

1           IN THE SUPREME COURT OF THE UNITED STATES

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3   WARNER-LAMBERT CO., LLC,                                 :

4   ET AL.,   :

5                                 Petitioners                         :

6                         v.   :   No. 06-1498

7   KIMBERLY KENT, ET AL.   :

8   - - - - - x

9   Washington, D.C.

10   Monday, February 25, 2008

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12                                 The above-entitled matter came on for oral  
13 argument before the Supreme Court of the United States  
14 at 11:05 a.m.

15 APPEARANCES:

16 CARTER G. PHILLIPS, ESQ., Washington, D.C.; on behalf  
17 of the Petitioners.

18 DARYL JOSEFFER, ESQ., Assistant to the Solicitor  
19 General, Department of Justice, Washington, D.C.; on  
20 behalf of the United States, as amicus curiae,  
21 supporting the Petitioners.

22 ALLISON M. ZIEVE, ESQ., Washington, D.C.; on behalf  
23 of the Respondents.

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|----|---|------|
| 1  | C O N T E N T S                           |      |
| 2  | ORAL ARGUMENT OF                          | PAGE |
| 3  | CARTER G. PHILLIPS, ESQ.                  |      |
| 4  | On behalf of the Petitioners              | 3    |
| 5  | DARYL JOSEFFER, ESQ.                      |      |
| 6  | On behalf of the United States, as amicus |      |
| 7  | Curiae, supporting the Petitioners        | 17   |
| 8  | ALLISON M. ZIEVE, ESQ.                    |      |
| 9  | On behalf of the Respondents              | 27   |
| 10 | REBUTTAL ARGUMENT OF                      |      |
| 11 | CARTER G. PHILLIPS, ESQ.                  |      |
| 12 | On behalf of the Petitioners              | 50   |
| 13 |   |      |
| 14 |   |      |
| 15 |   |      |
| 16 |   |      |
| 17 |   |      |
| 18 |   |      |
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| 20 |   |      |
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| 22 |   |      |
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| 24 |   |      |
| 25 |   |      |

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

2 (11:05 a.m.)

3 JUSTICE STEVENS: The Court will hear  
4 argument in Warner-Lambert against Kimberly Kent.

5 Mr. Phillips, whenever you're ready we will be  
6 happy to hear you?

7 ORAL ARGUMENT OF CARTER G. PHILLIPS

8 ON BEHALF OF THE PETITIONERS

9 MR. PHILLIPS: Thank you, Justice Stevens,  
10 and may it please the Court:

11 Six years ago, this Court in Buckman  
12 recognized that policing fraud against Federal agencies  
13 is hardly a field the states have traditionally  
14 occupied. Based on that premise, this Court in Buckman  
15 struck down a novel State tort that was based on the  
16 whole concept of fraud on the FDA.

17 And the Court concluded that that tortious  
18 analysis as a matter of State law would inevitably  
19 conflict with the FDA's responsibility to police fraud.  
20 A responsibility that the Court recognized was  
21 essentially cradle to grave covered by Federal law. It  
22 arises out of Federal law, it is regulated by Federal  
23 law and it is ultimately terminated by Federal law.

24 Michigan has adopted a unique product  
25 liability statute, and on the one hand confers a very

1 broad immunity of defense against all product liability  
2 claims for manufacturers who comply with the FDA's  
3 requirements.

4 But then on the other hand, withdraws that  
5 immunity for the defense, this is PDA App. 42A, if the  
6 manufacturer intentionally withholds from or  
7 misrepresents to the United States Food and Drug  
8 Administration information concerning the drug that is  
9 required to be submitted pursuant to -- and then it goes  
10 and lists very specific provisions of the Food, Drug,  
11 and Cosmetic Act -- and the drug would not have been  
12 approved or the Food and Drug Administration would have  
13 withdrawn approval.

14 It is difficult for me to imagine a statute  
15 that would more consciously and openly tread into  
16 exactly the same territory that this Court declared in  
17 Buckman as a matter of exclusive Federal and concern not  
18 available to the states to regulate.

19 JUSTICE SCALIA: Mr. Phillips, what if the  
20 statute didn't have that provision, but it just said you  
21 can bring a State tort action when the conditions  
22 approved by the FDA for the marketing of this drug have  
23 not been complied with? That's all it says. Now, would  
24 you knowlege that that -- that that suit could be  
25 brought?

1           MR. PHILLIPS: I will acknowledge that's a  
2 fundamentally different issue, Justice Scalia, because  
3 there you are talking about what duties are owed to the  
4 public that are enforced by the FDA and potentially are  
5 enforceable by the states as well.

6           But here we're talking about duties that are  
7 owed from the manufacturer exclusively --

8           JUSTICE SCALIA: It's a duty that is defined  
9 by the FDA. And I didn't hear your answer. Would that  
10 suit be allowable or not?

11          MR. PHILLIPS: That suit would not be  
12 barred, I don't think, by Buckman. I think the question  
13 there will really go to what the Court is going to  
14 decide next term in Wyeth as to how far when if you have  
15 FDA approval of certain activities that that has the  
16 effect of --

17          JUSTICE SCALIA: It doesn't seem to me --  
18 what I worry about is that if we say in this case it  
19 treads too much into the FDA's own responsibility to say  
20 what material should have been provided to the FDA, it  
21 seems to me the next what could be more central to the  
22 FDA -- to the FDA's job than determining whether the  
23 conditions the FDA prescribed for the marketing of the  
24 drug have indeed been observed? That's central as well.

25          MR. PHILLIPS: I don't think it is an

1 unreasonable next step, but it is clearly the next step  
2 that has to be taken. Because what this Court decided  
3 in Buckman -- and it's central and candidly we are here  
4 seeking a very narrow ruling from the Court is that when  
5 you're defining the relationship between the  
6 manufacturer and the seller of the drugs and the FDA in  
7 terms of the disclosure of information to that entity  
8 and the determination both whether that information is  
9 adequate to allow the agency to perform its business and  
10 then, more fundamentally, whether or not the agency is  
11 acting in accordance with its own exclusive authority to  
12 decide how to proceed --

13 JUSTICE SCALIA: But one can also reason in  
14 the opposite direction; that is to say, one can know  
15 from the medical devices portion of the FDA that  
16 Congress has no objection to private tort actions  
17 that -- where the medical device manufacturer has not  
18 observed the requirements that the FDA's approval  
19 impose, right? We know from that section that Congress  
20 has no objection to that there.

21 You can probably guess that Congress has no  
22 objection to it in the -- in the drug field as well as  
23 the medical devices field. And if I make that guess,  
24 what is so different about having a jury second-guess  
25 the provision of information portion?

1                   MR. PHILLIPS: It seems to me that the same  
2 argument you just made, Justice Scalia, would have led  
3 the Court to the opposite result in Buckman, because  
4 what's the -- you know, if Congress didn't care about  
5 allowing State tort law to be -- to serve as the  
6 enforcement mechanism, then why wouldn't you allow them  
7 to do that in that context as well?

8                   And this Court said the reason is because  
9 there is a very uniquely Federal interest in taking care  
10 of the business and the relationship between those two  
11 entities.

12                  JUSTICE SCALIA: Well, It is -- it is more  
13 of a stick in the eye of the Federal Government to  
14 create a cause of action that consists of defrauding the  
15 Federal Government, which is what was at issue in  
16 Buckman. The very cause of action was providing false  
17 information to the FDA. Here the cause of action is a  
18 standard tort cause of action for marketing a defective  
19 product.

20                  MR. PHILLIPS: Well, when you say "here"  
21 what we're talking -- what we're talking about here is a  
22 very unique State statute that is the sole basis on  
23 which the tort liability is set aside.

24                  We're not -- we're not pre-empting the  
25 underlying tort claims by the Federal law that's at

1 issue in this case. The State statute pre-empts the  
2 common law court claims. That first portion of the  
3 defense wipes those out. So it's not pre-emption of the  
4 traditional State law cause of action, as the Second  
5 Circuit wrongly evaluated it. What we're talking about  
6 here is a provision that in the most exquisite terms  
7 says: Allow the State, either by the court or the  
8 juries, to evaluate the adequacy of the information that  
9 the FDA required.

10 And it's important to understand how that  
11 plays out, because what it says is pursuant to those  
12 statutes. It specifically identifies provisions in the  
13 statutes. It doesn't say anything about how the FDA --  
14 how the FDA interprets those statutes.

15 JUSTICE GINSBURG: Mr. Phillips, isn't --  
16 isn't the standard -- in the standard tort claim, no  
17 Michigan statute, but a defense that's available to a  
18 drug manufacturer who is charged with putting on the  
19 market a defective drug, its regulatory compliance,  
20 right?

21 MR. PHILLIPS: Yes.

22 JUSTICE GINSBURG: And so the State of  
23 Michigan has said: Drug dealers -- I'm sorry -- drug  
24 sellers --

25 (Laughter.)



1 JUSTICE GINSBURG: -- drug manufacturers, we  
2 are going to give you an invigorated defense. Instead  
3 of just saying you show regulatory compliance, we're  
4 going to take you off the hook altogether, except if you  
5 didn't come clean with the FDA, if you withheld  
6 information or misrepresented information.

7 It seems to me that what -- you could say  
8 this is just like Buckman, but you could also say this  
9 is giving the manufacturer an invigorated regulatory  
10 compliance defense.

11 So why shouldn't it be looked at as the  
12 second, rather than the first?

13 MR. PHILLIPS: Well, I think what you're  
14 basically arguing for is an argument I think one of the  
15 amici made on the other side, which is: Does the  
16 greater power include the lesser power? That is, if we  
17 had the authority not to give you a defense in the first  
18 place, don't we have the authority to use this as a  
19 lever in order to allow us essentially to undertake to  
20 regulate in precisely the same way the FDA would?

21 And the answer is: No, because this is not  
22 a situation --

23 JUSTICE KENNEDY: You're arguing an  
24 unconstitutional condition, in effect.

25 MR. PHILLIPS: Well, I think it is an

1 unconstitutional condition. But I think the bottom line  
2 is it's not a question of us taking the bad with the  
3 good. The problem here is that the Federal Government  
4 has an independent interest, and it is the Federal  
5 Government's independent interest that is being  
6 essentially wiped away.

7 JUSTICE GINSBURG: If you're right in your  
8 argument, the Michigan statute provided two things: One  
9 good for the manufacturer, immunity; two, a  
10 qualification on it. It seems to me that those two  
11 can't be unstuck. So to strike out one, as was done in  
12 the Sixth Circuit case, and not the other is certainly  
13 not faithful to the Michigan legislature that put these  
14 two things together.

15 MR. PHILLIPS: Justice Ginsburg, that's  
16 clearly a question of State law. I mean, that's a  
17 severability issue to be sure. And I -- but I think  
18 it's not fair to condemn the way the Sixth Circuit  
19 analyzed this case.

20 What the Sixth Circuit said is if it's still  
21 available to the State to come in after the FDA has both  
22 found that there has been a material deception of one  
23 sort or another and that the FDA has decided to withdraw  
24 the product as a consequence of that, and that -- and  
25 then State law is allowed to come in and enforce product

1 liability claims under those circumstances, that the  
2 legislature would have been perfectly satisfied with  
3 that arrangement.

4 And, candidly, that is precisely what we  
5 have asked for before both the Second Circuit and this  
6 Court.

7 JUSTICE STEVENS: Mr. Phillips, May I ask  
8 this question that's related to Justice Ginsburg's, but  
9 not the same. You are saying that the defense is not  
10 pre-empted; the response to the defense is what is  
11 pre-empted here.

12 MR. PHILLIPS: Correct.

13 JUSTICE STEVENS: What if you didn't have a  
14 statute at all and you just had a common law lawsuit in  
15 which you defended on the ground of compliance with the  
16 Federal statute shows, the Federal program, shows a lack  
17 of negligence. And then it then came back with the  
18 rebuttal: Yes, but your compliance was tainted by  
19 fraud, the same kind of thing. Would that response be  
20 pre-empted in a common law lawsuit?

21 MR. PHILLIPS: I think the question goes to  
22 how far that response goes. If you in fact instructed,  
23 if the trial judge instructed the jury that if it found,  
24 and then just quoted the language of the statute that  
25 there's no, then I'd say, yes, that is pre-empted in

1 precisely the same way.

2 And the language the Court used in Buckman  
3 was "critical element." If the FDA's regulatory  
4 authority is a critical element of the case, then, yes,  
5 it is pre-empted.

6 Whether or not -- whether evidence by itself  
7 would be a critical element is harder to tell.

8 JUSTICE STEVENS: Let me just finish with  
9 one other thought before --

10 MR. PHILLIPS: Sure.

11 JUSTICE STEVENS: In one of your arguments  
12 and the government's argument, this is very burdensome  
13 to the FDA because we have all this litigation. In all  
14 the years we have had this kind of tort litigation, has  
15 this issue ever proved to be burdensome to the  
16 government in any of these -- these attempts to make out  
17 this charge and this defense?

18 MR. PHILLIPS: I mean, the government is  
19 probably in a better position to evaluate that than I  
20 am. But, you know --

21 JUSTICE STEVENS: Because It seems to me  
22 that we have three or four States that have these  
23 statutes.

24 MR. PHILLIPS: Right.

25 JUSTICE STEVENS: But most States don't have

1 these statutes. I wonder if the problem is really as  
2 serious as everybody --

3 MR. PHILLIPS: Well, I think what the Court  
4 said in Buckman about that probably applies equally  
5 here, which is that, rather than look to see whether  
6 there is, in fact, going to be an interference, we ought  
7 to recognize that this is a territory that is locked off  
8 exclusively to the Federal Government's control, and we  
9 shouldn't -- and there shouldn't be that external pull,  
10 the extraneous pull, that State law provides under these  
11 circumstances.

12 And the same logic obviously applied here  
13 would say: We don't wait until there's a serious  
14 interference with how the FDA is trying to do its job;  
15 we try to prevent that because there's no -- there's no  
16 legitimate State interest to be served here.

17 JUSTICE STEVENS: Do you think there can  
18 also be the same argument for pre-empting the section,  
19 the subpart (b) of Michigan statute, the bribery  
20 exception?

21 MR. PHILLIPS: No. I think there's a  
22 difference between the bribery statute, because again  
23 that doesn't go to the direct relationship between the  
24 manufacturer or the seller or the regulated entity and  
25 the FDA itself. That goes to the relationship

1     between -- that -- that is governed by a different set  
2     of laws.

3                     And I think it's traditionally been the case  
4     that States are in fact entitled to enforce laws against  
5     bribery of Federal officials. So I don't think the same  
6     -- as I say, what I'm looking for here is an extremely  
7     narrow ruling from this Court.

8                     JUSTICE SCALIA: What about the defense  
9     itself, which says that the defense is available if not  
10    only the drug was approved for safety and efficacy, but  
11    also if the drug and its labeling were in compliance  
12    with the FDA's approval at the time the drug left the  
13    control of the manufacturer?

14                    MR. PHILLIPS: Well, I think --

15                    JUSTICE SCALIA: Is it wrong to say that  
16    that's -- you know, that that's interfering with the  
17    FDA's bailiwick?

18                    MR. PHILLIPS: Well, I think when the --

19                    JUSTICE SCALIA: Are you going to let a jury  
20    decide that?

21                    MR. PHILLIPS: No, I'm not going to let a  
22    jury decide that.

23                    (Laughter.)

24                    MR. PHILLIPS: What the district court found  
25    here, obviously, was that there was compliance, because

1 the other side didn't challenge the compliance.

2 JUSTICE SCALIA: Uh-huh.

3 MR. PHILLIPS: And, candidly, I think that  
4 is going to happen 99.999 percent of the time, because  
5 that's not going to be the issue.

6 But, you know, could it eventually be a  
7 problem if a State jury -- if a State court were to  
8 decide that there hasn't been compliance? It seems to  
9 me that's much closer, again, to what you're going to  
10 take up again next term in Wyeth.

11 I think that is a legitimate issue, but it's  
12 a very different one from the question of how do you  
13 regulate the relationship between a -- the regulated  
14 entity and the FDA in terms of the information flow that  
15 goes between those two entities.

16 JUSTICE STEVENS: It seems to me what you  
17 are saying is: We're going to win this case even if  
18 there were no pre-emption.

19 MR. PHILLIPS: Even if there is no  
20 pre-emption on -- on the -- well, I hope I win this case  
21 regardless.

22 JUSTICE STEVENS: Because they have such a  
23 burden of proving that the drug wouldn't, in fact, have  
24 been withdrawn and so forth.

25 MR. PHILLIPS: Right, well -- you mean I

1 would have won this case on the merits of it?

2 JUSTICE STEVENS: Yes.

3 MR. PHILLIPS: Well, I mean, clearly we know  
4 that the FDA didn't withdraw this as a consequence of  
5 fraud. So in that sense, I suppose you're right, but --  
6 but the reality is that the more fundamental problem  
7 remains, whether or not these kinds of statutes are  
8 still out there, are going to create this -- as the  
9 Court said -- extraneous pull.

10 JUSTICE BREYER: Let's just say you use  
11 something like primary jurisdiction said that they  
12 actually have to -- to withdraw it. Now, if the FDA --  
13 this is what Justice Stevens said in his concurring  
14 opinion, which I thought had a lot to be said for it --  
15 that if you had a system where the FDA did withdraw it  
16 and found fraud, you could ask them, and then nothing  
17 wrong with the plaintiff going ahead there.

18 MR. PHILLIPS: We don't have any problem  
19 with that, Justice Breyer.

20 JUSTICE BREYER: You don't have any problem.

21 MR. PHILLIPS: No, we were very --

22 JUSTICE BREYER: That's not --

23 MR. PHILLIPS: If the Court wanted to go  
24 that way, that's fine. I don't think it's presented in  
25 this case, but that wouldn't present any problem for us.



