

UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE:)	
MEDTRONIC, INC.,)	Multidistrict
SPRINT FIDELIS LEADS)	Litigation
PRODUCTS LIABILITY LITIGATION)	File No. 08-1905
)	(RHK/JSM)
THIS DOCUMENT RELATES)	
TO ALL CASES)	Saint Paul, Minnesota
)	December 17, 2008
)	9:00 a.m.
)	

BEFORE THE HONORABLE RICHARD H. KYLE
 UNITED STATES DISTRICT COURT JUDGE
 AND THE HONORABLE JANIE S. MAYERON
 UNITED STATES DISTRICT COURT MAGISTRATE JUDGE
(MOTIONS TO DISMISS)

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1 Okay. Well, welcome to St. Paul on a very, as you
2 well know, very cold one. At least it's not snowing this
3 morning.

4 My understanding of the time table is we're going
5 to have one hour for the Defendant, and that's going to be
6 followed then by the Plaintiffs. Then 15 minutes for reply;
7 is that correct? And, Mr. Gustafson, you're going to be
8 arguing all except a portion of that, right?

9 MR. GUSTAFSON: All except for the TPP part.

10 THE COURT: And that TPP part is going to be part
11 of the total hour for Plaintiffs?

12 MR. GUSTAFSON: That's correct.

13 THE COURT: And you have worked all that out?

14 MR. GUSTAFSON: We have worked it out. We're
15 going to allocate 15 minutes to the TPP.

16 THE COURT: Okay. It's my intention to take a
17 break after the first argument. I think going two hours and
18 20 minutes or 15 minutes, it can be done but I think it's a
19 little tough on everybody, particularly the court reporter.
20 So let's get underway then. Counsel.

21 Now, I had another recent submission this morning
22 from Mr. Gustafson. Has everybody gotten a copy of that? I
23 think it's the third --

24 MR. RING: We received that in court this morning,
25 your Honor.

1 MR. GELLER: Good morning, your Honor.

2 THE COURT: Good morning.

3 MR. GELLER: It's a pleasure to be here today.

4 As the Court is aware, Plaintiffs have filed a
5 lengthy Master Consolidated Complaint in this case but when
6 a lot of the rhetoric in the complaint is set aside, it
7 basically presents routine state law product liability
8 claims challenging the safety of Medtronic's Fidelis leads.
9 It alleges defects in the design, manufacturing and warnings
10 related to that medical device.

11 Now, your Honor, we filed a Motion to Dismiss the
12 complaint on a number of grounds. I'd like to focus the
13 Court today on our principal ground which we believe is
14 dispositive of all of these claims, and that is that the
15 state court claims alleged in the complaint are all
16 preempted by 21 U.S.C. 360k(a), which is the express
17 preemption provision in the Medical Device Amendments to the
18 Federal Food, Drug, and Cosmetic Act.

19 Now, that section provides, your Honor, that state
20 tort law, state law, including state tort law, may not
21 impose any requirements on a medical device that's been
22 approved by the Food and Drug Administration if the
23 requirements would in any way be different from or in
24 addition to the requirements imposed on that device by
25 federal law.

1 And as your Honor is aware, I will be talking a
 2 lot today about the Supreme Court construed this very
 3 provision less than a year ago in the Riegel case. Now, the
 4 Court held in Riegel by a lopsided vote that when a medical
 5 device is approved through the Pre-Market Approval process,
 6 the FDA must find, as a matter of federal law, that the
 7 device is safe and effective and the FDA must also impose
 8 strict federal requirements that control the way the device
 9 is designed, manufactured, tested, marketed, and labeled.

10 Therefore, your Honor, any state law cause of
 11 action that's premised on the notion that the device as
 12 approved by the FDA is in fact unsafe or that depends on a
 13 finding that the device should have been designed,
 14 manufactured, tested, or labeled differently from the manner
 15 approved by the FDA, is preempted.

16 Now, the Supreme Court held in Riegel that section
 17 360k(a), and I think it's important here to quote the
 18 Court's own language, and I quote: "bars common law claims
 19 challenging the safety and effectiveness of a medical device
 20 given Pre-Market Approval by the FDA." Those are the
 21 Supreme Court's words just ten months ago.

22 Now, your Honor, in our view this case fits Riegel
 23 like a glove. Plaintiffs acknowledge in their complaint,
 24 this is I think at paragraph 21, that the Fidelis lead was
 25 approved by the FDA pursuant to the Pre-Market Approval

1 process. And there's no question that as part of that
2 rigorous approval process the FDA found that there were
3 reasonable assurances that the leads were safe and effective
4 for their intended use. There's also no question that as
5 part of the PMA process the FDA imposed on Medtronic a
6 number of requirements as to how the Fidelis leads had to be
7 designed, how they had to be manufactured, and what sort of
8 warnings had to be given to the users of that device.

9 On the other hand, as we've explained in our
10 briefs, every single one of Plaintiffs' tort claims in this
11 case is predicated on the notion that the device was not
12 safe and that the leads -- and I quote directly from the
13 complaint -- "were in a dangerous and defective condition,"
14 that's paragraph 119, "were designed improperly," paragraph
15 31, "were defectively manufactured," paragraph 124, and did
16 not contain, "adequate and timely warnings or instructions."
17 That's paragraph 121.

18 Your Honor, this is precisely the same situation
19 that the Supreme Court addressed in Riegel. Riegel also
20 involved a PMA approved device. Plaintiff in Riegel also
21 alleged that the device was defectively designed,
22 manufactured, and labeled under state law despite compliance
23 with the PMA. But the Supreme Court held that even though
24 that Plaintiff had been severely injured by the device, and
25 even though his complaint may have alleged a product

1 liability defect under state law, all of the Plaintiff's
2 claims were preempted because they would have imposed state
3 law requirements on the device that were different from or
4 in addition to, that's Congress's language, the requirements
5 imposed by the FDA.

6 Now, the Supreme Court in Riegel emphasized, and I
7 think it's important to mention here today, Congress's
8 determination that the FDA alone and not judges and juries
9 applying the tort law of 50 different states, which is what
10 we have in this case, has the responsibility to balance the
11 public health benefits against the potential patient risks
12 presented by PMA approved medical devices which are, after
13 all, the most sophisticated medical devices. The FDA alone
14 should determine the safety and efficacy of such medical
15 devices.

16 And we submit, your Honor, that the same result is
17 warranted here. And in our brief, as I think your Honor is
18 aware, we went claim by claim down the complaint to explain
19 why each count is clearly preempted under the test announced
20 just ten months ago in Riegel.

21 Now, your Honor, I think the Plaintiffs plainly
22 recognize the significant problem that Riegel presents for
23 their claims, and they've made a number of efforts in the
24 complaint to plead around the Supreme Court's recent
25 decision. In fact I think it's fair to say that our Motion

1 to Dismiss turns entirely on what the legal arguments that
2 they've presented as to why they Court should ignore Riegel
3 have any merit. Now, they have presented four such
4 arguments and with the Court's permission I would like to
5 run down each of those arguments as to why we believe they
6 are all insubstantial as a matter of law.

7 Now, Plaintiffs' principal argument, your Honor,
8 which interestingly they present in the very first paragraph
9 of their complaint because I think they are so concerned
10 about Riegel, is that any PMA-related preemption no longer
11 applies here because the Fidelis leads were recalled from
12 the market in October of 2007 following the company's
13 voluntary field action. We think that argument is cleanly
14 wrong for two reasons.

15 The first is just as a technical matter, recall of
16 a device doesn't in any way invalidate the device's
17 pre-market approval. Although the Fidelis leads aren't
18 currently being marketed, they are all still unquestionably
19 subject to a valid PMA as a matter of law. And recall of
20 the device and withdrawal or revocation of a PMA are
21 entirely different administrative procedures governed by
22 entirely different statutory sections and statutory
23 standards. The FDA has never taken any action to withdraw
24 pre-market approval of the Fidelis leads and Plaintiffs
25 don't allege that it has. The Fidelis lead PMA is still in

1 full force and effect as a matter of federal law.

2 More importantly, your Honor, even if the recall
3 somehow could have been said to have made the PMA no longer
4 effective after October of 2007, the date of the recall,
5 that would still have no impact on the preemptive force of
6 the PMA on Plaintiffs' claims because those claims all
7 challenge, they all challenge, the way the Fidelis leads
8 were designed, manufactured, and labeled in 2004 when the
9 leads were indisputably subject to a valid PMA.

10 So I think here is the critical point, your Honor.
11 At the point in time when Plaintiffs are contending in their
12 complaint that the leads should have been designed or
13 manufactured in one way, federal law clearly required that
14 they be designed or manufactured in a different way. And
15 under 360k(a) as construed in Riegel, your Honor, those
16 sorts of claims are plainly preempted. And I think it's
17 particularly telling that the Plaintiffs haven't been able
18 to cite a single case, not a single case, in support of
19 their recall argument. We have cited at least four or five
20 cases that have rejected that very argument for the reasons
21 I've given you.

22 Now, your Honor, the Plaintiffs' next attempt to
23 get around Riegel is, I think, less persuasive. They argue
24 that the Fidelis leads aren't entitled to Riegel preemption
25 because they were approved by the FDA pursuant to the PMA

1 supplement process. But the Supreme Court rejected that
2 very argument in Riegel itself. It stated that the FDA
3 evaluates PMA supplements under the same exact criteria as
4 the initial PMA submission. Has to make the exact same
5 finding of safety and effectiveness. And in fact although
6 Plaintiffs have chosen to ignore this point, the very
7 medical device at issue in Riegel was itself approved by the
8 FDA pursuant to a PMA supplement so that can't be a basis
9 for ignoring the preemptive effect in this case.

10 Now, your Honor, Plaintiffs next try to avoid
11 Riegel by suggesting in numerous places throughout their
12 complaint that Medtronic obtained or maintained the PMA by
13 violating various FDA reporting requirements. They
14 repeatedly allege, for example, that Medtronic withheld
15 material information from the FDA during the PMA supplement
16 process, and they actually baldly assert that the FDA, and
17 here I quote from paragraph 24 of the complaint, "could not
18 have approved the safety and effectiveness of the Fidelis
19 leads without knowledge of such withheld".

20 Now, your Honor, the complaint, I might add, never
21 actually identifies what specific information Medtronic is
22 supposed to have withheld from the FDA. And Plaintiffs also
23 assert, again I might add without any specificity and
24 contrary to fact, that after the PMA was granted Medtronic
25 repeatedly violated federal reporting requirements in

1 connection with the Fidelis leads.

2 Now, there are multiple problems with this
3 argument. The problem, first of all, in addition to having
4 no basis in fact and not satisfying the Twombly pleadings
5 standards which requires the pleading of facts and not mere
6 conclusions, the principal problem with this argument, your
7 Honor, is that these claims are all clearly barred by the
8 Supreme Court preemption ruling in the Buckman case.

9 Now, as your Honor is aware, the Supreme Court
10 held in Buckman, again by a lopsided vote, that private
11 litigants can't bring state law claims designed to
12 invalidate FDA approval of a medical device on the ground
13 that the manufacturer allegedly withheld information from
14 the FDA. But that's exactly what Plaintiffs allege here.
15 The Court said that those claims were preempted for two
16 reasons.

