

1 UNITED STATES DISTRICT COURT
2 DISTRICT OF MINNESOTA

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4 In Re: St. Jude Medical, Inc. 01-MD-1396 JRT/FLN
5 Silzone Heart Valves Products
6 Liability Litigation.

7 Minneapolis, Minnesota
8 July 10, 2003
9 9:50 a.m.

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11 TRANSCRIPT OF PROCEEDINGS
12 (Defendant's Motion for Summary Judgment)

13 BEFORE THE HONORABLE JOHN R. TUNHEIM,
14 UNITED STATES DISTRICT COURT JUDGE.

15 APPEARANCES:

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20 Michael Coren
21 Daniel W. Sigelman
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25 David M. Cialkowski
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1 THE COURT: Good morning. Good to see you all
2 again.

3 This is civil case number 01-1396, In Re: St. Jude
4 Medical, Incorporated, Silzone Heart Valves Products Liability
5 Litigation.

6 Counsel, would you note your appearances for the record
7 today?

8 MR. CAPRETZ: James Capretz for the class.

9 MR. ANGSTREICH: Steven Angstreich for the class.

10 MR. JACOBSON: Joe Jacobson for the Class II
11 plaintiffs.

12 MR. COREN: Michael Coren for the class.

13 MR. RUDD: Gordon Rudd and David Cialkowski from
14 Zimmerman and Reed for the class.

15 MS. LINDHEIM: Carolyn Lindheim for the class.

16 MR. SILVA: Mario Silva for Bonnie Sliger and Class
17 II.

18 MR. SIGELMAN: Dan Sigelman for the class.

19 MR. BOSCO: Michael Bosco for the class.

20 MR. MURPHY: Pat Murphy, plaintiff state liaison
21 counsel.

22 MR. JOHNSON: Fletcher Johnson for the class.

23 MR. MARTIN: James Martin, Your Honor, for St. Jude
24 Medical.

25 MR. KOHN: Steven Kohn for St. Jude Medical.

1 MR. STANLEY: Dave Stanley for St. Jude Medical.

2 MS. PORTER: Liz Porter for St. Jude Medical.

3 MS. VAN STEENBURGH: Tracy Van Steenburgh for St.
4 Jude Medical.

5 THE COURT: Good morning to all of you. We're ready
6 to proceed today with hearing defendant's motion for summary
7 judgment on the preemption issue.

8 Mr. Martin, are you ready to proceed?

9 MR. MARTIN: I am, Your Honor.

10 THE COURT: You may proceed.

11 MR. MARTIN: Thank you very much.

12 THE COURT: I think we have teed up an hour per
13 side, and we have a little time at the end to do a brief
14 status conference.

15 Go ahead, Mr. Martin.

16 MR. MARTIN: As the briefing here highlights, the
17 parties emphasize two very different approaches to preemption.
18 For its part, St. Jude Medical advocates an approach to stick
19 to the reasoning and analysis in the overwhelming majority of
20 federal and state cases, including the controlling Eighth
21 Circuit opinion in Brooks. It advocates an approach that
22 gives due regard for FDA review and its regulatory authority.
23 And finally and most importantly, it advocates an approach
24 that furthers the Congressional goals of protecting patients
25 by insuring uniformity in Class III device regulation and

1 encouraging Class III device availability.

2 The plaintiffs, Your Honor, take a very different tactic.
3 They want the Court to replace the expert regulatory judgments
4 with those of hired experts and ultimately lay juries. As
5 plaintiffs would have it, because their experts find fault in
6 St. Jude Medical submissions, and because they dispute the
7 basis of the FDA's regulatory approval, a jury issue is
8 created on preemption.

9 Under plaintiffs' approach, pure and simple, the
10 regulatory judgments and authority Congress sought to
11 preserve, and the policy goals Congress sought to further will
12 be displaced by ad hoc jury trials centering on how the FDA
13 approached its task, how it regulated the product, and whether
14 FDA approval for the product ultimately should have been
15 obtained. Plaintiffs suggest their approach to preemption
16 find support in their voluminous factual record, the
17 regulations that control Class III devices, the need to
18 provide consumers with a damage remedy to cure manufacturer
19 malfeasance. They contend a finding of preemption in this
20 context, Your Honor, would be unprecedented and would give
21 medical devices an unprecedented immunity from tort lawsuits.

22 But their factual evidence, expert or otherwise, cannot
23 change the nature of the legal issue that this Court
24 ultimately has to confront. And for a number of sound
25 reasons, we urge the Court to resist the wholesale innovation

1 of FDA decision-making and enforcement that the plaintiffs
2 propose.

3 To begin with, Your Honor, let's start with one basic
4 proposition: Class III medical devices are not every medical
5 device. Class III devices are those like St. Jude's heart
6 valve that operate to sustain human life, prevent impairment
7 of human health, or pose an unreasonable risk of illness or
8 injury. These devices can't be marketed without FDA approval
9 which is granted only after the FDA has been provided with
10 reasonable assurance that the device is safe and effective
11 after weighing the probable benefit to health against the
12 risks.

13 Second, for this narrow class of devices that have been
14 through this comprehensive approval process, the existence of
15 an express preemption provision changes the equation and it
16 changes it fundamentally. It provides a Congressional
17 declaration that products will not be regulated by litigation.

18 This is not a matter of factual debate. By choosing
19 express preemption and providing the comprehensive FDA review
20 and oversight, Congress has opted for uniformity and safety
21 regulation by the FDA, and determined that the FDA's decision
22 to approve the product should not be subject to second
23 guessing in tort lawsuits in the 50 states.

24 Now, the Congressional choice to provide for express
25 preemption and comprehensive FDA regulation and oversight are

1 made in the public interest. There is no room for factual
2 debate on this either. Congress has determined that the FDA
3 is in the best position to protect the patients while insuring
4 that they have access to important new medical devices, and
5 that manufacturers will continue to develop those devices.

6 Furthering the supremacy of FDA regulation is the most
7 effective way to get products to market and save lives.

8 Otherwise, the fear of exposure under state tort law will
9 stifle innovation, and it will deprive consumers of
10 life-saving products.

11 Now, respect for this Congressional choice barring tort
12 lawsuits is not a matter of factual debate either. Preemption
13 is based on a constitutional imperative drawn from the
14 supremacy clause. State law must give way when Congress
15 intends the result.

16 So in the end, Your Honor, whether plaintiffs want to
17 create a factual debate by casting it as fraud on the FDA, or
18 noncompliance, or violation of approval, it all amounts to the
19 same thing: They want a lay jury to invade the regulatory
20 process and substitute independent and different judgments for
21 those made or not made by the FDA.

22 Now, nothing in the case law charts this path. And it's
23 apparent why that's so. The entire FDA regulatory scheme is
24 intended to maximize patient health and safety by putting
25 responsibility in the regulatory agency and not in the

1 emotion-laden litigation context. Once the FDA makes its
2 decision, the better reasoned case law provides that the
3 preemptive force of the regulatory scheme attaches as a matter
4 of law.

5 Now, in making that determination, the controlling cases
6 start as they should, with the language of the clause itself.
7 The MDA expressly provides no state may establish or impose
8 any requirement with respect to a device that's different from
9 or in addition to any specific federal requirement, and which
10 relates to the safety or effectiveness of the device.

11 The cases then hold that FDA approval of a Class III
12 device through the PMA and PMA Supplement process does indeed
13 impose specific federal requirements that have preemptive
14 effect over any conflicting state requirements. The reason
15 for this conclusion is tied directly to the strictures of the
16 regulatory process itself. The FDA grants PMA and PMA
17 Supplement approval only after completing an in-depth
18 examination of the device and its testing, evaluating any
19 risks that might be associated with its use, and specifically
20 approving the testing, design, composition, method of
21 manufacture, labeling and marketing for the device in
22 question.

23 Once approved, Your Honor, moreover, the design,
24 manufacturing and labeling of the device may not be modified
25 without further direction and approval by the FDA.

1 Now, this is a different conclusion than was reached in
2 the Lohr case. But the case law explains the logic of that
3 distinction. Lohr involved the less rigorous 510(k) approval
4 process which focuses on device equivalence, not device
5 safety. With the PMA and PMA Supplement process, device
6 safety is the paramount issue, and the regulatory submissions
7 and regulatory oversight is directed to device safety as a
8 matter of statutory course.

9 THE COURT: It's certainly true relative to the PMA
10 process. It's less clear to me how rigorous that review is
11 for the Supplement process. Maybe you can talk about that for
12 a moment.

13 MR. MARTIN: I can talk about it now, or I can talk
14 about it a little further on. But the point of the PMA
15 Supplement process is that it has the same conditions in it as
16 the PMA process. There is no suggestion in the statutory
17 scheme that the FDA treats that any differently. And the
18 statutory requirements are the same.

19 By the same token, Your Honor, the case law has said that
20 the PMA Supplement process should be given the same specific
21 requirements and effects. Because it's a continuum, starting
22 with the PMA, going through the modifications, and proceeding
23 to PMA Supplement approval for any changes, what you get is a
24 total evaluation of the product aimed at the same issues:
25 design, methods of manufacture, labeling, marketing, and the

1 like.

2 And if there was any debate about it, Your Honor, the
3 record here addresses that issue. You can see from the
4 materials submitted that the FDA review through the PMA
5 Supplement process here was comprehensive and indeed
6 intensive. There was two years of exchanges between the FDA
7 and St. Jude Medical before the product ultimately was
8 approved. Those exchanges included discussions about design,
9 manufacture, methods of manufacture, and labeling. They
10 included discussions about the marketing of the product as
11 well.

12 In short, the better reasoned cases make no distinction
13 between the PMA and PMA Supplement process, because the same
14 level of regulatory oversight is provided for in the statute,
15 and it's given. And therefore, the regulatory decisions that
16 come out of that process do indeed impose specific federal
17 requirements as the case law insists.

18 Now, from the perspective of the courts that have looked
19 at this, whether the PMA or the PMA Supplement process -- and
20 I might add, Your Honor, there is no case that makes a
21 distinction between these two processes, and in fact holds
22 that the PMA Supplement process is not entitled to specific --
23 does not give rise to specific federal requirements that have
24 preemptive effect over conflicting state law. The courts then
25 find that state law tort claims that attack the results of

1 this regulatory process do impose conflicting requirements by
2 impermissibly interfering with the FDA comprehensive
3 regulatory oversight and decision-making.

4 And that conclusion, too, whether we're talking about the
5 PMA or the PMA Supplement process, is borne for respect for
6 the regulatory decision-making. Tort law by definition is
7 intended to assure compliance by the imposition of damage
8 awards. Whether couched in terms of strict liability,
9 defective design, defective manufacture, failure to warn,
10 negligence, express warning, implied warranty, or consumer
11 protection statutes, the causes of action represent a direct
12 attack on the FDA's decision, which was made with respect to
13 the PMA and the PMA Supplement here, that the device is safe
14 to market. That's an express conclusion drawn by the FDA in
15 this case, and a finding of liability on any of these causes
16 of action necessarily challenges or undermines or contravenes
17 that safety determination.

