

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.                       :

9   - - - - - x

10   Washington, D.C.

11   Tuesday, December 4, 2007

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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  
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3  
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15  
16  
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18  
19  
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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, Inc.

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 Amendment to the Food, Drug, and Cosmetic Act preempts 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 FDA's permission to market a Class 3 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 problem. 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 has 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 the 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 --

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 --

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 weight.

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 -- I think  
17 is what you are getting at -- Lohr's analysis and the  
18 analysis in Bates v. Dow Agrosociences, Inc. 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: Yeah.

3 MS. ZIEVE: It had to be substantially  
4 equivalent, 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 --

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: And how does it -- how  
23 does it compare with another process that the FDA looks  
24 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 understand 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 --

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? For 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 -- 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 approvals  
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 conflicts,  
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 if  
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 dos 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 State cannot impose requirements that are different from  
25 or in addition to what the FDA has said.

1 JUSTICE GINSBURG: Take a --

2 JUSTICE SCALIA: If it --

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 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: But if that's the theory of the  
6 case, I think that's basically the one-inch/two-inch  
7 hearing aid fix 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: That's 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's the point  
17 Justice Ginsburg was implying.

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 --

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

1 of the new device and that might take forever or at  
2 least a year, let's say. And what happens to patients  
3 in that year? They've got no device.

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

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

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

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

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

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

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

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

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

24 I find that extraordinary.

25 MS. ZIEVE: Well, any one of us might have

1 drawn the line differently. But the line Congress drew  
2 was when there is a specific Federal requirement, we  
3 looked for a device counterpart State requirement. And  
4 where they don't exist, there is no preemption.

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

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

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

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

23 JUSTICE BREYER: What is it about the design  
24 that you are saying is not safe? That is, you can't go  
25 into the court without having in your mind, as the

1 counsel, that some kind of specific thing that was wrong  
2 with this catheter, other than just using the words  
3 "design." I mean, how was it designed badly? What part  
4 of the design is not right?

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

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

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

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

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

16 JUSTICE BREYER: If you don't know how to  
17 design the balloon, what are you basing the design claim  
18 on?

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

23 JUSTICE GINSBURG: What about the label --  
24 that you're pressing? So you said you really don't know  
25 what the design defect was. How about the label? That

1 would be the other thing.

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

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

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

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

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

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

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

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

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

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

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

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

23 MS. ZIEVE: Of course, it -- I freely admit  
24 that at trial if the plaintiff couldn't articulate the  
25 design theory any better than I did here, the plaintiff

1 is not going to lose on the design claim. But there are  
2 other cases where there is quite a clear theory about  
3 what the design defect is.

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

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

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

15           ORAL ARGUMENT OF THEODORE B. OLSON  
16           ON BEHALF OF THE RESPONDENT

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

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

25           They did so by vesting this responsibility

1 in the experts, the expertise, the judgment, and the  
2 processes at the FDA.

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

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

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

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

24 And the argument is, as you well know, which  
25 was presented in Senator Kennedy's brief, that's what we

1 meant to do with the preemption provision. Nothing  
2 more.

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

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

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

24 CHIEF JUSTICE ROBERTS: What if the FDA  
25 hasn't done it? How are newly discovered flaws dealt

1 with? I mean, say where you have this catheter, and the  
2 FDA didn't look at the possibility of allergic reactions  
3 to the balloon plastic, and all of a sudden it turns out  
4 to be a serious problem.

5 How can you say that that's preemptive?

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

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

14 MR. OLSON: Yes --

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

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

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

25 JUSTICE KENNEDY: It takes time for the FDA

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

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

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

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

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

15 MR. OLSON: Yes, Justice Stevens, because in  
16 that case --

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

21 MR. OLSON: Yes. And that's a judgment that  
22 Congress made, because with the -- the manufacturer then  
23 would be violating the law, failing to tell the FDA what  
24 was going on, perhaps committing fraud, and be subject to  
25 criminal penalties, recall penalties, civil penalties,

1 and that sort of thing.

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

8 Because as I --

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

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

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

21 Does preemption still apply?

22 MR. OLSON: Yes, it does.

23 JUSTICE SOUTER: Okay.

24 MR. OLSON: And the reason for that, Justice  
25 Souter, is that someone must make a judgment. That --

1 the information that the manufacturer may have learned  
2 may be -- have some aspect of the safety or  
3 effectiveness of the device, but it still might be the  
4 best product available.

