

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF MINNESOTA

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

7 Minneapolis, Minnesota  
8 August 27, 2002  
9 1:00 p.m.  
10 -----

11 TRANSCRIPT OF PROCEEDINGS  
12 (Status Conference)

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

15 APPEARANCES:

16 On behalf of plaintiffs: James T. Capretz  
17 Tony Jensen  
18 Steven E. Angstreich  
19 J. Gordon Rudd, Jr.  
20 David Cialkowski  
21 Joe D. Jacobson  
22 Patrick J. Murphy  
23 Daniel W. Sigelman  
24 On behalf of defendant: Steven M. Kohn  
25 David E. Stanley  
Tracy J. Van Steenburgh  
Liz Porter  
Mitchell D. Rose  
Canadian Counsel: James M. Newland

26 Court Reporter: Karen J. Grufman  
27 U.S. Courthouse, Suite 1005  
28 Minneapolis, MN 55415  
29 612-664-5105



1 THE COURT: Good afternoon. On the Court's calendar  
2 today, civil calendar, is multidistrict litigation docket  
3 number 1396, In Re: St. Jude Medical Silzone Heart Valve  
4 Products Liability Litigation.

5 Let's see, would counsel note their appearances today,  
6 please?

7 MR. CAPRETZ: James Capretz for the class.

8 MR. ANGSTREICH: Steven Angstreich for the class.

9 MR. RUDD: Gordon Rudd for the class.

10 MR. JACOBSON: Joe Jacobson for the class.

11 MR. JENSEN: Tony Jensen for the class.

12 MR. SIGELMAN: Daniel Sigelman for the class.

13 MR. CIALKOWSKI: David Cialkowski for the class.

14 Mr. MURPHY: Pat Murphy, state liaison counsel.

15 MR. KOHN: Steven Kohn representing St. Jude  
16 Medical.

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

18 MS. PORTER: Liz Porter, in-house counsel at St.  
19 Jude Medical.

20 MS. VAN STEENBURGH: Tracy Van Steenburgh for St.  
21 Jude Medical.

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

23 THE COURT: Very well. Good afternoon to all of  
24 you.

25 Mr. Capretz, are we ready to proceed?

1 MR. CAPRETZ: Yes, we are, Your Honor.

2 I would like to start, if we may, with the Court's  
3 indulgence, introducing a gentleman who is not licensed before  
4 us in the United States of America, but is a very competent,  
5 capable lawyer in his own right in the Province of Ontario,  
6 Canada, who joined us, Mr. Newland, and ask him if he would  
7 like to come up and give you an opportunity, Your Honor, to  
8 meet him.

9 The Court inquired about the status of Canadian  
10 litigation, and Mr. Kohn has agreed to provide you quarterly  
11 with reports starting in October.

12 We thought we would let you say hello to him, ask any  
13 questions you might. He can give you a brief synopsis, I  
14 think, of where they are in Canada.

15 THE COURT: Okay.

16 MR. CAPRETZ: And anything else you two might want  
17 to talk about.

18 THE COURT: Very good.

19 Mr. Newland. Welcome to Minnesota.

20 MR. NEWLAND: Thank you, Your Honor. Thank you for  
21 hearing me.

22 I'm glad for the opportunity to just speak briefly about  
23 the Canadian litigation dealing with the Silzone heart valve.

24 First of all, I am the lead counsel for the Canadian  
25 National Class Action, which was commenced in Toronto,



1 Ontario. The action, assuming it is certified as a National  
2 Class Action, will basically encompass the entire country,  
3 with the exception of British Columbia, where another class  
4 action has been commenced and is specific to that province.

5 The Silzone valve was distributed in Canada and implanted  
6 from approximately July of '97, until the recall on January  
7 23, 2000. And there were approximately 2300 valves implanted  
8 across the country. And of course there were two implanting  
9 centers, one in Vancouver, one in Edmonton, where the AVERT  
10 trial was also conducted.

11 The class action system in Canada, basically, there are  
12 three main provinces with class action legislation. There is  
13 actually a fourth one now. Saskatchewan also has class action  
14 legislation.

15 In Canada, there are personal injury classes first and  
16 foremost. And that's somewhat different, as I understand it,  
17 than in the United States. So we are seeking a personal  
18 injury class, and additionally, a monitoring class as well.

19 At the present time, the defense has brought a Daubert  
20 motion, and that's returnable in the third week in September.  
21 And once that issue has been resolved, then we'll be  
22 proceeding towards the certification motion and cross  
23 examinations on affidavits and that sort of thing.

24 So we don't yet have a date for the certification motion.  
25 I would hope and expect that it would be before the end of the

1 year.

2 One thing that I would like to say and impress on Your  
3 Honor and thank you for is this aspect of cross border  
4 litigation. This class action is running basically on  
5 parallel tracks on both sides of the border.

6 The pretrial order that Your Honor assisted counsel with  
7 in terms of confidentiality and exchange of documents has been  
8 extremely helpful, I think to all parties, in focusing on the  
9 real issues, getting discovery out and on the table, and also  
10 assisting the plaintiff class counsel on both sides of the  
11 border in having an expeditious, cost effective litigation  
12 program.

13 So it's been extremely helpful. It has assisted, or  
14 influenced counsel on the plaintiffs' side of the courtroom in  
15 cooperating fully. And I think that's borne fruit already.

16 What the future holds with respect to further cooperation  
17 remains to be seen, but I think it has been very valuable to  
18 this point in time, and hopefully can be augmented in the  
19 future.

20 THE COURT: The class rules that you are proceeding  
21 under, are they the rules of a certain -- or laws of a certain  
22 province, or is it a national law?

23 MR. NEWLAND: Your Honor, it's the Province of  
24 Ontario. And we have a practice, I guess you would say, of,  
25 in, most often in class actions commenced out of Ontario, of



1 having them certified as a National Class Action.

2 Now, quite often accompanying that there will be class  
3 actions in other provinces which have class action  
4 legislation, such as British Columbia or Quebec.

5 But in terms of acting in concert and viewing with a  
6 great deal of comity the decisions of other provinces, and  
7 perhaps other states in the future, in certain class actions,  
8 the courts in those three provinces have, effectively, the  
9 judges have worked almost as a panel, and have approved  
10 settlements at the same time via teleconference, that sort of  
11 thing.

12 So that basically is the structure.

13 The other provinces, as I mentioned earlier, have passed,  
14 Saskatchewan in particular, has passed, other provinces now  
15 are looking to pass class action legislation specific for  
16 their province.

17 THE COURT: Have you engaged in significant  
18 discovery so far?

19 MR. NEWLAND: Cross examinations on experts'  
20 affidavits, some of those have been held. We have had  
21 discovery of documents as an ongoing process in conjunction  
22 with the U.S. MDL.

23 The case, once certified, will proceed to examinations  
24 for discovery.

25 THE COURT: I see.

1 MR. NEWLAND: The equivalent of depositions.

2 And one of the aspects of litigation, which I was  
3 alluding to earlier, has a possible way to cooperate further  
4 and assist the litigation process on both sides of the  
5 borders. This may be looking at a deposition process that on  
6 both sides of the borders works together, in the interest of  
7 saving costs.

8 THE COURT: Assuming just for a moment that the  
9 class, the two classes are certified, what would be a  
10 reasonable amount of time to expect before the case would be  
11 called for trial in something like this, this size? Is it a  
12 one-year, a two-year, a 16-month? Any rough estimates there?

13 MR. NEWLAND: As a rough estimate, I would say a  
14 year to no more than two.

15 THE COURT: Between a year and two. Okay.  
16 You said that there were 2300 valves that were implanted?

17 MR. NEWLAND: Yes, Your Honor.

18 THE COURT: Do you have any idea of the size of the  
19 injury class at this point or not?

20 MR. NEWLAND: Not until after the case has been  
21 certified and notice has gone out.

22 THE COURT: Then you'll find out more details?

23 MR. NEWLAND: Exactly. Because we're able to  
24 certify with I think relative ease, relative to some other  
25 jurisdictions, the injury class. Anyone who would have



1 incentive to bring an individual action in Canada might more  
2 often wait and see the results of the certification.

3 THE COURT: I see. Well, thank you, Mr. Newland.  
4 Very helpful. We will continue here to do what we can to  
5 coordinate and to work together with our Canadian counterparts  
6 to make sure that we don't have any unnecessary extra working  
7 done by anybody.

8 MR. NEWLAND: Thank you very much for having me.

9 THE COURT: Thank you for coming, and I will look  
10 forward to receiving Mr. Kohn's reports on a regular basis on  
11 the status of what's happening north of our border. Thank  
12 you.

13 MR. NEWLAND: Thank you, Your Honor.

14 THE COURT: Mr. Capretz.

15 MR. CAPRETZ: Thank you, Your Honor.

16 I would like to, if I may. This case is more entwined  
17 with the Canadian litigation, even though class actions are  
18 relatively new. I mean, it started somewhere in the late '80s  
19 or so, and basically took off in Canada, relatively speaking,  
20 quite behind the U.S. actions in the '90s.

21 But their structure is such that as James, Mr. Newland  
22 was pointing out, here it's more, with our class action law,  
23 more of a challenge for people to get a class of injured  
24 certified than it is in Canada, as he was saying. So that we  
25 know, because the individual -- as a result of that, we have a

1 lot of individual claims and cases. And there's no way for  
2 them to really tell, because a lot of practitioners, since the  
3 statute is tolled, will not do anything until they see if a  
4 class of injured persons is certified in Canada. So that's  
5 their challenge in monitoring trails.

6 Whereas in this case, in this situation, you know, it's a  
7 bit different. And we're working up the individual cases and  
8 claims.

9 And many of the experts, as the Court may have noticed so  
10 far, and certainly will if you haven't, are from our friends  
11 in Canada. As the Court may be well aware, the companies many  
12 times use our friends to the north for testing of their  
13 pharmaceutical drugs and medical devices there. Device agency  
14 is not nearly as restrictive as the U.S. So many times when a  
15 problem is announced, you will hear that it was sold in Europe  
16 and Canada, but not in the U.S. because they had not yet  
17 qualified for the U.S.

18 But as a result, there are quite a few very capable  
19 doctors that are involved in this litigation. So we're very  
20 much in tune with what's going on in Canada in this regard.

21 Your Honor, we would like to put you to work, if I may,  
22 early on. There are several substantive issues, as the Court  
23 is aware, today. And I might just highlight what I see those  
24 to be.

25 One is the status of the class cert motion and briefing.

1 We would like to address that first, if we might. I'll just  
2 cover the others of substance. If counsel has anything to  
3 add, certainly they may do so.

4 The other is the arguments on the preemption discovery,  
5 as to what the Court will allow us to cover.

6 MR. ANGSTREICH: Merits discovery.

7 MR. CAPRETZ: Merits discovery. We'll give you the  
8 status on the discovery as to where we are now, and where  
9 we're hoping to go.

10 And a report on the scheduling order. We're very close.  
11 I had a meeting with Mr. Stanley moments before the Court  
12 convened. And we'll give you an update on where we are with  
13 that. But we're ready to submit something, and we should have  
14 something to you through Mr. Stanley's offices within a day or  
15 so in that regard.

