

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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

Minneapolis, Minnesota
April 13, 2007
2:10 P.M.

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

(DAUBERT MOTIONS HEARING)

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1 2:10 P.M.

2 (In open court.)

3 THE COURT: You may be seated, everyone. Good
4 afternoon.

5 MR. ANGSTREICH: Good afternoon, Your Honor.
6 Your Honor, my apologies. Yesterday's appearance in Ramsey
7 County started out at 2:30 and was moved back to 1:30. I
8 had 2:30 in my mind for today as well, so I do apologize.
9 We thought we were going to be early.

10 THE COURT: That's all right. We'll proceed
11 here. I've got a telephone conference beginning at 3:30,
12 so that limits the time that we have. We have the MDL
13 case, In re St. Jude Medical Silzone Heart Valves Products
14 Liability Litigation, 01-1396.

15 Counsel, would you note your appearances today
16 for the record?

17 MR. ANGSTREICH: Jim?

18 THE COURT: Mr. Capretz, are you there?

19 MR. CAPRETZ: Oh, yes. Hello. I can hear you.
20 This is Jim Capretz for the class. Thank you, Your Honor,
21 for the offer to allow us to appear telephonically.

22 THE COURT: That's fine.

23 MR. ANGSTREICH: Your Honor, Steven Angstreich

24 for the class.

25 MR. RUDD: Gordon Rudd for the class.

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1 MR. MURPHY: Pat Murphy, state liaison counsel.

2 MR. CIALKOWSKI: David Cialkowski for the class.

3 THE COURT: Good afternoon to all of you.

4 MR. KOHN: Steve Kohn for St. Jude Medical, Your
5 Honor.

6 MR. STANLEY: Good afternoon. David Stanley for
7 St. Jude Medical.

8 MR. SYLVESTER: Court Sylvester also for St. Jude
9 Medical.

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

11 THE COURT: Good afternoon to all of you. We
12 have the motions that have been made concerning the expert
13 witnesses this afternoon. Who is going to proceed?

14 Mr. Kohn?

15 MR. KOHN: Yes, Your Honor. Good afternoon, Your
16 Honor. Steven Kohn for St. Jude Medical. Mindful of the
17 Court's schedule, I will try to move through this quickly,
18 and I have some slides which I hope will facilitate the
19 discussion.

20 Can the Court see them on the monitor?

21 THE COURT: I can.

22 MR. KOHN: Good. Thank you, Your Honor. I will
23 be discussing the challenges to all three of the experts in
24 my remarks. I think that will be more efficient than going
25 one at a time because really the issues that are presented

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1 are fairly common to all three, and I think that will save
2 some time.

3 THE COURT: That's fine.

4 MR. KOHN: First, I would at the outset like to
5 say that my discussions will be framed around all four of
6 the Daubert criteria: Namely qualifications, adequate
7 foundation, relevance and liability. I know the Court is
8 quite familiar with Daubert and the requirements, so I will
9 not dwell on this except to say that we make these motions
10 to the Court in its role as the gatekeeper with respect to
11 unreliable expert testimony and that the burden of proof
12 with respect to establishing reliability and admissibility
13 is on the plaintiffs, not on St. Jude Medical.

14 The analysis that I'm about to undertake is
15 really a four-step process. The first one will be
16 addressing whether the expert is qualified on the subject,
17 and Rule 702 sets out the requirements with respect to
18 that. It's our position that all three of the experts,
19 while maybe qualified in their individual areas of
20 specialty, namely surgery for Mr. Butchart, and I don't use
21 that term with any disrespect.

22 As you probably know, Your Honor, in the UK,
23 surgeons go by the term Mr. instead of doctor, and so I
24 will try to be mindful of that. There is no debate about
25 the fact that he is a qualified surgeon. There is no

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1 debate about the fact that Dr. Wilson is a qualified
2 pediatric pathologist, and there is no debate about the
3 fact that Dr. Healy is a biomaterials specialist.

4 What our challenge is about is the fact that all
5 three of the experts are providing expert testimony well
6 outside the bounds of their expertise and wandering into
7 other areas in which they are not qualified.

8 Step 2, aside from qualifications, is to look at
9 the foundation that has been laid by each of the experts
10 with respect to their opinions. In looking at this, the
11 Glastetter case in the Eighth Circuit, 2001 decision, is
12 quite instructive, particularly since it involves a
13 pharmaceutical Parlodel in an allegation of what that
14 pharmaceutical can or can't cause, so we will be talking
15 more about that case in some detail.

16 Specifically, the experts say so is not enough.
17 It's not enough for an expert to say, I know it when I see
18 it. There has to be some kind of foundation laid,
19 especially when the issues, as they are here, relate to an
20 alleged toxic effect of a medical device. The expert's
21 testimony must be based on sufficient facts or data.

22 The cases almost universally talk about how large
23 is the analytical gap between the data that is submitted by
24 the expert and the opinion that is ultimately offered, and
25 that's what I'll be talking about in some more detail.

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1 Step 2 is the question of whether there is
2 adequate foundation -- oops. Step 3 is the question of
3 relevance. Are we talking about apples to apples? In this
4 case, our position is that we're not at all talking about
5 apples to apples, that the experts in this case are relying
6 upon case reports which may be good for establishing a
7 hypothesis, but they are simply not admissible under almost
8 every course analysis for the purpose of establishing a
9 theory of causation.

10 And similarly relying on materials that are off
11 point, relying on articles that deal with another substance
12 or another device or tested an animal using a different
13 substance, all of which these experts do, does not
14 establish relevance. It's not an apples to apples
15 comparison.

16 Step 4, and the final step in the analysis, is
17 whether or not the opinions offered are reliable under the
18 Daubert criteria, and the ones that are most appropriate
19 here is whether the theories that are articulated can be
20 and have been tested, and our position is that a toxicity
21 theory and other opinions here haven't been tested, need to

22 be tested and shouldn't be admissible unless they have been
23 tested.

24 All of the opinions are litigation driven. They
25 haven't been published. They haven't been peer reviewed,

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1 and in large part, they rely upon case reports rather than
2 published peer reviewed epidemiological studies. I'm going
3 to quickly go through some of the more important cases that
4 are cited in our briefs and point out to the Court why I
5 think these cases are particularly on point in the Court's
6 deliberation regarding Daubert.

