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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, that on the one hand confers a very

1 broad immunity or 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 where the defense -- this is Pet. App. at 42a --
6 if the 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13 withdrawn approval."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 concern and 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 acknowledge 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: No, it's a duty that is
9 defined by the FDA. And I didn't hear your answer.
10 Would that 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 you have
15 FDA approval of certain activities, that that has the
16 effect of -- State law.

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

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

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

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

1 the provision-of-information portion?

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

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

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

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

25 We're not -- we're not preempting the

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

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

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

22 MR. PHILLIPS: Yes.

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

1 (Laughter.)

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

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

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

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

22 And the answer to that is: No, because this
23 is not a situation where you tend to take --

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

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

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

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

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

1 then State law is allowed to come in and enforce product
2 liability claims under those circumstances, that the
3 legislature would have been perfectly satisfied with
4 that arrangement.

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

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

13 MR. PHILLIPS: Correct.

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

22 MR. PHILLIPS: I think the question goes to
23 how far that response goes. If you in fact instructed,
24 if the trial judge instructed the jury that if it found,
25 and then just quoted the language of the statute that

1 there's no, then I'd say, yes, that is preempted in
2 precisely the same way.

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

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

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

11 MR. PHILLIPS: Sure.

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

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

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

25 MR. PHILLIPS: Right.

1 JUSTICE STEVENS: But most States don't have
2 these statutes. It sounds to me -- I wonder if the
3 problem is really as serious as everybody --

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

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

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

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

1 the FDA itself. That goes to a relationship
2 between -- that -- that is governed by a different set
3 of laws.

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

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

15 MR. PHILLIPS: I think -- well -- obviously,
16 as long as --

17 JUSTICE SCALIA: Aren't you going to say that
18 that's -- you know, that's interfering with the FDA's
19 bailiwick?

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

21 JUSTICE SCALIA: Are you going to let a jury
22 decide that?

23 MR. PHILLIPS: No, I'm not going to let a
24 jury decide that, probably.

25 (Laughter.)

1 MR. PHILLIPS: What the district court found
2 here, obviously, was that there was compliance, because
3 the other side didn't challenge the compliance.

4 JUSTICE SCALIA: Uh-huh.

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

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

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

18 JUSTICE STEVENS: It seems to me what you
19 are saying is: We're going to win this case even if
20 there were no preemption.

21 MR. PHILLIPS: Even if there is no
22 preemption on -- on the -- well, I hope I win this case
23 regardless.

24 JUSTICE STEVENS: Because they have such a
25 burden of proving that the drug wouldn't, in fact, have

1 been withdrawn and so forth.

2 MR. PHILLIPS: Right, well -- you mean I
3 would have won this case on the merits of it?

4 JUSTICE STEVENS: Yes.

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

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

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

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

23 MR. PHILLIPS: No, we were very explicit in
24 the reply brief--

25 JUSTICE BREYER: So that's not the --

1 MR. PHILLIPS: -- that if the Court wanted
2 to go that way, that's fine. I don't think it's
3 presented in this case, but that wouldn't present any
4 problem for us. I think what we -- what we have here is
5 the Second Circuit is wrong, and the judgment should be
6 reversed.

7 Thank you, Your Honors.

8 JUSTICE STEVENS: Thank you, Mr. Phillips.
9 Mr. Joseffer.

10 ORAL ARGUMENT OF DARYL JOSEFFER

11 ON BEHALF OF THE UNITED STATES,

12 AS AMICUS CURIAE,

13 SUPPORTING THE PETITIONERS

14 MR. JOSEFFER: Justice Stevens, and may it
15 please the Court:

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

23 JUSTICE SOUTER: Does your argument carry to
24 the point of the same argument when regulatory
25 compliance is raised as a defense, or regulatory

1 violation is raised as a ground for liability?

2 MR. JOSEFFER: It could depend, because in
3 our view what's preempted here is a State-court
4 determination -- under Buckman, what's preempted is a
5 State-court determination of whether the FDA was
6 defrauded as part of FDA's approval process. So, for
7 example, under any circumstance, if a jury is being
8 instructed to find whether FDA was defrauded as part of
9 its approval process, we'd say there's preemption.