17 One, they would conflict with 21 U.S.C. 337(a)
18 which provides that the federal statutes and regulations
19 regarding medical devices, including the reporting
20 requirements, may be enforced only by the federal
21 government. And secondly, the Supreme Court said that
22 claims such as the ones the Plaintiffs are bringing here are
23 preempted because they directly interfere with the FDA's
24 broad discretion to decide for itself how much information
25 to request as part of the PMA process, what actions to take

1 when more information may be required, and what sanctions to
2 impose if the reporting violations were heard.

3 The FDA regulations make it quite clear that the
4 FDA is not required to revoke a PMA even if fraud had been
5 found. In other words, your Honor, even at this stage of
6 the case if we were required to accept all of these
7 allegations of fraud on the FDA is true, they still wouldn't
8 entitle Plaintiffs to the relief they seek, which is
9 invalidation of the PMA and avoidance of Riegel preemption.
10 Buckman clearly holds that private litigants can't obtain
11 that relief under state law by collaterally attacking the
12 validity of the PMA on the ground that the FDA was somehow
13 deceived. Under Buckman, only the FDA can decide whether it
14 should have been given additional information and, if so,
15 what response, if any, is appropriate. And certainly only
16 the FDA can decide whether to revoke a PMA.

17 So as the case comes to this Court, I can't
18 emphasize enough it has to be taken as a given that at all
19 times the Fidelis leads were subject to a valid and
20 enforceable PMA.

21 Now, finally, your Honor, the Plaintiff's last-
22 gasp effort to plead around Riegel is to allege that some of
23 their state law claims are so-called parallel claims that
24 don't impose any requirements beyond those imposed by
25 federal law. Now, we agree that under 360k(a) a truly

1 parallel state law claim would not be expressly preempted
2 because it wouldn't impose any different or additional
3 requirements. But to satisfy this very narrow exception,
4 the alleged state law violation must be truly identical to a
5 readily ascertainable federal law violation. The Supreme
6 Court held that in the Bates case.

7 This complaint, your Honor, doesn't come close to
8 pleading any such claims. To begin with, there's not a
9 single allegation in this complaint that the Fidelis leads
10 failed to comply in any respect with the requirements of the
11 PMA. Plaintiffs don't allege that Medtronic deviated from
12 the design requirements of the PMA. They don't allege that
13 Medtronic deviated from the manufacturing process required
14 in the PMA. And they don't allege that Medtronic failed to
15 give the precise warnings mandated by the PMA.

16 In fact, your Honor, if you read this complaint
17 carefully, you'll see that despite its substantial girth,
18 it's 62 pages long or something like that, it actually
19 alleges only one design and manufacturing defect with any
20 specificity. Only one in this whole complaint. And that's
21 the decision to use resistance spot welding instead of
22 crimped coupling to connect the cables to the electrodes in
23 the Fidelis leads. Yet there's absolutely no allegation
24 anywhere in this complaint that the PMA or any other federal
25 requirement prohibited spot welding.

1 We think this is a telling and fatal defect in
2 this complaint. State law, under Riegel, state law can make
3 it a tort to engage in spot welding here only if, only if,
4 federal law prohibited spot welding. Yet there's no
5 allegation to that effect in this complaint, nor could there
6 be.

7 Now, there are in addition a couple of other
8 places in this complaint where the Plaintiffs refer to the
9 most vague and general terms to violations of the FDA's
10 manufacturing practices. But hereto, your Honor, there is
11 no allegation of a specific allegation of any mandatory GMP
12 requirement, nor could there be, because the FDA has never
13 found that Medtronic violated any of the GMPs in connection
14 with the Fidelis leads.

15 What's more, your Honor, as we explain in our
16 brief, these GMPs are all written by design in such broad
17 and flexible terms and give manufactures so much discretion
18 in how to interpret and implement them through an iterate
19 process with the FDA that it would be impossible,
20 impossible, for a judge or jury to find that federal GMP
21 violations had occurred here in the absence of any FDA
22 finding to that effect, much less to find that any state law
23 duty imposes the exact same requirements as a federal GMP.
24 Certainly this complaint doesn't make any effort to meet
25 that substantial burden.

1 So, your Honor, there is in fact not a single
2 allegation in this complaint, and we're here to judge the
3 validity and the adequacy of this complaint, there's not a
4 single allegation that Medtronic violated any state law
5 requirement that's identical to a specific and readily
6 ascertainable federal requirement. And, therefore,
7 Plaintiffs can't make an end run around Riegel on this
8 ground either.

9 Now, let me just say a final word about the
10 negligence per se claim that they brought which is the
11 fourth count of the complaint. This is nothing more than a
12 disguised effort to bring a private right of action to
13 enforce the Medical Device Amendments which the Supreme
14 Court has already said in Buckman is preemptive.

15 In deciding a claim such as this claim, if the
16 Court were to actually have to decide this negligence per se
17 claim, you would have to apply in state law, you'd have to
18 construe the federal -- the FDCA. You would have to decide
19 what the manufacturer's duties to the FDA were under federal
20 law. You would have to decide whether those federal duties
21 had, in fact, been violated. This claim, therefore, is
22 preempted for the exact same reasons that the Court gave in
23 Buckman. It's simply not the role of judges and juries
24 applying state law to supervise the relationship between the
25 FDA and the companies that it regulates under federal law.

1 That was, of course, the precise holding in Buckman and this
2 complaint runs up against it.

3 So for all these reasons, your Honor, we submit
4 that each and every one of the claims in the complaint
5 represents a direct challenge to the findings of the FDA
6 that the Fidelis lead was safe and effective under federal
7 law, and this complaint seeks to impose different or
8 additional state requirements in connection with that
9 medical device. The suit is nothing more, your Honor, I
10 think than an attempt to second guess the FDA's decision to
11 approve this device in 2004 and allow it to be marketed.

12 In light of the recent decision in Riegel, which
13 addressed this very situation less than a year ago, we
14 submit that this complaint has to be dismissed on preemption
15 grounds.

16 If your Honor has no questions, we'll save the
17 remainder of our time.

18 THE COURT: If this motion were granted and
19 dismissed, does that cover then every case that's been filed
20 and can be filed? What would be the implications of that?

21 MR. GELLER: Well, it would certainly cover any
22 case that falls within this Master Consolidated Complaint
23 because that's what we're here to judge today. It's
24 possible, I suppose, to bring some other claim that would
25 fall into one of the exceptions I addressed, such as this

1 parallel state claim exception if you could somehow manage
2 to draft a complaint that would do that.

3 But this complaint does not do that. You have to
4 show, first of all, that there was a violation of federal
5 law by Medtronic and the FDA has never found in connection
6 with the entire Fidelis process from the time of the PMA
7 approval to the recall that any violation had occurred.
8 That would be, I think, a very, very substantial burden in
9 proving any sort of parallel claim. But this complaint
10 certainly doesn't even allege that and, therefore, we think
11 this complaint has to be dismissed as a matter of law.

12 Thank you, your Honor.

13 THE COURT: Okay. Thank you.

14 There's a button in front of you right under your
15 tablet there that should raise that up. There we go.

16 MR. ROBINSON: Thank you, your Honor.

17 THE COURT: Bring it up as high as you want.

18 MR. ROBINSON: Good morning, your Honor. My name
19 is Rick Robinson. I'm with the law firm of Fulbright &
20 Jaworski and I'll be arguing the motion to dismiss the
21 third-party payor or TPP complaint. We've raised a lot of
22 arguments in our papers this morning, your Honor. If it's
23 okay with you, I would like to focus on the issues of
24 standing and ripeness.

25 We believe, as we have stated in our briefs, your

1 Honor, that the issue of standing is controlled by federal
2 law in this case even though this is a diversity case.
3 Article III standing requirements still need to be met for a
4 case filed in Federal Court which requires three things.
5 One, the third-party Plaintiffs have to allege an injury in
6 fact which is concrete and particularized, not derivative of
7 somebody else's injury. They have to allege that the injury
8 in fact has a causal connection to the Defendant's conduct.
9 And they have to show that the relief they seek can be
10 redressed through this lawsuit.

11 Now, I think, your Honor, the best way to analyze
12 the standing issue here is to look at the types of damages
13 that the third-party payors are seeking in this case and
14 they are basically seeking two types of damages. In Counts
15 I and III they seek recovery for the cost of leads that were
16 implanted in people that they insure. Everywhere else in
17 the complaint, including in Counts I and III, they seek the
18 cost of increased medical care for patients who were
19 implanted with the leads. And that's in every other count
20 of the complaint.

21 Now, your Honor, with respect to this
22 increased-cost-of-care theory, it's pretty clear that
23 there's no federal case that has ever allowed third-party
24 payors to recover cost paid for care provided to an insured
25 patient who needed additional treatment as a result of an

1 allegedly defective drug or device.

2 If you look at the cases that they cite, the
3 Warfarin case in the Third Circuit says that there could be
4 no TPP claims allowed for the increased costs related to
5 injuries suffered by the insureds. The Desiano case, the
6 Second Circuit case, also says that that type of claim is
7 derivative of the injury of the insured and cannot be
8 allowed in Federal Court.

9 Now, there are some federal cases that the TPPs
10 have cited here that would allow a third-party payor to
11 pursue an anti-trust or fraud case against a drug
12 manufacturer based upon the theory that the third-party
13 payor overpaid for the drug at issue, but those cases hold
14 that there's certain things that the third-party payor must
15 allege. The first is that it paid directly for the drug and
16 the second is that there were less expensive alternative
17 products available.

18 The best example of this, your Honors, is in the
19 Desiano case, the one that they cite from the Second
20 Circuit. There the third-party payors allege that they paid
21 pharmacies directly for the drug's purchase price and that
22 they would have bought a cheaper alternative drug had they
23 not been misled by the manufacturer's misrepresentations
24 about the drugs's safety and efficacy. And if you look at
25 footnote 9 of the Desiano opinion, you can see that they

1 gave some very specific allegations about their status as
2 purchasers and the availability of alternative products.

3 For example, they say they could have kept the
4 defective drug off their formulary. And formularies are
5 established lists of approved drugs by third-party payors
6 based upon a negotiation with the drug manufacturer. That
7 doesn't happen in -- there's no allegation that anything
8 like that happened in this case.

9 They also claim in the Desiano case that they
10 could have set a lower reimbursement amount for the
11 defective drugs, or they could have set a higher co-pay to
12 allow -- to kind of coerce or enforce or encourage the
13 patient to use a different drug. So there was some specific
14 allegations that established in the Desiano case both the
15 status of the third-party payor as a purchaser, and the
16 availability of less expensive alternative products.

17 In our case, however, there are no such
18 allegations of direct harm. There's no allegation in our
19 case that the third-party payors paid directly for the leads
20 that are at issue. There's no allegation that Medtronic
21 made any misrepresentations to the third-party payors that
22 caused them any harm or caused them to pay for the lead.

