

1 IN THE SUPREME COURT OF THE UNITED STATES

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3 DONNA S. RIEGEL, INDIVIDUALLY :

4 AND AS ADMINISTRATOR OF THE :

5 ESTATE OF CHARLES R. RIEGEL, :

6 Petitioner :

7 v. : No. 06-179

8 MEDTRONIC, INC. :

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10 Washington, D.C.

11 Tuesday, December 4, 2007

12

13 The above-entitled matter came on for oral
14 argument before the Supreme Court of the United States
15 at 10:11 a.m.

16 APPEARANCES:

17 ALLISON M. ZIEVE, ESQ., Washington, D.C.; on behalf of
18 the Petitioner.

19 THEODORE B. OLSON, ESQ., Washington, D.C.; on behalf of
20 the Respondent.

21 EDWIN S. KNEEDLER, ESQ., Deputy Solicitor General,
22 Department of Justice, Washington, D.C.; on behalf of
23 the United States, as amicus curiae, supporting the
24 Respondent.

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	C O N T E N T S	
1		
2	ORAL ARGUMENT OF	PAGE
3	ALLISON M. ZIEVE, ESQ.	
4	On behalf of the Petitioner	3
5	THEODORE B. OLSON, ESQ.	
6	On behalf of the Respondent	24
7	EDWIN S. KNEEDLER, ESQ.	
8	On behalf of the United States, as amicus	
9	curiae, supporting the Respondent	41
10	REBUTTAL ARGUMENT OF	
11	ALLISON M. ZIEVE, ESQ.	
12	On behalf of the Petitioner	50
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

1
2
3
4
5
6
7
8
9
10
11
12
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14
15
16
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18
19
20
21
22
23
24
25

P R O C E E D I N G S

(10:11 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in case 06-179, Riegel v. Medtronic, Incorporated.

Ms. Zieve.

ORAL ARGUMENT OF ALLISON M. ZIEVE

ON BEHALF OF THE PETITIONER

MS. ZIEVE: Mr. Chief Justice, and may it please the Court:

The question in this case is whether section 360k(a) of the Medical Device Amendments to the Food, Drug, and Cosmetic Act preempt State-law claims seeking damages for injuries caused by a device that received pre-market approval. Medtronic's view of the pre-market approval process is that it results in an FDA decision that a particular device must be designed, labeled, and manufactured in a particular way. This view is incorrect, and so I want to talk -- begin by talking about what pre-market approval is and what it isn't. PMA is the FDA's permission to market a Class III device. The manufacturer PMA device develops the design and chooses the -- choosing it on its own. After the company submits the application, the FDA evaluates it, based on information submitted, but it does no independent

1 testing, no product development, no comparison with
2 other products to see if this one is as good as or
3 better than existing products -- or even if it's the
4 best that it can be.

5 If the information submitted by the company
6 meets the statutory standard, reasonable assurance of
7 safety and effectiveness, the FDA grants PMA, thus
8 permitting the device to be sold. So the FDA approves
9 the design and labeling chosen by the manufacturer, but
10 the agency doesn't require the manufacturer to choose --
11 to make those choices.

12 Once on the market, a PMA device may prove
13 to be unsafe, because very often problems and hazards
14 come to light only after the device is in widespread
15 use. So --

16 CHIEF JUSTICE ROBERTS: Isn't that situation
17 addressed by the requirement that the manufacturer alert
18 the FDA to new information and at least file annual
19 reports, and then the FDA can pull back the pre-market
20 approval if they think these problems require it to do
21 so?

22 MS. ZIEVE: Well, yes and no. The
23 requirement about submitting adverse event reports and
24 the annual report are intended help the FDA to monitor
25 the device after it's on the market. But the

1 responsibility and the opportunity to improve the design
2 or labeling or to initiate a recall is really on the
3 manufacturer in the first instance, because the
4 manufacturer is the first one to learn about the
5 problems. The FDA has a more passive role. The FDA
6 receives the information that the manufacturer sends to
7 it --

8 JUSTICE SCALIA: What if the manufacturer
9 wants to make what you call an improvement? Can it
10 simply market the product with that improvement without
11 further FDA action?

12 MS. ZIEVE: Depending on whether it is a
13 design or labeling change, the answer is different. For
14 a labeling change, some changes can be made prior to FDA
15 approval. For design changes, any change that affects
16 safety and effectiveness can't be made without a further
17 submission to the FDA.

18 JUSTICE SCALIA: Even if it is designed to
19 improve safety and effectiveness?

20 MS. ZIEVE: That's right. And in that way a
21 PMA device is no different from the 510(k) device that
22 this Court considered in Lohr, because with respect to
23 those devices as well, any change that would have a
24 significant effect on safety and effectiveness had to
25 await a new submission and a new --

1 JUSTICE SCALIA: Right, but those devices
2 had not been -- they were just grandfathered. They had
3 not been specifically approved as safe and effective by
4 the FDA. Right?

5 MS. ZIEVE: Right. But the question isn't
6 what the level of pre-market scrutiny is. The question
7 is what requirements are imposed on the manufacturer at
8 the end of the process when the device enters the
9 market.

10 JUSTICE KENNEDY: Well, before that decision
11 is reached, let me ask you this -- under State law,
12 either generally or specifically under the law of the
13 State that you are trying to invoke here, does the jury
14 -- does the finder of fact weigh the potential risks of
15 injury and illness against the probable benefits to the
16 health of the patient? Is that one of the things the
17 jury does? In other words, suppose this was a very
18 important device, but it had a one-percent risk. Does
19 a jury consider that when it determines whether that's
20 been negligently sold?

21 MS. ZIEVE: Well, the standard in New York
22 is whether the product is unreasonably hazardous. I
23 think the term "unreasonably" takes into account --

24 JUSTICE KENNEDY: Alright, now isn't that
25 exactly what the FDA measured in the PMA process? The

1 FDA is specifically charged with weighing the risks
2 against the probable benefits.

3 MS. ZIEVE: That's right. And in that way,
4 the State law is mirroring--

5 JUSTICE KENNEDY: So the jury is doing the
6 same thing that the FDA did.

7 MS. ZIEVE: Yes. And as this Court said in
8 Lohr and in Bates, when the State law mirrors the
9 Federal law, there is no preemption.

10 JUSTICE KENNEDY: Well, but that was under
11 the expedited 510(k). That's different than PMA,
12 because in PMA there's a specific way.

13 MS. ZIEVE: What the FDA does before the
14 product reaches the market is different in the PMA
15 context as opposed to 510(k). But when it comes to
16 comparing the State and Federal requirements -- which I
17 think is what you are getting at -- Lohr's analysis and
18 the analysis in Bates v. Dow Agrosociences didn't turn
19 on how rigorous the FDA requirements are, but are they
20 parallel to the State requirements.

21 JUSTICE SCALIA: What was the State
22 requirement there? I mean, what was the Federal
23 requirement there? It was simply that the device had
24 been on the market before the law became effective.
25 Right?

1 MS. ZIEVE: The design requirement in Lohr?

2 JUSTICE SCALIA: Yes.

3 MS. ZIEVE: It had to be substantially
4 equivalent in safety and effectiveness to a device that
5 was grandfathered in, that's right. But Medtronic
6 argued in that case that it couldn't change the design
7 of that product without filing another submission to the
8 FDA, and that that was why there's preemption, and
9 that's the same argument that's made here --

10 JUSTICE SCALIA: Well, but the point is that
11 the -- to follow up on Justice Kennedy's question -- the
12 point is that the FDA in Lohr had never made a
13 determination of weighing the risks against the
14 benefits, as they do for the issuance of PMA's. And so
15 the jury was not replowing the same ground that the FDA
16 had already plowed in Lohr.

17 MS. ZIEVE: I don't think that goes to
18 preemption under 360k(a) which looks for a specific
19 Federal requirement, a State device requirement, and
20 then looks at -- compares the two to see if there are
21 counterparts.

22 JUSTICE GINSBURG: Ms. Zieve, how does it --
23 how does it compare with another process that the FDA
24 looks at very closely, I think even more closely than new
25 devices -- new drugs. New drugs also go through a very

1 long testing period. Is there -- and the FDA gives its
2 approval, and the drug is marketed, and it turns out it
3 has risks people didn't anticipate and there's a tort
4 suit. Is there -- is there a defense to the
5 manufacturer, "I followed to the letter the permission
6 that the FDA gave me"?

7 MS. ZIEVE: Under the common law of most or
8 all States, compliance with Federal law is a defense on
9 the merits, and it is not usually dispositive, but in
10 some States -- in some States it is.

11 JUSTICE GINSBURG: So it would certainly be
12 at least the same here, right? That compliance with the
13 Federal law would be a defense on the merits.

14 MS. ZIEVE: Absolutely. I don't think that
15 the PMA is irrelevant to the tort suit. It's just not
16 sufficient for preemption under 360k(a).

17 JUSTICE GINSBURG: Is there a reason -- as I
18 understand it, tort suits are not preempted with respect
19 to new drugs. Is there a reason to treat the two
20 differently -- the new medical devices and the new drugs?

21 MS. ZIEVE: Well, there is no express
22 preemption provision in the Food, Drug, and Cosmetic Act
23 with respect to drugs.

24 JUSTICE GINSBURG: So that's the difference.
25 So the question is what does the express preemption

1 provision mean?

2 MS. ZIEVE: Right. But I think in trying to
3 figure out what the express preemption provision means,
4 it's actually useful to consider why there's none for
5 drugs and there is one for devices. And the reason is
6 because drugs were regulated by the FDA since 1938.
7 Devices weren't regulated until 1976. So, in those
8 intervening 38 years, States had stepped in and started
9 to do some regulation on their own to fill that
10 regulatory void.

11 California is the most notable example, and
12 the one discussed the legislative history. So, when
13 drafting the medical device amendments and coming up
14 with the system for pre-market scrutiny, the question
15 arose, well, what about California? What about other
16 States that are regulating good manufacturing practices?
17 Or California had a PMA scheme of its own. And so the
18 legislative history makes clear that Congress, faced
19 with this dilemma, decided California shouldn't be able
20 to continue to regulate devices in that way. It
21 shouldn't be able to pre-screen devices once the FDA had
22 stepped in and filled the Federal void.

23 And that's why you didn't need an express
24 preemption provision for drugs. The States weren't
25 doing that in 1938, but because the government -- the

1 Federal government waited so long to regulate devices,
2 it was necessary to say what are we going to do about
3 these State regulations?

4 JUSTICE SCALIA: Does that mean that, under
5 the Food and Drug regulation, the States can issue their
6 own regulations that contradict the Federal approval?

7 MS. ZIEVE: Well, they couldn't issue
8 regulations that contradict the Federal approval
9 because of the express preemption provision. But
10 without it, California --

11 JUSTICE SCALIA: No. No. I'm talking about
12 drugs. Not medical devices. You say that --

13 MS. ZIEVE: That would be a conflict
14 preemption question.

15 JUSTICE SCALIA: Well, no. I mean, you can
16 comply with both. It's just additional -- you have to
17 go further to comply with the State rule, so there's no
18 conflict. It's easy to --

19 MS. ZIEVE: Well, if there's no conflict,
20 then there would be no preemption.

21 JUSTICE SCALIA: Then the States can issue
22 regulations that go beyond -- beyond what the FDA says
23 in drug matters? I would be surprised if that's the
24 case.

25 MS. ZIEVE: Well, if there's -- the only

1 basis for preemption with respect to drugs is conflict
2 preemption. So, if your question incorporates that
3 there's no conflict, then there would no preemption.
4 But --

5 JUSTICE SCALIA: And is that the only basis
6 here? Conflict -- there's no conflict? It's all okay
7 under the Medical Devices Act?

8 MS. ZIEVE: Well, here, if there is not a
9 specific Federal requirement that is the counterpart to
10 a State requirement, there is no preemption. That's
11 what -- that's the language that Congress wrote and --

12 JUSTICE SCALIA: They can add additional
13 requirements so long as -- and I suppose they can do
14 this by regulation -- so long as these additional
15 requirement do not prevent complying with the Federal
16 requirements? So long as there's no conflict, the
17 States can add additional requirements under the Medical
18 Devices Act? That's not my understanding of it.

19 MS. ZIEVE: No. That --

20 JUSTICE SCALIA: It is field preemption,
21 isn't it?

22 MS. ZIEVE: No, I don't think so. The --
23 when the FDA has spoken directly to a question, then the
24 States cannot impose requirements that are different from
25 or in addition to what the FDA has stated.

1 JUSTICE GINSBURG: Take a --

2 JUSTICE SCALIA: Different from --

3 JUSTICE GINSBURG: Take a concrete situation
4 where the FDA is asked: We'd like to make this
5 improvement. And the FDA says no, we don't think that
6 enhances safety. And then there's a tort suit based on
7 the failure to make that improvement. Wouldn't the FDA
8 rejection of permission to make that improvement --
9 wouldn't that at least be preemptive?

10 MS. ZIEVE: If the -- if 360k(a) ever
11 preempts tort claims, I think that would be a situation,
12 but if -- only if the tort claim is -- is specific in that
13 way, that you -- that the company failed in its duty of
14 care because it didn't design the device in the specific
15 way that the FDA had rejected.

16 JUSTICE SCALIA: Well, that's not the way I
17 would -- the jury has to say that?

18 I mean, in fact --

19 MS. ZIEVE: Well, that --

20 JUSTICE SCALIA: In fact, that's what's
21 going on, but it could have been safe if -- if they had
22 made the change that the FDA rejected. But the case
23 goes to the jury and that's, in fact, what's going on.

24 MS. ZIEVE: Well, the --

25 JUSTICE SCALIA: The trial is, you know, had

1 he -- had he made this change, it would have been safe,
2 but he didn't make the change and, therefore, you,
3 ladies and gentlemen of the jury, should hold the
4 company liable.

5 MS. ZIEVE: Well, if that's the theory of the
6 case, I think that's basically the one-inch/two-inch
7 hearing aid wire of Justice Breyer's example in Lohr.