18 THE COURT: Under the normal PMA approval process,
19 is it always the case that a device is found to be effective
20 at the end of that process?

21 MR. MARTIN: Generally, the conclusions are drawn in
22 terms of safety and effectiveness. But it isn't necessarily
23 true that that would be the case.

24 Here, the FDA made a specific admonishment about what St.
25 Jude Medical could or could not say about the effectiveness of

1 the device in a certain way. And I say in a certain way
2 because there's two things about this device that need to be
3 understood:

4 The first is that it's a heart valve. And that is its
5 primary purpose. And there is no doubt that the FDA approval
6 as to the safety and effectiveness of the device as a heart
7 valve is across the board. The St. Jude heart valve is the
8 gold standard. It's a very safe and effective product.

9 The issue about the effectiveness that was left open was
10 the question of whether the silver sewing cuff would fight
11 infection and how. And the labeling that the FDA required --
12 and by the way, the labeling that went out with the product --
13 included that reservation in it.

14 So on the device itself, there's no debate that the
15 approval here extended to the safety and effectiveness of it
16 to function as a heart valve. And the only other issue that
17 the FDA left open for further study and evaluation was the
18 question of the efficacy of the silver.

19 Now, on that point again, Your Honor, there's a continuum
20 here of FDA regulation and oversight which the plaintiffs
21 would ask the Court to invade. The FDA left the AVERT study
22 there to follow the patients who had the valve. And that was
23 its form of regulation to watch this open issue. So right up
24 until the end, with the withdrawal of the product from the
25 market, we have effective FDA oversight of this product, the

1 FDA making decisions based on the data or at least looking at
2 the data relative to that. It was not left open.

3 Now, the courts that apply the preemption analysis to
4 this process and find that tort claims conflicts are embracing
5 the Congressional policy choice that this FDA decision-making
6 process should not be second guessed. And juries are not the
7 place to attempt to override regulatory approval on
8 enforcement decisions. This conclusion, to be sure, Your
9 Honor, abrogates state law damage claims.

10 But that result is compelled by principles of federalism
11 and due regard for the FDA's regulatory role. It does not, as
12 plaintiffs would have it, leave the public or consumers with
13 no remedy.

14 The case law recognizes that the FDA is in the best
15 position to police its proceedings and the conduct before it.
16 And it has the power under the statute in the form of
17 injunction, civil penalties, and criminal fines to do so.

18 Now, coming back to our case, Your Honor, while the issue
19 gets cloudy when you get over into plaintiffs' story, the
20 substance of the approval process, and the facts that led to
21 the application of preemption in the dispositive cases are
22 present here.

23 The original Class III Master Series valve had PMA
24 approval. Subsequent device modifications had PMA Supplement
25 approval, including the heart valve in question here.

1 St. Jude's exhaustive submissions to the FDA, including
2 in the context of the PMA Supplement for this valve, had
3 detailed information on design, possible side effects,
4 postoperative complications, manufacturing procedures,
5 testing, proposed labeling, and everything else that would be
6 required in the PMA process.

7 As I noted, Your Honor, this process started in '95,
8 approval came over two years later, and the FDA expert took
9 significant time reviewing these applications, provided direct
10 input and comment on them, and eventually found that the
11 device was safe and effective and allowed marketing.

12 The FDA then imposed specific conditions in granting PMA
13 or PMA Supplement approval, and continued to evaluate the
14 safety of the device after approval.

15 Now, the case law supports the application of preemption
16 in this circumstance. Brooks is a parallel. The Eighth
17 Circuit in Brooks sitting en banc expressly preempted
18 plaintiffs' failure to warn claims. And in making that
19 determination, the court initially examined the premarket
20 approval, the history of the premarket approval of the
21 product, including the manufacturer's submissions to the FDA,
22 and determined whether the FDA's review of the submissions
23 constituted a specific federal requirement consistent with the
24 Lohr opinion.

25 And the court found that the PMA review process in the

1 FDA was rigorous and did impose specific requirements. And
2 the court was influenced by the same factors that our present
3 in this case. The manufacturer's submissions, like the ones
4 here, included detailed information concerning design,
5 manufacturing, processing, testing, and labeling.

6 The FDA took significant time in Lohr to retry, and the
7 court paid attention to that. The FDA found, as it did here,
8 that the device was safe and effective and allowed marketing.
9 And finally, the court noted that because the warning claim
10 hit at the FDA approved labeling, there was the conflict that
11 forms the essence of the preemption analysis.

12 Just like Brooks, the class-wide tort claims that
13 plaintiffs assert in this case would impose requirements that
14 conflict with the federal requirements. Whatever the state
15 law variations in these claims, Your Honor, each of them
16 depends on a core allegation that St. Jude Medical
17 manufactured an unreasonably dangerous and defective
18 mechanical heart valve. A jury imposing liability by reaching
19 that conclusion would differ from the FDA's conclusion that
20 the composition of the product was appropriate for marketing,
21 and it was safe to put it on the market.

22 Plaintiffs say that their class-wide consumer protection
23 claims are exempted from this, and they seek recovery on those
24 claims though on the same basis, that an unsafe product was
25 marketed and sold. They say, however, that there's a consumer

1 protection claims exemption in the C.F.R.s for unfair
2 competition statutes, so they fit within that no matter what
3 the express preemption provides.

4 The regulation read in full really pertains to suits that
5 would involve unfair competition, allegations that are not
6 present here, and not part of this case, and not safety
7 decisions.

8 And to the extent that plaintiffs would read that
9 regulation more broadly, their construction can't trump the
10 specific preemptive intent in the statute. The intent
11 forecloses attacks that are safety related no matter what
12 context they occur.

13 Plaintiffs seemingly acknowledge the import of Brooks and
14 these cases, but they say that Brooks is distinguishable, and
15 the cases that follow it are distinguishable, or these Silzone
16 valve cases are different.

17 For example, the Court is urged to disavow preemption
18 because St. Jude Medical allegedly or fraudulently procured
19 FDA approval in violation of FDA regulations.

20 Well, to start with, Your Honor, we vigorously dispute
21 that. But whatever the result of that debate, and we can join
22 that debate and we have joined it, those allegations, and
23 that's all they are, do not impact the application of a
24 preemption. No case holds that allegations of fraud coming
25 from a party litigant who is attacking the FDA process can be

1 relied on to, as plaintiffs would have it, invalidate FDA
2 approval.

3 Whether approval can or should be withdrawn for a device
4 is an issue within the exclusive purview of the FDA, and it's
5 controlled by the terms of the statute.

6 And in this context, at least, the Supreme Court's
7 opinion in *Buckman* tells us that the preemption analysis
8 starts with FDA approval, and does not look back at how
9 approval was obtained. That's particularly true where, as
10 plaintiffs invite here, the scrutiny would inevitably lead to
11 a jury decision passing an independent judgment that's
12 different or in contravention of the oversight decisions made
13 by the FDA.

14 Now, plaintiff has also suggested that the Court should
15 treat this case differently because the PMA and PMA Supplement
16 process, both, do not impose the specific federal requirements
17 necessary to support preemption. Let me take those
18 separately.

19 As *St. Jude Medical* has highlighted in its briefing, the
20 notion that either the PMA Supplement or PMA Supplement
21 process doesn't support specific federal requirements is a
22 distinct minority view. Only *Goodlin*, *Webster* and *Woods* among
23 the federal cases that are cited accept this view. And the
24 vast majority of cases, including *Brooks*, *Kemp*, and the other
25 circuit courts we've cited, reach a different result and are

1 to the contrary.

2 The issue about specific federal requirements, Your
3 Honor, Goodlin, Webster and Woods, they can't be right. The
4 PMA application and approval process is by its nature device
5 specific. The FDA looks comprehensively at every aspect, from
6 testing to manufacture to labeling. It requires adherence to
7 its standards, and it polices those standards. Those
8 standards are applied to each device, to safety and efficacy
9 by express Congressional design and directive.

10 That's the source of the preemptive force of the FDA.
11 Unlike the drug cases on which plaintiffs rely, there's no
12 reservoir of authority for St. Jude Medical to act
13 unilaterally here. The --

14 THE COURT: Isn't that an argument, Mr. Martin, that
15 the FDA process in and of itself is the federal requirement,
16 and if that's true, there would be no grounds for any cause of
17 action in any case involving a medical device?

18 MR. MARTIN: Your Honor, the argument doesn't go
19 quite that far. And I don't mean to suggest that it does.

20 If you look, if we look at the case law, in those
21 instances where noncompliance has resulted in causes of action
22 that avoid preemption, you find that there are deviations from
23 the specifications in the product. So that the problem that's
24 alleged is not with the process itself and the FDA's oversight
25 in review. But if you compare the product sold to the product

1 that the FDA reviewed and approved, it's different.

2 This was the equivalency issue this Court noted in
3 Chmielewski. That was a manufacturing defect. We aren't
4 suggesting that that preemption, at least for purposes of
5 today, would be applied in such a case, and the Court doesn't
6 need to reach that kind of issue because no manufacturing
7 defect is alleged here.

8 In fact, on this noncompliance point, the only other
9 things that you see in the cases fall into two categories.

10 One would be like the manufacturing defect, a deviation
11 from the design specifications themselves. So if the
12 ingredients were wrong and the product systematically produced
13 with the wrong ingredients, there is a reservoir of state
14 authority and possibility of a tort lawsuit.

15 And if the labeling was altered, Your Honor, it's an
16 objective thing you can compare. It doesn't require you to go
17 in and subjectively or objectively re-evaluate the results of
18 the regulatory process.

19 The last category, Your Honor, of noncompliance is the
20 Woods case. This is the one that plaintiffs suggest is the
21 launching pad for the Court to get at this issue and to undo
22 preemption. But there are several things about Woods that are
23 significantly different than this case.

24 In the first place, the Woods allegation and proof was
25 directed at specific fraud committed on consumers in the

1 manufacture and sale of the product. That was the allegation.
2 It was not going at the safety or design of the product, which
3 is what the class-wide claims are aimed at here.

4 But there are two other pivotal distinctions in the Woods
5 case that flesh out my point, Your Honor, on why there
6 wouldn't be an absolute blanket preemption. In Woods, the FDA
7 specifically found that the manufacturer had violated its
8 procedures and processes. And finally in Woods, the defendant
9 had been criminally charged and pled guilty to that.

10 Now, the Woods court has quite a thoughtful analysis on
11 this. And it was nervous about invading the FDA regulatory
12 process and providing a cause of action that got around it on
13 the basis of an evaluation of that process. And it didn't do
14 it -- I'm sorry, it did it, with reservations, but only
15 because these factors were present.

16 So what is the other case that would create a reservoir
17 of authority for the states? Specific and direct regulatory
18 findings by the FDA of conduct in violation of its practices
19 and procedures.

20 We don't have that in this case, Your Honor. The FDA
21 never took steps to withdraw approval of this product. It
22 never withdrew approval of the product. And there is no
23 specific sanction that it leveled against St. Jude in the
24 nature of a criminal finding of any kind that it evaluated the
25 regulatory process.