23 For example, in paragraph 55 of the complaint they
24 talk about the fact that there were no warnings given to
25 doctors. In paragraph 115 they talk about deceptive

1 promotional materials that were distributed to patients and
2 doctors. In paragraph 121 they claim that the patients and
3 doctors lacked accurate safety data. And in paragraph 127
4 they complained about a failure to warn consumers and
5 doctors. There are no allegations in the complaint anywhere
6 of any sort of direct interactions between the third-party
7 payors and Medtronic, and that distinguishes this case from
8 the cases that they have cited.

9 They also failed to allege that there was any less
10 expensive alternative lead available to their insureds and
11 there's no allegation in the complaint that the third-party
12 payors had any ability to control the cost of the lead. All
13 we have in this case is the bald assertion that appears in
14 their briefs that they were purchasers. Now, as this Court
15 held in Guidant, and is supported by the Supreme Court's
16 decision in Twombly, we do not have to accept that
17 allegation as true for purposes of this Motion to Dismiss.

18 One of the things that the third-party payors try
19 to do in their brief in order to get around their pleading
20 defects is to claim that some -- that they paid
21 artificially-inflated prices for the leads. But if you look
22 throughout the complaint you'll never see that allegation.
23 The closest they ever get is in Counts I and III where they
24 say they paid "substantial sums" for the leads. But they
25 never say they could have paid less if there had been some

1 other leads used in the case.

2 In fact, they really can't amend their way around
3 this defect, your Honors, because third-party payors in fact
4 don't pay for devices. The hospitals where these surgeries
5 are performed purchase the devices, and generally they are
6 reimbursed a flat rate amount by the insurance companies for
7 any surgical procedure involving the device. So what device
8 is used in a particular surgery has no impact on what the
9 third-party payor pays in this case.

10 So they couldn't actually allege that they would
11 have paid less to the hospitals where the surgeries were
12 performed if a different device had been used. And because
13 of that, they can't plead their way into this very narrow
14 line of cases such as the Warfarin case and the Desiano
15 case.

16 Basically, your Honors, what's happening here is
17 that the third-party payors are jumping the gun. If a
18 patient recovers from Medtronic after a damage award that
19 includes medical expenses that have been reimbursed by the
20 third-party payor, the third-party payor will have
21 subrogation claims to assert at that time. Suing now is
22 premature, it's entirely speculative, and their case is
23 simply not ripe in addition to the standing defects that
24 they have.

25 If there are any questions I would be happy to

1 answer them. Otherwise we'll reserve our time for rebuttal.

2 THE COURT: It's a little early to take a break.

3 MR. ROBINSON: Well, Mr. Soule is going to talk
4 about the state law issues.

5 THE COURT: I'm sorry. I didn't mean to cut you
6 off, Mr. Soule. You have been so silent back there.

7 MR. SOULE: Good morning, your Honors. Medtronic
8 also moves to dismiss the Plaintiffs' no-injury complaints
9 and the counts in which they are alleged are listed in our
10 motion. There's another ground beyond preemption to dismiss
11 the vast majority of these -- of the complaints period. And
12 I emphasize vast majority because most of the complaints do
13 not allege a physical injury that is not subject to our
14 motion today. And we submit, your Honors, that these claims
15 should be dismissed under the well-established body of law
16 that rejects no-injury claims.

17 The complaint alleges two categories of
18 Plaintiffs: Those who allege death, shock or explant, for
19 which we are not seeking dismissal on today's Motion to
20 Dismiss; and those that allege physical manifestations of
21 extreme emotional distress caused by an alleged increase in
22 the risk of fracture of the leads. And we submit that those
23 claims relating to emotional distress do not assert a
24 cognizable injury.

25 The Court is well versed in the law of no-injury

1 cases from its considering of the O'Neil case involving
2 cribs where the Court said that: "The Plaintiff must allege
3 a physical injury caused by an actual manifestation of the
4 alleged defect." And this is the black letter law that we
5 assert today in this motion.

6 This is a fundamental proposition of products
7 liability law applied in a variety of contexts and we've
8 cited the Briehl case in the Eighth Circuit involving brakes
9 and the Firestone Tire case. But more importantly the rule
10 is applied consistently in medical device cases in a vast
11 majority of the American jurisdictions. We cite the O'Brien
12 versus Medtronics case from Wisconsin in which a pacemaker
13 lead had been recalled but there was no evidence that the
14 alleged defect had manifested itself or that the Plaintiff
15 was injured by any manifestation of the alleged defect, and
16 that case was dismissed.

17 There was also well-settled law stemming from a
18 series of heart valve cases decided in the 1990s. No
19 injury, no cause of action. And that's the law in Minnesota
20 and in the states listed in Exhibit A where the courts have
21 decided the issue.

22 The Plaintiffs really don't take issue with our
23 argument that the no-injury rule applies in Minnesota, that
24 the rule bars claims for fear of failure of a medical
25 device, or that in order to avoid this rule they must allege

1 that they have suffered physical injury caused by a
2 manifestation of the alleged defect, nor do they dispute
3 that the rule bars no-injury claims in the states listed in
4 Exhibit A where the courts have decided the issue. They
5 have not disputed that in their response briefs.

6 They also don't dispute that a Federal Court
7 should not recognize a cause of action for no-injury claims
8 in the states that have not pronounced that rule -- have
9 gotten to that rule yet. But they do argue that they have
10 pleaded that every lead is defective. But of course all of
11 the no-injury cases allege a defect, negligence, or some
12 other fault with respect to all the products involved. And
13 the issue is whether the defect has manifested itself in
14 that situation and caused a physical injury.

15 The Plaintiffs also argue in their brief that all
16 of the devices involved in our case have already
17 malfunctioned because they were manufactured with damaged
18 wires and could not be trusted to reliably perform. But the
19 same argument could be made in every no-injury case that the
20 product could not be trusted to reliably perform.

21 In any event, the complaint tells a different
22 story in this case. The complaint alleges that the defect
23 has not manifested itself except for a small percentage of
24 users. The complaint alleges statistics showing that the
25 overwhelming majority of leads have not failed after 30

1 months.

2 It's not enough to plead that the leads cannot be
3 trusted to perform reliably. That's alleged in all
4 no-injury cases. The complaint also alleges, of course,
5 emotional distress from the fear of malfunction. And, once
6 again, this allegation is made in all the no-injury medical
7 device cases and it's not enough to cross the line. They
8 also allege physical manifestations of emotional distress
9 but this claim was rejected in a number of the no-injury
10 cases, including Khan in California and Angus in the Third
11 Circuit. In fact, the courts have drawn a bright line
12 regardless of the legal theory alleged requiring physical
13 injury caused by manifestation of the alleged defect, not by
14 emotional distress. Fear based on risk of failure is not
15 enough.

16 And there are good reasons behind this rule
17 because if every purported inability to rely on a product
18 constituted a malfunction or manifestation of a defect, then
19 every purchaser of an allegedly defective product could sue
20 based solely on the alleged fear that the alleged defect
21 might some day manifest itself and cause injury. And as a
22 result there may be fewer resources for those who truly have
23 present physical injuries, the cost of the medical devices
24 would be needlessly driven up and innovation may be stifled.
25 These are the policy reasons for the no-injury rule.

1 The Plaintiffs really only cite one case, and
2 that's the Guidant case with Judge Frank, where Judge Frank
3 found that the Plaintiff had alleged a cognizable injury
4 because there was a fact issue whether the alleged defect
5 had manifested itself requiring an explant surgery for the
6 Plaintiff.

7 Judge Frank acknowledged the Khan and O'Brien line
8 of no-injury cases and the no-injury rule but said this was
9 different across the line beyond no injury because the ICD
10 was explanted under doctor's recommendations. The explant
11 in the Guidant case constituted the injury under the
12 circumstances of the case, and we are not seeking dismissal
13 today of claims alleging explant.

14 Plaintiffs also argue that they have alleged
15 something more than fear of injury because defects in their
16 leads require them to undergo medical monitoring. When a
17 Plaintiff suffers physical injury, he may recover future
18 medical expenses reasonably likely to occur. There's no
19 such claim for Plaintiffs who have not suffered physical
20 injuries in a majority of the states that we've listed in
21 Appendix B.

22 Contrary to Plaintiffs' contention there is no
23 cause of action for medical monitoring in Minnesota, they
24 cite the Bryson versus Pillsbury case which involved
25 exposure to a chemical called Captan. It's a Minnesota

1 Court of Appeals case and I note that the Court of Appeals
2 does not create causes of action, at least in state court.
3 But the Court found that there was evidence that the
4 Plaintiff had suffered chromosome damage and there was a
5 fact dispute whether that translated into present injury and
6 an entitlement of future medical expenses just like Judge
7 Renner had done years earlier in the Werlein case. But it
8 did not create a cause of action for medical monitoring in
9 the absence of a present physical injury.

10 In the Thompson versus American Tobacco case,
11 Judge Magnuson said that given the novelty of medical
12 monitoring and that the Minnesota Supreme Court has yet to
13 recognize it as an independent theory of recovery, this
14 Court is not inclined at this time to find that such a tort
15 exists under Minnesota law.

16 Since the Supreme Court -- United States Supreme
17 Court decision in Metro-North versus Buckley, the trend has
18 been to reject such a claim for no-injury Plaintiffs,
19 including in pharmaceutical and medical device cases.

20 Plaintiffs also argue that Medtronic allegedly
21 advises patients and doctors to check the devices
22 periodically and that that advice or recommendation creates
23 a cause of action. But they cite no law, no case law, in
24 support of that conclusion. In fact, in many of the
25 no-injury cases cited in our brief, the Plaintiff had checks

1 on the device or condition and that did not create a cause
2 of action for medical monitoring.

3 Now, with respect to the no-injury claims and the
4 medical monitoring claim, Plaintiffs say wait. They say if
5 the cases survive the preemption challenge, then we can deal
6 with Plaintiffs and state laws one at a time. We can decide
7 later which laws apply to each Plaintiff and whether those
8 laws bar the claims.

9 But that approach defeats the purpose of the MDL
10 and a Master Complaint. Why should we not be able to
11 challenge the complaint on state law grounds? We raised
12 this issue in May in the reports that we filed with the
13 Court before our first meeting. And the alternative is to
14 wait and file hundreds of motions after some of the details
15 of where Plaintiffs live, etcetera, is resolved.

16 But we ask the Court to issue an order dismissing
17 all claims that do not allege a physical injury caused by a
18 manifestation of the defect, including those that allege
19 only a physical manifestation of emotional distress brought
20 under the law of Minnesota and the states listed on Appendix
21 A. We also ask the Court to dismiss Plaintiffs' medical
22 monitoring claims, Count XIX, brought under Minnesota law
23 and under the law of the states listed in Appendix B.

24 We don't have to decide choice of law issues now.
25 We're confident that if the court rules on these relevant

1 legal arguments, the details of how to identify the
2 appropriate law to individual cases can be worked out by the
3 parties. The overwhelming majority of the claims are no
4 injury and their dismissal would streamline this litigation,
5 make it more manageable and less costly.

6 I also want to comment just briefly, your Honor,
7 on Minnesota statutory fraud claims made by the Plaintiff
8 and Medicare as secondary payor claim. The Court is
9 familiar with the Minnesota statutory fraud and false
10 advertising statutes and their inapplicability in a product
11 liability case like this one. I've read the Easy Bake Oven
12 case and you also commented on it in the O'Neil crib case.

