

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

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

Peter Wislocki, as Trustee) Civil 05-2957 (DWF/AJB)
For the Spouse and Next of)
Kin of Louis Wislocki,) PLAINTIFF'S MOTION TO
Decedent,) REMAND
)

Plaintiff,)
)

-v-)
)

Guidant Corporation and)
Guidant Sales Corporation,)
)

Defendants.)

Patricia Machalowski,) Civil 05-2958 (DWF/AJB)
Individually and as Trustee)
For the next of kin of) PLAINTIFF'S MOTION FOR
John Machalowski,) REMAND
)

Plaintiff,)
)

-v-)
)

Guidant Corporation;)
Cardiac Pacemakers, Inc.;)
And Guidant Sales)
Corporation,)

11:35 o'clock, a.m.
March 8, 2006

Defendants.) Minneapolis, Minnesota

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BEFORE THE HONORABLE JUDGE DONOVAN W. FRANK
UNITED STATES DISTRICT COURT JUDGE
MOTION TO REMAND PROCEEDINGS

* * *

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1 (In open court.)

2 THE COURT: You may be seated. Let me find
3 out from counsel, generally, either through the calendar
4 clerk or through the lawyer they know exactly how much
5 time the Court allows for oral argument. 99 percent of
6 the time it is usually a half-hour each side, unless the
7 lawyers have called in in advance and asked for more
8 time.

9 What is the view of counsel? Then we will
10 decide if either we should hear some or all of this now
11 and proceed, because I don't have a strong view, or --
12 thank you very much.

13 Let's start with Plaintiffs' counsel.

14 MS. WIVELL: Your Honor, Martha Wivell for
15 Machalowski. I don't intend to take more than a half an
16 hour.

17 MR. BURTON: Mark Burton. I do have a
18 separate motion, but I can't imagine taking more than a
19 half-hour, either, especially since --

20 THE COURT: Would you agree with me that it
21 would be very difficult for a lawyer to distinguish the
22 two cases, that it is highly unlikely the result is
23 going to be different in one versus the other?

24 MR. BURTON: I would agree with you,
25 generally, Your Honor.

1 MS. WIVELL: I would agree also, Your Honor.

2 MR. CARPENTER: As would I, Your Honor.

3 THE COURT: What type of time do you think?

4 MR. CARPENTER: Your Honor, I don't need
5 anymore than a half-hour, probably less.

6 THE COURT: Well, my suggestion would be that
7 we do this, that we proceed with -- we will start with
8 this in mind, and then if one of you say, well, if that
9 is what you are going to do, let's go to plan B and just
10 break until 1:00, because that is certainly one
11 opposition.

12 What I would suggest is that we proceed, and
13 I don't really pay much attention on who files which
14 motion first. We can proceed with, to start with, one
15 of the arguments of the Plaintiffs, see where that
16 leaves us, and -- well, let me ask one other question.
17 We can handle these arguments without trying to minimize
18 their significance, but I think the issues are virtually
19 the same in both cases. That doesn't make the
20 individual Plaintiffs' cases and any other cases that
21 you respective counsel view are significant, but it may,
22 of course, affect the argument of Defense counsel.

23 There's one of two ways to proceed. We can
24 have one Plaintiff go, and then hear from Defendant, or
25 we can have both Plaintiffs go individually and then

1 hear from Defendant with any rebuttal. Do you have a
2 preference?

3 MR. CARPENTER: I have no preference, Your
4 Honor, either way is fine with me.

5 THE COURT: Does Plaintiffs have a
6 preference? Whether or not I hear from both of you,
7 individually, and then we will hear a response, since
8 almost everything Defense counsel is going to say is
9 going to be the same for both cases?

10 MS. WIVELL: I have no objection to that,
11 Your Honor.

12 THE COURT: Any thoughts on doing what I have
13 suggested? Let's proceed with the first argument, see
14 how everybody feels and where we are at, and then we
15 will decide if we need a short break, no break and then
16 proceed on? Is that --

17 MS. WIVELL: That is fine, Your Honor.

18 MR. BURTON: Sure.

19 THE COURT: All right, now, I will represent
20 to each of you that my Clerk and I have had a chance to
21 read all submissions made by the three parties. So, we
22 can proceed when you are ready.

23 MS. WIVELL: Thank you, Your Honor. My name
24 is Martha Wivell. And I must say that in 25 years of
25 practicing law, I hadn't even heard of Federal Officer

1 Removal jurisdiction until the Eighth Circuit decided
2 the Watson case last summer. And I had become somewhat
3 of an expert on it, having now written the briefs not
4 only in this remand motion, but also in the three light
5 cigarette cases that Judge Rosenbaum -- Judge
6 Rosenbaum --

7 THE COURT: That is better.

8 MS. WIVELL: That Judge Rosenbaum refused to
9 remand a couple of weeks ago. But, I must say, Your
10 Honor, that is was an entirely different issue. That
11 was on the question of the timeliness of Defendant's
12 removal of these motions.

13 We don't have that issue before us here
14 today. Instead, we have an issue that one Federal Judge
15 has already said stretches the Federal Officer Removal
16 to its breaking point.

17 And I am referring, of course, to the
18 decision of Judge Simon in the Parks versus Guidant
19 case, in a case virtually identical to the ones before
20 the Court this morning.

21 Defendant has removed this case only on
22 Section 1442(a). There is in the Machalowski case no
23 other basis for Federal Court removal that has been
24 asserted at this time.

25 And the Defendants have the burden of proving

1 that they can establish their right to this removal
2 jurisdiction. They have not done so. And on the basis
3 of this particular record in Machalowski, there is no
4 record.

5 I can tell the Court that in the Watson case,
6 because I am counsel in it, there are at least three
7 volumes of evidence that Philip Morris put into the
8 record about why they were entitled to Federal Officer
9 Removal jurisdiction.

10 And I think that is clear when you look at
11 the decision in Watson, which we don't agree with; but,
12 it is the law of the Eighth Circuit with regard to light
13 cigarette cases and the tobacco companies.

14 This record, if you compare the many inches
15 of evidence that Philip Morris put into the record, in
16 Mr. Machalowski's case, the Defendant put in not one bit
17 of relevant evidence, because they didn't even take this
18 case seriously enough to file a reply brief about the
19 very device that was put into Mr. Machalowski. They
20 filed a reply brief and all of their evidence and their
21 affidavits about an entirely different device.

22 But, Your Honor, I stood up a minute ago and
23 I said I don't think this essentially makes a wit of
24 difference, because even if my client had had the PRIZM
25 device, the result would be the same here.

1 THE COURT: And you know, I understand you
2 saying that, but I think given the quality of the
3 lawyers and what we are dealing with, I think what Mr.
4 Price and counsel said -- I don't really, frankly, read
5 anything whatsoever into what is a transcriptional
6 error. I mean, he did what good lawyers do. He takes
7 responsibility. I would do the same if it was me. I
8 understand what you said, but I think there is a -- that
9 is why I actually didn't think another follow-up
10 corrective brief was required, because I understood the
11 mistake, so --

12 MS. WIVELL: And that is why I say to you and
13 have stood up and said, I don't believe that there is a
14 difference between these two motions. Because Guidant
15 cannot under 1442 establish its right to removal
16 jurisdiction.

17 The U.S. Supreme Court has said that there
18 are three requirements for Federal Officer Removal
19 jurisdiction. Number one, you either have to be a
20 federal officer, or be acting under the direction of a
21 federal officer, have you to have a colorable federal
22 defense, that is the second point. And the defendant
23 must prove a causal nexus between the federal direction
24 and the exact acts which gave rise to the cause of
25 action.

1 And I am going to talk about the first and
2 the third of those elements, because we submit the
3 Defendant cannot meet the first element of the
4 requirements of Federal Officer jurisdiction.

5 I would like to turn to some of the history
6 that the Watson court put forth for this statute that
7 goes back to 1880.

8 THE COURT: Can I interrupt you one minute?

9 MS. WIVELL: Certainly.

10 (Discussion off the record.)

11 THE COURT: I'm sorry. Go ahead.

12 MS. WIVELL: No, that is all right. In 1880,
13 the Court talking about the original statute, 1442, that
14 has become 1442, was talking about Revenue officers.
15 And in the Watson case the Eighth Circuit found it
16 important to note that if their protection must be left
17 to the action of the State Court, the operations of the
18 general government may at any time be arrested at the
19 will of one of its members, the legislation of a state
20 may be unfriendly. It may affix penalties to acts done
21 under the immediate direction of the national
22 government, and in obedience to its laws. It may deny
23 the authority conferred by those laws.

24 The State Court may administer not only the
25 laws of the state, but equally Federal law in such a

1 manner as to paralyze the operations of the Government.

2 Even back then, the Court was stressing that
3 the acts that are to be done -- that are protected by
4 1442 are acts directed by the government, and which, if
5 they were tried by a State Court might paralyze the
6 operation of the government. We don't have that case
7 here. Guidant has not suggested it is a Federal
8 Officer. Instead, it says that it was acting under the
9 direction of a Federal Officer.

