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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re:) Civil 05-MD-1708 (DWF/AJB)
)
GUIDANT CORPORATION) DISPOSITIVE MOTIONS
IMPLANTABLE DEFIBRILLATOR) HEARING
PRODUCTS LIABILITY)
LITIGATION,)
)

This Document Relates)
To All Actions) 9:00 o'clock, a.m.
) May 18, 2007
) Minneapolis, Minnesota

THE HONORABLE JUDGE DONOVAN W. FRANK
UNITED STATES DISTRICT COURT JUDGE
CIVIL MOTION PROCEEDINGS

* * *

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1 (In open court.)

2 THE COURT: You may be seated, thank you.

3 Good morning, Counsel.

4 ALL COUNSEL: Good morning, Your Honor.

5 THE COURT: I will leave it to the discretion
6 of respective counsel. We can start with Plaintiffs.

7 What I mean by that, you can in addition to introducing
8 yourselves and if you wish in what capacity you are here
9 on, if there are others in the gallery, regardless of
10 who they may be that you would like to introduce,
11 whether it is clients, counsel, other individuals, I
12 will just assume whoever you feel appropriate you wish
13 to introduce, you may do so.

14 I am reminded of a story a few weeks ago
15 where I didn't say that and then I found out later that
16 the elderly parents of a lawyer in the courtroom, it was
17 the first time they had come and watched their son
18 argue a case.

19 And I said, "Well, those weren't your parents
20 back there, were they? You should have introduced them
21 to me. I could have really bragged you up a little bit
22 to everybody, if I would have known."

23 We can begin with respective Plaintiffs
24 counsel, and then I will just leave it to you who you
25 wish to introduce.

1 MR. DRAKULICH: Yes, Your Honor, Nick
2 Drakulich on behalf of the Plaintiffs Steering
3 Committee. And also appearing on behalf of Plaintiff
4 Leopoldo Duron.

5 And I would like to introduce, if I may, Your
6 Honor, Thomas Schultz, who is Mr. Duron's personal
7 counsel from California.

8 THE COURT: Good morning, Counsel. Welcome
9 to Minnesota.

10 MR. CUTTER: Brooks Cutter for the Plaintiffs
11 Steering Committee.

12 MR. LESSER: Your Honor, Seth Lesser, also
13 Plaintiffs Steering Committee.

14 MS. CABRASER: Good morning, Your Honor.
15 Elizabeth Cabraser for the Plaintiffs Steering
16 Committee.

17 THE COURT: Good morning.

18 MR. ZIMMERMAN: Good morning, Your Honor,
19 Charles Zimmerman for the Plaintiffs Steering Committee.
20 My parents aren't here, but had I invited them, they
21 could have been.

22 MR. ARSENAULT: Good morning, Your Honor,
23 Richard Arsenault, Plaintiffs Steering Committee.

24 MR. HOPPER: Good morning, Your Honor, Randy
25 Hopper on behalf of the Plaintiffs Steering Committee.

1 THE COURT: And unless there is anyone else
2 that you would like -- I mean, how far do you want to
3 take it? We can go right to the jury box, if you wish.
4 I see some, most lawyers going (waving motion) --

5 MR. DRAKULICH: Your Honor, we accept the
6 jury as present.

7 THE COURT: All right. Well, you know, I
8 usually will have a bench conference on "for cause"
9 strikes, so if you want to -- and the record will
10 probably appropriately reflect that everyone at
11 respective counsel tables and in the jury box, we have
12 all met on at least a variety of occasions before.

13 So, we can move over to Mr. Pratt and the
14 Guidant side of the courtroom.

15 MR. PRATT: Your Honor, Tim Pratt. If you
16 ever saw that movie, "300," as I look around, I feel
17 like we are outnumbered. But, we are trying to hold it
18 all together.

19 I am representing Guidant, this is Andy
20 Carpenter and Debbie Moeller of my office who will be
21 participating in the argument today. Joe Price, our
22 local counsel of Faegre & Benson and Jean Holloway, who
23 is in-house counsel for Boston Scientific/Guidant.

24 MR. PRICE: Good morning, Your Honor.

25 THE COURT: Good morning, Mr. Price. Good

1 morning to all.

2 The record should reflect, and I have no way
3 of knowing, but I think the response by me should be the
4 same, either way. As most of the lawyers know that are
5 in the gallery, including the well, including the jury
6 box, there has been some discussions with the Court and
7 counsel on the order of presentation, and how we are
8 going to proceed today before we came in to court
9 earlier in the week, and before.

10 So, I will just leave it to counsel, maybe
11 for the benefit, at least, of some of the other
12 individuals in the courtroom. And whether Plaintiffs do
13 it or Defense or you both do it, maybe if you want to
14 outline today, there were a few e-mails that we received
15 yesterday just kind of tweaking the schedule for today
16 in terms of the approximately nine motions that are on
17 and the five there will be oral argument on, including
18 an introductory factual overview by each party of
19 approximately 20 minutes each.

20 Why don't we -- I can hear from Plaintiffs'
21 counsel, or whoever wishes to kind of scope out the day
22 for us. I say "day," not being pessimistic, but I
23 assume we are going to be here, it looks like, about a
24 six-hour presentation to me. If it is less than that,
25 that is fine.

1 MR. DRAKULICH: Whatever your pleasure is,
2 Your Honor. Three of us will be arguing today, myself
3 Mr. Lesser and Ms. Cabraser. We are splitting up the
4 argument and I am going to attempt to cover some facts
5 that will be applicable to all of the motions. But,
6 however you would like to proceed, we are prepared to
7 move forward.

8 MR. PRATT: I think the agreement we have,
9 and I am trying do the math. I am not sure we get six
10 hours.

11 THE COURT: Well, I am just saying I have
12 saved the whole day.

13 MR. PRATT: Here is what we advised Your
14 Honor on about how we are going to proceed today. We
15 have five motions that we are prepared to argue after
16 the presentation of the facts at the beginning, so six
17 segments of the argument today. We are trying to keep
18 those to 20 minutes a side for each of the six segments.

19 After the presentation of the facts by the
20 parties, we will move into an argument on the
21 Plaintiffs' Choice of Law Motion. The next motion that
22 we'll argue will be the Consumer Protection Motion that
23 we filed. We then will follow that with the Preemption
24 Motion, then the No Injury Motion, and we will wrap up
25 today with the Punitive Damage Motion. So, that's, I

1 think, the way we are sequencing out the arguments
2 today.

3 Your Honor, of course, we can move and shake
4 in any way you want in connection with that, and we are
5 here at your disposal.

6 THE COURT: Is that acceptable to Plaintiffs'
7 counsel?

8 MR. DRAKULICH: Yes, Your Honor, if we could
9 have maybe some indulgence on the 20 minutes, we will
10 try to do that in the narrow package. As I suggested, I
11 am trying to cover facts throughout the entire motions
12 and --

13 THE COURT: All right. The only other thing
14 I would suggest, and I doubt there will be an objection
15 from either side of the aisle. This has always worked
16 well when we've had a group motions in the past.

17 It comes up, actually, more frequently in a
18 list of in limine motions, you know, a week or two
19 before trial where a decision has to be made by the
20 lawyers or the Judge, ultimately by the Judge. Well, do
21 we have the moving party get up, and then the response,
22 and that is irrespective of what has been said with any
23 rebuttal or surrebuttal. And selfishly, I think in
24 fairness to the parties, I have always found it very
25 helpful, and rarely, if ever, just pure repetition or

1 wasteful to turn to the moving party and say: Do you
2 want a brief response, which generally is, you know, two
3 minutes or less? And then I will usually give the last
4 word. So, there is an up and down, and sometimes
5 lawyers oftentimes will take the last word whether they
6 need it or not.

7 So, if that has always worked well, it is
8 that rare case where I feel we are retreading old
9 ground. So, that is probably how we will proceed today.
10 I will let a short rebuttal -- unless there is some
11 compelling issue or some of my questions, if it has
12 carried us over and so you haven't been able to get the
13 information to me that you need.

14 I will represent to you that myself, along
15 with, and most of the lawyers here, if not -- and most
16 of the lawyers here have met Amy Gernon, who is closest
17 to me, and Danielle Mair, both lawyer/law clerks in my
18 chambers.

19 We have essentially, I think it would be fair
20 to say, read everything that has been submitted. And we
21 can discuss at the end of the presentation today,
22 whenever that might be, some response times by the Court
23 getting decisions out.

24 For example, something to think about
25 throughout the day in a small number of cases, if the

1 lawyers agree, apart from the MDL nature of things --
2 although we do have the other cases sitting in right
3 behind Mr. Duron's case with some deadlines coming up as
4 soon as next week on briefing. And some of those issues
5 may come up today in some of my questions. But, at the
6 end of the day, if there are one or two or three key
7 issues where if the parties seem to agree that, well,
8 the quicker we could get the decision the better,
9 something I have done in the past, we may have done it
10 once or twice here over the course of the history of the
11 case, on a couple of these issues, because it is not
12 likely I will rule off the bench as my brother and
13 colleague Chief Judge Rosenbaum does with some frequency
14 on some matters. But, the other methodology that I use,
15 and I think it will be probably realistic and I will be
16 able to deliver on this and I will check in with you at
17 the end of the day. On two or three of these, if there
18 would be an agreement to say: Well, Judge, we will take
19 your one-page or one-paragraph decision if we can get it
20 in less than a week. And then I would follow it within
21 30 days, give or take a few days, with the memorandum
22 opinion.

23 There may be a couple of these that fit that
24 category where if you all agree that, well, if you are
25 willing to give us a decision, even though the reasoning

1 won't come with it, so we can act on it, then we'll
2 discuss that, whether one or more of these fall into
3 that category. Because I would be willing to do that,
4 and I think unless something happens that I don't
5 anticipate today, which I suppose is possible, I think
6 it is realistic to suggest to you that I would and could
7 do that in some of these motions. And it would probably
8 be -- I think it is apparent there's at least two that
9 might be helpful of the five, in addition to the other
10 four, approximately, four motions that aren't going to
11 be argued that are being submitted on the briefs.

12 We did send an e-mail yesterday, because I
13 said if there's other questions or I had an objection or
14 would like to hear additional oral argument on some of
15 the other motions, we would let you know yesterday.
16 Well, we just confirmed yesterday by e-mail that we were
17 in agreement with kind of the format that was set out.

18 With that, I would suggest that we can
19 proceed with -- I think we were going to open up with an
20 overview of the facts, unless I am mistaken. And the
21 last time the e-mails were exchanged, it wasn't clear to
22 me whether the Defense was going to proceed first with
23 that or the Plaintiff.

24 I take it by Mr. Pratt getting up, that it is
25 going to be you, unless you are getting up on behalf of

1 the Plaintiff and I don't think that is the case.

2 MR. PRATT: If they would permit me, Your
3 Honor, I would be pleased to.

4 THE COURT: If I may say, and I don't want to
5 create an issue today on one or more of the motions, and
6 I may, if I have a question -- and this is not a
7 substitute for some of those questions. But, as we are
8 going along, whether it is at a recitation of the facts
9 or during a motion, if it is the view of one or both
10 parties, this case has no dissimilarity, in our view,
11 from the bellwether trial sitting right behind it. Or,
12 it is entirely dissimilar. Because one of the issues
13 that's going to come up early on in the choice of law
14 argument, and I will sit tight until then, is a number
15 of -- just taking the bellwether cases, they all got
16 here in different ways.

17 And as recently as Judge Fallon's decision on
18 March 22nd of 2007, he had some discussion about that
19 and how unhelpful the rules are in the United States of
20 America on what all of the ways cases get into a
21 district in an MDL. But, apart from what Judge Fallon
22 has said, and others -- and that is just one issue.
23 But, back to what I just said about if it is obvious to
24 one or both sides that, well, in some of these motions,
25 if not the overview of the facts, what we say about this

1 case, keep in mind, Judge, we think it is going to be
2 the same for the others sitting right behind it.

3 I am not saying you are really obligated to
4 do that today, because it is going to come up as we
5 discussed after I've made decisions, because when the
6 other motions come in, that is one question we'll have
7 is: Well, is the next case or the case thereafter
8 distinguishable from the one that has been filed?
9 Probably enough said about that. If I have a question,
10 I will ask it. So, whenever you are ready, Mr. Pratt.

11 MR. PRATT: Thank you, Your Honor. This is a
12 bit of a challenge, what I have been tasked to do this
13 morning, which is to somehow in 20 minutes talk about
14 the facts that we believe to be important in connection
15 with the pending motions. So, I will not do service to
16 all of them.

17 I have read, since I have been involved in
18 defending Guidant in this litigation, I think, every
19 media article that has been published, from great
20 newspapers like the Wall Street Journal and Pioneer
21 Press and others. I have read them. I have read what
22 the Plaintiffs have filed here.

23 What I thought I would do is to perhaps spend
24 a little bit of time during my 20 minutes to talk about
25 the things that one may not appreciate from having just

1 read the popular press reports about my client, the
2 people of Guidant, about the PRIZM 2, and may not have
3 appreciated from reading what the Plaintiffs have filed
4 in connection with their motions.

5 One thing is we are here to talk about the
6 case of Leopoldo Duron. What may not be fully
7 appreciated is that Mr. Duron's device has been removed
8 from his body. It worked every minute it was in his
9 body. It delivered appropriate therapy to him. It was
10 removed because he electively decided to have it
11 removed, Guidant gave him a free device to replace that.
12 We tested it. There is going to be a lot of talk -- and
13 Mr. Drakulich is going to talk about degradation of
14 polyimide and how that may increase risk and all of
15 that.

16 The fact is, we have looked at Mr. Duron's
17 device and we have looked specifically at the polyimide
18 and whether it is degraded. And we have an agreement
19 from their expert and ours and everybody who has looked
20 at this, that this device has not failed, it has not
21 malfunctioned. It never failed to deliver therapy. The
22 polyimide insulation in the header of his Prizm 2 has
23 not degraded. It may not be appreciated from that.

24 The second thing that may not be appreciated
25 is the seriousness of sudden cardiac death. Sudden

1 cardiac death -- we know heart disease is a leading
2 killer of Americans. Within that group, the leading
3 killer is sudden cardiac death. Not a plumbing problem
4 with the heart, but an electrical problem in the heart,
5 where it starts to beat, it gets out of whack. It goes
6 too fast. It becomes inefficient. It falls into a
7 state of fibrillation, and the only thing that is going
8 to save that heart when it gets to that advanced stage
9 is a shock, either an external shock or an internal
10 shock.

11 And if you don't get a shock in a timely
12 fashion and you are suffering from an episode of sudden
13 cardiac death, you will die. Sudden cardiac death kills
14 about 1,000 Americans everyday. This is a deadly
15 disease. And the best form of therapy for this disease
16 are implantable cardioverter defibrillators, ICD's.

17 These are devices that have been developed.
18 In the beginning they used to be big. They used to go
19 right down here in your abdomen. You opened up your
20 chest and you hooked the wires to the chest. Now they
21 are small. They are small because of innovative
22 advances by companies like Guidant, where you put it up
23 here in the upper pectoralis region. You run the wires
24 through the veins inside. It monitors the heart. If
25 the heart goes into a state of tachycardia, it will

1 recognize that and it will give you a shock. And it
2 will wait. If it is not fixed, it will give you another
3 shock. That is the way it works. It is a lifesaving
4 device. Where more than 95 percent of people suffering
5 cardiac death would die because they didn't get shocked
6 in a timely fashion. If you have an ICD in your body
7 and you have a state of sudden cardiac death or
8 ventricular fibrillation or tachycardia, more than 95
9 percent of those people will survive.

10 So, we are talking in this courtroom about,
11 truly, a lifesaving device. But, it does have
12 limitations. It is run by a battery. It has to be
13 replaced every three years, four years, five years,
14 depending on the use, the entire device has to be
15 removed through a procedure where you opened up a
16 pocket, you take it out, you check the leads, you put it
17 back in, an outpatient procedure. You are not under
18 general anesthesia. But, you have to do this. You know
19 when you get one that it is going to have to be replaced
20 periodically.

21 These devices, and what one may not
22 appreciate from what you have read, these devices are
23 not perfect. They may shock you when you don't need a
24 shock. They may malfunction. These are man-made
25 devices, they have miniature computers, they have

1 miniature power plants in them. They are complicated.
2 And there is a risk that they will fail and not deliver
3 therapy in a timely and appropriate fashion.

4 We are certainly not proud of that, and
5 people at Guidant work every day to make these more
6 reliable. But, there is a background risk that these
7 devices will fail. And if anybody in this courtroom
8 gets an implantable defibrillator from an
9 electrophysiologist, that electrophysiologist is likely
10 to say, this device may fail. At what percent, it is
11 uncertain.

12 When you take a look at what the Heart Rhythm
13 Society has said, they say the rate can range from 1
14 percent, 1 out of 100 to 2.65 percent of these devices
15 having to be replaced because of a malfunction. Guidant
16 certainly does a whole lot better than that on the
17 reliability side of things, but that gives you some
18 sense of the background risk of failure with these
19 devices that is known to everybody.

20 It is known to the industry. Every member of
21 the industry. We have a warning in our label, an
22 FDA-approved warning that says that these devices may
23 fail to deliver therapy. Essentially, that is what that
24 warning says, the FDA-approved warning that accompanied
25 this device, Mr. Duron's device and everybody else's

1 device, that the amount is known to physicians. Every
2 physician we have taken in this litigation, every
3 physician, whether an expert or otherwise, will say, I
4 know there is a risk that these devices may fail. It
5 may not be fully appreciated; but, they do.

6 Another thing that may not be fully
7 appreciated from all that we have read is the important
8 role that the FDA plays in regulating these devices and
9 the companies that make them. They are regulatory
10 watchdogs. They have thousands of employees,
11 physicians, toxicologists, biomedical engineers, experts
12 in communication, experts in public health whose job it
13 is to regulate the people who make these devices, to
14 look at these devices, to pass judgment on whether they
15 are safe and effective, to determine whether they ought
16 to be available on the marketplace for people with
17 serious heart disease to have placed in their bodies, to
18 monitor them after they are on the market, to determine
19 whether they ought to stay on the market, whether
20 additional warnings ought to be placed or not. That is
21 the important role of the FDA and I am going to be
22 talking about it a whole lot more in connection with the
23 preemption defense. But, we are going to hear about
24 failures of these devices, we are going to talk about
25 the rarity of them. We are going to talk about it and

1 hear from Mr. Drakulich that there were short-circuit
2 reports of failures of these PRIZM 2 devices. Every one
3 of those reports went to the FDA, every one of them went
4 to the FDA, brought to the attention consistently with
5 the FDA regulations. And though we are going to hear
6 from Mr. Drakulich, we have heard from Plaintiffs'
7 experts in this litigation, that Guidant didn't do
8 things exactly right on the regulatory front, the FDA
9 has never so said.

10 The FDA has the enforcement authority over
11 Guidant. They have the ability to come in and inspect,
12 and indeed they do. They inspect our facilities on a
13 regular basis. If they see things wrong, they let you
14 know it.

15 They have looked since the 1861 recall in the
16 summer of 2005 at our facilities on many occasions, they
17 have an ability to say to us in an official way that you
18 did things wrong with respect to the 1861 in 2002, 2003,
19 2004, 2005. The FDA has never made that determination.
20 We hear it from them, but we have not heard it from the
21 FDA.

22 When you submit a request to the FDA for
23 approval of a device, you do reliability projections.
24 It will hurt your head to read this, because it is a
25 complicated reliability algorithm that you submitted

1 with your application. When Guidant submitted to the
2 FDA a request for the FDA to approve the Prizm 2 Model
3 1861, we submitted the reliability projection. And what
4 we said to the FDA was that the projected reliability of
5 this device over three years is 94.94 percent.

6 In other words, a little around 5 percent of
7 these would fail over three years for a whole variety of
8 reasons. 5 percent may fail for a whole variety of
9 reasons. That is what we told them. And with that
10 information, they approved it. 94.94 percent is what we
11 have told them. They approved it in August of 2000.
12 They have never withdrawn that approval, whatsoever.

13 We are going to hear about the polyimide
14 insulation. We are going to hear from the Plaintiffs
15 about how maybe that was not an appropriate insulation
16 to use in this application. What you may not hear, what
17 may not be appreciated from what they have filed is that
18 in 1992 the FDA gave Guidant permission to use polyimide
19 insulation in the header of their implantable
20 cardioverter defibrillators, in the header of their
21 cardioverter defibrillators.

22 And for ten years, ten years up until the
23 first report of a problem with the header in the PRIZM 2
24 in 2002, there was no problem of arcing because of a
25 failed polyimide insulation at all. Years and years and

1 years of successful use of that particular insulating
2 material.

3 One thing that I think has truly been lost in
4 all that has been filed, Your Honor, and all that has
5 been said about the people of Guidant and this device,
6 this Prizm 2, Model 1861 is the reliability of this
7 device. This device that is under attack in this
8 courtroom just happens to be one of the most reliable
9 ICD's ever marketed.

10 I think if you ask people, well, doesn't it
11 short-circuit? I thought you had a problem with the
12 header with this thing short-circuiting? And when you
13 ask them what the percentage is, I think you would get
14 some wild guesses of what the percentage is. What, 1
15 percent, 10 percent of these were short-circuit?

16 This device was approved in 2000. We are now
17 entering about the seven-year anniversary of this device
18 from its first marketing. And as of right now, we have
19 36 reports of short-circuiting problems out of the
20 population of 27,000 devices made before April of 2002.
21 It is that population that was subject to the FDA
22 recall. Those 27,000 devices, there have been 36
23 failures over the seven years since this product has
24 been put on the market, for a failure rate of .13
25 percent, just over one in a thousand, one-tenth of one

1 percent.

2 There are only -- and I don't say only
3 trivially, there have been three deaths or serious
4 injuries out of this 36, that is it. A very rare
5 phenomenon. So, when they come in to talk about the
6 claim that we exposed Mr. Duron to this significant risk
7 of failure, keep in mind, even now, .13 percent is the
8 risk of this device failing against the backdrop and
9 warned risk that these devices may fail for a variety of
10 reasons to deliver therapy.

11 And when you take a look at that in the
12 context, Your Honor, you look at the 5 percent, which is
13 what the projected liability was over three years, if
14 you take the industry average of 2.65 percent, or even
15 drop that back to 1 percent, which is what the Health
16 Heart Rhythm Society decided to be an alternative rate
17 of malfunction for implantable defibrillators. And you
18 compare it to the arcing failure rate on the right,
19 which started out at .01 percent, and really even now is
20 up to .1, .13 percent, it puts into context the rarity
21 of this event in the context of what we told the FDA and
22 what the industry background failure rate is.

23 So, I have been talking about short circuits.
24 Well, what about the malfunction rate, generally, from
25 all causes? I told you these things can fail for a

1 variety of reasons. What do we know about the PRIZM 2
2 after six years on the market? Remember, we said 5
3 percent failure rate from a variety of reasons. .42
4 percent malfunction rate for this product line, .42
5 percent. Hardly anybody is going to beat this in the
6 industry. This is the device that we are being accused
7 of sort of creating fear in people, that it has to come
8 out of people's body because of the great risk of
9 failure? .42 percent confirmed malfunction rate, and
10 that is in the 2007 product performance report.

11 But, the argument is, and we may hear it from
12 Mr. Drakulich. Yeah, but let's look at the recall
13 population. You are talking, Pratt, about all of these
14 devices from when they were marketed up until now. What
15 if we take the recall population before April of 2002
16 and compare it to the population after April of 2002.
17 Well, that has got to be a lot worse because we know
18 there was arcing in those early devices, as rare as it
19 was.

20 After April 16th, 2002, the survival
21 probability is 99.56 percent, that is pretty good with
22 the non-recall population. What about the recall
23 population? 99.45 percent. That, Your Honor, is a
24 statistical deadbeat in terms of the reliability between
25 the recall population of this device before April of

1 2002 and the devices made after April of 2002.

2 Just two other quick points I want to make,
3 Your Honor, because I am going to spend some time
4 talking to you about the appropriateness of how Guidant
5 handled the situation back in 2002. And you are going
6 to hear a lot about that today. I am going to talk
7 about it more in the punitive damage presentation.

8 The claim is, you should have warned the
9 world, you should have pulled things off the market and
10 all of that. I think it is important to discuss it in
11 the context of Mr. Duron, because this is his day, his
12 motion, just as it is our day on his case.

13 February 1, 2002 was the very first report
14 Guidant ever got of a short-circuit in the header of the
15 Prizm 2, February 1, 2002. Approved in August of 2000,
16 first report came in February 1 of 2002. We didn't get
17 the device in, but we got a report that there was a
18 problem in a person who had been dancing. She got
19 shocks. She wasn't hurt, but because they checked and
20 found the device wasn't functioning, they replaced it.
21 It came back, Guidant looked at it and said, we haven't
22 seen anything like this before. And they started an
23 investigation. One failure out of all of these
24 thousands of devices, they started an investigation.

25 March 9, 2002, with only one failure ever

1 reported like this with that product line, Mr. Duron got
2 his device. He started talking about punitive damages
3 and how unconscionable it was for the company. One
4 failure, still under investigation when Mr. Duron got
5 his device on May 9, 2002. We then continued the
6 investigation, March 16, 2002, when we made one change.
7 I will talk about that in a little bit. We didn't know
8 that that fixed really anything at the time.

9 We continued the investigation. After April
10 of 2002, we made another change in November of 2002, as
11 the matter was still under investigation. The failure
12 rate was hovering about 1 in 10,000 during this time.
13 And then after that, the rate remained pretty constant.

14 These are sort of the trigger dates, the key
15 events I just went through, Your Honor, from February 1,
16 2002, through the second change in November of 2002.
17 Over time, when you take a look at this, remember the
18 projected failure rate that we submitted to the FDA was
19 .1443 percent for implant month, and that is the way the
20 industry calculates these things is it gives you a sense
21 of whether the rate is going up over the increased time
22 that they are being used by patients.

23 The top line is the projected implant -- the
24 failure for implant month failure rate. The bottom line
25 will give you some sense of the implant failure rate per

1 month for this arcing failure, to show you the
2 comparison between how low and stable it remained during
3 that period of time. I will talk more about that when
4 we get to the other part of it.

5 I've got two other points to make, Your
6 Honor. One is that I think what has been lost in a lot
7 of this is the company, the people who make up the
8 company up there in Arden Hills, the people who are
9 dedicated to quality come to work every day to try to
10 make a better device, lifesaving device for people that
11 suffer from serious heart disease.

12 Guidant is an innovator, Your Honor, it was
13 the company that put the first commercial implantable
14 defibrillator on the market, came out with the first
15 transvenous lead that let's you not have to open up the
16 chest to put these leads on a heart. You could put it
17 in through the vein. Guidant did that.

18 It has the most advanced wireless monitoring
19 technology. We can sit at home and you can actually
20 monitor how your heart is doing, how your device is
21 doing. It gets uploaded to a website people can look at
22 it. Guidant is an innovator in that.

23 So, leader at the time, Your Honor, one thing
24 you are going to hear today and you are certainly going
25 to hear and you are certainly going to hear it over the

1 course of what we are here to do even beyond today, this
2 issue of when you notify physicians on low frequency
3 failures is an issue that is still under debate. There
4 is no consensus on it. Some doctors want a lot. Some
5 doctors want a little, the industry is participating in
6 that. Guidant, in particular, has been a leader in that
7 discussion.

8 They created the Independent Panel with the
9 goal to kind of say to this group, you tell us what you
10 think the trigger events ought to be for reporting on
11 low frequency failures. What process ought we have in
12 place?

13 Guidant participated in the Heart Rhythm
14 Society discussions which led to some recommendations
15 that the Heart Rhythm Society came out with. Guidant
16 has the most advanced product performance report on the
17 market, now. I don't think there is any question about
18 that, with more detail about failures and things like I
19 showed you a little bit ago that doctors can go to and
20 look at and evaluate in their discretion.

21 After the recall, Guidant offered free
22 devices to people, even though the failure rate was
23 extraordinarily low, a highly-reliable device, we told
24 people like Mr. Duron, if you want to have that device
25 replaced, it is your decision. We will give you a new

1 Guidant device and we will pay up to \$2,500 in
2 non-reimbursed medical expenses. We didn't have to do
3 that, but we did. And the final point I would make,
4 Judge, before I eat up my time and I may be beyond it,
5 is back to this slide on the milestones I just went
6 through, Your Honor, is this first bellwether case of
7 Mr. Duron.

8 I have got an 18-year-old daughter, and two
9 years ago I bought her a Jeep, a 2002 Jeep. And some
10 time, a year or so ago, we got a letter of Chrysler that
11 said there had been some reports of brake failures and
12 she was to take the Jeep in and have it sort of looked
13 at. She did. And it was taken care. And that was it.

14 There wasn't any thought on her part or mine
15 that she might have some lawsuit over that because she
16 may have been at peril of a brake failure, as low as
17 that risk was.

18 And I say that to Your Honor, because what
19 you are being asked to do by the Plaintiffs is to move
20 to an area where no one has gone. Mr. Duron, subject to
21 a recall, no question about it. The device did not fail
22 or malfunction, no question about that.

23 He wants to come in here and say, even though
24 I had no failure, I want you to compensate me on certain
25 product liability claims. Not only that, I want to rest

1 on the shoulders of other people so I can seek punitive
2 damages for that. And I know we get caught up in
3 litigation and devices and issues like that, like, well,
4 what does it mean -- and I am not trivializing
5 implantable defibrillators or lifesaving devices. I
6 understand that. But, the decision they are asking you
7 to make today doesn't just apply to implantable
8 defibrillators, it will apply to engines and Jeeps and
9 baby products. And if a person who has a perfectly
10 functioning device, who when you look at it there is
11 nothing wrong with it; that we are giving people like
12 that an opportunity to come into these great courtrooms
13 and say, not only pay me money, but give me punitive
14 damages. That is a jurisprudential leap that I think no
15 one has ever made. We will be talking about that during
16 the course of the day, Your Honor. And I think I have
17 probably exhausted my time. Thank you for your
18 attention.

19 THE COURT: Thank you. You wouldn't happen
20 to have an extra copy or two of that PowerPoint
21 presentation that you can give us?

22 MR. PRATT: Yeah, we will provide it.

23 THE COURT: In part because the screen
24 isn't -- did you turn that on, Amy, and it's not.

25 MS. GERNON: Yeah, and it keeps doing that.

1 MR. PRATT: Do you want me to do it all over
2 again, Judge?

3 THE COURT: I think you might have
4 misunderstood me, Mr. Pratt. I don't want to break,
5 now, but her screen isn't working.

6 MR. LESSER: Tim, can we get a copy, as
7 well?

8 MS. GERNON: Here, take this one.

9 MR. LESSER: Just make one for us later.

10 THE COURT: I will use the same format here
11 with Plaintiffs. I had some questions for Mr. Pratt. I
12 deliberately didn't ask him because I know that the
13 issues will come up in these individual motions, so I
14 viewed it kind of as some opening remarks, so I
15 deliberately didn't ask the questions. And I will do
16 the same, here. I will leave them for during the
17 motions, because, you know, most -- well, any issue that
18 was raised, I suspect the same will be with your opening
19 remarks, I will come back to the questions during the
20 motion, specifically. All right?

21 MR. DRAKULICH: Thank you, Your Honor. May
22 I approach?

23 THE COURT: You may. For all of you with
24 bifocals or trifocals, I won't look, you don't look at
25 me when I tilt my head down to get the right view, so --

1 MR. DRAKULICH: If I am doing the same to
2 you, Your Honor, it is only because --

3 THE COURT: All right, we can tilt.

4 MR. DRAKULICH: Good morning, Your Honor,
5 Nick Drakulich

6 THE COURT: Good morning.

7 MR. DRAKULICH: This is a case about
8 responsibility, the responsibility to carefully
9 manufacture a lifesaving device, the responsibility to
10 be honest as a manufacturer and share in not only the
11 good, but the bad, and even the ugly. After all, life
12 depends upon it with these devices, Your Honor. The
13 responsibility to place patient safety first.

14 I would submit to you, Your Honor, the facts
15 before you reflect that Guidant did not act responsibly.
16 They were not honest and truthful. Facts are tough
17 things, Your Honor, and no matter how hard they try,
18 they cannot wash away those facts.

19 Now, there was a board prepared for me for
20 this argument. I can't take credit for the board. I
21 was looking at it for the first time this morning and I
22 saw that they entitled it, "No SJ, the facts are in the
23 way." It is a clever lingo, but it applies in this
24 case.

25 And before I get off on that, Your Honor, I

1 wanted to shift gears a little bit just in terms of a
2 couple of things that counsel mentioned. And before
3 doing that, I noticed at the desk this morning when I
4 sat down that on our side, which is different in some
5 courtrooms I appear in. It says,
6 "Plaintiff/Government."

7 No case could be more appropriate than the
8 "Plaintiff/Government" in this case. Because this case
9 is also about a betrayal of trust. It is about the
10 betrayal of trust that the Government placed in Guidant
11 to play by the rules, and to follow the regulations.
12 And it is the betrayal of trust that doctors and
13 patients placed upon Guidant to be truthful.

14 So, with that in mind, I want to digress and
15 talk about my good friend's analogy about a brake
16 failure and the story that he was talking about
17 concerning his daughter and the recall of the car. And
18 I think no more appropriate way to place that in context
19 with this case and to focus upon what is really involved
20 here is to show you a slide.

21 And if you could put up the first slide,
22 Seth? And if you would turn, Your Honor, it would be in
23 this package. Do you have it on your screen?

24 THE COURT: I have got it right here.

25 MR. DRAKULICH: I am technically challenged,

1 so I need help from my friends from time to time. It is
2 entitled, "Market Share At All Costs." And
3 interestingly enough, what are we talking about, here?
4 We are talking about brake failure. The same thing that
5 Mr. Pratt mentioned. And who is talking about brake
6 failure? None other than Guidant's Medical Advisory
7 Board.

8 In June of 2005, after the recall, after the
9 public disclosure of these defects after, and for the
10 first time that their own Medical Advisory Board is
11 advised of the defect inherent in this device for over
12 three years and concealed it. And what to they say?

13 First of all, they want to know who knew
14 what and when, which is always a good starting question,
15 and we will talk about that a little bit this morning,
16 Your Honor. But, they say the biggest issue is that
17 Guidant continued to sell PRIZM devices after the
18 change. Example analogy: Cars and brakes.

19 The PRIZM issue isn't a random component
20 failure, it is a known failure. It was identifiable and
21 you could fix it. You wouldn't continue to sell cars
22 with a known brake failure mechanism, would you?

23 Now, it is a perfect analogy, because under
24 the facts before you, Guidant knew that they had a
25 defective product. They knew that they had a defective

1 insulation. They knew it way before Mr. Duron's device
2 was implanted, and I will speak about that more, Your
3 Honor, in February -- in March of 2002. But, what is
4 even more troubling is what they -- after discovering
5 the harm, Mr. Pratt talked about the company continued
6 to investigate, and continued to investigate after the
7 February 1st failure.

8 Well, Your Honor, they investigated over
9 three and a half years until they were forced to do
10 something by the public disclosure of the death of an
11 unfortunate young man, a death that could have been
12 prevented had they been honest, had they been truthful,
13 had they played by the rules.

