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UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Civil No. 05-1726(JMR/AJB)

MOTION

January 4, 2007

In Re Medtronic, Inc., Implantable Defibrillators
Products Liability Litigation

TRANSCRIPT OF PROCEEDINGS
HAD BEFORE CHIEF JUDGE JAMES M. ROSENBAUM
Minneapolis, Minnesota

Reported by: Dawn M. H. Hansen, RMR-CRR

A P P E A R A N C E S

1
2
3 For Plaintiffs: Daniel E. Gustafson
4 Gustafson Gluek PLLC
608 2nd Avenue South, Suite 650
5 Minneapolis, MN 55402
6
Charles S. Zimmerman
7 Ronald S. Goldser
Robert R. Hopper
8 Zimmerman Reed PLLP
651 Nicollet Mall, Suite 501
Minneapolis, MN 55402
9
Thomas M. Sobol
10 Hagens Berman Sobol Shapiro LLP
One Main Street, Fourth Floor
Cambridge, MA 02142
11
Hunter J. Shkolnik
12 Rheingold Valet Rheingold Shkolnik
& McCartney LLP
13 113 E. 37th Street
New York, NY 10016
14
Jean Paul Overton
15 Neblett, Beard & Arsenault
2220 Bonaventure Court
16 P.O. Box 1190
Alexandria, LA 71309
17
Nicholas J. Drakulich
18 Jennings & Drakulich LLP
2002 Jimmy Durante Blvd, Suite 400
19 Del Mar, CA 92014
20
21
22
23
24
25

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12
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16
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21
22
23
24
25

For Defendants: Donald M. Lewis
Halleland Lewis Nilan & Johnson
600 U.S. Bank Plaza South
200 South Sixth Street
Minneapolis, MN 55402

Lori G. Cohen
Jay B. Bryan
Greenberg Traurig, LLP
3290 Northside Parkway, Suite 400
Atlanta, GA 30327

Stephen J. Immelt
Hogan & Hartson LLP
111 S. Calvert Street
Baltimore, MD 21202

P R O C E E D I N G S

(Open court; 2 o'clock p.m.)

THE CLERK: Your Honor, the matter on the calendar is In Re Medtronic Inc., Implantable Defibrillator Products Liability Litigation, MDL Number 05-1726. Would counsel please stand and state their appearance?

MS. COHEN: Lori Cohen on behalf of defendant Medtronic.

THE COURT: Ms. Cohen.

MR. IMMELT: Steve Immelt for Medtronic.

MR. BRYAN: Jay Bryan for Medtronic.

MR. LEWIS: Donald Lewis on behalf of Medtronic, Your Honor.

THE COURT: Gentlemen.

MR. GUSTAFSON: Good afternoon, Your Honor, Dan Gustafson on behalf of the MDL plaintiffs.

THE COURT: Mr. Gustafson.

MR. ZIMMERMAN: Afternoon, Your Honor, Bucky Zimmerman on behalf of the plaintiffs.

THE COURT: Mr. Zimmerman.

MR. SOBOL: Good afternoon, Your Honor, Thomas Sobol on behalf of plaintiffs.

MR. HOPPER: Afternoon, Your Honor, Randy Hopper on behalf of the plaintiffs.

MR. OVERTON: Good afternoon, Your Honor, Jean

1 Paul Overton on behalf of the plaintiffs.

2 MR. SHKOLNIK: Andrew Shkolnik on behalf of
3 plaintiffs as well, good afternoon.

4 MR. DRAKULICH: Good afternoon, Your Honor, Nick
5 Drakulich on behalf of the plaintiffs.

6 MR. GOLDSER: Ron Goldser for plaintiffs.

7 THE COURT: Counsel. Good afternoon and Happy New
8 Year. It's nice to see you. You've been nice enough to
9 supply me with the residuum of about a half a forest. I've
10 read and have reviewed the materials. You may proceed.

11 MS. COHEN: May it please the Court.

12 THE COURT: Counsel.

13 MS. COHEN: Good afternoon, Chief Judge Rosenbaum.

14 THE COURT: Afternoon.

15 MS. COHEN: This is Lori Cohen on behalf of
16 defendant Medtronic and, Your Honor, I'm here today on
17 Medtronic's motion to dismiss the Master Consolidated
18 Complaint for individuals. And Mr. Immelt will address the
19 other two pending motions to dismiss related to the
20 third-party payer issues and the Medicare secondary payer.
21 This first motion is for failure to state a claim under Rule
22 12(b)(6) and also for failure to plead with particularity
23 under Rule 9(b).

24 And as Your Honor well knows, this is a products
25 liability action. There are 13 counts to the Master

1 Consolidated Complaint, which I may refer to at times as the
2 MCC, which is what we did in our briefing, but all of the
3 counts and all of the variations in the individual
4 complaint, which I'm addressing, really arise from products
5 liability issues. And to state it very generally, products
6 liability is supposed to be liability for injuries that
7 result from or are caused by a defect or a malfunction in a
8 product or a device. And that's what is missing in the
9 Master Consolidated Complaint for individuals. There's
10 simply no allegation that any plaintiff, umm, any
11 plaintiff's ICD failed or that any plaintiff's ICD or device
12 manifested or exhibited the alleged defect that's described
13 by the plaintiffs in their complaint. And in order to
14 maintain this products liability action, the plaintiffs are
15 supposed to plead in their complaint and later prove either
16 that they were actually injured by an actual malfunction or
17 defect, or alternatively --

18 THE COURT: It appears we don't have any deaths.
19 Am I correct about that?

20 MS. COHEN: There are some allegations of death.

21 THE COURT: There have been allegations, but I can
22 never quite get it pinned down as to whether or not they
23 claim anybody's device malfunctioned in a fashion which
24 caused somebody to die.

25 MS. COHEN: No. As far as, from what, the

1 information I have at this point, Your Honor, and, ah, the
2 Master Consolidated Complaint, there is no allegation, and
3 that's the big thrust of our motion that any device
4 malfunctioned.

5 THE COURT: All right. But there is a claim that
6 the devices had batteries which in an entirely unpredictable
7 way can de -- lose their energy or lose their capacitance
8 capabilities on a time schedule that is unpredictable.

9 MS. COHEN: That's correct, Your Honor, but
10 actually under two separate lines of cases that we address
11 in our motion to dismiss, there's what I will call the
12 Article III standing line of cases, and then there's also
13 what we call the no-defect/no-injury line of cases, which
14 are separate lines of cases. And under both of those, we
15 believe that Medtronic's motion to dismiss can and should be
16 granted --

17 THE COURT: Did any of the cases to which you
18 allude concern implantable devices?

19 MS. COHEN: Yes, Your Honor.

20 THE COURT: Which ones?

21 MS. COHEN: And those would be under the, umm, the
22 second line of cases which would be the no-defect/no-injury
23 cases, O'Brien versus Medtronic case, there's the Larsen
24 case, there's a whole series of cases in that sequence of
25 cases that deal with implantable devices. I will admit that

1 under the standing line of cases, the Article III cases,
2 they seem to deal more with environmental issues and other
3 issues as opposed to implantable devices. But yet I think
4 if you read the cases --

5 THE COURT: Somebody once called the practice of
6 law the art of reasoning by false analogy.

7 MS. COHEN: Um hmm. I think it is an appropriate
8 analogy.

9 THE COURT: I have no idea who that was, and they
10 probably were not talking about --

11 MS. COHEN: Probably wasn't me.

12 THE COURT: And we weren't talking about this
13 case, I should make it very clear.

14 MS. COHEN: I think that either the Article III
15 standing cases or the other line of cases, either or
16 supports the argument that I'm making, which is we're here
17 today just to give Your Honor --

18 THE COURT: Let's assume for a moment that it was
19 prudential for someone to go and visit doctors periodically,
20 more frequently than perhaps once every four or five years,
21 to find out how their implantable device was working. Would
22 that represent a cost which might be compensable?

23 MS. COHEN: Well, and in fact, not to not answer
24 that question, but in fact with these devices, people go in
25 and have them checked every, you know, four or five months,

1 depending on their underlying condition, depending on the
2 doctor's advice. So it's not as if they only go in at
3 extended periods of time. They actually go in very
4 regularly anyway. And so if we're talking about the
5 category of plaintiffs who still have the device implanted
6 as opposed to the category that has it explanted, and I'll
7 talk about those numbers in a moment, in terms of
8 monitoring, their monitoring would be exactly as it is
9 anyway. In other words, there's no reason for them to go in
10 and have extra monitoring, and that's one of the allegations
11 the plaintiff makes in the Master Consolidated Complaint, at
12 least tangentially, that perhaps there would be some
13 additional monitoring required. But they're not seeking
14 medical monitoring as a separate count of their complaint,
15 as I read it, at least in the Master Consolidated Complaint.

16 THE COURT: How about having something explanted
17 at a time other than every seven or eight years?

18 MS. COHEN: And, and I think that what the numbers
19 show is that typically these will go anywhere from three to
20 seven or seven to ten years, and so what we're talking about
21 --

22 THE COURT: Typically, but unless they discharge
23 prematurely.

24 MS. COHEN: Right.

25 THE COURT: If they discharge prematurely they may

1 have to do it tomorrow.

2 MS. COHEN: And to respond to your question about
3 whether that constitutes an injury, because that is the
4 plaintiffs' claim that having in replacement surgery, that's
5 what they say in their opposition, is the injury for the
6 category of plaintiffs that had their device explanted, and
7 I'm not talking about the other category right now. But
8 they would have had that replacement surgery inevitably
9 anyway, so they had the same surgery albeit somewhat
10 earlier.

11 THE COURT: Well, hold on a minute. Wait a
12 minute. If I were to get a device implanted today, and the
13 battery was working as it was supposed to, in seven or eight
14 years I might have to have surgery again.

15 MS. COHEN: Right, and it is --

16 THE COURT: Now let's assume for a moment it's
17 minimally invasive when it's not your body.

18 MS. COHEN: Right.

19 THE COURT: It's invasive when somebody touches
20 you, it seems to me, with a scalpel. Maybe I'm wrong. You
21 want to explain to me why I'm wrong about that?

22 MS. COHEN: I agree it is invasive because it is
23 affecting physically the body, but it's what's considered --

24 THE COURT: Now, let's assume I had one of these
25 devices implanted in me and I normally have a predictable

1 seven to eight years before it has to be explanted,
2 replaced, the battery fixed, whatever it is. Okay?

3 MS. COHEN: Yes.

4 THE COURT: Now let's assume for the moment the
5 possibility either as a prophylactic that I get one removed
6 right away because I have a battery that is unpredictable as
7 to when it's going to fail, or I go in on my regular
8 every-two-month monitoring, and they say, "Oh, my goodness,
9 your battery isn't working." Okay?

10 MS. COHEN: Right.

11 THE COURT: Would I have to have then an
12 additional invasive procedure at that point?

13 MS. COHEN: Well, it would be the same procedure
14 that you would have had eventually.

15 THE COURT: But I would -- yes. But I -- now
16 let's assume that I did this on day one, and on day five I
17 found out that the battery failed. Wouldn't I over time
18 have more of them, more invasive procedures done to fix it
19 than I might have otherwise?

20 MS. COHEN: Perhaps. And, and I think that would
21 depend again on so many varied factors in terms of the
22 underlying condition --

23 THE COURT: Well, what if my doctor said it's
24 prudential for me to do that?

25 MS. COHEN: Except in this case in the Master

1 Consolidated Complaint there is no such allegation that any
2 physician made a specific recommendation, and there are
3 cases, for example the O'Brien versus Medtronic case, which
4 again is in that second line of cases we talked about, the
5 no-injury/no-defect line of cases, where that was a specific
6 requirement that the court talked about, that in that case,
7 whether there was a physician who made a valid
8 recommendation or whether that plaintiff instead on his own
9 made the decision to have the replacement surgery when it
10 wasn't medically indicated or medically recommended. And
11 that became part of that court's analysis in terms of what
12 would constitute a no-injury/no-defect analysis.