10 But, 1442 requires that the acts that form
11 the basis of the suit must have been performed pursuant
12 to an officer's direct orders, or to comprehensive and
13 extensive regulation. There is nothing in this record
14 that shows any evidence of direct orders. The
15 defendants have cited no case where merely complying
16 with federal regulation is sufficient to make it a
17 Federal Officer, or to be acting under the direction of
18 a Federal Officer.

19 THE COURT: And doesn't that really bring us
20 to what may be the one thing that everybody agrees on
21 today? We have got the Defense saying to both of you,
22 hey, they don't appreciate the extent to which the
23 Federal Government controls the device approval process,
24 that is one thing they say.

25 And then they say something that I think is

1 very easy for both lawyers to respond to, or to one
2 another, is, and by the way, we are under more stringent
3 controls than the defendants were in the Watson case.
4 So, either that is an accurate -- those two are accurate
5 or they are not. It seems to me that is the key.
6 Because if it is as you say it is, then there is really
7 only one thing to do, remand the case.

8 If it is as they say it is, or I don't think
9 you would concede that, actually, I think you would say,
10 well, even if it is as they say it does, but we do
11 appreciate the extent to which we are controlled, then
12 the case should not be remanded. But, I mean, what you
13 just touched on, that is, I think, the issue.

14 MS. WIVELL: I agree with you, Your Honor. I
15 think that that is the essence of this case. And
16 whether, because it is their burden, whether they have
17 shown the regulation plus, which the Eighth Circuit and
18 several other courts say is required, it is not enough
19 merely to regulate. There are lots and lots and lots of
20 different industries which are subjected to Federal
21 regulation.

22 And the Court has said, and the Eighth
23 Circuit has said, mere participation in a regulated
24 industry is insufficient to support removal, unless the
25 challenged conduct is closely linked to detailed and

1 specific regulations.

2 THE COURT: Agreed.

3 MS. WIVELL: That is why I said, Your Honor,
4 in the Philip Morris cases, there was a stack of
5 evidence of interaction with the Federal Trade
6 Commission -- it is why I put the graph in my reply
7 brief, to show what the Eighth Circuit had before it
8 that they found was sufficient in that unusual case, a
9 case where the Defendant was neither an agent, nor an
10 employee, or acting under contract.

11 And they said, Judge, in -- the concurrent
12 said, that is where you usually find Federal Officer
13 Removal jurisdiction. But, here in Watson, we have all
14 of these things, a very unusual, unprecedented
15 involvement.

16 THE COURT: You liked all of the testing, I
17 think, that was --

18 MS. WIVELL: Exactly. There was actual
19 testing there. As we put forward in our reply brief,
20 there is no testing here. The FDA doesn't do that. And
21 Defendants paint with too broad a brush.

22 They are trying to say, well, everything we
23 do is regulated. That may be true, but the FDA doesn't
24 test, it doesn't tell them how to design, it doesn't
25 tell them how to manufacture. Basically, it doesn't

1 even tell them what to label. In fact, Your Honor, the
2 Federal Regulations allow them to change the
3 regulations, I'm sorry, to change their labeling without
4 even telling or getting permission from the FDA
5 beforehand. Under 21 CFR 814.39(d)(2) allows those
6 changes.

7 So, we have a substantially different
8 situation here than we had in Watson. We have a
9 substantially different situation than faced the Court
10 in the MTBE Litigation, where the Federal Government
11 required the manufacturers of the gasoline to use MTBE.
12 There is a substantially different situation than the
13 Agent Orange cases, where a contract with the Government
14 allowed the Government to establish the formula for
15 Agent Orange. The Government established the labeling
16 for Agent Orange. The Government knew more about Agent
17 Orange than the manufacturers and wouldn't allow them to
18 change their labels. That is not what we have here,
19 Your Honor.

20 Now, the FDA Regulation process may be
21 rigorous, Lohr versus Medtronic has said a PMA process
22 imposes no specific mandate on manufacturing or
23 procedures. The FDA didn't tell Guidant how to act. It
24 directed how to design or manufacture. And while this
25 process, as I said, may be rigorous, they haven't

1 provided, which is their burden, anything that points to
2 regulation plus.

3 They say we are regulated. We say, you are
4 right, you are regulated, but it is not regulation plus
5 that would bring them under the umbrella of 1442(a).
6 And absent detailed instruction or direction from the
7 FDA, that isn't enough.

8 So, unlike the tobacco companies, the gas
9 manufacturers, the Agent Orange manufacturers, the
10 Defendant failed to provide this Court with anything
11 that links Federal Regulation by the FDA or involvement
12 with the FDA like the FTC involvement in Watson. And
13 that is, again, why I did that chart, to show everything
14 that the Court had before it in Watson and what little
15 we have now.

16 So, since they can't point to anything that
17 directed them to design or manufacture the device in
18 question, we don't believe that this case should be
19 remanded.

20 As the Parks Court said, while the defense
21 has laid out a rigorous regulation scheme that requires
22 them to jump through many hoops to obtain and maintain
23 FDA approval, that is not enough.

24 And I would just like to end, Your Honor, by
25 saying that there is one more thing that is required,

1 and that is the third point, the causal nexus. They
2 have to show not only that they were regulated, but
3 also, that the direction by the Federal Court gave
4 rise -- I'm sorry, not Federal Court, FDA --

5 THE COURT: A lot of power, but not that
6 much.

7 MR. WIVELL: I know, I know, I apologize,
8 Your Honor. You have a lot of power, but I don't think
9 it goes that far. That the direction by the FDA gave
10 rise to the cause of action in this case. And they
11 can't show that. They haven't showed it.

12 In other words, there is a case, for example,
13 where a wrongful death case was brought against a dam
14 keeper, who opened a dam at the direction of a member of
15 the Corps of Engineers. The cause of action arose
16 because the Government ordered the dam to be open. We
17 don't have that here. There is no causal nexus and they
18 can't prove it.

19 And I would like to just end with the words
20 from the Parks decision where the Court remanded an
21 exactly similar Guidant case to State Court. Were the
22 Court to find this case sufficient to invoke the Federal
23 Officer Removal Statute, then there would be little to
24 stop every medical device manufacturer, indeed every
25 drug manufacturer sued in State Court, who can not avail

1 itself of diversity jurisdiction from removing any
2 garden variety products liability case to Federal Court.

3 Well, that is exactly what Guidant has done.
4 And they are continuing to do it. These are not the
5 only removed cases. They continue to remove cases from
6 State Court pursuant to 1442(a), and there are going to
7 be more motions like this, because we believe that in
8 the interest of Federalism, that this court does not
9 have jurisdiction. And we ask you to recognize that.

10 Judge Gruner, concurring in Watson, wrote to
11 emphasize that their decision should not be construed as
12 an invitation to every participant in a heavily
13 regulated industry, to claim that it, like Philip Morris
14 acts at the direction of a Federal Officer merely
15 because it tests and markets its products in accordance
16 with federal regulation, but that is exactly what
17 Guidant did. And we respectfully request that the Court
18 remand this case to State Court in Minnesota. Thank
19 you, Your Honor.

20 THE COURT: May I ask you a question? And I
21 will ask your fellow plaintiff's Counsel the same
22 question when we get there. I carefully concede in
23 advance of my question that your answer seems to me to
24 be entirely irrelevant to my decision. But, I am
25 just -- call it habit.

1 You know, the concern that I have, and just
2 keep in mind you don't panic at my question, that it is
3 concededly irrelevant to the jurisdiction issue. I am
4 actually concerned it may not be in the best interest of
5 a number of these parties to move, whether it is because
6 our MDL, assuming that you go, disrupts and obligates a
7 State Judge to stay and do as many as it promised to do
8 with me, work together and let us kind of do the heavy
9 lifting. I'm actually concerned I may be doing your
10 client a disfavor. It is not for me to say, but it is
11 of concern to me.

12 Let's say, for example, that you right on the
13 law. I could make the right decision and maybe have an
14 unintended consequence. And don't get me wrong, it is
15 not Federal snobbery, I spent 14 years on the State
16 Bench, so that has nothing to do with we can do it
17 better than they can. That is not what precipitates the
18 remark. But, I would just be more out of curiosity to
19 get a response, because your point is well taken that,
20 well, Judge, just to remind you, it doesn't really
21 matter what is in my client's best interest, you either
22 have got jurisdiction or you don't. I understand that,
23 but do you have a comment about that?

24 MS. WIVELL: I do, Your Honor, and the
25 reason I am smiling is that my good friend and former

1 partner, Mr. Messerli and I discussed this exact
2 question today.