1 And that's the rub, Your Honor. That's what makes this
2 case a problem, and that is why preemption gets triggered
3 here. Because it's that evaluation and review that would be
4 conducted de novo that is the issue.

5 Now, again -- excuse me.

6 THE COURT: Go ahead.

7 MR. MARTIN: Okay. On the PMA Supplement approval
8 process itself, Your Honor, let me come back to this for a
9 second. Because it does align with the PMA process. And
10 there should be no distinction between the two.

11 The statute doesn't say that the PMA Supplement process
12 is less rigorous. That is plaintiffs' characterization of it.

13 No case, as I said, holds that it is.

14 The FDA's own regulations establish that all procedures
15 and actions applicable to a PMA application apply with equal
16 force to a PMA Supplement application. The manufacturer must
17 provide the FDA with the detailed information that I talked
18 about concerning the design, the testing, the intended use,
19 labeling, performance standards, everything else. It's
20 spelled out in the regulations.

21 And in each case, PMA or PMA Supplement, after conducting
22 its review, the FDA can approve or deny the application,
23 demand further information, propose label modifications,
24 manufacturing modifications, and later can withdraw approval
25 if it determines that the process was ineffectual or that its

1 requirements were not met.

2 Now, Your Honor, in this particular case, that dialogue
3 took place. The facts of this case demonstrate the rigors of
4 this process. As I noted, there were several years of back
5 and forth exchanges of information. The FDA put specific
6 questions to St. Jude Medical. And St. Jude in fact supplied
7 the FDA with a wealth of data, clinical or otherwise,
8 including the adverse data that came in even after approval.

9 The FDA in this case, Your Honor, made an informed
10 decision to approve the device based on all this data. And
11 the FDA, as I said, never withdrew approval in the face of
12 the adverse data or in the face of anything that St. Jude
13 Medical did regarding a violation of conditions of approval or
14 anything else. It's simply not here.

15 And as I noted, Your Honor, and importantly, this
16 oversight and approval extended right up to the time of the
17 withdrawal with the AVERT study watching the people who had
18 taken it.

19 So I submit, Your Honor, what you're left with here is a
20 Class III medical device, FDA evaluated and approved with tort
21 causes of action that if recognized would conflict or override
22 the FDA's regulatory determination.

23 Now, these are the circumstances in which preemption has
24 been applied. And it should be applied, Your Honor, even in
25 the face of claims that the device should never have been

1 marketed.

2 THE COURT: What did the FDA refer to when the
3 recall was launched? Didn't they state in a letter that the
4 device was defective? I'm trying to remember exactly what the
5 language was, and whether that should be a finding of any
6 conclusive result in this case.

7 MR. MARTIN: Let me say no to that, Your Honor, for
8 a couple of reasons. And I think they're fundamental to,
9 again, the global points that I'm going to continue to make
10 about the regulatory process here and its effect.

11 But the adulterated and defective language that the
12 plaintiff picks on from the correspondence is drawn out of
13 context. It doesn't represent any regulatory finding or
14 conclusion. And it certainly did not result in the withdrawal
15 of the approval for the product.

16 And if we want to get into a debate about what the FDA
17 really thought at the end of the line after the recall, they
18 issued consumer background and other publications that said
19 St. Jude played by the rules. It submitted the data, we
20 evaluated it, we put the product on the market, it didn't
21 work, and they prudently recalled it.

22 Now, let's suppose that's now a matter of debate. Did
23 they intend to withdraw approval? Did they make a finding of
24 defectiveness? Or were we right this other piece of
25 correspondence indicates that in this case there was proper

1 approval and things were according to Hoyle because there is
2 no finding that St. Jude produced a defective product that
3 should have been withdrawn or whatever?

4 It's the fact of that debate, Your Honor, and how it's
5 going to get resolved that hits head on with preemption. The
6 way that the plaintiffs want to do it is to re-evaluate the
7 regulatory process, provide some expert testimony, and have
8 the jury decide it. And after that, St. Jude, I guess,
9 submits its own expert testimony, and then the jury looks at
10 it and they say, well, what did the FDA do? Why did it do it,
11 and what does it really mean? It's that perversion of that
12 whole series of issues by a lay jury that is the fundamental
13 problem with plaintiffs' approach.

14 And it doesn't get any better because the plaintiffs say
15 well, people got injured here. Congress knew, when it put
16 this preemptive provision in place, that injuries could occur
17 when these designs were less than what the companies or the
18 FDA might have hoped for.

19 Indeed, that's the situation where preemption is needed
20 the most and why it exists. Because providing preemption in
21 the case of that litigation, attacking the safety
22 determination promotes the availability of the products,
23 avoids undue deterrence for the manufacturers, and furthers
24 and encourages product development, so that the manufacturers
25 will do it knowing that they will not get sucked into the

1 morass of this kind of litigation that re-evaluates the
2 approval process.

3 Plaintiffs still say it doesn't work. This is a case of
4 noncompliance. And they define noncompliance as we've been
5 discussing to mean any purported factual debate over whether
6 the FDA's regulations were complied with before or after
7 approval. But whether one looks before or after, Your Honor,
8 you can't get to noncompliance on the facts of this case. You
9 can't make a jury issue out of it.

10 As I said before, no case that has considered the issue
11 of noncompliance has condoned or invited, even invited a
12 factual debate about what should or should not have happened
13 in the regulatory process. The most the courts have suggested
14 is that noncompliance can be shown where the evidence is that
15 the device, the defendant sold a device that was not the one
16 the FDA approved. In other words, the product itself was
17 noncompliant. Noncompliance has nothing to do with the
18 process or the company conduct in it.

19 And as I noted in this case, unlike the Woods case, there
20 is no evidence of that sort of noncompliance emanating from
21 the FDA. Plaintiffs haven't come forward with any evidence
22 because there is none that the FDA ever took any steps to
23 invalidate approval of this product, much less the steps that
24 are required in the statute. Yet that's exactly what they
25 want this Court or a jury to do. Nor has the FDA ever

1 sanctioned St. Jude Medical for marketing a device that was
2 not approved, or marketing a device in a way that was not
3 approved, that was inconsistent with approval. It didn't
4 happen.

5 Plaintiffs' expert evidence doesn't say anything
6 different, Your Honor. They don't point to any product sold
7 by St. Jude with an unapproved method of manufacture, design,
8 or altered label. Plaintiffs' expert suggests without
9 substantiation that St. Jude Medical violated FDA conditions
10 for marketing the product. But there's no evidence that the
11 FDA found that to be the case. And those are improper and
12 inadmissible expert opinions that are the product of their
13 affidavits alone.

14 Now, apart from the lack of legal support, there are a
15 number of fundamental problems with this noncompliance
16 argument. I will revisit them quickly, Your Honor.

17 The first is that it only gets out of the starting gate
18 by allowing their experts to independently re-evaluate St.
19 Jude Medical's conduct before the FDA, and opine on whether it
20 complied with what the FDA regulations required. Those sorts
21 of legal opinions, to begin with, are not proper bases for
22 expert testimony. But even more importantly, where what's at
23 issue is the legitimacy of the action taken by a regulatory
24 agency, the law doesn't invite courts or retained experts to
25 weigh in or opine on the decision-making de novo.

1 Proper respect for regulatory agencies, their
2 decision-making and their decisions themselves demands more
3 deference than that. And that's particularly true where we
4 have recognized experts who are making the evaluation as in
5 this case.

6 Second, the plaintiffs' noncompliance argument of
7 necessity and by design will involve the Court and the jury in
8 the most intrusive exercise possible. Inquiries into the
9 substance and the impact of the regulatory decision-making and
10 passing judgment on what the FDA approved and why. This is
11 precisely the sort of intrusion that principles of preemption
12 are intended to stop before it starts.

13 And although they profess otherwise, Your Honor,
14 plaintiffs' approach to noncompliance obviously puts them in a
15 position of enforcing the FDA regulations in court.

16 Plaintiffs contend they're not asking a court or jury to
17 invade the regulatory domain as a prerequisite to their causes
18 of action, but that's exactly what they're up to. Under their
19 approach to avoiding preemption, plaintiffs must litigate, and
20 a jury must find regulatory breaches to avoid the express
21 preemption clause. But this result, too, is prohibited by the
22 controlling law.

23 In *Buckman*, the Supreme Court rejected a theory that
24 would require a jury analysis of whether there was compliance
25 with the federal regulatory scheme, or violations of FDA

1 regulations. And it did so for reasons that apply in this
2 case. In *Buckman*, the court held that Congress left the
3 policing of the approval process to the FDA alone, because
4 that was a matter of federal, not state, concern. And the
5 plaintiffs' tort law claims which co-opted that for a court or
6 a jury conflicted with the exclusivity of the agency
7 regulation, and they were impliedly preempted.

8 In addition, in *Buckman*, the Supreme Court recognized
9 that the FDA's no prior right of action clause prohibited
10 private litigants from using the courts to enforce FDA
11 regulations. Only the federal government can do that.

12 And the courts reject private plaintiffs' efforts to use
13 authority lawsuits as a vehicle for enforcing the federal
14 standards. The reason for the bar is the same: To avoid
15 intrusions into the FDA's decision-making process and the
16 possible undermining of its regulatory role.

17 But plaintiffs say no, it's still okay. It's okay for a
18 jury to make these determinations in the context of a
19 preemption defense, and then as a precursor to bringing a tort
20 lawsuit.

21 But pleading fraud to avoid the exclusivity of FDA
22 regulation did not work in *Buckman*, and it shouldn't work
23 here. The agency interference that plaintiffs claims are
24 fraud or noncompliance would engender is just the sort of
25 interference with the FDA's regulatory function that the court

1 acted to stop in Buckman, and that Congress acted to stop by
2 statute.

3 It's the interference itself, Your Honor, not the label
4 on the cause of action that is prohibited by Congressional
5 direction and intent, irrespective of the conduct of which it
6 occurs.

7 In fact, it's hard to see, under plaintiffs' regimen,
8 what's left of FDA decision-making. As they put it, the first
9 thing the jury will have to hear is the story of the
10 regulatory process from start to finish, presumably with
11 witnesses from St. Jude and the FDA being called.

12 THE COURT: Let me ask you this, Mr. Martin: Did
13 the FDA, during the regulatory process, make a conclusive
14 determination that the valve with the Silzone coated cuff was
15 a medical device, as opposed to a medical device that had a
16 drug-related issue attached to it? Was there ever a
17 conclusive determination made there?

18 MR. MARTIN: The FDA did make that determination,
19 Your Honor. And it concluded, and there's a statement or
20 opinion given by Susan Albert, Doctor Susan Albert, on this.
21 And what she said was that this product was approved as a
22 medical device. It is a medical device, and it's not a drug.
23 Because the functioning of the device is not affected by the
24 Silzone cuff. The Silzone cuff is intended to resist
25 infection, not to deliver the silver into the bloodstream to

1 find infection. That's the fundamental distinction.

2 Your Honor, this issue that the Court just raised
3 underscores the problem that we have. The FDA approval
4 reflects that it was a drug -- I'm sorry, it was a device --
5 that's a Freudian slip -- and there it is. We have the record
6 of that. We have the FDA's reasoning on it.