7 And starting first with the two cases involving
8 toxicologists, the Jones case from the Seventh Circuit and
9 the Sutera case from the Southern District of New York.
10 Both of those cases are cases involving allegations of
11 toxic exposure, in the Jones case to manganese from welding
12 rods, and the Sutera case to benzene from bottled water.

13 The experts who were excluded in both of those
14 cases were experts who didn't have toxicology training.
15 They weren't board certified toxicologists, and similarly
16 in our case, none of the experts that we're talking about
17 today by their own admission are trained in toxicology.

18 The experts in Jones, the Court pointed out the
19 fact that the experts lacked any knowledge of how the
20 substances were absorbed in the body. The experts here
21 have no information at all about the amount of silver in

22 any individual plaintiff or in any group of plaintiffs.
23 Nor do they know how much silver, if any, would be needed
24 to cause the toxic response that they claim occurs.
25 None of the experts here, and this is pointed out

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1 in the Sutera case, have done any original research of
2 their own. Nor can they point to any by anybody else that
3 establishes that the Silzone coating is toxic, and finally,
4 all three of the experts point to each other as authority
5 for the proposition that the Silzone coating is toxic.

6 And I would submit to the Court that three
7 unqualified experts all citing each other does not in any
8 way enhance the opinion of any of them or all of them
9 collectively. Smith vs. Cangieter, Your Honor, is an
10 Eighth Circuit, 2006 case, and while the facts are very
11 different from ours and it involves an automotive
12 situation, I think why this case is important in terms of
13 what it teaches us is how wide the analytical gap needs to
14 be before an expert is excluded.

15 In that case, the expert hypothesized that a loss
16 of traction in a part-time four-wheel drive vehicle was
17 somehow predictive of the fact that it would occur. A loss
18 of traction and a rollover would occur in yet another
19 vehicle that had a different kind of four-wheel drive. As
20 support of that theory, there was no testing. There was no
21 data submitted, no calculations. No peer reviewed articles

22 were submitted.

23 And the Court found an analytical gap too wide to

24 be bridged by the theory and excluded it, and similarly

25 here, Your Honor, there has been no testing. There has

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1 been no supporting data submitted other than unpublished
2 articles, and there is no silver dosage calculations to
3 assess toxicity that have been submitted by any of the
4 experts.

5 Another toxic exposure case that goes to the
6 question of methodology is the Marmo vs. Tyson Meats case,
7 another Eighth Circuit case from 2006. That was an
8 individual toxic exposure case involving waste water, and
9 there I think the analogy is as follows:

10 This is a case where the toxicologist in question
11 didn't conduct any examination or analyze other toxic
12 exposures, didn't look at the underlying medical records,
13 didn't look at confounding factors or alternative causes,
14 and the court excluded the testimony as unreliable.

15 Here there has been very little, if any, review
16 of individual patient medical records. There has been very
17 little consideration or review of alternative causes, and
18 the important point to make here is that the so-called
19 abnormal healing or adverse events that are being described
20 by all three experts occur with every mechanical valve.
21 There is nothing unique. There is no signature injury in

22 this case.

23 The last case that I will talk about is the

24 Glastetter case that I mentioned a minute ago. That really

25 is on all fours with our case, particularly with respect to

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1 the question of the foundation for the opinions that are
2 being advanced. The Parlodel case involved a claim that
3 Parlodel post lactation medication would cause
4 intercerebral hemorrhage.

5 And the testimony of the expert relied on a
6 similar collection of evidence that is being advanced here,
7 namely case reports, medical treatises that reached
8 opinions that were contradictory, internal company
9 documents that were taken out of context and even a FDA
10 revocation, which we don't have in this case.

11 And the court ruled both collectively and
12 individually that that evidence did not support the
13 proposition, that it had not established that Parlodel, the
14 medication in question, could cause restriction of blood
15 vessels leading to intercranial hemorrhage. It was
16 speculative. It wasn't helpful to the jury, and it was
17 excluded. We submit for the same reasons the court found
18 in Glastetter the three opinions here should be excluded as
19 well.

20 Now I'm going to talk about each one of the three
21 experts very quickly individually and focus on the most

22 important opinions, starting with Dr. Healy. Dr. Healy has
23 labeled his opinion about mechanism or causation, the
24 chronic inflammatory response hypothesis, and it's really
25 the same as what Dr. Wilson and Mr. Butchart are advancing.

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1 And what he is essentially saying is that silver
2 comes off of the sewing cuff of the Silzone mechanical
3 valve. It creates what he calls a concentration gradient
4 in the tissue, and what that simply means is, there is too
5 much silver in his belief, and that causes something called
6 a chronic inflammatory response in the tissue resulting, in
7 his opinion, in various kinds of clinical outcomes, such as
8 paravalvular leak and thromboembolic events.

9 So again, it's a question of how much silver is
10 in the tissue and what does that quantity of silver do.
11 What has Dr. Healy done to really take a look and provide
12 any data whatsoever to support this hypothesis? The answer
13 is, number one, even if he had such data, I don't believe,
14 and we submit, he is not qualified to advance such an
15 opinion.

16 He's not a medical doctor. He's not an
17 epidemiologist. He's not a clinician who has treated a
18 patient. He has never looked at any individual patient
19 medical record. He is not a toxicologist to assess the
20 quantity of silver that would be necessary to create the
21 response that he is hypothesizing, but more importantly,

22 Your Honor, his methodology really isn't a methodology at
23 all.

24 In the first place, he has done no testing
25 whatsoever to prove or to corroborate his opinions. He has

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1 had a mechanical, Silzone mechanical valve in his
2 possession for quite a long time, and he told us in his
3 deposition that the reason he hasn't done any testing to
4 validate his opinion is because he hasn't been authorized
5 to do it by plaintiffs' counsel.

6 So he has no idea of how much silver is in the
7 tissue of any mechanical valve recipient. He doesn't even
8 know how much silver would be needed to create the kind of
9 response that he argues occurs. He doesn't know whether
10 any individual or collective group of patients has even
11 experienced this chronic inflammatory response. Nor is he
12 able to establish that in fact leads to any clinical
13 symptoms.

14 Even if he had, he says, patients that he could
15 test, he wouldn't be able to do it because the tests would
16 involve invasive procedures such as biopsies. This is an
17 opinion, Your Honor, that has been strictly created for
18 litigation. He has never published it. He has never
19 written about it. He has never presented it at any
20 scientific meeting.