3 I said to him, I believe Your Honor is going
4 to ask this question. And I said, and my response is
5 this: You are right, there may be some unintended
6 consequences; but, in the interests of Federalism, you
7 have got to remand these cases because they haven't met
8 their burden. And you are going to open up these courts
9 to a flood, a flood of litigation if your decision isn't
10 in accord with the Parks case, Your Honor.

11 THE COURT: And I don't -- you don't have to
12 worry about, well, I am going to -- I don't actually
13 have to subscribe to the word judicial activism because
14 I think it is a word that non-judges use when they don't
15 like what a judge does, or the judge won't do what
16 somebody thinks they should do.

17 No, I understand your concern, but whether it
18 is in the spirit of Federalism, aside, I mean, I don't
19 have any quarrel with what you said. It just is of
20 concern to me, but that can't tip the scales one way or
21 the other.

22 MS. WIVELL: And I apologize, Your Honor, it
23 just occurred to me that this is the first time in a
24 25-year legal career when I have told a judge that he
25 has to do something. And I apologize for that.

1 THE COURT: I don't know why you'd do that.

2 MS. WIVELL: I usually respectfully request
3 that they do something because I am arguing the right
4 side of the law, but --

5 THE COURT: I don't want to suggest that you,
6 that maybe you think you are breaking new ground, but I
7 have been told many times what I have to do. So --

8 MS. WIVELL: I just find it is a little
9 easier from my perspective, maybe it is being a woman,
10 that I respectfully suggest, instead of usually telling
11 judges what they have to do. I know that I have heard
12 some Federal Judges, whose names I have even invoked
13 here today who might take it not so correctly if someone
14 were to tell them, just inadvertently, that they have to
15 do something.

16 THE COURT: No, I know what lawyers say about
17 judges and much of it is justified. That is why I will
18 tell somebody in the Clerk of Court's Office, look, when
19 you go to see judge so and so, you have to make the
20 judge think it is his idea -- not your idea -- and it
21 will go smoothly. If they think otherwise, then you
22 might get sent out the door.

23 MS. WIVELL: Well, Your Honor, I think you
24 might have an excellent idea if you sent this case back
25 to State Court. Thank you.

1 THE COURT: Absent an objection, I think we
2 should just move along with the arguments.

3 (Discussion off the record.)

4 MR. BURTON: Mark Burton, Your Honor, for Mr.
5 Wislocki. You brought up an excellent point at the end,
6 there, which I will actually start with, which wasn't my
7 plan; but, let me explain that.

8 You have actually hit exactly what is
9 happening in this case, which is that I don't think the
10 Defendants truly believe in their legal hearts of
11 hearts, let's say, that there is Federal Officer
12 Jurisdiction, here. For instance, I am litigating many
13 other PMA device cases against Guidant right now in
14 other State Courts, not regarding defibrillators, but
15 regarding totally different devices, but that are PMA
16 approved. They never removed those cases based on
17 Federal Officer jurisdiction.

18 Interestingly, though, there is no MDL for
19 those cases. Now, what happens when an MDL is created,
20 is Defendants get their preference for wanting
21 everything consolidated into the MDL. So, that is
22 exactly what is going on here. And what they are
23 attempting to tempt you into is to say, listen, these
24 State Court cases -- this could cause this MDL Court a
25 lot of trouble.

1 And you are expressing that concern, I think.

2 THE COURT: Trouble wasn't on my mind, but
3 that is one way to put it, sure. Sure.

4 MR. BURTON: And what I have to emphasize is
5 that I have been involved in several MDL's as have
6 several counsel here. State litigation is not the enemy
7 of the MDL Court. It is an absolute friend. And not
8 only do we worry about this interest about, wouldn't we
9 be harming our client's interest by going to State
10 Court, as opposed to the MDL, but it also works the
11 opposite way. If we are not in State Court, we could be
12 hurting the interests of MDL Plaintiffs, as well. And,
13 as a matter of fact, I think if the Court were to adopt
14 what is actually a radical proposal, that all products
15 approved by the FDA, basically, have to go into Federal
16 Court as opposed to State Court which, you know, there
17 has been decades and decades worth of PMA litigation out
18 there, and no court has ever even hinted at such, at
19 giving approval to such a concept.

20 But, what would happen is that this Court
21 would be stuck with all of those cases. And let me tell
22 you, that is not something that the MDL Court wants.
23 And in their opposition brief, the first two pages don't
24 talk about the law regarding Federal Officer
25 jurisdiction at all. It all talks about me, Mark

1 Burton, and how I applied to be on the MDL PSC, the
2 Judge denied that, then I filed this Motion to Remand.
3 They didn't mention that is just how the timeline worked
4 out. Originally they said that I had filed the State
5 Court Complaint after I was denied an opportunity to be
6 on the PSC which wasn't the case. We filed that months
7 before the denial of my PSC application.

8 But, the point I am trying to make here is
9 that in other MDL's, and as you have seen, I think, from
10 the reaction you have received from State Court Judges,
11 the Federal Judges and the State Court Judges work
12 together, and they work together well. And there is no
13 frustration of the MDL, this Doom's Day that the
14 Defendants are always talking about that the State
15 Courts can cause to an MDL never happened.

16 THE COURT: Well, Texas might be a small
17 exception, but --

18 MR. BURTON: Well, actually, Your Honor, as
19 you have seen, that original trial date was moved.

20 THE COURT: Moved to April.

21 MR. BURTON: That is right. And I think, if
22 anything, that -- the pressure, because of that case,
23 has assisted the MDL in getting some cooperation out of
24 the Defendants and what they are willing to produce and
25 in moving the MDL case along.

1 I mean, I was here at the case management
2 conference. And relatively, things -- I mean, sure,
3 there are a lot of disputes going on, you have had to
4 make some rulings. But, relatively, there is starting
5 to be a lot of cooperation coming out of the Defendant's
6 side. And in part, I think that might be due to some of
7 the State Court litigation going on out there.

8 And if you look in the most recent MDL that I
9 have been involved in in a leadership role is the
10 Zyprexa MDL with Judge Weinstein in Brooklyn, in the
11 Eastern District of New York. Everybody knows Judge
12 Weinstein is a very strong judge. There is no hiding
13 that.

14 However, even though I was the one who argued
15 the MDL petition and actually requested Judge Weinstein,
16 who it was sent to, and I was on the PSC, led the
17 discovery in the science committees. I also had State
18 Court cases that were filed and were being litigated in
19 the state courts.

20 Now, those State Courts didn't interrupt what
21 was going on in the MDL, and now when there was a
22 settlement proposed to everybody, actually, that
23 settlement was coordinated between all of the states and
24 the MDL. It wasn't like MDL Plaintiffs were treated
25 different than the State Court Plaintiffs.

1 So, this implied disaster that can happen
2 when you have both State Court and Federal Court
3 litigation going on is really a bogeyman that does not
4 exist and it is really, actually, quite controllable.

5 Now, to move on to the actual merits of what
6 is going on here in this motion.

7 THE COURT: All right.

8 MR. BURTON: It needs to be pointed out that
9 the Watson court did not say, if you sue a tobacco
10 company regarding their cigarettes, Federal Officer, you
11 are in Federal Court now, what they specifically
12 actually distinguished some of the other cases in which
13 Federal Officer jurisdiction had been denied, so if you
14 look at -- on page 861, they cite Paldrmic, I think is
15 how you appropriately pronounce that. And they
16 distinguish Paldrmic from the case that was at hand in
17 Watson. They said, listen, the Paldrmic case had to do
18 with the design and manufacturing of the cigarettes,
19 themselves.

20 And they said, yeah, and that court remanded
21 the case back to State Court. And the Watson Court
22 specifically said, this case before us right now doesn't
23 have anything to do with the manufacture and design of
24 the cigarettes, themselves. As a matter of fact the
25 Court said, quote, "The FTC did not direct Philip Morris

1 in how to design and manufacture its products."

2 Now, what they did say was that in this
3 particular instance, and this is where this causal
4 connection comes in that -- I am only remembering Marty,
5 sorry. Ms. Wivell was speaking about. In other words,
6 it was only because the Government had developed this
7 specific test, and then they directed the tobacco
8 companies, this, is the test you have to use.

9 And when the tobacco companies actually came
10 to them and said, listen, we would like to use a
11 different test, we would like to publish some other
12 things, they specifically said: No, you can't do it.
13 Now, we don't have anything like that, here, with these
14 cases. And that is what the Court in Indiana pointed
15 out. The District Court there specifically said that in
16 order to prove this causal connection, there has to be,
17 quote, candid, specific and positive allegations.

18 Now, here, while I don't concede that there
19 is any admissible evidence for the Defendants to meet
20 their burden, it has to be pointed out, they are not
21 saying anything about the way the FDA regulates them
22 that caused them to do what they did in these cases.
23 The FDA -- these cases are about their failure to
24 properly test the devices, to properly manufacture and
25 design them, and then for hiding up the problems that

1 they were having with the devices. Nobody here, the
2 Defendants don't even suggest in their briefs that the
3 FDA said: Guidant, I know you want to tell the doctors
4 about these problems that you are having, but we just
5 can't let you do it, we can't let you do it. There is
6 nothing like that here, which is exactly what their was
7 in Watson. In Watson they said, this is how you are
8 going to do this testing. This is the information that
9 you are going to publish in your advertising, which is
10 exactly the issue in the case, was the testing, the tar
11 content, for example, and how that was published in
12 advertising.