7 The plaintiffs now want to get in behind that. And they
8 want to say, well, that's a fact issue. We need to have a
9 jury determine what they really meant. And once the jury
10 determines that, we're off to the races, and preemption may or
11 may not go by the board.

12 But the idea of putting the entire regulatory process on
13 trial and having it interpreted by expert witnesses to
14 determine the true regulatory story, to decide what the FDA
15 did, why it did it, is the precise problem that the case law
16 has confronted. And it's out of balance. You don't do it out
17 of respect for the decision-making. And you certainly don't
18 force the manufacturers to relitigate.

19 None of that squares with what Congress intended. You
20 can't put every step of the regulatory process on trial, have
21 it be reconstructed, second guessed with a jury trying to
22 decipher what the FDA did and why it did it.

23 The role of the FDA will in fact, in that context, be
24 usurped by juries in the 50 states. And ironically, the
25 preemption defense established by Congress in an effort to

1 achieve regulatory uniformity will become the vehicle by which
2 that uniformity is undone.

3 Perhaps even more fundamentally, nothing will be left at
4 that point of the Congressional policy choice that drove
5 enactment of the preemption clause in the first place.

6 Lawsuits, not the FDA, will become the consumer protection
7 device of choice, and the manufacturers indisputably will be
8 deterred in bringing life-sustaining medical devices to
9 market.

10 The losers will be -- and there's no irony here -- those
11 that Congress sought to benefit. The people who need medical
12 devices the most, and who need device innovation to support,
13 sustain, and maintain their lives. And while we recognize
14 that perhaps is a tough call and it dismisses the claims of
15 those who claim they are injured, the law provides no room for
16 litigation of the class-wide tort claims that these plaintiffs
17 have made.

18 Congress has left it to the FDA to police its own
19 regulatory process, and vested the FDA with considerable
20 enforcement powers to carry out that role. Those are powers
21 that the FDA does not hesitate to use. And plaintiffs'
22 invitation for the Court or a jury to supplant that regulatory
23 authority no matter what the basis in this case on these facts
24 goes too far.

25 Congress has acted. Preemption applies. And summary

1 judgment should be granted.

2 THE COURT: Thank you, Mr. Martin.

3 Let's take about a three-minute break before we start.

4 Mr. Angstreich, are you first?

5 MR. ANGSTREICH: Yes, I am, Your Honor.

6 THE COURT: Okay, let's take a three-minute break.

7 (A short recess was taken.)

8 THE COURT: Mr. Angstreich, you may proceed.

9 MR. ANGSTREICH: Thank you, Your Honor.

10 Your Honor, over a year ago, this motion was presented to
11 the Court. And along with the motion came what I have in my
12 hand here, which is the affidavit of Doctor Alan Flory,
13 together with, oh, I guess maybe four or five inches of paper,
14 to support a contention and a conclusion that St. Jude was
15 entitled to preemption on the basis of the fact that they
16 complied in all particulars with the FDA's rules and
17 regulations.

18 In addition to Doctor Flory opining on that compliance,
19 Diane Johnson opined on compliance with a guideline that
20 required for preemption to be applicable, but just to show the
21 extent to which St. Jude has gone to comply with regulations.

22 So one would assume that was done in order to meet the
23 summary judgment standard which requires that the defendant is
24 entitled to judgment, or any party is entitled to judgment as
25 a matter of law because there are no material issues of

1 genuine fact extant at the time, and therefore we complied in
2 all particulars, we're entitled to preemption.

3 Now we're told, oh, no, that was the standard. But when
4 the other side comes forward with evidence to show
5 noncompliance, not FDA failings and failures, but
6 manufacturers failings to comply, that no longer is the test,
7 because no jury and no judge is competent to discern these
8 factual disputes.

9 And it's very interesting, and Mr. Sigelman will deal
10 with it, the lengths to which St. Jude has gone to attack the
11 factual disputes, but then to tell Your Honor that we can't
12 have these factual disputes brought before you or a jury
13 because you're just not competent to resolve them. And
14 besides which it flies in the face of the statutory scheme for
15 preemption.

16 It's also very interesting, Your Honor, if in fact
17 deference to the decision of an administrative agency were
18 involved, we wouldn't need a statute for preemption. Because
19 under general law, where an agency has been given the field to
20 make decisions, courts defer, abstain or defer to the
21 decisions of the administrative agency. We don't need a
22 preemption statute to deal with deference.

23 But that's not what's at issue here. There have been no
24 FDA findings that you need to defer to, or the jury will need
25 to defer to.

1 In fact, one would assume that the FDA acted based upon
2 full knowledge. There is no evidence that's been presented by
3 St. Jude, despite the pounds and pounds of paper that they
4 provided the FDA, with all of the information that our experts
5 have provided to this Court, to deal with St. Jude's
6 noncompliance.

7 An agency is expected or presumed to act responsibly and
8 reasonably based upon the information that's been given to
9 them.

10 Interestingly enough, the Woods case was mentioned by Mr.
11 Martin, and he tried to distinguish it. He omitted a very
12 important distinction. In Woods, the company lied about the
13 results of a clinical study. They misrepresented the results.

14 Interestingly enough, one of the things that we have here
15 is a misrepresentation, almost I would go to the extent of
16 saying an outright lie by St. Jude about the very first sheep
17 study, and the death of the sheep we affectionately call Dolly
18 One. They told the FDA nothing about it. When they finally
19 came to disclose some information about it, they told them
20 that they didn't have any information about the cause of
21 death.

22 That's not a true statement. We provided you with the
23 testimony of St. Jude personnel dealing with that issue.

24 So we don't have any FDA finding.

25 Now, Mr. Martin made a statement when he said the FDA

1 found that this was a device and not a drug device. And he
2 told you about Doctor Albert. Interestingly enough, Your
3 Honor, that had nothing to do with the process, the approval
4 process. There was in fact no FDA finding on that issue.

5 The colloquy that occurred involving Doctor Albert
6 occurred after the PMA approval, and she talked in terms of
7 the issue of the therapeutic aspect of it. It's exhibit --
8 it's in appendix C, number 32. Doesn't talk about a drug
9 device, and there's no finding by the FDA to that effect.

10 But more importantly, Your Honor, that issue is still a
11 Court issue. As the case law that we cited to you applies,
12 and Mr. Coren, hopefully, with time, will address that issue
13 with you.

14 Let's look at the statute. The statute is very clear.
15 It's got to be a device. It's got to be a device at issue.
16 We know if in fact it's a drug device, it doesn't come under
17 360k. We know that there must be a "different from" or "in
18 addition to" requirement that's being placed upon the
19 defendant.

20 Well, no matter how St. Jude spins the spin here, we're
21 not asking for anything in addition to. We're saying you, St.
22 Jude, didn't comply. We're saying you, St. Jude, had duties
23 and obligations. Traditional case law that doesn't impose any
24 additional duties, and hopefully Mr. Jacobson will address
25 that when we have time to deal with that. And then it has to

1 relate to safety or effectiveness.

2 There's another major, major issue here, Your Honor. And
3 that is, did the FDA ever find the Silzone device effective?
4 The answer is categorically no. Absolutely, unequivocally,
5 they never -- you can put check marks in any box they want to
6 in their charts, the FDA never found the Silzone device to be
7 effective.

8 The attempt by St. Jude to point to it comes not in their
9 reply brief, but in Appendix B. And it's very interesting if
10 you go to Appendix B.

11 Specifically, you start with number three. It says, "St.
12 Jude Medical was not relying on its in vitro or lab bench
13 testing to establish efficacy and the FDA understood that."
14 The reason for that is that there was no St. Jude Medical in
15 vitro or lab bench testing to establish efficacy to find
16 endocarditis. And we all know that the only reason that this
17 product came out on the market was for the Silzone.

18 Then you go to number 13, Your Honor. It's on page
19 seven. And it says, "St. Jude Medical reported the relevant
20 and pertinent efficacy testing conducted pursuant to requisite
21 GLP's which constituted valid scientific evidence. This
22 testing, as well as additional in vitro and laboratory bench
23 testing done by Spire Corporation, established that Silzone is
24 effective in fighting the types of bacteria which cause
25 endocarditis."

1 We know from number three that St. Jude never did any in
2 vitro testing. And the deposition testimony of Doctor
3 Sioshansi and Mr. Bricault, which are part of our submission,
4 Your Honor, specifically Doctor Sioshansi at pages 177 through
5 79, 145, 233 and 234; Mr. Bricault at pages 56 through 58, 61
6 and 62, 66 and 67, make very clear, they had a Spi cuff.
7 That's where this thing started. And it was to be the
8 Silzone, although that's the trademark name, but it was the
9 same process, the Spi-Argent coating, and they are trying to
10 get it approved by the FDA as a 510k. And the FDA came back
11 and said it seems to us there are issues here that raise a new
12 drug application requirement. The thing fell apart.

13 But it was important to understand that that Spi cuff was
14 to be used with catheters. Had nothing to do with the heart.
15 Had nothing to do with endocarditis.

16 And the testimony of Doctor Sioshansi and Bricault make
17 it clear that they did not test for bacteria that become
18 involved in the endocarditis problem. And in fact, neither
19 the Spire Corporation nor St. Jude tested in vitro for that
20 bacteria.

21 So we know categorically that St. Jude cannot even come
22 within the statutory confines, because we have no effective
23 finding by the FDA.

24 Now, Your Honor, there are three mandates in order for
25 this preemption summary judgment to be granted:

1 Number one, there has to be compliance with the statute.

2 We've just looked at that.

3 Number two, we have to make certain that there's been
4 compliance with the regulatory mandates.

5 And number three, we have to make certain that this is
6 not a drug device, or a combination product.

7 The answer to any one of those three in favor of the
8 plaintiffs preclude preemption. So St. Jude must convince you
9 that they are entitled to summary judgment on all three of
10 those bases.

11 Now, it's important to recognize that we have provided
12 you with the expert affidavits. We've provided you with the
13 expert affidavits of Doctors Wilson, Healy, and Parisian, all
14 who go to the question of compliance by St. Jude Medical with
15 the FDA's regulations. We have not attempted to alter or
16 modify or add to the FDA's regulations. We've said here's the
17 universe of regulations. This is what they were required to
18 do. Our experts say they didn't comply.

19 It's interesting to look at the case law that St. Jude
20 wants to rely upon. Chmielewski recognized a noncompliance
21 exception to preemption.

22 Buckman has no place in this case. We have not brought
23 up an action for fraud on the FDA. And Buckman doesn't come
24 anywhere near the facts of this case. Buckman created the
25 concept of an implied preemption in the context of an implied

1 cause of action. And that's all that case deals with. We are
2 not seeking to bring that case before this Court. And you
3 can't find it in any of our moving papers.