13 These claims, as the claims in those cases, should
14 be dismissed because they fail to allege a public benefit.
15 They seek damages in this case. There's no public benefit
16 when the Plaintiff seeks only damages for himself or
17 herself, as they do in these cases, when the product is no
18 longer being sold as is the case here; and when they are not
19 seeking injunctive relief that would alter the Defendant's
20 practices.

21 They say, Well, medical monitoring is injunctive
22 relief but, first of all, it's not available; and secondly,
23 it's not the type of injunctive relief that's contemplated
24 by these statutory fraud and false advertising statutes
25 which are intended to allow someone to go to court to stop

1 the false advertising or the deceptive trade practice.

2 Finally, with respect to Medicare as a secondary
3 payor, we believe that the straightforward language of the
4 statute dictates the dismissal of that claim. And the
5 leading case which Plaintiffs doesn't comment on is the
6 Glover versus Liggett case in the 11th Circuit that said
7 there's no private right of action that could be brought
8 under the statute, federal statute, for failure to reverse
9 Medicare until the liability of the party and the primary
10 liable has been demonstrated. Here the complaint does not
11 allege that Medtronic's liability has been established. And
12 as Judge Rosenbaum said in the Medtronic Marquis case, the
13 cart is far before the horse.

14 Thank you, your Honor.

15 THE COURT: Thank you, counsel.

16 MR. SOULE: Your Honors.

17 THE COURT: Anybody else from the Defendant?

18 Are you going to go the full hour?

19 MR. GUSTAFSON: No. I'll follow my colleagues and
20 be very brief. Relatively brief. I would say about half an
21 hour.

22 THE COURT: Okay.

23 MR. GUSTAFSON: Or so.

24 THE COURT: Let's proceed then.

25 MR. GUSTAFSON: Your Honor, may I approach?

1 THE COURT: Surely.

2 MR. GUSTAFSON: I have a few exhibits that I'm
3 going to refer to. I also have put in a little outline of
4 my argument which is intended as a way for you to keep me on
5 track. And I hope it won't put me over the page limit.

6 THE COURT: You're not going to use any of our
7 fancy new equipment then?

8 MR. GUSTAFSON: You know, a lot of people on my
9 side suggested that we have some fancy things but it just
10 doesn't work for me.

11 THE COURT: I'm with you so you're okay.

12 MR. GUSTAFSON: All right. Again, your Honors,
13 thank you. Dan Gustafson on behalf of the Plaintiffs. I
14 will try to be brief as my colleagues have been.

15 Our argument is really three points, your Honor.
16 First of all, because of the recall and because of the
17 withdrawal of this product from the market, there are no
18 longer federal requirements that can conflict with the state
19 law claims that we make in this case.

20 Secondly, our complaint, for 10 or 15 pages, makes
21 allegations that are parallel to the federal law.

22 Essentially what we say is if Medtronic violated the federal
23 law which applies here, the FDCA, and the state law claim
24 provides a damages recovery for the same conduct, it's not
25 a -- it's not preempted because there's no conflict.

1 And finally, with respect to the injury, we make
2 two points. One is for the people who have had shocks and
3 have had surgery, there's no question. They don't even move
4 on those people, nor could they. And for the people who
5 haven't had shocks, our view is that because of the recall,
6 Medtronics said to these folks go see your doctor and get
7 these devices changed so that they can alarm you if you have
8 a problem, that's injury. It's not much injury, but it's
9 injury. If those people had insurance, they had to pay a
10 co-pay, and if they didn't have insurance they paid cash.
11 All we need to have to go forward on this is some injury and
12 it satisfies it.

13 Let me back up and talk for a minute about the
14 standard. I normally wouldn't do this, Judge, but Twombly
15 changed it. And it changed in every so slightly, as you
16 know. It still is all the facts have to be believed and it
17 still is all the inferences are drawn in the Plaintiff's
18 favor. But it changed this any set of facts from the Conley
19 case to plausible facts. Right? You have to -- I think as
20 the Court said, you have to nudge it over the line from
21 conceivable to plausible.

22 And I think it's important that we look at the
23 facts of this case so we can talk about whether what we
24 allege is plausible.

25 In 1992 Medtronic first submitted a PMA for these

1 Transvene Lead System. It was approved in 1993 by the FDA
2 on an expedited basis, and Medtronic commenced to file 30
3 some PMA supplements. It's not like Riegel where they filed
4 two supplements that dealt with the label. We're talking
5 about dozens of PMA supplements over the years. Those
6 supplements included the introduction of new products.

7 The first one that they introduced was the Sprint
8 Quattro line in October and December of 2001, and that was
9 different than the Transvene System.

10 November and December of 2003 they got to PMA
11 supplements 29 and 30 where they sought approval of this
12 generation of leads, the third generation, the Sprint
13 Fidelis leads. No clinical testing. No testing than other
14 than at Medtronic. And why is that important? It's
15 important because in Riegel it's true, it's true that Riegel
16 did make its holding based on a PMA supplement. But not 30
17 some PMA supplements.

18 Here we have a situation where they went from one
19 to the other to the other to the other to the other without
20 any testing. And although each of those supplements may
21 very well have been directly related to the product before,
22 there was never any comparison of supplement 25 to the
23 Transvene System or supplement 32 to supplement 16. And so
24 although it doesn't matter for this motion, because for this
25 motion we would concede that there's -- that they have PMA

1 approval.

2 But after discovery, we're going to develop the
3 record on these PMA supplements and Medtronic's abuse of the
4 PMA supplements system. It's not relevant today but it's
5 going to be relevant in the future. So FDA approves the
6 Sprint Fidelis in 2004, and it's subject to conditions. If
7 the conditions are violated, the PMA is invalidated.
8 Medtronic sells the Sprint Fidelis. It sells it over its
9 previous products; actively tells folks that it's better;
10 does a study that shows a 1 percent failure rate or so, and
11 even its own advisory panel finds that the studies that they
12 are citing to physicians is flawed.

13 By late 2006, early 2007, there's storm clouds on
14 the horizon. The medical community starts to see problems
15 with these leads. Dr. Hauser in particular -- and all this
16 is in our complaint -- talks to Medtronics about his
17 concerns. He says we're seeing a lot of failures in these
18 leads. Medtronic doesn't do anything. They don't tell the
19 FDA anything. They don't tell anybody anything.

20 In February of 2007, Dr. Hauser and other folks
21 from the Minneapolis Heart Institute again talk to Medtronic
22 about the problems and they tell them that they are going to
23 publish a paper that talks about the leads. We allege
24 Medtronic tried to dissuade them from publishing this paper.
25 They offered them additional research money.

1 But Hauser and his colleagues -- Dr. Hauser and
2 his colleagues at the Minneapolis Heart Institute published
3 the study anyway. And in this study in the spring of 2007
4 they identified a failure rate that was ten times that of
5 the Sprint Quattro leads.

6 What did Medtronic do? Nothing. They didn't tell
7 the FDA anything. They didn't tell the public anything.
8 They didn't do anything.

9 Then there was a Cornell study that came out that
10 had similar findings to Dr. Hauser's paper. Medtronic then
11 responds by sending out a Dear Doctor letter, and
12 essentially in the Dear Doctor letter at tab 3 of your book,
13 essentially what the Dear Doctor letter says in March of
14 2000 [sic] is two things. It says in the first paragraph it
15 says: "Current overall Sprint Fidelis performance is
16 consistent with other leads." That's not true. Dr. Hauser
17 had already demonstrated that that was false.

18 The second thing is, if you read this letter, what
19 they suggest essentially is it's not the leads problem, it's
20 the doctors-who-are-putting-them-in problem. They are doing
21 it wrong. They are bending them too often, etcetera,
22 etcetera. The suggestion from this letter is clear that
23 it's the doctors who are implanting them who are at fault.

24 What does Medtronic do then? This is important
25 because this is what Medtronic did in the Medtronic I case

1 before Judge Rosenbaum. They made a decision in May of
2 2007, now just a month or so after this Dear Doctor letter,
3 they made a decision to redesign the leads, to change them,
4 fix the problems that they were aware of. But they didn't
5 tell the FDA that they were fixing problems because the
6 Sprint Fidelis was having problems with patients that it was
7 implanting. What they told the FDA was that it was going to
8 increase robustness. That's the exact same phrase they used
9 in Medtronic when they were talking about the battery
10 problem in the defibrillator.

11 So when we're thinking about whether this claim
12 that Plaintiffs make is plausible, it's nearly identical to
13 the conduct that was alleged and litigated in the
14 Medtronic I case.

15 I'm not sure what robustness means. It's not a
16 word that I've used very often. But it doesn't mean we
17 found a problem and we're trying to fix it. It means
18 something other than that. But Medtronic made a decision,
19 they made a corporate decision, that the problem was
20 sufficient that they had to fix it for their corporate
21 welfare. That's fine, but they didn't tell the FDA. They
22 didn't tell the doctors.

23 Dr. Hauser talked to them again in July of 2007,
24 just before the FDA approved the new product. And when the
25 FDA approves the new product in July of 2007, they don't

1 take Sprint Fidelis off the market. They keep selling it.
2 They keep selling both of them, just like they did in
3 Medtronic I. Two products in the market. No information
4 given out to these physicians. No information given out to
5 the patients. As far as we can tell, no information to the
6 FDA. In September, they filed over a hundred adverse event
7 reports on the Sprint Fidelis for the first time telling the
8 FDA that they have a problem.

9 Then in October, and this is actually different
10 than Medtronic, in October on the 7th, Medtronic's
11 management makes a decision to take the Sprint Fidelis off
12 the market. For reasons we don't know yet, but discovery
13 will show us, they still don't make an announcement. They
14 wait eight more days. They wait eight more days before they
15 make a public announcement on October 15th that they are
16 going to recall this product, which they call a voluntary
17 field action. They tell doctors at that time to seek -- I'm
18 sorry -- they tell patients to contact your doctors and seek
19 medical attention to reprogram the device so it will alarm.

20 Now, the very next day the FDA, based on
21 information that Medtronic now has told them, classifies
22 this as a Class I recall, the most serious of all recalls.
23 And they say that because the product violates FDA law,
24 we're going to make this a Class I recall. The recall
25 letter of October 16th is at tab 4 of your book and there's

1 a subsequent letter which it appears to us they sent kind of
2 a follow-up letter on November 1st which is at tab 5 of the
3 book. If you look at tab 4 you'll see the classification as
4 a Class I recall, and requiring a notice program.

5 If you look at tab 5 on the third -- I'm sorry,
6 the fourth paragraph, the FDA tells Medtronic to begin
7 making plans to destroy the product or recondition to bring
8 it in compliance with the law. It's not in compliance with
9 the law. That's an important point. If you look at the
10 second page of tab 5, the very last -- it's the third
11 paragraph from the end, the last two are just sentences.