8 JUSTICE SCALIA: So it just --

9 MS. ZIEVE: But most tort claims --

10 JUSTICE SCALIA: It just has to be the
11 theory of the case. We have to look at each jury
12 verdict and decide whether that was the basis on which
13 the jury made the decision.

14 MS. ZIEVE: Well, it's -- it's not actually
15 that hard, because most tort claims are --

16 JUSTICE GINSBURG: I thought your response
17 was it wouldn't go to the jury if the FDA had said no,
18 you cannot make this, and the plaintiff's point is you
19 must make it in order to make this device safe.

20 I thought your answer to me was that the FDA
21 regulation -- the FDA's action in refusing to allow the
22 change to be made would be preemptive and you wouldn't
23 give it to a jury to second-guess that determination by
24 the FDA.

25 MS. ZIEVE: Yes. That's right. And I

1 thought, Justice --

2 JUSTICE SCALIA: Yes under State law, but
3 you -- you don't say that Federal preemption requires
4 that; you say that by the grace of New York State, that
5 may be the situation, but New York State can change that
6 law, as far as you're concerned, right?

7 MS. ZIEVE: Can -- I'm sorry. Can change
8 which law?

9 JUSTICE SCALIA: New York State can let it
10 go to the jury, despite -- despite what the FDA has
11 done. You've said that it's simply a defense under New
12 York State law and the law of most States. But it
13 doesn't have to be a defense under New York State law.

14 MS. ZIEVE: I think that's a different
15 point. Generally --

16 JUSTICE SCALIA: I thought that was the point
17 Justice Ginsburg was inquiring about.

18 JUSTICE GINSBURG: I was asking you, if it
19 was -- as a matter of Federal law, if the FDA says --
20 rejects --

21 MS. ZIEVE: Yes.

22 JUSTICE GINSBURG: -- a proposed change, can
23 a State court say, well, we think the FDA was wrong in
24 rejecting that, so we're going to let it go to the jury.
25 I thought the question I was posing to you is, isn't

1 Federal law preemptive in that situation, when the FDA
2 says you can't do it and the personal injury lawyer
3 wants it to convince the jury that they had to do it?

4 MS. ZIEVE: Yes. In a situation where the
5 FDA has said you are required not to market this
6 specific device and the State -- the plaintiff is
7 seeking to impose a common law duty that you must market
8 that specific design, then you would have counterpart
9 State and Federal regulations, but the --

10 JUSTICE GINSBURG: How about the --

11 MS. ZIEVE: The relevance of --

12 JUSTICE GINSBURG: Another variation -- the
13 FDA says you must include X in this device or we won't
14 give you the pre-market approval. And so the
15 manufacturer puts X in, and then there's a lawsuit that
16 wants to charge that putting X in made the device
17 dangerous.

18 Would the FDA's insistence that X be put in
19 take X out of any State court's tort litigation? That
20 is, wouldn't -- if the FDA says you must have it, a
21 State court couldn't put to a jury whether you should
22 have eliminated it?

23 MS. ZIEVE: Yes. I think that's Justice
24 Breyer's two-inch hearing aid fix, when the Federal
25 government says you must and the State law duty says

1 that you cannot.

2 But the -- that's not how tort claims are
3 litigated as a general matter. First of all, PMA's
4 don't say you must have this design feature. There's --

5 CHIEF JUSTICE ROBERTS: Right. I thought
6 that was your -- your theory was a little more nuanced.
7 In other words, they don't require you to market a
8 particular catheter. And you -- what I understood you
9 to be arguing is that there may be a better design and
10 that it was negligent for the manufacturer to market a
11 particular design, even though they're allowed to; they
12 don't have to.

13 MS. ZIEVE: Exactly.

14 CHIEF JUSTICE ROBERTS: They should have
15 made the change to make it safer, right?

16 MS. ZIEVE: That's right.

17 CHIEF JUSTICE ROBERTS: Well, if that's --

18 MS. ZIEVE: And if you look at the joint
19 appendix --

20 CHIEF JUSTICE ROBERTS: Well, if that's what
21 happens, what, as a -- what's going to happen for
22 patients at a time when your theory comes up, the
23 manufacturer looks at it and says, well, maybe this is a
24 better device; we don't want to risk these tort suits,
25 so we're going to stop selling our old device that's

1 been approved, but now we have got to get FDA approval
2 of the new device and that might take forever or at
3 least a year, let's say. And what happens to patients
4 in that year? They've got no device.

5 MS. ZIEVE: Well, first of all, if the
6 device is reasonably safe and effective, then the
7 company is just not going to stop marketing it because
8 of tort suits. And we know that because --

9 CHIEF JUSTICE ROBERTS: But your theory is
10 that although this device has been approved, here's a
11 better one. And it's negligent on the manufacturer's
12 part to market a device, even though approved by the
13 FDA, when there's a better one that would reduce the
14 risks.

15 MS. ZIEVE: Right. But we know that
16 manufacturers don't respond by taking devices off the
17 market, because PMA has coexisted with tort suits since
18 1976. For instance, recently --

19 CHIEF JUSTICE ROBERTS: What do you want
20 them to do if you think it's negligent for them to
21 market the approved product? Don't you want them to
22 take it off the market?

23 MS. ZIEVE: Well, I -- they should make
24 their devices as safe as they can be. And if a tort
25 suit points out that this device is not reasonably safe,

1 then the manufacturer --

2 CHIEF JUSTICE ROBERTS: Well, it's not that
3 it is not reasonably safe. It's that another design
4 would be safer. And you think that's a basis for
5 negligence because you say, yeah, the FDA approved it,
6 but that doesn't mean they required the manufacturer to
7 market that device.

8 MS. ZIEVE: That's right. And 360k looks to
9 requirements. It's not a matter of policy what the
10 effect of tort suits is. The question is what are the
11 requirements imposed by the PMA, what requirements are
12 imposed by State law.

13 JUSTICE SCALIA: Of course, this is all a
14 little unrealistic. It is not as though some expert
15 agency of the State has conducted a very scientific
16 inquiry and decided that there's something safer than
17 what the FDA approved or that it's negligent to issue
18 what the FDA approved.

19 What's going on is simply one jury has
20 decided that in its judgment, there was a safer device
21 that should have been used; and because of the judgment
22 of that one jury, the manufacturer is placed at risk in
23 selling a device that scientists at the FDA have said is
24 okay.

25 I find that extraordinary.

1 MS. ZIEVE: Well, any one of us might have
2 drawn the line differently. But the line Congress drew
3 was when there is a specific Federal requirement, we
4 looked for a device counterpart State requirement. And
5 where they don't exist, there is no preemption.

6 JUSTICE BREYER: I thought that was
7 something a little different than that. The question
8 that I have which might be helpful to me, if you can
9 answer it, is -- that's meant seriously -- I'd be
10 helped by knowing what the specific design defect is
11 that you claim? That is, in what respect was this
12 catheter -- and I'd like you to refer to the details of
13 the catheter -- in what respect, what material or what
14 shape or what -- what it is about this catheter that you
15 as the plaintiff think was designed defectively, if you
16 can tell me?

17 MS. ZIEVE: There's not a lot of discovery
18 about the design of the catheter.

19 JUSTICE BREYER: I know. But you must have
20 a theory.

21 MS. ZIEVE: The general theory is that the
22 design was unreasonably safe because the catheter should
23 not have -- should have been strong enough --

24 JUSTICE BREYER: What is it about the design
25 that you are saying is not safe? That is, you can't go

1 into the court without having in your mind, as the
2 counsel, that some kind of specific thing that was wrong
3 with this catheter, other than just using the words
4 "design." I mean, how was it designed badly? What part
5 of the design is not right?

6 MS. ZIEVE: The strength of the balloon and
7 the way in which --

8 JUSTICE BREYER: You are saying the material
9 of the balloon should have been of a different material
10 or a different thickness; is that right?

11 MS. ZIEVE: Or designed to burst in a
12 different way.

13 JUSTICE BREYER: What does that mean? How
14 do you design something to burst?

15 MS. ZIEVE: I don't know how you design a
16 balloon. But there -- Medtronic has --

17 JUSTICE BREYER: Well, if you don't know how
18 you -- how to design the balloon, what are you basing
19 the design claim on?

20 MS. ZIEVE: As I said, the design claim in
21 this case was not significantly developed. Perhaps it
22 would help to talk about the design claim in Horn v.
23 Thoratec, for example, which was another PMA device --

24 JUSTICE GINSBURG: What about the label? I
25 mean, this is the suit that you're pressing? So you

1 said we really don't know what the design defect was.
2 How about the label? That would be the other thing.

3 MS. ZIEVE: The labeling claim is that the
4 label was -- inadequately warned or was misleading
5 because although at one place it lists among 12
6 precautions not to inflate the balloon above the rated
7 burst pressure, which was eight, at another place it
8 says to -- it has a chart that shows inflation up to 13
9 atmospheres, and at another place in the instructions, it
10 says inflate to the nominal pressure, which is --

11 CHIEF JUSTICE ROBERTS: Well that's just like
12 a car speedometer. I mean, the speedometer goes up to
13 120 miles an hour, but that doesn't mean you are
14 supposed to drive it that fast.

15 MS. ZIEVE: But the car doesn't come with a
16 chart that shows you safe usage up to 100 miles
17 either. And the instructions --

18 JUSTICE KENNEDY: Was Medtronic free to
19 alter this label without the FDA's consent?

20 MS. ZIEVE: Yes. Under 814.39, Medtronic
21 could make changes to strengthen the warnings or clarify
22 the instructions without prior approval. And there's
23 one other part of the label that --

24 JUSTICE KENNEDY: What's the citation for
25 that?

1 MS. ZIEVE: 21 CFR 814.39(d).

2 JUSTICE BREYER: Let me tell you why I asked
3 my question, because I don't want to leave -- you
4 leave with an unfavorable impression in my mind on your
5 issue without your having a chance to see.

6 What's worrying me is that, of course, it's
7 a terrible thing when somebody is hurt in these kinds of
8 accidents. And the lawyers are trying to help. So the
9 lawyers will think, look, there's a problem here. There
10 must be. My client was seriously hurt. And he's not
11 supposed to be.

12 And then they'll work backward from that and
13 say well if he was hurt, there must be something wrong
14 with the design.

15 So every time there is an accident or
16 something bad happens, the lawyers assert a design claim
17 and they gear up discovery.

18 And in my mind, could Congress have intended
19 that kind of thing when what they're trying to do is
20 have a group of experts really look into this and decide
21 whether it should be marketed or not. That's what's
22 bothering me. And that's why I would like you to
23 respond to that.

24 MS. ZIEVE: Of course, it -- I freely admit
25 that at trial if the plaintiff couldn't articulate the

1 design theory any better than I did here, the plaintiff
2 is not going to lose on the design claim. But there are
3 other cases where there is quite a clear theory about
4 what the design defect is.

5 There are cases where the product has been
6 recalled because of a design defect; and in those cases,
7 could Congress have really intended to protect the
8 manufacturer from liability? After all, the Dalkon
9 Shield disaster where tons of people were hurt
10 because -- women were killed and injured because of a
11 design defect, was the impetus for the bill.

12 I would like to reserve the balance of my
13 time.

14 CHIEF JUSTICE ROBERTS: Thank you, counsel.
15 Mr. Olson.

16 ORAL ARGUMENT OF THEODORE B. OLSON

17 ON BEHALF OF THE RESPONDENT

18 MR. OLSON: Mr. Chief Justice, and may it
19 please the Court:

20 I think that the key, central focus of this
21 case was touched upon by Justice Kennedy's question.
22 Congress made a decision that it wanted to balance
23 reasonable safety and effectiveness of lifesaving
24 devices with the availability of lifesaving devices to
25 the public.

1 They did so by vesting this responsibility
2 in the experts, the expertise, the judgment, and the
3 processes at the FDA.

4 And preemption of potentially conflicting,
5 confusing, and burdensome State law requirements is
6 essential to this scheme.

7 JUSTICE GINSBURG: Why, Mr. Olson, is it
8 more essential to this scheme than the new drugs? I
9 would think that if everything that you said about new
10 devices would apply in bold letters for new drugs,
11 because the testing procedures are much longer, are they
12 not?

13 MR. OLSON: They're similar, but they're
14 also quite different, Justice Ginsburg. The principal
15 difference is this preemption provision that is the
16 fundamental issue in this case. Section 360k(a)(1),
17 that similar provision was not put by Congress in the
18 new drug --

19 JUSTICE GINSBURG: Well, there's an argument
20 that what it was intended to do was to cut out State
21 pre-market approval, where States like California came
22 in when there was a Federal void and said we shouldn't
23 let the manufacturers put out whatever they'd like.
24 Let's have a pre-market approval.

25 And the argument is, as you well know --

1 it's presented in Senator Kennedy's brief, that's what
2 we meant to do with the preemption provision. Nothing
3 more.

4 MR. OLSON: If there was such a State
5 pre-market approval process, it would be something like
6 the Federal process which would involve a very detailed
7 application which would have everything about the
8 design, the manufacture, and the warning labels in it.
9 Then California would come up with different
10 requirements, presumably or potentially, than what the
11 FDA had decided was a reasonable balance between safety
12 and effectiveness and availability. And so therefore,
13 there would be different requirements.

14 And, as Justice Breyer pointed out in his
15 concurring and dissenting opinion in the Lohr case, if a
16 State jury or a State court comes up with those
17 different requirements, it is the same problem:
18 Different States, different requirements under different
19 circumstances.

20 And it would be quite anomalous for Congress
21 to have given more power to juries in individual ad hoc
22 cases which don't do the weighing, Justice Kennedy --
23 they can't do the same amount of weighing because their
24 focus --

25 CHIEF JUSTICE ROBERTS: What if the FDA

1 hasn't done it? How are newly discovered flaws dealt
2 with? I mean, say we have this catheter, and the
3 FDA didn't look at the possibility of allergic reactions
4 to the balloon plastic, and all of a sudden it turns out
5 to be a serious problem.

