IN THE SUPREME COURT OF THE UNITED STATES

- x

MUTUAL PHARMACEUTICAL :

COMPANY, INC., :

Petitioner : No. 12-142

v. :

KAREN L. BARTLETT :

- x

Washington, D.C.

Tuesday, March 19, 2013

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

APPEARANCES:

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ANTHONY A. YANG, ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.; for United States, as amicus curiae, supporting Petitioner.

DAVID C. FREDERICK, ESQ., Washington, D.C.; on behalf of Respondent.

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P R O C E E D I N G S

(11:14 a.m.)

CHIEF JUSTICE ROBERTS: We will hear argument next in Case 12-142, Mutual Pharmaceutical Company v. Bartlett.

Mr. Lefkowitz.

ORAL ARGUMENT OF JAY P. LEFKOWITZ

ON BEHALF OF THE PETITIONER

MR. LEFKOWITZ: Mr. Chief Justice, and may it please the Court:

This is a classic case of impossibility preemption. Federal law required generic sulindac to have the same ingredients, the same warning and the same safety profile as the branded version. But a New Hampshire jury imposed liability because sulindac didn't have a different safety profile, meaning a different ingredient or a different warning.

And as Mensing recognized, that's an impossibility conflict. And there is no principle basis for treating design defect claims any differently from failure to warn claims.

JUSTICE KAGAN: Mr. Lefkowitz, could I understand something just about the scope of your argument? It -- it seems to me that in this case we are not really dealing only with generics, we are also

dealing with brand-named drugs.

And I guess the -- the thought there would be, in -- with -- with -- in this respect, as to design, as compared to warnings, but as to design, they're really all in the same boat. In other words -- you know, they have a design, that it is only that design that's approved. If they change their design there's no authority to continue marketing it. They have to go back to square one. And that's just as true of brand names as it is of generics.

So am I right about that? That -- that if we're just looking at a pure design defect claim, putting the warning card aside, where you are in a different position from the brand-name drugs, but as to design, don't the brand-name and the generics go hand in hand?

MR. LEFKOWITZ: Justice Kagan, it's -- it's certainly the position that the government takes in its brief. I'm sure Plaintiff's lawyers would find arguments to differ. But the important thing is that it's really a distinction without a difference in real life because in light of this Court's decision in the Wyeth case, what happens across the board is that design defect claims are brought either as they are in nearly every State where there is a warning component, or --

JUSTICE KAGAN: I want you to put that aside for me for just a second, and I understand that's a very significant thing in your argument to put aside. But let's just assume that there was a design defect claim that didn't have to do with warnings, where you are in a different position. Let's just assume on a pure design defect claim, am I right that generics and brand-name manufacturers are in the same position with respect to those claims?

MR. LEFKOWITZ: If you are hypothecating -- hypothesizing a pure design defect regime, we're not --

JUSTICE KAGAN: Just about how you make the drug?

MR. LEFKOWITZ: Correct. That is certainly the argument the government makes. I'm not sure whether or not the Court would find any type of distinction as the Court did in Wyeth, but that is certainly an appropriate interpretation of what the government is saying. But --

JUSTICE KAGAN: Not what the government is saying, I mean, I myself, I just can't figure out what distinction there would be.

MR. LEFKOWITZ: Your Honor --

JUSTICE KAGAN: So I'm asking you.

MR. LEFKOWITZ: As a legal matter, I'm not

sure reading the FDCA there is a matter. My point is simply that in the real world, the cases are going to be brought as failure to warn claims or as design defect claims with warnings components.

JUSTICE KAGAN: But, you -- but again, and I know that this is a big part of your argument, but to the extent that a warning was not involved in the claim, and it was just about the design of a drug, I guess I'm asking you, is there any possible way to distinguish between generics and brand-name manufacturers?

