IN THE SUPREME COURT OF THE UNITED STATES

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WARNER-LAMBERT CO., LLC, :

ET AL., :

Petitioners :

v. : No. 06-1498

KIMBERLY KENT, ET AL. :

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Washington, D.C.

Monday, February 25, 2008

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

APPEARANCES:

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

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

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

C O N T E N T S

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

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

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Drug, and Cosmetic Act -- and the drug would not have been approved or the Food and Drug Administration would have withdrawn approval.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. PHILLIPS: Yes.

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

(Laughter.)

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

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

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

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

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

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

MR. PHILLIPS: Well, I think it is an

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

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

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

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

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

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

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

MR. PHILLIPS: Correct.

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

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

precisely the same way.

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

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

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

MR. PHILLIPS: Sure.

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

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

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

MR. PHILLIPS: Right.

JUSTICE STEVENS: But most States don't have

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

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

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

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

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

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

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

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

MR. PHILLIPS: Well, I think --

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

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

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

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

(Laughter.)

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

the other side didn't challenge the compliance.

JUSTICE SCALIA: Uh-huh.

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

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

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

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

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

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

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

would have won this case on the merits of it?

JUSTICE STEVENS: Yes.

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

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

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

JUSTICE BREYER: You don't have any problem.

MR. PHILLIPS: No, we were very --

JUSTICE BREYER: That's not --

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

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

Thank you, Your Honors.

JUSTICE STEVENS: Thank you, Mr. Phillips.

Mr. Joseffer.

ORAL ARGUMENT OF DARYL JOSEFFER,

ON BEHALF OF THE UNITED STATES,

AS AMICUS CURIAE,

SUPPORTING THE PETITIONERS

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

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

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

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

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

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

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

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

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

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

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

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

offered as a mere matter of evidence.

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

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

MR. JOSEFFER: Well, no --

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

question of admissibility.

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

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

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

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

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

JUSTICE STEVENS: The whole theoretical problem.

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

JUSTICE STEVENS: The litigation is not, not new.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE STEVENS: I understand. Do you think --

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

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

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

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

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

Thank you.

JUSTICE STEVENS: Thank you very much.

Ms. Zieve.

ORAL ARGUMENT OF ALLISON M. ZIEVE

ON BEHALF OF THE RESPONDENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

Now, that it seems to me is Congress's

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

MS. ZIEVE: Well --

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

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

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

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

MS. ZIEVE: But that is not --

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

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

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

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

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

JUSTICE KENNEDY: I know your purpose is

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

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

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

(Laughter.)

MS. ZIEVE: I promise will.

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

There are other cases where the FDA has not

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

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

(Laughter.)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. ZIEVE: But, again --

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

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

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

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

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

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

JUSTICE BREYER: So --

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

JUSTICE BREYER: That's the next issue.

MS. ZIEVE: That's right.

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

JUSTICE BREYER: I see.

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

MS. ZIEVE: Absolutely.

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

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

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

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

JUSTICE BREYER: Thank you.

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

plaintiff's ability to prevail on it.

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

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

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

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

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

But only in Michigan not only is the

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE GINSBURG: No other State does that?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. ZIEVE: That's right.

JUSTICE STEVENS: I see. I missed that.

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

tied to the reason --

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

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

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

MS. ZIEVE: That's right.

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

If the Court has no further questions, thank you.

JUSTICE STEVENS: Thank you.

Mr. Phillips, you have five minutes.

REBUTTAL ARGUMENT OF CARTER G. PHILLIPS

ON BEHALF OF THE PETITIONERS

MR. PHILLIPS: Thank you, Justice Stevens.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

foreclosed.

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

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

MR. PHILLIPS: Exactly.

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

MR. PHILLIPS: Exactly.

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

JUSTICE STEVENS: Does restitution for victims include damages?

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

JUSTICE STEVENS: Well, you're not talking

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

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

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

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

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

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

JUSTICE GINSBURG: But The FDA doesn't have

to do anything about it?

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

If there are no further questions, Your Honors.

JUSTICE STEVENS: The case is taken under advisement.

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