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

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

18 MR. JOSEFFER: Well -- and what we would say
19 is not preempted -- I mean, it's hard to analyze this
20 in the abstract without a record as to what a jury was
21 actually being asked to do. But if you had a situation
22 where it was, say, a design defect claim, and the jury
23 was being asked to decide whether this design is
24 defective, and that's what it's looking at, and in
25 connection with that the jury is instructed that two

1 relevant things it can consider are, first, the fact of
2 FDA's approval determination and, second, the
3 circumstances surrounding that approval determination,
4 then that by itself, we would say, is not preempted by
5 Buckman, really for two reasons. One is that
6 preemption normally applies to legal theories, such as
7 claims or defenses, not the mere admissibility of
8 evidence; and the second is that FDA's core prerogatives
9 here, as the administrator of its own drug approval
10 process, are to determine whether it has been defrauded
11 and what to do about that. And if a jury is not being
12 asked to find those things, but instead is just
13 considering evidence in connection with something else,
14 we would say that that is what's not preempted.

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

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

25 JUSTICE SOUTER: But if you get beyond the

1 element of what the FDA would have done if it had known,
2 then it seems to me you get into an issue which is
3 likely to arise by -- whenever, by one side or the
4 other, the question of regulatory approval is -- is
5 offered as a mere matter of evidence.

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

20 JUSTICE SOUTER: No, but that's what you've
21 got here, except that the mere admissibility of the
22 evidence turns in part on what the -- the FDA would have
23 done.

24 MR. JOSEFFER: Well, no --

25 JUSTICE SOUTER: But essentially -- I mean

1 you -- the fact is the evidence of the FDA approval is
2 made admissible and conclusive, and whether that in fact
3 may be admitted is subject to the -- what is it --
4 clause (b) that you object to, but it comes down to a
5 question of admissibility.

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

20 And if I could illustrate the concern which
21 this Court explained in Buckman, it's that -- with just
22 two FDA regulations. The first explains that the
23 technical section of a new drug application must provide
24 information and data in sufficient detail to permit the
25 agency to make a knowledgeable judgment. Now, because

1 that is an extremely subjective standard, another FDA
2 regulation -- and by the way, these are on pages 142a
3 and 186a of the petition appendix -- the second goes on
4 to explain that the type and quantity of information
5 that must be submitted to FDA necessarily depends on the
6 particular drug.

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

16 MR. JOSEFFER: Nothing that's -- nothing
17 beyond the type of case that Buckman set --

18 JUSTICE STEVENS: It's a wholly theoretical
19 problem, isn't it?

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

22 JUSTICE STEVENS: This kind of litigation is
23 not, not new.

24 MR. JOSEFFER: Right, but the
25 product-specific approvals, and the desire to probe into

1 the circumstances surrounding a product-specific
2 approval, is of relatively modern vintage. And Buckman
3 itself stands for the proposition that that was not a
4 traditional State inquiry at that time. And Buckman
5 certainly has not encouraged a significant increase in
6 such litigation since then. So this is something that
7 there's not been a whole lot of.

8 JUSTICE KENNEDY: Leaving aside Buckman,
9 what's your strongest case in support of your position?
10 Beside -- it is a new problem.

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

1 JUSTICE GINSBURG: Mr. Joseffer, let's
2 assume that -- that you're right. The Second Circuit,
3 because it thought your position was wrong, never got
4 to the severance question. It had been decided by some
5 intermediate appellate court. But would it not be
6 appropriate then to leave it to the Second Circuit on
7 remand, if it chooses to use the Michigan certification
8 process to say, well, we want to find out from the
9 Michigan Supreme Court whether they think that the sweet
10 stays, but the bitter goes?

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

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

19 MR. JOSEFFER: It was. And one of the
20 things that that brings up, in the Sixth Circuit it was
21 actually the plaintiff who was advocating Federal
22 preemption there, because she thought that she would
23 then win on severability analysis and would thereby
24 knock out the entire State statute. What that
25 underscores is that the unusual Federal preemption

1 question here is not necessarily one that is even bad
2 for plaintiffs. It just protects the important Federal
3 prerogative of FDA's ability to administer its own drug
4 approval process.

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

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

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

1 circumstances.

2 And those are incredibly intrusive inquiries
3 that, one, distort manufacturers' incentives in dealing
4 with FDA in the first place; two, if this was seriously
5 going to be litigated would require, I assume, quite a
6 lot of discovery from FDA, which we would resist, but
7 that's not to say that we would necessarily succeed in
8 our objections.