21 So what we're left with with respect to Dr. Healy

22 and his chronic inflammatory response hypothesis is, number
23 one, his opinion that silver forms a concentration
24 gradient. There is absolutely no proof offered whatsoever
25 about that, other than his say so.

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1 With respect to his idea that it creates a
2 chronic inflammatory response, again there is no proof that
3 has been submitted. With respect to it causes these
4 various complications that occur with all mechanical
5 valves, there has been no proof submitted.

6 And then his final opinion, the largest gap in
7 the analysis, is the fact that he claims that every Silzone
8 patient, 28,000 people who have the Silzone valve, have
9 suffered damage of some kind because of this hypothesis and
10 are at increased risk, but in his deposition, and this is a
11 direct quote from his deposition, he says, It is anybody's
12 guess when or if a Silzone patient will experience
13 complications.

14 Your Honor, we submit that this is nothing more
15 than speculation. It's his say-so. It hasn't been tested,
16 and it shouldn't come in front of any injury. The second
17 opinion that he has set forth suffers from similar
18 problems, and this is a, what we have labeled as a legal or
19 regulatory opinion.

20 He's hypothesized that St. Jude Medical withheld
21 certain information from the FDA in its initial submission

22 for the Silzone valve, and in particular, he points to some
23 articles in the medical literature that he says if the FDA
24 had had somehow and considered perhaps they might not have
25 approved the valve. He also points --

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1 MR. ANGSTREICH: Excuse me, Your Honor. That's
2 one of the opinions that was presented as part of the
3 preemption argument of a long time ago. It is not part of
4 the generic expert opinions that Dr. Healy's testimony will
5 be used with respect to all of the other MDL proceedings.

6 And Mr. Kohn knows that, and to start arguing
7 about this I guess would then invoke the question as to,
8 well, they lost the preemption argument and maybe they
9 should move on because we don't intend to present this
10 again since preemption isn't in the case.

11 MR. KOHN: Well, Your Honor, it is in his expert
12 report. He testified about it in his deposition. This is
13 the first time that I'm hearing that it's no longer a part
14 of the case. If it's no longer a part of the case, I won't
15 address it. As far as I know until this moment it has been
16 part of the case, and his trial perpetuation testimony
17 hasn't been taken. So I have no idea what he is going to
18 say, but I do know this is in his report, and as far as we
19 know, this is his opinion.

20 MR. ANGSTREICH: Your Honor, it's in the case if,
21 as and when an issue of a preemption should ever come back

22 again. It is not part of the generic expert opinions.

23 THE COURT: Not for trial purposes?

24 MR. ANGSTREICH: Not for trial purposes.

25 THE COURT: All right. So we can go on.

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1 MR. KOHN: I will move on to something else then,
2 Your Honor, because that is --

3 THE COURT: That noise is probably a cell phone
4 or a Blackberry, and it can come from any direction. If I
5 brought one in up here, it might make noise.

6 MR. KOHN: It seems to have stopped, Your Honor.
7 All right. Just to wrap this up with respect to Dr. Healy,
8 it's our position, Your Honor, that the chronic
9 inflammatory response hypothesis flunks all four of the
10 criteria under Daubert. He isn't qualified to give it.
11 There is no foundation for it. It's neither relevant nor
12 reliable, so let me move on then to Dr. Wilson.

13 Dr. Wilson's opinion on the issue of causation
14 and causal mechanism is quite similar to Dr. Healy.
15 Instead of calling it a concentration gradient or a chronic
16 inflammatory response, he talks about it in terms of silver
17 toxicity, silver being a poison in his view from the
18 Silzone coating that leads to a variety of different
19 complications.

20 The first thing I would like to address, is
21 Dr. Wilson really qualified to give an opinion about

22 toxicology type issues? The answer I think is
23 unequivocally that he is not. He is not by his own
24 admission a biomaterials expert. He has no training
25 whatsoever in toxicology, and this is simply totally

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1 outside his area to talk about or even hypothesize that
2 silver is causing a toxic reaction.

3 His primarily experience is with pediatric
4 patients. He has absolutely no experience with any adult
5 mechanical valve over the last 25 years, and by his own
6 admission the healing in children is quite different than
7 in adults, and then with respect to his opinion about what
8 normal healing is, the only place you will find the
9 definition of normal healing is in his expert report.

10 There is no cite to the medical literature, nor
11 could there be any, because there is no agreement in the
12 world of cardiac pathologists as to what normal healing is.
13 With respect to Dr. Wilson's method to establish that his
14 opinion that silver is causing this toxic reaction, first
15 of all, he has looked at approximately 15 valves, and this
16 is not a randomized study. These are valves that have been
17 furnished to him by plaintiffs' counsel. They are all from
18 patients who experienced one kind of adverse event or
19 another.

20 Other than look at the pathology through the
21 microscope, he has done no testing to establish any kind of

22 a toxic response that occurred in these 15 patients, and he
23 has got no controls. He has not looked at any other kinds
24 of valves to establish that there is something unique about
25 the response that he is seeing.

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1 Using these 15 valves and without looking at
2 complete medical records from all these patients, he then
3 extrapolates, because of the presence of very microscopic
4 quantities of silver, to a much bigger universe and says it
5 must be the silver, and it must occur in all patients.

6 In doing so, he again cites to Mr. Butchart and
7 to Dr. Healy and to the same authorities that they rely
8 upon. Again, this is an opinion that has been created and
9 promoted only in this litigation. Dr. Wilson has never
10 published it. He has never presented on it, and it hasn't
11 been peer reviewed.

12 What we're left with with respect to Dr. Wilson
13 is an unproven hypothesis. He says that Silzone is
14 mechanically unstable because it comes off the cuff into
15 the local tissue in the myocardium or in the annular tissue
16 of the heart. He has no proof whatsoever for that other
17 than microscopic quantities of silver that he sees only
18 through the microscope and which has always been known from
19 the time of the FDA regulatory submission that was the way
20 Silzone worked.

21 It was supposed to leach off the cuff. That was

22 the way the silver worked. So there was nothing unusual or
23 particularly troubling about the fact that there is silver
24 in microscopic quantities in the local tissue.