1 I think what we -- what we have here is the Second  
2 Circuit is wrong, and the judgment should be reversed.

3 Thank you, Your Honors.

4 JUSTICE STEVENS: Thank you, Mr. Phillips.  
5 Mr. Joseffer.

6 ORAL ARGUMENT OF DARYL JOSEFFER,  
7 ON BEHALF OF THE UNITED STATES,  
8 AS AMICUS CURIAE,  
9 SUPPORTING THE PETITIONERS

10 MR. JOSEFFER: Justice Stevens, and may it  
11 please the Court:

12 The Michigan statute presents the same  
13 conflict this Court found in Buckman, because it  
14 requires the determination of fraud on the FDA as a  
15 necessary predicate for establishing liability. And as  
16 this Court explained in Buckman, the relationship  
17 between a Federal agency and the entities it regulates  
18 is inherently Federal. And that's --

19 JUSTICE SOUTER: Does your argument carry to  
20 the point of the same argument when regulatory  
21 compliance is raised as a defense, or regulatory  
22 violation is raised as a ground for liability?

23 MR. JOSEFFER: It could depend, because in  
24 our view what's pre-empted here is a State court  
25 determination -- under Buckman, what's pre-empted is a

1 State court determination of whether the FDA was  
2 defrauded as part of FDA's approval process. So, for  
3 example, under any circumstance, if a jury is being  
4 instructed to find whether FDA was defrauded as part of  
5 the approval process, we'd say there's pre-emption.

6 JUSTICE SOUTER: Well, whenever you --  
7 whenever you raise FDA compliance, there is at least the  
8 potential for a response that they -- they defrauded the  
9 FDA; they didn't tell them what they should have, and --  
10 you know, vice versa, when -- when it's raised on the  
11 other side.

12 So you always have the potential there for  
13 -- for just what concerns you, don't you?

14 MR. JOSEFFER: Well -- and what we would say  
15 is not pre-empted -- I mean, it's hard to analyze this  
16 in the abstract without a record as to what a jury was  
17 actually being asked to do. But if you had a situation  
18 where it was, say, a design defect claim, and the jury  
19 was being asked to decide whether this design is  
20 defective, and that's what it's looking at, and in  
21 connection with that the jury is instructed that two  
22 relevant things it can consider are, first, the fact of  
23 FDA's approval determination and, second, the  
24 circumstances surrounding that approval determination,  
25 then that by itself, we would say, is not pre-empted by

1 Buckman, really for two reasons. One is that  
2 pre-emption normally applies to legal theories, such as  
3 claims or defenses, not the mere admissibility of  
4 evidence; and the second is that FDA's core prerogatives  
5 here, as the administrator of its own drug approval  
6 process, are to determine whether it has been defrauded  
7 and what to do about that. And if the jury is not being  
8 asked to find those things, but instead is just  
9 considering evidence in connection with something else,  
10 we would say that that is what's not pre-empted.

11 JUSTICE SOUTER: So it's the withdrawal  
12 element, withdrawal of approval that kills it here?

13 MR. JOSEFFER: That's part of it but not all  
14 of it. I mean, in our view, FDA, as the administrator  
15 of its own approval process, needs absolute discretion  
16 to determine what must be submitted to it as part of its  
17 own approval process, whether it is misled as part of  
18 its own approval process; whether as you said it would  
19 have made a different determination in the absence of  
20 any fraud.

21 JUSTICE SOUTER: But if you get beyond the  
22 element of what the FDA would have done if it had known,  
23 then it seems to me you get into an issue which is  
24 likely to arise by -- whenever, by one side or the  
25 other, the question of regulatory approval is -- is

1 offered as a mere matter of evidence.

2 MR. JOSEFFER: Well, if it really is a mere  
3 matter of evidence, and that's not what the jury is be  
4 asked to find -- and by the way, it's not at all clear  
5 that there's -- that there's -- it's settled common law  
6 tradition in this type of litigation, because the  
7 context here, where a Federal agency does a  
8 product-specific approval based in part on a submission  
9 of information from a manufacturer, that's not a --  
10 that's a question that, first, is of relatively modern  
11 vintage and, second, is not terribly common. So there's  
12 not really a uniform, deeply rooted common law tradition  
13 here. But if all we were talking about was the mere  
14 admissibility of evidence, we would agree that that was  
15 not pre-empted. But if you look at --

16 JUSTICE SOUTER: No, but that's what you've  
17 got here, except that the mere admissibility of the  
18 evidence turns in part on what the -- the FDA would have  
19 done.

20 MR. JOSEFFER: Well, no --

21 JUSTICE SOUTER: But essentially -- I mean  
22 you -- the fact is the evidence of the FDA approval is  
23 made admissible and conclusive, and whether that in fact  
24 may be admitted is subject to the -- what is it --  
25 clause (b) that you object to, but it comes down to a

1 question of admissibility.

2 MR. JOSEFFER: Well, it's not because the  
3 statute expressly requires, as a predicate for  
4 liability, a finding that the information disclosure  
5 requirements of the Federal Food, Drug and Cosmetic Act  
6 were violated. The jury has to find what was required  
7 to be submitted to FDA, was it submitted to FDA and was  
8 FDA misled? And if you had a State administrative  
9 agency that was set up to tell companies what they must  
10 or must not submit to FDA, as part of FDA's own approval  
11 process, the conflict with FDA's ability to administer  
12 its own approval process would be manifest. And it's no  
13 different -- as in Regal, the juries instead of agencies  
14 would be making those determinations in individual  
15 cases.

16 And if I could illustrate the concern which  
17 this Court explained in Buckman, it's that -- just two  
18 FDA regulations. The first explains that the technical  
19 section of a new drug application must provide  
20 information and data in sufficient detail to permit the  
21 agency to make a knowledgeable judgment. Now, because  
22 that is an extremely subjective standard, another FDA  
23 regulation -- and by the way, these are on pages 142a  
24 and 186a of the petition appendix -- the second goes on  
25 to explain that the type and quantity of information

1     that must be submitted to FDA necessarily depends on the  
2     particular drug.

3                   JUSTICE STEVENS:   May I ask this sort of  
4     general question?  Apart from Buckman itself, which  
5     describes a very serious theoretical problem, as I  
6     understand it, there must have been a fair amount of  
7     litigation over the years where the regulatory  
8     compliance defense was raised or challenged or so forth.  
9     Is there -- are there any reported cases describing the  
10    magnitude of the problem to the government, when the --  
11    as the result of debate about these issues?

12                  MR. JOSEFFER:   Nothing that -- that that's  
13    beyond the --

14                  JUSTICE STEVENS:   The whole theoretical  
15    problem.

16                  MR. JOSEFFER:   Well, it's also a relatively  
17    new problem, and what -- because -- because it's --

18                  JUSTICE STEVENS:   The litigation is not, not  
19    new.

20                  MR. JOSEFFER:   Right, but the  
21    product-specific approvals, and the desire to probe into  
22    the circumstances surrounding a product-specific  
23    approval, is of relatively modern vintage.  And Buckman  
24    itself stands for the proposition that that was not a  
25    traditional State inquiry at that time.  And Buckman

1 certainly has not encouraged a significant increase in  
2 such litigation since then. So this is something that  
3 there's not been a whole lot of.

4 JUSTICE KENNEDY: Leaving aside Buckman,  
5 what's your strongest case in support of your position?  
6 Besides that it is a new problem.

7 MR. JOSEFFER: Well, it is. It's a novel  
8 type of situation where you're -- where you're talking  
9 about the Federal Government's prerogatives to  
10 administer its own approval processes. There hasn't  
11 been a lot of State court litigation on this, in part  
12 because it's so obviously a Federal matter. I mean, if  
13 a State supreme court wanted to tell litigants, private  
14 litigants before this Court what they could and couldn't  
15 say in their briefs to this Court, the conflict would be  
16 obvious and therefore the State supreme court would  
17 never do it. And you have a similar problem here where  
18 the State is essentially telling companies what they  
19 must or must not be telling FDA, and there's just an  
20 obvious intrusion there with FDA's ability to administer  
21 its own approval process.

22 JUSTICE GINSBURG: Mr. Joseffer, let's  
23 assume that -- that you're right. The Second Circuit,  
24 because it thought your position it was wrong, never got  
25 to the severance question. It had been decided by some

1 intermediate appellate court. But would it not be  
2 appropriate then to leave it to the Second Circuit on  
3 remand, if it chooses to use the Michigan certification  
4 process to say, well, we want to find out from the  
5 Michigan Supreme Court whether they think that the sweet  
6 stays, but the bitter goes?

7 MR. JOSEFFER: Right. And, I mean, as you  
8 know, we don't have a position on the State law  
9 severability question, because our concern here is  
10 protecting FDA's prerogative to administer its own  
11 process, not with whether the plaintiff or defendant  
12 ultimately wins.

13 JUSTICE SCALIA: It was decided by the Sixth  
14 Circuit, wasn't it?

15 MR. JOSEFFER: It was. And one of the  
16 things that that brings up, in the Sixth Circuit it was  
17 actually the plaintiff who was advocating Federal  
18 pre-emption there, because she thought that she would  
19 then win on severability analysis and would thereby  
20 knock out the entire State statute. What that  
21 underscores is that the unusual Federal pre-emption  
22 question here is not necessarily one that is even bad  
23 for plaintiffs. It just protects the important Federal  
24 prerogative of FDA's ability to administer its own drug  
25 approval process.



1                   But -- but to answer your question, I mean,  
2   we don't have a question -- a position on that analysis,  
3   but I mean, among the procedural options that are  
4   available, as you said, I mean, you're right. Michigan  
5   does have a State certification process that, if people  
6   thought appropriate, could be used.

7                   JUSTICE KENNEDY: This -- this tracks  
8   somewhat Justice Stevens' question. Do we know in this  
9   case, would this have taken two or three days of  
10   testimony? Was there discovery? Was it a thousand  
11   documents? Or three documents?

12                  MR. JOSEFFER: Right. I mean, this case was  
13   resolved promptly on a motion to dismiss. But if you  
14   were going to seriously litigate the question, you would  
15   have to know -- in order to put this in context, to  
16   determine things like withholding and materiality --  
17   you'd have to know everything that FDA had before it,  
18   what FDA thought was required as part of that process.  
19   You would then have to, I suppose, depose FDA witnesses  
20   as to what they would have found to be misleading and  
21   what decisions they might have made in hypothetical  
22   circumstances.

23                  And those are incredibly intrusive inquiries  
24   that, one, distort manufacturers' incentives in dealing  
25   with FDA in the first place; two, if this was seriously

1 going to be litigated would require, I assume, quite a  
2 lot of discovery from FDA, which we would resist, but  
3 that's not to say that we would necessarily succeed in  
4 our objections.

5 JUSTICE STEVENS: May I ask would you -- is  
6 the bribery exception also pre-empted, do you think?

7 MR. JOSEFFER: That's a -- there's a very  
8 different analysis there.

9 JUSTICE STEVENS: I understand. Do you  
10 think --

11 MR. JOSEFFER: But we do think that that  
12 would be pre-empted because -- for a slightly different  
13 reason, which is that the relationship between -- the  
14 bribery of a Federal official in connection with his  
15 Federal duties is obviously a matter of paramount  
16 Federal concern, and when the -- especially when the  
17 State is looking at that for purposes of essentially  
18 second-guessing the validity of a regulatory  
19 determination that FDA had made --

20 JUSTICE STEVENS: Supposing the -- supposing  
21 the official pleaded guilty to bribery. Would it be  
22 pre-empted then?

23 MR. JOSEFFER: Obviously, it still gets much  
24 closer, and at that point, I'm not sure that it would  
25 be.

1 JUSTICE STEVENS: It seems to me we've got a  
2 lot of theoretical litigation out here without much  
3 actual experience with any of these cases.

4 MR. JOSEFFER: You know, what I was going to  
5 say is there are a lot of interesting issues surrounding  
6 this case, but none of them actually seem to be  
7 presented in this case, because here -- I mean, the  
8 statute clearly requires a determination of fraud on the  
9 FDA, including all the elements I mentioned, as a  
10 necessary predicate for recovery; and, two, FDA has not  
11 made such a determination.

12 Thank you.

13 JUSTICE STEVENS: Thank you very much.

14 Ms. Zieve.

15 ORAL ARGUMENT OF ALLISON M. ZIEVE

16 ON BEHALF OF THE RESPONDENTS

17 MS. ZIEVE: Justice Stevens, and may it  
18 please the Court:

19 Warner-Lambert marketed a defective product.  
20 It withheld information about the injury the product  
21 could cause, and the product caused injury to a great  
22 many patients, including Respondents. They sued  
23 Warner-Lambert alleging traditional State law claims,  
24 such as product defect and failure to warn. I'd like  
25 to begin by explaining why the misrepresentation

1 exception to the Michigan defense does not implicate the  
2 concerns that were raised by the Court in Buckman.  
3 Specifically, the Court in Buckman identified three  
4 problems or concerns that it thought warranted  
5 pre-emption in that case: That the claim alleged would  
6 cause companies to submit too much information and slow  
7 down the 510(k) process; that the claim alleged might  
8 cause companies not to submit products for approval  
9 because of concern about off-label use; and that the  
10 claim would cause an unwarranted intrusion on the FDA's  
11 decisionmaking about how to police and enforce fraud  
12 against it.

13 So the question is: Does the Michigan law  
14 implicate these three concerns any more than traditional  
15 State tort litigation against a drug company?

16 I'll start with what I think are the easy  
17 ones. For three reasons, the Michigan statute creates  
18 no incentive for manufacturers to submit unnecessary  
19 information to the FDA. Unlike the streamlined 510(k)  
20 clearance process that was at issue in Buckman, in this  
21 case we have a drug approval. Drugs are required to go  
22 through a comprehensive pre-market approval process.  
23 The regulations require submission of, "all available  
24 information about the safety of a drug, including  
25 demonstrated or potential adverse effects." I was

1 quoting from 314.50(b)(5). As Warner-Lambert points out  
2 in its brief, a typical new drug application can be  
3 thousands of pages long. So there's not really -- not  
4 only is there not evidence that this 12-year-old statute  
5 will lead companies to submit information that the FDA  
6 doesn't want and doesn't need; but it's really unclear  
7 what such evidence would be because, after all,  
8 companies are required to submit all safety information  
9 to the FDA, and it's safety information that would be  
10 relevant to a finding under the Michigan exception.

11 JUSTICE KENNEDY: The converse of that is  
12 that the discovery is exhaustive and quite burdensome.  
13 I mean, you're trying to say, well, don't worry; there's  
14 thousands of documents here; they won't be submitting  
15 anything else. But, on the other hand, that cuts  
16 against you when we're talking about the intrusiveness  
17 on the Federal scheme because you have to have Federal  
18 regulators go back through all of this stuff again.

19 MS. ZIEVE: No, Your Honor. The discovery  
20 in a case like this -- there is no evidence to suggest  
21 it would be any broader or more burdensome than  
22 discovery in a typical product liability case against a  
23 drug company.

24 In that regard, Mr. Joseffer is wrong that  
25 there was no discovery in this case. These cases are

1 part of a multidistrict litigation and there was a  
2 significant amount of discovery.

3 JUSTICE BREYER: All that makes -- makes it  
4 worse, in a sense, because what you're saying to me  
5 anyway -- and you can explain why I'm not right -- that  
6 all of the three things that you mentioned are only  
7 aspects of something much more fundamental that  
8 underlies all these cases -- Medtronic, drugs, all of  
9 them. You came up and began and said this drug has side  
10 effects that hurt people. And that's a risk when you  
11 have a drug, and it's a terrible thing if the drug hurts  
12 people.

13 There's a risk on the other side. There are  
14 people who are dying or seriously sick, and if you don't  
15 get the drug to them they die. So there's a problem.  
16 You've got to get drugs to people and at the same time  
17 the drug can't hurt them.

18 Now, who would you rather have make the  
19 decision as to whether this drug is, on balance, going  
20 to save people or, on balance, going to hurt people? An  
21 expert agency, on the one hand, or 12 people pulled  
22 randomly for a jury role who see before them only the  
23 people whom the drug hurt and don't see those who need  
24 the drug to cure them?

25 Now, that it seems to me is Congress's

1 fundamental choice, and Congress has opted for the  
2 agency. And that's why we're here --

3 MS. ZIEVE: Well --

4 JUSTICE BREYER: -- because you want the  
5 jury to do it. And it seems to me, reading Buckman,  
6 that Buckman says the agency should do it. So that's  
7 what underlies all my reactions to this, and I might as  
8 well get it right out so that you can answer.

9 MS. ZIEVE: Well, I think I have a -- State  
10 law torts suits aren't seeking to make a determination  
11 about whether the product should have gone on the  
12 market. The purpose of the State law tort suit is to  
13 compensate injured patients. That's a fundamentally  
14 different role. It's complementary to the FDA's role,  
15 but it's different. And I think your question, though,  
16 really goes more to the broader issues that the Court  
17 will consider next term.

18 JUSTICE BREYER: Ms. Zieve, it doesn't  
19 object to a system where the -- a court -- the State  
20 would come in and give you your tort suit if it's really  
21 true that the agency would withdraw this drug. But what  
22 you want is to be able to convince the jury that there  
23 was fraud in a situation where the agency doesn't say  
24 there was fraud. So what you're doing is removing a  
25 drug from the market that they want out there.

1                   Now, that's the theory of Buckman. The  
2   theory of Buckman is --

3                   MS. ZIEVE: But that is not --

4                   JUSTICE BREYER: -- they want to save people  
5   whom you say they shouldn't because the drug shouldn't  
6   be there. I overstate it slightly. So, explain to me  
7   why.

8                   MS. ZIEVE: Well, this case doesn't seek to  
9   pull Rezulin from the market. Well, first of all,  
10   Rezulin was pulled from the market seven years ago. But  
11   that is not the goal of this case. The goal of this  
12   case is to pay -- to get compensation for people who  
13   suffered serious liver damage, every single one of them.  
14   About a third of the patient-respondents died from the  
15   liver damage caused by Rezulin, and what they're seeking  
16   here is not a regulatory remedy; they're seeking damages  
17   and compensation for that.

