

	C O N T E N T S	
1		
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		
19		
20		
21		
22		
23		
24		
25		

1
2
3
4
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6
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8
9
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11
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P R O C E E D I N G S

(11:05 a.m.)

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

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

ORAL ARGUMENT OF CARTER G. PHILLIPS

ON BEHALF OF THE PETITIONERS

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

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

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

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13 withdrawn approval.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

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

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

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

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

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

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

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

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

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

1				
11:05 1:14 3:2				
12 30:21				
12-year-old 29:4				
12:05 56:14				
14a 52:9				
142a 21:23				
17 2:7				
186a 21:24				
1930's 44:3				
1938 44:15				
2				
2008 1:10				
24 55:19				
25 1:10				
27 2:9				
3				
3 2:4				
314.50(b)(5) 29:1				
4				
4 49:5				
42A 4:5				
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99.999 15:4				