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

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

14 MR. OLSON: Well, all -- no, I don't know  
15 the answer to that specifically, Justice Alito. But I  
16 do know -- and this is the application, itself, which is  
17 not, unfortunately, in the record, but is available  
18 through the FDA. It goes into elaborate detail with  
19 respect to the burst pressures. This device -- the  
20 label on this device -- and that is in the record at  
21 A-174 of the court of appeals appendix -- specifically  
22 says it shouldn't be inflated higher than a burst  
23 pressure or atmospheric risk pressure at 8 atmospheres.  
24 This one was inflated to 10 atmospheres, notwithstanding  
25 the label requirements.

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

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

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

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

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

25           JUSTICE ALITO: If you look at the file of a

1 PMA proceeding after it is concluded, can you tell  
2 exactly which design features and which risks the FDA  
3 has considered?

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

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

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

21 JUSTICE GINSBURG: Why isn't there -- to --  
22 to take care of that kind of hypothetical where the FDA  
23 says this isn't it, to say that kind of suit can't be  
24 brought. But it is, indeed, mentioned that there's a  
25 category of suits that is simply saying: Manufacturer,

1 you didn't do what's in that pre-marketing approval?

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

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

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

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

20           CHIEF JUSTICE ROBERTS: You -- you agree  
21 that that was not preemptive.

22           MR. OLSON: That was -- we agree that was  
23 not preempted, and -- and the court of appeals came to  
24 that same conclusion, but affirmed the district court  
25 that dismissed it on summary judgment because there was

1 no evidence to support it.

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

5 MR. OLSON: That's correct, Justice  
6 Ginsburg.

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

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

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

25 And then the judgment of the Department of

1 Transportation, which was considering all of these  
2 things and wanting to encourage innovation with respect  
3 to restraints -- the same thing is true here.

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

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

24           MR. OLSON: Well, I think the real world  
25 answers that question. The manufacturers of these

1 products are always trying to produce better products  
2 that will be safer. They of course have to go through  
3 the process to justify to the experts at the FDA that  
4 they are indeed safe, or -- and the FDA then may make a  
5 judgment that the reasonableness -- if there is a much  
6 safer device that doesn't have the risks of the previous  
7 device, they can -- they can withdraw the approval of  
8 the previous device.

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

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

23           MR. OLSON: I don't think so,  
24 Justice Kennedy. I think that there may be marketplace  
25 incentives and other things that would cause a --

1 someone in the marketplace to say I found a better way.  
2 Someone in the marketplace might say well, it might be  
3 better, but it might be prohibitively expensive. There  
4 are all kinds of those judgments, and I think that  
5 illustrates the point.

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

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

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

23 So presumably that includes any nonclinical  
24 laboratory studies that the manufacturer itself  
25 conducted.

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

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

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

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

23           JUSTICE STEVENS: Right.

24           MR. OLSON: -- but there also are  
25 requirements -- and I haven't -- can't give you the

1 exact citation, there's a lot of subparagraphs in these  
2 sections -- with respect to information that comes into  
3 the possession of the manufacturer that's pertinent to  
4 adverse consequences or effects of the device that must  
5 be given promptly to the FDA.

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

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

18 JUSTICE STEVENS: But of course the FDA took  
19 this contrary position some years ago.

20 MR. OLSON: Yes, it did, and it -- and it  
21 learned from experience -- the unique experience that  
22 you described the FDA having, in your opinion in the  
23 Lohr case, has been brought to bear in this case; and  
24 there's a reasoned explanation for the FDA's -- the  
25 Government's position today, as to why it took one

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

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

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

24           That is a State requirement which is a  
25 counterpart to the Federal requirement, and this -- and

1 Congress made it explicitly clear that any requirement  
2 that is different or in addition to the Federal  
3 requirement is preempted if it has to do with safety or  
4 effectiveness of the device.