18                  And the -- the place where we started with  
19   the --

20                  JUSTICE KENNEDY: Your premise still is, is  
21   that the drug should not have been marketed, or is that  
22   your premise?

23                  MS. ZIEVE: Well, under Michigan law, the  
24   plaintiffs can only --

25                  JUSTICE KENNEDY: I know your purpose is



1 different, but the premise on which you operate is that  
2 the drug should not have been sold.

3 MS. ZIEVE: The -- if I can just back up to  
4 -- to the structure of the Michigan statute --

5 JUSTICE KENNEDY: You can back up as long as  
6 you want as long as you come forward and answer.

7 (Laughter.)

8 MS. ZIEVE: I promise will.

9 (Laughter.)

10 MS. ZIEVE: The Michigan statute takes as  
11 its starting point the notion that Federal approval is  
12 reliable evidence that a drug company has satisfied the  
13 duty -- State law duties of care owed to patients, and  
14 then it says: But there are a couple of situations  
15 where that reliability is drawn into question.

16 So, if the company bribes the FDA or the if  
17 the company misrepresented important information to the  
18 FDA, then the approval is no longer a sufficient basis  
19 on which we can just say that approval in and of itself  
20 means that the manufacturer satisfied State law duties.

21 And so, the -- the purpose of the finding  
22 about whether there was misrepresentation and what the  
23 results of it might have been is not to police  
24 enforcement with FDA requirements, and it is not to  
25 force the drug off the market. It is only a hurdle that

1 the plaintiff has to get past so it can litigate -- he  
2 or she can litigate her State law claim the same way  
3 plaintiffs will be litigating those claims, and did  
4 litigate those claims, with respect to Rezulin in States  
5 across the country.

6 JUSTICE KENNEDY: Aren't you going to tell  
7 this jury that the drug should not have been on the  
8 market?

9 MS. ZIEVE: Yes. In Michigan they will have  
10 to present evidence that if the company had been honest  
11 with the FDA, the product wouldn't have been approved.  
12 The discovery in this case shows that it doesn't -- at  
13 least in this case, that wouldn't present a big problem.

14 First of all, there is evidence in this  
15 case, testimony from the medical officer who reviewed  
16 the information, that Rezulin would not have been  
17 approved as a standalone therapy, that it is infused  
18 without insulin or another drug, if the company hadn't  
19 lied about -- withheld adverse event reports.

20 But certainly in the typical case a lot of  
21 the information that comes out with respect to what went  
22 on before the FDA, not only is it submitted in product  
23 liability cases in the first instance by the  
24 manufacturer to show all of the hurdles they had to go  
25 through to get on the market, doesn't that show our

1 product was safe, but a lot of it you can get in  
2 discovery from the company, themselves, as happened in  
3 this case. A lot of --

4 JUSTICE KENNEDY: I thought under the  
5 Michigan scheme you don't have to show that. You just  
6 show approval, and that's the end of the case in  
7 Michigan.

8 MS. ZIEVE: There are no Michigan cases  
9 explaining just what you need to show to satisfy the  
10 defense, so it is unclear whether you have to show that  
11 you met -- if it is the right chemical formula, with the  
12 label originally approved, or does compliance with  
13 approval mean that you also had to show -- one of the  
14 terms of approval is that you continued to update your  
15 label when you become aware of new safety information;  
16 would you have to show -- a manufacturer have to show  
17 that to show that the defense was satisfied.

18 There's no cases under Michigan law which  
19 tell us --

20 JUSTICE STEVENS: It seems to me that you  
21 could prove that the -- an exception to the defense  
22 applies and still lose your lawsuit?

23 MS. ZIEVE: Absolutely, we could. Showing  
24 that the exception applies is just the first step to  
25 being able to litigate this case the way plaintiffs

1 litigated these cases in California, and Illinois, and  
2 New York, and other States.

3           There was Rezulin litigation throughout the  
4 country. And, again, the point about discovery is that  
5 the broad discovery that was done, a lot from  
6 Warner-Lambert, some from the FDA, that was no different  
7 discovery really than would be required under Michigan.  
8 It's all there.

9           JUSTICE ALITO: Would you explain why you  
10 think Mr. Joseffer was wrong when he argued that having  
11 a jury decide whether the FDA would have approved the  
12 drug or would have withdrawn it from the market if  
13 additional or different information had been supplied is  
14 incorrect?

15           Doesn't that -- wouldn't that very seriously  
16 interfere with what the FDA is doing?

17           MS. ZIEVE: Well, of course, in the specific  
18 facts of this case it wouldn't, because Rezulin is off  
19 the market and unapproved. But even as a general matter  
20 it doesn't affect FDA's regulation because, as I said in  
21 response to Justice Stevens, the effect of making that  
22 showing and the jury agreeing that the product wouldn't  
23 have been approved is -- there's no regulatory effect.  
24 The effect is that the plaintiff can then go ahead and  
25 litigate her case like she could in any other State.

1                   And that's why -- that's because what  
2 Michigan is doing is not policing enforcement. It is  
3 just defining the parameters of the compliance --

4                   JUSTICE ALITO: There wouldn't be discovery  
5 of internal processes within the FDA? There wouldn't be  
6 experts testifying about what the FDA would or would not  
7 have done?

8                   MS. ZIEVE: Well, the parties may seek  
9 discovery. There hasn't been enough Michigan litigation  
10 for us to know exactly how it would work; but,  
11 certainly, the courts in Michigan should be trusted to  
12 use their discretion to keep discovery under control as  
13 they do in every case. The Rezulin litigation --

14                  JUSTICE GINSBURG: Wasn't -- in this case  
15 one of the charges was that the original FDA examiner  
16 had recommended against approval for this drug, and then  
17 something happened inside the FDA, and that examiner was  
18 taken off the matter, and another one who approved it  
19 was put on?

20                  Isn't that the kind of thing that the FDA  
21 would want to police itself and not have State courts  
22 look into?

23                  MS. ZIEVE: Well, those are some of the  
24 background facts that happened here. But I don't think  
25 those are the facts that go to a showing of what the FDA

1 would have done if Warner-Lambert had made honest  
2 disclosures, because actually those facts tend to  
3 suggest that the FDA did know what was going on.

4 But later the second medical officer, the  
5 one who did recommend approval -- the approval came in  
6 two stages. One was for use as a combination therapy  
7 with insulin and another drug called Metformin, and  
8 later there was an approval for use of Rezulin on its  
9 own.

10 That is the use that happened to affect all  
11 of my clients, and that's the use where we already have  
12 a medical officer who testified that the agency would  
13 not have approved for that use if the company hadn't  
14 withheld safety information.

15 JUSTICE ALITO: Well, what evidence would  
16 you introduce to prove the -- to prove the exception if  
17 the Second Circuit's decision stands?

18 MS. ZIEVE: Deposition testimony from that  
19 medical officer, for example. There are e-mails. We  
20 cited a couple of e-mails in the red brief of things  
21 that were stated at the time: One an e-mail to  
22 Warner-Lambert and one from a medical officer to his  
23 superior talking about the way in which Warner-Lambert  
24 made it harder -- to be kind to -- for them to assess  
25 what the true safety profile of the drug was.

1                   There is -- as I said, there was a very  
2   large amount of Rezulin discovery done in the MDL, most  
3   of which is under a protective order. So I don't know  
4   everything that's in there, but --

5                   JUSTICE GINSBURG: The question is: Would  
6   we be disrupting the FDA by taking depositions of  
7   examiners to find out what went on at the FDA?

8                   MS. ZIEVE: No more so than product  
9   liability litigation in any other State. As I said, the  
10   deposition that happened in this case, the plaintiff's  
11   committee asked -- they negotiated discovery with the  
12   FDA in the Rezulin cases in general, not looking at  
13   Michigan specifically at all. They got some discovery  
14   from the FDA and the deposition of the medical officer.

15                   There's also a lot of information about  
16   approved drugs that the FDA posts as a matter of course  
17   on its website, including the medical officer reviews  
18   that form the basis for the approval decision.

19                   But even in other cases, for instance, the  
20   Vioxx MDL that was pending in Louisiana, the -- in that  
21   case the FDA wasn't as interested in negotiating, and  
22   there was motions to suppress and a motion to compel.  
23   And the judge had to decide whether to allow an FDA  
24   medical officer to be deposed; and in that case, did.

25                   There are other cases where the FDA has not

1 wanted discovery and has successfully opposed it. The  
2 FDA has regulations about that, and there's no evidence  
3 that it's burdening the FDA to cooperate to some degree  
4 in discovery or the judges are allowing plaintiffs to  
5 overrun the FDA with requests they can't handle. But,  
6 more importantly --

7 JUSTICE SCALIA: I assume -- I assume -- you  
8 don't stop between sentences, so I hate to interrupt  
9 you.

10 (Laughter.)

11 JUSTICE SCALIA: I assume that if this drug  
12 were still on the market, you could bring forward the  
13 information that you have alluded to about the  
14 withholding of necessary data by Warner-Lambert, and the  
15 FDA would certainly be able to consider that and decide  
16 whether sanctions were necessary, withdrawing of the  
17 drug was necessary.

18 In this case, the drug has already been  
19 withdrawn. So I assume the FDA has at least a reduced  
20 incentive to go into these questions. I guess they  
21 still would want to go into them if Warner-Lambert were  
22 really a bad actor. They could impose some sanctions,  
23 couldn't they, even though the drug was already  
24 withdrawn?

25 MS. ZIEVE: I don't know if they still



1     could, but presumably sometime in the past they could  
2     have.

3                 JUSTICE SCALIA:  Do you think we could have  
4     two different rules:  One for drugs that are still out  
5     there and one for drugs that have since been withdrawn?  
6     Because I frankly see little incentive for the FDA, you  
7     know, to go back over past mistakes.  The drug now  
8     having been withdrawn, it doesn't matter.

9                 But if the drug was still out there, it  
10    seems to me you could come forward, and I would be much  
11    less sympathetic to what you're trying to do.  You could  
12    trust the FDA to do the job.

13                MS. ZIEVE:  Well, the job the FDA is going  
14    to do, even if it agrees with a plaintiff, is to  
15    sanction the company, perhaps, or to ask it for  
16    different information.  It does have the ability to  
17    withdraw approval --

18                JUSTICE SCALIA:  No, but once it sanctions  
19    the Plaintiff, the Government can't make the argument  
20    you are interfering; you are second-guessing the FDA.

21                The FDA would have said:  You didn't give us  
22    information that was necessary; and had we known this,  
23    we wouldn't have gone ahead.

24                MS. ZIEVE:  There's no way for a plaintiff  
25    to compel the FDA to look into a situation of a

1 manufacturer being dishonest for the -- or to -- even if  
2 the FDA starts a process for a plaintiff to compel the  
3 agency to make a finding that the company  
4 withheld material information, and we would not have  
5 approved it otherwise.

6 And even if the agency chose to do that, it  
7 wouldn't be of any help to the plaintiff because the  
8 plaintiff's family is seeking compensation because the  
9 breadwinner is dead, or the person is impeded in their  
10 ability to make a living in the future and has huge  
11 medical bills now.

12 And the FDA's finding that, yes, the company  
13 really acted badly isn't going to do anything to help  
14 that -- that family.

15 JUSTICE BREYER: Yes, but it will lead to  
16 the drug being withdrawn, in which case there may be  
17 just as many people on the other side who are dying,  
18 dead, no breadwinner, et cetera, because they didn't get  
19 a necessary drug. And that's why what worries me is  
20 what happens if the jury is wrong?

21 You are absolutely right when you say you  
22 cannot make the FDA go into this matter and withdraw a  
23 drug; and they are absolutely right when they say we  
24 cannot promise you that juries will be right.

25 MS. ZIEVE: But, again --

1 JUSTICE BREYER: So the the question is:  
2 Who is more likely to be right?

3 MS. ZIEVE: With respect, I don't think  
4 that's the question, because if the jury -- if a  
5 Michigan jury is wrong about what would have happened if  
6 Warner-Lambert hadn't acted so badly, the result is that  
7 Ms. Kent and the other Plaintiffs get to litigate their  
8 claims. The result is not -- there is no regulatory --

9 JUSTICE BREYER: Then you think they should  
10 be able to litigate a claim where the FDA has approved a  
11 drug.

12 Now, is that the law in most places? Where  
13 the FDA has approved a drug for use and the doctor  
14 follows the label and the label is all okay, is it the  
15 case that somebody can come in and say, despite that,  
16 this drug is on balance harmful, and I get compensation?

17 This is a serious question. I'm not sure  
18 how it works.

19 MS. ZIEVE: That is the law in every State.

20 JUSTICE BREYER: So --

21 JUSTICE GINSBURG: That's been contested,  
22 and we are going to hear that case next term.

23 JUSTICE BREYER: That's the next issue.

24 MS. ZIEVE: That's right.

25 JUSTICE GINSBURG: Right. But it's been --

1 JUSTICE BREYER: I see.

2 JUSTICE GINSBURG: -- at least since the  
3 1930's, State tort litigation of the very kind that  
4 Justice Breyer has described has gone on. Isn't that  
5 so? That you -- even though the FDA has approved a  
6 drug, an injured party can say this was a defective  
7 drug, and the manufacturer says regulatory compliance.  
8 That's a defense. And you would say it's a defense, but  
9 not a conclusive defense.

10 MS. ZIEVE: Absolutely.

11 JUSTICE GINSBURG: That's how -- that's how  
12 --

13 MS. ZIEVE: Yes. The FDA approval, Federal  
14 approval, and State tort actions have co-existed since  
15 1938.

16 JUSTICE BREYER: Why? That's where I am  
17 missing you. Why, then, does Michigan even have this  
18 thing? In other words, why -- you are saying if they  
19 didn't have it at all, you would go ahead and bring your  
20 tort action.

21 MS. ZIEVE: That's right. Michigan chose --

22 JUSTICE BREYER: Thank you.

23 MS. ZIEVE: -- to -- not to create a new  
24 claim as the plaintiffs tried to do in Buckman, but,  
25 rather, to take a traditional claim and restrict

1 plaintiff's ability to prevail on it.

2           This is not an expansion of State tort law.  
3 It is a considerable narrowing of State tort law.

4           JUSTICE GINSBURG: Well, would you say that  
5 my characterization of it when Mr. Phillips was  
6 presenting his case, that this is an invigorated  
7 regulatory compliance defense, that it is more  
8 favorable, far more favorable, to the manufacturer than  
9 the standard regulatory compliance because it says that  
10 the manufacturer is immune, totally immune, unless --  
11 and then the exception that we are debating here.

12           But it is a deliberately pro-manufacturer  
13 measure. It gives the manufacturer an immunity that the  
14 regulatory compliance defense does not.

15           MS. ZIEVE: And I would go even further.  
16 It's not just pro-manufacturer. This statute is the  
17 most deferential to the FDA of any State tort law in the  
18 country. Other States will allow a manufacturer to  
19 present evidence of compliance to show the product  
20 wasn't defective, and that's non-dispositive evidence in  
21 almost every State.

22           And then a plaintiff can come back and say:  
23 Oh, but look, they didn't comply in these ways. And  
24 that wouldn't be dispositive either in most States.

25           But only in Michigan not only is the

1 manufacturer's compliance defense dispositive in the  
2 majority of cases, but the evidence of non-compliance  
3 isn't even allowed as a rebuttal unless the plaintiff  
4 can show that it actually was a material non-compliance  
5 that would have made a difference.

6 JUSTICE KENNEDY: And in your view could a  
7 State prohibit introduction of evidence by the defendant  
8 that the drug was approved by the FDA?

9 MS. ZIEVE: Only to the extent that they  
10 simply thought it wasn't relevant. And there are  
11 States that --

12 JUSTICE KENNEDY: And all they say in the  
13 statute: We just think -- they just think this is  
14 irrelevant.

15 MS. ZIEVE: Sure. And there are States that  
16 don't allow compliance --

17 JUSTICE KENNEDY: But I don't think that's  
18 consistent with your position. There's no doubt about  
19 that.

20 MS. ZIEVE: There are States that don't  
21 allow compliance evidence if the plaintiff shows  
22 material misrepresentation, "material" being that it  
23 could have -- could have influenced the agency without a  
24 finding that it did or would have influenced the agency,  
25 but just that it was pertinent information.

1           And in those cases, this is discussed in  
2   common -- either the restatement. In such a case some  
3   States would say that the compliance evidence then can't  
4   come in. And it is sort of the same theory as  
5   Michigan's, but just not as strict against the  
6   plaintiffs, that if you can't trust the -- the  
7   compliance evidence isn't relevant. It's not meaningful  
8   if you can't trust it. Because the --

9           JUSTICE BREYER: So to me, which is a good  
10   answer, is you are saying: Look at the basic tort  
11   system here. And if you can do that, you can do this.  
12   Is that -- do you see where I'm --

13           MS. ZIEVE: If -- if the traditional tort  
14   system as it exists in most every State is not  
15   pre-empted, then Michigan's statute is not pre-empted.

16           JUSTICE GINSBURG: Ms. Zieve, how many  
17   States have a statute like Michigan's?

18           MS. ZIEVE: The Michigan statute is unique  
19   with respect to the finding -- the requirement that  
20   there be a finding of how the FDA would have acted if  
21   the manufacturer had not made certain representations.

22           JUSTICE GINSBURG: No other State does that?

23           MS. ZIEVE: Texas has a similar statute  
24   except it doesn't have that last element. And one of  
25   the questions on severability is whether -- if you think

1 just that element is pre-empted, whether you can --  
2 whether Michigan would want to sever that one element.

3 And then there are a number of States that  
4 limit punitive damages liability but along the lines of  
5 Texas, not Michigan. So, again, that last element is  
6 not required.