14 Because the elephant in the room and the one
15 that Guidant wants to ignore and to sweep under the rug
16 and to wash away the dirty stain, is the fact that in
17 June of 2002, following only three failures, only three
18 confirmed failures, Guidant did a health risk
19 assessment.

20 And what did this health risk assessment
21 tell them? Well, it told them that there was a problem
22 with the feedthru wire to the backfill tube shorting.
23 The same problem we will speak about with respect to Mr.
24 Duron, and the same problem unfortunately experienced by
25 that young man, Mr. Oukrop.

1 What is the product? It is the product we
2 are talking about here, the PRIZM 2. And what do they
3 say -- well, and also, there are 24,427 devices in the
4 market at that time, including the Plaintiffs'.

5 What do they say about the description of
6 this hazard? A breach in the polyimide tubing that
7 insulates the feedthru wire from other conductor
8 surfaces results in a shorted condition to the backfill
9 tube.

10 What are the factors mitigating this risk?
11 None. Who is at risk of this life-threatening defect?
12 All. Health consequences could be life threatening if
13 the patient requires tachy shock therapy after the shock
14 occurs.

15 And if you go to that next page, what did
16 Guidant know? They knew that the likelihood of injury
17 from this risk of the entire population was very likely,
18 10 percent. Life threatening. Death could result if
19 the patient requires tacky therapy prior to device
20 replacement.

21 Now, I agree with Mr. Pratt that there is an
22 issue with sudden cardiac death in the United States.
23 People will die if they do not get a shock. It is a
24 deadly disease. The Prizm 2 was a deadly, dangerous
25 defect. They knew it, but they hid it from the FDA,

1 they hid it from doctors and they hid it from
2 unsuspecting patients whose very lives were dependent on
3 that shock being delivered when required. And what does
4 the FDA say about when they finally, after the
5 disclosure, the sunshine given by Dr. Hauser, calling it
6 the death of his patient, who could not get a response
7 from his company to do the right thing, a company that
8 had an opportunity to do the right thing three years
9 previously; but, decided that market share was their
10 primary goal and I will support that as we proceed.

11 What did Dr. Hauser do? He was forced to go
12 to the New York Times so that the warning could get out
13 to the world. And a quick comment about Dr. Hauser, if
14 I may, Your Honor. He is a fine doctor here in
15 Minneapolis. He is head of the Minneapolis Heart
16 Foundation. He was one of the founding members of
17 NASPE, which became the Heart Rhythm Society, in
18 conjunction with our expert, Dr. Thiers in this case.

19 He was a former president of CPI. And it is
20 very interesting what transpired after Dr. Hauser left
21 CPI and doctors were pushed aside and marketing people
22 took over. You saw a dramatic change in how this
23 company conducted themselves with respect to patient
24 safety.

25 So, I moved off topic a little bit only in

1 response to Mr. Pratt's comments about how this company
2 has behaved appropriately, and discussing the analogy of
3 car brakes. But, before I proceed too much further in
4 my argument, Your Honor, I want to talk about Leopoldo
5 Duron, because this is his case. He is a real person.
6 He is not a statistic. He is not the statistic that
7 Guidant relies upon in deciding whether or not Leopoldo
8 Duron -- I should call him Leo, because the first time I
9 met him he said, "Nick, would you call me Leo? Everyone
10 calls me Leo." So, if you don't mind, Your Honor, it is
11 a little informal, but I will call him Leo today.

12 THE COURT: All right.

13 MR. DRAKULICH: You have a picture up on your
14 screen, Your Honor, of the Plaintiff Leopoldo Duron, and
15 he is there with his wife of 35 years, Irene.

16 And Leopoldo is described in the
17 deposition -- and, you know, they have taken a
18 deposition of every known person I think -- they have
19 taken the deposition of his daughters, his wives, his
20 mothers, his co-workers. What do they all tell us?
21 They tell us Leopoldo Duron is an extraordinary man. He
22 is 73 years old. He has worked his whole life. He
23 still works to this day. In fact, he regrets he can't
24 be here today because he is working, but he is here in
25 spirit and with his personal counsel.

1 He is a man who is described by his boss as
2 dependable, reliable, trustworthy individual, a peach of
3 a guy. Everyone loves Leo. And when we discuss what
4 Leo has been forced to endure because of this company's
5 conduct, I think you will have a better perspective, and
6 perhaps you already do, about the trauma that he and
7 thousands of people throughout the United States have
8 experienced because of this company's conduct. So, it
9 is nice to talk about statistics, and we will, but this
10 involves real people and real damage.

11 Now, I mentioned rush to market. And while I
12 say that, to give some context, Your Honor, you have
13 been provided -- what? A thousand pages of documents?

14 THE COURT: That might be a little low. And
15 I think you are going to have to get those numbers up.

16 MR. DRAKULICH: I think that is right. And
17 I don't know, probably an equal number of exhibits.

18 THE COURT: No complaints, no complaints.

19 MR. DRAKULICH: No, it is impressive that you
20 have been through that. That is quite a task. It is a
21 complicated device, Your Honor, but it is, I think, a
22 very simple story.

23 And the story revolves around what motivated
24 a company to not do the right thing, to not play by the
25 rules. And I think the answer is in their driving

1 concern for market share above patient safety. So, I
2 put up on your screen their marketing plan for this very
3 device. And what does that marketing plan in 1999 talk
4 about? It talks about their goal: We must introduce a
5 new product every 9 to 12 months.

6 And then it talks about their number one
7 driver, time-to-market. It explains why they
8 short-cutted safety. It explains why they did not
9 disclose. It explains a lot of things, Your Honor,
10 because look what it says. It says, we have got a
11 competitor out there and that competitor is named
12 Medtronic. And interestingly enough, I see Medtronic in
13 the courtroom even here today for this argument. And
14 they are concerned because they say it is a two-horse
15 race in this document. Medtronic has come out with a
16 smaller device. And if we don't compete and get to
17 market with our small device, we are going to lose
18 market share.

19 And Your Honor, you had a picture of these
20 devices. And I should have brought in -- and I was
21 thinking of doing it and maybe on the next occasion I
22 will. But, how these devices, from the very first
23 device, which is the one that Mr. Pratt refers to where
24 he says polyimide was first used 10 years ago, the PRx
25 device. I had Mr. Novak hold that up in a deposition

1 and it looked like a small cantaloupe. It is implanted
2 in the abdomen, abdomen of the body. Contrast that with
3 this miniaturized device that Guidant was pushing to get
4 out so that they would not lose market share to
5 Medtronic's device.

6 So, what are they told? "Shorten your
7 cycles." They use the exact language, "Move things
8 closer. Get this product out."

9 Now, a company that produces lifesaving
10 devices and benefits people should be rewarded. It is a
11 good service. And they should be a handsomely
12 compensated for doing that. But, a company that
13 shortcuts safety and is not honest and does not play by
14 the rules is not entitled to the same deference and
15 respect. And this company skipped all of the bases,
16 Your Honor.

17 And I put up this next slide just to show
18 this, their marketing strategy. And it is really a
19 curious comment. I first thought it was a joke, because
20 these documents were from Guidant. These facts are from
21 their documents, from their witnesses. This isn't a
22 plaintiff's spin. And what do they say their marketing
23 strategy is?

24 "Marketing department vision: We must strive
25 to be money hungry, market share at any cost to

1 individuals, whose sole purpose is to wildly promote
2 product."

3 Well, even if that is a joke, Your Honor, it
4 is a sad one. And quite frankly, the facts bare out
5 that their vision was accomplished with this device.

6 So we get to the next issue, Your Honor,
7 which is the issue of wrong stuff, the polyimide story.
8 Why do I say that, the wrong stuff? It is because since
9 1971, scientific literature widely available confirms
10 that this is the wrong stuff.

11 In 1992, there was a Navy paper published
12 that shows it was the wrong stuff; that when exposed to
13 stress and humidity and temperature, just like the
14 conditions within the human body, it will degrade and
15 will cause arcing and shorting.

16 Now, I've attached a copy of that paper, Your
17 Honor, but they knew, as well, it was the wrong stuff.
18 Why do I say that? Because in 1995 their own documents
19 say, we got to get this stuff out. At issue here are
20 insulation techniques, since the use of polyimide tape
21 will be highly discouraged. It's talking about a Mini
22 III device, a device, actually, Your Honor, that
23 preceded the PRIZM that had, according to Suzanne
24 Parisian, Former Chief Medical Officer for the FDA and
25 the Device Section had hundreds and hundreds of arcing

1 failures to the can.

2 Now, I would say, Your Honor, if Guidant knew
3 that they were having arcing failures to the can of the
4 device which is to be hermetically sealed, certainly
5 they had prior notice that a feedthru wire exiting
6 outside the can exposed to body fluids would suffer the
7 same issue.

8 I was trying to talk about this case with my
9 youngest son. I do this sometimes because I say, you
10 know, he always tells me, "Dad, talk like a person, will
11 you? Because you talk sometimes too much like a lawyer
12 and I don't understand what you are saying."

13 And when I talk to him and I explain this
14 thing about polyimide, arcing to the header and
15 degradation -- these guys are so much smarter than me.
16 First of all, he went on the internet and googled. And
17 he said, "Well, Dad, if you go up there, gee, there's
18 all kinds of stuff about polyimide. You can find out
19 everything you want to know. You can find out that in
20 1985 the United States Navy retrofitted all of their
21 planes to get this material out, because it was causing
22 plane crashes."

23 I said, "I didn't know that." And so, I
24 asked Mr. Novak when he was the Vice-President of their
25 Regulatory Affairs, "Do you guys have computers? Do you

1 ever Google? Because, you know, you are required, the
2 FDA regulations require you continually to monitor your
3 products and your critical components, to report to the
4 FDA when published or unpublished data indicates that
5 there may be problems with the material that you are
6 using, such as a critical insulating material.

7 And what do we have in this record, Your
8 Honor? We have since 1992 not one document filed with
9 the FDA by this company reflecting the widely-known fact
10 that this insulation was a problem.

11 Not only known in the scientific journals,
12 not only required by GAO reports, but known by the
13 company, itself. I mean, at one point I thought the
14 ostrich defense may be applicable, here, but it is not.
15 Because in the documents you have before you, you know
16 that Guidant acquired Intermedics in 1999, a
17 wholly-owned subsidiary of Guidant; that people within
18 Intermedics studied the use of polyimide years before
19 and determined it was suitable material for use.

20 People within the company knew, scientific
21 literature confirmed, and yet this company continued to
22 do nothing. In fact, if you go to the slide that says,
23 "Guidant knew but ignored." This is a slide prepared by
24 Keith Johnson, their Director of Engineering, and Fox,
25 the Director of their Research and Development. And

1 they prepared, they were preparing a paper for the FDA.

2 When this was finally disclosed and the FDA
3 brought them in and said, what do you guys -- you come
4 in. We want to know what you know and when you knew it
5 and what is the problem. They said: Well, maybe the
6 best thing to do is prepare a white paper and to tell
7 them, you know, what we know about polyimide and what we
8 didn't know.

9 And so, they prepared a draft white paper.
10 But, what you will see here from the draft, the final
11 product to the FDA, there is little change. And what
12 did they know and what did they say in the draft? In
13 August of 2004, materials people were added to the team
14 because of the Renewal 1 and 2 failures, the same
15 problem here, polyimide, that we are going to have for
16 the next series of trials, Your Honor, the same
17 defective insulation.

18 It is comforting to know that they finally
19 brought materials people to the team in August of 2004.
20 These individuals were aware of published information
21 about Polyimide stability in human conditions and of
22 polyimide research previously done by Intermedics, their
23 wholly-owned subsidiary.

24 Team focus quickly shifted to polyimide
25 breakdown as an important mechanism to understanding the

1 root cause. That focus, Your Honor, should have shifted
2 before they ever introduced this product to the
3 marketplace. That should have been their focus and that
4 is their obligation under the law when they make
5 applications to the FDA, to do the proper research and
6 testing before bringing a lifesaving technology to the
7 marketplace that contains life-threatening defects.

8 So, I say it is the wrong stuff, it is
9 confirmed it is the wrong stuff. They knew it was the
10 wrong stuff. Others in the industry, their competitors
11 who became subsumed by them knew it was the wrong stuff.

12 But, then we go next to this issue with
13 respect to the wrong place. And we have developed a
14 slide here, Your Honor. It is a schematic that we have
15 taken after from the documents from Guidant. And to
16 give you some perspective you will see the location of
17 the backfill tube, and you have heard a lot of
18 discussion about that, and the DF feedthru wire.

19 It was important that that DF feedthru wire
20 not be in contact with the backfill tube. Because when
21 you put metal upon metal or two wires together, you
22 don't have to be a scientist to know that can be a
23 problem.

24 So, it was important to have those separated.
25 It was important to have a space between them. It was

1 important that didn't have to become in contact like
2 they did after the explant, after the review of Josh
3 Oukrop's device, and as they do in this case with Mr.
4 Duron's device.

5 This is a manufacturing defect, clear and
6 simple. If you turn to the next page, Your Honor, if
7 you would, please, that is Mr. Duron's device. And you
8 can't determine this until after the explant. But, what
9 does it show? It shows the DF feedthru wire sitting
10 directly on top of the backfill tube. A clear
11 manufacturing defect is hard to imagine. Pictures speak
12 a thousand words, and this picture says it all, Your
13 Honor. He was sitting, within his chest -- I am sorry,
14 I am too close? They say I am too close to the
15 microphone. I apologize.

16 THE COURT: The sound systems in here, and
17 they are all the same in every courtroom, and they are
18 soon to be replaced, but they are bad.

19 MR. DRAKULICH: Well, I am loud, so I will
20 back-up. And I apologize if I was --

21 THE COURT: Actually, it is a combination of
22 cheap speakers and cheap microphones, to be quite
23 candid, so --

24 MR. DRAKULICH: And a loud lawyer, so --

25 THE COURT: I'm not sure about that,

1 actually.

2 MR. DRAKULICH: This is the proof of the
3 defect, Your Honor. Here it is, front and center. In
4 this device, at the time of explant, which could never
5 have been confirmed until he had his replacement.

6 As a matter of fact, Guidant acknowledges,
7 they sent letters to patients saying, we don't recommend
8 you replace these devices. But, by the way, there is no
9 way for you to practically test, you or the doctor, to
10 know whether or not you have that life threatening
11 defect in you. Nothing you can do. But, we have got
12 some statistics. And you should rest assured that our
13 statistics are correct, because, you know, your life
14 depends upon those statistics.

15 And we will talk about the statistics,
16 because I think the Mark Twain analogy and that famous
17 quote, and you will find it actually got in quotes, Mark
18 Twain, in here about "There are three types of lies -- "
19 that is a Guidant document. "Lies, dam' lies and
20 statistics." It applies in this case, Your Honor.

21 But quickly, this next slide is on
22 biocompatibility assessment, and just to give you a
23 flavor, to step back from the trees, Your Honor, because
24 you have had so many trees with documents and exhibits.
25 I am trying to give you an overview. And whenever you

1 produce a lifesaving device, the FDA says, you know,
2 make sure it works. Make sure you have done the proper
3 tests. Submit to us the biocompatibility assessment you
4 have done to prove it is going to withstand the
5 environment of the body. And here is the
6 biocompatibility assessment that Guidant produced to the
7 FDA in 2000.

8 And if you look at that, Your Honor, it
9 talks -- they say that materials that either directly or
10 indirectly are exposed to long-term tissue are listed in
11 this table. And you proceed to the next table, and they
12 list all of the materials, but there is one missing,
13 polyimide.

14 And then the next page, Your Honor, I called
15 this the "Needle in a haystack," because this is a
16 needle in the haystack. Mr. Novak during his deposition
17 was kind enough to bring me this exhibit to the left,
18 the head of Regulatory Affairs. And I put this little
19 thing to the right to give this some description.
20 Because I was asking him, would you give me the history
21 of the approval of the product and where you say that
22 you told the FDA about polyimide in 1992? So, he
23 prepared this chart, and it is kind of interesting,
24 because here is the device, the PRIZM 2, which was
25 approved in August of 2000. And he has got a chain to

1 try to get me through the haystack. Because the
2 predecessor device was the PRIZM 1. Then you go up to
3 the VENTAK AV device back in 1997. And then if you
4 really -- if you want to find the document that Mr.
5 Pratt is referring to after going through thousands and
6 thousands and thousands of pages of PMA submissions, and
7 PMA supplement submissions, you will find it over here
8 in 1992 with an unrelated family of device called PRx.

9 And you go through that entire submission
10 and the last page of the component qualification test,
11 you will find an interesting footnote. I had to get my
12 glasses on to read it. It is very small. Hopefully you
13 can see it in the materials submitted. And actually,
14 this is a document that the Defense have included, so
15 you will see it in their index list.

16 And on that footnote it says, "This
17 specification describes medical grade tubing, for use as
18 non-body contact insulation," for use as non-body
19 contact insulation. This is the test, and this is the
20 report that he is referring to that says that the FDA
21 approved it with respect to the Prizm 2 device, the one
22 here at the very bottom of this chart.

23 A limited component qualification test done
24 8 to 9 years previously for non-body contact. Did they
25 update that test in the eight to nine years before they

1 submitted to the Prizm 2? Did they look at the
2 scientific literature that existed with respect to what
3 was known or should have been known with respect to
4 polyimide in the nine years? Did they talk to people
5 within their own company to determine that this was a
6 defective and dangerous material?

7 If you turn to the next page, Your Honor,
8 please, it says, Defendant admits lack of polyimide
9 testing. And here it tells the story. This is a
10 document produced from Guidant, where after the FDA
11 finally said, what is in these devices -- how are you
12 using these devices and what is the problem, here, after
13 the New York Times article and they are brought into the
14 FDA and they have a series of meetings. And those are
15 very interesting memos that you have before you, Your
16 Honor, because they are very revealing.

17 And this is a memo from Kent Fox, again he
18 is the R & D Director. And he says, I'm trying to
19 revisit, what is the history. I am trying to find out,
20 myself. He is trying to find a needle in the haystack
21 that I went through in the deposition. I'm trying to
22 research where we used this material for the first time.
23 And where it was used, it was in 1994 with the PRx
24 device. It is that one with the arrow going up in the
25 prior draft, Your Honor, for the unrelated family. And

1 what is the admission, here? "Supporting analysis data
2 for the tubing in this application obviously did not
3 determine the dielectric breakdown could occur given
4 time, stress, and humidity." The Hazard Analysis
5 specifically addressed header arcing ... I was "...
6 unable to find any specific Peer Review documentation
7 regarding the use of polyimide tubing in the header."

8 It also talks to the reliability assessment
9 here that Mr. Pratt referred to. No assessment of
10 polyimide, none is provided. Zero with respect to the
11 use of polyimide.

12 MR. PRATT: Your Honor --

13 THE COURT: Mr. Pratt?

14 MR. PRATT: Your Honor, a point of order. I
15 don't think I in 30 years interrupted a counsel. But, I
16 am concerned about this. When we met yesterday for the
17 first time, the notion was we were going to spend 10 to
18 20 minutes talking about the factual background.

19 This morning it was 20 minutes is what I
20 heard. I significantly cut back everything I was going
21 to say. Mr. Drakulich has gone on for over 30
22 minutes --

23 THE COURT: 33 and a half, to be exact.

24 MR. PRATT: And as I look at it, he has got
25 much more to go. I mean, talk about playing by the

1 rules. I mean, I could have come in to have done my
2 hour and a half opening statement --

3 THE COURT: I would think these are more like
4 closing arguments than opening statements.

5 MR. PRATT: I have got a two-hour closing.
6 But, Your Honor, it is a little unfair, because I came
7 in with a 20-minute presentation on our case. He has
8 been able to go on 30 minutes, after they said they
9 would go 20. And he is nowhere near done.

10 Now, I just think it is unfair for this to be
11 a one-sided, document-laden, factual presentation by the
12 Plaintiff, when I was led to believe because of a
13 promise by them that it was going to be a general
14 overview of about 20 minutes. So, I mean, already I
15 have given him 10 minutes more than I had.

16 MR. DRAKULICH: Your Honor, I didn't realize
17 I had run over and I will try to move this quickly and
18 conclude it.

19 THE COURT: What really has happened here,
20 though? I mean, this started out a week ago, 10 to 20
21 minutes, then they ended at 20, we are at 33, now. Mr.
22 Pratt went over about 3 or 4 minutes. If this is a sign
23 of things to come -- it rarely happens, frankly, with
24 experienced lawyers in Federal Court. I rarely see it,
25 but can you sum up in five minutes, noting Mr. Pratt's

1 objections?

2 MR. DRAKULICH: Absolutely, Your Honor. And
3 I apologize. I did not realize -- I was looking for --
4 I am used to these times up here with the red button,
5 the yellow button, and the green button.

6 THE COURT: I try not to use those, but we
7 have got them. We have got them.

8 MR. DRAKULICH: You won't need them with me
9 again, Your Honor.

10 THE COURT: All right.

11 MR. DRAKULICH: I apologize if I overextended
12 the courtesy you have provided. There are a lot of
13 facts. I'm trying to get them out quickly. I think I
14 would be remiss if I didn't summarize by talking about
15 Leo Duron and his injuries.

16 THE COURT: All right.

17 MR. DRAKULICH: And if you could place up the
18 picture, please? This is the picture of Mr. Duron
19 following his explant surgery. Do you have that on your
20 screen?

21 THE COURT: I do now. I do.

22 MR. DRAKULICH: Mr. Duron had this device
23 implanted, as Mr. Pratt said in March. He had it in
24 '02. He had it explanted pursuant to the
25 recommendations of his physician that the evidence

1 before you is clear that it was the physician's call.

2 In fact, the same physician said he made his
3 patients who had the similar device sign a form if they
4 decided not to have them removed, because that was his
5 recommendation. But, following that surgery, Your
6 Honor -- and preceding it, of course, the evidence is
7 replete with the distress that he suffered after
8 learning about the recall, finding out that his device
9 was defective in reading about it in the paper. He
10 wrote his own obituary. He was concerned about dying.

11 And the record is also very full, Your Honor,
12 with the serious nature of injuries he suffered. I
13 mean, this is not just a car recall. This is a man who
14 had to have a device replaced, a device that was
15 determined to be defective by the FDA, a Class 1 recall,
16 a device that the FDA said could cause serious injury or
17 death, who had it replaced at the recommendation of his
18 physician and underwent complications, including before
19 the device having to inject himself for two weeks in his
20 own stomach to prepare for the operation.

21 And then following the operation, the
22 excessive bleeding and the bruising that you have seen
23 and the emotional distress that he has suffered, which
24 is real. It is real, as testified to by his treating
25 physician. It is real as has been testified to by the

1 experts that have been hired. So, I just thought, Your
2 Honor, I would be remiss without at least mentioning
3 that this is a real man with a real case who has been,
4 in fact, really injured.

5 And sometimes when we talk about statistics
6 and sometimes when we talk about graphs and charts,
7 sometimes we lose the fact that wrongful conduct has
8 consequences. And unfortunately, the consequences of
9 the wrongful conduct were borne by the patients in this
10 case and by the doctors who trusted this company to be
11 honest and play by the rules. Thank you.

12 THE COURT: Thank you.

13 What I would like to do is go to the opening
14 argument on the first case, if we could, take a late
15 morning break, if we could, and I could be persuaded to
16 break here. Why don't we go ahead?

17 Ms. Cabraser, I assume by the fact that you
18 stood up, you are ready to head to the podium?

19 MS. CABRASER: I am ready to head for the
20 podium, Your Honor. And this is a res ipsa argument.
21 When you see me coming, you know I am going to be short.
22 This is the Choice of Law Motion. And it is a motion of
23 endless fascination.

24 THE COURT: It is.

25 MS. CABRASER: To some people, including me.

1 And it has been handled differently by different MDL
2 courts, as Your Honor knows. And some of the
3 complications involved -- we are all fortunate here,
4 because whoever is to blame for anything else in the
5 case, factually or legally, neither side is to blame for
6 the state of the law on choice of law in the United
7 States. But, we all have to deal with it and we have to
8 deal with it in ways that advance the policy interests
9 of the states involved, satisfy the Constitution, and of
10 course advance the interests of this MDL. And so this
11 is a special case for choice of law as the courts have
12 begun to struggle with.

13 One reason that we can look at this a little
14 differently than some of the other MDL courts have is
15 that we have a separate -- we have a different set of
16 operative jurisdictional facts, unlike some MDL's, like
17 Vioxx, for example, we have a master complaint in this
18 complaint that covers not just the class action, but the
19 individual cases, as well.

20 And individual Plaintiffs like Mr. Duron had
21 a choice to adopt that master complaint by reference,
22 and file their own superseding complaints in this Court,
23 in the District of Minnesota, which is what Mr. Duron
24 did. He filed his Complaint by adoption. He
25 specifically asserted all of the damages and equitable

1 claims. He asserted all of the claims. He asserted the
2 Minnesota UDAP claim, specifically.

3 So, this is not the Vioxx situation in which
4 the Court wanted to try some cases. But, there wasn't a
5 master complaint and the Court was dealing with cases
6 that had been transferred in for pretrial purposes.

7 We to have an agreement here, by the parties
8 under Lexicon, that the representative cases can be
9 tried here; but, that is not the only reason the cases
10 can be tried here. Mr. Duron's case can be tried here
11 because it is a District of Minnesota case. This Court
12 has original jurisdiction. Minnesota is the forum
13 state. And so, the Minnesota choice of law rule would
14 apply.

15 THE COURT: When you say it is a Minnesota
16 case, it was originally filed in the state of
17 California.

18 MS. CABRASER: It was originally filed in the
19 state of California. And if Mr. Duron had not filed a
20 new complaint here in the District of Minnesota with a
21 new case number, he would be in the more conventional,
22 historically conventional MDL situation of just visiting
23 on the Monopoly board, ready for remand back to
24 California at the conclusion of these proceedings. And
25 there might be a special agreement among counsel to

1 enable his case to be tried here. And in fact, there is
2 an agreement among counsel that his case can be tried
3 here.

4 THE COURT: If I may ask, because I think the
5 answer to the question, even though we are only
6 concerned here today, appropriately so, with this
7 case -- I mean, it will have impact on others, even
8 though the other bellwether cases didn't all get in here
9 the same way. To use a phrase, and I would like to
10 think I would have asked it anyway -- I think I would
11 have -- even without Judge Fallon's comment that the
12 answer lies in a stipulation which addresses or
13 clarifies these issues.

14 I mean, I understand the agreement to try the
15 case, here. I understand that we are going to try it to
16 a conclusion. What I see missing is an agreement
17 between the parties, or any discussion -- and no
18 decision I make will be based upon some off-the-record
19 discussion we may or may not have had in chambers or
20 elsewhere during our conferences. But, we've taxed our
21 memories to say, where can we go and find, short of
22 interpretation of this new complaint procedure, where
23 the parties sat down and said, here is what it means for
24 choice of law by agreeing to these bellwether cases and
25 also agreeing to come in with a superseding complaint or

1 complaint by adoption. And it is difficult for me to
2 find anything where it says that -- in fact, I remember
3 from day one, people have hinted to me in some of these
4 areas there are going to be choice of law issues, which
5 seemed a little contrary to saying, we all agree that
6 the effect of this would be Minnesota is going to be the
7 choice of law. I don't see that anywhere, Ms. Cabraser.

8 MS. CABRASER: And I don't personally recall,
9 Your Honor, any express discussion with respect to,
10 well, are we going to agree on which law applies? Other
11 counsel may. I don't. In fact, it became apparent as
12 this case was being prepared for trial that it turned
13 out that the parties didn't agree on which law should
14 apply, which is why the Court is being asked on motion
15 to make a choice of law determination.

16 In other cases, this issue has been avoided
17 because the parties have happened to agree. There was a
18 chance, I would imagine, that we might have agreed on it
19 and it turned out that we didn't.

20 THE COURT: I am sorry to interrupt, but I
21 may be asking before we are done, that separate from the
22 decision I make, and this may be one of those that the
23 sooner you get a response from me, the better. But, I
24 will be curious to know whether it is during your
25 argument of both counsel or at the end is regardless of

1 how you see the issue, because your briefs, I don't
2 think, leave anything to my imagination in terms of,
3 well, here is how we see it. And that is whether there
4 are some counts in the Complaint where either of you are
5 going to say, well, regardless of how you come down on
6 this, we agree it is exactly the same under both
7 California and Minnesota law and it will be tried in
8 exactly the same way.

9 Now, you have isolated two counts where that
10 is not the case. The Defendant doesn't concede quite
11 that many. But, I will be curious when we are done here
12 on this issue, are there counts where people say, well,
13 either way, Judge, here is the way it is going to be.

14 MS. CABRASER: We were only able to identify
15 two areas in which we saw a clear distinction. And one
16 of them isn't so clear, and one of them is relatively
17 minor, the difference between \$5,000 and \$10,000 in an
18 individual case is relatively minor.

19 And with respect to the implied warranty
20 privity requirement, California law seems to indicate
21 that privity in the traditional sense would not be
22 required, either. It is not quite as clear as it is in
23 Minnesota, but probably not outcome dispositive, here.
24 I think the parties do have debates over who would win
25 and who would lose on the other counts under either

1 state's law. But, if you compare the jury instructions,
2 the CACI jury instructions in California and the CIVJIG
3 jury instructions in Minnesota on most of these issues,
4 this case at trial was going to be driven by the facts
5 and is going to be driven, you know, by the assessment
6 of those facts under the multi-factor test which both
7 states' law provide to the jury.

8 So, I think the real issue here and why there
9 is a dispute isn't because one side thinks it is going
10 to lose and the other side thinks it is going to win
11 depending on the choice of law outcome, it is that we do
12 have a situation where we have a plaintiff who filed a
13 case in the District of Minnesota, it was a superseding
14 complaint. This is the forum state.

15 The Minnesota choice of law rules would
16 govern the analysis of which law applies. We know,
17 constitutionally, there is no issue. I think the
18 parties agree on that.

19 THE COURT: I think that is true, that is
20 true.

21 MS. CABRASER: Either way, we have indicated
22 in our brief -- we have done the analysis, just to be
23 safe, under California's Comparative Impairment Test, as
24 well as Minnesota's Choice Influencing Factors, which by
25 the way were first published by Professor Leflar in the

1 University of California Law Review article. And it
2 comes out, in our view, it comes out the same way each
3 time. Minnesota has the primary interest because the
4 company is here. The pertinent acts and decisions for
5 design and manufacture and quality control were all made
6 here.

7 It is fortuitous that Mr. Duron received his
8 device in California. We know we have people across the
9 country with these devices. And I think where I am
10 really headed on this, just to cut to the chase, is that
11 some of the Minnesota Choice Influencing Factors are not
12 often evaluated, because they are not often relevant.
13 But, I think in the MDL context they are, because this
14 Court has a special task.

15 Through the conduct of representative trials,
16 it is tasked with helping the parties gain a view of the
17 merits and the values of the cases, to advance all of
18 the cases toward adjudication or resolution. And these
19 representative trials are a first step.

20 It seems to us far more efficient, far more
21 consistent, far more predictable to try these
22 representative cases under the law of the state which
23 Guidant knew it was charged with obeying, the law of its
24 place, the law of the place where the pertinent
25 decisions were made, rather than to have a series of

1 representative trials all tried in Minnesota, before a
2 Minnesota jury under varying states laws.

3 This Court, I am sure, can handle any state's
4 law and any state's jury instruction and counsel are
5 used to doing that, too. But, there is something to be
6 said for a district court trying the case to utilize the
7 forum state's law in a series of trials where one of the
8 primary reasons the Panel set the cases here, and it is
9 reflected in the Judicial Panel's decision, is that this
10 district and this state has a nexus to the events and
11 conduct at issue.

12 This case wasn't randomly sent by the panel
13 to Wyoming or Florida or Louisiana, in which case there
14 might be some very much more difficult issues with
15 respect to what law to choose for representative trials.
16 And unlike other MDL's, in this case, we did file a
17 Master Consolidated Complaint, not just for the class
18 actions, but for the individuals, too. That wasn't a
19 forced choice.

20 The individual Plaintiffs had the right to
21 decide whether to stay here as transferor cases and go
22 back at the end, or to make their choice and file in
23 Minnesota, and be bound by Minnesota choice of law, and
24 presumptively and predictably Minnesota substantive law,
25 so that their trial experience would be valuable and

1 determinative not only to them, but would advance the
2 MDL for everyone. So, when you look at the Minnesota
3 choice-influencing factors, and you look at some of
4 those which have not always been given a lot of
5 consideration, but those that impact the administration
6 of justice, those that impact the institutional issues
7 that would concern the Court, I think this Court as an
8 MDL court has the opportunity and is certainly justified
9 to view those factors in a way that enables it to do
10 what constitutionally it can do, what under Minnesota
11 choice of law factors it can do, and what under
12 California Comparative Impairment Factors it can do,
13 which is to choose Minnesota law to govern these claims.
14 We cited in our papers quite a bit, the St. Jude
15 decision. Done in a class action context in which a
16 choice of law was going to be imposed on people as
17 members of a class and their only choice would be to
18 opt-out on consumer claims. And the St. Jude Court
19 determined that that was appropriate using Minnesota
20 factors to apply Minnesota law to the nationwide claims
21 of a consumer class on conduct and products emanating
22 from Minnesota.

23 After we filed a reply brief, Judge
24 Montgomery, in whose courtroom we meet today, issued a
25 decision called Mooney versus Allianz Life Insurance

1 Company. It came out on May 10th, 2007. I wish it
2 could have been in our reply brief. The cite is 2007
3 WestLaw 1412549, another consumer class action, not
4 medical devices, not an MDL, utilizing Minnesota choice
5 of law principles to certify a nationwide class under
6 Minnesota Consumer Law, because there, as here, the
7 conduct at issue involved a Minnesota company and
8 largely occurred in Minnesota and the consumers,
9 themselves, came from around the country.

10 So, this District has a jurisprudence that is
11 faithful to the Minnesota choice of law regime; that an
12 MDL is another complex litigation involving the claims
13 of consumers, chooses Minnesota law in situations where
14 there is less choice for the Plaintiff to predict and
15 understand and appreciate and decide to be bound by that
16 law.

17 I think in this case it is a much easier task
18 for this Court to choose Minnesota law, because it is
19 not only theoretically fair, it doesn't only comply with
20 due process, it doesn't only make sense in terms of
21 where the conduct occurred, and it is not only extremely
22 helpful to making these representative trials as
23 valuable, effective and useful as they can possibly be.
24 Mr. Duron had an individual choice and he made an
25 individual choice. And he chose to come to this Court,

1 to submit his case to the decision making of a Minnesota
2 jury under Minnesota law. He can't be denied the
3 opportunity to do that. It is not unfair to him to
4 allow him to do it. It may well be unfair to him to say
5 he is branded California and can only proceed under
6 California law. And it is certainly not unfair or
7 unpredictable to Guidant to say, you chose to do
8 business here. You made your decisions here. You
9 designed your products, here. You worked with the FDA
10 here. You did everything here. You knew what the laws
11 were. They haven't changed since you have been here.
12 It is predictable for you to submit yourself to the
13 authority of those laws. And so when you face
14 individual trials in this nationwide litigation arising
15 from that conduct, the representative trials to be tried
16 here should be tried under Minnesota law.