6 How can you say that that's preemptive?

7 MR. OLSON: This is a continuous process.
8 Information must be given by the manufacturer. There is
9 a process by which doctors report consequences to the
10 FDA. Citizens may report information. This is a
11 continuous jurisdiction --

12 JUSTICE KENNEDY: Is the manufacturer free
13 to continue to sell the device after newly discovered
14 risks --

15 MR. OLSON: Yes --

16 JUSTICE KENNEDY: -- pending the FDA's
17 acting on the same information?

18 MR. OLSON: Yes, Justice Kennedy. And let
19 me explain why I think that is important to this case.

20 If the -- that information is then in the
21 possession of the FDA. The FDA can suggest to the
22 manufacturer -- it can require the recall. It can
23 change warnings. It can do all of those things. But
24 what it is doing, because it's continuously involved in
25 the process --

1 JUSTICE KENNEDY: Mr. Olson, we know it
2 takes time for the FDA to act. Let's assume that we
3 know it's going to take six months for the FDA to do this.
4 The manufacturer knows that there's a real problem. He
5 can continue to sell in the face of the knowledge of the
6 real problem?

7 MR. OLSON: What I'm suggesting is that the
8 FDA can act as promptly or as slowly as necessary --

9 JUSTICE KENNEDY: I was asking you about the
10 manufacturer's duty pending the FDA's action.

11 MR. OLSON: It's dependent upon the
12 manufacturer providing information to the one
13 centralized agency --

14 JUSTICE STEVENS: Mr. Olson, suppose the
15 manufacturer did not provide information. Would the
16 preemption nevertheless exist?

17 MR. OLSON: Yes, Justice Stevens, because in
18 that case --

19 JUSTICE STEVENS: At least as a theoretical
20 possibility, there could be a newly discovered risk that
21 the FDA never knew about. And, nevertheless, the claim
22 would be preemptive.

23 MR. OLSON: Yes. And that's a judgment that
24 Congress made, because with the -- the manufacturer then
25 would be violating the law, failing to tell the FDA what

1 was going on, perhaps committing fraud, and be subject to
2 criminal penalties, recall penalties, civil penalties,
3 and that sort of thing.

4 The choice is, Justice Stevens, in that
5 situation -- is to allow the agency that has the
6 expertise, that has spent 1200 hours or so on this
7 particular device, according to your opinion in the Lohr
8 case, to make a judgment with respect to whether this
9 product should be on the market or not.

10 Because as I --

11 JUSTICE SOUTER: Mr. Olson, that still
12 leaves the -- sort of the hiatus that Justice Kennedy's
13 question was addressed to. And I -- I don't think I
14 understand your answer to it.

15 His question was what if the manufacturer
16 has learned that there is -- that there's a problem that
17 somebody hadn't anticipated? The manufacturer has told
18 the FDA, and the FDA has not yet acted.

19 Leave open the question of whether the FDA
20 is slow or whether it just takes time, but there's a --
21 there's a hiatus here. And an injury occurs because of
22 marketing that took place during the hiatus.

23 Does preemption still apply?

24 MR. OLSON: Yes, it does.

25 JUSTICE SOUTER: Okay.

1 MR. OLSON: And the reason for that, Justice
2 Souter, is that someone must make a judgment. That --
3 the information that the manufacturer may have learned
4 may be -- have some aspect of the safety or
5 effectiveness of the device, but it still might be the
6 best product available.

7 As the government points out in its brief,
8 there are some devices that are used in situations where
9 a child might die. There's a 50-percent mortality rate
10 even with using the device. So there's got to be
11 individual judgments with respect to variations of risk
12 and safety and availability.

13 JUSTICE ALITO: Do you know whether the PMA
14 process in this case considered the design defects that
15 the Petitioner seems to be relying on?

16 MR. OLSON: Well, all -- no, I don't know
17 the answer to that specifically, Justice Alito. But I
18 do know -- and this is the application, itself, which is
19 not, unfortunately, in the record, but is available
20 through the FDA. It goes into elaborate detail with
21 respect to the burst pressures. This device -- the
22 label on this device -- and that is in the record at
23 A-174 of the court of appeals' appendix -- specifically
24 says it shouldn't be inflated higher than a burst
25 pressure or atmospheric pressure of -- at 8 atmospheres.

1 This one was inflated to 10 atmospheres, notwithstanding
2 the label requirements.

3 So what -- what I am saying is that the
4 elaborate nature -- everything in the label has to be
5 approved by the FDA. The safety indications, the
6 precautions, the hazards, the counter --
7 counterindications, and that sort of thing, there's a
8 professional judgment there.

9 My colleague says that well, it's not the
10 FDA's not imposing requirements, because this is a
11 design submitted by the manufacturer. Of course, it's a
12 design submitted by the manufacturer. That's how
13 devices are made.

14 But the FDA examines every little part of
15 that design -- the way it's manufactured, the way it's
16 labeled, the way it's marketed, the way it's going to be
17 used.

18 And it can say no, change that part of it,
19 or have you considered this? It's a dialogue between
20 the manufacturer and the FDA.

21 And then when the FDA is satisfied that it's
22 reasonably safe and effective -- and the word
23 "reasonable" is important. Nothing is perfectly safe.
24 You can make a car weigh a hundred tons, and it might be
25 perfectly safe, but balances have to be made, the same

1 with drug devices. So --

2 JUSTICE ALITO: If you look at the file of a
3 PMA proceeding after it is concluded, can you tell
4 exactly which design features and which risks the FDA
5 has considered?

6 MR. OLSON: No, I don't think you can. What
7 you can do, Justice Alito, is examine -- and Justice
8 Breyer's example of the two-inch versus one-inch wire in
9 the Lohr case is a good example.

10 The FDA will have examined, and presumably
11 done its job, with respect to every aspect of the
12 design, manufacture, and labeling and marketing of the
13 device.

14 Now, the choice is between that -- and I
15 think Congress made this judgment quite consciously,
16 because if a -- if a jury comes along in a particular
17 case, examining a particular infant or a particular ill
18 person and the facts of a particular situation, and says
19 well, the device should have had a one-inch nail -- a
20 wire, or it should have had a different tensile strength
21 of the balloon, or something like that, then the
22 manufacturer is in this dilemma.

23 JUSTICE GINSBURG: Why isn't there -- to --
24 to take care of that kind of hypothetical where the FDA
25 says this is it, to say that kind of suit can't be

1 brought. But Ms. Zieve mentioned that there's a
2 category of suits that is simply saying: Manufacturer,
3 you didn't do what's in that pre-marketing approval.

4 So we're kind of a backup to not doing
5 anything in conflict with the FDA's approval. We're
6 simply saying you didn't follow the labeling
7 requirement, or you didn't follow the design permission
8 that you --

9 MR. OLSON: I think that if there's a
10 violation of the requirements -- now, it's no -- it's no
11 question that there are requirements, because every
12 aspect of this approval incorporates the design and all
13 of those things.

14 If the manufacturer fails to comply with
15 those requirements, that's a parallel suit that may be
16 brought.

17 Now, in this case, the negligent
18 manufacturer -- a claim was made. It was dismissed on
19 summary judgment, which was affirmed by the Second
20 Circuit because there was no evidence to support it. So
21 --

22 CHIEF JUSTICE ROBERTS: You -- you agree
23 that that was not preemptive.

24 MR. OLSON: That was -- we agree that was
25 not preempted, and -- and the court of appeals came to

1 that same conclusion, but affirmed the district court
2 that dismissed it on summary judgment because there was
3 no evidence to support it.

4 JUSTICE GINSBURG: You would say the same
5 thing for -- for design and labeling if the manufacturer
6 did not do what the FDA approved?

7 MR. OLSON: That's correct, Justice
8 Ginsburg.

9 Now our -- the statute, I think, could not
10 be more clear with respect to every aspect of what the
11 Court talked about in the Lohr case. And I think that
12 the analysis that this Court articulated in the Geier
13 case having to do with the airbags, although that was
14 an implied preemption and conflict preemption -- case
15 and this is an express preemption case -- is very
16 illustrative.

17 The Court went through an analysis of what
18 manufacturers might do if they were required to put an
19 air bag in the car when the Department of Transportation
20 had decided that it wanted a little bit of play in the
21 marketplace with respect to different types of
22 restraints of individuals.

23 And the Court made it very clear that if a
24 trial court in Kansas or some other place decides that
25 cars must be manufactured in a certain way, that's what

1 would happen.

2 And then the judgment of the Department of
3 Transportation, which was considering all of these
4 things and wanting to encourage innovation with respect
5 to restraints -- the same thing is true here.

6 We want in this country for devices to be as
7 safe and effective as they possibly can be. But we
8 don't want to discourage the marketing of products that
9 might save our lives. And these are -- Class 3 devices
10 are all in the category of life-threatening or
11 life-saving devices here. So we want those available.
12 They may not all be perfect. They maybe work in some
13 situations, not work in other situations, but some
14 expert, centralized, that can take into consideration
15 all of those factors should be the place where that
16 decision is made.

17 JUSTICE GINSBURG: Mr. Olson, what about the
18 argument that once you've got this very valuable
19 pre-market approval, even though you could make that
20 device safer, you have no incentive to do that. You
21 have permission to market this product as is. Even if
22 you know that there's a better way to do it, there's a
23 disincentive to try to go through the process and make
24 the change. Why should you, when you have carte blanche
25 to continue without making the change?

1 MR. OLSON: Well, I think the real world
2 answers that question. The manufacturers of these
3 products are always trying to produce better products
4 that will be safer. They of course have to go through
5 the process to justify to the experts at the FDA that
6 they are indeed safe, or -- and the FDA then may make a
7 judgment that the reasonableness -- if there is a much
8 safer device that doesn't have the risks of the previous
9 device, they can -- they can withdraw the approval of
10 the previous device.

11 But the FDA may at the same time say well,
12 this one device might be safer under some circumstances
13 but less safe under other circumstances. It might work
14 in this critically ill patient, but not in this
15 critically ill patient. So the marketplace of doctors
16 and patients deserves to have more than one product out
17 there, even though someone might decide this one is
18 safer than the other one. That is the way Congress made
19 this judgment. And --

20 JUSTICE KENNEDY: If the manufacturer finds
21 just from its own laboratory experiments and not because
22 of any data it's received from doctors and patients that
23 there's a better way to do this, does it have the
24 obligation to notify the FDA?

25 MR. OLSON: I don't think so,

1 Justice Kennedy. I think that there may be marketplace
2 incentives and other things that would cause a --
3 someone in the marketplace to say I found a better way.
4 Someone in the marketplace might say well, it might be
5 better, but it might be prohibitively expensive. There
6 are all kinds of those judgments, and I think that
7 illustrates the point.

8 The FDA is the right place for these
9 decisions to be made and this balancing process to
10 occur, because an individual, ad hoc, not
11 scientifically trained jury that is not required to
12 consider the consequences for the marketplace as a
13 whole, cannot make those judgments.

14 As conscientious as a jury might be, that
15 judgment is in for that case and for that patient and
16 might say well gee, it should have been done differently
17 in this particular situation; a one-inch wire might have
18 been better in this particular case. But the --

19 CHIEF JUSTICE ROBERTS: Mr. Olson, I'm
20 looking at the government's brief on page 4 which says
21 that in the annual reports, the -- the manufacturer has
22 to disclose "unpublished reports of data from clinical
23 investigations or nonclinical laboratory studies
24 involving the device."

25 So presumably that includes any nonclinical

1 laboratory studies that the manufacturer itself
2 conducted.

3 MR. OLSON: Yes. I believe that's true, but
4 I think that was a slightly different point than
5 Justice Kennedy's one; if it was -- if it is the same
6 point, I agree with you, that there is an elaborate
7 process of information exchange from the manufacturer
8 and from doctors and from all over with respect to these
9 medical devices. It's described in considerable detail
10 in about six pages in the court of appeals decision, and
11 the Government's brief describes it quite thoroughly as
12 well.

13 That same balancing, the Government filed a
14 brief last week in this Court in the Warner-Lambert
15 case, that this Court will be hearing, I think in
16 January, which describes in even greater detail than it
17 does in the brief filed here about that balancing
18 process and the importance of the centralized --

19 JUSTICE STEVENS: Could you clarify one thing
20 for me on that part? Is that a -- as soon as they get the
21 information requirement, or is it an annual requirement
22 that they have to take --

23 MR. OLSON: That -- what the Chief Justice
24 was referring to was an annual requirement --

25 JUSTICE STEVENS: Right.

1 MR. OLSON: -- but there also are
2 requirements -- and I haven't -- can't give you the
3 exact citation, there's a lot of subparagraphs in these
4 sections -- with respect to information that comes into
5 the possession of the manufacturer that's pertinent to
6 adverse consequences or effects of the device that must
7 be given promptly to the FDA.

8 JUSTICE SCALIA: Mr. Olson, the other side
9 says well, you know, these are all horrors but, in
10 fact, we have had tort suits and manufacturers haven't
11 taken their products off the market. This is all just a
12 Chicken Little kind of a --

13 MR. OLSON: Well, I don't agree with that,
14 Justice Scalia. In the first place, I don't think we
15 know. Secondly, there are six of the seven circuits
16 that have considered this case, found that those tort
17 suits were preempted. So to the degree to which they
18 are out there, there is one circuit in which they might
19 --

20 JUSTICE STEVENS: Yes, but of course the FDA
21 took this contrary position some years ago.

22 MR. OLSON: Yes, it did, and it -- and it
23 learned from experience -- the unique experience that
24 you described the FDA having, in your opinion in the
25 Lohr case, has been brought to bear in this case; and

1 there's a reasoned explanation for the FDA's -- the
2 Government's position today, as to why it took one
3 position then -- there were some proposed regulations
4 that are no longer on the table -- but there's a
5 reasoned explanation by the agency that you said and
6 quite correctly in my judgment had a unique experience,
7 and unique capability of determining the effect of
8 take -- State tort suits on the process that it's
9 involved in, and that's reflected in the Government's
10 briefs that are filed in this case just earlier.