13 THE COURT: Kind of the no harm/no foul.

14 MS. COHEN: Exactly. Exactly.

15 THE COURT: Okay.

16 MS. COHEN: Umm, but in this case again, to start
17 with, there's no al -- there's no allegation, number one,
18 that there was any malfunction in any of the devices. So
19 that's our starting point. There's no allegation that there
20 was any defect. And then, in terms of these potential
21 future injuries, what the cases tell us, is that for
22 pleading purposes, which is the stage we're at now, and
23 certainly, umm, these can be addressed at a summary judgment
24 stage, and that's been discussed in the various filings, but
25 at this pleadings stage, the plaintiffs have the burden,

1 both for standing and also under the no-injury/no-defect
2 line of cases, to plead it with concreteness and
3 particularity, and so that it's not left up to possibilities
4 and conjecture and speculation and hypothetical potential
5 future injuries, and all the buzz words and adjectives that
6 are used in these cases. In this master complaint, if we
7 look at the way it's pled, because again, number one,
8 there's no pleading of the actual defect, or an actual
9 injury, and there could be that type of pleading. I mean,
10 the plaintiffs could have come forward in their consolidated
11 complaint and said, we have a category of plaintiffs, and X
12 number of them actually failed. We don't have that in this
13 complaint.

14 THE COURT: I presume the device is not the
15 plaintiffs'.

16 MS. COHEN: Yes, that's right. But there's no
17 such allegation of an actual failure or an actual injury, or
18 moreover, an actual failure that caused the actual injury,
19 which as I said earlier is what's required in a products
20 liability case, so when you don't fit within the actual
21 defect, or malfunction leading to an actual injury, then you
22 have to look at and analyze the pleading and see whether
23 this future injury, the way it's pled, is sufficient under
24 the case law, whether it be the standing cases that we can
25 talk about, or the no-defect/no-injury cases. And if you

1 look at this Master Consolidated Complaint, it's not enough,
2 it's just not sufficient. Because it's really one paragraph
3 that's most, umm, most critical on this, and it's the one
4 the plaintiffs cite to, and it talks about -- let's see if I
5 can find it -- it's paragraph 108, which is cited both by us
6 and by the plaintiffs. This, this is the paragraph where
7 they raise this potential future injury, and what they say
8 is replacement of the defective devices require surgery --

9 THE COURT: When you are reading from cold text,
10 one who already speaks quickly can speak very quickly.

11 MS. COHEN: I'm sorry.

12 THE COURT: That's okay, I have a court reporter.

13 MS. COHEN: Umm, it requires surgery that can
14 result in complications that may cause damage to the
15 patient's heart and other injuries to the patient. And so
16 that just fails to stand up under whether -- under the
17 standing test or the no-injury/no-defect test, because what
18 the standing cases tell you --

19 THE COURT: Well, take out the stuff about the
20 further injury. How about the fact that there's a second
21 surgery involved?

22 MS. COHEN: Well, and that brings me back to the
23 point that I was starting to make. If we look at the
24 category of plaintiffs, and I know these numbers I'm about
25 to give you aren't part of the motion per se, but Your Honor

1 is always interested in sort of the landscape of this
2 litigation, and so because of that, I looked at --

3 THE COURT: I read 87,000 devices in round
4 figures. 86,000?

5 MS. COHEN: 87,000. But in terms of this MDL
6 today, on January of 2007, at last count at least as of
7 today we have a total of 433 plaintiffs, just to give Your
8 Honor a sense of what we have. We have 215 of them who have
9 had the devices explanted. 196 of them have not had their
10 devices explanted, and 22 we couldn't sort it out based on
11 looking at the complaints and the information we have. What
12 that tells me, just out of interest, is that it's about
13 half, and that, as we've tracked it, has been pretty steady.

14 THE COURT: According to the statistics that
15 you've provided, it looks like we may be talking about
16 potential defect in as many as, in as few perhaps as a half
17 a percent, as many, perhaps, as two and a half percent.

18 MS. COHEN: Um hmm.

19 THE COURT: Okay? Two and a half percent of 18 --
20 of about 90,000 would be about, what, 1,800.

21 MS. COHEN: Except that I wouldn't say that the
22 explant versus no explant statistics would necessarily carry
23 over to the 87,000, and we know certainly that --

24 THE COURT: No, no, I'm not talking about
25 potential, which ones are defective. The problem is we

1 don't know which ones they are.

2 MS. COHEN: Well, what we do know, however, if you
3 look at, and this was attached as Exhibit A to my affidavit
4 that went with the motion to dismiss, what we do know is
5 that in the patient management information that went to the
6 physicians, and that is publicly available, and therefore,
7 we believe, should be considered as part of this motion to
8 dismiss, the upper limit in the second half of the device's
9 life is 1.5 percent. And so that, what that tells us is
10 that, again, looking at the standing line of cases, which I
11 know you're familiar with, that hardly constitutes the
12 standard that's necessary for future potential injuries.
13 You know, the cases talk about it needing to be a
14 significant probability of imminent injury, and if you look
15 at these statistics with 1.5 being on the upper end, that I
16 would say is in the possible speculative, hypothetical, and
17 conjecture side as opposed to the likely and imminent and
18 probable and certainly impending, which are the words
19 required under the standing line of cases. And so I think
20 actually the statistics are very supportive of this motion
21 to dismiss, in that sense, Your Honor.

22 THE COURT: All right.

23 MS. COHEN: And just again to take a step back,
24 umm, our --

25 THE COURT: Let me suggest that we take a step

1 forward. And the reason is, I still got two more motions
2 after that one.

3 MS. COHEN: Yes, Your Honor.

4 THE COURT: Okay.

5 MS. COHEN: Just to give Your Honor a sense of
6 where I guess I'm headed with this motion to dismiss, I
7 think you've seen this with the filing. We have the two
8 general arguments that apply to all 13 counts. The no
9 standing and the no defect/injury, which I'll talk about
10 briefly and then move on. And then we have some individual
11 arguments that apply to certain of the additional counts.

12 But if we talk for just a moment about again the
13 two groups of plaintiffs, because I don't want to lose that
14 thought before I move on, the first category of the
15 plaintiffs who have been explanted, as we talked about, for
16 the plaintiffs who have been explanted, what we know is that
17 they had an inevitable surgery somewhat earlier, but --

18 THE COURT: There's no such thing as an inevitable
19 surgery somewhat earlier. There's all kinds of
20 possibilities. Somebody may well have one of these heart
21 devices and get hit by a truck. Okay? Then they're not
22 going to have it explanted, true?

23 MS. COHEN: That's true.

24 THE COURT: Okay. But if somebody, it seems to
25 me, I'm going right to the core of your argument, and I

1 think it, it holds no water with me, at least it hasn't as
2 I've read it, and it's not getting clearer now.

3 MS. COHEN: Okay.

4 THE COURT: If it's explanted either as a
5 prophylactic or it's explanted because it has failed, that's
6 not an inevitable operation. It's charming to call it that,
7 but it's wrong. In an inevitable one is at the end of its
8 normal expiration of its battery life, then it has to be
9 replaced. But when you do one in between those two periods
10 of time, that's not an inevitable event. I don't understand
11 how it is. If I'm wrong, please clarify it for me.

12 MS. COHEN: For this, umm, what I'll say, 50
13 percent of the plaintiff population in this MDL, or whether
14 it's slightly more, slightly less depending on the day given
15 the numbers I said, what we know based on the pleadings is
16 that although they had this replacement surgery, and I won't
17 use the other descriptive term, although they had this
18 replacement surgery, their devices did not malfunction or
19 fail causing them to have the replacement surgery.

20 THE COURT: How could they know that?

21 MS. COHEN: But it's, but at this stage of the
22 litigation, looking at the Master Consolidated Complaint,
23 and looking at the way it's pled, which is the most
24 important issue for our purposes today, it's not pled that
25 way. It's not -- it, it is not pled in the Master

1 Consolidated Complaint that devices failed in these
2 plaintiffs and therefore they had the replacement surgery.
3 Rather, it is pled that they had the replacement surgery
4 because of information that they learned through their
5 doctors or publicly, and so what that tells us is that
6 again, especially under the no-defect/no-injury line of
7 cases, that there was no malfunction causing or resulting in
8 or leading to an injury, which is the essence of a products
9 liability case. So that's -- that's that group of
10 plaintiffs.

11 Now, if we look at the second group of plaintiffs,
12 again whether it's 50 percent, we want to call it, or 200
13 plaintiffs, we look at the second group of plaintiffs who
14 are today with their devices implanted, in place as ever
15 before. And those devices are working just as they should
16 have. There's no malfunction, there's no defect. And then
17 if we take that category of plaintiffs and look at the
18 Master Consolidated Complaint and the way it's pled, and the
19 Master Consolidated Complaint doesn't break it down as
20 smoothly as I'm talking about them, in other words, it
21 doesn't talk about Category I and Category II the way I am.
22 But if you look and try to get through the paragraphs and
23 the issues in that complaint, there's no allegation as to
24 those plaintiffs. And I guess my question to the
25 plaintiffs, to Mr. Gustafson if he's the one standing up

1 here, is what could be their damage? They are today with
2 devices that work as they should, devices that are saving
3 their lives, devices that are keeping them living the life
4 they want to live, and what possible damages could that
5 category of plaintiffs have? And again, paragraph 108,
6 which is the one that they refer to, if you look at the ones
7 they cite to, umm, if we talk about what's required under
8 the standing line of cases with the can and the may, it's
9 just not adequate under the case law. The Eighth Circuit
10 case that's most on point and really on all fours, is the
11 Shain v. Veneman case, which is the Eighth Circuit 2004
12 case. The plaintiffs in their opposition brief say any
13 heightened risk is enough to, umm, convey Article III
14 standing on plaintiffs, and we say that, that's wrong.
15 That's an incorrect and imprecise and improper reading of
16 the most important case, the Shain v. Veneman case, which
17 trails off of the U.S. Supreme Court decisions, the Lujan
18 case and then the Friends case, all of which is cited --

19 THE COURT: What was the issue, however, in Shain?

20 MS. COHEN: Well, in the Shain case, umm, in that
21 case, it's still, even though it's not an implantable
22 device, it still addresses the same issue of standing and
23 injury in fact and what constitutes injury in fact in the
24 Eighth Circuit. And the most important part I think of the
25 Shain case is that it says the increase in risk can't be

1 just any risk to confer standing on plaintiffs. But it has
2 to be a risk that is sufficient to take the probability of
3 harm out of the realm of the hypothetical speculative --

4 THE COURT: What was the fatality that caused the
5 risk in Shain?

6 MS. COHEN: I believe it was an environmental
7 issue.

8 THE COURT: Right. Why don't we move to a
9 different subject, and may I suggest we come to a
10 conclusion.

11 MS. COHEN: Okay. So again on standing, I've
12 addressed that. No-defect/no-injury cases, the most
13 important case in that would be the Briehl versus General
14 Motors case which we've cited in our brief and addressed in
15 our reply brief, so I don't need to dwell on that.

16 THE COURT: That wasn't implantable either.

17 MS. COHEN: It was not, Your Honor.

18 THE COURT: Not even close, it was --

19 MS. COHEN: It was not implantable, but I guess I
20 would differ and say I think that --

21 THE COURT: Tell me why the analogy fits.

22 MS. COHEN: Okay, first of all it was, I would say
23 it was a motion to dismiss --

24 THE COURT: Yeah, I know procedure. I'm not
25 talking about that. Tell me about the analogy between a

1 potential device that's implanted in your body which may
2 fail and cause your heart not to work and the General Motors
3 issue.

4 MS. COHEN: Well, I think in the --

5 THE COURT: What was the General Motors problem?

6 MS. COHEN: It was a brake issue.

7 THE COURT: A brake issue. Yes. What was the
8 problem? This was the stuttering brakes.

9 MS. COHEN: Right.

10 THE COURT: Yup.

11 MS. COHEN: And in that case, the issue was
12 whether, umm, the collection of plaintiffs that they were
13 trying to recover without any injury. And that's why I
14 think it's analogous to this case, and the Briehl case --

15 THE COURT: What surgery was necessary as to
16 whether the brakes were working?

17 MS. COHEN: Obviously there was no surgery that
18 was necessary.

19 THE COURT: Ah, just thought I'd ask.

20 MS. COHEN: I still think the Briehl case cites to
21 the line of cases that I'm talking about that includes cases
22 with the implantable devices, and we --

23 THE COURT: Ms. Cohen, I will accept that you have
24 completed your arguments.

25 MS. COHEN: Okay.

1 THE COURT: Were you guys able to square away
2 whatever the issues were with the newspapers?

3 MS. COHEN: Yes, umm, we are very close. We had a
4 meeting yesterday with them, and I think they were fairly
5 well satisfied. What we decided ultimately is that we would
6 prepare something in writing and send it to them, and I
7 think we're going to be able to resolve it to their
8 satisfaction and to ours.