7 JUSTICE GINSBURG: But was there any  
8 experience with this in Michigan? How many years was it  
9 in operation before the Sixth Circuit decision?

10 MS. ZIEVE: I believe it went into effect in  
11 March of '96. So, seven years.

12 JUSTICE GINSBURG: Have there been many  
13 trials to test this theory that it would be disruptive,  
14 that --

15 MS. ZIEVE: We were unable to find any  
16 reported cases or Westlaw discussion of --

17 JUSTICE SCALIA: What's the Sixth Circuit  
18 case? It must have involved this, no?

19 MS. ZIEVE: Well, in the Sixth Circuit the  
20 plaintiff said: We can't prove the exception, but it is  
21 pre-empted and not severable. So we -- so that the the  
22 statute would fall.

23 JUSTICE SCALIA: I see. What is your  
24 position on severability? Why shouldn't we -- you know,  
25 we usually accept the circuit court's determination as



1 to what the State law is. Michigan is in the Sixth  
2 Circuit. And I think it's overwhelmingly likely that  
3 the Second Circuit would defer to the Sixth Circuit's  
4 view. Don't you think?

5 MS. ZIEVE: Well, in footnote 4 of the  
6 Second Circuit's decision, Justice Calabrezze points out  
7 that certification to the Michigan Supreme Court would  
8 also be an option, and an option that the court doesn't  
9 -- that court didn't even get to.

10 JUSTICE GINSBURG: The discussion in the  
11 Sixth Circuit was not very extensive on this point, on  
12 this --

13 MS. ZIEVE: No, it wasn't. And this Court  
14 has no -- has no practice with respect to deferring to  
15 State law questions that were decided by courts of  
16 appeals in a different case. That is, this case didn't  
17 come to the Court from the Sixth Circuit.

18 JUSTICE STEVENS: I want to be sure I  
19 understand something. In the other case, the plaintiff  
20 is the one who argued there was pre-emption, and the  
21 whole statute was invalid, and not the defendant.

22 MS. ZIEVE: That's right.

23 JUSTICE STEVENS: I see. I missed that.

24 MS. ZIEVE: Yes. It was a good try. But I  
25 think that the severability argument is very closely

1 tied to the reason --

2 JUSTICE STEVENS: So the defendants kind of  
3 take the risk when they make the argument they are  
4 making. They have a chance to either lose or win.

5 MS. ZIEVE: Well, that's right. I mean, I  
6 think the fact that Michigan is such a pro-manufacturer  
7 State --

8 JUSTICE STEVENS: If there is no  
9 severability, the defense is gone, period.

10 MS. ZIEVE: That's right.

11 The -- and the reason for severability,  
12 though, was quite tied to the whole reason why we think  
13 there's not preemption in the first place, which is that  
14 the statute really needs to be looked at as a whole.  
15 You can't -- you can't understand what the exception is  
16 trying to accomplish without putting it in the context  
17 of the statute. After all, it is -- it's subparagraph  
18 (8) of subsection (5) of the Michigan statute.

19 If the Court has no further questions,  
20 thank you.

21 JUSTICE STEVENS: Thank you.

22 Mr. Phillips, you have five minutes.

23 REBUTTAL ARGUMENT OF CARTER G. PHILLIPS

24 ON BEHALF OF THE PETITIONERS

25 MR. PHILLIPS: Thank you, Justice Stevens.

1 Hopefully, I'll give you back some of that time, so you  
2 can get to lunch.

3 Justice Kennedy, I think the best case for  
4 us without Buckman would have been Hoyle versus United  
5 Technologies. That's a case involving again a uniquely  
6 federal interest. And the advantage of that particular  
7 case is it also reflects that pre-emption is not an all  
8 or nothing proposition. You can preempt out the  
9 specific parts that is offensive and retain the part of  
10 State law that is not offensive. And that's precisely  
11 what we're trying to do in this case.

12 JUSTICE KENNEDY: There was special  
13 consideration because of military considerations.

14 MR. PHILLIPS: Well, I think that's what  
15 made it a uniquely Federal interest. But I don't know  
16 that it's any more a uniquely Federal interest than this  
17 one. At least this is the way the Court has analyzed  
18 both of them in Buckman.

19 Justice Ginsburg, with respect to  
20 severability, I think, frankly, the Second Circuit  
21 already answered the question. They said that we would  
22 defer to the Sixth Circuit under Factors and then  
23 analyze certification. And it concluded that, given the  
24 clarity of the Sixth Circuit's decision in Garcia, that  
25 there's nothing left to be decided on that issue.

1 JUSTICE GINSBURG: I didn't think that the  
2 Second Circuit discussed severability, but I can go back  
3 and check.

4 MR. PHILLIPS: Well, if you -- if you --

5 JUSTICE GINSBURG: I thought that it had  
6 been raised there, but they didn't get to it because  
7 they --

8 MR. PHILLIPS: I would suggest you read the  
9 Petition Appendix 14a, where it says on the one hand,  
10 under Factors we are bound to follow Garcia's  
11 conclusions as to questions of Michigan State law, and  
12 then the footnote reflects that the Sixth Circuit in  
13 Garcia had clearly decided the severability issue here.  
14 So, frankly, if --

15 JUSTICE GINSBURG: In a very, very quick --  
16 it isn't a very thoroughly reasoned discussion. It's a  
17 is very -- it's just one paragraph.

18 MR. PHILLIPS: To be sure. But on the other  
19 hand, it does seem to me that it spoke specifically to  
20 the issue and recognized the right outcome.

21 JUSTICE GINSBURG: I mean, because it is  
22 odd -- I mean, it is odd that you'd have a statute that  
23 says: Manufacturer, we're going to give you immunity,  
24 but there's an exception. They seem so tied together  
25 and it really would be a case of letting one side keep

1 the sweet and get rid of the bitter. And it seems to me  
2 that there is -- that there was no discussion of that in  
3 the Sixth Circuit.

4 MR. PHILLIPS: Oh, but there is a discussion  
5 of that in the Sixth Circuit decision. Garcia  
6 specifically deals with that, because it says the bitter  
7 that you have to take is if the FDA in fact makes all of  
8 the very specific and intricate findings that are  
9 required by the exception and concludes that the product  
10 should be withdrawn for fraud, then in fact you get the  
11 bitter, which is that the lawsuit goes forward under  
12 those circumstances, and that that's the reasonable  
13 compromise that the State legislature had in mind or  
14 would have been satisfied with.

15 JUSTICE GINSBURG: But the question is  
16 whether the legislature would have passed the statute  
17 that it did if in a case like this one the manufacturer  
18 could have the immunity without the exception.

19 MR. PHILLIPS: All I'm saying is I think the  
20 Court addressed that in Garcia and specifically  
21 concluded that the legislature in fact would have passed  
22 that; And that traditionally, the Second Circuit would  
23 defer, as would this Court.

24 JUSTICE GINSBURG: It would be -- it would  
25 be open to the Second Circuit on remand because it's not

1     foreclosed.

2                   MR. PHILLIPS:  No, clearly it's not  
3     foreclosed.

4                   JUSTICE SCALIA:  Well, unless they choose  
5     not to change their mind.  I mean, they did say that  
6     they're bound by this by Garcia as to questions of State  
7     law.

8                   MR. PHILLIPS:  Exactly.

9                   JUSTICE SCALIA:  They said that:  We are  
10    bound by Garcia as to questions of State law.

11                  MR. PHILLIPS:  Exactly.

12                  Justice Scalia, I'd like to answer your  
13    question about if we were going forward with respect to  
14    withdrawal as opposed to looking back.  I mean, the FDA  
15    still has the authority to order disgorgement, to order  
16    restitution for victims.  I think the notion that the  
17    FDA is indifferent to claims of fraud is just -- is  
18    flatly offensive.  The reality is --

19                  JUSTICE STEVENS:  Does restitution for  
20    victims include damages?

21                  MR. PHILLIPS:  Well, whatever injuries --  
22    yeah, I mean, I don't know exactly what the sweep of  
23    restitution would be, but disgorgement of profits would  
24    certainly provide a mechanism for providing --

25                  JUSTICE STEVENS:  Well, you're not talking

1 about profits when you have an injured -- a patient who  
2 died as a result of malpractice or something. That's  
3 not disgorgement of profits. That's damages.

4 MR. PHILLIPS: I understand that. All I'm  
5 suggesting, Justice Stevens, is that there are remedial  
6 mechanisms still available to the FDA if in fact it  
7 concluded that there was some problem, and that those --

8 JUSTICE STEVENS: It couldn't give recovery  
9 to a class action of a couple of hundred plaintiffs who  
10 were injured, could it? No such remedy under the FDA,  
11 or am I wrong on that?

12 MR. PHILLIPS: Well, as I understood the  
13 FDA's position is that they have pretty broad remedial  
14 authority and that it extends to some form of  
15 restitution to the victims. So I --

16 JUSTICE GINSBURG: The government told us in  
17 its brief that the FDA has no system for addressing  
18 public complaints -- this was in their brief at page  
19 24 -- because that would divert attention from their  
20 primary mission. So there's no action for fraud that  
21 one can bring to the FDA.

22 MR. PHILLIPS: Well, I mean, there is a  
23 provision for citizen petitions that exists, that's  
24 cited. So, yes, there is a mechanism.

25 JUSTICE GINSBURG: But The FDA doesn't have

1 to do anything about it?

2 MR. PHILLIPS: Well, no. It entertains it.

3 In point of fact, there was a petition filed by Public

4 Citizen to withdraw Rezulin in this specific case, and

5 it was reviewed and it was rejected for exactly the

6 reason Justice Breyer identified, because if you took it

7 off the market, people would die. That was the concern

8 that drove the FDA to say: We're not going to do that

9 under these circumstances.

10 If there are no further questions, Your

11 Honors.

12 JUSTICE STEVENS: The case is taken under

13 advisement.

14 (Whereupon, at 12:05 p.m., the case in the

15 above-entitled matter was submitted.)

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|-------------------------|--------------------------|------------------------|------------------------|-------------------------|
| <b>A</b>                | 19:3 20:14,17<br>21:1    | <b>amici</b> 9:15      | <b>approved</b> 4:12   | 29:18 33:3,5            |
| <b>ability</b> 21:11    | <b>admissible</b>        | <b>amicus</b> 1:20 2:6 | 4:22 14:10             | 41:7 45:22              |
| 23:20 24:24             | 20:23                    | 17:8                   | 34:11,17 35:12         | 51:1 52:2               |
| 41:16 42:10             | <b>admitted</b> 20:24    | <b>amount</b> 22:6     | 36:11,23 37:18         | 54:14                   |
| 45:1                    | <b>adopted</b> 3:24      | 30:2 39:2              | 38:13 39:16            | <b>background</b>       |
| <b>able</b> 31:22 35:25 | <b>advantage</b> 51:6    | <b>analysis</b> 3:18   | 42:5 43:10,13          | 37:24                   |
| 40:15 43:10             | <b>adverse</b> 28:25     | 24:19 25:2             | 44:5 46:8              | <b>bad</b> 10:2 24:22   |
| <b>above-entitled</b>   | 34:19                    | 26:8                   | <b>argued</b> 36:10    | 40:22                   |
| 1:12 56:15              | <b>advisement</b>        | <b>analyze</b> 18:15   | 49:20                  | <b>badly</b> 42:13 43:6 |
| <b>absence</b> 19:19    | 56:13                    | 51:23                  | <b>arguing</b> 9:14,23 | <b>bailiwick</b> 14:17  |
| <b>absolute</b> 19:15   | <b>advocating</b>        | <b>analyzed</b> 10:19  | <b>argument</b> 1:13   | <b>balance</b> 30:19    |
| <b>absolutely</b> 35:23 | 24:17                    | 51:17                  | 2:2,10 3:4,7           | 30:20 43:16             |
| 42:21,23 44:10          | <b>affect</b> 36:20      | <b>answer</b> 5:9 9:21 | 7:2 9:14 10:8          | <b>barred</b> 5:12      |
| <b>abstract</b> 18:16   | 38:10                    | 25:1 31:8 33:6         | 12:12 13:18            | <b>based</b> 3:14,15    |
| <b>accept</b> 48:25     | <b>agencies</b> 3:12     | 47:10 54:12            | 17:6,19,20             | 20:8                    |
| <b>accomplish</b>       | 21:13                    | <b>answered</b> 51:21  | 27:15 41:19            | <b>basic</b> 47:10      |
| 50:16                   | <b>agency</b> 6:9,10     | <b>anyway</b> 30:5     | 49:25 50:3,23          | <b>basically</b> 9:14   |
| <b>acknowledge</b>      | 17:17 20:7               | <b>Apart</b> 22:4      | <b>arguments</b>       | <b>basis</b> 7:22 33:18 |
| 5:1                     | 21:9,21 30:21            | <b>App</b> 4:5         | 12:11                  | 39:18                   |
| <b>Act</b> 4:11 21:5    | 31:2,6,21,23             | <b>appeals</b> 49:16   | <b>arises</b> 3:22     | <b>began</b> 30:9       |
| <b>acted</b> 42:13 43:6 | 38:12 42:3,6             | <b>APPEARAN...</b>     | <b>arrangement</b>     | <b>behalf</b> 1:16,20   |
| 47:20                   | 46:23,24                 | 1:15                   | 11:3                   | 1:22 2:4,6,9,12         |
| <b>acting</b> 6:11      | <b>ago</b> 3:11 32:10    | <b>appellate</b> 24:1  | <b>aside</b> 7:23 23:4 | 3:8 17:7 27:16          |
| <b>action</b> 4:21 7:14 | <b>agree</b> 20:14       | <b>appendix</b> 21:24  | <b>asked</b> 11:5      | 50:24                   |
| 7:16,17,18 8:4          | <b>agreeing</b> 36:22    | 52:9                   | 18:17,19 19:8          | <b>believe</b> 48:10    |
| 44:20 55:9,20           | <b>agrees</b> 41:14      | <b>application</b>     | 20:4 39:11             | <b>best</b> 51:3        |
| <b>actions</b> 6:16     | <b>ahead</b> 16:17       | 21:19 29:2             | <b>aspects</b> 30:7    | <b>better</b> 12:19     |
| 44:14                   | 36:24 41:23              | <b>applied</b> 13:12   | <b>assess</b> 38:24    | <b>beyond</b> 19:21     |
| <b>activities</b> 5:15  | 44:19                    | <b>applies</b> 13:4    | <b>Assistant</b> 1:18  | 22:13                   |
| <b>actor</b> 40:22      | <b>AL</b> 1:4,7          | 19:2 35:22,24          | <b>assume</b> 23:23    | <b>big</b> 34:13        |
| <b>actual</b> 27:3      | <b>ALITO</b> 36:9        | <b>appropriate</b>     | 26:1 40:7,7,11         | <b>bills</b> 42:11      |
| <b>additional</b> 36:13 | 37:4 38:15               | 24:2 25:6              | 40:19                  | <b>bitter</b> 24:6 53:1 |
| <b>addressed</b> 53:20  | <b>alleged</b> 28:5,7    | <b>approval</b> 4:13   | <b>attempts</b> 12:16  | 53:6,11                 |
| <b>addressing</b>       | <b>alleging</b> 27:23    | 5:15 6:18              | <b>attention</b> 55:19 | <b>bottom</b> 10:1      |
| 55:17                   | <b>ALLISON</b> 1:22      | 14:12 18:2,5           | <b>authority</b> 6:11  | <b>bound</b> 52:10      |
| <b>adequacy</b> 8:8     | 2:8 27:15                | 18:23,24 19:5          | 9:17,18 12:4           | 54:6,10                 |
| <b>adequate</b> 6:9     | <b>allow</b> 6:9 7:6 8:7 | 19:12,15,17,18         | 54:15 55:14            | <b>breadwinner</b>      |
| <b>administer</b>       | 9:19 39:23               | 19:25 20:8,22          | <b>available</b> 4:18  | 42:9,18                 |
| 21:11 23:10,20          | 45:18 46:16,21           | 21:10,12 22:23         | 8:17 10:21             | <b>Breyer</b> 16:10,19  |
| 24:10,24                | <b>allowable</b> 5:10    | 23:10,21 24:25         | 14:9 25:4              | 16:20,22 30:3           |
| <b>Administration</b>   | <b>allowed</b> 10:25     | 28:8,21,22             | 28:23 55:6             | 31:4,18 32:4            |
| 4:8,12                  | 46:3                     | 33:11,18,19            | <b>aware</b> 35:15     | 42:15 43:1,9            |
| <b>administrative</b>   | <b>allowing</b> 7:5      | 35:6,13,14             | <b>a.m</b> 1:14 3:2    | 43:20,23 44:1           |
| 21:8                    | 40:4                     | 37:16 38:5,5,8         |                        | 44:4,16,22              |
| <b>administrator</b>    | <b>alluded</b> 40:13     | 39:18 41:17            | <b>B</b>               | 47:9 56:6               |
| 19:5,14                 | <b>altogether</b> 9:4    | 44:13,14               | <b>b</b> 13:19 20:25   | <b>bribery</b> 13:19    |
| <b>admissibility</b>    |                          | <b>approvals</b> 22:21 | <b>back</b> 11:17      | 13:22 14:5              |