4 Brooks recognized noncompliance. In fact, at page 798 of
5 the court's decision, they say Brooks presented no evidence
6 that Howmedica violated federal regulations or refused to add
7 warnings drafted by the FDA, changed FDA approved labels,
8 failed to meet regular reporting requirements, failed to
9 report a known hazard to the FDA, or failed to comply with
10 federal law in any other respects. That seems to suggest to
11 me that had the plaintiff in that case had those facts, we
12 would have had a different result.

13 In Martin, the cornerstone of the court's opinion was the
14 fact that Medtronic complied with the FDA's PMA process.

15 In Kemp, the plaintiff tried unsuccessfully to create a
16 factual dispute over what the actual PMA Supplement
17 specifications were, and were unable to do so. Now, the court
18 could have just as easily said there's no opportunity to do
19 that, because regulatory noncompliance is not a factor to be
20 considered.

21 In Mitchell, the court acknowledged authorities holding
22 that state claims that allege FDA requirements have not been
23 observed are not preempted.

24 THE COURT: Mr. Angstreich, what about this passage
25 that I see in quite a number of the cases that it is up to the

1 FDA to police its own process? That phrase seems to appear
2 again and again in the cases. Why wouldn't that extend to
3 noncompliance arguments as well?

4 MR. ANGSTREICH: Your Honor, the problem that exists
5 here is that the FDA, even to this day, is unaware of the
6 noncompliance, the full extent of the noncompliance from St.
7 Jude Medical. How would they then be policing it?

8 We go to the question that Your Honor asked of Mr.
9 Martin. And that is, did the FDA not find this product to be
10 defective? Did it not find this product to be adulterated and
11 misbranded?

12 And the fact of the matter is that it did. March 22,
13 2000, to Terry Shepherd from the Department of Health and
14 Human Services. "Mr. Shepherd is advised we have reviewed
15 your action and conclude that it meets the formal definition
16 of a recall. This is significant, as your action is an
17 alternative to a Food and Drug Administration legal action to
18 remove the defective products from the market."

19 We also have the internal FDA memorandum from March 20,
20 2000, which says, "We are classifying the firm's action as a
21 voluntary recall. We consider the devices to be adulterated
22 and misbranded because there is a statistically significant
23 higher rate of paravalvular leaks with the Silzone ion-coated
24 sewing cuffs leading to valve explants."

25 I think those are findings. They found adulterated,

1 misbranded. And yes, if St. Jude hadn't done a voluntary
2 recall, they would have pulled it off as a defective product.

3 Now, there is no speculation here as to what the FDA
4 would have done, because Doctor Flory admits that they cannot
5 remarket this product. He has testified, at page 258 of his
6 deposition, that if they want to go and remarket the product,
7 they will have to submit a new PMA Supplement to establish the
8 safety and effectiveness of the Silzone coated valve. That's
9 a far cry from a product that has been put on the shelf for a
10 little while, while the company decides that it might want to
11 remarket it.

12 So we do have this entire picture of a company that took,
13 that actually was a preemptive strike by the company to
14 prevent the FDA from doing just what we all know the FDA would
15 have done based upon the documentation that we see, as well as
16 acknowledged by Doctor Flory that they can't remarket this.

17 Now, exhibit B, or Appendix B to the reply brief identify
18 22 material issues of fact as it relates to regulatory
19 noncompliance by St. Jude, which they tell you that they had
20 to address, but it's important they really didn't need to,
21 because it's not relevant. You're not supposed to be deciding
22 this issue.

23 What is particularly disturbing to us, Your Honor, it
24 goes to one of the critical questions about the mislabeling
25 and false marketing of the product which Mr. Jacobson will

1 address. But it's on page nine, number 15. We have provided
2 to Your Honor letters, documents, deposition testimony of
3 admissions of employees taken by us in this case to establish
4 that they marketed this product in violation of the
5 conditional approval they got.

6 And what have they provided to you in opposition to it?
7 Deposition testimony of Burnett, not taken in this case, not
8 taken with the MDL present, to allegedly support a contention
9 that they didn't do what the other witnesses we offered have
10 provided to you.

11 That deposition testimony cannot be used on a motion for
12 summary judgment. It's hearsay. It wasn't taken in this
13 case. And we weren't present, having an opportunity to
14 address it. So you can't even consider that.

15 The only thing that we do have in the record is clear
16 documented evidence of violation. And we acknowledge that Mr.
17 Hosek, as well as Mr. Latvick, understood that a violation of
18 the conditional approval jeopardized the approval itself.

19 So if in fact the approval could be placed in jeopardy,
20 we now know that by showing the Court all of the facts that go
21 to this failure to comply, we are entitled now to have the
22 Court find that there has been a violation of the approval.

23 Very simple, Your Honor. The statute is not applicable
24 because there's no effective determination by the FDA. The
25 statute is not applicable because this is a combination

1 product. And that answers the other question, but it is in
2 fact a combination product.

3 And importantly, Your Honor, regulatory noncompliance,
4 that is noncompliance with the actual regulations, is an issue
5 that is within the jurisdiction of this Court to decide.

6 There is no basis to do anything other than that. Because in
7 reality, although Mr. Martin stepped back away from his pitch,
8 it would really be an issue of immunity. There should have
9 been a motion to dismiss this case initially.

10 And the last point, Your Honor, that I do think is
11 important to note, a year ago when this motion was filed, we
12 asked for discovery. They opposed it. They said to Your
13 Honor, there's no need for discovery here, because it's a
14 matter of law.

15 Your Honor said no, there are factual issues here. So we
16 went and we presented to you what we believe to be material
17 issues of fact at every level that entitle us to have this
18 motion defeated.

19 Mr. Jacobson will address the statutory aspects, Your
20 Honor. Thank you.

21 THE COURT: Thank you, Mr. Angstreich.

22 Mr. Jacobson.

23 MR. JACOBSON: Thank you, Your Honor.

24 I'm going to focus primarily on the issues of the
25 noncompliance on the failure to warn portion of the case,

1 because I think that that is typical and illustrative of the
2 entire case.

3 You've seen Section 360k. And you've seen in our brief
4 we talk about the parallel requirements, where state law
5 imposes requirements through a tort action that aren't
6 parallel, aren't in addition to those imposed by federal
7 regulations, there's no preemption. And I would rely on that
8 portion of our brief pages three through six. And then
9 there's count by count discussion at pages 13 through 19.

10 On the label requirement, the labeling violations are
11 important here, both because they show that we are simply to
12 the extent on these claims saying that you violated common
13 law, at the same time you violated the federal regulation,
14 we're not saying federal regulation creates a cause of action,
15 but also shows there in fact is no preemption at all. Because
16 the approval was invalidated.

17 The PMA Supplement approval letter is in our appendix to
18 our opposition to their motion at tab 60. It's a several-page
19 letter with a standard attachment portion and an initial part.
20 If you go to page two of the approval letter at tab 60, you'll
21 see at the top of the page it sets out the labeling
22 requirements. The labeling requirements. And then the
23 highlighted paragraph there below states that failure to
24 comply with the conditions of approval as attached invalidates
25 this approval order. Invalidates. Commercial distribution of

1 a device that is not in compliance with these conditions is a
2 violation of the act.

3 The defendants in the first position state the FDA never
4 took an action to invalidate the approval. And since they
5 didn't take an action, the approval is still in place. But
6 it's clear from this language, FDA doesn't have to take an
7 action. The failure to comply invalidates the approval, and
8 it does so as a matter of law without any need for any action
9 by the FDA. You comply with the regulation, you stay within
10 the regulation and requirements set out in the approval
11 letter, and you maintain your preemption -- protection to the
12 extent it applies. You step outside the lines, you violate
13 the approval letter, you have no protection at all. You're
14 going naked for liability purposes.

15 Here, the labeling violations are extensive. They are
16 discussed in the depositions of several of the defendants.
17 They are discussed in our expert's affidavit, Doctor Parisian,
18 at paragraph 71 details some of them.

19 I would like -- they say, okay, nice in theory. Nice in
20 theory to say there was violations, but you haven't given us
21 any evidence that they were violating these labeling
22 restrictions. Well, what is our evidence?

23 One piece of evidence is the affidavit of Doctor Graham.
24 That appears in our filings at tab 21. Doctor Graham was the
25 surgeon who planted the Silzone valve in Bonnie Sliger, the

1 individual I represent in Class II. Doctor Graham says the
2 St. Jude salesman told him, on the second page, paragraph
3 seven, told him that the Silzone valve fought heart valve
4 infections. That was the only reason why he chose it over the
5 less expensive Master Series valve. So there's a doctor
6 implanting and because of a statement that violates the
7 labeling requirements.

8 The testimony of Timothy Chase, which appears in our
9 filings at tab seven. And I'll give you page sites. But if
10 you look at deposition pages 224 through 237, 250 through 254,
11 265 through 269, and 277 to 279, Mr. Chase goes through a
12 series of letters that were sent by salesmen to individual
13 doctors, to a hospital. He goes through, and after each one
14 he agrees each of these letters violates the restrictions
15 imposed by the FDA, in most cases in three different
16 particulars. Some of them only violates two restrictions.
17 But all these letters going to doctors, and some being
18 approved of form letters to be used by salesmen generally that
19 these letters violate the FDA restrictions in the approval
20 letter which we discussed earlier. So we have pretty
21 widespread violations of these labeling restrictions.

22 Maggie Walner, in her deposition at pages 136 to 141,
23 discusses these salesmen letters and talks about the process
24 by which they're reviewed at the corporation. And these are
25 labeling, and they come to the corporation, and before these

1 letters go out they have to be reviewed.

2 So we have labeling restrictions. As a result, this
3 approval is invalid. There is no approval. And without
4 approval, there is no preemption, end of story, end of game.

5 Now, we talked a little bit, and defendants talked about
6 respecting Congress's choice. This is the issue of implied
7 preemption. I think it is pretty clear from the case law that
8 the fact there is an express preemption is pretty significant
9 when you look at implied preemption. Preemption is an attempt
10 to take Congress's intent and apply it. You should only have
11 preemption when Congress intends preemption. At least for the
12 most part.

13 Here you have Congress said a specific statute, 360k,
14 which says in very particular ways when you have preemption,
15 and suggests that St. Jude attempts to get preemption with
16 360, but loses it because they don't follow the statute, they
17 violate the regulations but still claim preemption under an
18 implied theory cuts right against Congress's intent and should
19 not be done.

20 At this point, having four minutes left, I would like to
21 send those over to the next person. Mr. Sigelman will now
22 show how St. Jude violated regulations and why there are
23 additional grounds for no preemption in this case.

24 THE COURT: Thank you, Mr. Jacobson.

25 Mr. Sigelman.

1 MR. SIGELMAN: Before I do this, I want to discuss
2 very briefly how low our burden is today. There are, as Mr.
3 Angstreich indicated, really three predominant issues here.

4 One is, was there at least a genuine issue of fact as to
5 whether FDA made an efficacy determination for the Silzone?

6 Two: Was this a combination drug device?

7 And three: Did the defendant comply?

8 All we have to do, Your Honor, is create a single fact
9 question that's material with respect to any one of those
10 issues. And I would submit that summary judgment must be
11 denied as a matter of law.