13 The FTC specifically said, not only is this
14 the way you are going to do it, you can't do it any
15 other way. And the tobacco companies had in fact asked
16 to do it a different way over the last twenty years.
17 And the FTC had said, no, we are not going to let you do
18 it a different way.

19 Here there is just a general set of
20 guidelines, you know, you have to show a medical device
21 is reasonably safe and effective, a reasonable assurance
22 that it is safe and effective. That applies to every
23 single medical device.

24 There is nothing specific among the FDA's
25 regulations about defibrillators or the 1861, or

1 anything else. And as a matter of fact, while I don't
2 believe what they have attached to their motion is
3 admissible, it you at what they have attached, none of
4 the approval letters from the FDA was a PMA approval
5 letter, which is going to take me to my next prong,
6 which is the colorable federal defense.

7 I don't think that there is a colorable
8 defense on preemption grounds, here. Not only -- this
9 was a device that changed often. In other words, at
10 some time, way, way back, we don't even know based upon
11 the papers that are submitted to the Court, there was a
12 defibrillator that received PMA approval. Over the
13 years, that device changed through PMA supplements.
14 Those PMA supplements don't go through the same sort of
15 testing the device went through in the first place.

16 As a matter of fact, the PMA supplements are
17 more like the 510K process that the United States
18 Supreme Court specifically dealt with in Medtronic
19 versus Lohr.

20 Now, given that, number one, and number two,
21 given the fact that according to the Defendant's own
22 papers, the FDA has classified this device with a Class
23 1 recall. And a Class 1 recall, which the Defendants
24 have freely admitted in their papers, means that the FDA
25 has found that there is a probability of serious injury

1 or death occurring from the product.

2 Now, you can't say that we have PMA approval,
3 and therefore that is why we have a preemption defense.
4 When the FDA has taken away your PMA approval, the
5 reason why the device is labeled the Class 1 recall is
6 because the FDA has already found that they were out of
7 compliance with the PMA.

8 Therefore, to say that now because the device
9 at one time was PMA approved, there is a preemption
10 defense, I think kind of -- it is illogical. And not
11 only is it illogical, it is impractical.

12 I have the transcript here from prior cases I
13 have been involved with with Guidant. Actually, this is
14 the criminal case regarding the Ancure device which has
15 been talked about in this litigation a little bit. And
16 in this transcript when Guidant pled guilty to several
17 felonies and paid many millions of dollars in fines, the
18 Judge specifically asked about restitution for the
19 victims. There were deaths involved in these cases.
20 And Guidant's response was that the civil litigation
21 will take care of the restitution element of this
22 criminal plea.

23 Now, the Ancure device was never classified
24 as a Class 1 recall by the FDA. There was never a
25 mandatory recall of the Ancure device, even though there

1 was criminal prosecution regarding it.

2 Now, Guidant seems to always want it both
3 ways. They can't say, listen, we don't pay restitution
4 back to the government because there is civil litigation
5 out there that will compensate new victims that can come
6 forward and put forth a legitimate claim, and then come
7 here and say: Listen, you can't ever -- we have a total
8 preemption defense where they can't even sue us because
9 of federal preemption.

10 They often kind of want this both ways. If
11 you look into the brief, this is another very important
12 point that I want to mention. In our complaint, Cardiac
13 Pacemakers Incorporated is not named as a defendant.
14 So, the Defendants' brief actually discusses how they
15 obtained PMA approval for their design and manufacture
16 of their device. But, in fact, it is confusing, because
17 like we have been talking about, there is no decent
18 evidence really before the Court, but it appears that
19 Cardiac Pacemakers, Incorporated, actually obtained PMA
20 approval for this device, which, let's say all of their
21 arguments were actually somehow feasible, that might
22 make Cardiac Pacemakers Incorporated a federal officer.

23 Now, how they go on to the next step, because
24 in their brief they specifically say Guidant Corporation
25 had nothing to do with the design and manufacture of the

1 device in question, here. So, if Guidant, who is the
2 Defendant in this case, had nothing to do with the
3 design, marketing, approval and manufacture of the
4 device, how can they be acting under the direction of a
5 federal agency? It is literally impossible. And if
6 Guidant is not responsible for those things, how can
7 they say that we were acting under the direction of the
8 Federal Government?

9 Again, there's a lot of things they say in
10 one place, the facts are this way, and then in another
11 place they go on to an opposite argument. But, I think
12 that is important, especially because we are talking --
13 all of the prior precedent talks about very specific
14 things. And MTBE, the Federal Government said, you have
15 to put MTBE into the gas.

16 In the Watson case, the Federal Government
17 said, you have to test the cigarettes this way and
18 publish the results in exactly this way. There is
19 nothing here that the Defendants can point out where the
20 Federal Government said, you know what? You have to do
21 it this way.

22 All the Government said was there was some
23 general regulations out there about showing reasonable
24 safety, and do they have to sometimes submit changes
25 when they want to make a change? Absolutely. And in

1 general, those changes are freely granted whenever they
2 want to make a slight change or modification of the
3 device. There is no evidence here that the FDA has ever
4 said to Guidant: Oh, wait, we know you think it is
5 better for the device to be designed this way or to be
6 tested in such a manner. But, we are going to insist on
7 a different design or testing method, or anything else
8 like that for this particular product, or for any of
9 their products.

10 THE COURT: Does it follow, then, just by the
11 nature of your argument, when Guidant is saying: Well,
12 Watson doesn't really cause us a problem because we are
13 under more stringent controls and regulations than the
14 defendant was in Watson. It follows, necessarily, that
15 you don't really agree with that, even, for maybe a
16 moment.

17 MR. BURTON: Actually, the Indiana District
18 Court, in part, specifically addressed that issue. And
19 the Court actually pointed out that Watson was a better
20 case for removal, because the controls were more
21 stringent in Watson.

22 The controls over Guidant here are not more
23 stringent than they were in Watson. If you look at the
24 power that the FDA exercises over Guidant, these are
25 mere applications that the company submits to the FDA.

1 For instance, they come up with all of their
2 designs, they come up with all of their testing. The
3 FDA, to my knowledge, has never hired an expert in
4 defibrillators to even do any designing or even
5 double-check any of their design work.

6 The FDA relies on the expertise of the
7 manufacturer and for them to be telling them the truth,
8 but relies on the expertise of the manufacturer. The
9 manufacturer submits those plans and they basically
10 stamp them and say, okay, you can go ahead and do this.

11 Now, meaning they can change what they are
12 doing to that device at any time. They can change the
13 design, they can change the warnings. And as a matter
14 of fact, we all see that the warnings on these products,
15 the software on these products, all of these sort of
16 things change often.

17 As a matter of fact, my understanding is that
18 there has almost been a monthly change in the
19 programming that is used on these defibrillators where
20 Guidant has tried to solve some of these problems that
21 these defibrillators are experiencing.

22 That just shows that Guidant can change the
23 design of the product without much interference by the
24 FDA. They can change what they tell doctors. They have
25 representatives out in the field telling doctors all

1 sorts of things. The FDA doesn't exercise a bunch of
2 control over that. And that was exactly the opposite
3 case in Watson. No matter how hard the tobacco
4 companies tried, they were not going to be able to use a
5 different testing method. There was evidence in the
6 record that they had actually tried to convince the FTC
7 to let them use a different testing method. And the FTC
8 said no. They had actually tried to be able to publish
9 the tar results and nicotine results in a different
10 manner in their advertising and the FTC said no.

11 Now, that is stringent. When the FDA just
12 merely requires that you tell them about the change that
13 you are making, and they briefly review it to make sure
14 that there is nothing too funny in their going on and
15 then they approve and let you do whatever it is you want
16 to the product, that is not as stringent as 30, 40 years
17 of mandating a specific test, trying to get that test
18 changed, and the government agency is saying, no, this
19 is the test that we designed, we developed, and as a
20 matter of fact, we performed for twenty years before we
21 said we are not going to do the testing ourselves
22 anymore, we are going to make the companies do it
23 themselves, that is very stringent.

24 Just to require that the manufacturers get
25 these approvals for what they want to do is not a

1 stringent regulation, even though it might require a lot
2 of paperwork or data that they submit to the FDA, that
3 doesn't necessarily make it more stringent, just
4 requiring that that be provided.

5 And as Ms. Wivell was pointing out, this
6 would require that every drug that has PMA approval,
7 every medical device, all of these cases would suddenly
8 now have to go to Federal Court. It is an unprecedented
9 argument for Federal Officer jurisdiction. And there
10 has never been, no matter how heavily the industry is
11 regulated, there has never been a court that has found
12 that because you are heavily regulated, you are a
13 Federal Officer.