25 Then he goes to the next step and says well, it's

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1 toxic. It's killing human cells. Well, he has yet to show
2 us a picture of either a cell in any of his specimens that
3 is damaged or has been killed by the silver that he claims
4 is toxic. So there is no proof whatsoever, nor could there
5 be, from looking at these 15 specimens.

6 He then goes on and says, because I see abnormal
7 healing, what he calls as -- what he calls abnormal,
8 somehow that must be the effect of silver toxicity, and
9 then he hypothesizes that all patients, all 28,000
10 patients, must have similar kinds of frustrated healing.

11 When asked in his deposition what have you done,
12 what have you done to prove up your theory, what he says
13 is, I haven't done any chemical measurements, physical
14 measurements of silver in the tissue. I have not
15 specifically been asked by plaintiffs' counsel to do so,
16 and in fact, I'm not set up myself to do such measurements.

17 In the reply -- sorry -- in the opposition to our
18 motions, counsel cites to a recent article, a peer reviewed
19 article by Dr. Butany, another cardiac pathologist at the
20 same institution or in Toronto as well, and Dr. Butany has
21 looked at more valves than Dr. Wilson and more Silzone

22 valves, that is, but he has also looked at valves from
23 other manufacturers.

24 And he unlike Dr. Wilson is not a pediatric
25 pathologist, but he is a cardiac pathologist who deals with

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1 adults, and in this peer reviewed article that Dr. Wilson
2 relies upon, Dr. Butany discusses the issue of silver
3 toxicity, and for Your Honor's reference, the Butany
4 article is attached at Exhibit 4 to Mr. Rudd's affidavit.

5 And Dr. Butany states in his article, he says
6 another possibility, he doesn't say probability, he says
7 another possibility in discussing adverse events with the
8 Silzone valve is that the paravalvular abscess seen is
9 related to a toxic effect of the silver on the myocardium.

10 And he goes on, and he says one way to confirm
11 this would be to study the concentration of silver in the
12 periannular periprosthetic tissues. So Dr. Butany is
13 saying, this is a possibility. If you wanted to know more
14 about it, you should take a look at the silver
15 concentration.

16 Again, Dr. Wilson hasn't done that. Why? He is
17 not set up to do it, and he hasn't been asked to do it.
18 Dr. Butany goes on and says, there is another way you could
19 do it. You could look at the effect of elemental silver
20 coated fabric on myocyte cultures. Once again, suggesting
21 another way of testing this theory, another thing that

22 Dr. Wilson could have done but apparently hasn't done.

23 I was planning to discuss Dr. Wilson's regulatory

24 opinions, but I take it from counsel's remarks that they're

25 not at issue?

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1 MR. ANGSTREICH: Well, as we stated in our
2 submissions, they're not at issue.

3 MR. KOHN: All right. So I will pass on that,
4 and I assume they will not be the subject of any
5 questioning in his MDL deposition.

6 To summarize all of this, Your Honor, and I will
7 leave aside the question of his criticisms of our
8 regulatory submission, we submit that all of Dr. Wilson's
9 opinions are nothing more than speculation, untested,
10 unproven, unreliable unpublished and only created for
11 purposes of this litigation.

12 They flunk every aspect of the Daubert test.
13 Lastly turning to Mr. Butchart, the analysis is much the
14 same. Now, counsel has made a great point in the
15 opposition of suggesting that somehow Mr. Butchart must be
16 qualified because St. Jude Medical engaged him to undertake
17 a study in Wales regarding the Silzone valve, and we
18 certainly don't dispute the fact that Mr. Butchart is a
19 qualified surgeon, and if he wasn't, we wouldn't have
20 engaged him to do the study.

21 But we didn't engage him to express opinions

22 about toxicology. If we wanted opinions about toxicology,
23 we would have engaged somebody who was qualified to talk
24 about toxicology, and by his own admission, Dr. Butchart,
25 Mr. Butchart, is not a toxicologist. He has no training in

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1 toxicology.

2 And at his deposition that was taken about a week
3 ago, when I asked him after he admitted that he wasn't a
4 toxicologist and hadn't done any testing and didn't know
5 how much silver was in the tissue, et cetera, his answer
6 was, I don't have to do any testing. I know it when I see
7 it.

8 Well, Justice Stewart might know pornography when
9 he sees it, but I submit that a surgeon looking at tissue,
10 whether it is through the microscope or otherwise, there is
11 no way in the world that he can say whether the response he
12 is looking at is toxic just by looking at it. That's the
13 same thing as saying, because I say so, it must be toxic.

14 So his hypothesis is, there is silver in the
15 tissue. He doesn't know how much. That damages either
16 platelets or red blood cells. He doesn't know which. He
17 says both mechanisms are hypothetical. He admits that, and
18 he says, this toxicity causes impaired healing resulting in
19 a wide range of adverse events, all of which occur in all
20 mechanical valves. There is nothing different or unique
21 about these adverse event.

22 With respect to his qualifications, as I said,
23 he's not a toxicologist. With respect to the foundation
24 for his opinions, there has been no testing, no data.
25 There has been no evidence whatsoever of the silver level

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1 either in his patients or in any other patients that anyone
2 else has ever looked at.

3 He has removed two Silzone mechanical valves, I
4 think maybe three by this time, out of the total 36,000
5 that were implanted. You can't extrapolate from two valves
6 that you have never tested for silver concentration to
7 reach an opinion that silver is toxic to cells.

8 He also relies upon an unpublished manuscript by
9 Dr. Goodman, and that manuscript which involved a
10 laboratory test not on blood but on plasma using the
11 Silzone coating, reached the conclusion that the silver
12 coating was likely to be favorable to healing and to result
13 in less thrombogenicity for the Silzone valve.

14 When doctor or when Mr. Butchart looks at that
15 same unpublished manuscript, he reaches a different
16 conclusion. He says that manuscript, which has never been
17 published or peer reviewed, stands for the proposition that
18 silver is toxic. So when I asked him about it in his
19 deposition recently, he said well, Dr. Goodman was
20 speculating in his manuscript when he said the results he
21 found in these studies were favorable, and I think he's

22 wrong, and my opinion is the results are unfavorable, and I
23 think he's speculating.

