

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re:	)	MDL No. 05-1726
	)	(JMR/AJB)
	)	
MEDTRONIC, INC.,	)	
IMPLANTABLE DEFIBRILLATORS	)	
PRODUCTS LIABILITY LITIGATION	)	
	)	Courtroom 8 East
	)	Thursday, March 9, 2006
	)	Minneapolis, Minnesota

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H E A R I N G   O N  
P L A I N T I F F S '   M O T I O N   T O   C O M P E L  
R E S P O N S E S   T O   U N L I M I T E D  
D I S C O V E R Y   R E Q U E S T S  
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D E F E N D A N T S '   M O T I O N  
F O R   P R O T E C T I V E   O R D E R

BEFORE THE HONORABLE ARTHUR J. BOYLAN  
UNITED STATES MAGISTRATE JUDGE

TIMOTHY J. WILLETTE, RDR, CRR  
Official Court Reporter - United States District Court  
1005 United States Courthouse  
300 South Fourth Street  
Minneapolis, Minnesota 55415  
612.664.5108

## A P P E A R A N C E S :

For Plaintiffs:

MILBERG, WEISS, BERSHAD  
& SCHULMAN, LLP  
By: Mitchell M. Breit, Esquire  
One Pennsylvania Plaza  
New York, New York 10119

RHEINGOLD, VALET, RHEINGOLD,  
SHKOLNIK & MCCARTNEY, LLP  
By: Hunter J. Shkolnik, Esquire  
113 East 37th Street  
New York, New York 10016

GUSTAFSON GLUEK, PLLC  
By: Daniel E. Gustafson, Esquire  
650 Northstar East  
608 Second Avenue South  
Minneapolis, Minnesota 55402

ZIMMERMAN REED, PLLP  
By: Timothy J. Becker, Esquire  
651 Nicollet Mall - Suite 501  
Minneapolis, Minnesota 55402

JENNINGS & DRAKULICH, LLP  
By: Nicholas J. Drakulich, Esquire  
2002 Jimmy Durante Boulevard  
Suite 400  
Del Mar, California 92014

HAGENS, BERMAN, SOBOL  
& SHAPIRO, LLP  
By: Lauren Guth Barnes, Esquire  
One Main Street - Fourth Floor  
Cambridge, Massachusetts 02142

## A P P E A R A N C E S : (Continued)

For Defendants:

GREENBERG TRAURIG, LLP  
By: Lori G. Cohen, Esquire  
Jay B. Bryan, Esquire  
The Forum  
3290 Northside Parkway - Suite 400  
Atlanta, Georgia 30327

HOGAN & HARTSON, LLP  
By: Stephen J. Immelt, Esquire  
111 South Calvert Street  
Baltimore, Maryland 21202

HALLELAND, LEWIS, NILAN  
& JOHNSON, P.A.  
By: Donald M. Lewis, Esquire  
600 U.S. Bank Plaza South  
220 South Sixth Street  
Minneapolis, Minnesota 55402-4501

MEDTRONIC, INCORPORATED  
By: Barbara Ashley  
Sr. Legal Counsel - Litigation  
710 Medtronic Parkway  
Minneapolis, Minnesota 55432-5604

\* \* \* \* \*

1 (8:00 a.m.)

2 P R O C E E D I N G S

3 I N O P E N C O U R T

4 THE COURT: You may be seated.

5 This is the matter of Medtronic, Inc., Court File  
6 No. 05-1726. Let's have counsel identify themselves for the  
7 record.

8 MS. COHEN: Good morning, your Honor. Lori Cohen  
9 on behalf of Medtronic.

10 THE COURT: Good morning.

11 MR. BRYAN: Good morning, your Honor. Jay Bryan on  
12 behalf of Medtronic.

13 MR. IMMELT: Steve Immelt, Medtronic.

14 MR. LEWIS: Don Lewis on behalf of Medtronic, your  
15 Honor.

16 MR. BREIT: Mitchell Breit on behalf of Plaintiffs,  
17 your Honor.

18 MR. GUSTAFSON: Good morning, your Honor. Dan  
19 Gustafson on behalf of the plaintiffs.

20 MR. SHKOLNIK: Good morning, your Honor. Hunter  
21 Shkolnik on behalf of Plaintiffs.

22 MR. BECKER: Good morning, Judge. Tim Becker on  
23 behalf of Plaintiffs.

24 THE COURT: Good morning to all. I'm sorry.

25 MR. DRAKULICH: Just a back --

1 THE COURT: Back benchers?

2 MR. DRAKULICH: Yes. Nick Drakulich on behalf of  
3 Plaintiffs.

4 MS. BARNES: Lauren Barnes on behalf of Plaintiffs.

5 MS. ASHLEY: Barbara Ashley, in-house, Medtronic.

6 THE COURT: Good morning to all. Who wants to  
7 start?

8 MR. BREIT: Your Honor, I think if I can get  
9 started, if that please the Court.

10 THE COURT: Fine, sure.

11 MR. BREIT: Good morning, your Honor. Mitchell  
12 Breit again for the plaintiffs. We are here on Plaintiffs'  
13 motion to compel responses to discovery and in opposition to  
14 the defendants' motion for a protective order.

15 Your Honor, as a threshold matter, I think what we  
16 have is a fundamental difference here on how the plaintiffs  
17 and how the defendants view preemption law in this circuit  
18 and with the type of discovery to which plaintiffs are  
19 entitled.

20 As the Court is well aware, Judge Rosenbaum has set  
21 a schedule, an aggressive schedule. He wants us to get to  
22 trial in 18 months and he wants to hear the preemption  
23 question first. In order to do that, Plaintiffs believe that  
24 in this circuit particularly there are certain items of  
25 discovery that are absolutely necessary. As the Brooks court

1 said, a failure to comply with FDA regulations is not  
2 preempted. The defendants' point of view, I believe, which  
3 comes from case law in other districts and in other circuits,  
4 is that Plaintiffs' discovery should be narrow, and that  
5 narrowing which the defendants are positing here is such that  
6 we would only be entitled, according to the defendant, to  
7 anything that they submitted to the FDA on their PMA process  
8 and on the supplement approval. We believe that is as a  
9 matter of law incorrect, and other courts in this district,  
10 including Brooks and Judge Tunheim in St. Jude, have said  
11 that we can go beyond just what was submitted to determine  
12 whether or not the defendant complied.