|  |  |  |   |   |
|--|--|--|---|---|
| 26:6,14,21<br><b>bribes</b> 33:16<br><b>brief</b> 29:2 38:20<br>55:17,18<br><b>briefs</b> 23:15<br><b>bring</b> 4:21 40:12<br>44:19 55:21<br><b>brings</b> 24:16<br><b>broad</b> 4:1 36:5<br>55:13<br><b>broader</b> 29:21<br>31:16<br><b>brought</b> 4:25<br><b>Buckman</b> 3:11<br>3:14 4:17 5:12<br>6:3 7:3,16 9:8<br>12:2 13:4<br>17:13,16,25<br>19:1 21:17<br>22:4,23,25<br>23:4 28:2,3,20<br>31:5,6 32:1,2<br>44:24 51:4,18<br><b>burden</b> 15:23<br><b>burdening</b> 40:3<br><b>burdensome</b><br>12:12,15 29:12<br>29:21<br><b>business</b> 6:9<br>7:10 | 25:9,12 27:6,7<br>28:5,21 29:20<br>29:22,25 32:8<br>32:11,12 34:12<br>34:13,15,20<br>35:3,6,25<br>36:18,25 37:13<br>37:14 39:10,21<br>39:24 40:18<br>42:16 43:15,22<br>45:6 47:2<br>48:18 49:16,16<br>49:19 51:3,5,7<br>51:11 52:25<br>53:17 56:4,12<br>56:14<br><b>cases</b> 21:15 22:9<br>27:3 29:25<br>30:8 34:23<br>35:8,18 36:1<br>39:12,19,25<br>46:2 47:1<br>48:16<br><b>cause</b> 7:14,16,17<br>7:18 8:4 27:21<br>28:6,8,10<br><b>caused</b> 27:21<br>32:15<br><b>central</b> 5:21,24<br>6:3<br><b>certain</b> 5:15<br>47:21<br><b>certainly</b> 10:12<br>23:1 34:20<br>37:11 40:15<br>54:24<br><b>certification</b><br>24:3 25:5 49:7<br>51:23<br><b>cetera</b> 42:18<br><b>challenge</b> 15:1<br><b>challenged</b> 22:8<br><b>chance</b> 50:4<br><b>change</b> 54:5<br><b>characterizati...</b><br>45:5<br><b>charge</b> 12:17 | <b>charged</b> 8:18<br><b>charges</b> 37:15<br><b>check</b> 52:3<br><b>chemical</b> 35:11<br><b>choice</b> 31:1<br><b>choose</b> 54:4<br><b>chooses</b> 24:3<br><b>chose</b> 42:6 44:21<br><b>circuit</b> 8:5 10:12<br>10:18,20 11:5<br>17:2 23:23<br>24:2,14,16<br>48:9,17,19,25<br>49:2,3,11,17<br>51:20,22 52:2<br>52:12 53:3,5<br>53:22,25<br><b>Circuit's</b> 38:17<br>49:3,6 51:24<br><b>circumstance</b><br>18:3<br><b>circumstances</b><br>11:1 13:11<br>18:24 22:22<br>25:22 53:12<br>56:9<br><b>cited</b> 38:20<br>55:24<br><b>citizen</b> 55:23<br>56:4<br><b>claim</b> 8:16 18:18<br>28:5,7,10 34:2<br>43:10 44:24,25<br><b>claims</b> 4:2 7:25<br>8:2 11:1 19:3<br>27:23 34:3,4<br>43:8 54:17<br><b>clarity</b> 51:24<br><b>class</b> 55:9<br><b>clause</b> 20:25<br><b>clean</b> 9:5<br><b>clear</b> 20:4<br><b>clearance</b> 28:20<br><b>clearly</b> 6:1 10:16<br>16:3 27:8<br>52:13 54:2<br><b>clients</b> 38:11 | <b>closely</b> 49:25<br><b>closer</b> 15:9<br>26:24<br><b>combination</b><br>38:6<br><b>come</b> 9:5 10:21<br>10:25 31:20<br>33:6 41:10<br>43:15 45:22<br>47:4 49:17<br><b>comes</b> 20:25<br>34:21<br><b>committee</b><br>39:11<br><b>common</b> 8:2<br>11:14,20 20:5<br>20:11,12 47:2<br><b>companies</b> 21:9<br>23:18 28:6,8<br>29:5,8<br><b>company</b> 28:15<br>29:23 33:12,16<br>33:17 34:10,18<br>35:2 38:13<br>41:15 42:3,12<br><b>compel</b> 39:22<br>41:25 42:2<br><b>compensate</b><br>31:13<br><b>compensation</b><br>32:12,17 42:8<br>43:16<br><b>complaints</b><br>55:18<br><b>complementary</b><br>31:14<br><b>compliance</b> 8:19<br>9:3,10 11:15<br>11:18 14:11,25<br>15:1,8 17:21<br>18:7 22:8<br>35:12 37:3<br>44:7 45:7,9,14<br>45:19 46:1,16<br>46:21 47:3,7<br><b>complied</b> 4:23<br><b>comply</b> 4:2 | 45:23<br><b>comprehensive</b><br>28:22<br><b>compromise</b><br>53:13<br><b>concept</b> 3:16<br><b>concern</b> 4:17<br>21:16 24:9<br>26:16 28:9<br>56:7<br><b>concerning</b> 4:8<br><b>concerns</b> 18:13<br>28:2,4,14<br><b>concluded</b> 3:17<br>51:23 53:21<br>55:7<br><b>concludes</b> 53:9<br><b>conclusions</b><br>52:11<br><b>conclusive</b> 20:23<br>44:9<br><b>concurring</b><br>16:13<br><b>condemn</b> 10:18<br><b>condition</b> 9:24<br>10:1<br><b>conditions</b> 4:21<br>5:23<br><b>confers</b> 3:25<br><b>conflict</b> 3:19<br>17:13 21:11<br>23:15<br><b>Congress</b> 6:16<br>6:19,21 7:4<br>31:1<br><b>Congress's</b><br>30:25<br><b>connection</b><br>18:21 19:9<br>26:14<br><b>consciously</b> 4:15<br><b>consequence</b><br>10:24 16:4<br><b>consider</b> 18:22<br>31:17 40:15<br><b>considerable</b><br>45:3 |
| <b>C</b>   |  |  |   |   |
| <b>C</b> 2:1 3:1<br><b>Calabrezze</b> 49:6<br><b>California</b> 36:1<br><b>called</b> 38:7<br><b>candidly</b> 6:3<br>11:4 15:3<br><b>care</b> 7:4,9 33:13<br><b>carry</b> 17:19<br><b>CARTER</b> 1:16<br>2:3,11 3:7<br>50:23<br><b>case</b> 5:18 8:1<br>10:12,19 12:4<br>14:3 15:17,20<br>16:1,25 23:5   |  |  |   |   |

|                                |                                  |                              |                                      |                                      |
|--------------------------------|----------------------------------|------------------------------|--------------------------------------|--------------------------------------|
| <b>consideration</b><br>51:13  | <b>co-existed</b> 44:14          | 27:24                        | <b>design</b> 18:18,19               | 49:10 52:16                          |
| <b>considerations</b><br>51:13 | <b>cradle</b> 3:21               | <b>defective</b> 7:18        | <b>desire</b> 22:21                  | 53:2,4                               |
| <b>considering</b><br>19:9     | <b>create</b> 7:14 16:8<br>44:23 | 8:19 18:20                   | <b>despite</b> 43:15                 | <b>disgorgement</b><br>54:15,23 55:3 |
| <b>consistent</b> 46:18        | <b>creates</b> 28:17             | 27:19 44:6                   | <b>detail</b> 21:20                  | <b>dishonest</b> 42:1                |
| <b>consists</b> 7:14           | <b>critical</b> 12:3,4,7         | 45:20                        | <b>determination</b><br>6:8 17:14,25 | <b>dismiss</b> 25:13                 |
| <b>contested</b> 43:21         | <b>cure</b> 30:24                | <b>defendant</b> 24:11       | 18:1,23,24                           | <b>dispositive</b><br>45:24 46:1     |
| <b>context</b> 7:7 20:7        | <b>curiae</b> 1:20 2:7           | 46:7 49:21                   | 19:19 26:19                          | <b>disrupting</b> 39:6               |
| 25:15 50:16                    | 17:8                             | <b>defendants</b> 50:2       | 27:8,11 31:10                        | <b>disruptive</b> 48:13              |
| <b>continued</b> 35:14         | <b>cuts</b> 29:15                | <b>defended</b> 11:15        | 48:25                                | <b>distort</b> 25:24                 |
| <b>control</b> 13:8            | <hr/> <b>D</b> <hr/>             | <b>defense</b> 4:1,5         | <b>determinations</b><br>21:14       | <b>district</b> 14:24                |
| 14:13 37:12                    | <b>D</b> 3:1                     | 8:3,17 9:2,10                | <b>determine</b> 19:6                | <b>divert</b> 55:19                  |
| <b>converse</b> 29:11          | <b>damage</b> 32:13              | 9:17 11:9,10                 | 19:16 25:16                          | <b>doctor</b> 43:13                  |
| <b>convince</b> 31:22          | 32:15                            | 12:17 14:8,9                 | <b>determining</b><br>5:22           | <b>documents</b><br>25:11,11 29:14   |
| <b>cooperate</b> 40:3          | <b>damages</b> 32:16             | 17:21 22:8                   | <b>device</b> 6:17                   | <b>doing</b> 31:24                   |
| <b>core</b> 19:4               | 48:4 54:20                       | 28:1 35:10,17                | <b>devices</b> 6:15,23               | 36:16 37:2                           |
| <b>Correct</b> 11:12           | 55:3                             | 35:21 44:8,8,9               | <b>die</b> 30:15 56:7                | <b>doubt</b> 46:18                   |
| <b>Cosmetic</b> 4:11           | <b>DARYL</b> 1:18                | 45:7,14 46:1                 | <b>died</b> 32:14 55:2               | <b>drawn</b> 33:15                   |
| 21:5                           | 2:5 17:6                         | 50:9                         | <b>difference</b> 13:22              | <b>drove</b> 56:8                    |
| <b>country</b> 34:5            | <b>data</b> 21:20 40:14          | <b>defenses</b> 19:3         | 46:5                                 | <b>drug</b> 4:7,8,10,11              |
| 36:4 45:18                     | <b>days</b> 25:9                 | <b>defer</b> 49:3 51:22      | <b>different</b> 5:2                 | 4:12,22 5:24                         |
| <b>couple</b> 33:14            | <b>dead</b> 42:9,18              | 53:23                        | 6:24 14:1                            | 6:22 8:18,19                         |
| 38:20 55:9                     | <b>dealers</b> 8:23              | <b>deferential</b><br>45:17  | 15:12 19:19                          | 8:23,23 9:1                          |
| <b>course</b> 36:17            | <b>dealing</b> 25:24             | <b>deferring</b> 49:14       | 21:13 26:8,12                        | 14:10,11,12                          |
| 39:16                          | <b>deals</b> 53:6                | <b>defined</b> 5:8           | 31:14,15 33:1                        | 15:23 19:5                           |
| <b>court</b> 1:1,13 3:3        | <b>debate</b> 22:11              | <b>defining</b> 6:5          | 36:6,13 41:4                         | 21:5,19 22:2                         |
| 3:10,11,14,17                  | <b>debating</b> 45:11            | 37:3                         | 41:16 49:16                          | 24:24 28:15,21                       |
| 3:20 4:16 5:13                 | <b>deception</b> 10:22           | <b>defrauded</b> 18:2        | <b>difficult</b> 4:14                | 28:24 29:2,23                        |
| 6:2,4 7:3,8 8:2                | <b>decide</b> 5:14 6:12          | 18:4,8 19:6                  | <b>direct</b> 13:23                  | 30:9,11,11,15                        |
| 8:7 11:6 12:2                  | 14:20,22 15:8                    | <b>defrauding</b> 7:14       | <b>direction</b> 6:14                | 30:17,19,23,24                       |
| 13:3 14:7,24                   | 18:19 36:11                      | <b>degree</b> 40:3           | <b>disclosure</b> 6:7                | 31:21,25 32:5                        |
| 15:7 16:9,23                   | 39:23 40:15                      | <b>deliberately</b><br>45:12 | 21:4                                 | 32:21 33:2,12                        |
| 17:11,13,16,24                 | <b>decided</b> 6:2               | <b>demonstrated</b><br>28:25 | <b>disclosures</b> 38:2              | 33:25 34:7,18                        |
| 18:1 21:17                     | 10:23 23:25                      | <b>Department</b><br>1:19    | <b>discovery</b> 25:10               | 36:12 37:16                          |
| 23:11,13,14,15                 | 24:13 49:15                      | <b>depend</b> 17:23          | 26:2 29:12,19                        | 38:7,25 40:11                        |
| 23:16 24:1,5                   | 51:25 52:13                      | <b>depends</b> 22:1          | 29:22,25 30:2                        | 40:17,18,23                          |
| 27:18 28:2,3                   | <b>decision</b> 30:19            | <b>depose</b> 25:19          | 34:12 35:2                           | 41:7,9 42:16                         |
| 31:16,19 49:7                  | 38:17 39:18                      | <b>deposed</b> 39:24         | 36:4,5,7 37:4,9                      | 42:19,23 43:11                       |
| 49:8,9,13,17                   | 48:9 49:6                        | <b>deposition</b> 38:18      | 37:12 39:2,11                        | 43:13,16 44:6                        |
| 50:19 51:17                    | 51:24 53:5                       | 39:10,14                     | 39:13 40:1,4                         | 44:7 46:8                            |
| 53:20,23                       | <b>decisionmaking</b><br>28:11   | <b>depositions</b> 39:6      | <b>discretion</b> 19:15              | <b>drugs</b> 6:6 28:21               |
| <b>courts</b> 37:11,21         | <b>decisions</b> 25:21           | <b>described</b> 44:4        | 37:12                                | 30:8,16 39:16                        |
| 49:15                          | <b>declared</b> 4:16             | <b>describes</b> 22:5        | <b>discussed</b> 47:1                | 41:4,5                               |
| <b>court's</b> 48:25           | <b>deeply</b> 20:12              | <b>describing</b> 22:9       | 52:2                                 | <b>duties</b> 5:3,6                  |
| <b>covered</b> 3:21            | <b>defect</b> 18:18              |                              | <b>discussion</b> 48:16              | 26:15 33:13,20                       |

|                         |                        |                         |                        |                          |
|-------------------------|------------------------|-------------------------|------------------------|--------------------------|
| <b>duty</b> 5:8 33:13   | <b>evaluate</b> 8:8    | <b>explains</b> 21:18   | 21:22 22:1             | 39:7 48:15               |
| <b>dying</b> 30:14      | 12:19                  | <b>expressly</b> 21:3   | 23:19 25:17,18         | <b>finding</b> 21:4      |
| 42:17                   | <b>evaluated</b> 8:5   | <b>exquisite</b> 8:6    | 25:19,25 26:2          | 29:10 33:21              |
| <b>D.C</b> 1:9,16,19    | <b>event</b> 34:19     | <b>extends</b> 55:14    | 26:19 27:9,10          | 42:3,12 46:24            |
| 1:22                    | <b>eventually</b> 15:6 | <b>extensive</b> 49:11  | 28:19 29:5,9           | 47:19,20                 |
| <b>E</b>                | <b>everybody</b> 13:2  | <b>extent</b> 46:9      | 33:16,18,24            | <b>findings</b> 53:8     |
| <b>E</b> 2:1 3:1,1      | <b>evidence</b> 12:6   | <b>external</b> 13:9    | 34:11,22 36:6          | <b>fine</b> 16:24        |
| <b>easy</b> 28:16       | 19:4,9 20:1,3          | <b>extraneous</b>       | 36:11,16 37:5          | <b>finish</b> 12:8       |
| <b>effect</b> 5:16 9:24 | 20:14,18,22            | 13:10 16:9              | 37:6,15,17,20          | <b>first</b> 8:2 9:12,17 |
| 36:21,23,24             | 29:4,7,20              | <b>extremely</b> 14:6   | 37:25 38:3             | 18:22 20:10              |
| 48:10                   | 33:12 34:10,14         | 21:22                   | 39:6,7,12,14           | 21:18 25:25              |
| <b>effects</b> 28:25    | 38:15 40:2             | <b>eye</b> 7:13         | 39:16,21,23,25         | 32:9 34:14,23            |
| 30:10                   | 45:19,20 46:2          | <b>e-mail</b> 38:21     | 40:2,3,5,15,19         | 35:24 50:13              |
| <b>efficacy</b> 14:10   | 46:7,21 47:3,7         | <b>e-mails</b> 38:19,20 | 41:6,12,13,20          | <b>five</b> 50:22        |
| <b>either</b> 8:7 45:24 | <b>exactly</b> 4:16    | <b>F</b>                | 41:21,25 42:2          | <b>flatly</b> 54:18      |
| 47:2 50:4               | 37:10 54:8,11          | <b>fact</b> 11:22 13:6  | 42:22 43:10,13         | <b>flow</b> 15:14        |
| <b>element</b> 12:3,4,7 | 54:22 56:5             | 14:4 15:23              | 44:5,13 45:17          | <b>follow</b> 52:10      |
| 19:12,22 47:24          | <b>examiner</b> 37:15  | 18:22 20:22,23          | 46:8 47:20             | <b>follows</b> 43:14     |
| 48:1,2,5                | 37:17                  | 50:6 53:7,10            | 53:7 54:14,17          | <b>Food</b> 4:7,10,12    |
| <b>elements</b> 27:9    | <b>examiners</b> 39:7  | 53:21 55:6              | 55:6,10,17,21          | 21:5                     |
| <b>encouraged</b>       | <b>example</b> 18:3    | 56:3                    | 55:25 56:8             | <b>footnote</b> 49:5     |
| 23:1                    | 38:19                  | <b>Factors</b> 51:22    | <b>FDA's</b> 3:19 4:2  | 52:12                    |
| <b>enforce</b> 10:25    | <b>exception</b> 13:20 | 52:10                   | 5:19,22 6:18           | <b>force</b> 33:25       |
| 14:4 28:11              | 26:6 28:1              | <b>facts</b> 36:18      | 12:3 14:12,17          | <b>foreclosed</b> 54:1   |
| <b>enforceable</b> 5:5  | 29:10 35:21,24         | 37:24,25 38:2           | 18:2,23 19:4           | 54:3                     |
| <b>enforced</b> 5:4     | 38:16 45:11            | <b>failure</b> 27:24    | 21:10,11 23:20         | <b>form</b> 39:18        |
| <b>enforcement</b> 7:6  | 48:20 50:15            | <b>fair</b> 10:18 22:6  | 24:10,24 28:10         | 55:14                    |
| 33:24 37:2              | 52:24 53:9,18          | <b>faithful</b> 10:13   | 31:14 36:20            | <b>formula</b> 35:11     |
| <b>entertains</b> 56:2  | <b>exclusive</b> 4:17  | <b>fall</b> 48:22       | 42:12 55:13            | <b>forth</b> 15:24 22:8  |
| <b>entire</b> 24:20     | 6:11                   | <b>false</b> 7:16       | <b>February</b> 1:10   | <b>forward</b> 33:6      |
| <b>entities</b> 7:11    | <b>exclusively</b> 5:7 | <b>family</b> 42:8,14   | <b>federal</b> 3:12,21 | 40:12 41:10              |
| 15:15 17:17             | 13:8                   | <b>far</b> 5:14 11:22   | 3:22,22,23             | 53:11 54:13              |
| <b>entitled</b> 14:4    | <b>exhaustive</b>      | 45:8                    | 4:17 7:9,13,15         | <b>found</b> 10:22       |
| <b>entity</b> 6:7 13:24 | 29:12                  | <b>favorable</b> 45:8,8 | 7:25 10:3,4            | 11:23 14:24              |
| 15:14                   | <b>exists</b> 47:14    | <b>FDA</b> 3:16 4:22    | 11:16,16 13:8          | 16:16 17:13              |
| <b>equally</b> 13:4     | 55:23                  | 5:4,9,15,20,22          | 14:5 17:17,18          | 25:20                    |
| <b>especially</b> 26:16 | <b>expansion</b> 45:2  | 5:23 6:6,15             | 20:7 21:5 23:9         | <b>four</b> 12:22        |
| <b>ESQ</b> 1:16,18,22   | <b>experience</b> 27:3 | 7:17 8:9,13,14          | 23:12 24:17,21         | <b>frankly</b> 41:6      |
| 2:3,5,8,11              | 48:8                   | 9:5,20 10:21            | 24:23 26:14,15         | 51:20 52:14              |
| <b>essentially</b> 3:21 | <b>expert</b> 30:21    | 10:23 12:13             | 26:16 29:17,17         | <b>fraud</b> 3:12,16,19  |
| 9:19 10:6               | <b>experts</b> 37:6    | 13:14,25 15:14          | 33:11 44:13            | 11:19 16:5,16            |
| 20:21 23:18             | <b>explain</b> 21:25   | 16:4,12,15              | 51:6,15,16             | 17:14 19:20              |
| 26:17                   | 30:5 32:6 36:9         | 17:14 18:1,4,7          | <b>field</b> 3:13 6:22 | 27:8 28:11               |
| <b>establishing</b>     | <b>explained</b> 17:16 | 18:9 19:14,22           | 6:23                   | 31:23,24 53:10           |
| 17:15                   | 21:17                  | 20:18,22 21:7           | <b>filed</b> 56:3      | 54:17 55:20              |
| <b>et</b> 1:4,7 42:18   | <b>explaining</b>      | 21:7,8,10,18            | <b>find</b> 18:4 19:8  | <b>fundamental</b>       |
|                         | 27:25 35:9             |                         | 20:4 21:6 24:4         | 16:6 30:7 31:1           |