12 It says: "Please be advised, this is the FDA
13 telling Medtronic, "Please be advised that the failure to
14 conduct an effective recall could result in seizure of the
15 violative product in commerce or other legal sanctions under
16 the Food, Drug, and Cosmetic Act." What they are telling
17 Medtronic is this product no longer satisfies the law. You
18 have to take it off the market. Same, same, by the way, as
19 Medtronic I. The only difference was Medtronic I was a
20 Class II recall.

21 All right. So here is our argument. The FDA's
22 recall voids the preemptive effect of the PMA approval.
23 Why? Because under 21 U.S.C. 360k(a) and Riegel, which by
24 the way we don't contest that Riegel applies. Riegel just
25 doesn't answer very many questions. It answers the question

1 of what the recall's statute says -- or I'm sorry, the
2 preemptive statute says. And under the facts of that case,
3 which were very different than the facts of this case, it
4 says those claims are preempted.

5 But what it says is that there's three things that
6 you have to show to get preemption. You got to show that
7 there's federal requirements. Okay. You have to show that
8 there's some dictate from the federal government that you
9 design, manufacture, and label this product that certain
10 way.

11 Then you have to show the conflicting -- that the
12 state law claims that a Plaintiff brings, which includes
13 common law claims, that issue was settled by Riegel, somehow
14 conflicts with those federal requirements and you have to
15 show that they are related to safety and effectiveness. For
16 the personal injury claims we don't contest that.

17 Here is the problem with whatever they say about
18 the recall. There's no federal requirements left. They
19 can't manufacture it. They cancel it. They can't label it.
20 They have to take it off the shelves and destroy it. So
21 let's just assume that we have a claim for strict liability
22 or a claim for negligence or all the other claims in our
23 complaint and let's assume that the jury finds that
24 Medtronic was negligent. It doesn't conflict with anything
25 that the federal government is making them do. They can't

1 sell it anyways. There's nothing they can do with that
2 product but destroy it. Right?

3 The lynchpin of preemption here is, as the Eighth
4 Circuit said in the Brooks case, is the interference with
5 state law claims and the federal regulatory scheme. There's
6 no interference. Now, they have a -- they would like you to
7 think that if the FDA doesn't initiate formal proceedings to
8 cancel this PMA, that somehow the preemptive effect stays
9 forever. Why would the FDA do that? The FDA can't do what
10 it's supposed to do on a regular basis. Why would they go
11 through the trouble of having a formal notice and hearing to
12 cancel a PMA when Medtronic has already voluntarily withdrew
13 these products from the market? The FDA has already
14 essentially canceled the PMA by issuing a recall.

15 And why would they do more than that? They don't
16 need to. They have accomplished what they want by getting a
17 recall. It doesn't seem fair. If I were sitting in your
18 shoes I would say to myself, Well, that doesn't seem fair.
19 Right? They got this PMA approval and they got to market
20 these devices and they operated under the assumption that
21 they had preemption. But it's not a question of fair. It's
22 a question of what Congress said in 360k(a) and whether or
23 not there's actually an interference between the federal
24 scheme and the state scheme.

25 If we were going to talk about fairness, we would

1 have to talk about the woman who has a case in this court in
2 which she was implanted on a Friday before Medtronic
3 announced the recall on Monday, after they had already made
4 the decision to take these products off the market and after
5 they had known for months that they had a problem. If this
6 were an equity test, we would have all sorts of evidence
7 about how unfair it would be to deprive people who were
8 injured by conduct that we allege was illegal, but it's not
9 about fairness.

10 As the Riegel Court told us on preemption, it's
11 about taking the statute and interpreting the words of the
12 statute. They rejected the notion that we should think
13 about what Ted Kennedy meant when he authored this bill back
14 in the 70s. They said, you know, the first thing we have to
15 do is construe this statute, and this statute requires
16 federal requirements. If there's no federal requirements
17 that allow you to market this device, there is no conflict.
18 That's the argument in which we -- that's why we say this
19 recall had an effect on preemption.

20 The second thing is -- there's an important second
21 thing and this is important because of the status of the
22 motion. The approval letter, which is at tab 1 of the book
23 that I gave you, on the second page, this is the approval
24 letter for some of the versions of the Sprint Fidelis leads,
25 it's approval number 29. On the second page, the second

1 paragraph, it says: "Failure to comply with the conditions
2 of approval as attached invalidates this approval order."

3 It doesn't say may invalidate it. It doesn't say
4 if we file a proceeding to withdraw the PMA it may
5 invalidate it. It says if you violate these conditions,
6 it's invalidated. It's self-executing. This is the
7 approval order that governs these products. So if we
8 demonstrate, as we have alleged, that Medtronic violated the
9 conditions of approval, the PMA is invalid by order of this
10 letter, by operation of this letter.

11 Now, if you look at tab 2, I have the -- there's a
12 December 2005 approval letter for PMA supplement I think
13 it's 32, and it has the conditions of approval attached to
14 it. These are not the same conditions. I don't have the
15 conditions from the letter in June. I think they are going
16 to be identical but I don't have them yet because we haven't
17 had a chance to do discovery. These documents were
18 publically available to us.

19 But I want to direct your attention to page 1 of
20 the conditions, which is page 3 of Exhibit 2 in my little
21 book. It starts out, "A PMA supplement must be submitted,"
22 must be submitted, "when unanticipated adverse effects
23 increases the incidence of anticipated adverse effects or
24 device failures." Our complaint is many allegations that
25 Medtronic did not tell the FDA. They didn't follow this

1 condition. They may have violated other conditions which we
2 allege in various places in our complaint; but let's just
3 take this one because this is one that our complaint clearly
4 sets forth which is: If you didn't tell the FDA that you
5 were experiencing adverse problems that may increase the
6 adverse consequences, this order is invalid. And if it's
7 invalid, there can't be any preemption.

8 All right. The second thing, the second argument
9 is that we allege parallel claims. Riegel acknowledges
10 parallel claims. This Court has three times in the
11 Medtronic, Guidant and St. Jude cases held that parallel
12 violations are an exception. There's just no argument. So
13 what do they say? Well, they say parallel means identical.
14 Parallel doesn't mean identical. The Supreme Court of the
15 United States has commented on exactly this language in the
16 Bates case, 544 US 431. It's a pesticide case but it has
17 the exact language. It uses -- and I can never remember
18 which one. This one uses "different from or in addition to"
19 and the Bates, the pesticide one, is "in addition to or
20 different from." Same exact words but reversed.

21 And the Court said it's not identical, it's
22 equivalent. Okay. It's a big difference. Equivalent. And
23 then it said it need not explicitly incorporate federal
24 standards. That's at page 447. And then they said it
25 requires the Court -- remember, what Bates did was they sent

1 it back to the Court of Appeals to assess whether it was
2 equivalent. And they said the Court needs to make sure that
3 the jury instructions, right, the jury instructions, point
4 out the fact that they have to be generally equivalent.

5 Now, your Honors both know that this Court is
6 called upon to have jury trials about federal statutes all
7 the time. I just finished a patent case in which the Court
8 had to instruct the jury on all sorts of different terms.
9 That case particularly was about obviousness. That seems
10 like a word that wouldn't need much definition, but it was
11 about five pages of jury instructions, comes out of the
12 statute, and it was obvious means this and obvious means
13 that. You do it all the time in criminal cases. You tell
14 the jury what willfulness means, what recklessness means,
15 and the jury then takes your instructions and they interpret
16 the facts according to the instructions.

17 This Court is not going to be asked to interpret
18 what the FDA would have done or might have done. What we're
19 going to do is say to the jury, here is what the FDA
20 regulation says. It says Medtronic must -- it's not going
21 to say Medtronic. It's going to say a PMA person must do
22 XYZ. Must make a report. And you're going to tell the jury
23 here is what it means. It means when they believe X, they
24 must do Y, and then the jury is going to take the facts of
25 this case and decide. That's no different than the

1 application of any other federal law.

2 Okay. And so -- and in Bates and in Riegel, the
3 case that Medtronic says is dispositive, both times the
4 Court said there's nothing in this preemption statute that
5 prevents a state from providing a damages remedy for conduct
6 that is otherwise a violation of federal law. That's all we
7 say. In pages 21 to 31 of our complaint, we go on and on
8 and on about the parallel violations. Okay.

9 And Medtronic says, Well, you don't say what the
10 requirements are and how we violate them. We don't know
11 what the requirements are. We don't have any discovery yet.
12 The courts are clear that the requirements are everything
13 that Medtronic submitted to the FDA. And let me just take
14 manufacturing as an example. They told the FDA how they
15 were going to manufacture these devices. They made all
16 sorts of submissions as required. And the FDA said not only
17 do you have to follow Good Manufacturing Practices, but you
18 have to do it in a way that you told us you were going to do
19 it. And if you didn't do it, it's a violation.

20 Okay. So we can't tell you right now whether
21 Medtronic has violated specific requirements because we
22 don't have them yet. We haven't done discovery. But we've
23 alleged it. We talk about the fact that they didn't
24 manufacture how they said they were going to manufacture.
25 We say that they didn't label it how they should have

1 labeled it. We say that they didn't design it the way they
2 should have designed it. So we did the best we could. And
3 all we have to do here is tell a story that's plausible. We
4 don't have to prove our case yet. All we have to do is make
5 a claim that's plausible. And this claim is plausible
6 because it almost mirrors exactly the Medtronic I.

7 Now, they come along and they say, Well, we
8 acknowledge that there's this parallel exception. Everybody
9 does. But Buckman covers it. It's impliedly preempted by
10 Buckman. First of all, this Court has rejected that
11 argument twice in the last year. They made this argument to
12 Judge Rosenbaum. They made this argument to Judge Frank.
13 It's been rejected. Why has it been rejected? Because,
14 first, we don't make a fraud on the FDA claim. We're not
15 suggesting that they got approval because they defrauded the
16 FDA. What we're saying is that they violated FDA
17 regulations and we're going to incorporate that standard of
18 care into our claim.

19 Remember, when we say -- when we say negligence
20 per se, all we're saying is in every state that we know of,
21 and Medtronic doesn't contest this, recognizes a version of
22 a negligence per se claim. Okay. All we're saying is that
23 rather than having the standard of care be what a good
24 doctor would do in Minneapolis, we're going to incorporate
25 the federal regulations as the standard of care. Okay.

1 So whatever they have to do with respect to the
2 FDA, that's the standard of care that we're going to
3 incorporate. That's what you do when you incorporate a
4 federal statute into a negligence claim. Negligence per se
5 is the label they use. So we don't make any fraud on the
6 FDA claims. We only make state law claims.

7 But more importantly, if this were the law, if
8 Buckman implicitly, impliedly preempted the different from
9 or in addition to exception, a parallel violation exception,
10 it would render that phrase meaningless.

11 Then the preemption law would be if you get FDA
12 approval, nobody can bring any claim for any reason under
13 any circumstances. Congress knew how to say that. Congress
14 in fact in the Airline Deregulation case that you may be
15 familiar with, Congress did say that. They said if there is
16 an issue that deals with rates, routes or services, you
17 can't bring any claims for any reason. And that has been
18 construed by the Supreme Court as broadly as Congress meant
19 it.