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

10 Thank you, Mr. Chief Justice.

11 CHIEF JUSTICE ROBERTS: Thank you,  
12 Mr. Olson.

13 Mr. Kneedler.

14 ORAL ARGUMENT OF EDWIN S. KNEEDLER,

15 ON BEHALF OF THE UNITED STATES,

16 AS AMICUS CURIAE,

17 SUPPORTING THE RESPONDENT

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

20 I think it might be useful to begin by  
21 focusing on the consequences of Petitioner's argument  
22 that the PMA approval of an application does not result  
23 in requirements that are preemptive for purposes of the  
24 preemptive provision. Under Petitioner's view, the day  
25 after the FDA gave PMA approval to a particular device,

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

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

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

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

24 MR. KNEEDLER: Yes, that is -- that is  
25 definitely true.

1 JUSTICE SCALIA: It is clear that Congress  
2 didn't want additional requirements.

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

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

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

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

19 MR. KNEEDLER: But it's important to  
20 understand why. Congress was not concerned about the  
21 PMA in the abstract or as a process; it was concerned  
22 about what the consequences of requiring the  
23 manufacturer to go through the PMA process were. And  
24 that was precisely because the result of the State PMA  
25 process could be to impose different requirements. The

1 labeling should read differently --

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

3 MR. KNEEDLER: -- the product should be  
4 differently.

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

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

20 That may be one explanation for why Congress  
21 wanted to be especially firm about imposing preemption  
22 with respect to Federally approved devices.

23 JUSTICE SCALIA: It was also a different  
24 Congress.

25 MR. KNEEDLER: It was a different Congress.

1 JUSTICE SCALIA: How much -- how many years  
2 later?

3 MR. KNEEDLER: This was 1976 when we --

4 JUSTICE SCALIA: Why did we expect them to  
5 come out with the same --

6 MR. KNEEDLER: Right, and they were only  
7 addressing devices in that -- these were not general FDA  
8 amendments; they were addressing -- they were addressing  
9 the --

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

15 MR. KNEEDLER: Well, the government filed a  
16 brief in -- in late 1997 taking a position that PMA  
17 approval did not -- did not have preemptive effect.  
18 That was issued together with FDA's issuance of a  
19 proposed rule to the same effect. FDA withdrew that  
20 proposed rule 7 months later. The government did not  
21 address this question again until 2004 in the brief  
22 you're referring to in the court of appeals.

23 And due in large part to examining the very  
24 things that I've been talking about, that in FDA's  
25 judgment, which this Court in the Lohr case said was

1 entitled to considerable deference, FDA recognized that  
2 there would be a serious undermining of FDA's approval  
3 authority and its balancing of the risks and benefits,  
4 if a State jury could reweigh those -- the balance that  
5 FDA had struck in the new Medical Device --

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

11 Can the manufacturer continue to sell new  
12 devices with the same label pending the annual report?

13 MR. KNEEDLER: Yes. I mean, let me just  
14 clarify.

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

21 JUSTICE KENNEDY: Just take --

22 MR. KNEEDLER: -- with what --

23 JUSTICE KENNEDY: Just take my hypothetical.

24 MR. KNEEDLER: And it -- what I was going to  
25 say is it's possible that the labeling would be regarded

1 as misleading for some reason. In that event, the  
2 manufacturer should apply to -- should submit what's  
3 called a supplemental PMA and request that the labeling  
4 be changed to clarify that.

5 JUSTICE KENNEDY: And you could -- and the  
6 manufacturer continued to sell the device knowing that  
7 the label is being misconstrued by very good doctors  
8 pending FDA action?

9 MR. KNEEDLER: Ordinarily, yes. If there  
10 was -- if there was a very serious risk to health and  
11 safety --

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

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

22 JUSTICE KENNEDY: Does the failure to give  
23 that notice subject the manufacturer to liability if the  
24 manufacturer continues to sell the device?

25 MR. KNEEDLER: It would not subject it to

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

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

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

22 If the only objective in the -- in the  
23 preemption clause were to preclude State PMA in addition  
24 to Federal PMA, there would have been no reason to  
25 include the phrase -- would there have been any reason

1 to include a preclusion of a requirement that is  
2 different from in addition to a preclusion of something  
3 which is in addition to?

