
6 legal and factual issues that Mr. Kohn and Mr. Nilan will
7 explore.

8 Before my overview, Your Honor, though, I would
9 like to address the threshold point that the plaintiffs
10 made that somehow invoking Rule 7 here limits the Court's
11 inquiry today. The plaintiffs contend in invoking that
12 rule that all the requirements associated with class
13 certification are conclusively laid to rest save for a
14 determination of how many subclasses we need, and that's
15 what St. Jude is supposed to be talking about.

16 No examination of any other class certification
17 issues are warranted, they say, or even permissible, and
18 all of that follows, Your Honor, according to plaintiffs
19 from this Court's original class certification order.
20 Well, Your Honor, the Court certainly made it clear in its
21 prior order that it believed the basis for class
22 certification existed here for the personal injury and
23 medical monitoring classes. No doubt about that.

24 But as we read the Court's order, it reached that
25 conclusion conditionally, and that is that a final

1 determination couldn't be made on those issues, including
2 class certification, until the effect of the controlling
3 law was fully and carefully examined and a subclass
4 proposal actually considered.

5 Apart from the language of the order, Your Honor,
6 the notion that the scope of the Court's inquiry for a
7 proposed division into subclasses here today is somehow
8 narrower than the initial class certification inquiry is
9 without merit.

10 As our second slide shows, Retired Chicago Police
11 Officers establishes that for subclasses that demands the
12 same rigorous inquiry on each of the requirements of
13 Rule 23 as the initial class certification decision, and
14 Your Honor, unanimous federal authority supports this view.

15 And Retired Chicago Police Officers is only one
16 of many federal cases that also establish that if the
17 subclasses fail under the requirements of the rule, they
18 should not and indeed they cannot be certified.

19 Finally, Your Honor, as our third slide shows, at
20 every stage of the proceedings, a court always has the
21 responsibility to examine the propriety of class
22 certification and to decertify the class if the record
23 supports it.

24 This responsibility comes directly from the
25 language of Rule 23. It's underscored by the Eighth

1 Circuit Hervey opinion, and further as the Supreme Court
2 noted in Falcon, this responsibility applies with
3 particular force when, as is the case today, class notice
4 has not yet issued.

5 Now, plaintiffs also contend that this Court has
6 predetermined that a class wide trial is feasible and
7 therefore any inquiry at this juncture into how these cases
8 would be tried in a subclass format is irrelevant or at the
9 very least premature, yet as our fourth slide shows, class
10 certification decisions aren't made in a factual vacuum,
11 and the material legal issues raised by any subclass
12 proposal do not arise in the abstract.

13 Rather as the controlling law again makes clear,
14 the focus in any class certification hearing, including one
15 contemplating subclasses, is always on how the cases will
16 be tried. The Court has to look at the specific elements
17 of the claims and defenses, what the parties will have to
18 prove or they will attempt to prove to determine whether
19 any kind of class wide trial is manageable or the superior
20 means for resolving the cases even as divided into
21 subclasses.

22 Once again, Sandwich Chef is not alone in making
23 this observation. The Supreme Court, federal circuit
24 courts and district courts are in agreement that any
25 decision regarding possible class or subclass certification

1 outside of the context of a proposed settlement class,
2 which is not on the table here, turns on whether an
3 efficient, effective, nonprejudicial class wide trial is
4 possible.

5 Now plaintiffs have decidedly avoided this
6 pivotal analysis. They brush aside these individual
7 factual issues on the elements of their claims or our
8 defenses as inconsequential, unimportant or both. That
9 reached its zenith here this afternoon where jury arguments
10 are made on what defenses will be proven and what won't and
11 what are valid and what won't.

12 What plaintiffs have offered instead, Your Honor,
13 is a color coded morass that they insist gives this court
14 everything it needs to know or wanted to know, and
15 apparently if we just keep moving forward, everything will
16 take care of itself.

17 But as Mr. Nilan will demonstrate in greater
18 detail, plaintiffs' subclass proposal comes up short, so
19 short, in fact, Your Honor, that their incomplete and
20 homogenized legal groups would if followed inject any class
21 wide trial with reversible error.

22 Mr. Nilan will also show, and our next slide
23 emphasizes, that any subclass proposal that properly
24 accounts for the material differences in state substantive
25 law will be complex and difficult in the extreme. Even

1 under plaintiffs' truncated analysis, there are nearly 30
2 subclasses, a burdensome, costly and confusing approach to
3 resolving these cases.

4 And when the material differences in state law,
5 which is what we will focus on, are accounted for, the
6 subclass total in fact reaches 51, one for each state,
7 exacerbating the burdens, cost and confusion, but it won't
8 end there. As Mr. Kohn will show, and our next slide
9 emphasizes, this complexity is exacerbated even further by
10 the individual trials which must follow because of the
11 discrete issues raised on the claims of the plaintiffs and
12 the manner in which St. Jude will and, Your Honor, is
13 constitutionally entitled to present its defense.

14 The net effect of Mr. Kohn's and Mr. Nilan's
15 presentation is that once the subclasses are properly
16 analyzed and the effect of the individualized proof
17 properly assessed with regard to the elements of the claims
18 and defenses, any proposed class wide trial would be
19 unworkable in practice and plainly not the most efficient,
20 effective or best method to resolve these cases.

21 The profound differences here among the punitive
22 class members' respective claims on liability, injury,
23 causation and damages are precisely the ones the case law
24 identifies as rendering class wide trial unsuitable, and as
25 our next slide highlights, this is not another day at the

1 office.

2 This is not just another complex federal case.

3 There is no road map out there for what we're attempting.

4 No federal court has undertaken to try a nationwide set of
5 cases like these, and no circuit court has even hinted that
6 such a trial is possible or should be attempted.

7 The layers of complexity in plaintiffs'
8 description here this morning is a signal as to why the
9 case law lines up this way. Elements of proof, jury
10 instructions and the rest of it compounded over claims and
11 causes of action is what injects the difficulty, and as our
12 next slide shows, there is no authority to the contrary.

13 Plaintiffs rely on Teletronics and say that that
14 provides a road map to class wide resolution, but as
15 Mr. Nilan and Mr. Kohn will conclusively show, these
16 Silzone cases as a matter of fact and law bear no
17 resemblance, Your Honor, to the lead fracture cases at
18 issue in Teletronics.

19 As this Court well knows, no class wide trial was
20 ever attempted in Teletronics, much less validated under
21 Rule 23's prerequisites. With these highlight points as a
22 backdrop, Your Honor, Mr. Nilan will now focus more fully
23 on why it is that plaintiffs' subclass proposal comes up
24 short under a careful examination of the applicable law
25 nationwide. Thank you.

1 THE COURT: Thank you, Mr. Martin.

2 Mr. Nilan?

3 MR. NILAN: Good afternoon, Your Honor. Your
4 Honor, once the Court granted conditional class
5 certification, the plaintiffs had the burden of coming
6 forward with a workable, constitutional, manageable trial
7 plan with appropriate subclasses. The plaintiffs have
8 failed to do that.

9 What the plaintiffs have done, Your Honor, is
10 they have seized on Rule 23(c)(4) to present a proposal
11 with a set of ill-defined subclasses that group residents
12 of numerous jurisdictions under broad theories of law with
13 little or no legal analysis supporting those subclasses.

14 In doing so, the plaintiffs would lead the Court
15 afoul of both the Erie doctrine and the rules enabling that
16 by grouping subclasses and law and jurisdiction that can't
17 be grouped together.

18 Although the Court indicated in its prior order
19 that it would consider and wanted subclasses based on only
20 significant differences in the law, the Court clearly did
21 that mindful that it needed subclasses that met the
22 constitutional requirements such that the character and the
23 outcome would not be affected as if tried in individual
24 jurisdictions.

25 The plaintiffs haven't given the Court that.

1 They haven't grouped the law in a manner that has the
2 constitutional prerequisites, but in addition, Your Honor,
3 the plaintiffs have failed to meet their burden of
4 demonstrating even in the most rudimentary manner that the
5 subclasses meet the typicality, adequacy and commonality
6 requirements of Rule 23.

7 Oddly, the plaintiffs appear to believe that once
8 the Court granted conditional class certification that the
9 subclasses don't have to meet the same Rule 23(a)
10 requirements as the class would have to meet. That's
11 clearly not the law.

12 To the extent that the plaintiffs believe
13 otherwise, Your Honor, they are simply wrong. Without
14 needing to go any further than this, the plaintiffs have
15 not given the Court what it needs in order to create
16 constitutional classes that it could certify.

17 What the plaintiffs have essentially done is give
18 some kind of general suggestions to the Court and have left
19 it in many respects for the Court to work out itself what
20 the subclasses are going to be and ultimately somewhere
21 down the line meet the rest of the requirements of
22 Rule 23(a).

23 That's not the plaintiffs' burden in this case.
24 Now should the Court go beyond this point and actually look
25 at the subclasses being proposed, even a cursory review of

1 the law is going to reveal that there are far more
2 subclasses than the plaintiffs suggest.

3 The reason that the plaintiffs have analyzed
4 state law with such a light touch and in such very broad
5 strokes is, even a modest review indicates the number of
6 subclasses far exceed what they have proposed to the Court.

7 Now, the plaintiffs' repeated response to
8 St. Jude pointing this out is simply that St. Jude is
9 parsing the law much too finely, that it is going beyond
10 the significant differences that the Court requested, but
11 what appear to be insignificant differences in the law to
12 the plaintiffs clearly impact the nature and the proceeding
13 and the outcome of the case.

14 Now, as the Court is aware, there are
15 commentators that have suggested, well, the law of the 51
16 jurisdictions isn't clearly 51 laws. There is a lot of
17 heavy borrowing from one jurisdiction to another, and the
18 laws can really be encapsulated in much smaller groups and
19 maybe even less than 10.