16 But if we could, Your Honor, we would like to first  
17 address the class cert issue.

18 And in conjunction with the briefing, and what is going  
19 to be allowed, in what time frame, we ask the Court's  
20 direction for the protocol that the Court wishes to follow at  
21 the hearing. I mean are you going to allow certain amounts of  
22 time to both sides? Do you have anything in mind as far as  
23 the class protocol is concerned?

24 There's been a request, too, by certain of our lawyers on  
25 the plaintiffs' side that if we could move the matter from the

1 designated time -- I think it's now either 12:30 or 1:30 -- to  
2 10:00 in the morning? So if any of these arguments take a  
3 little longer, we don't have people needing to dash to the  
4 airport, having made plans to leave.

5 THE COURT: Let's talk about the issue of live  
6 witnesses here. It was unclear to me from the plaintiffs'  
7 preliminary identification of witnesses who was intended to be  
8 live, or whose deposition was going to be read, or just simply  
9 affidavits provided. Until we get that matter resolved, and  
10 perhaps with input from the defendants as well, it's hard to  
11 set the time.

12 MR. ANGSTREICH: Your Honor, if I might speak to  
13 that?

14 THE COURT: Go ahead.

15 MR. ANGSTREICH: It was our understanding, in  
16 discussion with defense counsel, that this was argument, and  
17 argument only. That there would be no live presentations.

18 And in that regard, because we had a moment to speak  
19 before Your Honor came out, we did address the subject of  
20 timing. If it's agreeable with Your Honor, we thought 45  
21 minutes for each side, with a 15-minute rebuttal for the  
22 plaintiffs.

23 And if that is satisfactory with Your Honor, we don't see  
24 any need under that circumstance to change the time from 12:30  
25 to 10:00.



1        However, if Your Honor did not want to place limitations  
2 on speaking, and knowing the group that's here, we probably  
3 could start at 10:00 and go until 3:00. But the question,  
4 that became the question as to how Your Honor wanted.

5        And also, if there were any specific topics or areas that  
6 Your Honor thought would be the specific ones that we should  
7 be directed towards, that might be helpful also to shortening  
8 the argument.

9        I assume that there are certain issues that,  
10 notwithstanding the defense's opposition to them in the  
11 submissions, that in reality they are not the areas that we  
12 need to spend a whole lot of time on.

13        So if Your Honor had some guidance on that, it might also  
14 help towards the time we need.

15        THE COURT: Well, a plan for 45 minutes per side  
16 with 15-minute rebuttal, with the understanding that if the  
17 Court had some additional questions that we might spill over a  
18 little bit probably is the best way to proceed.

19        Unfortunately, I've developed a conflict on the 10th.  
20 And I have quite a few possibilities for changing the date.  
21 I've been trying the last few days to resolve it, and I'm not  
22 able to.

23        It would be -- I could do the morning of the 9th. I have  
24 to leave in the afternoon of the 9th. So it's not ideal.  
25 Otherwise, that week is taken. The week of the 23rd is pretty

1 well open, as is the week of the 30th.

2 MR. CAPRETZ: Your Honor, I'm overseas on a case  
3 assignment on the 23rd, through that week. So that wouldn't  
4 be available. The week following would be, from my  
5 perspective --

6 MR. ANGSTREICH: Your Honor, if I could turn on my  
7 computer?

8 THE COURT: Go ahead.

9 MR. JACOBSON: Your Honor, for myself the week of  
10 the 30th will be fine.

11 THE COURT: Mr. Kohn, what do you think?

12 MR. KOHN: Our preference would be to go forward on  
13 the 9th than to delay it any further than it's been delayed.  
14 If that doesn't work, I guess the only option that's open  
15 would be to go to the week of the 30th.

16 MR. CAPRETZ: We're concerned about the -- because  
17 this is an important issue, hearing, as the Court is well  
18 aware, and we really don't want the time limitation that might  
19 be a problem if we have to split the arguments. I don't think  
20 that's really to anyone's benefit.

21 I think my colleague is a bit deficient with his argument  
22 about 45 minutes each, I dare say, even with our best efforts.  
23 And we would like to get together and talk about the  
24 presentation. And we would like to use a power point  
25 presentation.



1 THE COURT: That would be fine.

2 MR. CAPRETZ: A weekend, it would difficult. If we  
3 did run the 9th -- a couple of reasons -- we wanted sooner  
4 rather than later, too. Any other time before, not before the  
5 9th, but before the 30th, other than the week of the 23rd, is  
6 fine with us.

7 THE COURT: Well, the week of the 30th, does that  
8 pose any difficulties, Mr. Kohn or Mr. Stanley?

9 MR. KOHN: Your Honor, I have to check with one of  
10 my colleagues who will be part of that hearing. I could  
11 possibly do that at a recess, if I can get a hold of him. If  
12 not, I would have to get back to you after today.

13 THE COURT: You're back then, Mr. Capretz?

14 MR. CAPRETZ: Yes, Your Honor, on the 27th.

15 THE COURT: Mr. Angstreich?

16 MR. ANGSTREICH: The week of the 30th is fine, Your  
17 Honor.

18 THE COURT: The week of the 30th, Monday the 30th or  
19 Wednesday the 2nd, both are wide open.

20 MR. ANGSTREICH: Wednesday the 2nd would be  
21 preferable.

22 MR. CAPRETZ: Yes.

23 MR. KOHN: Wednesday the 2nd is fine, Your Honor.  
24 The first opportunity, I'll call my office and see if I can  
25 confirm that.

1           THE COURT: What kind of time do you want? We can  
2 start that right away in the morning, if you want to do that.

3           MR. CAPRETZ: I would advocate we do it in the  
4 morning. I don't know about right away. But certainly by  
5 10:00 would be --

6           THE COURT: 10:00 would be fine. Is that  
7 acceptable?

8           MR. ANGSTREICH: 10:00 would be very good.

9           MR. KOHN: That's fine.

10          THE COURT: Set it for 10:00.

11          And in terms of the timing, I'm open to any reasonable  
12 suggestion. We'll presume right now the 45 minutes per side  
13 with a 15-minute rebuttal. If you want to discuss that and  
14 expand that a little bit, I'm not going to quibble with that.  
15 I would like to have a time plan going into it that gets  
16 expanded only if I want you to go into some other areas. But  
17 whatever you agree upon is fine with me.

18          MR. CAPRETZ: Well, I appreciate that remark.  
19 Because I think that does -- we have not had an opportunity,  
20 or taken the opportunity to try to speak about it. But with  
21 most things, we've been able to work things through and out.

22          So if we could do that. Because I don't know what  
23 defense wants or needs or desires. We can work with them and  
24 then approach the Court if we have any particular problem.

25          MR. KOHN: Your Honor, preliminarily, 45 minutes is



1 ample for us. The issue has been fully briefed on both sides.

2 I don't think we have to rehash what's in the briefs. I think

3 45 minutes is fine.

4 If counsel thinks they need more time, we can talk about

5 that.

6 THE COURT: Okay.

7 MR. CAPRETZ: Well, we'll talk about that and see.

8 I do pick up on the suggestion, or comment that Mr.

9 Angstreich made. And that is if the Court, after its initial

10 reading of the briefs has areas that would like to have us

11 talk more, you know, emphasize. Because as Mr. Kohn says, the

12 arguments should be fairly well set out in the briefs. But if

13 there are certain areas you would like to hear from either/or

14 both sides, I think that would help with our planning and help

15 make this more efficient in our arguments.

16 THE COURT: Okay, that's fine. I will spend some

17 time with it ahead of time and alert the parties if there's

18 any particular area that I would like to have additional

19 argument on.

20 MR. ANGSTREICH: Your Honor, with respect to the

21 courtroom, I think it might be helpful if we could be in here

22 around 9:30, to make certain that everything is functional.

23 Because I seem to have not been able to get my computer to log

24 in. And I want to make sure that the, the presentation works

25 well.

1 THE COURT: We won't schedule anything in addition  
2 to this argument for that morning. So you can come in as  
3 early as you want.

4 MR. ANGSTREICH: Thank you.

5 MR. CAPRETZ: Could we now, Your Honor, address this  
6 briefing issue?

7 THE COURT: Yes.

8 MR. CAPRETZ: And I would ask my colleague, Mr.  
9 Rudd, to approach the podium, since he has been working with  
10 the Court.

11 THE COURT: Certainly.

12 Mr. Rudd.

13 MR. RUDD: Thank you, Judge. I want to address our  
14 motion to exceed the page limitation.

15 I know Friday afternoon late I heard from Your Honor's  
16 law clerk about the ruling on us revising our reply brief and  
17 allowing St. Jude to have a surreply. And you hadn't had the  
18 benefit of that time of reviewing my correspondence with  
19 regard to what has transpired here. And I would request the  
20 Court to consider that letter.

21 And I would like to note that originally when we filed  
22 our opening brief on May 3, St. Jude had initially identified  
23 several experts they intended to call in opposition to class  
24 certification. And then nearly three weeks after we filed our  
25 brief, they identified other experts. And indeed, their



1 opposition is largely made up of what those experts have to  
2 say.

3 That was part of why we brought the motion to strike that  
4 we argued before Your Honor the last time.

5 But the main argument that St. Jude made in its request  
6 was that we were making arguments that could have been  
7 addressed in the opening brief. And we really take exception  
8 to that statement. Because in fact those arguments could not  
9 have been addressed.

10 We believe that in April, when we had requested leave to  
11 file briefs of 90 pages, we alerted the Court that we may be  
12 seeking a further extension if St. Jude's response warranted  
13 it. We believe every that argument we presented in the reply  
14 brief directly corresponds to an argument raised in the  
15 opposition. And given the significance of the issues before  
16 the Court in an MDL proceeding, it's appropriate for us to  
17 have the ability to respond to every argument.

18 I would note, for instance, we have a long section in our  
19 reply brief on choice of law issues. We didn't anticipate  
20 that as being an issue.

21 St. Jude, in one of the transfer motions from a case in  
22 St. Louis, had argued that Minnesota law was the appropriate  
23 law to apply as a basis for part of its transfer. So we  
24 thought that that issue was conceded by St. Jude. In fact,  
25 they've raised it, and we needed to spend a substantial amount

1 of pages, which we did not anticipate before, responding to  
2 that issue.

3 So we believe it's warranted for us to exceed the page  
4 limit. Although we do readily admit that we've submitted  
5 voluminous materials to Your Honor.

6 Lastly, on the surreply, we believe that the moving  
7 party, we should really have the last submitted brief. We  
8 carry the burden. Essentially, we're entitled to more pages  
9 than St. Jude under even the local rules. And providing a  
10 surreply when we're the moving party really puts us as a  
11 severe disadvantage.

12 So we would request that the Court reconsider the ruling  
13 on Friday, and grant our motion to exceed the page limitation,  
14 not permit a surreply, and obviously entertain all arguments  
15 that need to be addressed at the hearing on October 2.

16 THE COURT: Well, typically, Mr. Rudd, the rules  
17 provide for a requirement that if you're going to file briefs  
18 in excess of the page limit, you ask permission ahead of time  
19 to do that.

20 And then secondly, the, one of the standard points of  
21 briefing schedules here in this Court is that we generally  
22 give equal number of pages to each side.

23 So those were the two principles that I was relying upon  
24 in deciding on Friday that we had to change the, what was then  
25 the status quo.