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

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

8 MR. KNEEDLER: Right. Right. Right.

9 JUSTICE SOUTER: Okay.

10 MR. KNEEDLER: And also I think the FDA  
11 regulations promulgated when this was put out, soon  
12 after the '76 amendments were passed, I think reinforced  
13 the conclusion that -- and, in fact, there was a  
14 regulation that specifically talks about the application  
15 of general adulteration standards in a way that might  
16 require a specific label change to be made by a  
17 manufacturer, and we think that's basically precisely  
18 this lawsuit. It's the application of general tort law  
19 that would require the manufacturer or a standard of  
20 care under common law that would say that what the  
21 manufacturer had done specifically approved by FDA was  
22 -- was improper as a matter of State law. We think that  
23 that is in the teeth of the preemption provision. I  
24 think Justice Alito asked the question about the issue  
25 of whether FDA focused or didn't focus on a particular

1 aspect of the design. We don't think that a preemption  
2 test can really realistically turn on that. That would  
3 require extensive and intrusive inquiry into what FDA  
4 had done. We think that the best way to look at this is  
5 what the end product was; what was the application that  
6 was finally approved and the labeling associated with  
7 it, much like the filed rate doctrine. You look at what  
8 was put before the agency and what was approved, not  
9 what might have gone into -- into consideration.

10 CHIEF JUSTICE ROBERTS: Thank you,  
11 Mr. Kneedler.

12 MR. KNEEDLER: Thank you.

13 CHIEF JUSTICE ROBERTS: Ms. Zieve, you have  
14 4 minutes remaining.

15 REBUTTAL ARGUMENT OF ALLISON M. ZIEVE

16 ON BEHALF OF THE PETITIONER

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

23 Some States had hearing aid packaging  
24 requirements. There was a State that had a requirement  
25 about the grants of prescription glasses, lenses. So

1 it's -- it is broader than just --

2 JUSTICE SOUTER: And how do you draw the  
3 line between those instances and the ones that you say  
4 are not preempted?

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

7 JUSTICE SOUTER: They -- they were  
8 requirements, in other words, of positive law? They  
9 were State regulations?

10 MS. ZIEVE: Addressed specifically to  
11 devices, and they had --

12 JUSTICE SOUTER: So the --

13 MS. ZIEVE: -- direct Federal counterparts.

14 JUSTICE SOUTER: Okay. So the line is  
15 simply enactment of positive law versus jury award?  
16 That's the line?

17 MS. ZIEVE: I think that's what Congress was  
18 intending.

19 JUSTICE SOUTER: No, I just want to make  
20 sure --

21 MS. ZIEVE: I think under --

22 JUSTICE SOUTER: -- what your position is.  
23 That is where you draw the line then?

24 MS. ZIEVE: Yes.

25 JUSTICE SOUTER: Okay.

1 MS. ZIEVE: I don't --

2 CHIEF JUSTICE ROBERTS: Didn't the Court --  
3 didn't the majority of the Court reject that line in  
4 Lohr?

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

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

22 As for the FDA's current views, it is not  
23 actually correct that in Lohr the government gave weight  
24 to the FDA's amicus brief. The government gave weight  
25 to the FDA's regulation, 808.1(d). That regulation is

1 still in effect, and it hasn't been modified since --  
2 since Lohr was issued.

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

7 MS. ZIEVE: Without prior approval?

8 JUSTICE KENNEDY: Yes.

9 MS. ZIEVE: 814.39(d).

10 CHIEF JUSTICE ROBERTS: Thank you.

11 MS. ZIEVE: After FDA approved the PMA, any  
12 of the listed changes can be placed into effect prior to  
13 the receipt of a written FDA order approving the PMA  
14 supplement.

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

20 MS. ZIEVE: Right.

21 CHIEF JUSTICE ROBERTS: Well, doesn't that  
22 obvious mean if the blockage is clear, you don't keep  
23 inflating it to the bursting pressure. You think that  
24 doctors read that as saying you can inflate it past the  
25 bursting pressure unless -- if the blockage isn't

1 cleared?

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

8 CHIEF JUSTICE ROBERTS: Even though the  
9 label said eight is the bursting pressure?

10 MS. ZIEVE: The rate at burst pressure,  
11 yeah.

12 CHIEF JUSTICE ROBERTS: Okay.

13 MS. ZIEVE: I also want to mention -- we  
14 don't come to this case on a blank slate. We come to it  
15 in light of Lohr. The Court has already interpreted  
16 Section 360k(a). In finding no preemption in Lohr of  
17 any of the claims, the Court looked to the labeling  
18 regulation 801.109 was applicable to the device there.  
19 That is the same exact regulation that is applicable to  
20 the device here.