13 Your Honor, we have submitted what we believe are  
14 interrogatories and requests for production that go directly  
15 to that point. The defendant has argued that we're off the  
16 reservation. But in order for us to determine what they did  
17 and what they didn't do, we've got to have a look at the  
18 background documents.

19 The plaintiffs requested broad areas of discovery  
20 and those broad areas were related to the devices, including  
21 safety surveillance, complaints and reporting. That's the  
22 first area.

23 The second area which the Court has already ordered  
24 must be produced are regulatory matters, including  
25 submissions to the FDA and foreign regulatory bodies. I

1 believe in Guidant, Judge Frank recently required the  
2 defendant to submit those documents in discovery. We're  
3 looking for design and manufacturing documents and sales and  
4 marketing and promotion documents, all which tie directly to  
5 what is required of the defendant in the approval process and  
6 in the post-approval process. There are obligations and  
7 those obligations are documented and the defendant has told  
8 us they don't want to turn them over.

9           We have had a meet-and-confer. We've made an  
10 effort to get beyond what are these broad global differences.  
11 I think you're going to hear from the defendant today that  
12 all we're entitled to are what they submitted and that what  
13 we're trying to do is to show a fraud on the FDA. Nothing  
14 could be further from the truth and the St. Jude court  
15 directly addressed that in a similar situation. What we're  
16 trying to show is that if Defendant did not comply with the  
17 FDA regulations, then our claims, our common-law claims, are  
18 not preempted.

19           Your Honor, I've prepared a chart that I'm happy to  
20 give to the Court that sets forth every single interrogatory,  
21 every request for production and our rationale behind it. I  
22 don't know that the Court wants to go there. I'm happy for  
23 us to do so if necessary.

24           What I would suggest, your Honor, is that if you  
25 could give us guidance on what areas globally the plaintiffs

1 are entitled to discover, we might be able then to sit down  
2 with the defendant with your guidance and come up with a  
3 structure that would be more effective than what we tried to  
4 do, which was to sit down and have diametrically opposed  
5 positions. I believe that with your guidance we could  
6 probably make some progress. Certainly at this point we are  
7 at loggerheads, and when you come to the table with two  
8 points of view -- and as I've said, we believe that their  
9 point of view is just off base in this circuit -- there's  
10 nowhere to go. So we would ask the Court if that's  
11 appropriate to help us with that and give us some guidance.

12 THE COURT: I think it may be appropriate despite  
13 that -- and if the Court decides to go in that particular  
14 fashion in fashioning its order or in drafting its order --  
15 to still have the charts that you have prepared at least  
16 handed to the clerk so that we can have that.

17 Have you seen those, Ms. Cohen?

18 MS. COHEN: Not yet, your Honor.

19 THE COURT: Okay. So let's make sure that  
20 Ms. Cohen gets a copy of those and we can take a look at  
21 those after I take the matter under advisement.

22 (Documents distributed to the Court and defense counsel)

23 MR. BREIT: Your Honor, just so the Court is aware,  
24 what they contain are an exact verbatim description of each  
25 request, the response by the defendant and then Plaintiffs'

1 rationale, which is included in our briefing.

2 THE COURT: Okay.

3 MR. BREIT: Your Honor, I would add that I think  
4 it's important on this question, which is a global question  
5 that I assume Defendant is going to want to take further if  
6 they can, that a full record is absolutely necessary.  
7 Plaintiffs will be, I believe, prejudiced by being limited to  
8 only what the Defendants' narrow view of what we're entitled  
9 to is. In other words -- maybe I can say this a little more  
10 artfully.

11 The defendant wants us to be constrained by case  
12 law that is supportive of their position on preemption, not  
13 in this circuit but elsewhere, and with those constraints  
14 they then want to limit the discovery as they believe it  
15 should be limited based upon case law that is not applicable  
16 here. We believe that with a more full record we will be  
17 able to at least determine whether in fact there were  
18 violations of the FDA regulations. Even the approval letter  
19 says if there are -- if you don't follow the process, then  
20 your approval is essentially invalidated. That means there's  
21 no preemption and we need to be able to discover those types  
22 of documents at least to determine what they did and what  
23 they didn't do. For Plaintiffs to be in a position where we  
24 can't see what they may have because they didn't submit it to  
25 the FDA we believe prejudices our position. So for that

1 reason, your Honor, I believe that we should be entitled to  
2 the discovery responses to those interrogatories and requests  
3 that we propounded.

4 In addition, as to the 30(b)(6) depositions, again,  
5 they are in the same broad areas, and really what we're  
6 trying to determine, again, as a threshold matter, is what  
7 they have, how they keep their documents. The defendant will  
8 tell you that they've been doing a rolling production. Thus  
9 far, as they promised, that rolling production has only to do  
10 with what they submitted to the FDA and to certain related  
11 documents that they may have in what they call their PMA file  
12 which they did not give to the FDA. What they don't -- at  
13 least what we've seen so far is, they don't tell us where  
14 they come from, who the custodian was, to what request they  
15 are responding, so we have no idea, really, what we're  
16 getting. But again, as a threshold matter, they are limiting  
17 that response. And that would include, by the way, your  
18 Honor, a limitation on manufacturing documents and I think  
19 the defendants would concede that manufacturing defects are  
20 not preempted. We're entitled to them. What they've told us  
21 is they will give us manufacturing information only as to  
22 individual plaintiffs, but we want to know and we think we're  
23 entitled to know whether there were manufacturing defects in  
24 other devices not related to these particular named  
25 plaintiffs, because that will show a pattern. Indeed, the

1 MHRA, which is the regulatory body in England, has stated  
2 that they found manufacturing defects. That's why we request  
3 foreign regulatory information. That is absolutely relevant  
4 to what they may or may not have submitted to our own  
5 regulatory agencies. So in that regard, a 30(b)(6)  
6 deposition at least to determine first what they've got, who  
7 keeps it, who's responsible for it we believe we are entitled  
8 to. They don't want us to go down that road. They have  
9 named some individuals who are responsible for the FDA  
10 submissions and of course we would want to depose them, but  
11 that is how they limit it and we do not believe we should be  
12 so limited.