9 JUSTICE STEVENS: May I ask would you -- is
10 the bribery exception also preempted, do you think?

11 MR. JOSEFFER: That's a -- there's a very
12 different analysis there.

13 JUSTICE STEVENS: I understand. Do you
14 think it's preempted?

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

24 JUSTICE STEVENS: Supposing the -- supposing
25 the official pleaded guilty to bribery. Would it be

1 preempted then?

2 MR. JOSEFFER: Obviously, it still gets much
3 closer, and at that point, I'm not sure that it would
4 be.

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

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

16 Thank you.

17 JUSTICE STEVENS: Thank you very much.

18 Ms. Zieve.

19 ORAL ARGUMENT OF ALLISON M. ZIEVE

20 ON BEHALF OF THE RESPONDENTS

21 MS. ZIEVE: Justice Stevens, and may it
22 please the Court:

23 Warner-Lambert marketed a defective product.
24 It withheld information about the injury the product
25 could cause, and the product caused injury to a great

1 many patients, including Respondents. They sued
2 Warner-Lambert alleging traditional State-law claims,
3 such as product defect and failure to warn. I'd like
4 to begin by explaining why the misrepresentation
5 exception to the Michigan defense does not implicate the
6 concerns that were raised by the Court in Buckman.
7 Specifically, the Court in Buckman identified three
8 problems or concerns that it thought warranted
9 preemption in that case: That the claim alleged would
10 cause companies to submit too much information and slow
11 down the 510(k) process; that the claim alleged might
12 cause companies not to submit products for approval
13 because of concern about off-label use; and that the
14 claim would cause an unwarranted intrusion on the FDA's
15 decisionmaking about how to police and enforce fraud
16 against it.

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

20 I'll start with what I think are the easy
21 ones. For three reasons, the Michigan statute creates
22 no incentive for manufacturers to submit unnecessary
23 information to the FDA. Unlike the streamlined 510(k)
24 clearance process that was at issue in Buckman, in this
25 case we have a drug approval. Drugs are required to go

1 through a comprehensive pre-market approval process.
2 The regulations require submission of, "all available
3 information about the safety of a drug, including
4 demonstrated or potential adverse effects." I was
5 quoting from 314.50(d)(5). As Warner-Lambert points out
6 in its brief, a typical new drug application can be
7 thousands of pages long. So there's not really -- not
8 only is there not evidence that this 12-year-old statute
9 will lead companies to submit information that the FDA
10 doesn't want and doesn't need; but it's really unclear
11 what such evidence would be because, after all,
12 companies are required to submit all safety information
13 to the FDA, and it's the safety information that would
14 be relevant to a finding under the Michigan exception.

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

23 MS. ZIEVE: No, Your Honor. The discovery
24 in a case like this -- there is no evidence to suggest
25 it would be any broader or more burdensome than

1 discovery in a typical product liability case against a
2 drug company.

3 In that regard, Mr. Joseffer is wrong that
4 there was no discovery in this case. These cases are
5 part of a multidistrict litigation and there was a
6 significant amount of discovery.

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

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

22 Now, who would you rather have make the
23 decision as to whether this drug is, on balance, going
24 to save people or, on balance, going to hurt people? An
25 expert agency, on the one hand, or 12 people pulled

1 randomly for a jury role who see before them only the
2 people whom the drug hurt and don't see those who need
3 the drug to cure them?

4 Now, that it seems to me is Congress's
5 fundamental choice, and Congress has opted for the
6 agency. And that's why we're here --

7 MS. ZIEVE: Well --

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

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

22 JUSTICE BREYER: No, it says right here -- it
23 doesn't object to a system where the -- a court -- the
24 State would come in and give you your tort suit if it's
25 really true that the agency would withdraw this drug.

1 But what you want is to be able to convince the jury
2 that there was fraud in a situation where the agency
3 doesn't say there was fraud. So what you're doing is
4 removing a drug from the market that they want out there.

5 Now, that's the theory of Buckman. The
6 theory of Buckman is --

7 MS. ZIEVE: But that is not --

8 JUSTICE BREYER: -- they want to save people
9 whom you say they shouldn't because the drug shouldn't
10 be there. I overstate it slightly. So, explain to me
11 why.