21 If Medtronic's PMA device complies with  
22 801.109, then it is deemed to be not misbranded, but  
23 that is a moving target. What is adequate instructions  
24 for use changes as the manufacturer learns about use of  
25 its product in the real world. The same process for

1 making design changes exists in this case as existed in  
2 Lohr.

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

9 Thank you.

10 CHIEF JUSTICE ROBERTS: Thank you,  
11 Ms. Zieve.

12 The case is submitted.

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

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

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

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

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

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

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

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

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

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

<p>22:11,11  <b>spent</b> 29:4  <b>spoken</b> 12:23  <b>standard</b> 4:6          6:21 49:19          54:7  <b>standards</b> 49:15  <b>started</b> 10:8  <b>State</b> 3:13 6:11          6:13 7:4,8,16          7:20,21 8:19          11:3,17 12:10          12:24 15:2,4,5          15:9,12,13,23          16:6,9,19,21          16:25 19:11,14          20:3 25:4,19          26:3,15,15          40:6,24 42:1,1          42:7,9,12          43:10,11,12,24          46:4 48:1,23          49:6,22 50:18          50:24 51:9          52:9,10 55:3,4  <b>statement</b> 53:4  <b>States</b> 1:1,14,23          2:8 9:8,10,10          10:8,16,24          11:5,21 12:17          15:12 25:20          26:17 41:15          42:12 43:16          50:23  <b>statute</b> 34:7  <b>statutory</b> 4:6  <b>stenosis</b> 52:17  <b>stepped</b> 10:8,22  <b>Stevens</b> 28:12          28:15,17 29:2          38:17,23 39:18  <b>stop</b> 17:24 18:6  <b>strength</b> 21:5          32:18  <b>strengthen</b>          22:20  <b>strong</b> 20:22</p>	<p><b>struck</b> 46:5  <b>studies</b> 37:21,24  <b>subject</b> 28:24          47:23,25 48:4  <b>submission</b> 5:17          5:25 8:7 33:5  <b>submit</b> 47:2  <b>submits</b> 3:24  <b>submitted</b> 3:25          4:5 31:9,10          42:19 55:12,14  <b>submitting</b> 4:23  <b>subparagraphs</b>          39:1  <b>substantially</b>          8:3  <b>sudden</b> 27:3  <b>sufficient</b> 9:16  <b>suggest</b> 27:20  <b>suggesting</b> 28:5  <b>suit</b> 9:4,15 13:6          18:24 32:23          33:13 40:14  <b>suits</b> 9:18 17:23          18:7,16 19:9          32:25 39:8,15          40:6  <b>summary</b> 33:17          33:25  <b>supplement</b>          53:14  <b>supplemental</b>          47:3  <b>support</b> 33:18          34:1  <b>supporting</b> 1:23          2:9 41:17  <b>suppose</b> 6:17          12:13 28:12          46:6  <b>supposed</b> 22:13          23:10 46:16  <b>Supreme</b> 1:1,14  <b>sure</b> 51:20  <b>surprised</b> 11:23  <b>system</b> 10:14</p>	<p style="text-align: center;"><b>T</b></p> <p><b>T</b> 2:1,1  <b>table</b> 40:2  <b>take</b> 13:1,3          16:19 18:1,21          28:1 32:22          35:12 38:20          40:6 46:21,23          47:14 