14 There has always been some very, very
15 specific directive by the Federal Government. You have
16 to put MTBE in the gasoline. You have to make Agent
17 Orange just like this, and it has to have these levels.

18 And it wasn't the company that came up with
19 those labels, it was the Federal Government that came up
20 with those labels. And it was the Federal Government
21 that came up with the formula for Agent Orange. These
22 are very specific things.

23 And to think about it, it is in part an issue
24 of fairness. In other words, if a gasoline manufacturer
25 is required to put MTBE in their gasoline, by Federal

1 law, should a State Court be saying: That was something
2 bad you did putting MTBE in your gasoline? Or in the
3 cigarette case, if the FTC says, listen, you have to use
4 this test, and you have to publish the results of this
5 test exactly this way, well, really, can you have a
6 lawsuit in a State Court saying, you shouldn't have used
7 that test, and you shouldn't have published those things
8 in that way? There is nothing here that the Defendants
9 can get up and say: We did what we did in this case.
10 We didn't tell doctors about the problem we were having.
11 We did the design of the 1861, specifically this way,
12 because we were told by the Government that this is the
13 way it had to be. And if you look at how this
14 litigation erupted, it wasn't until there was about to
15 be an article published in the New York Times, and some
16 whistle blower doctors that had gone to the New York
17 Times that Guidant finally said, voluntary recall. The
18 FDA didn't say to Guidant, hey, you need to recall these
19 devices, and that is why Guidant acted. As a matter of
20 fact, this shows that they were not acting under the
21 direction of the Federal Government.

22 If there was a directive by the Federal
23 Government that they had to sell these devices and they
24 had to sell them in exactly this manner, how would they
25 have been able to voluntarily recall them, themselves?

1 It just wouldn't have been able to happen.

2 So, not only is that evidence that the
3 Defendants do act on their own, not at the direction of
4 the FDA, but it kind of shows you this whole concept of
5 Guidant didn't do what they did in regards to their
6 conduct regarding the 1861, because the FDA said this is
7 what you have to do. They could have come up with a
8 different design. There is no argument that we couldn't
9 have designed it differently because of the FDA, there
10 is no argument that we couldn't have changed the
11 warnings because the FDA wouldn't have let us, there is
12 no argument that we couldn't use this other testing or
13 that we couldn't tell doctors, hey, we have been having
14 problems with these devices. Nothing of the sort.

15 THE COURT: Thank you. They paint a pretty
16 bleak picture.

17 MR. CARPENTER: I think I have got some
18 answers for that, Your Honor. May it please the Court?
19 Andrew Carpenter for Guidant. Before I start addressing
20 the specifics that Plaintiffs' Counsel brought up, I
21 want to talk about what the overarching question is that
22 these remand motions bring up. It is a question of
23 whether there is going to be a Federal Court that
24 decides the extent to which the FDA's comprehensive and
25 specific regulatory framework preempts cases like this,

1 or whether these cases, and whether the preemption
2 issues is going to be decided by State Courts that are
3 not necessarily going to be as sensitive or cognizant of
4 Federal issues and Federal regulatory schemes as a
5 Federal Court would.

6 Guidant respectfully submits that this Court
7 and this MDL is the proper forum for that, and that
8 removal jurisdiction is absolutely proper pursuant to
9 Federal Officer jurisdiction.

10 We all agree on the legal standards. I won't
11 belabor those. We disagree as to whether they are met.
12 I think the key in this case is realizing, number one,
13 unlike most removal statutes and doctrines, the Federal
14 Officer Removal jurisdiction is to be given a broad and
15 effective interpretation, not a narrow interpretation,
16 so as to effectively ratify its purpose and to
17 accomplish its statutory goals, which is to avoid having
18 State Courts deciding key federal issues. Obviously, it
19 is an exception to the Well-Pleaded Complaint Rule.

20 Number two, what we have got, I think, is a
21 fundamental disagreement and difference in
22 characterization over the PMA approval process for Class
23 3 regulatory devices. And that is what I am going to
24 focus on, primarily. I think it is important to focus
25 on that so the Court understands what Defendants are

1 asking it to rule and what we are not asking it to rule.

2 Let me say right now, we are not asking the
3 Court to rule that Federal Officer jurisdiction exists
4 because Defendants operate in a highly regulated
5 industry. That is clearly not enough and we clearly
6 exceed that standard.

7 Our position is that in marketing, designing
8 manufacturing, labeling these Class 3 medical devices,
9 both the ICD's that both of the Plaintiffs have,
10 Defendants were acting under the direction of the FDA
11 after they approved the PMA application. And they were
12 also operating pursuant to the type of comprehensive and
13 specific regulations identified by the Eighth Circuit in
14 the Watson case, that frankly outstrip the FTC's
15 regulations in a lot of ways.

16 It is important to understand that the
17 Medical Device Act creates three types of medical
18 devices. And I think this answers the floodgates
19 argument that Plaintiffs' Counsel have brought up
20 repeatedly. Most medical devices are not Class 3
21 medical devices. We are not asking this Court to rule
22 on Class 1 medical devices, which are tongue depressors,
23 and things like that. We are not asking this Court to
24 rule on Class 2 medical devices, which are also subject
25 to some very high regulation. What we are talking about

1 are the most rigorously regulated and strongly
2 controlled by the FDA medical devices out there, Class 3
3 medical devices.

4 Those are medical devices that are purported
5 for use in supporting or sustaining human life, or in
6 preventing the impairment of health, or that present a
7 potential unreasonable risk of illness or injury. I.e.,
8 they are devices that potentially provide great benefits
9 to the human user, but also because of their nature have
10 to be highly regulated.

11 Class 1 medical devices can be regulated by
12 general controls, i.e., general standards, things like
13 prohibitions on mislabeling, requiring good accounting
14 procedures. Class 2 medical devices like oxygen masks
15 can be regulated through stringent regulation, things
16 like performance standards, post-market surveillance,
17 patient registries.

18 Class 3 medical devices require a level of
19 regulation above and beyond any of those. They have to
20 be regulated either through the 510K process or the PMA
21 application process. And part of the PMA application, I
22 will cover this later, is also the PMA supplement
23 process.

24 The vast majority of even Class 3 devices
25 never make it to the PMA application process. They are

1 covered by the 510K process, which is much, much less
2 rigorous than the PMA application process.

3 Approximately 80 percent of all Class 3
4 medical devices go through the 510K process. And that
5 means they are substantially similar to devices that
6 were already on the market before the medical device
7 amendments were passed in 1976, so they are grand
8 fathered in. It takes about 20 person hours for the FDA
9 to approve a 510K device application for a Class 3
10 medical device. It takes about 1,200 FDA hours to
11 approve a PMA application for a Class 3 medical device.
12 It is a much more rigorous, much more exhaustive
13 process.

14 And I think the regulatory statement of the
15 goals of the PMA process will inform this Court as to
16 exactly how stringent and comprehensive it is. The
17 purpose of the PMA process is to, quote, "to facilitate
18 the approval of PMA's for devices that have been shown
19 to be safe and effective, and that otherwise meet the
20 statutory criteria for approval, and to deny PMA
21 approval for devices that do not.

22 A PMA application has got to be exhaustive.
23 I won't go into too much detail on that. That is all in
24 our briefing. But, you have got to give all reports of
25 all clinical investigations, adverse or supportive. You

1 have to identify all principles of operation. You have
2 got to give a full description of the methods used in
3 the facilities and the controls used for the
4 manufacturer, the processing, the packaging, the
5 installment. You have got to give all unpublished data
6 if you can find it. You have to discuss any data,
7 whether it is yours or someone else's that is relevant
8 to the safety of the device, whether it is published or
9 unpublished, whether it is in the United States or
10 whether it is foreign data. You have to identify that
11 kind of data whether you have got it or whether it is
12 reasonably obtainable to the applicant. You have to
13 give examples of the labelling you propose and, quote,
14 "adequate directions," end quote, for use of the
15 product. It is an extremely rigorous process.

16 Now, what is important to understand is, once
17 the applicant gets this massive amount of information
18 together, and for example, the PRIZM 2 PMA supplement
19 involved at least 17,000 pages of documents for their
20 PMA supplement. That was a lot, obviously. And that
21 was obvious, and I will cover this later, building on
22 prior PMA approvals and prior devices, so it is a
23 building process.

24 When the FDA gets the PMA application,
25 Plaintiffs have told you that the FDA pretty much just

1 stamps the approval and the applicant does whatever the
2 heck it wants to. Absolutely not true.

3 Once the PMA application gets to the FDA, the
4 applicant loses control over it. The FDA takes over.
5 The FDA and the scientists within the FDA carefully
6 evaluate all of the data submitted with the PMA
7 application, which, incidentally, has to be periodically
8 updated and reviewed during the application process. It
9 doesn't stop there. It is not a passive process in
10 which the FDA takes the applicant's word for what is
11 going on.