9 THE COURT: I do appreciate it, thank you. Mr.
10 Gustafson.

11 MR. GUSTAFSON: Good afternoon, Your Honor.

12 THE COURT: Good morning -- afternoon.

13 MR. GUSTAFSON: It is --

14 THE COURT: What are the damages, and why do
15 people with nonexplanted devices have standing?

16 MR. GUSTAFSON: Well, I think --

17 THE COURT: And why don't you raise the lectern up
18 for yourself a little bit, there.

19 MR. GUSTAFSON: This button?

20 THE COURT: Yup.

21 MR. GUSTAFSON: Up would work better for me. All
22 right. I actually think, Judge, the standing is pretty, ah,
23 pretty clear-cut.

24 THE COURT: Ms. Cohen was not of a mind that
25 you're correct, so she said that's the question she wanted

1 to ask you, so I ask you.

2 MR. GUSTAFSON: I agree with you. I think if you
3 look at the standing cases, there is clear --

4 THE COURT: My mother doesn't, but let's assume
5 she does. She's got an implanted device, she's had it for
6 two years, she, ah, seems to be taking nourishment and
7 functioning on a regular daily basis. She's got what you
8 claim to be a potentially defective battery, but we don't
9 know if it is or not. What's her damages?

10 MR. GUSTAFSON: Well, on the standing issue first,
11 Judge, it's a pretty clear line of cases from Sutton through
12 St. Jude and on down, they're in our brief at page 7, that
13 say the increased risk of failure plus medical monitoring or
14 additional medical, ah --

15 THE COURT: She says there's no additional medical
16 monitoring.

17 MR. GUSTAFSON: Well, there is. In the patient
18 advisory they tell 'em to go in every three months and tell
19 'em to get a magnet and sweep it over their implant every
20 single day so they can hear the beep and make sure they're
21 still going to be alive in the morning. So I don't think
22 that's nothing. Maybe it's not a lot, but they're going to
23 the physician more often, and they're taking this --

24 THE COURT: She says people who have these devices
25 tend to go to a doctor every two to three months anyway, or

1 they're supposed to.

2 MR. GUSTAFSON: Well, I don't know about that, I
3 don't know because we don't have discovery on that yet, but
4 what we do know is their advisory said for them to have
5 regular checkups every three months.

6 THE COURT: All right, what's the damages for
7 somebody who has to wave something over an implanted device,
8 probably over here?

9 MR. GUSTAFSON: Well as to the standing issue, I
10 started with the standing issue, I think the case law is
11 clear, if you look at Sutton out of the Sixth Circuit, St.
12 Jude, your colleague, Mr. -- Judge Tunheim, they say that's
13 enough to confer the injury in fact that Article III
14 requires, that small injury. If you talk, if you get to the
15 no injury cases, there's two cases that are really on point
16 here, Judge, that aren't brake cases and aren't motorcycle
17 cases. There's Larsen out of Hawaii, which I think is on
18 all fours with this case. It's an implantable device, it's
19 a pacemaker, the issue is leads in that case, not the device
20 itself, and the O'Brien case in Wisconsin. They come out
21 opposite ways.

22 THE COURT: Now, your sister tells me I should
23 refer to O'Brien. Tell me why I should or shouldn't.

24 MR. GUSTAFSON: The reason you shouldn't refer to
25 O'Brien is because in O'Brien the physician told him not to

1 get it explanted. He told him to leave it alone, that there
2 was, that the risk of explant was higher than if he left it
3 alone. He insisted, pestered the doctor, I mean, it's
4 pretty clear from the opinion that the doctor finally gave
5 up and said, okay, I'll do it, and he got it explanted.

6 Larsen's the opposite situation. Larsen's the
7 situation where he went in, the physician said, yes, you're
8 at risk here, you got explanted, he had surgery, he had
9 complications, which I think is irrelevant, because I think
10 cutting open your chest and changing out a pacemaker or
11 defibrillator is an invasive injury regardless of whether
12 you have complications.

13 THE COURT: Your sister tells me it's inevitable.

14 MR. GUSTAFSON: Of course it's inevitable, but
15 it's just like changing the oil on my car only a little more
16 serious. If Chrysler comes out tomorrow and says I have to
17 change the oil immediately today because they put bad oil
18 in, and then every 4,000 miles hence, I gotta change it more
19 often, just so my bad -- I get this notice from Medtronic
20 through my physician that says by the way, the battery might
21 die any day, and my physician says I have to have it
22 explanted, it's only been in, it's only possible that it's
23 been in me for four years because the first battery was
24 manufactured in 2001, so the maximum is four years. So I'm
25 not even close to the end of my cycle yet. I've now

1 shortened up the cycle. I get one at four years, at the
2 most. Some of 'em could have been two days, and then I've
3 got to go seven years, seven years, seven years.

4 THE COURT: All right. Now what if your doctor
5 says, ah, got a 1.5 percent possibility of a failure, and
6 it's not a, you know, this is no fun procedure, don't worry
7 about it.

8 MR. GUSTAFSON: Well, if you believe the 1.5, that
9 may be the advice you get. I wouldn't agree that those
10 people aren't injured in any event, because I think there
11 are injuries that stem from the medical monitoring and the
12 pain and suffering. But that 1.5 percent is a misleading
13 number, and I'll tell you why it's misleading. Because
14 Medtronic doesn't go out and collect all of these devices,
15 they only collect the ones that come back to them, okay?
16 They don't go, in your analogy, when you get hit by the
17 truck, you know, they don't go and search that, ah, that
18 dead person out and pull out that, ah, defibrillator or
19 pacemaker and test it. So the ones they tested --

20 THE COURT: I presume -- I assumed, and I'm not,
21 at this point I have no data, but I make it clear, that the
22 1.5 percent is based on some sort of a statistical analysis
23 rather than a nose count.

24 MR. GUSTAFSON: It's based on a statistical
25 analysis of their bench testing, as I understand it. It's

1 not based on a statistical analysis of the population of
2 defibrillators and implantable devices that they pulled out.
3 And that's one of the things that we're going to have to
4 find out when we do discovery is whether they in fact, you
5 know there's 35, I think their last public statement on this
6 issue was August 2006, there's 34,000 of these devices that
7 have been pulled out of people --

8 THE COURT: Okay, let's talk about real injuries
9 for a minute. What real injuries have we got? I mean, for
10 the moment I will assume, since I raised it, and so did you,
11 but that explanation is an assault, a battery, and an
12 injury of some sort, ah, for the moment. But I'm talking
13 about, have you got any cases of somebody who had some
14 untoward moment as a result of a battery failure?

15 MR. GUSTAFSON: Not that I'm aware of.

16 THE COURT: All right.

17 MR. GUSTAFSON: But, but you know you need to keep
18 in mind first that we're here, we haven't done discovery on
19 that issue, but we wouldn't --

20 THE COURT: Let me put it this way: I got a
21 sample of 300 people who are carrying or had these devices
22 who are represented by no less than this armada of,
23 battalion of lawyers over here, and believe me, if there was
24 blood all over the place one of them would tell me, I think.

25 MR. GUSTAFSON: I think there are some death

1 cases. I don't know the answer to that, Your Honor.
2 Candidly. But I think there are some cases that haven't
3 been filed that have allegations of death. I think there
4 are some allegations of failure. Umm, in the last public
5 report they had 16 people who had to go immediately to their
6 physician because they felt the device warming, which is a
7 sign that it's failing, so we know --

8 THE COURT: Feel a short?

9 MR. GUSTAFSON: I don't think they feel it, I
10 think it just gets hot.

11 THE COURT: No, don't feel a short but a short
12 creates hot.

13 MR. GUSTAFSON: Right, exactly. So half the field
14 failures from the last report were people who, you know,
15 were wandering around and, you know, started getting warm
16 and stuff like that. Umm, I don't know the answer to
17 whether there's actual injuries caused by the device not,
18 ah, not working, so to speak, but I want you to understand,
19 Judge, that --

20 THE COURT: Let me back up. Your sister tells me
21 also that I need to be concerned about the, umm, sequence
22 the brakes on General Motors vehicles, nobody gets hurt with
23 one. It's too bad you got one, but they'll fix the car up
24 and everybody walks away.

25 MR. GUSTAFSON: Well, of course, I don't think

1 that case has any application here. As you know, that case
2 was not even about a defect. That case was about brakes
3 that worked perfectly, and the plaintiffs didn't like the
4 fact that it was different from the old days when you --

5 THE COURT: They chattered and the car bucks.

6 MR. GUSTAFSON: Pardon?

7 THE COURT: They chattered and the car bucks.

8 MR. GUSTAFSON: Right. You used to have to pump
9 the brakes when I was a kid because they didn't have
10 anti-lock brakes, so they thought they should make anti-lock
11 brakes that way. If you read the case, you're not even
12 alleging a product defect, you're alleging something here
13 that works. You just don't like the way it works and you
14 should have told us that. I think that case is easily put
15 aside. I think that case is easily put aside.

16 Umm, I think that Minnesota law is not clear on
17 the no injury. I think Larsen's the best case, but I think
18 you can look at why Larsen is decided the way it is, and I
19 think you can decide that Minnesota case law, Minnesota's
20 going to come down the same way when they rule on it, and
21 the three factors that the Larsen case looked at was the
22 expectations of the person that were frustrated and the
23 costs of the injury borne by the manufacturer and promotes
24 safety. Those were the three factors they looked at. If
25 you look at the Duxsbury, if I'm saying it right, 681 N.W.2d

1 at 393, that's a Minnesota appellate court case that said a
2 product is defective if the user could not have anticipated
3 the danger posed by the product. I think that's a clear
4 signal that they're going to find --

5 THE COURT: That the court of appeals --

6 MR. GUSTAFSON: That the court of appeals -- well,
7 they cite to a Supreme Court case, but not for that part of
8 the opinion. They do cite to it for the elements of product
9 defects. But again, we've alleged in our complaint that
10 this product was defective, it was defective when it left
11 Medtronic's control, and that it caused injury to the
12 plaintiffs. That's all we have to do at the 12(b) stage.
13 Evidence is going to show whether these people suffered an
14 injury. I think it's pretty clear as to the people who had
15 to have the surgery to have it replaced, I think it's pretty
16 clear as to the people who had, you know, had a heart attack
17 because it didn't work, but we don't know the answers to
18 those questions until we get a chance to do discovery.

19 THE COURT: Your sister, because of a arbitrary
20 and difficult jurist, was not able to argue her Rule 9
21 motion. Claiming that you are woefully inadequate on the
22 specifics of the fraud and misrepresentation claims. Am I
23 close?

24 MS. COHEN: That's correct, Your Honor.

25 THE COURT: See?

1 MR. GUSTAFSON: I'm not sure she said woefully
2 inadequate, but I'm certain she said Rule 9(b) didn't,
3 button didn't get pushed. Let me say that --

4 THE COURT: Some recalcitrant and difficult person
5 in a black outfit just cut her off.

6 MS. COHEN: I didn't say that.

7 THE COURT: I did.

8 MR. GUSTAFSON: I didn't mean to. Well, of course
9 I disagree. I mean, we have, ah, we have 10, 15 --

10 THE COURT: Tell me, where are the allegations of
11 fraud in this case?

12 MR. GUSTAFSON: Well, first of all, Judge, most of
13 this is fraud by omission. So it's awfully hard to say what
14 they said and when they said it, and where they said it when
15 they didn't say it. And we made pretty clear in our
16 preemption brief what we thought --

17 THE COURT: But the trouble is is you have a
18 problem here because this is a collateral that swallows the
19 whole thing. I mean, what didn't they say? They didn't say
20 a lot of things.