12 Interestingly, the defendant has had almost 60 pages of
13 briefing compared to our 35. And in those 60 pages of
14 briefing, we've had exactly three sentences on an issue for
15 which we had countless pages in declarations and five pages of
16 briefing in our brief on the drug device issue.

17 On the issue of whether the FDA actually said that the
18 Silzone, which is the subject of the PMA Supplement, was
19 effective, there was absolutely no argument that I could see,
20 it wasn't even mentioned in their briefing, I would submit on
21 those bases alone summary judgment must be denied.

22 Now, there is the issue of compliance.

23 Could you first of all go to number 27, PR 27?

24 Interestingly, the defendant in its brief admitted, Your
25 Honor, that cases like Lohr and Brooks do state that the MDA's

1 express preemption clause is not a barrier to noncompliance
2 claims.

3 Can we go to the next one, 28?

4 And in the Ramsey County Court, Judge Gearin, in a case
5 involving St. Jude and the Silzone valve, recently denied
6 defendant's motion for summary judgment. In their papers,
7 they didn't really present the main reason that she did that.
8 And she did it primarily, as the next will indicate, because
9 many of the state law causes of action in this lawsuit are
10 based on state law duties that parallel federal requirements
11 rather than add to or conflict with them, as the next PR will
12 indicate.

13 PR 2, please.

14 About one year ago, Your Honor, the defendant came
15 forward with its motion for summary judgment. And they told
16 Your Honor that, "It is incontrovertible that St. Jude Medical
17 at all times complied with FDA's requirements." And they did
18 so relying on Doctor Flory's affidavit at paragraphs 19 and
19 66, which made assertions to that general effect.

20 But now what does St. Jude say? It's no longer
21 incontrovertible, Your Honor. In fact, to the contrary, it's
22 so controvertible that we can't permit a jury to even consider
23 the question.

24 They started out saying they're entitled to judgment as a
25 matter of law because there was no genuine issue of material

1 fact. And now they're conceding that there are innumerable
2 such facts. At least facts in dispute.

3 In fact, Your Honor, this is what the defendant has just
4 submitted. There are no questions of fact, Your Honor. I can
5 barely lift this. Yet we have several inches of
6 documentation. We just want to deny this, but it's not
7 material. Obviously, something is awry here, Your Honor.

8 In fact, I would submit that what's happened is the
9 defendant has actually turned the standard for summary
10 judgment completely on its head. Because now they say they're
11 entitled to summary judgment because there are disputed facts.
12 It's heads I win, tails you lose. Heads I win when there are
13 no genuine questions of material fact, and tails you lose when
14 there are. Obviously, Your Honor, both can't be the
15 situation.

16 Now, Mr. Martin came up here and talked about how
17 noncompliance, according to the case law, can only be
18 manifested when there is a product that's been marketed that
19 is not the approved product. And I want to ask the defendant
20 to cite a single case that stands for that proposition that
21 says the only kind of noncompliance that can defeat preemption
22 is noncompliance where someone was marketing a product not
23 approved by the FDA. Because the cases don't say that.

24 The language that the Brooks case had in it that Mr.
25 Angstreich read to you didn't say that. It said, for example,

1 that Brooks provided no evidence that they violated federal
2 regulations. That they refused to add warnings drafted by the
3 FDA. That they failed to meet regular reporting requirements,
4 or failed to report a known hazard to the FDA. Did they
5 articulate that standard? I would submit they did not. And
6 there isn't a single case that does.

7 Now, let's go to PR 14. We're going to start talking
8 about some of the noncompliance.

9 First of all, this defendant, we would submit, failed to
10 comply with the premarket disclosure requirements applicable
11 to it. And here are some examples.

12 And all we have to present here, Your Honor, is a fact
13 question that's material. We do not have to prove right now
14 to a preponderance of the evidence that in fact it violated
15 federal law.

16 The next one, P 40.

17 This is a pathology report for Dolly One, KTMV-2, the
18 sheep that died in that study. You note there was a clot that
19 actually obstructed the leaflet, that there was a paravalvular
20 dehiscence, where the valve comes off the annulus of the
21 heart. It created a leak that probably killed this animal.

22 And we have a clot possibly killed the animal. The clot
23 obviously stopping the leaflet. And number five, the black
24 particulate material, according to witnesses, was silver.
25 Silver that leached. Oh, we've heard silver doesn't leach.

1 That's not what this particular animal showed.

2 And none of that was reported to the FDA. The FDA did
3 not get this report. Ultimately, they got a statement
4 belatedly from St. Jude an animal had died from causes
5 unknown. Our experts submit, especially Doctor Parisian, that
6 violated clearly the PMA disclosure requirements.

7 Could we go on to the next one?

8 And here's a picture of the heart. See the spatula
9 there? It's pointing at that area of dehiscence. This was a
10 photograph that wasn't submitted to the FDA. Photographs
11 requested by the FDA. Had they seen this and seen the
12 attention that St. Jude obviously put on that particular
13 dehiscence, that might have enlightened them to a problem with
14 this particular animal.

15 Can we go to PR 15? Photograph N.

16 This summarizes some of the withholding that was involved
17 in this particular animal. We're right out of the gate, Your
18 Honor. The first animal study ever done of the Silzone
19 product when used to coat a heart valve, and already
20 one-fifth, or 20 percent of the data were withheld.

21 Let's go on to P 45.

22 Your Honor, this is a document that was generated in
23 August of 1996. And the document expresses concern on the
24 part of Mr. Holmberg of St. Jude. They had two large
25 concerns. One was leaching. He's stating we are seeing a

1 significant amount of silver migration in the animal study.
2 Obviously, this is right after what we found, for example,
3 with KTMV-2. And these issues are likely to slow down or stop
4 this if not addressed properly.

5 Going on to P 57, page 111. This is from the notebook of
6 a scientist at St. Jude, Matthew Ogle. And the significant
7 thing in this particular entry is looking at what is now being
8 pointed to there. And you will see that this was a study
9 involving six animals with Silzone valves and three animals
10 without Silzone valves that had obviously heart valves. And
11 what was being measured was the aggregate amount of silver
12 lost during a mere ten weeks. And you had an average, if you
13 look at it in terms of percent retained of a 22 percent loss,
14 which is probably a staggering amount, but you had one animal
15 that lost almost one-half of the silver in ten weeks.

16 Question: Was this reported to the FDA? Answer: No.

17 We pointed this out in our papers. This is a piece of
18 data, for example, that was completely ignored even in the
19 appendices of the defendant. According to our experts, a
20 patent violation of the premarket disclosure requirements of
21 the Food Drug and Cosmetic Act in implementing regulations.

22 Let's go on to PR 16.

23 This is just a summary, Your Honor, of the many ways in
24 which the defendant failed to comply with requirements that
25 were applicable after the PMA Supplement was submitted to the

1 FDA but before the FDA approved it. Update requirements.
2 These are some of the kinds of data. This is again in our
3 papers.

4 Go on to PR 17.

5 Here are some areas where our experts have said,
6 especially Doctor Parisian, that the defendant failed to
7 comply with regulations and statutory requirements prohibiting
8 untrue statements of material fact made to the FDA. And the
9 next slide is more such facts that were not submitted to the
10 FDA in violation of law and regulation.

11 Let's go on to P 105.022.

12 This is part of the PMA Supplement. If you notice down
13 toward the bottom, they're talking about that study where we
14 had the KTMV-2 animal die. And they're telling the FDA that
15 that study of a mere five animals showed excellent healing
16 response with Silzone, and superior pannus organization. And
17 obviously, that's totally inconsistent with KTMV-2.

18 But moreover, one of our experts, Doctor Wilson, has
19 actually looked at the slides. He's a cardiovascular
20 pathologist, and he emphatically concludes those are false
21 statements. The pannus, for example, was not how it was
22 represented, pannus being the surface tissue growth after
23 thrombus, disappears in the healing process. Even with
24 respect to the testimony as to KTMV-2 in that study. Again,
25 we've created a fact question that's material.

1 Let's go to P 105.008.

2 This is part of the PMA Supplement. And here, St. Jude
3 is telling the FDA that the evidence they have suggests that
4 direct contact of the microorganism -- that would be the
5 bacteria or the fungi that are trying to be resistant -- with
6 the silver surface is necessary for inhibition. In other
7 words, there has to be direct and immediate contact.

8 That's what consistently they told the FDA. But the
9 records show something different.

10 P 42.

11 This is a memorandum from a scientist at St. Jude. In it
12 she says we do believe that oxidized silver compounds, that
13 the compounds that actually move off of the cuff after
14 oxidation, they're not necessarily in direct contact with
15 bacteria that come onto the cuff while they're being
16 stationary, that these compounds are responsible for the
17 majority of the antimicrobial activity they thought was being
18 exerted by the Silzone.

19 I would like now to have played for you a clip from the
20 deposition of Mr. Runquist, the FDA liaison for St. Jude,
21 where he testifies that he never informed the FDA that St.
22 Jude believed that the release of compounds was as she said in
23 that memo:

24 Q. What do you mean by zone of inhibition?

25 A. Well, the zone of inhibition, again, this goes back to

1 the migration or the leaching issue. What that means is, if
2 the material is placed in the Petri dish of, of organisms,
3 there's very little zone that is set by, by the material. In
4 other words, it doesn't leach out torque and kill organisms as
5 it moves through.

6 Q. All right. It needs direct contact. It doesn't have a
7 zone where it will kill bacterial microorganisms?

8 A. That's correct.

9 Q. Doesn't leach; right? Is that what you were telling the
10 FDA, that this is more evidence that it doesn't leach?

11 A. Or that it has minimal leaching.

12 Q. All right. It doesn't achieve its effectiveness by
13 leaching.

14 A. That's correct.

15 Q. Is that what you're telling the FDA?

16 A. That's correct.

17 Q. And you were assuring the FDA of this. Correct?

18 A. At this, at this point in time, this was the best of our
19 knowledge.

20 Q. And was there any regulatory significance attached to the
21 fact that the silver coating does not set a zone of
22 inhibition?

23 A. There was, actually. The mode of action with, with
24 Silzone, again, the organism has to come in direct contact
25 with the material. And by being minimally leaching, it

1 doesn't spread out into -- it gets down to the drug device

2 distinction, so --

3 Q. Please explain what you mean.

4 A. Because the metallic coating does not leach out or has
5 minimal leaching, that basically distinguishes it from a drug.

6 Q. All right. So if had more than minimal leaching, then it
7 might be a drug?

8 A. It has a potential to.

9 Q. So part of what you were doing was trying to assure FDA
10 that this wasn't a drug?

11 A. Well, what we were trying to assure FDA of was the fact
12 that the silver ions were not massively leaching into
13 surrounding tissue or into the bloodstream.

14 MR. SIGELMAN: Could you go to P 1 now.

15 This is an excerpt from the deposition of Doctor Flory,
16 where he affirms if St. Jude failed to comply with the
17 conditions of approval, the continued basis of approval of the
18 valve was invalidated.

19 Then he was asked, "And so you would have to comply with
20 these conditions in order to legally continue to have an
21 approveable valve?"

