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UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re: ) Civil 05-MD-1708 (DWF/AJB)  
)  
GUIDANT CORPORATION ) STATUS CONFERENCE  
IMPLANTABLE DEFIBRILLATOR ) AND DISPOSITIVE MOTIONS  
PRODUCTS LIABILITY ) IN THE DURON AND CLASBY  
LITIGATION, ) CASE  
)

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This Document Relates )  
To All Actions ) 10:00 o'clock, a.m.  
) June 19, 2007  
) St. Paul, Minnesota  
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THE HONORABLE JUDGE DONOVAN W. FRANK  
UNITED STATES DISTRICT COURT JUDGE  
STATUS CONFERENCE PROCEEDING

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1 (In open court.)

2 THE COURT: You may be seated. Thank you.  
3 Do we have enough seats for everyone?

4 Now, I am hoping that everybody was on the  
5 same page. I know that the lawyers who were back with  
6 me were, that this was set at 10:00 today, not earlier.  
7 And after this, I think a relatively short status  
8 conference -- we'll soon see -- we'll probably without a  
9 break move right into the dispositive motions that are  
10 set to be heard today.

11 And I think that that is agreeable to every  
12 one on both Plaintiffs' side and Defendants' side?

13 MR. ARSENAULT: Yes, Your Honor.

14 THE COURT: Mr. Zimmerman, would you like to  
15 lead off?

16 MR. ZIMMERMAN: Sure. If it please the  
17 Court? Good morning, Your Honor. Charles Zimmerman for  
18 the Plaintiffs' Steering Committee.

19 We have just concluded a pre-hearing status  
20 conference with Your Honor, and we are going to go  
21 through now our formal agenda which was posted last  
22 night, the proposed joint agenda for the status  
23 conference of June 19, 2007.

24 The parties have been working very, very hard  
25 as the Court knows and everyone involved knows, in

1 preparing the representative trial, the first one, the  
2 Duron case for trial which will commence at the end of  
3 July. So, a lot of our efforts have been focused on  
4 that, of course.

5 But, we are here to provide a status report  
6 on all of the cases and report to you on the  
7 processes and the things that are both individual and  
8 generic to these cases.

9 The status of cases filed in Federal Court  
10 and transferred into the MDL, as well as the status of  
11 State Court matters, Tim Pratt will provide that to Your  
12 Honor in terms of the number of cases, the growth, or  
13 reduction of cases, and what is pending in State Courts  
14 around the country.

15 MR. PRATT: Good morning, Your Honor.

16 THE COURT: Good morning.

17 MR. PRATT: Tim Pratt. In terms of the case  
18 number, the total number of Federal Court cases that are  
19 pending against Guidant is 1,672. Of those 1,672 cases,  
20 all but 51 are pending here before you in the District  
21 of Minnesota. There are 51 cases pending in an MDL  
22 transfer by the Judicial Panel, so that brings us up to  
23 the total of 1,672.

24 As of the last information I had, which was  
25 just about four days ago, there were 100 State Court

1 cases pending against Guidant. As always, some of those  
2 are appropriate candidates for removal. We hope and  
3 expect that a percentage of them will end up in Federal  
4 Court, but that brings the total number of State and  
5 Federal cases pending against Guidant to 1,772.

6 Of the Plaintiffs -- of the cases in the MDL,  
7 it appears that the total number of plaintiffs captured  
8 by those -- as Your Honor knows, there are some cases in  
9 which multiple plaintiffs have been joined in one single  
10 case. If we do the math on the cases pending in the  
11 MDL, there are about 3,235 individual Plaintiffs. And  
12 by Plaintiffs, I mean device users represented by those  
13 MDL cases. So, that is the current status of cases,  
14 Your Honor.

15 MR. ZIMMERMAN: Unless there are any  
16 questions on that, Your Honor, we can go on to the next  
17 one.

18 THE COURT: Now, we discussed ever so briefly  
19 in chambers, I don't think it needs to be taken up here,  
20 that there might be a spike of sorts, because of some  
21 statute of limitations issues where people either have  
22 to -- may have to file other cases, but we discussed  
23 that briefly. I have no questions on that.

24 MR. ZIMMERMAN: Then the next item, Your  
25 Honor, is the report on the representative trial

1 process. I am going to leave for item five, the MDL  
2 process next steps, to the end of the calendar. I am  
3 just going to report on the representative trial  
4 process, which is really the focusing of the five  
5 representative trials, and especially the Duron case,  
6 which is the first, the first up.

7           We spent a lot of time discussing various  
8 matters of pretrial organization, how to manage these  
9 cases, this case, the Duron case, so that we can get if  
10 tried in the ten days provided, a deadline of July 10th  
11 as an absolute deadline for the filing, and the turnover  
12 of fact discovery and documents and consequences that  
13 might lie if all documents are not appropriately turned  
14 over. I don't think any of that we have to burden the  
15 Court with at this time, but I think we know the status  
16 of that.

17           The Court has a July 9th final pretrial  
18 conference set, and that we are going to meet and confer  
19 and try and come up with a manageable trial plan or  
20 management scheme for this trial by first meeting and  
21 conferring, and see how we can really narrow down the  
22 disclosed witnesses and the disclosed exhibits down to  
23 something that we can really do in the ten days and  
24 present a good case by both sides so we can get the  
25 issues in that case fairly resolved in the ten-day

1 period that the Court has allotted and the parties have  
2 agreed for this trial.

3           There is going to be a lot of work involved,  
4 there has been a lot of work involved, but it is going  
5 to be requiring both parties to sit down and really look  
6 at, what are we really going to present, what are the  
7 witnesses that are really going to be presented, what  
8 are the documents that are really going to be presented.  
9 A lot of that will then be also defined by the Court's  
10 ruling on the Daubert hearing, the Daubert motions which  
11 are fully briefed and before Your Honor, and the motions  
12 in limine, some of that documentation is still coming  
13 in, although I think most of it is in at this point.

14           I don't know how much more the Court wants on  
15 the representative trial process, other than from the  
16 Plaintiffs' side, it is a lot of work. We are doing it  
17 well. We are getting a vigorous defense. Many motions  
18 have been filed. The most recent Order of this Court, I  
19 think it was dated June 12th, gave -- the Court gave us  
20 all direction with regard to the nine summary judgment  
21 motions that had been filed. We now know the choice of  
22 law decisions that were filed by the Court, and we are  
23 proceeding to have that trial commenced as scheduled. I  
24 believe it is the --

25           THE COURT: 30th.

1 MR. ZIMMERMAN: The 29th?

2 THE COURT: 29th. 27th, three strikes and  
3 you are out. So, 27th of July.

4 MR. ZIMMERMAN: The 27th of July. And my  
5 understanding is, for the record, that is going to be in  
6 Minneapolis.

7 THE COURT: That is true.

8 MR. ZIMMERMAN: In a courtroom that I don't  
9 know has been designated yet, but will be designated --

10 THE COURT: All of the trials will be in  
11 Minneapolis. Well, it is obvious why. We are packed in  
12 here now. We have already agreed to that, so --

13 MR. ZIMMERMAN: Right. The other issues that  
14 have to do with the other trials and what is going to  
15 unfold next, as I indicated we will talk about a little  
16 bit later in the calendar because both parties have made  
17 submissions on that and we are continuing to have  
18 dialogue and discussion. And the Court has given us a  
19 lot of direction.

20 With regard to the management plan, the  
21 question is, how are we going to get this done in ten  
22 days, and the parties are going to put their heads  
23 together and come up with that. And I think Judge  
24 Boylan and Your Honor are going to help us to manage  
25 that trial plan so that we will get it done.

1           The Court was very clear to us that it will  
2 be 10 days. It won't be 11, it won't be 14, and that we  
3 will do everything we have to to get that case tried,  
4 the Duron case tried in the appropriate time allotted.

5           So, in summary, on the representative trial  
6 process, it is going very well. We are getting a lot of  
7 direction from the Court. We are working hard with the  
8 other side. We have a lot of issues, but we are going  
9 to get there. And this case is going to start on time  
10 and it will be tried to its conclusion, barring any  
11 resolution that might occur.

12           THE COURT: Mr. Pratt?

13           MR. PRATT: I'm not sure there is much more I  
14 can add. We are at the stage of the trial process where  
15 the Court is fully aware of all of the activity going  
16 on, because you are engaged in the process. We are  
17 filing motions, you're responding to motions. We have  
18 the Daubert briefs that have been submitted and fully  
19 briefed at this point. We just submitted to the Court  
20 the motions in limine. We will be providing responses  
21 to those by the deadline.

22           I agree with Mr. Zimmerman, there is a lot of  
23 work that is going on, but a lot of work that may need  
24 to be done in the next six weeks or so to streamline the  
25 cases, to get accommodation on both sides on which

1 witnesses are going to be called.

2 We have submitted per the Court's Scheduling  
3 Order our respective witness list, exhibit list and  
4 deposition designations. I think we all confessed to  
5 you this morning that we overreached on every one of  
6 those. And part of what we are trying to do in the next  
7 six weeks is to limit those by agreement. To the extent  
8 we cannot agree, they will be further limited by the  
9 Court orders on motions in limine and the Daubert  
10 motions.

11 It is a challenge, but a welcome one from our  
12 standpoint. So, we expect to pick a jury on July 27th  
13 give our opening statements on July 30, and pack a lot  
14 of activity in the two weeks of trial time. And to try  
15 to recover in two weeks and get ready, as they say, and  
16 roll it up again. So, that is the way it is standing.

17 There is an issue, not just about succeeding  
18 trials, and we talked about that today in terms of what  
19 happens after these five bellwether cases are tried.  
20 Again, I think that is the point on the agenda, five MDL  
21 proceedings, next steps.

22 We are also, in addition to getting the Duron  
23 case ready for trial, as you know, we are dealing with  
24 motion practice and discovery with respect to succeeding  
25 bellwether cases. The Clasby case is next, and we are

1 spending a lot of time getting that ready, and then from  
2 there on. So, even during the course of -- it is going  
3 to be interesting to see when we are on trial in Duron  
4 how we are going to be dealing with sort of the trial  
5 issues in bellwether case number five, because it is a  
6 time-consuming process. But, we are moving ahead,  
7 Judge, and we are ready to go. Thank you.

8 MR. ZIMMERMAN: I believe I stated this on  
9 the record, Your Honor, but if I didn't, I want to  
10 restate it again, that there is a firm July 10 deadline  
11 for production of documents that has been established by  
12 Order of the Court. And it was very clearly provided to  
13 us today in chambers, that documents that could be and  
14 should be relevant to that case must be produced by that  
15 time or appropriate sanctionable conduct and or  
16 exclusion and or continuance would be undertaken to be  
17 heard at that time if the documents are not produced by  
18 that time. And I am not going to go into anymore  
19 dialogue about it. I just wanted to make sure it is on  
20 the record.

21 THE COURT: What about the "S" word or the  
22 "C" word? Especially the "C" word, continuance, but  
23 it's anathema to me. If it is necessary, it is  
24 necessary. But, I think in fairness to both parties,  
25 there was some significant discussion on some discovery

1 issues. There is not, entirely, a meeting of the minds.  
2 But, I don't think that puts the case -- whether it is  
3 an MDL case or non-MDL, bellwether or non-bellwether, I  
4 think what we did is we put a July 10th -- I put a July  
5 10th date on. And then we will just see where the  
6 parties are at. I mean, that is the date. And the  
7 result of that, you don't agree on on both sides. So,  
8 Mr. Pratt wants to be heard in response to that, so --

9 MR. PRATT: One point of clarification, Your  
10 Honor. Are you going to submit a written order that  
11 contains your July 10th deadline of what the parties  
12 need to do? Or is your comment this morning going to be  
13 --

14 THE COURT: Well, I think to minimize the  
15 informality -- and well, frankly, I don't need to decide  
16 what I would do if it was a non-MDL, one stand-alone  
17 case, and we just didn't have a pretrial. But, we will  
18 just do a one or two-liner, just so -- because they are  
19 sitting out there somewhere by stipulation. It is a May  
20 date. On the other hand, I won't be saying a lot, other  
21 than what I said in chambers. I don't think there is  
22 much clarification needed, because there is a difference  
23 of opinion about the agreements on rolling discovery and  
24 what was contemplated.

25 I am just saying that July 10th is the date.

1 And whether the parties have a meeting of the minds or  
2 not, we will soon find out given some of the comments  
3 back there. But, yeah, there won't be any memorandum  
4 that comes with it, but July 10th is the discovery  
5 cutoff for these trials.

6 And there is a difference of opinion about,  
7 well, what does that mean on the PRIZM 2 discovery? And  
8 we had that discussion. Now, if one or all of you say,  
9 well, we would like you to address what, specifically,  
10 is meant, then I guess you should say so. And we will  
11 have it out before the next -- probably before the day  
12 is out.

13 MR. PRATT: No, Your Honor, that really isn't  
14 my point. We will come to some disagreements on that.

15 THE COURT: Well, I am quite certain we will.

16 MR. PRATT: I just wanted to be sure, we  
17 spent a lot of time talking about it before this formal  
18 conference. I didn't want Mr. Zimmerman's thirty-second  
19 summary of his sense of what he believed the obligations  
20 were imposed on Guidant to be sort of the final word on  
21 it. I think it is going to require some further  
22 discussion about the scope of this.

23 We said there is no way that at any point we  
24 are going to have produced every document in the company  
25 that has the PRIZM 2, 1861 referenced in it. So, I just

1 wanted to be sure that we were getting something and we  
2 would be able to deal with it, Your Honor, when it comes  
3 in.

4 THE COURT: Well, I will draw an order. It  
5 will either go on the web today or tomorrow. And it  
6 will encompass what I believe I intended to say back  
7 there. And then if one or both parties say, well, that  
8 is not what we think you said. Or, if it is, we don't  
9 agree with it, then I assume that I will hear from one  
10 or both of you. Because I am not asserting there was a  
11 stipulation reached back there. I don't think that  
12 would be fair to Plaintiffs or Defendants. I don't  
13 claim that the parties had a meeting of the minds on  
14 that particular issue, because there is not.

15 So, all right?

16 MR. ZIMMERMAN: Appreciate that, Your Honor.

17 THE COURT: I will file it in the normal way,  
18 but we will put it out on the web, too. But, I will do  
19 that. If it doesn't get done today, it will be done by  
20 tomorrow.

21 MR. ZIMMERMAN: Understood, Your Honor, thank  
22 you.

23 THE COURT: If I may say, just not on that  
24 issue, but I won't repeat what we -- because we talked  
25 at some significant length about the representative

1 trial process in chambers, because both parties have  
2 addressed it in writing in the last few days. And all I  
3 will say is that, one, as far as I am concerned, that we  
4 are on schedule. And whether there is an issue of  
5 compliance with all aspects of the Court's orders as  
6 contemplated by the parties, we will soon find out as we  
7 would in any trial as we move into the pretrial and  
8 begin to get ready for trial.

9           One thing we didn't discuss back there, to  
10 the extent there is some mechanics on the two ways to  
11 send out the jury questionnaire, we will be in touch  
12 with -- we will agree on that. Because there are two  
13 ways to submit it, and one takes more advance notice  
14 when it goes out with the summons, than the other,  
15 having the jurors come in, which is not my preference  
16 and fill it out on site. But, we can talk about that,  
17 we have talked about that not today, it has actually  
18 been a month or two. And I have sent out that proposed  
19 jury questionnaire. But, we will get back to you on  
20 that. I don't think there will be any significant  
21 disagreement.

22           I am more optimistic on the trials. Now, I  
23 will knock -- this isn't wood up here, but something.  
24 That is very heavy steel down there, but -- I, actually,  
25 in my 23 years plus as a judge never had a trial that

1 went more than one day over the scheduled time, so maybe  
2 this will be the first. I mean, July 27th -- which  
3 means that the lawyers get more credit than the Judge,  
4 because in most of those trials, there wasn't an  
5 arbitrary cutoff by the Judge saying day number 10 is  
6 over. What we planned for, we -- it was just good  
7 planning by the lawyers saying, here is the time frame.  
8 For another reason, you don't tell a jury panel ten days  
9 and then -- I mean, it has happened to a number of  
10 people, and that is where you get very angry,  
11 disillusioned jurors and then take 15 or 20 and probably  
12 lose a few along the way. Because the lawyers know that  
13 have talked to me, we will start with 12 jurors. I do  
14 in all civil cases. And hopefully end up with 12.

15 But, I am optimistic, actually, that we will  
16 get the issues by Court decision, or agreement, meet and  
17 confer, or a combination of all three. So it will be --  
18 and, of course, my job is to deliver a fair trial to  
19 both parties.

20 My larger concern is trying to set the trial  
21 up, as we talked at some length back there, we all used  
22 the words, and I am kind of disappointed nobody  
23 commented on our little footnote in the last Order on  
24 the history of bellwether in the order, because I  
25 believe there are some common issues in these

1 representative trials that should be of help to many  
2 Plaintiffs and to Guidant out there. And they will  
3 become, I think, more clear as we get ready for trial.  
4 I think they are probably relatively clear, so there are  
5 individual aspects to each of these cases.

6           There's also some issues where many other  
7 Plaintiffs out there are going to say, that looks like  
8 my case, at least on one or more issues. So, I think I  
9 am quite optimistic about that. But, we will soon find  
10 out.

11           But, other than that, we are on schedule  
12 as far as I am concerned. And yes, everybody is logging  
13 the time, but I guess that is what trial lawyers and  
14 lawyers do.

15           MR. ZIMMERMAN: We are very aware of bellling  
16 and weather to the male sheep who leads the flock, Your  
17 Honor.

18           THE COURT: All right.

19           MR. ZIMMERMAN: The next item on the  
20 calendar, or on the agenda, excuse me, is the motion  
21 practice for the Duron and the Clasby case, which I  
22 understand we are going to, by agreement have heard  
23 after we finish with the status --

24           THE COURT: Probably without any break, I  
25 will defer in part to how long we are in here, without

1 much if any break at all. We will move right into the  
2 dispositive motion practice. And I think there has  
3 been -- from our point of view, unless we will soon find  
4 out some good communication between the parties. So, I  
5 believe we understand on which motions oral argument has  
6 been requested -- much like the Duron case, where  
7 obviously all of the motions weren't argued, but we put  
8 them all in the same order, except for the learned  
9 intermediary.

10 MR. ZIMMERMAN: Which brings us then to the  
11 MDL process and the next steps. I think all I will say  
12 right now for the record is that the Plaintiffs made a  
13 submission in a document entitled, "Plaintiffs'  
14 submission concerning representative trials and further  
15 proceedings," and the Defendants made a submission on  
16 the same topic, which I believe we discussed briefly,  
17 actually not so briefly, with the Court this morning.  
18 Further discussion with regard to these issues will be  
19 required. And what we're really trying to do, Your  
20 Honor, from the Plaintiffs' side is make sure we  
21 understood what we've learned from the first bellwether  
22 proceeding, the preparation, the amount of effort, the  
23 amount of motions, the amount of work required to get  
24 this case tried, and then what we will learn from it as  
25 we try it to help us focus on issue resolution, on

1 streamlining, on efficiency, on appropriate protection  
2 of everyone's rights in the cases going forward.

3           What we really are asking the Court to do and  
4 asking, really, more the parties to do, is start  
5 focusing on the purpose of bellwethering, are we  
6 achieving the purpose, are we spending too much time,  
7 are we spending too little time, are we getting the  
8 issues and the lead cases, are we getting from them that  
9 information we need? And without answering that  
10 question, we are raising the question -- and I think  
11 more discussion on that is going to be regarded, because  
12 we are learning as we go.

13           I mean, these are -- we can't say we are  
14 painting on an empty slate, because we are not, we have  
15 been involved with bellwethers before. But, every case  
16 takes on new dimensions, and we are trying to learn as  
17 we go what we can take from these, how we can streamline  
18 them going forward, how we can make them more efficient  
19 for the 3,200 people that are waiting in the cue to have  
20 their cases resolved.

21           So, from the Plaintiffs' point of view, we  
22 are trying to find the best, most expedient, most  
23 cost-effective way to do it. From an MDL jurisprudence  
24 point of view, we are trying to make sure this MDL works  
25 well from the question of jurisprudence, so that people

1 look to it for guidance in their case, and know how hard  
2 we are working to help them, Plaintiffs and Plaintiffs'  
3 lawyers with cases, getting those cases resolved from  
4 the standpoint of pure efficiency that we do in a way  
5 that is effective, cost effective and time effective.

6           There is a lot more that can be said on that,  
7 Your Honor, Defendants can certainly be heard; but, from  
8 our point of view and from the submission that we  
9 provided, we just want to keep looking at that, asking  
10 those questions, to make sure we are focused.

11           We are committed to the trials, we are  
12 committed to the -- and the Court indicated we will have  
13 the trials, they will take place as part of the plan  
14 that we have all signed on to, and we are fully  
15 committed to that.

16           We just want to make sure that as we go  
17 forward, we learn from everything we do, as opposed to  
18 just repeat them and add more work to everybody, because  
19 that is not our intention. I don't know if the Court  
20 wants anything more from the Plaintiffs' side on this.  
21 I just wanted to let you know that the letters are out  
22 there, the submissions are out there, the discussion is  
23 occurring, the focus is there, and we will continue to  
24 do so.

25           THE COURT: Thank you. Mr. Pratt?

1           MR. PRATT: Like so much in litigation,  
2 between the two sides there are points of agreements and  
3 points of disagreements. I think in substantial part, I  
4 agree with many of the points Mr. Zimmerman just raised.  
5 We are all learning from the process.

6           We want things to be effective. We want  
7 things to be cost efficient. We want to keep things as  
8 reasonably short as we can to reach closure on the MDL  
9 process.

10           I think we also acknowledge that the first  
11 bellwether cases are 1861 cases. There are other  
12 product lines at issue, here. We had to work with Your  
13 Honor, and work with Plaintiffs' counsel to try to come  
14 up with reasonable ways to address the other product  
15 lines.