21 MR. GUSTAFSON: Right.

22 THE COURT: But a lot of 'em may not have anything
23 to do with this lawsuit.

24 MR. GUSTAFSON: Well, no, that's not true. We set
25 it out in the complaint and, and, umm, I'll tell you that,

1 I'll tell you the page it's on because there's so many
2 citations to the Master Consolidated Complaint it would take
3 me forever. Page 21, it takes the whole page. They knew in
4 January of 2003 that they had a battery problem, at least by
5 then; they didn't tell anyone. They knew, they made a
6 company decision that they needed a new battery by mid April
7 of 2003. Didn't tell anybody. In September of 2003 they
8 did a draft to the FDA that explained the true nature of the
9 battery problem and why they were redesigning it. They
10 covered that up. In October of 2003 when they sent the real
11 submission to the FDA. In December of 2003, they started
12 making the new battery. All the way along 2003 still
13 selling the old battery claiming they weren't sure it was
14 defective. Never saying to anybody, by the way we're
15 worried about this. All through 2004 they sold both
16 batteries, the corrected one and the old one. They had
17 reports of field failures in 2004, didn't tell the public,
18 didn't tell the physicians. Not until February 10th or 11th
19 of 2005 do they finally disclose publicly that they've been
20 selling for the better part of two -- two years and two
21 months, batteries which they suspected were defective, then
22 knew were defective, knew had the possibility of being
23 defective. And the most troubling of all is that you didn't
24 have to pick that battery. You could have picked one that
25 didn't have this possible defect from December of 2003 all

1 the way to February of 2005. That's all laid out in the
2 complaint. That sounds like a lot of who, what, where and
3 when to me.

4 THE COURT: All right.

5 MR. GUSTAFSON: My turn?

6 THE COURT: Um hmm.

7 MR. GUSTAFSON: I want to go back, I want to go
8 back one more time to the injury thing. You know, this
9 injury, this whole injury thing was caused by Medtronic.
10 They were the ones who told the physicians that this product
11 was, was potentially going to fail. They put in motion this
12 whole series of events that caused people to have this
13 invasive surgery. 34,000 people went under the knife.
14 That's the latest counts, probably more like 40 by now. I'm
15 not sure what it's like to live every day with a device
16 that's keeping you alive, wondering whether you're going to
17 wake up the next morning because you didn't have a chance to
18 swipe the battery over it because you were sleeping. I'm
19 not sure what that feels like, but I have a feeling that
20 it's not a very comfortable feeling. I have a feeling that
21 it's a very anguished kind of situation. They put that in
22 motion by, this is not something like the Star Tribune wrote
23 an article and people got all whipped up about some rumor.
24 They were the ones who said that it didn't work or might not
25 work. And the FDA, my favorite is, I showed you in the

1 preemption argument, the FDA followed that up immediately
2 with a letter that said, we agree, your product is
3 defective. Get it off the market.

4 THE COURT: That was where the "Dear Physician"
5 became a recall.

6 MR. GUSTAFSON: That's where the "Dear Physician"
7 became a recall, because the FDA decided that that product,
8 based on the information that they were told in February of
9 2005, this product is defective, and get it off the market
10 or we're going to get it off the market for you. So for
11 them to come in here and suggest somehow that there's no
12 injury because these devices haven't killed anybody yet,
13 when they put in motion this whole chain of events that
14 caused the injury, I think is a little bit disingenuous.

15 If you have other questions I'd be happy to answer
16 'em. I know you've got a long day today, so I could sit
17 down as well, but --

18 THE COURT: Well --

19 MR. GUSTAFSON: I have more. As you know, I could
20 go on.

21 THE COURT: It's always a pleasure to see you, but
22 unless you feel supremely motivated, I cannot say that your
23 briefs were masterpieces of concision, but I think they
24 covered the issues.

25 MR. GUSTAFSON: I would just like to point you to

1 one other case, Judge, and that's, ah, Femrite, I think I'm
2 saying it right, and that's the question on negligence per
3 se, and I think that case answers the question for
4 Minnesota. It says that you can use a federal statute even
5 if there's not a private right of action, and I think that
6 covers negligence per se. But I think the rest is in the
7 brief.

8 THE COURT: I thank you.

9 MR. GUSTAFSON: Thank you, Your Honor.

10 THE COURT: Mr. Immelt. Good afternoon, counsel.

11 MR. IMMELT: Good afternoon, Your Honor. I'll try
12 to just start and build off of what Ms. Cohen has already
13 argued, because there obviously is some overlap between the
14 two complaints, and I would also --

15 THE COURT: You can even build off the part that
16 that recalcitrant judge didn't let her argue.

17 MR. IMMELT: There's a few points I might be able
18 to add to the discussion. I would like at the outset to
19 note --

20 THE COURT: We're talking now about the
21 third-party payers.

22 MR. IMMELT: Exactly. In the third-party payer
23 complaint there were initially --

24 THE COURT: Sounds like happily a number of them
25 have resolved themselves.

1 MR. IMMELT: Well, four of them were dropped, and
2 they were the traditional tort-type claims: Negligence,
3 negligence per se, strict liability, misrepresentation by
4 omission wasn't mentioned, but it's not addressed anywhere
5 in the briefing, so our assumption is that was dropped as
6 well, and we think that does reflect a clear reading of the
7 case law as it, as it, we move from plaintiffs, who are, ah,
8 consumers, and the patients who got these devices, to
9 third-party payers. You go another ring outward in that
10 whole analysis of standing.

11 THE COURT: Give me a little help with this. As I
12 understand it, Medtronic has assured the recipients of these
13 devices that they will pay the excess above whatever medical
14 costs are insured for explantation. Is that correct?

15 MR. IMMELT: Ah, it's up to --

16 THE COURT: And then they'll replace it with a
17 device that doesn't have this particular battery --

18 MR. IMMELT: Based on the physician's judgment,
19 they will provide a device without cost, and then up to --

20 THE COURT: The devices, we're square on the
21 device --

22 MR. IMMELT: Yup. Up to \$2,500 of medical
23 expenses that are not otherwise covered by insurance.
24 That's the, that's the --

25 THE COURT: Then the question I will ask you is,

1 why should the insurance companies, or the healthcare
2 providers have to -- this may touch and trench on your
3 sister's observations about it being inevitable, but if
4 somebody has one done a little earlier than they might
5 otherwise have expected, why should that procedure have to
6 be paid for twice?

7 MR. IMMELT: Well --

8 THE COURT: Let's assume that I had it put in, ah,
9 you know, in October, and November, ah, let's assume I had
10 it installed in January, and in February 5, February 12,
11 whatever the date is, the FDA says, you know, we're going to
12 recall these things. Why should that insurance company have
13 to pay for that twice?

14 MR. IMMELT: What the insurance company has
15 committed itself to pay for contractually is for reasonable
16 and necessary medical care, and the issue is, has there been
17 some wrongful action that has given rise to that, the need
18 for that treatment? So your question is, in a sense,
19 supposing that the need for that additional care is brought
20 about by some wrongful legal action, which I think is very
21 much still in dispute as it relates to --

22 THE COURT: I don't say it's wrongful, but the FDA
23 said they should recall 'em.

24 MR. IMMELT: The FDA said that they should give
25 notice to the physicians who had implanted the device, the

1 information about the particular devices, but in fact the
2 FDA didn't say, you must explant those devices, the FDA said
3 you need to make available the information that physicians
4 need to make judgments about the care of these patients.
5 And you really would need to go on a case-by-case basis to
6 understand what type of thought process a physician went
7 through in deciding whether for a particular patient, it may
8 very much depend on the way that patient uses the
9 defibrillator, or the defibrillator the physician assesses
10 it is --

11 THE COURT: I will be frank to tell you I don't
12 know what you mean by how the patient uses the
13 defibrillator.

14 MR. IMMELT: Sure. Well, Your Honor, there are a
15 whole range of medical conditions that may call for the
16 implantation of the defibrillator --

17 THE COURT: Particularly the tendency to
18 fibrillate. Very few people do it volitionally.

19 MR. IMMELT: It's a question of what the condition
20 of the heart is, and whether it triggers the device, the
21 life-saving therapy that the device delivers.

22 THE COURT: I will set aside the morning
23 newspaper's recitation about the numbers of defibrillator
24 devices that are being implanted, but that's a different
25 question.

1 MR. IMMELT: But there's a whole range of medical
2 conditions, and in some of those conditions it is the device
3 is called upon regularly to provide a, a, ah, electrical
4 charge that will assure a proper heart rhythm. In other
5 cases, the device is not called on with the same degree of
6 regularity, and how often the device is called upon, which
7 the physician, because of the technology that Medtronic has
8 developed, the physician can understand that by querying the
9 device and can make a judgment about where is this device in
10 terms of the usage of the battery, because it, the more the
11 device is used, it's not just simply a matter of time, Your
12 Honor, it's also a matter of usage, that's why you have such
13 a broad span as to when these devices may need to be
14 replaced.

15 THE COURT: So -- but some of them are pacemaker
16 defibrillators. A pacemaker, these are a separate battery
17 for the defibrillation --

18 MR. IMMELT: I believe there's a single battery.

19 THE COURT: That's what I thought.

20 MR. IMMELT: But the amount of charge for a
21 pacemaker is relatively small. But, but, but pacemakers
22 are, it's the defibrillator --

23 THE COURT: Start a car with a defective set of
24 brakes?

25 MR. IMMELT: Yes, I understand, but I think again,

1 what the question is, from the third-party payer standpoint
2 is, they have committed themselves contractually to pay for
3 the reasonable and necessary medical care. They've
4 evaluated, ah --

5 THE COURT: Let me tell you where you got a
6 problem in this argument, and I have no problem telling you
7 where I think you have it. They did contract for reasonable
8 medical care. The fact that somebody might put out a device
9 that needs to be taken out on an irregular basis may not be
10 the reasonable care for which they contracted.

11 MR. IMMELT: But, Your Honor, the question is
12 whether that is a legal injury that allows them to come into
13 court directly and skip the patient who got the device and
14 say, you, Medtronic, have committed a legal wrong against
15 us, the insurance company. There's a critical step that
16 you've got to, these are still derivative claims here that
17 all depend upon the circumstance of the individual patient
18 and the judgment that the physician makes with regard to
19 those patients, and there can be a wide range of decisions
20 that are made, and it simply can't be the case that every
21 time something happens it causes an insurance company to pay
22 more for medical care that might otherwise want to or plan
23 to that that is a wrongful act by some third party.

24 THE COURT: This is not an act of God. I will
25 assume for a moment that until February 2003, or January

1 2003, up until that time when Medtronic had no basis to
2 assume that its device was not perhaps working the way they
3 had planned. Up till then I might walk with you. But
4 things get a lot shakier over time, it seems to me, counsel,
5 and tell me why I'm wrong.

6 MR. IMMELT: It, it, well, Your Honor, with regard
7 to these claims by these plaintiffs, the insurance
8 companies, I think there is, there's simply not a
9 relationship running from Medtronic to these insurance
10 companies --

11 THE COURT: First of all, I have to be careful
12 about it. I'm not exactly sure what all expenses we're
13 talking about, and I don't know how enormous they are, but
14 it just seems to me that once Medtronic, and I'm for the
15 moment only assuming that the truth of the statements in the
16 complaints, once Medtronic had information that said that
17 there was a potential defect in these devices, at that point
18 you are now selling a product that no longer can be said to
19 be, you know, we're producing a product that's really
20 working well and everybody can be happy about it, and why
21 don't you buy this on a regular basis or at least fund the
22 implantation of these, and every seven years it's gonna go
23 because things start to change at this point. Then you
24 start getting field reports, it seems to me, things are
25 starting to change a lot faster. But notice isn't being

1 given perhaps to, ah, to the FDA at this point.

2 MR. IMMELT: But that's an issue, perhaps an issue
3 with Medtronic and the FDA, although we believe --

4 THE COURT: No, I'm talking about the insurance
5 company that has to pay a second time.

6 MR. IMMELT: No, but the question when they do pay
7 a second time, it is after Medtronic has gone to the FDA and
8 has made the field action, provided the information, the FDA
9 has done its review of that field action, it's only at that
10 point in time after the FDA processed its work that there's
11 an issue about the need, or the decision to explant or
12 reimplant.

13 THE COURT: Perhaps I misunderstood him, but I
14 think Mr. Gustafson said 45,000 or 46,000 people have had
15 these things explanted.

16 MR. IMMELT: Well, I don't know whether that is
17 accurate --

18 THE COURT: Call him a liar, make it 20,000.

19 MR. IMMELT: Whatever happened happened after
20 Medtronic came forward and said here's the information, ah,
21 that we've now developed about these devices, and the
22 experience with these devices, and, and reported that to the
23 FDA and the FDA did not order the devices to be removed.
24 It, it, it said --

25 THE COURT: Have they ever ordered implantable

1 devices to be removed? That's very difficult for me to
2 imagine that even the United States of America could issue
3 an order saying all of these devices must be removed.