1 I should perhaps hear from, I don't know Mr. Kohn or Mr.  
2 Stanley here, unless you had something else, Mr. Rudd.

3 MR. RUDD: One other issue, Your Honor, which was  
4 that in the response that St. Jude submitted, they had several  
5 documents they submitted. They had their opposition brief,  
6 which was 73 pages. They also submitted the document entitled  
7 Objections to Evidence, which really goes to issues  
8 surrounding the class certification according to St. Jude.

9 So the total number of pages they submitted, just in  
10 terms of briefing and argument, was over a hundred pages in  
11 their opposition. We believe that by entitling a document  
12 with a different title essentially was exceeding the page  
13 limits that were allowed, because they've already submitted  
14 briefing in excess of a hundred pages on issues related to  
15 class certification.

16 So we would ask the Court to take that into account as  
17 well.

18 THE COURT: Mr. Kohn.

19 MR. KOHN: Thank you, Your Honor.

20 Counsel and I have very different perspectives on what  
21 has occurred here. And I'm always reluctant to use the term  
22 "sandbagging," but I think, I can't frankly think of another  
23 word that characterizes what I saw in the brief.

24 Because contrary to what counsel said, there are numerous  
25 issues that are raised that weren't in the opening from the

1 plaintiffs that without the opportunity for surreply, we'll be  
2 prejudiced.

3 So I endorse the Court's tentative ruling which I  
4 understood to be that they would narrow down the volume of  
5 pages in their brief, and we would have an opportunity for a  
6 scaled-down surreply.

7 My only request would be that since the class  
8 certification hearing has been put over for about three weeks,  
9 that instead of having our surreply due right after the Labor  
10 Day weekend, if we could have another week on that, since  
11 there's no time crunch anymore. That would be extremely  
12 helpful.

13 But I do believe that would be fair to both sides. And I  
14 don't think it would be productive for me to go through the  
15 litany of new issues that I think are in their moving papers,  
16 or even address the issue of the volume of their brief or the  
17 late disclosed experts that we didn't hear about until the  
18 brief was filed. I just think fairness dictates that we be  
19 given the chance to be heard on these new matters.

20 Thank you.

21 MR. ANGSTREICH: Your Honor, if I may just make a  
22 small comment?

23 THE COURT: Sure.

24 MR. ANGSTREICH: Because I stood before you  
25 objecting to the fact that six new experts were identified



1 three weeks after we filed our brief.

2 And I heard counsel say, well, you know, we told you we  
3 were going to be supplementing. Well, to stand up here and to  
4 say that they've been sandbagged, because we had to go and get  
5 experts to address certain of the issues that their experts  
6 Rodricks and Jones came forward with, especially after I  
7 appeared before you and said, with respect to Doctor Jones,  
8 that we needed to get all of the underlying data to our  
9 experts, is just not appropriate.

10 The AVERT study that they're relying upon is not the  
11 AVERT study that came out as published by the AVERT personnel.  
12 It's an interpretation by Doctor Jones. That was not put  
13 forward in any answer to interrogatories or any defense that  
14 they've offered us in this case. Consequently, we needed  
15 experts to address those issues.

16 With respect to Doctor Rodricks, there was never an  
17 attempt to argue the efficacy or safety of silver simply as  
18 silver. And that was not a defense that was offered before.  
19 And consequently, we had to go and get Doctor Hubbard to  
20 address that.

21 They knew what issues we raised in our brief. They went  
22 out, and not only did they attack that in the 73 pages, but  
23 then sought to strike all of our experts. And every one of  
24 their experts attempted to attack the experts that we offered.

25 We went and we got two experts. One a statistician; and

1 Doctor Hubbard, whose area of expertise relates to the very  
2 subject that Doctor Rodricks opined on.

3 That's not sandbagging. That's addressing what has been  
4 presented to us that we had no right, or expectation to feel  
5 that we had to defend against.

6 As Mr. Rudd pointed out, to argue the issue of 50 state  
7 laws addressing the unfair and deceptive trade practice  
8 statutes, when you brought or tried to bring every single case  
9 from every single federal court to Minnesota, on the basis  
10 that Minnesota law should apply, and then to argue that it  
11 becomes unmanageable because of 50 different state laws,  
12 forces us in a reply to spend page after page addressing that.

13 To stand up here and say that we came forward with new  
14 arguments, without identifying one alleged new argument that  
15 we've come forward with, is just inappropriate.

16 We responded, that's exactly what we did, we responded to  
17 the arguments that were made. It is unfortunate, and we do  
18 apologize to the Court that we ran as long as we did. But  
19 when you are addressing not only a hundred pages of writing,  
20 but three feet, approximately, of declarations, where each of  
21 their experts not only gives an opinion, but makes argument on  
22 the very subject of their opinion, means that we have to  
23 respond.

24 And to say that it's unfair without a surreply, basically  
25 says that there's something new that they want to address.



1 That I thought is what argument is intended. We have to  
2 rebut. We have to reply to that which they bring forward.

3 And one other thing, which has nothing to do with that  
4 issue. But do you know how difficult it will be to take 64  
5 pages down to 30? That is a job that if we could have written  
6 it in 30 pages or 34 pages, Your Honor, we certainly would  
7 have done that. It was not our mission to do the weight of  
8 the evidence by the weight of the paper.

9 So we ask that Your Honor reconsider it. Thank you.

10 THE COURT: Mr. Rudd, did you have anything else?

11 MR. RUDD: No, nothing further.

12 THE COURT: Mr. Kohn?

13 MR. KOHN: No, Your Honor.

14 THE COURT: Well, this is what I'm going to do. I'm  
15 going to require the brief be shortened. Just shorten it down  
16 to 50 pages rather than the 30, which should be easy enough to  
17 do.

18 The defendants, I will give you a surreply opportunity,  
19 but please reply only to issues that you consider to be new  
20 issues that have been raised by the plaintiffs' reply, rather  
21 than any rehash of issues that were already there. That  
22 likely means that you won't need the entire number of pages.  
23 But I will keep the number of pages equal between the two  
24 sides.

25 MR. RUDD: May we modify the schedule for when those

1 will be due?

2 THE COURT: When was it going to be due?

3 MR. RUDD: This Thursday, the 29th.

4 THE COURT: What would you like? I would like to  
5 have everything in, if possible, by the 20th. That will give  
6 me enough time to do a thorough review of the papers ahead of  
7 time.

8 MR. ANGSTREICH: How much time do you need?  
9 If we had until the 10th, and they had until the 20th?

10 THE COURT: That would be fine with me. Okay?

11 MR. KOHN: That's fine, Your Honor.

12 THE COURT: Okay.

13 Okay, next issue, Mr. Capretz?

14 MR. CAPRETZ: Yes, Your Honor.

15 Before I segue to the next issue, Your Honor, I would  
16 like to ask the Court, in that particular order that you just  
17 rendered, that the Court keep an open mind, take no action we  
18 move not for this, but I think it's a pretty cardinal  
19 principle in these situations that the plaintiff does have the  
20 last word. Things are getting quite verbose, and there will  
21 an lot of pages, and there may not be a need. But we ask that  
22 the Court keep an open mind if something is introduced by St.  
23 Jude that if it's necessary for us to defend our position,  
24 that we have --

25 THE COURT: If you think there's something that's



1 entirely new, you can let me know, Mr. Capretz. And I'll  
2 decide.

3 MR. CAPRETZ: Appreciate that. Thank you.

4 Okay, on some of the discovery issues, Your Honor, one is  
5 one that we had in a joint status report, and that concerns  
6 the pathology slides to plaintiffs' experts on the animal  
7 studies.

8 Now, we had requested photographs of those slides. And  
9 St. Jude, after meeting and conferring, has agreed and  
10 tendered those photographs to us. We are at loggerheads on  
11 the pathology slides. Although I think counsel may concede  
12 that it's quite customary in clinical investigations and  
13 research for pathology slides to be transmitted to others for  
14 review and evaluation and analysis, their position announced  
15 to me was, well, this is litigation, and we do not think -- we  
16 do not believe that we should be required to send the  
17 pathology slides to your expert. Instead, if your expert  
18 wishes to view the slides, then they must make a visit to the  
19 Minneapolis area.

20 And both sides, I believe, I can say tried in good faith  
21 to find a protocol that would work. Mr. Stanley said if you  
22 have another suggestion, let us know. But quite honestly, I  
23 don't think if we have any other suggestion. I don't know of  
24 any other solution than one or the other winning, so to speak,  
25 on this point.

1 MR. STANLEY: I might have one. Actually, it was  
2 Steve's idea this morning when we were talking about this,  
3 Your Honor.

4 What makes this a little bit different than the usual  
5 situation is that if something were to happen to these slides,  
6 we don't have re-cuts to go to. We can't make new slides. So  
7 we're very concerned about making sure that these aren't  
8 damaged.

9 THE COURT: How many are we talking about?

10 MR. STANLEY: I'm not exactly sure. But what Steve  
11 suggested is maybe if there was a courier, hand courier who  
12 came and picked them up and transmitted them to their expert.  
13 And then when the expert was done with them, pick them up. So  
14 we would have one person in charge of it in instead of putting  
15 it in Federal Express. Something like that. Maybe that would  
16 work.

17 MR. ANGSTREICH: That's no problem. We'll pick a  
18 courier and do it that way. And that courier would be  
19 responsible for bringing them back.

20 MR. STANLEY: And we can just have an agreement how  
21 long the expert needs. Two weeks or --

22 MR. ANGSTREICH: I assume it would be before the  
23 case is over.

24 MR. STANLEY: But I'm sure we can work those details  
25 out.



1           MR. ANGSTREICH: We'll work out the timing of that,  
2 Your Honor. I certainly wasn't competent to say how long the  
3 expert will need the slides.

4           THE COURT: Well, I'm sure the experts will have  
5 something to say about that. But that sounds like a good  
6 solution. Pick a courier that's reliable, we should be all  
7 right.

8           MR. CAPRETZ: That resolves the issue as far as  
9 we're concerned at this point, Your Honor.

10          The next item on the agenda is the Spire depositions. A  
11 dispute arose concerning the appropriateness of certain  
12 testimony about the two sides conferring under joint defense  
13 agreement. I think both have tendered briefs on the point.

14          Mr. Angstreich took the depositions. He appropriately is  
15 the one to speak to the argument. And we'll let the Court  
16 decide.

17          THE COURT: Mr. Angstreich.

18          MR. ANGSTREICH: Your Honor, I said everything that  
19 I thought was necessary to be said in the letter submission.

20          Spire came before you, sought to be dismissed from the  
21 one tag-along individual case, months after the time to join  
22 additional defendants had passed, had been in communication  
23 with us about arranging for the production of documents.

24          And quite honestly, if there had been any indication that  
25 there was, quote, a joint defense, and St. Jude was getting

1 access to the documents that were being turned over to us in  
2 advance, or having an opportunity to meet with their former  
3 employees -- I mean that's the worst part. You're talking  
4 about Doctor Sioshansi and Raymond Bricault, who are no longer  
5 employees of Spire, who they spent I don't know how long,  
6 because they wouldn't even let me find out how long the  
7 meeting was, who was in attendance, how many meetings took  
8 place.

