

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re:)	MDL No. 05-1726
)	(JMR/AJB)
)	
MEDTRONIC, INC.,)	
IMPLANTABLE DEFIBRILLATORS)	
PRODUCTS LIABILITY LITIGATION)	
)	Courtroom 15
)	Monday, July 10, 2006
)	Minneapolis, Minnesota

H E A R I N G O N D E F E N D A N T ' S M O T I O N
 F O R S U M M A R Y J U D G M E N T
 R E : F E D E R A L P R E E M P T I O N

BEFORE THE HONORABLE JAMES M. ROSENBAUM
 CHIEF UNITED STATES DISTRICT JUDGE

TIMOTHY J. WILLETTE, RDR, CRR
 Official Court Reporter - United States District Court
 1005 United States Courthouse
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* * * * *

1 (9:15 a.m.)

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

3 IN OPEN COURT

4 THE COURT: Thank you. Please be seated.

5 THE CLERK: Your Honor, the matter on the calendar
6 is In re: Medtronic, Inc. Implantable Defibrillators
7 Products Liability Litigation, MDL Case 05-1726.

8 Would counsel please stand and state their
9 appearance.

10 MR. GUSTAFSON: Good morning, your Honor.
11 Dan Gustafson on behalf of Plaintiffs.

12 THE COURT: Mr. Gustafson, good morning.

13 MR. BROWN: Good morning, your Honor. Michael
14 Brown on behalf of Medtronic.

15 THE COURT: Mr. Brown, good morning.

16 MR. ZIMMERMAN: Good morning, your Honor. Charles
17 Zimmerman on behalf of the plaintiffs.

18 THE COURT: Mr. Zimmerman, good morning.

19 MR. HOPPER: Good morning, your Honor. Randy
20 Hopper on behalf of the plaintiffs.

21 THE COURT: Mr. Hopper.

22 MR. SHKOLNIK: Good morning, your Honor. Hunter
23 Shkolnik on behalf of the plaintiffs.

24 THE COURT: Mr. Shkolnik.

25 MR. ARSENAULT: Good morning, Judge. Richard

1 Arsenault here on behalf of Plaintiffs.

2 THE COURT: Mr. Arsenault.

3 MR. BECNEL: Good morning. Dan Becnel on behalf
4 of Plaintiffs.

5 THE COURT: Mr. Becnel.

6 MS. COHEN: Good morning, your Honor. Lori Cohen
7 on behalf of Medtronic.

8 THE COURT: Ms. Cohen, good morning.

9 MR. IMMELT: Steve Immelt for Medtronic.

10 THE COURT: Mr. Immelt.

11 MR. LEWIS: Donald Lewis on behalf of Medtronic,
12 your Honor.

13 THE COURT: Mr. Lewis. And I also see
14 Ms. Symchych. Good morning.

15 MS. SYMCHYCH: Good morning, your Honor.

16 THE COURT: I apologize. I take it as a matter of
17 pride that I'm almost always very much on time, and I'm 15
18 minutes late because there was a miracle that happened this
19 morning at 5:49 a.m. My eldest daughter gave birth to
20 Anastasia.

21 (Applause)

22 THE COURT: Anastasia Lilia, weighing in at
23 seven pounds four and 20 inches, is beautiful and you're
24 lovely also --

25 (Laughter)

1 THE COURT: -- but I had a visit to make before I
2 started, so I thank you.

3 I have read and reviewed the briefs and am
4 familiar, I think, with most of the law and you may proceed.

5 Counsel, you may feel comfortable to reach to the
6 left side of that lectern, way over on the side. There you
7 go. There's a button toward the front.

8 MR. BROWN: There we go. Okay.

9 Good morning again, your Honor. Michael Brown on
10 behalf of Medtronic. May it please the Court.

11 THE COURT: Mr. Brown.

12 MR. BROWN: There are three reasons why the
13 plaintiffs' claims as articulated in the master complaint are
14 barred by federal preemption.

15 Number one, the statutory requirements necessary to
16 trigger the express preemption provision involved here have
17 been met, because there are both device-specific federal
18 requirements as well as conflicting state requirements.

19 Second, the judicial criteria for applying those
20 statutory requirements as articulated in Brooks vs. Howmedica
21 also have been met here.

22 And third, a finding of preemption in this case
23 would be consistent with what the Brooks court described as
24 one of the explicit goals of the medical device amendments,
25 that being national uniformity in product regulation.

1 And at the outset, let me just note that this
2 express preemption provision in 21 U.S.C., Section 360(k),
3 does not apply to every medical device on the market. In
4 fact, as the Second Circuit just recently recognized, it
5 applies to a very small subset of medical devices, but for
6 those devices in this small subset, Class III --

7 THE COURT: This is the Class IIIs which have
8 received the PMAs.

9 MR. BROWN: Right, Class III, lifesaving,
10 life-sustaining devices like the Marquis family of devices,
11 preemption principles should be followed and applied, and in
12 this case in particular preemption should apply, because
13 Medtronic did the right thing here. It identified a
14 potential issue, it investigated it thoroughly, it came up
15 with a solution and it applied to the FDA for a redesign of
16 the battery and received FDA approval.

17 THE COURT: Well, let me back you up for a minute.
18 When did it identify the concern?

19 MR. BROWN: It was identified in January of 2003,
20 your Honor, and it was identified --

21 THE COURT: And this was bench testing which
22 revealed some sort of an anomaly, as they styled it.

23 MR. BROWN: Yes, your Honor.

24 THE COURT: All right. And when did they first
25 receive field reports that what they had seen in the

1 laboratory may have existed in the world?

2 MR. BROWN: The first confirmed field report of
3 this particular shorting mechanism was April of '04, your
4 Honor.

5 THE COURT: All right. And when was the new
6 device, the new battery, produced?

7 MR. BROWN: It was produced -- it received
8 approval in October of '03 and was prepared for production
9 and then produced in January of '04, your Honor.

10 THE COURT: It was produced in January of '04?

11 MR. BROWN: Right.

12 THE COURT: And the first field report came in in
13 April of '04.

14 MR. BROWN: That's correct, your Honor.

15 THE COURT: How soon thereafter were further
16 reports from the field realized?

17 MR. BROWN: The next report was July of '04, and
18 then there was a handful of additional reports in the
19 October-to-November time period, to the point where by the
20 end of the year in '04, there were approximately nine field
21 returns, and that coupled with the testing that had been
22 going on from the very beginning and the analyses that had
23 been done led the company essentially to come to the
24 conclusion the testing results indicated that for the second
25 half of life, the percentage of potential failure may be

1 greater than what it was originally predicted, one in ten
2 thousand to 0.2 percent, to possibly as high as 1.5 percent.
3 And it was at that point, your Honor, in January and early
4 February that the company decided to do a voluntary field
5 action, and ultimately that was done in coordination with the
6 FDA and the field action took place in mid to late February,
7 notices went out to doctors with patient guidelines, and the
8 FDA came into Medtronic --

9 THE COURT: When did they ship the last C-H-I
10 whatever, Chi-something battery, out the door?

11 MR. BROWN: Your Honor, I think -- I don't know
12 the last date of shipment. I think that the last one was
13 implanted perhaps in July of '04.

14 THE COURT: All right. Under the statute, let us
15 assume -- and I do not assume -- that this device had a
16 characteristic that would cause it to explode, and let us
17 assume that the FDA had approved the device, and of course
18 they can't manufacture any device that's not approved by the
19 FDA.

20 What is the company's obligation when it learns
21 that and what does either 360(k) or any other federal
22 regulation say about that?

23 MR. BROWN: Well, your Honor, the reporting
24 regulations --

25 THE COURT: And I realize somebody said that legal

1 thinking is the art of reasoning by false analogy, so I'm
2 perfectly comfortable with that.

3 MR. BROWN: Your Honor, all the activities,
4 including reporting, are governed by statute and regulation
5 with respect to something that occurs in the field with the
6 device -- and I'm not certain if your hypothetical included a
7 device happening in a patient. But if there was a field
8 return, there are medical device reports that need to be
9 followed. If in fact that we find information that relates
10 to a clinical performance even if it's not a field return,
11 there are regulations governing reporting of that as well.

12 And again, one of the things -- and it seems that
13 the plaintiffs argue that somehow the post-approval
14 requirements are somehow less rigorous than the preapproval
15 requirements. That is not the case. There is continuous
16 reporting obligations under the regulations, including
17 periodic and annual reports. But if there is in fact a
18 failure, something that meets the definition of the
19 regulation, that needs to be reported, and here, when we did
20 get field returns, in fact, those were reported on a timely
21 basis to the FDA.

22 THE COURT: All right. And what about -- is there
23 any obligation concerning either continued manufacture or
24 continued shipping when there's a defect -- my exploding
25 device is known to the company?

1 MR. BROWN: Your Honor, it's something -- it's not
2 specified specifically in the regulations, but is certainly
3 something that the FDA could impose upon any manufacturer.
4 In other words, once they find out and assess the situation
5 -- so take our example for a minute.

6 When we got the redesign of the new battery,
7 certainly the FDA had all the authority it needed to say, "We
8 don't want you to manufacture or send out the old battery at
9 all." That's not what happened. And in fact, because as of
10 the time we received FDA approval per the PMA supplement for
11 the redesign, it had not manifested itself in the field at
12 all. In fact, as of that time, we didn't know whether it
13 even could ever occur clinically.

14 THE COURT: You had the first field report
15 April 4, but you'd already gotten the application and gotten,
16 what, in 15, 17 days or something approval in October '03 to
17 produce this second battery.

18 MR. BROWN: That's correct, your Honor.

19 THE COURT: Okay. All right.

20 MR. BROWN: So in terms of meeting the
21 requirements of the statute, again, the statute says that
22 there can't be a state requirement that's different from or
23 in addition to a federal requirement. And in applying those
24 criteria -- and we look to Brooks there as an example, and
25 Brooks and the overwhelming majority of circuit courts of

1 appeal have established that the PMA process, along with the
2 conditions of approval, impose device-specific federal
3 requirements on that. The plaintiffs contest that. They
4 rely on the lone circuit court decision Goodlin vs.
5 Medtronic.

6 THE COURT: That's the Eleventh.

7 MR. BROWN: It's the Eleventh Circuit.

8 THE COURT: And everybody seems to think -- or
9 your argument is that there's -- if you want an anomaly, that
10 may be one.

11 MR. BROWN: That would be one, your Honor, because
12 there have been at least five circuits that have had the
13 benefit of the Goodlin court's reasoning, and each one of
14 them, most importantly the Eighth Circuit in Brooks, have
15 elected not to follow it. So, with respect -- and in looking
16 at Brooks and applying the facts of our case there, what
17 Brooks wanted to know was, was there FDA interaction on a
18 preapproval basis, was there FDA interaction on a
19 post-approval basis, and our record establishes that we have
20 both. In fact, there was significant preapproval interaction
21 with the FDA, and even once approved there was interaction
22 with the FDA, so we meet the statutory requirements that are
23 called for by Brooks with respect to establishing the federal
24 requirement prong of the preemption analysis.

25 Likewise, the state requirement prong also has been

1 met and again we look to Brooks for guidance on that. And
2 what Brooks said was that a state law tort suit or a jury
3 verdict calling for either a different warning, a different
4 design or a different anything, would result in a state
5 requirement that conflicts with the federal requirement.

6 THE COURT: Well, we don't have -- I realize
7 Brooks was a warning case and a warning case is somewhat
8 different at least intuitively, although it analyzes the
9 statute, but it seems to me that there the words of the
10 warning are approved by FDA and they negotiate and whatever
11 it is.

12 But once again, I'm particularly troubled here and
13 I will tell you that it's a place where my interest is very
14 thoroughly piqued here. What happens when you know that
15 whatever it is that's been approved by everybody and they
16 tell you this is what you make is not working the way it's
17 supposed to? Not negligent design, not fraudulent design,
18 not anything else. For a moment I'm saying you now know that
19 the thing's not doing what it's supposed to do. What's
20 supposed to happen?

21 MR. BROWN: Your Honor --

22 THE COURT: And what section of the law and what
23 does Brooks say about it?

24 I will tell you that Lohr is impenetrable, but I'm
25 willing to keep banging at it as long as you're willing, and

1 if you have a gloss on it -- by the way, I should make it
2 clear. Judge Murphy's definition and explanation is
3 pristine, clear, and I am thoroughly dedicated to it.

4 MR. BROWN: Your Honor, impenetrable is a good
5 word. As I told someone, I had a state court judge in
6 Milwaukee say that he had a severe headache after reading
7 Lohr --

8 THE COURT: If I did, I don't know if I'd take the
9 medicine that was prescribed.

10 MR. BROWN: Well, your Honor, you're right.
11 Brooks -- the only claim involved in Brooks was failure to
12 warn, but the analysis that Brooks applied certainly applies
13 to design, manufacturing and all the others.

14 Now, to your question with respect to once the
15 situation -- once, for example, a manufacturer decides it's
16 going to voluntarily withdraw the product, does that do
17 anything to the preemption analysis or to the PMA approval --
18 and Plaintiffs have suggested it did, but as we indicated and
19 cited to the Court in our reply brief on page 4, footnote 2,
20 there are cases out there that indicate that in fact even
21 withdrawn products are subject to preemption as well. And
22 the reason is, and was probably best put by a district court
23 in Michigan, the Kemp vs. Pfizer case, which talked about the
24 whole idea of these innovative devices and having to go
25 through the rigorous PMA process, is that manufacturers go

1 there with the idea that -- without the threat of tort
2 litigation in front of them. And if in fact experience
3 proves later on that the expectations weren't met and the
4 device should be either voluntarily or even ordered
5 withdrawn, that it doesn't change the preemption analysis.
6 And I think the court had a very catchy phrase there. It
7 said if the manufacturers knew that their umbrella was going
8 to be snatched away once it began to rain, they'd have no
9 incentive to ever venture outside, meaning that they go in
10 knowing, they go through the process and get PMA approval.
11 No one can anticipate every single thing that may happen down
12 the line. So the device's status as having been withdrawn
13 doesn't change anything.