11 The fact is that there are specific detailed
12 requirements with respect to every aspect of the device
13 that's approved by the FDA; and any jury, just like any
14 regulatory body, Justice Breyer, will impose a different
15 requirement. The fundamental -- you asked about,
16 what's the basis of this suit, there was some answer to
17 it, but the fact is there's some effort to explain why,
18 if it was designed according to the approval, by the
19 FDA, that wasn't good enough.

20 There was something wrong with that design
21 that was approved. Something wrong with that label that
22 was approved. And a jury at the end of the day will be
23 expected then to render a different requirement by
24 saying you are liable for damages because you did it the
25 way the FDA approved.

1 That is a State requirement which is a
2 counterpart to the Federal requirement, and this -- and
3 Congress made it explicitly clear that any requirement
4 that is different or in addition to the Federal
5 requirement is preempted if it has to do with safety or
6 effectiveness of the device.

7 And if juries require products to be
8 changed, they will by definition be either less safe or
9 less available than the FDA has determined is in the
10 best interests of the public according to the
11 responsibility vested in them by Congress.

12 Thank you, Mr. Chief Justice.

13 CHIEF JUSTICE ROBERTS: Thank you,
14 Mr. Olson.

15 Mr. Kneedler.

16 ORAL ARGUMENT OF EDWIN S. KNEEDLER,

17 ON BEHALF OF THE UNITED STATES,

18 AS AMICUS CURIAE,

19 SUPPORTING THE RESPONDENT

20 MR. KNEEDLER: Mr. Chief Justice, and may it
21 please the Court:

22 I think it might be useful to begin by
23 focusing on the consequences of Petitioner's argument
24 that the PMA approval of an application does not result
25 in requirements that are preemptive for purposes of the

1 preemptive provision. Under Petitioner's view, the day
2 after the FDA gave PMA approval to a particular device,
3 State legislatures or State regulatory agencies could
4 adopt laws or regulations that would direct the
5 manufacturer to manufacture or design the product or to
6 give labeling that would conflict with what the FDA had
7 just approved. And we don't think that Congress could
8 have intended, in enacting the express preemption
9 provision here, to allow State regulatory agencies or,
10 even more so, individual juries that could vary, even
11 within a State --

12 JUSTICE GINSBURG: I thought that you
13 conceded that there would be conflict preemption, that
14 the States could not -- either through a State agency or
15 through a jury -- come up with a requirement that would
16 conflict with an FDA requirement.

17 MR. KNEEDLER: But we think that the express
18 preemption provision embodies that very important
19 conflict, or maybe in this context it is best to
20 conceptualize it as field preemption, of the things that
21 are included within the application that is submitted to
22 the FDA and the labeling.

23 JUSTICE SCALIA: Additional requirements are
24 not necessarily conflicting requirements. You
25 can comply with --

1 MR. KNEEDLER: Yes, that is -- that is
2 definitely true.

3 JUSTICE SCALIA: It is clear that Congress
4 didn't want any additional requirements.

5 MR. KNEEDLER: That's -- that's entirely
6 correct, and if I could just elaborate on that --

7 JUSTICE BREYER: How are they not
8 conflicting? Go ahead; go ahead -- elaborate.

9 MR. KNEEDLER: Well, what I was going to say
10 -- to elaborate on the point that I made, Petitioner
11 concedes that if there is an FDA PMA requirement, the
12 State may not impose its own PMA requirement; and that
13 has to be correct, because in the State PMA approval,
14 the State could withhold its approval unless the
15 manufacturer changed the device or changed the labeling
16 in some way to get it cleared through --

17 JUSTICE GINSBURG: Everybody agrees that
18 far, that the States were not to be in the business of
19 issuing PMA's. The question is does the preemption
20 clause mean any more than that?

21 MR. KNEEDLER: But it's important to
22 understand why. Congress was not concerned about the
23 PMA in the abstract or as a process; it was concerned
24 about what the consequences of requiring a manufacturer
25 to go through the PMA process were. And that was

1 precisely because the result of the State PMA
2 process could be to impose different requirements. The
3 labeling should read differently --

4 JUSTICE GINSBURG: Isn't it -- isn't it --

5 MR. KNEEDLER: -- the product should be
6 designed differently.

7 JUSTICE GINSBURG: If you compared drugs,
8 which -- I think you will -- you will concede -- go
9 through a very arduous process, new drugs, why -- maybe
10 you think that the same preemption applies there,
11 although there's no preemption clause.

12 MR. KNEEDLER: There is -- there is no
13 express preemption clause there. One -- one possible
14 explanation might be is that a -- that a device is a
15 tangible concrete item, an item of commerce that is --
16 that has extensive design and planning and blueprints in
17 a way that a drug doesn't quite have that same -- that
18 same characteristic. I mean, like other -- like
19 automobiles or something, that they have a tangible
20 aspect and a long lead time in the design and
21 manufacture.

22 That may be one explanation for why Congress
23 wanted to be especially firm about imposing preemption
24 with respect to federally approved devices.

25 JUSTICE SCALIA: It was also a different

1 Congress.

2 MR. KNEEDLER: It was a different Congress.

3 JUSTICE SCALIA: How much -- how many years
4 later?

5 MR. KNEEDLER: This was 1976 when the new drug
6 amendment --

7 JUSTICE SCALIA: Why would we expect them to
8 come out with the same --

9 MR. KNEEDLER: Right, and they were only
10 addressing devices in that -- these were not general FDA
11 amendments; they were addressing -- they were addressing
12 the --

13 JUSTICE GINSBURG: Did anyone -- when this
14 preemption clause was put in the new Medical Device, did
15 the government -- when was the government change? Was
16 it 2004? The government's position, the FDA's position,
17 was 180 degrees different --

18 MR. KNEEDLER: Well, the government filed a
19 brief in -- in late 1997 taking the position that PMA
20 approval did not -- did not have preemptive effect.
21 That was issued together with FDA's issuance of a
22 proposed rule to the same effect. FDA withdrew that
23 proposed rule seven months later. The government did not
24 address this question again until 2004 in the brief
25 you're referring to in the court of appeals.

1 And due in large part to examining the very
2 things that I've been talking about, that in FDA's
3 judgment, which this Court in the Lohr case said was
4 entitled to considerable deference, FDA recognized that
5 there would be a serious undermining of FDA's approval
6 authority and its balancing of the risks and benefits,
7 if a State jury could reweigh those -- the balance that
8 FDA had struck in --

9 JUSTICE KENNEDY: Suppose that a label is
10 approved in a very specific form under PMA, and then a
11 year later, it turns out, unforeseen by anyone, that
12 doctors are just -- many good doctors are just reading
13 it the wrong way and it's dangerous.

14 Can the manufacturer continue to sell new
15 devices with the same label pending the annual report?

16 MR. KNEEDLER: Yes. I mean, let me just
17 clarify.

18 If the -- if the -- there are incident
19 reports that -- that a manufacturer is supposed to give
20 to FDA. There is often a difficult judgment as to
21 whether the injury that is associated with a device is
22 some problem with the device or whether it's some problem
23 --

24 JUSTICE KENNEDY: Just take --

25 MR. KNEEDLER: -- with what --

1 JUSTICE KENNEDY: Just take my hypothetical.

2 MR. KNEEDLER: And it -- what I was going to
3 say is it's possible that the labeling would be regarded
4 as misleading for some reason. In that event, the
5 manufacturer should apply to -- should submit what's
6 called a supplemental PMA and request that the labeling
7 be changed to clarify that.

8 JUSTICE KENNEDY: And you could -- can the
9 manufacturer continue to sell the device knowing that
10 the label is being misconstrued by very good doctors
11 pending FDA action?

12 MR. KNEEDLER: Ordinarily, yes. If there
13 was -- if there was a very serious risk to health and
14 safety --

15 JUSTICE KENNEDY: Yes, it's very serious.

16 MR. KNEEDLER: In that event, FDA has a
17 variety of tools that it can take and so does the
18 manufacturer. One of them is what's sometimes called a
19 "Dear Doctor" letter, which is notification -- this is
20 provided for under 360h(a) of the Act -- is a
21 notification to physicians or other users of the product
22 that there may be some previously unrecognized problem
23 or misrepresentation or what could be misconstruction of
24 the label.

25 JUSTICE KENNEDY: Does the failure to give

1 that notice subject the manufacturer to liability if the
2 manufacturer continues to sell the device?

3 MR. KNEEDLER: It would not subject it to
4 State tort liability, no. If there was -- if there was
5 a situation where the manufacturer knew of a serious
6 problem and did not report it to it FDA, that could
7 subject the manufacturer to criminal penalties with
8 respect to FDA for either misrepresenting or withholding
9 information. But that's really the Buckman -- this
10 Court's Buckman decision, that that's the relationship
11 between FDA and the manufacturer, and that's the
12 incentive.

13 I think someone asked about what incentive
14 does the manufacturer have. The manufacturer has a
15 powerful incentive because of the criminal penalties and
16 other sanctions that can be taken by FDA if -- if the
17 manufacturer does not report something to the FDA.
18 Plus, manufacturers have an important reputational
19 interest, that they don't want to be seen to be flouting
20 possible problems.

21 JUSTICE SOUTER: Mr. Kneedler, let me ask
22 you to -- a textual question which perhaps would be
23 better directed to counsel for the Petitioner, but let
24 me get your take on it.

25 If the only objective in the -- in the

1 preemption clause were to preclude State PMA in addition
2 to Federal PMA, there would have been no reason to
3 include the phrase -- would there have been any reason
4 to include a preclusion of a requirement that is
5 different from, in addition to a preclusion of something
6 which is in addition to?

7 MR. KNEEDLER: I -- if it was just -- I
8 think that's a good point. If it was just a question of
9 going through a duplicative State PMA process --

10 JUSTICE SOUTER: "Addition to" would be --

11 MR. KNEEDLER: Right. Right. Right.

12 JUSTICE SOUTER: Okay.

13 MR. KNEEDLER: And also I think the FDA
14 regulations promulgated when this was put out, soon
15 after the '76 amendments were passed, I think reinforced
16 the conclusion that -- and, in fact, there was a
17 regulation that specifically talks about the application
18 of general adulteration standards in a way that might
19 require a specific label change to be made by a
20 manufacturer, and we think that's basically precisely
21 this lawsuit. It's the application of general tort law
22 that would require the manufacturer or a standard of
23 care under common law that would say that what the
24 manufacturer had done specifically approved by FDA was
25 -- was improper as a matter of State law. We think that

1 that is in the teeth of the preemption provision. I
2 think Justice Alito asked the question about the issue
3 of whether FDA focused or didn't focus on a particular
4 aspect of the design. We don't think that a preemption
5 test can really realistically turn on that. That would
6 require extensive and intrusive inquiry into what FDA
7 had done. We think that the best way to look at this is
8 what the end product was; what was the application that
9 was finally approved and the labeling associated with
10 it, much like the filed rate doctrine. You look at what
11 was put before the agency and what was approved, not
12 what might have gone into -- into consideration.

13 CHIEF JUSTICE ROBERTS: Thank you,
14 Mr. Kneedler.

15 MR. KNEEDLER: Thank you.

16 CHIEF JUSTICE ROBERTS: Ms. Zieve, you have
17 4 minutes remaining.

18 REBUTTAL ARGUMENT OF ALLISON M. ZIEVE
19 ON BEHALF OF THE PETITIONER

20 MS. ZIEVE: First of all, it's not our
21 position, Justice Souter, that only State PMA's are
22 preempted. California had good manufacturing practice
23 requirements that were preempted to the extent they were
24 different from or in addition to the Federal
25 requirement.

1 Some States had hearing aid packaging
2 requirements. There was a State that had a requirement
3 about the strength of prescription glasses, lenses. So
4 it's -- it is broader than just --

5 JUSTICE SOUTER: And how do you draw the
6 line between those instances and the ones that you say
7 are not preempted?

8 MS. ZIEVE: Those were specific requirements
9 for devices, and they had counterparts --

10 JUSTICE SOUTER: They -- they were
11 requirements, in other words, of positive law? They
12 were State regulations?

13 MS. ZIEVE: Addressed specifically to
14 devices, and they had --

15 JUSTICE SOUTER: So the --

16 MS. ZIEVE: -- direct Federal counterparts.

17 JUSTICE SOUTER: Okay. So the line is
18 simply enactment of positive law versus jury award?
19 That's the line?

20 MS. ZIEVE: I think that's what Congress was
21 intending.

22 JUSTICE SOUTER: No, I just want to make
23 sure --

24 MS. ZIEVE: I think under --

25 JUSTICE SOUTER: -- what your position is.

1 That is where you draw the line then?

2 MS. ZIEVE: Yes.

3 JUSTICE SOUTER: Okay.

4 MS. ZIEVE: I'd also like to --

5 CHIEF JUSTICE ROBERTS: Didn't the Court --
6 didn't a majority of the Court reject that line in
7 Lohr?

8 MS. ZIEVE: The holding of Lohr didn't
9 reject it. Five justices disagreed with me, and I don't
10 think you need to agree with me on that point to find
11 for me here. We talked about some examples that Justice
12 Ginsburg offered, in which a State common-law duty could
13 become so specific that it effectively imposed a State
14 device requirement.

15 I also want to correct the point that
16 manufacturers can't make labeling changes without FDA
17 approval. Again, 814.39(d) allows them to do so. And
18 so the catheter's label, where it says "inflate the
19 balloon gradually to higher pressure up to the rated
20 burst pressure or until the stenosis resolves," the
21 narrowing resolves, to me that's ambiguous as to whether
22 you can go above the rated burst pressure. Medtronic
23 could have clarified that instruction without running
24 afoul of any FDA regulation.

25 As for the FDA's current views, it is not

1 actually correct that in Lohr the government gave weight
2 to the FDA's amicus brief. The government gave weight
3 to the FDA's regulation, 808.1(d). That regulation is
4 still in effect, and it hasn't been modified since --
5 since Lohr was issued.