9 These are clearly third-party witnesses whose testimony  
10 is critical to the plaintiffs' case, who now I think have had  
11 an opportunity to meet with defense counsel. And I'm not so  
12 sure that their presentation that was given to us was as it  
13 could have been if they had not been prepared by counsel.

14 I simply submit that former employees shouldn't get a  
15 benefit of a joint defense privilege. There is no continuing  
16 agreement between Doctor Sioshansi and Raymond Bricault about  
17 cooperating with St. Jude -- I mean with Spire. Because Spire  
18 got them to agree to appear for a deposition, that does not  
19 make them within the proper circle. Nobody advanced an  
20 argument that there was a continuing relationship.

21 In fact, Doctor Sioshansi and Ray Bricault made it clear  
22 that there is no relationship between Spire and them going  
23 forward or their company.

24 And most importantly, when did this joint defense  
25 agreement allegedly come to the fore? After they were



1 dismissed from the tag-along MDL case from Nebraska? Before?

2 We don't know any of the ramifications of that.

3 And I think that at a minimum, we ought to know that.

4 Your Honor should see the joint defense agreement. But more  
5 importantly, it should not apply to former employees. Because  
6 that just prevents open dialogue with these individuals.

7 Thank you.

8 THE COURT: Mr. Kohn.

9 MR. KOHN: Thank you, Your Honor.

10 As we indicated in our brief, we would be pleased to  
11 submit the joint defense agreement in camera, if the Court  
12 pleases.

13 I would only add, counsel has not cited any law, and I'm  
14 not aware of any, that a former employee, particularly  
15 employees who were at the level of these two executives with  
16 Spire could not ask to be represented by counsel at their  
17 deposition, which they did.

18 We've cited ample law in our brief, I believe, that  
19 whether or not Spire is a current defendant in the MDL is not  
20 the pivotal question. The pivotal question is whether the two  
21 companies have a common interest.

22 And as you know, they are co-defendants in numerous Texas  
23 cases. And there's nothing to prevent Spire from being sued  
24 tomorrow or the next day in another federal court case, or  
25 even a state court case that could be removed to be before

1 Your Honor.

2 So the interests are aligned. I think the law speaks for  
3 itself. And if the Court wishes to have the agreement, we'll  
4 be pleased to submit it.

5 MR. ANGSTREICH: Your Honor, I just have to comment  
6 on one thing.

7 Neither Doctor Sioshansi nor Mr. Bricault indicated that  
8 they had requested that St. Jude represent them. That was not  
9 a representation.

10 I would agree that if they had retained St. Jude's  
11 counsel to represent them, that might be a different issue.  
12 But both of them acknowledge that their counsel was Susan  
13 Fieber at that deposition. And the only reason that St. Jude  
14 was present was because of the joint defense agreement.

15 And there is a serious question as to whether or not  
16 companies could enter into joint defense agreements where  
17 there isn't a reasonable prospect of being made a defendant.

18 That means that St. Jude could go to the fabric  
19 manufacturers whose fabric was used in this case, enter into a  
20 joint defense agreement because their interests were aligned  
21 because their fabric was used. Or any of the other myriad of  
22 third parties. Or their advertising agency. Or the AVERT  
23 people. Or anybody else that they ever did business with  
24 because their interests are aligned.

25 It's not a question of whether their interests are



1 aligned. It's whether there's a reasonable prospect of being  
2 made a defendant in the proceeding.

3 Also, simply because they may be a defendant in Texas,  
4 under the rules that we have here, unless Texas agrees to  
5 participate in our proceeding under the Common Benefit Fund  
6 procedure and agree to all of the other ramifications of the  
7 MDL, they do not get access to the deposition transcripts. So  
8 that the depositions that were taken which were not cross  
9 noticed are not discoverable in those other proceedings.

10 Now, I would agree if there was a cross notice of  
11 Sioshansi and Bricault with the Texas defendants, that might  
12 be a different issue. But that wasn't the circumstances that  
13 we had before us.

14 Thank you.

15 THE COURT: Are we dealing with just these two  
16 former Spire employees, or are there current Spire employees  
17 who are covered by all of this as well?

18 MR. ANGSTREICH: That's an interesting point. The  
19 two current employees, more current employees, Eric Tobin and  
20 John Barry, whose depositions were taken last week, neither  
21 met with anyone from St. Jude, according to their testimony.

22 So I don't know if there are other Spire people that we  
23 might want to depose, present Spire people. But at least  
24 there isn't an issue with respect to Barry and Tobin.

25 THE COURT: So as of right now, it's limited to just

1 these two individuals?

2 MR. ANGSTREICH: That's correct, Your Honor.

3 MR. KOHN: Your Honor, I was not at those  
4 depositions, but, so there's no misunderstanding, they did  
5 meet with counsel for St. Jude. I have not seen their  
6 testimony. If they said that they didn't, that would  
7 definitely be an error. So I want to correct that for the  
8 record.

9 MR. ANGSTREICH: Well, Mr. Fletcher Johnson took  
10 their depositions. And in the report to me, he said he asked  
11 them and they both testified that they had not met with any  
12 counsel from St. Jude. Maybe they didn't realize that the  
13 counsel -- in fact, according to Fletcher Johnson, they both  
14 testified that only Susan Fieber was present. Now we'll have  
15 to wait to see the transcript. But I think it would then  
16 apply to them as well. I would be more troubled if in fact  
17 the transcript indicated that they didn't meet with St. Jude  
18 and in fact they did.

19 THE COURT: Anything else, Mr. Kohn?

20 MR. KOHN: No, Your Honor.

21 THE COURT: I'm going to deny the motion to compel  
22 the testimony of the two former Spire employees. I think the  
23 standard here is a common interest.

24 Clearly, the two companies, in my view, have a common  
25 interest. They are joint defendants in 50 some cases in the

1 state of Texas. They were a defendant in one of the cases  
2 that's part of the multidistrict litigation until recently. I  
3 don't know if that's been appealed. They may come back as a  
4 defendant at some point in time. I don't know.

5 I think the common interest rule would apply though even  
6 though Spire is not currently a defendant. So I'm going to  
7 deny the motion, at least as to the employees that have been  
8 deposed thus far.

9 If there's going to be a dispute over additional former  
10 Spire employees, please let me know ahead of time. But I  
11 think from what I've heard thus far, it's reasonable to  
12 presume that both parties have a common interest in potential  
13 litigation. And I think there still remains a reasonable  
14 prospect of Spire being a defendant, either here or certainly  
15 in some of the state cases where they are current defendants.

16 Let's see, what's next, Mr. Capretz?

17 MR. CAPRETZ: Your Honor, I can't help but add  
18 parenthetically, these are the two gentlemen that talked about  
19 a 45-minute limit on class certification. I wanted to time  
20 them, but I won't do that.

21 The next thing, Your Honor, is the deposition schedule.  
22 We have -- we're currently scheduled -- the deposition in  
23 Texas cases, Mr. Flory --

24 MR. KOHN: Next week.

25 MR. CAPRETZ: September 4th. And then depositions



1 were set through the Robins Kaplan firm in the Ramsey County  
2 cases, Elizabeth Burnett for 9/11, Don Guzik for 9/19, Bill  
3 Holmberg for 9/25, and Steve Healy for 9/27.

4 And the only -- and the Notice of Intent to Cross Notice  
5 was issued by St. Jude in these matters. And our concern,  
6 Your Honor, would be on, at least on the Holmberg and Healy  
7 depositions, that pun intended, that's on the heels of the  
8 class cert hearing. And we would be troubled by having to  
9 attend and participate in these two very substantive  
10 depositions currently scheduled for the 25th and the 27th.

11 Other than that, I suppose we would have no objection if  
12 they cross notice the Burnett and Guzik depositions.

13 MR. ANGSTREICH: Your Honor, the Flory deposition  
14 was initially scheduled for September 4th, when we had every  
15 expectation of being here the 9th and 10th for the class  
16 certification. So nobody made arrangements for the 4th.

17 I'm the designated Flory questioner. And I couldn't make  
18 it on the 4th, and I let them know that.

19 But more importantly, that also ties into the scope of  
20 discovery that we're going to do with respect to preemption.  
21 Because Doctor Flory, the veterinarian, is the one who  
22 submitted the declaration with a set of exhibits yea high in  
23 connection with preemption. So clearly, there's no question  
24 in my mind that at least one full day of his deposition will  
25 be necessary for preemption before we ever get to merits.

1       And so the 4th is a very significant problem for us. So  
2 we have that, and the 25th and 27th as problem issues.

3       As far as the other dates, if we can find people who will  
4 be there.

5       The suggestion that I had made to defense counsel was  
6 that it's our expectation that plaintiffs' counsel in these  
7 cases are going to take a full day of anybody's deposition. I  
8 would be surprised if that weren't the case. And while these  
9 individuals, according to, I don't remember whether it was Mr.  
10 Kohn or Mr. Stanley, have agreed to make themselves available  
11 for several days, one of the more appropriate ways of doing it  
12 is getting the transcript from the full day, and then using  
13 that as a springboard for our time.

14       It makes more sense so that you have the transcript, you  
15 know what the issues are. And also, most of the people that  
16 have been identified are crossover to both preemption and  
17 merits discovery.

18       We need a substantial amount of time. So we'll try to  
19 accommodate those that we can. But we do ask the Court to  
20 recognize that we're not just talking about one day, two hours  
21 or three-hour kind of witnesses where everybody gets a chance  
22 to ask their question. These are full day depositions.

23       MR. CAPRETZ: Your Honor, I may be able to respond  
24 to St. Jude on one issue. I think maybe Mr. Angstreich thinks  
25 Mr. Flory was cross-noticed. There was a notice of a desire



1 to do that, but it was not cross-noticed. So Mr. Flory has  
2 not been formally cross-noticed because there's no time to do  
3 that.

4 But maybe we could address this issue. I mean, we really  
5 have not talked. We talked briefly, the sides have.

6 THE COURT: So we're just talking about Holmberg and  
7 Healy?

8 MR. CAPRETZ: Well, the ones I was addressing,  
9 Holmberg and Healy, yes, because those --

10 THE COURT: The 25th and the 27th. Is it possible  
11 to change the date of those or not?

12 MS. VAN STEENBURGH: Your Honor, I think this might  
13 be a little premature, because those were dates when the  
14 witnesses were available. But I think it's possible to move  
15 those around. We haven't gotten notices from the Robins firm.  
16 And I'm waiting to hear confirmation from that firm as to  
17 those dates. Perhaps we can talk about it before we come back  
18 to court.

19 THE COURT: That would be a good idea. And if those  
20 two in particular could be pushed back just a little bit, I  
21 think that would be helpful. That would be a difficult week  
22 for the plaintiffs, I would think.

23 MR. CAPRETZ: That's fine, Your Honor. And we  
24 appreciate the courtesy of counsel in that regard.

25 THE COURT: Incidentally, did I hear correctly that

1 Judge Bjorkman has been reassigned juvenile court, or  
2 something like that?

3 MS. VAN STEENBURGH: Yes, Your Honor.

4 MR. CAPRETZ: That is correct, Your Honor. It's on  
5 our agenda. We will be talking about that. Right now, there  
6 is no judge.

7 THE COURT: I hope no one does that to me.

8 (Laughter.)