16           I think we do have a point of disagreement  
17 with respect to the discovery that has taken place, how  
18 much of it relates to all product lines, how much  
19 relates to just the PRIZM 2, 1861. We clearly have a  
20 disagreement on that. We discussed it with Your Honor  
21 this morning.

22           I think these are matters that as we are  
23 moving through the next few weeks of hectic bellwether  
24 trial preparation and trial, we probably don't need to  
25 move them to the front burner. But, I do think they are

1 sort of in the middle of the stove in terms of when we  
2 have to get these things addressed. I think it is a  
3 matter of talking to Plaintiffs' counsel, seeing what  
4 points of agreement we truly have and where we want to  
5 go, the path forward. And to the extent there are  
6 disagreements, we need to get Your Honor involved in a  
7 discussion of where you want it to go, obviously. I  
8 think that is where we stand in the discussion taking  
9 place and we will continue to do so.

10 MR. ZIMMERMAN: The next item on the  
11 agenda --

12 THE COURT: Before you roll in -- you can  
13 just stay there. I will be brief. But, I again remain  
14 optimistic. While I agree with what has been said, to  
15 the extent there have been those subject matters or  
16 issues where there is agreement, disagreement, there are  
17 none of those areas from where I see it, and I suspect  
18 from the most part the lawyers agree, that are going to  
19 cause a delay in anything.

20 I didn't say this in chambers, but I frankly  
21 would respectfully challenge the notion. Nobody has  
22 suggested that notion in this group, but to the extent  
23 there are onlookers saying, well, this is an MDL, and we  
24 are wondering how soon our case can get decided or some  
25 of these common issues, whether it is an evidentiary

1 issues, a liability issue, damage issue, or some other  
2 legal issue, fact issue, I would challenge the notion we  
3 are not going to make some headway and resolve some  
4 issues with or without settlement.

5 I mean, let's be candid, here, we are living  
6 in a country where a lot of reputable lawyers are  
7 disturbed about less than a 5 percent jury trial rate.  
8 Most of us older folks in the room grew up with trial  
9 rates of at least ten or more percent. But, we are down  
10 to around 3 nationwide in State or Federal Court.  
11 Whether that is a good thing or bad thing, we are 3 to 5  
12 percent.

13 I think, statistically apart from what  
14 happens in this case, again I am more optimistic that we  
15 will hopefully serve the interests of all clients. And  
16 so, to the extent -- and again, nobody raised the notion  
17 this morning that, well, how are these going to benefit?  
18 I guess to the extent they don't, I will accept my  
19 responsibility.

20 But, I think we are heading in the right  
21 direction. And I would agree we are probably going to  
22 have to refine some things so that it becomes more  
23 apparent, well, how can trying some of these bellwether  
24 cases serve the interests of the onlookers saying, well,  
25 how is this going to help my case, whether it is to try

1 it, settle it, or do something else, or dismiss it, or  
2 whatever the -- it could be any or none of those. I am  
3 mostly optimistic when I said -- perhaps I am naive. I  
4 will admit that many of you said, there is a very fine  
5 line here, Judge.

6 MR. PRATT: I apologize for that, Your Honor.

7 THE COURT: There is indeed a very fine line,  
8 here.

9 MR. ZIMMERMAN: Genius and insanity, they  
10 say --

11 THE COURT: We will see where that  
12 demarcation comes. We will move on.

13 MR. ZIMMERMAN: Thank you, Your Honor. The  
14 next item on the agenda is the IME scheduling of the  
15 Beranek matter. And I think we are still trying to work  
16 that out, and we are confident that we will. We trust  
17 we may not be in need of the Court's intervention, but  
18 we are having some difficulty with it because of  
19 particularized circumstances.

20 THE COURT: I am familiar with those. You  
21 brought those to my attention. I mean, the worst case  
22 scenario is that each term or condition of working out  
23 this IME isn't worked out and there is more than one way  
24 to resolve it. We will just -- I am a phone call away.  
25 We will figure it out.

1                   MR. ZIMMERMAN: We understand there is a van  
2 that might be available. We talked about that.

3                   THE COURT: Yeah, I had in my old days, with  
4 five kids under seven, I had a kid cab that was -- I  
5 won't even repeat the miles per gallon it got back in  
6 those days, it was nice over the road, but I no longer  
7 have it.

8                   MR. ZIMMERMAN: The next item on the agenda,  
9 Your Honor, is the next status conference which I think  
10 we are not going to set, it is my understanding.

11                  THE COURT: Right. With all of the dates we  
12 are going to be back together. If you go through the --  
13 for those that weren't in the conference this morning,  
14 if you look on the website, we have a lot of dates we  
15 are going to be together. And to the extent we need to  
16 add on agenda items, since most of you are going to be  
17 in town -- in part it might be something we can do by  
18 phone, that is fine, whether it is on or off the record.  
19 Because you're going to be making many trips between  
20 coming into the Twin Cities and trial prep.

21                  So, another status conference, just to say we  
22 had it, I think we agree we are going to be getting  
23 together frequently enough so we can cover any issues.

24                  MR. ZIMMERMAN: Right. And it is my  
25 understanding, Your Honor, on the Higgins motion we set

1 a date of response.

2 THE COURT: June 29th. And that wasn't  
3 arbitrarily selected. We have been having a select  
4 amount of time to make a response, and I am handling  
5 that the same way as other motions, which actually is  
6 how I handle non-MDL cases, which is whether I say yea  
7 or nay to oral arguments, you can read the briefs and  
8 you can have an immediate turnaround time, or say we  
9 would like to get you in for oral argument or on the  
10 phone on an issue, which is how we have handled the  
11 others.

12 MR. ZIMMERMAN: Right. And then on the other  
13 things that the Court provided to us about a motion, a  
14 stay of motions with regard to individual cases --

15 THE COURT: We will just have those -- I  
16 don't think there is any need to discuss that part of  
17 it.

18 MR. ZIMMERMAN: And then there is a motion to  
19 intervene that is tracking through -- nothing needs to  
20 be said about that, it's just that it is out there.

21 THE COURT: The intervention, the motion is  
22 probably -- it is on ECF, because the motion, itself, it  
23 is an intervention for public access by some media  
24 organizations.

25 MR. ZIMMERMAN: Right, and that is tracking

1 through -- the PSC will provide their position to the  
2 Court on that at the appropriate time. And I believe  
3 that concludes --

4 THE COURT: And I might add, the reason I  
5 singled out the -- and said what the moving party was,  
6 is the last motion to intervene on a case in this  
7 district was not by a -- not in this case, but in United  
8 Healthcare was not by an interest group, it was a  
9 Justice Department who came in, recently.

10 So, that is why I said, well, there are all  
11 sorts of people who could intervene. Well, this just  
12 happens to be Paul Hannah on behalf of the news  
13 organization.

14 MR. ZIMMERMAN: We have seen it in the  
15 Medtronic litigation and we have seen it in the Baycol  
16 litigation.

17 THE COURT: Same thing.

18 MR. ZIMMERMAN: So, we are familiar with it,  
19 and it will get teed up appropriately. Thank you, Your  
20 Honor, that concludes the status conference portion,  
21 unless the Court or counsel have any comment?

22 THE COURT: Mr. Pratt?

23 MR. PRATT: Nothing on the status conference,  
24 Your Honor.

25 THE COURT: The only thing I conclude on the

1 status conference is, actually, just a footnote to what  
2 I said earlier is, again, there was no naysayers in  
3 chambers, but when a judge takes an MDL case, at least  
4 this is my understanding, since it is not forced upon a  
5 judge, you agree to take it. And I think most of us  
6 find it interesting, important, worthwhile work for a  
7 lot of different reasons. Because, obviously, unlike  
8 the random assignment of a case, you can say no.

9 To the extent there is anyone out there --  
10 again, they probably wouldn't be in this courtroom, so I  
11 am talking to the choir. But, says, well, what happens  
12 on an MDL is the other judge's cases come first, and  
13 then the MDL. But, that is not the case. There is  
14 nothing -- my other caseload won't interfere with moving  
15 as quickly as we need to in these cases. And every  
16 judge, in my understanding, agrees when the MDL Panel  
17 contacts you to give priority to the case.

18 And if you wanted specifics, and you haven't  
19 asked for any, we could go right down here to these two  
20 fine lawyers. And I won't have Danielle or Amy tell you  
21 how much they have worked on this case, either, because  
22 that is what we are here to do.

23 It will get the attention it needs, so that  
24 is not an issue, either. Nobody has called or asked,  
25 but if they would call and say, well, is this getting

1 bumped because of some other work, here, or because  
2 there is all sorts of publicity?

3 I am not a bean counter, but some people are.  
4 There is publicity lately at all of the conferences in  
5 Minnesota, without the MDL's here, it is the second  
6 busiest district in the country. While that is true,  
7 because of the patent work, I don't know of any judges  
8 complaining. We have Senior Judges working full time,  
9 essentially.

10 We don't have any backlog, there is no court  
11 congestion that I know of, because that is sometimes a  
12 question on an MDL. Well, it is not a question in my  
13 case or the other judges who have them. And I will  
14 challenge that notion, as well. Enough said. We can  
15 move right in.

16 People are free to stay, they are free to go.  
17 We are going to move into the dispositive motion oral  
18 arguments at this time, unless one or more parties want  
19 to take a short break. I think we should move right in,  
20 at least move right into the -- then we will take a  
21 break sometime, but we will move right into the motions.

22 Do one of you, one party for each side, a  
23 representative from Plaintiffs and Defendants want to  
24 just kind of set the stage? I believe I know which  
25 motions are going to be argued, because we have been in

1 contact with one another the last -- but, for those of  
2 you who may be sitting in the courtroom who are  
3 wondering -- and maybe there is no one, maybe everybody  
4 knows exactly what is about to happen -- well, I wonder  
5 what motions the Judge is going to hear.

6 I will just ask one counsel for each party to  
7 indicate what you believe the course of events will be  
8 this morning, and then we will go from there. And  
9 everybody else who needs to take their leave for other  
10 commitments, I will leave that to them.

11 Mr. Carpenter?

12 MR. CARPENTER: Your Honor, I think today we  
13 are planning on arguing the Duron Learned Intermediary  
14 Motion, the Clasby Learned Intermediary Motion, some  
15 aspects of the Clasby Choice of Law Motion, and the  
16 Clasby No Injury Motion.

17 THE COURT: Does that meet with the  
18 Plaintiffs --

19 MR. LESSER: And there is also the Motion to  
20 Strike, for Mr. Armstrong.

21 THE COURT: And I think I indicated in  
22 chambers, it is likely because of time issues on the  
23 Motion to Strike on Mr. Armstrong, I'm prepared to,  
24 unless something unusual happens here, to rule off the  
25 Bench on that today.

1 MR. PRATT: Your Honor, with your permission  
2 we have another judge that wants to chat with us, may I  
3 be excused?

4 THE COURT: Certainly.

5 MS. HOLLOWAY: Your Honor, I need to catch a  
6 plane. I apologize for having to leave.

7 THE COURT: That is no problem.

8 We can proceed with whatever motion you would  
9 like to tee up first. I didn't have a preference. And  
10 I had them down, but I don't know if there is an order  
11 of presentation you've agreed to, so we can proceed in  
12 whatever order you would like to go.

13 MR. CARPENTER: Your Honor, we are pretty  
14 flexible on how we need to proceed. And since the Court  
15 has a tentative decision in the Armstrong Motion, why  
16 don't we hear that one? We think it probably obviates  
17 any need for oral argument on the issue, correct?

18 MS. STRIKIS: That is correct, Your Honor.  
19 Our arguments are summarized in the brief, unless you  
20 want to take some positions on the record.

21 THE COURT: I didn't mean to scare anybody  
22 off back there in chambers.

23 Well, the record before me is the Motion to  
24 Strike. I think it is a four-page supplemental report  
25 by Mr. Armstrong that was, I believe, submitted

1 recently. And my ruling is this, then I won't ask for  
2 re-argument; but, if there is a request for  
3 clarification, because I am also going to suggest that  
4 if there is a similar issue on a subsequent case, Clasby  
5 or others, and there may be, then I will probably give  
6 you at least an idea of what may happen.

7           Obviously, there are two ways, at least two  
8 ways to resolve it, and you have each suggested those in  
9 your briefing. The case law is not in flux. It is  
10 crystal clear what a judge's discretion is when a report  
11 comes in untimely behind a deadline. It is really the  
12 reasons for it, there is not much dispute about what day  
13 it came in. And for the record, I believe we are  
14 talking about the May 20th report with the May 1st  
15 deadline, if my notes serve me correct.

16           It is the history behind it that is in  
17 substantial dispute. The dates are not. The two common  
18 remedies -- and there is no ruling I am going to make  
19 today so it is clear. It is tied to the specific facts  
20 of the dispute between the parties, but you won't hear  
21 me say, well, because this is part of an MDL, this is my  
22 ruling if it wasn't an MDL, it would have been  
23 different. I don't believe -- I think the issues are  
24 the same, either way; but, there is an explanation to  
25 the history that does account for some of this.

1           We have had, not -- typically, not unseen in  
2 major single complex cases, apart from MDL, non-MDL,  
3 rolling discovery. Much of it has been by agreement of  
4 the parties, some has not, it has been by Court  
5 decision. And so some of these discovery deadlines have  
6 been worked out, and some have not. And there is  
7 ongoing -- there have been some ongoing agreements,  
8 ongoing disputes because of the global nature of the  
9 discovery on just not the so-called experts, but on the  
10 discovery.

11           In this case, we have got Guidant  
12 asserting -- and actually, the Plaintiffs, as well.  
13 Well, apart from the dates, Judge, look at how long they  
14 have had some of the information. And then, of course,  
15 the crucial issue for the Plaintiffs is, the report is  
16 case specific, the supplemental report. So, my ruling  
17 is the same, whether it is viewed as a new report, a  
18 supplemental report. So, the two primary options are  
19 these, as they are in most cases. One is to do what  
20 Guidant has asked me to do, and that is to shut off the  
21 report and exclude it.

22           The second, the Plaintiffs' view is that  
23 would be prejudicial in a substantial way from their  
24 point of view, because we admit that this report  
25 specifically addresses the individual case set to go.

1           My view is, there are valid points to what  
2 both parties have said.

3           MR. CARPENTER: And I think that anybody that  
4 looks at this, the discovery issues -- well, I am not  
5 asking the parties to look at it in any particular way.

6           I just think both parties have to own to some  
7 extent as we discussed in chambers, some of the  
8 complexities of the discovery, because I don't really  
9 believe, until it is shown to me otherwise, that anyone  
10 has proceeded in bad faith.

11           But, looking at how we got into this  
12 situation with rolling discovery and the nature of the  
13 report, that shouldn't come as a significant surprise in  
14 my judgment to Guidant. Noting Guidant's objection, the  
15 Motion to Strike is denied. I think the prejudice is --  
16 I can minimize -- I can't outweigh it to the Plaintiff.  
17 I can for the Defendant. That does not mean I will  
18 grant a continuance of the trial.

19           I will direct that Mr. Armstrong is made  
20 available on for deposition on a schedule acceptable to  
21 both parties, especially Guidant, and that the  
22 Plaintiffs will be responsible for the costs of that  
23 deposition of Mr. Armstrong in response to the  
24 supplemental report. Noting the objection to the  
25 Plaintiff to that piece of it, noting the objection of

1 the Defendant to deny their motion to strike, I would  
2 suggest that if we have similar issues in the next case  
3 or two coming down the line, unless there is a factual  
4 history to the discovery and a substantially different  
5 issue that would set the history of the case apart from  
6 this particular one in front of me, that you can expect  
7 exactly the same ruling and should proceed accordingly.

8           The reason not to do this is, of course,  
9 someone could make the argument that, well, then really  
10 deadlines don't mean anything. But, I really think that  
11 that is not what this decision means, whatsoever, if one  
12 looks at the situation. And nobody really engineered it  
13 this way. I reject that notion. I am not so sure that  
14 either party is saying that. But, given the nature of  
15 the report and the remedy I have available, I believe it  
16 is the proper exercise of my discretion to handle it in  
17 this way.

18           Have I excluded reports in the past?  
19 Certainly. May I in the future? Certainly. This is  
20 the remedy I choose today. A request for clarification  
21 from the Plaintiff?

22           MS. STRIKIS: No, Your Honor, thank you.

23           THE COURT: Defendant?

24           MS. MOELLER: No, Judge, thank you.

25           THE COURT: We can go on, then, with the

1 dispositive motions.

2 MR. CARPENTER: Your Honor, why don't we  
3 start with the Duron Learned Intermediary Motion?

4 THE COURT: That's perfectly fine.

5 MR. CARPENTER: I hear no objections from Mr.  
6 Lesser.

7 THE COURT: Excuse me.

8 MR. CARPENTER: May it please the Court, Your  
9 Honor, Andy Carpenter for Guidant. We are here today on  
10 several motions. This one is the Motion to Dismiss  
11 Leopoldo Duron's failure to warn claims. No matter what  
12 theory they are brought under under Guidant's motion,  
13 based primarily on the Learned Intermediary Doctrine.

14 At the outset of this motion, I think it is  
15 important to note that Guidant is constantly in  
16 communication with EP's who prescribe and implant these  
17 devices. Guidant does provide explicit warnings to  
18 these learned intermediaries who implant these devices.  
19 Guidant warrants the physicians explicitly, particularly  
20 through the Physicians' Manual.

21 One particular warning is, quote, "The ICD  
22 pulse generator is subject to random component failures.  
23 Such failure could cause inappropriate shocks, induction  
24 of arrhythmias, and could lead to the patient's death."

25 Another warning in that Physicians' Manual

1 also points out the danger of, quote, "Potential  
2 mortality due to inability the defibrillate or pace."

3 I think the analysis has to start out with  
4 what the duty to warn is under California law. And I  
5 think we all agree that California law applies to these  
6 claims.

7 THE COURT: At least we do now.

8 MR. CARPENTER: We do now, thanks for the  
9 Court's Orders. Thank you.

10 California law does not impose absolute  
11 liability on manufacturers, particularly manufacturers  
12 of life-saving medical devices. California follows the  
13 Restatement Second Torts 402A, Comment K. It is not  
14 absolute liability. It is not guarantor liability, it  
15 is not an insurance liability. It is a reasonable  
16 standard.

17 Under California law, the manufacturer of a  
18 medical device is not strictly liable for injuries  
19 caused by a prescription device, so long as the device  
20 was properly prepared and accompanied by warnings of its  
21 dangerous propensities that were either known, or  
22 reasonably scientifically known at the time of  
23 distribution.

24 In other words the standard is known or  
25 reasonably knowable at the time of distribution and

1 implant. It is also important to note that California  
2 imposes no duty whatsoever to warn physicians of dangers  
3 and issues of which they are already aware. Those  
4 standards are set forth in the Brown case and in the  
5 Plenger -v- Alza case.

6           What this means is that I think the Court's  
7 analysis has got to focus on what Guidant knew March  
8 9th, 2002, when the Leopoldo Duron was implanted with  
9 the PRIZM 2 device. It has got to focus on what Guidant  
10 knew, what it reasonably could have known, under the  
11 information available to Guidant at that particular  
12 time.

13           Now, Plaintiffs bring up later in their  
14 opposition papers the issue of continuing duty to warn.  
15 And I'm not going to get into under what circumstances a  
16 continuing duty to warn arises, or doesn't arise, under  
17 California law because it is a largely a red herring,  
18 Your Honor.

19           In this case, this Court has basically  
20 already ruled that to the extent Mr. Duron can state an  
21 injury, it is based on having to have his device  
22 explanted because of a recall. Nothing Guidant did or  
23 didn't do, in terms of the continuing duty to warn  
24 affected that injury or could have avoided it after  
25 March 9th, 2002.

1           Once he was implanted with that device, the  
2 die was fairly cast in terms of that particular theory  
3 of injury. In other words, there is no relation between  
4 any particular breach of a continuing duty to warn after  
5 implant and any damages caused to Leopoldo Duron.

6           So again, I focus the analysis on March 9th,  
7 2002, which brings us to the question, what did Guidant  
8 know, or reasonably could have known on March 9th, 2002?  
9 Well, it knew there was one arcing incident, one, a  
10 single arcing incident. February 1st it occurred.  
11 Guidant got the information February 2nd and was looking  
12 into it. Once incident out of approximately 17,000  
13 PRIZM 2 devices implanted nationally in U.S. citizens as  
14 of March 9th, 2002.

15           And the evidence is unequivocal. Guidant  
16 hadn't even opened a trend, hadn't figured out what the  
17 root cause. The MedWatch report, Exhibit 15, that has  
18 been submitted unequivocally demonstrates that there was  
19 only a suspected cause, and that the failure was  
20 consistent at that time, viewed as consistent with a  
21 random component failure. There is no evidence that  
22 Guidant knew what the root cause of that was.

23           I think it is important to emphasize, again,  
24 these devices had an extremely reliable track record.  
25 They were working in numbers that well exceeded

1 projections to the FDA, competitor's devices, other  
2 devices.

3 At the time Mr. Duron's device was prescribed  
4 and implanted, Guidant knew of a single arcing failure  
5 out of a body of 17,000 devices. Guidant promptly  
6 reported that to the FDA as per regulations. The FDA  
7 saw no reason to issue warnings based on that once  
8 incident.

9 Under California law, regulatory action or  
10 inaction is powerful evidence of whether a legal duty to  
11 warn exists. The FDA didn't think so at that point in  
12 time. In hindsight later on, it made a different  
13 decision years down the road, but on March 9th, 2002,  
14 the FDA decided to take no action. And that is an  
15 important fact.

16 Plaintiffs' position is that Guidant had an  
17 obligation to provide warnings to physicians, to  
18 patients -- I am not precisely sure to whom -- based on  
19 that single failure. They say that in their opposition  
20 briefs. I submit, Your Honor, that is a preposterous  
21 standard. I have never seen any case anywhere that  
22 proposes such a Draconian, and pointless, may I add,  
23 warning standard.