14 And the same is true for the fact that there was
15 approval for a new battery. Again, we have a situation --
16 there's no authority cited by the plaintiffs, although they
17 argue it in their case, that somehow that invalidated in some
18 way the original approval. And throughout their papers
19 there's a certain revocation as a matter of law argument that
20 pervades it, but that's not how the process works.

21 THE COURT: That seems to be somewhat the
22 suggestion of Ms. Parisian, as I recall.

23 MR. BROWN: Well, yeah. They use Ms. Parisian --
24 I mean, basically, they take the notion of parallel
25 requirements or failure to comply and try to plead around or

1 otherwise avoid preemption. And for contextual purposes,
2 where this comes from, it comes from Lohr, where essentially
3 Lohr said that nothing in 360(k) precludes the application of
4 requirements that are genuinely equivalent or parallel. So
5 when people say failure to comply, really what they're
6 talking about, are there parallel requirements. And there
7 are some examples of how that works in real life and some of
8 the circuits have dealt with it, including most recently the
9 Second Circuit in Regal where they said if you have a device
10 that did not comply with the federal requirements -- it
11 usually comes up in the manufacturing standpoint -- then you
12 wouldn't have a preempted claim. Why? The reason is because
13 you wouldn't have met the federal requirement prong and
14 therefore the state action would merely be parallel to the
15 federal action.

16 Now, all of the cases that talk about that talk
17 about it in the context of the device not complying with the
18 federal requirements, and we've taken the position all along
19 that if there's any plaintiff in this proceeding that has
20 evidence that his or her device was something different than
21 what the FDA approved, in other words, they got a different
22 design, they got a different warning, the manufacturing
23 process wasn't followed, then that wouldn't be a preempted
24 claim, but we don't have that in this record. So when we
25 filed this motion in March of this year, at the same time we

1 also produced to the plaintiffs the actual manufacturing
2 records for each of the plaintiffs that we had in the MDL at
3 that time. Some have been added since then and we'll
4 certainly produce those, but --

5 THE COURT: And you showed that that device
6 matched the FDA requirements.

7 MR. BROWN: Exactly. So even though Dr. Parisian
8 has lots to say about a lot of issues, nowhere is there an
9 allegation that any particular plaintiff's device did not
10 conform to the FDA-mandated manufacturing design or warning
11 specification.

12 So that's what the parallel requirements and
13 failure-to-comply cases talk about. They like to impose
14 something that's a general failure to comply and they use a
15 kitchen sink type of approach. And we won't get to whether
16 Dr. Parisian is admissible or not, but just even the types of
17 claims they allege.

18 I mean, number one, there is no general
19 failure-to-comply exception. A case that was cited in our
20 brief that's worth taking a look at is a district court case
21 called Kerry vs. Shiley, which again said noncompliance as to
22 the particular plaintiffs' device is important and would
23 result in a nonpreempted claim, but noncompliance that's not
24 related to that is irrelevant for purposes of the preemption
25 analysis.

1 THE COURT: So the short version of your argument
2 is, we were told to produce -- we were approved to produce X,
3 we consistently produced X, and whether or not it worked is
4 irrelevant.

5 MR. BROWN: Right.

6 THE COURT: That's the short version.

7 MR. BROWN: Well, it's the short version of it.
8 Of course, if in fact it doesn't work later on in their field
9 returns, like everything else, there are statutes and
10 regulations that need to be followed and authority, and here,
11 you know, that process played out. What the plaintiffs like
12 to say is that -- and they point to four or five different
13 scenarios.

14 THE COURT: Then help me again. What was Justice
15 Stevens talking about with the parallel state regulations
16 which they didn't seem to find onerous?

17 MR. BROWN: Well, your Honor, under that
18 regulatory scheme it makes perfect sense and the same result
19 was reached last term with the Bates court, but there you
20 need to look --

21 THE COURT: Well, Bates was FIFRA.

22 MR. BROWN: Was FIFRA, right. So I mean, the
23 important part of doing the parallel requirements analysis is
24 looking at the regulatory scheme involved. Justice Stevens
25 was quite right, frankly, in that there were only parallel

1 requirements because there was no specific federal
2 requirement there. Again, that's different than the PMA
3 process where there are specific federal requirements.

4 So, this issue was dealt with last year by the
5 Seventh Circuit in a case called McMullen vs. Medtronic,
6 where the plaintiffs argued -- and argued Justice Stevens'
7 and Lohr's discussion of parallel requirements. There they
8 said: Medtronic, you learned of a danger and you didn't warn
9 about it soon enough, very similar to the argument here. And
10 the court said: Wait a minute. I've read the parallel
11 requirements and I've also read Bates, and Bates says they
12 need to be genuinely equivalent. But imposing on the
13 manufacturer a duty to warn whenever the plaintiffs say we
14 should have warned is not a general requirement. That is a
15 specific requirement that would be in addition to or
16 different from the federal requirement and they're not
17 genuinely equivalent.

18 So, the short answer or argument on that point,
19 your Honor, is, if you have PMA requirements for the device
20 that have been met, they can never be genuinely equivalent.
21 And in fact, the only three medical device cases that cite
22 Bates all stand for the proposition advocated by us here, and
23 that is the McMullen case in May, the Regal vs. Medtronic
24 case, and the Texas Court of Appeals case Baker vs. St. Jude
25 Medical. So, there really -- on the parallel requirements,

1 again, there when you have no specific federal requirement,
2 they can in fact be parallel and they can in fact be
3 equivalent and that's what Justice Stevens was talking about.

4 So, going back to the arguments that Plaintiffs
5 make here, again, sort of a revocation as a matter of law,
6 what they do is point to the approval letter for the device,
7 which has language in it -- and again these letters do,
8 current ones don't, but I'll get to that in a second -- that
9 if there's been a failure to comply with the conditions of
10 approval --

11 THE COURT: That's what it says -- then the
12 approval is withdrawn.

13 MR. BROWN: It says it's invalid or withdrawn,
14 but --

15 THE COURT: All right. Now, is it invalid
16 ab initio? Is it invalid when somebody brings that to the
17 attention of the FDA? Is it declared invalid on a certain
18 date? That was not very clear to me.

19 MR. BROWN: Well, it's not clear, your Honor, and
20 they've since changed it. And in fact, while the language
21 says what it says in the letter, the fact is that's not how
22 the process works. Like everything else, there's a
23 regulation for this. 21 C.F.R. 814.46 controls how a PMA
24 would become invalidated or withdrawn and there's a notice
25 and comment period. And as I think this Court observed in

1 another case, even the FDA couldn't ipse dixit declare it
2 invalid. You'd have to follow the regulatory procedures and
3 there would have to be an enforcement proceeding here.

4 And in fact now --

5 THE COURT: There's a reg, but does it become
6 invalidated as a matter of law and the reg just gives a
7 prescription for how you effectuate it?

8 MR. BROWN: No, your Honor, because actually,
9 814.46, as well as 21 U.S.C., Section 360(e) both talk about
10 the procedure and process that would have to go into place
11 before it would ever become invalidated. And so again, there
12 is no such thing as revocation as a matter of law, and again
13 there's no case support cited by the plaintiffs for that
14 proposition and there would need to be a proceeding, and that
15 didn't happen here. And in fact -- and Mr. Samsel testified
16 to this in his deposition -- the letters, to use the
17 pejorative term, boilerplate that go along with it now say
18 that failure to comply with conditions of approval would be a
19 ground for invalidation. That's consistent with what the
20 regulation says, 814.82, so I think that's the situation.

21 Same argument is made that because after our
22 voluntary withdrawal, the FDA later declared that it was a,
23 quote, Class II recall. And again, any product voluntarily
24 withdrawn from the market will be declared a, quote, recall.

25 THE COURT: Now, tell me -- all right. This is a

1 Class II recall, it was a Dear Doctor letter that was sent,
2 and then the FDA termed it, or did the FDA then make it a
3 requirement that it was a Class II recall?

4 MR. BROWN: Once you have a situation where
5 product is actually removed from the market, the FDA has to
6 by definition, by statute, make a classification of one kind
7 or another. Class I through III recall. So the mere fact --
8 any time any manufacturer withdraws a product even
9 voluntarily, it will be deemed a, quote, recall. Here it was
10 deemed a Class II recall, which doesn't affect preemption
11 purposes, but for factual purposes means that the probability
12 of serious adverse health effects was remote.

13 So the question then is and Plaintiffs seem to
14 argue somehow that that changes the preemption analysis, but
15 again, the cases we cited, even voluntarily withdrawn
16 products have enjoyed preemption for the same rationale and
17 reason before. So again, it doesn't invalidate the PMA in
18 any respect as well.

19 So, again, there's a general failure to comply
20 argument they make which is unsupported, there's the approval
21 letter basis of revocation as a matter of law, there's the
22 classification of it as a Class II recall, and the status as
23 a withdrawn product. Each of those Plaintiffs argue would
24 turn into a jury issue, and again, under their argument
25 essentially there never would be preemption, because --

1 THE COURT: That's all right. Under yours there
2 never wouldn't, so it's sort of a horse apiece.

3 Let me swing, if I can, away from this for a minute
4 and back to basic things for a minute. Let me try and pick
5 up some of the threads that I think are implicit in the
6 arguments that have been advanced at least by the plaintiffs.

7 The first is that there never really was an FDA
8 approval exactly of this device. The thesis, as I understand
9 it, is, there was some device that over time using the PMA
10 system they kept modifying until it transmogrified into this
11 device that became the items that are concerned here. And
12 therefore, there was never really the kind of global
13 consideration. It was kind of a series of step-by-steps that
14 never got that full layout and that full work-through. Would
15 you comment on that.

16 MR. BROWN: Absolutely, your Honor. It's simply
17 the PMA and PMA supplement process. And again, the original
18 or, quote, root PMA was approved in October of 1998 for a
19 product called GEM and after that there were PMA supplements.
20 Again, it's governed by regulation and statute and each time,
21 if the manufacturer goes to the FDA and says, "This is what
22 we have in mind. We'd like to do this by PMA supplement," if
23 the FDA thinks, "Wait a minute. This is a different product,
24 you're trying to do something," they'll just say, "No, you
25 have to file a PMA."

1 THE COURT: But that's also -- but that's the
2 choice of which entity?

3 MR. BROWN: It's the choice of the manufacturer to
4 approach FDA and say, "FDA, we would like to do this via the
5 PMA supplement process," at which point in time the FDA can
6 say, "That's very nice, but frankly, there's too much here.
7 We think you need to go and file a new original PMA." Or
8 they can say, "Yes, you can do it this way, but we're going
9 to make you do one more clinical test."

10 THE COURT: So your answer is this is the FDA's
11 decision, which has the right -- the company could obviously
12 ask for the full PMA process, but they would likely to want
13 to go to the PMA supplement.

14 MR. BROWN: Absolutely, your Honor. In fact --

15 THE COURT: It's cheaper and it's faster.

16 MR. BROWN: In most instances, yes, your Honor,
17 because it is building on existing data. So in other words,
18 it's not a shortcut method to get approval without having
19 laid the foundation, because that is done -- and in fact, the
20 entire PMA is considered as part of the PMA supplement
21 process. The same argument Plaintiffs have made with respect
22 -- there's another process called real time review where you
23 get review in a little bit more expedited fashion which
24 happened for the PMA supplement concerning the battery.
25 Again, the FDA can say: "I'm sorry. I don't think this is

1 appropriate for real time review. We'll put you on the
2 normal schedule." It's something that is totally within
3 their control.

4 And in fact, when the first Marquis battery was
5 approved in March of '02, in November of 2001 there was a
6 meeting with the FDA and there are minutes that are attached
7 as Exhibit G to Mr. Samsel's affidavit where the FDA reviewer
8 was saying, "You know, we're going to need more time than is
9 scheduled for this review because there's a lot here."
10 Again, that's not uncommon. They get to dictate whenever the
11 schedule is. If there's a lot of information, perhaps it'll
12 take a longer time; if there's less information, perhaps
13 it'll take a shorter period of time.

14 THE COURT: All right. Then they make an
15 argument -- they say they would like you to define the
16 requirement so that I can contrast it with state or the local
17 requirement. Take the three-step analysis that Judge Murphy
18 focused on, all right? What's the requirement?

19 MR. BROWN: The requirement is, as the Kemp court
20 and Brooks court said, the totality of the design,
21 manufacturing and warning requirements.

22 Here, taking it to our particular devices, your
23 Honor, I point you to Exhibits B through S of Mr. Samsel's
24 affidavit, we've probably got some examples of that here
25 where specifically there are specific requirements for the

1 battery: Requirements about manufacturing, requirements
2 about welding, requirements about electricity, all of those.
3 Those make up the specific requirements here. And so these
4 are not general requirements that apply to any device on the
5 market. These are requirements that are specific to the very
6 device as well as the very battery involved. And again,
7 those are part of the record, Exhibits B through S would make
8 up the requirements and we can go over them in detail, but
9 they talk about the design, they talk about the testing, they
10 talk about environmental tests, safety tests, what the
11 assembly specifications are to be. There is not a lack of
12 specificity. In fact, this meets the Brooks test quite
13 nicely in terms of specificity, but even without that, the
14 process -- and courts like Kemp and Brooks say once you
15 receive approval, there's the assumption that has already
16 been done, but we have it here as examples of the specific
17 device and specific battery in question.