20 But that's not what Congress did here. What
21 Congress did here is they said except for when the claims
22 impose the same duties, right, which the Supreme Court has
23 now said is equivalent duties, right, there's no preemption.
24 They made that exception. If you adopt the Buckman
25 argument, you essentially are writing out the exception that

1 Congress wrote in. It would render that phrase "different
2 from and in addition to" meaningless. And that can't be
3 what Congress had intended because Congress could have said
4 it differently if they meant to say it that way.

5 Finally, your Honors, I would like to talk just
6 for a moment about the injury thing. Again, they don't
7 argue that the people who got shocks and had surgery were
8 injured. That's not their motion and they acknowledged on
9 their -- in their argument that that was not the case. It's
10 just for that group that's fortunate enough to not have
11 suffered those shocks so far. And they say to those people,
12 No injury because there's no failure.

13 Let me make an example. It's going to sound a
14 little silly but I think it makes the point. What if
15 Medtronic had manufactured these leads and instead of wire
16 in the middle of them they had put in plastic cables that
17 didn't conduct electrical signals. They would put them in
18 somebody and the person would be wandering around and they
19 would never know that something is wrong because until you
20 have a heart attack and you need to get a shock, you don't
21 know whether the cable is going to work or not. But we
22 wouldn't have an argument about whether they were defective.
23 We would know they were defective because they are
24 manufactured in such a way that they are damaged, they don't
25 have wire in them.

1 That's all we say here. What we say here is that
2 they made these wires in such a way, by welding them the way
3 they did and handling them the way they did, that they are
4 damaged. That when it comes time to shock you, when you
5 need that shock, it won't work.

6 So we allege, remember, Rule 12, we're not here to
7 prove it, we allege that all of the cables are defective.

8 All right. Set it aside. I'll be the first one
9 to acknowledge that the cases in this area are very
10 difficult to reconcile. It seems to me that you can take
11 several things away from them but it's harder to find a rule
12 of law. One thing you might take away is that where there's
13 economic damages alleged and not serious personal injury,
14 that those cases tend to find no standing or no injury. You
15 can take a more cynical view and you could say when they are
16 lawyer-driven kinds of class action cases in which nobody
17 seems to really be hurt or care, that the courts are even
18 more inclined to find no injury. But I think it's hard to
19 take all of the cases and find a rule.

20 But here, here we have a situation that gets by
21 it. And it's what I said at the very beginning. These
22 people were told contact their doctors and go get the
23 devices changed so they put the alarms on and changed the
24 impedance testing. It's a technical thing that's kind of
25 above me, but they went and they suffered injury. If I went

1 to the doctor extra, I would have to pay \$25 or whatever it
2 is co-pay. If I would have to spend the time and money to
3 get there. And I acknowledge it's not much in injuries, but
4 it is enough to satisfy the threshold that's required under
5 the law here.

6 Two last points. By the way, I think that
7 Medtronic will take a very different view in front of your
8 Honors if any statute of limitations cases come up. I don't
9 think they are going to take the view that until you have
10 been shocked and had surgery, you don't have to file a case
11 under the statute of limitations. I suggest that their
12 argument will be different. And now they say in response to
13 our argument that this is not such an easy analysis because
14 you got to decide whose law works. In order to do that, you
15 got to know something about the claimants and things like
16 that. So we think this inquiry ought to be delayed in any
17 event until we have some more information.

18 Now, you may recall when we were talking about
19 tolling in this case, we suggested that the purpose of the
20 MDL was to make things efficient and that we ought to have a
21 tolling rule that covered everybody. And Medtronic's
22 argument was no, we need to know more information because
23 these are facts specific, on and on and on, to which I said
24 we're going to have hundreds of motions, right? You
25 remember that discussion?

1 Now they want it to be the other way. Now, they
2 want it to be the rule of efficiency and they want you to
3 dismiss all of these cases because it sounds easier. But
4 the law isn't that way. The law requires us to make an
5 analysis about which law applies. It may be that Minnesota
6 law applies. It may be that it's easy to make this analysis
7 but we don't know because we haven't had the discovery, we
8 don't know what the contexts were, we don't know who was
9 involved in the representations and elections.

10 All right. I'm almost finished, Judge. Last
11 thing. Yesterday the Supreme Court decided the Altria case,
12 if I'm saying it correctly, and it does two things. As far
13 as I can tell it's a preemption case about the light
14 cigarettes. It does two things that I think are relevant
15 here. First of all, it says that if you have some doubts
16 about preemption, if there's some ambiguity about how the
17 preemption statute ought to be read, you ought to read it
18 against preemption. And there's a vigorous dissent by
19 Justice Thomas, he doesn't like it, but the vote was 5 to 4
20 and that's now the law on preemption just yesterday, not ten
21 months ago, but just yesterday.

22 And the second thing they said was you know what?
23 This is a Consumer Fraud Statute. This is not a statute in
24 which we're talking about health and safety. What we're
25 talking about here is whether in this case the cigarette

1 companies lied to the public.

2 I would suggest that that case supports the notion
3 that consumer fraud cases and Deceptive Trade Practices Act
4 cases are now outside the bounds of preemption because they
5 don't go to the issue of whether Medtronic's product is safe
6 or not. They go to the issue about whether Medtronic
7 deceived the public. Surely enough the jury will have to
8 decide if the statements are true or false, just like they
9 do in any other case; but they won't have to decide whether
10 the products are safe. They will only have to decide
11 whether Medtronic told truths in its public statements.

12 Finally, we acknowledge that there has to be a
13 public benefit. We seek injunctive relief and that includes
14 the affirmative medical monitoring. It's not a medical
15 monitoring claim as Medtronic has set forth today. What
16 we're saying is that if Medtronic lied about these products
17 or they committed fraud or they committed negligence or
18 anything else, one of the remedies we're going to seek is to
19 require them to pay for -- affirmatively pay for the medical
20 monitoring for these folks until we find out if they are
21 going to need to have these devices explanted. Okay.

22 It's different than a medical monitoring claim and
23 we acknowledge that that's all over the board. What we're
24 saying here is that the public benefit is that we're going
25 to enforce these Consumer Fraud Acts so that Medtronic now

1 tells the public what it should have told the public before
2 and we're going to ask you to enter an affirmative equitable
3 provision if we're successful.

4 If you don't have any questions, I'm finished.
5 Thank you.

6 THE COURT: Thank you, sir. Why don't we take our
7 break and we'll start with you, sir, when we get back.
8 Let's make it 20 minutes. We'll come back at 20 to 11:00.
9 So we're in recess until that time.

10 (Recess taken from 10:18 to 10:42 a.m.)

11 THE COURT: Counsel, do you want to proceed again.

12 MR. DAHLBERG: Thank you, your Honors. Thank you
13 for the opportunity to discuss the third-party payor aspect
14 of this claim. I'll keep my comments relatively brief this
15 morning.

16 Your Honors, the complaint that is at issue here,
17 the Master Complaint, is based nearly identically upon the
18 complaint which was upheld by Judge Rosenbaum In re
19 Medtronic. Almost identical circumstances, virtually
20 identical complaint, and that complaint was upheld under
21 these same circumstances. And in large part the allegations
22 that are set forth in the Master Complaint are done so for
23 that very reason because they were upheld by Judge Rosenbaum
24 already in a very, very similar setting.

25 Addressing some of the issues that have been

1 raised by Medtronic in this case, when you listen to the
2 arguments after reading through the briefs, but if you
3 listen to the arguments today, you hear the same thing over
4 and over again. A failure to allege acts. A failure to
5 allege why. Could have alleged it differently under
6 Desiano. Could have alleged it differently under a
7 different circumstance. The matter that we have before us
8 here today is a 12(b)(6), and don't confuse their allegation
9 that Plaintiffs could not plead X, Y or Z with what they are
10 actually saying which is they don't believe that Plaintiffs
11 could prove X, Y or Z. Two completely different matters.

12 And it's a little bit of an awkward situation to
13 be here before you today arguing the validity of the Master
14 Complaint under these circumstances where the Master
15 Complaint was not something that a third-party payor
16 representative had an opportunity to be involved with in the
17 drafting because there isn't a third-party payor
18 representative on the steering committee. And so the
19 arguments of counsel that the complaint isn't perfect,
20 number one, missed the point because the issue isn't what
21 can Plaintiffs prove. It's what does the complaint say.

22 Number two is, the point I would like to make, is
23 if the complaint isn't perfect, if the allegations -- if the
24 allegations are bare, then the remedy isn't to dismiss an
25 entire nation of third-party payors, an entire body of

1 third-party payors under a Master Complaint. The remedy is
2 to allow the matter to be re-pled. And then based upon the
3 allegations that are made, do the discovery, figure out what
4 the relationships are between the third-party payors and
5 Medtronic and determine whether or not the proof was there.

6 Now, going to the issue of the complaint for
7 today, is the complaint that's before us today, does it
8 state a claim? Is there standing under Article III? The
9 answer to all of that is yes.

10 The argument boils down to basically two things.
11 One is injury and fact, and the other is this argument about
12 ripeness. With respect to the ripeness issue, as Judge
13 Posner indicated, it would be awkward at best, it would be
14 cumbersome to say that the third-party payor needs to be
15 separated out, wait for the resolution of the entire claim
16 before they can come forward and be heard in court to be
17 able to set forward their claims.

18 In subrogation law the rights of the insurer are
19 independent or codependent in almost every state in the
20 union to be able to go forward with their insured at the
21 time that they are make their claims to be able to state
22 that they are the real party in interest. And they are a
23 proper party in Minnesota, in Wisconsin, in most states in
24 the land.

25 And so to say that they have to wait until some

1 future day when the statute of limitations may or may not
2 have run on their claims to be able to have their rights
3 heard in court and not to be present on this action, is --
4 ignores the reality of the way the medical marketplace works
5 and, more to the point, it's not judicially efficient. It's
6 going to require that those issues comes along later. And
7 I'll give you an example of how it ends up working.

8 In the Paxil litigation that we just got done
9 resolving here in front of Judge Davis, the GlaxoSmithKline
10 separated out the two, separated the third-party payors from
11 the consumers. And in doing so were able to reach a
12 settlement with the consumers for their out-of-pocket
13 expense leaving the third-party payors out. Then when the
14 third-party payors moved forward to complete the recovery,
15 moved to dismiss all of those claims.

16 And so you ended up with two litigations where it
17 could have been one. And ultimately the third-party payors
18 in front of Judge Davis had standing, reached a settlement,
19 and went forward; but it took an additional two years' worth
20 of litigation, additional dispositive motions, etcetera,
21 when the conduct is the same. The conduct is uniform. The
22 proof is the same.

23 So to separate out the rights of the third-party
24 payors when they do have their own standing as a result of
25 the injuries to the -- to their insureds and directly by

1 their own choices, by their own purchasing, by their own
2 formularies and contracts with their insureds, they are both
3 direct and indirectly harmed in this case.

4 And to set them back on an argument of ripeness
5 that's made in a footnote in the Guidant case is simply to
6 put that matter off for another day when it could be had
7 right here in this same court, and to ignore the standing
8 that third-party payors have as real parties in interest.