24 These are complex devices. Field failure  
25 reports and incidents are not uncommon. That doesn't

1 apply just to Guidant's devices, but Medtronic's, St.  
2 Jude's, any manufacturer's devices. Were Guidant  
3 required to warn EP's or the public or anyone beyond the  
4 FDA, which it does and it did as soon as it receives  
5 field reports of device failures, physicians would be  
6 inundated. They would be getting them constantly. They  
7 would mean nothing, especially without the root cause  
8 identified yet.

9           What they would basically be receiving is a  
10 report, you know, every few days. We've seen another  
11 random component failure, don't know what it is yet,  
12 just thought you would like to know. It would mean  
13 absolutely nothing in terms of a physician's ability to  
14 gauge the risk, make an intelligent learned decision.

15           I submit, Your Honor, there is no authority  
16 anywhere mandating such a duty to warning.

17           THE COURT: So, how -- they make much of the  
18 fact that your Independent Panel, or maybe not so  
19 independent panel would -- one instance alone, but your  
20 response is: Well, this wasn't systemic, or the phrase  
21 is define basis for malfunction, or I think we agree  
22 another phrase that has been used to characterize both  
23 is root cause. Who makes that decision, whether it is a  
24 root cause?

25           I mean, in other words, the Panel says --

1 whether the Panel or someone else said it, well, one may  
2 be enough if it is systemic or it is a defined -- who  
3 makes that decision, and when it is made? Is it what  
4 you just said, down the road a piece when the cause is  
5 identified?

6 MR. CARPENTER: I think ultimately the  
7 company, itself, has to make the decision, it has to  
8 figure out what the root cause is. And Guidant tries to  
9 do that. It is constantly working to improve the  
10 reliability and the quality of its products. Because  
11 the duty to warn lies with the company. And the  
12 question is, what are you warning of? Until you know  
13 what the root cause is, there is nothing to warn of that  
14 is effective. All you could do is tell EP's, or the  
15 public, there may be a problem in this one device out of  
16 17,000. That means nothing.

17 Now, after the company has affirmatively  
18 figured out exactly what happened, then perhaps it is in  
19 a position to provide more reliable information. And I  
20 do think Your Honor picked up on a correct distinction  
21 that the Independent Panel talks about the duty to warn  
22 really occurs in the context where you know it is a  
23 systemic failure, or you can identify the root cause.

24 There is really no upside, no policy  
25 advantage and no practicality to warning that there may

1 be some problem in this one device out of 17,000. We  
2 don't know what it is, but FYI. It doesn't really help  
3 anybody. Physicians would be inundated with meaningless  
4 shotgun warnings constantly. Because, frankly, device  
5 failures for all devices, for all manufacturers, are  
6 reported fairly constantly. These things happen. They  
7 have got a known failure rate for all devices. So,  
8 pretty much every day in a company you are going to be  
9 getting them coming in. That is just the way the  
10 businesses work.

11           Plaintiff alternatively argues that Guidant  
12 had a duty to warn of the generalized use of polyimide  
13 in its products. There is absolutely no evidence in the  
14 record demonstrating that Guidant had any reason to  
15 believe that polyimide, as used in the context of these  
16 PRIZM 2 devices was a problem.

17           If you really look at what Plaintiffs are  
18 talking about, Your Honor, it is not even a warning  
19 claim. What that is is a back door design defect claim.  
20 Think about what the warning would be. Warning, this  
21 product contains polyimide. That means nothing.

22           Warning, the United States Navy has  
23 determined that polyimide is inappropriate for use in  
24 Navy fighter jets. That means absolutely nothing.  
25 Guidant had used polyimide for a decade or more in a

1 variety of ICD's completely successfully. Guidant had  
2 used polyimide in 17,000 different PRIZM 2's, implanted  
3 in the population up to that point with no empirical  
4 evidence of failure.

5           Guidant used five times the amount of  
6 polyimide necessary to stand the charge given in the  
7 PRIZM 2 as a redundancy feature, plus it used a triple  
8 redundancy feature relying not just on polyimide, but on  
9 spacing, medical adhesive. So, the point is, until  
10 Guidant has specific evidence, knowledge, that polyimide  
11 is inappropriate for this particular use, it means  
12 nothing whatsoever to point to a vague study that says  
13 under certain chemical positions, situations in the  
14 abstract, Guidant may under a certain point degrade when  
15 exposed to a certain amount of water in these particular  
16 test conditions. That would impose ridiculous  
17 obligations on manufacturers.

18           If you take a step back and look at it, all  
19 component parts have their pros and cons, it is a design  
20 trade-off issue. Every component part will eventually  
21 degrade. Every component part could have a problem,  
22 depending on what happens. Plaintiffs' argument taken  
23 to its logical conclusion would require a blast warning  
24 of all component parts, their theoretical possible pros  
25 and cons on the side of every package or every

1 Physicians' Manual given to EP's. And that is useless  
2 information. No EP wants that. It doesn't help anyone.  
3 It doesn't help patients. The FDA doesn't want that.  
4 The EP's don't want that. Patients don't want that.

5           So, I would submit that there is absolutely  
6 no evidence that in March of 2002, Guidant was in  
7 possession or should have been in possession of any  
8 specific knowledge that PRIZM 2 was inappropriate for  
9 the uses in the header that would require an additional  
10 warning. And even if it did, that is not really a  
11 warning claim, Your Honor. That is a back door design  
12 defect claim which California does not recognize under  
13 Comment K and that Plaintiffs have already voluntarily  
14 dismissed, because they know that they can't assert that  
15 claim under California law.

16           Plaintiffs have also made the argument, more  
17 so in the Clasby case, but also somewhat in the Duron  
18 case that Guidant should have warned of engineering  
19 change orders. Well, again, engineering change orders  
20 are constant in this industry. The product is  
21 constantly being improved to a certain extent.

22           Guidant deals with about 1,500 ECO's per  
23 quarter. That would mean the EP's, physicians, or the  
24 public, whoever this warning is supposed to get to would  
25 get multiple ECO warnings every week. They would mean

1 nothing. They don't tell you anything. I don't think  
2 there is any duty, whatsoever, to warn of ECO's in the  
3 abstract.

4 I think it is important to note, Your Honor,  
5 that three people who agree with this motion that it  
6 should be granted are Plaintiffs' expert witnesses Dr.  
7 Swerdlow, Mr. Armstrong, and Dr. Parisian.

8 If you look at their testimony, these three  
9 Plaintiffs' expert witnesses all agree that Guidant had  
10 no duty to warn about these dangers until well after Mr.  
11 Duron's device was implanted.

12 Dr. Swerdlow has stated that Guidant's first  
13 duty to communicate the arcing problem arose in April of  
14 2002 when the ECO change was made. Mr. Armstrong agrees  
15 that April of 2002 was the first time he had seen  
16 documentation of any recognition by Guidant of an arcing  
17 problem.

18 And Dr. Parisian who -- frankly, whose  
19 testimony should be struck for other reasons we won't  
20 get into here. But, even she recognizes and has  
21 testified that Guidant was not aware of the root problem  
22 in these devices until June of 2002. That is all  
23 decided in our brief, Your Honor. I think that is  
24 incredibly dispositive.

25 I think at the end of the day, there is no

1 evidence that Guidant was in possession or should have  
2 been in possession of facts putting on a duty to provide  
3 additional warnings, other than the ones it did.  
4 Possibility of random component failure, or possible  
5 inability to pace. At that point, based on what Guidant  
6 knew, that was a random component failure, one incident  
7 out of 17,000.

8 Let's talk about causation. Even assuming  
9 Guidant had the duty to provide additional warnings,  
10 which it did not, the question is: Did the failure to  
11 give these additional or different warnings cause Mr.  
12 Duron's injuries? I.e., if he had been given different  
13 warnings, could he have avoided his explant injuries?

14 There is no evidence to indicate that  
15 Guidant's failure to provide additional warnings,  
16 whatever they may be, Plaintiffs are still not clear on  
17 this, injured Mr. Duron.

18 The legal standard is that California does  
19 not recognize and has explicitly rejected a heating  
20 presumption. California law requires plaintiff to prove  
21 "not only that no warning was provided or that warning  
22 was inadequate, but the inadequacy of the warning caused  
23 the plaintiff's injury."

24 Several cases, including the Motus -v- Pfizer  
25 case cite that. There is no presumption that had a

1 different or better or alternative warning been given  
2 that the prescribing physician would have listened to it  
3 or that it would have made a difference to them.

4           These cases are unanimous that a product  
5 warning defect, quote, "cannot survive summary judgment  
6 if stronger warnings would not have altered the conduct  
7 of the prescribing physician." That is from the Motus  
8 -v- Pfizer case. That applies to the vengeance in this  
9 case, Your Honor. There is not only no evidence that  
10 different warnings would have made a difference, but  
11 there is affirmative evidence disproving that whatever  
12 warnings Plaintiffs want or claims that should have been  
13 given would have changed Dr. Higgins' prescription.

14           Dr. Higgins unequivocally testified that he  
15 knew, and this is important. Not only does he testify  
16 that had I been given this information, it wouldn't have  
17 changed my diagnosis at all; but, he testifies that he  
18 basically knew already the facts that Plaintiffs say  
19 really should have been disclosed to him, because he is  
20 an educated EP. He relies on a broad variety of sources  
21 for his information.

22           He knew that ICD's can sometimes fail to pace  
23 and may cause death. All EP's know that. That is in  
24 paragraph 5 of his declaration.

25           Also, he testified that news of some isolated

1 short-circuitings would not have affected his decision  
2 to implant Mr. Duron with the PRIZM 2 device. It would  
3 have made no difference to him.

4 THE COURT: Now, of course, on this causation  
5 issue, unlike the others, although I am certain I am  
6 going to hear something about the statistics and what  
7 was measured in terms of this 1 out of 24,000 or 1 out  
8 of 17,000, I'm certain Plaintiff is going to get up here  
9 in a moment and say, I have to accept or assess the  
10 credibility of Dr. Higgins and ignore his relationship  
11 with Guidant in order to say, you must take Dr. Higgins  
12 at his word. That is right where that piece of it, not  
13 the prior, is going to go.

14 MR. CARPENTER: Yeah. Two responses to that,  
15 Your Honor. First of all, no, you don't have to listen  
16 to what Plaintiffs do. Their attempts to undermine Dr.  
17 Higgins are not evidence at all and they don't really  
18 create any kind of a jury issue. He was reasonably  
19 compensated for his time as an EP and he thinks Guidant  
20 is a great company because Guidant makes great devices  
21 that saves people's lives. The record shows that. I  
22 don't think that creates any kind of a credibility  
23 issue.

24 If that creates a credibility issue, any EP  
25 is going to be subject to that and there is never going

1 to be any summary judgement on issues of warning  
2 causation. Because all EP's who work with companies,  
3 and many, many, many of them do, have to get compensated  
4 for their time. There is nothing untoward about that.

5 But, for sake of argument, assume that  
6 Plaintiffs' attacks on Dr. Higgins, which are meritless,  
7 absolutely succeed? Take his affidavit out of the mix,  
8 entirely. Assume they entirely negate what he is  
9 talking about, Plaintiffs still lose. At most,  
10 Plaintiffs have eliminated our affirmative evidence  
11 disproving the causation element that is theirs to prove  
12 of their case. This Court is left with no evidence,  
13 either way, that different warnings would have changed  
14 the conduct. And that is in the Motus -v- Pfizer case.  
15 It is very important. The Court notes, after rejecting  
16 plaintiffs' credibility challenge as not being based on  
17 any substantial evidence, that plaintiffs would still  
18 lose, even if they won the credibility issue. I'm  
19 looking at page 998.

20 Furthermore, there is precedent for the  
21 proposition that even if Dr. Trostler, the prescribing  
22 physician in that case, were discredited at trial,  
23 plaintiffs still might not be able to prove causation  
24 and it cites the Plummer case, noting, quote, "It may be  
25 true that the prescribing doctor was an interested

1 witness, but his was the only testimony on the issue of  
2 proximate cause. Even if the jury failed to credit him,  
3 the Plaintiff still has not proven an essential element  
4 of his case.

5           It cites the Strumph case which quotes,  
6 quote, "Even if there were a basis for doubting the  
7 credibility of the doctor's deposition testimony, such  
8 doubts would not provide a sufficient foundation for an  
9 affirmative jury finding that plaintiff established by a  
10 preponderance of the evidence that more prominent  
11 warnings of the risks in the PDR would have altered the  
12 doctor's decision to prescribe Trilafon, the drug at  
13 issue in that case.

14           So, the point is, there is really no  
15 credibility issue as to Dr. Higgins. He has done  
16 absolutely nothing untoward and his admiration for  
17 Guidant is entirely understandable and pretty typical of  
18 the vast majority of EP's as we are going to see later  
19 on in this litigation.

20           Number two, even if Plaintiffs' attacks on  
21 him were somehow sufficient to completely negate his  
22 credibility, they still lose. There is no evidence,  
23 even if you take his affidavit out of the mix that any  
24 different warnings would have changed the prescribing  
25 doctor's opinion.

1           Plaintiffs cite a couple of things that are  
2 absolutely zero evidence. They cite Hauser's opinion,  
3 they cite Dr. Tyres and they cite Dr. Sardul Singh's  
4 opinion. None of them were his prescribing physician.  
5 None of them opine on what a prescribing physician would  
6 have done on March 9th, 2002, if they had had the  
7 particular warnings -- whatever they are, Plaintiffs  
8 never identified them that Plaintiffs say should have  
9 been given.

10           Dr. Hauser merely in an out-of-court e-mail  
11 hearsay declaration complains to the FDA about the  
12 marketing of post-April ECO mitigation devices. He's  
13 not even talking about the same subject matter. And I  
14 don't even think Dr. Hauser, and the Plaintiffs can  
15 correct me, I don't think he is even an EP. I don't  
16 think he is even qualified to talk about that issue,  
17 despite the fact that it is hearsay and he is not the  
18 prescribing physician.

19           Dr. Sardul Singh didn't testify about that,  
20 either. He just states that he explanted several of  
21 these devices in retrospect after the recall came out.  
22 He offers no opinions on what he or a prescribing  
23 physician would have done, or particularly Mr. Duron's  
24 prescribing physician would have done had he been given  
25 the warnings Plaintiffs claim they should have been.

1           Dr. Tyres tells you absolutely nothing.  
2    Again, not even an EP, not qualified to opine on it, but  
3    states basically that he is in favor of full disclosure  
4    in retrospect. Well, sure, probably everybody is; but,  
5    that has nothing to do whatsoever with the issues in  
6    this case.

7           So, I submit to Your Honor that Plaintiffs'  
8    evidence that the different warnings would have resulted  
9    in a different result is nonexistent. Defendants'  
10   evidence disproving this element is absolutely powerful.

11          Now, I want to point out one thing about  
12   credibility. The cases Plaintiffs cite on the  
13   credibility issue are very different than what they are  
14   arguing. They cite some California cases that  
15   credibility can create maybe an issue as to the  
16   reliability of the prescriber's opinion.

17          Those cases deal with the equivocal or  
18   unequivocal nature of the statements. And those cases  
19   Plaintiffs point out, cite to, the courts only find  
20   statements have credibility issues if they are  
21   wishy-washy, or if the physician is using hindsight and  
22   says he didn't know that information already.

23          They don't talk about getting paid reasonable  
24   dollars, they don't talk about admiration for the  
25   company, that is not the kind of credibility issue those

1 cases talked about. Those cases are talking about weak,  
2 flimsy opinions.

3 In this case, Dr. Higgins opinion was rock  
4 solid, unequivocal, and absolutely fatal to the  
5 Plaintiffs' case. Attacking Dr. Higgins, in other  
6 words, just doesn't substitute for Plaintiffs' utter  
7 lack of evidence on the causation issue.

8 THE COURT: You are suggesting that I don't  
9 have to go there, anyway, because I shouldn't get to  
10 causation.

11 MR. CARPENTER: No, duty -- you don't have to  
12 worry about causation, Your Honor, absolutely right. I  
13 think it fails on two accounts for that.

14 So, in conclusion, Your Honor, I will wrap  
15 this up. I think it is clear that the evidence in the  
16 record shows that based on what Guidant knew on March  
17 9th of 2002, there was no information known or  
18 reasonably known that would impose on it a duty to  
19 provide additional or different warnings. Plaintiffs  
20 have never even really identified what those warnings  
21 should be.

22 And number two, even if there were, which  
23 there is not, there is no indication, no evidence that  
24 different or alternative warnings would have changed the  
25 prescription and avoided Mr. Duron's alleged injury.

1 THE COURT: Thank you.

2 Whenever you are ready, Mr. Lesser?

3 MR. LESSER: Yes, thank you. Seth Lesser on  
4 behalf of Plaintiff Leopoldo Duron. We just covered a  
5 lot of ground. And I am trying to figure out where is  
6 the best place to start.

7 THE COURT: One place we could start --

8 MR. LESSER: Okay.

9 THE COURT: Maybe not just with you, but I  
10 could ask you jointly with Mr. Carpenter, is we are  
11 trying to figure out the exact counts that are failure  
12 to warn. In other words -- and maybe Guidant should be  
13 the first one to ask. They are relying on Duron's  
14 Original Complaint, and we want to just make sure which  
15 counts we are addressing. That probably isn't where you  
16 intended to start, Mr. Lesser.

17 MR. CARPENTER: Yeah, I believe they  
18 encompass all of the claims that sound in warning  
19 theory, regardless, and I believe the Amended Complaint  
20 includes a, was it strict liability warning and  
21 negligent failure to warn, it would include the consumer  
22 protection claims to the extent they are based on a  
23 failure to warn theory -- Scott, am I missing anything?

24 MR. KAISER: Yeah, I think that is about  
25 right.

1 THE COURT: All right.

2 MR. LESSER: Okay. Let me begin at the end,  
3 as it were, which is -- well, there are two pieces,  
4 here. Strictly speaking, the motion was, and I  
5 understood it directed at learned intermediary. Learned  
6 has two pieces. Learned intermediary has two pieces, it  
7 is two words, learned and intermediary. And both have  
8 to be met. And I can go from either direction to show  
9 that they both are not met, here.

10 But, I, unfortunately, do not have copies of  
11 this, so I am going to have to read it and hand it up,  
12 one of the recently produced documents. And it goes  
13 directly to the argument that Guidant -- that apparently  
14 Plaintiffs now have the burden of showing -- disproving  
15 something here today. And the question, of course, is  
16 and without repeating everything we heard only a few  
17 weeks ago, that Plaintiffs have made more than a slight  
18 case that Guidant as of anytime in the history of this  
19 particular device should have warned and should have  
20 known as to the propensities of polyimide to degrade,  
21 and the like.

22 We put on several weeks ago the evidence  
23 about it is an acquisition accelerant company, as well,  
24 and there was not knowledge known of the accelerant  
25 about this. And that was not disclosed. But, let me

1 just read from a, as I said, a document that at least  
2 Plaintiffs believe they should have seen a long time  
3 ago, and at least as far as we can tell, we did have it  
4 just disclosed to us.

5 And this goes directly to the point about  
6 whether or not Guidant knew or should have known. And  
7 the reason it is knew or should have known is because  
8 Mr. Carpenter keeps returning to the point that Guidant,  
9 itself, didn't know.

10 Well, the critical point is under California  
11 law, not slightly, but clearly, the issue is not known,  
12 neither known nor knowable, because that -- in the  
13 Carlin case, California Supreme Court, the cite cites  
14 two cases. And let me just explain this before I get to  
15 the document. In California in the Carlin case, the  
16 defendant argued the standard as to when a duty to  
17 disclose arises should be known or knowable, which is  
18 essentially everything we just heard.

19 In actuality, the California Supreme Court  
20 took it to a higher level, or at least a more rigorous  
21 level. And the claim, failure to warn of a known or  
22 reasonably scientifically knowable defect. That is  
23 Carlin, 13 Cal.4th at 1118. So, the focus is the  
24 objective one, not necessarily what Guidant knew or was  
25 knowable to Guidant, even though we submit, based upon,

1 and I won't repeat it but if Your Honor wishes to I  
2 could pull out our papers from the last hearing, that  
3 Guidant, itself, had knowledge. But Guidant knew or  
4 should have known -- and indeed, what I have in my hand,  
5 which I will read now, is really an extraordinary  
6 mission, because this document is in 2004, September  
7 15th, 2004.

8           It arises in not the PRIZM context, but the  
9 RENEWAL 1 and 2 context. But, the RENEWAL 1 and 2 issue  
10 also relates to polyimide. And it is an e-mail from the  
11 Quality and Reliability Assurance Manager of Guidant  
12 Corporation to two individuals.

13           And basically, he says, I want to take a  
14 moment to talk about a couple of items. It seems the  
15 RENEWAL 1 and 2 investigation is finding that polyimide,  
16 tubing is breaking down when coming in contact with the  
17 body fluid. Further redundant insulation that may have  
18 been pressed away from the wire through the  
19 manufacturing process. Sounds pretty close because the  
20 CONTAK story is the next device, same story, once again,  
21 same problem.

22           Here is the critical point. I believe there  
23 are several learning points that we need -- I believe  
24 there are several learning points that we need to  
25 integrate and watch for in future designs. One,

1 material interaction with bodily fluids, a simple  
2 material search for polyimide tubing would have  
3 identified that it would break down in the presence of  
4 moisture. That is our point, a simple search by Guidant  
5 at anytime prior to Mr. Duron's implantation would have  
6 shown that it breaks down in the presence of bodily  
7 fluids. It isn't merely the Navy study, it isn't merely  
8 that as we have heard before because we heard it last  
9 time that salt water is different in the Navy study from  
10 what the human body is. This one document alone and all  
11 of the others we put in previously last month, shows  
12 that Guidant -- this is an admission that says Guidant  
13 -- a simple search would have discovered polyimide is a  
14 problem, it breaks down. The document -- I guess I  
15 should perhaps mark, at least hand up, and I  
16 unfortunately don't have copies, but it was attached to  
17 our submission. It is the very first document in the  
18 submission that was filed on the representative trial  
19 process. It is CPI 185-00-14215A. I will hand it up,  
20 but the Court does have it?