4 That's just not possible.

5 MR. IMMELT: Well, they certainly would, could
6 order --

7 THE COURT: Can you imagine coming into this court
8 and asking me to send a marshal out to make sure somebody
9 explants a device?

10 MR. IMMELT: No. But more important than that,
11 the FDA accepted the information that Medtronic communicated
12 to the physicians about the device. What the experience
13 was, what the failure rate was that, that had been observed,
14 and the FDA did not require any further communication on
15 that particular issue.

16 But my only point here really, as a motion to
17 dismiss phase, is have they articulated a legal claim from
18 an insurance company running to Medtronic? And on what
19 basis does that claim rise? Because it's really not on the
20 basis of a negligence or any type of tort duty. The cases
21 are clear that there isn't a tort duty that runs from a
22 manufacturer such as Medtronic and an insurance company.
23 They've acknowledged that by dropping those claims.

24 So what else is there? They have in their
25 complaint warranty claims, but the insurance company is not

1 a purchaser of these products. That the patient who
2 received the implantation may have the ability to assert a
3 warranty claim.

4 THE COURT: You know, it's interesting. Has
5 anybody taken a look at whether or not the insurance company
6 is the purchaser of an implantable device?

7 MR. IMMELT: Well, I'm not aware of any case law
8 that would suggest that. And when you think, Your Honor, of
9 the ever changing way that insurance companies and
10 healthcare is provided in this country, where your insurance
11 company one year may not be the same insurance company the
12 next year, and the plans constantly change, the idea that
13 the insurance company is somehow the owner of the device I
14 think flies in the face of experience. So I don't think
15 that they are a purchaser --

16 THE COURT: I don't think they're the owner of it.
17 The person who gets it implanted in them is the owner of it.

18 MR. IMMELT: And I don't think they are the
19 purchaser in any U.C.C. sense that would allow the extension
20 of warranties to them. So I think the warranty theories in
21 this case do not work. Again, on the basis of saying the
22 insurance companies had a direct cause of action against
23 Medtronic. Umm, what, what the other theories that they're
24 relying on --

25 THE COURT: Your sister tells me the plaintiffs

1 don't have a cause of action either. So now we've got, if
2 this is correct, you win. Because if you don't have -- they
3 don't have a claim individually, they don't have a claim for
4 the person who paid the money to buy it, we might as well go
5 home, and everybody can save a lot of money here.

6 MR. IMMELT: We would accept that.

7 (Laughter.)

8 THE COURT: I understand that is your theory, that
9 is precisely your theory, that's why I thought I'd make it
10 clear.

11 MR. IMMELT: I think what's important about the
12 third-party payer claims is they're derivative claims.
13 Those claims come into action, come into being only if
14 there's been established that there was some wrongful
15 conduct vis-a-vis the patient who got the device. That's my
16 point really is that all these claims are derivative claims,
17 and, and --

18 THE COURT: Nobody performed an operation on
19 explantation on an ERISA plan, I got that.

20 MR. IMMELT: Well, the issue, any one of these
21 explantations is why was it done? Was it, was it done for a
22 reason that is attributable in some way to something
23 Medtronic did or didn't do? Is there liability based on
24 that decision? And until that has happened with respect to
25 a particular patient, plaintiff, our position is there isn't

1 a basis for an insurance company to come into court and say,
2 you know, we're suing Medtronic directly, because we had to
3 pay more money for these particular procedures.

4 THE COURT: Is that a Rule 12 claim or are we
5 talking a damages issue?

6 MR. IMMELT: I think it's a Rule 12 claim, Your
7 Honor, because I think it goes to whether there's injury
8 that is a cognizable injury under the principles of
9 standing, remoteness, ripeness. So we, we believe it is a
10 motion that is properly brought, and that if you look at
11 what the claims are in the complaint, the traditional tort,
12 strict liability, they're out, they've dropped 'em.

13 The warranty claims, we don't think there's a
14 legal basis for asserting the warranty claim where they're
15 not a purchaser under any of the controlling Minnesota
16 precedents. That leaves us with the consumer fraud action,
17 and the, ah, the Minnesota consumer statutes, and we, ah, we
18 question whether even under those statutes a claim can be
19 asserted by an insurance company incident with the Article
20 III requirements of a direct injury, plus under Minnesota
21 there's a requirement of public benefit. In this case here,
22 the cases all were brought after there was a disclosure by,
23 by Medtronic through the February, ah, ah, communication to
24 physicians after the FDA had looked at this and made its
25 regulatory determinations, what we have now is --

1 THE COURT: Counsel, how could it conceivably have
2 been any other way?

3 MR. IMMELT: Well, the --

4 THE COURT: How could it conceivably have been any
5 other way?

6 MR. IMMELT: Exactly. So that's why this type of
7 case is not suitable for Minnesota --

8 THE COURT: Okay, this is a nonjusticiable
9 question.

10 MR. IMMELT: Pardon, Your Honor?

11 THE COURT: This is a nonjusticiable question.

12 MR. IMMELT: Right. Right.

13 THE COURT: Okay.

14 MR. IMMELT: And this is not the type of situation
15 that these consumer fraud statutes were meant to, meant to
16 address. In other words, an insurance company or a class of
17 insurance companies bring in an action where the real
18 essence is they want money to cover their outlay for what
19 they say were medical procedures that shouldn't have
20 occurred. I think the case law in this court is the
21 Behrens case, the Evangelical Union case, both stand for the
22 proposition that a damage action, ah, is not in and of
23 itself, no matter how many people were affected, no matter
24 how big the claim, that doesn't establish public benefit for
25 purposes of the Minnesota consumer fraud statute. So, so

1 that we, we, we look at each of these ways in which the
2 insurance companies attempt to come into court and assert a
3 direct claim, and none of them we think actually establish a
4 legal basis.

5 And the final claim that's out there that I wanted
6 to address was this subrogation determination. We
7 understand that an insurance company could have a claim for
8 subrogation, umm, what we don't understand is what this
9 claim is and the way it's being asserted in this --

10 THE COURT: Kind of a backwards subrogation. This
11 one says the insurance company has to pay a second time and
12 then they're subrogated for doing so.

13 MR. IMMELT: Which our view is that's, it's the
14 other way around. You first have to say there was something
15 that happened, that the patient has to establish that they
16 were the victim of some sort of tort or other misconduct
17 that involved the insurance company paying, and then there's
18 a right of subrogation.

19 THE COURT: Okay.

20 MR. IMMELT: So I think on the other aspects of
21 this we would submit on the papers, Your Honor.

22 THE COURT: Get most of the high points?

23 MR. IMMELT: I think so. I think one of the --

24 THE COURT: Ah, another high point.

25 MR. IMMELT: One other, simply unjust enrichment.

1 We think the unjust enrichment claim again is fully covered
2 by the analysis under remoteness, Article III standing, just
3 as there's not standing to assert a tort claim, there's not
4 standing to assert an unjust enrichment claim. Same, same
5 analysis.

6 THE COURT: I thank you.

7 MR. IMMELT: Thank you, Your Honor.

8 THE COURT: Counsel.

9 MR. SOBOL: Good afternoon, Your Honor, Thomas
10 Sobol from Cambridge, Massachusetts.

11 THE COURT: Mr. Sobol.

12 MR. SOBOL: Pleasure to be before you, Your Honor.

13 THE COURT: Oh, you don't have to say that.
14 Nobody believes that anyway.

15 MR. SOBOL: Only so far, Your Honor.

16 THE COURT: All right.

17 MR. SOBOL: Okay. I thought it would be helpful
18 first to just describe the kinds of third-party payers that
19 are before you in connection with the case because they,
20 just very briefly, there are three that I understand that
21 are before you, first there are insurance --

22 THE COURT: There are insurance companies; there
23 are various plans, then there's self-insurers, then there's
24 the companies who bear them themselves. You told me that in
25 the brief.

1 MR. SOBOL: Correct. And so when we look at a
2 situation, the Kinetic Company, which is from Wisconsin,
3 relatively small company that is in the, ah, machining
4 business, and it had an employee who had been with the, them
5 for a long period of time, and as a result --

6 THE COURT: Counsel, your brother tells me that
7 these are insurance companies, they bought a risk. The risk
8 is that they're going to have to pay for somebody to have a
9 medical procedure.

10 MR. SOBOL: Correct.

11 THE COURT: They are having to pay for medical
12 procedures. Good-bye. The case is over.

13 MR. SOBOL: As between, yes --

14 THE COURT: Why does that argument either not
15 prevail with you or, or carry some weight?

16 MR. SOBOL: Sure. It certainly would carry an
17 awful lot of weight if the case was an issue between the
18 insured and the insurer. Which is that is the relationship
19 between the insurance company and the insurer. That is not
20 what the law provides, particularly here in Minnesota,
21 between the insurance company and wrongdoers that cause the
22 increase of the expenses for healthcare. Ah, as Your Honor
23 knows in the Group Health case here in Minnesota from the
24 Supreme Court here, a holding squarely on point under the
25 statutes that we bring, umm, in the first counts of our

1 complaint, if an insurance company, whether it's Blue Cross
2 Blue Shield, ah, of Minnesota --

3 THE COURT: Those are similar cases.

4 MR. SOBOL: Right. It is that line and that line
5 of cases is, to be sure, a departure, in fact a marked
6 departure from the common law, and we recognize that, that's
7 why we're not pressing the common law tort claims. But the
8 state legislators here in Minnesota, and throughout the
9 United States, have stepped into and have created new law
10 which enables, in health insurance companies particularly,
11 when they are saddled with extra costs associated either
12 with increased pharmaceuticals, or a defective defibrillator
13 in this situation, or something else like that, that causes
14 healthcare premiums to go up to be able to offset the costs
15 they've otherwise incurred, and that's what we certainly
16 have here.

17 THE COURT: Well, let's, let's just talk about
18 this for a moment. I gave an easy example. I gave an
19 example of an explantation after two months, or after a
20 month. What about an explantation after five or six years?

21 MR. SOBOL: More troubling to be sure, and our
22 damages model, not our 12(b)(6) test, but our damages model,
23 must and will accommodate that. In other words, in this
24 case, taking a little bit outside the hypothetical of one
25 situation, in this situation of 87,000 devices that, ah,

1 were sold in the United States, beginning in 2001 and going
2 forward, as of now according to Medtronic, in August 2006,
3 34,000 had been explanted, within the first five years. Our
4 damage model would need to accommodate for the 34,000
5 explants that have occurred in the United States, how many
6 of those explants might have occurred at a particular period
7 of time such that you are accommodating both the reality, A,
8 of the inevitability of it occurring, number one, and number
9 two, that some of those explants may have occurred in any
10 event, but that's a damage issue, not a 12(b)(6) issue in
11 our view. And I would also comment that it's not as if,
12 umm, if Medtronic had clearly told the truth about the
13 batteries from the outset of the information that it first
14 got, people wouldn't have had a first implantation, they
15 would have had a correct or a good implantation to begin
16 with. Okay? But in any event, Your Honor's correct, a
17 damage model will need to accommodate that, and we intend to
18 do that.

19 THE COURT: All right.

20 MR. SOBOL: Umm, the, umm, causes of action --

21 THE COURT: Your brother also says that this
22 claim, if any exists, really has to be a claim made by the
23 individuals, who then have to have incurred the cost, which
24 is then a compensable cost. What you're asking for is a
25 prepayment of this, obviously for the 34,000 or 45 or, ah,

1 Mr. Gustafson's mendacious 24,000 or whatever it is, ah,
2 that's a sump cost, that's a past cost. Oughtn't there
3 perhaps to be a question about whether or not there is some
4 kind of a backwards subrogation going on here?

5 MR. SOBOL: Well, umm, taking each of those in
6 parts to make sure that I both understood Your Honor's
7 question correctly and answer it correctly, as to the 34,000
8 explants, obviously our, I've already given you the answer
9 to the previous --

10 THE COURT: That's an expended cost. Somebody's
11 already paid for that.

12 MR. SOBOL: That's correct. To the extent that
13 there would be no medical event that occurred between a
14 patient and a doctor for which there was a coverage, so, for
15 instance, there's this notice that goes out but someone
16 simply didn't go to the doctor, right, and someone has not
17 gone to the doctor, and they don't plan to go to the doctor,
18 then there is not capable for us to have injury and we don't
19 intend to model a damage on the basis of that, and I don't
20 think our complaint seeks that.