17 If there is a need to try cases for some
18 reason, as yet unrevealed under other state's law, that
19 could be done by this Court. It would more
20 appropriately be done before a California jury, either
21 on remand to transferor courts or by this Court sitting
22 by designation in another court. For example, in the
23 Welding Rods litigation, Judge O'Malley after holding a
24 number of representative trials in Cleveland has decided
25 to hold the next representative trial in Mississippi

1 before a Mississippi jury under Mississippi law in a
2 case that was transferred in to her and does not include
3 an Ohio-filed complaint. So, there are many techniques
4 the courts use.

5 I think in this case, given the attention
6 both sides have paid to making this an efficient
7 mechanism, having the trials teed up one after another,
8 using time limits, trying to streamline everything
9 possible, except perhaps, I am not so sure any more,
10 oral argument this morning.

11 It makes absolute sense to utilize what can
12 properly be utilized in this case, the application of
13 Minnesota law to make the process that much more
14 predictable, to reduce the number of variables that
15 would otherwise confound the meaningfulness and utility
16 of the outcomes of these cases.

17 THE COURT: Is there -- this doesn't really
18 relate to the bellwether case, but -- this one, it may
19 in two of the five. But, then in cases, to use Judge
20 Fallon's words, a direct file case, where then he
21 posits -- well, then, what happens if the case goes
22 back? Then basically, if I understand the reasoning,
23 even though the rules don't get us there, you invert the
24 transferor to transferee. In other words, it doesn't
25 mean that you stay with Minnesota law. You do on the

1 direct-filed cases --

2 MS. CABRASER: Yes.

3 THE COURT: And those that go back because
4 they were transferred in. Then what you do is you -- if
5 the case isn't resolved in the MDL Court, it goes back,
6 you revert back to the transferors -- in other words,
7 you kind of invert the choice of law on that one.

8 MS. CABRASER: That is right. The choice of
9 law analysis could be deferred until you know which
10 cases are going back. The Duron case stays in
11 Minnesota, so it is not affected by that. As a matter
12 of fact, I know counsel cited the Bridgestone/Firestone
13 case. It happened in that case that there was a master
14 complaint. The parties either agreed or conceded that
15 because that Master Complaint was filed in Indiana,
16 Indiana choice of law applied.

17 They disagreed vehemently about what Indiana
18 choice of law was or meant. The outcome, the
19 certification order went to the Seventh Circuit. The
20 Seventh Circuit disagreed with the District Court. And
21 as a result of that a number of cases were filed in
22 state courts around the country on the same claims.

23 And I can tell you this from personal
24 experience, I just experienced this two weeks ago. When
25 we were back in Indiana and were arguing that Michigan

1 law, the law of Ford's place of business and conduct
2 applied, Ford was adamant that it didn't, and that law
3 of every Explorer owner's state had to apply. They
4 ultimately prevailed on that with the Seventh Circuit
5 when we were heading to trial in our California State
6 Class Action and we got to the summary judgment stage on
7 choice of law. Ford came in and argued that Michigan
8 law applied, not California law, because all of the
9 conduct had occurred in Michigan.

10 We all kind of did a head shake on that one,
11 but the fact of the matter is, and you know this, Your
12 Honor, there's strategical, strategic and tactical
13 reasons that parties make choice of law arguments.

14 You can't avoid that. What you can do is use
15 the framework of the Minnesota choice of law rule, the
16 constitutional -- the constitutional threshold, which is
17 met in this case, and exercise your discretion to do
18 what you think is fairest to both sides and is in the
19 best interests of the case management responsibility
20 with which this Court has been entrusted by the Judicial
21 Panel.

22 THE COURT: Thank you. Why don't we go
23 forward, absent an objection, with a response, if we
24 can? And then we will take a break after that.

25 MR. CARPENTER: May it please the Court.

1 Andrew Carpenter for Guidant. I will say between myself
2 and Ms. Cabraser, it will be both a short argument for
3 both of us.

4 I agree with a couple of things Ms. Cabraser
5 said. The terrain is complicated and it is a
6 fascinating area. I think there is a clear answer for
7 the Court.

8 The first question is -- well, before I get
9 to the first question, there are four reasons why we
10 believe that California law applies to Mr. Duron's
11 claims. First of all, California law applies by default
12 to the extent there are no conflicts under California
13 Choice of Law Rules.

14 Second, only California has got a legitimate
15 interest in applying its laws to these claims, Minnesota
16 really doesn't. It's what you call a false conflict.

17 Number three, to the extent those interests
18 actually are in conflict, California's interests vastly
19 outweigh Minnesota's.

20 And finally, even if you were to apply the
21 five-factor Leflar Test under Minnesota Choice of Law
22 Rules, you get the same result, California law applies.

23 First question is, what is the forum state?
24 We all know in diversity cases, the old chestnut, the
25 law, the Federal Court sitting in diversity has to apply

1 the substantive law of the forum state.

2 Well, what is that, here? Plaintiffs would
3 have you believe it is Minnesota, because Mr. Duron
4 filed an addendum adopting various aspects of the Master
5 Complaint. I think that is dead wrong. And the reason
6 it is wrong is the forum state in an MDL or any
7 situation where there is a venue transfer, and that is
8 all 28 U.S.C. 1407 is, Your Honor, it's a venue statute.
9 It's always the state in which the action is originally
10 filed.

11 How do you know that? You go back and look
12 at the three Supreme Court cases that lay out why we
13 apply these diversity rules to choice of law rules like
14 that.

15 Erie, they decided that it makes no sense to
16 have one result in a federal court and a different
17 result in a state court sitting right down the street
18 from each other in the same state. Uniformity of
19 results is what drives the Erie Doctrine. We all know
20 that.

21 In Klaxton -v- Stentor, the Supreme Court
22 applied that concept, the choice of law rules. They
23 said that choice of law rules are substantive. The
24 Federal Court sitting in diversity needs to apply the
25 choice of law rules of the District and the State in

1 which it sits.

2 Why? Uniformity. If you applied different
3 choice of law rules, you are going to get different
4 results. Federal courts and state courts should have
5 the same results and the same law being applied
6 regardless of the accident of whether a party provides
7 diversity jurisdiction.

8 Van Dusen, the third case, the Supreme Court
9 found that when venue is transferred, the choice of law
10 rules of the transferor district apply. And what
11 happens after the transfer can't change choice of law
12 rules.

13 Why? It is very simple to do so. And to do
14 what Ms. Cabraser advocates would gut the Erie Doctrine
15 and create ridiculous results. As the Court said, we
16 should ensure that the accident of federal diversity
17 jurisdiction does not enable a party to utilize a
18 transfer to achieve a result in federal court which
19 could not have been achieved in the courts of the state
20 in which the action was filed. That is the uniformity
21 concept.

22 THE COURT: And I agree with everything that
23 you have said. I think this is hornbook law that even a
24 scholar like Ms. Cabraser probably could not disagree
25 with. And I will sit tight if you are going to roll in

1 there, but what do we do with the MDL, the consent to
2 try the case here, what, if anything, does that change
3 in this day and age when we throw this in, and my
4 responsibilities in the case?

5 MR. CARPENTER: This is exactly where I am
6 going.

7 THE COURT: All right.

8 MR. CARPENTER: Lexicon doesn't matter a bit.
9 The fact that we waived Lexicon has no application to
10 these proceedings today or choice of law. Lexicon has
11 nothing to say on choice of law. It just says the Court
12 can't remand to itself for trial.

13 THE COURT: I don't disagree with that.

14 MR. CARPENTER: Right. We waived that -- we
15 never waived choice of law. Nowhere in our pretrial
16 conferences or in open court has Guidant said that
17 Minnesota law can apply to all of these cases, that is
18 well known.

19 Furthermore, Lexicon is a red herring, Your
20 Honor. This Court has always had the power to find out
21 what the appropriate choice of law is and rule on
22 dispositive motions. Lexicon has got not a thing to do
23 with what we are doing today and what laws apply to
24 these motions right now. The disposition of cases and
25 pretrial motions is proper pretrial preparation over

1 which this Court already had jurisdiction.

2 But, even for trial purposes, Erie, Van
3 Dusen and Klaxton indicate that even if the parties do
4 agree to waive the Lexicon remand right, it doesn't
5 matter where the case is tried. The forum state for
6 purposes of Erie and uniformity has to be the original
7 transferor state. Otherwise, you get un-uniform results
8 and get law applied that could never have been applied
9 if not for diversity jurisdiction and a transfer.

10 Does the Master Complaint matter? Not a
11 bit. The Master Complaint is a procedural artifice.
12 Plaintiffs know it. It is in the second paragraph of
13 the Master Complaint. They say, it is to serve only the
14 administrative functions of efficiency and economy and
15 to present certain common claims and common legal
16 questions of fact for appropriate action by the Court.
17 It doesn't supersede. It doesn't encompass. All it is
18 is a procedural device and a housekeeping measure.

19 The fact that Mr. Duron filed an addendum
20 adopting various aspects of the Master Complaint does
21 not change the fact that California remains the
22 transferor court and California choice of law applies.
23 Any other result would be incredibly unfair.

24 What that would basically mean was any
25 plaintiff whose case was transferred in the MDL, if

1 there is a master complaint, has got the right to either
2 take the law originally of his transfer or jurisdiction,
3 or if he likes the law better where he got transferred,
4 I will take that law. There is no authority giving them
5 that right.

6 Do Defendants have the right to have a
7 master complaint brought and then apply that law if they
8 like that better than the original transferor's state's
9 law? Absolutely not. How do we know? They have tried
10 it before. In re: Propulsid, In re: Vioxx, the
11 Defendants have all said, hey, these are MDL's. We have
12 got a master complaint. Let's use the choice of law
13 rules where the master complaint was filed. And in both
14 instances, the Court said, absolutely not. It is a
15 procedural device. You look to the law of the
16 transferor court, not the law where the master complaint
17 is.

18 THE COURT: What has changed, if anything?
19 Unlike those cases, we have your client here in
20 Minnesota, we have your client who manufactured the
21 device here in this state, and it seems to me that kind
22 of puts this case -- as you say, it shouldn't change the
23 result, but it does make it a rather interesting issue
24 when the suggestion is here, this is more of a strategic
25 argument going on, because even though both California

1 and Minnesota are kind of pro-consumer states,
2 apparently -- I don't think a judge looks at a statute
3 and puts that characterization on it.

4 It is just unusual for Guidant to be in the
5 posture of, well, you are on our home turf and we don't
6 want -- we don't want the laws on our home turf to apply
7 to this case. It is a little different and I think that
8 is what Ms. Cabraser is trying to suggest to me that,
9 well, take a close look, because Arden Hills is right up
10 the road, here. Should that make a difference here?

11 MR. CARPENTER: I agree with Your Honor, it
12 is a rather strange position. As a defense lawyer, I
13 feel like I am about to burst into flames by arguing
14 that California law should apply. It hurts my mouth.
15 But, I think that is the right result. I think anything
16 is antithetical and creates real uniformity and
17 federalism and comity problems. I think it is counter
18 to the venue statutes. I think it guts Erie. I think
19 it creates real problems.

20 And I am going to get to this later, but
21 Plaintiffs' supposition that all of the events were
22 centered in Minnesota is dead wrong and it is not
23 supported by the record. And I will get to that later,
24 but there is no support for that. Guidant operates in
25 many states and California is really where the rubber

1 meets the road in this case.

2 Anyway, what does that mean? California
3 remains the transferor court, the forum court.
4 California's choice of laws should apply. Under
5 California's choice of laws, it is the governmental
6 interest test.

7 First question, do the substantive laws of
8 California and Minnesota conflict? I think there is
9 more of a conflict than Plaintiffs let on. Clearly
10 implied warranty, clearly strict liability, there are
11 differences in emotional distress claims that may be
12 dispositive. There's clear differences in consumer
13 protection law. But, if this Court believes that there
14 is no conflict, California law applies by default. And
15 Plaintiffs claim there is none in almost all of the
16 causes of action in their brief. So, if you take them
17 at their word, it is a relatively easy decision.

18 Going back to the test, the second question
19 is, if each jurisdiction has a legitimate -- if there is
20 a conflict, are there legitimate policy issues that
21 clash? I.e., does one state have a genuine issue in
22 having its law applied?

23 And number three, if so, which state's policy
24 would be most impaired? Well, I think the answer is
25 that California has got an interest; Minnesota doesn't.

1 Look at Mr. Duron's original Complaint. All of the
2 events giving rise to this action occurred in the County
3 of San Diego, State of California. This is the county
4 in which Defendants sold and distributed and Plaintiff
5 received the device, which is the subject of this
6 lawsuit.

7 I think that says it all, Your Honor.
8 California is the state with the interest in this case,
9 not necessarily Minnesota. California, accordingly, has
10 a strong interest in applying its laws to Mr. Duron's
11 claims. Number one, to ensure the appropriate level of
12 compensation for California, a lifelong California
13 resident who got the device from California, who had it
14 explanted in California, who allegedly was injured in
15 California.

16 In addition, California has got a strong
17 interest in limiting Guidant's liability. California
18 has got policies where it recognizes the value of
19 medical device manufacturers and it gives certain
20 protections. It is balanced with that prior interest in
21 compensating people. It is a complex system. That is
22 part of how the system of laws work.

23 And finally, California has got an interest
24 in regulating and deterring companies doing business,
25 selling devices within their state, within their

1 borders, which Guidant did in this case.

2 Minnesota, on the other hand, has got really
3 no interest in this. Plaintiffs wrongly assume that all
4 of the alleged wrongful conduct took place in Minnesota.
5 That is actually not true if you looked at the record.
6 For instance, Mr. Duron's device was largely
7 manufactured and assembled, including the header, which
8 is the specific subject, in Clonmel, Ireland.

9 Plaintiffs' own expert says significant
10 design decisions were submitted and approved and
11 processed by the facility in Ireland. In addition,
12 Plaintiffs in their Master Complaint allege that all
13 sales and advertising decisions run out of the Indiana
14 corporation, Guidant Sales Corporation.

15 It is important to also bear in mind, Guidant
16 doesn't operate only in Minnesota. Guidant has sales
17 representatives throughout the country to interact with
18 doctors and patients. So, basically, Plaintiffs theory
19 that Minnesota is the center of gravity is not supported
20 by the record, and massively oversimplifies the
21 situation.

22 I am not claiming for a second that the law
23 of Ireland should really apply to this case, or even
24 Indiana; but, I do think that illustrates the
25 unworkability and unrealism of Plaintiffs' theory that

1 Minnesota has the most operative issues, here.

2 Minnesota, in addition, has no interest in
3 regulating conduct through personal injury actions,
4 tort, breach of warranty, breach of contract, strict
5 liability, the primary state interest is in compensating
6 residents. Minnesota has got no interests in
7 compensating, necessarily, a California resident.

8 Now, Plaintiffs cite several cases indicating
9 that Minnesota does have a certain interest in
10 compensating people who may not necessarily be
11 residents, but if you look at the cases, the Plaintiffs
12 in all of those cases were either a Minnesota resident
13 where the accident took place in Minnesota, or there was
14 as big Minnesota connection, much more so than in this
15 case with Mr. Duron.

16 Minnesota has got really no interest, Your
17 Honor in encouraging this kind of forum shopping. Look
18 at the Jepsom case. In that case, a Minnesota resident
19 engaged in an automobile insurance contract in North
20 Dakota for vehicles registered in North Dakota.

21 And when he didn't like North Dakota's
22 application of insurance laws that prevented stacking of
23 policy benefits tried to argue Minnesota law should
24 apply. And he basically made the argument Mr. Duron and
25 Plaintiffs make, is that Minnesota should have an

1 interest in seeing that I am properly compensated. The
2 Minnesota Supreme Court absolutely rejected that and
3 said we have got no interest in encouraging people who
4 don't like the rules and the recovery they get in their
5 resident states, with little connection to Minnesota,
6 forum shopping.

7 Now, to the extent this Court may find that
8 Minnesota does have some vestigial interest in applying
9 its laws, and I don't think it does, California's
10 interests massively outweigh them. If you look at it,
11 Mr. Duron was a lifelong California resident. His
12 device was prescribed in California. It was implanted
13 in California, it functioned in California. Any
14 statements or representations allegedly made to him or
15 his prescribing physician were in California. His
16 doctor was in California. It was explanted in
17 California. And any alleged damages that occurred, if
18 they occurred, happened in California.

19 As a result, cases like this have held that
20 where a product is manufactured in one state and
21 disseminated through prescriptions, i.e., usually
22 medical drug cases, the state with the real interest is
23 the state of the residence. It is the state where the
24 medical device is prescribed, used, ingested, where
25 injury happens. That is the Vioxx case, the Blain -v-

1 SmithKline, and the Roe -v- Hoffman-LaRoche case. All
2 of those cases look, and they find that the relationship
3 is centered in the state of the residence of the people
4 who used the product. That is where the injury-causing
5 conduct occurred. That is where the place of injury
6 occurred, and that is where the interest of comity and
7 interstate interests favor applying the laws of the
8 state where the people lived, where they really used the
9 product, where the product either works or doesn't.

10 Even if you try to apply the Minnesota Leflar
11 factors, the same result happens, Your Honor. The first
12 Leflar factor, and I will do these very quickly because
13 the Court is well familiar with them. Predictability of
14 results. The Jepsom case emphasized that. Just like in
15 the Jepsom case, predictability of results and the
16 parties' reasonable expectation indicate California law
17 should apply.

18 Mr. Duron never had any idea when he was
19 getting his device that he was subjecting himself to the
20 laws of Minnesota. He didn't even know it was a Guidant
21 device. And if he did, he never would have know that
22 Guidant is a Minnesota corporation. He got it down the
23 street at his local doctors, used it in California, and
24 expected California law would apply.

25 How do we know? He filed his first case in

1 California, obviously. Guidant, conversely, markets its
2 products nationally. Guidant is fully aware of the risk
3 that if something happens, it may be haled into court in
4 any of the fifty states in which it sells its products.
5 Guidant does not necessarily expect it to have Minnesota
6 law govern all of its claims.

7 Second Leflar factor, the maintenance of an
8 interstate order. Again, I think that goes back to the
9 forum shopping issue and California's large substantive
10 rights that would be impaired were Minnesota law to
11 displace them.

12 Three, simplification of the judicial task.
13 Now, this is interesting because this is an MDL and Ms.
14 Cabraser talked about that. I frankly disagree with her
15 idea of what would benefit and move this litigation
16 forward. She believes that applying Minnesota law would
17 be more useful.

18 In an MDL context, Your Honor, as you well
19 know, the goal is to get these cases trial ready and
20 send them back, remand them. All of the cases, except
21 for the ones originally filed in Minnesota, they are
22 going back to their states. They are going to be tried
23 and resolved under state law. It doesn't advance the
24 ball, I submit, to artificially engraft Minnesota law on
25 to these cases that if not for the accident of venue

1 transfer would never have been in Minnesota. It is much
2 more realistic, much more useful and much more helpful
3 to the parties in evaluating these cases, to try them
4 under the real law they would be tried on if they were
5 remanded. That is going to advance the ball and advance
6 the purposes of these representative trials and this MDL
7 much, much more.

8 The final Leflar test is governmental
9 interest. And again, we have covered this. Minnesota
10 has little to no interest in applying its law to a
11 lifelong California resident injured in California for a
12 device prescribed in California, explanted in
13 California.

14 Minnesota simply doesn't have much of a dog
15 in this particular fight. To the extent it does, and
16 Plaintiffs may argue that Minnesota's Consumer
17 Protection Laws require the vindication of regulation of
18 Guidant, I want to leave the Court with this thought.
19 Minnesota's Consumer Protection Laws are Private
20 Attorney General's rights that allow the enforcement of
21 public interests. Were this one case sitting alone, I
22 would like to say Plaintiffs might have a better
23 argument.

24 However, there are many cases both sitting in
25 this MDL and down the street in front of Judge Leary in

1 which real Minnesota Plaintiffs are advancing Minnesota
2 Consumer Protection Claims.

3 To the extent Guidant's conduct needs to be
4 brought to the fore or needs to be regulated through the
5 application of Consumer Protection Statutes in
6 Minnesota, other cases are much more appropriate to do
7 that. So, Minnesota's interest in having its Consumer
8 Protection Acts applied to this factual scenario would
9 not be frustrated if they weren't applied in this
10 particular case. They are going to get applied in
11 others.

12 And as this Court knows, and I don't need to
13 remind anyone, this litigation has not exactly fallen
14 under the radar of public attention thus far. People
15 are well aware of it.

16 Finally, that is about all I have got to say,
17 a couple takeaways. I think California law clearly
18 applies. I think under California's interest analysis
19 test, Your Honor, California's interests are clearly
20 paramount. I think even under Minnesota's choice of law
21 test, Your Honor, California law has got to apply.

22 If the Court has any specific questions, I
23 would be happy to answer them.

24 THE COURT: What is the -- I'm not suggesting
25 that the answer to this question should or does control

1 the exercise of the Court's discretion, but what is the
2 most unfair aspect or prejudicial aspect of an
3 application of Minnesota law in the Duron case, or cases
4 like it? Because even though some cases got here
5 differently than Duron in the first group of bellwether
6 cases, what is the most adverse effect of a ruling like
7 that, versus California law, on your client?

8 MR. CARPENTER: Are you talking about the
9 specific context of this trial or on a macro level, Your
10 Honor?

11 THE COURT: Well, both. It is a good
12 comeback, because I don't think I was clear; but, both,
13 both, I guess.

14 MR. CARPENTER: On a macro level, it puts
15 Guidant in a really difficult situation and any other
16 defendant in an MDL of allowing plaintiffs to basically
17 pick whatever choice of -- whatever law they want
18 applied. They can have either, whether they originally
19 filed it under Ms. Cabraser's theory, or the law of the
20 forum state -- or the law of the transferee MDL court,
21 whichever suits them best.

22 So, basically, they are not fettered. They
23 have an option of choosing whichever they like best, and
24 they could probably under Ms. Cabraser's theory reverse
25 course at various points and argue alternatively, which

1 create huge headaches for the court and really
2 disadvantages defendants.

3 I don't think anyone would argue that
4 Guidant has got an analogous right to require a master
5 complaint to be filed to have cases transferred over
6 here, and then to say to Plaintiffs: I am sorry. I
7 know you filed this case under Wisconsin law and you
8 have these Wisconsin claims. We want to apply Minnesota
9 law. And because we are an MDL, and there is a master
10 complaint, we are going to do that.

11 By the way, maybe Minnesota law is much
12 worse and your claims are dismissed, where they would
13 have survived under Wisconsin law. It is a patently
14 unfair, uneven and intellectually -- it doesn't make any
15 sense with the reasons underlying Erie.

16 In the specific context of this case, it is
17 hard to say. For instance, Minnesota law prejudices
18 Guidant because California will not allow under
19 Restatement, Comment k, strict liability design claims
20 against manufacturers of medical devices. That is a
21 very clear difference that really prejudices my client.
22 I think --

23 THE COURT: Well, I acknowledge in the briefs
24 you set out, and the two of you don't agree on -- they
25 have singled out two counts in the Complaint where they

1 feel there is a conflict. You have singled out
2 significantly more than that. So --

3 MR. CARPENTER: Yeah, I do think there are
4 differences, Your Honor. Some of them may very well be
5 dispositive.

6 THE COURT: Thank you.

7 MR. CARPENTER: Thank you, Your Honor.

8 MS. CABRASER: Very briefly, Your Honor.
9 I'll make no more comment, then, just facts and the law.

10 The difference here that in all of the cases,
11 other MDL cases that have been decided, is that we are
12 dealing with an operative pleading that is not an
13 addendum to a master complaint. Mr. Duron did not file
14 an addendum to a master complaint.

15 Now, the Plaintiffs fact sheet, it is not an
16 administrative document, it is a complaint. It was
17 filed in the District of Minnesota. It demands a jury
18 trial. It has its own number, and paragraph one of the
19 device recipient, the Plaintiff's Complaint by adoption
20 says, Plaintiff Leopoldo Duron, Junior, states his
21 claims against Defendants indicated below as follows,
22 and incorporates by reference the relevant portions of
23 the Master Complaint. And this is a very specific
24 Complaint. It picks out specific claims and sections of
25 the Master Complaint that it adopts, incorporates by

1 reference, and Mr. Duron's original Complaint. Mr.
2 Duron won't be going back to California. He doesn't
3 have a transferred action. He has a District of
4 Minnesota action. By choice, the same choice that
5 anyone could make, because venue is appropriate here
6 against Guidant to file that complaint as their first
7 complaint in the first place. He doesn't have two
8 complaints today. He has one complaint. He has this
9 one. He is not going to be remanded. He is not going
10 back. He is here for trial. And that is why the
11 Minnesota Choice of Law Doctrine governs the choice of
12 law determination of his claim.

13 THE COURT: Of course, that, in not going
14 back, separate from the Complaint -- it probably doesn't
15 answer the question, because in any change of venue
16 case, the case never goes -- in a non-MDL setting, the
17 case never goes back.

18 In other words, if you transfer the case here
19 in a non-MDL setting, I may have to apply California
20 law, but knowing the case isn't going back. You are
21 saying, well, that may be physically the fact, but it is
22 the nature of this Complaint that creates -- is the
23 reason why it is not going back.

24 MS. CABRASER: That is correct, Your Honor.

25 THE COURT: He chose to file his Complaint.

1 MS. CABRASER: That is correct, Your Honor,
2 he chose to file here. In Vioxx there was a Master
3 Complaint that never applied to individual claimants.
4 The individual claimants didn't refile in the MDL
5 District. They have always retained the option of going
6 back.

7 So, the difference this makes is that it
8 requires the application of the forum state's choice of
9 law criteria, which would be Minnesota's. That doesn't
10 answer the ultimate question as to which state's law
11 apply. We simply flip the takeaways that you saw on the
12 screen from Guidant, just flip Minnesota and California.
13 Under either Minnesota and California choice of law
14 analyses, Minnesota has the greatest interest. Its
15 interest would be more impaired if its law were not
16 chosen. And we say that not simply because we are in
17 Minnesota and it is a Minnesota corporation, but
18 Minnesota courts, including most recently Judge
19 Montgomery's decision in the Mooney case cite the United
20 States Supreme Court case, the CTS Corporation case.
21 And you see Minnesota courts cite this over and over
22 again for a fundamental proposition with respect to
23 choice of law. And that is the state in which a
24 corporation is headquartered and in which it is doing
25 business and in which it is engaging in the relevant

1 conduct has a, quote, substantial interest in preventing
2 the corporate forum from becoming a shield for unfair
3 business dealing. That is the primary interest.

4 Minnesota has it, here. It would have it
5 under either state's choice of law rubric. And it would
6 lead to the same appropriate result.

7 The other thing I wanted to mention about the
8 facts is that every one of the slides you saw in our
9 opening fact presentation, and I think every one of
10 those slides that is in the booklet, that you might not
11 have seen, with the sole exception of the picture of Leo
12 Duron, every one of those is a Guidant document that
13 comes out of Minnesota. That is the Plaintiffs' case in
14 the Duron case. It is a Minnesota case. It is most
15 appropriate to try it under Minnesota law.

16 So, whatever has happened in our MDL's and
17 however little guidance we may have in this post-Lexicon
18 world, what has happened in this case with respect to
19 the pleadings that were filed, and the outcome with
20 respect to Mr. Duron is that it is a District of
21 Minnesota action.

22 I think that my argument would be much harder
23 if that were the only reason, and if it were an
24 arbitrary reason that Minnesota law would apply. But,
25 our real point here is the same point that Guidant is

1 making. We just disagree on the outcome. Whether you
2 apply Minnesota or California choice of law rules, if
3 you look at the respective interests of Minnesota and
4 California and the conduct at issue in this case, and
5 you compare the two, whether you are dealing with the
6 comparative impairment test from California, or the
7 choice influencing factors test from Minnesota, the
8 choice of Minnesota law arises or emerges as the
9 appropriate choice. And I think that is most
10 predictable from Guidant's point of view.

11 Would we be horrified to proceed under
12 California law? Absolutely not. We think California is
13 good law for the Plaintiffs in this case.

14 Does it make more sense for all of the
15 reasons we indicated to apply Minnesota law? We believe
16 it does. Thank you.

17 THE COURT: I will give you the last word,
18 Mr. Carpenter, if you want it.

19 MR. CARPENTER: Thirty seconds is all that
20 is required, thanks.

21 One thing I wanted to point out in Mr.
22 Duron's Amended Complaint addending to the Master
23 Complaint, even in that he checks Count 7, California
24 Unfair Deceptive Trade Practices Act. Even at that
25 point he is still claiming California law applies to his

1 claims. I think that is very important.

2 Number two, I don't think the cases indicate
3 that filing a different complaint or an amended
4 complaint or anything you do after transfer, pursuant to
5 venue transfer can really change choice of law. And in
6 our PowerPoints look at the In re: Ski Train Accident
7 MDL. I think that is very dispositive.

8 In those cases you had cases originally
9 filed in one district, transferred to the Southern
10 District of New York, pursuant to an MDL. A
11 consolidated master complaint was done and even amended,
12 and the court agreed for purposes of determining what
13 counts were in play, we are going to look at the master
14 complaint. But, the plaintiffs in that case said, let's
15 re-evaluate choice of law because we have added new
16 parties pursuant to the master complaint. The court
17 said, no. The original complaint is filed and the
18 transferor court is what determines choice of law. And
19 I think those are dispositive of what is going on.

20 And I think so is Judge O'Malley's opinion
21 in the Welding Rod Fumes decision. If you look at her
22 Order of August 26, 2006, which I happen to have with
23 me, Judge O'Malley, although she is doing representative
24 trials says what she is trying to do is she wants a
25 broad variety of diagnoses, plaintiffs' attorneys and

1 applicable states law. Clearly, Judge O'Malley doesn't
2 believe that merely having a master complaint and trying
3 cases changes the applicable choice of law.

4 She recognizes that you want a bunch of
5 different states law. That advances the ball and is
6 much more representative. So, I think that is a good
7 example, and I think that demonstrates why Guidant's
8 approach to this makes more sense, Your Honor. Thank
9 you.

10 THE COURT: We are going to take the recess,
11 but you kind of bolted up out of your chair, Ms.
12 Cabraser. Was I just imagining things or --

13 MS. CABRASER: I really think I did that.

14 THE COURT: Bolt might be an overstatement by
15 me.

16 MS. CABRASER: And I was taking no umbrage,
17 it was because I forgot to mention when it was my turn,
18 and it is no longer my turn. And we will submit for the
19 Court's convenience a copy of the Duron Complaint that
20 we were all talking about.

21 It does check a box for the California
22 Statute, which is Count 8. It also checks a box for the
23 Minnesota Statute, which is Count 9, incorporates the
24 allegations of the Master Complaint with respect to that
25 count, which are the allegations set forth in great

1 detail under consumer law. They go on from paragraph
2 327 to 339. It is something that you need to see rather
3 than hear about. And we will submit -- we will submit
4 that in a form that you can take a look at it.

5 THE COURT: All right.

6 MS. CABRASER: The point is that what emerges
7 from the context of these two documents is clearly an
8 election by the Plaintiff to be here under Minnesota law
9 in trial.

10 THE COURT: You just didn't get up just now,
11 Mr. Carpenter, but if you would like to finish up before
12 we --

13 MR. CARPENTER: Your Honor, it has got to end
14 sometime.

15 THE COURT: Well, it's important issues. For
16 those of you who just came into the courtroom, we
17 haven't recessed since nine, so let's come back in at
18 11:30, then I would suggest, absent some unintended
19 interference with the schedules you have over the noon
20 hour that we would take an hour from 11:30 to 12:30 and
21 come back, unless we need an hour and fifteen minutes.

22 MS. GERNON: You mean 12:30 to 1:30?

23 THE COURT: I mean 12:30 to 1:30, sorry about
24 that. That would be difficult to do that. And then one
25 thing -- we can go off the record, and you can certainly

1 stand up if you want to stretch.

2 (Discussion off the record.)

3 (Recess.)

4 THE COURT: You may be seated, if you wish.
5 Now, I will assume, whether it is from the Plaintiffs'
6 side of the aisle or Defendant's, whether you have any
7 new associates or summer associates here with you today,
8 you are free to introduce them. So -- and usually, if
9 you tell me that, I try to say something real
10 complimentary about the supervising attorney, so --

11 MR. PRICE: Whether it is true or not.

12 THE COURT: Well, no, you said that, Mr.
13 Price, I didn't.

14 We can proceed with the next motion. I think
15 we switch gears here to Guidant.

16 MR. CARPENTER: Thank you, Your Honor. The
17 next motion up for consideration is Guidant's motion to
18 dismiss Plaintiffs' Consumer Protection Claims. And I
19 will endeavor to slow down during this argument, so as
20 not to make the Court Reporter crazy. Thank you.

21 And I think this is a fairly straightforward
22 argument, Your Honor, so I am not going to spend
23 probably the whole 20 minutes on it. Our first argument
24 is that regardless of whether you are talking about the
25 Minnesota Consumer Protection Claims or California's,

1 Mr. Duron has real standing problems under any of them.
2 The first argument is simple. Mr. Duron's claims under
3 the Consumer Protection Statutes are derivative of his
4 other claims.

5 In other words, it is all based on the same
6 alleged liability contact, and his failure to warn,
7 strict liability, negligence claims, and to the extent
8 because those claims fall for various reasons, so too
9 must the liability for his consumer protection claims.
10 I won't belabor that point further.

11 I think the real issue with the California
12 and the Minnesota claims is standing. First of all,
13 under the California CLRA, the main problem is that Mr.
14 Duron failed to file the appropriate notice of intent to
15 sue. The CLRA statutorily requires that an individual
16 who is going to file a suit for damages under the CLRA
17 has to, 30 days ahead of time, send by certified
18 registered mail a notice of intent to sue letter laying
19 out what his problem is, what relief he would like. It
20 is intended to facilitate pre-litigation resolution of
21 these issues and it is mandatory. It is strictly
22 enforced by California courts.

23 Now, we got this, a notice of intent to sue
24 letter, but we got it about 25 days ago, about a year
25 and a half after Mr. Duron filed his original Complaint

1 and about seven and a half months after he filed his
2 amended addendum to the Master Complaint. The case law
3 is clear, that has got to be filed in advance. That is
4 ineffective. Really, the only effect this has is as
5 something of an admission by Plaintiffs' counsel that
6 they didn't do this properly the first time.

7 California law is very clear. Cases
8 consistently, Court's consistently dismiss cases for
9 failure to comply with this pre-suit notice requirement.
10 Plaintiffs' point out one case, an unreported case
11 called Deitz in which the plaintiff was let off the
12 hook. It is a very different case and its facts really
13 don't apply.

14 In that case, the Plaintiffs' claim was
15 almost entirely for injunctive relief. And under the
16 California statutory system, you don't have to give
17 notice of intent to sue under the CLRA for just an
18 injunctive claim. This case, and in that case, the
19 Court said, well, you allude to damages, but you are
20 almost all injunctive relief, so we are going to give
21 you a mulligan on that one.

22 In this case, Mr. Duron's claim is all about
23 damages. I don't think there is an injunctive claim in
24 any of his Complaints. And if there is, it is certainly
25 not for dominant cause of action. Clearly, Mr. Duron

1 failed to comply with the CLRA's notice provision. In
2 his case his CLRA claim should be dismissed,
3 accordingly.