21 THE COURT: We have it.

22 MR. LESSER: Very good.

23 THE COURT: And by representative submission,  
24 that was on the letter that came with the attachments  
25 that I got from each of you this past week.

1 MR. LESSER: Yeah, it wasn't in a letter, per  
2 se --

3 THE COURT: No.

4 MR. LESSER: It was actually a filing which I  
5 think we labeled it submission, filed as a report, I  
6 believe.

7 THE COURT: Right.

8 MR. LESSER: On ECF. So, on the learned  
9 side, it is not merely a question of what Guidant knew  
10 as of that particular date. It is what Guidant should  
11 have known throughout and should have known continually.

12 This is not a back door of creating a  
13 separate claim. It is an independent claim. It is a  
14 claim, in essence of fraud and failure to warn. What we  
15 don't get, under the Court's ruling a few weeks ago is  
16 all of the advantages of those strict products liability  
17 design claim, that is, certain other things that you  
18 have to show or not show. But, it is a separate  
19 independent claim, so it can certainly be asserted under  
20 all of the causes of action that we just heard.

21 THE COURT: Is it a back door design defect  
22 claim as Mr. Carpenter has suggested?

23 MR. LESSER: We no longer have the right to  
24 bring a design defect claim. It is a strict liability  
25 claim under California law. But, we certainly have the

1 right, of course, to bring a claim that would sound in  
2 fraud or something akin to fraud or negligence. We then  
3 have to prove other aspects of the claim.

4           So, is it, in essence, that the company  
5 should have designed this differently and warned  
6 differently? Of course it is; but, it is a separate  
7 cause of action. It is a harder cause of action,  
8 perhaps, to succeed on, but it is a separate cause of  
9 action. So that, by itself, does not in any way, shape  
10 or form defeat the claim merely to say it is a back  
11 door. The same issues come up.

12           THE COURT: So the argument goes, it was  
13 reasonably scientifically knowable, as the California  
14 quote goes, and therefore goes the allegation, if it was  
15 reasonably scientifically knowable, then that invokes  
16 the duty to warn?

17           MR. LESSER: Correct, absolutely. That is  
18 exactly it, Your Honor. And to say that there is not a  
19 material issue of fact, here, given the reports of  
20 people like Mr. Armstrong and Mr. Tyres and the like, we  
21 can't even begin to get there.

22           There are certainly triable issues of fact  
23 about whether it should have been built this way,  
24 designed this way, warned this way and what should or  
25 should not have been said.

1           THE COURT:  So, where -- and if you are going  
2 to get to it in the argument, then I will sit tight.  
3 But, where in that context, on that issue, do we put Mr.  
4 Carpenter's 1 in 24,000 failures, or one in 12,000 --  
5 and if that is all they knew about, how could they  
6 possibly, one, have a duty to warn, apart from the  
7 argument of they losing doctors or other entities with,  
8 you know, this failure or that failure?

9           MR. LESSER:  It is continual.  It is not  
10 always the end post of every incident every time  
11 something walks in the door one has to warn of it.  I  
12 mean, our argument in the first place is it shouldn't  
13 have been out there, irrespective.

14           In other words, Guidant didn't need to wait  
15 for the incident reports of the PRIZM 2's to come in.  
16 It shouldn't have been an issue in the first place.  
17 But, even as to when the incidents come in, there is a  
18 continuum.  It depends on what is the nature of the  
19 issue.

20           And here -- and we have it in our earlier  
21 submissions, repeatedly, Guidant's own executives  
22 admitted, this was a safety issue.  And the Independent  
23 Panel evidence is of, I think, 1,400?

24           MR. SHKOLNIK:  1,400 reports.

25           MR. LESSER:  Of 1,400 reports, only 40 were

1 safety. So, you asked the important question, you know,  
2 who makes the decision when to issue a warning or not?  
3 Of course it is Guidant, it has to. Nobody else knows  
4 what Guidant knows.

5 But, Guidant's decision making has to be  
6 driven by the materiality and the significance of what  
7 it knew or should have known, or in this instance,  
8 indeed, what it knew. So, for summary judgment  
9 purposes, we go one step beyond to what it should have  
10 known. We go to what it actually knew.

11 And while Guidant wishes to downplay the  
12 significance of document number one, CPI 35, which  
13 discusses the suspected root cause -- if Your Honor  
14 looks through many of these incident reports, it is rare  
15 one actually has a suspected root cause identified at  
16 the very beginning.

17 And in addition, this suspected root cause,  
18 and this is what the testimony had, and this is what  
19 Plaintiffs' experts say, is one that should well have  
20 been apparent to raise a significant red flag. Because  
21 it is -- and Dr. Tyres goes at some length to explain  
22 this. This is not a random failure, which is what  
23 Guidant says we warned about, and that is all we have to  
24 do. Guidant walks off the hook every time it puts in a  
25 failure -- a statement, a warning, that randomly devices

1 might not succeed. But, when they are systemic of this  
2 sort, because this was arising out of the very nature of  
3 the way this was designed, and indeed from the very  
4 beginning Guidant knew that there was a suspected root  
5 cause, and indeed Guidant ended up being correct. That  
6 is a higher level. And that is why the Heart Rhythm  
7 Society and the Independent Panel both say, one can be  
8 enough.

9           So, to say that anytime something comes in  
10 the door misses the point, it has to be what is that one  
11 that comes in the door. And although Guidant somehow  
12 wishes to claim that Dr. Hauser may not know what he is  
13 talking about, as he said, his testimony is clear, had  
14 you warned of this risk, no physician in America would  
15 have implanted it.

16           Now, certainly, Dr. Higgins disagrees, and I  
17 will get to that. But, to argue or imply that Dr.  
18 Hauser, who is the nonretained expert is somehow  
19 suspect, because that was the position taken in the  
20 reply brief, I would just like to hand up two points.

21           THE COURT: And before you leave the  
22 September 14th, '04 statement of, document, if I recall,  
23 the implant on Mr. Duron was March 9th of 2002.

24           MR. LESSER: Right.

25           THE COURT: So, that's --

1           MR. LESSER: But, my point on that is, that  
2 document is about as clear of an admission you have,  
3 admittedly afterwards, but you don't have admissions  
4 before you do things. It is an admission that a simple  
5 search would have determined that this is a real  
6 problem, and polyimide degrades. And we have in this  
7 motion again, a defense that, well, we really couldn't  
8 have expected to have known this.

9           That document, of course it is after the  
10 fact, but you only get admissions after the fact, but in  
11 retrospect, the company is now admitting, we should have  
12 known this. It is a simple search. Nothing could be  
13 clearer. I would like to hand up two documents simply  
14 to address --

15          THE COURT: And they are already part of the  
16 record, I assume?

17          MR. LESSER: Are these -- yes.

18          THE COURT: As long as it is discovery or  
19 something that everybody has, it is not something new,  
20 do you have copies? Do they?

21          MR. LESSER: Yes. I just gave a copy. The  
22 only reason I am handing these up is, the reason these  
23 are significant, I believe these were both of Dr.  
24 Hauser's Deposition. They are marked Dr. Hauser's  
25 Deposition. To claim that Dr. Hauser maybe suspect or

1 does not know what he is talking about, is not  
2 respected, or what he has to say does not have meaning,  
3 is these are both in the last 12 months, the two leading  
4 groups in the world on heart rhythm devices and the  
5 like, who is they ask to talk about Guidant and talk  
6 about what occurred, here? It would have to be Dr.  
7 Hauser. These are his PowerPoint presentations. He is  
8 probably -- although it is easy for a lawyer to stand up  
9 and say, he has not much respect, or otherwise. He has  
10 it. He singularly has it. He is the person leading  
11 groups in the world today still ask to talk about what  
12 occurred here.

13 He says, and at least this creates an issue  
14 of fact sufficient for the moment on the learned part of  
15 learned intermediary, he says, had we been warned, had I  
16 been told, he thinks no reasonable physician would have  
17 implanted it. Dr. Tyres, of course, says pretty much  
18 the same thing. And he explains at length why this is  
19 indeed a systemic type of concern and should have been  
20 recognized as much. And, of course, Dr. Tyres is  
21 therefore impugned, as well.

22 And I would like to hand up Dr. Tyres C.V..  
23 To suggest because he is not an EP, this is also part of  
24 the record, this is his C.V. as part of his report  
25 before the Court. To suggest that Dr. Tyres can be

1 impugned when he says, yes, this was significant. Yes,  
2 this shouldn't have occurred. Yes, this should have  
3 been warned about at the beginning. To say that he  
4 doesn't know what he is talking about or impugning his  
5 reputation, I think, is ridiculous. He was one of the  
6 founders of the Heart Rhythm Society. This goes on for  
7 page after page after page after page, his 200 articles,  
8 his speaking engagements, his awards, he is considered,  
9 without doubt, and indeed he talks to every group in the  
10 world about these issues. He is, without a doubt, one  
11 of the leading people in his field, hands down.

12           So, for purposes of whether or not the  
13 warning -- the company should have warned, we don't have  
14 to go to -- this goes to causation, as well. We have  
15 two experts, unquestionably credentialed, who do explain  
16 in their reports, do explain in their testimony, as to  
17 why Guidant should have warned and why it matters that  
18 Guidant didn't warn, and how that effects physicians.

19           Let me move on. I would like -- let me move  
20 on to the other half of Learned Intermediary. And this  
21 is the causation argument. As I understand the  
22 causation argument, it is, because Plaintiffs have not  
23 shown that the person who put the device in Dr. Higgins  
24 would have done anything different, Plaintiffs  
25 necessarily lose the case on failure to warn. And it

1 does not matter, therefore, that Dr. Higgins was not  
2 simply admiring of Guidant, and it's not simply that  
3 every EP in the country would be disqualified -- but,  
4 let me get to that in a second.

5           First what is the standard of independentness  
6 in California? And indeed, by the way, when we get to  
7 the Clasby motion, it is really the exact same thing.  
8 The leading case -- there are really two cases. One is  
9 the Carmichael case from 1971. The Carmichael case  
10 says, in essence, although it doesn't use the word,  
11 term, Learned Intermediary, in fact that is a term  
12 California Courts don't really like much, it has to be  
13 independent judgment.

14           If we are going to look at what occurred with  
15 an individual person, it has to be independent judgment.  
16 In the Stevens case, which is the California Supreme  
17 Court decision we cite, there the doctor said: I knew,  
18 and I still with put it in. I knew the risk from the  
19 drug, and I still put it in. That is what Dr. Higgins  
20 is saying here today: A, I knew; and B, I would have  
21 put it in anyway. None of this would have changed my  
22 mind.

23           The California Supreme Court said -- the  
24 California Supreme Court rejected it, as long as there  
25 could be an issue, a reasonable issue that this doctor,

1 this doctor's testimony could be questioned as to what  
2 he would have done -- and bias comes in, right in the  
3 door, then the jury -- then that is a matter that goes  
4 to the jury. That is absolutely the holding of the  
5 Stevens case.

6           The Court says, this is 9 Cal.3d at 55 and  
7 56. The jury could reasonably infer from the above  
8 circumstantial evidence, and there the circumstantial  
9 evidence wasn't about Dr. Beilin, himself, it was  
10 generally about what the Defendant Parke-Davis was  
11 doing, from the above circumstantial evidence that the  
12 company engaged in promotions, that Dr. Beilin was  
13 induced by the manufacturer's activities to prescribe  
14 the drug and the jury were entitled to reject Dr.  
15 Beilin's testimony to the contrary.

16           So, for present purposes, if one can create  
17 an inference that the learned intermediary is not an  
18 intermediary who is independent, then you can have a  
19 jury issue. And again, it is not the extreme. It isn't  
20 that every EP in America, whoever accepted money from  
21 Guidant would be disqualified, because this is almost --  
22 this is almost tautological. If there ever was an  
23 individual who is less representative of EP's in America  
24 and their view of Guidant and what they will say and  
25 what they have to convince a jury, it is Dr. Steven

1 Higgins. When Dr. Steven Higgins is not flying -- I  
2 would suspect, I don't know if this is true, but I would  
3 suspect there is no other individual EP in America who  
4 flew to Ireland with the President, with Mr. McCoy, for  
5 his birthday. I would suspect there is no other EP in  
6 America who routinely invited the very top Guidant  
7 executives to his house, who also went to -- when they  
8 weren't going to yacht clubs and other golf tournaments  
9 or the like.

10 Dr. Higgins, internally, his clinic at  
11 Scripps is called Guidant West. This is all in the  
12 record by Guidant representatives. Dr. Higgins and his  
13 group obtained, well over -- approximately, at least a  
14 million dollars, although we were supposed to get under  
15 an earlier Court Order, the complete records of the  
16 compensation -- Plaintiffs have yet to receive them, by  
17 the way. So there may be more in addition to the nearly  
18 a million dollars. They had a golfing tournament with  
19 Messieurs Nock, McCoy and Sparks, all top Guidant people  
20 in Utah.

21 He called himself, within the company he is  
22 called a friend of the company, a leading ambassador for  
23 Guidant. He was considered price insensitive by  
24 Guidant. Most significantly, let's look at Dr. Higgins,  
25 himself. He offers himself to this company as, quote, a

1 hitman for the company, when people start criticizing  
2 the company. He signs e-mails to the company saying, I  
3 am your alter-ego. This is all in the record. This man  
4 is --

5 THE COURT: And you want his opinion stricken  
6 from the --

7 MR. LESSER: We absolutely do. We absolutely  
8 do.

9 THE COURT: Anyway, that is left for another  
10 day, but --

11 MR. LESSER: Absolutely, that is another day.  
12 They think he is an agent. He is a self-admitted agent  
13 of the company. So, he cannot possibly be a learned  
14 intermediary. He is a learned, perhaps not learned,  
15 that is what I was arguing before --

16 THE COURT: I think he also said you could  
17 have a mulligan without a recall.

18 MR. LESSER: He did indeed, after -- and I  
19 could have kept on going, yes, absolutely, another  
20 colorful point.

21 So, in order to be a learned intermediary,  
22 you have to have learnedness. And I have argued that on  
23 an objective basis, you don't have learnedness. And you  
24 have to have an intermediary. He is not an  
25 intermediary. He, himself, is a self-confessed

1 alter-ego for the company. So, under the California  
2 cases, it is certainly true under the Stevens case, it  
3 is true under the Plenger case, it is true under the  
4 Carmichael case. It is true for all of the cases that  
5 we have cited at pages 27 to 29 of our opposition.

6 If there can be an issue as to the  
7 objectivity of the learned intermediary and whether or  
8 not the jury will believe what he says as to what he  
9 would have done and the sufficiency of what he was told,  
10 that goes to the jury. That is the Freeman case of the  
11 Second Circuit, and we cite case after case after case.  
12 So, it cannot be the extreme that nobody can get on the  
13 stand and make that argument.

14 Lastly, he -- I think I have covered it all.  
15 I think I have covered learnedness. I think I have  
16 covered intermediary. I think I have covered causation,  
17 because as I said, Dr. Hauser, Dr. Tyres addressed it,  
18 there is a short -- the burden is on the Defendant, not  
19 on Plaintiff to disprove something. The burden is on  
20 the Defendant to show, contrary to our experts and the  
21 testimony here today, that there are triable issues of  
22 fact that go to the jury in sufficiency of what Guidant  
23 did and did not warn about. Thank you.

24 THE COURT: Well, it should be, we won't take  
25 it up today, and apart from how I rule on this motion,

1 it should be an interesting trial, because I think we  
2 will be seeing Dr. Higgins. So, I haven't had a  
3 response yet from Guidant, but it should be interesting  
4 direct and cross.

5 Any brief response, Mr. Carpenter?

6 MR. CARPENTER: Just two minutes, Your Honor,  
7 maybe three. I love this document Mr. Lesser handed up.  
8 It proves my point, precisely. It is 2004. It is in  
9 retrospect. Sure, they say we could have done a search  
10 and found the general principle that polyimide is  
11 capable of degrading under some circumstances.

12 It is not useful until, as he says up here,  
13 our investigation is finding evidence that polyimide  
14 tubing is breaking down. That kind of academic "could  
15 have" possibility is useless to a manufacturer without  
16 empirical evidence.

17 This, retrospectively, in 2004, two years  
18 after the operative date, yeah, Guidant is taking  
19 subsequent remedial measures. This isn't even  
20 admissible. It just says, a subsequent remedial  
21 measure. But, if it were, all that would say, that  
22 Guidant, like any fine manufacturer, is looking back and  
23 saying, in retrospect, based on what we know now in  
24 2004, now we have got so many failures, yes, we can draw  
25 conclusions from that. But, one failure? Absolutely

1 worthless.

2           This literature search that would reveal this  
3 information -- and I am sure it did, I am sure Guidant  
4 was aware of that problem. I don't know if they were or  
5 not, but that doesn't make any difference in the absence  
6 of real data indicating that polyimide, as it is used in  
7 the PRIZM 2, not in a lab, not in a test tube, but five  
8 times the strength in part of the triple redundant  
9 safety features wasn't working. That is the only kind  
10 of information that would put a reasonable manufacturer  
11 on duty to provide additional warnings. That is a  
12 fabulous document and I am glad Mr. Lesser gave that.

13           THE COURT: It is a wonderful exercise for  
14 the young lawyers and interns and summer associates in  
15 the courtroom, if there are any, to see two lawyers get  
16 up and they're saying, are they both talking about the  
17 same document?

18           Anyway, I guess it is what you call the  
19 beauty of zealous advocacy by both sides. Because I  
20 think one thing I think for sure is, you both can't be  
21 correct. So, we will soon find out.

22           MR. CARPENTER: We will leave it to Your  
23 Honor.

24           THE COURT: All right.

25           MR. CARPENTER: The Stevens case doesn't have

1 any application to the facts of this case. The Stevens  
2 case, there was substantial evidence in the record that  
3 the company's promotion activities had directly  
4 influenced the physicians' prescribing techniques. Zero  
5 of that in this case.

6 All they can show is that he liked Guidant.  
7 It's a good company. And he went on an occasional golf  
8 trip. There is zero evidence indicating that Dr.  
9 Higgins did not use his own independent judgment in  
10 selecting devices. And that is the real issue.  
11 Plaintiffs have nothing on that.

12 I do want to clarify, no one is wearing down  
13 Dr. Hauser. I am sure Dr. Hauser is very qualified.  
14 Dr. Tyres, I'm sure he is a great doctor. I don't know  
15 the gentleman. They just don't speak to this issue.  
16 Neither that excerpt by Dr. Hauser, nor Dr. Tyres'  
17 report, nor anything Dr. Singh says addresses the issue  
18 of what even they would have done had they had the  
19 warning information that Plaintiffs claim they should  
20 have had in 2002, March 9th, much less what another  
21 physician would have done. They're just not talking to  
22 the issue. Thank you, Your Honor.

23 THE COURT: Were you going to make additional  
24 argument, or deal separately, I take it, with Clasby?

25 MR. CARPENTER: Yeah, and I think this gets

1 us a lot of the way we need to go. Why don't I just  
2 role into that?

3 THE COURT: Any objection to that?

4 MS. STRIKIS: No.

5 THE COURT: All right.

6 MR. CARPENTER: Let me grab a different  
7 outline real quick.

8 THE COURT: Can we do that, Jeanne? We are  
9 going to take a break right here.

10 Well, let's finish -- did you want the last  
11 word on this one, Mr. Lesser? Have you said what you  
12 needed to say?

13 MR. LESSER: I think it is quite clear by the  
14 two ways that one document is looked at, there's a  
15 triable issue of fact.

16 THE COURT: Bear with me just one moment.

17 (Discussion off the record.)

18 What I would like to do, if I don't trample  
19 on somebody's health condition or whatever you need, if  
20 we take a half-hour here, and then with the idea that we  
21 would hear the balance of the motions, will that work  
22 for everybody?

23 MR. HARKE: I'm sorry, Your Honor?

24 THE COURT: Take a half-hour here, but I will  
25 hear the remaining motions, which I think are three, if

1 I have counted them correctly.

2 MR. CARPENTER: Correct, Your Honor.

3 THE COURT: That is what I would try to  
4 accomplish here, unless one of you would say, that seems  
5 a bit harsh on us. Will that work for everybody?

6 MS. STRIKIS: That is fine, Your Honor.

7 MR. CARPENTER: That is fine, Your Honor.

8 Did Your Honor want to hear the Clasby aspect before the  
9 break or --

10 THE COURT: Why don't we just break here and  
11 what I could do to be a little more reasonable in  
12 approach, it is quarter to twelve. What about reconvene  
13 at 12:30 and then just see it through? I mean, I tend  
14 to take shorter breaks and forget about the effect on  
15 other people.

16 It is a little relevant to -- not so much my  
17 ears, but to a Court Reporter when -- I think it would  
18 be safe to say there is some rapidity to your argument.  
19 You are quick, fairly quick, both of you, so they have  
20 to be fairly nimble. She is top of the line Court  
21 Reporter, but it is quick, quick, quick.

22 So, 12:30, and then we will run straight  
23 through, is that -- can everybody --

24 MR. CARPENTER: That's great, Your Honor.

25 (Noon recess.)

1                   THE COURT: You may be seated. You know,  
2 Lowell, since you are retiring on July 3rd, if you  
3 really want to stay in the courtroom and watch all of  
4 this --

5                   THE CLERK: I have so many retirement things  
6 I have got to work on.

7                   THE COURT: Are you sure?

8                   THE CLERK: Well, of course. You're the  
9 boss.

10                  THE COURT: See you later. Whenever you are  
11 ready?

12                  MR. CARPENTER: Thank you, Your Honor. I  
13 think we left it off with we were going to proceed with  
14 the Clasby Failure to Warn Motion.

15                  THE COURT: We did.

16                  MR. CARPENTER: And I am only sorry Mr.  
17 Lindquist couldn't stay for my retirement gift of this  
18 fine oratory.