9 Go ahead. I'm sorry.

10 MR. CAPRETZ: We all appreciate your efforts in this  
11 case and value your presence. We hope you stay here, too.

12 THE COURT: There's been no new judge assigned  
13 though. Is that correct?

14 MR. CAPRETZ: No new judge. Judge Mott, the  
15 presiding judge, has that under consideration. He's asked for  
16 input from counsel. It's up to him to appoint somebody.

17 So everything's in abeyance, in essence.

18 MS. VAN STEENBURGH: We anticipate a hearing this  
19 week, Your Honor. He gave us three options. He thought he  
20 would have this issue decided this week.

21 THE COURT: Okay.

22 MR. CAPRETZ: The final thing on depositions.  
23 Plaintiffs have a list of preferred depositions, which we'll  
24 be tendering, just for the Court's edification, to counsel.  
25 We have not yet given this to St. Jude. And so maybe in the



1 deposition planning we can work with getting those depositions  
2 scheduled. They should be to defense certainly this week, and  
3 maybe within a day or so.

4 Third parties subpoenas. We've had some interesting  
5 situations. It seems as though the joint defense agreement  
6 goes maybe beyond the literal one that St. Jude has with  
7 Spire. But certain of the third parties, namely, Sulzer  
8 Carbomedics, which is a competing company, but which looked at  
9 this Silzone issue, and passed on using the product, and --  
10 who was the other one we had trouble with?

11 MR. ANGSTREICH: We've had trouble with everybody.

12 MR. CAPRETZ: Well, yeah. That's right.

13 I mean, let's just say it's been difficult to get the  
14 cooperation. And there have been some discussions, and there  
15 seems to be no clear understanding about these third-party  
16 subpoenas and the power of this Court versus the power of an  
17 issuing court in a district where the defendant is located.

18 If I might, I would call upon Tony Jensen to brief us on  
19 this issue. It should be a very short one. Maybe the Court  
20 has some guidance on it. This does not involve St. Jude  
21 directly.

22 THE COURT: Mr. Jensen.

23 MR. JENSEN: Thank you, Your Honor. Good afternoon.

24 Just very briefly, as the plaintiffs apprised the Court  
25 in the status report, there is an outstanding subpoena to

1 Sulzer Carbomedics at this time.

2 And although there has been some difficulties on a few  
3 other subpoenas, we have had substantial cooperation from many  
4 of the parties we've subpoenaed. And the basic strategy has  
5 been to issue the subpoenas from the MDL Court, namely, the  
6 District of Minnesota.

7 In this case, however, I've been informed by the attorney  
8 for Sulzer Carbomedics that they object to the issuance of a  
9 subpoena from this Court, among other reasons, because the  
10 plaintiffs attempted to make the production requested more  
11 convenient for them by requesting that it be in Texas.

12 So essentially, I think, Your Honor, what I've come up  
13 here to tell you is merely that what we intend to do is to  
14 issue a subpoena out of the Western District of Texas, and  
15 proceed on that basis. But if Your Honor had any other  
16 suggestions as to how to proceed so as to maintain the  
17 streamlined nature of MDL discovery --

18 THE COURT: Where is that company located?

19 MR. JENSEN: They are located in Texas. More  
20 specifically in Austin, Texas.

21 THE COURT: So they want to have a subpoena from  
22 that court?

23 MR. JENSEN: Yes, that's what their counsel has  
24 requested, that it issue from the Western District of Texas.

25 It raises some minor but fairly interesting issues under



1 Rule 45, just because in this modern age, the question of  
2 where documents are actually produced is a little murky,  
3 inasmuch as everything is being produced electronically and  
4 can easily be over-nighted throughout the country.

5 So really the question I guess becomes if significant  
6 objections are raised, where should they best be litigated?  
7 And I think it's plaintiff's position that it is most  
8 efficient to litigate them here in Minnesota.

9 THE COURT: Mr. Kohn, do you have any thoughts on  
10 this matter?

11 MR. KOHN: Not really, Your Honor. I don't know  
12 anything about what Sulzer's objection is.

13 One thing that comes to mind is if for some reason they  
14 had an objection to the scope of the subpoena, where would  
15 that objection be raised? I don't know if that's what's  
16 behind the request or not. It's come up with other third  
17 parties, when there's been issues that have arisen to the  
18 scope of documents requested and the burden imposed on the  
19 third parties, as to where they have to go to get a remedy if  
20 they had to do that.

21 THE COURT: But you haven't heard anything back  
22 substantively on the scope of the subpoenas. Is that correct?

23 MR. JENSEN: That's correct. Because when I spoke  
24 with Sulzer's counsel, I was informed that any further  
25 objections would not be raised until a further subpoena was

1 issued.

2 THE COURT: Well, why don't we go ahead with  
3 subpoenas in the Western District of Texas, issue them there.  
4 If there are difficulties, then perhaps we're going to have to  
5 summon the lawyers for that company up here to talk about  
6 enforcement of the subpoena, and see what the nature of the  
7 problem is.

8 MR. JENSEN: Very good, Your Honor.

9 THE COURT: That's at least a possibility. But  
10 let's try to resolve it here through subpoenas in that  
11 district.

12 MR. JENSEN: Thank you, Your Honor.

13 MR. CAPRETZ: There is one remaining issue on the  
14 discovery that's confidentiality designations. I think that's  
15 up in the air.

16 Mr. Stanley, do you want to --

17 MR. STANLEY: Your Honor, under the pretrial order  
18 that you signed a couple of weeks ago, we went back to their  
19 third-party subpoenas and we designated the documents that we  
20 felt were confidential.

21 Our pretrial order calls for, if there's going to be a  
22 dispute, that there's a 14-day period where the parties meet  
23 and confer in good faith. And then after that, if they can't  
24 resolve it, then there's 21 days for us to file a motion.

25 So what I expect is that when they review those



1 documents, I'll get either a phone call or an e-mail or a  
2 letter from someone saying: We disagree with some of your  
3 designations; we would like to meet and confer. And we start  
4 that process.

5 But instead what I got was a letter from Mr. Coren that  
6 says all of your designations are, you know what, and go file  
7 your motion. And with no efforts to meet and confer.

8 So that's all we want, Your Honor. We're happy to meet  
9 and confer with them on the confidentiality designations.  
10 We've done it before. We've resolved issues before. And  
11 instead of them automatically turning the clock on for us to  
12 file a motion, it just makes it more difficult.

13 MR. ANGSTREICH: Well, Mr. Coren is not here to  
14 defend himself, but I did discuss that issue with him. And  
15 there were four categories of third-party documents. Three of  
16 them are only at issue. And in fact, it is our position that  
17 there are no documents produced by Doctor Butany, Doctor  
18 Grunkemeier, or -- I forget who the third one was -- Doctor  
19 Goodman -- which are entitled to be protected by any  
20 confidentiality designation.

21 I guess we could have listed every single document, and  
22 then opposite each single document said why they were not  
23 confidential in our opinion. Instead of doing that, we  
24 basically said we don't believe that any of them are  
25 appropriately confidential. The 14 days to meet and confer

1 now begins. If there's any that you want to explain why it  
2 should be confidential, please feel free to do that.

3 With respect to documents we got from the University of  
4 Pittsburgh, the overwhelming majority of the documents that  
5 were identified as confidential did in fact have patient names  
6 and things that could come within the scope of confidential  
7 information. And we did not oppose those designations.

8 But with respect to the others, there's no basis for it.  
9 So we've asked St. Jude to explain why they should be deemed  
10 confidential. And we'll be happy to discuss it.

11 But the process, as we understood it, was for us to say  
12 it's not confidential, the burden shifts to you. Try to  
13 explain why. And we're waiting -- or at least we thought we  
14 would be hearing from them -- with an explanation.

15 The last time we went through this, they came back with a  
16 list of specific categories that they recognized would not be  
17 confidential, and a specific list of documents that they  
18 wanted to invoke the confidentiality as to. And we haven't  
19 had a problem doing it that way. We thought that that would  
20 be the proper process.

21 So the ball should really be in St. Jude's court right  
22 now to let us know what documents, if any, they truly believe  
23 should be kept confidential.

24 Thank you.

25 MR. STANLEY: Again, Your Honor, the letter I



1 received was: All your designations are wrong. File your  
2 motion.

3 That being said, Tom Freeman from my office told me this  
4 morning that he called Mike Coren to start the meet and confer  
5 process. And we're glad to do that.

6 THE COURT: Let's go through the meet and confer  
7 process. Maybe it won't work particularly well in this case.  
8 And hopefully, it will. But let's try to follow that process  
9 on all of these issues.

10 MR. CAPRETZ: At this time, Your Honor, I'm pleased  
11 and proud to introduce another member of the class team. This  
12 gentleman is a member of the firm of Kellogg and Sigelman.  
13 And he's quite bright, competent, and capable.

14 And I can say that because I offered him a job about 20  
15 years ago. But he didn't elect to stay with myself and my  
16 partner. Notwithstanding that.

17 But we're pleased to have him. He had a couple of cases  
18 along with his partner, South Carolina cases that were  
19 resolved amicably through settlement with St. Jude. And he  
20 has since joined our team. And he's prepared to argue the  
21 preemption discovery issue.

22 THE COURT: Very well.

23 MR. ANGSTREICH: Your Honor, Mr. Sigelman and I have  
24 discussed it. And what we would like to do, with Your Honor's  
25 permission, because we addressed the discovery aspect as

1 opposed to preemption, I would like to focus on discovery.  
2 And to the extent that Your Honor has any questions or feels  
3 the need that we address preemption per se, then Mr. Sigelman  
4 will get up and address it.

5 As Your Honor knows, St. Jude has taken the position that  
6 no discovery is needed except the gratuitous discovery of  
7 allowing us to depose Mr. Flory -- or Doctor Flory, and Ms.  
8 Johnson.

9 The problem that jumps out at you immediately with  
10 respect to that which they've offered us is the fact that  
11 Flory knows nothing. His certification indicates he knows  
12 nothing. Every document that he has attached to his  
13 declaration or affidavit is a document produced by somebody  
14 else, some other employee, or some other person as to which he  
15 has no personal knowledge and no information whatsoever.

16 The same is true with Ms. Johnson. As it relates to  
17 allegedly complying with FDA regulations, she wasn't there.  
18 She has no personal knowledge of anything.

19 You start with the first question of the case law  
20 establishes that the issue of preemption is fact sensitive.  
21 If it's fact sensitive, then we have a right to examine the  
22 facts so that we can establish that there are material issues  
23 of fact that require us to go forward with a trial or, for  
24 that matter, that there are no material issues of fact, and in  
25 fact preemption doesn't apply here.



1 In order to do that, we need discovery. And we have  
2 articulated what we believe to be the appropriate areas of  
3 discovery.

4 Compliance with the FDA rules and regulations in  
5 connection with the supplemental PMA is a critical area of  
6 discovery. And as we have set out in our opposition papers --  
7 or in our support papers in support of our requests for  
8 discovery, we have given Your Honor each of the sections of  
9 the rules and regulations to which discovery is permissible,  
10 and how that discovery relates to those areas of inquiry.  
11 Whether it deals with the studies that were conducted before  
12 they came forward with the supplemental PMA. Whether it deals  
13 with the communications with the FDA. There is a myriad of  
14 areas that we've articulated as it relates to that.