13 So, your Honor, we believe that as a matter of law  
14 and as a matter of liberal discovery, which is really what is  
15 applicable here -- it's not whether or not we should follow  
16 Medtronic's point of view. It really comes down to whether  
17 or not under liberal discovery rules we should be entitled to  
18 at least look. It's not a fishing expedition. We believe  
19 that what we are seeking -- and the document requests are  
20 tailored to that information. What we are seeking goes  
21 directly to whether or not there was compliance with federal  
22 rules, and in that regard, if there is noncompliance, there  
23 is no preemption.

24 Unless the Court has any questions, I'm --

25 THE COURT: No. I know that we've been talking

1 about this thing for weeks and have got plenty of briefing on  
2 it, so I don't think you're going to find that the Court is  
3 going to have a lot of questions this morning.

4 Ms. Cohen?

5 MR. BREIT: Thank you, your Honor.

6 MS. COHEN: Thank you, your Honor.

7 Your Honor, if I may, I also have a couple of  
8 charts that I'd like to present. One of them is actually  
9 just a production chart and it just shows the documents that  
10 we've produced thus far for ease of reference. The others, I  
11 was going to actually bring a PowerPoint in and I thought it  
12 might be too disruptive this morning given that it was a  
13 discovery dispute and we were on the responding side, but I  
14 do have a printout of it and if your Honor would like to  
15 follow along with it --

16 THE COURT: Sure. That would be fine.

17 MS. COHEN: -- as opposed to us coming in here with  
18 the screens and all of that.

19 THE COURT: Do you have an extra one for the clerk?

20 MS. COHEN: Sure.

21 (Documents distributed to the Court and Plaintiffs'  
22 counsel)

23 MS. COHEN: Your Honor, to start with, I know  
24 you've had plenty of briefing on this, like you said, and I  
25 know you've seen the actual discovery requests and the notice

1 attached to the various motions probably multiple times. And  
2 when you look at the discovery requests and the notice,  
3 30(b)(6) notice of deposition, you know, I think what strikes  
4 everyone who looks at it -- and we've had multiple people  
5 take a look at it -- is, if those requests were responded to,  
6 there would be nothing left in merits discovery, and the same  
7 with the 30(b)(6) deposition notice.

8 And the other sort of general overriding feeling I  
9 have, especially last night as I read the plaintiffs'  
10 response to our motion for protective order that came in  
11 yesterday, your Honor, when I read that and saw the response  
12 with regard to particular subparts and topics of the notice  
13 of deposition, my response to that was, well, if that's what  
14 they really wanted, why didn't they just ask for that, and  
15 I'll get into some of the specifics of that. There is a  
16 disconnect between what the requests and what the 30(b)(6)  
17 deposition notice list in many subparts and multiple parts  
18 versus how they're being described. And, you know, in some  
19 ways we may be able to address some of those and reach an  
20 agreement on some of the deposition notice topics now that  
21 I've seen how they describe that.

22 As a starting point, it appears that the plaintiffs  
23 have asked for everything in the world. And just as an  
24 example of that, if I may, your Honor --

25 THE COURT: Sure.

1 MS. COHEN: -- I just bring it the Court's  
2 attention before I get into the PowerPoint.

3 This is a set of interrogatories from the Vantosh  
4 case, which is one of the cases -- and we've attached this to  
5 my affidavit as well. This is a case that was pending in  
6 Florida and became part of the initial transfer order to the  
7 MDL. This is a case that Mr. Breit and Mr. Shkolnik were  
8 handling. And I studied this last night as well as the prior  
9 discovery requests and 30(b)(6) deposition notices that  
10 preceded this multi-district litigation.

11 And if you look at this Vantosh deposition notice,  
12 reminding the Court, of course, that this was in a case where  
13 they were dealing with full merits discovery, the  
14 interrogatories that were served in this multi-district  
15 litigation is exactly the same. And so the plaintiffs took  
16 the full-merits interrogatories in Vantosh, they added the  
17 label "Preemption" in the title, and they added two  
18 additional ones. Numbers 5 and 17 were the only two  
19 different ones and we answered both of those, because one of  
20 them asked specifically who at the FDA we spoke with and that  
21 goes to the issue of preemption.

22 So as a starting point, what we feel has happened  
23 is that the plaintiffs started serving full-merits discovery,  
24 a full-merits 30(b)(6) deposition notice, and that was the  
25 starting point, and what we're trying to do is just get the

1 discovery into the limited phase that your Honor has ordered  
2 under the pretrial order.

3 Just going through just for your Honor's -- to give  
4 you a little bit of the background, on January 20th the  
5 pretrial order specifically limited discovery to preemption  
6 and any issues raised in dispositive motions. We will be  
7 filing those next week, but suffice it to say that preemption  
8 is going to be the big legal issue and I think all of us  
9 anticipated that.

10 On January 31st we did the first production and  
11 you'll see that on the chart, where we produced what we call  
12 our PMA file, which is not -- as Mr. Breit announced a moment  
13 ago -- which is not just what we submitted to the FDA. And  
14 I'll have another page that shows, but it's Medtronic's PMA  
15 file, which means it covers the root PMAs, it covers the  
16 supplements, it covers communications to and from the FDA,  
17 and I'll go through some of those categories as we move  
18 forward. It was an enormous production and we could have  
19 limited it. We decided that rather than starting off and  
20 saying, well, we'll just give what the Court ordered us to  
21 produce on February 1st, we will give the entire file to try  
22 and move this forward and that's what happened with the  
23 72,000-plus pages.

24 And then we received the plaintiffs' unlimited  
25 discovery requests, 19 interrogatories and 38 requests for

1 documents, again tracking the merits discovery that we had  
2 seen before. We have responded to eight of the  
3 interrogatories and nine of their requests, we have produced  
4 a privilege log, so we've been trying to work through the  
5 process as we believe we should in good faith in trying to  
6 comport with the Court's order.

7 We met and conferred on February 15th, and then a  
8 week later the motion to compel came in asking for full  
9 responses to the unlimited discovery.

10 And then on February 27th we received the first  
11 deposition notice. And again, I will get into that a little  
12 bit in the context of our motion for protective order, but we  
13 believe there was just no effort at all to limit the topics,  
14 again, picking up on supercopying prior deposition notices  
15 which were merits notices and bringing them into this,  
16 labeling them preemption.