21 THE COURT: So my person who gets hit by a truck,
22 that insurance company is not going to get, or that company
23 or self-insurer or plan or whatever they've got is not going
24 to get anything.

25 MR. SOBOL: Well, ah, if they had an explant, by

1 reason of a, you know, a prophylactic explant-type
2 situation, we would be seeking damages in that situation
3 because it would have occurred at a point, obviously there
4 would have been no explant for that person, so. In the
5 in-between situations where there obviously are many tens of
6 thousands of cases, umm, A, there, by definition we will
7 have a medical event that has occurred that would not
8 otherwise have occurred, whether it's a single doctor visit
9 or multiple doctors' visits, that kind of thing, and whether
10 or not there's routine monitoring that occurs.

11 Now, answering your question candidly, have we
12 determined how we would model those damages either by
13 counting them or on an aggregate basis? No, we have not
14 done that. But in theory, if there are medical events that
15 have occurred that would not otherwise have occurred but for
16 Medtronic's failure to disclose the defect in the device,
17 that will be compensable for the 12(b)(6) purposes today.

18 THE COURT: Is it of interest to you, or of
19 interest to me, whether or not the insurance company is the
20 purchaser of this device?

21 MR. SOBOL: Some claims depend, depend on that,
22 and other claims do not. So, for instance, under --

23 THE COURT: Tell me why or how you think it is the
24 purchaser of the device.

25 MR. SOBOL: Okay. Ah, okay, just to make clear,

1 as to the consumer protection claims, particularly under
2 Minnesota and other law, you need not be a purchaser.
3 That's square law there, so we're not talking about those
4 causes of action. Instead it would pertain --

5 THE COURT: I will be frank to tell you that the
6 consumer protection does not appear to make, require a
7 purchaser, but I'm not altogether sure that it covers an
8 insurance company.

9 MR. SOBOL: Okay, well, I think that what, what it
10 is clear is that under Minnesota law, which of course most
11 of our counts and the other counts apply to, that a health
12 insurer can recover for health expenditures. Now, it may
13 not apply to all insurers, I don't know, I haven't looked
14 into that issue, but the Supreme Court in Minnesota has
15 looked into the issue as to whether a health insurer has
16 standing under that statute. It's clearly held at least
17 twice that it does. But putting that aside and turning to
18 your purchaser question, there are counts, the warranty
19 counts under the U.C.C. that would require a health insurer,
20 or any insurer, that the plaintiff needs to be a purchaser.

21 In this situation we suggest that, yes, they are a
22 purchaser. Why? Well first, they're a purchaser because
23 they are ultimately the entity that is at risk for the, the
24 product that it ends up being, you know, put through the
25 healthcare chain, number one. Second, they're a purchaser

1 because under the definitions in the U.C.C. that define
2 purchaser, they define purchaser as one who takes, and
3 there's a series of litany by lien, so --

4 THE COURT: This is, I've been fair to tell your
5 colleagues when I thought that they were really wandering
6 off into the sort of the nether area. You are joining them.

7 MR. SOBOL: Yes.

8 THE COURT: Tell me about this lien.

9 MR. SOBOL: I'll tell you about the lien --

10 THE COURT: You said the U.C.C. -- let me put it
11 this way: I think you picked lien because you couldn't fit
12 under anything else. But this doesn't fit real well.

13 MR. SOBOL: Well, it, it, it, I had a conversation
14 actually with my counsel --

15 THE COURT: I bet you didn't convince them either,
16 but go ahead.

17 MR. SOBOL: Actually they convinced me of the
18 following, Your Honor, what's actually interesting about
19 this particular fact pattern is this, the lien, which there
20 is a lien that the health insurer has for the recovery that
21 the person might get for their medical expenses associated
22 with a wrongdoing, okay? Because there is that lien, for
23 the health expenses that would be paid to the individual by
24 reason of the wrongdoing of the, of the, here the defendant
25 Medtronic, the lien that exists in this case is actually a

1 more persuasive lien to have the insurer step into this
2 claim than simply a lien on the purchase of the product
3 itself. Here the lien goes to the direct chosen action
4 that's being asserted by the health insurer. I know that
5 sounds a little bit heavy and, you know, and I'm not citing
6 any particular case --

7 THE COURT: I believe that that's true.

8 MR. SOBOL: But I accept all of that, but it is an
9 interesting observation about when you have a health insurer
10 having a lien --

11 THE COURT: It's a good lawyer's interesting
12 argument, it's an interesting lawyer's argument.

13 MR. SOBOL: Sure.

14 THE COURT: All right. Like I said, this is not
15 -- I've read this with a great deal of care, and a good deal
16 of interest, and not a great deal of belief. So okay.

17 MR. SOBOL: I understand that. In a last ditch
18 effort, though, also to perhaps bring you back a little bit
19 to this notion of a health insurer being a purchaser, there
20 has in recent years been a series of cases where the federal
21 courts and the state courts have been looking at health
22 insurers as purchasers of pharmaceutical products. And
23 because of the high rise of products and because of some
24 allegations that have been made about either antitrust or
25 consumer protection violations, there's a whole litany of

1 cases, including the Desiano case, the Third, the Second
2 Circuit decision, holding and treating health insurers as if
3 they are the purchasers of pharmaceutical products. Now, in
4 this situation, it would be not, I would suggest, too far
5 afield to go from saying, well, if it, if the courts and the
6 federal courts in the Second Circuit's, you know, not too
7 bad an authority --

8 THE COURT: It's part of the --

9 MR. SOBOL: Still part of the United States, not
10 the Eighth Circuit -- they're holding that a drug, a health
11 insurer can be a purchaser for a pharmaceutical product, why
12 is it so far afield then that the health insurer is also
13 buying a medical device too, particularly when we know the
14 economic reality is it falls on them when all is said and
15 done. So.

16 THE COURT: All right.

17 MR. SOBOL: Umm, I would just also want to address
18 briefly, because certainly the other points I think are
19 relatively straightforward, just the public benefit, then
20 the subrogation issue, then my remarks, at least my
21 voluntary remarks, are completed.

22 THE COURT: All right.

23 MR. SOBOL: As to the public benefit, two points.
24 First, it can't be the case under Minnesota law that if your
25 claim is a damages claim it can't survive under the Consumer

1 Protection Act. Because the statute itself explicitly
2 provides the ability for someone to bring a damages action
3 under the statute. And so it can't be the case that the
4 statute gives with one but takes with another, merely
5 because --

6 THE COURT: You don't know Minnesota law very
7 well.

8 (Laughter.)

9 MR. SOBOL: Right. Here in this situation, of
10 course, one need not get on too much of a high horse, but
11 we're talking about 87,000 recalled devices and 34,000
12 explants, and that is a serious public issue. And being
13 able to therefore hold a defendant, if they are ultimately
14 able by way of the proofs that the plaintiffs put forward,
15 hold them liable for explants for 34,000, umm, ah,
16 situations, that's a very important public benefit, because
17 otherwise there would be no economic incentive whatsoever
18 for a company in the future in Medtronic's shoes to do
19 anything other than what Medtronic historically did, which
20 is let's just continue on, we've got this product on the
21 shelves, we'll keep on shipping this product out, and if it
22 turns out that we're beholden to, you know, this at some
23 point in time, we'll just start shipping the new product off
24 of our shelf, but the transactional costs of the
25 replacements, we won't be responsible for. So this is a

1 public benefit, hold a company accountable. Again, we have
2 to prove it, this is just 12(b)(6), but if it gets proven
3 that it's a public benefit to hold them accountable to that.

4 Finally, as to the subrogation determination,
5 this, ah, I would suggest is novel. The kind of
6 declaratory, if you will, or injunctive kind of claim that
7 we've put forward here, but there's a twist factually in
8 this case that you rarely --

9 THE COURT: This is what I referred to I think as
10 the reverse subrogation.

11 MR. SOBOL: Right. In this situation, normally in
12 a subrogation, and we plain admit, the health insurer,
13 whoever he is, has to be able to identify by name the
14 subrogee, or --

15 THE COURT: Subrogee.

16 MR. SOBOL: Subrogee, thank you, ah, in this
17 situation is actually the defendant that has the
18 information, far more plainly than the insurers, because the
19 claims that are paid by health insurers, the claims are paid
20 on a basis that does not identify the name of the product.
21 But Medtronic does and is capable --

22 THE COURT: They know who these things, when they
23 --

24 MR. SOBOL: Exactly. And so if a function of this
25 Court is to accommodate justice for trying to find out the

1 information and find out the scope of the 34,000 and who
2 they are to be able to enable the most efficient
3 identification of that, then we have pled this, umm, reverse
4 subrogation count for that purpose.

5 THE COURT: Thank you, counsel.

6 MR. SOBOL: Thank you, Your Honor.

7 THE COURT: Mr. Immelt, do I understand you'll
8 also be speaking about the secondary payers?

9 MR. IMMELT: Yes, Your Honor. Well, we saved the
10 simple one for last.

11 THE COURT: I thank you.

12 MR. IMMELT: Umm, actually, Your Honor, I think
13 this is a pretty simple issue as it now is before the Court.
14 When this complaint was filed, I would say the Medicare
15 secondary payer theory was a novel theory. And one that had
16 been addressed in a relatively few number of courts. But
17 since, ah, we briefed this issue, the Eleventh Circuit has
18 issued --

19 THE COURT: Seems to have picked up a little.

20 MR. IMMELT: It has picked up, and I think every
21 court that has looked at this issue has pretty conclusively
22 decided that this effort to take the Medicare secondary
23 payer statute and turn it into some type of quasi
24 representation statute that allows a private person to sue
25 on the part of government is, is not well grounded in the

1 statute or in the law, and I just want to very quickly go
2 through the two broad areas. I think the Court has a sense
3 of how this statute's intended to operate, just logically
4 want to be sure that Medicare --

5 THE COURT: It is being argued that it is kind of
6 a, umm, a *qui tam* tagalong.

7 MR. IMMELT: That's the effort they're trying to
8 make. Because clearly Ms. Stubblefield has no Article III
9 standing in and of herself to assert claims on behalf of the
10 United States. Ah, so the only --

11 THE COURT: Unless Congress gave her that right.

12 MR. IMMELT: And the way Congress could give her
13 that right, and that's what the Stevens case stands for in
14 the Supreme Court, is if there's a statute that it
15 specifically assigns to a private citizen the right to bring
16 a case on behalf of the United States. And we don't have
17 that here. First of all, the statute doesn't say that.
18 The statute doesn't say that, ah, there's an action that a
19 person can bring on behalf of the United States. It simply
20 says there's a private right of action, and in the same
21 statute separately provides for the government to bring
22 actions to seek double damages and penalties.

23 But more importantly, when in the case, the, the
24 instance where everybody I think wants to point to as
25 analogous, which is the federal False Claims Act, which, ah,

1 I guess coincidentally, the key amendments to the False
2 Claims Act happened the exact same month and year as when
3 the MSP statute was amended, and that we see a completely
4 different legislative expression through the statute the,
5 that the False Claims Act clearly says, and I think I've got
6 it here -- a person, a person may bring a civil action for
7 the person and for the United States government. That's how
8 the government, or the Congress speaks when it intends to
9 make this type of assignment.

10 THE COURT: What was Senator Grassley trying to
11 tell us?

12 MR. IMMELT: Well, Senator Grassley has his own
13 perspective on this, and I think we can respect that, but I
14 don't think that an individual senator is necessarily the
15 one who can establish congressional intent when you've got
16 this type of clear legislative language.

17 And the other thing that's important to note about
18 the False Claims Act, if we're trying to say, could this be
19 a *qui tam*, should it be treated as a *qui tam*, is all the
20 protections Congress put into the False Claims Act to make
21 sure the government's interests were going to be
22 safeguarded. There has to be notice to the government, the
23 complaint has to be served on the government, has to be
24 filed under seal so the government can --

25 THE COURT: And it has to be accepted by the

1 government.

2 MR. IMMELT: Has to be accepted by the government.
3 The government has the right to control the case and decide
4 how to proceed with the case, whether to settle it, whether
5 to dismiss it, what to do, there are limits put on what
6 percentage.