|  |                                   |                              |                               |                                   |
|--|-----------------------------------|------------------------------|-------------------------------|-----------------------------------|
| <b>fundamentally</b><br>5:2 6:10 31:13 | 53:11                             | 43:22                        | <b>including</b> 27:9         | <b>interfere</b> 36:16            |
| <b>further</b> 45:15                   | <b>going</b> 5:13 9:2,4           | <b>help</b> 42:7,13          | 27:22 28:24                   | <b>interference</b><br>13:6,14    |
| 50:19 56:10                            | 13:6 14:19,21                     | <b>honest</b> 34:10          | 39:17                         | <b>interfering</b><br>14:16 41:20 |
| <b>future</b> 42:10                    | 15:4,5,9,17                       | 38:1                         | <b>incorrect</b> 36:14        | <b>intermediate</b><br>24:1       |
| <hr/>                                  | 16:8,17 25:14                     | <b>Honor</b> 29:19           | <b>increase</b> 23:1          | <b>internal</b> 37:5              |
| <b>G</b>                               | 26:1 27:4                         | <b>Honors</b> 17:3           | <b>incredibly</b> 25:23       | <b>interprets</b> 8:14            |
| <b>G</b> 1:16 2:3,11                   | 30:19,20 34:6                     | 56:11                        | <b>independent</b><br>10:4,5  | <b>interrupt</b> 40:8             |
| 3:1,7 50:23                            | 38:3 41:13                        | <b>hook</b> 9:4              | <b>indifferent</b><br>54:17   | <b>intricate</b> 53:8             |
| <b>Garcia</b> 51:24                    | 42:13 43:22                       | <b>hope</b> 15:20            | <b>individual</b> 21:14       | <b>introduce</b> 38:16            |
| 52:13 53:5,20                          | 52:23 54:13                       | <b>Hopefully</b> 51:1        | <b>inevitably</b> 3:18        | <b>introduction</b><br>46:7       |
| 54:6,10                                | 56:8                              | <b>Hoyle</b> 51:4            | <b>influenced</b><br>46:23,24 | <b>intrusion</b> 23:20            |
| <b>Garcia's</b> 52:10                  | <b>good</b> 10:3,9 47:9           | <b>huge</b> 42:10            | <b>information</b> 4:8        | 28:10                             |
| <b>general</b> 1:19                    | 49:24                             | <b>hundred</b> 55:9          | 6:7,8,25 7:17                 | <b>intrusive</b> 25:23            |
| 22:4 36:19                             | <b>governed</b> 14:1              | <b>hurdle</b> 33:25          | 8:8 9:6,6 15:14               | <b>intrusiveness</b><br>29:16     |
| 39:12                                  | <b>government</b><br>7:13,15 10:3 | <b>hurdles</b> 34:24         | 20:9 21:4,20                  | <b>invalid</b> 49:21              |
| <b>Ginsburg</b> 8:15                   | 12:16,18 22:10                    | <b>hurt</b> 30:10,17,20      | 21:25 27:20                   | <b>invigorated</b> 9:2            |
| 8:22 9:1 10:7                          | 41:19 55:16                       | 30:23                        | 28:6,19,24                    | 9:9 45:6                          |
| 10:15 23:22                            | <b>government's</b><br>10:5 12:12 | <b>hurts</b> 30:11           | 29:5,8,9 33:17                | <b>involved</b> 48:18             |
| 37:14 39:5                             | 13:8 23:9                         | <b>hypothetical</b><br>25:21 | 34:16,21 35:15                | <b>involving</b> 51:5             |
| 43:21,25 44:2                          | <b>grave</b> 3:21                 | <hr/>                        | 36:13 38:14                   | <b>irrelevant</b> 46:14           |
| 44:11 45:4                             | <b>great</b> 27:21                | <b>identified</b> 28:3       | 39:15 40:13                   | <b>issue</b> 5:2 7:15             |
| 47:16,22 48:7                          | <b>greater</b> 9:16               | 56:6                         | 41:16,22 42:4                 | 8:1 10:17                         |
| 48:12 49:10                            | <b>ground</b> 11:15               | <b>identifies</b> 8:12       | 46:25                         | 12:15 15:5,11                     |
| 51:19 52:1,5                           | 17:22                             | <b>Illinois</b> 36:1         | <b>infused</b> 34:17          | 19:23 28:20                       |
| 52:15,21 53:15                         | <b>guess</b> 6:21,23              | <b>illustrate</b> 21:16      | <b>inherently</b> 17:18       | 43:23 51:25                       |
| 53:24 55:16,25                         | 40:20                             | <b>imagine</b> 4:14          | <b>injured</b> 31:13          | 52:13,20                          |
| <b>Ginsburg's</b> 11:8                 | <b>guilty</b> 26:21               | <b>immune</b> 45:10          | 44:6 55:1,10                  | <b>issues</b> 22:11               |
| <b>give</b> 9:2,17                     | <hr/>                             | 45:10                        | <b>injuries</b> 54:21         | 27:5 31:16                        |
| 31:20 41:21                            | <b>H</b>                          | <b>immunity</b> 4:1,5        | <b>injury</b> 27:20,21        | <hr/>                             |
| 51:1 52:23                             | <b>hand</b> 3:25 4:4              | 10:9 45:13                   | <b>inquiries</b> 25:23        | <b>J</b>                          |
| 55:8                                   | 29:15 30:21                       | 52:23 53:18                  | <b>inquiry</b> 22:25          | <b>job</b> 5:22 13:14             |
| <b>given</b> 51:23                     | 52:9,19                           | <b>impeded</b> 42:9          | <b>inside</b> 37:17           | 41:12,13                          |
| <b>gives</b> 45:13                     | <b>handle</b> 40:5                | <b>implicate</b> 28:1        | <b>instance</b> 34:23         | <b>Joseffer</b> 1:18 2:5          |
| <b>giving</b> 9:9                      | <b>happen</b> 15:4                | 28:14                        | 39:19                         | 17:5,6,10,23                      |
| <b>go</b> 5:13 13:23                   | <b>happened</b> 35:2              | <b>important</b> 8:10        | <b>instructed</b> 11:22       | 18:14 19:13                       |
| 16:23 28:21                            | 37:17,24 38:10                    | 24:23 33:17                  | 11:23 18:4,21                 | 20:2,20 21:2                      |
| 29:18 34:24                            | 39:10 43:5                        | <b>importantly</b><br>40:6   | <b>insulin</b> 34:18          | 22:12,16,20                       |
| 36:24 37:25                            | <b>happens</b> 42:20              | <b>impose</b> 6:19           | 38:7                          | 23:7,22 24:7                      |
| 40:20,21 41:7                          | <b>happy</b> 3:6                  | 40:22                        | <b>intentionally</b> 4:6      | 24:15 25:12                       |
| 42:22 44:19                            | <b>hard</b> 18:15                 | <b>incentive</b> 28:18       | <b>interest</b> 7:9 10:4      | 26:7,11,23                        |
| 45:15 52:2                             | <b>harder</b> 12:7                | 40:20 41:6                   | 10:5 13:16                    | 27:4 29:24                        |
| <b>goal</b> 32:11,11                   | 38:24                             | <b>incentives</b> 25:24      | 51:6,15,16                    | 36:10                             |
| <b>goes</b> 4:9 11:21                  | <b>harmful</b> 43:16              | <b>include</b> 9:16          | <b>interested</b> 39:21       |                                   |
| 11:22 13:25                            | <b>hate</b> 40:8                  | 54:20                        | <b>interesting</b> 27:5       |                                   |
| 15:15 21:24                            | <b>hear</b> 3:3,6 5:9             |                              |                               |                                   |
| 24:6 31:16                             |                                   |                              |                               |                                   |

|   |  |   |   |  |
|---|--|---|---|--|
| <b>judge</b> 11:23<br>39:23   | 47:9,16,22<br>48:7,12,17,23  | <b>L</b>  | <b>limit</b> 48:4   | 22:10  |
| <b>judges</b> 40:4  | 49:6,10,18,23  | <b>label</b> 35:12,15<br>43:14,14   | <b>line</b> 10:1  | <b>majority</b> 46:2   |
| <b>judgment</b> 17:2<br>21:21   | 50:2,8,21,25<br>51:3,12,19   | <b>labeling</b> 14:11   | <b>lines</b> 48:4   | <b>making</b> 21:14<br>36:21 50:4  |
| <b>juries</b> 8:8 21:13<br>42:24  | 52:1,5,15,21<br>53:15,24 54:4  | <b>lack</b> 11:16   | <b>lists</b> 4:10   | <b>malpractice</b><br>55:2   |
| <b>jurisdiction</b><br>16:11  | 54:9,12,19,25<br>55:5,8,16,25  | <b>language</b> 11:24<br>12:2   | <b>litigants</b> 23:13<br>23:14   | <b>manifest</b> 21:12  |
| <b>jury</b> 6:24 11:23<br>14:19,22 15:7<br>18:3,16,18,21<br>19:7 20:3 21:6<br>30:22 31:5,22<br>34:7 36:11,22<br>42:20 43:4,5  | 56:6,12  | <b>large</b> 39:2   | <b>litigate</b> 25:14<br>34:1,2,4 35:25<br>36:25 43:7,10  | <b>manufacturer</b><br>4:6 5:7 6:6,17<br>8:18 9:9 10:9<br>13:24 14:13<br>20:9 33:20<br>34:24 35:16<br>42:1 44:7 45:8<br>45:10,13,18<br>47:21 52:23<br>53:17  |
| <b>Justice</b> 1:19 3:3<br>3:9 4:19 5:2,8<br>5:17 6:13 7:2<br>7:12 8:15,22<br>9:1,23 10:7,15<br>11:7,8,13 12:8<br>12:11,21,25<br>13:17 14:8,15<br>14:19 15:2,16<br>15:22 16:2,10<br>16:13,19,20,22<br>17:4,10,19<br>18:6 19:11,21<br>20:16,21 22:3<br>22:14,18 23:4<br>23:22 24:13<br>25:7,8 26:5,9<br>26:20 27:1,13<br>27:17 29:11<br>30:3 31:4,18<br>32:4,20,25<br>33:5 34:6 35:4<br>35:20 36:9,21<br>37:4,14 38:15<br>39:5 40:7,11<br>41:3,18 42:15<br>43:1,9,20,21<br>43:23,25 44:1<br>44:2,4,11,16<br>44:22 45:4<br>46:6,12,17 | <b>K</b><br><b>keep</b> 37:12<br>52:25<br><b>Kennedy</b> 9:23<br>23:4 25:7<br>29:11 32:20,25<br>33:5 34:6 35:4<br>46:6,12,17<br>51:3,12<br><b>Kent</b> 1:7 3:4<br>43:7<br><b>kills</b> 19:12<br><b>Kimberly</b> 1:7<br>3:4<br><b>kind</b> 11:19<br>12:14 37:20<br>38:24 44:3<br>50:2<br><b>kinds</b> 16:7<br><b>knock</b> 24:20<br><b>know</b> 6:14,19<br>7:4 12:20<br>14:16 15:6<br>16:3 18:10<br>24:8 25:8,15<br>25:17 27:4<br>32:25 37:10<br>38:3 39:3<br>40:25 41:7<br>48:24 51:15<br>54:22<br><b>knowledge</b> 4:24<br><b>knowledgeable</b><br>21:21<br><b>known</b> 19:22<br>41:22 | <b>law</b> 3:18,21,22<br>3:23,23 7:5,25<br>8:2,4 10:16,25<br>11:14,20 13:10<br>20:5,12 24:8<br>27:23 28:13<br>31:10,12 32:23<br>33:13,20 34:2<br>35:18 43:12,19<br>45:2,3,17 49:1<br>49:15 51:10<br>52:11 54:7,10<br><b>laws</b> 14:2,4<br><b>lawsuit</b> 11:14,20<br>35:22 53:11<br><b>lead</b> 29:5 42:15<br><b>leave</b> 24:2<br><b>Leaving</b> 23:4<br><b>led</b> 7:2<br><b>left</b> 14:12 51:25<br><b>legal</b> 19:2<br><b>legislature</b><br>10:13 11:2<br>53:13,16,21<br><b>legitimate</b> 13:16<br>15:11<br><b>lesser</b> 9:16<br><b>letting</b> 52:25<br><b>let's</b> 16:10 23:22<br><b>lever</b> 9:19<br><b>liability</b> 3:25 4:1<br>7:23 11:1<br>17:15,22 21:4<br>29:22 34:23<br>39:9 48:4<br><b>lied</b> 34:19 | <b>litigated</b> 26:1<br>36:1<br><b>litigating</b> 34:3<br><b>litigation</b> 12:13<br>12:14 20:6<br>22:7,18 23:2<br>23:11 27:2<br>28:15 30:1<br>36:3 37:9,13<br>39:9 44:3<br><b>little</b> 41:6<br><b>liver</b> 32:13,15<br><b>living</b> 42:10<br><b>LLC</b> 1:3<br><b>locked</b> 13:7<br><b>logic</b> 13:12<br><b>long</b> 29:3 33:5,6<br><b>longer</b> 33:18<br><b>look</b> 13:5 20:15<br>37:22 41:25<br>45:23 47:10<br><b>looked</b> 9:11<br>50:14<br><b>looking</b> 14:6<br>18:20 26:17<br>39:12 54:14<br><b>lose</b> 35:22 50:4<br><b>lot</b> 16:14 23:3,11<br>26:2 27:2,5<br>34:20 35:1,3<br>36:5 39:15<br><b>Louisiana</b> 39:20<br><b>lunch</b> 51:2 | <b>manipulate</b> 21:12<br>22:10<br><b>majority</b> 46:2<br><b>making</b> 21:14<br>36:21 50:4<br><b>malpractice</b><br>55:2<br><b>manifest</b> 21:12<br><b>manufacturer</b><br>4:6 5:7 6:6,17<br>8:18 9:9 10:9<br>13:24 14:13<br>20:9 33:20<br>34:24 35:16<br>42:1 44:7 45:8<br>45:10,13,18<br>47:21 52:23<br>53:17<br><b>manufacturers</b><br>4:2 9:1 25:24<br>28:18<br><b>manufacturer's</b><br>46:1<br><b>March</b> 48:11<br><b>market</b> 8:19<br>31:12,25 32:9<br>32:10 33:25<br>34:8,25 36:12<br>36:19 40:12<br>56:7<br><b>marketed</b> 27:19<br>32:21<br><b>marketing</b> 4:22<br>5:23 7:18<br><b>material</b> 5:20<br>10:22 42:4<br>46:4,22,22<br><b>materiality</b><br>25:16<br><b>matter</b> 1:12 3:18<br>4:17 20:1,3<br>23:12 26:15<br>36:19 37:18<br>39:16 41:8<br>42:22 56:15<br><b>MDL</b> 39:2,20<br><b>mean</b> 10:16<br>12:18 15:25 |