6 JUSTICE KENNEDY: What do I read in order to
7 verify your statement that the -- that manufacturers can
8 cure the label without FDA approval? Where do I find
9 that?

10 MS. ZIEVE: Without prior approval?

11 JUSTICE KENNEDY: Yes.

12 MS. ZIEVE: 814.39(d).

13 JUSTICE KENNEDY: Thank you.

14 MS. ZIEVE: After FDA approves a PMA, any
15 of the listed changes can be placed into effect prior to
16 the receipt of a written FDA order approving the PMA
17 supplement.

18 CHIEF JUSTICE ROBERTS: If I could -- I'm
19 sorry -- I've been thinking about your example of
20 ambiguity. You're saying it is ambiguous when they say
21 you can inflate it up to the bursting pressure or until
22 the blockage is cleared?

23 MS. ZIEVE: Stenosis resolves. Right.

24 CHIEF JUSTICE ROBERTS: Well, isn't that
25 obviously mean if the blockage is cleared, you don't keep

1 inflating it to the bursting pressure. You think that
2 doctors read that as saying you can inflate it past the
3 bursting pressure unless -- if the blockage isn't
4 cleared?

5 MS. ZIEVE: Yes. It says either one. It
6 doesn't say up to a maximum. There is testimony from
7 the doctor in this case that he thought that the label
8 showed testing up to 13. And that based on the
9 directions, he thought that going up to 10 was fine and
10 that it was standard use among the cardiologists.

11 CHIEF JUSTICE ROBERTS: Even though the
12 label said eight is the bursting pressure?

13 MS. ZIEVE: The rated burst pressure,
14 yeah.

15 CHIEF JUSTICE ROBERTS: Okay.

16 MS. ZIEVE: I also want to mention -- we
17 don't come to this case on a blank slate. We come to it
18 in light of Lohr. The Court has already interpreted
19 Section 360k(a). In finding no preemption in Lohr of
20 any of the claims, the Court looked to the labeling
21 regulation, 808.109, that was applicable to the device there.
22 That is the same exact regulation that is applicable to
23 the device here.

24 If Medtronic's PMA device complies with
25 808.109, then it is deemed not to be misbranded, but

1 that is a moving target. What is adequate instructions
2 for use changes as the manufacturer learns about use of
3 its product in the real world. The same process for
4 making design changes exists in this case as existed in
5 Lohr.

6 And on the State law side, we really are
7 talking about identical State duties of care, which this
8 Court said their generality -- the majority held that the
9 generality of these duties left them outside the
10 category of requirements that 360k envisioned to be with
11 respect to the devices.

12 Thank you.

13 CHIEF JUSTICE ROBERTS: Thank you,
14 Ms. Zieve.

15 The case is submitted.

16 (Whereupon, at 11:11 a.m., the case in the
17 above-entitled matter was submitted.)

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A	<p>ago 39:21 agree 33:22,24 38:6 39:13 52:10 agrees 43:17 Agrosciences 7:18 ahead 43:8,8 aid 14:7 16:24 51:1 air 34:19 airbags 34:13 alert 4:17 Alito 30:13,17 32:2,7 50:2 allergic 27:3 ALLISON 1:17 2:3,11 3:7 50:18 allow 14:21 29:5 42:9 allowed 17:11 allows 52:17 Alright 6:24 alter 22:19 ambiguity 53:20 ambiguous 52:21 53:20 amendment 45:6 amendments 3:12 10:13 45:11 49:15 amicus 1:23 2:8 41:18 53:2 amount 26:23 analysis 7:17,18 34:12,17 annual 4:18,24 37:21 38:21,24 46:15 anomalous 26:20 answer 5:13 14:20 20:9 29:14 30:17 40:16</p>	<p>answers 36:2 anticipate 9:3 anticipated 29:17 appeals 30:23 33:25 38:10 45:25 APPEARAN... 1:16 appendix 17:19 30:23 applicable 54:21 54:22 application 3:24 26:7 30:18 41:24 42:21 49:17,21 50:8 applies 44:10 apply 25:10 29:23 47:5 approval 3:15 3:16,20 4:20 5:15 9:2 11:6,8 16:14 18:1 22:22 25:21,24 26:5 33:3,5,12 35:19 36:9 40:18 41:24 42:2 43:13,14 45:20 46:5 52:17 53:8,10 approved 6:3 18:1,10,12,21 19:5,17,18 31:5 34:6 40:13,21,22,25 42:7 44:24 46:10 49:24 50:9,11 approves 4:8 53:14 approving 53:16 arduous 44:9 argued 8:6 arguing 17:9 argument 1:14 2:2,10 3:3,7</p>	<p>8:9 24:16 25:19,25 35:18 41:16,23 50:18 arose 10:15 articulate 23:25 articulated 34:12 asked 13:4 23:2 40:15 48:13 50:2 asking 15:18 28:9 aspect 30:4 32:11 33:12 34:10 40:12 44:20 50:4 assert 23:16 associated 46:21 50:9 assume 28:2 assurance 4:6 atmospheres 22:9 30:25 31:1 atmospheric 30:25 authority 46:6 automobiles 44:19 availability 24:24 26:12 30:12 available 30:6 30:19 35:11 41:9 await 5:25 award 51:18 A-174 30:23 a.m 1:15 3:2 55:16</p>	<p>badly 21:4 bag 34:19 balance 24:12 24:22 26:11 46:7 balances 31:25 balancing 37:9 38:13,17 46:6 balloon 21:6,9 21:16,18 22:6 27:4 32:21 52:19 based 3:24 13:6 54:8 basically 14:6 49:20 basing 21:18 basis 12:1,5 14:12 19:4 40:16 Bates 7:8,18 bear 39:25 behalf 1:17,19 1:22 2:4,6,8,12 3:8 24:17 41:17 50:19 believe 38:3 benefits 6:15 7:2 8:14 46:6 best 4:4 30:6 41:10 42:19 50:7 better 4:3 17:9 17:24 18:11,13 24:1 35:22 36:3,23 37:3,5 37:18 48:23 beyond 11:22,22 bill 24:11 bit 34:20 blanche 35:24 blank 54:17 blockage 53:22 53:25 54:3 blueprints 44:16 body 40:14 bold 25:10</p>
		B		
		<p>B 1:19 2:5 24:16 back 4:19 backup 33:4 backward 23:12 bad 23:16</p>		

bothering 23:22	24:21 25:16	CHARLES 1:5	34:10,23 41:3	concrete 13:3
Breyer 20:6,19	26:15 27:19	chart 22:8,16	43:3	44:15
20:24 21:8,13	28:18 29:8	Chicken 39:12	cleared 43:16	concurring
21:17 23:2	30:14 32:9,17	Chief 3:3,9 4:16	53:22,25 54:4	26:15
26:14 40:14	33:17 34:11,13	17:5,14,17,20	client 23:10	conducted 19:15
43:7	34:14,15 37:15	18:9,19 19:2	clinical 37:22	38:2
Breyer's 14:7	37:18 38:15	22:11 24:14,18	closely 8:24,24	conflict 11:13,18
16:24 32:8	39:16,25,25	26:25 33:22	coexisted 18:17	11:19 12:1,3,6
brief 26:1 30:7	40:10 46:3	37:19 38:23	colleague 31:9	12:6,16 33:5
37:20 38:11,14	54:7,17 55:4	41:12,13,20	come 4:14 22:15	34:14 42:6,13
38:17 45:19,24	55:15,16	50:13,16 52:5	26:9 42:15	42:16,19
53:2	cases 24:3,5,6	53:18,24 54:11	45:8 54:17,17	conflicting 25:4
briefs 40:10	26:22	54:15 55:13	comes 7:15	42:24 43:8
broader 51:4	category 33:2	child 30:9	17:22 26:16	confusing 25:5
brought 33:1,16	35:10 55:10	choice 29:4	32:16 39:4	Congress 10:18
39:25	catheter 17:8	32:14	coming 10:13	12:11 20:2
Buckman 48:9	20:12,13,14,18	choices 4:11	commerce 44:15	23:18 24:7,22
48:10	20:22 21:3	choose 4:10	committing 29:1	25:17 26:20
burdensome	27:2	chooses 3:23	common 9:7	28:24 32:15
25:5	catheter's 52:18	choosing 3:23	16:7 49:23	36:18 41:3,11
burst 21:11,14	cause 37:2	chosen 4:9	common-law	42:7 43:3,22
22:7 30:21,24	caused 3:14	circuit 33:20	52:12	44:22 45:1,2
52:20,22 54:13	central 24:20	39:18	company 3:23	51:20
bursting 53:21	centralized	circuits 39:15	4:5 13:13 14:4	conscientious
54:1,3,12	28:13 35:14	circumstances	18:7	37:14
business 43:18	38:18	26:19 36:12,13	compare 8:23	consciously
	certain 34:25	citation 22:24	compared 44:7	32:15
	certainly 9:11	39:3	compares 8:20	consent 22:19
	CFR 23:1	Citizens 27:10	comparing 7:16	consequences
	chance 23:5	civil 29:2	comparison 4:1	27:9 37:12
	change 5:13,14	claim 13:12	compliance 9:8	39:6 41:23
	5:15,23 8:6	20:11 21:19,20	9:12	43:24
	13:22 14:1,2	21:22 22:3	complies 54:24	consider 6:19
	14:22 15:5,7	23:16 24:2	comply 11:16,17	10:4 37:12
	15:22 17:15	28:21 33:18	33:14 42:25	considerable
	27:23 31:18	claims 3:13	complying	38:9 46:4
	35:24,25 45:15	13:11 14:9,15	12:15	consideration
	49:19	17:2 54:20	concede 44:8	35:14 50:12
	changed 41:8	clarified 52:23	conceded 42:13	considered 5:22
	43:15,15 47:7	clarify 22:21	concedes 43:11	30:14 31:19
	changes 5:14,15	38:19 46:17	conceptualize	32:5 39:16
	22:21 52:16	47:7	42:20	considering
	53:15 55:2,4	Class 3:21 35:9	concerned 15:6	35:3
	characteristic	clause 43:20	43:22,23	context 7:15
	44:18	44:11,13 45:14	concluded 32:3	42:19
	charge 16:16	49:1	conclusion 34:1	continue 10:20
	charged 7:1	clear 10:18 24:3	49:16	27:13 28:5

<p>35:25 46:14 47:9 continues 48:2 continuous 27:7 27:11 continuously 27:24 contradict 11:6 11:8 contrary 39:21 convince 16:3 correct 34:7 43:6,13 52:15 53:1 correctly 40:6 Cosmetic 3:13 9:22 counsel 21:2 24:14 48:23 counter 31:6 counterindica... 31:7 counterpart 12:9 16:8 20:4 41:2 counterparts 8:21 51:9,16 country 35:6 course 19:13 23:6,24 31:11 36:4 39:20 court 1:1,14 3:10 5:22 7:7 15:23 16:21 21:1 24:19 26:16 30:23 33:25 34:1,11 34:12,17,23,24 38:10,14,15 41:21 45:25 46:3 52:5,6 54:18,20 55:8 court's 16:19 48:10 criminal 29:2 48:7,15 critically 36:14</p>	<p>36:15 cure 53:8 curiae 1:23 2:9 41:18 current 52:25 cut 25:20</p> <hr/> <p style="text-align: center;">D</p> <hr/> <p>D 3:1 Dalkon 24:8 damages 3:14 40:24 dangerous 16:17 46:13 data 36:22 37:22 day 40:22 42:1 dealt 27:1 Dear 47:19 December 1:11 decide 14:12 23:20 36:17 decided 10:19 19:16,20 26:11 34:20 decides 34:24 decision 3:16 6:10 14:13 24:22 35:16 38:10 48:10 decisions 37:9 deemed 54:25 defect 20:10 22:1 24:4,6,11 defectively 20:15 defects 30:14 defense 9:4,8,13 15:11,13 deference 46:4 definitely 43:2 definition 41:8 degree 39:17 degrees 45:17 Department 1:22 34:19 35:2 dependent</p>	<p>28:11 Depending 5:12 Deputy 1:21 described 38:9 39:24 describes 38:11 38:16 deserves 36:16 design 3:22 4:9 5:1,13,15 8:1,6 13:14 16:8 17:4,9,11 19:3 20:10,18,22,24 21:4,5,14,15 21:18,19,20,22 22:1 23:14,16 24:1,2,4,6,11 26:8 30:14 31:11,12,15 32:4,12 33:7 33:12 34:5 40:20 42:5 44:16,20 50:4 55:4 designed 3:17 5:18 20:15 21:4,11 40:18 44:6 despite 15:10,10 detail 30:20 38:9 38:16 detailed 26:6 40:11 details 20:12 determination 8:13 14:23 determined 41:9 determines 6:19 determining 40:7 developed 21:21 development 4:1 develops 3:22 device 3:12,14 3:17,21,22 4:8 4:12,14,25</p>	<p>5:21,21 6:8,18 7:23 8:4,19 10:13 13:14 14:19 16:6,13 16:16 17:24,25 18:2,4,6,10,12 18:25 19:7,20 19:23 20:4 21:23 27:13 29:7 30:5,10 30:21,22 32:13 32:19 35:20 36:8,9,10,12 37:24 39:6 40:12 41:6 42:2 43:15 44:14 45:14 46:21,22 47:9 48:2 52:14 54:21,23,24 devices 5:23 6:1 8:25 9:20 10:5 10:7,20,21 11:1,12 12:7 12:18 18:16,24 24:24,24 25:10 30:8 31:13 32:1 35:6,9,11 38:9 44:24 45:10 46:15 51:9,14 55:11 dialogue 31:19 die 30:9 difference 9:24 25:15 different 5:13 5:21 7:11,14 12:24 13:2 15:14 20:7 21:9,10,12 25:14 26:9,13 26:17,18,18,18 32:20 34:21 38:4 40:14,23 41:4 44:2,25 45:2,17 49:5 50:24</p>	<p>differently 9:20 20:2 37:16 44:3,6 difficult 46:20 dilemma 10:19 32:22 direct 42:4 51:16 directed 48:23 directions 54:9 directly 12:23 disagreed 52:9 disaster 24:9 disclose 37:22 discourage 35:8 discovered 27:1 27:13 28:20 discovery 20:17 23:17 discussed 10:12 disincentive 35:23 dismissed 33:18 34:2 dispositive 9:9 dissenting 26:15 district 34:1 doctor 47:19 54:7 doctors 27:9 36:15,22 38:8 46:12,12 47:10 54:2 doctrine 50:10 doing 7:5 10:25 27:24 33:4 DONNA 1:3 Dow 7:18 drafting 10:13 draw 51:5 52:1 drawn 20:2 drew 20:2 drive 22:14 drug 3:13 9:2,22 11:5,23 25:18 32:1 44:17 45:5</p>
--	--	--	---	---