12 The FDA can and often does request additional
13 information, as necessary to provide a complete and
14 accurate record of the device's safety. That happened
15 in the PRIZM 2 application process, for instance. They
16 demanded more information as the process went through.
17 They demanded clarification of a whole series of
18 questions they had about it. The FDA can and often does
19 supplement its own in-house expertise by farming out and
20 submitting the PMA application to independent scientific
21 bodies for comment and analysis of the PMA application.

22 In addition, the FDA is authorized to look at
23 any relevant data, regardless of whether it is in the
24 package of data submitted by the PMA applicant, any
25 relevant data to determine whether the device is going

1 to be safe and reasonably effective. It is a very
2 rigorous process. And while I'm talking about that, let
3 me just mention the PMA supplement process.

4 Plaintiffs are correct, the PRIZM 2 and the
5 Vitality were approved, these particular models,
6 pursuant to a PMA supplement process, which is pretty
7 much the same process as a PMA application, except it
8 recognizes that the device has previously gone through
9 the entire PMA application approval process, and the
10 Defendants want to change one particular aspect of it.

11 And in that case, the manufacturer or the
12 applicant has to submit a PMA supplement, not on the
13 entire device because it has already been approved, but
14 on the particular aspect that they want to change. So,
15 in essence, it builds on the pre-existing PMA
16 application analyses that have been done in the past.

17 It is an incredibly rigorous process. And
18 courts have universally recognized that the PMA
19 supplementation process is just as rigorous and does
20 provide the precise type of specific requirements on a
21 manufacturer as the original PMA application process.

22 For instance, the Kemp case cited in our
23 briefs by the Sixth Circuit recognizes that explicitly,
24 Your Honor.

25 THE COURT: I doubt that will become the

1 issue here, only because I don't think the Plaintiffs
2 are saying, well, we agree with the Defense, if it was
3 the straight application process, then we wouldn't be
4 here. But, since it is a supplemental process, I think
5 their suggestion is that either way, the result should
6 be the same. So --

7 MR. CARPENTER: I think that is right, Your
8 Honor, and I disagree completely with that
9 characterization. Another important thing to understand
10 is once the FDA has gone through all of this analysis,
11 which is independent, they decide how the device is
12 going to be manufactured. They don't rubber stamp the
13 applications.

14 They -- sometimes they can grant the PMA
15 application exactly the way it is submitted, but
16 usually, and in the case of these two devices at issue,
17 they give an approval letter with specific conditions
18 for use.

19 They regulate, they add their own conditions
20 based on what the FDA thinks is appropriate. The FDA
21 will often in the approval letter specify specific
22 restrictions on sale, restrictions on distribution,
23 often the FDA approval letter will require additional
24 post-approval studies and information to be submitted.

25 The important point to remember, Your Honor,

1 is that once the FDA approves a PMA application through
2 an approval letter under whatever conditions the FDA
3 decides to, which often differ from what the applicant
4 submits, those are specific device specific requirements
5 that the manufacturer can't deviate from. That is how
6 the device has to be manufactured, designed, labeled.
7 There is no discretion. The manufacturer cannot change
8 its mind and say, we want to do it a different way.

9 Now, the FDA system of regulations has
10 certain procedures by if you are acting in this
11 regulatory framework, you can apply to and make certain
12 changes. For instance, you can make a miniscule change
13 as long as it is inconsistent with the manufacturing
14 parameters approved in the PMA application, so you can
15 technically change something very slightly, but it has
16 got to be consistent with how the FDA approved it.

17 The FDA regulations kick in at the FDA
18 application approval point and govern conclusively from
19 there. Failure to comply with the way the FDA approved
20 your Class 3 medical device application is a violation
21 of the terms and conditions and will result in -- it's
22 obviously breaking the law and will result in
23 termination of your PMA approval. It simply can't be
24 done.

25 So, the point is, even though the FDA doesn't

1 submit the initial design or manufacturing
2 specifications or labelling for the device, it takes it
3 at the point the application is submitted, it makes its
4 own, it exercises its own independent values and
5 judgments as about how the device should be designed,
6 labeled, marketed, manufactured. And what it does, in
7 essence, it enacts device-specific regulations to the
8 PMA approval process. And that is why Class 3 medical
9 devices are so special. It is not general controls on
10 Class 1 devices, it is not even stringent are he guy
11 legs i.e., through what they call specific conditions on
12 Class 2 medical devices. The FDA recognizes that Class
13 3 medical devices are so important and have to be
14 regulated so importantly, that it basically has a system
15 by which it enacts device-specific regulations that can
16 only be changed by FDA regulations and procedures.

17 If you compare the scope of FDA regulations
18 in Class 3 medical devices to the scope of FDA medical
19 regulation of the tobacco industry's ability to test its
20 products pursuant to the Cambridge filter method, and to
21 advertise its products as lights, it compares very
22 favorably. Clearly, the FTC does have pervasive
23 regulation over the tobacco companies with respect to
24 issues.

25 However, there is a lot more regulation going

1 on through the FDA of Class 3 medical devices. For
2 instance, just for starters, this is clearly obvious,
3 the FTC regulates one small aspect of the cigarette
4 advertising, how you are able to describe lights and the
5 measurement through the Cambridge filter process.

6 In contrast, the FDA regulates the design,
7 the label, the manufacturing process, basically every
8 single process. In addition, the FDA also regulates
9 communications, even post-market approval.

10 The FDA characterizes communications as
11 recalls. Now, that is a term of art. It doesn't mean
12 necessarily you are yanking the device back off the
13 market. But, if you want to communicate, you either
14 have to do so, number one, in a way that is consistent
15 with the labelling approval and your PMA application
16 approval, or number two, you have got to coordinate with
17 the FDA and communicate in a way that is consistent in
18 following the regulations that are applicable. So, the
19 point is not that you can never, ever change anything,
20 but if you do, you have got to do it according to the
21 way the FDA sales you have to do it. That is why it is
22 a pervasive, comprehensive regulatory scheme that vast
23 exceeds that of the FTC.

24 I will go ahead and address at this point the
25 specific arguments of Plaintiffs' counsel at this point.

1 Feel free to stop me if you have a point.

2 THE COURT: Okay.

3 MR. CARPENTER: Mr. Burton made a point that
4 Defendants clearly must not agree in Federal Officer
5 Removal jurisdiction in these cases because we haven't
6 always employed it. I can assure you, we do. The
7 Watson decision from the Eighth Circuit, it is
8 relatively recent. And until that point, it was
9 difficult, frankly, to conceive of good authority by
10 which to do it. Post-Watson? Absolutely, we believe in
11 the efficacy of Federal Officer Removal for Class 3
12 medical devices that go through the PMA application
13 process.

14 And in this case, we believe removal of such
15 cases are absolutely consistent with the purpose of the
16 Federal Officer jurisdiction. We believe that Federal
17 Courts, such as this one, should be deciding the extent
18 to which the FDA's pervasive regulatory scheme preempts
19 State law claims that would require different warnings,
20 different procedures, different designs, otherwise the
21 entire Federal regulatory system could be possibly
22 undermined.

23 Let me talk about the nexus issue for a
24 minute, Your Honor. Plaintiffs' Counsel have repeatedly
25 emphasized that there is no -- they claim there is no

1 nexus between the FDA-directed behavior, and the
2 allegations in their complaint for which they seek
3 recovery.

4 I don't think Your Honor has to go much
5 farther than just read their complaints, even the first
6 couple of pages to see that that is not an accurate
7 argument. These are wide ranging complaints. They have
8 got negligence claims, they have got strict liability
9 claims, they have got breach of warranty claims, they
10 have got fraud claims, they have got consumer protection
11 claims. And the essence of all of these claims, if you
12 read the paragraph's language, and I am not going to
13 waste the Court's time with it, it is there available to
14 you. But, they allege that Defendants' manufactured,
15 designed, labeled, tested these devices, either
16 negligently or incorrectly, or that the devices are
17 defective because they are not reasonably safe or
18 effective for their use.

19 These are the precise issues that the FDA
20 regulations and directions govern. The FDA directs the
21 procedure by which you test and determine whether these
22 devices are fit for their intended use and fit to be
23 placed on the market in the stream of commerce. The FDA
24 determines how they are going to test and evaluate your
25 proposed design and manufacturing procedures.

1 Claims such as negligence that attack not
2 just the device, but the entire process of developing
3 the device clearly are counter to and undermine the
4 regulatory framework.

5 In addition, the strict liability claims, the
6 claim that these devices are clearly defective because
7 they are not safe and they are not effective run
8 directly counter to the FDA's specific determinations by
9 granting application through the PMA application
10 process.