MR. LEFKOWITZ: I'm not sure, Your Honor, that there is a way to distinguish. If you were dealing in a regime in a State statute or a State tort regime where the only issue was design, unlike in the New Hampshire design defect, where as we know from PA 18 where the First Circuit made clear that it, in fact, was the lack of an adequate warning that in fact made the drug more dangerous under the design defect case, the Supreme Court's case Vautour, which is the leading New Hampshire case. And in fact the jury instruction in this case was a binary choice. It specifically said, if you find that the drug is unreasonably dangerous, then you have to take a look at was the warning sufficient or not.

We have a case here that is directly

controlled by Mensing because the warning was critical to the design defect case. We also have a case here that even if it were just purely a design defect case, at least with respect to a generic drug company, the Federal sameness mandate, the same Federal sameness mandate that applied in Mensing to warnings, applies in design defect cases. And therefore it is a classic impossibility case, just as the Court found in Mensing.

JUSTICE SOTOMAYOR: So tell me, is -- is it now your position, and it seems to be, that any time the FDA approves a product that there can never be a tort liability claim because the FDA's approval is now the ceiling of what you can do?

MR. LEFKOWITZ: Absolutely not, Justice Sotomayor.

JUSTICE SOTOMAYOR: They approve nonprescription drugs. They approve a lot of things.

MR. LEFKOWITZ: Absolutely. And Justice Sotomayor, as this Court made clear in Mensing -- in Wyeth and as Justice Thomas made clear in his concurring opinion in that case, just because a drug is granted an approval by the FDA does not mean that it's entitled to have the same label for all time. The distinction, though, that the Court articulated was that in Wyeth a brand company has the authority, and indeed

as this Court found, the obligation to update its warnings. A generic --

JUSTICE SOTOMAYOR: But that's not true with respect to the active ingredients. An active ingredient requires a new FDA approval process.

MR. LEFKOWITZ: But -- but we were talking in that case about the warning.

JUSTICE SOTOMAYOR: But -- but we came back to the same point, which is -- and we are sort of dancing around the argument -- which is what happens with a truly dangerous drug, and we can posit one, that has nothing to do with a warning of whether it's adequate or not, but a drug that on its face no reasonable practitioner -- I'm going to the restatement third formulation -- no reasonable practitioner, knowing all the benefits and risks, would ever prescribe this drug.

Because your adversary basically took that position at trial.

MR. LEFKOWITZ: Well --

JUSTICE SOTOMAYOR: It doesn't matter -- there were other, safer, one-molecule drugs, no one should have prescribed this, no matter what the label.

MR. LEFKOWITZ: Actually, Justice Sotomayor, that is not the position my adversary took at trial. My

adversary specifically put on a case about the warnings and said, the fact that SJS/TEN was warned about in the adverse reaction section and cross-referenced within the warning section was not sufficient. If it had been in the warning section like the FDA later said it should be, that would have made the difference.

JUSTICE SOTOMAYOR: We can argue. But let's go to the point I raised, which is, I think what you are arguing now is that no truly bad drug, that shouldn't be on the market, would there ever be a tort claim that anybody could bring --

MR. LEFKOWITZ: Absolutely not --

JUSTICE SOTOMAYOR: -- because the FDA approved it.

MR. LEFKOWITZ: Absolutely not. That's not our argument at all. Our argument, first of all, is a very narrow argument --

JUSTICE SOTOMAYOR: So what tort claim could they bring?

MR. LEFKOWITZ: Well, they could bring --

JUSTICE SOTOMAYOR: Both, against, the brand could manufacture and the generic.

MR. LEFKOWITZ: Right now if the Plaintiff -- the Respondent here had taken the brand-name drug Clinoril instead of the generic

sulindac, in the New Hampshire law, as it exists and as it existed at the time of the lawsuit, she would have had both a design defect claim and a failure to warn claim.

JUSTICE SOTOMAYOR: How? The FDA approved the design.

MR. LEFKOWITZ: Because the design defect claim --

JUSTICE SOTOMAYOR: And they couldn't change it without FDA approval.

MR. LEFKOWITZ: But they could change the warning, and that's the essential component, as the First Circuit made clear. At PA 18 what the First Circuit said was the label was relevant to the design defect claim. The lack of a clearer warning made the product itself more dangerous under the risk/benefit tests prescribed by Bextra. That's the design defect standard.