17 On March 3rd we did our second rolling production.  
18 And I know that Mr. Breit said that all we want to produce  
19 were things that fall within the FDA submissions. We've  
20 actually gone beyond that already, and if you look at the  
21 production chart, what it'll show is that another 25,000  
22 pages were produced on March 3rd -- your Honor, I should make  
23 this clear.

24 These are not just documents from the PMA file, but  
25 we've actually gone through the custodial files, the

1 witnesses at Medtronic who had dealings with the FDA, who had  
2 dealings with regulatory, who had dealings with the PMA  
3 issues, and we've actually been producing documents from  
4 their individual files as part of this production and that  
5 began on March 3rd. And so again, we produced an additional  
6 25,000 pages as of March 3rd.

7           And then March 8th we continued and produced an  
8 additional 27,000 pages, which included, again, not just FDA  
9 submissions, but any memos, any e-mails, any communications  
10 between and amongst people at Medtronic. We went through and  
11 found any draft PMAs, because the plaintiffs had specifically  
12 asked for draft PMAs, so we did a broad search and went  
13 beyond the PMA submission file and the documents in the  
14 manner in which it was kept and produced the drafts.

15           We've also as of this week, because the plaintiffs  
16 requested this, produced labeling. In other words, we  
17 produced all of the various manuals that go with the specific  
18 devices, and as the Court knows, there are eight specific  
19 devices referenced in the field action notice. We have  
20 produced now manuals, also considered to be in some part  
21 labeling related to the devices. We've produced annual  
22 reports of Medtronic. We've produced product performance  
23 reports. We've produced the document retention policy that  
24 was applicable at the time, because that was a specific  
25 request that they asked for. And we've produced all of the

1 clinical information that was previously withheld on the  
2 grounds that it was confidential and listed on our privilege  
3 logs. We've gone through and redacted all of those and  
4 produced those as well.

5           If your Honor would look at the page that has --  
6 we've actually attached this as Exhibit H to my affidavit.  
7 This is a listing of everything that the first batch  
8 contained within the PMA file. And I know Plaintiffs  
9 complain that they don't know who the custodian was, they  
10 don't have an index, they don't know exactly, you know, where  
11 each document came from. We made a concerted effort to tell  
12 them that they were producing the PMA file in the exact  
13 manner in which it was kept on Medtronic's electronic file  
14 system called Documentum. We produced it with subfolders,  
15 with titles. Instead of taking all of that out, we said:  
16 "We want you to have it the way we have it" and we gave them  
17 an exact replica.

18           And so as part of their deposition taking -- and  
19 they're allowed six deponents to depose in this limited phase  
20 of discovery -- if we put up a regulatory person as our  
21 30(b)(6) deposition in some of the categories I mentioned  
22 that would be appropriate, they can certainly ask the  
23 questions of how that file was created, how it was  
24 maintained, to that person. To ask that we provide them with  
25 an index and a written explanation of how it was kept goes

1 beyond what is required of us. They can ask those questions  
2 of the 30(b)(6) witness on those regulatory PMA issues.

3 And so the next page shows -- and I've touched on  
4 this already, but the types -- not just PMA submissions as  
5 Plaintiffs would have the Court believe, but I've listed the  
6 nine categories of documents that we believe -- that  
7 Plaintiffs are entitled to that we believe are relevant to  
8 this phase of discovery. A lot of these I've mentioned  
9 already and we're also including documents regarding  
10 post-approval FDA communications. We've started producing  
11 those. We will continue producing those. We have no quarrel  
12 with producing those as listed in category 3 and we've told  
13 them that. So I think we have actually -- even though the  
14 case law is clear that preemption is a matter of law and  
15 preemption can be decided without any discovery at all, we  
16 have gone beyond the specific categories you ordered and  
17 produced all of these various types of documents.

18 The next few pages on the PowerPoint, your Honor,  
19 are just examples. It's not a complete chart and I'll skip  
20 through this quickly, but you'll have these to review much  
21 like you'll have the Plaintiffs' chart. What I've done here  
22 is, we've just listed some of the really objectionable  
23 requests and the plaintiffs' justification. And if you read  
24 through it -- and I haven't read their chart because we just  
25 received it. If you read through it, for the most part, the

1 responses that came back in Plaintiffs' motion to compel and  
2 then again last night in the response to the motion for  
3 protective order is, this information is relevant to whether  
4 Medtronic complied with the FDA. This information is  
5 relevant to determine whether the PMAs were truthful and  
6 complete. Those are the two big categories of documents that  
7 the plaintiffs are seeking and believe that we're not  
8 producing.

9           Number one, we are producing things that go beyond  
10 just the submissions.

11           Number two, the areas of inquiry that they are  
12 getting into are areas that cannot be reasonably calculated  
13 to lead to the discovery of admissible evidence, because they  
14 go to claims that undoubtedly would be preempted under the  
15 Buckman decision, which is not just this circuit as  
16 Plaintiffs would suggest. That is the unanimous Supreme  
17 Court decision that makes it clear that any claims that  
18 either are directly fraud on the FDA or may be phrased a  
19 different way but in essence a fraud on the FDA are preempted  
20 and that there's no getting around the Supreme Court  
21 decision.

22           I'll just point your Honor to the slide that says:  
23 "Plaintiffs Argue [that] Everything Relates To Preemption  
24 [and] What They're Really After Is Merits Discovery," and it  
25 comes after some of the examples. There are seven categories

1 and they're found on page 11 of the plaintiffs' motion to  
2 compel. They list for the Court and for us seven categories  
3 that they believe they're entitled to. And if you look at  
4 all of them -- and I think this is what we've done with this  
5 PowerPoint. If you look at number 1, "Whether Medtronic  
6 complied with conditions of approval," that is without a  
7 doubt fraud on the FDA and it would be impliedly preempted by  
8 the Supreme Court decision in Buckman.

9           Number 2, "Whether Medtronic made representations  
10 to FDA during the approval process," that's crystal clear in  
11 the Buckman decision that that is a fraud-on-the-FDA claim  
12 and it's preempted. Those claims have no business in this  
13 private tort lawsuit. They will be preempted and those are  
14 impliedly preempted.

15           Number 3, "Whether Medtronic concealed information  
16 relating to risks associated with the its devices," again,  
17 what they're talking about is was Medtronic truthful in its  
18 communications with the FDA that led to the original FDA  
19 approval of the devices. That's the same thing as fraud on  
20 the FDA and there is no private right of action for that.  
21 That's preempted.