20 Well, it is far easier said than done when
21 looking at the specific claims as to how far they can be
22 subgrouped. In fact, Judge Davis said in the recent Baycol
23 decision relative to class certification on just this
24 issue, Judge Davis said, Differences in state law, no
25 matter how slight, are important and must be determined

1 prior to certification because such differences may swamp
2 any common issues and defeat predominance.

3 For plaintiffs to suggest that the Court can
4 review the state laws and create appropriate subclasses at
5 some later date is not sufficient to meet their burden to
6 demonstrate that class certification is appropriate.

7 That is exactly what the plaintiffs have done in
8 this case, Your Honor. Rather than carefully articulate
9 the law and define the subclasses, in essence, I believe,
10 what the plaintiffs have done is simply defer to
11 Teletronics that that is the road map and that is the
12 basis from which the Court can ultimately create subclasses
13 in this case.

14 Your Honor, first of all, I believe that Judge
15 Spiegel in Teletronics was struggling to do justice in the
16 situation where there was some concern that justice might
17 not otherwise be done. Judge Spiegel acknowledged early on
18 in that case that a number of circuit courts had been
19 highly critical of the use of class action and mass tort,
20 but he concluded that there were unique situations in
21 Teletronics that allowed him to go forward and certify a
22 class, unique circumstances that are not present in this
23 case.

24 The Court said among other things, Here there is
25 a danger that the expense of the litigation and potential

1 for large damage awards threatens to bankrupt the defendant
2 and leaves some class members without a remedy. That's not
3 the situation in this case, Your Honor. There has been no
4 suggestion by the plaintiffs that the assets of the
5 carriers and St. Jude are not sufficient to respond to the
6 claims in the Silzone cases.

7 In addition, there are numerous factual
8 differences that Mr. Kohn is going to go through in a
9 little more detail, but on the legal side, there were
10 significantly less claims in Telectronics. I think there
11 were three or four as opposed to the five here. There were
12 no failure to warn claims. There were no warranty claims
13 in Telectronics.

14 And the factual differences are extreme to the
15 point that Telectronics does not provide any road map for
16 the Court here in analyzing subclasses. What I would like
17 to do is get to the specifics of the claims in this case
18 and the problems they present in trying to define
19 appropriate subclasses.

20 Let me start first with the design defect claim.
21 Now, as plaintiffs' counsel indicated, they divided into
22 four broad categories evidence of defect, evidence of an
23 unreasonably dangerous product, the risk utility test and
24 the consumer expectation test giving four broad categories,
25 but the plaintiffs even in their own brief and appendix

1 indicate as they have to that there are other states that
2 use combinations of those theories, so even under
3 plaintiffs' proposal, there are six different subclasses.

4 But the distinctions that the plaintiffs make,
5 Your Honor, are not so easily drawn. For example, under
6 the risk utility test, there are two states, California and
7 Colorado, that use the risk utility test. It comes from, I
8 believe, a California case, the Barker v. Lull test.

9 They would both most appropriately be categorized
10 under the risk utility, but there are significant and
11 important differences between how the risk utility test is
12 used in Colorado and how it's used in California, and it
13 has to do with the burden of proof.

14 In California, the plaintiff has the burden to
15 show that the product is defective. The burden then
16 switches to the defendant to show that the benefit,
17 however, outweighs the risk.

18 In Colorado, that burden is flipped. It is the
19 plaintiffs' burden from the beginning to show that the risk
20 outweighs the benefit. To suggest that who has the burden
21 of proof is not important and a significant difference in a
22 products liability case is not the cases I've tried when
23 counsel argue at great length at the end of the case who
24 has a burden on a particular issue.

25 Now, interestingly, the way the plaintiffs appear

1 to deal with this is, they simply take Colorado out of the
2 risk utility test whatsoever. In fact, they have
3 categorized Colorado under the unreasonably dangerous
4 category. They've categorized Colorado with Alabama and
5 Louisiana that have extensive statutory schemes in dealing
6 with products liability.

7 Whatever it is, Colorado isn't with Alabama and
8 Louisiana. That's not how they can account for this. Even
9 if it's put in the proper group where it should be in risk
10 utility, you have completely different burdens of proof.
11 That has to be a significant difference.

12 Similarly, trying to deal with the jury
13 instructions that would be given simply in the design
14 defect becomes mind boggling. For example, there are a
15 number of states that require evidence of unreasonably
16 dangerous product. However, Pennsylvania has specifically
17 held that it is reversible error to even instruct the jury
18 on whether and when a product is unreasonably dangerous.

19 So now you have to come up even if you were able
20 to divide the classes, you would have to come up with a set
21 of instructions that didn't run afoul of Pennsylvania's law
22 that would hold that it was reversible error to even
23 instruct a jury relative to unreasonably dangerous
24 products.

25 We're not the only ones, Your Honor, that suggest

1 that it is difficult in the design defect arena to
2 construct classes. In the class action case that was MDL'd
3 to the Eastern District of Louisiana, the Masonite board
4 cases that was before Judge Feldman a few years ago, what
5 he said on just this topic was, Adjudicating the claims of
6 the national class on strict liability defect would require
7 not only more than five subclasses but also several juries.

8 Within a given plaintiff defined doctrinal group,
9 states have different definitions of defectiveness. Some
10 of these instructions could not possibly be given to the
11 same jury. States employ presumptions based on different
12 triggering conditions. States have different formulations
13 of the burden of proof.

14 Even in a liability only trial, composite
15 instructions accounting for all these differences would
16 hazard a cast that seems counter intuitive to the spirit of
17 Rule 23. That's why there isn't a fully defined set of
18 classes that the plaintiffs have put forward.

19 It is a mind boggling job to suggest that, well,
20 we can do it easily with four, maybe six cases so
21 understates it as to be extraordinary. I think
22 Mr. Jacobson suggested, if I put this down wrong or have
23 this correctly, the quote something to the effect of, This
24 simply won't be that difficult, and the instructions will
25 not even be that complicated.

1 Whatever else I am reasonably sure of, Your
2 Honor, is that that isn't correct. The instructions on a
3 nationwide class action on defect, if nothing else, are
4 going to be complicated, but then let me turn to the
5 affirmative defenses because not only do you have the
6 differences relative to how the various jurisdictions
7 handled defect, you have significant, important differences
8 as to how they handled the affirmative defenses.

9 St. Jude has pled some six affirmative defenses.
10 One is the avoidably unsafe product which triggers Comment
11 k to 402A of the restatement. Different states handle
12 Comment k in very different manners. Similarly, the state
13 of the art defense, St. Jude has pled and will introduce
14 evidence that the Silzone valve was state of the art.

15 The differences on how states handle state of the
16 art are also significant. For example, Montana imputes
17 knowledge of defect to the manufacturer and does not allow
18 a state of the art defense. In contrast, manufacturing to
19 the state of the art is an absolute defense in Arizona.

20 Similarly, we have no alternative designs to at
21 least a number of counts. We have the learned intermediary
22 defense. Now the plaintiffs seem to indicate that the
23 learned intermediary defense there can't possibly be a
24 defense of learned intermediary.

25 In fact, there has to be a defense because

1 learned intermediary is simply a doctrine where the
2 manufacturer doesn't have to directly warn the consumer if
3 there is a learned intermediary in between them, which is
4 certainly the case in this situation. Some states allow
5 learned intermediary. Some states do not.

6 And then finally, the affirmative defense of
7 contributory and comparative fault, states handle that in
8 an extraordinary number of different ways down to the point
9 of how they handle the percentage of fault found on the
10 plaintiff. Some it's 50 percent will preclude liability.
11 Some you need 51 percent and so on.

12 Now, interestingly, rather than deal with these
13 and even suggest any subclasses among the states on how
14 they relate to affirmative defenses, what the plaintiffs
15 really say is, the defendant doesn't have any affirmative
16 defenses.

17 Well, as a practical matter, we do have
18 affirmative defenses. We have pled those affirmative
19 defenses. As Mr. Kohn will state, if you go to the AVERT
20 study, and it is our position now that once we are several
21 years out, there is little, if any, difference between
22 Silzone valves and background rate.

23 That is certainly a defense, but more
24 importantly, at the point the plaintiffs bring summary
25 judgment and at the point the Court grants summary judgment

1 on the affirmative defenses, then that's one thing, but to
2 suggest at this point in the litigation where we have
3 evidence that we will introduce that support those
4 affirmative defenses, for the plaintiffs to suggest that
5 the Court can simply ignore them, don't worry about them,
6 they don't come into play is, I believe, Your Honor, at a
7 minimum incorrect.

8 It is something that plaintiffs have to consider
9 in proposing a set of subclasses. Taking all of this into
10 account and trying to create appropriate subclasses for the
11 design defect, including the affirmative defenses, we
12 believe that there are 28 separate subgroups relative to
13 design defect that have significant material differences.

14 This, Your Honor, is ignoring entirely the fact
15 that there are at least ten states that have important
16 unanswered questions relative to design defect, but doing
17 the best we could to include those and not make another
18 category of question marks, we come up with 28 different
19 groups.

20 Now, even if after extraordinary effort the Court
21 were able to divine a set of subclasses relative to design
22 defect that it was comfortable with, the problems only
23 compound themselves once you start adding additional
24 claims, and let me start with the failure to warn claim.

25 The plaintiffs have four subclasses relative to

1 failure to warn, but even then ignore important differences
2 in the law of failure to warn. For example, there are
3 states that look at the reasonableness of the
4 manufacturer's conduct relative to failure to warn which
5 simply cannot be reconciled with states that hold
6 manufacturers liable for inadequate warnings even where the
7 risks are unknowable.