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

22 And the -- the place where we started with
23 the --

24 JUSTICE KENNEDY: Your premise still is, is
25 that the drug should not have been marketed, or is that

1 your premise?

2 MS. ZIEVE: Well, under Michigan law, the
3 plaintiffs can only --

4 JUSTICE KENNEDY: I know your purpose is
5 different, but the premise on which you operate is that
6 the drug should not have been sold.

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

9 JUSTICE KENNEDY: You can back up as long as
10 you want so long as you come forward and answer.

11 (Laughter.)

12 MS. ZIEVE: I promise I will.

13 (Laughter.)

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

20 So, if the company bribed the FDA or if
21 the company misrepresented important information to the
22 FDA, then the approval is no longer a sufficient basis
23 on which we can just say that approval in and of itself
24 means that the manufacturer satisfied State-law duties.

25 And so, the -- the purpose of the finding

1 about whether there was misrepresentation and what the
2 results of it might have been is not to police
3 enforcement with FDA requirements, and it is not to
4 force the drug off the market. It is only a hurdle that
5 the plaintiff has to get past so it can litigate -- he
6 or she can litigate her State-law claim the same way
7 plaintiffs will be litigating those claims, and did
8 litigate those claims, with respect to Rezulin in States
9 across the country.

10 JUSTICE KENNEDY: Aren't you going to tell
11 this jury that the drug should not have been on the
12 market?

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

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

24 But second of all, in the typical case a lot
25 of the information that comes out with respect to what

1 went on before the FDA, not only is it submitted in
2 product liability cases in the first instance by the
3 manufacturer to show all of the hurdles they had to go
4 through to get on the market, doesn't that show our
5 product was safe, but a lot of it you can get in
6 discovery from the company themselves, as happened in
7 this case. A lot of --

8 JUSTICE KENNEDY: I thought under the
9 Michigan scheme you don't have to show that. You just
10 show approval, and that's the end of the case -- in
11 Michigan.

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

22 There's just no cases under Michigan law
23 that tell us --

24 JUSTICE STEVENS: It seems to me that you
25 could prove that the -- an exception to the defense

1 applies and still lose your lawsuit.

2 MS. ZIEVE: Absolutely, we could. Showing
3 that the exception applies is just the first step to
4 being able to litigate this case the way plaintiffs
5 litigated these cases in California, and Illinois, and
6 New York, and other States.

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

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

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

21 MS. ZIEVE: Well, of course, in the specific
22 facts of this case it wouldn't, because Rezulin is off
23 the market and unapproved. But even as a general matter
24 it doesn't affect FDA's regulation because, as I said in
25 response to Justice Stevens, the effect of making that

1 showing and of the jury agreeing that the product
2 wouldn't have been approved is -- there's no regulatory
3 effect. The effect is that the plaintiff can then go
4 ahead and litigate her case like she could in any other
5 State.

6 And that's why -- that's because what
7 Michigan is doing is not policing enforcement. It is
8 just defining the parameters of a compliance defense.

9 JUSTICE ALITO: There wouldn't be discovery
10 of internal processes within the FDA? There wouldn't be
11 experts testifying about what the FDA would or would not
12 have done?

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

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

25 Isn't that the kind of thing that the FDA

1 would want to police itself and not have State courts
2 look into?

3 MS. ZIEVE: Well, those are some of the
4 background facts that happened here. But I don't think
5 those are the facts that go to a showing of what the FDA
6 would have done if Warner-Lambert had made honest
7 disclosures, because actually those facts tend to
8 suggest that the FDA did know what was going on.

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

15 That is the use that happened to affect all
16 of my clients, and that's the use where we already have
17 a medical officer who testified that the agency would
18 not have approved for that use if the company hadn't
19 withheld safety information.

20 JUSTICE ALITO: What evidence would
21 you introduce to prove the -- to prove the exception if
22 the Second Circuit's decision stands?

23 MS. ZIEVE: Deposition testimony from that
24 medical officer, for example. There are e-mails. We
25 cited a couple of e-mails in the red brief of things

1 that were stated at the time: One an e-mail to
2 Warner-Lambert and one from a medical officer to his
3 superior talking about the way in which Warner-Lambert
4 made it harder -- to be kind to -- for them to assess
5 what the true safety profile of the drug was.