22           Number 4, "Whether Medtronic failed to take  
23 appropriate action to warn patients and their physicians of  
24 dangers," that's specifically preempted by some of the cases  
25 that we cite to, the Cupek decision, the McMullen decision,

1 and it's more along the same of fraud on the FDA.

2 Number 5, 6 and 7 are the same. So all of these  
3 categories -- and I'll leave them for your Honor to read  
4 further and to look at in our briefing, but all of these  
5 categories, they're couched in more words and additional  
6 language, but no matter how you cut it, they are either fraud  
7 on the FDA or fraud on the public, neither of which lend  
8 itself to a claim that the plaintiffs can bring in this  
9 private lawsuit.

10 THE COURT: In this circuit and in this particular  
11 district, does the St. Jude case argue against your stated  
12 position this morning, at least this last -- go ahead.

13 MS. COHEN: I'm sorry. I didn't mean to cut you  
14 off, your Honor. No, the St. Jude decision is an aberrant  
15 decision and I think we addressed it in our briefing. We  
16 have the -- you know, the plaintiffs cite to St. Jude,  
17 understandably. St. Jude looks at the Goodwin decision,  
18 which is in the minority view. And I think we've discussed  
19 this at prior hearings also, but the case law is clear and  
20 the Buckman decision is clear, and our position is that the  
21 St. Jude decision was decided improperly. And if you look at  
22 cases that follow that -- for example, there are Texas  
23 District Court cases that related to the exact device with  
24 St. Jude. They came out a different way. And so we do not  
25 believe that that aberrant minority decision in St. Jude

1 should be binding precedent on this Court in light of the  
2 Supreme Court decisions and all of the circuits that follow  
3 that and the Brooks decision, because Brooks is squarely on  
4 point with the defense position in this case.

5           And the Brooks decision, I know Plaintiffs want to  
6 cite to the Brooks decision for the proposition that they're  
7 entitled to a full evidentiary record and full discovery  
8 before the preemption motion is decided. I've looked -- and  
9 I'm sure you've read the Brooks decision also and everyone in  
10 this courtroom, I'm sure, has read it several times. The  
11 Brooks decision does not state that. There is one comment in  
12 the procedural history of the case that says after discovery  
13 was completed a motion for summary judgment on preemption was  
14 filed, and that's what the plaintiffs hang their hat on to  
15 suggest to the Court that they need a full evidentiary  
16 discovery record before preemption can be decided. And we  
17 have cited in string cites and multiple citations from all  
18 over the country that preemption can and is decided without  
19 any discovery. And so in this case, when we come forward  
20 under your court's ruling and direction that already exists  
21 and produce the abundant evidence that we've produced, all of  
22 the communications with the FDA, both before approval, after  
23 approval, leading up to when the redesign took place in  
24 December of 2003, we have gone beyond what the plaintiffs  
25 would need to respond to any dispositive motions, and we

1 think that the Court has been absolutely fair with the  
2 plaintiffs in allowing this limited discovery despite the  
3 abundance of case law limiting -- you know, calling  
4 preemption a legal motion.

5 So just moving on to my next point, if I may, your  
6 Honor. Our position is that the plaintiffs are not entitled  
7 to -- and I have five categories listed here just to try and  
8 summarize it in a way that makes sense with all the pages and  
9 all the documents I know that you have.

10 Number 1, merits discovery. And I know your Honor  
11 will read the actual requests. When you read them, you know,  
12 you think about whether any products lawyer in this country  
13 could read those and other than the fact that preemption was  
14 stamped on the front page would think that they're anything  
15 other than merits discovery. So the first point is  
16 Plaintiffs should not be entitled to merits discovery right  
17 now.

18 If the preemption motion goes the way the  
19 plaintiffs think it will and should go, then that comes in  
20 the next phase, but to do that now is not only time  
21 consuming, but it's inefficient and it's contrary to the  
22 order of the Court already.

23 Number 2, the non-Marquis field action device  
24 information. I know we've talked about this with your Honor  
25 several times and this is now the subject of the motion

1 that's pending and waiting to be heard and this issue runs  
2 through all of this briefing.

3 THE COURT: Does it make a particular -- does it  
4 matter that we're talking about discovery in this motion? I  
5 know that you've got the other motion pending before Judge  
6 Rosenbaum, but here we're talking only about discovery. And  
7 on this particular subpoint, does the fact that we're talking  
8 about discovery and there are broader questions of relevancy  
9 in reference to discovery than at trial even if you were to  
10 prevail on that motion with Judge Rosenbaum make a  
11 difference?

12 MS. COHEN: Well, I think the problem is -- and  
13 we're working well with the plaintiffs on what we're calling  
14 the non-field action devices. In other words, if there are  
15 Marquis devices, but they're not within that subset with the  
16 right serial number, I think we've been able to work that  
17 out. That's not as big an issue. Also, on occasion we've  
18 seen some non-Marquis devices slip in and I think for the  
19 most part we've been able to work those issues out well also.  
20 So those two categories which is part of the motion to strike  
21 and sever I think we're okay on.

22 The problem, though, lies with the GEM and Micro  
23 Jewel issues, because we are not producing documents related  
24 to the GEM and Micro Jewel. They're not part of our  
25 collection process. We do not have any lawsuit with -- and I

1 know I've already argued this before you and this being saved  
2 for Judge Rosenbaum, but we do not have a named plaintiff in  
3 this MDL court who is claiming any injury related to Micro  
4 Jewel and GEM, and so the documents that we are producing and  
5 have collected relate to the Marquis devices, and so that's  
6 the reason that that motion becomes so important on that  
7 issue.

8           Now, I will say that the PMA production, because  
9 the GEM and Micro Jewel are part of the root PMAs, those have  
10 been addressed to that extent with the PMA production, but in  
11 terms of communications and documents between and amongst  
12 Medtronic employees regarding the GEM and Micro Jewel, that  
13 is not part of our production because we've had no reason or  
14 basis for producing them at this point other than the fact  
15 that they're mentioned in your Honor's preservation order. I  
16 don't want to make light of that, but without a named  
17 plaintiff there hasn't been a reason.