drugs 8:25,25 9:19,20,23 10:5,6,24 11:12 12:1 25:8,10 44:7,9	encourage 35:4 enhances 13:6 enters 6:8 entirely 43:5 entitled 46:4 envisioned 55:10 equivalent 8:4 especially 44:23 ESQ 1:17,19,21 2:3,5,7,11 essential 25:6,8 ESTATE 1:5 evaluates 3:24 event 4:23 47:4 47:16	expertise 25:2 29:6 experts 23:20 25:2 36:5 explain 27:19 40:17 explanation 40:1,5 44:14 44:22 explicitly 41:3 express 9:21,25 10:3,23 11:9 34:15 42:8,17 44:13 extensive 44:16 50:6 extent 50:23 extraordinary 19:25	18:1,13 19:5 19:17,18,23 25:3 26:11,25 27:3,10,21,21 28:2,3,8,21,25 29:18,18,19 30:20 31:5,14 31:20,21 32:4 32:10,24 34:6 36:5,6,11,24 37:8 39:7,20 39:24 40:13,19 40:25 41:9 42:2,6,16,22 43:11 45:10,22 46:4,8,20 47:11,16 48:6 48:8,11,16,17 49:13,24 50:3 50:6 52:16,24 53:8,14,16	filing 8:7 fill 10:9 filled 10:22 finally 50:9 find 19:25 52:10 53:8 finder 6:14 finding 54:19 finds 36:20 fine 54:9 firm 44:23 first 3:4 5:3,4 17:3 18:5 39:14 50:20 Five 52:9 fix 16:24 flaws 27:1 flouting 48:19 focus 24:20 26:24 50:3 focused 50:3 focusing 41:23 follow 8:11 33:6 33:7 followed 9:5 Food 3:12 9:22 11:5 forever 18:2 form 46:10 found 37:3 39:16 fraud 29:1 free 22:18 27:12 freely 23:24 fundamental 25:16 40:15 further 5:11,16 11:17
<hr/> E <hr/>		<hr/> F <hr/>	FDA's 3:21 14:21 16:18 22:19 27:16 28:10 31:10 33:5 40:1 45:16,21 46:2 46:5 52:25 53:2,3 feature 17:4 features 32:4 Federal 7:9,16 7:22 8:19 9:8 9:13 10:22 11:1,6,8 12:9 12:15 15:3,19 16:1,9,24 20:3 25:22 26:6 41:2,4 49:2 50:24 51:16 federally 44:24 field 12:20 42:20 figure 10:3 file 4:18 32:2 filed 38:13,17 40:10 45:18 50:10	
due 46:1 duplicative 49:9 duties 55:7,9 duty 13:13 16:7 16:25 28:10 52:12 D.C 1:10,17,19 1:22	event 4:23 47:4 47:16 Everybody 43:17 evidence 33:20 34:3 exact 39:3 54:22 exactly 6:25 17:13 32:4 examine 32:7 examined 32:10 examines 31:14 examining 32:17 46:1 example 10:11 14:7 21:23 32:8,9 53:19 examples 52:11 exchange 38:7 exist 20:5 28:16 existed 55:4 existing 4:3 exists 55:4 expect 45:7 expected 40:23 expedited 7:11 expensive 37:5 experience 39:23,23 40:6 experiments 36:21 expert 19:14 35:14	face 28:5 faced 10:18 fact 6:14 13:18 13:20,23 39:10 40:11,17 49:16 factors 35:15 facts 32:18 failed 13:13 failing 28:25 fails 33:14 failure 13:7 47:25 far 15:6 43:18 fast 22:14 FDA 3:16,24 4:7 4:8,18,19,24 5:5,5,11,14,17 6:4,25 7:1,6,13 7:19 8:8,12,15 8:23 9:1,6 10:6 10:21 11:22 12:23,25 13:4 13:5,7,15,22 14:17,20,24 15:10,19,23 16:1,5,13,20		
E 2:1 3:1,1 earlier 40:10 easy 11:18 EDWIN 1:21 2:7 41:16 effect 5:24 19:10 40:7 45:20,22 53:4,15 effective 6:3 7:24 18:6 31:22 35:7 effectively 52:13 effectiveness 4:7 5:16,19,24 8:4 24:23 26:12 30:5 41:6 effects 39:6 effort 40:17 eight 22:7 54:12 either 6:12 22:17 41:8 42:14 48:8 54:5 elaborate 30:20 31:4 38:6 43:6 43:8,10 eliminated 16:22 embodies 42:18 enacting 42:8 enactment 51:18				<hr/> G <hr/>
				G 3:1 gear 23:17 gee 37:16 Geier 34:12 general 1:21 17:3 20:21 45:10 49:18,21

<p>generality 55:8 55:9</p> <p>generally 6:12 15:15</p> <p>gentlemen 14:3</p> <p>getting 7:17</p> <p>Ginsburg 8:22 9:11,17,24 13:1,3 14:16 15:17,18,22 16:10,12 21:24 25:7,14,19 32:23 34:4,8 35:17 42:12 43:17 44:4,7 45:13 52:12</p> <p>give 14:23 16:14 39:2 42:6 46:19 47:25</p> <p>given 26:21 27:8 39:7</p> <p>gives 9:1</p> <p>glasses 51:3</p> <p>go 8:25 11:17,22 14:17 15:10,24 20:25 35:23 36:4 43:8,8,25 44:8 52:22</p> <p>goes 8:17 13:23 22:12 30:20</p> <p>going 11:2 13:21 13:23 15:24 17:21,25 18:7 19:19 24:2 28:3 29:1 31:16 43:9 47:2 49:9 54:9</p> <p>good 4:2 10:16 32:9 40:19 46:12 47:10 49:8 50:22</p> <p>government 10:25 11:1 16:25 30:7 38:13 45:15,15 45:18,23 53:1 53:2</p>	<p>government's 37:20 38:11 40:2,9 45:16</p> <p>grace 15:4</p> <p>gradually 52:19</p> <p>grandfathered 6:2 8:5</p> <p>grants 4:7</p> <p>greater 38:16</p> <p>ground 8:15</p> <p>group 23:20</p> <hr/> <p style="text-align: center;">H</p> <hr/> <p>happen 17:21 35:1</p> <p>happens 17:21 18:3 23:16</p> <p>hard 14:15</p> <p>hazardous 6:22</p> <p>hazards 4:13 31:6</p> <p>health 6:16 47:13</p> <p>hear 3:3</p> <p>hearing 14:7 16:24 38:15 51:1</p> <p>held 55:8</p> <p>help 4:24 21:22 23:8</p> <p>helped 20:10</p> <p>helpful 20:8</p> <p>hiatus 29:12,21 29:22</p> <p>higher 30:24 52:19</p> <p>history 10:12,18</p> <p>hoc 26:21 37:10</p> <p>hold 14:3</p> <p>holding 52:8</p> <p>Horn 21:22</p> <p>horribles 39:9</p> <p>hour 22:13</p> <p>hours 29:6</p> <p>hundred 31:24</p> <p>hurt 23:7,10,13 24:9</p>	<p>hypothetical 32:24 47:1</p> <hr/> <p style="text-align: center;">I</p> <hr/> <p>identical 55:7</p> <p>III 3:21</p> <p>ill 32:17 36:14 36:15</p> <p>illness 6:15</p> <p>illustrates 37:7</p> <p>illustrative 34:16</p> <p>impetus 24:11</p> <p>implied 34:14</p> <p>importance 38:18</p> <p>important 6:18 27:19 31:23 42:18 43:21 48:18</p> <p>impose 12:24 16:7 40:14 43:12 44:2</p> <p>imposed 6:7 19:11,12 52:13</p> <p>imposing 31:10 44:23</p> <p>impression 23:4</p> <p>improper 49:25</p> <p>improve 5:1,19</p> <p>improvement 5:9,10 13:5,7,8</p> <p>inadequately 22:4</p> <p>incentive 35:20 48:12,13,15</p> <p>incentives 37:2</p> <p>incident 46:18</p> <p>include 16:13 49:3,4</p> <p>included 42:21</p> <p>includes 37:25</p> <p>Incorporated 3:5</p> <p>incorporates 12:2 33:12</p> <p>incorrect 3:19</p>	<p>independent 3:25</p> <p>indications 31:5</p> <p>individual 26:21 30:11 37:10 42:10</p> <p>INDIVIDUA... 1:3</p> <p>individuals 34:22</p> <p>infant 32:17</p> <p>inflate 22:6,10 52:18 53:21 54:2</p> <p>inflated 30:24 31:1</p> <p>inflating 54:1</p> <p>inflation 22:8</p> <p>information 3:25 4:5,18 5:6 27:8,10,17,20 28:12,15 30:3 38:7,21 39:4 48:9</p> <p>initiate 5:2</p> <p>injured 24:10</p> <p>injuries 3:14</p> <p>injury 6:15 16:2 29:21 46:21</p> <p>innovation 35:4</p> <p>inquiring 15:17</p> <p>inquiry 19:16 50:6</p> <p>insistence 16:18</p> <p>instance 5:3 18:18</p> <p>instances 51:6</p> <p>instruction 52:23</p> <p>instructions 22:9,17,22 55:1</p> <p>intended 4:24 23:18 24:7 25:20 42:8</p> <p>intending 51:21</p> <p>interest 48:19</p>	<p>interests 41:10</p> <p>interpreted 54:18</p> <p>intervening 10:8</p> <p>intrusive 50:6</p> <p>investigations 37:23</p> <p>invoke 6:13</p> <p>involve 26:6</p> <p>involved 27:24 40:9</p> <p>involving 37:24</p> <p>irrelevant 9:15</p> <p>issuance 8:14 45:21</p> <p>issue 11:5,7,21 19:17 23:5 25:16 50:2</p> <p>issued 45:21 53:5</p> <p>issuing 43:19</p> <p>item 44:15,15</p> <hr/> <p style="text-align: center;">J</p> <hr/> <p>January 38:16</p> <p>job 32:11</p> <p>joint 17:18</p> <p>judgment 19:20 19:21 25:2 28:23 29:8 30:2 31:8 32:15 33:19 34:2 35:2 36:7 36:19 37:15 40:6 46:3,20</p> <p>judgments 30:11 37:6,13</p> <p>juries 26:21 41:7 42:10</p> <p>jurisdiction 27:11</p> <p>jury 6:13,17,19 7:5 8:15 13:17 13:23 14:3,11 14:13,17,23 15:10,24 16:3 16:21 19:19,22</p>
---	--	---	---	---

26:16 32:16 37:11,14 40:13 40:22 42:15 46:7 51:18 Justice 1:22 3:3 3:9 4:16 5:8,18 6:1,10,24 7:5 7:10,21 8:2,10 8:11,22 9:11 9:17,24 11:4 11:11,15,21 12:5,12,20 13:1,2,3,16,20 13:25 14:7,8 14:10,16 15:1 15:2,9,16,17 15:18,22 16:10 16:12,23 17:5 17:14,17,20 18:9,19 19:2 19:13 20:6,19 20:24 21:8,13 21:17,24 22:11 22:18,24 23:2 24:14,18,21 25:7,14,19 26:14,22,25 27:12,16,18 28:1,9,14,17 28:19 29:4,11 29:12,25 30:1 30:13,17 32:2 32:7,7,23 33:22 34:4,7 35:17 36:20 37:1,19 38:5 38:19,23,25 39:8,14,20 40:14 41:12,13 41:20 42:12,23 43:3,7,17 44:4 44:7,25 45:3,7 45:13 46:9,24 47:1,8,15,25 48:21 49:10,12 50:2,13,16,21 51:5,10,15,17	51:22,25 52:3 52:5,11 53:6 53:11,13,18,24 54:11,15 55:13 justices 52:9 justify 36:5 <hr/> K Kansas 34:24 keep 53:25 Kennedy 6:10 6:24 7:5,10 22:18,24 26:22 27:12,16,18 28:1,9 36:20 37:1 46:9,24 47:1,8,15,25 53:6,11,13 Kennedy's 8:11 24:21 26:1 29:12 38:5 key 24:20 killed 24:10 kind 21:2 23:19 32:24,25 33:4 39:12 kinds 23:7 37:6 Kneedler 1:21 2:7 41:15,16 41:20 42:17 43:1,5,9,21 44:5,12 45:2,5 45:9,18 46:16 46:25 47:2,12 47:16 48:3,21 49:7,11,13 50:14,15 knew 28:21 48:5 know 13:25 18:8 18:15 20:19 21:15,17 22:1 25:25 28:1,3 30:13,16,18 35:22 39:9,15 knowing 20:10 47:9 knowledge 28:5	knows 28:4 <hr/> L label 21:24 22:2 22:4,19,23 30:22 31:2,4 40:21 46:9,15 47:10,24 49:19 52:18 53:8 54:7,12 labeled 3:17 31:16 labeling 4:9 5:2 5:13,14 22:3 32:12 33:6 34:5 42:6,22 43:15 44:3 47:3,6 50:9 52:16 54:20 labels 26:8 laboratory 36:21 37:23 38:1 ladies 14:3 language 12:11 large 46:1 late 45:19 law 6:11,12 7:4 7:8,9,24 9:7,8 9:13 15:2,6,8 15:12,12,13,19 16:1,7,25 19:12 25:5 28:25 49:21,23 49:25 51:11,18 55:6 laws 42:4 lawsuit 16:15 49:21 lawyer 16:2 lawyers 23:8,9 23:16 lead 44:20 learn 5:4 learned 29:16 30:3 39:23 learns 55:2	leave 23:3,4 29:19 leaves 29:12 left 55:9 legislative 10:12 10:18 legislatures 42:3 lenses 51:3 letter 9:5 47:19 letters 25:10 let's 18:3 25:24 28:2 level 6:6 liability 24:8 48:1,4 liable 14:4 40:24 lifesaving 24:23 24:24 life-saving 35:11 life-threatening 35:10 light 4:14 54:18 line 20:2,2 51:6 51:17,19 52:1 52:6 listed 53:15 lists 22:5 litigated 17:3 litigation 16:19 little 17:6 19:14 20:7 31:14 34:20 39:12 lives 35:9 Lohr 5:22 7:8 8:1,12,16 14:7 26:15 29:7 32:9 34:11 39:25 46:3 52:7,8 53:1,5 54:18,19 55:5 Lohr's 7:17 long 9:1 11:1 12:13,14,16 44:20 longer 25:11 40:4 look 14:11 17:18	23:9,20 27:3 32:2 50:7,10 looked 20:4 54:20 looking 37:20 looks 8:18,20,24 17:23 19:8 lose 24:2 lot 20:17 39:3 <hr/> M M 1:17 2:3,11 3:7 50:18 majority 52:6 55:8 making 35:25 55:4 manufacture 26:8 32:12 42:5 44:21 manufactured 3:18 31:15 34:25 manufacturer 3:22 4:9,10,17 5:3,4,6,8 6:7 9:5 16:15 17:10,23 19:1 19:6,22 24:8 27:8,12,22 28:4,12,15,24 29:15,17 30:3 31:11,12,20 32:22 33:2,14 33:18 34:5 36:20 37:21 38:1,7 39:5 42:5 43:15,24 46:14,19 47:5 47:9,18 48:1,2 48:5,7,11,14 48:14,17 49:20 49:22,24 55:2 manufacturers 18:16 25:23 34:18 36:2 39:10 48:18
--	---	--	--	--