24 I said, well, in other words, he's speculating,
25 and you're not. He said, no, no. I'm speculating, too,

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1 but I think my speculation is better than Dr. Goodman's.
2 You know, it doesn't really matter. Juries are not
3 supposed to hear experts speculating about unpublished
4 articles that don't establish what they say the article
5 stands for.

6 Similarly, he relies on two articles, and these
7 are found at Exhibit 5 of our motion. By the way, the
8 Goodman paper, abstract, is at Exhibit 4 to our motion,
9 Your Honor. At Exhibit 5 are two outdated articles not
10 involving the Silzone valve. They're 40 years old. They
11 don't say anything at all about silver toxicity.

12 And Mr. Butchart, who is not a material
13 scientist, who is not a toxicologist, relies on these two
14 outdated articles for the proposition that silver shouldn't
15 have been used and is somehow toxic. His hypothesis
16 involves no truth of any dosage. It doesn't involve
17 testing by him or anyone else.

18 He has not ruled out alternative causes for the
19 events that he is describing. He has looked at predictors
20 in his own study, but he hasn't looked at all of them. He
21 hasn't looked at all of the postsurgical issues in his own

22 patients or anybody else's.

23 The evidence that he has looked at is

24 scientifically unreliable, such as the unpublished Goodman

25 reference, and by his own admission, both in his published

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1 paper about his own patients and in his deposition, he
2 admits that his toxicity theory is nothing more than a
3 hypothesis that would be very difficult to prove.

4 The second opinion I will address is
5 Mr. Butchart's opinion about increased risk, and he
6 believes and the underpinning for this opinion really is
7 his toxicity opinion. So if his toxicity opinion falls,
8 this opinion about increased risk should fall as well.

9 He says in his report that the Silzone causes a
10 higher incidence of complications in almost every
11 conceivable outcome for mechanical valve patients, from
12 thrombosis to thromboembolism to tissue overgrowth,
13 et cetera. Well, first of all, he's not a biostatistician
14 and he's not an epidemiologist. So to voice that opinion I
15 think is beyond his qualifications, but even giving him
16 some credence for his qualifications, his methodology is so
17 flawed that it's hard to create a single graphic that would
18 list all the flaws in his methodology.

19 First of all, and I'm sure you may hear that
20 Mr. Butchart formed all of his opinions long before he was
21 retained as an expert. Well, that is absolutely untrue.

22 He has undertaken something called the Late Cardiff Review
23 that has been done and is still going on after he was
24 retained as an expert, and it serves as the basis for much
25 of what he had to say in his expert report.

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1 He published an article in 2003 about his 51
2 Silzone patients that had very limited findings which
3 didn't really express an opinion about toxicity other than
4 a hypothesis, which didn't talk about anything other than a
5 risk of thromboembolic events in one subset of patients,
6 patients who had a mitral valve and only patients that had
7 a major thromboembolic event such as a stroke.

8 He didn't say anything at all about aortic valve
9 patients, about patients who had minor thromboembolic
10 events, et cetera. Now he has gone on as a litigation
11 consultant to take a look at his Silzone patients in this
12 Late Cardiff Review. That hasn't been published and is
13 strictly something he has done for litigation.

14 In doing this, he has disregarded the AVERT trial
15 and any other published report. There has been at least
16 ten other published reports about Silzone valve patients,
17 and Mr. Butchart disagrees with all of them. He relies on
18 case studies and adverse event reports, which are excluded
19 under Glastetter and many other cases.

20 And with respect to his own small study in
21 Cardiff involving 51 patients, only 13 of whom had mitral

22 valves -- that's the only place he found any kind of an
23 increased risk -- he extrapolates from that study to a
24 whole wide range of adverse events where he didn't find in
25 his study, nor has any other study found, an increased

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1 risk.

2 For example, he admitted in his deposition that
3 when you add in all the events in his own study, even in
4 the mitral position, when you put in all of the minor
5 thromboembolic events and blend them all together and you
6 look at Silzone, Silzone is not a predictor, is not a
7 predictor, but other things are, such as postsurgical kinds
8 of risks that these patients have.

9 More importantly, he admitted that there is no
10 other study other than his small 51 patient study that has
11 the same findings that he had. He admitted there is no
12 study that shows an increased risk of thrombus, no study
13 that shows a long term risk of paravalvular leak, no study
14 that shows an increased risk of thromboembolism in aortic
15 valve patients.

16 So, Your Honor, you can't extrapolate from a 51
17 patient study in 13 patients that found a single finding
18 regarding the mitral valve to the universe of Silzone
19 patients and then say every other adverse event somehow the
20 risk must be increased.

21 In summary, Your Honor, with respect to this

22 particular aspect of his testimony, we submit that the
23 support he has offered for the opinion that Silzone
24 increases the risk of this wide ranging set of adverse
25 events is not admissible. It doesn't support his opinions.

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1 He is relying on his Late Cardiff Review which hasn't been
2 published. It does not have a control group.

3 He is relying on the top account survey which is
4 nothing more than a case series, and he is relying on one
5 case report which shows cancer, but even in that case
6 report did not suggest a causal mechanism. He's relying
7 upon field reports from St. Jude Medical, and he's relying
8 upon statistically insignificant results in AVERT and other
9 studies, which under Glastetter and also under the Good
10 case, which is cited, Your Honor, would not be admissible
11 to the Court as an opinion.

12 I was planning on talking about his medical
13 monitoring and treatment opinions, and counsel in the
14 opposition has indicated that they're not on the table, and
15 if that's the case and we have the assurance they're not
16 going to be discussed in his deposition or offered in any
17 individual case that might get remanded by this Court, I'm
18 willing to defer this for another day.

19 MR. ANGSTREICH: I told you that on the phone.

20 MR. KOHN: I know you did.

21 MR. ANGSTREICH: I don't know why you need to

22 bring it up again.

23 THE COURT: He probably just wants to get it on

24 the record.

25 MR. KOHN: I would like to get it on the record.

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1 MR. ANGSTREICH: It's in our submission, Your
2 Honor. We said it's not on the table for the generic
3 opinions. We did file that with Your Honor.

4 MR. KOHN: Okay. Fair enough. In summary, Your
5 Honor, we feel that both the toxicity opinion and the
6 increased risk opinion fail the Daubert criteria on all
7 four prongs. There is no support whatsoever. He lacks the
8 qualifications to set them forth.