18           Number 3, the foreign regulatory information, which  
19 is another broad category that cuts across both motions and  
20 it's discussed in all the briefing. Just to respond to what  
21 Mr. Breit said earlier about this MHRA, which some would call  
22 the counterpart to the FDA, but it's different. And the  
23 issue that is being raised by the plaintiffs about this  
24 manufacturing defect from 2004 is a wholly different issue  
25 from the issue in this lawsuit related to the Marquis

1 devices.

2 And I don't know in how much depth I need to get  
3 into this with your Honor, but suffice it to say that this  
4 2004 MHRA foreign regulatory issue relates to a completely  
5 different failure mode. It's called a bent anode, which is  
6 part of the device we're talking about, and it's different  
7 from what is called in this litigation and in the field  
8 action that Medtronic took in 2005 the mesh anode failure  
9 issue. They're separate issues. And so plaintiffs want to  
10 jumble them together, mix them up and suggest that because  
11 there was an issue in 2004 regarding a manufacturing issue  
12 that the MHRA took a notice on, that again is not related to  
13 the devices and the field action and the issues before this  
14 Court in this multi-district litigation. Separate issues.  
15 It's as if, you know, the plaintiffs would pick a field  
16 action from ten years ago and say, well, we need to look at  
17 that information too. There's a year's difference, but  
18 still, it's that disconnected.

19 Number 4, medical device reports, I probably don't  
20 need to belabor the point on this. I think you've seen our  
21 position as stated in a letter. I think I argued it last  
22 time and it's in the briefs. Again, these are not admissible  
23 in a civil action. We've cited the federal regulatory  
24 language on this.

25 And then number 5, to the extent any of the

1 plaintiffs' requests and also the deposition notice call for  
2 attorney-client and work-product privileged information, I  
3 mean, we stand on our objections to those. I will tell the  
4 Court and I will tell the plaintiffs this, that we have not  
5 withheld any documents from any of our three productions thus  
6 far as outlined on this chart on the grounds of  
7 attorney-client and work product to date. When and if we do  
8 that, we're obliged to and we'll be happy to do the  
9 continuing privilege log. So we haven't held anything out,  
10 but we didn't want to waive those objections, which is why we  
11 included those in there.

12 "Preemption Is Purely A Matter Of Law." I've  
13 already touched on this and I probably don't need to dwell on  
14 this much more because you have the briefing, but the  
15 plaintiffs have not cited a single case to show that  
16 preemption is not a matter of law. They cite to that  
17 language in Brooks which I've already explained. It's just  
18 part of the procedural history.

19 Much of our briefing -- and I just have a few more  
20 comments on the motion to compel and then I'll move to the  
21 motion for protective order briefly. Much of our briefing  
22 relates to this issue of noncompliance.

23 And I think I've mentioned this already, but the  
24 way the federal regulations stand and apply as applied to  
25 medical device manufacturers and applied to the FDA, the

1 Secretary of Health and Human Services has the exclusive  
2 authority to revoke or invalidate a PMA. Plaintiffs cite to  
3 the language in one of the conditions of approval letters,  
4 and while that language may be contained therein, there is no  
5 automatic revocation. You know, in order for a PMA to be  
6 invalidated or for it to be revoked or the approval to be  
7 revoked, there would have to be a process that's specified in  
8 the federal regulations. Due notice would be accorded to the  
9 manufacturer. They'd have an opportunity to be heard. And  
10 what is being talked about there as a basis for that is where  
11 there is a significant deviation from design, manufacturing,  
12 labeling as part of the PMA, and there's some examples that  
13 are given in cases.

14 Plaintiffs in the motion they filed last night say  
15 in all of your 125,000 pages you produced, you haven't  
16 produced one document showing significant noncompliance or  
17 significant deviation, and my response to that is of course  
18 we haven't, because there is no such documentary evidence,  
19 there is no significant noncompliance or deviation, and if  
20 there was such, then that action would lie with the FDA, not  
21 with the plaintiffs in this case.

22 Now, I have a slide here that says: "What The FDA  
23 Can Do ... But Did Not [Do] As To Medtronic." The FDA has an  
24 arsenal of enforcement actions and things that they can do.  
25 They did none of those with respect to Medtronic. The FDA

1 and the Secretary, there was no attempt to invalidate or  
2 revoke the PMA approval. The PMA approval stood as it was.  
3 And the cases that talk about noncompliance and evidence of  
4 that talk about, again, significant deviations, and that is  
5 the type of information that the plaintiffs would already  
6 have in the production that we've given them, in all of the  
7 PMA file, because the PMA file goes from 1998 up through 2003  
8 and plus all of the additional information that we've given  
9 them. So the approval of the original eight devices -- and  
10 one of them was an IDE, or investigational device approval,  
11 so it was somewhat different, but the approval of those  
12 devices was at no time invalidated and all of the  
13 communications contained in the PMA file were post-approval,  
14 so they have that information.

15           There are some cases that the plaintiffs cite. One  
16 is Davenport and the other is Kozen, if I'm remembering the  
17 name correctly -- Kozma -- are the two cases. What those  
18 cases -- the plaintiffs cite to those, we cite to those.  
19 What those cases make clear is that on the issue of  
20 noncompliance, if the defendant comes forward with  
21 traceability records, in other words, individual  
22 manufacturing records, that is the type of substantial  
23 evidence that can be produced to counter any suggestion of a  
24 manufacturing defect of the type Plaintiffs mentioned would  
25 not be preempted.

1           And that's why even though we don't believe that  
2           the individual traceability, manufacturer records -- and we  
3           attached one example for your Honor from the Dudek case that  
4           I think had been pending before you previously. We gave that  
5           as an example. We have agreed to produce, as I said on one  
6           of my slides, all of the individual manufacturing device  
7           history records, traceability records, because these cases  
8           say that that's the type of evidence that can be produced to  
9           counter the suggestion that there's a manufacturing defect,  
10          so we're willing to produce that for all of the named  
11          plaintiffs and we've told the plaintiffs that.

12           I just have a couple of quotes, first one from  
13          Buckman, that says: "The FDCA leaves no doubt that it is the  
14          Federal Government rather than private litigants who are  
15          authorized to file suit for noncompliance with the medical  
16          device provisions," and that's exactly the point that we've  
17          tried to make in our briefing and I've tried to make here  
18          today and in the chart. No matter how they couch their  
19          requests, those seven categories that the plaintiffs laid out  
20          on page 11 of the motion to compel fall squarely within that,  
21          and so that evidence cannot be relevant to the inquiry of  
22          preemption that is before the Court in this limited phase of  
23          discovery.