19                  THE COURT: He has only been here 33 1/2 half  
20 years. His father was the late Leonard Lindquist of  
21 Lindquist & Vennum. He died last year at the age of, I  
22 think, 91 or 92, and practiced law pretty much full time  
23 right until the day that he died. And I had asked him,  
24 you know, it comes up at bar admissions. I had asked  
25 him, so, why is it that people like your dad and Earl

1 Larson and Gerald Toomey were kind of ahead of their  
2 times. They were organizing women in nurses' unions,  
3 women teachers when nobody would pay them the same  
4 salary as men, back in the forties they were doing all  
5 of this.

6 He said, well, I can tell you about my dad, I  
7 can't speak for the rest. He said my dad was the oldest  
8 of, I can't remember how many, it was a large family.  
9 His dad died when he was a young kid. He helped his  
10 mother, below his grandmother, raise the family. And  
11 everyday I remember, as I got older, my grandmother,  
12 Leonard's mother, saying the same thing. When you live  
13 in a country where you are lucky to succeed, what it  
14 means to be an American is to go help someone who hasn't  
15 been so lucky. And then if you don't get that, then you  
16 don't really get what it means to live in this country.  
17 And he said, every day that is what we got, every single  
18 day from my grandmother, from the time I was a little  
19 kid. And he said that is why my dad was going out and  
20 not being paid or taking any retainer fees or  
21 representing people that nobody else would represent  
22 back in the forties. But, yeah, that's his father. No  
23 lawyers in Leonard's family, so -- all right.

24 MR. CARPENTER: Clasby failure to warn  
25 motion, otherwise known as the Learned Intermediary

1 Motion. And I am going to make a conscious effort to  
2 speak at a slower pace during this motion, by the way.

3 I think a lot of similarities and parallels  
4 apply to this motion from the Duron one, although there  
5 are different legal standards, similar, but very  
6 different facts, as well. They are very different  
7 motions. In this case I think the Court is going to  
8 find that the duty to warn, there is even less evidence  
9 supporting a duty to warn in this case than the Duron  
10 case. And there is, if possible, even less causation  
11 evidence in this case, if it is possible to have less  
12 than none.

13 Again, the Learned Intermediary Doctrine  
14 applies to Florida law. I don't think there is any  
15 disagreement about that. Again, there is no requirement  
16 under Florida law that a manufacturer of a medical  
17 device, or any other product, warn of every conceivable  
18 risk. It is not insurer liability, it is not absolute  
19 liability. Instead, manufacturers are only required to  
20 warn, quote, "Those risks which are known or knowable in  
21 light of generally recognized, and prevailing best  
22 scientific medical knowledge available at the time of  
23 manufacture and distribution." That is the Griffin -v-  
24 Kia Motors case.

25 So, again, I think the Court's focus needs to

1 be on what was known or reasonably knowable at the time  
2 of Dr. Clasby's implant, which in this case happened  
3 December 20th -- December 30th, excuse me, 2002, about  
4 seven months after Mr. Duron's PRIZM 2 was implanted.

5           The question then is what did Guidant know or  
6 did it reasonably -- or what it reasonably should have  
7 known on December 30th, 2002? Well, this case is  
8 different because -- and I think it is important to  
9 point this out. Dr. Clasby's device was slightly  
10 different than Mr. Duron's device. His device was  
11 manufactured pursuant to the post-April 2002 engineering  
12 change order. Those devices were different. Those  
13 devices were never recalled by the FDA at any point.

14           When Dr. Clasby's device was implanted, there  
15 had been about 20,000 PRIZM 2's implanted in people  
16 around the United States after that point, including pre  
17 and post-April ECO changed devices.

18           At that point, there were only four total  
19 arcing incidents known out of 20,000. Again, those are  
20 incredible reliability numbers. Again, there is no  
21 evidence that I am aware of in any of the record that I  
22 have seen that Guidant had identified the root cause.  
23 But, I think it is more important to point out that  
24 there were zero incidents reported of arcing problems in  
25 post-April ECO devices by December 30th, 2002, when Dr.

1 Clasby was implanted. There was no basis for Guidant to  
2 think that there still existed a problem with any of  
3 these devices. As a matter of fact, history has borne  
4 that out. If you apply 20/20 hindsight, as Plaintiffs  
5 often invite this Court to do, which I submit is not  
6 appropriate, anyway, there has been one, one reported  
7 arcing incident of a post-April ECO device out of about  
8 10,000 implanted. Those are incredible reliability  
9 rates. Those far exceed the projections given to the  
10 FDA, far exceed other devices, and far exceed Guidant's  
11 competitors reliability rates. It's a fabulous reliable  
12 device.

13 It is important that the post-April ECO  
14 devices were never recalled at any point because there  
15 was never any indication that there was additional  
16 information to be given about them. And it is important  
17 to remember what a recall is in the FDA context. It is  
18 not that you have to take the devices back or have it  
19 explanted, it is a requirement for some additional  
20 information to be given. The FDA never required that,  
21 the kind of device that Dr. Clasby had.

22 Clearly, there is no basis for imputing to  
23 Guidant a duty to warn of possible arcing problems of  
24 this device when it didn't exist at all at the time Dr.  
25 Clasby's device wasn't implanted, and they certainly

1 don't even exist in retrospect.

2           Plaintiffs alternatively claim that we should  
3 have warned of the April engineering change order,  
4 again, we covered that in the last argument.  
5 Engineering change orders are fairly much a constant in  
6 this industry, and if we had to warn about every single  
7 one of them, the warnings would never stop. They would  
8 be ceaseless.

9           Alternatively, Dr. Clasby claims that we  
10 should have warned about the possibility of unnecessary  
11 shocks. Well, we did. I think that is important in  
12 this case. Dr. Clasby's case is different from Mr.  
13 Duron's case, as well. Dr. Clasby is proceeding, and it  
14 really didn't hit home to me how exclusively he his  
15 proceeding on the theory of improper shocks.

16           I looked at the discovery responses we sent  
17 him, where we asked him interrogatories and RFP's, to  
18 identify exactly what the malfunction is in his device,  
19 and he said, cause of injury. He doesn't talk about  
20 polyimide degradation, he doesn't talk about recall, he  
21 talks about improper shocking.

22           THE COURT: Which you say was the way the  
23 device was programmed.

24           MR. CARPENTER: Yeah, there is no evidence  
25 that the device was defectively causing shocking.

1 Devices shock at certain levels depending on how they  
2 are programmed and what their parameters are. That is  
3 how they work. There is no evidence that Dr. Clasby's  
4 device was shocking him due to a defect in the device,  
5 as opposed to how it was manufactured. But, I think  
6 more importantly, Your Honor, in the context of this  
7 motion being a failure to warn motion, there is no  
8 dispute that the danger of inappropriate shocks is right  
9 there in the Physicians' Manual. That is very  
10 explicitly warned about. There is no EP around who  
11 doesn't know that that is a danger, regardless of what  
12 Guidant tells them. And Guidant very specifically warns  
13 about that. So, to the extent the Clasby case is  
14 premised on any kind failure to failure to warn about  
15 shocks, that has got to be dismissed, as well.

16           Again, Plaintiffs try to point to the general  
17 duty to warn of the inchoate dangers of polyimide in the  
18 abstract. I think we covered that. I won't belabor  
19 that issue. I think we covered that during the Duron  
20 motion.

21           Basically, just as in the Duron case, there  
22 is no evidence at the time that Dr. Clasby's device is  
23 implanted that Guidant should have been on notice that  
24 polyimide was failing as used in PRIZM 2's, because  
25 there was just no evidence of that. Particularly,

1 post-April PRIZM 2's, which Dr. Clasby got, even today  
2 there is no evidence that polyimide was inappropriate as  
3 used in those devices. It clearly wasn't inappropriate,  
4 those devices worked fabulously.

5 Let's talk about the causation issue. Again,  
6 Plaintiffs concede that Florida has not recognized a  
7 heeding presumption. There is no authority indicating  
8 that Florida will recognize a heeding presumption.  
9 Absent that heeding presumption, which Florida won't  
10 recognize, there is no evidence, whatsoever, that had  
11 whatever warnings Plaintiffs claims should have been  
12 given, that Dr. Clasby's prescribing physician would  
13 have done anything differently. There is a complete  
14 absence of any evidence in the record.

15 Plaintiffs claim this motion is premature. I  
16 don't know how the motion can be premature, we have had  
17 this scheduled for three months, and the trial is going  
18 to start shortly thereafter, the next month after this.  
19 Plaintiffs haven't taken the depositions. Maybe they  
20 are going to come back when they get done with deposing  
21 other doctors and try to offer more evidence, but at  
22 this point we will have to deal with that maybe at a  
23 later date. But, there is zero evidence as to what Dr.  
24 Clasby ever would have done had different warnings been  
25 given.

1 I also think it is important to point out in  
2 the context of this case that there really isn't any  
3 indication that the different warnings Plaintiffs demand  
4 would have avoided the particular injuries alleged in  
5 this case, on two points.

6 This device was never recalled. And in the  
7 Duron case, the Court emphasized that to the extent  
8 Plaintiffs had to state an injury, it is an injury based  
9 on having to have explant surgery as reasonably  
10 necessary, and under la doctor's opinion to explant the  
11 recalled device. That is not the case here.

12 Nothing that Guidant didn't say or failed to  
13 warn about resulted in Dr. Clasby getting a recalled  
14 device. I think it is important for the Court to bear  
15 in mind, the entire reason Dr. Clasby's device was  
16 explanted was he and his explanting physician made a  
17 mistake. They thought this device was a recalled  
18 device. They thought that right up until the day of  
19 their depositions.

20 THE COURT: Even though some of the discovery  
21 we were snooping around in suggested that his office  
22 called a nurse at Guidant and said that this was not on  
23 the recall list.

24 MR. CARPENTER: Exactly. Guidant provided  
25 accurate information that this device was not on the

1 recall list. Dr. Feldman right up until the time --

2 THE COURT: There is not a name associated, I  
3 don't think, with -- was there? But it said registered  
4 nurse.

5 MR. CARPENTER: Correct, it is impossible to  
6 tell precisely who it was, but it was certainly someone  
7 connected with Dr. Clasby's healthcare professionals.  
8 And his device was explanted due to -- I am not  
9 criticizing Dr. Feldman, but it was a misimpression. It  
10 was Dr. Clasby's misimpression, as well. Dr. Clasby,  
11 you know, despite consulting with an attorney early on  
12 continued to believe the device was a recalled device  
13 right up to his deposition when defense counsel had to  
14 clear that up.

15 THE COURT: Well, isn't this case different  
16 because Dr. Clasby reads about this recall in May of  
17 2005, and actually after consulting, himself, with a  
18 lawyer and others, it was a year later that a decision  
19 was made to take it out by a doctor. You said if it  
20 hadn't been recalled -- or he thought it was recalled --  
21 he wouldn't have recommended that it be explanted.

22 MR. CARPENTER: That is correct, Your Honor,  
23 it is a very different case from the Duron case. Dr.  
24 Clasby read about the recall. The first thing he did  
25 was went to see his lawyer. He didn't see his doctor

1 about it for months. And then went on an extended  
2 vacation in Maine, came back, and I think it was nine or  
3 eleven months later when it was convenient for his  
4 teaching schedule, went ahead and got it explanted. And  
5 it seems that he did so under a mistake about its recall  
6 status, both a mistake that he and his explant physician  
7 was under.

8           So, I would submit to the Court that this is  
9 a fairly distinctive fact pattern where the mistaken  
10 assumption by the physician and the Plaintiff is a  
11 superseding, intervening cause that cuts off any  
12 proximate causation that could have been caused by  
13 Guidant's failure to warn about anything.

14           No warning failure resulted in Dr. Clasby  
15 getting a device that was recalled or had to be  
16 surgically explanted. And I think that is a very  
17 salient distinction between these cases that  
18 demonstrates why they are not similar at all.

19           So, basically, I think at the end of the day,  
20 this case suffers from the same two types of fatal  
21 defects as the Duron warning case goes. There is no  
22 evidence, whatsoever, that Guidant knew or should have  
23 known in December 30th of 2002 that its devices were  
24 defective, or that a warning was required, particularly,  
25 the post-April ECO devices which to this day continue to

1 function at a fabulous rate and have not been recalled.

2 And number two, even if there were some kind  
3 of a duty, which I don't believe there is, there is no  
4 evidence that the breach of any duty to warn caused Dr.  
5 Clasby's particular injuries, which seem to be the  
6 result of a mistake by he and his explanting physician,  
7 or appear to be entirely related to shock issues which  
8 Guidant clearly warned about.

9 THE COURT: Thank you.

10 MR. CARPENTER: Thank you.

11 THE COURT: So which of these differences are  
12 relevant, if any?

13 MR. LESSER: There are some significant  
14 differences. First of all, I think Mr. Carpenter just  
15 misspoke. The explanting physician was not Dr. Feldman,  
16 he was the cardiologist. The explanting physician has  
17 not been deposed, although we have offered dates, and we  
18 have yet to have them.

19 Learned Intermediary begins and ends -- the  
20 burden is on the defendant to prove up its affirmative  
21 defense of learned intermediary. And once again, it is  
22 trying to be shifted to the plaintiff. But, these  
23 individuals have not been yet deposed, therefore is no  
24 evidence that they would have acted differently, or to  
25 prove the intermediary, Learned Intermediary defense.

1 And this is straight out of the Duron brief by Guidant,  
2 under the Learned Intermediary Doctrine in Guidant's  
3 brief, page 10, dispositive issue of causation depends  
4 on whether Mr. Duron's physician, not other physicians  
5 or some reasonable physician, would have changed his  
6 recommendation to implant the PRIZM 2 presented with the  
7 warnings proposed by Mr. Duron.

8 In the Duron case, of course, the significant  
9 difference is, Dr. Higgins says, I would have done  
10 nothing different. Here, the record has not been made  
11 as to what the explanting physician would have done or  
12 not have done, which is why I offered repeatedly for the  
13 last two days, this is not ripe to be heard. Which is  
14 why -- but, nonetheless --

15 THE COURT: So, what is the role of Dr.  
16 Feldman in this?

17 MR. LESSER: He is the cardiologist. He is  
18 Dr. Clasby's cardiologist and he recommended -- he  
19 recommended it. He might have been confused, but the  
20 actual testimony is actually equivocal. I am reading  
21 from pages 103 of the Feldman testimony, which was  
22 quoted. It says here by Mr. Moeller, Guidant's counsel,  
23 "Okay, and if in fact it wasn't subject to a recall,  
24 then you would not have recommended that it be replaced,  
25 true?"

1                   Answer, Dr. Feldman, the cardiologist, "Well,  
2 I think given the information I had at the time and  
3 given his concern over having a Guidant device, in  
4 general, it certainly would have impacted me. But, I  
5 might have actually recommended an explant." It is  
6 equivocal. "But, in a general sense, I was working from  
7 the impression that this was a device that was to be  
8 explanted."

9                   If he was confused, he still said, I might  
10 have, and it was equivocal. And he is not the  
11 explanting physician. We have yet to have Dr. Berg  
12 deposed. But, I submit that the Learned Intermediary  
13 defense has not been proven up at all, because the  
14 burden is on Guidant to show how the doctor would have  
15 reacted by their own argument in their briefs.

16                   Beyond that, otherwise going to learnedness,  
17 as compared to the intermediary, I discussed this  
18 earlier --

19                   THE COURT: So, if Feldman played no role as  
20 a learned intermediary, why did we mess around with his  
21 deposition if the doctor who made the decision, nobody  
22 has even talked to him or deposed him yet? What do we  
23 care what Feldman said?

24                   MR. LESSER: Feldman is his cardiologist. He  
25 talks to his cardiologist. It is the wrong doctor for

1 this motion. Dr. Berg, has, I believe, offered dates --

2 MR. SHKOLNIK: Dr. Interian is the one who  
3 implanted him, too.

4 MR. LESSER: And we know the implanter hasn't  
5 been deposed yet, so --

6 THE COURT: So, the other two doctors are  
7 going to say, we don't really care what Feldman said,  
8 but we made the decision, along with our patient, we  
9 decided, and here is what we would have done. And what  
10 Feldman said -- we don't really -- it doesn't matter  
11 what he said, here is what we were going to do.

12 MR. LESSER: I don't know what they are going  
13 to say, Dr. Interian was actually, oddly enough, and I  
14 understand why the Clasby case was not bounced by  
15 Guidant. He was another member of the Medical Advisory  
16 Board of Guidant, just like Dr. Higgins. We did not  
17 know that at the time, so I understand why the case -- I  
18 think Guidant believes that he would be more favorable.  
19 But, dates have been offered. It was our view -- we  
20 did -- Plaintiffs said, this has to wait until the full  
21 record. But, as we stand here today, the record wasn't  
22 made as to whether or not the doctors of the implanter  
23 or the explanter would have done. And as I said, I  
24 offered to put it off.

25 THE COURT: I didn't miss -- I don't

1 generally see lawyers engaged in the 56(f) practice, but  
2 I didn't see a final 56 (f) approach by Plaintiffs  
3 saying, flat out premature, discovery is not done. We  
4 shouldn't have to even be in here defending this thing  
5 because we don't -- they have not deposed the people who  
6 may be the only people that mattered.

7 MR. LESSER: Right. Well, it is not our -- I  
8 submit the motion fails for lack of proof. I don't have  
9 to support their proof.

10 THE COURT: That is true.

11 MR. LESSER: It is premature. And as I said,  
12 I thought we were doing the right thing by offering to  
13 push it off. But, the proof isn't here. And under  
14 their -- the way they put together learned intermediary,  
15 I believe it fails.

16 On the learnedness side, on the science side,  
17 it is the exact same issue. Dr. Clasby got the same  
18 device. Indeed we know in retrospect that the partial  
19 fixes of April were not included in his device. When it  
20 was actually examined, it had no medical adhesive. That  
21 is actually the supplemental report.

22 THE COURT: You are saying -- and I  
23 understand the piece of the medical adhesive. You are  
24 saying the April changes were not in his device?

25 MR. LESSER: Correct. They were supposed to

1 have plenty of medical adhesive to therefore create some  
2 insulation, there. And in his device, at least, it was  
3 not there. So, in some sense, you would say, thank God  
4 that it was taken out. Because he might have been the  
5 one that well might have been more likely to fail than  
6 otherwise. But, it is the same reports, it is the exact  
7 same expert reports. It is the exact same position, it  
8 is the exact same testimony. We're back to Dr. Hauser  
9 again, and his testimony, if he would have known of the  
10 issue he would never have implanted it. No reasonable  
11 physician would have implanted it. Obviously, Dr.  
12 Higgins would disagree, but there is an issue of fact  
13 there. We have Dr. Armstrong's report, Dr. Their's  
14 reports, the exact same issue, and the recall doesn't  
15 change whether there is a claim or not. One does not  
16 need a recall in this world to have a claim. So, on  
17 that side of the scientific ledger, it is the same. I  
18 don't believe there is anything else. That is it.

19 THE COURT: Mr. Carpenter?

20 MR. CARPENTER: Just real briefly. I can  
21 clear up a little confusion.

22 THE COURT: Well, maybe I am the only one  
23 confused.

24 MR. CARPENTER: No, Your Honor, you're not,  
25 believe me. Dr. Feldman is the EP who recommended

1 explant. The cardiologist did it, but it was Feldman's  
2 decision. And our point is that Feldman recommended it  
3 under the misimpression that it was a recalled device.  
4 So, that is why that is important testimony. He didn't  
5 physically take it out, but it was his decision. The  
6 record is unequivocal about that.

7 THE COURT: And so my question to Mr. Lesser  
8 was, so is the doctor who was the explanting physician  
9 going to say, it wasn't my decision, it was Feldman's?

10 MR. CARPENTER: Absolutely, absolutely. The  
11 Medical records indicate that.

12 THE COURT: But how do you --

13 MR. CARPENTER: I think the medical records  
14 indicate that and Dr. Feldman testified that it was his  
15 decision.

16 Number two, I want to clear something up,  
17 too. Mr. Lesser states that it is our burden to prove  
18 causation in their case. Not at all. The element of  
19 proving that had the warnings been given that Plaintiffs  
20 claim should have been, whatever those are, they still  
21 haven't been identified yet, they would have changed the  
22 doctor's diagnosis. That's causation, that is not an  
23 affirmative defense, that is their burden. They haven't  
24 deposed the doctors needed to do it, yet. They haven't  
25 deposed to the people that they say are going to do

1 this. We have got no burden to go out and depose --  
2 although we did it in Duron with Dr. Higgins, we  
3 affirmatively disproved that element of their case.  
4 That is not our burden in every case. Plaintiffs are  
5 the ones with the burden to prove causation. And the  
6 cases, whether they are in Florida or in California are  
7 crystal clear that causation, unless there is a heeding  
8 presumption, which there is not, is an element of  
9 Plaintiff's case. We don't have the burden to go out  
10 and depose the prescribing physicians and make them  
11 disprove the causation element.

12 As far as proving what was given to the  
13 learned intermediary -- well, Guidant gives those  
14 warnings I spoke about at the beginning of the Duron  
15 case. They're in the Physicians' Manual, all EP's get  
16 them. All EP's who get Guidant devices get those. They  
17 are standard materials. So, there is no doubt,  
18 regardless of the fact of whether these particular  
19 prescribing physicians have been deposed yet. They have  
20 got this material. Guidant puts those out and there is  
21 no issue of fact as to that one.

22 The only issues in this case are the fact  
23 that Dr. Clasby's device was explanted due to a mistake  
24 of the recommending EP; that there is no evidence now,  
25 and I suspect there won't be one even after these

1 depositions are taken, that a different warning would  
2 have changed any prescribing physicians' position  
3 recommending the PRIZM 2.

4 I don't think this motion is premature.  
5 Plaintiffs haven't done all of their discovery yet, but  
6 this Court has had this scheduled on the docket for  
7 quite a while. And I frankly don't feel comfortable  
8 taking this down and creating a specific track for this  
9 without specific permission from the Court. I don't  
10 think that makes sense.