18 THE COURT: All right. You may proceed.

19 MR. BROWN: Okay. Well, your Honor, I think the
20 first requirement as dictated by Brooks in terms of a federal
21 requirement has been met. Again, the second requirement has
22 been met with respect to what the plaintiffs' claims -- and
23 again, I think Brooks said it best when it talked about -- it
24 said the state requirement in this case would come from a
25 common law duty as applied by an individual jury. So I don't

1 think, frankly, there's -- even though the plaintiffs have
2 contested this, I don't think there's much debate even after
3 the Bates decision that common law duties can form the basis
4 of state requirements that would conflict with federal
5 requirements.

6 I think I've addressed -- and if you then say we've
7 met the statutory requirements of federal and conflicting
8 state, then you apply them to the causes of action in this
9 case. And so the question is once you do that are the claims
10 preempted, and the answer is yes.

11 And if you look at the claims that have been
12 asserted here, very similar to claims in a lot of other
13 cases: Design, warning, warranty, manufacture, all of that,
14 the answer -- and there's case law to support the fact that
15 all of those claims would be preempted, including a
16 manufacturing claim with the following caveat. If in fact
17 the claim is that the manufacturing process that the FDA
18 imposed was insufficient or deficient or defective, that is a
19 preempted claim, as I mentioned before. If any particular
20 plaintiff received a device that was not made in conformance
21 with the manufacturing requirement, that would not be a
22 preempted claim, but we don't have that in this --

23 THE COURT: And you've indicated that at least for
24 those you were able to identify, you tracked them and you
25 know they were made that way.

1 MR. BROWN: Right.

2 THE COURT: All right. Now, let me -- they also
3 suggest that in the notification to the FDA there was a
4 reference to this as some kind of an anomaly, and you said --
5 and then it said something like but battery failure is a
6 known problem. The suggestion is offered that this was a
7 ruse in the sense that while battery failure is possible in
8 any battery, this was in fact not the known problem. This
9 was a different problem in kind, degree and known to the
10 manufacturer, and in that regard, that the statement made was
11 at least problematic and the extent to which it's
12 problematic, I guess, is thrown up on my bench and I get to
13 worry about it.

14 MR. BROWN: Your Honor, I'm not aware -- I know
15 the argument. I'm not aware that it was in the notification.

16 THE COURT: Well, I think it wasn't in the
17 notification I think is really what their complaint is. As I
18 looked at their brief, as I recall, it was in that little --
19 they put together a little cell of some sort saying that they
20 had actually stated it -- see, I have an approval over
21 (indicating) here. I have one of their lawyers who nods his
22 head when he thinks I'm on a theme that he likes. At least
23 he doesn't nod his head when I don't. But in there -- we
24 call those appellate courts.

25 (Laughter)

1 THE COURT: At any rate, there actually was
2 language which would have notified the FDA that there was a
3 serious problem, but it was either modified or toned down in
4 a fashion which suggested to the FDA that, oh, we've picked
5 up one of those things we've always been concerned about, the
6 black spots or whatever it is.

7 MR. BROWN: Okay. I think I know where you are,
8 your Honor. In terms of the PMA supplement that went to the
9 FDA with the redesign, I think that's what we're talking
10 about.

11 THE COURT: Yes.

12 MR. BROWN: And the question is whether or not we
13 told the FDA what the reason for the change is, and I do
14 think we have a slide about that as well. There was no
15 secret there. What we said was that we had -- we uncovered
16 something that had the potential for internal shorting and we
17 were making these changes to enhance the safety of the
18 device. Now, as it relates to whether it was a known
19 shorting mechanism or not --

20 THE COURT: Their argument in short is what one of
21 my professors said, "That may have been a statement that was
22 true, but was it enlightening?"

23 MR. BROWN: Certainly, your Honor. I mean, the
24 reason for the change is stated. The entire supplement goes
25 through chapter and verse about what it is that was found,

1 what was tested, what the, quote, any anomalies were, so --
2 and there was some claim that somehow we didn't submit all
3 the data or the design verification report. In fact, you
4 know, we submitted this appendix. We did and the record is
5 clear about that.

6 But again, for preemption purposes, the issue
7 really wouldn't be relevant for the following reasons.

8 I mean, number one, the issue about, yes, all
9 devices can fail and all batteries can have shorts of one
10 kind or another, this was a new shorting mechanism to us. No
11 doubt about it. There seems to be some argument that, well,
12 therefore, then the FDA didn't know about some new shorting
13 mechanism before it happened -- of course they didn't,
14 because it hadn't happened yet -- that that should somehow
15 change the analysis.

16 THE COURT: But were they told that it was a new
17 shorting mechanism?

18 MR. BROWN: Yes, they were told it was a new
19 shorting mechanism.

20 THE COURT: Was it only in the appendix or was it
21 in the declaration?

22 MR. BROWN: I'm not sure what the declaration --
23 it was in the submission. It was in the PMA supplement
24 application, both the letter that went with it as well as the
25 submission itself.

1 THE COURT: All right.

2 MR. BROWN: So --

3 THE COURT: What did it say, if you have that
4 convenient? And I realize I'm pulling small things out of a
5 large pool here. And if you don't have it, that's fine.
6 I'll chase it.

7 MR. BROWN: I don't have it and maybe at a break
8 after the plaintiffs talk I can track it down. But again,
9 the reason for the change and what was found was laid out in
10 detail -- and again, something that I think is important and
11 seems to get lost here is that once all of this happened, so
12 once we have a field action, the FDA comes in to inspect and
13 audit us to see whether or not we played according to Hoyle
14 and did all the right things. And at no point have they
15 suggested that somehow: "Well, gee, you didn't tell us it
16 was a new shorting mechanism" or: "You used language that
17 somehow was a little different or whatever." But the point
18 is, that's something that if the FDA felt like we hadn't been
19 straight with them, they have the enforcement power to do
20 things to us that we certainly don't like. What can't happen
21 is that -- to have an expert come in and just declare that
22 somehow -- that we misled or deceived the FDA. Those are
23 claims that frankly have been rejected by the Supreme Court
24 in Buckman and lower courts that have dealt with it also, and
25 it really is the nature of the claim.

1 And I think where this is best summarized in the
2 plaintiffs' brief is on page 23 of their opposition. They
3 list A through C of all the supposedly bad things we did. If
4 you look at that, all of it gets down to that somehow we
5 misled the FDA. Well, the Supreme Court in Buckman said,
6 well, even if fraud was committed with respect to the
7 application process, that's going to be a preempted claim.
8 Putting that into real life in a case called Webster vs.
9 Pacesetter, the court there said you can't bootstrap a
10 failure to warn claim by claiming that you failed to report
11 adverse events, the same claim that's being made here. The
12 argument there --

13 THE COURT: I think you're getting a supplemental
14 bit of information there. Your sisters have been working
15 furiously.

16 MR. BROWN: Okay. On the known failure rate, I'm
17 told that it's on the screen now. No, that's the failure to
18 report claims.

19 But just quickly, this is from the Webster case,
20 where essentially the plaintiffs there made an argument
21 similar to the argument being made here, and that is that the
22 company failed to report adverse events and had the FDA known
23 that, they either wouldn't have approved the product or would
24 have required some different warning. That's essentially
25 what we have here through their expert. The Webster court

1 said that's an impliedly preempted claim. And to the extent
2 that Plaintiffs are saying, "Well, what we're really doing is
3 just trying to enforce federal regulations," that claim fails
4 as well, because there is no private right of action for
5 individual plaintiffs merely to enforce. The Buckman court
6 says that, Ray vs. Medtronic in the District Court of
7 Minnesota says that. It's a pretty universal theory.

8 So back to the reason for the change, your Honor.
9 This is from the actual supplement that was submitted to the
10 FDA, it's certainly one page of it right there, and it
11 indicates what it is we knew and what the reason for the
12 change was. So there it says: "Internal shorts in the
13 outermost battery have been observed" --

14 THE COURT: You need to speak a little closer to
15 the mike.

16 MR. BROWN: Okay, your Honor. And it says:
17 "Internal shorts are a known failure mode that can result in
18 rapid cell depletion, heating," et cetera, and it goes on to
19 describe it. So the question is -- and in fact, is that
20 helpful or whatever. The idea is, we were telling the FDA
21 that we had detected a shorting mechanism. In fact, as part
22 of this supplement, they clearly knew about it, because one
23 of the things that we did was to design a new test called a
24 shorting susceptibility test that had not been part of the
25 previous application because it applies --

1 THE COURT: I'll be frank to tell you I don't
2 recall -- I have no doubt you're accurate. I don't recall
3 this part in the brief, which is fine with me, but I just
4 don't recall that.

5 MR. BROWN: You're right, your Honor. It's
6 probably not in the brief and frankly I don't think it really
7 bears on the preemption analysis, but --

8 THE COURT: Continue. It's interesting.

9 MR. BROWN: No, it is in the sense that, again,
10 part of the whole investigative process, they're trying to
11 determine is it materials, is it manufacturing, is it design,
12 what is it, and as part of this process in coming up with the
13 new design, they had a test called the shorting
14 susceptibility test. And again, that was a test that hadn't
15 been submitted before and in fact it was designed for
16 purposes of addressing this. And so as part of our
17 application to the FDA, we laid out exactly why we thought
18 this was a helpful test, what the results were and all of
19 that. So this idea that somehow they didn't know it was a
20 new mechanism for shorts is just not borne out by the record.

21 So with respect to that, your Honor, I think in
22 terms of the requirements that we met and what Brooks calls
23 for -- and I think we may have slide 30 up there -- I think
24 we've met the statutory requirements and we've also met the
25 judicial criteria for applying that, meaning we have federal

1 requirements, we have state requirements that would conflict
2 with them, and the plaintiffs' attempts to plead around or
3 otherwise avoid preemption simply don't fly, because nowhere
4 in the record is there any triable issue of fact that any
5 particular plaintiff's device failed to conform with the
6 requirements. All this other stuff, this essentially misled
7 the FDA, is something that the Supreme Court has dealt with
8 in Buckman, other courts have dealt with, there is no private
9 right of action, and we think we have met our obligation here
10 and that the motion, respectfully, should be granted.

11 THE COURT: Have you hit most of the high points?

12 MR. BROWN: Those are the high points, your Honor.

13 THE COURT: Thank you.

14 MR. GUSTAFSON: Your Honor, if I might approach
15 and hand you up some paper. I'm not quite as skilled as he
16 is with the computer, but there's two things I'm giving you.
17 One is a brief skeleton of my argument and the other is a
18 PowerPoint that may or may not work depending on how my
19 skills go today. I've provided copies to counsel for
20 Medtronic.

21 (Documents handed to the Court)

22 MR. GUSTAFSON: Good morning again, your Honor.
23 Dan Gustafson on behalf of the MDL plaintiffs.

24 THE COURT: Mr. Gustafson.

25 MR. GUSTAFSON: Your Honor, in their briefs and

1 argument today, Medtronic basically tells you that PMA
2 approval equals complete preemption of all Plaintiffs' state
3 law claims. But because they have to acknowledge that the
4 express preemption statute doesn't reach that far, they rely
5 on Buckman to sweep up whatever falls through the cracks.
6 And while that argument may have some surface appeal, if we
7 were writing on a clean slate, it might be different, but
8 we're not writing on a clean slate. We're writing on a slate
9 that's controlled by Lohr, Brooks, and to a certain extent
10 this Court's decision in St. Jude, and each of those courts
11 have all rejected such an expansive reading of the express
12 preemption under the FDA -- MDA and its FDA regulations.

13 THE COURT: What does it take -- your brother was
14 quit zealous to tell me and I think the short version of his
15 argument was: We had approval to build a device that had
16 these steps taken and these elements in it. We have looked
17 at all of the injured people or people who claim injury and
18 every one of their devices, and while he didn't post them on
19 the wall, he said each one of these shows we did every one of
20 the steps that were required by the process and therefore
21 this case is over, okay? Where is he wrong?

22 MR. GUSTAFSON: Well, two reasons.

23 First of all, Brooks requires more than that. It's
24 made clear in Brooks that PMA approval -- there was a
25 previous Eighth Circuit case that's discussed in Brooks, and

1 they said: We previously held that PMA approval alone was
2 enough. But after Lohr we have to back up from that. We
3 have to modify that. And if you read Brooks, the
4 modification is you have to look at the PMA approval, you got
5 to look at the specific federal requirements, do that careful
6 comparison that you talked about earlier, your Honor, to
7 determine if there truly are the conflicts, the direct
8 conflicts that Judge Murphy acknowledged in Brooks were the
9 key test to whether there was preemption.

10 THE COURT: All right. So now Brooks tells me I
11 have a dance to do.

12 MR. GUSTAFSON: That's right.

13 THE COURT: All right. What's the first step?
14 What am I looking at?

15 MR. GUSTAFSON: Well, the first step is, you got
16 to look at whether there's been federal requirements imposed
17 on these devices.

18 THE COURT: What federal requirements were
19 imposed?

20 MR. GUSTAFSON: I can't answer that question, your
21 Honor, and I'll tell you why I can't answer it.

22 They submitted about two inches of materials which
23 were excerpts and certain information related to the various
24 PMA supplements and PMAs that are at issue in this, but I
25 can't glean from that what they think the requirements are.