So had the Respondent taken the brand-name drug, she would have had a cause of action, even under the articulation of the sameness standard under Hatch-Waxman that we are articulating here.

CHIEF JUSTICE ROBERTS: One of our cases --

JUSTICE GINSBURG: And she didn't take -- she didn't take the -- the brand-name drug because the

pharmacist gave her the generic, but she didn't know brand, generic, isn't that correct?

MR. LEFKOWITZ: That's correct, Justice Ginsburg, and that's exactly the same issue that we had in the Mensing case a couple years ago. Obviously we understand that not all consumers get to select on their own; their doctors select or maybe their State Medicaid laws make this choice, or the pharmacy, but the standards -- again, conflict preemption comes when the State is imposing a requirement or an obligation or enforcing a standard that you simply can't comply with under Federal law without violating Federal law.

JUSTICE ALITO: Suppose that New Hampshire had a real strict liability regime, so that you -- you sell a drug, and whether it's unreasonably dangerous or not it causes an injury, you pay, to spread the costs. Would there be a problem with that?

MR. LEFKOWITZ: Justice Alito, I think if we had what would really be an absolute liability scheme, I think is really what you are suggesting, something similar to the kind of vaccine compensation program that we heard about this morning, that would not raise impossibility preemption problems at all. It might or might not raise obstacle issues; it would depend perhaps

on the scope of the program, whether it was singling out certain types of drugs, how expensive it was; but that would be a very different situation.

JUSTICE SOTOMAYOR: Isn't there a First Circuit --

JUSTICE ALITO: Mr. Frederick argues that that -- that's the thrust of the -- of the New Hampshire law. Why is he wrong on that?

MR. LEFKOWITZ: Well, he's wrong because -- Price v. Dick -- the New Hampshire Supreme Court case, says very clearly, "We do not have an absolute liability system. We do not make manufacturers insurers of their product." And in fact, Mr. Frederick on page 21 of his brief articulates the standards for liability in this very case where he said, it has to be found unreasonably dangerous.

And we know from Judge Boudin's statement that I just read that that -- that condition of unreasonable dangerousness is premised in large part on the question of the warning. And it makes sense because drugs are unavoidably dangerous. If you have --

JUSTICE ALITO: Can I just ask this one more follow-up?

MR. LEFKOWITZ: Sure.

JUDGE ALITO: Why -- why would -- why is a

generic manufacturer in a worse position under the absolute liability scheme than it would be under the New Hampshire scheme?

MR. LEFKOWITZ: Well --

JUDGE ALITO: Because under the absolute scheme they might say, if that's the cost, we are not going to sell this drug at all? Is that the reason?

MR. LEFKOWITZ: No, it's -- it's not a question of -- of policy choices, it's a question of operation of law. The issue here -- States are free to do lots of different things. They only are not free to do things when they conflict directly with Federal obligations. Basically, the Supremacy Clause sets up a rule of priority.

And you have that rule of priority come into play when you have a State requirement and you have a Federal requirement. Here the vaccine program does not hinge on a question of whether or not the generic company violated a safety standard, whether the State is saying, your drug is too dangerous either because of the warning or because of the design.

It is simply saying, we are going to charge manufacturers $1 dollar per prescription or --

JUSTICE GINSBURG: Mr. -- Mr. Lefkowitz, then what you are saying is that the FDA's approval is

not only what everyone agrees it is, a floor to enable you to market, but it is also a ceiling. That is you meet the FDA -- you get the FDA approval and that gives you a right to market, not simply an access to market, but it -- it operates as a ceiling?

MR. LEFKOWITZ: With respect to the question, Justice Ginsburg, as the Mensing Court made clear, when this very issue came up with respect to warnings which are commanded as a sameness requirement by Federal law in exactly the same way as the molecule, the design, the Federal regime does operate as a floor and as a ceiling.