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

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

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

20 There's also always a lot of information
21 about approved drugs that the FDA posts as a matter of
22 course on its website, including the medical officer
23 reviews that form the basis for the approval decision.

24 But even in other cases, for instance, the
25 Vioxx MDL that was pending in Louisiana, the -- in that

1 case the FDA wasn't as interested in negotiating, and
2 there was a motion to suppress and a motion to compel.
3 And the judge had to decide whether to allow an FDA
4 medical officer to be deposed; and in that case, did.

5 There are other cases where the FDA has not
6 wanted discovery and has successfully opposed it. The
7 FDA has regulations about that, and there's just no
8 evidence that it's burdening the FDA to cooperate to
9 some degree in discovery or the judges are allowing
10 plaintiffs to overrun the FDA with requests they can't
11 handle. But, more importantly, there's no difference --

12 JUSTICE SCALIA: I assume -- I assume -- you
13 don't stop between sentences, so I hate to interrupt
14 you.

15 (Laughter.)

16 JUSTICE SCALIA: I don't know how else to do it.
17 I assume that if this drug were still on the market, you
18 could bring forward the information that you have alluded
19 to about the withholding of necessary data by Warner-
20 Lambert, and the FDA would certainly be able to consider
21 that and decide whether sanctions were necessary,
22 withdrawing of the drug was necessary.

23 In this case, the drug has already been
24 withdrawn. So I assume the FDA has at least a reduced
25 incentive to go into these questions. I guess they

1 still would want to go into them if Warner-Lambert were
2 really a bad actor. They could impose some sanctions,
3 couldn't they, even though the drug was already
4 withdrawn?

5 MS. ZIEVE: I don't know if they still
6 could, but presumably sometime in the past they could
7 have.

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

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

18 MS. ZIEVE: Well, the job the FDA is going
19 to do, even if it agrees with a plaintiff, is to
20 sanction the company, perhaps, or to ask it for
21 different information. It does have the ability to
22 withdraw approval --

23 JUSTICE SCALIA: No, but once it sanctions
24 the plaintiff, the government can't make the argument
25 you are interfering; you are second-guessing the FDA.

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

4 MS. ZIEVE: There's no way for a plaintiff
5 to compel the FDA to look into a situation of a
6 manufacturer being dishonest for the -- or to -- even if
7 the FDA starts a process for a plaintiff to compel the
8 agency to make a finding that the company
9 withheld material information, and we would not have
10 approved it otherwise.

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

17 And the FDA's finding that, yes, the company
18 really acted badly isn't going to do anything to help
19 that -- that family.

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

1 You are absolutely right when you say you
2 cannot make the FDA go into this matter and withdraw a
3 drug; and they are absolutely right when they say we
4 cannot promise you that juries will be right.

5 MS. ZIEVE: But, again --

6 JUSTICE BREYER: So the question is: Who
7 is more likely to be right?

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

14 JUSTICE BREYER: Then you think they should
15 be able to litigate a claim where the FDA has approved a
16 drug.

17 Now, is that the law in most places? Where
18 the FDA has approved a drug for use and the doctor
19 follows the label and the label is all okay, is it the
20 case that somebody can come in and say, despite that,
21 this drug is on balance harmful, and I get compensation?

22 This is a serious question. I'm not sure
23 how it works.

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

25 JUSTICE BREYER: So --

1 JUSTICE GINSBURG: That has been contested,
2 and we are going to hear that case next term.

3 JUSTICE BREYER: That's the next issue.

4 MS. ZIEVE: That's right.

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

6 JUSTICE BREYER: I see.

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

15 MS. ZIEVE: Absolutely.

16 JUSTICE GINSBURG: That's how -- that's how
17 --

18 MS. ZIEVE: Yes. The FDA approval, Federal
19 approval, and State tort actions have co-existed since
20 1938.

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

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

2 JUSTICE BREYER: Thank you.

3 MS. ZIEVE: -- to -- not to create a new
4 claim as the plaintiffs tried to do in Buckman, but,
5 rather, to take a traditional claim and restrict
6 plaintiff's ability to prevail on it.