22 And he said yes. Nothing about whether FDA had to take
23 action or anything of that sort. You wouldn't have a legally
24 approveable valve.

25 And if you go to PR 20 and then 21.

1 We list the various violations that were manifest of the
2 conditions of approval by St. Jude of this valve.

3 Next one, PR 21.

4 And here are some more.

5 So again, we had numerous areas where they violated the
6 conditions of approval.

7 We heard from Mr. Martin about the Woods case.

8 One additional thing I would like to say, is that this
9 defendant has insisted on a confidentiality order in this
10 case. We're not at liberty to tell the FDA about Dolly One
11 and what really happened in Dolly One. We're not at liberty
12 to talk about all the positive findings of hemolysis or
13 destruction of red blood cells in numerous tests that weren't
14 reported to the FDA. We're not at liberty to tell the FDA
15 what the sales representatives really did in the field with
16 respect to promoting this product. All of that's under
17 confidentiality. So how would the FDA take action if they
18 don't know about the violations?

19 Let's move to PR 13.

20 Here are some statements, mostly admissions, if you
21 actually read the testimony. Mr. Guzik of St. Jude just
22 openly admitted all of these things in his deposition about
23 the increased risk or risks of this valve as observed in the
24 field based on what was coming into St. Jude.

25 Go to thirteen two to give another flavor for some of the

1 things that he admitted.

2 In fact, you may have read some things about Mr.
3 Butchart, and how Mr. Butchart was really way out there with
4 his reports of thromboembolic events, strokes, and similar
5 kinds of events.

6 We got an admission from Mr. Guzik after he was seeing
7 all the evidence that Mr. Butchart was not an outlier. He was
8 basically coming within the kinds of data that had been
9 generated.

10 Let's go now to number three.

11 Now, in light of all this, we'll see an ad which says
12 with over 30,000 implants, the St. Jude Silzone coating helps
13 them to continue our tradition of excellent clinical
14 performance.

15 Mr. Guzik was asked about that. He was asked, "It's not
16 continuing that tradition of excellent clinical performance;
17 correct?" And he volunteered, "Right, it's questionable."
18 And that was after all of these revelations about what they
19 were getting from the field.

20 So what do we have here then? We would have clear
21 misbranding, false and misleading statements about the safety
22 of the valve in an advertisement. This is a restricted valve,
23 which means that it can only be used as per prescription. And
24 under the regulations, misbranding of a restricted valve is a
25 violation of the particular condition of approval of this

1 valve.

2 That's another way in which you could come around and see
3 how again they violated the conditions of approval of the
4 valve.

5 Let's go to PR 33.

6 This is a colloquy, as it were, between me and Doctor
7 Flory about a comparison between the Silzone heart valve as
8 compared with the nonSilzone coated heart valve, and the
9 Silzone coated annuloplasty ring that St. Jude manufactured
10 versus the nonSilzone coated ring.

11 Basically what he was being asked is the difference
12 between the Silzone coated ring and the nonSilzone coated ring
13 essentially the same as between the Silzone coated heart valve
14 and the nonSilzone coated heart valve. Essentially, he said
15 yes. He said the departure wouldn't be particularly greater
16 between the two products, because the difference between those
17 two products, whether you're talking about the ring or you're
18 talking about the heart valve, is simply the Silzone.

19 Now, why am I bringing all this up? Your Honor asked
20 about the PMA Supplement process and whether it was more or
21 less rigorous.

22 Now, remember, why did we have this PMA Supplement? We
23 had it for one reason: The addition of silver. That's the
24 only reason. Otherwise, the Master Series valves that was
25 used with the Silzone valve was identical to the Master Series

1 valve without Silzone. What the FDA said was when you have a
2 PMA Supplement -- this is in our pages -- this has to be shown
3 to be effective as well as safe.

4 And again, I would like to challenge the defense on one
5 point. They said, you know, we've had all this case law, and
6 they haven't distinguished between the requirements for PMA
7 Supplement and full PMA's. I would like them to cite a case
8 where they were dealing with a PMA Supplement for a device in
9 a preemption case, a reported case, where there was no
10 determination by the FDA that the thing for which the
11 supplement was submitted to the FDA had not been shown to be
12 effective. Because there isn't such a case. You have to look
13 at the facts of this case. This is a distinctive case. And
14 it's a case for which there is no precedent.

15 Now, if you look lastly at this particular slide, and
16 then I'm going to turn it over to Mr. Coren.

17 What you have here on the top is the Silzone coated ring,
18 minus the conventional ring, equals Silzone. And what was the
19 approval method? The 510(k) for just the Silzone. We heard
20 the 510(k) is less rigorous. We heard that Lohr says 510(k)
21 doesn't even cover preemption ever.

22 Okay, now, excuse me, I misspoke. Let me start over.

23 Below are the two rings. It's 510(k) for those. Okay,
24 that's the difference. And everything I said before applies.

25 At the top, you have the heart valve, the Silzone coated

1 heart valve less the conventional heart valve. Again, the
2 same difference is Silzone.

3 And it just so happens that you have to have a PMA
4 Supplement, because you started with a PMA. That's the only
5 reason. But the difference is one in the same.

6 So we have this incredibly anomalous situation where we
7 have the Silzone being subjected to a less rigorous process
8 for clearance, the 510k, and the supplemental process which
9 they claim is so rigorous. They're elevating form over
10 substance, Your Honor. It's a distinction without a
11 difference.

12 This wasn't that rigorous. They haven't told us how long
13 the FDA spent reviewing the PMA, full PMA for the underlying
14 valve versus the PMA Supplement here.

15 And it also goes to another interesting point, and that
16 is that the FDA, when they were talking about Silzone-coated
17 annuloplasty rings, said that the difference which, is the
18 Silzone difference, is one that doesn't make the
19 Silzone-coated annuloplasty ring substantially different from
20 the nonSilzone-coated ring. In other words, those two
21 products are substantially equivalent because this Silzone
22 isn't a substantial difference.

23 Okay, if that's the case, then why suddenly is there such
24 a substantial difference when we get to the heart valve? This
25 underscores the point we were trying to make in our papers,

1 Your Honor, which is for that all intents and purposes, the
2 Silzone-coated heart valve was deemed to be substantially
3 equivalent to the nonSilzone-coated Master Series heart valve.

4 With that, I'm going to turn it over to Mr. Coren.

5 THE COURT: Okay, thank you.

6 MR. COREN: Your Honor, could I address you from
7 here?

8 THE COURT: That's fine.

9 MR. COREN: Thank you. I appreciate that.

10 THE COURT: As long as you speak loud enough.

11 MR. COREN: I'll try, with my skills in Philadelphia
12 with a subway running under it.

13 Your Honor, I want to stay on this last exhibit, this PR
14 4 slide that we've presented to you. Our position, and Your
15 Honor addressed it with Mr. Martin, is that this is a
16 combination product, Your Honor.

17 And that is that you're taking the Silzone -- I'm going
18 to go reverse on the equation. You're taking the Silzone,
19 which is a silver that's coating on the conventional cup
20 valve, and that gives you the Silzone cuffed valve. So the
21 only difference was the Silzone.

22 And as part of the company's strategy to get this on the
23 market -- because as Mr. Angstreich earlier told you, Spire
24 tried to get a 510(k) approved, and the FDA rejected the
25 510(k) because they saw the silver as being a drug. And they

1 wanted a clinical study. And St. Jude didn't want to do
2 clinical studies before putting these products on the market.
3 They rejected that strategy when they looked at a different
4 anti-bacterial coating. And what Kathleen Tweden, in her
5 deposition, testified to was they didn't want to go to the
6 expense.

7 Doctor Healy, Doctor Parisian have the references to
8 here, so I'm not going to put them up on the screen or read
9 them to Your Honor. They're embodied in Doctor Healy and
10 Doctor Parisian's affidavits. But the concept here is that if
11 this product leaches, that the silver is coming off, the FDA
12 may look at it as a drug.

13 And one of the documents that we had up, Your Honor, one
14 of the strategies that they used, according to the
15 Billingsworth document, was that they emphasized its contact
16 inhibition. But as Mr. Sigelman showed Your Honor, when we
17 looked at that lab notebook, 45 percent, a bolus of silver was
18 coming off of the cuff.

19 This was, according to our experts, and looking at the
20 record, Doctor Healy, a bioengineer; Doctor Parisian, a
21 pathologist and Medical Review Officer, said, okay, let's look
22 at the statute. We now understand how this product worked.
23 It emits the silver ions.

24 How do the silver ions get off of the product? It gets
25 off of the product by having the fluids of the body react to

1 the silver. That's a chemical reaction. That's what Doctor
2 Healy says. That's what doctor Parisian says.

3 Excuse me, Your Honor. I want to bring up a particular
4 document.

5 The issue here is that how does the FDA treat these
6 combination products.

7 And how it treats these combination products is, first of
8 all, Congress says they're different. They recognize that.

9 And they created a procedure. And part of the procedure, they
10 told the FDA, come up with a way to administratively handle
11 the combination products.

12 And this is what they did. They came up with this
13 particular agreement. And in the agreement, they actually
14 have examples.

15 See if I can enlarge this so Your Honor can read it.

16 These are examples. Two, devices incorporating a drug
17 component with the combination product having the primary
18 intended purposes of fulfilling a device function.

19 And one of them are, as Your Honor will see, one of them
20 is a percutaneous cuff, coated with an antimicrobial agent.

21 And what is the status that FDA assigned such things?
22 Combination product.

23 This is the regulations. This isn't us coming up with
24 it. This is how the FDA, through the administrative review
25 process, giving notice to everyone, taking in all of the

1 comments and using the regulatory authority, it's a
2 combination product. Okay.

3 But we have to go back and say, okay, well, we're here on
4 360k. What we emphasize to Your Honor is that it says it's a
5 device. Not a combination product.

6 Mr. Martin got up here earlier today, Your Honor, and
7 told you that the FDA ruled that this was a device. They did
8 not. You could search the record high, you could search the
9 record low. You will find no administrative finding.

10 So what do they cite Your Honor to? They cite Your Honor
11 to their own statements in their PMA, where they're drawing
12 the conclusion that this is a device because it doesn't act
13 with metabolism within the body. That is an incorrect
14 statement of what the regulations require.

15 The case turns on whether or not this is a device. This
16 is the definition of a device. What distinguishes a device
17 from a drug is not the numbers one, two, and three. Because
18 those are the same in the definition of a drug. It's the
19 exclusions.

20 One: Does it -- does it achieve its primary intended
21 purposes through chemical action? Well, the testimony that
22 you heard, Mr. Runquist and through the experts, is that it
23 does achieve its action through a chemical reaction.
24 Ionization of the silver.

25 Secondly: It's not dependent upon being metabolized.

1 Doctor Healy in his affidavit lays to rest any question that
2 this drug acts through metabolism. It acts through metabolism
3 by the fact that the silver is not radioactive. It doesn't
4 emit on itself. You have to have fluids from the body and the
5 serum in the body act on it. That's metabolism.