11 Plaintiffs also raise the issue as to whether
12 there is a colorable Federal defense. There clearly is.
13 Several decisions such as the Kemp decision, for
14 instance, have found that Class 3 medical devices, the
15 regulations surrounding Class 3 medical devices preempt
16 State claims seeking to impose other requirements.

17 We don't need to get into the merits of that
18 issue and we are not asking you, clearly, to decide the
19 preemption issue. That is for a later day. As the
20 Watson court eloquently wrote, we are not going to
21 require the Defendant to prove its defense before
22 determining whether there is Federal Officer
23 jurisdiction.

24 I think based on the authority around the
25 country, there is clearly a colorable preemption

1 defense, but we won't ask you to decide that today.

2 Let me cover a couple more issues, and I
3 think I will be ready to conclude here shortly unless
4 the Court has any particular questions. Plaintiffs
5 emphasize the Parks decision as a decision this Court
6 should look to for guidance.

7 THE COURT: And you say it was wrongly
8 decided?

9 MR. CARPENTER: I say two things, Your Honor,
10 no disrespect to the Judge, I think it is wrongly
11 decided, if you look at the Court's decision, they say
12 that the regulatory scheme under which the FDA regulates
13 the Class 3 devices isn't as pervasive as the FTC's
14 regimen over tobacco products. I vehemently disagree
15 with that. And I think the record in these cases proves
16 otherwise.

17 Number two, no disrespect to that Judge,
18 because the District Court in that case did not have the
19 benefit of the Watson decision. And as a matter of
20 fact, the Parks Court specifically discounted the Watson
21 decision as being an outlyer from other tobacco cases
22 that have not found Federal Officer Removal
23 jurisdiction.

24 I submit that if that same judge were in the
25 Eighth Circuit, a very different result might be

1 reached. And I would also submit that the Watson
2 Court's analysis is an excellent template for this Court
3 to rule on.

4 Finishing up, I think it is important to look
5 one last time at the Watson decision and see exactly
6 what they decided and why they decided that Federal
7 Officer jurisdiction existed. They found a clear nexus
8 between the claims of the Plaintiffs in that case and
9 the federally-directed conduct.

10 And the Court didn't just look at the claims
11 regarding the cigarettes. The Court looked at the
12 claims regarding the entire process, just as the
13 Plaintiffs in the Watson case challenged, as the Court
14 observed, not just the cigarette design, itself, but
15 also Philip Morris' marketing and promotion of low-tar
16 cigarettes, and nicotine cigarettes. They challenged
17 Philip Morris' representations, they challenged its
18 alleged deception of consumers. Plaintiffs in this
19 case essentially challenged the entire process of Class
20 3 medical device approval, and allowing such devices to
21 be marketed and their accompanying warnings, and their
22 accompanying labels and the design of the manufacturing,
23 all approved, and after it was approved, mandated by the
24 FDA.

25 Just as the FTC defined what is not

1 misleading in terms of advertisements for light
2 cigarettes and tar, so does the FDA in this case define
3 what assurances and what testing procedures and what
4 type of Class 3 medical devices give assurances of
5 safety and effectiveness. To allow Plaintiffs to
6 continue to say there is no nexus ignores basically
7 Plaintiffs' allegations are an stack on the regulatory
8 system.

9 Finally, one last point, Plaintiffs'
10 emphasized or tried to communicate to this Court their
11 belief that the specific regulations, the specific terms
12 of the approval of these devices do not create specific
13 requirements on the manufacturer. Well, let me read to
14 you what the FDA's view is on this issue, and bearing in
15 mind that the agency whose regulations and statutory
16 construing is entitled to considerable weight.

17 This is a quotation from the FDA amicus brief
18 submitted as one of the exhibits. Quote, "We second
19 emphasized that the requirements imposed by FDA approval
20 of a PMA are no less effective, because the design has
21 been proposed by the manufacturer. FDA can impose
22 requirements by rule or order regardless of whether or
23 not the requirements were initially suggested to the
24 agency by an outside party. The FDA does not and has
25 never used notice and comment regulations to approve

1 individual products or to establish product-specific
2 requirements for manufacture, performance, labelling and
3 use. Rather, a PMA order is better conceptualized as an
4 individual adjudication that imposes, quote, specific
5 requirements, end quote, on the device. Although the
6 PMA approval order did not, itself, expressly reiterate
7 all of the specific features the device's design,
8 labelling and manufacturing processes must have, it
9 specifically approves as a matter of Federal law those
10 features as set forth in the application and binds the
11 manufacturer to produce and market the product in
12 compliance with the specifications as approved by the
13 FDA."

14 I think that is the key point. If Your Honor
15 has no further questions?

16 THE COURT: Thank you.

17 MR. CARPENTER: Thank you, Your Honor.

18 MS. WIVELL: May I, Your Honor?

19 THE COURT: Yes. So, would you agree that
20 the -- would it be a fair characterization in some way
21 of your complaint that it is an attack on the regulatory
22 process?

23 MS. WIVELL: Not at all, Your Honor, I would
24 not agree with that. I believe that there is a very
25 substantial defense to their preemption motion that does

1 not begin nor does it end with the FDA's regulation, its
2 own regulation, which states that state or local
3 requirements are preempted only when the Food and Drug
4 Administration has established specific counterpart
5 regulations, and there are other specific requirements,
6 other specific requirements applicable to a particular
7 device under the Act.

8 I would note that under -- in Lohr versus
9 Medtronic, the Supreme Court has said in the majority
10 decision, the NDA does not broadly preempt all state law
11 damage claims against device manufacturers.

12 I would point out that the Supreme Court has
13 found complete preemption in only two types of cases,
14 certain causes of action under the Labor Management
15 Relations Act and under ERISA. And that the Supreme
16 Court when it took up the issue of Federal preemption in
17 Lohr versus Medtronic did not find that all of
18 plaintiff's claims were preempted. And that the Court
19 held in its five to four majority that the manufacturing
20 defect and failure to warn claims were not preempted,
21 even were they based on duties that went beyond duties
22 imposed by Federal requirements for device manufacturing
23 and labeling. I could go on, but I disagree strongly
24 with what I believe the Court asked me.

25 I want to point out that Defendants started

1 with something that is not even a Supreme Court
2 consideration under 1442. It says, we have a right to
3 have you, Judge Frank, decide this. But, that is not
4 one of the three requirements for Federal Officer
5 jurisdiction that the Supreme Court set out in Jefferson
6 City versus Mesa.

7 All they had to do was say they have a
8 colorable defense. But, they want you to say, Judge,
9 take this and decide it yourself, because no State Court
10 should be deciding it. And that has not been the law.
11 It is not one of the 1442 requirements.

12 I heard a lot about regulation, but I heard
13 absolutely nothing about regulation plus. I heard words
14 like comprehensive and pervasive and rigorous, but I
15 didn't hear FDA directed us to do this. That is
16 regulation plus. And that is what every single court
17 who has addressed 1442(a) in the context of either
18 medical devices or drugs has said was missing.

19 For example, in Guckin versus Nagle, the
20 Court said the device manufacturer is not involved in a
21 direct contract with the Federal Government to provide
22 specified products and services to the Government.
23 Rather, the device manufacturer had the right to develop
24 its product as it chose. But, could only sell that
25 product to the public if it complied with applicable

1 government regulations. That is what we have here.

2 Thus, the device manufacturer, like the
3 Defendant in Jamison acted merely as a participant in a
4 highly-regulated industry, a fact that does not provide
5 a viable basis for removal under 28 U.S.C. 1442.

6 Similarly, in Jamison versus Purdue Pharma,
7 the Court, producing a drug, said drug manufacturers do
8 not take governmental orders or follow commands. Two,
9 their actions must conform to government regulations,
10 but they are under no duty or direction to act at all.

11 These Defendants have neither shown nor
12 suggest that their actions were taken at the behest of a
13 Federal Officer. Stated simply, they were not directed
14 to act either by law or by contract. They did so of
15 their own volition. Accordingly, the integrity of the
16 Federal sovereign is not compromised by a suit against
17 them in State Court. There is just no regulation plus
18 here.

19 There is also no evidence, and I listened
20 very careful to hear the evidence of causal nexus. They
21 say FDA has this regulation and FDA has this regulation,
22 but every single court that has addressed that issue has
23 required more, Your Honor. And we suggest that you
24 should, too.

25 Finally, Defendants try to step away from

1 Parks. I heard Defendants say, and we -- I said did he
2 say that? That the Court there did not have the benefit
3 of the Watson decision. That is absolutely not true,
4 Your Honor. The Court in its Parks decision says
5 Defendants heavily rely on Watson versus Philip Morris,
6 and then it goes on in multiple paragraphs to
7 distinguish Watson. It had Watson, it knew about
8 Watson, and so I believe that for them to represent that
9 it was wrongly decided would have been decided
10 differently if it were in this jurisdiction. I don't
11 believe that is correct. So, I would again ask this
12 Court respectfully to remand this case where it belongs,
13 to State Court.