48:21  <b>taken</b> 39:9 48:13  <b>takes</b> 27:25          29:18  <b>talk</b> 3:19 21:21  <b>talked</b> 34:9 52:8  <b>talking</b> 3:19          11:11 45:24          55:4  <b>talks</b> 49:14  <b>tangible</b> 44:13          44:17  <b>target</b> 54:23  <b>teeth</b> 49:23  <b>tell</b> 20:15 23:1          28:23 32:1  <b>tensile</b> 32:18  <b>term</b> 6:23  <b>terrible</b> 23:6  <b>test</b> 50:2  <b>testimony</b> 54:3  <b>testing</b> 4:1 9:1          25:10 54:5  <b>textual</b> 48:19  <b>Thank</b> 24:13          41:10,11 50:10          50:12 53:10          55:9,10  <b>THEODORE</b>          1:19 2:5 24:15  <b>theoretical</b>          28:17  <b>theory</b> 14:5,11          17:6,21 18:8          20:19,20 23:25          24:2  <b>they'd</b> 25:22  <b>thickness</b> 21:9  <b>thing</b> 7:6 21:1</p>	<p>22:1 23:6,18          29:1 31:5 34:3          35:3 38:17  <b>things</b> 6:16          27:22 33:11          35:2 36:25          42:18 45:24  <b>think</b> 4:20 6:23          7:16 8:17,24          9:14 10:2          12:22 13:5,11          14:6 15:14,23          16:23 18:19          19:3 20:14          23:8 24:19          25:8 27:18          29:11 32:4,13          33:7 34:7,9          35:24 36:23,24          37:4 38:2,13          39:12 41:20          42:5,15 44:6,8          48:10 49:5,10          49:12,17,22,24          50:1,4 51:17          51:21 52:7          53:23  <b>thinking</b> 53:16  <b>Thoratec</b> 21:22  <b>thoroughly</b> 38:9  <b>thought</b> 14:16          14:20 15:1,16          15:25 17:5          20:5 42:10          54:4,6  <b>time</b> 17:21 23:14          24:12 27:25          29:18 36:9          44:18  <b>today</b> 39:25  <b>told</b> 29:15  <b>tons</b> 24:8 31:22  <b>tools</b> 47:14  <b>tort</b> 9:3,15,18          13:6,11,12          14:9,15 16:19          17:2,23 18:7</p>	<p>18:16,23 19:9          39:8,14 48:1          49:18  <b>touched</b> 24:20  <b>trained</b> 37:9  <b>Transportation</b>          34:17 35:1  <b>treat</b> 9:19  <b>trial</b> 13:25 23:24          34:22  <b>true</b> 35:3 38:1          42:25  <b>try</b> 35:21  <b>trying</b> 6:13 10:2          23:7,18 36:1  <b>Tuesday</b> 1:11  <b>turn</b> 7:18 50:2  <b>turns</b> 9:2 27:3          46:8  <b>two</b> 8:20 9:19  <b>two-inch</b> 16:24          32:6  <b>types</b> 34:19</p> <p style="text-align: center;"><b>U</b></p> <p><b>undermining</b>          46:2  <b>understand</b> 9:3          9:18 29:12          43:20  <b>understanding</b>          12:18  <b>understood</b> 17:8  <b>unfavorable</b>          23:3  <b>unforeseen</b> 46:8  <b>unfortunately</b>          30:17  <b>unique</b> 39:21          40:4,5  <b>United</b> 1:1,14,23          2:8 41:15  <b>unpublished</b>          37:20  <b>unrealistic</b>          19:13  <b>unreasonably</b></p>