1 They basically say everything we submitted to the FDA that
2 was approved as a requirement and therefore no matter what it
3 is, it's a requirement and it's covered. But if you read
4 Brooks, that's not how it reads. What Brooks does is, it
5 takes the warning label and it looks at it, and then it looks
6 at the information that it had and it looks at what the FDA
7 said and looks at what the company responded, and they go
8 through five iterations of the label. The company says this
9 and the FDA says, "No, change the label. Do that," so on and
10 so forth.

11 THE COURT: Once again, in some regards, while
12 Brooks is enlightening, it's a labeling case, not quite the
13 same as this one. This one is a manufacturing case and deals
14 with a device where there was a set of manufacturing steps,
15 and every one of these things other than the fact that some
16 failed and some didn't is pretty much -- it's an assembly
17 line. They were produced one after another, they were all
18 essentially identical, each model was identical to itself.
19 Where am I here?

20 MR. GUSTAFSON: Well, two things. One, we haven't
21 -- as you know, we had limited discovery and so we haven't
22 actually done any --

23 THE COURT: We fought that battle and on that
24 issue you lost.

25 MR. GUSTAFSON: I understand I lost, but we don't

1 know whether there were any defects in the manufacturing,
2 because we don't know what their processes were, their
3 quality assurances were. We are left by saying the
4 traceability records which they provided attached to
5 Mr. Brown's affidavit show that they satisfied each of the
6 tests required by the FDA. That doesn't mean -- let me give
7 you sort of an extreme example.

8 That doesn't mean there wasn't a hole in the roof
9 and that water was pouring into the manufacturing line and
10 creating rust inside of each of these devices. We don't know
11 that.

12 THE COURT: All right.

13 MR. GUSTAFSON: But that would be a manufacturing
14 defect that would not be covered by the requirement, because
15 I'm certain -- at least reasonably certain -- that the FDA
16 regulations say don't have holes in your roof. I don't think
17 that's one of the requirements. I have the manufacturing
18 requirements that they submitted here, Judge, and if I could
19 put them up on the ELMO, I'd like to show them to you.

20 THE COURT: Feel free.

21 (Pause)

22 THE COURT: They're beautiful.

23 (Laughter)

24 MR. GUSTAFSON: They're not particularly legible.

25 THE COURT: That's what I was thinking.

1 MR. GUSTAFSON: This copy is not particularly
2 legible either, your Honor.

3 THE COURT: I can assure you at this moment,
4 Mr. Gustafson, I'm unlikely to read it in more than a little
5 detail here.

6 MR. GUSTAFSON: Well, the point I want to make is
7 it reads like a table of contents, your Honor. It doesn't
8 read like any sort of requirement. I mean, the first one,
9 7.2, basically says manufacture these things, you know, and
10 make sure that they're done properly and safely, or, you
11 know, general words to that effect. I don't have it in front
12 of me, but --

13 THE COURT: I'm in favor of those things.

14 MR. GUSTAFSON: Yeah, sure, me too. But the point
15 is that those kind of requirements, if those are in fact the
16 manufacturing requirements, which is what they say they
17 are --

18 THE COURT: Well, I think the manufacturing
19 requirements, at least for the nonce, I have to assume they
20 say things at some point, like they need to have a battery
21 which produces a certain amount of voltage, it needs to have
22 a certain capacitance, it needs to have a number of things.
23 I presume it doesn't say make things that make people feel
24 better. It's just not my idea of a manufacturing
25 requirement.

1 MR. GUSTAFSON: Well, I think the things that you
2 mention are probably closer to the design requirements, but I
3 think the manufacturing requirements would be, you know, have
4 a clean room, have a quality assurance program, those kinds
5 of things. And in Lohr they made clear that those kind of
6 general requirements are not specific enough to create
7 specific federal device requirements.

8 THE COURT: Well, let me pick up then one of the
9 things that Lohr was fascinating about, and when Mr. Brown
10 comes back I will ask him what I would regard as otherwise an
11 omitted question.

12 Justice Breyer was fascinated by a one- or a
13 two-inch wire.

14 MR. GUSTAFSON: Sure.

15 THE COURT: All right. Do we have any indication,
16 A, that there was not all the one-inch wires that were
17 supposed to be there, A; B, would a jury verdict in your
18 favor be tantamount to saying there should have been a
19 two-inch wire?

20 MR. GUSTAFSON: Let me answer the question this
21 way. I think Justice Breyer's example was concerning -- was
22 concerned with the notion of whether a jury verdict was a
23 requirement, and I think it's clear from his example that a
24 jury verdict that was based on a finding that you had to use
25 a two-inch wire as opposed to a one-inch wire could

1 constitute a requirement, but I don't think a general verdict
2 that you negligently manufactured your product rises to the
3 level of the specificity that Justice Breyer required.

4 And in the Bates, even though it's an FIFRA case,
5 the language in Bates is almost identical to the preemption
6 language here. It's requirements in addition to -- different
7 from or in addition to. They use the word "requirements" --

8 THE COURT: And they were clear that they were
9 applying at least in some regard the same analytic.

10 MR. GUSTAFSON: That's right. They cite to Lohr
11 several times in the case and use analogies from Lohr, and
12 what they say in that case is that a general jury verdict is
13 not a requirement, because it doesn't require in this case
14 Medtronic to do anything other than perhaps pay the judgment
15 or satisfy the verdict. It's not a specific requirement
16 applicable to a medical device.

17 The whole argument that they make here is based on
18 the fact that a jury verdict will induce them to change their
19 conduct, and Bates rejects that inducement test. And I don't
20 know how you can read the Bates case as saying requirements
21 are, you know, a command of law that must be obeyed and jury
22 verdicts are merely actions which might induce or motivate a
23 decision. I don't see how you can read that as supporting
24 the notion any longer that a common law jury verdict that
25 doesn't have the specificity of Justice Breyer's

1 two-inch/one-inch in the verdict could possibly be a
2 requirement. Bates wrote that out of the requirements.
3 They're not going to define requirements differently because
4 they particularly cited to Lohr and they particularly said in
5 Lohr: We held that a damages verdict is perfectly proper. I
6 think the way they said it is: Nothing in the statute
7 prevents Florida from imposing a damages remedy separate from
8 the requirements. And it makes perfect sense.

9 You know, if this product is defective, which by
10 the way, we now know it is because the FDA has said it is --

11 THE COURT: I think your brother's argument is
12 that they said it because any time there's a Dear Doctor
13 letter issued, there's a de facto declaration that it's some
14 kind of a recall, and if that means it's defective, I guess
15 you win the point, but it's a closed circle.

16 MR. GUSTAFSON: I don't think so.

17 THE COURT: Okay.

18 MR. GUSTAFSON: I mean, if you put up document 2,
19 here, Judge, you'll see that when they issued this recall
20 letter --

21 THE COURT: Just hold on a second here. I have to
22 get to a different motif.

23 MR. GUSTAFSON: It's in the paper if you'd rather
24 look at it that way, too.

25 THE COURT: I'm happy.

1 MR. GUSTAFSON: Okay. They did their voluntary
2 recall, what they called a field action, and the FDA looked
3 at it and they say: We have reviewed your action and we
4 conclude that it meets the formal definition of a recall,
5 okay? So they're right about that point. I don't
6 necessarily agree with them that all field actions result in
7 recalls, but what goes on in the letter is more important:

8 This is significant, because it's an alternative to
9 an FDA action, legal action, to remove your defective product
10 from the market.

11 That's more than just saying it's defective. It's
12 saying: If you hadn't taken this recall, we would have taken
13 legal action or could have taken legal action to remove this
14 product from the market.

15 And then if you look at the next document, document
16 number three, what you see is the FDA concluding that if you
17 don't conduct this effective recall that you've promised to
18 do, in my words, it could result in seizure of the violative
19 product or other legal sanctions under the FDCA. They're
20 basically telling them, look, you took a voluntary field
21 action. That's permissible under 21 C.F.R. 7.46. They have
22 the right to do it at any time, but when they do, if it
23 qualifies as a recall, it carries with it legal consequences,
24 and the legal consequences are take your product off the
25 market, and if you don't take it off the market, we're going

1 to take it off the market for you.

2 THE COURT: Now, let me ask you because I asked
3 your colleague.

4 If you had a manufacturer who was producing
5 according to the prescribed and agreed upon standards and
6 found out that it was an explosive device, what's its duty,
7 what's its obligation?

8 MR. GUSTAFSON: I think it has two duties, your
9 Honor. I think it has a duty to warn the public and I think
10 it has a duty to tell the FDA under the various regulations,
11 and that's what this case is all about. It's not an
12 explosive product, but it's a defective product.

13 THE COURT: All right. So your duty is to warn
14 the FDA and to withdraw it from the market.

15 MR. GUSTAFSON: No, no, no. I think you have two
16 duties. I think you have a duty to warn the public and then
17 I think you have a duty to tell the FDA. They may be
18 concurrent in their timing, but I don't think there's
19 anything inconsistent about a state law duty to warn and a
20 duty to warn under the Code of Federal Regulations.

21 THE COURT: All right. Is there any case that's
22 recognized that, or is it encompassed in the statement that
23 there's nothing to keep Florida from issuing a verdict?

24 MR. GUSTAFSON: No. I think Brooks recognizes --
25 I can't give you the internal page cite without shuffling

1 through my outline, but Brooks recognizes that 21 C.F.R.
2 814.39(a) requires the manufacturer to file a PMA submission
3 if there's any change in the device which affects safety or
4 effectiveness. So under your hypothetical, if I learn that
5 my device is exploding, I now know that there's a change
6 necessary that affects safety and effectiveness, so I have an
7 affirmative obligation under 814.39(a) to file a PMA
8 supplement to change the label to say, hey, this thing blows
9 up, okay? You ought to be advised of that. Now, of course,
10 you know because you've talked about it in other opinions
11 there's also .39(d)(1), which gives the manufacturer the
12 right to issue a voluntary warning any time they get
13 information. That's what they did here. There's no evidence
14 in the record that that Dear Doctor letter was approved by
15 the FDA before it was sent out. It may have been. I don't
16 know, we don't have discovery on that, but -- that was
17 another one we lost, but the fact is, there's nothing in the
18 record that suggests that before they sent that Dear Doctor
19 letter in February '05 warning of this new problem, that they
20 got FDA approval of that document or the -- or the language
21 within it. And the question, Judge, in this case -- this is
22 a simple case, in my view --

23 THE COURT: Thank goodness.

24 (Laughter)

25 MR. GUSTAFSON: The case itself, not the

1 preemption argument necessarily. But this is a simple case.

2 They found out in January 2003 that they had a
3 problem. They started working on the new battery in
4 April 2003. They did that for a reason. I'm not sure what
5 the reason is, we don't have full discovery on that yet, but
6 they started working on it for a reason. I would suggest to
7 you it's because they thought that they had a serious problem
8 here.

9 In any event, they continue to test the battery
10 through the summer of 2003 and they start doing draft
11 submissions to the FDA that talk about what the problem is,
12 and in October they ask -- and by the way, those drafts are
13 far more specific and far more detailed than the actual
14 submission, but let me just show you the draft, because it's
15 important -- it's document number five it starts with. It's
16 important to understand what the company knew at the time and
17 what they told the FDA.

18 Now, this is the draft submission. There's lots of
19 drafts, but this is one of the draft submissions in
20 September, one month before they file it.

21 The first thing it shows here is, it's got a
22 picture of the problem, which granted is not a good picture
23 and nobody could find the original and we're left with the
24 copies of the copies, but what it shows is the shorting
25 mechanism that they've discovered. It's a shorting mechanism

1 because there's holes in the grid and I can show you more
2 detailed pictures in the back of this thing if you want to
3 see them, but it also has a diagram that shows how the
4 battery swells and it comes out and it goes through the
5 cracks and it touches the cathode and it shorts out, okay?

6 THE COURT: My sense is without having a full
7 explanation or a full understanding, the cathode and anode
8 are divided by some sort of a membrane. In the process the
9 thing is rolled or coiled in some fashion which induces
10 probably some kind of strain in this membrane. As a result
11 of that, there's either a cracking or some sort of
12 impermissible break in the barrier and that's the shorting
13 mechanism, but --

14 MR. GUSTAFSON: You're pretty close, Judge.

15 THE COURT: That's just a small-town boy from
16 St. Paul trying to work his way through this.

17 MR. GUSTAFSON: I consider myself in that
18 category, but not St. Paul.

19 THE COURT: All right.

20 MR. GUSTAFSON: You're fairly close.

21 What happens is, when the cracking gets near one of
22 the holes, it bushes out and the actual hole in the cathode
23 tears the poly -- tears the liner and lets the two come
24 together and there's a short.

25 THE COURT: Okay.

1 MR. GUSTAFSON: All right. So in this draft
2 there's other stuff.

3 If we look at the next document, number 6, they
4 list the reason for the change as a previously undetected
5 failure mode occurred. It's very important, Judge.

6 If you go to the next slide, they talk about the
7 fact that these failures have been traced to a battery
8 population produced during a certain time period, and this
9 draft has X to X.

10 If you go to the next slide, they say the reason
11 for the change, the failure mode is more likely to be
12 observed in the later half of the battery.

13 THE COURT: This was when -- the original concern
14 was that apparently in the second half of its useful life --
15 although as I understood it, that may not have been what they
16 detected in the bench work and it was sometime later when
17 they first saw it in the field from -- in the first and
18 earlier part of the battery life.