8 Now what the plaintiffs' response is that it's
9 all a matter of semantics, that it's really, you know, all
10 the same law, that we're again parsing it too finely, but
11 if you look at the actual law of the states, that isn't
12 true. For example, contrary to the plaintiffs' assertions
13 in their brief, if you look at the law of Montana and South
14 Dakota, those states explicitly impute knowledge of defect
15 to a product manufacturer.

16 The Supreme Court in Montana said in the
17 Sternhagen case, In answer to the question certified, we
18 conclude that in a strict products liability knowledge of
19 any undiscovered or undiscoverable dangers should be
20 imputed to the manufacturer.

21 Now, the plaintiffs' assertion in their reply
22 brief that Sternhagen somehow stands for the proposition
23 that it's a knew or should have known standard is simply
24 contrary to the Supreme Court of Montana's statement.

25 In addition in South Dakota, where the plaintiffs

1 claim, well, this is really just another knew or should
2 have known standard, in the Peterson case, the Supreme
3 Court of South Dakota said, In strict liability, the
4 plaintiff need not prove scienter of the defendant, i.e.,
5 the defendant know or should have known of the harmful
6 character of the product without warning.

7 For purposes of strict tort claims, knowledge of
8 the potential risk is imputed to the manufacturer.
9 Similarly, Hawaii, Florida, Arizona all have the same
10 strict liability failure to warn. Those are not accounted
11 for in the plaintiffs' theories.

12 If you take the failure to warn claims and divide
13 them among the significant differences, you end up with
14 what we believe are eleven subclasses. Now, what happens
15 in the strict liability where you have 28 different
16 subclasses, if you look at some of the states, say taking
17 South Dakota, North Dakota and Minnesota, at least relative
18 to strict liability, those states are similar.

19 I think they could be grouped the same, but now
20 if you add eleven different groupings of failure to warn
21 and then look at even Minnesota, South Dakota and North
22 Dakota, it starts breaking down.

23 Now you've got Minnesota separate from North
24 Dakota and South Dakota, who both have similar failure to
25 warn and defect claims, but now what happens when you add

1 the warranty claims? Adding the plaintiffs' three warranty
2 claims creates an almost imponderable level of complexity
3 to the subclass issue.

4 There are states that break down into requiring
5 proximate cause for express warranties but not implied
6 warranties. Oddly there are states that require not
7 proximate cause but privity, require privity for implied
8 warranties but not express warranties. There are states
9 that have done away with the privity requirement entirely.

10 There are still some states that have privity for
11 both express and implied, and then you get to reliance and
12 meaningful reliance, the states break down. It was just a
13 few weeks ago, Your Honor, I was in the Pennsylvania Court
14 of Appeals with at least one of my brethren on the other
15 aisle on a completely unrelated case.

16 But the issue before the Pennsylvania Court of
17 Appeals was whether privity and reliance were required
18 relative to an express warranty. We submitted over 100
19 pages of briefing on just that issue, just in Pennsylvania.
20 The Pennsylvania Court of Appeals at the hearing said, it's
21 not clear. The Supreme Court hasn't ruled on this issue.

22 To approach that on every state where there is
23 either ambiguity or not resolved becomes an enormous issue,
24 but doing the best we can and trying to divide the warranty
25 claims, we come up with some 30 subclasses.

1 Now, I think tacitly the plaintiffs recognize
2 this because what they say is, well, warranty is really,
3 incorporates Minnesota law, so you don't have to get there.
4 Well, setting aside as to who is rearguing issues the Court
5 has already decided, the Court has decided appropriately so
6 that the forum states law will apply.

7 The implantation took place there. As Judge
8 Davis said, the Eighth Circuit has given very little
9 credence to the forum of the manufacturer in applying that
10 jurisdiction's law. The Court has already decided the
11 various jurisdictions' law will apply. The law is not the
12 same.

13 To the extent the plaintiffs cite the Fetters
14 case and say that it is dispositive, in fact, I believe
15 they said St. Jude never even responded to this dispositive
16 case that Minnesota law should apply relative to warranty.
17 Well, the reason we didn't respond is, Fetters deals with
18 the repossession and sheriff's sale of collateral located
19 in Minnesota.

20 It was clear Minnesota law applied. There was no
21 contest otherwise. The choice of law under the UCC was
22 referred to in passing in a footnote. Fetters has
23 absolutely nothing to do with the law of Minnesota applying
24 in a national class action warranty case.

25 Once you get to these additional 30 classes, Your

1 Honor, relative to warranty, what happens is you now have
2 another 30 subclasses, but if you now look at Minnesota,
3 North Dakota and South Dakota, once you add three claims,
4 not even North Dakota and South Dakota are the same. Now
5 you have three separate subclasses.

6 Then you move to negligence. Negligence is not
7 straightforward, either, Your Honor. The plaintiffs have
8 stated, well, negligence is really all the same. It's
9 duty, breach of duty, causation and damages, and one way or
10 another, it's all really one group. It's not quite that
11 easy, Your Honor.

12 Even setting aside New Jersey law, which doesn't
13 recognize negligence in a product liability case that can
14 be dealt with somehow after the verdict, there are states
15 like Minnesota that require in a products liability case,
16 as I'm sure the Court is aware, that before the plaintiff
17 can go to the jury, the plaintiff has to elect whether they
18 are going to go on a negligence theory or a defect theory.

19 So then at least you've got Minnesota now in a
20 separate class, but in addition to that, there are states
21 and maybe most states utilize the reasonably prudent
22 standard.

23 But there are a set of states that have a higher
24 standard that use a professional care standard relative to
25 manufacturers. It is unquestionably a higher standard. As

1 I understand the plaintiffs' response to that, how they're
2 going to deal with that is the suggestion well, first we'll
3 charge the jury relative to the reasonable care standard.

4 If the jury comes back and finds that there was
5 reasonable care, then we'll recharge the jury on the higher
6 standard of care and then see how they come out. Well,
7 setting aside the procedural and constitutional problems
8 that I think that implicates, it is really the sum total of
9 the plaintiffs' argument in many respects is just certify
10 this, Your Honor, because at the end of the day we'll
11 figure out how it all comes out and somehow, some way we'll
12 work it out, and if we get problems, we'll just work them
13 out at that point.

14 That's not the plaintiffs' burden, Your Honor.
15 Their burden is to right now come up with appropriate,
16 definable subclasses that can be certified, not somehow,
17 some day we'll figure it out.

18 Your Honor, if you take the negligence subclasses
19 where we think that there are significant differences in
20 the law in how the jury would be charged, we come up with
21 an additional eight subgroups, but then you get to medical
22 monitoring.

23 There are, as I understand it, Your Honor, six
24 states that have accepted a medical monitoring claim in a
25 situation without an injury. There is at least one, if not

1 more, states that have rejected medical monitoring without
2 an injury, and there are 40 some states in which the law
3 isn't clear.

4 But even among those states that have accepted
5 medical monitoring without an injury, there are significant
6 differences between those states. For example, Utah
7 requires proof that early detection be beneficial and
8 advisable.

9 Pennsylvania and West Virginia have specifically
10 rejected that requirement. That has to be a significant
11 difference between those two. You cannot instruct a jury
12 in the same manner on the law of medical monitoring
13 relative to those three states.

14 Maybe most difficult for the Court, however, is
15 you have now got 40 some states that under the Erie
16 doctrine the Court is going to have to determine how the
17 highest court in those states would rule on medical
18 monitoring, and if the Court has gotten into medical
19 monitoring cases, which I'm sure it has, this is not an
20 easy area. There are conflicting lower court decisions in
21 almost every state. The policies are different.

22 They treat it different. Some states treat it as
23 a cause of action, some as a damage. It is an enormously
24 difficult area, but setting that aside, you still come up
25 with what we believe are eight different subgroups, with

1 the eighth subgrouping all of the states that we don't know
2 what the answer is relative to medical monitoring, and at
3 some point the Court is going to have to look at that.

4 Then if you add onto that the differences in
5 states' law relative to how wrongful death is handled,
6 you've got 21 different groups relative to wrongful death
7 that have significant differences in how those states
8 address wrongful death.

9 The final result of all of this, Your Honor, if
10 you put all of these together and try and take each one of
11 these states on those five legal theories, you can no
12 longer find any one -- two states that match. Every state
13 now has some significant difference from the other state,
14 and as the Court knows, you can't have a member in one
15 subclass for one claim and another subclass for another
16 claim.

17 Their claims have to match up. That's how we get
18 to 51 jurisdictions. It isn't the overstatement, the sky
19 is falling, you can never do this. It is, in fact, with
20 any modest analysis of the law, it is a very difficult area
21 to find workable subclasses under the 51 jurisdictions.

22 But, Your Honor, just for the purposes of
23 argument, say that St. Jude is vastly overstating this.
24 Let's just go with the plaintiffs' theory on how this would
25 work, going through the same analysis. If you start with

1 the plaintiffs' design defect, their charts show six
2 subclasses, the four we talked about and they have two or
3 three states that have a combination.

4 Now, if you add to that the plaintiffs' four
5 classes relative to failure to warn. Then you add, there
6 are two classes relative to breach of implied warranty, two
7 different classes relative to breach of express warranty,
8 and those states don't match up. You skip negligence
9 because they say there is just one group, and we'll accept
10 that.

11 You take their three medical monitoring claims
12 and then try and match the states up. Taking just the
13 plaintiffs' theory that it's presented the Court so far
14 that we believe is woefully inadequate and matching the
15 states, you ultimately get 28 separate subclasses.

16 The bottom line, Your Honor, is, this isn't
17 necessary. This isn't a better way to do this. This
18 situation isn't remotely close to a negative value class
19 action where if the Court doesn't find a way to proceed on
20 a class basis it isn't going to happen.