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<p>6:22,23 20:21  <b>unrecognized</b> 47:19  <b>unsafe</b> 4:13  <b>usage</b> 22:15  <b>use</b> 4:15 54:7,24 54:24  <b>useful</b> 10:4 41:20  <b>users</b> 47:18  <b>usually</b> 9:9</p> <hr/> <p style="text-align: center;"><b>V</b></p> <p><b>v</b> 1:7 3:4 7:18 21:21  <b>valuable</b> 35:16  <b>variation</b> 16:12  <b>variations</b> 30:9  <b>variety</b> 47:14  <b>verdict</b> 14:12  <b>verify</b> 53:4  <b>versus</b> 32:6 51:15  <b>vested</b> 41:9  <b>vesting</b> 24:25  <b>view</b> 3:15,18 41:24  <b>views</b> 52:22  <b>violating</b> 28:23  <b>violation</b> 33:7  <b>void</b> 10:10,22 25:21</p> <hr/> <p style="text-align: center;"><b>W</b></p> <p><b>waited</b> 11:1  <b>want</b> 3:19 17:23 18:18,20 23:2 35:4,6,9 43:2 48:16 51:19 52:12 54:13  <b>wanted</b> 24:21 34:18 44:21  <b>wanting</b> 35:2  <b>wants</b> 5:9 16:3 16:16  <b>warned</b> 22:3  <b>Warner</b> 38:12  <b>warning</b> 26:7</p>	<p><b>warnings</b> 22:20 27:22  <b>Washington</b> 1:10,17,19,22  <b>wasn't</b> 40:17  <b>way</b> 3:18 5:20 7:3 10:20 13:13,15,16 21:6,11 31:13 31:13,14,14 34:23 35:20 36:16,21 37:1 40:23 43:14 44:15 46:10 49:15 50:4  <b>week</b> 38:12  <b>weigh</b> 6:14 31:22  <b>weighing</b> 7:1 8:13 26:21,22  <b>weight</b> 7:12 52:23,24  <b>went</b> 34:15  <b>weren't</b> 10:7,24  <b>We'll</b> 3:3  <b>we're</b> 15:24 17:24 33:2,3  <b>widespread</b> 4:14  <b>wire</b> 32:6,18 37:15  <b>withdraw</b> 36:7  <b>withdrew</b> 45:19  <b>withhold</b> 43:12  <b>withholding</b> 48:5  <b>women</b> 24:9  <b>word</b> 31:20  <b>words</b> 6:17 17:7 21:2 51:8  <b>work</b> 23:11 35:10,11 36:11  <b>world</b> 35:24 54:25  <b>worrying</b> 23:5  <b>wouldn't</b> 13:7,9 14:17,22 16:20  <b>written</b> 53:13</p>	<p><b>wrong</b> 15:23 21:1 23:12 40:18,19 46:10  <b>wrote</b> 12:11</p> <hr/> <p style="text-align: center;"><b>X</b></p> <p><b>x</b> 1:2,9 16:13,15 16:16,18,19</p> <hr/> <p style="text-align: center;"><b>Y</b></p> <p><b>yeah</b> 8:2 19:4 54:11  <b>year</b> 18:2,3 46:8  <b>years</b> 10:8 39:19 45:1  <b>York</b> 6:21 15:4 15:5,9,12,13</p> <hr/> <p style="text-align: center;"><b>Z</b></p> <p><b>Zieve</b> 1:17 2:3 2:11 3:6,7,9 4:22 5:12,20 6:5,21 7:3,7,13 8:1,3,17 9:7,14 9:21 10:2 11:7 11:13,19,25 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 18:4,14,22 19:7,25 20:16 20:20 21:5,10 21:14,19 22:2 22:14,19,25 23:23 50:13,15 50:17 51:5,10 51:13,17,21,24 52:1,5 53:7,9 53:11,20 54:2 54:10,13 55:11</p> <hr/> <p style="text-align: center;"><b>0</b></p> <p><b>06-179</b> 1:7 3:4</p> <hr/> <p style="text-align: center;"><b>1</b></p>	<p><b>10</b> 30:24 54:6  <b>10:11</b> 1:15 3:2  <b>100</b> 22:15  <b>11:11</b> 55:13  <b>12</b> 22:4  <b>120</b> 22:12  <b>1200</b> 29:4  <b>13</b> 22:7 54:5  <b>180</b> 45:14  <b>1938</b> 10:6,25  <b>1976</b> 10:7 18:17 45:3  <b>1997</b> 45:16</p> <hr/> <p style="text-align: center;"><b>2</b></p> <p><b>2004</b> 45:13,21  <b>2007</b> 1:11  <b>21</b> 22:25  <b>24</b> 2:6</p> <hr/> <p style="text-align: center;"><b>3</b></p> <p><b>3</b> 2:4 3:21 35:7  <b>360h(a)</b> 47:17  <b>360k</b> 19:7 55:7  <b>360k(a)</b> 3:12 8:18 13:10 54:16  <b>360k(a)(1)</b> 25:15  <b>38</b> 10:8</p> <hr/> <p style="text-align: center;"><b>4</b></p> <p><b>4</b> 1:11 37:18 50:14  <b>41</b> 2:9</p> <hr/> <p style="text-align: center;"><b>5</b></p> <p><b>50</b> 2:12  <b>50-percent</b> 30:7  <b>510(k)</b> 5:21 7:11 7:15</p> <hr/> <p style="text-align: center;"><b>7</b></p> <p><b>7</b> 45:20  <b>76</b> 49:12</p> <hr/> <p style="text-align: center;"><b>8</b></p> <p><b>8</b> 30:23  <b>801.109</b> 54:18</p>	<p>54:22  <b>808.1(d)</b> 52:25  <b>814.39</b> 22:19  <b>814.39(d)</b> 22:25 52:14 53:9</p>
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