4 Second of all, Mr. Duron lacks standing to
5 sue under the CLRA because Guidant already remediated
6 the alleged wrongs. The CLRA, Section 1762 provides
7 that if, after you get the notice of intent, the
8 defendant gives the appropriate correction, repair,
9 replacement or other remedy, then the Plaintiff has no
10 standing to sue for damages.

11 In this case, it is undisputed that Guidant
12 provided a free replacement device. Now, Plaintiffs say
13 there may be an issue of fact as to whether that was an
14 appropriate replacement. I don't think so. And we know
15 that because it was prescribed by a medical
16 professional, Dr. Singh. So, there really can't be any
17 argument as to whether that was an appropriate
18 replacement or not. Clearly, Mr. Duron lacks standing
19 under the CLRA for that reason, as well.

20 Three, Mr. Duron lacks standing under the
21 CLRA because he's not really a consumer within the
22 meaning of that statute and prescription implantable
23 medical devices as regulated by the FDA really aren't
24 consumer goods, as defined by the CLRA.

25 Now, the CLRA clearly applies only to

1 transactions for the purchase or lease of consumer
2 goods. As all consumer protection statutes, this is
3 intended to remediate unequal bargaining power and to
4 control unfair and sharp practices in the sale of goods.

5 It is important to note that it makes no
6 sense to apply a consumer protection statute like this
7 to the context of a regulated medical device that you
8 can only get from a learned intermediary physician. You
9 have got to go to an electrophysiologist in order to get
10 this device prescribed for you. It is not an
11 over-the-counter situation.

12 And Mr. Duron is clear in the record that he
13 had no input into this; he didn't select it. He didn't
14 even know he had a Guidant device until much later after
15 the fact. That is not his fault. That is very typical
16 of how these devices work. The doctor makes the
17 decision.

18 So, if you look at it, the policy reasons
19 for applying the CLRA to a claim like this just don't
20 apply. And if you look at other states' laws, and I
21 will concede, there is no law -- there is no decision in
22 California directly on point saying that for purposes of
23 the CLRA a medical prescription device is or isn't, but
24 other states have found that, that these devices are not
25 covered by their analogous consumer protection laws.

1 And if you look at analogous federal statutes like the
2 Consumer Product Safety Act from which statutes like the
3 CLRA were derived, they clearly in their definitions
4 explicitly define out medical devices as regulated by
5 the FDA as not being consumer goods.

6 In addition, California law in cases have
7 explicitly found medical devices prescribed by
8 physicians are not consumer goods under the
9 Magnuson-Moss Act. And that is very persuasive because
10 the Magnuson-Moss Act defines consumer goods exactly the
11 same way the CLRA does. So, I submit for that reason,
12 also, Mr. Duron does not have standing as a consumer,
13 purchasing a consumer good to bring these claims.

14 Let's talk about Minnesota. Depending on
15 what choice of law is ultimately applied, Mr. Duron
16 lacks standing to pursue his claims under the three
17 Minnesota Consumer Protection Statutes. First of all,
18 he brings claims under the Deceptive Trade Practices
19 Act. That statute only provides a private right of
20 action for injunctive relief. He is not seeking
21 injunctive relief. He wants money. He wants damages.
22 He has no standing to pursue that.

23 Second of all, Mr. Duron can't bring a cause
24 of action under the Minnesota False Advertising Act.
25 That Act only applies to false advertising in the state

1 of Minnesota. There is no evidence Mr. Duron ever saw
2 any advertising by Guidant in Minnesota. Actually,
3 there is no evidence Mr. Duron ever saw any advertising
4 by Guidant, period, until after his device was already
5 implanted.

6 There is no evidence Mr. Duron has ever been
7 to Minnesota. Clearly the cases construing the statute
8 make it clear you have to see the alleged false
9 advertisement in the state of Minnesota to have a
10 standing to sue.

11 Mr. Duron does not. That claim should be
12 dismissed. Then you get to Mr. Duron's Prevention of
13 Consumer Fraud Act claim under Minnesota. And we talked
14 about that some. We talked about all of these issues in
15 the context of the PP argument, so I am going to try not
16 to retread that ground, the Court is well aware of
17 these.

18 But, the Consumer Fraud Act is basically a
19 private analogous attorney general right where an
20 individual can bring a suit to vindicate the Minnesota's
21 public interest.

22 Now, I'd submit that under cases like Ly -v-
23 Nystrom, you have to ask yourself, would the Minnesota
24 Attorney General have jurisdiction and authority to
25 pursue this action? The answer is no, neither would a

1 private litigant like Mr. Duron. And I think for all of
2 the reasons we pointed out in the choice of law issue,
3 this is a California issue. And I can't concede that
4 the Minnesota Attorney General would be advancing Mr.
5 Duron's claims.

6 So, for that reason, I believe it is outside
7 standing for a California resident injured in California
8 as a result of a California transaction to bring this
9 claim under this particular consumer fraud provision.

10 In addition, this provision only applies to
11 cases brought for the public benefit. There is a long
12 line of Minnesota cases defining what that is, but the
13 long and the short of it is, cases like Evangelical
14 Lutheran Church indicate, where it is just a private
15 recovery action and it is just an action for one
16 litigant to get money, compensation, that is not a
17 public benefit.

18 Furthermore, cases like Behrens -v- United
19 Vaccines indicate that where the subject of the
20 litigation is a product that has already been recalled
21 and removed from the market, there is no public benefit.
22 Remember, that was the mink distemper case, which is
23 always interesting. So, I think for all three of those
24 reasons, Mr. Duron lacks standing to bring him any of
25 those three Minnesota Statutes.

1 Which brings us to his senior citizen's
2 claims. Clearly, Mr. Duron chronologically qualifies
3 under either California or Minnesota, but the senior
4 citizen's claims are supplemental and derivative of his
5 freestanding consumer protection claims. And because
6 those claims fail, so do his senior citizen claims.

7 In addition, Your Honor, I think it is
8 important to emphasize that there is no evidence here
9 that would allow any reasonable jury or the Court to
10 find that Guidant committed unfair or deceptive acts
11 within the meaning of the Minnesota Statutes, within the
12 meaning of the CLRA in California, within the meaning of
13 the UCL in California. And I won't belabor these. I
14 think Mr. Pratt covered them admirably, but the key
15 facts are Guidant was aware of only one malfunction when
16 Mr. Duron's device was implanted.

17 At the time Mr. Duron's device was
18 implanted, Guidant didn't know the root cause of that
19 one malfunction. Guidant adequately warned Dr. Higgs,
20 Mr. Duron's physician, of the risk of random component
21 failure at the time, which is all they knew at that
22 time. Guidant never concealed the failure mechanism to
23 the FDA or anyone.

24 Mr. Duron never relied on anything Guidant
25 said or didn't say or represented in selecting his

1 device. Mr. Duron voluntarily chose to have his device
2 explanted independently before talking to any medical
3 professionals. And most importantly, Your Honor, Mr.
4 Duron's device never failed. It worked perfectly.

5 And finally, Guidant supplied Mr. Duron with
6 an adequate replacement device at no cost. I don't
7 think those facts are sufficient at all to support any
8 kind of consumer protection claim.

9 Finally, I want to leave the Court with the
10 argument the California UCL claims. The UCL is a
11 statutory unjust enrichment statute based on equitable
12 considerations that allows the restitution of money
13 taken from a plaintiff through alleged unfair deceptive
14 trade practices.

15 In the Korea Supply Company case, the
16 California Supreme Court held that the disgorgement of
17 profits allegedly obtained by means of an unfair
18 business practice is not available where these profits
19 are neither money taken from a plaintiff, nor funds in
20 which the plaintiff has an ownership interest.

21 What is our point? Our point is that Mr.
22 Duron wasn't out of pocket anything in these
23 transactions. His device was paid for. His medical
24 expenses were paid for directly by insurance. Anytime
25 he had to take off of work, he didn't lose any money

1 because he had adequate sick time and leave time.

2 Now, Plaintiffs say the Collateral Source
3 Rule prevents consideration of that. But, I have never
4 seen the Collateral Source Rule applied to an equitable
5 unjust enrichment cause of action to generate a loss
6 where there really is none, in reality, to in essence
7 create a loss and allow a plaintiff to actually come out
8 ahead on the deal, financially.

9 I don't think the Collateral Source Rule
10 should be applicable to a situation like this and in my
11 research haven't seen it been used so. So, therefore, I
12 submit to the Court that Mr. Duron not out of pocket any
13 money fails to satisfy the standing requirements of the
14 UCL as having suffered an out-of-pocket pecuniary loss
15 caused by this alleged unjust or sharp consumer sales
16 practice.

17 So, in conclusion, Your Honor, I think
18 whether you look at Minnesota law or California law, Mr.
19 Duron has serious standing problems. And his consumer
20 protection claims should be dismissed under either
21 state's laws. Thank you

22 THE COURT: Thank you. No questions at this
23 time.

24 So, do the two respective sides try to team
25 up so you have the same adversaries on each motion so we

1 are going to go back to back, here?

2 MS. CABRASER: It wasn't planned, and it
3 might not always hold true. We try to match by height,
4 so that it is fair.

5 You know, Your Honor, combined with the
6 arguments that you heard last time and which culminated
7 in your decision on the TPP claimants not having
8 standing under the consumer statutes because they are
9 not the consumers, and now it turns out the consumers
10 aren't the consumers, either; that really is essentially
11 a nihilistic argument that nullifies the consumer
12 statutory schemes of both states. And it is not
13 warranted or justified under either state's law.

14 Under Minnesota law, as a number of Judges of
15 this District have applied it in the medical device
16 arena, we know the Minnesota Statute applies to the
17 recipients of medical devices. That is not anything
18 that can or should be revisited as a matter of the law
19 or common sense.

20 And with respect to California's statute,
21 there is no statutory exception for medical devices in
22 that statute, and it is impossible to read one in.
23 There is no case law that exempts or accepts those
24 devices. What Guidant is asking you to do is make new
25 California law. It is the type of question that if it

1 were in doubt ought to be certified to the California
2 Supreme Court for an answer, but it is simply not
3 justified by either the statutory language, itself, or
4 the way the California Courts have applied the statute.
5 This is something that is inherently for personal use.
6 There is nothing more inherent, inherently personal,
7 than an implanted medical device.

8 And if the argument is that the sales job was
9 really done on the doctors, not the clients, I know we
10 recently submitted a supplemental authority in
11 connection with the warranty claim, a deposition
12 transcript of a Guidant sales rep who says that the
13 recipient is the customer. They consider the recipient
14 to be the customer.

15 When Mr. Duron's recall device was explanted,
16 Guidant's sales representative was there in the
17 operating room. Mr. Duron remembers seeing his face.
18 That is a very direct relationship; that is a very
19 personal relationship. And there are many consumer
20 goods that are --

21 THE COURT: Is that Kaiser or --

22 MS. CABRASER: It is not Kaiser, Kaiser is
23 the explant --

24 THE COURT: In any event, all right.

25 MS. CABRASER: His name is Kevin Fosdick, I

1 believe, and that is in our Duron fact statement.

2 THE COURT: That's right, it is.

3 MS. CABRASER: The CLRA, under California
4 law, applies to components that are put into
5 manufactured goods, such as automobiles that are then
6 sold through dealership networks to the public. So, if
7 you try to use any analogy to defeat the common sense
8 proposition that the device recipients are consumers
9 either under Minnesota law or California law, it fails.

10 These claims are stand-alone claims. They
11 are not derivative claims. These claims are created by
12 statute. They neither eliminate common law claims --
13 Plaintiffs aren't required to make an election between
14 their statutory claims and common law claims. And in
15 many cases consumers bring only the statutory claims.
16 They don't bring the product liability claim, or the
17 negligence claim, or the common law fraud claim. There
18 are many cases in which those statutory claims are the
19 only claims that are asserted by Plaintiffs, either as
20 individuals or member of classes.

21 So, to say those claims are derivative simply
22 flies in the face of the statutory language, itself, for
23 both claims, and the way those claims are utilized
24 either independently or in conjunction with other
25 claims. They don't require personal injury. They

1 require some form of economic or monetary loss or
2 damage, so they are independent of personal injury
3 claims. Sometimes they are filed in conjunction with
4 personal injury claims where there are physical injuries
5 and emotional distress injuries as there are here, but
6 that is not required.

7 With respect to the standing argument under
8 the CLRA, just assuming *arguendo* that that were to
9 apply, rather than Minnesota law, Guidant makes the
10 point, and it is belied by the device recipient
11 plaintiff complaint by adoption, that there is really
12 only a claim for damages under California law and under
13 the CLRA there had to be a 30-day letter preceding those
14 claims.

15 The fact of the matter is that Mr. Duron's
16 Complaint incorporates by reference, and itself asserts
17 entitlement to recover damages and or restitution. That
18 is paragraph four. The Minnesota consumer claim that is
19 adopted and incorporated by reference from the Master
20 Complaint, which is set forth in great detail in
21 paragraphs 327 through 339 of the Master Complaint,
22 itself, sets forth the damage, the damages, as well as
23 injunctive and equitable relief.

24 The UCL claim under California law is an
25 equitable/injunctive claim. That is the disgorgement

1 unjust enrichment claim that doesn't require a pleading
2 or proof of damages, and it is not bound by the CLRA
3 30-day letter.

4 So, the fact of the matter is Mr. Duron did
5 assert equitable and injunctive relief claims under the
6 CLRA. He was entitled to do that without sending the
7 letter beforehand. To the extent that he would be
8 required to send the letter before amending the
9 Complaint or going forward to assert damages, he has
10 done that. Guidant has the letter. They argue about
11 the technicalities of that, but we think the better case
12 on that is the Deitz versus Comcast case which we cite
13 in our brief. And the sequence of events here shows
14 that even under the most Draconian and technical
15 interpretation of that 30-day requirement, he would
16 still have a CLRA equitable and injunctive claim, which
17 he has asserted, and he would be entitled to amend his
18 complaint on the 31st day after sending out that letter
19 again, if the requirement was that he send out the
20 letter again via certified or registered mail. But, it
21 doesn't defeat his standing and it is not going to
22 defeat his ability to pursue that claim at trial if the
23 Court decides that California law applies at trial.

24 Now, with respect to the fact that Guidant
25 asserts, and it is obviously a disputed material fact,

1 that there is no basis for a claim under the CLRA
2 because Guidant has fixed the problem, Guidant has acted
3 appropriately to correct the problem, that is very much
4 at issue. The entire course of Guidant's conduct is at
5 issue.

6 Whether or not the product is subject to a
7 design defect is very much at issue. Whether or not it
8 is subject to a manufacturing defect is very much at
9 issue. Whether these products were other than as
10 represented, marketed and sold, which is the operative
11 issue under both Minnesota and California statutes, is
12 very much at issue.

13 This Court is not able to weigh and sift the
14 conflicting evidence on that point that you have heard
15 this morning and it has been submitted to you by both
16 sides, and decide as a matter of law or as a matter of
17 fact that Guidant has fixed the problem and isn't
18 subject to a CLRA claim anymore. That is Guidant's
19 view.

20 Guidant's view is they fixed the problem.
21 They did the recall. They argue elsewhere in their
22 brief that Mr. Duron should not have availed himself of
23 the recall, and it was unreasonable for him to go in and
24 elect replacement surgery and get it. But, for purposes
25 of the consumer claim, they say that fixed the problem.

1 And by the way, the device didn't fail. Well, it was
2 never called upon to work. And what that device looks
3 like after explant, you saw it this morning, is a device
4 that is flawed by a manifest manufacturing defect with
5 the wire and the tube touching, that is an arc waiting
6 to happen. That is a failure waiting to happen.

7 That is a defective device. And we will deal
8 with that later in the day under either state's law.
9 And it is not just that Mr. Duron got lucky for
10 litigation purposes and unlucky in life, because it so
11 happened that the device explanted from him exhibited
12 the very manufacturing defect we have been talking
13 about.

14 As we note in our fact submission, Guidant's
15 own examinations reveal that 73 percent of the Prizm 2
16 devices have the manufacturing defect, where the
17 feedthru wire rests directly against the backfill tube.

18 Mr. Duron, very unfortunately for him and for
19 the majority of the Plaintiffs in this case was not an
20 exception. He had a device which was very much the
21 opposite of what it was represented and sold as, and
22 what the doctors were told it was and what the doctors
23 told their patients it was.

24 And that process demonstrates both standing
25 and the factual predicate which is at this point in

1 dispute for a consumer claim under either statute.
2 Neither Minnesota nor California has a privity
3 requirement in their consumer statutes, and that is
4 effectively what Guidant has been arguing to you this
5 morning. But, that is not a requirement. It is not in
6 either statute, and it has been rejected by the case
7 law. The exception for medical devices is not in either
8 statute, and it has been rejected, specifically by the
9 case law in Minnesota, and it has certainly never been
10 decided in California that medical devices were not
11 consumer goods and were beyond the purview of the CLRA,
12 or the UCL. The UCL, by the way, deals with practices
13 and courses of conduct and can involve any type of
14 either a product or service.

15 And by the way, yes this is a heavily
16 regulated industry, or at least it is supposed to be.
17 And the FDA tries probably the best it can to keep track
18 of what is going on and to regulate Guidant. But, the
19 FDA also says the consumer fraud claims aren't
20 pre-empted or exempted. 808(1)(d)(1), the FDA has done
21 nothing, will do nothing and can do nothing to interfere
22 with the ability of consumers and medical devices, and
23 drugs for that matter, to bring consumer claims when
24 consumer fraud is the conduct at issue, as it is here.
25 Thank you.

1 THE COURT: Can I ask you -- I should have
2 asked -- it will come up again on a couple of the other
3 motions. We will stick with this motion for now.

4 Is there any -- acknowledging as the parties
5 in the room are aware, at least the direct lawyers that
6 the Daubert Motion is coming down the road, we timed all
7 of this, I think, by agreement and deliberately the way
8 it has been.

9 Do any of the issues you have just raised on
10 this motion turn on any, do you say that -- because
11 occasionally a lawyer will say, well, the only way for
12 opposing counsel to get in the door is if this -- the
13 Court buys, hook, line and sinker, to use a Minnesota
14 phrase, the expert's opinion in this area or that area,
15 is there anything on this motion that -- because it will
16 come up more appropriately in some of the motions to
17 follow, that either side is relying on to get in the
18 door here on this motion, in your view?

19 MS. CABRASER: I can't speak for Guidant, but
20 I don't think that any of our arguments or facts on the
21 consumer claims would be dependent on the outcome of the
22 Daubert Motion.

23 THE COURT: I am not implying that I thought
24 it was by asking, but I just -- because the word defect
25 is thrown -- not thrown around, but there is a lot of

1 disagreement in the record on that issue.

2 MS. CABRASER: Well, there is. As a matter
3 of California law, Your Honor, neither the CLRA nor the
4 UCL requires the demonstration of a defect. They are
5 not product liability statutes, although they often crop
6 up in a product liability context. And the California
7 courts have held repeatedly that when a product, a
8 product is actionable under the consumer statutes when
9 it differs in quality, characteristics, kind, degree, et
10 cetera, from the way it was represented to be. And that
11 does not necessarily mean that you need to prove a
12 defect, as you would in a probably liability case.

13 THE COURT: Thank you. Would you like
14 rebuttal, Mr. Carpenter?

15 MR. CARPENTER: One minute.

16 THE COURT: All right.

17 MR. CARPENTER: I think it is important to
18 clarify the Plaintiffs' reliance on the Deitz case is
19 inappropriate. Number one, it is now line the vast
20 majority of these cases just dismissed the CLRA claims.
21 That is the only one I have seen that even gave a second
22 chance.

23 Second of all, in that case it was almost
24 all injunctive relief and almost no damages. Even if
25 you believe that Mr. Duron does really seek some

1 injunctive relief -- and what they are seeking is
2 equitable relief, restitution. That is not an
3 injunction. An injunction is stopping a procedure,
4 making a defendant stop doing something. Even if you
5 believe there is some level of injunctive relief, it is
6 predominantly damages. I think they would admit that.
7 Therefore, the CLRA claim should be dismissed.

8 The adequacy of the replacement device. Ms.
9 Cabraser talked at length about various issues she
10 thinks are factual issues. None of those matter if the
11 device was adequately replaced and a proper replacement
12 device was given. That trumps all the attendant
13 liability issues that might otherwise have to be
14 resolved under a CLRA.

15 So, I think the points she raised really
16 don't go to that issue. And as long as Guidant
17 adequately replaced his device, what she identifies as
18 potential factual issues, you never have to get to and
19 they just aren't relevant.

20 Finally, Ms. Cabraser points out or argues
21 that California has rejected the idea that a
22 prescription medical device can be a consumer good.
23 California hasn't rejected that idea. It just hasn't
24 rules explicitly one way or another yet in the context
25 of the CLRA. And as I said in my argument, I commend

1 the Court to California's analysis in the status of the
2 contest of the Magnuson-Moss Act.

3 I obviously disagree with Ms. Cabraser's
4 points about the defect waiting to happen. I think the
5 key is, if your device works and never failed, you got
6 what you transacted for. And there is nothing unfair or
7 wrong with that transaction. I will leave it to Ms.
8 Moeller on the No Injury Motion for Summary Judgment to
9 further flesh that concept out.

10 And I think our end point at the end of the
11 day is, if you have got a fully functioning device and a
12 free replacement, nothing unfair about that transaction,
13 Your Honor. Thank you.

14 THE COURT: Would you like the last word, Ms.
15 Cabraser, on that?

16 MS. CABRASER: Other than to say, Your Honor,
17 that there is no California case that supports the point
18 that the Defendant can unilaterally decide whether or
19 not its action in response to a CLRA demand is
20 appropriate or sufficient. The statute provides for any
21 and all, resulting in actual damages. So, for example,
22 if there are damages, loss of use, lost wages, while you
23 are waiting for something to be fixed, damages and costs
24 in connection with getting it fixed -- for example, the
25 replacement wasn't free to Mr. Duron, it wasn't free to

1 Kaiser, there was costs involved, there was lost work
2 involved, there were lost damages, there were physical
3 injuries and complications involved. All of those had
4 an economic impact. None of those were paid by Guidant
5 in connection with its replacement of the device. The
6 device, itself, may have been offered free of charge;
7 but, in the process of availing himself of that
8 replacement device on medical advice, Mr. Duron lost
9 work, paid directly or indirectly for medical treatment,
10 hospitalization, physical damages, et cetera, all of
11 which have an economic impact, and all of which we need
12 to prove at trial, and all of which will be evaluated by
13 the trier of fact.

14 And it is for the trier of fact to determine
15 whether under the statutory language of the CLRA Guidant
16 did in fact step up to the plate and fix the problem
17 such that Mr. Duron hasn't been ignored in this.

18 THE COURT: Do you want to put an exclamation
19 point on that or something other than that, Mr.
20 Carpenter? It is up to you.

21 MR. CARPENTER: It has got to end sometime,
22 Your Honor.

23 THE COURT: Why don't we -- I am flexible,
24 here. But, it seems to me, given where we are at,
25 rather than begin the next one, which we can do, we can

1 take our hour and five minutes or so here so by the time
2 you roll out you get the full hour. So, if you get back
3 here at -- and I don't have to -- we can make it 12:30
4 if somebody wants to leave the building or make it
5 12:20.

6 MS. HOLLOWAY: 1:20?

7 THE COURT: I don't know how concerned you
8 are about your time. Pardon?

9 MS. HOLLOWAY: 1:20 or 1:30, you meant.

10 THE COURT: Oh, yes, yes, that might give us
11 five minutes, thank you.

12 MS. HOLLOWAY: We are fast eaters.

13 THE COURT: Why don't we shoot for 1:25, and
14 then we will go until we are through? The only reason
15 to go forward with another motion now is I have found
16 that when you run them -- whether it is in limine
17 motions or dispositive motions -- when they are grouped
18 together, there is a wear-down factor, so the arguments
19 get shorter during the day, as the day goes on. That
20 may not apply to a couple of these.

21 MR. PRICE: They also get closer in proximity
22 to lunch, or shorter in proximity to lunch.

23 THE COURT: So, nobody will be in here over
24 the noon hour. You are free to stay in here. We will
25 stand in recess until 1:25, if that is agreeable to

1 counsel. All right?

2 And if you want an inquiry to either Amy or
3 Danielle about those three cases or what rolled in here
4 yesterday, they could probably tell you right now. You
5 may be aware of what they are. So, if we talk about a
6 way to handle those as the next few weeks go by -- I
7 don't know if you have a question or not. So, all
8 right?

9 (Noon recess.)

10 (In open court.)

11 THE COURT: Thank you. You may be seated.
12 Whenever you are ready, we can proceed.

13 MR. PRATT: Ready, Your Honor?

14 Good afternoon. We are here on the next
15 motion, Guidant's Motion for Summary Judgment on the
16 grounds of Preemption.

17 A lot has been written on this, Your Honor.
18 I'm watching the time very carefully, here, and 20
19 minutes on presumption is a bit of a challenge. 20
20 minutes to cover all that has been done.

21 There may be a lot of discussion about how
22 much or what the scope of preemption is, but I will tell
23 you, it has got to mean something. Preemption is a real
24 thing. And we have a 125-page Master Complaint here
25 involving allegations that there is something wrong with

1 the Class 3, FDA-approved medical device. And the
2 Plaintiffs say that not a single claim in that claim is
3 preempted. I think they are wrong.

4 Before getting into sort of a detailed
5 discussion, I want to spend a minute talking about two
6 things: One, the policy behind it; and two, kind of
7 what is going on here on this motion in this courtroom
8 by the Plaintiff.

9 The policies are clear. I mean, we see it
10 when we see the Brooks case in the Eighth Circuit when
11 they talk about there is a need for national uniformity,
12 which means that you can't have the Federal Government
13 saying, do this, and state juries and state agencies and
14 legislatures saying do something different, or do
15 something in addition to it.

16 You see it when you take a look at what the
17 FDA, itself, has said when it says the state common law
18 tort actions encourage second-guessing of the balancing
19 of benefits and risks of a specific device. They don't
20 want that.

21 The FDA has repeatedly said that is not the
22 role of the state court common law system. We see it in
23 the Buckman case, when it says that FDA claims have also
24 caused applicants to fear that their disclosures to the
25 FDA, although deemed appropriate by the FDA, will later

1 be judged insufficient in state court.

2 Those are the policy considerations built
3 into the congressional law that says that states,
4 including state court juries cannot impose on
5 manufacturers like Guidant requirements that are
6 different or in addition to what the FDA requires.

7 National uniformity, no second-guessing.
8 What is going on here? Lots of words through all of
9 this, Judge, lots in their briefs, lots of allegations,
10 but the bottom line is simply, Guidant did nothing
11 wrong.

12 We violated all kinds of FDA regulations, we
13 should have used a different design, we manufactured it
14 wrong, we should have given different warnings at
15 different times, everything they say is a requirement
16 they are trying to impose that is in addition to or
17 different from what the Federal Government has required
18 Guidant to do with respect to the PRIZM 2.

19 And there is a reason for preemption. And
20 the reason for preemption is because of Suzanne
21 Parisian. Suzanne Parisian worked for the FDA back in
22 the 1990's. She is now a well-paid plaintiff's expert
23 that goes around the country doing what she did in this
24 case, which is to take a look at a medical device
25 manufacturer's situation, go through and prepare a 30,

1 40-page report saying, they violated FDA regulations.
2 They didn't meet my expectation and my standards of what
3 should have been followed. She creates her own
4 standards and then she says the company didn't honor her
5 standards. The point is, the FDA hasn't agreed with
6 respect to any one of these opinions. So, if you are a
7 medical device manufacturer like Guidant and you have
8 got FDA approval, the point of preemption is that you
9 don't have to go get a check off from people like
10 Suzanne Parisian to make sure you don't get
11 second-guessed down the road. When the FDA has made the
12 determination, as they have with respect to the PRIZM 2,
13 that this is a safe and effective device. They looked
14 at all of the information and material that the company
15 set. That ought to be enough. We ought not have to
16 follow a Parisian checklist. And this is what the FDA
17 said, they even said in a Tennessee State Court action,
18 that in this respect, Parisian is wrong. The FDA is
19 even disagreeing with her. Now, that is a point to be
20 made.

21 The second point is to be made, why in the
22 world are we in the Tennessee State Court when the FDA
23 and Suzanne Parisian are kind of fighting over whether
24 the company did the right thing? That is not what
25 preemption is all about.

1 Let me go through quickly the regulatory
2 approval. Guidant submitted information with respect to
3 the design, the manufacturing processes, the labeling.
4 All of this was submitted to the FDA. They approved it
5 in August of 2008(SIC) by the way of a supplemental PMA.

6 The approval of that device in August of 2000
7 set forth the design that Guidant was required to
8 follow, the manufacturing process that Guidant was
9 required to follow, and a labeling requirement that
10 Guidant was required to follow.

11 So, the question is, what are the federal
12 requirements that we are to follow? They said, well,
13 they haven't even specified them. They know what they
14 are, because court after court after court said these
15 are the federal requirements. The federal requirements
16 are the totality of the design, manufacturing processes
17 and labeling that represent the specific federal
18 requirement.

19 Case after case, including Brooks in the
20 Eighth Circuit has said just that, that when the FDA
21 approves a Class 3 medical device, the highest-rated
22 medical device, that the totality of that approval,
23 design, manufacturing, and labeling are device specific
24 requirements. And a state can't come in and say, you
25 ought to do it a different way on design, you want to

1 manufacture it a different way, or impose warnings or
2 labeling beyond those required by the FDA.

3 I do want to make one point, Your Honor, and
4 that is, I want to correct a misstatement in our brief.
5 We made a statement in our brief by mistake that the
6 Rattay case, R-a-t-t-a-y, was a Fourth Circuit case.
7 It was not. It is an opinion from the District of West
8 Virginia. It is going to the Fourth Circuit. I think
9 and I hope it will become a Fourth Circuit case in line
10 with all of the other circuits that grant preemption in
11 these types of situations. But, that is a mistake.
12 Rather than send a letter to you -- and if not, I just
13 thought I would tell you right now. We apologize for
14 it.

15 But, when you take a look at the law on this,
16 Your Honor, you are not writing on sort of a blank
17 tablet on this. This is the 360k provision. You know
18 it. States cannot impose requirements that are
19 different from or in addition to any requirement
20 applicable to this device. Device-specific federal
21 requirements, design, manufacture, labeling, all
22 approved by the FDA.

23 These are the Circuit Courts that have looked
24 specifically at 360k, the preemption clause of the
25 Medical Device Amendments in 1976 to determine whether

1 there is preemption.

2 There are two forms of preemption that come
3 into play, here. Express preemption under 360k of the
4 medical device amendments, and implied preemption under
5 Buckman. You can have one or both of them. The Guyer
6 case, the passive restraint case out of the United
7 States Supreme Court confirms that you can have both of
8 them in consideration with respect to the same product.
9 Virtually all circuits, save one, the Goodman case in
10 the Eleventh Circuit that looks specifically at 360k to
11 determine whether a Class 3 PMA-approved device is
12 deserving of preemption. And they have concluded, 7 of
13 them, that the answer is yes.

14 I am going to go through some, because I want
15 you to just get a sense of some of the types of claims
16 that these circuit courts have preempted. Riegel went
17 through negligent strict liability. Horn, failure to
18 warn, preempted design defect. Martin out of the Fifth
19 Circuit, Papike, Kemp out of the Sixth Circuit, a long
20 listing of claims that these courts have looked at and
21 said they are preempted and can not be pursued to in
22 state courts in states within those circuits.

23 The one back here, Mattingly is an
24 interesting case because I am sure we are going to hear
25 a little bit about Judge Rosenbaum's opinion in

1 Medtronic.

2 THE COURT: Oh, I am sure we are.

3 MR. PRATT: The Mattingly case, let me
4 suggest to you, is another case in Federal Court, not in
5 this great state of Minnesota who looked at the issue
6 post-Brooks most recently, 2007, and reached a
7 conclusion that is far more in line with what we believe
8 the law to be.

9 Found preemption on negligence, strict
10 liability, negligent failure to warn and breach of
11 warranty. And that was actually an implantable
12 defibrillator case, as well. That, I think, is a fair
13 reading of Brooks than what we got from Judge Rosenbaum,
14 with due respect to him.

15 This is an opinion of McMullen versus
16 Medtronic case in the Seventh Circuit that I commend to
17 the Court. It is actually very close in some respects
18 to what we have in this case. It is a Medtronic case,
19 not a heart device case. It is a tremor control case,
20 in which the claim was that there was a post-sale
21 warning that was given, but it wasn't given in a timely
22 fashion. They waited too long after the implantation to
23 give the warning.

24 And the Seventh Circuit took a look at that
25 and they acknowledged that 21 CFR 814.39 does allow

1 manufacturers under certain circumstances to make
2 temporary warnings. They have to be approved ultimately
3 by the FDA, but you can do that.

4 But, they preempted that post-sale claim that
5 the warning wasn't timely by saying, where Federal
6 requirement permits a course of conduct, as 814.39 does,
7 and they are trying to impose, the state is, a
8 requirement that it's obligatory, permissive federal
9 court, federal law, obligatory state law, then that
10 state law on the obligatory nature of it is a
11 requirement that is in addition to or different from the
12 federal requirement, and it is preempted, very much like
13 the same arguments we are making here, Your Honor.

14 There is no question here, Your Honor, that
15 the conflicting state court judgment can come in a
16 number of forms, but most significantly as seen by the
17 Lohr case, and more recently by the Bates case, if a
18 device manufacturer is faced with a claim from a state
19 court in front of a state court jury that would impose a
20 requirement in addition to or different from what the
21 federal government has required, then that is clearly a
22 preempted claim. That is what Lohr said, that state
23 court jury verdicts constitute and can constitute
24 conflicting and therefore preempted state court
25 requirements.

1 In connection with this, there is a lot of
2 talk about Judge Breyer's two-inch wire rule.

3 THE COURT: There sure is.

4 MR. PRATT: I mean, I think it is concurring
5 opinion. I mean, it is amazing much traction that has
6 gotten. And his argument, simply stated, is if the
7 Federal government, let's say the FDA requires a
8 two-wire, and the state court jury says you should use a
9 one-inch wire, then that is a preemptive claim. State
10 court, that is a different or additional standard beyond
11 what the FDA has. Then I listen to polyimide, I listen
12 to presentation that polyimide was a bad insulator, it
13 shouldn't have been used.

14 Polyimide was approved by the FDA in 1992 for
15 this particular use. They never said that you have to
16 us that you have to withdraw polyimide as an insulator
17 there. We are going require that. They haven't done
18 that. They haven't withdrawn their approval for that
19 particular insulator. It is a good insulator, as
20 evidenced by the fact that it has been used for years
21 and years and years without consequence, with this
22 particular application, the rarity of the failure shows
23 that it is consistent with the good, long-term use of
24 it.

25 But, the point of it is that this is what --

1 this is what Justice Breyer said about the two-inch
2 wire, two-inch versus one-inch. How is that different?
3 If the FDA by approving our use of polyimide as an
4 insulator in the header, we therefore had to use
5 polyimide in the header as an insulator. We could
6 switch it to silicone, or polyurethane or whatever
7 whimsical material we picked. We had to use polyimide.
8 That was a federal agency design requirement.

9 If they prove in their argument that you
10 should have used something other than polyimide, and
11 they want to state that to a jury here to determine
12 under state common law rules that you should not have
13 used polyimide, but that is clearly a requirement they
14 are trying to impose on the company that is different
15 from and in addition to the federal requirement that we
16 use polyimide.