6 Doctor Healy gives you a classic definition of metabolism
7 from the World Health Organization, because believe it or not,
8 the FDA, the Food and Drug Cosmetic Act, nor the regulations
9 define metabolism.

10 So he goes to an accepted medical authority, the World
11 Health Organization, and he applies that definition.

12 In that definition, he finds that, yes (1) it changes the
13 silver. So you're having a metabolic process. And (2), how
14 does the silver act upon the target cells? Be that target the
15 benign fiberglass, or the bacterial fungi which you're trying
16 to kill, it does that in two ways, both of which Doctor Healy
17 explains are metabolic. One, it enters in and binds with the
18 DNA; and number two, it denatures.

19 So the fact -- there's a fact question raised by our
20 experts, Your Honor, of whether this was a drug. They
21 maintain it is.

22 Now, the law. In the Searle cases -- because this is not
23 the first time this issue has presented itself to the courts,
24 including this Court in the Kociemba case -- the Searle cases,
25 where they put, took an IUV and put a copper wire in it; and

1 in the cases, and the one that we're going to refer Your Honor
2 to in particular is Tarallo.

3 The Tarallo case held that, first of all, we don't care,
4 this is the court saying we don't care what the FDA is saying.
5 This is a job for the court to determine whether or not a
6 device with a drug or a device with a heavy metal coating --
7 silver and copper are both heavy metals -- is a combination
8 product or a drug.

9 And in that case, Tarallo, they had evidence strikingly
10 similar to here. The Copper 7 worked. Its claimed benefits
11 was it emitted copper ions in the uterus. What's the claimed
12 benefit at issue? The silver emits silver ions in or around
13 the heart tissue. Strikingly similar. And in that case,
14 Tarallo, the court rejected a similar preemption motion
15 seeking summary judgment, saying that there was an outstanding
16 material question of fact.

17 This case is on all four squares with Tarallo. And
18 Tarallo was not alone. The Kociemba here, several other
19 Copper 7 cases held that a combination product doesn't get 360
20 preemption.

21 Your Honor, we filed --

22 MR. KOHN: Your Honor, he's significantly over his
23 hour. We had reserved at least ten minutes to reply. He's
24 into our time at this point.

25 THE COURT: You can wrap up, Mr. Coren.

1 MR. COREN: I don't mean to go on.

2 Your Honor, in our reply, we set a number of issues up.

3 And it is quite clear that the defendants in the reply have

4 not responded to these issues. Their sole claim is the FDA

5 found it was a drug -- excuse me, a device. We claim that the

6 record doesn't hold that, and the factual evidence shows

7 there's material questions of fact. Numerous, numerous issues

8 that we set forth in tabular form, Your Honor, went

9 unanswered. And that is telling.

10 Thank you.

11 THE COURT: Thank you, Mr. Coren.

12 Mr. Martin.

13 MR. MARTIN: Your Honor, I will move with deliberate

14 speed here, given the time constraints. Let me just pick up

15 on this drug versus device issue quickly and address first off

16 these Copper 7 cases.

17 The Court asked me if there was anything in the record

18 that indicated that the FDA considered a heart valve to be a

19 device. I answered the question that there was evidence in

20 the record of that. And the statement of Susan Albert and her

21 analysis of the drug versus device issue is in the record, and

22 it says what I represented.

23 The valve is a device. It's a device because the silver

24 is not necessary for the heart valve to function. The valve

25 does not fit the definition of a drug because the silver is

1 just there to resist bacteria. It is not delivered
2 systematically to fight infection.

3 And finally, the Copper 7 cases most certainly don't
4 change either one of those conclusions. You'll see that the
5 issue of fact arose in the Copper 7 cases because of a
6 historical clarification issue that emanated from the FDA.
7 Not from expert declarations after the fact.

8 And finally, it was clear that the copper was delivered
9 as part of the functioning of the product, and its essential
10 essence as a birth control device that is different than the
11 heart valve here.

12 Your Honor, if one thing has been proven in this argument
13 this morning, and if it was a matter of debate before, it
14 certainly isn't now, this Court and the jury will be expected
15 to usurp the role of the FDA. We will be engaged in jury
16 litigation of purported fraud on the FDA. And somebody, a
17 court or a jury, is going to be asked to enforce the FDA
18 regulations in order to achieve that result.

19 No case suggests that that's an appropriate role for
20 experts to adopt. No case suggests or hold that that's an
21 appropriate role for a court to adopt.

22 Furthermore, Your Honor, there is no case that's been
23 cited that suggests that there is somehow automatic
24 invalidation of an FDA approval based on expert conclusions
25 after the fact and their view of what happened in the

1 regulatory process. No case cited suggested that. The
2 statute certainly doesn't say that at all.

3 The cases about noncompliance, what I attempted to do for
4 the Court was synthesize them. I think if you look at those
5 cases closely, you'll see they bear out what he said. The
6 idea is if there is objective evidence that the product
7 doesn't comply, that doesn't require evaluation of the FDA
8 process, then noncompliance would be appropriate.

9 That happens in a case with a manufacturing defect. You
10 don't need to ask the FDA about that. It happens where it's
11 plain as a matter of fact that the specifications deviate from
12 what the FDA approved. And it happens when there is direct
13 evidence of altering of labeling that FDA approved.

14 Apart from that, Your Honor, you only have one instance
15 where a court actually addressed the issue of noncompliance
16 and found that the case could go forward. And I commend the
17 Court to the Woods case again for its careful treatment of
18 this issue.

19 But what was in Woods, and what most certainly is not
20 here, was a specific finding by the FDA and a criminal
21 admission by the defendant that the regulatory process had
22 been violated.

23 As far as the Brooks list of issues on this, let's
24 remember what Brooks held. There was no evidence to
25 substantiate noncompliance. Brooks did not go on to determine

1 how that would be proved or what would meet the definition.

2 Those statements are pure dicta.

3 Now, Buckman. Buckman is the road map here, Your Honor,
4 that shows that where the plaintiffs are headed is not a place
5 that this Court should go. If you look beyond the cause of
6 action that was in Buckman, and look at the principle that the
7 Supreme Court was espousing, you'll see two things:

8 First, that the FDA has to be free to exercise its
9 discretion.

10 Second, that the FDA places its regulatory scheme without
11 interference from litigants.

12 Those principles extend beyond the confines of that case.
13 And they accord respect to the regulatory agency that Congress
14 intends.

15 And Buckman's call for deference is not unique. As the
16 cases that we've cited in our reply brief show, both federal
17 and Minnesota, courts don't invade agency processes and make
18 de novo judgments about what has gone on.

19 Now, as far as this whole noncompliance issue in general,
20 I will not go back through any point-by-point criticisms about
21 their views of the evidence. But I will say a few things.

22 First, it is this factual debate that they join about
23 how, what, when, and why happening in the regulatory process
24 that is the issue. That is what we demonstrated with our
25 reply brief. That those would be the kinds of issues that

1 were joined. Those factual disputes are irrelevant to the
2 resolution of this summary judgment and should be, because
3 it's not a place that a Court or jury should go.

4 No matter what the basis, plaintiffs demand an
5 independent review and re-evaluation of the FDA process to
6 make new and different findings that are based on their own
7 construction of the regulations furnished through their
8 experts. That's what the Court heard they intend to do; it is
9 most certainly what they are going to do. But it's just this
10 sort of intrusion and second-guessing that the controlling law
11 cuts off.

12 Experts can't declare regulatory violations after the
13 fact and invalidate FDA approval. Whether that's through the
14 PMA process or the PMA Supplement process, that role is
15 reserved exclusively for the FDA.

16 I said it in my opening, Your Honor, and I will conclude
17 with it here: What will be left of preemption if the template
18 that plaintiffs ask this Court to adopt becomes the rule?
19 What do we do? We go out and hire experts who are not in the
20 field, without specialized experience on the issues, have them
21 parse through the regulatory process for something the
22 manufacturers or the FDA should have done, put it in the form
23 of an argumentative legal conclusion in an affidavit, declare
24 the approval invalid no matter what the nature of the
25 regulatory infraction, and whether it goes to the safety of

1 the product or not, and give it to a jury to determine what
2 the FDA should have done and why.

3 What does this do? This insures costly litigation over
4 the entire ambit of the regulatory process.

5 This is not what Congress intended. It is not what it
6 had in mind when it enacted the express preemption provision.
7 It is not what the Supreme Court said courts should be doing
8 in Buckman. It is not what is consistent with the statutory
9 bar on private rights of action for enforcement.

10 And who will be the losers, Your Honor, if we go down
11 this path? This costly litigation will become a deterrent,
12 and the losers will be the people who need device innovation.
13 The losers will be those people who need these life-sustaining
14 products, because the companies will be deterred. And they
15 won't engage in the development efforts because the end result
16 will be the very lawsuits Congress said should not exist.

17 Thank you, Your Honor.

18 THE COURT: Thank you, Mr. Martin.

19 I think that we -- Mr. Angstreich?

20 MR. ANGSTREICH: There is one issue we really need
21 to address. And I know Your Honor wanted to leave by 12:00.
22 And we have three minutes.

23 Mr. Ladner's deposition is scheduled for next Thursday.
24 Part of the subject matter that I did want to cover with Mr.
25 Ladner related to documents, many of which are on the

1 privilege log, which was the subject of earlier argument.

2 My question to the Court is, is there any likelihood that
3 between now and next Thursday Your Honor will rule on that
4 issue? And if not, we will just put Mr. Ladner's deposition
5 off until that ruling.

6 THE COURT: I hope that we can wrap that up by that
7 time. How about if I let you know by Tuesday morning? I
8 understand that you need it, need the rulings for the Ladner
9 deposition.

10 MR. ANGSTREICH: Thank you, Your Honor.

11 THE COURT: I think I need to run to this other
12 meeting that's scheduled. If there are any other topics that
13 we need to discuss before the next status conference, we can
14 hold a brief telephone conference either tomorrow or Monday or
15 Tuesday, or something like that. Is that okay?

16 MR. CAPRETZ: Excuse me. Could we set a status
17 conference date? Because we haven't had -- the last live one
18 was April.

19 THE COURT: How about toward the latter part of
20 August? August 20, 21, or 22? Any of those dates work?

21 MR. CAPRETZ: It's workable here.

22 THE CLERK: Is this at 1:30?

23 MR. ANGSTREICH: Yes.

24 The 21st would be fine, Your Honor.

25 MR. CAPRETZ: At 1:30. Is that workable?

1 MR. STANLEY: That's fine.

2 THE COURT: Let's set it for the 21st. If anybody
3 notes a specific conflict, let Ms. Gleason know.

4 MR. CAPRETZ: Finally, Ramsey County, take judicial
5 notice, we do have also in Ramsey County the deposition of Mr.
6 Ladner. So that getting a ruling on that particular issue is
7 going to have to precede going forward with the deposition.

8 THE COURT: Very well. The Court will take the
9 motion under advisement.

10 Very interesting issues and excellent arguments this
11 morning. We'll get the ruling out shortly. Thank you.

12 (Court recessed at 12:03 p.m.)

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20 CERTIFIED:
21 Karen J. Grufman
22 Official Court Reporter

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