7 This is not an expansion of State tort law.
8 It is a considerable narrowing of State tort law.

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

17 But it is a deliberately pro-manufacturer
18 measure. It gives the manufacturer an immunity that the
19 regulatory compliance defense does not.

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

1 almost every State.

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

5 But only in Michigan not only is the
6 manufacturer's compliance defense dispositive in the
7 majority of cases, but the evidence of non-compliance
8 isn't even allowed as a rebuttal unless the plaintiff
9 can show that it actually was a material non-compliance
10 that would have made a difference.

11 JUSTICE KENNEDY: And in your view could a
12 State prohibit introduction of evidence by the defendant
13 that the drug was approved by the FDA?

14 MS. ZIEVE: Only to the extent that they
15 thought it wasn't relevant. And there are States that --

16 JUSTICE KENNEDY: No, they say in the
17 statute: We just think -- we just think this is
18 irrelevant.

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

21 JUSTICE KENNEDY: But I mean, that's
22 consistent with your position. There's no doubt about
23 that.

24 MS. ZIEVE: There are States that don't
25 allow compliance evidence if the plaintiff shows

1 material misrepresentation, "material" being that it
2 could have -- could have influenced the agency without a
3 finding that it did or would have influenced the agency,
4 but just that it was pertinent information.

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

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

17 MS. ZIEVE: If -- if the traditional tort
18 system as it exists in most every State is not
19 preempted, then Michigan's statute is not preempted.

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

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

1 JUSTICE GINSBURG: No other State does that?

2 MS. ZIEVE: Texas has a similar statute
3 except it doesn't have that last element. And one of
4 the questions on severability is whether -- if you do
5 think just that element is preempted, whether you can --
6 whether Michigan would want to sever that one element.

7 And then there are a number of States that
8 limit punitive damages liability but along the lines of
9 Texas, not Michigan. So, again, that last element is
10 not required.

11 JUSTICE GINSBURG: But was there any
12 experience with this in Michigan? How many years was it
13 in operation before the Sixth Circuit decision?

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

16 JUSTICE GINSBURG: Have there been many
17 trials to test this theory that it would be disruptive,
18 that --

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

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

23 MS. ZIEVE: Well, in the Sixth Circuit the
24 plaintiff said: We can't prove the exception, but it is
25 preempted and not severable. So we -- so the statute

1 would fall.

2 JUSTICE SCALIA: I see. What is your
3 position on severability? Why shouldn't we -- you know,
4 we usually accept the circuit court's determination as
5 to what the State law is. Michigan is in the Sixth
6 Circuit. And I think it's overwhelmingly likely that
7 the Second Circuit would defer to the Sixth Circuit's
8 view. Don't you think?

9 MS. ZIEVE: Well, in footnote 4 of the
10 Second Circuit decision, Justice Calabresi points out
11 that certification to the Michigan Supreme Court would
12 also be an option, and an option that the court doesn't
13 -- that court didn't even get to.

14 JUSTICE GINSBURG: The discussion in the
15 Sixth Circuit was not very extensive on this point, on
16 this --

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

22 JUSTICE STEVENS: I want to be sure I
23 understand something. In the other case, the plaintiff
24 is the one who argued there was preemption, and the
25 whole statute was invalid; they knocked out the defense.

1 MS. ZIEVE: That's right.

2 JUSTICE STEVENS: I see. I missed that.

3 MS. ZIEVE: Yes. It was a good try. But I
4 think that the severability argument is very closely
5 tied to the reason --

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

9 MS. ZIEVE: Well, that's right. I mean, I
10 think the fact that Michigan is such a pro-manufacturer
11 State, with respect to product liability laws --

12 JUSTICE STEVENS: If there is no
13 severability, the defense is gone, period.

14 MS. ZIEVE: That's right.

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

23 If the Court has no further questions,
24 thank you.

25 JUSTICE STEVENS: Thank you.

1 Mr. Phillips, you have five minutes.

2 REBUTTAL ARGUMENT OF CARTER G. PHILLIPS

3 ON BEHALF OF THE PETITIONERS

4 MR. PHILLIPS: Thank you, Justice Stevens.
5 Hopefully, I'll give you back some of that time, so you
6 can get to lunch.

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

16 JUSTICE KENNEDY: There was special
17 consideration because of military considerations in that
18 case.

19 MR. PHILLIPS: Well, I think that's what
20 made it a uniquely Federal interest. But I don't know
21 that it's any more a uniquely Federal interest than this
22 one, at least as the way the Court has analyzed
23 both of them in Buckman.