17 So, it is very much like the two-inch rule in
18 that respect, because the design defect claims are
19 preempted here, Your Honor. The California Consumer
20 Expectation Test, the California Risk Benefit Test,
21 either one of those would require the jury to go through
22 the process, the very same process that the FDA engaged
23 in in determining if this device, this PRIZM 2 device is
24 safe, is effective, and that the company is to follow
25 the requirements of design, manufacture and labeling.

1 The warning and fraud claims are preemptive
2 because what they are trying to do is to say you should
3 have done something more than what was done in the
4 labeling that accompanied this product. We said in the
5 labeling that these devices may fail, essentially. I
6 showed you the language earlier. They may fail to
7 deliver therapy when you need it. That is what we say.
8 They are saying you should do some additional warnings.
9 Should have said something specific about polyimide.
10 You should have said something specific about arcing.
11 The FDA has not so determined that. They have the
12 responsibility to do that. They had information about
13 arcing, they had information about changes we made.
14 They didn't require it. So, we have an FDA-required
15 labeling which we followed.

16 What they are trying to do is to get the jury
17 to impose on us a warning requirement that is different
18 from or in addition to the federal requirement that was
19 imposed on us by the approval of the PMA. The Cupek
20 case out of the Sixth Circuit is pretty interesting,
21 because it is, any claim under state law ... a defendant
22 fails any claim under state law, the defendant failed to
23 warn patients beyond the warnings required by the FDA
24 would constitute state regulation different from or in
25 addition to the FDA requirements.

1 That is exactly what they are trying do here,
2 Your Honor.

3 These are the cases, the Brooks case out of
4 the Eighth Circuit, Horn, Kemp, Papike, McMullen, all
5 cases in which the Court preempted failure to warn
6 claims in circumstances similar to these.

7 And it also extends to, as the Court in the
8 Mitchell opinion quoted here, to the extent that a claim
9 of fraud through misrepresentation is an effort to
10 impose a requirement on the company beyond what the
11 federal requirements are, that too is preempted.

12 THE COURT: So, you are probably headed that
13 way, but in at least three or four places the Plaintiffs
14 say, well look, look carefully at the Judges in
15 Medtronic and St. Jude in your own District is, on the
16 risk warning issue, and preemption, our case is on all
17 four squares with those.

18 Obviously, one of the things that is my
19 responsibility, not just in an MDL context at issue, is
20 to say, well, how do I distinguish those two cases? Or
21 is it as simple as, well, you don't distinguish them.
22 One or both were wrongly decided. Now, there are some
23 nuances. I mean, Judge Rosenbaum didn't agree with the
24 entire holding of Judge Tunheim. But -- and you don't
25 need to interrupt your argument, because obviously that

1 is one thing that I will do, is either distinguish them,
2 not distinguish them. Maybe I will even use the
3 language of Judge Rosenbaum where he says: Well, at
4 least on the portion that says -- on the footnote, I
5 will have to depart from my brother, Judge Tunheim, or
6 as sometimes he and I do, he says, well, I don't mean to
7 gainsay my colleague in the other town there across the
8 river, but -- so, what do I do with those two? I mean,
9 that is the assertion by the Plaintiffs, plain and
10 simple.

11 MR. PRATT: Sure, sure, and I understand
12 that. And it certainly makes logical sense to them,
13 because they want you to follow what we consider to be
14 very aberrational rulings from Judge Tunheim and Judge
15 Rosenbaum.

16 On the Medtronic side of things, the more
17 recent opinion, I think it is fair to say that Judge
18 Rosenbaum put a lot of weight on the fact that Medtronic
19 knew sometime in 2003 that they had a problem with the
20 battery from the bench testing, did not tell the FDA
21 anything about it. Continued to submit PMA supplements
22 to the FDA without bringing that to the attention. And
23 it really didn't do anything until a year plus, two
24 years later, when they started getting field events.

25 That is a factually different thing than what

1 we have right here in our litigation, Your Honor. We
2 have the February 1, 2002 report was the first report
3 that came in. We talked about that this morning. Made
4 the change in April of 2002, made the change in November
5 of 2002. The November of 2002 change was brought to the
6 attention of the FDA with the annual report filed the
7 following year. But, every one of these events that we
8 got we submitted to the FDA. We told them what had
9 happened to the device.

10 And I have one up here which is a 2003,
11 October 2003 MedWatch. Because the claim is we hid it
12 from everybody, including the FDA. We didn't tell them
13 about these changes. It isn't true. We told them about
14 the change in November of 2002 in the annual report.

15 And this is just one example of an MDR that
16 we sent to the FDA. We told them in October of 2003 in
17 connection with this report that there is this event
18 that just happened, one in the arcing of the headers of
19 the PRIZM 2.

20 We also said to them, although the occurrence
21 of this failure had been very low, Guidant implemented
22 manufacturing enhancements in April and November of 2002
23 to correct this issue. So, we don't have a situation as
24 in Medtronic, factually, where we had information we
25 didn't share with them about the events we were

1 receiving from the field, or we had made changes that we
2 simply didn't tell the FDA about. So, that is factually
3 a different situation.

4 But, you know I am not naive. I am not here
5 to try to say that Judge Rosenbaum -- that you can make
6 that sort of square opinion fit into the round whole
7 that we are creating for you. His approach to it, he
8 was right with respect to the PMA approval did
9 constitute device --

10 THE COURT: And that is way he departed from
11 Judge Tunheim.

12 MR. PRATT: He departed from Judge Tunheim.
13 Beyond that, you know, he made some passing reference to
14 maybe they lost their approval with the recall. There
15 is no evidence regulatory, or legal, or otherwise for
16 that. He didn't rule on that, he made a passing
17 reference to it.

18 His approach to it in terms of how the
19 withholding of information from the FDA in that case
20 cost the company preemption. I don't think you can fit
21 that under the Brooks analysis. I don't think you can
22 fit it under the 360k, or under the jurisprudence of all
23 of the Circuit Courts.

24 But, I think there is a lot in Judge
25 Rosenbaum's opinion that we disagree with. I think

1 there is a much greater weight of authority out there
2 from the Eighth Circuit and beyond, that if you apply it
3 to the facts here, you are going to conclude that there
4 is preemption of all of the claims we identify in the
5 brief.

6 And, you know, if this case isn't appropriate
7 for preemption, Your Honor, when you have an
8 extraordinarily rare event where the company brought it
9 to the attention of the FDA right along, and they are
10 arguing that you should have used a different design,
11 different manufacturing process, you should have warned
12 differently, I can't hardly think of a case in which
13 preemption wouldn't apply. So, we suggest to you that
14 preemption is appropriate in this case for all of the
15 claims we identify. We agree with them that a true
16 manufacturing defect claim -- in other words, we deny
17 that there is one in this case, but he agree that a
18 manufacturing defect claim is exempted out of the reach
19 of 360k. And we will probably quarrel with them over
20 what that means, but this motion would not address that
21 specific issue, Your Honor.

22 THE COURT: I'm not sure what I expect in
23 response. I will ask the same question of opposing
24 counsel on this; but, you know, listening to the
25 argument and going way back to the opening remarks this

1 morning, you know, how -- I suppose maybe it is called
2 good advocacy, but I don't think either one of you are
3 going to probably characterize it that way in a moment,
4 and you will mean it respectfully to the other side.
5 But, you describe the history of the lack of
6 concealment, the lack of being entirely forthright with
7 the FDA. That is quite different than the opening
8 remarks this morning of counsel where everything was
9 said short of a criminal conspiracy, in terms of not
10 being forthright with the FDA. You both can't be
11 correct.

12 MR. PRATT: Yeah, but -- well, I'm right.

13 THE COURT: And like I said, regardless of
14 how I look at that, that still makes Judge Rosenbaum's
15 decision an anomaly. But, you both described the
16 history entirely different.

17 I mean, I don't think it would be easy to
18 describe it as two sides to the same story, because I
19 mean, I have got I don't know how many documents in my
20 chambers, in my Clerks' chambers, but I don't think you
21 can just say, well, they are just two different versions
22 of the same events. But, how do I reconcile those?

23 MR. PRATT: I think that they are trying to
24 overcomplicate the issue, Your Honor. I think the issue
25 of whether we submitted every scrap of paper to the FDA

1 is not an issue that denies us the right to preemption.
2 Preemption, if you read these cases, as I am sure you
3 do, it is a far simpler process than they have
4 described.

5 They have used Dr. Parisian to overcomplicate
6 it. They have created these interpretations of
7 regulations and said, look, the company didn't comply
8 with this and this and this. The point is, we have been
9 require by the federal FDA to follow a certain design,
10 follow a certain manufacturing process and follow
11 labeling requirements.

12 What they do, are doing, simply put, is
13 trying to impose on us additional state court
14 requirements. The argument that we may have defrauded
15 the FDA, which we deny is absolutely not the case is
16 clearly a preempted claim under Buckman.

17 Buckman says that you cannot submit a claim
18 to the jury where the claim is you didn't submit
19 everything to the FDA. So, the argument that they are
20 making about, did we play square with the FDA, which we
21 did and they allege otherwise is a preemptive fraud on
22 the FDA claim under the Buckman case out of the United
23 States Supreme Court. And it goes to the very heart of
24 preemption.

25 We can't have in front of state court juries

1 the kind of debate over, did this piece of paper go? I
2 mean, should things have been done differently? It is
3 the FDA's job to make a determination on whether there
4 has been an adequate submission or not, whether the
5 company ought to change its warnings or not, or whether
6 the manufacturing process and design schematic ought to
7 be changed or not. That is their job. It is not a job
8 of state court litigants to get in front of a jury and
9 to lay out everything that happened with the FDA in
10 hopes that the jury, plaintiff's hope, the jury will
11 say, well, the company really didn't do it the way it
12 should have been done. Dr. Parisian has a different
13 standard. Maybe you should have tested polyimide in
14 this way before it was submitted.

15 The point is, we submitted the test material
16 on polyimide to the FDA in 1992, no question about that.
17 They deemed it acceptable because they approved
18 polyimide. Now, the idea that we should have done some
19 additional testing, and maybe they would have done a
20 different thing, is the very heart of preemption. Those
21 types of claims ought not be played out in courtrooms
22 involving state common law theories, Your Honor.

23 THE COURT: Which brings me to the question
24 that I think you already answered, where Plaintiffs
25 begin their briefs, then they come back and end them

1 that way. I think I have written it down, here. Well,
2 I guess it is my paraphrase, but a separate issue, in
3 the end they say the truth of the matter is, we deny
4 that any of our claims impose any device-specific
5 requirements that are in any way different from or in
6 addition to the device-specific requirements of the FDA,
7 or federal law. So, that is in the end what -- they
8 start and finish with saying, well, you can look at our
9 claims anyway you want, but we don't believe we are,
10 there is anything in our claims. So, obviously, there
11 is a significant point of departure between Plaintiff
12 and Defendants on that, as well.

13 MR. PRATT: They have to say that, because
14 otherwise they are dead on preemption.

15 THE COURT: That is true.

16 MR. PRATT: All I would say is that as you
17 read Dr. Parisian's expert report, as you read what the
18 Plaintiff's say, put yourself in the mind of a medical
19 device manufacturer and think whether those requirements
20 they are trying to impose on us, on Guidant, are not
21 indeed additional to what the FDA has required.

22 I mean, they are -- the testing, you should
23 have done it in a different way. Everything they say is
24 in addition to or different from what the FDA has
25 required.

1 So, I understand why they saw it, because it
2 is boilerplate in these types of things. But, you
3 cannot read Dr. Parisian's report, you cannot read their
4 briefing without concluding that is exactly the contrary
5 of what they are trying to do here, Your Honor.

6 THE COURT: Thank you. Mr. Lesser, whenever
7 you are ready?

8 MR. LESSER: Thank you, Your Honor. There's
9 a lot of ground one could cover. I am going to agree
10 with Tim on that, to cover preemption in 20 minutes is
11 not necessarily easy. However, in some respects,
12 actually, I submit it is rather easy today, because the
13 argument that we have just heard, which is, quote, "It
14 ought to be enough that the FDA approve this device," is
15 exactly the argument, not only that your Judge next
16 door, Judge Tunheim rejected in his case in St. Jude,
17 and Chief Judge Rosenbaum rejected in Medtronic, the
18 argument that the Eighth Circuit rejected in Brooks,
19 head-on rejected in Brooks. It is the argument the
20 Supreme Court rejected in Lohr, it is the argument the
21 Supreme Court reaffirmed with emphatic policy
22 consideration with the various policy things that Mr.
23 Pratt referred to in the Bates case two years ago, 7 to
24 2 majority, which I think the goal was to shrink the
25 confusion created by Lohr.

1 All of the argument that we had today is on
2 the first of two steps. In other words, for present
3 purposes, I actually believe, by the way, that Brooks
4 and the issue that the footnote of disagreement between
5 your two brethren, here, I am not going to argue that
6 disagreement at all. For the moment, for further
7 argument, I concede it. I think Bates actually shifted
8 the ground significantly away from that. And that is,
9 it is a two-step process.

10 The Eighth Circuit took the argument that we
11 just heard, "It ought to be enough," and said in its
12 decision -- and indeed, I will just explain why both as
13 a policy matter and a legal matter we fall full square
14 within Brooks before I'm done.

15 In first glance, and I am reading now from
16 the Eighth Circuit's decision. At first glance the
17 preemption issue presented here under 360 might seem
18 quite simple, and according to Mr. Pratt is quite
19 simple, since the state law result sought by Brooks
20 relates to safety, and would impose different or
21 additional requirements on the product warning for
22 Simplex. That is the second argument. That was the
23 argument that Helmedica made in Brooks. The FDA looked
24 at this? They deferred to the FDA because it approved
25 it. Of course, the case goes on.

1 The next sentence says, that the issue is not
2 so simple as evidenced by Medtronic -v- Lohr. And Judge
3 Tunheim and Judge Rosenbaum actually recognized
4 expressly it is a two-step process. Everything we have
5 heard about in all of these citations to all of these
6 other Federal Courts go to the question which I won't
7 challenge for the moment today, whether or not the FDA
8 process, the process of getting a medical device
9 approved is itself a requirement. That is where the
10 Eleventh Circuit took issue. And for present purposes,
11 I will concede -- think it is wrong under Bates, but I
12 will concede that it is a requirement.

13 But then, and this is what Medtronic is all
14 about, this is what Brooks is all about. You have to go
15 to the second step. And indeed, both Judges Rosenbaum
16 and Tunheim say you have to go to the second step.

17 You then have to drill a good deal deeper.
18 It is not merely because of the fact that the FDA
19 approved it, you then have to ask yourself whether or
20 not the claims in the case relative to what occurred,
21 including what occurred vis-a-vis the FDA are preempted.
22 Both of them say that.

23 Now, before I get to the heart of it, I would
24 like to clear off some of the clear underbrush, if I
25 may. Mr. Pratt admitted a manufacturing defect claim is

1 not preempted. Well, there are actually one or two
2 other claims in this case that are clearly not
3 preempted. The first is the claim for express warranty.
4 And in Bates, two terms ago, seven Justices of the
5 Supreme Court agreed, a claim, a cause of action on an
6 express warranty asks only that the manufacturer make
7 good on the contractual commitment that it voluntarily
8 undertook by placing that warranty on the product.

9 In other words, express warranty says, you
10 manufacture. You got approval from the Government, in
11 that case it was FIFRA, that old insecticide act, but by
12 golly, the two acts are identical in their preemptive
13 provisions, except the one says in addition to or
14 different from -- the other says, different from or in
15 addition to; that is the only difference. I don't think
16 that is a difference.

17 You created your own contractual warranty.
18 You are not preempted. You voluntarily, in the world,
19 have gone out and done that.

20 The second point that is not preempted, and
21 Ms. Cabraser alluded to this. We can put it up on this
22 screen. This is from the implementing regulation, 21
23 CFR 808(1)(d)(1). And this is what the FDA, after
24 full -- and this is entitled, unlike FDA, amicus letters
25 to show in deference for other cases. Then, it says,

1 Section 512(a), which is what we are talking about, does
2 not preempt state or local requirements of general
3 applicability, where the purpose of the requirement
4 relate either to other products in addition to devices,
5 e.g., requirements such as general electric codes, and
6 the Uniform Commercial Code, warranty of fitness. The
7 other claims for implied warranty and UCC claims.

8 This, by the way, is cited by Brooks, decided
9 by your brethren. That claim is not preempted. The FDA
10 expressly recognizes it, 808(1)(d)(1). He goes on, or
11 to unfair trade practices in which the requirements are
12 not limited to devices. That would be all the consumer
13 fraud claims because those are unfair trade practice
14 claims. This is the FDA, itself. Because, remember,
15 the background to preemption is that unless there is a
16 clear and manifest intent by the government to preempt
17 the cause of action, clear and manifest. And what
18 Medtronic teaches us and Bates teaches us, it has to be
19 exactly clear. Those two sets of claims, laws of
20 general applicability and consumer protection claims are
21 not preempted by 360k(a). That is what it is talking
22 about in 808(1)(d)(1). That is the other piece of the
23 underbrush.

24 To the extent we are making corrections to
25 our briefs, Your Honor, I would like to make one. And

1 in our opposition on preemption, we state that the
2 unjust enrichment claim is not preempted because of this
3 provision.

4 That is not accurate, actually. The reason
5 the unjust enrichment claim gets us back to the majority
6 of claims, takes us to Brooks, takes us to Bates, takes
7 us to Lohr. And this is what we did not hear about, one
8 word, and this is where the argument ends. This has to
9 do with what are called parallel requirements. And this
10 is from Brooks, 273 F.3d 798-99. Brooks is correct in
11 her assertion that a claim for failure to comply with
12 FDA regulations is not preempted by the MDA. This is
13 the second step of the analysis. We are willing to say
14 the MDA is a law that has preemptive effect.

15 Now you have to go to the second step,
16 because that is what occurred in Medtronic -v- Lohr.
17 You have to then say, the specific claims at issue with
18 regard to the specific matters are preempted. So, in
19 Lohr it says exactly the same thing. This is at 518
20 U.S. 495, 497, two pages found at 495. It is clear that
21 the lawyers' allegations may include claims that
22 Medtronic has to the extent that they exist violate FDA
23 regulations. At least these claims, they suggest, can
24 be maintained without being preempted by 360k. And we
25 agree. That's Lohr.

1 Is there any doubt this is still the law?
2 No. Because in Bates, two years ago, once again -- and
3 to the extent one hears in medical device cases Bates
4 doesn't affect us because we are not under FIFRA, we are
5 under the MDA -- we are under the 360k, excuse me.

6 Well, Bates actually has a whole two pages on
7 Medtronic. The preemptive language is the same. And in
8 Bates, the Supreme Court two years ago made the critical
9 point, a state cause of action that seeks to enforce a
10 federal requirement, quote, "Does not impose a
11 requirement that is different from or in addition to the
12 requirements under federal law."

13 To be sure, this is seven Justices by the
14 way, the threat of damages remedy will give
15 manufacturers an additional cause to comply. In other
16 words, you might be liable. If you didn't comply with
17 what the CFR's tell you to do, you might be liable. And
18 that is an additional reason you should comply. But,
19 the requirements imposed upon them under state and
20 federal law do not differ.

21 So, in other words, the state law claim is
22 parallel to the federal claim, and that fits this case
23 like a glove, and I will explain that in one second. It
24 is not preempted. In fact, what I just read to you from
25 544 U.S. at 448, is actually the Bates court quoting

1 Justice O'Connor's concurrence in Medtronic and
2 reaffirming it.

3 As a policy matter, the very next page of the
4 Bates decision goes on, and it takes the exact same
5 argument that Mr. Pratt says can't be right. And it
6 rejects it. Because Dow, joined by the United States as
7 amicus curiae, the United States government, itself,
8 argues a parallel requirements reading, the section at
9 issue which parallels, would give juries in fifty states
10 the authority to give content to FIFRA's misbranding
11 prohibition, establishing a crazy-quilt of
12 anti-misbranding requirements different from the one
13 defined by FIFRA." That is exactly what we just heard
14 Mr. Pratt say is contrary to 360k, the exact same
15 provision, exact same argument. The Court rejects it.
16 And it says, to hold, to rule that way is to not give
17 meaning to "in addition to or different from." It reads
18 it out and changes the words.

19 This is what the Supreme Court said, "This
20 amputated version would no doubt have clearly and
21 succinctly commanded the preemption of all state
22 requirements concerning labeling." The exact argument
23 was rejected two terms ago, in other words, by the
24 Supreme Court.

25 It goes on, and says, even if we weren't sure

1 of that, to the extent you are unsure, the background
2 rule is there is no preempt. To the extent there is a
3 dispute, in other words. And we strongly have a dispute
4 as to whether the CFR's here were complied with.

5 Now, let me go back to Brooks for a second,
6 because Brooks was the Circuit Court here en banc.
7 Brooks, when you get to the port is a case where the
8 system worked, in effect. Because what is really going
9 on with preemption is, if you play by the rules, you get
10 the preemptive past, because that is what occurred in
11 Brooks. And there are two pieces of Brooks that
12 Guidant's argument here has to read out of the decision.

13 The first are the two pages where the Eighth
14 Circuit went through the history of the label at issue.
15 And what Helmedica told the FDA, and what the FDA and
16 Helmedica agreed to and how the label changed.

17 Under the argument that we have here, it is
18 enough that the FDA approved it. Those two pages are
19 complete surplusage. But, the reason they are not
20 surplusage is the critical decision. Because in the
21 case, as Helmedica learned -- the case involved bone
22 cement, you may recall. And the bone cement had a
23 solvent in it which was irritating and allergic to some
24 people. And over time, Helmedica learned that there
25 were more adverse reactions, types of adverse reactions.

1 And Helmedica went to the FDA, and that is
2 what those two pages are all about. And said: We have
3 this -- change the label, what he should we do? And the
4 Court said, you play by the rules, in essence.

5 And then at the end of the decision should
6 there be any doubt about really if that is what is going
7 on, the Brooks Court goes back to what I read to you a
8 few minutes earlier. It says to Ms. Brooks, "Brooks is
9 correct in her assertion that a claim for failure to
10 comply with FDA regulations is not preempted by the MDA.
11 That is the holding of the Eighth Circuit. So, if you
12 can claim and show -- and by golly, Your Honor, we have
13 shown, and I think you alluded to, in essence, a few
14 minutes ago, the Court has a triable issue of fact,
15 whether or not the Code of Federal Regulation provisions
16 at issue are or were not complied with. If you can show
17 that you were not complying with the FDA regulations,
18 this Court of Appeals in this Circuit said, that is not
19 preempted by the FDA.

20 And, of course, in that case, the very last
21 section of the decision is Ms. Brooks hadn't shown it,
22 there was no argument in the record, so there was indeed
23 preemption.

24 In this case, it is not simply a history of
25 Ms. Parisian offering her opinions as to what the

1 standards are. I submit, Your Honor, if you take
2 anymore of Ms. -- Dr. Parisian, not Ms. Parisian. Dr.
3 Parisian's Affidavit, what she does is go through facts.
4 And she goes through the history of this device in
5 excruciating detail, and indeed, it goes paragraph after
6 paragraph after paragraph. And then she says, by the
7 way, there is a Code of Federal Regulations that says,
8 if you go to the FDA and ask for the approval of a
9 device as an opening or as a supplemental, you have to
10 give the FDA -- let's take 812.20. Actually, it is
11 repeated there, place after place after place, same idea
12 is at issue. 21 CFR 814.20 says when you apply, when
13 you file an application for a device with the FDA, there
14 has to be an identification, discussion and analysis of
15 it. Any other data, information or report, relevant to
16 an evaluation of the safety or effectiveness of the
17 device known to or reasonably should be known to the
18 applicant from any source, including those derived from
19 commercial market experience, or otherwise.

20 What you heard this morning was Mr. Drakulich
21 begin to give -- and more of it is in our statement of
22 facts, some of the many things regarding, for instance,
23 polyimide, which Guidant when it went to the FDA in its
24 rush to get this device to market so it could beat out
25 its competitor across town, Medtronic, didn't tell the

1 FDA -- it didn't tell the FDA about the Navy study. It
2 didn't tell the FDA about issue after issue. It didn't
3 tell about the arcing in the similar device. That is
4 all material information. And we know that is material
5 information, Your Honor, because, by golly, if anything
6 has been forgotten in this room today, this device was
7 recalled as a Class 1 recall. That doesn't happen
8 lightly or everyday. That was material information. It
9 materially changed ultimately FDA's view of it. That is
10 noncompliance with this CFR. It does not impose
11 something in addition to or different, because they are
12 parallel.

13 This morning as I listened to Mr. Drakulich,
14 I realized for the most part he was telling you a
15 story not -- and I would actually put into his top 10
16 list some of the CFR references, because I thought they
17 were important for preemption. Mr. Drakulich didn't
18 actually refer to them very often, but he told you an
19 entire story of a failure to warn, a history of a
20 device, what occurred prior to and after approval of the
21 device, without referring to the regulations. So, he
22 was describing a tort case, a negligence case, a strict
23 liability case, without having fraud on the FDA, which
24 is a critical distinction in Buckman in this case.

25 So, take us back to Brooks, again. What we

1 have alleged and set forth are many facts -- not one or
2 two or three, but many. Let me take the one example we
3 had when Mr. Pratt was up here, which had to do with a
4 2003 MDR, which is a medication device experience
5 report.

6 Let me show you something about another MDR.
7 Can you read that? I don't believe -- I am not sure we
8 put this in as an exhibit in our motion, but since we
9 are showing MDR's from later periods of time, this is an
10 interesting one. In the highlighted language in the
11 event summary from '04, which is exactly the one we
12 heard, it says in April of 2002, submitted by Guidant to
13 the FDA, "Guidant obtained FDA approval and implemented
14 steps in manufacturing to mitigate this issue," the
15 issue that we have in this case, the arcing problem.
16 Your Honor, that did not occur.

17 Not only is this MDR dead false, that did not
18 occur. And yet under the CFR's, it is required that if
19 you change a device in such a way as to change anything
20 regarding its safety, you have to then, at that time,
21 tell the FDA, that is 814, CFR 814.39. And we cite
22 that, of course, in our brief, so does Dr. Parisian. It
23 is not her standard, it is the Code of Federal
24 Regulations standard.

25 And what we know, further -- I could go back,

1 testimony. The change in 2002 after Mr. Duron, this
2 goes, of course, to the post-sale issue, ultimately, in
3 the case, but not to the preemption issue.

4 In 2002, when this device was changed,
5 conveniently as you know, and I don't even think Mr.
6 Drakulich necessarily mentioned it after all of the ones
7 in inventory were sold out before the change was
8 actually really included in the ones that went out to
9 the consuming public.

10 This is Brian Novak, 30(b)(6) designee for
11 Guidant on FDA compliance. And he agrees in this clip,
12 in this selection -- I can show others, of the deponents
13 who agree, that the change in 2002, Guidant made changes
14 to the device.

15 That is correct, they made changes to the
16 device.

17 Amazingly enough -- and, on by the way, on
18 page 331 of his testimony which is part of the record,
19 he agrees this change was not submitted to the FDA as a
20 PMA supplement, correct?

21 That is correct, it was not submitted.

22 A year later, two years later realizing it
23 was a mistake, they literally lied and told the FDA it
24 was submitted. It was not submitted.

25 Do you know when it was submitted, Your

1 Honor? You heard something about late notice letters.
2 Whether that is playing by the rules or not, at least
3 for the CLRA claim of California law, and I think it is
4 a little more serious talking when talking about the
5 FDA. The supplemental PMA for this change was submitted
6 in 2005, three years later. That is really backfilling,
7 Your Honor.

8 Those are the smallest portion of the facts I
9 can go through. But, what the CFR's require, 21 CFR
10 812.27(b)(1) and (b)(2), 21 CFR 814.20, 21 CFR 814.39.
11 They are listed in our brief. There are page after page
12 of them. There are at least a dozen. This is what the
13 FDA requires to be done. Had they been done, we might
14 not be here today. It is about doing the right thing.
15 That is why, in Bates, in Lohr, in Brooks, every one of
16 the courts said that if you can show that the FDA was
17 not -- its rules were not complied with, you don't get
18 preemption.

19 And why is this so? Because, let's face it,
20 the FDA may be a large government agency, but it can't
21 possibly -- in fact we have testimony from Mr. Novak, I
22 believe, that there are only eight people at the FDA
23 that review all of these hundreds of submissions a year.
24 And each of these submissions looks like the ones you
25 have, Your Honor. They are hundreds and hundreds and

1 hundreds of pages long. And the FDA reviewers don't
2 have the wherewithal, don't have the ability in the real
3 world to go through and search out footnotes on
4 documents that were submitted ten years earlier, which
5 by the way Mr. Drakulich pointed out, not only is it the
6 only time when Guidant is asked, where do you have the
7 two-inch wire, in essence, in this case? The response
8 is the 1992 document which Mr. Drakulich points out to
9 the Court does not actually show that there was a
10 biocompatibility study done for this. That indeed
11 represented that polyimide was for non-tissue contact,
12 and of course it was tissue contact which is why it
13 degrades, which is why we are here.

14 The last point I would like to address very
15 briefly. So, in other words, what we have here is a
16 claim. Mr. Drakulich presented a potential tort claim.
17 It is consistent with the Federal Regulations. And when
18 you are consistent, as I said, Brooks is explicit, the
19 United States Supreme Court is explicit, Judge Tunheim
20 and Judge Rosenbaum agreed.

21 And the Mattingly case, for instance, does
22 not disagree at all. Those are rather brief little
23 decisions, and I assume your clerks can provide it to
24 you off of WestLaw. You go through the whole decision,
25 and you are not really sure what is at issue, you are

1 not sure if they are enhancing the device, you are not
2 sure what the presentation was, but at the end of the
3 decision in the Mattingly case, one claim in that
4 case -- and I don't really know what the facts were but
5 the decision is seemingly vague, survives preemption.
6 It is a negligence, per se, claim.

7 The negligence, per se, is the failure to
8 comply with the FDA regulations. So, the Judge
9 basically allowed amendments, allowed the case to go
10 forward into discovery. Did Medtronic in that case
11 comply with the FDA regulations? If it had not, with
12 the claims we are making here, it would not be
13 preempted. That is the last two claims of the Mattingly
14 decision. What happened to the earlier claims, I don't
15 know because the decision, frankly, is so vague.

16 So, let us -- you look at Brooks, and you
17 fall full square within Brooks. Helmedica went to the
18 FDA and told FDA what it knew, how it knew it and worked
19 with the FDA. Guidant absolutely did not. And I have
20 given you a few of those examples, but they go on for
21 page after page after page of Dr. Parisian's Affidavit.
22 And it is not her standard. She is citing these CFR's
23 like the one I just read to you, and I can read them all
24 to you, but they make it quite clear. So, I get to
25 Buckman at the end.

1 The fallback position of Guidant in this case
2 is that Buckman must have changed it, because in
3 essence, the argument goes, plaintiffs are saying you
4 did not tell the FDA anything. Are you not alleging
5 fraud on the FDA? And is that not what Buckman says you
6 can't do?

7 Well, again, I could refer Your Honor to the
8 two opinions your brethren stress that on. If that were
9 so, of course, the Brooks opinion is wrong. But, I
10 cited from the Brooks opinion, its last holding, a claim
11 of failure to comply with parallel FDA Regulations are
12 not preempted.

13 Unfortunately, of course, Brooks came down
14 after Buckman. The Eighth Circuit knew about Buckman.
15 So did Bates, so did the Bates decision, two terms it
16 came after Buckman. Because Buckman was a very odd and
17 indeed limited situation. Buckman you will recall was a
18 situation where there was an MDA claim. So it's like we
19 have here, a device claim against a manufacturer; but
20 also sued as a defendant in the case was the consultant
21 that prepared the documents that went to the FDA.

22 The device manufacturer settled out. The
23 only party left in the case was in fact the consultant
24 who prepared the documents going to the FDA. The only
25 claim left in the case, therefore, the only duty that

1 could be alleged vis-a-vis that consultant was that you
2 defrauded the FDA, because that is all the role the
3 consultant had in the facts of the case. It had nothing
4 to do with the manufacturing, it had nothing to do with
5 the labeling or otherwise. It was, this person is
6 liable because it submitted false documents to the FDA.

7 So, the claim indeed was fraud on the FDA.
8 In other words, there was is no way -- here is an easy
9 way of saying Buckman, I never assumed I'd say it this
10 way, but this is what it is actually holding. There is
11 no way that case could have begun, whatsoever, without
12 having the fraud on the FDA be the facts of the case.

13 That is why the holding is, you can't have a
14 cause of action of fraud on the FDA. Why? Because the
15 states traditionally, under traditional preemption
16 analysis -- it is not a hard case -- actually, have no
17 right to police what is given to the FDA. But, when you
18 have parallel requirements -- I said a few minutes ago,
19 the most interesting about Mr. Drakulich's presentation
20 this morning was, you didn't have to have the references
21 to the FDA in its rules, whatsoever.

22 The facts of the case, the failure to warn,
23 for instance, is the failure to warn that polyimide was
24 the wrong thing to use. It has nothing to do with the
25 FDA. You can take the FDA out of the picture. The

1 entire case goes in without it. There is not fraud on
2 the FDA. The fact the FDA was defrauded -- not
3 defrauded. The fact that the FDA regulations were not
4 followed are absolutely parallel. But, the difference
5 is the case can go in without having the fraud on the
6 FDA be part of the case, whatsoever, and it could. But,
7 we are allowed to use them in the case because the
8 Supreme Court said so. It said so in Medtronic. It
9 said so in Bates. The Eighth Circuit said so. It said
10 so in Brooks.

11 So, to come back to where I started, Your
12 Honor, preemption analysis for this case today, I will,
13 for purposes of this argument, concede that the MDA is a
14 requirement. So, all of those Federal Circuit Court
15 cases I absolutely agree with. But, as the Eighth
16 Circuit said in Brooks, that is only the first of the
17 two steps. You then have to go to the second step. And
18 on the second step, this is not even close.

19 There are claims that exist in common law.
20 There are claims that the FDA recognizes are not
21 preempted, there are claims that the Supreme Court says
22 the express warranty are not -- recognized, and all of
23 the other claims are ones that have parallel
24 requirements under state law.

25 And finally, to address the policy, I would

1 recommend that you look at the Bates decision, because
2 the Supreme Court absolutely rejected the idea. It
3 rejected it in two places. The idea that it states,
4 find liability, because you didn't tell the consumers,
5 just as Guidant didn't tell the FDA, you didn't tell the
6 consumers. There is nothing wrong with that. The FDA
7 has to depend on these companies, such as medical device
8 companies to play by the rules, to tell it everything,
9 just as these CFR's require it. Everything, you don't
10 hide it. You have to be forthright. You don't lie as
11 we saw in that medical device report. If you make a
12 change that effects safety, Mr. Novak agrees this was a
13 change to represent safety. There is a CFR that says
14 you have to file a supplemental PMA. And you can't wait
15 three years to do it until the New York Times has blown
16 it up in your face.