<p>52:16 53:7 manufacturer's 18:11 28:10 manufacturing 10:16 50:22 market 3:21 4:12,25 5:10 6:9 7:14,24 16:5,7 17:7,10 18:12,17,21,22 19:7 29:9 35:21 39:11 marketed 9:2 23:21 31:16 marketing 18:7 29:22 32:12 35:8 marketplace 34:21 36:15 37:1,3,4,12 material 20:13 21:8,9 matter 1:13 15:19 17:3 19:9 49:25 55:17 matters 11:23 maximum 54:6 mean 7:22 10:1 11:4,15 13:18 19:6 21:4,13 21:25 22:12,13 27:2 43:20 44:18 46:16 53:25 means 10:3 meant 20:9 26:2 measured 6:25 medical 3:12 9:20 10:13 11:12 12:7,17 38:9 45:14 Medtronic 1:8 3:4 8:5 21:16 22:18,20 52:22 Medtronic's 3:15 54:24</p>	<p>meets 4:6 mention 54:16 mentioned 33:1 merits 9:9,13 miles 22:13,16 mind 21:1 23:4 23:18 minutes 50:17 mirroring 7:4 mirrors 7:8 misbranded 54:25 misconstruction 47:23 misconstrued 47:10 misleading 22:4 47:4 misrepresenta... 47:23 misrepresenting 48:8 modified 53:4 monitor 4:24 months 28:3 45:23 morning 3:4 mortality 30:9 moving 55:1</p> <hr/> <p style="text-align: center;">N</p> <p>N 2:1,1 3:1 nail 32:19 narrowing 52:21 nature 31:4 necessarily 42:24 necessary 11:2 28:8 need 10:23 52:10 negligence 19:5 negligent 17:10 18:11,20 19:17 33:17 negligently 6:20</p>	<p>never 8:12 28:21 nevertheless 28:16,21 new 4:18 5:25 5:25 6:21 8:24 8:25,25 9:19 9:20,20 15:4,5 15:9,11,13 18:2 25:8,9,10 25:18 44:9 45:5,14 46:14 newly 27:1,13 28:20 nominal 22:10 nonclinical 37:23,25 notable 10:11 notice 48:1 notification 47:19,21 notify 36:24 notwithstandi... 31:1 nuanced 17:6</p> <hr/> <p style="text-align: center;">O</p> <p>O 2:1 3:1 objective 48:25 obligation 36:24 obviously 53:25 occur 37:10 occurs 29:21 offered 52:12 okay 12:6 19:24 29:25 49:12 51:17 52:3 54:15 old 17:25 Olson 1:19 2:5 24:15,16,18 25:7,13 26:4 27:7,15,18 28:1,7,11,14 28:17,23 29:11 29:24 30:1,16 32:6 33:9,24 34:7 35:17</p>	<p>36:1,25 37:19 38:3,23 39:1,8 39:13,22 41:14 once 4:12 10:21 35:18 ones 51:6 one-inch 32:8,19 37:17 one-inch/two-i... 14:6 one-percent 6:18 open 29:19 opinion 26:15 29:7 39:24 opportunity 5:1 opposed 7:15 oral 1:13 2:2 3:7 24:16 41:16 order 14:19 53:6 53:16 Ordinarily 47:12 outside 55:9</p> <hr/> <p style="text-align: center;">P</p> <p>P 3:1 packaging 51:1 page 2:2 37:20 pages 38:10 parallel 7:20 33:15 part 18:12 21:4 22:23 31:14,18 38:20 46:1 particular 3:17 3:18 17:8,11 29:7 32:16,17 32:17,18 37:17 37:18 42:2 50:3 passed 49:15 passive 5:5 patient 6:16 36:14,15 37:15 patients 17:22 18:3 36:16,22</p>	<p>penalties 29:2,2 29:2 48:7,15 pending 27:16 28:10 46:15 47:11 people 9:3 24:9 perfect 35:12 perfectly 31:23 31:25 period 9:1 permission 3:21 9:5 13:8 33:7 35:21 permitting 4:8 person 32:18 personal 16:2 pertinent 39:5 Petitioner 1:6 1:18 2:4,12 3:8 30:15 43:10 48:23 50:19 Petitioner's 41:23 42:1 phrase 49:3 physicians 47:21 place 22:5,7,9 29:22 34:24 35:15 37:8 39:14 placed 19:22 53:15 plaintiff 16:6 20:15 23:25 24:1 plaintiff's 14:18 planning 44:16 plastic 27:4 play 34:20 please 3:10 24:19 41:21 plowed 8:16 Plus 48:18 PMA 3:21,22 4:7,12 5:21 6:25 7:11,12 7:14 9:15</p>
--	---	--	---	--

10:17 18:17 19:11 21:23 30:13 32:3 41:24 42:2 43:11,12,13,23 43:25 44:1 45:19 46:10 47:6 49:1,2,9 53:14,16 54:24 PMA's 8:14 17:3 43:19 50:21 point 8:10,12 14:18 15:15,16 37:7 38:4,6 43:10 49:8 52:10,15 pointed 26:14 points 18:25 30:7 policy 19:9 posing 15:25 position 39:21 40:2,3 45:16 45:16,19 50:21 51:25 positive 51:11 51:18 possession 27:21 39:5 possibility 27:3 28:20 possible 44:13 47:3 48:20 possibly 35:7 potential 6:14 potentially 25:4 26:10 power 26:21 powerful 48:15 practice 50:22 practices 10:16 precautions 22:6 31:6 precisely 44:1 49:20 preclude 49:1	preclusion 49:4 49:5 preempt 3:13 preempted 9:18 33:25 39:17 41:5 50:22,23 51:7 preemption 7:9 8:8,18 9:16,22 9:25 10:3,24 11:9,14,20 12:1,2,3,10,20 15:3 20:5 25:4 25:15 26:2 28:16 29:23 34:14,14,15 42:8,13,18,20 43:19 44:10,11 44:13,23 45:14 49:1 50:1,4 54:19 preemptive 13:9 14:22 16:1 27:6 28:22 33:23 41:25 42:1 45:20 preempts 13:11 prescription 51:3 presented 26:1 pressing 21:25 pressure 22:7,10 30:25,25 52:19 52:20,22 53:21 54:1,3,12,13 pressures 30:21 presumably 26:10 32:10 37:25 prevent 12:15 previous 36:8,10 previously 47:22 pre-market 3:15 3:15,20 4:19 6:6 10:14 16:14 25:21,24	26:5 35:19 pre-marketing 33:3 pre-screen 10:21 principal 25:14 prior 5:14 22:22 53:10,15 probable 6:15 7:2 problem 23:9 26:17 27:5 28:4,6 29:16 46:22,22 47:22 48:6 problems 4:13 4:20 5:5 48:20 procedures 25:11 proceeding 32:3 process 3:16 6:8 6:25 8:23 26:5 26:6 27:7,9,25 30:14 35:23 36:5 37:9 38:7 38:18 40:8 43:23,25 44:2 44:9 49:9 55:3 processes 25:3 produce 36:3 product 4:1 5:10 6:22 7:14 8:7 18:21 24:5 29:9 30:6 35:21 36:16 42:5 44:5 47:21 50:8 55:3 products 4:2,3 35:8 36:3,3 39:11 41:7 professional 31:8 prohibitively 37:5 promptly 28:8 39:7	promulgated 49:14 proposed 15:22 40:3 45:22,23 protect 24:7 prove 4:12 provide 28:15 provided 47:20 providing 28:12 provision 9:22 10:1,3,24 11:9 25:15,17 26:2 42:1,9,18 50:1 public 24:25 41:10 pull 4:19 purposes 41:25 put 16:18,21 25:17,23 34:18 45:14 49:14 50:11 puts 16:15 putting 16:16 <hr/> Q <hr/> question 3:11 6:5,6 8:11 9:25 10:14 11:14 12:2,23 15:25 19:10 20:7 23:3 24:21 29:13,15,19 33:11 36:2 43:19 45:24 48:22 49:8 50:2 quite 24:3 25:14 26:20 32:15 38:11 40:6 44:17 <hr/> R <hr/> R 1:5 3:1 rate 30:9 50:10 rated 22:6 52:19 52:22 54:13 reached 6:11	reaches 7:14 reactions 27:3 read 44:3 53:6 54:2 reading 46:12 real 28:4,6 36:1 55:3 realistically 50:5 really 5:2 22:1 23:20 24:7 48:9 50:5 55:6 reason 9:17,19 10:5 30:1 47:4 49:2,3 reasonable 4:6 24:23 26:11 31:23 reasonableness 36:7 reasonably 18:6 18:25 19:3 31:22 reasoned 40:1,5 REBUTTAL 2:10 50:18 recall 5:2 27:22 29:2 recalled 24:6 receipt 53:16 received 3:14 36:22 receives 5:6 recognized 46:4 record 30:19,22 reduce 18:13 refer 20:12 referring 38:24 45:25 reflected 40:9 refusing 14:21 regarded 47:3 regulate 10:20 11:1 regulated 10:6,7 regulating 10:16 regulation 10:9
---	---	--	--	---

11:5 12:14 14:21 49:17 52:24 53:3,3 54:21,22 regulations 11:3 11:6,8,22 16:9 40:3 42:4 49:14 51:12 regulatory 10:10 40:14 42:3,9 reinforced 49:15 reject 52:6,9 rejected 13:15 13:22 rejecting 15:24 rejection 13:8 rejects 15:20 relationship 48:10 relevance 16:11 relying 30:15 remaining 50:17 render 40:23 replowing 8:15 report 4:24 27:9 27:10 46:15 48:6,17 reports 4:19,23 37:21,22 46:19 reputational 48:18 request 47:6 require 4:10,20 17:7 27:22 41:7 49:19,22 50:6 required 16:5 19:6 34:18 37:11 requirement 4:17,23 7:22 7:23 8:1,19,19 12:9,10,15 20:3,4 33:7 38:21,21,24	40:15,23 41:1 41:2,3,5 42:15 42:16 43:11,12 49:4 50:25 51:2 52:14 requirements 6:7 7:16,19,20 12:13,16,17,24 19:9,11,11 25:5 26:10,13 26:17,18 31:2 31:10 33:10,11 33:15 39:2 40:12 41:25 42:23,24 43:4 44:2 50:23 51:2,8,11 55:10 requires 15:3 requiring 43:24 reserve 24:12 resolves 52:20 52:21 53:23 respect 5:22 9:18,23 12:1 20:11,13 29:8 30:11,21 32:11 34:10,21 35:4 38:8 39:4 40:12 44:24 48:8 55:11 respond 18:16 23:23 Respondent 1:20,24 2:6,9 24:17 41:19 response 14:16 responsibility 5:1 25:1 41:11 restraints 34:22 35:5 result 41:24 44:1 results 3:16 reweigh 46:7 Riegel 1:3,5 3:4 right 5:20 6:1,4	6:5 7:3,25 8:5 9:12 10:2 14:25 15:6 17:5,15,16 18:15 19:8 21:5,10 37:8 38:25 45:9 49:11,11,11 53:23 rigorous 7:19 risk 6:18 17:24 19:22 28:20 30:11 47:13 risks 6:14 7:1 8:13 9:3 18:14 27:14 32:4 36:8 46:6 ROBERTS 3:3 4:16 17:5,14 17:17,20 18:9 18:19 19:2 22:11 24:14 26:25 33:22 37:19 41:13 50:13,16 52:5 53:18,24 54:11 54:15 55:13 role 5:5 rule 11:17 45:22 45:23 running 52:23	13:6 24:23 26:11 30:4,12 31:5 41:5 47:14 sanctions 48:16 satisfied 31:21 save 35:9 saying 20:25 21:8 31:3 33:2 33:6 40:24 53:20 54:2 says 11:22 13:5 15:19 16:2,13 16:20,25,25 17:23 22:8,10 30:24 31:9 32:18,25 37:20 39:9 52:18 54:5 Scalia 5:8,18 6:1 7:21 8:2,10 11:4,11,15,21 12:5,12,20 13:2,16,20,25 14:8,10 15:2,9 15:16 19:13 39:8,14 42:23 43:3 44:25 45:3,7 scheme 10:17 25:6,8 scientific 19:15 scientifically 37:11 scientists 19:23 scrutiny 6:6 10:14 Second 33:19 Secondly 39:15 second-guess 14:23 section 3:11 25:16 54:19 sections 39:4 see 4:2 8:20 23:5 seeking 3:13 16:7	seen 48:19 sell 27:13 28:5 46:14 47:9 48:2 selling 17:25 19:23 Senator 26:1 sends 5:6 serious 27:5 46:5 47:13,15 48:5 seriously 20:9 23:10 seven 39:15 45:23 shape 20:14 Shield 24:9 showed 54:8 shows 22:8,16 side 39:8 55:6 significant 5:24 significantly 21:21 similar 25:13,17 simply 5:10 7:23 15:11 19:19 33:2,6 51:18 situation 4:16 13:3,11 15:5 16:1,4 29:5 32:18 37:17 48:5 situations 30:8 35:13,13 six 28:3 38:10 39:15 slate 54:17 slightly 38:4 slow 29:20 slowly 28:8 sold 4:8 6:20 Solicitor 1:21 somebody 23:7 29:17 soon 38:20 49:14 sorry 15:7 53:19
S				
		S 1:3,21 2:1,7 3:1 41:16 safe 6:3 13:21 14:1,19 18:6 18:24,25 19:3 20:22,25 22:16 31:22,23,25 35:7 36:6,13 41:8 safer 17:15 19:4 19:16,20 35:20 36:4,8,12,18 safety 4:7 5:16 5:19,24 8:4		