9 On the no-injury issue, there is direct harm as a
10 result of paying for a product that the Defendant knew was
11 faulty. As counsel elaborated on, and I won't discuss at
12 length again, one of the troubling aspects here is the delay
13 in recalling the product and so the product ends up in the
14 marketplace longer than it should have been. And for a
15 period of time, the circumstances that arise are exactly
16 those that arise in the no-efficacy cases, which is that the
17 no-injury claims, if you talk about the no-injury case law,
18 and for example in Rivera, the case that's cited by Guidant,
19 which is cited over and over by Medtronic, the issue there
20 is that the no-injury issue comes to play because there was
21 no benefit of the bargain. And so in our situation where
22 there's no benefit of the bargain, the no-injury doctrine
23 simply doesn't apply.

24 So in the situation where an individual purchases
25 a product that does work for them because there's a latent

1 defect waiting to harm them, the case law will say those
2 people don't have an injury and can't step forward with the
3 claim, that circumstance isn't present here.

4 There is injury as elaborated on. There is a
5 period of time where there's no efficacy. The products
6 simply shouldn't have been on the market so the economic
7 harm is the purchase in the first place, just like in the
8 Gertz v SKV (phonetically spelled) case. The purchase of
9 the product in the first instance when there is no benefit
10 of the bargain for the consumer is the harm.

11 So the third-party payors paid for the product in
12 the past tense on behalf of their insureds. They are paying
13 for the product in the present tense in the context of
14 medical monitoring, and they are going to be paying for it
15 in the future in the context of explantation.

16 This isn't like the no-injury cases that have been
17 cited by Medtronic because of the fact that it shouldn't
18 have been in the marketplace in the first place and because
19 of the attendant injuries that the economic losses also are
20 intertwined with.

21 Medtronic relies heavily upon Guidant. Again, the
22 Medtronic ruling is directly opposed. The extensive case
23 law cited in our briefing where third-party payors have
24 standing, I won't reiterate those issues here. But again,
25 the issue of whether or not these individuals -- these

1 third-party payors have suffered an injury, you need to look
2 no farther than the way that everyone in this courtroom and
3 out on the streets understands medical services to work in
4 the United States. Who is it that's paying for that
5 implant? Who is it that's paying for the explantation? Who
6 is it that pays for that product in the first place?
7 Seventy to eighty percent of that money is paid by
8 third-party payors.

9 In their oral argument they discussed the
10 allegations that they found to be absent. In fact, reading
11 the complaint, the Master Complaint in the light most
12 favorable to Plaintiffs, those allegations are there. These
13 purchases were made at a demand-inflated price. They
14 artificially created demand; and the price that's paid for
15 that, not only that completely sidesteps the issue of any
16 price that's paid for a product that shouldn't be on the
17 market, is an inflated price. But the allegation of demand-
18 inflated pricing is contained in the complaint.

19 The comparison to alternatives is alleged in the
20 complaint at paragraphs 51 and 61 where it talks about their
21 knowledge of the difference between the performance of this
22 product and other products on the market. I believe that it
23 goes without saying that withholding that information from
24 the public and from the purchasers leaves them in a position
25 of paying for something where they don't know what they are

1 paying for. The comparison to alternatives requires that
2 you have some ability to compare it. And if they withhold
3 the information, that material information that allows you
4 to do that, that is material. That doesn't allow the third-
5 party payors to make those informed decisions.

6 And the issue isn't that Medtronic doesn't believe
7 that that relationship exists or that it can be proven. The
8 issue is whether or not it's alleged.

9 Misrepresentation of the quality to induce
10 purchase of that product rather than another. Again, an
11 allegation made in my clients' complaint. That allegation
12 set forth in -- not in those terms but in the discussion of
13 the -- of the withholding of information about alternatives
14 and in the demand-inflated pricing, is it set forth exactly
15 as we set it forth in our complaint? No. Is it there in
16 our complaint when it's read in the light most favorable to
17 the Plaintiffs? Yes.

18 Incurring additional health costs in the Master
19 Complaint at 118. Paying money for a product that they
20 would not have paid for but for the conduct of the
21 Defendant. In the Master Complaint at 116 and 127. And the
22 delay in recalling this device and, therefore, causing
23 economic injury.

24 Paying for something that never should have been
25 on the marketplace in the first place, 132 and 134.

1 Medtronic has withheld the information and put the
2 third-party payors in a position of having to pay for a
3 product that they never should have had to pay for. Of
4 paying for medical expenses that they never should have had
5 to pay for. And to say that their claims are premature when
6 they are the ones that paid for that product, as alleged in
7 the complaint, is simply adding judicial resources and
8 effort to get to the point where ultimately this litigation
9 needs to go, and that is compensating those who have paid
10 and have suffered economic loss. And no one has suffered
11 more economic loss than the third-party payors.

12 With respect to whether or not they are a
13 purchaser, I believe that counsel for Medtronic indicated
14 that Plaintiffs could not amend to make a claim that they
15 paid for the devices because of the way that the purchasing
16 of the products through the hospitals work, I would submit
17 to you that's not the way that it works for every
18 third-party payor in America. The complaint indicates that
19 the third-party payors are purchasers. The complaint on its
20 face states a claim and states standing. Discovery and
21 additional information about the relationship between the
22 third-party payors and Medtronic will surely be had, and
23 surely there's another hill to climb on this issue down the
24 road.

25 But to say that the manufacturer of a lawn mower

1 isn't responsible to the person who it hurts because they
2 sold it to Sam's Club at a discounted price, I don't think
3 rules the day. The purchaser is the person who paid the
4 money for the product in the end and that -- that is the
5 consumer and the third-party payor. And the lion's share of
6 that responsibility falls on the third-party payors.

7 Your Honor, when it comes to the equity of the
8 situation that we have before us where the actions of the
9 Defendant have resulted in direct economic loss to the
10 third-party payors, to say that they are swept out to sea by
11 this Master Complaint and the potential res judicata effect
12 that that may have on them, the opportunity to try to
13 separate these claims out and to delineate out-of-pocket
14 expenses from third-party payor expenses, ignores the fact
15 that insurers have standing. It ignores the fact that they
16 are the real party in interest. That they are the ones that
17 paid for this product. That they are the ones that suffered
18 the economic harm, and they should have their day in court.

19 If this complaint isn't perfect, I would love to
20 redraft it and come back and have this issue with this Court
21 again. I would much more like the opportunity to have the
22 discovery with Medtronic and to have the -- this argument in
23 the proper place where it should be, which is a Summary
24 Judgment motion, over a forum where we can discuss what the
25 actual discovery and the circumstances of each of the

1 individual Plaintiffs allege. But the complaint as it
2 stands states a claim. There is a direct loss and it's
3 suffered by the third-party payors. Thank you.

4 THE COURT: Thank you, counsel.

5 Reply? Are you going to be the only counsel
6 arguing?

7 MR. GELLER: I don't know.

8 THE COURT: If you use up 15 minutes you will be.

9 MR. GELLER: I won't use up that much, your Honor,
10 I promise. I only have a few things to say.

11 Your Honors, Mr. Gustafson has spent a lot of his
12 time arguing the facts today, your Honors. We agree with
13 him that we're not here today to decide the facts. But the
14 one point that I want to make is that these facts are all
15 within the exclusive jurisdiction of the FDA, not the Court
16 supplying the state law. That was the holding of the
17 Supreme Court in both Buckman and in Riegel. The
18 relationship between the FDA and manufacturers of Class III
19 medical devices is committed exclusively to the FDA's
20 jurisdiction and they simply refuse to accept that.

21 Now, it's also important to I think point out,
22 however, that the FDA was in fact aware of a lot of the
23 things that Mr. Gustafson mentioned today. He has talked
24 about Dr. Hauser and Dr. Hauser's coming forward with his
25 study to Medtronic. Dr. Hauser also shared that study

1 almost simultaneously with the FDA in March of 2007. The
2 FDA requested some information from Medtronic in March of
3 2007 and Medtronic complied within a month. The FDA decided
4 that no regulatory action was required.

5 The Plaintiffs would have this Court decide as a
6 matter of state law that some other sort of regulatory
7 action should have been required. This suit is nothing more
8 than a collateral attack, as I said earlier, on the decision
9 of the FDA on a matter committed to the FDA's exclusive
10 jurisdiction. And the FDA ultimately was involved in
11 discussions with Medtronic in terms of recalling this
12 product. Recall isn't inconsistent with the PMA. Recall is
13 a regulatory action, one of many, that the FDA has in its
14 options in connection with a valid PMA.

15 Now, Mr. Gustafson's principal argument today, as
16 in the brief, was that because of the recall there's no --
17 as he puts it -- no irreconcilable provision of state and
18 federal law. Therefore, no conflict. With all due respect,
19 your Honors, I think that's nonsense. The Plaintiffs in
20 this lawsuit are not seeking injunctive relief to take the
21 Fidelis leads off the market. If they were seeking
22 injunctive relief to take the leads off the market, there
23 would still be a preemptive claim but it wouldn't be
24 inconsistent with the federal decision to take the devices
25 off the market. What they are instead seeking here are

1 damages saying Medtronic should have done something quite
2 different between 2004 and 2007 in its marketing, design,
3 and manufacture of this device than the federal requirements
4 imposed at that time on Medtronic. So it's hard to see a
5 clear case for preemption.

6 Your Honors, in many ways it's like the Geier
7 case. I'm not sure if the Court's familiar with the Supreme
8 Court's decision in Geier but that was a state law claim
9 alleging that Honda should have included an airbag in one of
10 its 1984 model cars. Now, at the time that that case was
11 argued in the Supreme Court in the year 2000, by federal law
12 all cars had to have airbags. So Plaintiffs, just like
13 Mr. Gustafson, said, Well, there's really no collision
14 between the state law requirement that this car have an
15 airbag and a federal requirement. What the Court said is
16 no, you have to look back at 2004 and see whether the
17 state -- 1984, I mean. You have to look back at when the
18 car was manufactured to see whether there was a
19 collision between the state and federal requirements.

20 The same thing here today. Between 2004 and 2007,
21 this lead was subject to a lot of federal requirements.
22 This complaint says that under state law it should have been
23 subject to a lot of different or additional state law
24 requirements. That's the point in time that matters and
25 that's why the claim is preempted.

1 Now, they mention these conditions of approval in
2 one of their tabs. I don't have the right number. The
3 point here, again, your Honors, is that the FDA has never
4 found a violation of any condition of approval in regard to
5 the Fidelis lead. So once again it's a Buckman type
6 situation, which they simply refuse to accept. Even though
7 the FDA, which has exclusive authority under Section 337(a)
8 to enforce the Medical Device Amendment to the FDCA has
9 found that there is no regulatory violation here. They
10 purport to have a trial in this Court as to whether the
11 conditions of approval were satisfied. That's precisely the
12 sort of inquiry that the Supreme Court in Buckman and in
13 Riegel said that courts like this, with all due respect, are
14 not supposed to get into.

15 Court supplying -- and think about the road that
16 Plaintiffs would have this Court walk down. You would have
17 Court supplying state laws deciding whether FDA conditions
18 of approval were satisfied with the result that if this
19 Court were to find in some case that a condition of approval
20 was not satisfied, the PMA was not valid, the device might
21 have to be taken off the market, even though the FDA wants
22 the device on the market. That is not the system I believe
23 that Congress set up or that the Supreme Court interpreted
24 in Riegel and in Buckman.