|  |   |  |   |   |
|--|---|--|---|---|
| 16:3 18:15<br>19:14 20:21<br>23:12 24:7<br>25:1,3,4,12<br>27:7 29:13<br>35:13 50:5<br>52:21,22 54:5<br>54:14,22 55:22<br><b>meaningful</b> 47:7<br><b>means</b> 33:20<br><b>measure</b> 45:13<br><b>mechanism</b> 7:6<br>54:24 55:24<br><b>mechanisms</b><br>55:6<br><b>medical</b> 6:15,17<br>6:23 34:15<br>38:4,12,19,22<br>39:14,17,24<br>42:11<br><b>Medtronics</b> 30:8<br><b>mentioned</b> 27:9<br>30:6<br><b>mere</b> 19:3 20:1<br>20:2,13,17<br><b>merits</b> 16:1<br><b>met</b> 35:11<br><b>Metformin</b> 38:7<br><b>Michigan</b> 3:24<br>8:17,23 10:8<br>10:13 13:19<br>17:12 24:3,5<br>25:4 28:1,13<br>28:17 29:10<br>32:23 33:4,10<br>34:9 35:5,7,8<br>35:18 36:7<br>37:2,9,11<br>39:13 43:5<br>44:17,21 45:25<br>47:18 48:2,5,8<br>49:1,7 50:6,18<br>52:11<br><b>Michigan's</b> 47:5<br>47:15,17<br><b>military</b> 51:13<br><b>mind</b> 53:13 54:5 | <b>minutes</b> 50:22<br><b>misleading</b><br>25:20<br><b>misled</b> 19:17<br>21:8<br><b>misrepresenta...</b><br>27:25 33:22<br>46:22<br><b>misrepresented</b><br>9:6 33:17<br><b>misrepresents</b><br>4:7<br><b>missed</b> 49:23<br><b>missing</b> 44:17<br><b>mission</b> 55:20<br><b>mistakes</b> 41:7<br><b>modern</b> 20:10<br>22:23<br><b>Monday</b> 1:10<br><b>motion</b> 25:13<br>39:22<br><b>motions</b> 39:22<br><b>multidistrict</b><br>30:1<br><hr/> <b>N</b><br><hr/> <b>N</b> 2:1,1 3:1<br><b>narrow</b> 6:4 14:7<br><b>narrowing</b> 45:3<br><b>necessarily</b> 22:1<br>24:22 26:3<br><b>necessary</b> 17:15<br>27:10 40:14,16<br>40:17 41:22<br>42:19<br><b>need</b> 29:6 30:23<br>35:9<br><b>needs</b> 19:15<br>50:14<br><b>negligence</b><br>11:17<br><b>negotiated</b><br>39:11<br><b>negotiating</b><br>39:21<br><b>never</b> 23:17,24<br><b>new</b> 21:19 22:17 | 22:19 23:6<br>29:2 35:15<br>36:2 44:23<br><b>non-compliance</b><br>46:2,4<br><b>non-dispositive</b><br>45:20<br><b>normally</b> 19:2<br><b>notion</b> 33:11<br>54:16<br><b>novel</b> 3:15 23:7<br><b>number</b> 48:3<br><hr/> <b>O</b><br><hr/> <b>O</b> 2:1 3:1<br><b>object</b> 20:25<br>31:19<br><b>objection</b> 6:16<br>6:20,22<br><b>objections</b> 26:4<br><b>observed</b> 5:24<br>6:18<br><b>obvious</b> 23:16<br>23:20<br><b>obviously</b> 13:12<br>14:25 23:12<br>26:15,23<br><b>occupied</b> 3:14<br><b>odd</b> 52:22,22<br><b>offensive</b> 51:9<br>51:10 54:18<br><b>offered</b> 20:1<br><b>officer</b> 34:15<br>38:4,12,19,22<br>39:14,17,24<br><b>official</b> 26:14,21<br><b>officials</b> 14:5<br><b>off-label</b> 28:9<br><b>Oh</b> 45:23 53:4<br><b>okay</b> 43:14<br><b>once</b> 41:18<br><b>ones</b> 28:17<br><b>open</b> 53:25<br><b>openly</b> 4:15<br><b>operate</b> 33:1<br><b>operation</b> 48:9<br><b>opinion</b> 16:14 | <b>opposed</b> 40:1<br>54:14<br><b>opposite</b> 6:14<br>7:3<br><b>opted</b> 31:1<br><b>option</b> 49:8,8<br><b>options</b> 25:3<br><b>oral</b> 1:12 2:2 3:7<br>17:6 27:15<br><b>order</b> 9:19 25:15<br>39:3 54:15,15<br><b>original</b> 37:15<br><b>originally</b> 35:12<br><b>ought</b> 13:6<br><b>outcome</b> 52:20<br><b>overrun</b> 40:5<br><b>overstate</b> 32:6<br><b>overwhelmingly</b><br>49:2<br><b>owed</b> 5:3,7<br>33:13<br><hr/> <b>P</b><br><hr/> <b>P</b> 3:1<br><b>page</b> 2:2 55:18<br><b>pages</b> 21:23 29:3<br><b>paragraph</b><br>52:17<br><b>parameters</b> 37:3<br><b>paramount</b><br>26:15<br><b>part</b> 18:2,4<br>19:13,16,17<br>20:8,18 21:10<br>23:11 25:18<br>30:1 51:9<br><b>particular</b> 22:2<br>51:6<br><b>parties</b> 37:8<br><b>parts</b> 51:9<br><b>party</b> 44:6<br><b>passed</b> 53:16,21<br><b>patient</b> 55:1<br><b>patients</b> 27:22<br>31:13 33:13<br><b>patient-respo...</b><br>32:14 | <b>pay</b> 32:12<br><b>PDA</b> 4:5<br><b>pending</b> 39:20<br><b>people</b> 25:5<br>30:10,12,14,16<br>30:20,20,21,23<br>32:4,12 42:17<br>56:7<br><b>percent</b> 15:4<br><b>perfectly</b> 11:2<br><b>perform</b> 6:9<br><b>period</b> 50:9<br><b>permit</b> 21:20<br><b>person</b> 42:9<br><b>pertinent</b> 46:25<br><b>petition</b> 21:24<br>52:9 56:3<br><b>Petitioners</b> 1:5<br>1:17,21 2:4,7<br>2:12 3:8 17:9<br>50:24<br><b>petitions</b> 55:23<br><b>Phillips</b> 1:16 2:3<br>2:11 3:5,7,9<br>4:19 5:1,11,25<br>7:1,20 8:15,21<br>9:13,25 10:15<br>11:7,12,21<br>12:10,18,24<br>13:3,21 14:14<br>14:18,21,24<br>15:3,19,25<br>16:3,18,21,23<br>17:4 45:5<br>50:22,23,25<br>51:14 52:4,8<br>52:18 53:4,19<br>54:2,8,11,21<br>55:4,12,22<br>56:2<br><b>place</b> 9:18 25:25<br>32:18 50:13<br><b>places</b> 43:12<br><b>plaintiff</b> 16:17<br>24:11,17 34:1<br>36:24 41:14,19<br>41:24 42:2,7 |
|--|---|--|---|---|

|   |  |  |   |  |
|---|--|--|---|--|
| 45:22 46:3,21<br>48:20 49:19<br><b>plaintiffs</b> 24:23<br>32:24 34:3<br>35:25 40:4<br>43:7 44:24<br>47:6 55:9<br><b>plaintiff's</b> 39:10<br>42:8 45:1<br><b>plays</b> 8:11<br><b>pleaded</b> 26:21<br><b>please</b> 3:10<br>17:11 27:18<br><b>point</b> 17:20<br>26:24 33:11<br>36:4 49:11<br>56:3<br><b>points</b> 29:1 49:6<br><b>police</b> 3:19<br>28:11 33:23<br>37:21<br><b>policing</b> 3:12<br>37:2<br><b>portion</b> 6:15,25<br>8:2<br><b>position</b> 12:19<br>23:5,24 24:8<br>25:2 46:18<br>48:24 55:13<br><b>posts</b> 39:16<br><b>potential</b> 18:8<br>18:12 28:25<br><b>potentially</b> 5:4<br><b>power</b> 9:16,16<br><b>practice</b> 49:14<br><b>precisely</b> 9:20<br>11:4 12:1<br>51:10<br><b>predicate</b> 17:15<br>21:3 27:10<br><b>preempt</b> 51:8<br><b>preemption</b><br>50:13<br><b>premise</b> 3:14<br>32:20,22 33:1<br><b>prerogative</b><br>24:10,24 | <b>prerogatives</b><br>19:4 23:9<br><b>prescribed</b> 5:23<br><b>present</b> 16:25<br>34:10,13 45:19<br><b>presented</b> 16:24<br>27:7<br><b>presenting</b> 45:6<br><b>presents</b> 17:12<br><b>presumably</b><br>41:1<br><b>pretty</b> 55:13<br><b>prevail</b> 45:1<br><b>prevent</b> 13:15<br><b>pre-empted</b><br>11:10,11,20,25<br>12:5 17:24,25<br>18:15,25 19:10<br>20:15 26:6,12<br>26:22 47:15,15<br>48:1,21<br><b>pre-empting</b><br>7:24 13:18<br><b>pre-emption</b> 8:3<br>15:18,20 18:5<br>19:2 24:18,21<br>28:5 49:20<br>51:7<br><b>pre-empts</b> 8:1<br><b>pre-market</b><br>28:22<br><b>primary</b> 16:11<br>55:20<br><b>private</b> 6:16<br>23:13<br><b>probably</b> 6:21<br>12:19 13:4<br><b>probe</b> 22:21<br><b>problem</b> 10:3<br>13:1 15:7 16:6<br>16:18,20,25<br>22:5,10,15,17<br>23:6,17 30:15<br>34:13 55:7<br><b>problems</b> 28:4<br><b>procedural</b> 25:3<br><b>proceed</b> 6:12 | <b>process</b> 18:2,5<br>19:6,15,17,18<br>21:11,12 23:21<br>24:4,11,25<br>25:5,18 28:7<br>28:20,22 42:2<br><b>processes</b> 23:10<br>37:5<br><b>product</b> 3:24 4:1<br>7:19 10:24,25<br>27:19,20,21,24<br>29:22 31:11<br>34:11,22 35:1<br>36:22 39:8<br>45:19 53:9<br><b>products</b> 28:8<br><b>product-specific</b><br>20:8 22:21,22<br><b>profile</b> 38:25<br><b>profits</b> 54:23<br>55:1,3<br><b>program</b> 11:16<br><b>prohibit</b> 46:7<br><b>promise</b> 33:8<br>42:24<br><b>promptly</b> 25:13<br><b>proposition</b><br>22:24 51:8<br><b>protecting</b> 24:10<br><b>protective</b> 39:3<br><b>protects</b> 24:23<br><b>prove</b> 35:21<br>38:16,16 48:20<br><b>proved</b> 12:15<br><b>provide</b> 21:19<br>54:24<br><b>provided</b> 5:20<br>10:8<br><b>provides</b> 13:10<br><b>providing</b> 7:16<br>54:24<br><b>proving</b> 15:23<br><b>provision</b> 4:20<br>6:25 8:6 55:23<br><b>provisions</b> 4:10<br>8:12<br><b>pro-manufact...</b> | 45:12,16 50:6<br><b>public</b> 5:4 55:18<br>56:3<br><b>pull</b> 13:9,10<br>16:9 32:9<br><b>pulled</b> 30:21<br>32:10<br><b>punitive</b> 48:4<br><b>purpose</b> 31:12<br>32:25 33:21<br><b>purposes</b> 26:17<br><b>pursuant</b> 4:9<br>8:11<br><b>put</b> 10:13 25:15<br>37:19<br><b>putting</b> 8:18<br>50:16<br><b>p.m</b> 56:14<br><hr/> <b>Q</b> <hr/> <b>qualification</b><br>10:10<br><b>quantity</b> 21:25<br><b>question</b> 5:12<br>10:2,16 11:8<br>11:21 15:12<br>19:25 20:10<br>21:1 22:4<br>23:25 24:9,22<br>25:1,2,8,14<br>28:13 31:15<br>33:15 39:5<br>43:1,4,17<br>51:21 53:15<br>54:13<br><b>questions</b> 40:20<br>47:25 49:15<br>50:19 52:11<br>54:6,10 56:10<br><b>quick</b> 52:15<br><b>quite</b> 26:1 29:12<br>50:12<br><b>quoted</b> 11:24<br><b>quoting</b> 29:1<br><hr/> <b>R</b> <hr/> <b>R</b> 3:1<br><b>raise</b> 18:7 | <b>raised</b> 17:21,22<br>18:10 22:8<br>28:2 52:6<br><b>randomly</b> 30:22<br><b>reactions</b> 31:7<br><b>read</b> 52:8<br><b>reading</b> 31:5<br><b>ready</b> 3:5<br><b>reality</b> 16:6<br>54:18<br><b>really</b> 5:13 13:1<br>19:1 20:2,12<br>29:3,6 31:16<br>31:20 36:7<br>40:22 42:13<br>50:14 52:25<br><b>reason</b> 6:13 7:8<br>26:13 50:1,11<br>50:12 56:6<br><b>reasonable</b><br>53:12<br><b>reasoned</b> 52:16<br><b>reasons</b> 19:1<br>28:17<br><b>rebuttal</b> 2:10<br>11:18 46:3<br>50:23<br><b>recognize</b> 13:7<br><b>recognized</b> 3:12<br>3:20 52:20<br><b>recommend</b><br>38:5<br><b>recommended</b><br>37:16<br><b>record</b> 18:16<br><b>recovery</b> 27:10<br>55:8<br><b>red</b> 38:20<br><b>reduced</b> 40:19<br><b>reflects</b> 51:7<br>52:12<br><b>Regal</b> 21:13<br><b>regard</b> 29:24<br><b>regardless</b> 15:21<br><b>regulate</b> 4:18<br>9:20 15:13<br><b>regulated</b> 3:22 |
|---|--|--|---|--|



|   |  |  |  |   |
|---|--|--|--|---|
| 13:24 15:13<br><b>regulates</b> 17:17<br><b>regulation</b> 21:23<br>36:20<br><b>regulations</b><br>21:18 28:23<br>40:2<br><b>regulators</b> 29:18<br><b>regulatory</b> 8:19<br>9:3,9 12:3<br>17:20,21 19:25<br>22:7 26:18<br>32:16 36:23<br>43:8 44:7 45:7<br>45:9,14<br><b>rejected</b> 56:5<br><b>related</b> 11:8<br><b>relationship</b> 6:5<br>7:10 13:23,25<br>15:13 17:16<br>26:13<br><b>relatively</b> 20:10<br>22:16,23<br><b>relevant</b> 18:22<br>29:10 46:10<br>47:7<br><b>reliability</b> 33:15<br><b>reliable</b> 33:12<br><b>remains</b> 16:7<br><b>remand</b> 24:3<br>53:25<br><b>remedial</b> 55:5<br>55:13<br><b>remedy</b> 32:16<br>55:10<br><b>removing</b> 31:24<br><b>reported</b> 22:9<br>48:16<br><b>reports</b> 34:19<br><b>representations</b><br>47:21<br><b>requests</b> 40:5<br><b>require</b> 26:1<br>28:23<br><b>required</b> 4:9 8:9<br>21:6 25:18<br>28:21 29:8 | 36:7 48:6 53:9<br><b>requirement</b><br>47:19<br><b>requirements</b><br>4:3 6:18 21:5<br>33:24<br><b>requires</b> 17:14<br>21:3 27:8<br><b>resist</b> 26:2<br><b>resolved</b> 25:13<br><b>respect</b> 34:4,21<br>43:3 47:19<br>49:14 51:19<br>54:13<br><b>Respondents</b><br>1:23 2:9 27:16<br>27:22<br><b>response</b> 11:10<br>11:19,22 18:8<br>36:21<br><b>responsibility</b><br>3:19,20 5:19<br><b>restatement</b><br>47:2<br><b>restitution</b><br>54:16,19,23<br>55:15<br><b>restrict</b> 44:25<br><b>result</b> 7:3 22:11<br>43:6,8 55:2<br><b>results</b> 33:23<br><b>retain</b> 51:9<br><b>reversed</b> 17:2<br><b>reviewed</b> 34:15<br>56:5<br><b>reviews</b> 39:17<br><b>Rezulin</b> 32:9,10<br>32:15 34:4,16<br>36:3,18 37:13<br>38:8 39:2,12<br>56:4<br><b>rid</b> 53:1<br><b>right</b> 6:19 8:20<br>10:7 12:24<br>15:25 16:5<br>22:20 23:23<br>24:7 25:4,12 | 30:5 31:8<br>35:11 42:21,23<br>42:24 43:2,24<br>43:25 44:21<br>49:22 50:5,10<br>52:20<br><b>risk</b> 30:10,13<br>50:3<br><b>role</b> 30:22 31:14<br>31:14<br><b>rooted</b> 20:12<br><b>rules</b> 41:4<br><b>ruling</b> 6:4 14:7<br><hr/> <b>S</b><br><b>S</b> 2:1 3:1<br><b>safe</b> 35:1<br><b>safety</b> 14:10<br>28:24 29:8,9<br>35:15 38:14,25<br><b>sanction</b> 41:15<br><b>sanctions</b> 40:16<br>40:22 41:18<br><b>satisfied</b> 11:2<br>33:12,20 35:17<br>53:14<br><b>satisfy</b> 35:9<br><b>save</b> 30:20 32:4<br><b>saying</b> 9:3 11:9<br>15:17 30:4<br>44:18 47:10<br>53:19<br><b>says</b> 4:23 8:7,11<br>14:9 31:6<br>33:14 44:7<br>45:9 52:9,23<br>53:6<br><b>Scalia</b> 4:19 5:2,8<br>5:17 6:13 7:2<br>7:12 14:8,15<br>14:19 15:2<br>24:13 40:7,11<br>41:3,18 48:17<br>48:23 54:4,9<br>54:12<br><b>scheme</b> 29:17<br>35:5 | <b>second</b> 8:4 9:12<br>11:5 17:1<br>18:23 19:4<br>20:11 21:24<br>23:23 24:2<br>38:4,17 49:3,6<br>51:20 52:2<br>53:22,25<br><b>second-guess</b><br>6:24<br><b>second-guessing</b><br>26:18 41:20<br><b>section</b> 6:19<br>13:18 21:19<br><b>see</b> 13:5 30:22<br>30:23 41:6<br>44:1 47:12<br>48:23 49:23<br><b>seek</b> 32:8 37:8<br><b>seeking</b> 6:4<br>31:10 32:15,16<br>42:8<br><b>seller</b> 6:6 13:24<br><b>sellers</b> 8:24<br><b>sense</b> 16:5 30:4<br><b>sentences</b> 40:8<br><b>serious</b> 13:2,13<br>22:5 32:13<br>43:17<br><b>seriously</b> 25:14<br>25:25 30:14<br>36:15<br><b>serve</b> 7:5<br><b>served</b> 13:16<br><b>set</b> 7:23 14:1<br>21:9<br><b>settled</b> 20:5<br><b>seven</b> 32:10<br>48:11<br><b>sever</b> 48:2<br><b>severability</b><br>10:17 24:9,19<br>47:25 48:24<br>49:25 50:9,11<br>51:20 52:2,13<br><b>severable</b> 48:21<br><b>severance</b> 23:25 | <b>show</b> 9:3 34:24<br>34:25 35:5,6,9<br>35:10,13,16,16<br>35:17 45:19<br>46:4<br><b>showing</b> 35:23<br>36:22 37:25<br><b>shows</b> 11:16,16<br>34:12 46:21<br><b>sick</b> 30:14<br><b>side</b> 9:15 15:1<br>18:11 19:24<br>30:9,13 42:17<br>52:25<br><b>significant</b> 23:1<br>30:2<br><b>similar</b> 23:17<br>47:23<br><b>simply</b> 46:10<br><b>single</b> 32:13<br><b>situation</b> 9:22<br>18:17 23:8<br>31:23 41:25<br><b>situations</b> 33:14<br><b>Six</b> 3:11<br><b>Sixth</b> 10:12,18<br>10:20 24:13,16<br>48:9,17,19<br>49:1,3,11,17<br>51:22,24 52:12<br>53:3,5<br><b>slightly</b> 26:12<br>32:6<br><b>slow</b> 28:6<br><b>sold</b> 33:2<br><b>sole</b> 7:22<br><b>Solicitor</b> 1:18<br><b>somebody</b> 43:15<br><b>somewhat</b> 25:8<br><b>sorry</b> 8:23<br><b>sort</b> 10:23 22:3<br>47:4<br><b>SOUTER</b> 17:19<br>18:6 19:11,21<br>20:16,21<br><b>special</b> 51:12<br><b>specific</b> 4:10 |
|---|--|--|--|---|