21 These are significant claims that will be handled
22 much more efficiently, much more judiciously, much more
23 effectively to let them go through the MDL process, send
24 them back to their jurisdiction of origin and let them be
25 resolved.

1 It is hard to ultimately know, of course, Your
2 Honor, but I suspect if we try to proceed forward on a
3 class action given these issues that this case will be
4 going much, much longer, much more difficultly with many
5 more issues than if the MDL simply proceeds through. The
6 discovery is completed. These cases are sent back.
7 They're going to be addressed.

8 These aren't negative value cases. These are all
9 significant cases, and the Court won't have to undertake
10 and undergo the kind of heroic effort that the plaintiffs
11 are suggesting here. So with that, Your Honor, I'm going
12 to turn it to Mr. Kohn to talk about how some of the
13 individual factual differences impact the inability to
14 create appropriate subclasses.

15 THE COURT: Very well. Before we do that, let's
16 take about a seven minute break.

17 (Recess taken.)

18 (In open court.)

19 THE COURT: You may be seated.

20 Mr. Kohn?

21 MR. KOHN: Good afternoon, Your Honor.

22 THE COURT: Good afternoon.

23 MR. KOHN: Mr. Nilan has laid out the legal
24 complexity that faces the Court and counsel in great
25 detail. I will now turn my attention to the factual

1 complexity and address how that will affect how these cases
2 will be tried in a subclass format.

3 In doing so, I will also attempt to address some
4 of the comments made by Mr. Angstreich particularly with
5 respect to his contention that St. Jude Medical's
6 affirmative defenses are of no moment because I think the
7 factual variations in these cases will show the Court that
8 that is not the case.

9 When you overlay the legal complexities that
10 arise because of the differing laws of the states onto the
11 factual complexities that arise because of the nature of
12 the injuries, it's our contention that the class action
13 format, regardless of how subclasses are grouped, is simply
14 not the superior method for resolving these cases.

15 The starting point for a discussion of the
16 factual issues in these cases is really medical causation
17 because at root, these are personal injury product
18 liability cases, and so it's necessary to look closely at
19 the causation issue, both in the sense of generic causation
20 or general causation, how it affects a group of people as a
21 whole, and specific causation as to how it might impact an
22 individual plaintiff asserting his or her claim.

23 At the outset, there are six very important
24 factors that really define medical causation related to the
25 St. Jude Medical Silzone heart valve. First and foremost,

1 that the injuries being claimed here are really medical
2 conditions or complications which for the most part with a
3 few exceptions are latent in their nature.

4 They are not sudden. They are not immediate.
5 They are conditions which and oftentimes are very difficult
6 to diagnose, and they are diagnosed when and if they do
7 occur, not necessarily always by the same kinds of medical
8 specialties.

9 For example, a thromboembolic event might well be
10 something that would be diagnosed and treated by a
11 neurologist, whereas a paravalvular leak by a cardiologist
12 or a cardiac surgeon. Also important is the fact that the
13 risk of developing these complications not only differs
14 from one complication to another but also is different over
15 time so that at different points in time after a valve is
16 implanted, the risk will be different for a variety of
17 reasons.

18 Also important is the fact that each of these
19 claimed conditions or complications involve multiple risk
20 factors, and the risk factors differ from one complication
21 to another which I will get to in a minute. These
22 complications are not unique to the Silzone heart valve.
23 These complications occur in patients with every kind of
24 mechanical heart valve. They also occur in individuals who
25 don't have mechanical heart valves.

1 For example, thromboembolic events occur in the
2 population as a whole. Stroke obviously occurs in the
3 population as a whole, heart attack the same. Endocarditis
4 can occur in a person in their native valve who doesn't
5 have a mechanical heart valve.

6 MR. ANGSTREICH: Excuse me, Your Honor. With all
7 due respect to Mr. Kohn, this entire argument that he is
8 making is the very argument that was made for class
9 certification. It has nothing to do with independent
10 applications with respect to subclasses.

11 This is an attempt to reargue that each
12 individual plaintiff is unique. That was an argument that
13 was made and dealt with in your original certification
14 order, and I really think it's inappropriate for us to
15 spend the time now re-addressing that. That was not what
16 we were supposed to do.

17 And with due respect to the Court, we did not
18 bring that back to the Court or attempt to readdress it,
19 and I would ask that Mr. Kohn not be permitted to reargue
20 the issue of the individualities of each of the plaintiffs.
21 Thank you.

22 THE COURT: I will let Mr. Kohn try to tie it
23 into the subclasses, so go ahead.

24 MR. KOHN: All right. Thank you, Your Honor, and
25 I will do just that. Let me start in that connection with

1 the issue of the background rate that exists with these
2 respective complications.

3 What I'm showing on this slide, Your Honor, are
4 what is called objective performance criteria, which are
5 incidence rates of complications that are published by the
6 FDA based upon a review of the medical literature. And
7 just by way of illustration, the background rate for
8 thromboembolism for patients with mechanical heart valves
9 is 3 percent per patient year.

10 What that says is that if 100 patients this week
11 have their valves implanted, over the next year, in all
12 likelihood three of those individuals will experience a
13 thromboembolic event. The point here in terms of how this
14 impacts the subclasses is as follows:

15 In every single subclass, whether it's a personal
16 injury class or whether it is medical monitoring, the
17 plaintiff here has the burden of showing that there is an
18 injury and an injury that is caused by Silzone.

19 In order to do that, that has to be compared to
20 the background rate to see whether in fact there is an
21 increased incidence or whether the claimed injury in any
22 subclass or -- whether it's medical monitoring or personal
23 injury is something that would have happened anyway.

24 Similarly, Your Honor, with respect to these
25 background rates, and I'll get to this in a minute. These

1 involve different risk factors. They involve different
2 kinds of testimony, and the trial of these cases, depending
3 upon which of these injuries is being tried, is going to be
4 very different, different mechanisms of action, different
5 causes and different risk factors.

6 Turning your attention to paravalvular leak, I'm
7 only going to talk about three of the multiple
8 complications that are being alleged here. There are at
9 least a dozen individual risk factors that will need to be
10 assessed in any individual or group subclass that is
11 formed, any individual case or any subclass, before it can
12 be determined whether or not the alleged injury is caused
13 by Silzone, whether there is an increased incidence, or
14 whether this complication would have manifested itself
15 anyway because of these different risk factors.

16 It's also important in analyzing the subclass
17 issue to see how the risk varies over time and as this
18 chart demonstrated, and this is based on the AVERT data,
19 Your Honor, on the left axis we have the probability that
20 an individual will experience a paravalvular leak at
21 different time intervals after implantation.

22 On the right axis is the months after
23 implantation, and what we see from this is that not only is
24 the alleged risk of paravalvular leak in the Silzone
25 population low, but that at a particular point in time, the

1 risk is actually less or actually the same with the Silzone
2 valve as it is with the conventional valve.

3 That will certainly go to alternative design.
4 That will certainly go to the other affirmative defenses,
5 including Comment k that Mr. Angstreich would trivialize,
6 but the reality of the situation is that when the risks are
7 the same, Comment k is going to be a factor and the other
8 affirmative defenses will be as well, including state of
9 the art.

10 Turning the Court's attention to the causation
11 factors involved with thromboembolic events, here what I
12 want to focus on at the outset is the first five: Smoking,
13 obesity, inactivity, inappropriate use of anti coagulation
14 therapy and high cholesterol are all things that come into
15 play in the arena of comparative fault.

16 So in any group or for that matter individual
17 case where a thromboembolic event is an issue, these
18 factors will have to be analyzed, and if smoking, obesity
19 and the other comparative fault type issues are in play,
20 that will have to be considered, and that will affect both
21 bifurcation and how the case can be tried in a subclass
22 format.

23 If we look at the risk over time, the same
24 comments I made a minute ago with respect to paravalvular
25 leak are applicable here. The fact that there has never

1 been a statistically significant difference between
2 thromboembolic events in the Silzone population versus
3 patients with other kinds of valves, the fact that the risk
4 varies over time and the fact that the risk has
5 consistently been below the FDA's objective performance
6 criteria all shows that regardless of how this plays itself
7 out, there will be a debate.

8 There will be contrary evidence presented by both
9 sides in a subclass trial on this issue, and the plaintiffs
10 will have to meet this evidence when these cases go to
11 trial, and St. Jude will be able to demonstrate using this
12 data and other data that in terms of thromboembolic events,
13 the Silzone valve was the state of the art, that it was the
14 best alternative design and that Comment k applies.

15 With respect to endocarditis, the same analysis
16 applies, and I'll go through this very quickly. Here we
17 have different risk factors, not the same ones that we saw
18 with paravalvular leak or thromboembolism.

19 Again, we have the issue of comparative fault
20 being introduced because the first item on the list is
21 whether or not the individual plaintiff did or didn't
22 comply with their prophylactic antibiotics, for example,
23 when they go to the dentist. If they didn't and they
24 developed endocarditis, that brings comparative fault into
25 play.

1 Similarly, if we look at the risk over time, my
2 comments about thromboembolism and paravalvular leak are
3 equally applicable here. The risk is low. The risk is the
4 same. The same affirmative defenses will be introduced in
5 any trial where the claim is that Silzone increases the
6 risk of a thromboembolic event.

7 When we turn to medical monitoring and we talk
8 about the subclasses that may or may not be grouped in
9 medical monitoring, these same issues will come into play
10 with equal force. In the case of monitoring, and I would
11 address the Court's attention to the affidavit of
12 Dr. Mizgala which was submitted along with our brief --

13 MR. ANGSTREICH: Excuse me, Your Honor. With
14 respect to Dr. Mizgala, that was inappropriate and an
15 inappropriate submission. It should not be considered, and
16 I would like the record to reflect that we strongly object
17 to that. It should not be before the Court. It has
18 nothing to do with an issue of subclasses.