11 I do want to address one last issue, is Mr.  
12 Lesser's claim that Dr. Clasby's device in hindsight,  
13 taken apart and submitted to a battery of his experts,  
14 doesn't show all of the post-April 30th ECO changes.  
15 First of all, that is wrong, but that is a fact issue  
16 and I am not even going to rely on that.

17 Even assuming that, it has got nothing to do  
18 with what Guidant knew or didn't know in December of  
19 2002. There is no way that Guidant could have looked at  
20 that device and known that if, assuming what Plaintiffs  
21 say are true, that the April ECO changes weren't fully  
22 effected. That is hindsight that is based on an  
23 after-the-fact reverse engineering of the device that  
24 Guidant didn't have access to at that point.

25 In December of 2002 Guidant knew that there

1 were zero failures in post-April 30th ECO devices.

2 Thank you, Your Honor.

3 MR. LESSER: Can I try to clarify a few  
4 things?

5 THE COURT: All right.

6 MR. LESSER: Earlier today we heard the  
7 argument that Dr. Hauser -- or was it Dr. Tyres, was not  
8 an EP, therefore his view on what people should or  
9 should not do should be given into account.

10 Dr. Feldman is a cardiologist. He is not an  
11 EP. The EP who put the device in just happened to be  
12 Dr. Myerburg, interestingly enough in this litigation --

13 THE COURT: The other thing is, even Dr.  
14 Myerburg aside, is Duron focused solely on implantation.  
15 And we're focusing here on explanation, for some reason.  
16 In other words, our focus was entirely on what did the  
17 doctors say, why did they -- what happened and who made  
18 the decision to implant, and now we have actually gone  
19 to the explant side of the equation.

20 MR. LESSER: Right. The reason the learned  
21 intermediary is an issue here is Dr. Clasby, himself,  
22 said had I known about all of the problems with the  
23 Guidant devices, I wouldn't have had this device  
24 originally put in.

25 So, the issue is, does the affirmative

1 defense of learned intermediary step in the way? That  
2 is Dr. Clasby's testimony in this litigation, and his  
3 wife's testimony, too. So, causation exists. He says,  
4 had I known, had you told me, Guidant -- that is his  
5 testimony. He has now created causation for himself,  
6 personally. Learned intermediary is when you say,  
7 despite what the Plaintiff now claims, is there an  
8 affirmative defense that steps in the way?

9 So, causation is shown. The question is, has  
10 Guidant dealt -- covered its burden on interposing the  
11 learned intermediary defense? And the answer, Your  
12 Honor, is no. The implanter testimony which they admit  
13 is necessary to make that is not in the record. The  
14 explant -- I agree, we are talking about the explant  
15 here, instead, which has nothing to do with the  
16 implantation, anyway. You are absolutely right.

17 And you pointed that out to us and perhaps I  
18 should have recognized that, myself, Your Honor. But,  
19 this is a defense. At the moment Dr. Clasby is  
20 affirmatively, and this is in the record in the full  
21 statement of facts that he would not have had this  
22 device, and his wife so testified, had they known -- so  
23 the question is, did Guidant take advantage of a learned  
24 intermediary imposition of a defense? And the answer  
25 is, they have not made the record, and therefore the

1 motion fails.

2 THE COURT: And he hasn't sued his doctor?

3 MR. LESSER: He has not sued Dr. Myerburg or  
4 Dr. Feldman, no, nor does he have to, of course.

5 MR. CARPENTER: Your Honor, ten seconds. I  
6 find it amazing that Mr. Lesser tries to make an issue  
7 of causation fact as to what Dr. Clasby would have done  
8 and what device he would have chosen had he been given  
9 the facts. It was the doctor's decision. Dr. Clasby  
10 was completely unconscious from the time he passed out  
11 on the tennis course until after the device was in his  
12 chest. He played no role whatsoever in the selection of  
13 this device. It is completely counterfactual for Mr.  
14 Lesser to say that. It was the EP's decision, having  
15 the materials given to him by Guidant. Thank you, Your  
16 Honor.

17 MR. LESSER: I don't have to respond because  
18 the point is, this is so -- first of all, it is not  
19 true. And I will let Mr. Shkolnik address it since he  
20 handled the deposition.

21 MR. SHKOLNIK: Your Honor, I did the  
22 deposition last week. Dr. Clasby was treated at one  
23 hospital. Dr. Feldman, who was his cardiologist  
24 assigned to that hospital, I believe it was Miami  
25 Baptist -- Miami Hospital, one of them. He made

1 arrangements with Dr. Myerburg, his mentor, at Jackson  
2 University of Miami. They transferred him. He was  
3 awake. It was days, if not weeks later, where he was  
4 evaluated by Myerburg who is being deposed next week in  
5 Miami. Myerburg then brings in Dr. Interian, who was  
6 the actual EP who implanted. We have not heard from  
7 either Interian or Myerburg. And he was certainly  
8 awake. He had come out of his coma after the heart  
9 attack and he transferred to a completely different  
10 institution for the implanting of the device.

11 MR. LESSER: In short, Your Honor, are there  
12 issues of fact? I think so.

13 THE COURT: Mr. Carpenter?

14 MR. CARPENTER: Your Honor, that issue of  
15 fact doesn't matter, and I don't think it is right. I  
16 will check up on that.

17 THE COURT: All right.

18 MR. CARPENTER: It is irrelevant that the EP  
19 made the decision.

20 THE COURT: I will just make the observation,  
21 MDL or non-MDL aside, it is maybe one of five cases out  
22 of hundreds I have heard where this kind of discovery  
23 is, by agreement, done after dispositive motion  
24 deadlines. And I will predict that apart from any  
25 decision I make, I am going to be hearing, either

1 before, during or after a decision I make, the right to  
2 reconsider or supplement or do something, because it  
3 looks to me like there is a couple of people here  
4 that -- people are going to be chatting with, one  
5 already.

6 In any event, I will deem this matter  
7 submitted and we will play the hand out. We can move on  
8 to the next motion, unless I inadvertently cut somebody  
9 off, here.

10 MR. CARPENTER: Your Honor, why don't we  
11 address next the Clasby choice of law motion?

12 THE COURT: Is that agreeable with --

13 MR. HARKE: Yes, it is.

14 MR. LESSER: Before we start?

15 Lance Harke, who is Dr. Clasby's original  
16 attorney, who is also on the Plaintiffs Steering  
17 Committee, will be addressing this. I'm not sure he has  
18 been introduced to the Court so far in this litigation.

19 THE COURT: Good afternoon. I assumed that  
20 is who you were. I would have gotten around to asking  
21 you, but, all right.

22 MR. CARPENTER: Choice of law in the Clasby  
23 case. In the context of the Duron motions, we made a  
24 lot of progress on this issue, we decided the law of the  
25 forum state's choice of law rules apply, and that the

1 forum state is the case -- from which the case was  
2 originally transferred from. And this case, that is  
3 Florida. We can go ahead and stick to the point, we  
4 know that Florida's choice of law rules apply. Florida  
5 follows the significant relations test as set forth in  
6 the Restatement Second of the conflicts of laws. It is  
7 the exact same test followed by the Federal Courts, as  
8 employed by the Eastern District of Louisiana in the  
9 Vioxx cases. And as a result, I think the Vioxx  
10 analysis is extremely persuasive in this case.

11 The significance relation test focuses first  
12 on determining which states' contacts with the case are  
13 most prevalent, and then looks at a series of different  
14 contacts and interests analysis to determine which  
15 contacts are most significant.

16 The contact at issue under the significant  
17 contacts relationships test are the place where the  
18 injury occurred; number two, the place where the conduct  
19 causing the injury occurred; and number three, the  
20 domicile and residence of parties; and number four, the  
21 place where the relationship between the parties was  
22 centered.

23 Principles that determine which states'  
24 contacts and interests are most significant include the  
25 needs of the interstate system, the relevant policies of

1 the forum, the relevant policies and interests of the  
2 other states, the protection of justified expectations  
3 of the parties, the basic policies underlying the laws,  
4 the certainty, predictability of results, and ease in  
5 determination.

6 THE COURT: And how, if at all, do they  
7 differ in your view from the California?

8 MR. CARPENTER: Excellent question.  
9 California applies an interest impairment analysis,  
10 which is one small subpart of the spectrum that the  
11 forum looks at.

12 Number two, Florida under the significant  
13 relationships test applies a bunch of important  
14 presumptions. Under Florida law, there is a powerful  
15 presumption that the law of the state where the injury  
16 occurred should apply. That is Florida.

17 There is a strong presumption, you have got  
18 to show a substantial evidence that another states' law  
19 has a more compelling interest. In addition,  
20 Restatement 148, also part of that significant  
21 relationships test, presumes that where fraud and  
22 misrepresentation claims are in issue, the law of the  
23 state where the alleged reliance on these  
24 misrepresentations or fraud will control, absent a  
25 strong showing to the contrary.

1           Finally, this choice of law system also  
2 provides a strong presumption of lex loci contractus,  
3 absent a strong showing to the contrary, the law of the  
4 state where the contract was made is going to apply.

5           Plaintiffs have a powerful burden of showing  
6 that Minnesota's interests strongly outweighs Florida's  
7 in this case, which is different in California law.  
8 There was no such presumption in that case.

9           The next question is, what cause of action  
10 are we really fighting about in this case? What outcome  
11 determinative conflicts are there? Plaintiffs concede  
12 there is one, negligent infliction of emotional  
13 distress. Florida really doesn't recognize that as a  
14 separate cause of action, per se, it is more of a  
15 parasitic cause of action where you have to show  
16 resulting substantial physical injuries such as stroke  
17 or death. Minnesota does not require that.

18           There is probably a conflict in implied  
19 warranty, Florida requires privity in order to recover.  
20 Minnesota does not. There's, I think, some other  
21 differences. Clearly the consumer protection schemes  
22 are markedly different. Is it outcome dispositive?  
23 Hard to say at this point. The Plaintiffs don't seem to  
24 really be fighting about that. They have responded in  
25 terms of Florida's application of law to our Motion to

1 Dismiss the Florida Deceptive and Unfair Trade Practices  
2 Act, so they pretty much conceded that. So, I want to  
3 focus on negligent infliction of emotional distress and  
4 implied warranty privity aspect.

5 The first question is which state has got the  
6 most significant contacts with this case? Florida, no  
7 doubt about that. Florida is the place where the injury  
8 occurred. Nobody denies that. Florida is the place  
9 where the alleged misrepresentations or nondisclosures  
10 were relied upon. Florida is also the place where the  
11 relationship between the parties is centered.

12 This Court need look no further than the  
13 Vioxx case, the Blaine -v- SmithKline case, the Rowe  
14 case defined that where a -- and we talked about this  
15 last time in the context of the Duron case. Where a  
16 product is marketed nationally, a medical prescription  
17 product, the place where the relationship is centered,  
18 where the injuries take place, and where most of the  
19 conduct-causing injury happens is the state where it is  
20 prescribed and used, and the injury takes place. That  
21 is Florida in this case, Dr. Clasby's own state.

22 The place where the conduct allegedly causing  
23 the injury, that is also primarily Florida. Now,  
24 Plaintiffs have always tried to emphasize that Minnesota  
25 is the focus of Defendants alleged misconduct in this

1 case. We pointed this out in the Duron case, and it is  
2 equally applicable in this case, as well. There is no  
3 evidence that all of the alleged facts that they claim  
4 Defendants wrong took place in Minnesota.

5 As a matter of fact, we have disproven that  
6 fact. Dr. Clasby's device, its header, as well as  
7 important parts of it -- the header is what is at issue  
8 in these cases, Your Honor, it's made in Ireland, not in  
9 Minnesota. It was tested there. A lot of other  
10 important tests were done there. To the extent  
11 Plaintiffs are claiming misrepresentations,  
12 nondisclosures, we have all known for quite some time  
13 that Guidant's sales Corporation is centered out of  
14 Indiana, not Minnesota. And we have also known that  
15 Guidant's sales force is on the ground in all 50 states.  
16 They interact with EP's on a regular basis, and it is  
17 not confined to Minnesota.

18 So, to the extent Plaintiffs are going to  
19 claim that this is a Minnesota centered case just  
20 because Guidant is headquartered, or CPI is  
21 headquartered in Minnesota, absolutely misleading and  
22 not really dispositive. And as we will point out later,  
23 not really the important focus of the contacts in this  
24 case.

25 It brings us to the next question, which

1 state has the most significant relationships with the  
2 issues in this case based on these contacts? It is  
3 Florida.

4 First of all, you have to look at the  
5 relevant policies of the forum state. Why does Florida  
6 care about having its laws applied in these contacts?  
7 Well, first of all, Florida has made a conscious  
8 decision in the context of warranty that it has through  
9 you the West -v- Caterpillar adopted strict liability in  
10 torts, superseding the outmoded warranty claims that are  
11 the basis of that strict liability doctrine.

12 Florida in West -v- Caterpillar was very  
13 explicit, saying that states is going to make a decision  
14 that cases involving physical injury from products will  
15 be governed under strict liability. And strictly  
16 financial contract claims are going to be governed under  
17 contract law. And those require privity of contracts.

18 If I could indulge the Court, the Florida  
19 court in Affiliates for Evaluation, 500 So.2d 688 at  
20 page 691 explains why Florida has made a conscious  
21 policy decision to require that contractual recovery be  
22 based on actual contracts requiring privity.

23 The distinction rests on an understanding of  
24 the nature of the responsibility a manufacturer must  
25 undertake in distributing its product. He can

1 appropriately be held liable for physical injuries  
2 caused by defects, requiring his goods to match a  
3 standard of safety defined in terms and conditions that  
4 created unreasonable risks of harm, strict liability.

5           He cannot be held for the level of  
6 performance of his products in the consumer's business,  
7 i.e. financial injury, unless he agrees that the product  
8 was designed to meet the consumer's demands. In other  
9 words, Florida has made a conscious policy decision not  
10 to allow people to recover contractual financial damages  
11 unless there is a real contract, i.e. privity, a real  
12 relation and an actual understanding, meeting of the  
13 minds as to that level of product performance.

14           It doesn't think the defendants should be  
15 liable for that, it doesn't think people should be able  
16 to recover for that. It is a very conscious policy  
17 decision. The same is true regarding Florida's  
18 restrictions on negligent infliction of emotional  
19 distress.

20           There are many cases in Florida recognizing  
21 the speculative, difficult to prove nature and  
22 problematic nature of these kinds of esoteric claims.  
23 And Florida, very explicitly has rejected them in the  
24 absence of the present physical injury requirement that  
25 lends some element of reliability to them.

1           In the Humana, the R.J. -v- Humana of Florida  
2 case, the Court discussing the physical impact rule  
3 explained why. As explained by one commentator, the  
4 underlying basis for the rule is that allowing recovery  
5 for injuries resulting from purely emotional distress  
6 would open the floodgates for fictitious or speculative  
7 claims.

8           It goes on to point out, as this Court has  
9 stated in Saunders, compensatory damages for emotional  
10 distress are spiritually intangible, are beyond the  
11 limits of judicial action, and should be dealt with  
12 through legislative action, rather than through judicial  
13 decisions.

14           Another commentator has stated that the  
15 requirement of a physical impact gives courts a  
16 guarantee that an injury to the plaintiff is genuine.

17           Further, without an impact requirement,  
18 defendants would not be sure whom they had injured or  
19 where they may have injured a person, thus paralyzing  
20 their ability to defend themselves.

21           My point, Your Honor, is not whether  
22 ultimately at the end of the day we think that is a  
23 great rule, bad rule, the point is that Florida has well  
24 considered it. Florida courts have decided that they do  
25 not want people in Florida to be able to make these

1 types of claims, contract claims without privity,  
2 emotional distress claims without physical damages, and  
3 they don't want businesses that do business in Florida  
4 to be subjected to these kind of claims. Florida has a  
5 substantial interest based on these cases in applying  
6 its version of negligent infliction of emotional  
7 distress, and privity of contract to these claims.

8           The second interest factor is the policies  
9 and interests of the other state. In this case it is  
10 Minnesota. And I submit to the Court that Minnesota has  
11 little to no interest in applying its version of implied  
12 warranty or negligent infliction of emotional distress  
13 to this case.

14           Again, I point the Court to the Minnesota  
15 Supreme Court's decision in the Jepsom case. The Court  
16 remembers that was the case in which the plaintiff tried  
17 to take advantage of Minnesota law where he could not  
18 recover under Wisconsin law. And the Court pointed out  
19 that it has got no interest in letting people forum shop  
20 and try to take advantage of Minnesota's more expansive  
21 laws to recover the things that they couldn't recover in  
22 the places where the contract was made. That is true in  
23 this case.

24           In addition, I would ask the Court to look at  
25 the Nodak case, in which the Minnesota Supreme Court

1 notes after going through Minnesota's choice of law  
2 analysis, that all things being equal, Minnesota has  
3 basically got an interest in having the state where the  
4 accident occurred apply its laws to govern the claims.  
5 So, Minnesota really does at the end of the day kind of  
6 come out the same place where the Florida presumption  
7 does.

8           The third significant interest is the  
9 protection of justified expectations. Again, the Jepsom  
10 case is instructive. Dr. Clasby had this device  
11 implanted in Florida by a Florida EP. It was explanted  
12 in Florida for whatever reasons. Clearly, to the extent  
13 there were any expectations that some state's law would  
14 govern these claims, it was Florida. There's no  
15 indication that Dr. Clasby had any idea that Guidant was  
16 a Minnesota company and that Minnesota law would govern  
17 his claims. So, to the extent that factor is relevant,  
18 it clearly favors the application of Florida law.

19           THE COURT: So, if not in this context, the  
20 MDL aside, just Dr. Clasby's cause of action, if not in  
21 this context, if Minnesota is a state that has some  
22 interest in regulating how corporations who make such  
23 devices behave and conduct business, how does Minnesota  
24 effectuate that? Because you are saying it isn't this  
25 way. Florida has a substantial interest, not Minnesota.

1 So, where would they -- where would that policy decision  
2 by Minnesota -- where would they do it if not here?

3 MR. CARPENTER: Sure, there are a lot of ways  
4 they would do it. First of all, I think it is important  
5 to point out that these causes of action are not  
6 regulatory. The purposes behind these causes of action  
7 are compensatory.

8 THE COURT: That is true.

9 MR. CARPENTER: We are talking about contract  
10 and we are talking about a tort claim. That is not the  
11 primary purpose of these causes of action.

12 Number two, I would say that in this context,  
13 Guidant is heavily regulated already. The FDA is a  
14 severe watchdog over these types of issues. And I would  
15 submit that Minnesota doesn't necessarily have any  
16 interest in the situation where the FDA is already all  
17 over the case in applying its laws to a Minnesota  
18 corporation.

19 Third, I would point out that this is in the  
20 context of an MDL. There will be -- I was just in Judge  
21 Leary's courtroom yesterday. There are plenty of  
22 Minnesota individuals ready to apply Minnesota law to  
23 vindicate these issues. It doesn't have to be a Florida  
24 resident who carries the banner for this issue. These  
25 cases have not escaped attention and this will be

1 indicated at some point. This is not the proper case to  
2 do it. So, even if Minnesota were not to apply its laws  
3 to Guidant's behavior in this case, clearly it is going  
4 to be applied at some point. Not so therefore,  
5 Minnesota's interests will not be denied in the larger  
6 scheme of things. I think that is an important  
7 distinction.

8 I also think it is important for the Court to  
9 look at, I believe it is, the Foster -v- St. Jude case  
10 in which Judge Kyle in addressing the propriety of the  
11 proposed transaction on ICD's points out that under  
12 choice of law rules, he clearly would apply the law of  
13 the state for the device is implanted, not the law of  
14 Minnesota or the state where the device was  
15 manufactured.

16 So, I think there is strong, persuasive  
17 authority that maybe Minnesota might have some vestigial  
18 interest because there is a Guidant connection, but it  
19 is not a big interest. And it is certainly outweighed  
20 by Florida's interests in this case over its resident,  
21 conduct that happened in Florida, an action that  
22 happened in Florida, damages that happened in Florida.

23 The next issue to consider in the interest  
24 analysis is the basic policies underlying the laws. I  
25 think I just touched on that. These are compensatory

1 causes of action, not regulatory. Therefore, the state  
2 where the individual resides has a much stronger  
3 interest in seeing to what extent and in what limits the  
4 individual should be compensated.

5 Finally, the last two parts of the  
6 significant analysis test is the certainty of results  
7 and the better rule of law. Those are rarely relied on.  
8 I don't think either one is particularly dispositive or  
9 helpful in this case. I think they are a wash, at best.

10 In conclusion, Your Honor, Florida has  
11 clearly got more significant contacts with the facts of  
12 this case. Florida clearly has more interest in  
13 applying its version of negligent infliction of  
14 emotional distress, and implied warranties, privity  
15 requirement. Florida law has strong presumptions that  
16 absent a powerful showing to the contrary, the place  
17 where the accident took place, the place where the  
18 contract was made, and the place where the  
19 representations were relied upon will apply.

20 I think Florida law applies, Your Honor.  
21 Thank you.

22 THE COURT: Thank you.

23 Good afternoon.

24 MR. HARKE: Good afternoon. Thank you, Your  
25 Honor. Although Mr. Lesser introduced me, I would like

1 to introduce myself, since it is my first time in front  
2 of the Court.

3 THE COURT: It seems like the right thing to  
4 do.

5 MR. HARKE: My name is Lance Harke. I am a  
6 Miami attorney and I am a member of the PSC. And I am  
7 privileged and honored to be in front of Your Honor.  
8 Professor Clasby, who is my client, has two children,  
9 both daughters. His oldest daughter, Allison, is my  
10 wife. We met in law school.