|  |  |  |  |  |
|--|--|--|--|--|
| 36:17 51:9<br>53:8 56:4<br><b>specifically</b> 8:12<br>28:3 39:13<br>52:19 53:6,20<br><b>spoke</b> 52:19<br><b>stages</b> 38:6<br><b>standalone</b><br>34:17<br><b>standard</b> 7:18<br>8:16,16 21:22<br>45:9<br><b>stands</b> 22:24<br>38:17<br><b>start</b> 28:16<br><b>started</b> 32:18<br><b>starting</b> 33:11<br><b>starts</b> 42:2<br><b>State</b> 3:15,18<br>4:21 7:5,22 8:1<br>8:4,7,22 10:16<br>10:21,25 13:10<br>13:16 15:7,7<br>17:24 18:1<br>21:8 22:25<br>23:11,13,16,18<br>24:8,20 25:5<br>26:17 27:23<br>28:15 31:9,12<br>31:19 33:13,20<br>34:2 36:25<br>37:21 39:9<br>43:19 44:3,14<br>45:2,3,17,21<br>46:7 47:14,22<br>49:1,15 50:7<br>51:10 52:11<br>53:13 54:6,10<br><b>stated</b> 38:21<br><b>states</b> 1:1,13,20<br>2:6 3:13 4:7,18<br>5:5 12:22,25<br>14:4 17:7 34:4<br>36:2 45:18,24<br>46:11,15,20<br>47:3,17 48:3<br><b>statute</b> 3:25 4:14 | 4:20 7:22 8:1<br>8:17 10:8<br>11:14,16,24<br>13:19,22 17:12<br>21:3 24:20<br>27:8 28:17<br>29:4 33:4,10<br>45:16 46:13<br>47:15,17,18,23<br>48:22 49:21<br>50:14,17,18<br>52:22 53:16<br><b>statutes</b> 8:12,13<br>8:14 12:23<br>13:1 16:7<br><b>stays</b> 24:6<br><b>step</b> 6:1,1 35:24<br><b>Stevens</b> 3:3,9<br>11:7,13 12:8<br>12:11,21,25<br>13:17 15:16,22<br>16:2,13 17:4<br>17:10 22:3,14<br>22:18 25:8<br>26:5,9,20 27:1<br>27:13,17 35:20<br>36:21 49:18,23<br>50:2,8,21,25<br>54:19,25 55:5<br>55:8 56:12<br><b>stick</b> 7:13<br><b>stop</b> 40:8<br><b>streamlined</b><br>28:19<br><b>strict</b> 47:5<br><b>strike</b> 10:11<br><b>strongest</b> 23:5<br><b>struck</b> 3:15<br><b>structure</b> 33:4<br><b>stuff</b> 29:18<br><b>subject</b> 20:24<br><b>subjective</b> 21:22<br><b>submission</b> 20:8<br>28:23<br><b>submit</b> 21:10<br>28:6,8,18 29:5<br>29:8 | <b>submitted</b> 4:9<br>19:16 21:7,7<br>22:1 34:22<br>56:15<br><b>submitting</b><br>29:14<br><b>subparagraph</b><br>50:17<br><b>subpart</b> 13:19<br><b>subsection</b><br>50:18<br><b>succeed</b> 26:3<br><b>successfully</b><br>40:1<br><b>sued</b> 27:22<br><b>suffered</b> 32:13<br><b>sufficient</b> 21:20<br>33:18<br><b>suggest</b> 29:20<br>38:3 52:8<br><b>suggesting</b> 55:5<br><b>suit</b> 4:24 5:10,11<br>31:12,20<br><b>suits</b> 31:10<br><b>superior</b> 38:23<br><b>supplied</b> 36:13<br><b>support</b> 23:5<br><b>supporting</b> 1:21<br>2:7 17:9<br><b>suppose</b> 16:5<br>25:19<br><b>supposing</b> 26:20<br>26:20<br><b>suppress</b> 39:22<br><b>supreme</b> 1:1,13<br>23:13,16 24:5<br>49:7<br><b>sure</b> 10:17 12:10<br>26:24 43:17<br>46:15 49:18<br>52:18<br><b>surrounding</b><br>18:24 22:22<br>27:5<br><b>sweep</b> 54:22<br><b>sweet</b> 24:5 53:1<br><b>sympathetic</b> | 41:11<br><b>system</b> 16:15<br>31:19 47:11,14<br>55:17<br><hr/> <b>T</b><br><hr/> <b>T</b> 2:1,1<br><b>tainted</b> 11:18<br><b>take</b> 9:4 15:10<br>44:25 50:3<br>53:7<br><b>taken</b> 6:2 25:9<br>37:18 56:12<br><b>takes</b> 33:10<br><b>talking</b> 5:3,6<br>7:21,21 8:5<br>20:13 23:8<br>29:16 38:23<br>54:25<br><b>technical</b> 21:18<br><b>Technologies</b><br>51:5<br><b>tell</b> 12:7 18:9<br>21:9 23:13<br>34:6 35:19<br><b>telling</b> 23:18,19<br><b>tend</b> 38:2<br><b>term</b> 5:14 15:10<br>31:17 43:22<br><b>terminated</b> 3:23<br><b>terms</b> 6:7 8:6<br>15:14 35:14<br><b>terrible</b> 30:11<br><b>terribly</b> 20:11<br><b>territory</b> 4:16<br>13:7<br><b>test</b> 48:13<br><b>testified</b> 38:12<br><b>testifying</b> 37:6<br><b>testimony</b> 25:10<br>34:15 38:18<br><b>Texas</b> 47:23<br>48:5<br><b>thank</b> 3:9 17:3,4<br>27:12,13 44:22<br>50:20,21,25<br><b>theoretical</b> 22:5 | 22:14 27:2<br><b>theories</b> 19:2<br><b>theory</b> 32:1,2<br>47:4 48:13<br><b>therapy</b> 34:17<br>38:6<br><b>thing</b> 11:19<br>30:11 37:20<br>44:18<br><b>things</b> 10:8,14<br>18:22 19:8<br>24:16 25:16<br>30:6 38:20<br><b>think</b> 5:12,12,25<br>9:13,14,25<br>10:1,17 11:21<br>13:3,17,21<br>14:3,5,14,18<br>15:3,11 16:24<br>17:1 24:5 26:6<br>26:10,11 28:16<br>31:9,15 36:10<br>37:24 41:3<br>43:3,9 46:13<br>46:13,17 47:25<br>49:2,4,25 50:6<br>50:12 51:3,14<br>51:20 52:1<br>53:19 54:16<br><b>third</b> 32:14<br><b>thoroughly</b><br>52:16<br><b>thought</b> 12:9<br>16:14 23:24<br>24:18 25:6,18<br>28:4 35:4<br>46:10 52:5<br><b>thousand</b> 25:10<br><b>thousands</b> 29:3<br>29:14<br><b>three</b> 12:22 25:9<br>25:11 28:3,14<br>28:17 30:6<br><b>tied</b> 50:1,12<br>52:24<br><b>time</b> 14:12 15:4<br>22:25 30:16 |
|--|--|--|--|--|

|  |  |   |  |  |
|--|--|---|--|--|
| 38:21 51:1<br><b>told</b> 55:16<br><b>tort</b> 3:15 4:21<br>6:16 7:5,18,23<br>7:25 8:16<br>12:14 28:15<br>31:12,20 44:3<br>44:14,20 45:2<br>45:3,17 47:10<br>47:13<br><b>tortious</b> 3:17<br><b>torts</b> 31:10<br><b>totally</b> 45:10<br><b>tracks</b> 25:7<br><b>tradition</b> 20:6<br>20:12<br><b>traditional</b> 8:4<br>22:25 27:23<br>28:14 44:25<br>47:13<br><b>traditionally</b><br>3:13 14:3<br>53:22<br><b>tread</b> 4:15<br><b>treads</b> 5:19<br><b>trial</b> 11:23<br><b>trials</b> 48:13<br><b>tried</b> 44:24<br><b>true</b> 31:21 38:25<br><b>trust</b> 41:12 47:6<br>47:8<br><b>trusted</b> 37:11<br><b>try</b> 13:15 49:24<br><b>trying</b> 13:14<br>29:13 41:11<br>50:16 51:11<br><b>turns</b> 20:18<br><b>two</b> 7:10 10:8,9<br>10:10,14 15:15<br>18:21 19:1<br>21:17 25:9,25<br>27:10 38:6<br>41:4<br><b>type</b> 20:6 21:25<br>23:8<br><b>typical</b> 29:2,22<br>34:20 | <b>U</b><br><b>Uh-huh</b> 15:2<br><b>ultimately</b> 3:23<br>24:12<br><b>unable</b> 48:15<br><b>unapproved</b><br>36:19<br><b>unclear</b> 29:6<br>35:10<br><b>unconstitutio...</b><br>9:24 10:1<br><b>underlies</b> 30:8<br>31:7<br><b>underlying</b> 7:25<br><b>underscores</b><br>24:21<br><b>understand</b> 8:10<br>22:6 26:9<br>49:19 50:15<br>55:4<br><b>understood</b><br>55:12<br><b>undertake</b> 9:19<br><b>uniform</b> 20:12<br><b>unique</b> 3:24<br>7:22 47:18<br><b>uniquely</b> 7:9<br>51:5,15,16<br><b>United</b> 1:1,13,20<br>2:6 4:7 17:7<br>51:4<br><b>unnecessary</b><br>28:18<br><b>unreasonable</b><br>6:1<br><b>unstuck</b> 10:11<br><b>unusual</b> 24:21<br><b>unwarranted</b><br>28:10<br><b>update</b> 35:14<br><b>use</b> 9:18 16:10<br>24:3 28:9<br>37:12 38:6,8<br>38:10,11,13<br>43:13<br><b>usually</b> 48:25 | <b>V</b><br><b>v</b> 1:6<br><b>validity</b> 26:18<br><b>versa</b> 18:10<br><b>versus</b> 51:4<br><b>vice</b> 18:10<br><b>victims</b> 54:16,20<br>55:15<br><b>view</b> 17:24<br>19:14 46:6<br>49:4<br><b>vintage</b> 20:11<br>22:23<br><b>violated</b> 21:6<br><b>violation</b> 17:22<br><b>Vioxx</b> 39:20<br><b>W</b><br><b>wait</b> 13:13<br><b>want</b> 24:4 29:6<br>31:4,22,25<br>32:4 33:6<br>37:21 40:21<br>48:2 49:18<br><b>wanted</b> 16:23<br>23:13 40:1<br><b>warn</b> 27:24<br><b>Warner-Lam...</b><br>1:3 3:4 27:19<br>27:23 29:1<br>36:6 38:1,22<br>38:23 40:14,21<br>43:6<br><b>warranted</b> 28:4<br><b>Washington</b> 1:9<br>1:16,19,22<br><b>wasn't</b> 24:14<br>37:14 39:21<br>45:20 46:10<br>49:13<br><b>way</b> 9:20 10:18<br>12:1 16:24<br>20:4 21:23<br>34:2 35:25<br>38:23 41:24<br>51:17<br><b>ways</b> 45:23 | <b>website</b> 39:17<br><b>went</b> 34:21 39:7<br>48:10<br><b>Westlaw</b> 48:16<br><b>we're</b> 5:6 7:21<br>7:21,24,24 8:5<br>9:3 15:17<br>29:16 31:2<br>51:11 52:23<br>56:8<br><b>we've</b> 27:1<br><b>win</b> 15:17,20<br>24:19 50:4<br><b>wins</b> 24:12<br><b>wiped</b> 10:6<br><b>wipes</b> 8:3<br><b>withdraw</b> 10:23<br>16:12,15 31:21<br>41:17 42:22<br>56:4<br><b>withdrawal</b><br>19:11,12 54:14<br><b>withdrawing</b><br>40:16<br><b>withdrawn</b> 4:13<br>15:24 36:12<br>40:19,24 41:5<br>41:8 42:16<br>53:10<br><b>withdraws</b> 4:4<br><b>withdrew</b> 16:4<br><b>withheld</b> 9:5<br>27:20 34:19<br>38:14 42:4<br><b>withholding</b><br>25:16 40:14<br><b>withholds</b> 4:6<br><b>witnesses</b> 25:19<br><b>won</b> 16:1<br><b>wonder</b> 13:1<br><b>words</b> 44:18<br><b>work</b> 37:10<br><b>works</b> 43:18<br><b>worries</b> 42:19<br><b>worry</b> 5:18<br>29:13<br><b>worse</b> 30:4 | <b>wouldn't</b> 7:6<br>15:23 16:25<br>34:11,13 36:15<br>36:18,22 37:4<br>37:5 41:23<br>42:7 45:24<br><b>wrong</b> 14:15<br>16:17 17:2<br>23:24 29:24<br>36:10 42:20<br>43:5 55:11<br><b>wrongly</b> 8:5<br><b>Wyeth</b> 5:14<br>15:10<br><b>X</b><br><b>x</b> 1:2,8<br><b>Y</b><br><b>yeah</b> 54:22<br><b>years</b> 3:11 12:14<br>22:7 32:10<br>48:8,11<br><b>York</b> 36:2<br><b>Z</b><br><b>Zieve</b> 1:22 2:8<br>27:14,15,17<br>29:19 31:3,9<br>31:18 32:3,8<br>32:23 33:3,8<br>33:10 34:9<br>35:8,23 36:17<br>37:8,23 38:18<br>39:8 40:25<br>41:13,24 42:25<br>43:3,19,24<br>44:10,13,21,23<br>45:15 46:9,15<br>46:20 47:13,16<br>47:18,23 48:10<br>48:15,19 49:5<br>49:13,22,24<br>50:5,10<br><b>0</b><br><b>06-1498</b> 1:6 |
|--|--|---|--|--|

|  |  |  |  |  |
|--|--|--|--|--|
| <div>1</div> <div>11:05 1:14 3:2</div> <div>12 30:21</div> <div>12-year-old 29:4</div> <div>12:05 56:14</div> <div>14a 52:9</div> <div>142a 21:23</div> <div>17 2:7</div> <div>186a 21:24</div> <div>1930's 44:3</div> <div>1938 44:15</div> |  |  |  |  |
| <div>2</div> <div>2008 1:10</div> <div>24 55:19</div> <div>25 1:10</div> <div>27 2:9</div>   |  |  |  |  |
| <div>3</div> <div>3 2:4</div> <div>314.50(b)(5)</div> <div>29:1</div>  |  |  |  |  |
| <div>4</div> <div>4 49:5</div> <div>42A 4:5</div>  |  |  |  |  |
| <div>5</div> <div>5 50:18</div> <div>50 2:12</div> <div>510(k) 28:7,19</div>   |  |  |  |  |
| <div>8</div> <div>8 50:18</div>  |  |  |  |  |
| <div>9</div> <div>96 48:11</div> <div>99.999 15:4</div>  |  |  |  |  |