24           The Cupek case from the Sixth Circuit, a recent  
25          decision of 2005, states: "Any claim under state law that

1 the Defendant failed to warn patients beyond warnings  
2 required by the FDA, or that the Defendant failed to recall a  
3 product without first going through PMA Supplement process  
4 would constitute state requirements different from or in  
5 addition to the requirements of the ... PMA approval  
6 process," and that's -- again, those seven categories, at  
7 least the bottom half of them, fall squarely within Buckman  
8 and Cupek, and that's why I give those particularly helpful  
9 quotes on that.

10 I'll skip the next slide and just go to the last  
11 slide. Our position on the motion to compel and discovery  
12 requests, your Honor, is that the only critical evidence  
13 regarding the preemption defense is not as Plaintiffs would  
14 suggest what we want them to have. I've heard that and seen  
15 that in briefing. Our position has always been the approval  
16 letter is sufficient and under the case law is sufficient,  
17 because this is purely a matter of law that can be decided on  
18 the four corners of the pleadings. I've made that argument  
19 before. But given the Court's ruling, given that this is now  
20 in the multi-district litigation, without waiving our  
21 position on that, you know, we agree that we will produce and  
22 that the plaintiffs are entitled to have certain evidence  
23 related to preemption. And the categories that we think are  
24 appropriate given the case law and your Honor's ruling would  
25 be:

1           Number one, information supplied to the FDA. We've  
2 either produced that or we're in the process of producing  
3 that. As we comb the custodial records, anything we find  
4 that relates to this we're in agreement we will produce,  
5 whether it's electronic or hard documents.

6           The second, approval and conditions set by the FDA  
7 during the PMA process. We have produced that and will  
8 continue to produce that as part of the PMAs, the  
9 supplements, the FDA responses. You know, we've produced in  
10 our PMA production memos about the PMA process, memos about  
11 what the FDA wants. E-mails are part of that. So they have  
12 what they're requesting, but they're looking for more.  
13 They're looking for merits.

14           And then as I say in the last point: "Though not  
15 critical to preemption," which is our position, in order to  
16 do away with the suggestion of an individual manufacturing  
17 defect of the type Mr. Breit mentioned, we're willing to  
18 produce and will produce individual manufacturing/  
19 traceability records. So that's our position on that.

20           I don't want to take up too much more of your  
21 Honor's time, but I do want to just mention --

22           THE COURT: I want to give Mr. Breit a chance to  
23 respond, because I know that we're kind of lumping all these  
24 motions together and it's my intention hopefully to hold this  
25 to an hour. As you know, I have some other matters, but I

1 think that your comments have been more or less directed to  
2 both motions and I think that's very appropriate in the  
3 Court's view.

4 MS. COHEN: Should I hold my comments --

5 THE COURT: No. I didn't mean to cut you off.

6 MS. COHEN: I'll be brief on this, your Honor.

7 THE COURT: Sure.

8 MS. COHEN: Just on the motion for protective order  
9 -- and this is where -- I guess going back to my original  
10 point, which was if that's what they wanted, why didn't they  
11 state it that way, which is how I viewed some of the writings  
12 that came in.

13 And looking at the opposition motion that came in  
14 last night from Plaintiffs, I just direct the Court's  
15 attention to -- for example, on page 5 Plaintiffs say they  
16 seek to depose Medtronic's decisionmaking representatives on  
17 Medtronic's maintenance of, search of, production of  
18 documents responsive to Plaintiffs' discovery requests. We  
19 don't have any objection to that when it's stated that way.  
20 They can depose whoever the regulatory person is. Because  
21 all of these documents relate to that process, that person  
22 would be more than happy to speak to those issues and we'd be  
23 more than happy to put a person up on that.

24 Medtronic's policies and procedures regarding  
25 regulatory reporting, submissions made to the FDA. Again, if

1 they had phrased it that way, we don't have any problem with  
2 that.

3           On page 9: "It is clear that Plaintiffs must be  
4 allowed to inquire about the documents Plaintiffs have  
5 received, the order they have been assembled in and what they  
6 represent." Again, if they depose a regulatory person under  
7 the 30(b)(6) deposition notice, they will get at all that and  
8 our position is we don't believe we should have to produce  
9 somebody in addition to that to speak to those issues,  
10 because there may not be anybody who actually can speak to  
11 those issues any better than the regulatory person we would  
12 put up.

13           And so if you look at the plaintiffs' opposition to  
14 the motion for protective order, you know, what caught my eye  
15 was that when they describe what they're really after, it's  
16 far different from the 32 categories listed in the 30(b)(6)  
17 deposition notice.

18           And so we just ask the Court, as Mr. Breit said,  
19 for guidance on that and to have clear direction in the areas  
20 that should be covered.

21           THE COURT: Okay. Thank you.

22           MR. BREIT: Thank you, your Honor.

23           I suppose you can tell from Ms. Cohen's argument  
24 that we are really at opposite ends and that is in fact why I  
25 think we need the Court's guidance.

1           One concern I have in the defendants' approach to  
2 this which I think we should be mindful of is that if we get  
3 before Judge Rosenbaum on the ultimate preemption question, I  
4 don't think the judge is going to want to have an incomplete  
5 record. And so I think that just basically in terms of  
6 discovery -- we're not talking about the preemption argument,  
7 which I think the defendant really wants to make right here  
8 as a matter of law. When we get to discovery, I think that  
9 Judge Rosenbaum is going to want to have a complete record  
10 and I believe the plaintiffs are entitled to it.

11           Again, going back to the disconnect between how we  
12 view the law and how the defendant views the law, if the  
13 Court will bear with me, I just want to read from Brooks to  
14 clarify the record. What Brooks said is:

15           "Moreover," referring to the plaintiff Brooks,  
16 "Brooks has presented no evidence of how Medica violated  
17 federal regulations, or refused to add warnings drafted by  
18 the FDA, changed FDA-approved labels, failed to meet regular  
19 reporting requirements, failed to report a known hazard to  
20 the FDA, or failed to comply with federal law in any other  
21 respect."

22           What the Brooks court is saying is, I have no  
23 record before me of that, and were there a record, then we  
24 may have reached a different conclusion.