11 She practices with me and we have four young  
12 boys that she also raises.

13 THE COURT: I have five daughters, so that  
14 would be quite a mix.

15 MS. MOELLER: The Brady Bunch.

16 THE COURT: I have two sets of twins that  
17 complicates things.

18 MR. HARKE: Well, I'm not done yet. My --

19 MR. LESSER: Your Honor? May I? I have four  
20 daughters, and I am thinking if these four are anything  
21 like their dad, I'm hoping, to get away.

22 MR. HARKE: Professor Clasby's youngest  
23 daughter is my law partner, Sarah. And she has two  
24 young twin daughters. So, when Mr. Carpenter talks  
25 about Professor Clasby seeing a lawyer, there is no one

1 else for him to see. His wife is a professor of English  
2 also at the University of Miami, so he could call either  
3 one of his two daughters who practice with me, or he  
4 could call me. Whoever he calls, he is likely to call a  
5 lawyer if he has a question about something that is  
6 happening in the newspapers.

7 I am a history buff, so I appreciated your  
8 footnote with regard to the bellwethers.

9 THE COURT: Bellwether?

10 MR. HARKE: And I think that the Duron Choice  
11 of Law Order actually answered a lot of the questions  
12 with regard to Professor Clasby's case. And I don't  
13 disagree with a lot of what Mr. Carpenter said.

14 As Your Honor already held, Florida conflict  
15 of law rules are going to govern this case. We agree  
16 there is no outcome determinative conflict with regard  
17 to Florida and Minnesota law with regard to all of the  
18 claims with the exception of the breach of the implied  
19 warranty claim, which is Count 5, and the negligent  
20 infliction of emotional distress claim, which is Count  
21 10.

22 So, with regard to all of the other counts,  
23 the personal injury counts, which are Counts 1 through 4  
24 and 11 through 12 of the Amended Complaint by adoption.

25 The fraud and deceit claims, which are Counts

1 6 through 9, and the unjust enrichment count, which is  
2 Count 17, there is no issue. So, we are only left at  
3 this point with two counts. And Your Honor has, I  
4 think, already provided a roadmap through the prior  
5 order with how to handle those two counts. And I don't  
6 want to belabor very much of this at this point.

7           With regard to the negligent infliction of  
8 emotional distress, that is Count 10. Both Florida law  
9 and Minnesota law require proof of physical  
10 manifestation of impact. There is no conflict there.  
11 And we don't dispute what Mr. Carpenter says. And  
12 historically, the reason why that is the case and why we  
13 will also get to the implied warranty is Florida, like a  
14 lot of these emerging jurisdictions that arose during  
15 the early 20th century, during the Lockner era when the  
16 railroads were coming into states like Arizona and  
17 California, Florida there was a concern that there not  
18 be an economic impediment to the development of the  
19 industries in these areas. And courts at different  
20 times impose requirements like the kind we are talking  
21 about here today. But, there is no conflict between  
22 Florida and Minnesota law with regard to the physical  
23 manifestation --

24           THE COURT: Now, I think Mr. Carpenter was  
25 suggesting, and actually my recollection, actually,

1 would suggest that there is a physical manifestation  
2 required in Minnesota.

3 Now, you concede that, but I think Mr.  
4 Carpenter just got up and said he believes there is a  
5 conflict, namely that Florida requires that Minnesota  
6 does not.

7 Mr. Carpenter, am I right about that, that  
8 your view is Minnesota does not require -- I know I am  
9 interrupting counsel's argument, but does not require --

10 MR. CARPENTER: Your Honor, I would have to  
11 check my notes. I know that Florida, at least,  
12 requires -- I think Minnesota has some level of physical  
13 manifestation. Florida's is much more severe, death,  
14 paralysis, or something like that. So, I think there is  
15 a conflict to that extent.

16 Frankly, I agree there may not be a conflict  
17 because I don't think Dr. Clasby can prove either, but  
18 to the extent there is, Florida is more stringent.

19 THE COURT: All right.

20 MR. HARKE: I don't know anything about  
21 Minnesota's physical manifestation of impact, however  
22 Your Honor concluded in the Duron Order that Minnesota  
23 has that requirement. I do know about Florida's  
24 physical manifestation rule, and I think we more than  
25 abundantly meet that with regard to the implantation,

1 the explanation, the second explanation, the removal of  
2 the leads.

3           There is no question under Florida law that  
4 there exists necessary facts for meeting that particular  
5 requirement, although that is not what is before you at  
6 this moment. Like California in the Duron case, Florida  
7 courts have in the past held that the negligent  
8 infliction of emotional distress claim is parasitic, and  
9 rather than independent. I think that might be a  
10 distinction without a difference here because, you know,  
11 it is our belief that we have more than a sufficient  
12 number of ancillary tort and statutory claims to support  
13 an additional claim for negligent infliction, even under  
14 Florida law.

15           I can tell you again that parasitic, and the  
16 courts that talk about the parasitic nature of those  
17 claims are older courts that were dealing again with  
18 concerns about the development of the railroads and  
19 other industries in the state of Florida. In the last  
20 30 or 40 years, many, many Florida courts, and we have  
21 cited to a bunch of them, just talk about that cause of  
22 action without any discussion about whether it is  
23 parasitic, or an independent tort. So, I don't know  
24 whether for purposes of choice of law it makes any  
25 difference, really.

1           So, our view, though, Judge, because there is  
2 no real difference, they both require proof of physical  
3 manifestation, there might be an issue about whether it  
4 is parasitic under Florida law, where it is independent  
5 under Minnesota law, we believe that your analysis in  
6 Duron should until apply, which was based on the  
7 Governmental interest test. Although, you will see that  
8 if you look at the restatement, that is a significant  
9 interest. That is a significant interest, as well as  
10 the place where the device was manufactured, and the  
11 corporation of the Defendant.

12           Your Honor already ordered on page 12 of the  
13 Duron Order that this was a rare instance where Guidant  
14 is in Minnesota and it was a very unique fact, also on  
15 page 12, in your footnote 5, that Guidant is located in  
16 the state where the MDL court sits, and the fact that  
17 the device at issue was manufactured in Minnesota.

18           So, with regard to negligent infliction, we  
19 would contend that Minnesota's overriding interest  
20 should apply, irrespective of whether or not you used  
21 the Restatement or you used the governmental interest  
22 test to reach that conclusion.

23           We all know that these things are mostly  
24 results oriented, anyway. Courts highlight particular  
25 factors based on which interest they consider to be more

1 important at the time.

2 With regard to the other open issue, the  
3 breach of implied warranty, that is Count 5. Again, as  
4 Your Honor concluded in the Duron Choice of Law Opinion,  
5 like California, Florida requires privity, so that is  
6 the same as Duron, whereas Minnesota does not.

7 And again, applying that most significant  
8 relationships test, Section 145 lists the various  
9 factors. We think the same analysis that the Court  
10 employed in Duron should be employed here.

11 Your Honor analyzed those interests at pages  
12 9 and 10, both states have a legitimate interest, but  
13 Minnesota, again, is the location where the device at  
14 issue was manufactured. Your Honor concluded in the  
15 Duron case that Minnesota's laws would be more  
16 significantly impaired. And we think that, again,  
17 whether you use the governmental interest test, you use  
18 the Restatement, Your Honor should reach the same  
19 conclusion with regard to Professor Clasby's device.

20 If you look at the other factors of Section  
21 145, they also weigh in favor of Minnesota. You have  
22 got, Guidant is culpable of illegal corporate activity,  
23 which we argue occurred in Minnesota. The device was  
24 designed, manufactured, quality checked, sold out of  
25 Minnesota. Minnesota's location of the headquarters,

1 principal place of business is in St. Paul, all of the  
2 same factors that Your Honor already concluded with  
3 respect to Duron should reach the same result here.

4 THE COURT: Thank you.

5 MR. HARKE: Thank you, Your Honor.

6 THE COURT: A brief rebuttal if you would  
7 like, Mr. Carpenter?

8 MR. CARPENTER: Thank you, Your Honor. The  
9 only thing I have to say in response to that is, no, the  
10 device was not designed, manufactured, quality checked  
11 out of Minnesota. Most of the parts that are at issue  
12 were done in Ireland. They keep stating that, that it  
13 is still not true.

14 I do want to clear up an issue from the last  
15 round of argument about Dr. Clasby's causation issue.  
16 Dr. Clasby testified that he does not remember anything  
17 between when he experienced ventricular fibrillation on  
18 the tennis court and when he woke up in the hospital  
19 after he had already received his PRISM 2. Clasby  
20 Deposition, transcript page 136, lines 4 to 23; 138,  
21 lines 12 to 22. That is at page 104 of our brief, Your  
22 Honor.

23 THE COURT: Thank you.

24 MR. CARPENTER: Thank you.

25 THE COURT: Ms. Moeller?

1 MS. MOELLER: Almost done, Judge.

2 THE COURT: I heard you -- I don't know who  
3 said Mueller (PH), and I heard you say, Moeller.

4 MS. MOELLER: You heard me? I thought I was  
5 speaking more softly than that. I apologize for that,  
6 Judge. It was actually my husband and not me, anyway.

7 THE COURT: Well, I knew that. I thought that  
8 is why you expressly said it.

9 MS. MOELLER: It was, actually, it was.

10 THE COURT: All right.

11 MS. MOELLER: Judge, this is our motion to  
12 dismiss based on no malfunction and no injury.

13 THE COURT: If I may stop you, did you want  
14 me to wait?

15 MR. HARKE: No, we are ready.

16 THE COURT: All right. I don't object to  
17 anybody coming and going, I just want to make sure if  
18 they are saying, well, they are starting quicker than we  
19 thought, so we are missing -- okay, we are fine.

20 MR. HARKE: We just changed seats.

21 MS. MOELLER: And actually, a lot of the  
22 factual support that I am going to be speaking of, you  
23 have all addressed briefly in the failure to warn  
24 motion, so I will try to cut down my argument so that we  
25 can get out of here. I do want to point out some of the

1 factual differences between Professor Clasby's case and  
2 Mr. Duron's case as it relates to this motion and as it  
3 relates to the ruling that you have in Mr. Duron's  
4 Motion.

5           One of the most significant differences, of  
6 course, is that Professor Clasby's device has never been  
7 subject to any FDA recall or FDA notice or FDA advisory.  
8 It is not subject to the same Class 1 recall as the  
9 device which Mr. Duron received.

10           Professor Clasby's device was manufactured  
11 after April of 2002 in which there was a manufacturing  
12 change that later was determined to have ameliorated the  
13 arcing problem, virtually eliminated it in that  
14 population of devices.

15           Now, the Plaintiffs are going to try to say,  
16 you will hear them say later today that they are going  
17 to try to make Professor Clasby's device fit within that  
18 prior population by saying it doesn't show that there is  
19 the design -- the change that was in April of 2002.

20           We dispute that, but for purposes of this  
21 motion, that doesn't matter. So, we will get to that,  
22 Judge, but I don't want you to be led astray by that  
23 argument by them. What the Plaintiffs are asking the  
24 Court to allow is a cause of action for a perfectly  
25 functioning device that the Plaintiff mistakenly

1 believed was recalled. I mean, that is what all of  
2 these facts boil down to, Your Honor, is that they want  
3 to extend a cause of action for Professor Clasby,  
4 despite the fact that he had a device that functioned  
5 within his body perfectly fine, functioned appropriately  
6 during the entire period of time he had it. It never  
7 malfunctioned, it never arced, it was not subject to  
8 polyimide degradation. There was nothing about his  
9 device. There was nothing wrong about his device that  
10 led to his decision to have it taken out.

11 So, this is much different than in the Larson  
12 case where the decision to recall was forced upon the  
13 plaintiff because of the recall in that decision, as you  
14 said. The facts are just nowhere near that scenario.

15 Mr. Carpenter pointed it out earlier, but  
16 this device, unlike Mr. Duron's device, was called upon  
17 to fire, to have a shock during the period of time it  
18 was implanted in Mr. Clasby. Now, it turns out that  
19 shock was not a life-saving shock, it was what the  
20 industry terms an inappropriate shock. But, in a  
21 counter-intuitive way, an inappropriate shock actually  
22 demonstrates that the device is working appropriately,  
23 because it is firing at the level that the physician has  
24 programmed it for that particular patient. And the fix  
25 for that is usually relatively easy. The physician can

1 simply reprogram the device to a lower arrhythmia  
2 setting, to a lower heart rate setting, and that in most  
3 instances will take care of inappropriate firing. But,  
4 as Andy pointed out, that is a well-known,  
5 well-accepted, and in fact desired risk of these  
6 defibrillators. Because physicians would much rather  
7 have a device that fires when it is not necessary, than  
8 one that doesn't fire when it is necessary.

9           So, that is something that since the  
10 inception of these devices has been known and accepted  
11 with this. And it is not only not a malfunction, it is  
12 proof that the device is functioning appropriately for  
13 that person. So, there was nothing about the device  
14 while it was implanted, nothing wrong with the device  
15 while it was implanted in his body that led to the  
16 explant.

17           Now, I didn't realize until we got here that  
18 the Plaintiffs were going to dispute that the device was  
19 being explanted due to a mistaken belief that it was  
20 recalled. They were the ones that had chosen to depose  
21 Dr. Feldman. And really, it doesn't matter what the  
22 decision is, if it was because the device was  
23 inappropriately shocking, or whether it was due to the  
24 mistaken belief of recall. There is nothing about the  
25 device, per se, that led to this decision. This was a

1 voluntary decision at some level, whether it be mistaken  
2 about the recall, whether it be because he wanted to  
3 have it taken out by the inappropriate shocks, any of  
4 those reasons have nothing to do with anything wrong  
5 with the device. There is no defect that was harmful  
6 that led to the explant decision.

7           And let's talk a little bit about the explant  
8 decision, because you actually noted this a little bit  
9 earlier, Your Honor. And it is a little bit  
10 interesting, the timeline. Professor Clasby was  
11 actually one of the first individuals in the country  
12 that filed a lawsuit against this company in the summer  
13 of 2005. And as you pointed out, he waited almost a  
14 year later until May of 2006 to have his device taken  
15 out of him.

16           Coincidentally, that coincided with the  
17 beginning of the bellwether selection process. But  
18 regardless of that, there was, unlike the Duron case,  
19 there was a significant delay in him determining to have  
20 his device taken out.

21           Plaintiffs point to four alleged defects in  
22 their brief as evidence of why this -- our motion should  
23 fail. And those are really red herrings, because under  
24 Florida law, evidence of defect, alone, is  
25 inconsequential. It has to be harmfully defective. And

1 there is a good quote, actually in the Hartman versus --  
2 and I don't know how to say this, Opelika case which  
3 Plaintiffs actually cite on page 97 of their brief.

4 An if you go to page -- it is 414 So.2d 1105,  
5 and I'm going to pages 107, carrying over to 108.  
6 Following the quote that the Plaintiffs cite in their  
7 brief, it goes on, as Professor Wade has observed, and  
8 this is a treatise on the nature of strict liability for  
9 products.

10 A product may be defective and still not be  
11 likely to cause injury. An automobile, for example, may  
12 have something wrong with the ignition, so that it will  
13 not start properly, or the clock or the radio may not  
14 work correctly. If so, it is obviously defective, but  
15 it is not harmfully defective. And that is the key  
16 under Florida law, that there has to be a harmful  
17 defect.

18 And Professor Clasby's device simply does not  
19 contain a defect that is potentially harmful to him. He  
20 has not been harmed, or there is nothing about his  
21 device that puts him at any kind of increased risk. If  
22 you look at the post-April devices, of which Mr. Clasby  
23 received, the risk of an arcing failure is .009 percent.  
24 That does not represent any increased risk to him than  
25 the underlying failure rate that occurs with all of

1 these devices. It's substantially lower than both what  
2 was predicted to FDA, and what the company had -- what  
3 the company's standard was. In fact, this was one of  
4 the most reliable devices the company has ever made.  
5 And it the post-April devices, the specific risk of the  
6 arcing failure is only .009 percent.

7           The first of the four quote, unquote, defects  
8 which for purposes of this motion we disagree with, but  
9 is simply the -- and they are careful about the way they  
10 phrase it, Judge, and there is a reason for that. And  
11 they say the decision to use polyimide in the product,  
12 that is a red herring for several reasons.

13           First of all, in Mr. Armstrong's report,  
14 which is now part of the record, he concedes that the --  
15 that Mr. Clasby's device on explanation had no polyimide  
16 degradation. It had not degraded. Even had -- and it  
17 doesn't really matter, because polyimide degradation,  
18 alone, is not sufficient to cause the arcing failure.  
19 There are multiple things that have to come together.  
20 We call it in our brief, triple redundancy. And it is a  
21 design concept that is well known. So, you can't look  
22 at any one of those -- polyimide, in and of itself when  
23 it is fully functional, as it was in Mr. Clasby's  
24 device, Mr. Carpenter said five times the dielectric  
25 strength -- it is actually ten times the dielectric

1 strength. He was being conservative. But, it was  
2 sufficient to withstand the amount of energy that goes  
3 through the wire at that location.

4 THE COURT: You know that is quite a  
5 diplomatic way to say your partner made a mistake.

6 MR. CARPENTER: I was wrong.

7 THE COURT: I will remember that, being  
8 conservative.

9 MS. MOELLER: Anyway, the -- again, the next  
10 two we dispute, the next two are also -- they say no  
11 space, that there is no evidence of the April 2002  
12 change. Those are essentially the same argument. And  
13 polyimide, alone, is sufficient in those instances, as I  
14 just stated.

15 And more than that, there is nothing, as Mr.  
16 Carpenter pointed out earlier, anytime you are going to  
17 take something out of the body, look at it and pull it  
18 apart, it is not surprisingly that you could find  
19 something that might not be exactly ripe, but it doesn't  
20 matter if there is a quote, unquote, defect which we're,  
21 for purposes of this motion, only talking about.

22 It has to be harmfully defective. And there  
23 is nothing about the post-April devices, the type of  
24 device that Mr. Clasby got that put him in an increased  
25 risk, had a propensity to fail, was anything different

1 than any of the other devices that were being marketed,  
2 and the reliability of other devices.

3           This was not a situation like Mr. Duron's  
4 where he was concerned because of a Class 1 recall and  
5 what those words said and how he interpreted those. And  
6 if he did, it is a mistake, because his device clearly  
7 was not on the recall list. As you pointed out, when a  
8 healthcare provider, we don't know who it was, called  
9 Guidant, the correct information was provided to them.  
10 Guidant has a look-up tool where you can insert  
11 someone's serial number and determine whether or not it  
12 is on the recall list. So, there are many avenues, and  
13 especially by that time there had been litigation for  
14 over a year, and there had been -- there were many  
15 avenues to get that correct information.

16           So, just to shorten up, what they are asking  
17 is an extension of the law that no one else has  
18 recognized. It would really open up a Pandora's box of  
19 frivolous litigation if you allow someone who gets a  
20 device with a higher liability, actually, than what was  
21 anticipated, that had evidence of working appropriately  
22 during the period of time that it was implanted, was not  
23 subject to any recall, and there was no reason related  
24 to that device at any level that led to the decision to  
25 have it taken out. And so, for all of those reasons,

1 Professor Clasby's case is different than Mr. Duron's  
2 case. And summary judgment should be entered in  
3 Defendant's favor on this issue.

4 THE COURT: Thank you. Whenever you are  
5 ready?

6 MR. HARKE: Thank you, Your Honor. I got a  
7 little lost. I wasn't positive what issues, exactly, we  
8 were talking about. Ms. Moeller argued a number of  
9 different things. But, I think we were supposed to be  
10 arguing the no injury due to a lack of malfunction.  
11 And, you know, Your Honor has already ruled with regard  
12 to the supplemental expert report of Mr. Armstrong. And  
13 that, coupled with Your Honor's June 12th, 2007 Order, I  
14 think, really lays the ground work for analyzing  
15 Professor Clasby's case.

16 THE COURT: So I guess, then the real issue  
17 becomes, which I am quite certain is where you are  
18 headed is, well, are there distinctions to be made as  
19 suggested by Ms. Moeller that would send me the other  
20 way.

21 MR. HARKE: A different direction, right.  
22 And the distinction that Ms. Moeller referred to is the,  
23 you know, lack of a Class 1 recall with regard to  
24 Professor Clasby's device.

25 And, you know, I have read your June 12th

1 order many, many times, now. And although Your Honor  
2 references the existence of a Class 1 recall with regard  
3 to Mr. Duron's device, at no point does Your Honor rely  
4 on that, standing alone, as being some sort of legal  
5 standard by which you could determine whether or not an  
6 injury has occurred or whether or not there has been a  
7 design defect or whether or not there has been a  
8 malfunction.

9 THE COURT: That is true.

10 MR. HARKE: Your Honor analyzes the facts of  
11 Mr. Duron's case very carefully based on certain  
12 predicate facts, and then you apply the law to those  
13 facts later on in your opinion. And as a substantive  
14 manner, particularly when you read Mr. Armstrong's  
15 supplemental report, those facts are identical. The  
16 label of the Class 1 recall is different. You know,  
17 Guidant gave it a euphemistic, or I would perhaps  
18 suggest an Orwellian phrase that Professor Clasby's  
19 device was subject to a supplemental warranty program.  
20 That is what their website says when you punch in his  
21 number. Those labels, to me, aren't significant. And I  
22 don't think the law makes a distinction based on those  
23 labels.

24 The fact of the matter is that both parties  
25 agree and Mr. Armstrong's report references it. Mr.

1 Armstrong says that Guidant's visual observations of Mr.  
2 Clasby's explanted ICD reported there isn't a space  
3 between the DF wire and the backfill tube.

4           So, in that regard, Mr. Duron's device and  
5 Professor Clasby's device, and perhaps thousands of  
6 other devices within the category of Professor Clasby's  
7 supplemental warranty program also have that same design  
8 defect.

9           In addition, there was no medical adhesive  
10 between the -DF wire and the backfill tube. That was  
11 the purported April of 2002 change. As Mr. Armstrong's  
12 report indicates and Guidant doesn't dispute, the  
13 medical adhesive wasn't there. So, the only insulation  
14 is the polyimide insulation.