7 THE COURT: Or the government can disavow it and
8 allow the person to proceed on their own claims.

9 MR. IMMELT: There's a whole mechanism under the
10 False Claims Act as to how these things work, and a whole
11 jurisprudence, but that is what you would expect if you
12 thought Congress was intending to assign to a private person
13 the right to bring claims on the part of the government.
14 There actually is no provision in this that would say what
15 percentage the person keeps versus what the government
16 keeps.

17 THE COURT: As I read it, I think they want to
18 keep it all.

19 MR. IMMELT: The statute is silent on that. So
20 that's why I think the courts have so resoundedly rejected
21 the notion that a private person has standing under Article
22 III under this statute because there hasn't been a proper
23 assignment of the claim. And I think that is the first
24 primary argument. We don't need to go beyond it, but beyond
25 that I think there is a powerful argument that the statute

1 itself, even if we put standing aside, that the private
2 cause of action isn't triggered under this circumstance
3 because it is based on a failure by a primary plan to make a
4 payment once it's been determined that they have
5 responsibility. And --

6 THE COURT: Well, if their argument is that your
7 notice that said we will take care of this, we will pay for
8 the explantation, or at least the dollar amount above the
9 cost of explantation under your coverage, we'll provide a
10 new device, makes you an insurer.

11 MR. IMMELT: But if you look at the relevant
12 language, it's not -- insurer isn't the relevant statutory
13 language, it's primary plan, which they, which the statute
14 defines as a group health plan, a workman's compensation
15 plan, a automobile or liability insurance policy, or a
16 no-fault insurance policy. Which can be self-insured. It
17 doesn't say a warranty, and the warranty here doesn't say,
18 we will cover all medical expenses associated with this,
19 this situation. The warranty says medically indicated we'll
20 make a replacement device available and pay for medical
21 expenses that are not otherwise covered. So that isn't,
22 that doesn't create any liability or responsibility for
23 other, ah, expenses that Medicare may cover.

24 Think about a gap insurance cov -- many seniors
25 have gap insurance that basically covers simply the

1 co-payment amount, and the mere fact that you had gap
2 insurance wouldn't make that company a primary payer under
3 this statute. So you really have to look at this in terms
4 of what was it that Medtronic did. It made, and I think
5 it's a good thing to make these types of benefits available
6 to, to, ah, the patients, umm, but it doesn't create
7 liability under the Medicare secondary payer statute.
8 Because there still has to be a determination of
9 responsibility that goes beyond what is in that, that, that
10 plan.

11 Umm, and then, so stat -- the statutory analysis
12 following the principles that use them *generis*, there has to
13 be a judgment, a settlement or some other means which we,
14 we'd say has to be something that clearly establishes the
15 responsibility to pay, which we do not have here. And the
16 Medtronic warranty doesn't establish any type of duty to pay
17 interest, all of the, ah, costs that might be associated
18 with, ahm, decisions made by physicians. So, umm, the case
19 law here is, ah, the very recent developing case law was all
20 in the direction of dismissing these types of claims both
21 under Article III, and alternatively under failure to state
22 a claim under 12(b)(6).

23 Unless the Court has further questions about that,
24 I would submit --

25 THE COURT: I do not, and I thank you. Mr.

1 Goldser.

2 MR. GOLDSER: Good afternoon, Your Honor, Ron
3 Goldser for plaintiffs. I'm glad Mr. Immelt has decided to
4 focus on two of the easier issues. I'm sure he's not
5 conceded the rest of them, but if he thinks those are his
6 best arguments I'm glad he's chosen those, because I think
7 those are easy to circumvent.

8 There are two fundamental principles that you need
9 to focus on. Number one, the United States government on
10 behalf of Medicare can sue Medtronic directly. The statute
11 gives them a direct --

12 THE COURT: There was no question, and that is not
13 an issue. The United States can do what it chooses.

14 MR. GOLDSER: Once the private citizen under the
15 private cause of action stands in the shoes of the United
16 States government, then the private citizen can also bring
17 the cause of action to establish responsibility to establish
18 the judgment, and that takes care of Mr. Immelt's last
19 argument. So it comes down to --

20 THE COURT: Well, what did the Eleventh Circuit
21 say about that?

22 MR. GOLDSER: The Eleventh Circuit unfortunately
23 has made a lot of errors in the decision, and the primary
24 error that it talked about --

25 THE COURT: Let me -- normally it is not for a

1 district judge to correct the errors of the Eleventh
2 Circuit. There is a different body that does that.

3 (Laughter.)

4 MR. GOLDSER: Absolutely, and happily for my
5 standing here that's the Eleventh Circuit and not the
6 Eighth, and you have the ability to make an independent
7 decision about what the statute says and about what the
8 regulations say and what Medicare in its manual has said
9 about this issue. And all of those things say that the
10 United States can bring the cause of action that private
11 citizens have the ability, and this is in the Medicare
12 manual, which we have quoted extensively in our briefing,
13 that the private citizen has the ability to bring this cause
14 of action. And much of this law developed post 2003 with
15 the Medicare Modernization Act, and with regulations that
16 were passed in 2006, and the manual which was promulgated
17 after the regulations later in 2006. So much of the case
18 law that's being relied upon is really no longer germane.
19 Much of the case law that is out there gives us the dots but
20 nobody's yet connected them. And this case connects all the
21 dots, having been given the road map of how to do so. Let
22 me tell you how --

23 THE COURT: Well, as I see it, Ms. Stubblefield
24 has foresworn any of her tort claims and all of those, those
25 are subsumed by the master complaint.

1 MR. GOLDSER: She has her own individual tort
2 claim, they are within the master client --

3 THE COURT: That's not part of the third party.

4 MR. GOLDSER: That's not part of it.

5 THE COURT: Just, just, just relax.

6 MR. GOLDSER: But --

7 THE COURT: Just relax a little. We'll all get
8 there, you'll get your shot, unless I cut you off. And I
9 get to do that unless I want --

10 MR. GOLDSER: I'll forget.

11 THE COURT: I'll remind you. Why couldn't I have
12 brought this claim?

13 MR. GOLDSER: Erin Brockovich wouldn't bring this
14 claim.

15 THE COURT: I'm not Erin Brockovich --

16 MR. GOLDSER: Because you and Erin Brockovich
17 stand in the same situation.

18 THE COURT: There's remarkable things for both of
19 us.

20 (Laughter.)

21 MR. GOLDSER: Neither one of you has Medicare, at
22 least you don't to my knowledge. Neither one of you has a
23 Medtronic device that was recalled and explanted. Neither
24 one of you had Medicare pay for that recalled and explanted
25 device. The cases that talk about standing fail because the

1 plaintiff didn't meet those circumstances. Billie
2 Stubblefield does.

3 THE COURT: All right. And was I correct in my
4 assumption that Miss Stubblefield wishes to claim all of
5 this money for herself?

6 MR. GOLDSER: Miss Stubblefield has a right to
7 make a claim for statutory damages, that's the right.
8 Medicare has a right to make a claim for double damages.
9 That's the statutory right. It is unequivocal, the language
10 of the statute does not talk about how to divide it. That's
11 going to be a negotiation or a litigation with Medicare.

12 THE COURT: Or with Miss Stubblefield who will be
13 a very wealthy woman.

14 MR. GOLDSER: Well, Medicare has a subrogation
15 right on any claim brought by an individual to recover on
16 Medicare's behalf. Medicare is going to have some claims
17 against Miss Stubblefield. Medicare --

18 THE COURT: And what, and do I understand that
19 Medicare has at least thus far not entered into the
20 litigation?

21 MR. GOLDSER: That's correct. Medicare has
22 promulgated regulations that talk about how at least
23 attorney's fees and costs are handled with regard to that.
24 So those, that piece of the puzzle is out there. How much
25 Miss Stubblefield gets is left for another day. Happily we

1 don't have to cross that bridge on this 12(b)(6) motion.

2 THE COURT: Miss Stubblefield sustained injury,
3 according to herself, but that is subsumed again in the
4 master complaint. Your argument is, she has standing
5 because she had a device, it was explanted, and that was
6 both the implantation and explantation were paid for by
7 Medicare?

8 MR. GOLDSER: Correct.

9 THE COURT: Okay.

10 MR. GOLDSER: Who better, who else under the cases
11 has the ability to bring this private cause of action?

12 THE COURT: How about Rachel Paulose?

13 MR. GOLDSER: Here's where I have trouble with the
14 Eleventh Circuit and with Mr. Immelt's argument. We've got
15 a statute that says there's a private cause of action, we
16 have a statute that says the United States can bring a
17 direct right of action. To give meaning to those two
18 statutes, what are the circumstances that allow for that?
19 The Eleventh Circuit said subrogation. An individual brings
20 his or her own claim, makes the claim for medical cost
21 reimbursement, and Medicare is subrogated. Well, that's
22 happened forever. There's no news with that. So what does
23 this private cause of action mean, that Billie Stubblefield
24 can bring her own, her own cause of action and then have to
25 pay out subrogation? That's not new news. If not that,

1 then what? What does the private cause of action part of it
2 mean? Mr. Immelt says it doesn't mean anything. The
3 slippery slope of his argument eviscerates that statute.
4 Think about where that statute is laid in the context of the
5 overall statutory scheme. (B)(ii) -- little -- capital B,
6 little Roman numerals iii and iv, give the United States the
7 direct right of action and separately gives the United
8 States a subrogation right. (B)(iii), right after it, says
9 there is a private cause of action. Well, what else can it
10 mean? Other than if the United States hasn't brought the
11 action for recovery under (B)(ii), then a private citizen
12 has the ability to do that. There are many --

13 THE COURT: You didn't make the numerical argument
14 in your brief, as I recall. I do recall the grammatical
15 argument. Weren't we concerned about the language -- there
16 was a rather extended exegesis of the grammar involved in
17 the statute too.

18 MR. GOLDSER: I do recall having made that
19 argument in the brief, but I didn't study that one for
20 purposes of today, so I'll rest on the brief for that one.

21 THE COURT: Fair enough. But this one wasn't made
22 in the brief.

23 MR. GOLDSER: Okay.

24 THE COURT: So now I got one that's X the brief
25 and one that's in the brief you're not making so I can live

1 with either one of those. All right.

2 MR. GOLDSER: If you buy off on either one of
3 those I'd be very happy.

4 THE COURT: And surprised.

5 (Laughter.)

6 MR. GOLDSER: Now you have both of them. But the
7 point is that you do have the ability to go back and press
8 the statute, the new statute and the new regulations and in
9 the case of Glover to deal with the statute that Glover did
10 not deal with. It did not deal with the direct right of
11 action. It did not deal with this notion that subrogation
12 already exists, and the only hypothetical example that the
13 Eleventh Circuit gave about when you can use MSP is for
14 purposes of subrogation. But then that completely
15 eliminates MSP as a statutory scheme, and it certainly
16 undercuts the policy that Congress and many courts, I'm
17 thinking about Brown in the Fourth Circuit now, talk about
18 why this statute exists. It's to make sure that Medicare is
19 a secondary payer, and that the primary payer, the liability
20 insurance or the self-insured, is responsible for the wrongs
21 that it commits. If the United States is not going to step
22 in, why shouldn't the private citizen be able to do that?

23 THE COURT: And in your view, the warranty that
24 Medtronic has makes them a primary on this.

25 MR. GOLDSER: There are a variety ways Med --

1 THE COURT: Is there any case law that says that
2 somebody who has a warranty becomes a primary insurer?

3 MR. GOLDSER: No one has tried that theory yet, so
4 there's no case law that says yes or no. But what there is
5 is the Medicare manual which specifically has a provision in
6 it that says a warranty claim shall be treated for recovery
7 purposes just like liability insurance, and you have that in
8 the brief.

9 THE COURT: But that's a regulation. It is
10 neither a contract nor a warranty and it's by at this point
11 somebody who's a stranger to the claim.

12 MR. GOLDSER: Well, first off, the United States
13 stands in the shoes of the individual beneficiary. That's
14 the Dow Corning case. So they're not a stranger to the
15 claim. Second, umm, there is no contract here, Medicare is
16 not a contractual entity, it's a statutory entity, so you've
17 got to throw out those contractual principles when you deal
18 with the United States having the ability to stand in the
19 shoes of the Medicare beneficiaries whose rights are
20 governed by statute, and the beneficiary does have the
21 ability at that point in time to make the warranty claim, as
22 has been made earlier today in both of the earlier motions,
23 ah, and I think that claim does succeed, and whether or not
24 the warranty is limited is not a question before you today,
25 it's a question of what's the scope of the warranty?