9 He extrapolates from studies that don't say what
10 he says they say or stand for the proposition that would
11 support any of the complications that he is claiming. And
12 for all of those reasons, Your Honor, his opinion regarding
13 increased risk and silver toxicity we respectfully submit
14 should be excluded.

15 Thank you, Your Honor.

16 THE COURT: Thank you, Mr. Kohn.

17 Mr. Angstreich?

18 MR. ANGSTREICH: I apologize that I don't have a
19 slide show, but I have to correct a number of misstatements
20 that were made. Dr. Wilson is not a pediatric pathologist.
21 He's a cardiac pathologist. He happens to deal with

22 children because he's with the Children's Hospital in
23 Canada. However, he has testified repeatedly about his
24 ability as a pathologist to deal with dead tissue and
25 analyze dead tissue.

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1 And one little statement that I think belies
2 really what this whole motion is about, during Dr. Wilson's
3 deposition, he presented a slide of an area of a valve with
4 respect to a particular patient, and Mr. Kohn said to him,
5 point out the dead cells. And Dr. Wilson said, you can't
6 point out dead cells unless at the instant the picture was
7 taken, a cell died because once it dies, it disappears.

8 However, you see all these spaces in the
9 thrombus, all this white area, all the missing cells?
10 That's where cells were. That's evidence that they're
11 dead. So while he couldn't point to a picture of a dead
12 cell, he pointed to repeated areas in this particular valve
13 where cells had been killed.

14 We're talking about the Daubert standard dealing
15 with principles and methods and not conclusions. We
16 understand that they don't like the conclusions of these
17 witnesses and these experts. The fact of the matter is,
18 they were all set to publish Mr. Butchart's results of the
19 thromboembolic study that they went to him to include the
20 Silzone valves in.

21 It was an ongoing study, and they were all

22 prepared to publish the results, and lo and behold in a
23 small sample of mitral valves, 13, there was an
24 overwhelmingly statistically significant thromboembolic
25 event, major thromboembolic event. And he met with them,

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1 and he worked with them, and he went over all of that with
2 them. Unfortunately, he published a contrary report which
3 was peer reviewed and approved, and it is in literature.

4 Now, citing to Glastetter, I saw a picture apples
5 equals apples. Glastetter doesn't equal Silzone, and the
6 reason that Glastetter doesn't equal Silzone is, there was
7 an attempt to take a drug and say that that drug is the
8 equivalent of another drug because of a chemical component
9 of it.

10 Well, that's not what we're doing here. Silver
11 is silver, and Dr. Healy went to the silver literature and
12 found the silver literature that said that the silver kills
13 cells. Now, there is a disagreement between Dr. Goodman's
14 paper and Mr. Butchart's analysis of it because there is
15 evidence in that paper that silver kills platelets.

16 Now, something that wasn't mentioned with respect
17 to this paper, the third author of the paper is a St. Jude
18 Medical author. The e-mail chains that have been presented
19 in this case establish that they didn't publish the paper
20 because it was not going to be helpful to them.

21 So if in fact Dr. Goodman's conclusions were that

22 this fostered healing and it didn't kill the tissue, you
23 would have seen it in the literature, especially in
24 literature which Dr. Bodnar may be the head of the journal
25 because of a relationship with St. Jude Medical.

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1 Now, you also didn't hear that Dr. Butany, the
2 pathologist out of Canada who went to St. Jude in the
3 beginning of this whole situation in 1998 and told them
4 that there was an increased number of explants in the
5 hospitals there which resulted, by the way, in Toronto
6 General and Sunnybrook stopping implanting Silzone before
7 the recall, about a year and a half before the recall, you
8 didn't hear that Dr. Butany is a St. Jude Medical
9 consultant.

10 I think that's a pretty important piece of
11 information, but there is some other things that I need to
12 point out. We have been chastised that, Dr. Healy and
13 Dr. Wilson has been chastised. You didn't do any tests.
14 You don't know what the level of silver is. You don't know
15 what the level of toxicity is. We didn't put this in the
16 stream of commerce. We didn't tell people that this
17 product was safe and use it and implant it in 28,000
18 people.

19 Now, Dr. Factor, who is one of their experts, has
20 testified under oath, and he says, basic science issues
21 relate to silver being toxic. Could you please tell us

22 what the silver toxicity level of tissue is? In which
23 tissue? Heart tissue. His answer is, I don't know, nor do
24 I think it has been reported, nor do I know how it would
25 even be measured. Now, that's their expert, but our expert

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1 is being chastised by St. Jude because he didn't do the
2 test. Their expert says he doesn't know how to measure it.

3 Now, as between the recipient of the heart valve
4 and the company that puts it out, who had the burden? Who
5 had the responsibility to assure that the silver wasn't
6 toxic? Now, Mr. Butchart did say I know it when I see it
7 because what he saw is something called necrotic tissue
8 around the heart valve, sewing cuff. What is necrotic
9 tissue? It's dead tissue. Something killed that tissue.
10 As a doctor, he has methods of determining what killed it.

11 Well, as he testified in his deposition, it could
12 be because of infection. It could be because of that
13 infection, and therefore you have, not only do you have the
14 dead tissue there, the necrotic tissue, but you have a
15 paravalvular leak. In patients where there was no
16 bacteria, no infection, there was necrotic tissue, and
17 differential diagnoses, which is part of the methodology
18 that is recognized, is to rule out other causes.

19 Well, what else caused it? Silver is known to
20 kill cells. It's in the literature. Dr. Healy had, did a
21 literature search, and Dr. Healy found that it killed

22 cells, and there is no denial of it. It's basic science.
23 Dr. Factor admits it. Now, did this person's problem, was
24 that person's problem caused by the Silzone coating? We
25 don't know, nor do we intend to deal with that. That's an

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1 individual causation issue.

2 So when you're trying to deal with individual
3 causation, you have to go beyond that. You have to look at
4 the individual valve. You have to look at the individual's
5 medical records. Dr. Healy, Dr. Wilson and Mr. Butchart
6 are not testifying that Mrs. Jones' thromboembolic event
7 was caused by the silver.

8 What they have all said is, silver does this.
9 Now, the concept that thrombus is a normal complication in
10 all valves is just an overstatement and really has no
11 scientific validity. In fact, thrombus is what causes the
12 valve to heal. If there is no thrombus, the valve can't
13 heal.