19 It has to do only with the individual issue that
20 was confronted before, the last time, and with due respect
21 to Mr. Kohn, what Mr. Kohn has said with respect to all of
22 the issues is that it doesn't matter what the subclass is,
23 we're going to face these arguments.

24 So for him to now say that he is somehow tying in
25 this attack on class certification irrespective of

1 subclasses is just being disingenuous. This is an attack
2 across the board regardless of what the subclass is, and I
3 would ask Mr. Kohn to tell us how this impacts on a
4 specific subclass or how it changes our subclasses that we
5 presented to Your Honor because he hasn't done that yet.

6 THE COURT: Go ahead, Mr. Kohn.

7 MR. KOHN: Thank you, Your Honor. I'm going to
8 turn from what I've just concluded talking about to the
9 plaintiffs' toxicity theory, which again will affect how
10 these cases are tried and whether or not they're manageable
11 and whether or not the subclass format that has been
12 proposed by plaintiffs is in fact the superior format.

13 With respect to Dr. Tyers in his affidavit filed
14 with this Court, what he claims is that the Silzone valve
15 deposits toxic concentrations of silver at the local level
16 in local tissue and that it's the effect somehow of these
17 toxic concentrations of silver that has an impact on
18 healing and gives rise to injury in some way.

19 The problem with that theory is that it requires
20 individual analysis, and I say this because if you look at
21 Dr. Rodricks' affidavit, toxicity depends on two things.
22 It depends on the unique characteristics of the individual
23 receiving the dose, and it depends on the dose of the
24 substance.

25 For example, if we look at five of the plaintiffs

1 in the MDL, we can see that there is going to be a big
2 difference, at least we will claim there is a big
3 difference, and I'm not saying we won't dispute this
4 toxicity theory because we will.

5 But giving it all the deference to which it is
6 entitled, there certainly will be a difference between the
7 alleged toxic doses of silver that Mr. Crawford who had his
8 valve explanted at one month may have been exposed to
9 versus Ms. Sliger who had her valve in for 12 months versus
10 Ms. Bailey who has had her valve in for five years and as
11 far as we know is not experiencing any problems.

12 It requires individual analysis. It makes
13 subclasses unmanageable and not the nonsuperior method.
14 Similarly, we don't have in this case a common course of
15 conduct, and this is critical because it will affect what
16 evidence can be introduced at particular trials that may
17 take place.

18 For example, Your Honor, the valve was brought to
19 market in March of 1998, and the plaintiffs, the 11,000
20 purported class members, were implanted over a two and a
21 half year period, during which time the state of medical
22 knowledge changed because of adverse event reporting and
23 other items that appeared, other things that appeared in
24 the medical literature.

25 The point is that different evidence may be

1 admissible for different plaintiffs because of the date of
2 implant. So, for example, in Ms. Sliger's case, arguably
3 anything that happened before August of 1999 could
4 potentially be admissible in her case, but for Beatrice
5 Bailey, who was implanted in January of 1999, a lot of
6 events that occurred after that would arguably be
7 inadmissible.

8 And similarly with respect to the premarket
9 testing that St. Jude Medical undertook, different testing
10 was designed to address different kinds of complications.
11 So the testing that was aimed at the thrombogenicity of the
12 valve would not be admissible in a case involving
13 paravalvular leak and so forth, so not a common course of
14 conduct.

15 The unique facts and the unique legal issues, I'm
16 going to be very brief with this, are easily demonstrated
17 by looking at two of the proposed class representatives.
18 I'll start with Mr. Sanchez. Here the claim is as far as
19 we can tell he has a paravalvular leak and experienced a
20 transient ischemic attack.

21 What we learned from a scrutiny of his medical
22 records is that he had a paravalvular leak and a thrombus
23 on his valve as well as endocarditis with a valve that he
24 had before he ever got a Silzone valve, only demonstrating
25 the last point I made earlier that these injuries occur

1 with every mechanical valve.

2 Similarly, there will be a number of affirmative
3 defenses that St. Jude will introduce in any class that
4 Mr. Sanchez is designated to represent. In particular with
5 respect to, and he's been put forth as a representative
6 both of the injury and the monitoring class.

7 We will claim that his valve is functioning
8 normally after four and a half years, that he doesn't have
9 a paravalvular leak, that his transient ischemic attack was
10 related not to Silzone but to a sleeping medication that he
11 took against medical advice or inappropriately, and we will
12 also introduce evidence that the AVERT data shows no
13 increased risk of paravalvular leak or transient ischemic
14 attack.

15 Turning finally to Ms. Sliger who claims to have
16 had a paravalvular leak and an explant, St. Jude will
17 introduce evidence that she didn't have a paravalvular
18 leak, that all of the echocardiograms done before her
19 explant were negative, that her explant in fact was done
20 against medical advice of all of her physicians.

21 And when the valve was explanted, they found good
22 healing of the Silzone valve. In fact the reason for her
23 explant related to her desire to stop anti coagulation
24 medication, and the unique facts and unique legal issues
25 don't stop with Mr. Sanchez and Ms. Sliger who are the only

1 two designated representatives of the injury class.

2 We don't have any designated representatives for
3 any of the injuries that are listed on this exhibit, Your
4 Honor. Bonnie Sliger and Joe Sanchez have not had any of
5 these injuries, but it really doesn't matter because if the
6 plaintiffs are allowed to come forward at some later time
7 and designate class representatives who they claim are
8 typical and adequate to represent the class with respect to
9 these injuries, the same kind of scrutiny and the same kind
10 of individual analysis is going to be mandated.

11 Now turning to the Teletronics decision which
12 Mr. Nilan mentioned largely in the context of the legal
13 ramifications of that case and why that case can and
14 shouldn't be relied upon by the plaintiff here, the
15 starting point of the analysis is that case involved a
16 fractured lead where it generated a signature wound, a
17 wound to a vessel or to the heart itself that couldn't
18 really have been caused by anything else.

19 The Court in Teletronics noted that that's very
20 different than the situation we have here where we have
21 latent, difficult to diagnose diseases. In fact there was
22 only one credible cause for the puncture wound in
23 Teletronics. Causation wasn't even seriously debated in
24 that case.

25 Here regardless of who wins or loses the debate,

1 regardless of how that plays itself out, the fact of the
2 matter is, in every single case, subclass or individual
3 case, there is going to be a debate about general and
4 specific causation because of the issues that are portrayed
5 on this slide.

6 And that's true because there are so many
7 different reasons why these diverse injuries occur.
8 They're wholly unrelated to the fact that someone had a
9 Silzone valve. So comparing Telectronics across the board,
10 what we find is in Telectronics, causation was obvious. It
11 was uncontested. That's not true here.

12 Telectronics involved a signature injury, a
13 direct and immediate wound. That's not true here. The
14 failure rate in Telectronics was so high that no other
15 cause was likely. Here, the failure rates are
16 extraordinarily low, so low, in fact, that they're below
17 the FDA background rate almost across the board.

18 In Telectronics, the defendant admitted that
19 monitoring was needed. Here we vigorously dispute that
20 these Silzone valve patients need any increased monitoring
21 beyond what they already get. In Telectronics there was a
22 single course of identical conduct, not the case here. In
23 Telectronics, you had a defendant facing insolvency, which
24 is certainly not the case here.

25 Another case I believe that is instructive is a

1 recent decision by Judge Davis in the Baycol litigation,
2 and I think a quick comparison to that case will be helpful
3 to the Court.

4 In rejecting class certification there, both in
5 the injury class and the monitoring class, one of the
6 reasons cited was the fact that it involved, the facts
7 there involved a complex course of conduct -- the same is
8 true here -- that occurred over an extensive period of
9 time. The same is true here.

10 It also involved factually unique plaintiffs. It
11 also involved an alleged defect that was related to dose,
12 which is true here for the reasons I've already said. It
13 involved affirmative defenses peculiar to each plaintiff,
14 and it involved inconsistent goals of the class
15 representatives, which certainly is true here for the
16 reasons I've talked about with respect to Mr. Sanchez and
17 Ms. Bailey.

18 And finally in conclusion, Your Honor, the
19 overarching issue in Baycol and the overarching issue here
20 is medical causation. There are multiple diverse injuries
21 alleged here. That was also true in Baycol. The same
22 injuries that occur in Baycol occur in people who never
23 took Baycol.

24 The same injuries that occur in many instances
25 here occur in people with -- who never had a mechanical

1 valve, and they certainly occur in all patients who have
2 had mechanical valves. There are multiple risk factors for
3 each injury, and that was true in Baycol. It's certainly
4 true here.

5 We're dealing with latent injuries, not sudden or
6 immediate injuries. The risk definitely varies for each
7 patient based upon their unique medical history, and most
8 importantly, individual issues must be taken into account
9 to determine proximate cause in every case.

10 So, Your Honor, for all of these reasons, I
11 respectfully submit that both because of the legal
12 complexity that was discussed by Mr. Nilan and because of
13 the immense factual diversity and complexity that I have
14 talked about, the subclasses should not be certified.

15 Thank you, Your Honor.

16 THE COURT: Thank you, Mr. Kohn.

17 MR. CAPRETZ: Your Honor, if I may. We listened
18 somewhat patiently to the gentleman. I think we're here
19 for the purposes of discussion and argument on the
20 subclasses as presented by the Court. This is another
21 technique by St. Jude Medical to do a motion by ambush. We
22 don't appreciate, and we don't respect it.