19 MR. GUSTAFSON: It depends who you ask, all right?
20 I mean, again, we've done limited discovery, but in September
21 of '03, somebody in the engineering department put this in
22 the draft because they believed that it had exhibited
23 symptoms that would make the failure more likely in the
24 second half. And by the way, it only makes common sense,
25 because this failure is caused because the battery swells --

1 as it loses its charge, this battery swells, and so the more
2 it depletes, the more it swells and the more it pushes on the
3 cracks and the holes.

4 Okay. So that's what they knew in September.
5 Those three key facts they knew in September.

6 And now if we go to what they actually told the FDA
7 in October, okay -- first of all, they told the FDA that
8 we're making three minor changes so we can make a better
9 battery, safer battery, better battery, okay, and then they
10 say internal shorts are a known failure mode.

11 Now, Judge, you don't have to make any sort of
12 decision here. You can just put yourself in the shoes of the
13 FDA and you can say on the previously undetected failure mode
14 or known failure mode. Those raise different red flags for
15 me. If it's something --

16 THE COURT: Now, your brother tells me, however,
17 that the support data that came in with it -- I use the term
18 "true but not enlightening," but I'm not exactly sure that I
19 find anywhere either in the statute or anywhere else a
20 requirement that things be stated as charmingly as you or I
21 might wish in the benefit of hindsight. I just am not sure
22 that there's a legal requirement for that and I'm willing to
23 listen to you as you like, but it was my recall that he said
24 that this was supported, however, in the background data
25 which was submitted with it -- I think he called it the

1 appendix -- which had all of the observed information, I
2 guess, from which -- I don't know whether for sure at this
3 point I might have been able to find that this was a
4 different form of battery failure, but battery failure is a
5 known problem with batteries.

6 MR. GUSTAFSON: Except this one was not known.
7 This was one they learned of that was a defect -- all
8 batteries -- all of these batteries in these devices have
9 potential for shorting. As you referenced, the black spots,
10 you know, you get a tear in the separator, you get
11 something -- all of these batteries have potential for
12 shorting, but that's not what we're talking about here. What
13 we're talking about here is a previously undetected problem
14 with this battery that --

15 THE COURT: Mr. Gustafson, I have no problem that
16 this is a bang-up closing argument. The question is where
17 does it fit in the preemption argument.

18 MR. GUSTAFSON: Where it fits in the preemption
19 argument is that in September of '03, they knew that this was
20 a previously undetected short. In October of '03 when they
21 tell the FDA that they're putting out a new battery, they
22 don't tell them the information that they know in September
23 of '03. They gloss it over.

24 If you look at the two side by side, which is slide
25 ten, I believe, it conveys a different message, Judge. I

1 didn't know that the thing might blow up. I'm going back to
2 your hypothetical. I didn't know the thing might blow up.
3 Or I've always known the thing was going to blow up and I'm
4 just trying to make it so that it doesn't blow up as much.
5 It connotes a huge difference. And so if I'm sitting at the
6 FDA saying, hey, all of a sudden they've discovered this
7 thing might blow up, that's a completely different inquiry
8 than if I say, well, of course we've always known they were
9 going to blow up. This is just a question of whether we can
10 minimize the impact of the explosion. It raises a whole
11 different level of inquiry in the FDA's mind.

12 THE COURT: Now, this is the submission in October
13 of '03.

14 MR. GUSTAFSON: That's right.

15 THE COURT: All right. As I understand it, in '03
16 they had found in bench testing this anomaly, this previously
17 undetected mode. How extensive was the information in their
18 hand at this point?

19 MR. GUSTAFSON: I don't know for sure, but I do
20 know this.

21 THE COURT: As I understand it, the field reports
22 did not really begin to come in until '04.

23 MR. GUSTAFSON: I think it's February, actually,
24 but -- February or April. It's in '04.

25 THE COURT: But that's -- so the first field

1 reports, at least thus far, the information I have, will
2 post-date this instruction to the FDA, am I correct?

3 MR. GUSTAFSON: You are correct, Judge, but I
4 don't know how much they knew, but I know this much: I know
5 that they knew in April of 2003 that they decided they needed
6 a new battery. They didn't wait till '04 when they got the
7 field reports to decide they needed a new battery. They
8 didn't wait till they had multiple field reports to decide
9 they needed a new battery. They decided they needed a new
10 battery way back in April of 2003, maybe even March, because
11 it took a process to develop it, so that by October of 2003
12 they had in place the new battery development testing, all
13 the rest of it, so they could submit it to the FDA, so I know
14 they knew that much.

15 THE COURT: Once they knew that they had received
16 approval, which would have been in October of '03, did they
17 continue to implant or install the previous battery
18 thereafter?

19 MR. GUSTAFSON: Absolutely.

20 THE COURT: And they did that and continued to
21 ship those until sometime when, in January -- no, the last
22 one was implanted in July '04, as I recall.

23 MR. GUSTAFSON: There's a dispute about that.
24 It's '04. We have clients that got the 006, which is the
25 defective battery, implanted later than July of '04, but it's

1 between July and, say, November of '04. They continued to
2 ship what they they knew to be the defective battery all
3 along from October of '03 when they told the FDA that they
4 were redesigning the battery to make it better, when in fact
5 I suggested already to you that the real reason is they
6 redesigned it to make it safer because they knew they had a
7 problem, but during that time period they continued to ship
8 all the way to sometime in '04, but prior to the February '05
9 field action. And that's an important part of this case,
10 Judge, because --

11 THE COURT: What, if anything, does Lohr or
12 does 360 say about continuing to ship or implant battery A
13 when battery B had been approved for use in October?

14 MR. GUSTAFSON: I don't think the fact that they
15 got a new battery design approved in October -- I agree with
16 Mr. Brown on that. I don't think the fact that they got a
17 battery approved in October of '03 precluded them from
18 shipping the batteries that had previous approval, the 006.
19 We're talking about the 006 and 007 here.

20 But what I do suggest to you is that they had an
21 obligation to warn the public. They had an obligation to
22 tell the FDA: "We now have two batteries. One is
23 susceptible to a previously undetected failure mode which can
24 render your battery useless, or we have a new one which we've
25 fixed the problem," but they didn't do that. They continued

1 to ship both.

2 You know, they've admitted in the Randall case,
3 which we've put in our papers -- the Randall case is a
4 California case that came here via the MDL. They've admitted
5 that they didn't tell anyone that there was the old and new
6 battery, they admitted that when they sold the old battery
7 they didn't tell them that they had redesigned a new battery,
8 and they didn't tell anybody that the new design solved a
9 problem that was known to them in the old battery.

10 THE COURT: Now, your argument then is, at least
11 as I understand it, is that at this point they had a duty to
12 warn the public.

13 MR. GUSTAFSON: Sure.

14 THE COURT: Is this a requirement in any fashion
15 that conflicts with a previously imposed requirement that the
16 FDA had imposed upon them? I'm looking now, if you will, at
17 Judge Murphy's analysis again in Brooks.

18 MR. GUSTAFSON: I'm sure --

19 THE COURT: You have declared now that there is a
20 duty and the question is do I have a conflict in a duty
21 between one imposed by the FDA and one imposed by either
22 state law or a jury.

23 MR. GUSTAFSON: I suggest to you no for the
24 following reasons.

25 First of all, under Section 814.39(a), they have an

1 affirmative obligation -- it's not a voluntary obligation.
2 They have an affirmative obligation to submit a PMA
3 submission that changes the label of a device when safety or
4 effectiveness is at issue. When they submitted the October
5 '03 battery change PMA supplement, why didn't they submit a
6 warning that said: Oh, by the way, batteries that were
7 manufactured before this change have a particular shorting
8 mechanism that puts you at risk? I say they have an
9 affirmative obligation under 814.39(a) and Brooks
10 acknowledges that.

11 THE COURT: Does this in any fashion striate or
12 divide the plaintiff group in the MDL? Is this October 2003
13 date of consequence in terms of whether or not you have a
14 cause of action?

15 MR. GUSTAFSON: I don't believe so.

16 THE COURT: Do you understand the question? I was
17 trying to figure out how inartfully I could state that. But
18 you have indicated that at least in October '03 they now have
19 FDA permission to put out a safer battery which is not
20 susceptible to this known anomaly or known defect or whatever
21 it is, and I'm asking whether or not there's a break in time
22 here, whether their assentions, their knowledge of the
23 problem divides the group in any fashion. I do not consider
24 it a class, by the way.

25 MR. GUSTAFSON: Not yet. If I understand it

1 correctly, your Honor --

2 THE COURT: I also read another Eighth Circuit
3 case on this subject. We'll deal with that on a different
4 day if necessary.

5 MR. GUSTAFSON: We will, and we'll have that
6 argument another time.

7 As I understand it, your Honor, it does not, but
8 let me point out that that's not the only time that I think
9 that they should have warned the public. I'm saying that's
10 the question in this case, is, should it have been January,
11 should it have been April, should it have been May, should it
12 have been 2003 October, should it have been February 2004?
13 There's potential here for different triggering points where
14 they should have warned, perhaps more than once, but I think
15 October of '03 is a clear point, because there they actually
16 made a PMA submission, changed the battery, and they were
17 fully aware of the shorting mechanism in the old battery, so
18 all they had to do was say to the FDA: This new battery is
19 better, safer, blah, blah, blah, for the following reasons.
20 And by the way, you should know that the old battery has this
21 shorting problem.

22 THE COURT: Now, Mr. Gustafson, just wait one
23 second.

24 (Discussion off the record between the court reporter
25 and the Court)

1 IN OPEN COURT

2 THE COURT: Mr. Gustafson, I realize what a
3 terrible thing it is to do, but I'm going to take 15 minutes.

4 MR. GUSTAFSON: You know, I'm fine with that, your
5 Honor. I need the rest room.

6 THE COURT: Well, all right. I'll let you fire
7 yourself back up and you can come back at me again.

8 MR. GUSTAFSON: All right. Thank you.

9 THE COURT: We'll be in recess.

10 (Recess taken at 10:30 a.m.)

11 * * * * *

12 (10:45 a.m.)

13 IN OPEN COURT

14 THE COURT: Thank you. Please be seated.
15 Counsel?

16 MR. GUSTAFSON: Your Honor, just a couple
17 housekeeping kind of things.

18 I'm told at the break that we actually have
19 plaintiffs in this case that had the old battery implanted in
20 '05, so it continues throughout the year of '04.

21 The second thing, you had asked me the regulation
22 and I focused on the duty to warn regulation, but under the
23 submissions, the regulations that govern submissions, they
24 have a duty of candor, of course, to the FDA, and so in their
25 '03 submission 814.3 defines the statement of material facts

1 that they make to the FDA and it explains that omissions are
2 included in what's a misleading fact. So by omitting
3 information that was important to the understanding of the
4 battery problem at issue here, that's also a regulation
5 that's implicated.

6 THE COURT: Let me pick up with you. You
7 suggested that under 814.39(a) there was a duty to submit an
8 additional warning. What does the reg say and what did the
9 Seventh Circuit say about this duty?

10 MR. GUSTAFSON: In McMullen?

11 THE COURT: Yes, sir.

12 MR. GUSTAFSON: Okay. Well, I think that the --
13 first of all, the regulation puts the obligation on the
14 applicant to make the determination.

15 THE COURT: It's permissive.

16 MR. GUSTAFSON: No, that's 39(d). I'm talking
17 about 39(a).

18 THE COURT: Okay.

19 MR. GUSTAFSON: But the regulation makes clear
20 that the burden is primarily on the applicant to determine if
21 such a submission needs to be made, which of course suggests
22 that when they come into information that requires such a
23 submission, it's their burden to make that decision. That's
24 no different than sort of a negligence standard or something
25 like that.

1 And so what I'm saying to you is that when they
2 decided that they had to make a submission in October
3 of '03 --

4 THE COURT: To the FDA.

5 MR. GUSTAFSON: -- to the FDA to get this new
6 battery approved, when they knew about the problems in the
7 old battery, that was the time when that complete and full
8 submission should have included a new warning for the old
9 battery.

10 THE COURT: Okay. Your argument is not that they
11 were obligated -- they may have had a moral obligation to
12 give such information to the public, but they had an
13 affirmative obligation as part of their submission to tell
14 the FDA that this would be an appropriate warning?

15 MR. GUSTAFSON: Well, I think it's more than a
16 moral obligation to the public. I think it's a state law
17 legal duty to warn the public.

18 And remember, on these parallel violations --
19 Mr. Brown suggested to you that the parallel violations
20 requirement is only with respect to devices that violate the
21 regulations, but that would exclude all claims of warning or
22 anything like that, because --

23 THE COURT: I think that's his argument.

24 MR. GUSTAFSON: I know, but it can't be right,
25 because you clearly can -- if the state duty to warn is

1 substantially equivalent to the FDA regulation about duty to
2 warn, the parallel requirements doesn't say except for claims
3 that only deal with devices. Some courts may have suggested
4 that, but the statute itself says different from or in
5 addition to. It doesn't make any distinction about the
6 duties either under state law or federal law.

7 But let me take you back to slide 13 -- slide 12,
8 because I think it's important here, Judge, that when they do
9 decide the warn to public, when they do decide to warn the
10 public, the warning they give the public is not consistent
11 with what they told the FDA in '03 in October, but it is
12 consistent with what they told -- what they drafted to tell
13 the FDA in September of '03. What was omitted from the
14 actual submission is back in the doctor warning.

15 First of all, it says it's got batteries that are
16 manufactured prior to December 2003. They identify a
17 specific battery, a specific section -- selection of
18 batteries that have this problem.