sort 29:3,12 31:7	2:8 9:8,10,10 10:8,16,24	suits 9:18 17:24 18:8,17 19:10	teeth 50:1	44:8,10 48:13
Souter 29:11,25 30:2 48:21	11:5,21 12:17 12:24 15:12	33:2 39:10,17 40:8	tell 20:16 23:2 28:25 32:3	49:8,13,15,20 49:25 50:2,4,7
49:10,12 50:21 51:5,10,15,17 51:22,25 52:3	25:21 26:18 41:17 42:14 43:18 51:1	summary 33:19 34:2	tensile 32:20	51:20,24 52:10 54:1
specific 7:12 8:18 12:9	State-law 3:13	supplement 53:17	term 6:23	thinking 53:19
13:12,14 16:6 16:8 20:3,10 21:2 40:11	statute 34:9	supplemental 47:6	test 50:5	Thoratec 21:23
46:10 49:19 51:8 52:13	statutory 4:6	support 33:20 34:3	testimony 54:6	thoroughly 38:11
specifically 6:3 6:12 7:1 30:17 30:23 49:17,24 51:13	stenosis 52:20 53:23	supporting 1:23 2:9 41:19	testing 4:1 9:1 25:11 54:8	thought 14:16 14:20 15:1,16 15:25 17:5 20:6 42:12 54:7,9
speedometer 22:12,12	stepped 10:8,22	suppose 6:17 12:13 28:14 46:9	textual 48:22	time 17:22 23:15 24:13 28:2 29:20 36:11 44:20
spent 29:6	Stevens 28:14 28:17,19 29:4 38:19,25 39:20	supposed 22:14 23:11 46:19	Thank 24:14 41:12,13 50:13 50:15 53:13 55:12,13	THEODORE 1:19 2:5 24:16
spoken 12:23	stop 17:25 18:7	sure 51:23	theoretical 28:19	theory 14:5,11 17:6,22 18:9 20:20,21 24:1 24:3
standard 4:6 6:21 49:22 54:10	strength 21:6 32:20 51:3	surprised 11:23	they'd 25:23	today 40:2
standards 49:18	strengthen 22:21	system 10:14	thickness 21:10	told 29:17
started 10:8	strong 20:23		thing 7:6 21:2 22:2 23:7,19 29:3 31:7 34:5 35:5 38:19	tons 24:9 31:24
State 6:11,13 7:4,8,16,20,21 8:19 11:3,17 12:10 15:2,4,5 15:9,12,13,23 16:6,9,19,21 16:25 19:12,15 20:4 25:5,20 26:4,16,16 40:8 41:1 42:3 42:3,9,11,14 43:12,13,14 44:1 46:7 48:4 49:1,9,25 50:21 51:2,12 52:12,13 55:6 55:7	struck 46:8		things 6:16 27:23 33:13 35:4 37:2 42:20 46:2	tools 47:17
standards 49:18	studies 37:23 38:1		think 4:20 6:23 7:17 8:17,24 9:14 10:2 12:22 13:5,11 14:6 15:14,23 16:23 18:20 19:4 20:15 23:9 24:20 25:9 27:19 29:13 32:6,15 33:9 34:9,11 36:1,25 37:1,6 38:4,15 39:14 41:22 42:7,17	tort 9:3,15,18 13:6,11,12 14:9,15 16:19 17:2,24 18:8 18:17,24 19:10 39:10,16 40:8 48:4 49:21
started 10:8	subject 29:1 48:1,3,7		they'd 25:23	tortured 24:21
State 6:11,13 7:4,8,16,20,21 8:19 11:3,17 12:10 15:2,4,5 15:9,12,13,23 16:6,9,19,21 16:25 19:12,15 20:4 25:5,20 26:4,16,16 40:8 41:1 42:3 42:3,9,11,14 43:12,13,14 44:1 46:7 48:4 49:1,9,25 50:21 51:2,12 52:12,13 55:6 55:7	submission 5:17 5:25 8:7		thick 21:10	trained 37:11
standards 49:18	submit 47:5		thing 7:6 21:2 22:2 23:7,19 29:3 31:7 34:5 35:5 38:19	Transportation 34:19 35:3
started 10:8	submits 3:24		things 6:16 27:23 33:13 35:4 37:2 42:20 46:2	treat 9:19
State 6:11,13 7:4,8,16,20,21 8:19 11:3,17 12:10 15:2,4,5 15:9,12,13,23 16:6,9,19,21 16:25 19:12,15 20:4 25:5,20 26:4,16,16 40:8 41:1 42:3 42:3,9,11,14 43:12,13,14 44:1 46:7 48:4 49:1,9,25 50:21 51:2,12 52:12,13 55:6 55:7	submitted 3:25 4:5 31:11,12 42:21 55:15,17		think 4:20 6:23 7:17 8:17,24 9:14 10:2 12:22 13:5,11 14:6 15:14,23 16:23 18:20 19:4 20:15 23:9 24:20 25:9 27:19 29:13 32:6,15 33:9 34:9,11 36:1,25 37:1,6 38:4,15 39:14 41:22 42:7,17	trial 13:25 23:25 34:24
standards 49:18	submitting 4:23		things 6:16 27:23 33:13 35:4 37:2 42:20 46:2	true 35:5 38:3 43:2
started 10:8	subparagraphs 39:3		think 4:20 6:23 7:17 8:17,24 9:14 10:2 12:22 13:5,11 14:6 15:14,23 16:23 18:20 19:4 20:15 23:9 24:20 25:9 27:19 29:13 32:6,15 33:9 34:9,11 36:1,25 37:1,6 38:4,15 39:14 41:22 42:7,17	try 35:23
State 6:11,13 7:4,8,16,20,21 8:19 11:3,17 12:10 15:2,4,5 15:9,12,13,23 16:6,9,19,21 16:25 19:12,15 20:4 25:5,20 26:4,16,16 40:8 41:1 42:3 42:3,9,11,14 43:12,13,14 44:1 46:7 48:4 49:1,9,25 50:21 51:2,12 52:12,13 55:6 55:7	substantially 8:3		things 6:16 27:23 33:13 35:4 37:2 42:20 46:2	trying 6:13 10:2 23:8,19 36:3
standards 49:18	sudden 27:4		think 4:20 6:23 7:17 8:17,24 9:14 10:2 12:22 13:5,11 14:6 15:14,23 16:23 18:20 19:4 20:15 23:9 24:20 25:9 27:19 29:13 32:6,15 33:9 34:9,11 36:1,25 37:1,6 38:4,15 39:14 41:22 42:7,17	Tuesday 1:11
started 10:8	sufficient 9:16		things 6:16 27:23 33:13 35:4 37:2 42:20 46:2	turn 7:18 50:5
State 6:11,13 7:4,8,16,20,21 8:19 11:3,17 12:10 15:2,4,5 15:9,12,13,23 16:6,9,19,21 16:25 19:12,15 20:4 25:5,20 26:4,16,16 40:8 41:1 42:3 42:3,9,11,14 43:12,13,14 44:1 46:7 48:4 49:1,9,25 50:21 51:2,12 52:12,13 55:6 55:7	suggest 27:21		think 4:20 6:23 7:17 8:17,24 9:14 10:2 12:22 13:5,11 14:6 15:14,23 16:23 18:20 19:4 20:15 23:9 24:20 25:9 27:19 29:13 32:6,15 33:9 34:9,11 36:1,25 37:1,6 38:4,15 39:14 41:22 42:7,17	turns 9:2 27:4 46:11
standards 49:18	suggesting 28:7		things 6:16 27:23 33:13 35:4 37:2 42:20 46:2	two 8:20 9:19
started 10:8	suit 9:4,15 13:6 18:25 21:25 32:25 33:15 40:16		think 4:20 6:23 7:17 8:17,24 9:14 10:2 12:22 13:5,11 14:6 15:14,23 16:23 18:20 19:4 20:15 23:9 24:20 25:9 27:19 29:13 32:6,15 33:9 34:9,11 36:1,25 37:1,6 38:4,15 39:14 41:22 42:7,17	two-inch 16:24
State 1:1,14,23			things 6:16 27:23 33:13 35:4 37:2 42:20 46:2	

32:8 types 34:21	verify 53:7 versus 32:8 51:18 vested 41:11 vesting 25:1 view 3:15,18 42:1 views 52:25 violating 28:25 violation 33:10 void 10:10,22 25:22	weighing 7:1 8:13 26:22,23 weight 53:1,2 went 34:17 weren't 10:7,24 We'll 3:3 we're 15:24 17:25 33:4,5 widespread 4:14 wire 14:7 32:8 32:20 37:17 withdraw 36:9 withdrew 45:22 withhold 43:14 withholding 48:8 women 24:10 word 31:22 words 6:17 17:7 21:3 51:11 work 23:12 35:12,13 36:13 world 36:1 55:3 worrying 23:6 wouldn't 13:7,9 14:17,22 16:20 written 53:16 wrong 15:23 21:2 23:13 40:20,21 46:13 wrote 12:11	4:22 5:12,20 6:5,21 7:3,7,13 8:1,3,17,22 9:7 9:14,21 10:2 11:7,13,19,25 12:8,19,22 13:10,19,24 14:5,9,14,25 15:7,14,21 16:4,11,23 17:13,16,18 18:5,15,23 19:8 20:1,17 20:21 21:6,11 21:15,20 22:3 22:15,20 23:1 23:24 33:1 50:16,18,20 51:8,13,16,20 51:24 52:2,4,8 53:10,12,14,23 54:5,13,16 55:14	<hr/> 3 <hr/> 3 2:4 35:9 360h(a) 47:20 360k 19:8 55:10 360k(a) 3:12 8:18 9:16 13:10 54:19 360k(a)(1) 25:16 38 10:8 <hr/> 4 <hr/> 4 1:11 37:20 50:17 41 2:9 <hr/> 5 <hr/> 50 2:12 50-percent 30:9 510(k) 5:21 7:11 7:15 <hr/> 7 <hr/> 76 49:15 <hr/> 8 <hr/> 8 30:25 808.1(d) 53:3 808.109 54:21 54:25 814.39 22:20 814.39(d) 23:1 52:17 53:12
<hr/> U <hr/> undermining 46:5 understand 9:18 29:14 43:22 understanding 12:18 understood 17:8 unfavorable 23:4 unforeseen 46:11 unfortunately 30:19 unique 39:23 40:6,7 United 1:1,14,23 2:8 41:17 unpublished 37:22 unrealistic 19:14 unreasonably 6:22,23 20:22 unrecognized 47:22 unsafe 4:13 usage 22:16 use 4:15 54:10 55:2,2 useful 10:4 41:22 users 47:21 usually 9:9	<hr/> W <hr/> waited 11:1 want 3:19 17:24 18:19,21 23:3 35:6,8,11 43:4 48:19 51:22 52:15 54:16 wanted 24:22 34:20 44:23 wanting 35:4 wants 5:9 16:3 16:16 warned 22:4 Warner-Lam... 38:14 warning 26:8 warnings 22:21 27:23 Washington 1:10,17,19,22 wasn't 40:19 way 3:18 5:20 7:3,12 10:20 13:13,15,16 21:7,12 31:15 31:15,16,16 34:25 35:22 36:18,23 37:3 40:25 43:16 44:17 46:13 49:18 50:7 week 38:14 weigh 6:14 31:24	<hr/> X <hr/> x 1:2,9 16:13,15 16:16,18,19 <hr/> Y <hr/> yeah 19:5 54:14 year 18:3,4 46:11 years 10:8 39:21 45:3 York 6:21 15:4 15:5,9,12,13 <hr/> Z <hr/> Zieve 1:17 2:3 2:11 3:6,7,9	<hr/> 0 <hr/> 06-179 1:7 3:4 <hr/> 1 <hr/> 10 31:1 54:9 10:11 1:15 3:2 100 22:16 11:11 55:16 12 22:5 120 22:13 1200 29:6 13 22:8 54:8 180 45:17 1938 10:6,25 1976 10:7 18:18 45:5 1997 45:19 <hr/> 2 <hr/> 2004 45:16,24 2007 1:11 21 23:1 24 2:6	
<hr/> V <hr/> v 1:7 3:4 7:18 21:22 valuable 35:18 variation 16:12 variations 30:11 variety 47:17 vary 42:10 verdict 14:12				