23 We were here to argue the subclass issue. We
24 heard a reeducation issue as to whether or not we had valid
25 class representatives, as to why this valve is a safe

1 valve, as to why our cause and complaints are not
2 well-founded.

3 We're going to move that all of that testimony be
4 struck from the record as inappropriate and irrelevant.
5 Unless we have the proper notice, due process requires the
6 classes have notice of what matters are and issues are
7 going to be presented to the Court. We have the right to
8 brief those issues and argue those issues.

9 Mr. Kohn was doing nothing more than trying to
10 reeducate the Court. May I remind Mr. Kohn that this Court
11 certified unconditionally a class under Minnesota law, and
12 the only thing we're talking about at this hearing, at
13 least what was on the agenda for today, was the briefing on
14 subclasses.

15 I heard nothing from Mr. Kohn except indirect,
16 diverse references to how it fit into the subclass
17 argument. So I ask that the Court respect our request that
18 the testimony, and it was testimony by Mr. Kohn, be
19 struck -- be stricken from the record.

20 THE COURT: Well, I'm going to deny the request
21 to strike the argument. It's just that. I will take it
22 for what it's worth and consider it as I move forward on
23 the consideration of the subclasses. Some of it the Court
24 views relevant. Other parts may be less relevant, but I
25 don't consider it to be inappropriate.

1 Mr. Martin, you wanted to finish up, I think, for
2 the defendants.

3 MR. MARTIN: Your Honor, getting back to the
4 beginning, the focus here today for purposes of the
5 subclass issues is on how these cases in fact will be tried
6 given their legal elements and factual elements, and that's
7 the issue the Court left open. The question was, was a
8 subclass format going to be a superior method to resolve
9 these cases.

10 We submit that after the showing that Mr. Nilan
11 and Mr. Kohn have made on the record before this Court
12 there is no objective case to be made that the class wide
13 trial is the superior method. Your Honor, no matter what
14 plaintiffs might say in rebuttal, they can't escape like
15 Houdini and make any of the complexity or confusion
16 explored by Mr. Nilan and Mr. Kohn go away.

17 It's the nationwide litigation that plaintiffs
18 propose that creates the need for multiple complex
19 subclasses on design defect, on warning, on warranty, on
20 negligence and for medical monitoring.

21 It's the nationwide litigation that the
22 plaintiffs propose that creates the need for repeated and
23 complicated Erie analyses that further compound the
24 difficulties of trying these cases, and it's the nationwide
25 class litigation that the plaintiffs propose and the

1 injuries they allege and want to recover for that raises
2 the discrete individual issues on their claims and on
3 St. Jude's defenses that creates a level of complexity that
4 is the antithesis of what streamlined litigation under
5 Rule 23 is supposed to be about.

6 When it's contemplated that the laws of 51
7 jurisdictions will be involved to try five different causes
8 of action, a like number of affirmative defenses under
9 different legal standards with different burdens of proof,
10 federal courts are unanimous. Any notion of efficient or
11 effective class wide resolution breaks down completely.

12 In fact, to chisel these cases into the subclass
13 format as the plaintiffs propose is to ask this Court to go
14 where no federal court has gone before, and it's to ask the
15 Court to go where federal courts have repeatedly said we
16 shouldn't go for reasons, as the arguments demonstrated,
17 that are directly applicable to these reasons.

18 Where is the compelling reason to stretch the
19 law, to stretch the parties, to stretch the resources of
20 the Court in pursuit of this endeavor? It's not there. Do
21 the cases as filed at present present a threat to overwhelm
22 the judiciary? No. There is less than 50 federal cases,
23 and they are spread out nationwide.

24 Is there a need to manage the cases in a class
25 wide format? No again. The MDL provides a workable,

1 appropriate and efficient case management tool. Is there a
2 need for remedy? No. The injured parties here with viable
3 causes of action are perfectly capable of bringing
4 individual lawsuits, and they've done it.

5 Is there an unchecked risk? No. The AVERT data
6 establishes that with this patient population, the Silzone
7 valve doesn't present a statistically significant risk, and
8 all heart valve patients already receive extensive and
9 individualized medical monitoring.

10 Is a class wide trial the only case resolution
11 option? Well, no, it's not. As Mr. Nilan noted, these
12 cases can easily be sent back to their jurisdictions of
13 origin for trial and avoid the Erie complications and the
14 potential for juror confusion.

15 Is class wide resolution here compelled by a
16 controlling precedent? No. The law is uniformly against
17 class wide resolution in cases of this complexity. Is it
18 driven by the policies underlying Rule 23? No. The Amchem
19 court tells us to act with caution in cases like these,
20 stick strictly to the requisites of the rule and don't get
21 innovative with class action procedures.

22 How about principles of federalism? Well,
23 principles of federalism are usurped, not advanced, by the
24 class wide trial that the plaintiffs propose, and is there
25 a constitutional mandate? The answer again is no. Due

1 process, full faith and credit and the Seventh Amendment
2 are violated, not furthered, by plaintiffs' demand for
3 class wide resolution.

4 As our next slide shows, the Supreme Court has
5 established in Amchem that a class action should be
6 utilized only when it achieves economies of time, effort
7 and expense and without sacrificing procedural fairness or
8 bringing about other undesirable results.

9 No matter how much well intentioned effort or
10 good faith is applied, fundamental principles of federalism
11 and constitutional safeguards will have to be breached to
12 even begin to attempt to organize or homogenize these cases
13 into the subclass trial plaintiff proposes.

14 Once that step is taken, which itself will be
15 reversible error, everything from class notice to the
16 introduction of evidence, to the instructions, to the
17 verdict form will present further opportunities for error.
18 These are indeed, Your Honor, the very cases that Rule 23's
19 drafters had in mind when they said class wide litigation
20 will not be suitable.

21 There is no single happening or event giving rise
22 to liability, no one set of operative facts, no
23 representative plaintiff, no single proximate cause, no
24 legal consensus and multiple affirmative defenses.

25 Many federal cases have also observed that the

1 most efficient and most effective resolution of these cases
2 is not through the class action device. That's what the
3 weight of authority is. These cases provide instead that
4 the answer is to manage the cases within the confines of
5 the MDL and return the cases to their jurisdiction of
6 origin for resolution, settlement or trial.

7 That result protects the interest of all the
8 parties and will avoid the difficulties, complexities,
9 inefficiencies and unfairness that will inevitably invade
10 any subclass trial here. Moreover, Your Honor, the track
11 record developed by those narrowly focused individual cases
12 will provide a more efficient means of case evaluation and
13 permit those plaintiffs with viable claims to recover more
14 quickly.

15 Now, Your Honor, there have been much analysis
16 today about what is on the Court's plate and what is not
17 and what is properly before it, but there is no debate
18 about one thing. Rule 23 empowers this Court at this
19 juncture to reject plaintiffs' subclass proposal and reject
20 any conclusion that these cases can be tried on a class
21 wide basis.

22 Congress, the Supreme Court and multiple federal
23 cases have declared that courts should take the
24 responsibility to decertify classes when the record before
25 the Court shows that class wide litigation is not the

1 superior or best method for case resolution.

2 Your Honor, that is at the end of the day where
3 we are here on the presentation that St. Jude has made, and
4 we are urging the Court to reject plaintiffs' subclass
5 proposal in its entirety and decertify the designated
6 classes.

7 THE COURT: Has the Canadian court ruled on the
8 motion for class certification yet?

9 MR. CAPRETZ: Class certification, we tendered
10 that to the Court. As a matter of fact, the Court also
11 ruled on the reliability and trustworthiness and usefulness
12 of the plaintiffs' testimony.

13 There was a Daubert like motion brought by
14 St. Jude Medical which failed. The court held the
15 credibility of the experts used in Canada in addition to --

16 MR. ANGSTREICH: Certifying the class.

17 MR. CAPRETZ: That has been tendered to the
18 Court, Your Honor.

19 MR. MARTIN: Thank you, Your Honor.

20 MR. ANGSTREICH: I feel like General Custer, Your
21 Honor. I came to the courtroom this morning because Your
22 Honor said it is evident from the parties' briefs that they
23 did not focus on the possibility of certifying subclasses.
24 Therefore, the Court will request briefing from the parties
25 on what minimum number and type of subclasses would be

1 appropriate for plaintiffs, negligence, strict liability,
2 breach of warranty and monitoring claims.

3 That's what I thought we were here for. I didn't
4 know that we were here for a, quote, de-certification of a
5 conditional certification or for de-certification of the
6 unconditional certification of the consumer fraud claim
7 that Your Honor certified under Minnesota law. I think
8 it's highly disingenuous of all of these attorneys to stand
9 up here and make those kind of arguments.

10 I think it's more obscene when an attorney stands
11 here and argues the very claims and contentions that he
12 made the last time and lost on and offered you nothing new
13 because even if there was a right to a de-certification now
14 and even if waiving the flag and the Constitution and all
15 of the rules that at any time you can attempt to ask the
16 Court to reconsider its ruling, they should have presented
17 something new.

18 They presented nothing new. Nothing new to
19 change Your Honor's finding at page 6 of your opinion that
20 while St. Jude is correct that there may be individual
21 variations in the factual circumstances of some class
22 members, that is not enough to defeat commonality. Nothing
23 new. Same old argument.

24 Your Honor then went on to say that even if the
25 named plaintiffs' cases do exhibit different factual

1 circumstances, and I remember I saw Sanchez and Sliger up
2 here. I think I saw them the last time we argued this.
3 Each of them clearly arises from the same event or practice
4 or course of conduct that gives rise to the claims of the
5 other class members and is based on the same legal
6 theories.

7 That's page 7 of Your Honor's opinion. Now,
8 apparently something different has happened. I didn't hear
9 it. I don't know if the Court did. To suggest that there
10 is something new, again nothing.