14 THE COURT: Thank you.

15 MR. BURTON: I will be very brief, Your
16 Honor.

17 THE COURT: All right.

18 MR. BURTON: The Defendant was arguing that
19 once these design, manufacturing, labeling proposals by
20 the manufacturer are approved by the FDA, that somehow
21 they become, quote, regulations. That is absolutely not
22 true. There are actual CFR's, there are actual Federal
23 regulations that the FDA can use to govern a product.

24 For instance, even though tampons are not a
25 Class 3 medical device, there is an actual CFR

1 describing the warnings that tampons must contain.

2 There are no CFR's regarding 1861 or any
3 other defibrillator that I know of. We have heard a lot
4 about how the FDA can request additional information,
5 they can appoint independent scientific bodies, they can
6 do testing, they can -- it is a whole list of horrors,
7 it sounds like.

8 There is no distinction there between what
9 the FDA can do with a PMA device as opposed to a 510K
10 device. The FDA can appoint an independent scientific
11 body regarding the 510K device. The FDA can require
12 that the manufacturer submit additional information
13 regarding the 510K device. If the manufacturer of the
14 510K device wants to change its labeling, just like with
15 the PMA device, that labeling has to be submitted and
16 approved by the FDA.

17 None of what they were describing is
18 different between a 510K and a PMA regarding the FDA's
19 oversight of those products. The thing that is
20 different is that because this is a brand new product
21 that no one has ever seen or used one out in the general
22 public, the initial clinical testing of the device has
23 to be submitted to the FDA. That is the most
24 significant thing. And that only makes sense if you
25 have a brand new product that has never been used out in

1 the community and nobody knows exactly how it is
2 functioning, there hasn't been years of precedence in
3 its use, you have got to submit clinical results showing
4 this thing actually works. That isn't particularly
5 burdensome, I don't think. I don't think the Defendants
6 are crying: It is a totally unreasonable regulation,
7 but we have to comply with it anyway, Your Honor.

8 And in regards to this, there has been a lot
9 of talk about, well, a 510K approval, that is 20 hours,
10 and a PMA is 1,200 hours. Not only is there no evidence
11 in front of the Court about how many hours we are taking
12 to approve the PMA supplement or the original PMA on
13 this device, but let's just think about that for one
14 moment. I have heard this 1,200 hours described as
15 rigorous. I believe most of the PMA documents for this
16 device have been produced in this litigation. I think
17 it adds up.

18 Maybe the Defendant can help me out, here,
19 but I think it is somewhere on the order of a million
20 pages of documents. 1,200 hours, if that is what the
21 FDA put into looking over what Guidant submitted to it
22 regarding this device, you wouldn't even be able to read
23 a fraction of what was submitted to the FDA in 1,200
24 hours. And in fact, much of what is submitted doesn't
25 get rigorously and thoroughly reviewed by the FDA.

1 They look at the results that are reported at
2 the end, the summaries, the results that the
3 manufacturer says resulted from this testing. And they
4 rely on the manufacturer being honest and truthful about
5 that.

6 There was one point that I wanted to address
7 because somehow the Defendants are arguing that these
8 lawsuits are an affront to the FDA and frustrate the FDA
9 because the FDA approved these devices and the FDA found
10 these devices to be safe and effective. And now
11 Plaintiff's complaint comes along and says, these
12 devices were not safe and effective. However, there was
13 no mention, there has been a recall.

14 The FDA has actually determined these devices
15 are not safe and effective. There is nothing in the
16 Plaintiffs' Complaint that is not consistent with what
17 the FDA has done and determined themselves, actually,
18 here.

19 I submit to you that if there was a huge
20 problem regarding the multi-billion dollar industry of
21 not only newly approved drugs, but then medical devices,
22 as well, and that State Court lawsuits were such a
23 frustration to the federal agency of the FDA and their
24 jurisdiction and their purpose, I doubt for the last 50
25 years the FDA and the Federal Government would have been

1 allowing State Court lawsuits to proceed without taking
2 action. Thank you.

3 THE COURT: Thank you. Would you like the
4 last word, Mr. Carpenter?

5 MR. CARPENTER: Just very briefly, Your
6 Honor.

7 THE COURT: All right.

8 MR. CARPENTER: Number one, Your Honor,
9 Plaintiffs reliance on Lohr -v- Medtronic isn't
10 particularly helpful in this case. That case dealt with
11 the construction of preemption through the 510K process
12 and doesn't have anything to say about the PMA
13 application process.

14 Number two, Plaintiff's citation to cases
15 like the Jamison case and the Guckin -v- Nagle case,
16 none of those are relevant post-Watson. Those were
17 cases that were decided, and basically the basis for
18 their decision was that these were not Federal
19 directions, they were private for profit companies.
20 Clearly, Watson's analysis surpasses that. Plus, the
21 Guckin -v- Nagle case was pursuant to the IDE exception,
22 didn't deal with a Class 3 device that ever went through
23 the PMA application process.

24 Last point, I don't want to belabor this,
25 Plaintiffs' emphasize that the device was recalled at

1 some point. Well, the point is, the Defendants in doing
2 the recall and in reporting medical device incidents to
3 the FDA acted completely within the scope of the FDA
4 rules. That is an FDA issue. That is compliance with
5 FDA regulations.

6 There is no allegation that Defendants failed
7 to follow any of the applicable FDA rules regarding
8 recalls and communications and labeling issues in the
9 scope of that. So, I think, Your Honor, that is a
10 complete red herring. And that just goes to show how
11 pervasive the FDA regulation of these products are.

12 Having said that, if the Court has no further
13 questions, I will end.

14 THE COURT: Thank you. I will deem it
15 submitted, but I do have a question for all of you.
16 Given the nature of the motion and how it comes to me --
17 it is not the first time, I won't spend a lot of time on
18 this, because it is a very simple question for you.

19 There are two ways I can make a decision.
20 Either way you end up with a memorandum, opinion and
21 order. However, in the interest of time, unless you ask
22 me not to, in less than a week's time I can draft a -- I
23 will just ballpark it, a two-page decision, give or take
24 a couple of paragraphs.

25 So, you can get the decision and people can

1 kind of move on one way or the other so it doesn't hold
2 anything up, with a memorandum and opinion to follow a
3 few weeks after that.

4 I say it in part, because this -- no
5 complaints, but really, apart from the MDL, it is a very
6 busy, busy time these days in getting opinions out. So,
7 I can do it that way and get something into your hands
8 within a few days, unless you say, no, we will just sit
9 tight. I can't think of any prejudice to either side by
10 bringing -- by sending that to you. So, I will start
11 with the Plaintiffs.

12 MS. WIVELL: Your Honor, my reaction, without
13 talking to him would be that that would be a good way to
14 go, because they do continue to remove on Federal
15 Officer Removal jurisdiction, other cases. And I am
16 hoping that if you get us a good order, one that I
17 like --

18 THE COURT: That is justice.

19 MS. WIVELL: That will stop. Because we have
20 to bring remand motions within 30 days. It is an
21 expensive process. I will tell you that I spent --
22 well, a lot of time on this, and I know Mr. Burton did,
23 too. But, I would urge you to do that as quickly as
24 possible so that the parties have some sense of where
25 you are going so that it we have to bring our motions,

1 we bring them.

2 If you rule for them, we may not bring them.
3 But, I think it is very important that you do so as
4 quickly as possible and stop this removal of
5 inappropriately removed cases. That is my opinion.

6 THE COURT: Mr. Burton, any reason not to
7 give you a quick decision followed by --

8 MR. BURTON: That is fine.

9 MR. CARPENTER: Your Honor, we would be happy
10 to have the Court's guidance as soon as we can.

11 THE COURT: The reason I didn't pick door
12 number three, which is in between the two, and that is,
13 well, I will just truncate the decision and get it out,
14 is that I do want to set out reasoning, just because
15 there are other cases, other people affected. And not
16 just the result, but the reasoning may determine what
17 parties do with, well, in light of this, we are going to
18 go forward, or in light of it -- so, I will handle it
19 that way. I will get something to you. I will put it
20 up on the --

21 MR. BURTON: Your Honor, it might be the only
22 silver lining that your staff would have, as well, they
23 won't have to transfer as many files back and forth
24 between State and Federal Court. And I apologize if we
25 went through lunch.

1 THE COURT: No, no, no, no, that is fine.
2 The more effect -- I am better, I am getting better as I
3 get older with just not running through the end of the
4 day. They all are glad I am getting older and mellowing
5 ever so slightly. But, thank you for your arguments.
6 Anything further on behalf of the Plaintiffs?

7 MS. WIVELL: Nothing, Your Honor.

8 THE COURT: The Defendants?

9 MR. CARPENTER: Nothing, Your Honor.

10 THE COURT: All right, we are adjourned.

11 Thank you.

12 (Adjournment.)

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Certified by: _____

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Jeanne M. Anderson, RMR-RPR
Official Court Reporter

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