17 This case isn't even close, I submit under
18 the Brooks two-step analysis to preemption. Oh, one
19 last point. I would like to go back to something which
20 I think was a very interesting insight, at least
21 jurisprudential insight by Judge Rosenbaum in Medtronic.
22 I don't think I have talked all that much about Judge
23 Rosenbaum or his decision today, but I mentioned it a
24 few times.

25 At the end of his decision, he asks a very

1 interesting question. He goes back to Judge Breyer's
2 two-inch wire. He asks the question that really was
3 true in his case and it is really true in our case.
4 What happens when the FDA approves a two-inch wire if
5 the FDA wasn't told that the wire was subject to
6 corrosion and rust? This is the very end of Judge
7 Rosenbaum's Medtronic decision. And he says, I don't
8 see how you can have preemption. I agree with Judge
9 Rosenbaum. You shouldn't have preemption, because as
10 the rules are, you are supposed to tell everything. I
11 actually say in our case, that is a violation of exact
12 CFR's and FDA regulations. But, he says, it doesn't
13 really make much sense to me. And I suspect that given
14 in the Bates decision where all of these points are
15 underlined, I think it wouldn't make sense to the seven
16 member of the Supreme Court. Thank you.

17 THE COURT: Rebuttal, if you would like it,
18 Mr. Pratt?

19 MR. PRATT: Briefly. I am glad that we have
20 the agreement from the other side that you should read
21 the Mattingly case. It does have a lot of good
22 jurisprudence to review.

23 Let me start with a couple of three points.
24 I was interested in this idea that somehow they weren't
25 creating new and additional requirements, but they were

1 creating parallel requirements. And I heard Plaintiff
2 counsel talk about Parisian and show you 814.20. And
3 what she did is to say, here is what you have to have
4 for approval. And these are the things that Guidant
5 didn't submit to the FDA for approval. We deny those
6 things, but that is the very type of claim that has to
7 be preempted.

8 If you don't preempt those kinds of
9 allegations, there will never be preemption. There is
10 always going to be a Dr. Parisian, probably Dr.
11 Parisian, herself, walk into a medical device case, and
12 say, let me go through these regulations, because I'm
13 going to find something the company didn't do right. I
14 am going to find something.

15 Now, apparently the FDA, apparently, was
16 duped, because they didn't figure it out. That was
17 their argument. Because the FDA approved it. If the
18 FDA wanted more information, the FDA could have asked
19 for it. But, after the fact of approval, to allow
20 someone like Dr. Parisian and Plaintiffs' counsel come
21 in and say, let's now deconstruct the approval process
22 and identify all of the things that we, non-FDA people
23 believe should have been submitted. If that kind of
24 claim is not preempted, then we can take the Seventh
25 Circuit Court opinion and we can take 360k and we can

1 flush it down the toilet, then, because it will destroy
2 preemption.

3 Everything Dr. Parisian says is an effort to
4 impose something new and different, not just on Guidant,
5 but on every medical device manufacturer.

6 I do want to spend a moment, though, talking
7 about parallel requirements and violations of FDA
8 regulations. There is a lot of talk about that. I will
9 talk about the Bates case. Now, the idea that a mere
10 allegation of an FDA regulation, whether material or not
11 somehow gets her around preemption is not the law. The
12 Bates case, itself, was a FIFRA case that said -- this
13 is what the Bates U.S. Supreme Court opinion says.
14 States cannot require different labeling rules. But,
15 State Courts can adopt rules that are consistent with
16 Federal Court rules.

17 So, in other words, not in addition to or
18 different from, but consistent with it, parallel with
19 it. For example, if the State Court has the same rule
20 as the Federal Court, the federal requirement, and the
21 company violates the federal requirement, then the state
22 can provide a remedy for that violation, because there
23 is no new different requirement. It is the same
24 requirement, parallel, for which a remedy is to be
25 granted.

1 What the Bates court did say, though, very
2 applicable here, is that this state law labeling
3 requirement must in fact be equivalent to a requirement
4 under FIFRA in order to survive preemption. You cannot
5 require the word danger to be in the labeling when the
6 agency has required the word caution to be in the
7 labeling.

8 In other words, you can't require the wording
9 to be different. Everything they said about Guidant
10 here is we should have said something different at a
11 different time. That is in addition to and different
12 from the Federal requirements we were operating from at
13 the time.

14 I am interested in the Buckman case for a
15 couple of reasons. The idea that the FDA was defrauded
16 and here they are claiming that plaintiff was defrauded,
17 I know courts have said that, but it is a difference
18 without meaning.

19 I urge the Court in that implied preemption
20 case to take a look at the policy underlying that
21 driving decision. And that is, you can't have State
22 Courts be policing FDA regulations. You can't have 50
23 states creating different rules interpreting the FDA
24 regulations, because it detracts from what the FDA
25 requirements are.

1 Take a look at the policy of Buckman, also
2 take a look at the language of Buckman when it talked
3 about the Medtronic versus Lohr case, and it said
4 although Medtronic can be read to allow certain state
5 law causes of action that parallel federal states'
6 requirement, it does not and cannot stand for the
7 proposition that any violation of the Food Drug and
8 Cosmetic Act will support a state law claim. That is
9 what the U.S. Supreme Court said in interpreting the
10 prior Lohr decision. Any violation of the FDCA will
11 support a state law claim. Those are preempted under
12 the jurisprudence from the United States Supreme Court.

13 The idea I think they are trying to get at is
14 that the FDA has the authority to police the FDA
15 regulations, has the authority to police the company
16 subject to those regulations. If there is a violation
17 of those regulations, it is the FDA under Buckman that
18 has a responsibility to enforce it.

19 Because if we don't do that and we keep it
20 open to any litigant, or any Plaintiff's expert in the
21 country to come in and say something different, you are
22 inherently dealing with requirements, State Court
23 requirements that are different from or additional to
24 the requirements imposed on the companies by the Federal
25 regulations.

1 Just a couple of quick points I will make
2 here, Your Honor. You asked about Medtronic and St.
3 Jude. Those preemption motions are both applicable
4 generally to all of the cases.

5 What we have done here is to file a
6 preemption motion specific to Mr. Duron. So, the idea
7 that an MDR that was submitted with admittedly mistaken
8 language, that it was approved, the April 2002 change,
9 after Mr. Duron's device was in place, might not have a
10 whole lot of relevance to anything. The fact that we
11 didn't tell doctors about this low frequency failure for
12 months or years after we knew about it, what effect does
13 that have on Mr. Duron and his device which was
14 implanted in March of 2002?

15 So, the point of all of this is that I think
16 this motion has to be decided in the context of Mr.
17 Duron, not in the context of someone who may have
18 received a device much later in the game whose situation
19 factually may be different than Mr. Duron.

20 The final point I will make, Your Honor, is
21 that the arguments about rushing to judgment -- I mean,
22 rushing to the market, we heard that this morning, we
23 heard it a little bit a while ago, you know, the FDA
24 doesn't rush any faster than it wants to rush.

25 You can't make the FDA gallop when they want

1 to trot. You can't make them run when they want to
2 walk. They are the ones responsible for taking the time
3 to decide whether a particular application is going to
4 be approved or not. That is the not the responsibility
5 of the company to dictate that to the FDA, we have never
6 done that.

7 And all of this discussion about polyimide
8 and what was known about it and the use of polyimide in
9 aircraft wiring under circumstances where the
10 temperatures went to extraordinarily high,
11 extraordinarily low, they were exposed to solvents and
12 chemicals and under stress, under conditions that these
13 polyimide wires were never subjected to in the human
14 body really has no relevance. I understand why they are
15 trying to construct some relevance out of it, because
16 they want to get around the idea that the FDA in 1992
17 approved polyimide as an insulator in the header of this
18 device.

19 They also want to get around the idea that
20 this being Mr. Duron's case, that this polyimide wiring
21 was not degraded, that although it was close to or on
22 the backfill tube, the insulation around it provided him
23 10,000 volts of insulating protection. And the highest
24 shock he would ever get was about 800 volts.

25 So, in his device, his polyimide insulation

1 had not degraded. It had certainly served its purpose
2 during the course of the time it was in his body until
3 he elected to have it replaced and to get a new device
4 from Guidant.

5 So, those are the points of preemption, Your
6 Honor, I want to make. I just urge the Court to take a
7 look, as I know you will, at the case. Because what you
8 heard from Mr. Lesser, what you have seen from the
9 Plaintiffs is the new cache, which is to try to confuse
10 the regulatory process to try to get judges to think
11 that, boy, these are factual issues that I can't deal
12 with. How can they deal with them? Well, it is pretty
13 innovative, but it ought not allow them to get around
14 the full force and effect of 360k, which is when you cut
15 through it all, they are trying to require this company
16 to have done something different with respect to design,
17 manufacturing and labeling than the federal requirements
18 from the FDA imposed on us. That is the core of what
19 they are doing and there is no factual issue about that.
20 We urge you to grant the motion. Thank you.

21 THE COURT: Mr. Lesser, is that the core of
22 what you are doing, Mr. Lesser?

23 MR. LESSER: No. And that is what Bates
24 says. Guidant, or at least Guidant's counsel, doesn't
25 like Medtronic and doesn't like Bates, because Bates is

1 explicit, because Bates says, the case involved
2 insecticides. And the claim in the case was that you
3 hadn't warned fully what Dow knew about the insecticide.
4 It is the exact same thing we are arguing here, that
5 Guidant didn't tell the FDA what it should have told the
6 FDA under the FDA's own regulations. That is what we're
7 saying. They should have told about the arcing, should
8 have told about polyimide. They shouldn't have misled
9 the FDA in 2000 -- in 1992 and say, it won't come in
10 contact with human tissue.

11 THE COURT: Then if that is the case, and
12 they don't concede that, if that is the case, Mr. Pratt
13 suggested if I look carefully at some, if not all of
14 these cases stamped for the proposition that that
15 violation doesn't create an independent claim for your
16 client, in other words, that is the FDA's
17 responsibility, not --

18 MR. LESSER: Well, Brooks did say, Medtronic
19 did say, Bates did say, the claim that that item comply
20 with the FDA is not preempted. It cannot be clearer,
21 Your Honor. It says these claims are not preempted.

22 Mr. Pratt's argument is, the FDA approved it
23 at the end of the day, therefore they are preempted.
24 And he says it is the new mantra. Plaintiffs want to
25 come forward and get some expert. Well, it didn't

1 happen in Brooks because Helmedica did the right thing.
2 It went to the FDA as it learned of the dangers of the
3 solvent and worked out a new label. And that is why in
4 Bates, the Supreme Court underlines the fact that is
5 required. Again, let me go to the facts that Bates
6 required, for one second. Bates involved a label on the
7 insecticide that the FDA had approved. The argument we
8 have today is that that is the FDA's area of expertise,
9 that is enough. In a state court the claimant came
10 forward and said, wait. You knew other things, Dow,
11 that weren't in the label. It was an insufficient
12 label, in other words. You didn't tell the FDA, that
13 was also part of the case, underlying the case.

14 Mr. Pratt was right, that claim would be
15 preempted. The Supreme Court of the United States, 7 to
16 2, said it is not preempted. That is the -- read the
17 cases. Read Mattingly, for instance. At the end of the
18 case it says, well, there is also a claim you didn't
19 comply with the FDA regulations, Medtronic, and gave
20 this device to market. That one goes forward. That
21 claim goes forward. You don't get to beat preemption
22 easily.

23 The Buckman case was brought by a leading
24 plaintiff's firm in America. That was all that was left
25 of the case. And the case is fraud on the FDA, clock

1 fraud on the FDA as a cause of action, not a parallel
2 set of FDA requirements.

3 Ultimately, that is where it begins, that is
4 where it ends. The policy cuts the other way. That's
5 what Bates is about, and the law cuts the other way.

6 And ultimately, you heard today this case is
7 all about responsibility, and that is right. Guidant
8 was under an obligation, under multiple Code of Federal
9 Regulation requirements, 812, 814, 820, to say
10 everything it knew about this device, its history,
11 everything that somebody wanting to look at this device
12 objectively, sitting in a cubicle at the FDA, getting
13 hundreds of these a year who have wanted to know. And
14 it wasn't done.

15 Why does the post-Duron sale matter? First
16 of all, preemption isn't determined for some of the
17 Plaintiffs in this case and not for others, it is all
18 the same reason. But, it certainly goes to the
19 non-preemptive effect of the post-sale duty to warn,
20 because the FDA has such a requirement that it can make
21 a change. And there is the testimony in the record, if
22 you make a change, you have to tell the FDA once so the
23 FDA independently can determine it.

24 And in this case that wasn't done at the
25 time. It wasn't done until 2005, actually. That is

1 some supplemental PMA for what we are talking about,
2 here. So, this case ultimately, I submit, put aside all
3 of these cases and how you interpret these words. It is
4 all about doing the right thing, and playing by the
5 rules. If you do so, preemption can protect you. If
6 you don't do so, you can indeed be sued.

7 THE COURT: Thank you. Last word, Mr. Pratt,
8 on this?

9 MR. PRATT: Yes, thank you, Your Honor. The
10 more you talk through this, the more you think the
11 clearer it comes. And then I was cued to this notion
12 because Mr. Lesser says that Brooks says the starting
13 point is the MDA of federal requirement, he concedes
14 that, and then there are two steps.

15 Didn't tell the FDA what they should have
16 told the FDA, that is kind of at the heart of what they
17 say. But, the reason that is preemptive is because that
18 is only the beginning of it. The next step is that the
19 FDA would care about it; that the FDA would have wanted
20 that information, and would have cared to get it.
21 Secondly, that if so, they would have done something
22 different than what they had originally done, thus
23 imposing a requirement that is in addition to or
24 different from what the company did.

25 So, when you start off with the idea you

1 violated the regulation, when you move down one step,
2 two steps beyond that, you are getting to the point
3 where you are asking a jury to say: We want you to find
4 that the company should have done something different
5 from or additional to the requirement that they
6 followed, because we believe the violation existed. We
7 believe the FDA would have cared about it. And we
8 believe the FDA would have required you to do that.
9 That is exactly the type of claim under 360k and Buckman
10 that ought not be -- that that destroys the entire
11 approach of Suzanne Parisian in cases just like this,
12 Your Honor. Thank you.

13 MR. LESSER: Four words, five words.

14 THE COURT: Five words?

15 MR. LESSER: 544 U.S. at 448, that is 449,
16 the Supreme Court disagreed with their argument.

17 THE COURT: Thank you.

18 Move on to the next -- it has got to be
19 either punitive damages, or injury in fact.

20 MS. MOELLER: This is no malfunction, no
21 injury, Your Honor.

22 THE COURT: All right. We really only had
23 one particular malfunction. We only had one today, and
24 it has been that monitor. So, we are probably due for
25 some malfunction down here in the equipment, but --

1 MS. MOELLER: I hope it is not mine, because
2 I need that to do my argument. Debbie Moeller, Judge,
3 Motion for Partial Summary Judgment Based on Lack of
4 Injury Caused by Malfunction.

5 It is axiomatic that there can be no recovery
6 in a products liability case in the absence of a product
7 failure. That makes sense and that is what we are here
8 to talk about today. A fear of some kind of failure in
9 the future is just not compensable under the products
10 liability scheme.

11 The leading case on that is the California
12 case of Khan versus Shiley. This is in the Shiley Heart
13 Valve Litigation. Where plaintiff alleges that a
14 product is defective, proof that the product
15 malfunctioned is essential to establish liability for an
16 injury caused by the defect. So, a claim of defect,
17 alone, is not enough. The product has to malfunction in
18 order for there to be recovery.

19 Let's look at the facts of the Khan case. It
20 involved a woman who had an implantable heart valve put
21 inside her. After having it implanted, it was
22 discovered that they would degrade. She went to see her
23 doctor. It was determined that she had the type of
24 valve that was subject to this. And there was
25 eventually a Class 1 recall on those devices.

1 The plaintiff claimed there was an inherent
2 defect in her device. At that time there were 243
3 fractures out of 81,000 valves. And the plaintiff
4 alleged that the valve could malfunction without any
5 notice, resulting in death.

6 The plaintiff claimed physical symptoms and
7 she had treatment upon hearing about the recall. The
8 key finding in determining that there could be no
9 recovery under strict liability, negligence or warranty
10 was the fact that the valve had not fractured.

11 Let's line Duron up under the facts of Khan.
12 Here we have an implantable cardiac device, subject to a
13 Class 1 recall. Plaintiff claims there is an inherent
14 defect in the device. Plaintiff claims that the defect
15 could -- that the device can malfunction without notice,
16 resulting in death. The plaintiff out of fear had
17 replacement surgery upon hearing about the recall, so
18 had medical treatment upon hearing about the recall.
19 Mr. Duron's device never arced or malfunctioned. This
20 fits squarely within the facts of Khan.

21 THE COURT: Do you accept the factual
22 distinction? Plaintiffs may say, well, it is factual,
23 but it has a legal result. They are factual -- I
24 probably won't use the most eloquent words, here, but
25 that it was functioning in the Khan case, because it

1 would be like continuous current, as opposed to, well,
2 what was Mr. Duron to do, wait to see when he needed
3 this help and then see what would happen? And if that
4 is the case, why would you explant any unit from any
5 person?

6 MS. MOELLER: They are actually factually
7 very similar in that regard, Judge.

8 THE COURT: All right.

9 MS. MOELLER: First of all, Mr. Duron's
10 defibrillator functions every minute that it is in him.
11 It is always pacing him, listening to the heart rhythm,
12 and determining what therapy to provide, if any. And in
13 fact, he had therapy. We will get to that in just a
14 minute.

15 Also, in Khan, at the time, the risk of a
16 replacement surgery was said to be higher than the risk
17 of the device malfunctioning. That is on all fours.
18 The other thing is -- the other point that you raised --
19 oh, about not having to wait until it malfunctioned.
20 The same type of death without any notice was a risk of
21 that valve malfunction, as well, Judge.

22 It is not a matter of having to wait and have
23 it malfunction, it is a matter of what is compensable.
24 Mr. Duron could choose to have his device replaced.
25 That does not make that decision compensable. That is

1 the distinction there.

2 I mean, he had a fully-functioning device the
3 entire time it was in his body. It never malfunctioned.
4 He chose to have it out. He clearly has the right to
5 have that taken out. That does not turn it from
6 something that is actionable -- not actionable, into
7 something that is actionable.

8 THE COURT: Does it matter, the photo I have
9 seen -- photo is probably not the right word, of the
10 device once it was removed from Mr. Duron.

11 And they are saying, well, just take a look.
12 If he needed it, it wouldn't have been there. There
13 would have been a short and he probably would be dead.

14 MS. MOELLER: Factually, we know that that
15 is not correct. And their own expert concedes that.
16 And let's look at --

17 THE COURT: What is the relevance of its
18 condition? They referred to it as a manufacturing
19 defect. What is the relevance of that, if any, to this?

20 MS. MOELLER: To this, none. We do not
21 agree that there is a manufacturing defect at all, but
22 that doesn't matter to you deciding this case.

23 THE COURT: All right.

24 MS. MOELLER: Because look back at Khan,
25 there is a claimed inherent defect. The claimed

1 inherent defect is not what makes the case -- it's not
2 what gets us, then, the cause of action. Look back
3 at -- where plaintiff alleges that a product is
4 defective, here they allege there is a manufacturing
5 defect. Proof that the product actually malfunctioned
6 is essential to establish liability. So, the allegation
7 of defect, or even the proof of the defect is not alone
8 unless that defect causes a malfunction. So, there is
9 no malfunction in this case, Judge. During the entire
10 period of time that Mr. Duron had this device in his
11 body, it worked every single day for over three and a
12 half years, provided him therapy, monitored his heart,
13 just as it was supposed to.

14 On the explant testing, the device was
15 returned and subjected to a series of tests that
16 verified performance, and one of the tests they run is a
17 voltage test. They do high shocks to that device. They
18 do five shocks at the same voltage that would have
19 happened if Mr. Duron would have needed therapy. And
20 the device didn't arc. It was not a device, as Ms.
21 Cabraser said earlier, where it was just waiting for an
22 arc to happen. We know in fact it didn't happen even
23 after it was explanted. It clearly didn't happen while
24 it was in him, and it didn't happen when it was
25 subjected to shock testing after it was taken out.

1 And it is something that their expert, Mr.
2 Armstrong agreed. He agreed that the amount of
3 polyimide tubing that is on that wire even on top of
4 that backfill tube is sufficient to withstand shock
5 energy at this period of time.

6 He also could not opine for how long a period
7 of time the device would have to remain in the body for
8 the polyimide to degrade to have ever even gotten to the
9 point where Mr. Duron may have had a risk of an arc.
10 So, he can't quantify at what specific risk Mr. Duron is
11 of having had an arc during the period of time if the
12 device had been implanted long enough.

13 So, this is not a case where this was an arc
14 waiting to happen. We know that it didn't and we know
15 that it would not have. Let's go back. There are four
16 different people have looked at the device or evaluated
17 it in some manner. The device was returned as part of
18 ordinary return product testing.

19 We had our expert, Dr. John Moalli,
20 MIT-trained polymer scientist look at it. They had
21 their expert look at it. And the plaintiff's explanting
22 surgeon saw it upon explant. And they are all in
23 agreement about several things.

24 They are all in agreement it never arced when
25 in Mr. Duron's body. And they are in agreement the

1 device worked appropriately during the period of time it
2 was in him, not that it was just sitting there, but it
3 was actually working appropriately during the period of
4 time he had it.

5 We have gone over what the Reliability
6 Assurance Lab found, no arcing, passed the test that
7 deals with device functionality. The polymer scientist
8 that we had look at it, there were noticeable cracks on
9 the tubing, the location of stress on the wire was
10 sufficiently remote from the backfill tube that even if
11 cracking would have occurred, it would not have occurred
12 in an area that is close enough to the backfill tube for
13 an arc to have existed. And he also thought then that
14 the device was functioning appropriately.

15 Mr. Armstrong: I saw no evidence of arcing.

16 He had no -- there was no evidence that the
17 device was not functioning during the period of time it
18 was in Mr. Duron's body.

19 He doesn't have any evidence of a
20 malfunction. Mr. Duron suffered no adverse event during
21 the period of time the device was implanted in him. I
22 did not see a manifest failure event in the data
23 provided to me.

24 So even their own expert concedes that there
25 was no failure event in Mr. Duron.

1 Further, let me skip ahead, here, this is Mr.
2 Armstrong's Deposition, again.

3 "Question: You would not be able to
4 calculate the duration that would be necessary for the
5 polyimide in Mr. Duron's device to reach a point where
6 it would degrade to the point that would enable an arc
7 to occur in his device, is that correct?

8 "Answer: I can not calculate the amount of
9 time remaining for the polyimide.

10 "Question: Is it possible that had Mr.
11 Duron's device been implanted for 41 additional months,
12 that the polyimide might never have degraded to the
13 point where it would have enabled an arc?

14 "Answer: There is that possibility.

15 And finally, he said that he was at the time
16 of implant at risk of failure, at risk of failure. I
17 cannot give you a percentage of chance on that.

18 That is simply not sufficient to survive a
19 summary judgment motion on these product claims. A risk
20 of a failure is not sufficient.

21 THE COURT: What would be sufficient?

22 MS. MOELLER: A malfunction, an actual
23 malfunction. And in certain instances, if there was a
24 risk that was so high that it was certain that Mr. Duron
25 might have -- would have suffered it. And the facts in

1 this case, the undisputed facts, do not support that.

2 THE COURT: So, I am sitting with this
3 implant, and I read this last one, recall, causes
4 serious adverse health consequences or death. You are
5 saying that, well, really, unless there is some
6 statistical probability it is going to happen -- in
7 other words, even though my doctor is saying, it has got
8 to go, take it out today?

9 MS. MOELLER: That is right, Judge, and that
10 is an outlier case. All of the mainstream cases say you
11 have to have the malfunction, risk isn't enough.

12 Even if you look at the outlier case, the
13 risk has to be sufficient for that particular plaintiff,
14 otherwise you are opening up causes of action for two
15 huge groups of people. I mean, if every person who has
16 a recall device then has a cause of action for strict
17 liability or negligence or warranty, regardless of the
18 risk to them, regardless of whether or not the risk to
19 them is increased based on what device was given to
20 them, that would open up the floodgates for product
21 liability litigation. And it is inherently unfair in
22 the context of devices -- the equities just don't favor
23 it in areas where devices like these that save people's
24 lives and have a lot of public benefit.

25 If you look at the case that the Plaintiffs'

1 cite, if you read that case closely, it actually
2 supports the decision that Mr. Duron is not in the class
3 of device recipients at a higher risk to whom -- in
4 which case he should survive a summary judgment motion.
5 The Judge in the Larsen case, the pacemaker case where
6 the plaintiff had his device taken out and had horrible,
7 horrific complications from that replacement surgery.

8 In that specific instance, the Court found
9 that the decision to replace the device was forced upon
10 him. And that was because of a very specific medical
11 condition that he had. He was pacemaker dependent. He
12 could not survive if the pacemaker in fact failed and
13 there were very few people that fit that classification.

14 And there was a recommendation from the
15 manufacturer in that case, was to replace the device
16 because of the high risk of failure. Contrast that here
17 where there is no such recommendation from either the
18 manufacturer or from FDA to replace the device because
19 of the low risk that you saw in Mr. Pratt's factual
20 presentation this morning.

21 And there he suffered great surgical
22 complications. I was interested to note that they were
23 talking about Duron's complications this morning, since
24 Mr. Duron is the case that Plaintiff chose to be a
25 non-complications explant case. I think there must be

1 some confusion there, because Mr. Duron did not suffer
2 complications from his explant surgery.

3 But, in any event, the facts of Larsen
4 support the fact that you can't give a wide brush to
5 establish liability where none should exist. And where
6 it should exist is if the device malfunctions. In this
7 case it didn't; and therefore, there is no basis for
8 strict liability, warranty or negligence.

9 THE COURT: Thank you. And I am certain you
10 will be back up there again on rebuttal.

11 Number three? Number three, Ms. Cabraser,
12 you are up?

13 MS. CABRASER: Okay. Khan versus Shiley is a
14 California Intermediate Appellate Court decision from
15 1990. It hasn't fared very well in California since
16 then. And it doesn't relate to the factual scenario of
17 this case.

18 If you wanted to look at a case, the case
19 that is most closely on all fours factually with this
20 case, in terms of a cardiac device that was implanted,
21 was explanted pursuant to a recall on medical device
22 with physical injuries, that is the Larsen versus
23 Pacesetter case. And that case also has the most
24 thoughtful exposition of the defect concept.

25 It looks at Khan versus Shiley very closely

1 and very carefully because Kahn versus Shiley was very
2 new at the time. Larsen is a 1992 case. Larsen looked
3 at it from the standpoint of implied warranty and held
4 that even though the pacemaker installed in the body of
5 the patient did not malfunction, it was in defective
6 condition sufficient to support an action for breach of
7 implied warranty of merchantability, because other units
8 of the same machine had been found to malfunction and
9 the patient was dependent on it.

10 And it was necessary to perform surgery to
11 recover the device to eliminate that risk. Mr. Duron
12 was at an elevated risk. The FDA recall letter said so.
13 The letter he got from Kaiser said so. The letter he
14 got from Kaiser, which is in the factual materials from
15 Mr. Drakulich's presentation this morning advised him
16 that while Guidant would pay for part of the necessary
17 procedure if his doctor advised it, if he could
18 withstand the risk, Kaiser would be paying part of it
19 and Mr. Duron would be paying part of it. We have
20 economic injury.

21 We have physical injury. You saw Mr.
22 Duron's picture this morning. That was an injury. It
23 looks like an injury. It felt to him like an injury.
24 His co-workers and family testified as to what he went
25 through, no doubt about it, to get that defibrillator

1 explanted and replaced, because his doctor, after
2 consulting with Guidant's sales representative, the one
3 who dealt with all of the surgeries in Kaiser, the two
4 of them agreed, Mr. Fosdick and Dr. Singh agreed that
5 everybody should have that defibrillator out. And in
6 fact Dr. Singh testified that he advised all of his
7 patients to have it out. He took it out. And if they
8 refused to have the explant, it was against his medical
9 advice. These surgeries were essentially forced upon
10 these patients, not by anything they did, not by any
11 independent decision anybody else made, but because they
12 were in a defective condition.

13 The majority of them, according to Guidant's
14 own records, were defectively manufactured. They had
15 manufacturing defects which could at any time create an
16 arc and a failure when the device was called upon to
17 function.

18 Now, remember, a defibrillator is not a
19 pacemaker. A defibrillator is not a heart valve. A
20 heart valve functions continuously. A pacemaker
21 functions continuously. You heard that a defibrillator
22 functions continuously; but, it really doesn't.

23 What it is called upon to do in a specific
24 time in response to a specific episode, to shock the
25 heart, which it can't do effectively if it shorts. You

1 can't test it reliably. You can't examine it reliably
2 while it is in the body. You don't find out the
3 condition of that defibrillator until it is explanted.
4 Mr. Duron is very lucky. He had it explanted.

5 It is defectively manufactured. Yes, Guidant
6 performed some tests on it. By the way, it passed some
7 tests, it failed others. It came back, fail, fail.
8 That is in our fact submission. There is going to be an
9 expert dispute and there is an expert dispute about what
10 all of that means. Can Mr. Armstrong, as an expert,
11 calculate to the Nth degree Mr. Duron's chances if he
12 hadn't had the explantation and replacement?

13 Maybe, it is possible. It is possible that
14 that defective device in a defective condition, in a
15 manifested defective condition, it's just possible it
16 might have worked when called upon to do so, and it
17 might have worked more than once if called upon to do so
18 more than once. But, we don't know. Who should bear
19 that risk?

20 We don't live in a Clint Eastwood world where
21 we say to Mr. Duron: Do you feel lucky? And we don't
22 live in a world where we say to Mr. Duron: You are a
23 pretty irresponsible person, aren't you?

24 Your doctor got a recall notice. Kaiser sent
25 that information to you. And I don't know what is wrong

1 with you. You are some kind of a wuss or something.
2 You go in and you get the device explanted because you
3 don't want to take that risk. Because we know there is
4 a reasonably enhanced risk of serious injury or death,
5 the FDA says so. But, we don't know for sure you are
6 going to die of this and we don't know how soon. And
7 the only way to find out is to die. That wasn't the
8 only way to find out in Khan versus Shiley, you can
9 monitor heart valves. If a heart valve isn't fully
10 functioning, the patient feels it. It is not a simply
11 yes or no, open and shut, alive or dead situation.

12 There is medical monitoring for heart valves.
13 When the Shiley heart valve cases were settled two years
14 after Khan versus Shiley for millions and millions of
15 dollars, millions of dollars were put into a medical
16 monitoring fund and other millions of dollars were put
17 into a replacement fund, to monitor patients and to
18 effect a replacement. That's a federal settlement from
19 1992, the case is Bolling versus Pfizer. Unfortunately,
20 we don't have medical monitoring for these
21 defibrillators in any real effective sense. And so, the
22 only way to mitigate your damages, to eliminate your
23 risk, to ensure your life and your health when you get a
24 recall notice like this if you can stand the risk of the
25 surgery is to get the explantation, because that is the

1 only way you can be sure. That is the only way you can
2 eliminate the risk.

3 By the way, if the Khans had litigated their
4 case four years after they did, they would have had a
5 recovery on their negligence cause of action. Because
6 the 1994, the California Supreme Court, not Intermediate
7 Appellate Court, recognized a claim for medical
8 monitoring and did not require physical injury and did
9 not require a malfunctioning device or product defect.
10 And said, basically, if you are in a situation where
11 someone else's negligence has place you at increased
12 risk of future harm, you are entitled to mitigate your
13 damages and to reduce your risk. And if you can prove
14 that the negligence of the Defendant placed you in that
15 position of enhanced risk, the defendant is required to
16 pay you for the costs, for example, of periodic
17 diagnostic monitoring so you can diagnose the condition
18 or assess a risk at the earliest possible time and do
19 something about it.

20 The problem with this case is because of the
21 nature of this device. It is not a heart valve. It is
22 not even a pacemaker. We can't do medical monitoring.
23 The only effective medical monitoring is explantation.
24 And our point is that the costs of that explantation
25 pursuant to a recall, pursuant to medical advice,

1 pursuant to agreement of a Guidant representative that
2 that was appropriate and called for, should be borne by
3 the company whose fault caused that sequence of events
4 to occur.

5 Potter versus Firestone would award that
6 money under a California negligence theory if California
7 law applied. Hicks versus Kaufman & Broad, another
8 later California case would grant damages under an
9 implied warranty theory because Hicks versus Kaufman &
10 Broad again distinguished Khan versus Shiley and said,
11 you don't need a manifest malfunction to have a defect.
12 Hicks was a case about an allegedly faulty foundation
13 component that was in homes that might or might not be
14 corroding or eroding, that might or might not cause
15 massive property deterioration at some future time.
16 But, it was placing homeowners at risk. And under an
17 implied warranty theory, all the homeowners, whether
18 they bought their homes from the original developer or
19 not, were entitled to that implied warranty recovery.

20 We also know that a malfunction, or even a
21 defect is not required to recover under fraud, because
22 Khan versus Shiley, itself, said so. It at least said,
23 common law fraud, you can recover. It is about conduct,
24 misrepresentation, concealment, it is not about a
25 product malfunction. And of course, under the Consumer

1 Fraud Statute, the same is true. Khan versus Shiley
2 doesn't apply with any precedential effect or force in
3 Minnesota, and it certainly doesn't apply anywhere,
4 including California, beyond its very limited, very
5 unique fact pattern. And Larsen versus Pacesetter
6 proves that.

7 The Khan case was a fear of future injury
8 case. It wasn't a case to recover the costs of injuries
9 and damages attendant on a reasonable action taken by a
10 plaintiff in response to and caused by a defendant's
11 fault in the dissemination and implantation of a product
12 in a defective condition. It is very tempting to say,
13 for a product defect, you have to have a defective
14 product; and therefore, you have to have a
15 malfunctioning product, because the way to tell if a
16 product is defective is that it has malfunctioned. And,
17 of course, that is one way to tell. It is not the only
18 way to tell under either California law or Minnesota
19 law.

20 Under the design and manufacturing defect
21 jury instructions currently in effect based on current
22 state law in both California and Minnesota, a
23 malfunction is not required. It is not found in the
24 jury instructions.

25 California's newly rewritten current state of

1 the art patterned jury instruction on manufacturing
2 defect, which is CACI 1202 -- we call it Casey (PH),
3 although it is probably properly pronounced khaki (PH),
4 we just don't want to go there -- explains a
5 manufacturing defect. A product contains a
6 manufacturing defect if the product differs from the
7 manufacturer's design or specifications or from other
8 typical units of the same product line.

9 Mr. Duron's product contains a manufacturing
10 defect under California law. The same is true with
11 respect to Minnesota law. And Minnesota's instruction,
12 which is CIVJIG 75.30 on manufacturing defects called,
13 "Deciding when a product is defective," because this is
14 a question of fact. A product is in a defective
15 condition, unreasonably dangerous to the ordinary user
16 or consumer if he or she could not have anticipated the
17 danger the product created. In deciding if the danger
18 could have been anticipated, assume the user or consumer
19 had the knowledge common to the community about the
20 product's characteristics and common use, and finally
21 the defect in the product may be caused by the way it
22 was manufactured, assembled, inspected, packaged and
23 tested.