25 And Mr. Gustafson says that if this motion is

1 denied, what he intends is to have discovery and to focus on
2 every single PMA supplement here to see whether Medtronic
3 complied with all the federal requirements, even though the
4 FDA has never found at any time that there was a violation
5 of any of these requirements. We submit, your Honor, this
6 is the exclusive role of the FDA.

7 Now, in terms of the parallel claims requirement
8 which they relied on, I think in order to fall within this
9 narrow exception, parallel state requirements, Plaintiff has
10 to show three things. First, that there's a specific and
11 identifiable federal requirement related to the device.
12 Second, that there's an independent state law requirement
13 that's identical or equivalent to that federal requirement.
14 And third, that the manufacturer's conduct violated both the
15 federal requirement and the state requirement.

16 Unless the complaint alleges that, and in our view
17 it does not state a non-preemptive claim -- now, I want to
18 repeat again, your Honors, that this complaint, in this
19 complaint Plaintiffs haven't alleged any of these three
20 things. They certainly haven't alleged them with the
21 specificity required by Twombly which requires the
22 Plaintiffs to plead more than labels or conclusions.
23 Plaintiffs haven't alleged that any specific federal
24 requirement was violated. As I said earlier, there's not a
25 single allegation in this complaint that Medtronic failed to

1 follow any requirement in the PMA as to design, manufacture,
2 labelling, marketing of the Fidelis leads. All they do is
3 make the most specific unsupported -- unspecific and
4 unsupported allegations that Medtronic somehow failed to
5 follow some vague Good Manufacturing Practices and reporting
6 requirements. But the FDA has never found any such
7 violations and Plaintiffs have not provided any support for
8 these wild assertions.

9 As I said, the complaint identifies only a single
10 defect in this device, the use of spot welding. But nowhere
11 did they allege that the use of spot welding violated any
12 federal requirement. I think that's a fatal flaw in this
13 complaint.

14 And second, the state law claims are in no way
15 parallel because they don't impose the exact same
16 requirements as federal law. For example, take the federal
17 reporting requirements which they say Medtronic violated.
18 These federal reporting requirements impose requirements
19 only on what has to be reported to the FDA. But their state
20 law failure warning claims, which they claim are parallel,
21 only impose requirements on what has to be reported to the
22 public. So as a matter of law, that is not a parallel claim
23 under Riegel.

24 I might say that we're aware of only one case in
25 which any court has ever allowed this sort of parallel claim

1 to go forward post Riegel. That is the Purcel case which we
2 cited in our brief. And what's significant about the Purcel
3 case is that the court pointed out that the FDA had found a
4 violation there. So once the FDA has found a violation,
5 then you can allow a parallel state claim to proceed.
6 There's been no such finding in this case of any violation.

7 Now, your Honors, let me talk about the Good case
8 or the Altria case which they referred to which was decided
9 by the Supreme Court earlier this week. I think it's
10 astounding that they think this decision helps them because
11 the Good case, which involved a completely different
12 statute, the cigarette labelling act, both the majority and
13 the dissent in the Good case reaffirmed Riegel. They
14 specifically distinguish Riegel on the ground that product
15 liability claims fall in the heartland of what the Federal
16 Food, Drug, and Cosmetic division sought to avoid. And they
17 also pointed out that the FDCA provision is much broader
18 than that in the cigarette labelling act.

19 So it's hard to see anything in the Good case
20 that's helpful to them. You have all nine justices in that
21 case, including the dissenters in Riegel, reaffirming their
22 holding in Riegel.

23 Now, the final point that I want to make, your
24 Honors, is this notion of fraud on the FDA which I think
25 pervades their complaint. But here again they simply refuse

1 to accept the holding of Buckman. They hear -- they read
2 the notes but they don't hear the music. Buckman doesn't
3 turn on what the specific cause of action is under state
4 law. Doesn't turn on whether the claim is denominated a
5 fraud on the FDA claim. What Buckman preempts is any state
6 law claim, any state law claim, that depends on showing that
7 the federal approval of a device should be invalidated
8 because the FDA was not given the information it needed.

9 The Supreme Court said that it's for the FDA alone
10 to decide whether it's gotten adequate information and if it
11 hasn't, they would request additional information or what
12 remedy or what sanctions it would impose. So that's exactly
13 what the allegations are in this complaint. Pervasive
14 allegations that material was withheld from the FDA. We
15 think that that's all preempted by Buckman.

16 Now, your Honor, the last several weeks, I'm sorry
17 we have inundated this Court with the decisions, we're happy
18 to supply them. In the last several weeks alone there have
19 been several District Court decisions that have dismissed
20 complaints very similar to these on the grounds of Riegel
21 preemption, rejected many of the arguments that the
22 Plaintiffs made here today, and we urge this Court to do the
23 same. Thank you.

24 THE COURT: Thank you, counsel.

25 MR. ROBINSON: I'll leave it where it is this

1 time, your Honor.

2 Two brief points. When Mr. Gustafson was up here
3 arguing, I heard a lot about allegations of
4 misrepresentations made to patients, doctors, and the FDA.
5 And then when counsel for the third-party Plaintiffs came up
6 I didn't hear anything about misrepresentations made to any
7 third-party payors. But if you look in the complaint, they
8 don't actually allege that there were misrepresentations
9 made to third-party payors.

10 Instead what counsel talked about was harm that
11 the third-party payors have suffered which, in his words,
12 were both direct and indirect harms. And clearly under the
13 cases that they cite, there's no recovery for indirect
14 harms. Desiano and Warfarin all say that the effort to --
15 by third-party payors to recover their out-of-pocket --
16 their costs of care for their insurers are all indirect and
17 can't be recovered in a Federal Court.

18 Then in describing his direct harm allegation, I
19 think he said that harm is the lack of benefit of the
20 bargain for the patient. So, again, it's completely
21 derivative of the harm to the insureds. And under all the
22 decisions that have been cited by both sides, that kind of
23 recovery is not allowed.

24 Now, I was hoping to get out of here today without
25 having to discuss the Guidant and Marquis opinions and the

1 obvious tension between the two. Since counsel mentioned
2 the Medtronic Marquis case, I feel obligated to say that we
3 don't really know what was the rationale behind Judge
4 Rosenbaum's decision in that case. There's no written
5 analysis of the grounds for the failure to bring a
6 dismissal.

7 On the other hand, in the Guidant case we have a
8 very, very detailed analysis by Judge Frank. We can look at
9 the cases and see that he's exactly right. That the case is
10 about -- the drug cases are very different than what happens
11 in the device world. And we would respectfully suggest that
12 the Guidant decision is the one that should be given
13 somewhat more weight in this case.

14 Thank you.

15 THE COURT: Thank you.

16 Mr. Soule.

17 MR. SOULE: Three points, your Honors.

18 One, Plaintiffs argue that the fact that, as they
19 have in their no-injury argument in the notebook they
20 prepared this morning, additional time and expense imposed
21 by doctors visits should give them an injury circumventing
22 the no-injury rule. And I assume they want to bootstrap
23 emotional distress claims because some of their Plaintiffs
24 have made co-payments for additional checkups. This sort of
25 logic was rejected in the medical monitoring cases where the

1 claim is even if there's no injury, we should get medical
2 monitoring.

3 And the Supreme Court in the Buckley case and the
4 Supreme Court in the Henry case wonder why, because when
5 there were medical devices at issue, extra monitoring costs
6 over and above those otherwise recommended, the
7 identification of those extra costs will pose special
8 difficulties for judges and juries.

9 And secondly, they will create a flood of less
10 important cases, unlimited and unpredictable liability.

11 So instead we have a bright line and we've cited
12 the cases to you and they haven't cited any cases to the
13 contrary. And the bright line is physical injuries over
14 here, claim is allowed at least on a stated claim basis. No
15 physical injury, no claim. Financial expense because you
16 have to go to the doctor and have your device checked falls
17 on this side of the line.

18 And we've cited several cases to your Honor where
19 people did go have their devices checked in the medical
20 device arena. The O'Brien case in Wisconsin, the Walus case
21 and the Khan case in California and the Angus case from the
22 Third Circuit also had claims that people went to have their
23 devices checked and incurred expenses.

24 Secondly, they say medical monitoring is just a
25 remedy but in fact it's Count XIX of their complaint. It is

1 a separate cause of action alleged in the complaint.

2 And third, as to, you know, this is going to be
3 difficult to figure out if the Judge -- if the Court rules
4 in our favor on the no-injuries claims, I submit not. I
5 submit that Mr. Gustafson, Mr. Shelquist, Mr. Ring, and I or
6 someone on our side can sit around the table and we can
7 figure this out. If you live in Wisconsin, have your
8 medical treatment in Wisconsin, your claim is likely to be
9 barred unless you have a physical injury. I submit that
10 it's probably easier than counting ballots.

11 THE COURT: Mr. Gustafson, do you want 30 seconds?

12 MR. GUSTAFSON: Boy that's tempting, Judge, but I
13 want to pass. I couldn't add anything other than to say
14 happy holidays to everyone on your staffs and we'll see you
15 next year.

16 THE COURT: I'll take the motions under
17 advisement.

18 There was a status conference scheduled for today.
19 We received a report from counsel there are really no issues
20 to be resolved. Judge Mayeron has an issue that she would
21 like to meet with the committee on.

22 MAGISTRATE JUDGE MAYERON: With the Plaintiffs
23 steering committee, I realize that you had submitted to me a
24 proposed order to address accounting of attorneys' fees and
25 costs and I've got a few questions. So what I would like to

1 do, if you're still available, if the Plaintiffs steering
2 committee would come down to my chambers, it's 632, and I'll
3 just briefly raise those questions with Plaintiffs' counsel.
4 It's not something that I need to consult with defense
5 counsel on that particular order.

6 MR. GUSTAFSON: We'll come down right after we're
7 finished.

8 MAGISTRATE JUDGE MAYERON: That would be great.
9 Thank you.

10 THE COURT: The motions are under advisement.
11 I'll try to get out an order promptly. I learned a lesson
12 to refrain from defining what I mean by promptly. Sort of
13 like lawyers saying I'm not going to take very long.

14 But let me just say this is about as interesting a
15 case, and I think, frankly, about as well briefed and today
16 well argued a case as I have had in a long, long time. And
17 I don't say that routinely to lawyers but it really is. It
18 makes life enjoyable. I'd probably enjoy it a lot more if I
19 weren't a little under the weather and I apologize for the
20 coughing. I should have turned off the microphone.

21 But happy holidays to everybody here and thank you
22 for coming in. Those of you who are from out of town, have
23 a safe trip home and we'll see everybody probably sometime
24 in 2009.

25 MR. GUSTAFSON: Thank you, your Honor.

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THE COURT: We are in recess.

(Court adjourned at 11:18 a.m.)

* * *

I, Carla R. Bebault, certify that the foregoing is
a correct transcript from the record of proceedings in the
above-entitled matter.

Certified by: s/Carla R. Bebault
Carla R. Bebault, RPR, CSR