15 In addition to that, you have the question of whether or  
16 not and to what extent post approval conduct vitiates the  
17 approval itself. There were conditions placed upon this  
18 product. Those conditions being that they couldn't directly  
19 or indirectly reference the Silzone coating being efficacious  
20 for fighting endocarditis.

21 The discovery that we seek goes to that issue as well,  
22 whether it's by way of depositions or documents or  
23 interrogatories.

24 So the first question is, if it's a fact-sensitive issue,  
25 which we believe it is, we're entitled to the discovery, at

1 least to the areas of discovery that we believe are absolutely  
2 necessary and critical.

3 Then you go to the question of how do you test the  
4 certification of Flory and Johnson if the only discovery that  
5 you get is Flory and Johnson? Jonas Runquist, for example,  
6 one of the individuals that we've asked to depose, wrote all  
7 of the letters to the FDA, was the liaison with the FDA.

8 The submission that we gave Your Honor with respect to  
9 Flory's testimony that was taken as part of the class cert  
10 issues, he was asked about his involvement, and he had none.  
11 So we've shown you that everything that was done was done by  
12 Jonas Runquist.

13 Now, if somebody is going to come forward and argue that  
14 simply because Runquist wrote a letter, and that was within  
15 his job description, that letter becomes a business record,  
16 and therefore becomes admissible, and therefore Flory's  
17 certification allows that to come forward in violation of Rule  
18 56, which says that the moving party has to do it first based  
19 on personal knowledge and not hearsay, then how do you test  
20 that alleged business record without taking Jonas Runquist's  
21 deposition? And it goes on and on and on.

22 We wanted to be all-inclusive. We did not want to come  
23 back to the Court and say, oh, by the way, there's some  
24 additional areas of discovery, whether they're interrogatories  
25 or requests for documents or depositions.



1 By the same token, we tried to also be circumscribed in  
2 the discovery that we sought, because we know that we have to  
3 relate it to facts necessary to address preemption. If in  
4 fact the Court believes that preemption is the equivalent of  
5 immunity, and therefore it's not fact sensitive, and therefore  
6 it's a closed issue, then really the submissions of Flory and  
7 Johnson are irrelevant.

8 But once those submissions become relevant to the issue,  
9 we must have full opportunity. And we've given Your Honor the  
10 reasons with respect to each category of documents.

11 So from the perspective of are we entitled to the  
12 discovery we seek, we say we are. And we believe that the  
13 discovery is tailored to the very issues that impact upon  
14 preemption.

15 Thank you.

16 THE COURT: Thank you, Mr. Angstreich.

17 Mr. Sigelman, did you have anything else?

18 MR. SIGELMAN: Not really, Your Honor. Everything  
19 is fairly well outlined in the brief.

20 It's clear that the express preemption standard upon  
21 which the defendant relies is a standard that says that if  
22 you're imposing some rule additional to and different from a  
23 federal rule, there's preemption, at least according to the  
24 cases they've talked about.

25 It therefore follows as a corollary, that if you're doing

1 the opposite, which is you're imposing -- you're basically  
2 talking about enforcement, or an imposition of a standard that  
3 is consistent with the federal standard, that in fact there is  
4 no preemption if your basic position is that they have  
5 violated the federal standard.

6 And the case law is very, very unequivocally clear, that  
7 if you can come up with evidence that federal regulations have  
8 been violated, preemption doesn't apply. The cases that  
9 happen to hold preemption, they held preemption in a sense  
10 because they turned on a fact, the fact being that the  
11 plaintiff, in the mind of the court, didn't come up with the  
12 factual evidence.

13 So I just don't think there's any dispute.

14 And I think Your Honor yourself recognized that in the  
15 Chmielewski case -- I don't know if I pronounced it  
16 correctly --

17 THE COURT: Chmielewski.

18 MR. SIGELMAN: Chmielewski. Where in fact you not  
19 only recognized the principle, but you in fact partially  
20 denied summary judgment on the grounds that the plaintiff had  
21 the opportunity to go forward, try to discover evidence on the  
22 negligent manufacturing claim, that would be equivalent to in  
23 Your Honor's opinion with the federal standard.

24 But if there are specific questions later that Your Honor  
25 may have about specific discovery, and how they relate both to



1 the statutory requirements of the Food, Drug and Cosmetic Act  
2 and the relevant provisions of 21 C.F.R. that apply to medical  
3 devices, I'll be happy to do that.

4 THE COURT: Thank you, Mr. Sigelman.

5 Mr. Kohn.

6 MR. KOHN: Thank you, Your Honor.

7 I think there's two fundamental questions that the Court  
8 needs to resolve with respect to the degree to which discovery  
9 is allowed before the motion is set for hearing and the  
10 opposition is requested.

11 The first one is whether this Court can second guess the  
12 FDA. And ultimately, I guess whether a jury down the road,  
13 once these cases are remanded, can be put in the position of  
14 second guessing the FDA, or calling the decision-making power  
15 and authority and thoroughness of the FDA in question in the  
16 context of an ultimate trial.

17 Because that's exactly what the plaintiffs' discovery  
18 which focuses on the premarket -- I'm going to focus on the  
19 premarket at the outset -- attempts to do.

20 What they would like to do is go behind the FDA and look  
21 at what testing was done, why it was done, why perhaps other  
22 testing wasn't done. Whether the FDA did or didn't require  
23 St. Jude to do any particular type of testing, whether it be  
24 animal studies in vitro or clinical studies.

25 And there simply is no case law to support that kind of

1 inquiry. Because it only leads to one place. It only leads  
2 to the place where you have to second guess either what St.  
3 Jude submitted, either they didn't submit enough in the  
4 plaintiffs' allegations, or they didn't submit a particular  
5 kind of test that they should have.

6 And all you have to do is turn to the affidavit that they  
7 filed with Doctor Tyers to see he's claiming they didn't test  
8 enough animals, they didn't do enough testing in humans, and  
9 on and on and on. All of that will do nothing more than  
10 second guess the FDA.

11 So turning specifically to what they've asked for, they  
12 want to depose the people who conducted the animal studies.  
13 Doctor Tweden, the pathologist who looked at the animal  
14 studies. Presumably, they can go to the University of  
15 Minnesota and depose the researchers. Where is that all going  
16 to lead? The answer is, it's all going to lead to second  
17 guessing the FDA.

18 Because in the very documents that they have obtained  
19 from the FDA, one of them, the Bates number is FDA 19761, it's  
20 an August 12, 1997 memo, internal FDA memo that is written by  
21 the FDA scientist who reviewed the animal studies. And the  
22 conclusion is unequivocally clear: The ten-week study  
23 adequately demonstrates the safety of this device. It was a  
24 well-performed study.

25 They have this document. What they would like to do is



1 try to challenge the FDA's review and call that into question.

2 There's no preemption case that would support that.

3 If you look at other discovery they want. They would  
4 like to -- the person most knowledgeable for an entirely  
5 different device that was, for which St. Jude sought approval.  
6 The annuloplasty ring. On page 15 of their brief, they make a  
7 three-page argument that discovery of all aspects of the  
8 annuloplasty ring -- which is a totally separate class, it's a  
9 Class II and not a Class III device, went through a 510(k)  
10 process -- is somehow relevant to preemption.

11 St. Jude is not seeking preemption for the annuloplasty  
12 rings. It has nothing to do with our summary judgment.

13 So for them to conduct a lot of discovery on the 510(k)  
14 for the annuloplasty ring, it's totally irrelevant, it can't  
15 lead to anything that's helpful, and it's an entirely  
16 different device. It's never been the subject of an MDR or  
17 PMA supplement by the FDA. So again, it doesn't lead  
18 anywhere.

19 Just turning for a second to the post market issues.  
20 They would like to look over every nook and cranny of what  
21 happened with this valve once it received FDA approval. They  
22 want to look at the post market surveillance by St. Jude.  
23 Whether it did or didn't timely submit medical device reports  
24 to the FDA. Whether it doesn't violate innumerable standards  
25 set forth in this document that they submitted under seal.

1       The problem with all of that is that it runs directly  
2 into the Buckman case. There is no private right of action.  
3 There is no private right of action that allows these  
4 plaintiffs to try and make this case into an FDA enforcement  
5 action.

6       They have pled a garden variety products liability case,  
7 alleging failure to warn, inadequate testing, and the usual  
8 things you see in a products case. By this pleading, they are  
9 attempting now to make themselves into an FDA enforcement.

10       And the U.S. Supreme Court decision in the Buckman case I  
11 think is very clear. If there's no private right of action  
12 when there's a claim of fraud against the FDA, then how could  
13 there be a private right of action when there's a failure of  
14 someone to, for example, submit a Medical Device Report?

15       Now, just a couple more seconds and I'll be done.

16       If you look at a couple examples in the post market  
17 context of what they're asking for, it becomes evident that  
18 again they're asking this Court to second guess the FDA, and  
19 ultimately a jury to decide whether or not the FDA did its  
20 job. Whether or not St. Jude complied with the regulations.  
21 This action is not brought in the name of the United States.  
22 And there's no right for them to do that.

23       They would like to depose Doctor Butany in Canada, a  
24 pathologist; Doctor Butchart, United Kingdom, a cardiac  
25 surgeon; Doctor David, a cardiac surgeon in Toronto, all of



1 whom raised safety concerns about the Silzone valve at one  
2 time or another. All of whom were, whose patients were the  
3 subject of Medical Device Reports submitted to the FDA. The  
4 internal FDA documents that counsel has obtained shows that  
5 the FDA was all over these issues.

6 Reading from FDA 17435, a memo from Doctor Saperstein at  
7 the FDA, he's talking about Medical Device Reports on August  
8 6, 1999. This is a good seven or eight months before the  
9 recall. He says, "The MDR information on the first year of  
10 this valve's marketing experience is important. But we should  
11 be cautious in not overreacting to these reports. MDRs are  
12 relatively inaccurate instruments for capturing event  
13 incidents."

14 Goes on to talk about discussing the concerns with  
15 researches at the AVERT trial, and says that he thinks the  
16 AVERT trial is the best way to address any concerns about  
17 product safety.

18 Similarly -- and this addresses the two specific  
19 depositions that they've asked for, Doctor Butany and Mr. --  
20 Doctor Butchart. There is comprehensive criticism in the FDA  
21 documents by an FDA biostatistician. This is FDA 17325, where  
22 they call into question the accuracy and the relevance of Mr.  
23 Bouchard's data. And they talk about the fact that you need a  
24 more scientifically collected data. You need a different  
25 study. And they characterize it as a small, non-randomized

1 study. They say, "However, the statistical evaluation of the  
2 data involved in the use of methods greatly overstates the  
3 problem." And on and on and on.

4 The same thing is true of the Toronto study of Doctor  
5 Butany, 18827, in which they say, referring to Toronto, and  
6 this is again a biostatistician, "The study was not designed  
7 for comparing the impact of adding Silzone coating to an  
8 existing heart valve. This is the most serious deficiency."  
9 And they go on and on to critique Doctor David in the Toronto  
10 study.

11 So what counsel would like to do is to suggest that the  
12 FDA should have done something different than what's reflected  
13 in these memos. Or St. Jude should have done something  
14 different in terms of reporting to the FDA.

15 The same arguments would go to the overpromotion. They  
16 want to go out and depose quite a number of sales  
17 representatives and doctors to try to discover what the  
18 marketing campaign was. That has nothing to do with  
19 preemption.