24 There is dispute about the post-explant
25 condition of Mr. Duron's specific device, if that were

1 the sine qui non of a product defect claim. It isn't
2 with respect to any of the other claims, under Minnesota
3 or California law. Even then, summary judgment could
4 not be granted because the testimony is disputed. There
5 is an indication, for example, that the reason the
6 polyimide does not look as degraded or cracked as it may
7 be is that it was smeared with medical adhesive.

8 It is not possible to go farther than that or
9 necessary to go farther than that to ultimately decide
10 the precise condition of that device. The problem with
11 that device is you could test it today. It might work
12 or it might not work. If it doesn't work, that proves
13 conclusively it malfunctioned, if that is the test.
14 But, if it does work, that proves nothing, because it
15 has to work every time. It has to work when it is
16 called on to work. It has to work when it is in the
17 body of Mr. Duron. And whether or not it would have
18 worked, whether it was reasonable for Mr. Duron to take
19 the increased risk and hope it worked, Mr. Armstrong
20 couldn't go there. The experts can't go there. Nobody
21 can tell him that it is more reasonable than
22 unreasonable to keep that device in his body,
23 post-recall, and hope it works, notwithstanding the fact
24 that most of the units had manufacturing defects.

25 All of them had the design defect of

1 polyimide and there had been failures resulting in death
2 and serious injury. If Mr. Duron had toughed it out and
3 said, no explant for me. I am going to take my chances.
4 I like them. I don't care what my doctor says or the
5 Guidant sales rep says or the FDA says or Kaiser says, I
6 am going to take my chances. And if he hadn't been
7 lucky and if he had a wrongful death claim in this Court
8 today, would the defense be assumption of the risk?

9 THE COURT: Failure to mitigate?

10 MS. CABRASER: Failure to mitigate? We
11 wonder. But, that sounds like where these arguments are
12 going and we don't think that is where the law strikes
13 the balance. We think a jury could strike the balance
14 elsewhere. And we think under either Minnesota or
15 California law, we are entitled to go to the jury and
16 ask the finders of fact those questions.

17 THE COURT: Let me ask this. I will probably
18 ask Ms. Moeller the same question. What, then, becomes
19 the -- and I am not suggesting by the question that you
20 really haven't answered it from Plaintiffs' point of
21 view, and that is true of when I asked the same -- the
22 same thing would be true of Ms. Moeller. But, if
23 somebody who just walked in, and I'm not thinking of
24 anyone in particular out in the audience, was listening,
25 they would say, well, the lawyer up there sounds very

1 convincing, Ms. Cabraser, but I wonder what the
2 triggering event is because I hardly ever heard the word
3 malfunction. And then if they were here for Ms.
4 Moeller, they would say, she used the word malfunction
5 more than any other word during her presentation, and so
6 we wonder what the triggering event is, because they
7 argued about -- they address the same issue.

8 I guess -- you hardly touched on the word
9 malfunction, and I am certain there is a reason for
10 that.

11 MS. CABRASER: Because a malfunction is one
12 way, but not the only way to prove a defect.
13 Malfunction and defect are not synonymous. They are not
14 synonymous in California law. The little excerpt that
15 you saw from Khan versus Shiley seems to suggest that.
16 But, if you read the case in chief and its fact pattern,
17 and you read the Larsen versus Pacesetter and its fact
18 pattern, if you read the later California cases and
19 their fact patterns, and if you read Potter versus
20 Firestone, which deals with mitigation, the
21 responsibility to do that and the compensability of
22 those costs and damages, you see that it is like the
23 world of Venn diagrams where the malfunction is a very
24 small circle. A defect is a larger circle. And you
25 prove a manufacturing defect as the California and

1 Minnesota jury suggestions instruct. You prove a design
2 defect by showing that what the design of the device
3 leads to these heightened risks, unreasonable risks of
4 product failure. And you have to assess those risks
5 based on the consequences. That is what the Minnesota
6 jury instructions say, as do the California jury
7 instructions.

8 If the risk of harm is, you know, your car,
9 your car radiator may fail prematurely and strand you at
10 the side of the road, that is a different risk in terms
11 of going in and getting your car fixed pursuant to that
12 recall, than if you are the car and something implanted
13 in you could fail at any moment with fatal consequences.
14 And to say that the company that put you at that peril
15 by selling a device that has that defect is not liable
16 for any of the reasonable costs, for any of the
17 expenses, injuries and damages that occur because you
18 take the responsible actions that you are advised to do
19 in response to learning of the risk, which the company
20 knew, but didn't disclose, you have to look at all of
21 those things.

22 What we know, after the fact, fortunately,
23 because Mr. Duron did have the explant is that the
24 device does have defects. It does have a manufacturing
25 defect.

1 We know it didn't malfunction, because he is
2 alive. And being lucky, despite a manufacturer's
3 defective design, defective manufacture, fraudulent
4 concealment, negligence, is not the sole legal remedy.

5 Mr. Duron is lucky because he did what he
6 should have done and his doctor told him to do. He had
7 to do that because of what Guidant did and failed to do.
8 And the costs of that lie with the manufacturer who
9 caused the harm. And you have to look at that on a
10 factual basis. You have to look at it on a case-by-case
11 basis. When you do the calculus, it may be different
12 between a non-safety related automotive defect and
13 recall, to a safety-related medical device recall. We
14 are at the very high end of the scale, here, because we
15 are dealing with a device that can't be monitored on a
16 daily basis. You can't tell if it is gradually failing.
17 You can't see while it is in the body whether or not the
18 polyimide is degrading, whether the adhesive has come
19 off, whether the wires are touching. All you know is
20 how the device is when it goes in, which nobody was told
21 to look for, and what it looks like after it has come
22 out. And in between, the risk is entirely on the
23 patient.

24 And when a manufacturer's conduct or product
25 causes that risk and the patient expends money,

1 undergoes physical injury, suffers emotional distress,
2 then the process of doing the responsible and prudent
3 thing to eliminate or alleviate that risk, a jury is
4 entitled to decide under Minnesota or California law
5 that all or a part of that cost should lie with the
6 manufacturer.

7 THE COURT: Thank you. Ms. Moeller?

8 MS. MOELLER: Judge, I think I can answer
9 your question about the disconnect between the use of
10 the word defect and the use of the word malfunction.

11 Khan, the leading California case, we cite
12 numerous other cases in our brief that go along with
13 Khan. A California case, plaintiffs argue, the owner of
14 a product functioning as intended, but containing an
15 inherent defect which may cause the product to fail in
16 the future has a cause of action against the
17 manufacturer.

18 Plaintiffs are mistaken. You can't get to a
19 cause of action simply by alleging a defect. The defect
20 has to cause an injury. The defect has to manifest
21 itself in a way that causes harm. In Mr. Duron's case,
22 it is undisputed that that did not happen during the
23 entirety of the three and a half years that it
24 functioned appropriately in his body.

25 There are several factual errors that I want

1 to try to clean up. One thing that Ms. Cabraser said
2 that is just simply flat out wrong is that
3 defibrillators are not pacemakers. In fact, they are.
4 They have both functions, defibrillation therapy and
5 pacemaker therapy. We took Mr. Duron's medical records,
6 and we have outlined and it is in our brief, showing the
7 functionality of Mr. Duron's device during the entirety
8 of the time he had it. He had numerous checks. At
9 every checkup his device was checked and found to be
10 functioning appropriately, and there were times when it
11 also treated him. The truth of the matter is that is
12 irrelevant to this motion, because -- in terms of
13 whether it was continuously functioning or not. The
14 relevance is that it worked appropriately and it did not
15 malfunction during the period of time that he had it.

16 In terms of the risks that Mr. Duron faced
17 and the argument that he was lucky, we are glad that Mr.
18 Duron did not have a malfunction, there is no dispute
19 about that. But, the concept of whether or not he had
20 to take his device out and whether or not that is
21 compensable is what we are here to talk about. And the
22 fact of the matter is, because he got a device that did
23 that not malfunction, that didn't cause his harm, he has
24 no causes of action for summary judgment, warranty, and
25 strict liability.

1 Now, I do agree with Ms. Cabraser, fraud is
2 not thrown out under Khan, that cause of action
3 survives. But, the others, without a malfunction, do
4 not survive.

5 Talking about the risk to Mr. Duron, these
6 are man-made complicated devices. Every patient who
7 gets a defibrillator is at risk that that device might
8 not function when that person needs it. That is just
9 the inherent nature of the device. It can't be made
10 completely risk-free. And in fact, what we have seen is
11 over time, the risk of having this device for this
12 specific failure mechanism are astronomically low. It
13 is an incremental risk of this arcing happening.

14 Ms. Cabraser said that there is some question
15 about whether or not Mr. Armstrong could talk about
16 whether there was degradation on the polyimide tubing.
17 That is not correct. I took Mr. Armstrong's Deposition
18 and asked him specifically that question.

19 The medical adhesive in the header impede
20 your ability to determine whether or not there was
21 polyimide degradation?

22 And he said, it did not. He was able to see
23 what he needed. And he said, he saw no degradation. He
24 said that there was sufficient degradation (SIC) in the
25 place to prevent an arc, and he could not predict when

1 or if an arc would occur in the future.

2 MR. PRICE: Insulation.

3 MS. MOELLER: What did I say?

4 MR. PRICE: Degradation.

5 THE COURT: What did Mr. Price say?

6 MS. MOELLER: He said that I said degradation
7 instead of insulation. Apparently everybody up there is
8 asleep because no one else noticed.

9 THE COURT: I was just seeing if Mr. Price
10 would get it, that is all. It is that wear-down factor.

11 MS. MOELLER: Just a few other points. There
12 is no dispute about the post-explant testing, Judge.
13 Mr. Armstrong had no opinions regarding that at his
14 deposition or in his report. The post-explant -- he
15 agreed there was nothing in the post-explant testing
16 that indicated there was a problem with Mr. Duron's
17 device.

18 In terms of the decision to explant, it is in
19 our brief, but I just wanted to point out that Mr. Duron
20 had decided in advance of going to see his doctor that
21 because of fear of future failure, he wanted to get his
22 device out. The Kaiser doctors had come to a business
23 decision that because the company was offering a
24 supplemental warranty program, that they would explant
25 all of their patients so they could get a free device.

1 And so, Dr. Singh also specifically testified
2 that he didn't weigh any risk, specific for Mr. Duron,
3 in determining whether or not Mr. Duron should be
4 explanted.

5 What the plaintiffs are asking you to do, and
6 Mr. Pratt touched on it earlier, is to expand products
7 liability cases where no one else has gone before to
8 simply a recall providing a cause of action for products
9 liability, warranty and negligence in the absence of any
10 malfunction causing an injury. It's not the law. It is
11 not good public policy. And it is contrary to the
12 numerous cases that we cited in our brief.

13 The Larsen case that I touched on earlier and
14 that Ms. Cabraser talked about, the thing I did not
15 mention, that is actually a Hawaii case. It is not a
16 California case. It is a Hawaii case. And it is really
17 the only one out there that finds the way it did. And
18 if you read that very carefully, it seems to be a very
19 result-oriented case. And it talks about it is applying
20 different public policy issues in this specific and very
21 limited set of circumstances. And in fact, one of the
22 important points upon which the Court rested its
23 decision was the fact that this decision impacted a very
24 limited class of recipients. It was important to that
25 Court not to open up causes of action for an unlimited

1 class of device recipients.

2 And unless you have anything further, Judge?

3 THE COURT: Would you like the last word
4 before we -- what I thought we would do is take a --
5 hold to 10 minutes stretch/restroom break after Ms.
6 Cabraser, and then finish up the -- I think it's one
7 more, unless I miscounted?

8 MR. PRATT: Punitive damages.

9 THE COURT: Punitive damages, and that should
10 give us a couple of minutes after any other housekeeping
11 matters. So, Ms. Cabraser?

12 MS. CABRASER: Thank you, Your Honor. There
13 is a huge factual record on this case and there are a
14 lot of disputed facts. I think one thing that can't
15 fairly be disputed is that despite what you heard about
16 the defibrillator and the fact that it may have some
17 pacemaker functions, Mr. Duron's defibrillator was never
18 called upon to fire as a defibrillator while it was in
19 his body, fortunately. He got it taken out before it
20 was called upon to do so.

21 By the way, Mr. Duron actually has a Khan
22 versus Shiley type claim now. He hasn't asserted it,
23 there is no reason to do it, although it bothers him
24 quite a bit. His replacement device, the name of that
25 device, the Vitality device, is now on the recall list

1 as of April of 2007, I think.

2 It is not his serial number, so his
3 particular device hasn't been recalled, yet. That is
4 the Khan claim. I am worried. I am worried. I am not
5 doing anything about it, but I am worried. He hasn't
6 asserted that claim. He has asserted the claim that
7 involved a defect and a real injury.

8 Khan versus Shiley does not affect or limit
9 warranty claims, implied warranty claims in California.
10 Hicks versus Kaufman & Broad case made that very clear.
11 There is an extensive discussion of Khan versus Shiley
12 at pages 920 through 922 of that decision. And
13 actually, the case that applies is another California
14 case, the Anthony case that involved a whole line of
15 products, tire rims, I think, most of which never
16 actually failed or malfunctioned, but all of which
17 suffered from a breach of warranty and merchantability
18 and all of which were replaced at the company's expense.
19 Finally the Bolling versus Pfizer cite. The
20 Pfizer settlement that involves the medical monitoring
21 fund and the procedures and replacement procedures for
22 the Shiley heart valve is 143 FRD 141.

23 The settlement is quite complex, and we cite
24 that only for the proposition to reinforce the point
25 here that a heart valve is a monitorable device. And

1 your choices aren't limited to take it out or suffer
2 irreparable consequences.

3 And so, in that situation, where the election
4 was made not to replace the valve and there hadn't been
5 a malfunction, the Court was faced with a tort that did
6 not involve any physical injury or economic loss, but
7 was a pure emotional distress for fear of future heart
8 claim; that is not our claim.

9 Finally, Larsen versus Pacesetter was indeed
10 a Hawaii case, the Hawaii Supreme Court, don't hold that
11 against it. Hawaii follows California law. And this is
12 not a mere policy discussion, this is a multi-page
13 analysis of the Restatement Second of Torts, and the
14 leading California case, Greenman versus Yuba Power.

15 This Court was a very careful Court not to go
16 off on a policy tangent, but to look at the facts before
17 it, which are the closest facts of any other reported
18 decision of a high state court to our case, and to
19 ground its analysis in the good old-fashioned
20 Restatement Second of Torts, which is what California
21 follows to this day, and which is also entirely
22 consistent with Minnesota law.

23 So, this is not an extension of traditional
24 existing product liability tort law in either state.
25 This is merely bringing those established legal

1 precedents and those principles to bear on the facts of
2 this case, which, like it or not, are not the facts of
3 Khan versus Shiley.

4 THE COURT: Thank you.

5 I can tell you have got something on your
6 mind, Ms. Moeller.

7 MS. MOELLER: Just to be clear, Mr. Duron's
8 current device is not recalled, it is not on the recall
9 list. And the Plaintiffs know it. There is a look-up
10 tool, and you can find that out. And Mr. Duron's
11 current device is not recalled. And what they are
12 asking you to do is to open up the floodgates for any
13 device that is recalled, and any person then can bring a
14 cause of action. That is just not the current law, nor
15 should it be.

16 There has to be some type of malfunction,
17 something that leads to an injury in the plaintiff. You
18 can't just allege a defect or allege a recall, and then
19 have a basis for a lawsuit.

20 In this instance, the decision to be
21 explanted was not forced upon him. The FDA did not
22 recommend explant with the risk that this device, this
23 failure mechanism has. Guidant didn't recommend it and
24 his own physician did not contemplate any kind of risk
25 analysis when the decision was made for him to be

1 explanted. And the facts of Larsen really aren't even
2 close in terms of injury. And it was not simply the
3 fact of an explant that the Court found was an injury.
4 It was the fact there were very significant
5 complications, including multiple surgeries, infection,
6 multiple complications, and leads having to be sewn into
7 the man's heart, that were what was the turning point in
8 that case, and the fact that he had no choice.

9 In this case, Mr. Duron was not exposed to
10 any increased risk. We saw the low risk numbers this
11 morning. And he clearly had no malfunction in his
12 device. That basically ends the inquiry on this for
13 this motion.

14 THE COURT: Deem it submitted. Let's take
15 ten minutes. Try to hold to that so we can get -- I
16 think some of you have people coming to pick you up or
17 something at five -- if you would like to stay the
18 evening, we could arrange that.

19 (Recess.)

20 THE COURT: You may be seated, if you wish.

21 We can proceed with punitive damages. Are we
22 saving the best for last, Mr. Pratt? Or how does that
23 work, exactly?

24 MR. PRATT: I don't know if you are talking
25 about the motion, the argument or the counsel.

1 THE COURT: I didn't single any particular
2 thing out.

3 MR. PRATT: Well, it has been a long day,
4 Your Honor. We have heard lots of things. The time
5 limits have kind of gone by the wayside a little bit.

6 THE COURT: Well, you know, I think for the
7 most part, though, I mean, if you would take out, not at
8 your request, but my kind of propensity to let people go
9 back and forth a little bit, which with few exceptions I
10 always find that more helpful than not.

11 We have been in the ballpark, I think.
12 Actually, with all due respect to Webber, they ran out
13 of money in this building right when they finished it
14 up, or came close to it. So, they went low end on the
15 sound system. So, another issue that no court -- at
16 least we haven't dealt with as a district, usually with
17 a cell phone or blackberry or something, if you are so
18 many feet away from a microphone or a pickup, it won't
19 be the constant buzzing like we have had today, but
20 these systems in this building seem more susceptible to
21 it than I think the higher quality system, the less
22 interference you get. These you have to be a ways. I
23 actually stopped bringing my blackberry and cell phone
24 in here, because even sitting here, they must trigger a
25 buzz or something, and it is just not a vibrate, it is

1 just a signal. These systems in this building are about
2 the worst I have seen for that.

3 MR. PRATT: Yeah, I have noticed that, too.

4 THE COURT: I think we are in the
5 neighborhood, so --

6 MR. PRATT: Okay. Well, let me get going.
7 The final motion, Your Honor, we are here to argue today
8 is our motion to strike the punitive damage claim. We
9 have heard lots of things today. And I have watched
10 documents being put up there from the marketing group, I
11 mean, joking documents about money hungry, that is all
12 they were. And they get presented as if this is what
13 this company is made of. This company that goes to work
14 to make devices better and better and looks at devices
15 as they come back. And we get hit with a joking memo or
16 slide in open court as if that represents the company.

17 There has been, I think, some
18 overzealousness, here, in presenting some views, but I
19 want to try to bring things back to the punitive damage
20 context. I have never been in very many cases in which
21 there is not a request for punitive damages. And I
22 think there is always the question to be raised, well,
23 is this the kind of case that is appropriate for
24 punitive damages? I think here, resoundingly, the
25 answer is no.

1 There is an extraordinarily high standard for
2 punitive damages. You have dealt with punitive damage
3 issues before in Minnesota. You have dealt with them in
4 the case of Schwartz versus Thomas, in which you said,
5 even despite the fact that there were factual issues,
6 the evidence presented to you was not high enough to
7 justify adding punitive damages to the case. This is a
8 California standard. Punitive damages are disfavored
9 and are granted with great caution because they lead to
10 excess compensation for the plaintiff, beyond
11 compensatory damages.

12 The purpose is to punish a wrongdoer for the
13 conduct that harmed the plaintiff. We are going to keep
14 coming back to that. Constitutionally, that is the
15 focus. What is the conduct that harmed, harmed Mr.
16 Duron? And when did that occur? And that is what I
17 want to focus on here, Your Honor. I want to talk about
18 the standards that we have to follow, which is clear and
19 convincing evidence, extraordinarily high standard. And
20 in California, it has to be one of three things: Either
21 malice; oppression; or fraud.

22 Malice, meaning you intended to cause harm.
23 Guidant never intended to cause harm. That it
24 constitutes despicable and willful and knowing disregard
25 of the rights and safety of another? That evidence

1 isn't here.

2 Oppression, despicable conduct exposing cruel
3 and unjust hardship and knowing disregard to the rights
4 of Mr. Duron, the Plaintiff?

5 Fraud, we intentionally misrepresented or
6 concealed a material fact intending to harm Mr. Duron?

7 Those are the kinds of standards we are
8 dealing with here. And they are not light years close
9 to the evidence in this case. I am going to spend some
10 time talking about the evidence in this case.

11 I'm going to first talk about the evidence
12 before Mr. Duron's implant was placed on March 9 of
13 2002. There was law we cited in our brief that that is
14 the operative time to focus. What did Guidant do? What
15 have they done before that date? And when you take a
16 look at Plaintiffs' punitive damage cases, virtually all
17 of them deal with knowledge and conduct well before the
18 plaintiff got exposed to the product, and a real injury
19 for the plaintiff. That is what those cases are like.
20 These are not those kinds of cases.

21 Before March 9 of 2002, what we had was an
22 FDA-approved device deemed to be safe and effective by
23 the FDA. We had a warning that accompanied that device
24 that said: This device may fail and not deliver
25 therapy. It came with that warning.

1 There was one arcing report before Mr. Duron
2 got his device, and that was the one on February 1,
3 2002, an incident that was still under investigation at
4 the time he got his device. Plaintiff was advised of
5 the risk of the ICD by his physician Dr. Stephen
6 Higgens. Dr. Higgens' Affidavit has been submitted here
7 in terms of his knowledge, that he would not have wanted
8 to know of that one report out of thousands of devices.
9 It is not meaningful information to him. And he would
10 not have done anything different had he known of that
11 report.

12 So, if you look at before the date of
13 implantation, there is virtually no knowledge there to
14 justify anything like punitive damages. It is
15 implicitly conceded by the Plaintiffs, because they
16 don't spend much time talking about the pre-implant
17 conduct. All they want to talk about are things that
18 happen after the implantation. They want to talk about
19 things that happen to people other than Mr. Duron. They
20 want to talk about Mr. Oukrop. They want to talk about
21 the few instances of failures that occurred, because he
22 didn't have the failure and he wasn't hurt. And these
23 things didn't happen before his implant was placed.

24 Those are the constitutional limits that come
25 into play on this. But, I want to spend some time

1 talking about the post-March 9, 2002 conduct because
2 they talk about it, and they distort it. And I want to
3 be sure the record is clear about what this company did
4 and what it knew in 2002 and beyond.

5 And what it knew was, in April of 2002, they
6 made one small change in the manufacturing process, an
7 engineering change order on April 16th, 2002. At that
8 point they had two reports of problems with this device,
9 short-circuiting in the header, one in the field, one
10 after it was taken out of the patient on the bed. So,
11 they really had one clinical failure within a patient.
12 The patient that got shocked, who came out without an
13 injury, that is what was going on in April of 2002 when
14 the company is still in the process of trying to figure
15 out what is going on, here. We know we have a
16 short-circuit. We know there had to have been an
17 insulation breach, but we don't know what caused the
18 insulation breach. We don't know why it occurred in 1
19 of 10,000 devices. We don't know that. We know it is
20 occurring so rarely, it is well under the FDA
21 reliability projections on an implant failure per month.
22 We didn't know that there would be future failures, and
23 if so, what the incidence would be, because the root
24 cause was still being determined. And we didn't know
25 what the further investigation that the company was

1 doing in April of 2002 and beyond would show.

2 So, the idea that we had information in April
3 of 2002 that would have been meaningful to doctors is
4 absolutely untrue. Dr. Higgins supports that. So do
5 our experts. There is no meaningful information you can
6 give doctors, if you say we have 1 out of 10,000 devices
7 that have failed, we don't know why, we don't know why
8 the insulation breached, we don't know what you can do
9 about it. That is the kind of non-meaningful
10 information that even today, I think, the experts would
11 say, there is no reason to support it. Even their
12 experts say there wasn't any obligation to do this
13 before April of 2002 to make a notification of the
14 company. So, there was the change made as the
15 investigation continued.

16 Why do I say the investigation continued?
17 Why do I say they were still focusing on it? This
18 document, June of 2002. They showed a document this
19 morning that they highlighted -- that they didn't
20 highlight that they said the risk was very low in that.
21 In this document we say we are still trying to figure
22 out what is causing this. Could it have been a problem
23 in the manufacturing of those two devices? Couldn't it
24 have been something else?

25 Further investigation was underway to assess

1 the effectiveness of the change that we made on April
2 16th of 2002. Proof, Your Honor, that on April 16th,
3 2002, the date they say we should have told the world
4 about this, and we should have never sold another
5 product made before that after that date, we didn't know
6 what caused it. We were still investigating it and we
7 were dealing with an implant failure of 1 in 10,000.
8 That is what we knew in June of 2002. That is not
9 punitive conduct. This is laudatory conduct by the
10 company who is trying to figure this out based upon an
11 extraordinarily low number of failures.

12 Could the company have said that the devices
13 made on April 17 were better than the devices made on
14 April 14? They couldn't have said that because there
15 was no basis to say that. And if it would have been
16 said, the evidence shows it would have been untrue, Your
17 Honor. Because based upon what I showed you this
18 morning, reliability between those made before April
19 16th and those made after April 16th is essentially the
20 same statistic.

21 So, the argument that we hid information is
22 absolutely untrue. We were trying to figure out what
23 was going on, in evidence of the fact that we continued
24 to look for ways to resolve this problem as rare as it
25 was, so that in November of 2002 we made yet one other

1 change to this, a change we advised the FDA of in the
2 next annual report. We put a little insulation around
3 the backfill tube.

4 The point of this is that from April of 2002,
5 May, June, July, August, the company was continuing to
6 sell these devices that were made before April 16th
7 because they still had not figured out what the cause
8 was. There was certainly no trigger date there for them
9 to notify physicians, or to do anything about
10 withholding the inventory. I think it is a critical KAL
11 event, Your Honor, to keep in mind that this company was
12 investigating, monitoring this through the period of
13 time of 2002, also important to point out that none of
14 this affected Mr. Duron.

15 Mr. Duron's device was in place during this
16 time. None of this had a direct effect on him. Whether
17 we would have told him November of 2002, November of
18 2003 or May of 2005 would not have changed his
19 situation, whatsoever. So, this conduct went through
20 2002. We continued to monitor the trend after November
21 of 2002, continued to watch it, continued to get a few
22 isolated rare reports that this was happening.

23 Again, no death or serious injury before Mr.
24 Oukrop in March of 2005. And when you take a look at
25 this in March of 2005, what you had was the chart I

1 showed you today, which shows the implant failure per
2 month being fairly stable across the bottom there,
3 compared to what was the projected implant failure per
4 month at the top, the red line, a dramatic difference.
5 This is what the company knew.

6 The company knew that this in May of 2005
7 after the very first death or serious injury with young
8 Oukrop that was mountain biking up in Moab, Utah, and
9 suffered an event, the device short-circuited. And it
10 was evaluated by the company. And we started
11 discussions with his physicians, Dr. Maron and Dr.
12 Hauser, because they wanted to talk to the company about
13 what was known about it.

14 We gladly went to Drs. Hauser and Maron. We
15 talked to them about what we knew about this. We told
16 them about the low incidents of this report. We showed
17 them evidence that this is one of the most reliable
18 ICD's ever made and we talked about patient safety with
19 them, Your Honor. We talked about patient safety. Drs.
20 Hauser and Maron thought patient safety was promoted by
21 the idea of giving all of this information out to the
22 doctors so they could deal with patients.

23 Guidant's position was, again from a patient
24 safety standpoint, that when you provide information to
25 doctors about low frequency failures that may drive

1 unnecessary explants, you are going to increase a
2 greater risk of problems in the patient population
3 because they can run the risk of getting infections, and
4 sometimes those infections can cause death. So, there
5 is a balance even today over what is the trigger point
6 between what you tell doctors and what they can do with
7 it, because there's increasing evidence from the
8 published literature that the complication rate with
9 unnecessary explants may be 2 percent, may be as high as
10 5 percent in one study out of Canada published in the
11 Journal of the American Medical Association, as high as
12 8 percent. That is the balance. That is what is going
13 on right now as a part of the discussion. That was the
14 kind of discussion that was had with Drs. Maron and
15 Hauser.

16 This is the comparative failure rate I showed
17 you this morning, which sort of puts into context this,
18 and it sort of keys to some things that Ms. Cabraser
19 said, and that is, well, you have this arcing failure
20 here of .1 to .13 percent. That is extraordinarily low.
21 It is low. But, you also have the background risk of
22 failure, industry-wide, of 1 to 2.65 percent, or
23 whatever it happens to be, that is just the HRS numbers.
24 So, the point is that anybody who has got a device in
25 this room, including Mr. Duron's new device has a

1 background risk of failure that is probably higher than
2 the .42 percent that we have with the PRIZM 2. You
3 can't monitor for that.

4 If I have a defibrillator in my body, there
5 is no way that I am going to go week to week, month to
6 month, year to year, that it is always going to be
7 there. You can't monitor for that. That probably
8 creates anxiety.

9 And if you tell Mr. Duron, or any other
10 patient -- you tell me. Let's put me. You tell me, Mr.
11 Pratt, you have a 1 percent chance of your defibrillator
12 failing, how does that make you feel? Well, I wish it
13 were none, but I understand that. And the risk of it
14 arcing is .1 percent.

15 So, I have a background risk of failure of
16 whatever cause of 1 percent, I have an arcing failure
17 risk of .1 percent. Why is that .1 percent going to
18 drive me to the doctor to have this thing taken out of
19 my body when the risk of background failure is so much
20 greater than that? That is the context in which these
21 issues, I think, have to be addressed. That is, if it
22 is a one in a million chance that you know, and you have
23 a background failure rate of 1 percent, why does the one
24 in a million trump the 1 percent? Those are the kind of
25 considerations we have. The discussion we had with Dr.

1 Maron and Dr. Hauser, do we communicate? The FDA had
2 received reports on all of these failures, had received
3 reports of the changes we had made in April of 2002 and
4 November of 2002 in the MDR submissions we made. This
5 is the example of the one I showed you, of one in 2003
6 where we told them of the event and the changes.

7 I want to go through this quickly, Your
8 Honor, because I know we have got time limitations, but
9 there is the argument out there that the only reason
10 Guidant communicated was because the New York Times was
11 going to come out with an article, so therefore we
12 reacted to that. That is simply not true. And I am
13 going to give you in about a minute a much more extended
14 needed discussion of this issue, but this is eight days
15 in May. This is May.

16 Remember, on May 23rd, we sent a letter to
17 the physicians on the 1861. We started having
18 discussions with Dr. Hauser and Dr. Maron in the early
19 part of May.

20 We agreed with them, we, Guidant, that we
21 would collaborate on an article with them in which we
22 discussed Mr. Oukrop's death. We would discuss the 1861
23 short-circuit failures. We were going to agree on an
24 article that would have an accelerated publication. In
25 fact, there was an article prepared. It was published

1 in late May online. So, that is the time frame we are
2 talking about. Guidant said to those doctors, we will
3 agree to collaborate on an article. That was on May 12.
4 On May 14th, we started preparing drafts of editorials
5 that will accompany them, so that not only are they
6 going to get the article that we are collaborating on,
7 we are going to submit an editorial that provides more
8 detail about the incident to be published at the same
9 time.

10 We also, then, on May 17th start talking
11 about getting together with Dr. Hauser to work on the
12 mechanics or the technical aspect of this. We confirm
13 internally we are going to help him. On May 18th --
14 this is a critical day. On May 18th, Dr. Joe Smith our
15 Chief Medical Officer, May 18 is a day before we heard
16 anything about the New York Times being interested in an
17 article, had not heard about it at all. May 18 our
18 Chief Medical Officer Dr. Joe Smith says, I think based
19 upon the developments we see, that there is going to be
20 a publication. We're going to do an editorial. Based
21 upon that, I believe we ought to communicate with
22 physicians. And they started drafting a "Dear Doctor"
23 letter. And they went through a draft of the "Dear
24 Doctor" letter. They were working on it and that is
25 when they heard the New York Times was going to come out

1 with an article. So, we decided to communicate,
2 certainly collaborate with the Doctors, Maron and Hauser
3 well before the New York Times became involved. Once we
4 heard the New York Times was going to publish an
5 article, we had a fairly decent sense it probably wasn't
6 going to give the whole story. So, the company said we
7 have got to get this information out to doctors before
8 they read it in the New York Times, because it is going
9 to scare patients. So, we accelerated the sending out
10 of the Dear Doctor letter, did it on May 23rd. The New
11 York Times article came out on May 24th. So, the idea
12 we simply reacted to New York Times is not true.

13 This, Your Honor, is not punitive conduct.
14 When you take a look at the low failure rate we are
15 dealing with over time, when you take a look at the fact
16 that there is the background warning that accompanied
17 this device from the very beginning, when you keep in
18 mind that the failure rate of this device, overall, even
19 now is .42 percent, none of this amounts to malice, none
20 of this amounts to oppression, none of this amounts to
21 fraud directed to Mr. Duron.

22 This was a company that was trying to deal
23 with this information over time. At any given time, any
24 medical device manufacturer is going to have with
25 respect to any product line certain failures that they

1 are evaluating. That is just the nature of the
2 business.

3 And as you evaluate those, you don't tell the
4 doctors every time you get one. Doctors say, we don't
5 want to get an e-mail from you every day saying, hey, I
6 have got something else in the field. So, I think there
7 is a sense out there, certainly from our standpoint,
8 that we complied with the reasonable and expected
9 communication criteria. We honored them. And that when
10 you take a look at the constitutional principles here,
11 it is that you cannot punish a defendant for injury it
12 inflicts on non-parties, that is the Williams case, the
13 brand new one. So, when they come in, they talk about
14 everybody else. They talk about circumstances that are
15 completely unrelated to Mr. Duron, a guilty plead from a
16 sister corporation out in California that the people
17 here in Arden Hills had absolutely nothing to do with,
18 that has no bearing on any punitive damage conduct
19 toward Mr. Duron. The failures that -- they talk about
20 the failures Mr. Duron didn't have. They talk about Mr.
21 Oukrop. Clearly we are not here to talk about his case.
22 They are trying to take this minimal risk of failure,
23 much smaller than the background risk of failure that
24 Mr. Duron was facing from the mere fact that he had an
25 implantable defibrillator, and springboard that into a

1 punitive damage opportunity for everybody caught up in
2 the recall. If this argument they are making applies,
3 that means not only that everybody who gets a recall
4 notice is going to have a right to sue, but they then
5 can use that as a springboard to seek punitive damages,
6 not because of something that happened to them, but
7 based upon conduct that is unrelated to what happened to
8 them and after the fact of their implantation. That
9 simply cannot be the law. It certainly doesn't make
10 legal sense. It doesn't make public policy sense, and
11 it doesn't make common sense. So, the unrelated conduct
12 that we hear about here, the idea that maybe some
13 devices made before April 16 were sold after April 16, I
14 told you why the company did that. What does that have
15 to do with Mr. Duron? His device was made well before
16 March 9 of 2002, when he had it implanted.

17 What does Mr. Oukrop's situation have to do
18 with Mr. Duron? Mr. Oukrop's device failed. Mr.
19 Duron's did not fail. And I think we have to take a
20 look at, sort of, the overall context of punitive damage
21 law, which we discuss in our brief, Your Honor. And I
22 am trying to keep this as short as I can, because
23 factually there is no basis for punitive damages in this
24 case.