11 The Court then went on to say, The Court finds
12 that plaintiffs all have the same incentive to pursue
13 claims against St. Jude. Now, I thought I saw in one of
14 the slides that there was something different about each of
15 the plaintiffs there.

16 The Court finds no conflict of interest that
17 would render plaintiffs inadequate representatives of the
18 classes. That's at page 9. Same argument, nothing new, no
19 new case law, and Canada has said, this incident is
20 appropriate for class certification. Now they only have
21 2500 in their class. We have 11,300.

22 Now, Your Honor also adopted, I believe, Judge
23 Spiegel's considerations in Teletronics. That was not
24 plaintiffs' argument, although we made it to Your Honor at
25 the time of the class certification, but at page 22 of Your

1 Honor's opinion, the Court quotes from Teletronics.

2 If the elements of the cause of action are the
3 same and the legal standards are important, meaningful,
4 significant, pivotal issues are substantially similar, the
5 state laws can be grouped for purposes of class
6 certification. Then Your Honor went on to say, The Court
7 envisions a minimal number of subclasses and will find that
8 only significant variations in state law will be sufficient
9 to require different subclasses.

10 Now, I think I just heard Mr. Martin say that
11 Your Honor would be committing reversible error if you
12 certify this case. I assume that he is also suggesting
13 that Your Honor's conclusion that only significant,
14 meaningful, important and pivotal issues are what should be
15 focused on because I think both Mr. Martin and Mr. Nilan
16 both said that you have to look at every little subtle
17 nuance.

18 That's not what you directed us. That's not what
19 Teletronics says. That's not what Rule 23 requires in
20 creating subclasses. I have to comment on a couple of
21 misstatements that were made.

22 The learned intermediary doctrine, I heard
23 Mr. Nilan say that the learned intermediary doctrine has to
24 apply here because you don't have to give consumers
25 warnings when there is a learned intermediary. I think he

1 left out some very important point.

2 You have to warn a doctor. I didn't hear him say
3 that. Nor have I seen any evidence because he says and
4 said that we pled it and we presented evidence. Maybe they
5 pled it, but they haven't presented a shard of evidence
6 that they warned the doctors about these risks. In fact
7 they lied to the doctors.

8 They told them that there were no risks when they
9 had the results of Mr. Butchart, Dr. Butany and others and
10 their own tests, the death of Dolly I, and we have gone
11 over this. We went over it in preemption, and we went over
12 it in class certification.

13 And for him to stand up here and say we're going
14 to argue learned intermediary when there is no warning to
15 the doctors is disingenuous. For Mr. Kohn and Mr. Nilan to
16 say that oh, yes, Comment k applies across the board,
17 Comment k requires a warning. Show us the warning.

18 I will agree that that's a valid defense. Show
19 me the warning. Learned intermediary is a valid defense.
20 Show me the warning. You can't stand up here. It is the
21 same argument when you file a motion for summary judgment,
22 somebody says well, we pled that these facts exist.

23 Where is the evidence? You can't stand up and
24 say we have valid defenses and make arguments without any
25 support for it. There is no warning. State of the art?

1 How dare he argue state of the art. They were creating or
2 attempting to create it, and the FDA wouldn't even allow
3 them to advertise it for what they claimed it was for.

4 The state of the art was the conventional Masters
5 Series valve not the Silzone valve. To argue that it was
6 unavoidably dangerous, it was an unavoidably dangerous
7 product when it had a value when it wasn't efficacious for
8 endocarditis is disingenuous.

9 Yes. They pled the defenses, but they cannot in
10 good conscience ever persevere on them or present them
11 because it is clearly foolish, and if in fact the evidence
12 was there, why wasn't that part of the argument for summary
13 judgment?

14 If they could eliminate all the people from
15 Louisiana, from Pennsylvania, from New Jersey on any of
16 these arguments, why didn't they make that part of their
17 summary judgment?

18 We've also overlooked one very important thing as
19 it relates to class certification. I didn't want to
20 reargue class certification, but if we're going to focus on
21 class certification again, I think there is an overarching
22 defense called preemption, which unless there is a
23 certification can't possibly apply across the board so that
24 as Your Honor knows, it's common questions of fact or law
25 whether it's defenses or claims, and if you want to go back

1 to whether or not this case should be certified at all,
2 their preemption argument requires certification across the
3 board.

4 The final point I want to make because we have
5 been arguing and discussing this for a long time is, I
6 really didn't think that Your Honor expected superimposed
7 subclasses. I thought Your Honor said, How many subclasses
8 would there be for medical monitoring? Two. How many
9 subclasses would there be for breach of warranty, express
10 or implied? Two.

11 How many subclasses would there be for strict
12 liability? Three under failure to warn, four under design
13 defect. And by the way, Your Honor, we never addressed the
14 issue of the UCC application of Minnesota law when we
15 talked about application of choice of law, conflict of law
16 rules. We did not focus in on the UCC's separate and
17 specific choice of law provision, which depending upon the
18 circumstances can, as the courts have said and as our brief
19 addresses, alter the governmental interest analysis and
20 allow for Your Honor to apply Minnesota law.

21 I believe that reargument or reconsideration
22 where the issue was not before the Court or was not raised
23 before the Court is at least one of the areas where you can
24 bring it back to the Court's attention.

25 So we submit that we did not expect, and I don't

1 think the Court expected when the Court said you envisioned
2 a minimal number of subclasses that we were superimposing
3 through this plastic sheet over on top of the United States
4 51 or 28 or 40, trying to find the state that had each of
5 the appropriate theories.

6 We submit that we have done the analysis. This
7 is a proper case for class certification for the reasons
8 Your Honor originally found. Nothing new has been added.
9 Again, it's proper with preemption and our subclasses are
10 manageable.

11 Thank you.

12 THE COURT: Thank you, Mr. Angstreich. Let's
13 turn to the status conference that we want to get in here.
14 I know some of you probably have plane flights, and we
15 should wrap up as quickly as possible.

16 Mr. Capretz?

17 MR. KOHN: Your Honor, could we have two minutes
18 to respond to a couple of the points that were just made?

19 THE COURT: Go ahead.

20 MR. KOHN: Thank you.

21 MR. MARTIN: Two things, Your Honor. On the
22 warning issue, Your Honor, our warning information was part
23 of the approval process with the FDA and went out with the
24 product. The warning is in the record. It's before the
25 Court. It will be a part of the cases.

1 Second, on the preemption defense which was new
2 in rebuttal, the issue of the certification of preemption
3 as an affirmative defense arose in the Agent Orange cases,
4 and I commend that opinion to the Court. The government
5 contractor defense was the overarching defense in that
6 case.

7 It's the only issue on which the court certified
8 class, and it did so because it thought the government
9 contractor defense was going to be viable, and it would be
10 dispositive of the cases and save litigation. When the
11 Court got to the personal injury claims that are at issue
12 in a case like this one, it said Rule 23 absolutely doesn't
13 permit certification.

14 The factual and legal variances are too great,
15 and I commend the Court to that opinion for the analysis
16 because it's dispositive of this point on preemption here.
17 Thank you.

18 THE COURT: Thank you, Mr. Martin.

19 MR. ANGSTREICH: Your Honor, if we're going to go
20 back in history to what courts viewed, and we argued this
21 when we talked about certification, times change. We have
22 a re-called product with a latent defect that has been
23 acknowledged by the defendant that any injury is latent.

24 That's why medical monitoring is needed. It's a
25 different case. Thank you.

1 THE COURT: Let's turn to the status conference.
2 Mr. Capretz?

3 MR. CAPRETZ: Thank you, Your Honor. The
4 principal thing on the status conference agenda, Your
5 Honor, is a very serious and critical one in my view.
6 That's the privilege log document release and appointment
7 of a special master request.

8 The parties have briefed by letter briefs dated
9 the 3rd respectively for the classes and for the defense,
10 as well as the 10th. The issue as the Court well recalls,
11 31 of approximately I think 66 documents were reviewed in
12 an exemplar mode as to whether or not the privilege log
13 exception should be honored.

14 The Court ordered that 31 of these documents be
15 released. As we stand here today October the 14th, the
16 classes have not received one. This is a disobedience of
17 the Court order and the only -- and we ask that the Court
18 take this matter very seriously. We thought about asking
19 for sanctions.

20 We suggested since most of this litigation has
21 gone in a civilized and professional manner that it would
22 be inappropriate at this point and one other opportunity
23 should be afforded St. Jude Medical to release these
24 documents, but we're there, Your Honor. We cannot proceed
25 with the discovery we need.

1 We know, and the Court may recall, we held in
2 abeyance the further deposition of Mr. Ladner until we
3 received the documents. We haven't received the 31
4 documents. We're also asking and suggesting that of the
5 450 approximately documents that are still hidden behind
6 this privileged log, there are other evidence, there is
7 other critical evidence that might be available to the
8 classes that plaintiffs are entitled to receive.

9 And in that regard, we're seeking that the Court
10 appoint a special master to review those documents and
11 decide which might be not privileged and released and
12 should be released to the plaintiffs.

13 St. Jude Medical has afforded no defenses as to
14 why the documents should not be released. They have
15 instead asked for an order for clarification, which again
16 to use a word that my colleague used over and over again,
17 disingenuous. There is a Rule 7.1(g), local rule, which
18 says if you want to do a motion for reconsideration, that's
19 the proper procedure to file it.

20 Did St. Jude Medical do it? No, they did not.
21 They instead asked for a clarification. We don't think
22 that makes any sense. How can we possibly participate in a
23 meet and confer or the Court give clarification when the
24 plaintiffs are not privileged to what the documents say.
25 There is no way. It would be a one-way street.