15           Further, Mr. Armstrong advises and Guidant  
16 does not dispute that there was moisture in the header.  
17 And as Your Honor analyzed on page 4 of the Duron  
18 opinion, polyimide can degrade and lose its insulation  
19 property under certain conditions. Moisture in the  
20 header is one of the conditions that Mr. Armstrong  
21 contends, and certainly for purposes of summary judgment  
22 provides adequate evidence that the device was not only  
23 designed improperly, but also was malfunctioning, or in  
24 the process of malfunctioning through the polyimide  
25 degradation.

1           THE COURT:  Is there a difference in this  
2 case -- and even if you say, well, I suppose you could  
3 say, well, that is a difference Ms. Moeller mentioned,  
4 but it is not one that makes a difference in result.

5           That is to say, the record would suggest that  
6 unlike Mr. Duron, Professor Clasby was called upon to  
7 deliver a shock, albeit it wasn't the right shock, but  
8 it was -- and it wasn't, apparently, a life-threatening  
9 circumstance.  But, it was -- so the argument goes, it  
10 was called upon, so that unknown potential malfunction,  
11 or malfunction as I define it in the Order, well, here  
12 it did deliver it, appears it did deliver a shock.  Does  
13 that change the presence or the absence of a  
14 malfunction?

15           MR. HARKE:  I would say it didn't.  I mean,  
16 in terms of chronology, you have to bear in mind that  
17 Mr. Duron's device was in his body longer than Professor  
18 Clasby's.  So, the presence of the polyimide degradation  
19 would be more accelerated in Mr. Duron's device than  
20 Professor Clasby.

21           But, the inappropriate shock that Ms. Moeller  
22 referenced and your question raises was delivered a mere  
23 two and a half months after the implantation of  
24 Professor Clasby's device.  So, it is true within the  
25 space of a couple of months after the implantation, the

1 device inappropriately shocked him. That is conceded.

2 THE COURT: But, then -- and I'm sorry to  
3 interrupt -- but then if Ms. Moeller were standing where  
4 you were, she would say, well, that was proof that it  
5 was functioning and it is proof there was no  
6 malfunctioning, because, actually, it was working. And  
7 of course, we have the issue of whether it was the  
8 parameter setting and why it was delivering the shock,  
9 but it actually delivered the shock.

10 MR. HARKE: Yeah, it is clearly indicia of  
11 the fact that the device shocked him. You know, whether  
12 or not that is the totality of whether -- of how his  
13 device should function and whether or not for the  
14 lifetime of the device it would continue to function in  
15 that manner given the other features of his device, I  
16 think is a question that is in material dispute for  
17 purposes of summary judgment.

18 Your Honor also ruled, as a matter of fact,  
19 on page 4 of your Order that polyimide can degrade and  
20 lose its insulation properties under certain conditions,  
21 or when it is improperly bent. And Mr. Armstrong  
22 concludes that Professor Clasby's device was improperly  
23 bent, and that there was bending at the point of impact.

24 So, you have the same facts that would  
25 indicate that Professor Clasby's device was in every

1 respect the same as Mr. Duron's. The only evidence,  
2 again, is the webpage that it was subject to a  
3 supplemental warranty program. So, with that in mind, I  
4 think Your Honor already laid the ground work on  
5 analyzing this on page 30 of your Order where you set  
6 forth the differences between the Larson case and the  
7 Wisconsin case and the California case.

8 Here, those same exact features apply with  
9 regard to Professor Clasby. Because unlike the case  
10 involving the sewing machine from Florida, which I will  
11 get to that Ms. Moeller talks about, we have the same  
12 exact set of distinguishing features.

13 And Your Honor did, I think, a very clean and  
14 logical analysis. The defibrillator feature of the  
15 PRIZM 2 functions only when called upon. So, you're  
16 right, it was called upon in April of '02, but we have  
17 no idea whether or not in light of the polyimide  
18 degradation, in light of the fact that there was no  
19 medical adhesive, in light of the fact that the wire was  
20 bent, in light of the fact that there was no spacing,  
21 which was a design defect, it is unclear, and certainly,  
22 again, there is a material fact, as Your Honor already  
23 concluded in Duron, whether it would be called upon  
24 again to function, whether or not it would function or  
25 not. And as Your Honor also concluded, second, the

1 PRIZM 2 cannot be monitored to determine if a  
2 malfunction occurred or is likely to occur. It is the  
3 same case. When Professor Clasby became aware of the  
4 recall and he spoke with Dr. Feldman and others and they  
5 recommended the explant, he had no ability to monitor  
6 the polyimide degradation, which Your Honor has already  
7 concluded was both a malfunction and a design defect, at  
8 least with regard to Mr. Duron.

9 Third, a patient with a pacemaker, or a valve  
10 malfunction will exhibit symptoms prior to a complete  
11 failure to allow a patient to have some treatment. Here  
12 if the PRIZM 2 failed to defibrillate, the patient will  
13 be severely injured or die.

14 In the case, again, of Professor Clasby,  
15 Professor Clasby's device had none of the April '02  
16 manufacturing fixes that Guidant contended would render  
17 it a device that would be functional and operate as  
18 intended.

19 Fourth, Your Honor concluded that the device  
20 defect could worsen over time, unlike a heart valve,  
21 which would lessen. You have the same issue here,  
22 Professor Clasby's device was only implanted in December  
23 of '02. But, given the fact that there was moisture in  
24 the header, there was no space, no adhesive, it was a  
25 bent tube, there are at a minimum genuine issues of

1 material fact about whether or not Professor Clasby's  
2 PRIZM 2 device would have worsened over time. And  
3 again, that is the same analysis that Your Honor already  
4 concluded with regard to Duron.

5 I want to just briefly talk about some of the  
6 Professor Clasby's injuries, and I'm not sure -- I  
7 heard -- there was some discussion about whether or not  
8 Professor Clasby was injured or not as a result of, you  
9 know, this is an explant with complications case.

10 THE COURT: Right.

11 MR. HARKE: And there is no question,  
12 although Professor Clasby scheduled his explant to occur  
13 after the conclusion of the school year, the record is  
14 replete, and our factual summary identifies substantial  
15 evidence that he was injured psychologically from  
16 learning of the problems with the Guidant device.

17 He testified he thought it was a shock to him  
18 that he had a potentially serious threat to his health.  
19 His wife testified he became irritable, jumpy, he had  
20 trouble sleeping, he lost interest in exercise, he  
21 wouldn't go on walks. He had digestive problems.  
22 Physically, he went down hill. He lost weight. His  
23 wife thought he was afraid for his life. His fear was  
24 something that haunted him on a daily basis.

25 His psychologist Dr. Incera said the device

1 is seen as a safety net. And if the safety net is not  
2 there, it makes a person feel much more vulnerable. And  
3 when you find it out after the fact, it undermines all  
4 sorts of things, all sorts of things.

5           And to me, it is a little disingenuous for  
6 Guidant to write as it does in its response that the  
7 implant -- the person who receives the implant should be  
8 aware there is a potential psychological impact of  
9 having a device that functions normally without any  
10 incident problems, or any recall or anything else, that  
11 there is a potential psychological impact that the  
12 patient should be aware of from the implantation of that  
13 type of device in your system. But, then here when the  
14 disclosures of the various problems come out with regard  
15 to the device, Guidant takes the position that they are  
16 not responsible for any of those psychological impacts  
17 and that none of those impacts are legitimate or  
18 compensable.

19           And Dr. Clasby testified and his doctors  
20 support his testimony that he had anxiety and  
21 depression. Dr. DelGaudio testified that having a  
22 defective device on him will exacerbate and increase the  
23 anticipatory anxiety that he had.

24           With regard to his physical injuries, he is  
25 different from Mr. Duron in regard that he had two

1 explant surgeries after the original implantation. The  
2 first explant was a difficult experience. The doctor,  
3 and the medical personnel had difficulties with his  
4 I.V.. He was required to be defibrillated during the  
5 course of his first explant. He had complications. It  
6 turned out he had a life-threatening infection as a  
7 result of the first explant. This necessitated a second  
8 explant, not just the defibrillator, but the leads that  
9 had already been embedded in his body running to his  
10 heart had to be removed. The situation was so grim that  
11 Professor Clasby, who is a devout Catholic, and his wife  
12 who -- and he sings at his church and his wife writes  
13 about -- writes about religion and literature. They are  
14 very religious people. He had his Priest administer the  
15 last rights prior to his second explant. He said his  
16 last good-byes in a meeting with his daughters. And he  
17 had a very painful explant experience.

18           He was in the hospital for five days. He  
19 went for hours without eating or drinking. He was  
20 catheterized. He had painful spasms in his bladder. He  
21 was required to have general anesthesia for both of  
22 those operations. And he had an infection that had to  
23 be resolved, and he had to have a third device  
24 implanted.

25           Briefly, Your Honor, I also want to respond

1 with regard to Florida law on the two cases that I think  
2 are most relevant. Ms. Moeller referenced the Opelika  
3 machine case for the standard that there needs to be a  
4 harmful defect. We cited that case. That is a 1982  
5 case involving a sewing machine, or part of a sewing  
6 machine at a Monsanto textile plant in north Florida.

7           That is an interesting case because we cite  
8 it for the exact opposite proposition that Ms. Moeller  
9 cites it for. In that particular case, there was a  
10 trial with regard to strict liability and an implied  
11 warranty claim. The Court granted summary judgment on  
12 the strict liability, but sent the implied warranty case  
13 to the jury. There was a question about whether or not  
14 the jury instructions were proper with regard to what  
15 was submitted to the jury. On appeal, the Court  
16 concluded quite the opposite of what Ms. Moeller  
17 contends. The Court found that the failure to charge  
18 the jury on a product's potential affinity for causing  
19 injury is a serious omission. In other words, it is not  
20 that there needs to be a harmful defect, harmfully  
21 defective, it is the exact opposite. It's the potential  
22 affinity for a -- potential affinity for causing injury,  
23 which was the omission which led to the reversal, and  
24 which led the court to tell the lower court to provide a  
25 jury instruction that provided for the potential

1 affinity for causing injury.

2 Now, the Court does cite to language that  
3 includes the words harmfully defective, and that is from  
4 a 1973 Law Review article that was published in the  
5 Mississippi Law Journal. But, what the Court is talking  
6 about there is you can have devices that don't -- that  
7 don't cause injury, because they are not harmful.

8 You can have an automobile that has an  
9 ignition problem, but it doesn't cause the death or  
10 potential serious injury of someone simply because it  
11 doesn't work correctly. So, the question is whether or  
12 not there is physical harm, the potential for physical  
13 harm. It is not that it has to be harmfully defective,  
14 the question is whether or not it causes, or could  
15 cause, or has the potential affinity to cause physical  
16 harm. And clearly, this device which could lead to  
17 someone's death satisfies the criteria set forth in that  
18 case.

19 Later on, the Court makes it crystal clear,  
20 because the instructions given below fail to suggest to  
21 the jury that the alleged offending product's potential  
22 for causing physical harm to the user, it was in our  
23 judgment an incomplete and misleading instruction and it  
24 didn't advise the jury there could be an alleged  
25 offending product's potential for causing physical harm.

1 And clearly, with the fact that this device was  
2 manufactured not according to design specifications,  
3 with all of the other problems that Mr. Armstrong  
4 identified and even Guidant concedes, there is no  
5 question that that standard has been met.

6 Finally, I want to bring to Your Honor's  
7 attention another Florida case that we think applies  
8 here. Certainly with respect to the deceptive and  
9 unfair trade practices claim. And it fits right into  
10 Your Honor's analysis of the unique life-saving nature  
11 of the defibrillators, and the fact that they can't  
12 otherwise be readily monitored and determined to be  
13 whether or not they operate properly or whether they  
14 were designed properly, simply by visual inspection.

15 And that involves the Chrysler case, the  
16 Collins versus Daimler Chrysler Corporation case which  
17 we cite to, a 2005 case that involves a defective  
18 seatbelt in certain Chrysler automobiles. And the  
19 question before the appellate court was whether or not  
20 you needed to have the device to fail, you know whether  
21 the seatbelt needed to actually not operate, potentially  
22 hurt somebody before you could state a claim for  
23 deceptive and unfair trade practice. And the Court  
24 there concluded that because of the unique life-saving  
25 nature of a seatbelt, and the special considerations

1 that obtained, which is exactly what Your Honor talked  
2 about in the Duron opinion, that you can't wait, nor  
3 would it make common sense or sound policy to wait for a  
4 seatbelt to fail and kill someone or a small child  
5 before you are allowed to bring a cause of action for a  
6 defective seatbelt design. And I would contend that is  
7 the exact same situation here that Your Honor talked  
8 about on pages 30, 31 and 32.

9 THE COURT: The difference, of course, is I  
10 could have somebody look at -- I don't think you would  
11 approve of Dr. Higgins, probably, or somebody else -- I  
12 shouldn't make light of it. The other -- Feldman -- I  
13 better get a couple in here of the seatbelt. But, I  
14 mean --

15 MR. HARKE: That makes our case stronger,  
16 because in the seatbelt case you can get a Dr. Higgins  
17 to come in and, golly, there is no problem with this  
18 seatbelt. You have not stated a claim.

19 Whereas here, the only way to get a Dr.  
20 Higgins to even look at and analyze the Professor's  
21 device would be to have to pull it out of him and learn  
22 as we learned in this case that the medical adhesive  
23 wasn't applied, learn that it was designed improperly,  
24 that there was no space between the wire and the in-fill  
25 tube, and all of the other problems. The wire was bent,

1 and all of the other problems that we've identified.

2 THE COURT: All right.

3 MR. HARKE: Thank you, Your Honor.

4 THE COURT: Ms. Moeller, if Mr. Pratt will  
5 let you around there, in front or back.

6 MS. MOELLER: You'll see me kick him under  
7 the table.

8 MR. PRATT: One lawyer per side per motion,  
9 Your Honor, that is a great rule.

10 MS. MOELLER: I will be real brief, Judge.  
11 The bottom line here is Professor Clasby got his device  
12 explanted because he mistakenly believed it was  
13 recalled. It wasn't. Those facts were available to him  
14 and his healthcare providers as we have established in  
15 the record.

16 One of the distinguishing factors about Mr.  
17 Duron was that his explant surgery was medically  
18 necessary based on the FDA Class 1 recall. That  
19 situation did not exist for Professor Clasby.

20 Also, one of the open-ended questions that  
21 was a basis of your decision in Mr. Duron's case was  
22 whether a life-saving shock could have been delivered.  
23 We have that answered in Professor Clasby's case. A  
24 life-saving shock, although not life-saving, was  
25 delivered on multiple occasions. Not only could it

1 have, it was. We also have Mr. Armstrong's concession  
2 that there was no polyimide degradation on explant. Mr.  
3 Duron and Professor Clasby's devices were actually in  
4 almost the exact same period of time. Mr. Duron's from  
5 March of 2002 to August of 2005. Professor Clasby's  
6 from December of 2002 to May of 2006. My math skills  
7 are a little rusty, but there is not a significant  
8 difference in those two implantations, contrary to Mr.  
9 Harke's position.

10 But, basically, Your Honor, there are  
11 significant differences between Professor Clasby's case  
12 and Mr. Duron's case, and those significant  
13 differences should result in a different outcome. So,  
14 unless you have any further questions?

15 THE COURT: I don't.

16 MR. HARKE: Judge, just one moment?

17 THE COURT: Sure.

18 MR. HARKE: Just to respond briefly to what  
19 Ms. Moeller said. The device did shock in April of '03,  
20 but that is exactly what is needed in order to create  
21 the arc. There has to be a charge in order for it to  
22 arc, anyway. And you have no way of knowing whether or  
23 not six months from now it would work again, in light of  
24 all of the features that we talked about.

25 And again, if I could just briefly refer Your

1 Honor to page 31 of your Order, this is exactly what  
2 Guidant argued in Duron, and it's arguing now.

3           Guidant's entire motion rests on the premise  
4 that the only malfunction would be failure of Duron's  
5 PRIZM 2 device to deliver a life-saving shock while  
6 implanted in his body. The record before the Court does  
7 not allow such a limited view of malfunction. There  
8 were genuine issues of fact with respect to whether the  
9 device malfunctioned in the following manner. Duron's  
10 device contained polyimide, which malfunctions over time  
11 by degrading, which in turn necessitates the surgery.  
12 We have the exact same factual record before Your Honor  
13 with regard to Professor Clasby.

14           THE COURT: Anything else, Ms. Moeller?

15           MS. MOELLER: I just dispute that final thing  
16 because the reason -- no. Judge, we will let it in  
17 there.

18           THE COURT: Are you sure?

19           MS. MOELLER: We will let it in there.

20           THE COURT: All right. I will deem those  
21 matters submitted. I think we agreed to put these on  
22 your desk by no later than July 10th.

23           Let me do two things. I will first bring up  
24 something that is unrelated -- well, let me bring up  
25 something that is related to the motions today and then

1 I will drop back and give you a -- I think I promised  
2 the group in chambers this morning we would discuss  
3 Daubert rulings, and then there will be a quid pro quo  
4 in here. I will get to that in just a minute.

5 But, one thing on a serious note, and  
6 obviously I would have behaved the same way today, there  
7 were a couple of lighter moments in the courtroom this  
8 morning and afternoon, because they are long days for  
9 the lawyers, even if clients had been here for either  
10 side. But, when we have some humor, whether it is  
11 pointing out to Ms. Moeller's creative lawyering, rather  
12 than saying Mr. Carpenter made a mistake, saying he took  
13 a more conservative view, or something Plaintiffs did, I  
14 don't make light of the seriousness of this to the  
15 Plaintiffs and your clients.

16 I am quite certain I would have done the same  
17 thing and make the same comments. So, I wouldn't want  
18 to construe it that way, because I am sure it is no  
19 humorous matter to either Guidant or to the individual  
20 Plaintiffs. And obviously, it isn't to the lawyers, but  
21 on the other hand sometimes it is helpful not to take  
22 one another and their selves too seriously during these  
23 long days, so probably enough said about that. But, it  
24 is not because I think they aren't serious matters.

25 MR. CARPENTER: Your Honor, I can take it.

1 THE COURT: Pardon?

2 MR. CARPENTER: I can take it, Your Honor.

3 THE COURT: The objections or responses, you  
4 can use either phrase you like on the in limine motions,  
5 this goes back to this morning, and the Daubert and in  
6 limine motions are due by June 29th. I would like them  
7 by noon on June 25th. I won't rule on them by the end  
8 of the week as I will in the Daubert motions.

9 My point is those are due on June 29th on the  
10 in limine responses. If I can have those by noon on  
11 Monday, the 25th, then at least it gives me a chance to  
12 read the responses. And then either by the end of next  
13 week or the following Monday at the latest, I will file  
14 all of the decisions in the Daubert motions.

15 We will still have any argument, and we will  
16 address in limine issues at the pretrial when that is  
17 scheduled on July 9th, I believe it is. But, it will at  
18 least give us a chance to read and have the context  
19 of -- which is what I am really after, in any event,  
20 even though it may be true they don't relate directly,  
21 or maybe even indirectly to some of the key Daubert  
22 motions.

23 On the other hand, it does give me the  
24 context of what the relevant issues and the issues of  
25 concern are to both parties. And the quid pro quo, of

1 course I got my piece, but the piece for counsel, which  
2 really, frankly, I would agree with, anyway, I am much  
3 more concerned about that than I am about -- I am sure  
4 we can reach an agreement about pushing back the  
5 objections and decisions on exhibits, because that  
6 rarely interferes with any trial I have been involved  
7 in. And actually, in some cases, even though my  
8 Pretrial Order reads pretty much the same here as it  
9 does in individual cases, oftentimes I will say unless  
10 or until we are certain who the witnesses are going to  
11 be or what aspects of the depositions are going to --  
12 let's not have me run through all of these objections or  
13 exhibits until we are certain what they are going to be.

14           Because even if that means having you do it,  
15 as long as it is outside of the jury's time of nine to  
16 five, whether that is me reviewing a deposition, with or  
17 without counsel present, it will be outside of those  
18 hours.

19           I would rather do that and have a fraction of  
20 the number, which I think that is what trials are about,  
21 and say, well, I don't care if you are going to submit  
22 these. You made the objections. Let's go through the  
23 whole -- I am really much less concerned about that. It  
24 rarely, if ever, holds up a trial. So, that should --  
25 and we will have a short order out on the web on two

1 items. One just came up right away this morning on the  
2 July 10th issue on discovery. And the second issue will  
3 be just some suggestions that may be on the category of  
4 meet and confer, a suggestion the Court has on where do  
5 we go from here, apart from the bellwether trials. So,  
6 we will roll that out in the next 24 hours. We had a  
7 chance to talk about it a little bit over the noon hour.

8 Anything further on behalf of the Plaintiffs  
9 today?

10 MR. LESSER: No, Your Honor, thank you.

11 THE COURT: Defendants?

12 MR. PRATT: Nothing from Guidant's side.

13 Thank you, Your Honor.

14 THE COURT: Now, is there anybody else you  
15 want to introduce? Do you have any people doing a lot  
16 of the hard work?

17 MR. HARKE: Yes. As a matter of fact, this  
18 is my partner, Howard Bushman, here, from Miami.

19 THE COURT: I saw somebody coming back and  
20 forth from the back. Usually there are people doing  
21 some heavy lifting.

22 MS. PETERSON: Elizabeth Peterson doing all  
23 of our heavy lifting.

24 THE COURT: Oh, hi, Ms. Peterson. You and I  
25 talked yesterday. When she called, I think a group of

1 you, including Ms. Moeller, you were with. And she  
2 said, is this Lowell Lindquist's office?

3 Well, it says Frank.

4 Oh, all right. I will get your direct number  
5 and we decided to have a telephone conference. We are  
6 adjourned. Thank you.

7 (Adjournment.)

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Certified by: \_\_\_\_\_

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Jeanne M. Anderson, RMR-RPR  
Official Court Reporter

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