1 We allege the scope of the warranty is far broader
2 than Medtronic wants to limit it to, and particularly in
3 light of your comments of who is supposed to bear this loss?
4 With Medicare as the secondary payer, always seeking to make
5 sure that the primary plan pays, which is good public policy
6 and will be a hot issue in Congress as it has now just
7 convened today. Medicare should not be the one to bear this
8 loss. These statutes should be read for purposes of
9 allowing this kind of recovery from a tortfeasor or from a
10 party that stands in a quasi health insurance status; i.e.,
11 a warrantor.

12 THE COURT: At this point, on what basis is
13 Medtronic a tortfeasor?

14 MR. GOLDSER: On the basis that you've heard
15 argued earlier today. We can stand in the shoes, we, the
16 United States, we Billie Stubblefield on behalf of the
17 United States, can stand in the shoes of all of the claims
18 that have been made for purposes of tort claims as
19 individuals and as third-party payers. We get to ride those
20 coattails completely.

21 THE COURT: I thank you, counsel.

22 MR. GOLDSER: Thank you very much.

23 THE COURT: The motion filed by the defendants,
24 defendant, to dismiss the Master Consolidated Complaint, and
25 the Master Complaint concerning third-party payers is

1 denied. Defendant's motion to dismiss the Medicare
2 Secondary Payer Act claims is granted.

3 It appears to the Court, and based upon the
4 pleadings, that the plaintiff, Billie Stubblefield has filed
5 her complaint, now amended, to be the Master Consolidated
6 Complaint for Medicare as Secondary Payer, or the MSP
7 complaint. She purports to base her claim on the Medicare
8 as Secondary Payer statute 42 United States Code 1395y(b),
9 and she seeks to act as a private attorney general and asks
10 the Court to award her double damages for all the Medicare
11 expenditures incurred as a result of defendant Medtronic's
12 allegedly tortious conduct in supplying defibrillators. The
13 matter comes before the Court on the defendant's motion to
14 dismiss the MSP Master Complaint under Rule 12(b)(6), and
15 the defendant has argued that the claims should be dismissed
16 for lack of standing and for a failure to state a claim.
17 The Court grants those motions.

18 For the purposes of this motion, I treat the
19 factual allegations set forth in the MSP Master Complaint as
20 true. I cite Coons versus Mineta at 410 F.3d 1036 at 1039,
21 Eighth Circuit 2005. Defendant Medtronic obviously
22 researches, manufactures and sells implantable devices
23 including the implantable cardiac defibrillators and cardiac
24 resynchronization therapy defibrillators at issue in this
25 multidistrict litigation. In February 2005 Medtronic issued

1 a warning to physicians about the potential of batteries
2 shorting action in several of its defibrillators, and
3 offered to replace the devices and pay for some of the
4 patients' out-of-pocket expenses incurred as a result of the
5 replacement. The offer did not include reimbursement for
6 expenses covered by a patient's health insurer or Medicare.
7 The FDA classified the warning as a recall in March of 2005.

8 Plaintiff Billie Stubblefield, a Medicare
9 beneficiary, was implanted with one of the later recalled
10 devices in May 2003, and upon issuance of the recall, she
11 had her implantable cardiac defibrillator explanted and
12 replaced in March of 2005. Medicare paid the medical costs
13 for the explantation and the replacement.

14 The plaintiff's MSP Master Complaint claims to be
15 based on the Medicare as secondary payer stature. She
16 claims Medtronic is liable for all expenses paid by the
17 United States Medicare system on behalf of Medicare
18 beneficiaries, and as a result of the recalled
19 defibrillators. It is her argument that Medtronic has
20 liability as a first-party insurer, based upon its
21 declaration that it would pay certain out-of-pocket medical
22 costs involved in the recall, including the replacement of
23 the potentially faulty devices, and for providing certain
24 express and implied warranties. Based upon this declaration
25 by Medtronic, she argues that the company is somehow liable

1 as a third-party insurer for having a liability insurance
2 policy or plan or being self-insured. In her self-appointed
3 role as private attorney general under the MSP statute, it
4 is her assertion that she is personally entitled to double
5 damages for Medicare's expenditures based on Medtronic's
6 failure to meet its responsibility to make payment as a
7 first- and third-party insurer. She would support her claim
8 under MSP by alleging state tort claims of negligence,
9 strict liability, breach of implied and express warranties,
10 and misrepresentation by omission as well as certain
11 statutory claims under the Minnesota False Statement in
12 Advertisement Act, and the Minnesota Prevention of Consumer
13 Fraud Act. She files these claims on behalf of herself and
14 all other Medicare beneficiaries who have been implanted
15 with the recalled devices.

16 The defense claims that the plaintiff lacks
17 standing to sue under the MSP statute for failure to allege
18 an injury in fact, which it claims is a precedent for
19 Article III standing, and further that she fails to meet the
20 requirements for prudential standing. A federal court's
21 subject matter jurisdiction under Article III is limited to
22 actual cases and controversy. This entirely unshocking
23 statement is again reiterated in DaimlerChrysler versus Cuno
24 at 126 S. Ct. 1854 at 1860 and 61. This saying -- or this
25 past year. Standing requires a showing that a plaintiff

1 suffered injury in fact, that the cause of the injury may be
2 fairly traceable to challenged action by the defendant, and
3 the relief plaintiff seeks will redress the injury. This is
4 from Lujan versus Defenders at 504 U.S. 555 at 561, 1992.

5 The injury-in-fact alleged must be concrete and
6 particularized, either actual or imminent, and be a direct
7 injury resulting from the challenged conduct, citing McClain
8 versus American Erconomy at 424 F.3d 728 at 731, Eighth
9 Circuit 2005. These Article III standing requirements are
10 the mandate of the United States Constitution and may not be
11 overridden by Congress, or legislative action. And here I
12 cite Raines versus Byrd -- or refer to Raines versus Byrd at
13 521 U.S. 811 at 820, note 3, out of 1997.

14 Upon reviewing Miss Stubblefield's Master
15 Complaint, the Court finds she has alleged no injury in
16 fact. She paid no out-of-pocket expenses for replacement of
17 her defibrillator. The plaintiff disclaims personal injury
18 claims for her MSP -- in her MSP Master Complaint, having
19 stated in paragraph 11 that any personal claim for injury is
20 subsumed in the Master Individual Complaint. Now, in
21 response to the defendant's motion relating to the MSP
22 Master Complaint, she argues that Congress partially
23 assigned the United States' own injury-in-fact to her,
24 through the device of the MSP statute. At 42 U.S.C. Section
25 1367y(b)(3)(A). She then asks this Court to analogize the

1 private action created in the MSP statute to the assignment
2 of a claim created under the False Claim Act, *qui tam*
3 provision, that's 31 United States Code 3710. The Court
4 declines the invitation.

5 The Supreme Court has certainly found the False
6 Claims Act's partial assignment of the government's right to
7 sue confers standing upon a private citizen, a relator, who
8 brings a *qui tam* action in the name of the United States. I
9 cite Vermont, or reference Vermont Agency against The United
10 States at 529 United States 765 at 772, 2000. This is,
11 however, not the same role as that chosen by Miss
12 Stubblefield and which she seeks to play in this court.
13 Even assuming for the purpose of this motion that the
14 government has a claim to assign in this case, the Court
15 finds the analogy fails. This is because the MSP does not
16 confer standing on a private party by assignment of the
17 government's claims. The two statutory regimes are markedly
18 different. This is done by simply comparing on the first
19 levels 31 United States Code 3730 with 42 United States Code
20 1395y(b)(3)(A). The Medicare as Secondary Payer Act has
21 none of the False Claims Act's procedural provisions which
22 protect the government's interests. At the same time, the
23 MSP has no language indicating the government has partially
24 assigned any of its interests in any claim it might have to
25 a private party. And again I reference Vermont Agency at

1 773, 777 which discusses the government's partial assignment
2 of rights to *qui tam* relators and how the history of *qui tam*
3 action supports the conclusion that such relators have
4 Article III standing. If anything, a comparison of the MSP
5 and the FCA highlights how clearly Congress can evidence its
6 intent to do so when it wishes to assign a claim, as it does
7 in the False Claims Act, as opposed to the MSP.

8 The Court therefore finds Miss Stubblefield lacks
9 standing to proceed and bring her claims. As a consequence,
10 the Court lacks subject matter jurisdiction over the MSP
11 Master Complaint which must, therefore, be dismissed.

12 Even were the Court to find that the plaintiff
13 possesses Article III standing, the MSP complaint must still
14 be dismissed for failure to state a claim. When making this
15 determination, the Court is well aware of its obligation to
16 construe Miss Stubblefield's complaint in the light most
17 favorable to the nonmoving party, and may grant the motion,
18 quote, only if it is clear that no relief can be granted
19 under any set of circumstances that could be proved
20 consistent with the allegations, closing the quote, from
21 Hishon v. King & Spaulding at 467 U.S. 69 at 73, 1984.

22 The MSP does confer a private right of action for
23 double damages to a Medicare beneficiary. It does so,
24 quote, in the case of a primary plan which fails to provide
25 for primary payment or appropriate reimbursement in

1 accordance with paragraphs (1) and (2)(A), close quote, of
2 the MSP statute. That's a cite from 1395y(b)(3)(A).

3 Plaintiff's complaint alleges that Medtronic must
4 be considered a primary care, or primary plan which has or
5 had responsibility to make payment for the entire costs
6 related to its recalled defibrillators, under that statute.
7 The plaintiff asks the Court to find Medtronic to be a
8 primary plan which is obligated to reimburse Medicare based
9 on liability for its tortious conduct.

10 But at this point, the plaintiff has placed the
11 cart far ahead of the horse. This Court has not at all
12 determined that Medtronic has engaged in any tortious
13 conduct at all. Plaintiff's problem is that absent tortious
14 conduct, there's no right to any, let alone double, damages.
15 In the absence of a determination that the defendant has
16 committed a wrong, the plaintiff's claim fails to fall
17 within the private cause of action, even that which is
18 afforded by MSP at 1395y(b)(3)(A).

19 The Eleventh Circuit has squarely faced this
20 issue, and very recently. It considered whether the MSP
21 statute requires a determination of the tortfeasor's
22 responsibility as a predicate to an MSP claim in Glover
23 versus Liggett at 459 F.3d 1304, Eleventh Circuit 2006,
24 rehearing and rehearing en banc being denied at citations
25 not yet available. It occurred on October 31, 2006. It

1 found that such a predicate was required. In so finding,
2 the Eleventh Circuit affirmed a ruling that, quote, section
3 1395y(b)(3)(A) supports no private cause of action against
4 an alleged tortfeasor where the defendant's responsibility
5 to pay for healthcare expenses of a Medicare beneficiary has
6 not been already established. I cite from that case at
7 1307.

8 The plaintiff is permitted to tap dance as it
9 chooses around the Eleventh Circuit's decision, but this
10 Court finds the Eleventh Circuit has directly addressed, and
11 logically resolved the precise question at issue here.
12 While this Court sitting as it does in the Eighth Circuit is
13 not bound by the Eleventh Circuit's opinion, the Court finds
14 the Eleventh Circuit's reasoning instructive and adopts it
15 as its own. Based on this reasoning, the Court finds that a
16 demonstration of the defendant's responsibility to pay for a
17 Medicare beneficiary's expenses is a condition precedent to
18 the defendant having an obligation to reimburse Medicare.
19 That cites again the case at 1309. An allegation of tort
20 liability simply does not suffice. Until or if Medtronic
21 has demonstrated an obligation to reimburse Medicare and
22 fails to do so, there is no MSP private right of action.

23 For these reasons, the defendant's motion is
24 granted. The MSP Master Complaint is dismissed. I thank
25 you, counsel. Now I'd like to talk to counsel if I can, for

1 a few moments.

2 MR. GUSTAFSON: Thank you, Your Honor.

3 (Recess.)

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CERTIFICATE

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I, Dawn Marie Higby Hansen, do certify that the above and foregoing transcript is a true, correct, and accurate transcription of my stenographic notes taken in the above proceedings.

Dawn Marie Higby Hansen
Official Court Reporter