19 Secondly, they call it a specific internal battery
20 shorting mechanism. They don't call it a previously known
21 battery failure or -- a previously known battery failure.

22 And then that third thing, if you turn to the next
23 slide, 13, they say this rate may increase over the second
24 half of the device life, information that was in the '03
25 draft submission, taken out, not given to the FDA in October

1 of '03, but by February of '05 it's back in when they warn
2 the public.

3 THE COURT: But now they're giving a more dramatic
4 warning than they had given or suggestion than they had given
5 to the FDA.

6 MR. GUSTAFSON: Right.

7 THE COURT: And your argument is that that's a
8 failure?

9 MR. GUSTAFSON: It's a failure because they knew
10 that information in '03. In the draft submissions they had
11 that information in '03, in September --

12 THE COURT: Here we go with the draft submissions,
13 but were there in the appendices the same information?

14 MR. GUSTAFSON: I'm not sure what Mr. Brown means
15 when he says that in the appendices we identified it as an
16 undetected failure mode. I'm not seeing anything in the
17 submission that suggests that. What's in the appendices in
18 general is test results, but they would not describe the
19 character of the -- they would just be test results. Perhaps
20 he can point it to us. But the part that's important here
21 is, what the FDA focuses on is what you tell them the reason
22 for the change is. It's a big difference between saying we
23 found a way to make this battery better and we're going to
24 take care of some known shorting problems and all in all
25 everything's going to be safer. There's a big difference

1 between saying we found an exploding device and now we're
2 going to correct it. It's a huge difference.

3 And here's the point, Judge: When they disclose in
4 February of '05 the Dear Doctor letter, what happens? The
5 FDA immediately issues a recall and they say this recall
6 means that your device is defective, it violates federal law
7 and you got to take it off the market, all right?

8 So what I'm suggesting to you is that had they done
9 that in '04 --

10 THE COURT: Had they given the same information in
11 October of '03, the FDA would have made the same
12 determination?

13 MR. GUSTAFSON: That's right.

14 THE COURT: All right.

15 MR. GUSTAFSON: That's right exactly.

16 THE COURT: You know, as long as you talk slow, I
17 got a shot at tracking these arguments. All right.

18 (Laughter)

19 MR. GUSTAFSON: Well, I got to explain a little
20 bit more too.

21 And if you look at the next slide -- and this is
22 clear from the regulations and they admit -- Mr. Samsel
23 admits it -- there was absolutely nothing prohibiting
24 Medtronic from conducting a field action in 2003. No federal
25 regulation -- in fact, 7.46 allows them to do it at any time

1 in their discretion. So instead of continuing to sell these
2 batteries to which there was a known defect all the way up to
3 at least '04 and I think now '05, they could have recalled
4 these batteries in October of '03 and that's the crux of this
5 case, because we know that when they recalled them, the FDA
6 said take them off the market. They didn't say glad you're
7 doing it, hope it all works out.

8 THE COURT: But they didn't issue a blanket
9 prohibition saying you can't continue to install them, or did
10 they?

11 MR. GUSTAFSON: Absolutely did. They said this
12 product is defective and you remove it from the market or
13 recondition it. And in St. Jude -- I don't think there's any
14 dispute. They cannot market that battery any longer without
15 future FDA approval.

16 THE COURT: And is shipping previously ordered
17 considered -- constitute marketing?

18 MR. GUSTAFSON: I think shipping's included in
19 misbranding. If you look at the FDA recall letter, there's a
20 recall protocol or a recall policy that -- we don't have all
21 the recall documents because that's not part of the discovery
22 that we had, but the FDA talks in that letter about the
23 recall policy and one of the things is to make sure you go
24 out and get these batteries back that are in commerce, you
25 know, make sure your field reps go out and collect the

1 inventories and don't ship any more. There's some talk in
2 the letter about the fact that you got to make sure they
3 don't get mixed up with batteries that are otherwise good and
4 things like that.

5 THE COURT: Mr. Gustafson, you raised a question
6 about really a fraud on the FDA. What, if anything, does
7 Buckman say about that vis-a-vis the claim you would be
8 making?

9 MR. GUSTAFSON: Well, I think first of all that
10 Buckman says you can't make claims of fraud on the FDA and we
11 don't take any issue with that, but I think you have to look
12 at Buckman and you'll see some obvious distinctions.

13 First of all, Buckman only made a claim of fraud on
14 the FDA. The claim was not for personal injury or products
15 liability. In fact, the claim was made against the -- the
16 agent -- I think it's Accumed or something like that was the
17 company, the orthopedic bone screws company, but this guy was
18 is the agent who filed the submissions. They were trying to
19 recover for his fraud on the FDA.

20 Secondly, I think what's important about Buckman is
21 that --

22 THE COURT: This is the off-label one?

23 MR. GUSTAFSON: Yeah, the off-label bone screws.
24 And remember, the personal injury and product liability cases
25 had already been resolved by the time Buckman comes to the

1 Supreme Court, so there was really no issue there.

2 And the reason that they come with implied
3 preemption is because -- the 360(k)(a) doesn't apply, because
4 there's no federal requirements and there's no device at
5 issue. There's no way to make 360(k)(a) apply. That's not
6 the case here. Here we make only make state law claims, we
7 don't make any claims of fraud on the FDA, and we don't make
8 any claims that are a misrepresentation, as Mr. Brown somehow
9 said, you know, is disguised as a fraud on the FDA, because
10 that's not how it works.

11 As you know, your Honor, what our claim is -- let's
12 say our claim is failure to warn as an example and the
13 elements are X, Y and Z under Minnesota law. Their failure
14 to report to the FDA is nothing more than evidence that they
15 violated their state law duties. You need to look at it from
16 the state perspective when you talk about whether we're
17 trying to enforce the FDA. We don't care what the FDA does
18 or doesn't do with respect to these devices. If the
19 negligence per se or negligence or anything else requires a
20 showing of a duty of due care and we can show that by
21 violating the manufacturing regulations that that's evidence,
22 evidence of a violation of due care under Minnesota law,
23 that's all the parallel requirements means.

24 THE COURT: Do you view the -- let me back this up
25 a little bit.

1 In Bates, is there a suggestion that a jury verdict
2 is in fact a requirement or a specific requirement?

3 MR. GUSTAFSON: I think there's --

4 THE COURT: Because the short version of your
5 argument is: Judge, a general verdict that simply says pay X
6 is not equivalent of a specific requirement, which is sort of
7 the corollary of his argument. Under that, I can't imagine
8 that either Lohr or Brooks means anything.

9 MR. GUSTAFSON: Well, first of all, I think Bates
10 calls into serious question the narrow part of Brooks which
11 says that the jury verdict will require Howmedica to change
12 its label. I think that calls it into serious question. I
13 think Bates -- although it's not expressly stated, I think
14 implicitly in Bates they recognize that certain jury verdicts
15 could be requirements.

16 THE COURT: But jury verdicts don't occur in the
17 air. Jury verdicts occur after instruction. I mean, I don't
18 ask them to give me was there a duty to warn, was there a
19 breach, was there proximate causation, was there damages. I
20 say was there negligence, and if so, how much money. But
21 implicit in each of those, because I define each of those
22 terms as I give the jury that question, there are a set of
23 requirements, if you will, at least in the form of the
24 instructions so that the jury knows that they just can't say:
25 "Well, we don't like the Glotts Company. Let's just nail

1 them for 'X' dollars." There has to be some requirements.
2 Does even a general verdict then become the equivalent of a
3 requirement?

4 MR. GUSTAFSON: It doesn't, it doesn't, and here's
5 why: Because it doesn't put any future obligation on the
6 company.

7 THE COURT: Well, it would have a future
8 obligation to not have to lose money in jury verdicts, I
9 presume.

10 MR. GUSTAFSON: They don't. That's just what
11 Bates says. Bates says exactly that, Judge. They say a jury
12 verdict that motivates or induces a company to do something
13 is a decision left for the accountants of the company.

14 By the way, let me just say, that's particularly
15 true in this case, because these products all the way from
16 the root device, all the way through these six Marquis
17 devices that are in issue in this case, are all off the
18 market. They can't sell them anymore. They don't sell them
19 anymore.

20 You know, we can argue forever about whether, you
21 know, they issued a formal withdrawal of the PMA or anything
22 like that. As a practical matter, Judge, the PMA is gone
23 because they said you can't sell them unless you fix them,
24 and so in order to sell any of these devices, they would have
25 to correct the defect and sell them, but that's not going to

1 happen because they have a new battery and they're selling
2 their devices and they're working fine as far as I know. But
3 think about Bates in this context and think about Lohr. Lohr
4 said there's nothing to suggest that Florida can't provide a
5 damages remedy. Bates expanded on that and said a damages
6 remedy or a jury verdict that awards damages on a general
7 thing doesn't put on requirements because it doesn't make the
8 company do anything. In this case it's particularly true,
9 because even if the jury found them negligent, found it was a
10 lousy design, found it was -- it wouldn't matter what the
11 jury found. It wouldn't impose any requirements, because the
12 requirements are gone, you know?

13 They like to suggest that because the requirements
14 were in place at one time preemption lasts forever, but
15 remember, this statute has a savings clause in it and it's
16 unclear what exactly that clause means. It's found in an odd
17 part of the statute.

18 THE COURT: I will be frank to tell you it's
19 difficult for me always to discern exactly what savings
20 clauses mean in any of these things.

21 (Laughter)

22 MR. GUSTAFSON: I think the Supreme Court would
23 agree with you on that since there's about 20 or 30 ERISA
24 savings clause decisions and they keep changing their mind.
25 But not only does it evidence congressional intent not to, of

1 course, have complete preemption, but the savings clause
2 appears in a section of the statute that deals with FDA
3 actions related to recalls, corrections, modifications,
4 things like that, and the court in Goodlin suggested if
5 nothing else that it applies to actions in which the FDA
6 takes recalls or takes corrective measures.

7 THE COURT: Does it count when the FDA -- the FDA
8 never issued this recall or its Class II, whatever the heck
9 they called it, when they had the information that we had a
10 battery which was doing something it was not supposed to to
11 the extent that a company is now deciding to make a new
12 battery, the FDA sits and does nothing --

13 MR. GUSTAFSON: Correct.

14 THE COURT: -- other than gives approval for
15 production of the new battery. Once the company issues a
16 Dear Doctor letter, the FDA now clicks into gear. What, if
17 anything, do I derive from this?

18 MR. GUSTAFSON: The company's finally told the FDA
19 what the real problem was. That's what I derive from it.
20 They had to tell the FDA. There's a whole list in 21 C.F.R.
21 7.4(1) through 59 or whatever it is that talks about the
22 firm-initiated recall. There's a whole list of information
23 you have to provide to the FDA. We don't know.
24 Unfortunately, Judge, we lost this one too. We didn't --

25 THE COURT: You had a rough go.

1 (Laughter)

2 MR. GUSTAFSON: Well, you know. And after that
3 first order, I didn't want to have another round.

4 THE COURT: Then it worked.

5 (Laughter)

6 MR. GUSTAFSON: It worked. That's right. So I
7 don't know what they told the FDA, but presumably they told
8 the FDA, "We have a serious shorting problem here" and the
9 battery can fail without warning, and if it fails, it's not
10 going to work and these people are dependent upon it. I
11 don't know, but it was sufficient enough that the FDA put a
12 stamp Class II recall on it. And what I suggested to you
13 earlier was if they told them earlier, whatever they told
14 them, we would have seen a Class II recall earlier and we
15 would have prevented -- I think the key here is that we would
16 have prevented hundreds, thousands, I don't know, of
17 implantations of those devices that were still on the market
18 after the new battery was developed all the way through at
19 least '04 and probably early '05.

20 THE COURT: All right.

21 MR. GUSTAFSON: Back to my outline?

22 THE COURT: Have we hit most of the high points or
23 do you want to keep going?

24 MR. GUSTAFSON: Your Honor, summary judgment
25 should be -- I never got to my outline.

1 THE COURT: That's your problem.

2 (Laughter)

3 MR. GUSTAFSON: I want to make a couple points
4 about this requirements issue, because Mr. Brown said, you
5 know, everything we submitted, everything the FDA approved is
6 requirements and they didn't provide complete data, but I'm
7 sure your Honor wouldn't have wanted it, because it would
8 have, you know, been ten feet tall or a truckload or
9 something like that.

10 But, you know, he also acknowledged that in this
11 parallel violations, although he limits it to device, he
12 acknowledged that if we can find fault with their compliance
13 with these requirements, right, then we have a claim, we have
14 a claim no matter what, because the different from or in
15 addition to language is limiting, but until we know what all
16 the requirements are, we can't challenge whether in fact they
17 complied with them, and that's the problem here. You know,
18 by putting in excerpts and, you know, summary -- Mr. Samsel
19 says we had a bunch of conversations with the FDA and we had
20 a bunch of amendments that we made and blah, blah, blah,
21 blah, and here comes the approval letter. Well, we can't
22 challenge any of that as a factual matter because we don't
23 know what those conversations are. That's a portion of our
24 argument where I say you got to tell us what the federal
25 requirements are. It's not just PMA approval. And if it's

1 just PMA approval and just --

2 THE COURT: Let me ask you a question, however. I
3 haven't seen much of this in any of the case law, but I'm
4 analogizing for a moment to a patent where there is, first of
5 all, a duty of candor, but secondly, once the patent's
6 issued, you don't go back into the mind of the patent
7 examiner. When the FDA issues an approval letter, to what
8 extent, if at all, is it either relevant or admissible or
9 even permitted to start to look at what the FDA did and what
10 the negotiation, if you will, was? The issue was, they
11 issued the approval letter. They gave the PMA.