14 However, the problem isn't with thrombus
15 initially. It's with excessive thrombus, with the
16 inability of the tissue to heal in in an organized fashion
17 so that it heals into the Dacron cuff as well, and what
18 happens with mechanical valves, the paralytic carbon valve
19 in this case, is that it has a Dacron cuff, and the
20 difference between the normal valve and the Silzone valve
21 is the silver.

22 In mechanical valves, you have a regime for
23 anticoagulants, and there is a reason for that, and that is
24 that with the blood rushing through, blood being sticky,
25 you don't want the blood to clot on the mechanism, on the

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1 leaflets and on the hinges, but everybody recognizes, and
2 there doesn't have to be a study about this.

3 Everybody recognizes that that's not the case
4 with respect to the sewing cuff, and the proof, and how do
5 we know that is that there are bioprosthetic valves, which
6 are made from animal which have the same Dacron sewing cuff
7 as the unSilzone Dacron sewing cuff, and those patients
8 after the first three months have no anticoagulants.

9 Why? Because thrombus doesn't grow on the sewing
10 cuff if it's properly healed in, and you don't have to
11 worry about thrombus on the animal part, whether it's a pig
12 valve or whatever sheep, whatever it happens to be. You
13 don't have the same problem. You have to have an
14 anticoagulant regime with a mechanical valve to prevent
15 clotting not on the cuff, but on the leaflets and hinges.

16 And the problem that has been seen with this
17 valve is that thrombus grows three and four and seven years
18 after implantation on the cuff, and the reason for that is
19 not because there is infection, but because the silver
20 kills the tissue, because that's the necrotic tissue that
21 is observed.

22 So when you point to individual cases dealing
23 with an individual expert's attempted analysis to draw a
24 conclusion that Mrs. Jones' injury or her illness or her
25 stroke or whatever it was is caused, was caused by this

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1 particular product, it's a different analysis than the
2 question of, does it, can it cause it.

3 Now, the AVERT study, this is also very
4 fascinating, Your Honor. The AVERT study, which was
5 supposed to be the randomized gold standard program, 4,000
6 people, half Silzone, half not Silzone, got to about 800
7 when there was a statistically significant incidence of
8 paravalvular leaks, and they stopped enrolling people.
9 800. At the time that study was initially created, it was
10 only created to look at paravalvular leaks, no other
11 problems.

12 A year, more than a year later when the UK
13 equivalent of the FDA, the MDA, said to them Dr. Butchart's
14 analysis shows us a high incidence of thromboembolic
15 events, we need you to have your questionnaires modified,
16 January 1999, they modified their questionnaires to find
17 that information about thromboembolic events.

18 So when they talk about this randomized
19 prospective study, it might have been randomized, and it
20 might have been prospective as it related to paravalvular
21 leaks, but it was retrospective with respect to every other

22 problem. Also as Dr. or Mr. Butchart has testified, there
23 is an issue in this study about what do you call it? There
24 is thrombus on the valve, excessive thrombus on the valve
25 but a paravalvular leak. It's a paravalvular leak. No

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1 mention of thrombus. That's part of it.

2 It's also interesting that the evidence in the
3 case shows that subsequent to all of the litigation that
4 has been initiated, AVERT is continuing on, and AVERT
5 continuing on as a litigation aid, and St. Jude Medical's
6 personnel have made that very clear. It is intended as
7 part of this litigation. Now, every year that goes by, the
8 sample size gets smaller and smaller and smaller.

9 So what they want to do is, they want you to say
10 well, this is the appropriate answer to the question. This
11 study is not appropriate, and quite frankly, that goes to
12 the question of the conclusion, not the question of the
13 methodology because I heard nothing, and I saw nothing in
14 the papers that suggests that Mr. Butchart's study, the
15 CERF study, wasn't done in accordance with proper methods.

16 In fact, as he testified, his protocol was given
17 to St. Jude Medical, and they approved it. So we're not
18 talking about an issue of an improper method or improper
19 science. We're talking about, we just simply don't like
20 what you have to say, and that's what we have.

21 We have highly qualified experts in all of the

22 fields, and they simply don't like the results, and it's
23 perfectly proper. Dr. Wilson tested tissue and found
24 silver. He did the test. He tested it. He found the
25 silver, and Dr. Healy relies upon it. You don't have to be

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1 a medical doctor, by the way, to rely upon the expert
2 analysis of other experts, and Wilson did the test. There
3 is silver there.

4 In fact, and it's very interesting because I
5 didn't know. I wasn't sure as to whether or not there was
6 really an admission that the silver was intended to leach
7 off because part of the issue in this case is, if it's
8 leaching off, if its intent is to fight bacteria away from
9 the cuff, that makes it a drug. And I think that if you go
10 back in all of the discussions that we had a long time ago,
11 they fought very hard and very long to make it clear that
12 it was a killer on the cuff and not a killer off the cuff,
13 but yet, we also now know that it kills the tissue that is
14 adjacent to the cuff, and those are the facts.

15 Those are the facts and those are the opinions
16 that have been advanced, and pointing to the cases which
17 deal with an individual person's causation just don't
18 apply. Glastetter, as I said, isn't remotely on point, not
19 let alone being on all fours with it. I'm also unclear as
20 to what case, because I didn't see it on the charts, what
21 case requires an expert opinion to have been peer reviewed

22 in connection with a litigation matter?

23 I didn't know that if you were a litigation

24 expert that you had to first get somebody else to review it

25 and approve it. That's not a criteria that I'm aware of,

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1 and in fact, none of the litigation expert opinions that
2 have been presented by Dr. Rodricks, Dr. Factor, none of
3 them have been peer reviewed.

4 It's interesting also on the one hand we have a
5 nonprofessional expert, and he's chastised because he's not
6 a professional expert witness. On the other hand,
7 professional expert witnesses who make their living only
8 giving expert opinions are questioned, and that goes to the
9 weight of their opinions. It certainly doesn't go to the
10 ability to render an opinion, as we have cited in our
11 papers. There is a first time for every expert to testify.

12 In Canada they made the same arguments with
13 respect to these experts. We've given Your Honor the
14 Court's conclusions there. Their test, their standard as
15 gatekeeper is very similar to Daubert. Dr. Wilson and
16 Dr. Healy were both found to be qualified and that their
17 opinions certainly could not be excluded, that if there
18 were issues with respect to those opinions, it went to the
19 weight but certainly not their admissibility, and that's
20 what we're faced with in this case.