20 So in conclusion, Your Honor, they may be entitled to  
21 some discovery, to look at the four corners of the affidavits  
22 and the documents that we submitted in support of our motion,  
23 but there is no case law that would allow them to in essence  
24 turn the company inside out, to make this court into a super  
25 FDA enforcement agency, and ultimately make some jury try to



1 decide whether the FDA did or didn't do the right thing when  
2 it approved the valve.

3 Thank you.

4 THE COURT: Thank you, Mr. Kohn.

5 Mr. Angstreich.

6 MR. ANGSTREICH: Your Honor, I have one point to  
7 make, and then Mr. Sigelman will speak further.

8 It's interesting that Mr. Kohn gets up here and suggests  
9 that what we're asking for is for you to second guess the FDA,  
10 or to do something that the FDA didn't do, when the very  
11 opposition to our class certification motion submitted the  
12 declaration of Doctor Rodricks, who goes on and on and on and  
13 on and on, testifying about the appropriateness of silver, and  
14 how this was really efficacious, and seeks to have you make a  
15 determination that issues that the FDA did not consider should  
16 be found in their favor.

17 The fact of the matter is, we're not asking you to second  
18 guess the FDA. We're asking this Court to determine whether  
19 or not St. Jude has complied with their obligations under the  
20 Food, Drug and Cosmetic Act, and as Mr. Sigelman will explain  
21 further.

22 But the point is, you can't have it both ways. You can't  
23 ask Your Honor to make determinations that the FDA in fact has  
24 found against them by finding that this was a misbranded and  
25 adulterated device and ask Your Honor to find it to be

1 appropriate.

2 MR. SIGELMAN: Following up on something that Mr.  
3 Angstreich just said.

4 The issue is not second guessing the FDA. It's being  
5 consistent with the case law upon which this very defendant  
6 has vociferously relied in its last brief. It's whether or  
7 not we're going to be consistent with Your Honor's rulings.  
8 With the Supreme Court's ruling in Medtronic versus Lohr.  
9 With the Eighth Circuit precedent that is unambiguous in  
10 Brooks. Whether we're going to be consistent with the Martin  
11 case that the defendant relies on. Whether we're going to be  
12 consistent with the Kemp case that the defense relies on.  
13 Whether we're going to be consistent with the Seventh Circuit  
14 Mitchell case that the defense relies on.

15 This is what the law entitles us to do. They put at  
16 issue, they opened the door on their compliance with federal  
17 law by (1) suggesting that they had an affirmative defense of  
18 preemption, and (2) asking for summary judgment on it now.  
19 And all we're doing is what the law entitles us to do.

20 Now, Mr. Kohn said, well, we're getting into whether the  
21 FDA is going to require additional testing. No, we're not.  
22 We're asking: Did this defendant comply with the regulations?  
23 It had specific regulations with which it must comply.  
24 They're part of the premarket application regulations that  
25 have been incorporated by reference in the regulations



1 applicable to supplemental PMA's that they comply with those  
2 regulations.

3 Did the submission that they made to the FDA have  
4 everything in it that they were supposed to include, including  
5 data that may be adverse to the safety of this device that the  
6 FDA didn't learn about because they didn't comply with the  
7 regulations?

8 Did they properly label this drug? Or is this drug  
9 misbranded within the meaning of the Food, Drug and Cosmetic  
10 Act and other regulations, including regulations applicable to  
11 restricted devices of which this is one?

12 And there are a plethora of other things.

13 So that's really what is at issue.

14 A lot of the rest of what Mr. Kohn said is really not on  
15 point. It's almost a red herring. He said, well, what about  
16 animal studies? What relevance could it have to take  
17 discovery of people involved in animal studies?

18 Well, I can think of one thing. What if there were raw  
19 data, Your Honor? Let's say there were data that had to do  
20 with histopathology that were absolutely critical, that were  
21 incredibly illuminating and were highly relevant to the  
22 toxicity of the Silzone coating, that could have been  
23 discerned from a controlled trial, say, in an animal, where  
24 you had animals getting Silzone in one control group and  
25 animals getting heart valves without Silzone in the other

1 group such that you could really try to assess the impact of  
2 Silzone, and that somehow that rose to the significance that  
3 not including some cautionary statement about it would  
4 misbrand this device as a matter of law?

5 Now, in order to see whether that's the case, we have to  
6 establish a factual predicate. And how do you do that? You  
7 take the deposition testimony of people involved with the  
8 studies and you find out: What did this company have? What  
9 did they know? And how was it channeled through in terms of  
10 the submissions to the FDA? And the way they labeled this  
11 product, etcetera.

12 Then Mr. Kohn starts talking about the annuloplasty rings  
13 that we referenced. And at the time, Your Honor, I must tell  
14 you that the annuloplasty rings were a Class III device. And  
15 that's significant in terms of the reporting requirements.

16 Yes, it is true the annuloplasty rings were approved  
17 under a different process. It was called a 510(k) clearance,  
18 which is a device by which, a medical device to get on the  
19 market by claiming it's substantially equivalent to a  
20 predicate device. And the FDA says go on the market if you  
21 can show it substantially equivalent.

22 The reason that's relevant is, among other things, there  
23 are certification requirements applicable to 510(k) devices  
24 that would require this defendant to have submitted data, for  
25 example, concerning the toxicity of Silzone or silver to the



1 FDA.

2 If the FDA, after approving the Silzone valve, was  
3 ignorant of certain things, then the question emerges: Well,  
4 what about those Silzone coated annuloplasty rings that the  
5 FDA cleared not long afterwards? Because the only difference  
6 between the Silzone and the predecessor device to which they  
7 were compared is the silver. And there were specific  
8 requirements on this defendant to alert FDA, for example, to  
9 toxicity concerns about the difference between the Silzone  
10 annuloplasty ring and the predecessor or predicate device that  
11 doesn't have Silzone. It's clearly relevant. It's clearly  
12 relevant.

13 Then Mr. Kohn talks about most market issues. Talks  
14 about MDR reporting and labeling. What could this possibly  
15 have to do with preemption?

16 Well, I have two answers.

17 The first one are the regulations. Regulations say that  
18 if the FDA conditions approval on meeting certain  
19 requirements, then in fact if you don't do that, that's a  
20 violation of the Act.

21 But more specifically, the approval letter for this  
22 device said if you don't meet certain requirements -- and it  
23 was a plethora of requirements. It was all kinds of labeling  
24 requirements about which Mr. Angstreich told you. It was  
25 Medical Device Reporting requirements. It was advertising

1 requirements. It was manufacturing requirements. It was  
2 promotion requirements.

3 You know what the FDA said? If you don't meet that, this  
4 approval is invalidated. So you don't meet things like  
5 medical requirements and labeling, you no longer have a, an  
6 approveable device. It goes to the very continued  
7 approveability of the device.

8 Then we get to the Buckman argument. No private right of  
9 action. Let me say this: We have never said we have a  
10 private right of action.

11 Now, let's make it clear what we are not doing. Because  
12 I think that the defense is very much confusing the issue.

13 We are not seeking to enforce the Food, Drug and Cosmetic  
14 Act. We are not private attorneys general. And we don't seek  
15 to be.

16 We are not challenging the FDA's exclusive authority to  
17 enforce the Act.

18 We have not, if you look at our complaint, prayed for  
19 damages for any violation of the Food, Drug and Cosmetic Act.  
20 And we have basically not pleaded any violation of the Act in  
21 our complaint.

22 All we are doing, consistent with the cases on which the  
23 defendant relies, is seeing whether this defendant has  
24 complied with the requirements of the Food, Drug and Cosmetic  
25 Act, and we are entitled to do that. And that's consistent



1 with the cases that I told you.

2 Then Mr. Kohn talks about people like Mr. Butchart and  
3 Butany and Tirone David and their analyses and experiences  
4 with this device. And he starts giving you what really I  
5 think would be the kind of argument that we could maybe be  
6 having a few months down the road when we've done our  
7 discovery.

8 You say, well, this data aren't very conclusive. This  
9 person at FDA said this. This person at FDA said that.

10 I'm not going to go into the details right now of what  
11 the FDA said or didn't say at that point, and the extent to  
12 which this company did or did not comply with the Medical  
13 Device Reporting requirements and other requirements of law  
14 that would have required them, among other things, to have  
15 given FDA the full story on the extent to which there may be  
16 statistically significance differences between the clinical  
17 experience they observed with the Silzone valve and with  
18 nonSilzone coated valves. Those kinds of analyses which are  
19 involved, for example, in the studies of Tirone David and  
20 Doctor Butany.

21 So the arguments they've given right now are in a sense  
22 merits arguments on this discovery issue. More down the road  
23 after we've done our discovery. I think the kind of analysis  
24 that he's doing right now is premature.

25 We want the discovery. And I don't think that he's given

1 you a valid reason why we can't go into the extent to which  
2 this company may not have disclosed things of critical  
3 interest to the FDA. And particularly in light of the  
4 subsequent events, namely, that this product came off the  
5 market and is no longer on the market because it was  
6 associated, among other things, with a statistically  
7 significant increased risk of explantation, especially in  
8 connection with paravalvular leak.

9 Lastly, Mr. Kohn talks about marketing. He says, you  
10 know, we want to take the depositions of all these marketing  
11 representatives. It's true, we do. And why is that?

12 Let's go back to that approval letter. What did the  
13 approval letter say, Your Honor? The approval letter said,  
14 you know, you've got to comply here. You cannot even imply,  
15 much less state outright that this device is efficacious in  
16 preventing and/or reducing the incidence of endocarditis.

17 And the FDA regulations are very clear. That labeling,  
18 for example, includes much more than advertising copy. It  
19 includes oral statements made by sales representatives.

20 Now, how are we going to pierce the veil, as it were, of  
21 what's really going on in the field? What is really causing  
22 our explanting surgeons to decide to use that Silzone valve?

23 Clearly, it's discoverable. It's reasonably calculated  
24 to lead to the discovery of admissible evidence on whether  
25 this defendant complied with the promotion and advertising



1 requirements of the FDA, as stated, for example, in the  
2 approval letter, the violation of which goes to the very  
3 continued approveability of this medical device.

4       So Your Honor, I believe we clearly come within the very  
5 case law that these gentlemen have relied upon. And I think  
6 what we have proposed is circumscribed, but yet is  
7 sufficiently encompassing that it will give us the kind of  
8 discovery that we need to go forward with our burden of  
9 presenting a genuine issue of material fact on whether this  
10 company complied with the requirements of federal law and  
11 regulation, and whether they are in fact as a factual matter  
12 entitled to preemption as a matter of law.

13       Thank you, Your Honor.

14       THE COURT: Thank you, Mr. Sigelman.

15       Did you have anything else, Mr. Kohn?

16       MR. KOHN: Just briefly, Your Honor.

17       Everything Mr. Sigelman says I don't disagree with.  
18 There are regulations that provide that St. Jude must comply  
19 on a whole variety of fronts. And that's exactly why the FDA  
20 is the arbiter of those regulations. The FDA decides whether  
21 St. Jude did or didn't comply. There has been no finding by  
22 the FDA at any time that St. Jude violated any of these  
23 regulations.