25 I don't think it is close to the creation of

1 a meeting of the standard of malice, oppression and
2 fraud required under California law. It comes nowhere
3 close to clear and convincing evidence, even if
4 Minnesota law were to apply. The same principles come
5 into play, and punitive damages wouldn't be appropriate
6 there, either. This is not the case for that, the
7 injection of punitive damages.

8 The conduct that Guidant directed toward Mr.
9 Duron was reasonable conduct. We provided him with a
10 device that was among the most reliable ever made. It
11 did not have a manufacturing defect. And it served him
12 well the entire time he chose to have it in him. And
13 the bad acts toward others, it has no nexus to the type
14 of injury that he is claiming here. And under Williams
15 versus Philip Morris under the Gore cases, under the
16 jurisprudence we just discussed, including State Farm,
17 this case does not justify the injection of punitive
18 damages, Your Honor.

19 So, I will see what Mr. Drakulich has to say
20 and I would be pleased to respond to any questions you
21 have or respond to Mr. Drakulich.

22 THE COURT: All right. Just one question
23 that I think you may have answered. You are not
24 suggesting the result is any different whether it is
25 Minnesota or California. You have implied that the

1 California standard, as you define malice, may be -- may
2 or may not be, but you are saying, one, under either one
3 they are not entitled it; and secondly, they are
4 somewhat similar, and I think we will probably then
5 agree to California or Minnesota.

6 MR. PRATT: I will say that there is no basis
7 for punitive damage either state's statute. I think,
8 though, that if we end up having to proceed with this
9 case, and I hope the motions today will perhaps
10 eliminate that possibility, we are going to have to
11 really sort out which state's law apply, because they
12 really do have different principles that come into play
13 from an instruction standpoint.

14 But, it really doesn't make any difference.
15 When you take a look at the law, you look at the cases
16 they cite, they are nowhere near anything that we have
17 in this case, but the instructions might look a little
18 different, Your Honor.

19 THE COURT: All right.

20 MR. DRAKULICH: Good afternoon, Your Honor.

21 THE COURT: Good afternoon.

22 MR. DRAKULICH: You asked earlier, did you
23 save the best for last? In my case I am going to,
24 because I am going to allow Ms. Cabraser to follow my
25 argument. So, if I go on a little bit long, then I am

1 going to have -- Mr. Lesser is going to pull me aside so
2 I can reserve time for the best for last, and she will
3 address the law with respect to Plaintiffs' position,
4 Your Honor.

5 THE COURT: I'm not sure, actually what you
6 just said.

7 MR. DRAKULICH: Well, you were asking about
8 the best for last.

9 THE COURT: But, I'm not sure about kind of
10 the tag team, that is what I'm --

11 MR. DRAKULICH: Oh, I'm sorry.

12 THE COURT: The two of you, what you are
13 going to address and what she is going to address. And
14 I can tell by the reaction of counsel over here, it is
15 the first time maybe they have heard we are going to
16 have two lawyers arguing the same motion.

17 MR. DRAKULICH: I was going to address the
18 facts for ten minutes she was going to address the law.

19 THE COURT: All right, I will do that.

20 MS. CABRASER: Three minutes.

21 THE COURT: What did you say, Ms. Cabraser?

22 MS. CABRASER: I'm sorry. I will address the
23 law in three minutes.

24 THE COURT: In three? Go ahead.

25 MR. PRATT: Could I be the timekeeper, Your

1 Honor?

2 MR. DRAKULICH: You usually are.

3 THE COURT: Go right ahead.

4 MR. DRAKULICH: Thank you, Your Honor. You
5 also asked the question, does it matter whether it is
6 California or Minnesota? And having tried, and been
7 involved in punitive damage cases in both states, I can
8 tell you with this evidence, Your Honor, it is clear and
9 convincing and it meets the standard for both California
10 and Minnesota.

11 We earlier discussed the Medical Advisory
12 Board, and what their own board's opinion of the conduct
13 of Guidant. Do you recall that slide, we talked about
14 defective brakes?

15 THE COURT: Uh-huh.

16 MR. DRAKULICH: Well, Mr. Pratt spent a lot
17 of time talking about Dr. Hauser. He is not here to
18 speak for himself, so I am going to let one document
19 speak for him, if I may.

20 I am going to read on the elmo if I may, Your
21 Honor. This is a letter dated May 27th that Dr. Hauser
22 wrote to the FDA.

23 "Susan, Guidant continued to sell our
24 hospital PRIZM 2, 1861 units that were manufactured
25 prior to April of 2002, and thus these units did not

1 have the manufacturing changes introduced to avoid
2 abrupt failure during shock delivery. We implanted 18
3 such units in patients between May of 2002 and January
4 of 2003. Had Guidant informed us of this flaw, we would
5 not have implanted these units. I doubt there is a
6 physician in the United States who would have done so.

7 Of the 58 pre-2002 units that were implanted
8 in our hospital, 18, or 31 percent, were implanted after
9 Guidant discovered the flaw and implemented changes.

10 If this percentage translates nationally,
11 then thousands of pre-April 2002 PRIZM 2 1861's were
12 implanted, after Guidant found the defect.

13 In our view, this is an egregious act by a
14 manufacturer of lifesaving devices, an egregious act by
15 a manufacturer of lifesaving devices. And you know, Dr.
16 Hauser is not alone in that opinion, Your Honor.

17 If we also look as to -- well, let's look at
18 even their own independent panel. What did they say? I
19 will read while that is coming up, Your Honor, to save
20 time.

21 "If the independent panel says during the
22 period of approximately one year after the correction
23 was taken in response to the observation of arcing, more
24 than 4,000 of the pre-mitigated devices continue to be
25 implanted. Approximately 1,300 of which were shipped

1 directly from CRM's inhouse inventory."

2 Now, if we can go back to this document, and
3 I think my co-counsel earlier today made a comment about
4 res ipsa. And I would submit to you, Your Honor, that
5 this document is the poster child of conscious
6 disregard.

7 They don't want to talk about it much, but I
8 can't recall a case that I had, a punitive damage case
9 where I had a document from a company three years before
10 a recall, a Class 1 recall, where they assessed the risk
11 of serious injury or death to 26,000 people in the
12 United States, and they regarded that as very high.

13 Facts are tough things, and this is a very,
14 very tough fact. This fact alone, I would submit to
15 Your Honor, meets a clear and convincing standard.
16 Because what did the FDA finally do when they found out,
17 when Guidant was forced to reveal, when Dr. Hauser went
18 to the New York Times?

19 What did the FDA immediately do? They issued
20 a Class 1 recall, which is what I submit they would have
21 done three years ago had Guidant informed the FDA and
22 the medical community. And they said, this device
23 presents a serious risk of serious injury or death.

24 And I find it ironic that Guidant says:
25 Well, we don't want to bother doctors with e-mails all

1 of the time. Doctors don't need those e-mails all of
2 the time. Well, maybe they don't want e-mails all of
3 the time, Your Honor, but it is not for Guidant to
4 decide when a doctor in consultation with his patient
5 should be informed of a life-threatening risk of a
6 device. That is for the doctors.

7 That is why you see Dr. Hauser speak up.
8 That is why he went to the New York Times. I mean, he
9 is not -- this is the former president of this company
10 and he speaks to this conduct as egregious.

11 They quoted in their briefs the Heart Rhythm
12 Society Task Force. What does the Heart Rhythm Society,
13 again, Dr. Hauser and our Dr. Thiers, the founders, say
14 about, just generally, about companies?

15 "Timely detection and communication of
16 malfunctions that have the potential to be widespread,
17 particularly those malfunctions that are life
18 threatening are critical to patient safety and to
19 ongoing device improvement."

20 They are critical. It was absolutely
21 reprehensible, I would submit, Your Honor, that this
22 company decided they would hide this defect -- this is
23 not a random defect that is common in all devices, Your
24 Honor. This is a diagnosed, specific, life-threatening
25 defect that they decide they are not going to tell

1 anyone. And they are going to continue to sell the
2 inventory. They are going to wipe out the inventory on
3 their shelves to unsuspecting doctors and patients
4 because they don't have a right to know. That is
5 Guidant's decision to make. That is conscious
6 disregard.

7 THE COURT: And the relevance that Mr. Duron
8 just placed in him on February 21st of 2002?

9 MR. DRAKULICH: They decided -- I don't know
10 how else you can take this information and not come to
11 the conclusion that they decided if Mr. Duron needed
12 that therapy and that defect appeared, which they said
13 would be 10 percent, that was the risk if somebody
14 needed a shock and that defect appeared, that that death
15 was statistically insignificant.

16 They let him sit with a device for three
17 years in his body every single day, believing that it
18 would work, when they knew they had diagnosed a
19 life-threatening risk of death. I mean, I would just
20 think common decency, let alone medical ethics, would
21 say that he has a right to know that. His doctor should
22 be informed of that. Doctors around the United States
23 should know that so they could make a medical judgment
24 with their patients.

25 THE COURT: And the relevance that Mr. Pratt

1 has suggested, that, well, the statistics are the
2 background risk from the non-arcing problem is actually
3 higher than the risk that is involved here? Granted
4 that there is not an agreement on just what exactly all
5 these numbers are, but that is in part what was said.

6 MR. DRAKULICH: Yeah, well, I will take their
7 numbers.

8 THE COURT: All right.

9 MR. DRAKULICH: And what does their number
10 tell us? 10 percent, 10 percent of a 26,000 population
11 if that event occurs and the therapy is delivered. 10
12 percent. I mean, if I am reading the board correctly,
13 it says, "very likely." If that -- can I move, Your
14 Honor? I apologize. My eyesight is --

15 THE COURT: Sure.

16 MR. DRAKULICH: That is what it says. "If
17 the potentially hazardous event occurs, likelihood of
18 injury occurring in the population at risk ..." -- and
19 they previously told us the population at risk was
20 everyone, 26,000 people, that it was "very likely," plus
21 3, 10 percent. That is what I am reading from their
22 document.

23 THE COURT: But, aren't you -- the preface to
24 that is if the event occurs, that is a part of it, what
25 it is about.

1 MR. DRAKULICH: Right, but who gets to
2 make -- here they have this information in their
3 possession. They know that if this event occurs, people
4 are likely going to be injured or die. They decide they
5 don't have to tell doctors. They don't have to tell
6 patients. That is their decision to make. They can't
7 play God, Your Honor. A doctor has a right to know. A
8 patient has a right to know.

9 Isn't that what the Heart Rhythm Society --
10 that is what the panel, itself, said, the commission.
11 They hired their own panel. And what did their own
12 panel say? Look at the report of the independent panel,
13 Your Honor, and they say on several occasions, the
14 independent panel strongly believes that under no
15 circumstances, this is their panel, should a potential
16 or manifest risk of preventable death be superseded by a
17 statistical analysis that indicates the performance
18 remains within general guidelines of estimated failures.
19 Under no circumstances.

20 And, you know, I listen very carefully to
21 this one slide that they put up on June 20th in response
22 to the June 14th health risk assessment. And it
23 mentions that further investigation is underway to
24 assess the effectiveness of the ECO, and to determine if
25 further correction action is indicated.

1 What does that say? That says that the fix
2 they thought they made, they don't know if it is going
3 to work. How else can you interpret that? In my mind,
4 Your Honor, that is even further evidence of a conscious
5 disregard. They made a fix. They assessed the
6 likelihood of serious injury or death, but they are
7 saying on June 20th, they don't even know if that fix is
8 going to work. So, again, no disclosure of doctors, no
9 disclosure to patients. It is, as Dr. Hauser said, the
10 former president of this company said, a former founder
11 of the Heart Rhythm Society, a leading doctor in the
12 United States in this very community who is concerned
13 for his patients, this is an egregious act by a
14 manufacturer of lifesaving devices.

15 So, in conclusion, Your Honor, I would say
16 that I don't think you need much more to get to the
17 conclusion that we have met our standard sufficient for
18 a trier of fact to determine, based upon the conduct
19 that I have spoken about today and is in our briefs,
20 that Guidant clearly and consciously put patients at
21 risk, and the public's safety, as well. And then if I
22 may, Your Honor, I will turn to --

23 THE COURT: All right. Ms. Cabraser?

24 MS. CABRASER: Thank you, Your Honor. I
25 think the best thing I can do is stick with the U.S.

1 Supreme Court, and one case each from the California
2 State Courts. Mr. Pratt is absolutely correct, this
3 issue, in terms of the legal issues, is really governed
4 by the most recent Supreme Court decisions on the
5 subject, because the Supreme Court has created a federal
6 constitutional common law of punitive damages within
7 which any differences among the states are really
8 secondary. Because to get it -- to do it right, you
9 have to do it the way the Supreme Court says to do it.

10 The way that the Supreme Court says to do it,
11 and this is reflected both in the first case, the
12 earliest the case, the Gore verse BMW case, and more
13 recently the State Farm versus Campbell case, is to look
14 at three guideposts. The degree of reprehensibility of
15 the defendant's misconduct. The second is the disparity
16 between the actual or potential harm suffered by the
17 plaintiff and the punitive damages award. And the
18 third, if it is relevant in the case, is the difference
19 between the punitive damages award imposed by the jury,
20 and comparable civil penalties authorized or imposed in
21 comparable cases. That is probably the least used
22 factor.

23 But, the most important factor in both Gore
24 and BMW -- or Gore and State Farm say this, quote, "The
25 most important indicia of the reasonableness of the

1 punitive damage award is the degree of reprehensibility
2 of the Defendant's conduct, degree of reprehensibility.
3 That is a nuance determination. It is fact based. The
4 Supreme Court helpfully supplies five factors that it
5 has instructed courts to use to determine where on the
6 reprehensibility scale a defendant's conduct lies.

7 And these five factors are whether the harm
8 was physical as opposed to economic, whether the
9 tortious conduct events and indifference to are a
10 reckless disregard of the health or safety of others.
11 And that is the very language that both the Minnesota
12 and California Supreme Courts and jury instructions use.

13 Whether the target of the contact had
14 financial vulnerability, whether the conduct involved
15 repeated actions or was an isolated incident, and
16 whether it was the result of intentional malice,
17 trickery, or deceit, or a mere accident.

18 Now, both California and Minnesota would take
19 that "mere accident" right out of the calculus. When a
20 court or a jury is looking at the degree of
21 reprehensibility, Williams says -- and this is the most
22 recent final last word on the subject from the highest
23 court, the jury may consider harm to others to determine
24 the degree of reprehensibility. That is why the entire
25 course of conduct is relevant, here, not just because it

1 kept Mr. Duron at an increased risk of potential harm,
2 which is all punitive damages jurisprudence requires;
3 but, because it impacts the calculus of
4 reprehensibility. And reprehensibility is the
5 multiplier that the jury and the Court apply to the
6 baseline of actual damages, resulting from real or
7 potential harm.

8 THE COURT: But, the harm to others, it
9 certainly must be relevant when that harm occurred. If
10 you concede some level of harm or knowledge, in other
11 words whether I knew something about that three years
12 ago, or I just learned about it today --

13 MS. CABRASER: True. And in this case, what
14 happens is once Mr. Duron is implanted in 2002, he isn't
15 taken out of the equation. An implant of a
16 defibrillator isn't a one-time event. He has got it in
17 him every day. So, what Guidant knows and what Guidant
18 chooses to do or not do about it with respect to the
19 FDA, with respect to the medical community, with respect
20 to its customers and its patients, is highly relevant to
21 the degree and duration of real or potential harm to
22 which Mr. Duron, himself, was exposed. And that is the
23 harm factor. It can be real or potential, says
24 Williams, and also the multiplier factor, the degree of
25 reprehensibility.

1 The problem that Williams was trying to solve
2 was the propensity of courts and juries to get these two
3 criteria confused. And Williams, helpfully or not,
4 supplies new jury instructions for all of us to look at
5 and use which are consistent with both states' laws.

6 But, basically what Williams says is, Philip
7 Morris does not deny that a plaintiff may show harm to
8 others in order to demonstrate reprehensibility, nor do
9 we. This is at page 1064 of 127 Supreme Court.

10 Evidence of actual harm to non-parties can
11 help to show that the conduct that harmed the plaintiff
12 also posed a substantial risk of harm to the general
13 public and so was particularly reprehensible.

14 Although counsel may argue in a particular
15 case that conduct resulting in no harm to others
16 nonetheless posed a grave risk to the public, or the
17 converse.

18 Williams also reiterates, quote, we have said
19 it may be appropriate to consider the reasonableness of
20 the punitive damages award in light of the potential
21 harm the Defendants' conduct could have caused. But, we
22 have made clear that the potential harm at issue was
23 harm potentially caused the plaintiff.

24 So, we have two concepts, here, both are
25 entirely consistent with reviewing the entire course of

1 conduct involved in this litigation, not just cabined by
2 the date of Mr. Duron's initial implant, but by what
3 happened after. Because the less this is an isolated
4 incident, the more it is a course of conduct, the more
5 knowledge the defendant has without doing something
6 about it, the greater the reprehensibility factor.

7 It is always cabined by the real or potential
8 harm to the plaintiff, which is the controlling factor
9 the Supreme Court was very, very careful to emphasize in
10 Williams. This is entirely consistent, of course, with
11 the standard for punitive damages under both Minnesota
12 and California law, both because the Supreme Court
13 borrowed statutory language from Minnesota and
14 California in terms of the conscious or reckless
15 disregard to the rights or safety of others in crafting
16 its jurisprudence; but, also because in turn, it is a
17 feedback group. Both California and Minnesota have
18 revised and notated their jury instructions to reflect
19 adherence with the Supreme Court precedence.

20 So, while you heard a lot about malice, the
21 fact of the matter, under both Minnesota and California
22 law, is that the standard of conduct one must show by
23 clear and convincing evidence is that, to quote the
24 Minnesota statute, the Defendant deliberately proceeds
25 to act with indifference to the high probability of

1 injury to the rights or safety of others, probability of
2 injury to the safety of others, or the rights of others,
3 because sometimes it is only economic harm at stake.

4 And California is exactly the same. Grimshaw
5 versus Ford Motor Company, which is the infamous Ford
6 Pinto case states it very, very plainly. The statute
7 means, quote, "Conduct evincing a conscious disregard of
8 the probability that the actor's conduct will result in
9 injury to others is sufficient."

10 In both states, the economically motivated
11 choices the Defendant makes in improving or not
12 improving a product are highly relevant to punitive
13 damages at any point along that way.

14 The Grimshaw versus Ford Motor case was the
15 case where the company wanted to build a 2,000-pound car
16 to sell for \$2,000 decided not to spend \$15.30 per car
17 to make sure that when and if that car was hit in a
18 certain way behind, that it would not burst into flames.
19 That accident rarely occurred. Most days most people
20 drove their Pintos safely. Most Pintos didn't get
21 rear-ended in just that way, but when they did, they
22 burst into flames. And that could have been avoided for
23 \$15.30.

24 The case for Minnesota is the Grye case which
25 we cited, G-r-y-e, that is the flame-retardant case.

1 The company knew that it was complying with Federal
2 standards for flame-retardant fabrics in children's
3 pajamas.

4 They decided that was good enough. It was
5 good enough for the Feds. But, they also knew there was
6 a better way. And they knew not to do that better way
7 was risky, but they decided not to do it because no one
8 else was doing it. And because it was too costly. The
9 state of the art wasn't there yet. They had a great
10 state of the art defense. It wasn't good enough. The
11 Minnesota Supreme Court upheld a \$1,000,000 punitive
12 damages award.

13 Your Honor, throughout this course of conduct
14 you know from facts that economic choices were made.
15 There is nothing wrong with making economic choices.
16 But, when you are dealing with a product that people
17 depend on for their lives that implicate safety, whether
18 it is a compact car, a child's pajamas or a
19 defibrillator, you have to be very careful with those
20 choices, and you have to be honest about those choices.
21 And in this case among other economic choices the
22 company made was not to spend \$9,000 to change out a
23 tool to avoid the arcing problem that is at issue in
24 this case. And they decided not to take that change
25 because they would have to sell thousands of units

1 before that change would cost nothing.

2 As it was, they sold thousands of units after
3 they decided to not to make the \$9,000 change. Had they
4 made it, it would have cost pennies per unit. It could
5 have been reflected in the cost to the consumer. They
6 just chose not to do it.

7 It wasn't a \$15 per unit cost on a \$2,000
8 car, it was a pennies per unit cost on defibrillators
9 that cost over \$15,000 a piece. It was a conscious
10 decision. It has had consequences in terms of risk of
11 potential harm and harm to many people.

12 A jury is entitled to assess that and all of
13 the other facts, including all of the facts that Guidant
14 wants to put up to explain why that might have made
15 sense and why that was logical, to determine where on
16 the range of reprehensibility this conduct lies, and to
17 assess punitive damages accordingly. That will be
18 subject to de novo review by this Court, as the Supreme
19 Court has demanded. There are safeguards, here. There
20 is no runaway jury on punitive damages anymore, if there
21 ever was.

22 This Court has the obligation to assess on a
23 de novo basis any punitive damages award a jury here
24 returns, and the appellate courts likewise have the
25 obligation to conduct a de novo review at the request of

1 either side.

2 As a result, punitive damages have been
3 moderated, they have been reduced, they have been
4 mediated, and they have a constitutional dimension.
5 But, in the first instance, the initial determination as
6 to whether and how much to assess is a fact-based
7 determination that has to be made based on an airing of
8 disputed facts on each side.

9 There are more than enough facts to entitle a
10 jury to impose a punitive damages award in this case.

11 THE COURT: Thank you. Mr. Pratt?

12 MR. PRATT: That it would be based on facts,
13 not on fiction, Your Honor; that argument that was just
14 made that these decisions were driven on an economic
15 basis is absolutely untrue, absolutely untrue.

16 I understand the motivation in the
17 Plaintiffs' counsel to come into a courtroom, open
18 courtroom, and make allegations about, well, if only
19 they had spent \$9,000. That was their interest in not
20 making this change. That is unsupported by the
21 evidence. There is no evidence that what was done on
22 April 16th was driven by any economic motive,
23 whatsoever.

24 The only thing that she could even be
25 thinking about in a million years is in connection with

1 the 2002 discussions that were going on within the
2 company, not at the highest level. There was never a
3 decision made on April 16, let's just keep selling these
4 things. Let's not notify the company. There was never
5 a decision.

6 This was moving along a spectrum in which
7 people were evaluating the situation, as I showed in
8 June of 2002. There was a discussion that we made the
9 change in April of 2002. Did it work, did it not. We
10 made the change in November of 2002. Did it work, did
11 it not. There was also some discussion about do we also
12 need to change the header? Do we need to change the
13 header in some way?

14 When the decision was made ultimately that we
15 don't need to change the header, they determined that
16 the changes that were made in April and November of 2002
17 fixed the problem. So, there wasn't any decision made
18 when they still had thought they resolved it that they
19 were going to try to save money and not do something.

20 I don't mind arguments based on facts, Your
21 Honor, but the idea that this company somehow made
22 decisions in 2002 based upon some desire to protect the
23 company's reputation or to save money is absolutely
24 untrue and insulting to the people of Guidant.

25 Now, I want to talk about a few things that

1 were made, and I want to mention this over here. Mr.
2 Drakulich, I will assume he just made a good faith
3 mistake, is completely misreading this. What is not
4 shown here, because they didn't blow it up is what is
5 the risk of this happening? What is the risk of this
6 event happening in this population? And they called the
7 risk very low.

8 At this point, the risk was .01 percent. One
9 out of 10,000 devices had manifested this problem. The
10 10 percent says that if you happen to be one of those
11 extraordinarily rare device users who suffered this rare
12 event, then there is a 10 percent chance of a
13 potentially hazardous -- of a likelihood of injury
14 occurring. That is what the 10 percent is. And this
15 document that he held up as what he called the punitive
16 damage poster child is being completely misread and
17 distorted.

18 June of 2002, the evidence we show is that we
19 didn't know what caused the problem. We were still
20 investigating. And the idea that -- I want to talk
21 about Dr. Hauser. Dr. Hauser made that comment in May
22 of 2005. I don't know what Dr. Hauser knew about what
23 the company knew on April 16 of 2002 when they made the
24 change.

25 First of all, I know of one thing, it has

1 nothing to do with Mr. Duron, who did not get a device
2 after April 16 that was made before. For him to
3 piggyback on the backs of those people I think is
4 extraordinarily unfair and certainly not supported by
5 the punitive damage jurisprudence.

6 So, I don't know at this point what Dr.
7 Hauser knew and believed when he made the comment about
8 this egregiousness. I do know it had nothing to do with
9 Mr. Duron. I also know that it was on April 16th, as
10 evidenced by the documents that this company truly did
11 not know whether they fixed the problem. And we get
12 condemned for that, that we are trying to figure this
13 out, we are making changes, we are not sure, we are
14 investigating, we are making other changes, and somehow
15 that process is what, punitive? So, what should we have
16 done as a company, nothing?

17 What if we had not looked? What if we had
18 not acted? Can you imagine the condemnation we would
19 have received on the other side?

20 The HRS standard that was discussed, there is
21 nobody who has said that if there is one failure, you
22 ought to tell doctors. HRS, independent panel, nobody
23 has said there is a magical number of one that triggers
24 a communication. In other words, they don't want to get
25 a magical number of one because they don't know what to

1 do with it. Everybody gives a company an opportunity to
2 investigate it, to seek information that will now have
3 been meaningful information to be conveyed to the
4 medical profession.

5 But, the argument that they are making is, if
6 you get one, one day, and you start investigating it the
7 next, you already hid it in one day. That is not the
8 way the process works. At any given time these medical
9 device manufacturers are going to have some failures in
10 a product line that are under investigation. They may
11 be at such an extraordinary level that it wouldn't
12 trigger a communication. And the idea that those
13 companies are hiding failures and not providing this
14 information, I think, certainly represents a
15 misunderstanding of doctors' expectations and how
16 companies run their business.

17 In terms of what Ms. Cabraser had to say,
18 this is getting into a little bit of a nuance, but I
19 think it is an important nuance; and that is, what does
20 reprehensibility have to do with anything?

21 We cited the case law from State Farm and
22 from Williams versus Philip Morris that says you really
23 have to take a look at whether the conduct harmed the
24 Plaintiff. There is a discussion in Williams about the
25 reprehensibility to other -- the evidence of damage to

1 other parties as part of reprehensibility. They said
2 that bad acts evidence must be of the same type of
3 conduct that harmed the plaintiff. That is one of the
4 standards constitutionally under due process. And in
5 order to serve as evidence, the conduct has to also pose
6 a substantial risk of harm to the general public, and so
7 was particularly reprehensible. I want to make two
8 points about that statement, that it posed a substantial
9 risk of harm to the general public, and so was
10 particularly reprehensible. All of those cases, whether
11 it is Gore, whether it is State Farm, whether it is
12 Williams, is an assessment of the claimed excessiveness
13 of a punitive damage award. They are looking back at
14 evidence to determine whether the award was too large,
15 whether it met a due process constitutional standard.

16 We are here today to talk about entitlement.
17 We are here to talk about whether Plaintiff has proved
18 an entitlement to damages, not to an amount,
19 entitlement. And when you take a look at the jury
20 instructions in California under malice, and oppression
21 and fraud, those entitlement type things speak not to
22 reprehensibility to the general public, but to harm or
23 conduct that harmed the plaintiff. And I think that is
24 an important distinction with regard to this.

25 If that distinction doesn't hold and the

1 reprehensibility standard comes into play, I want you to
2 focus on also posed a substantial risk of harm to the
3 general public. I wrote this down because Ms. Cabraser
4 said this. The probability of injury to others is
5 something else she said was a standard. The probability
6 of danger to others, something else she said. The more
7 isolated the conduct, the more isolated the conduct, the
8 less reprehensible.

9 All right, if that is true, we are talking
10 about a failure rate in a device that has a background
11 and warned against failure rate of well over the rate
12 that was seen here. You have an arcing incidence of .01
13 percent in the very early stages, 1 out of 10,000, with
14 an implant failure rate per month staying pretty steady
15 all the way through, extraordinarily low all the way
16 through.

17 So, the probability of harm to Mr. Duron, the
18 probability of harm to the users of these 1861's over
19 time was extraordinarily low. It was clearly a fraction
20 of the risk that every one of these patients faced,
21 simply because they had an implantable defibrillator in
22 their bodies.

23 And even now if someone has an 1861 in their
24 body with a failure rate reported of .13 percent under
25 the most recent disclosures -- keep in mind the

1 confirmed failure rate is .42 percent. So, you have a
2 greater chance of suffering a failure beyond arcing,
3 than you do arcing under those statistics. So, this
4 probability of harm to others, probability of injury to
5 others; extraordinarily low.

6 It has been a long day, Your Honor. This is
7 a company that has a lot said about it. The facts are
8 coming out. I think the information about the New York
9 Times didn't drive the fact of communication. The
10 reliability of this device, the low incidents of these
11 failures, what the company was doing, trying to do in
12 2002 to investigate the problem, to do the best they
13 could as a continuous improvement to make the device
14 better, that evidence doesn't justify liability. It in
15 no way justifies an entitlement of Mr. Duron to an award
16 of punitive damages under a claim that somehow this
17 company exhibited malice, oppression and fraud to him,
18 fraud that we intended to hurt him. Not even close,
19 Your Honor. Thank you.

20 THE COURT: Thank you. A brief response, if
21 you like?

22 MR. DRAKULICH: Thank you, Your Honor, very
23 brief. And I rise to the defense of my co-counsel who
24 needs no defense, Your Honor, because the documents
25 speak for themselves. We aren't making this information

1 up. We are relying upon and citing Guidant documents
2 for our statements. It is not advocacy in the sense
3 that we are making up facts from whole cloth, we are
4 relying upon what they say.

5 And I would just ask the Court, if they
6 would, to look at -- it is CPI 870002803 to 2804, which
7 supports the very statement that Ms. Cabraser says
8 concerning the election to not modify the header in the
9 shape of rerouting the wires because it was not cost
10 effective. I can put it up for you if you like, Your
11 Honor.

12 THE COURT: All right. It is on the screen.

13 MR. DRAKULICH: Okay, thank you. There it
14 is, Your Honor. And we'll go to the next slide. Good
15 to go.

16 So, when we make statements, Your Honor, we
17 do so in good faith and with full confidence that they
18 are supported by the record. When I say what I said
19 about this risk assessment, I do so because that is what
20 the document provides.

21 Counsel says I have not provided you the
22 documents. You have them in your package, Your Honor.
23 There is nothing that has been omitted by anything we
24 have done. There is no reason no hide the facts. The
25 facts speak for themselves. And the facts are

1 overwhelming, here. They are clear, they are
2 convincing, and the stain cannot be washed away. Thank
3 you, Your Honor.

4 THE COURT: Mr. Pratt?

5 MR. PRATT: I will only say, Your Honor, that
6 this is not the document that explains why the company
7 did not make that change in the header. The document
8 that reflects that says we did not make the change in
9 the header, because the changes we already made in April
10 and November of 2002 had fixed the problem. That is all
11 I have, Your Honor.

12 THE COURT: Anything further?

13 MR. DRAKULICH: No, Your Honor, thank you.

14 THE COURT: I will deem those submitted. I
15 will deem those submitted. I realize the hour, but I
16 would like to -- I don't think that there is anything we
17 need to discuss on scheduling.

18 I started the morning out by asking you to
19 think about whether there is any of these decisions -- I
20 think we have agreed to get, Amy, everything out, and
21 Danielle, on or before June 12th. So, the question is,
22 with that as the outside, June 12, are there any, are
23 there one or more of these decisions of these motions,
24 both those that were argued orally and the ones that
25 were submitted on the briefs that you are saying, well,

1 there are one or two in particular. If you are willing
2 to roll out a decision up or down, we know it will be
3 followed by an opinion.

4 MR. ZIMMERMAN: Could we confer on that a
5 second, Your Honor?

6 THE COURT: All right, that is fine. And
7 actually, if you want to confer on it because you think
8 it has been a long day and you want to chat, and get
9 back to me at the beginning of the week, that is fine,
10 or you can tell me now. It doesn't matter to me.

11 MR. PRATT: Excuse me. Your Honor, I think
12 that the sense of the community here -- it's a small
13 village -- is that the one that may be advantageous
14 ahead of the others is your indication on the choice of
15 law.

16 We have some bellwether briefing to take
17 place downstream, so how you deal with that might
18 affect --

19 THE COURT: Just give me a moment. May I see
20 the two of you?

21 (Discussion off the record.)

22 THE COURT: What we will -- more handouts,
23 Ms. Cabraser?

24 MS. CABRASER: Not more handouts. This is
25 just very late in the day, the Duron Complaint and the

1 Master Complaint that I kept referring to, and said I
2 would present to the Court. So, it is already in the
3 record. It is not new, but it is for convenience. And
4 I apologize for being so late.

5 THE COURT: What I would suggest in light of
6 counsel's comments, we can have -- we'll stick with the
7 overall decision on the issuance of the opinion, the
8 outside being June 12th. We can have it to you by no
9 later than the middle of next week, Wednesday, an up or
10 down decision.

11 The memorandum and opinion will probably not
12 be with it, but we can give you the choice of law
13 decision by mid-week.

14 MR. DRAKULICH: That would be great, Your
15 Honor.

16 MR. PRATT: Great.

17 MS. CABRASER: Great, thank you.

18 MR. DRAKULICH: One small thing I forgot to
19 mention. You were kind enough to place this in one of
20 our status conferences, but we reserve the right to
21 supplement the record with respect to issues concerning
22 Dr. Higgens --

23 THE COURT: That is correct.

24 MR. DRAKULICH: -- and we are taking his
25 deposition next week. So, we will have a lot to say on

1 that subject, I think.

2 THE COURT: All right. Mr. Pratt, were you
3 trying to get my attention on something?

4 MR. PRATT: Was I what, sir?

5 THE COURT: I didn't know if you were trying
6 to get my attention.

7 MR. PRATT: I was waving good-bye. Do you
8 want me for a conference --

9 THE COURT: I don't think we -- I think
10 because of some small discussion you had on the answer
11 issue and amendment issue, I don't know that we need to,
12 unless there is something you want, other than that, I
13 think -- why don't we put on the record we have moved
14 the status conference to the 19th. I think that we
15 discussed that earlier during the break. Do we have a
16 time of day for that? The same time?

17 MS. MAIR: Probably the same, followed by
18 the --

19 THE COURT: So, it would be the same, is it
20 8:00 or 8:15, followed by the 9:00?

21 MS. MAIR: 8:00 followed by 9:00.

22 THE COURT: 8:00 followed by 9:00 on the
23 19th, not the 18th. I think we are in agreement there.

24 Did I hear somebody else say there are some
25 other issues you want to discuss?

1 MS. FLEISHMAN: No, I think we have addressed
2 them.

3 THE COURT: Thank you, everybody, for coming
4 in. I hope wherever your flights are, wherever your
5 transportation is, people think Federal Judges have
6 helicopters, we do not. I don't have a helicopter
7 waiting to take you to the airport. So, unless there is
8 anything further on behalf of the Plaintiffs?

9 MR. DRAKULICH: Nothing further. Thank you,
10 Your Honor.

11 MS. MOELLER: Nothing further, Your Honor.

12 THE COURT: All right, we are adjourned.

13 Thank you.

14 ALL COUNSEL: Thank you, Your Honor.

15 (Adjournment.)

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Certified by: _____

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Jeanne M. Anderson, RMR-RPR
Official Court Reporter

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