21 We have a world reknowned cardiac surgeon sought

22 out by St. Jude Medical who has come up with opinions and
23 conclusions prior to being retained, and his studies went
24 on. Now, there is another thing. Dr. or Mr. Butchart is
25 chastised because he's not an epidemiologist. He's not a

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1 statistician. He has a statistician that works with him.

2 That's standard procedure.

3 In fact, again, Dr. Factor, who is their expert,
4 was questioned about that issue, and he acknowledged that
5 he's not an epidemiologist, but the practice is that you
6 have a biostatistician's job, and it was the
7 biostatisticians's job to choose the type of analysis that
8 was done.

9 Then you generate results, and then you would get
10 the end product results from which you would then draw your
11 conclusion, fair? Answer: Yes. That is the common,
12 modern way research is done in a collaborative process,
13 given the highly technical area that research is now being
14 engaged in, correct? His answer is, I would agree.

15 So you don't expect your clinician to be the
16 statistician, the pathologist, the toxicologist all rolled
17 in one. We agree, they don't all have those exact hats,
18 but they know what they see. And they know what they rely
19 upon, and 702 allows them to rely upon them. You're
20 talking about, one of the arguments is, well, he is not
21 board certified in the United States. That's Mr. Butchart.

22 He is a visiting and was a visiting professor at Yale, a
23 researcher at Harvard. His credentials go on and on and
24 on.

25 Again, we have, we have an attack on Dr. Healy

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1 because he is rendering a clinical opinion, but when the
2 clinician, Mr. Butchart, gives his opinion, then it's not a
3 clinical opinion anymore, and Mr. and Dr. Healy can't rely
4 upon Mr. Butchart. When it's all said and done, and
5 unfortunately a few more trees have fallen over this, but
6 when all is said and done, this is a dispute over the
7 conclusions, cutting it completely apart.

8 The conclusions are what are being attacked. The
9 credentials can't be attacked. These are credentialed
10 people in the fields in which they have rendered their
11 opinions. Their opinions are scientifically valid from
12 review of the literature directly on silver, unlike
13 Glastetter. You look at the literature on silver. You
14 come up with an opinion on silver.

15 That's what happened, and as I said, our briefs
16 address all of the other points, and unless Your Honor has
17 specific questions, I don't think that -- although I've
18 left Mr. Kohn 15 minutes of potential rebuttal with Your
19 Honor's 3:30 conference call, maybe I should just keep
20 talking, but I'm at the point where unless Your Honor has
21 some specific questions, I will rely upon our papers.

22 THE COURT: Okay. That's fine. We'll see if

23 Mr. Kohn has anything else.

24 MR. ANGSTREICH: I wouldn't be surprised.

25 MR. KOHN: I hate to surprise Mr. Angstreich, but

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1 I actually have a couple of minutes, Your Honor, no more.

2 I will respond to a couple of points that were made.

3 First, it goes back to the original point I made about

4 Rule 702 and the Daubert criteria.

5 It's not St. Jude Medical's burden to show that

6 silver is not toxic. If the experts for the plaintiffs in

7 this case were going to hypothesize that it is, it's up to

8 them to provide support. We haven't heard any, and they

9 haven't furnished any. They haven't done any testing that

10 would establish it.

11 There is not one word in any of their reports

12 about it. The notion that silver kills cells, any

13 substance on the planet will kill cells in sufficient

14 quantity. What matters is the dose, and they have not

15 articulated or even hypothesized what the dose that is

16 necessary might be.

17 With respect to what Your Honor heard about the

18 necrotic tissue that was allegedly observed by

19 Mr. Butchart, that is not in his expert report, and as far

20 as we know, he has only explanted two valves. One of those

21 valves, by his own admission, was an infected valve that

22 had endocarditis.

23 Now, if that is the necrotic tissue that he is he

24 is describing, that explains it. Anyway, it's not in the

25 expert report, and I don't believe there is any support in

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1 the literature that says you can identify tissue as dead
2 simply by a gross observation as opposed to a microscopic
3 evaluation.

4 Finally, with respect to the issue of whether you
5 do or don't need a statistician or a biostatistician, I
6 would submit, Your Honor, that if you are going to advance
7 opinions about increased risk, then you need to either have
8 statistical support for it or be a statistician yourself.

9 And Mr. Butchart has available to him
10 statisticians who could have supported his wide ranging
11 opinions about all these myriad adverse event that occur,
12 and he hasn't done it. The only statistical analysis that
13 has been done is this 2003 publication which stands only
14 for the limited proposition that I mentioned earlier, that
15 in 13 patients there was an increased risk of TE,
16 thromboembolic events, in the mitral position and only in
17 the first three months, and that is all that is found in
18 his study.

19 There are no other conclusions that were made.
20 So if he's going to go beyond that, he needs some
21 statistical support, and he doesn't have it. Thank you,

22 Your Honor.

23 THE COURT: Mr. Angstreich?

24 MR. ANGSTREICH: I just need to correct a

25 statement. Mr. Kohn knows that there is a biostatistician,

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1 and that the biostatistician did the analysis.
2 Mr. Butchart's testimony was taken on April the 3rd, so
3 that's not that long ago. He identified the
4 biostatistician that has worked with him from the beginning
5 of the CERF study and did the analysis, and he so testified
6 that he has relied upon the biostatistician.

7 THE COURT: Thank you. Thank you,
8 Mr. Angstreich.

9 If there is nothing else, the Court is going to
10 take the motion under advisement. We will try to reach a
11 conclusion and issue a written order as quickly as possible
12 to get this matter moving along. Once this is out, then I
13 think at that point we will schedule another status
14 conference.

15 Does that sound okay?

16 MR. ANGSTREICH: That's fine.

17 MR. KOHN: Yes, Your Honor.

18 THE COURT: We will have the full score at that
19 point in time. Okay?

20 MR. ANGSTREICH: Thank you, Your Honor.

21 MR. KOHN: Thank you, Your Honor.

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* * *

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1 I, Kristine Mousseau, certify that the foregoing
2 is a correct transcript from the record of proceedings in
3 the above-entitled matter.

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7 Certified by:
Kristine Mousseau, CRR-RPR

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