24       And so it all comes back to again what I said at the  
25 outset: Is this Court going to allow these plaintiffs to

1 second guess the FDA, and ultimately a jury to second guess  
2 the FDA? And is there or isn't there a private right of  
3 action for them to act as a second enforcement agency?

4 THE COURT: If there's nothing else, with respect to  
5 this issue, I am going to let the discovery go forward, defer  
6 ruling on the summary judgment motion on the preemption issue.  
7 I think potentially there are factual issues requiring  
8 discovery here, and I think it's appropriate to allow it to go  
9 forward as proposed.

10 I would, however, like to have a report, a joint report  
11 in November as to the status of the plaintiffs' preemption  
12 discovery. This issue should be resolved sooner rather than  
13 later. And if we can return to this issue in November, the  
14 Court can get a report on exactly where things are at, then  
15 we'll have a better idea about when we can sort out the  
16 preemption issue, which I think should be sorted out as soon  
17 as we can get to it.

18 MR. ANGSTREICH: Your Honor, we will do that.

19 And in addition, because we want to move things along as  
20 expeditiously as possible, the initial depositions that we'll  
21 take on preemption will also be individuals that we would be  
22 deposing on the merits aspects of it. And in that regard, to  
23 get Your Honor's guidance.

24 Those kind of individuals we firmly believe the "one  
25 day/seven hour" rule would not be appropriate. And I



1 certainly wouldn't want to schedule, for example, Doctor  
2 Flory's deposition, and finish preemption in six hours or six  
3 and a half hours, and then say why not stay the next day,  
4 schedule it for the next day to take merits.

5 THE COURT: Who are the individuals?

6 MR. ANGSTREICH: The individuals at this moment that  
7 we've identified, who are both fact and preemption witnesses,  
8 would be Flory, Billingsworth, Doctor Tweden, initially.  
9 Those three clearly fall both in the category of merits and  
10 preemption.

11 THE COURT: What kind of time do you need?

12 MR. ANGSTREICH: I would request that we have two  
13 days set aside. If we don't need the full second day, that  
14 would be terrific. But we would at least look at two days,  
15 seven hours each day.

16 THE COURT: Any objection?

17 MR. KOHN: No, no objection, Your Honor.

18 THE COURT: Okay, that's fine for those three  
19 individuals.

20 Okay, Mr. Capretz.

21 MR. CAPRETZ: We're ready to move right along now,  
22 Your Honor. I think we've done most of the substantive  
23 matters.

24 Next was the pretrial order scheduling order which we  
25 mentioned earlier. Mr. Stanley and myself have conferred. We

1 seem to have an agreement. He's in agreement with the last  
2 revision that we made to the protocol for the designation of  
3 generic experts. So within a matter of days, we should be  
4 presenting that for the Court's signature.

5 MR. STANLEY: Does Your Honor need to hear what we  
6 proposed?

7 THE COURT: I'm sorry?

8 MR. CAPRETZ: Would you like him to?

9 MR. STANLEY: What we proposed is for the case  
10 specific discovery in the individual cases, that begin to go  
11 forward on September 1st. And on April 1st.

12 There are some provisions in here about when we can do  
13 medical examinations. After the initial, after April 1st, and  
14 the plaintiffs will have 30 days to designate case specific  
15 experts. And we'll then, after they've disclosed, we'll have  
16 30 days. And then they'll have, 30 days later, they'll have  
17 their supplemental experts.

18 And then it also calls for, after all of this has been  
19 done, to submit a joint report on any specific case. Just  
20 identifying either that all the discovery is complete and the  
21 case is ready for remand, or that there are some issues out  
22 there and there may need to be some additional work done, and  
23 the Court can make further orders extending the deadlines.

24 That's basically what we've mapped out.

25 THE COURT: Okay, excellent.



1           MR. CAPRETZ: I want to add a comment, Your Honor,  
2 that we are hoping to put together a letter to send to the MDA  
3 PDL attorneys to get an update what is going on. Particularly  
4 now that we've reached the point of asking for a scheduling  
5 order.

6           Plaintiffs lawyers many times come dragging and screaming  
7 to MDLs, claiming that they go into a dark hole, and only  
8 lawyers working the cases at the MDL level really know what's  
9 going on, and they have no control, and sit back and say,  
10 okay, try the case.

11          So hopefully we're going to be able to ameliorate some of  
12 those concerns and keep them informed in a better fashion. So  
13 we hope to get a letter off shortly to the list of plaintiffs  
14 involved.

15          And that is growing a bit. And with the Court's  
16 permission, I would like to call to the podium Mr. Murphy, the  
17 state liaison counsel here, to report on the case list and  
18 filings, and on --

19          MR. MURPHY: Sit down.

20          I think we already talked about Ramsey County. We don't  
21 have a judge.

22          THE COURT: Judge Mott, the Chief Judge, is deciding  
23 among the group? Is that what's going on right now?

24          MS. VAN STEENBURGH: Yes, he provided us with three  
25 names of available assignments. And we submitted each on our

1 own without disclosure of our rankings.

2 MR. MURPHY: And then he's going to flip a coin, I  
3 guess.

4 MR. CAPRETZ: Probably.

5 One other thing. Depositions are going, as you heard,  
6 following the Ramsey County cases, Robins Kaplan namely having  
7 instituted that action. And we have a similar discussion over  
8 preemption discovery and briefs have been tendered to whomever  
9 the judge might be. We don't have a status conference  
10 scheduled yet because we don't know who the judge is.

11 MR. RUDD: One issue on the judge selection in  
12 Ramsey County. There hasn't been any agreement that the  
13 parties still won't have removal rights on that issue. So we  
14 don't know exactly what's going to happen once Judge Mott  
15 gives us some indication of the status. In other words, the  
16 judges he provided names of aren't necessarily the exclusive  
17 list if people still maintain their removal rights.

18 THE COURT: Do those rights still remain at this  
19 stage?

20 MR. RUDD: Yes, I believe they do.

21 MS. VAN STEENBURGH: I think there's an issue about  
22 that. At any rate, we'll get that worked out.

23 MR. MURPHY: Perhaps you could toss the coin.

24 THE COURT: As soon as a judge is selected, would  
25 someone let me know, so I can be in touch?



1 MS. VAN STEENBURGH: I would be happy to take that  
2 responsibility, Your Honor.

3 THE COURT: Very well. Thank you.

4 MR. MURPHY: Thank you, Your Honor.

5 The official count right now is 36 federal court actions,  
6 105 state court actions. My learned colleague, Mr. Capretz,  
7 says apparently three more federal cases are on their way,  
8 which raise it to 39. Your competent court clerk stated she  
9 knew two. And apparently, Mr. Capretz knows of one  
10 additional.

11 So that's the current list and where they are.

12 As Your Honor should be aware, I provided you a copy of  
13 the letter that went out to all of the counsel in the case  
14 requesting their input. I just talked to my office about I  
15 guess about three hours ago, and they said we're finally  
16 getting some responses on that on the coordination of efforts  
17 and coordination of discovery.

18 THE COURT: I've gotten several responses I guess  
19 from judges in response to the letter that I sent out. I did  
20 have a lengthy talk with the judge in Texas, who has most of  
21 the cases -- Benton?

22 MR. MURPHY: Yes, Judge Benton.

23 THE COURT: And who is quite appreciative of the  
24 discussion and was very cooperative, I thought.

25 MR. MURPHY: If there's ever a time, Your Honor,

1 where perhaps we should, we could have some kind of a joint  
2 meeting where we could talk about what's going on, maybe with  
3 the judges and the people that are going to be involved in our  
4 case and want to coordinate with us. Maybe sometime down the  
5 road that would be a good thing.

6 THE COURT: Probably would be a good idea. The  
7 question is just how to organize it. Maybe you can give that  
8 some thought.

9 MR. MURPHY: I will, Your Honor. Thank you.

10 THE COURT: Good. Thank you, Mr. Murphy.

11 MR. CAPRETZ: What counsel didn't say, I guess  
12 indirectly, is that in Las Vegas, his wife is head of the  
13 Convention Bureau.

14 MR. MURPHY: No, she's director of sales.

15 MR. CAPRETZ: But Mr. Rudd's office has some  
16 experience working with Judge Davis in setting up these  
17 meetings. Judge Davis is meeting next month in Baycol in  
18 Philadelphia. And he traveled to California in June.

19 But I'm sure some mutual grounds -- Las Vegas might not  
20 be all that bad. If we can stay focused on business.

21 But I think, Your Honor, we are there. There are no last  
22 minute items that I know of.

23 We should probably look at the question of a status  
24 conference for September. Did you want to try that  
25 telephonically?



1 THE COURT: What's the preference?

2 MR. STANLEY: I'm not sure if we need one.

3 THE COURT: If we're going to be gathering for the  
4 class certification hearing, that's into October, it's a  
5 little over four weeks away.

6 MR. CAPRETZ: I would feel more comfortable if we  
7 schedule a telephone conference, in case we run into glitches  
8 on third-party or deposition scheduling that we would need the  
9 Court's guidance. I would think we can do that over the  
10 phone.

11 THE COURT: Maybe the 23rd or 24th?

12 MR. CAPRETZ: Those are dates I'm in London.

13 MR. ANGSTREICH: The week of the 16th I thought was  
14 a problem for Your Honor.

15 THE COURT: That's a problem.

16 MR. ANGSTREICH: So if the 16th is no good, and the  
17 23rd --

18 MR. CAPRETZ: Well, we can do it without me.

19 MR. STANLEY: Why don't we wait and see if we have  
20 issues. And we can call Lou Jean if we need a conference.

21 THE COURT: Let's just set a time on the 24th, in  
22 case it's necessary, and you will let Ms. Gleason know whether  
23 it's necessary. We can do 9:00 that day?

24 MR. ANGSTREICH: 9:00 a.m. your time?

25 THE COURT: Let's consider time zones here. I'm

1 sorry.

2 MR. ANGSTREICH: That would be good. I think that's  
3 7:00 their time. They'll be up and around.

4 THE COURT: Let's say 2:00 Central?

5 MR. CAPRETZ: I have to tell you an anecdote.

6 This is some years ago. But I had one of my partners at  
7 an early meeting in Pittsburgh. And I had a phone call, and I  
8 was in the shower.

9 I came out of the shower. There was a judge on the line.  
10 The partner -- since I was the person in charge of the case I  
11 could not make because of a conflict. And he was quite  
12 disturbed about something. And I was not a happy camper. And  
13 since I was far away, I was quite, shall we say, short to the  
14 Court in telling him I thought he was not correct, and that we  
15 weren't about to consider any further changes or proposals.

16 It all seemed to work out well. When I got back, my  
17 partner got into the office saying, "I was the one sitting  
18 there. You were giving him a hard time on the phone."

19 So those early morning conferences can be difficult.

20 THE COURT: Well, we'll have to stay away from the  
21 shower time.

22 Anything else anyone has for today?

23 Mr. Newland, thank you again for coming. We appreciate  
24 having you here.

25 MR. NEWLAND: Thank you, Your Honor.



1 THE COURT: Very well. We will talk if necessary in  
2 a few weeks, and look forward to seeing everyone for the class  
3 certification hearing.

4 Court is in recess.

5 (Court recessed at 2:50.)

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21 CERTIFIED:

Karen J. Grufman  
Official Court Reporter

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