12 MR. GUSTAFSON: Well, if their position --

13 THE COURT: And I'm wondering, because I've not
14 seen much about this in any of the cases.

15 MR. GUSTAFSON: I think you're right. I don't
16 think there is that kind of discussion, although there's some
17 suggestion in Brooks that the continuing interaction with the
18 FDA is what actually creates the federal preemption. But if
19 their position is the requirements are only the PMA approval
20 letter, that's one thing, but if their position is the
21 preemptive effect of the FDA approval is everything that they
22 submitted to the FDA and everything that the FDA approved --

23 THE COURT: Oh, I think that's what he said.

24 MR. GUSTAFSON: Right. Then that's completely
25 different, because the approval letter is pretty generic. I

1 mean, it basically says follow the law and do this kind of
2 stuff and, you know, don't do bad things. I mean, it's
3 longer than that, but if it's everything they said, then
4 there's no way we can test -- there's no way we can test the
5 parallel requirements based on what they submitted to this
6 Court.

7 THE COURT: I think you summarized his argument.

8 MR. GUSTAFSON: But if we can't test them, then we
9 can never know whether they violated them.

10 THE COURT: Well, you got the last part of his
11 argument now. Okay.

12 MR. GUSTAFSON: Okay. And if they violated them,
13 if the device violated any of those requirements and the
14 state-law claim doesn't impose different requirements, not
15 preempted. So on this record, I suggest, your Honor, that
16 none of our claims could be preempted because none of their
17 claims -- they can't demonstrate any conflict between a
18 federal requirement and a state requirement because they
19 haven't set out the federal requirements. They've just said
20 generally it's a truckload and it's everything, but you can't
21 rule as a matter of law on that.

22 And the second part of that is that they've said --
23 the only state requirement that I've heard so far is a jury
24 verdict, and I commend to you the Bates decision, because I
25 don't think you can get around it. The only way to get

1 around it as they do in the footnote, they say, geez, it's a
2 FIFRA case and so, you know, it doesn't apply. The language
3 of the two express statutes are almost identical, the court
4 acknowledges Lohr and the parallel requirements holding and
5 the fact that nothing in Lohr prevents Florida from doing --
6 giving someone a damages remedy, and they make
7 clear --

8 THE COURT: Well, let me back you up.

9 MR. GUSTAFSON: Just when I was about to --

10 THE COURT: Yeah, I know that. That's the reason
11 I hit you.

12 Let's assume that you are correct that the line on
13 the verdict -- I want to get back to framing the case. The
14 line on the verdict says: Therefore, you owe "X" number of
15 dollars. That's a general verdict, that's a general number,
16 but there has to be a basis and the jury would have to find
17 either that there was a defect, that there was a failure to
18 manufacture properly, that there was a failure to warn. I
19 don't know which one we would pick at the time, but is that a
20 requirement which differs from the federal requirement?

21 MR. GUSTAFSON: Let me -- I think that's a good
22 question, your Honor. Let me --

23 THE COURT: Write that down. That was a good
24 question.

25 MR. GUSTAFSON: Just when I was about to drive

1 that point home which I've now forgotten, you asked a good
2 question. Let me point to negligence.

3 I can't conceive of whatever the manufacturing
4 requirements in this case are somehow less than negligence,
5 are somehow less than negligence. I mean, I can't conceive
6 that the FDA would say manufacture these devices without
7 using due care or reasonable care or whatever words you want
8 to use, so I can't imagine that the negligence verdict could
9 impact the manufacturing requirements no matter what they
10 are.

11 THE COURT: But does your argument prove too much?
12 If your argument is correct, then there would be no
13 preemption of negligence claims anywhere on a product that
14 was produced with an FDA approval, it seems to me.

15 MR. GUSTAFSON: No, I disagree, and I think this
16 is where we go back to Justice Breyer. If the verdict is
17 based on the fact that you're negligent because you didn't
18 use a two-inch wire as opposed to one-inch wire -- and I can
19 no longer remember which way it goes, but I know there's two-
20 and one-inch. If your verdict is that you should have used a
21 one-inch wire and therefore you're negligent -- and, by the
22 way, the device is still on the market, so it would be
23 subject to that requirement -- then I think that could be a
24 requirement, but just a general verdict that says pay a
25 million dollars or pay a hundred thousand dollars, Bates

1 makes clear that you don't have to do anything. You can
2 continue -- although it smacks, kind of, of the Ford Pinto
3 case -- but what they basically are saying is you can
4 continue to pay those verdicts over and over again if it's
5 more economical than changing the device. That's what Bates
6 is saying. In fact, they talk, by the way, in Bates -- and I
7 can't pull up the language in my mind right now. They talk
8 about the fact that the Court should be cognizant to defend
9 its jury instruction request with respect to the specificity
10 that the defendant wants, so I think that's an acknowledgment
11 of the question you're asking, that under certain
12 circumstances it could be, but I -- Judge, I totally disagree
13 with those cases they cite. I think it's in footnote 2 of
14 their reply brief that recalls don't make any difference.
15 This product can't be marketed. There is nothing a jury
16 could do to this case that would interfere with any federal
17 interest. That's what Brooks says.

18 THE COURT: Let me back you up again.

19 MR. GUSTAFSON: Just when I get on a roll, Judge.

20 THE COURT: I can't help it. That's when you get
21 me all inspired, because I thought about it when you made the
22 first part of the argument. That argument says, if you will,
23 this was a recalled product and therefore there's no
24 preemption at all.

25 MR. GUSTAFSON: Not quite.

1 THE COURT: Pardon?

2 MR. GUSTAFSON: Not quite.

3 THE COURT: Okay, but close.

4 MR. GUSTAFSON: Well, I'll give you close, but not
5 quite.

6 THE COURT: Okay. Well, where's the quite?

7 MR. GUSTAFSON: Well, here's the not quite: The
8 statute says no state requirements that are different from or
9 in addition to federal requirements. There's no federal
10 requirements left on these devices.

11 THE COURT: That's what I thought I just said and
12 therefore there's no preemption left on a recalled item.

13 MR. GUSTAFSON: Right. Makes perfect sense to me.

14 THE COURT: There we go. Now it's quite.

15 MR. GUSTAFSON: I mean, it also makes sense with
16 respect to the savings clause.

17 THE COURT: Is there a case that says on an FDA
18 recalled device federal preemption is no longer applicable?

19 MR. GUSTAFSON: Not yet.

20 THE COURT: Okay. I can handle that.

21 MR. GUSTAFSON: I couldn't find a case, although I
22 have to say the cases that they cite to don't do justice to
23 this issue. I mean, they do talk about the fact that the
24 recall doesn't affect it and so on and so forth, but I don't
25 think there's extensive analysis. And let me just make one

1 point on what I think you should think about.

2 The savings clause is in the section of the statute
3 360(h)(d), which is in that portion of the section that deals
4 with notification to patients, recall, refund, replacement,
5 repair, so on and so forth, and it says if you comply with an
6 order under this section, you're not free from liability
7 under state or federal law, okay? No court that I'm aware of
8 has ever, ever evaluated the savings clause with respect to a
9 recall, but I would suggest to you that if it were an
10 FDA-initiated recall, there would be no question in my view
11 that the savings clause would apply, okay? The only question
12 is whether by doing it voluntarily and then having the FDA
13 say we agree it qualifies as a recall, that that somehow
14 shoehorns us into 360(h), okay? That's the only question I
15 think that's left, but otherwise, there's no question that
16 the savings clause would apply. But I'm not aware of any
17 court that has analyzed the two together and I invite you to
18 undertake it if you wish, because I think it makes perfect
19 sense. Why would the Federal Government care if a jury
20 imposed any requirements on devices that were no longer
21 marketable? How would that interfere with the any federal
22 interest? In fact, it not only doesn't interfere with any
23 federal interest, right --

24 THE COURT: Well, let me offer one way. It would
25 be a powerful disincentive for a company to do

1 after-production and after-marketing testing, it strikes me
2 intuitively. Their remedy, if they want to stay under the
3 preemption with your argument, is, once they get the PMA,
4 they produce this product and do nothing but keep making them
5 until they get field reports that the things are blowing up
6 all over town. Now, tell me why that argument fails.

7 MR. GUSTAFSON: You mean it's a disincentive for
8 them to issue a recall?

9 THE COURT: And to continue to do research on the
10 products that they've manufactured to make sure that they're
11 still safe. If the loss of their -- if it's recalled,
12 they're told to take it off the market, why would they want
13 in January to test this battery ever again?

14 MR. GUSTAFSON: Well, first of all, because if you
15 provide an incentive by having jury verdicts that make them
16 pay money, they have every incentive to recall these products
17 as soon as they find out that they're defective because it
18 lessens their liability. But let's don't forget, Judge,
19 let's don't forget this statute was enacted in the face of
20 the Dalkon Shield catastrophe.

21 THE COURT: And you were nice enough to point it
22 out and it was the idea of protecting the public --

23 MR. GUSTAFSON: Right.

24 THE COURT: -- which I'm looking very hard in
25 there to see where it says anything about protecting the

1 public other than in the statement of its author.

2 MR. GUSTAFSON: Well, I can tell you what it
3 doesn't say. It doesn't say we enacted this statute to
4 protect manufacturers from state damage claims. You won't
5 find that language anywhere.

6 THE COURT: Take a look at all the reported
7 opinions.

8 MR. GUSTAFSON: Well, not binding on this Court.
9 But apart from that, apart from that, they pick out this --
10 again, I would direct you to Bates. They pick out this --
11 there's this common thing.

12 First of all, we can't let juries make decisions
13 like this because they're too stupid. That's what they
14 really say.

15 Secondly, we're going to have this patchwork quilt
16 of 50 different states applying --

17 THE COURT: It's your turn to get an e-mail.

18 MR. GUSTAFSON: Pardon?

19 THE COURT: You're --

20 MR. GUSTAFSON: I'm getting an e-mail.

21 (Pause)

22 MR. GUSTAFSON: Okay. That was distracting.

23 THE COURT: Do you want to hear what you were
24 saying?

25 MR. GUSTAFSON: No, no, no.

1 THE COURT: Give him back his deathless prose,
2 about three --

3 MR. GUSTAFSON: No, that's all right.

4 THE COURT: Okay.

5 MR. GUSTAFSON: It wasn't that --

6 THE COURT: But you're saying juries are too
7 stupid to handle these matters.

8 MR. GUSTAFSON: Well, that's basically what
9 underlies their argument, is, you can't let lay juries talk
10 about this stuff because the FDA is expert and lay juries are
11 too stupid, but, Judge, you know better than that. You have
12 juries in here once a week, once a month, who put people in
13 prison for violating federal statutes. They have to decide
14 all the time complicated mail fraud, wire fraud, RICO.
15 That's not a reason and Bates acknowledges that. Juries make
16 decisions like this all the time.

17 And the second thing is, this notion that we're
18 going to have this wild explosion of a patchwork of various
19 requirements being imposed all the time, two points on that.

20 First of all, Bates says it doesn't happen, you
21 haven't shown anything like that and I think they haven't
22 shown anything like that either.

23 But the second thing is, it's no different than
24 what other manufacturers face. Every manufacturer faces
25 different state laws, different UCC provisions, different

1 this --

2 THE COURT: Not if they can get to Congress.

3 MR. GUSTAFSON: Yeah, not if they can get to
4 Congress and get --

5 THE COURT: And this is also as thoroughly
6 regulated an industry as we have just about.

7 MR. GUSTAFSON: I'm not sure about that.

8 THE COURT: Okay.

9 MR. GUSTAFSON: I mean, I was just about to say
10 this is not like the railroad industry where they said if the
11 Department of Transportation or whoever it was issues
12 regulations in a subject matter, state-law claims are
13 preempted. That's not this statute. This statute has lots
14 of, pardon the pun, requirements. Not only does it have to
15 be a federal requirement specific to the device, the state
16 requirement has to be with respect to a device, then there
17 has to be a direct conflict because of the different from or
18 in addition to language, then there's a savings clause, and
19 then there's this notion that -- in my view this notion that
20 when the requirements go away, so goes away any conflict.
21 But this is a limited preemption statute.

22 THE COURT: All right. Have we pretty much gotten
23 through most of the high points of your outline?

24 MR. GUSTAFSON: We've gotten through the high
25 points of my outline. I'd like to just show you slide 15 and

1 16, Judge. These are in our brief, but these are regulation
2 violations that are in addition to the ones we talked about,
3 omitting information, failing to report things, failing to
4 timely report, you know, some of the post-approval things.
5 You know, it's not just the October supplement or the October
6 PMA supplement that we're talking about here. You know, they
7 didn't disclose some of these manufacturing anomalies early
8 on in the battery and those kind of things on which we
9 haven't had discovery. I'm sure I've said that more than you
10 need to hear today, but --

11 THE COURT: I got the subtle hint that you would
12 have liked more.

13 MR. GUSTAFSON: Yes. Well, I had to file that
14 Rule 56 affidavit, because if you're going to rule that we
15 didn't put up facts, of course, then I got to have more
16 discovery, but I think you're thinking about this as a legal
17 matter and so I don't think that's all that relevant.

18 I want to say one last thing. They have some
19 motions to strike Dr. Parisian and my affidavit and a bunch
20 of other motions that they filed. I didn't file a motion to
21 strike their 27- or 30-page factual comparison that they
22 submitted which seems to me to be outside the rules and just
23 an attempt to get 30 additional pages, but I'll tell you why
24 I didn't move to strike it.