1 So we're not sure what St. Jude Medical wants,
2 and we'll let them, of course, have an opportunity to speak
3 to this issue from the Court, but we think it's clear that
4 the documents should be released, and they should be
5 released now, and we ask also that a special master be
6 appointed.

7 I'll let St. Jude Medical respond, and we will go
8 back to the other items, if you will, unless the Court has
9 a question.

10 THE COURT: That's fine.

11 Go ahead, Mr. Kohn.

12 MR. KOHN: Thank you, Your Honor. Just a little
13 bit of history which I know the Court is familiar with.
14 The whole concept of having the Court review, and I know
15 this is a painstaking and painful process because of the
16 volume of documents, the 50 odd documents, was with a view
17 towards, if we were able to get a ruling on those documents
18 and understand how the Court viewed the privilege issue, we
19 would then be able to have a meaningful meet and confer as
20 to the remaining documents on the privilege log.

21 And I thought until today that both sides were in
22 agreement that some clarification by the Court as to its
23 reasons for declaring particular documents either
24 privileged or not would be helpful in the meet and confer.

25 I think it would be terribly wasteful of the

1 Court's resources, and especially a special master, to have
2 450 documents deposited with a special master without some
3 kind of guidance as to what criteria need to be utilized.

4 Also I think it's terribly wasteful to do that without the
5 parties first engaging in a meet and confer.

6 The plaintiffs certainly can look at the 450
7 documents on the privilege log, and I submit they could
8 easily identify a considerable number that there wouldn't
9 even be an argument about, but to say that all 450 should
10 go to a special master with the record that we now have it
11 seems to me is wasteful of the resources of the parties.

12 So what we would request is that the Court
13 consider our request for clarification, and with that
14 clarification, I believe we can have a meaningful meet and
15 confer. To the extent that we can't agree on the other 450
16 documents, those I believe can be submitted to a special
17 master with appropriate briefing as was done with the
18 documents that were submitted to Your Honor, and we can get
19 this entire issue resolved.

20 We are not standing in the way of plaintiffs
21 having something that they're entitled to. We only want to
22 be sure that we understand the Court's reasons for its
23 rulings and that we act accordingly.

24 Thank you, Your Honor.

25 MR. ANGSTREICH: Your Honor, Mr. Stanley and I

1 have attempted to resolve the issue before, and that's what
2 brought us to you. It's very difficult, as Mr. Capretz has
3 said, for us to sit and meet and confer with Mr. Kohn or
4 Mr. Stanley.

5 We could do that if we had the 450 documents
6 available to us, and we could look at them and then decide
7 which was or was not privileged. In the absence of that,
8 as Mr. Capretz has said, we really would be listening to
9 them looking at the privilege log.

10 We looked at the privilege log. We contended
11 that they weren't privileged anymore. Your Honor agreed
12 that 31 of the 65 were not privileged. Now, we agree and
13 recognize that Your Honor didn't tell anybody why the 34
14 were remaining privileged and the 31 were not remaining
15 privileged.

16 That really doesn't address the plaintiffs'
17 position that we should have the 31 now. Whether you
18 clarify your position or your decision and tell us the
19 reason why the 31 fell outside privilege, that's fine.
20 That may help us with the others.

21 I don't know how we'll do that, but
22 notwithstanding that, what does clarification have to do
23 with giving us the 31 documents in the first place? Maybe
24 if we had those 31 documents in our hands, this argument
25 could have been avoided, and maybe we might have been in

1 the position then to understand what it was about those 31
2 documents versus what it said on the privilege log that
3 convinced Your Honor that they were no longer or
4 inappropriately designated privileged.

5 In the absence of the 31 documents, in the
6 absence of the other documents, we can meet and confer and
7 discuss the remaining ones but certainly two things have to
8 happen. One is, we have to get the 31 documents; and two,
9 if Your Honor believes that giving us a road map to why
10 those 31 were declassified would assist the parties in
11 resolving the remaining privilege log, we'll attempt to do
12 it that way.

13 If we can't get that, and that's an imposition on
14 the Court as to providing us with more reasoning than what
15 the order needed to provide us with, then we think a
16 special master has to be the way to go, and Your Honor
17 could provide the special master with the instructions, and
18 we don't even have to know what they are, and we will not
19 participate in it, but we've got to have the 31 documents.

20 Thanks.

21 MR. CAPRETZ: Yes, Your Honor. Just to add on
22 that that in a role reversal, my colleague has become more
23 kinder and gentler. I don't believe we can afford to take
24 the time. This litigation has been protracted as is. We
25 have many serious issues on the table. Many things will

1 probably be appealed.

2 These patients are out there without monitoring.

3 We believe they need monitoring. The litigation must go

4 forward. Number one, the documents should be released.

5 There is no excuse. We've heard nothing said as to why

6 they shouldn't be released in our possession this week.

7 Number two, I doubt seriously the ability of the

8 parties to agree, even with so-called guidelines

9 promulgated by this Court as to which they would release.

10 Certainly there would be a dispute.

11 Certainly we'll wind up with a special master or

12 with this Court reviewing those documents. So I would take

13 a little harder view and stricter view, if you will, than

14 Mr. Angstreich and suggest that a special master be

15 appointed now to review these documents and let us know

16 whether or not there is evidence that we need to

17 successfully prosecute these pending cases.

18 THE COURT: Mr. Kohn?

19 MR. KOHN: I wasn't intending to go through our

20 ten page memorandum but just to highlight a couple of

21 things, Your Honor. There are documents that the Court

22 indicated should be released that are literally identical

23 to documents that were deemed to be confidential.

24 I think if the Court looks at what is in our

25 brief, it may well come to the conclusion that some of the

1 documents it considered to be released should not have been
2 released and vice versa. For us to release the 31
3 documents now, seems to me, to serve no purpose because it
4 may well be that the 31 will change when the Court takes a
5 look at what we pointed out in our ten page letter brief
6 and issues clarification to the parties.

7 The other problem is, Your Honor, to try and
8 apply this to the remaining documents on the privilege log
9 is extremely prejudicial to St. Jude without some kind of
10 guidance from the Court. There are significant attorney
11 client work product privileges at issue.

12 These may or may not need to be looked at by a
13 higher court, and I think having the Court's reasons in
14 front of us will be helpful to everyone in determining how
15 to act. I can't imagine why a short delay while the Court
16 acts on our motion for clarification can possibly prejudice
17 the plaintiffs.

18 They've had discovery of literally dozens of
19 company witnesses. They've got hundreds of thousands of
20 documents, and for them to stand up here and say that these
21 31 are pivotal to their case I think -- I hate to use their
22 word which they used repeatedly -- is disingenuous.

23 Thank you, Your Honor.

24 THE COURT: Do you have anything else, Counsel?

25 MR. CAPRETZ: No. I think we'll leave the

1 decision up to the Court. Your Honor, this Court well
2 understands. It has the motion for summary judgment. It
3 has the finalization of class certification proceedings
4 before it. I think the Court has ruled. We should obey
5 the ruling and move forward.

6 THE COURT: Well, I'm going to take the request
7 under advisement, but I will issue a ruling shortly on the
8 matter just trying to clarify to the extent that is
9 possible.

10 What else did we need to talk about today?

11 MR. CAPRETZ: The only other items on the agenda
12 were the report update on the Canadian class action
13 litigation, which we did a few moments ago. The classes
14 were certified in Ontario Province, and endorsement was
15 issued October 9th, basically saying St. Jude Medical
16 pushed the justice for a decision on a Daubert like ruling.
17 He issued it.

18 Unfortunately for St. Jude Medical and
19 unfortunately for the classes, he upheld the
20 trustworthiness and credibility of the experts presented by
21 the plaintiffs in that case. In the Ramsey County
22 litigation, there are still pending matters before the
23 Court, and the first trial should begin in -- next year,
24 2004.

25 THE COURT: Is there a date set for that yet?

1 MR. CAPRETZ: The first trial is set for January
2 19th of 2004. We have a pending motion for a continuance
3 on that, and the only other item that I would have would be
4 the next status conference, except Mr. Stanley might want
5 to add any last minute or urgent matters. I have to keep
6 picking on him.

7 MR. STANLEY: I don't have anything to add.

8 THE COURT: At least we had a chance to hear from
9 you today Mr. Stanley. Okay. Next status conference, any
10 suggestions on timing? I think we were looking at about a
11 month from now, 17th, 19th, 24th of November? Any of those
12 dates work?

13 MR. CAPRETZ: 17th works here.

14 THE COURT: 17th is a Monday.

15 MR. CAPRETZ: That's fine.

16 MR. ANGSTREICH: I think it should work, Your
17 Honor.

18 THE COURT: Let's tentatively set it for the 17th
19 midday, and check your schedules when you get back home.
20 Let Ms. Gleason know if there is any significant problem.
21 We have some other dates that week and the next week that
22 we can move it to if there is a problem anyone has.

23 MR. ANGSTREICH: Your Honor, we're talking about
24 1:30?

25 THE COURT: Yes. Right. Unless you want to work

1 around some other event that is occurring in the Ramsey
2 County case if there is anything like that, but I'm going
3 to presume that we're going to start at 1:30 on these
4 hearings unless you tell me that that's going to be
5 difficult given what is going on. Okay?

6 MR. CAPRETZ: Thank you.

7 MR. ANGSTREICH: Thank you, Your Honor.

8 THE COURT: Anything else for today? Okay.

9 Thank you for your arguments here today, Counsel, and the
10 Court will get these matters resolved as quickly as it can.
11 Thank you.

12 * * *

13 I, Kristine Mousseau, certify that the foregoing
14 is a correct transcript from the record of proceedings in
15 the above-entitled matter.

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19 Certified by:
20 Kristine Mousseau, CRR-RPR

21 Dated: October 21, 2003.

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