25           The Brooks court -- the determination in Brooks was

1 based purely on what was not correctly pled. That's how they  
2 got to where they got to. Implicit in what they're saying is  
3 that the plaintiff -- had the plaintiff brought forward  
4 evidence of FDA failure to report properly, then there would  
5 be no preemption. And in fact, notwithstanding the fact that  
6 the defendant would want this Court to believe that Judge  
7 Tunheim is off the reservation in St. Jude, if I may, I'd  
8 like to read a little of that analysis with respect to  
9 Buckman.

10 "Defendant argues that plaintiffs' claims are  
11 nonetheless preempted, because to prove that the FDA was  
12 unaware of a given risk, plaintiffs will essentially have to  
13 prove fraud on the FDA -- the inquiry rejected in Buckman.  
14 Defendant apparently would have the Court read Buckman so as  
15 to preempt any and all claims in which any inquiry into the  
16 FDA regulatory process is necessary.

17 "It is difficult to accept such an expansive  
18 reading of Buckman, and such a reading would be difficult, if  
19 not impossible, to reconcile with the decision announced in  
20 Lohr. In addition" -- and this is where Judge Tunheim cites  
21 specifically to Brooks -- "the Brooks court had the benefit  
22 of the Buckman opinion, and nonetheless reasoned that the  
23 result might be different had plaintiff shown that the FDA  
24 was unaware of certain information."

25 That's precisely what we're arguing here. The

1 court went on to say that:

2 "Similarly, Brooks does not dictate a result in  
3 defendant's favor. Unlike the plaintiff in Brooks, the  
4 plaintiffs here have alleged, and have supported with  
5 specific evidence, that the FDA was not aware of the risk  
6 that the Silzone valve presented. In short, plaintiffs have  
7 raised disputed issues of material fact such that their  
8 inadequate warning and labeling claims survive summary  
9 judgment on the ground of preemption."

10 Again, implicit in what the court is saying,  
11 Plaintiffs have to have an opportunity to at least discover  
12 whether that evidence exists and that's precisely where we  
13 are with our discovery requests.

14 Briefly to get to the point about whether this is  
15 merits and whether this is preemption discovery, your Honor,  
16 there's necessarily going to be some overlap. Ms. Cohen  
17 points to an interrogatory in a case in Florida, in Vantosh.  
18 At that time, just to give a little factual background, there  
19 was already a summary judgment motion pending. We had  
20 submitted affidavits in opposition to that. It really is  
21 disingenuous to say that there was full-blown merits  
22 discovery there. Really, those interrogatories were targeted  
23 to preemption.

24 I find it interesting that the defendant in its  
25 presentation has basically said to the Court this is what the

1 law on preemption is, this is what it should be, and so  
2 plaintiffs are not entitled to these following categories  
3 because they're merits discovery. The defendant would have  
4 the Court -- even though Judge Rosenbaum has declined to rule  
5 on the motion to strike as to the Jewel and the GEM --

6 THE COURT: At least at this time.

7 MR. BREIT: At this time, but the defendant has  
8 said, well, we're still not going to give you that stuff. We  
9 don't believe that's a correct reading of where Judge  
10 Rosenbaum wants this to be.

11 THE COURT: I don't think he's declined to rule. I  
12 think he's just said that he's going to hear the motions at a  
13 later time, which is a little different.

14 MR. BREIT: It is, and perhaps that was a  
15 mischaracterization. Nevertheless, as of now, those cases  
16 are still in this litigation, and in fact, we know of at  
17 least six GEM and Micro Jewel cases that have been filed  
18 directly in this district, so there are plaintiffs with those  
19 claims and so we believe we're entitled to them.

20 Foreign regulatory information. As I pointed out,  
21 the Guidant court -- and I won't read directly from it, but  
22 Judge Frank has ruled that those documents must be produced  
23 and they are entirely relevant.

24 And as to the MHRA, the different manufacturing  
25 defect, that begs the question that goes to the heart of what

1 we're looking for. What did they say, manufacturing defect,  
2 design defect? What did they report to the MHRA? And I  
3 think that's why Judge Frank got to where he got to with that  
4 ruling. What they may have said there is entirely relevant,  
5 particularly if they didn't say it here. There are reporting  
6 requirements, FDA reporting requirements in this country that  
7 if they were violated would invalidate this preemption  
8 argument. We would like to know, if they made presentations  
9 to the foreign regulatory agencies that they did not make  
10 here, whether or not there is a violation. That's why we're  
11 entitled to them.

12 Medical device reports, essentially the same  
13 argument. We're entitled to the medical device reports, the  
14 C.F.R. says we're entitled to them, and we have set that  
15 forth entirely in our briefs.

16 As to this question of noncompliance, the  
17 defendants in fact concede in their brief at page 18 that in  
18 some instances noncompliance can support nonpreemptions of  
19 state-law claims, and if they concede that point, then I  
20 cannot for the life of me determine why we would not be able  
21 to at least determine what they have that would show  
22 noncompliance. They would have us in a box where everything  
23 that they did that they say is compliant is all we can see.  
24 We then therefore, a fortiori, cannot prove noncompliance.

25 And finally as to the manufacturing claims. Again,

1 they've said we'll give you the traceability documents as to  
2 individual plaintiffs. What we believe we're entitled to is  
3 traceability documents where devices failed and were  
4 returned. That is absolutely direct evidence of  
5 manufacturing issues that are not preempted and so we believe  
6 we'd be entitled to those as well.

7 Unless the Court has questions, I have nothing  
8 further.

9 THE COURT: No, I don't. I'm going to take this  
10 matter under advisement and I thank both sides. Off the  
11 record for just a moment.

12 (Scheduling discussion off the record)

13 (Proceedings concluded at 9:00 a.m.)

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## C E R T I F I C A T E

I, TIMOTHY J. WILLETTE, Official Court Reporter  
for the United States District Court, do hereby  
certify that the foregoing pages are a true and  
accurate transcription of my shorthand notes,  
taken in the aforementioned matter, to the best  
of my skill and ability.

TIMOTHY J. WILLETTE, RDR, CRR  
Official Court Reporter - U.S. District Court  
1005 United States Courthouse  
300 South Fourth Street  
Minneapolis, Minnesota 55415-2247  
612.664.5108

TIMOTHY J. WILLETTE, RDR, CRR  
(612) 664-5108