25 First of all, I knew you could handle it if you

1 wanted to, and secondly, it brilliantly illustrates the
2 disputed facts in this case. It goes on and on at some
3 length to contest what we say are the facts and they say are
4 the facts, and to the extent that you have any doubt that
5 they're parallel requirements, violations of disputed facts
6 here, they made the case for me.

7 Thank you, your Honor.

8 THE COURT: Thank you, Counsel.

9 UNIDENTIFIED ATTORNEY: Your Honor, sorry for the
10 interruption, but several of us have to appear before Judge
11 Magnuson at noon and we have to leave.

12 THE COURT: Well, finally you'll be in front of a
13 good judge. Have a pleasant trip.

14 UNIDENTIFIED ATTORNEY: Thank you, your Honor.

15 THE COURT: Mr. Brown?

16 MR. BROWN: Thank you very much, your Honor.

17 THE COURT: And if you'd be good enough, I think
18 we've covered most of the meat of this thing, but you can
19 pick up anything that's left lying around if you like.

20 MR. BROWN: I will. Thank you, your Honor.

21 When the Court early on in Mr. Gustafson's argument
22 said that this was a case about manufacturing issues, I was
23 planning on getting up here to say, well, actually it relates
24 to design, because what we had was really a design change of
25 the new battery, but after listening to Mr. Gustafson's

1 argument, I now think it's a failure-to-warn case. Because
2 what he said was, essentially, that Medtronic had an
3 affirmative duty to warn the public, physicians and the FDA
4 about this January finding, and he used the basis of his
5 affirmative duty as 21 C.F.R. 814.39. And again, that issue
6 was precisely the issue before the Seventh Circuit last year
7 in McMullen vs. Medtronic. An unknown danger was discovered,
8 a warning was issued, and the debate was when should it have
9 been warned, such as in this instance. Should it have been
10 February? Should it have been October? Should it have been
11 some other month? And there -- and I think it's illustrated
12 on slide 36, if we could put that up -- the court said, in
13 fact, 814.39 is something that is permissive, not mandatory,
14 and in fact, to impose an obligation to warn when -- outside
15 of what the FDA has imposed would create a requirement in
16 addition to or different from. That's also the issue that
17 was --

18 THE COURT: Are you of a mind that if Medtronic
19 found out that somehow this was a dangerous device, they were
20 unable or somehow barred by either law or regulation from
21 issuing a public statement to that effect prior to being
22 approved by the FDA?

23 MR. BROWN: That's the very purpose of 814.39.

24 THE COURT: It's permissive.

25 MR. BROWN: It's permissive, but the point being

1 is, any warning that has to be regulated by the FDA.

2 814.39 --

3 THE COURT: No. If I'm correct -- and I may be
4 wrong -- any warning can be modified and changed by the FDA,
5 but I don't think if you have a safety warning you can give
6 it early. Am I wrong?

7 MR. BROWN: Respectfully, yes, your Honor.

8 THE COURT: That's fair.

9 MR. BROWN: The Brooks court dealt with that
10 specifically. In fact, the original Eighth Circuit decision
11 in Brooks, Judge Bye's opinion, said to the defendants that's
12 a fatal flaw in your argument because the manufacturer can in
13 fact warn without the FDA approval. The en banc panel, Judge
14 Murphy, who was the dissenter in the original decision, said
15 no, in fact, the manufacturer may not unilaterally make that
16 change. And here's the difference: They can make it
17 temporarily, but there has to be a premarket approval
18 supplement pending, and the change doesn't go into effect
19 until the FDA has ruled on it, which makes it a little bit
20 different than the drug regulations. And so Brooks
21 specifically -- and maybe we could get that slide up, slide
22 35 -- which actually talked about it, that was one of the key
23 distinctions about why the result differed in the en banc
24 decision of Brooks, was on that very point.

25 And so I think here, your Honor, what we have is

1 the plaintiff arguing that we could have, should have, must
2 have issued a warning to somebody at some point in time, that
3 814.39 requires us to do so. We have two courts, again, the
4 one most controlling here, Brooks, that was the very issue
5 and it was the very distinction in the en banc panel, and
6 McMullen both saying that is not the case. It's a misreading
7 of 814.39.

8 THE COURT: Now, your brother also makes an
9 argument which I don't think was really fully developed in
10 the briefs, but it certainly was an element in his argument
11 here. That once the FDA has given an instruction that the
12 product is to be either removed from the market or is no
13 longer permitted, that basically the preemption vaporizes.
14 There's no preemption at that point because, A, there's no
15 federal requirement and therefore there's no state
16 requirement in contravention.

17 MR. BROWN: Your Honor, that's been dealt with.

18 Number one, the PMA approval has not been withdrawn
19 even to this day.

20 THE COURT: Well, now, what did the Class II
21 instruction from the FDA say?

22 MR. BROWN: Well, your Honor, at this point in
23 time, it's important to remember all the devices are already
24 off the market. Plaintiffs' argument made it sound like the
25 FDA came in and said, "Get them all off. Take them away

1 immediately." The voluntary action we took was something
2 that after the fact was classified as a Class II recall. It
3 had already been done. And so the question is whether or not
4 that creates or invalidates in any way the premarket
5 approval, and the answer, I submit, is no, and the cases
6 we've talked about -- maybe we could put up slide 24, which
7 is from a case called Kemp vs. Pfizer, the District Court of
8 Michigan, which talked about why it is that this part of the
9 process -- that the medical device amendments allow and
10 encourage new medical devices without the threat of
11 litigation, and that if -- once a device that doesn't meet
12 expectations later goes off the market, if that was going to
13 take away preemption, again, that's where we get to maybe
14 slide 25, which is the umbrella-being-snatched-away analogy.
15 Again, the point is -- and the Court, I think, picked up on
16 it -- it provides a disincentive here to do the right thing
17 like we did.

18 I think it's important to remember, at the time we
19 submitted this premarket approval supplement application in
20 October of 2003, we did not have any clinical evidence that
21 this could happen in the field. We only had bench testing.
22 So this idea that we should have warned somebody when we
23 didn't even know at that point in time whether it could
24 happen clinically, we did that voluntarily. And so in return
25 for voluntarily doing that, there's no incentive. If

1 preemption would only apply, we just keep it on the market,
2 see how many come in, and nevertheless, because there would
3 be premarket approval we'd get preemption, there's something
4 ironic about that. That can't be what Congress intended.

5 THE COURT: Well, let me continue that for a
6 moment, if I may. The company knew there was a problem with
7 the battery, the what, 06 or the 05? I can never remember
8 which is which.

9 MR. BROWN: 06 is the original battery.

10 THE COURT: All right, with the 06, to the extent
11 that they developed the 07. Once you had approval on the 07,
12 why or how could you continue to ship the 06?

13 MR. BROWN: Your Honor, the reason we did that was
14 because --

15 THE COURT: Other than the fact you had a wall
16 full of them and they pull them off the shelf.

17 MR. BROWN: No, not at all, your Honor. In fact,
18 the 06 was providing necessary, important, vital therapy to
19 patients --

20 THE COURT: I got that part, but now you got the
21 07, which can do the same thing.

22 MR. BROWN: Okay, except that the 06 at this point
23 in time is performing better than competitive devices and
24 better than our existing devices. And, yes, once we did have
25 approval of the 07 and we tested it and certainly had high

1 expectations for it, it didn't have the benefit of field
2 performance. So while we certainly hoped it was going to do
3 quite well, we didn't have it for sure. And in fact, at this
4 point in time when we got approval, the 06 had not shown the
5 possibility it could actually happen.

6 And then after that when we got the first field
7 return, there seems to be some suggestion that we didn't
8 notify the FDA. When we got a field return, we followed the
9 FDA regulations and filed a medical device report. We did
10 that timely for every single one of them that came in. And
11 again, at the time we made the decision to voluntarily
12 withdraw it, there was a one in 10,000 chance that this could
13 happen.

14 Now, part of the reason we thought --

15 THE COURT: Which you found out was understated by
16 what, a hundred times?

17 MR. BROWN: No. We found out -- and part of the
18 reason we decided to make the voluntarily withdrawal is that
19 based on our testing --

20 THE COURT: But didn't you tell me that it
21 ultimately showed to be .15, up to .15?

22 MR. BROWN: Up to .15. What we predicted --
23 again, this was something we did on our own -- was that we
24 thought that that rate could go from .2 percent to 1.5, or
25 two in a thousand to in the thousand, and as a result of that

1 we made the decision to do that. We could have -- now, as it
2 turns out, there I think are 30, 31 returns that have
3 occurred where this shorting mechanism has occurred. I think
4 one of those patients is a plaintiff in the MDL and the
5 others are not. And so again, under the reasoning, had we
6 decided not to do anything, we may not have any lawsuit, we'd
7 have preemption that would apply. The system has to have
8 incentives to encourage companies to do the right thing like
9 we did, which is to find it on our own, investigate it, come
10 up with a solution.

11 THE COURT: Okay. I already made this argument
12 for you.

13 MR. BROWN: Okay.

14 THE COURT: Probably -- undoubtedly not as well.
15 All right. Is there anything else we ought to -- other than
16 telling me that I was right, is there anything else that
17 you'd like to tell me?

18 MR. BROWN: Well, your Honor -- and again, I think
19 the plaintiffs have conceded that certainly we could sell it.
20 There's case law. We have one in the Marquis case where --
21 this original versus new battery issue. The court said
22 there's two separate approvals. They're both fine from a
23 preemption standpoint separate from factually and a policy
24 standpoint.

25 With respect to -- again, I know the explosion is a

1 hypothetical and not the facts in this case, but all
2 post-approval activities are regulated. There is a statute
3 and a regulation that shows everything that can be done here.

4 THE COURT: What are your thoughts about the
5 question of whether or not a verdict, as in Bates'
6 description, is a specific requirement or is it not a
7 specific requirement?

8 MR. BROWN: In this context it absolutely is.

9 THE COURT: Well, let's back up. In which context
10 isn't it then and then tell me why it is here.

11 MR. BROWN: It's not in Bates and it wasn't in
12 Lohr, because there was no specific federal requirement. In
13 other words, a state jury verdict would not be conflicting
14 with a specific federal requirement. That's the reason those
15 are parallel and genuinely equivalent. The reason it's not
16 applicable here and why the Brooks court -- and frankly,
17 Lohr, as impenetrable as it was, if we get there, five
18 justices said that a common law duty could in fact create a
19 state court requirement. In 2000, the Supreme Court --

20 THE COURT: But at one point they said -- five of
21 them said it didn't.

22 MR. BROWN: No, the end result on that issue --
23 and again, Justice O'Connor's group that Justice Breyer
24 joined -- was that a state tort verdict could be a state
25 requirement. To the extent there was any ambiguity left in

1 that, in 2000, the Supreme Court in Geier, even Justice
2 Stevens recognized they had done that in Lohr. And then
3 again in Bates, interestingly, Bates sent back two claims to
4 the Fifth Circuit to see whether or not there was a conflict.
5 They might be preempted. So in that situation they didn't
6 preempt the design claims, because the labeling statute in
7 Bates didn't have anything to do with design. So the Bates
8 court even contemplated that there could be a preempted claim
9 there, and so if in fact was dictated by the statute, you'd
10 have a specific requirement and then a jury verdict would
11 indeed --

12 THE COURT: Now, Mr. Brown, I have one more
13 question. Then I think you're very close to concluding.

14 MR. BROWN: Okay.

15 THE COURT: Even closer than you might think.

16 (Laughter)

17 THE COURT: Where is the two-inch requirement that
18 the plaintiffs seek to impose?

19 MR. BROWN: Okay. The two-inch requirement takes
20 many forms. If they're saying that the design -- that we
21 should have had a different design, the equivalent is it's a
22 standard-of-care behavior. That's how Justice Breyer
23 described his hypothetical. So, to the extent that they're
24 saying we should have had a different design earlier, sooner,
25 that's a standard-of-care behavior that would be the two-inch

1 requirement. If in fact what they're saying, which I think
2 I'm hearing today, is that we should have warned differently,
3 that also is the equivalent of the two-inch/one-inch. In
4 other words, we warned here, they think we should have warned
5 at some other time. That's a standard-of-care behavior.
6 Justice Breyer happened to use it in the context of a
7 manufacturing item, but it applies equally to all of them.

8 So, with respect to that, I think that is exactly
9 what Justice Breyer was contemplating here, was that if
10 you're going to impose a standard-of-care behavior on the
11 company, that's the kind of state requirement that becomes
12 different from or in addition to.

13 And again, with respect to protecting the public
14 and the like, you know, we never said juries are stupid.
15 That's not the argument. We're talking about congressional
16 intent. And in fact, Brooks probably was as eloquent as any
17 of the circuit courts have been on the public policy issue
18 and in fact said that the explicit goal of national
19 uniformity in product regulation was not only a reason the
20 express preemption provision was put in there. It was the
21 reason. That's found in Brooks. And of course, for all of
22 those circuits that have found preemption, they had to have
23 found congressional intent. And as the Regal court, the
24 Second Circuit, last month said, that the 510(k) process
25 meant to preserve the status quo. The PMA process brought in

1 a whole different regime of ensuring public safety through
2 increased federal oversight and regulation, and again, that's
3 the public policy issue there, and again, that's the position
4 of the FDA.

5 And I'm pretty much done, your Honor. Thank you
6 very much.

7 THE COURT: Counsel, I appreciate the argument on
8 both sides and the quality and the level of sophistication.
9 It was very interesting. The matter is taken under
10 advisement.

11 (Proceedings concluded at 11:40 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.

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