24 Justice Ginsburg, with respect to
25 severability, I think, frankly, the Second Circuit

1 already answered the question. They said that we would
2 defer to the Sixth Circuit under Factors and then
3 analyze certification. And it concluded that, given the
4 clarity of the Sixth Circuit's decision in Garcia, that
5 there's nothing left to be decided on that issue.

6 JUSTICE GINSBURG: I didn't think that the
7 Second Circuit discussed severability, but I can go back
8 and check.

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

10 JUSTICE GINSBURG: I thought that it had
11 been raised there, but they didn't get to it because
12 they --

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

20 JUSTICE GINSBURG: In a very, very quick --
21 it isn't a very thoroughly reasoned discussion. It's a
22 very -- it's just one paragraph.

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

1 JUSTICE GINSBURG: Because -- because it is
2 odd -- I mean, it is odd that you'd have a statute that
3 says: Manufacturer, we're going to give you immunity,
4 but there's an exception. They seem so tied together
5 and it really would be a case of letting one side keep
6 the sweet and get rid of the bitter. And it seems to me
7 that there is -- that there was no discussion of that in
8 the Sixth Circuit.

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

20 JUSTICE GINSBURG: But the question is
21 whether the legislature would have passed the statute
22 that it did if in a case like this one the manufacturer
23 could have the immunity without the exception.

24 MR. PHILLIPS: All I'm saying is I think the
25 court addressed that in Garcia and specifically

1 concluded that the legislature in fact would have passed
2 that; and that traditionally, the Second Circuit would
3 defer, as would this Court.

4 JUSTICE GINSBURG: It would be -- it would
5 be open to the Second Circuit on remand because it's not
6 foreclosed.

7 MR. PHILLIPS: No, clearly it's not
8 foreclosed.

9 JUSTICE SCALIA: Well, unless they choose
10 not to change their mind. I mean, they did say that
11 they're bound by this by Garcia as to questions of State
12 law.

13 MR. PHILLIPS: Exactly. They said that
14 specifically.

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

17 MR. PHILLIPS: Exactly.

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

25 JUSTICE STEVENS: Does restitution for

1 victims include damages?

2 MR. PHILLIPS: Well, whatever injuries --
3 yes, I mean, I don't know exactly what the sweep of
4 restitution would be, but disgorgement of profits would
5 certainly provide a mechanism for providing --

6 JUSTICE STEVENS: Well, you're not talking
7 about profits when you have an injured -- a patient who
8 died as a result of malpractice or something. That's
9 not disgorgement of profits. That's damages.

10 MR. PHILLIPS: I understand that. All I'm
11 suggesting, Justice Stevens, is that there are remedial
12 mechanisms still available to the FDA if in fact it
13 concluded that there was some problem, and that those --
14 would extend to the plaintiffs.

15 JUSTICE STEVENS: No, but -- they couldn't
16 give recovery to a class action of a couple of hundred
17 plaintiffs who were injured, could it? No such remedy
18 under the FDA, or am I wrong on that?

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

23 JUSTICE GINSBURG: The government told us in
24 its brief that the FDA has no system for addressing
25 public complaints -- this was in their brief at page

1 24 -- because that would divert attention from their
2 primary mission. So there's no action for fraud that
3 one can bring to the FDA.

4 MR. PHILLIPS: Well, I mean, there is a
5 provision for citizen petitions that exists, that's
6 cited. So, yes, there is a mechanism.

7 JUSTICE GINSBURG: But the FDA doesn't have
8 to do anything about it?

9 MR. PHILLIPS: Well, no. It entertains it.
10 In point of fact, there was a petition filed by Public
11 Citizen to withdraw Rezulin in this specific case, and
12 it was reviewed and it was rejected for exactly the
13 reason Justice Breyer identified, because if you took it
14 off the market, people would die. That was the concern
15 that drove the FDA to say: We're not going to do that
16 under these circumstances.

17 If there are no further questions, Your
18 Honors.

19 JUSTICE STEVENS: The case is taken under
20 advisement.

21 (Whereupon, at 12:05 p.m., the case in the
22 above-entitled matter was submitted.)

23

24

25

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