And when Federal law authorizes you to market a drug in interstate commerce by granting you the ANDA, that comes with it enormous protections. In fact, Congress has established --

JUSTICE GINSBURG: Is there something in the -- in the Act that says that the States have no role with respect to the safety and efficacy of the drug -- the drug, it's only the FDA approval, that's it?

MR. LEFKOWITZ: There is no express preemption clause here. However, as we know from Mensing where the Court articulated it in footnote 5 and as we know from Geier where the Court went and said ordinary conflict principles apply. In fact, even when

we have an express preemption clause and we have a savings clause, that they don't apply, we have to use ordinary operation of conflict --

JUSTICE KAGAN: But, Mr. Lefkowitz, I think in describing the FDCA just now, you used the word "authorizes," and typically, when we think about impossibility, it's not enough that a State law penalizes what Federal law authorizes.

What we -- something is impossible when a State law penalizes what Federal law requires or maybe -- or, where State law penalizes what Federal law gives you a right to do. But it's not enough for impossibility that State law penalizes what Federal law permits.

And it seems as though what we have in the FDCA is a statute that authorizes, that says, you can sell this. But it doesn't say you must sell it, and it doesn't give you a right to sell it.

MR. LEFKOWITZ: Your Honor, Justice Kagan, I'd like to give you two answers to that. The first as to the impossibility, for over 50 -- 50 years exactly now, this Court has been articulating as the paradigmatic example of impossibility preemption.

The example from Florida Lime and Avocado Growers where the Federal government said you can't sell

an avocado with less than 7 percent and you can't sell -- and the State said you can't sell the avocado with more than 8 percent oil. Now, clearly, there is no Federal obligation to sell avocados.

I would submit that Congress is not agnostic about the sale of drugs, but the key is that the quintessential example of impossibility has nothing to do with a Federal right at all. It is simply conflicting standards.

JUSTICE KAGAN: Well, that is your best case, but -- you know, there are quite a number of cases where we've really held when a Federal law permits something, typically, a State can do more if it wants to.

MR. LEFKOWITZ: Justice Kagan, the very same issue came out in Mensing as well. After all, PLIVA was not obligated in any way to sell metoclopramide in Mensing. But, of course, this Court found that that was a case of impossibility conflict. And moreover, Congress has -- as I said, is not agnostic here.

Congress had established a regime where in order to take a drug off the market, Congress had said the FDA has to provide the company with all sorts of due process protection, direct appeal to the Federal court, and in fact, Congress, in 1997, specified that any

people at the FDA involved in the drug approval process at all, withdrawing drugs or approving drugs, has to have special technical, scientific expertise, very different from what we have in lay jurors.

But simply stated, Your Honor, from a impossibility perspective, this is not only the Florida Lime example, this is the Mensing case as well.

Now -- you know, the -- the Respondent doesn't really take issue with either the sameness requirement of design or the sameness requirement of warning. The Respondent recognizes that our hands are tied.

The Respondent also doesn't really try to do much with salvaging the First Circuit's dodge on supremacy by saying we could stay out of the market. Instead, what the Respondent does is he tries to carve out a distinction between strict liability and negligence claims.

And all I will say before reserving my time is there's simply no basis in the law. This Court made clear in Riegel and in Cipollone and in several other cases that with respect to preemption, the same rules apply, strict liability or negligence imposed requirements by this case.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Yang?

ORAL ARGUMENT OF ANTHONY A. YANG,

FOR UNITED STATES, AS AMICUS CURIAE,

SUPPORTING THE PETITIONER

MR. YANG: Mr. Chief Justice, and may it please the Court:

New Hampshire law applies a hybrid design-defect standard that imposes liability for harm caused by a product if the product, in light of the manufacturer's warnings, is unreasonably dangerous.

Now, that standard falls within the traditional way that this Court has looked at impossibility preemption in Mensing. It's also implicit in Levine because the analysis of the courts -- the analysis in Levine reflects an implicit judgment that the manufacturer could simply stop selling the product. You know, if that were enough to avoid a Federal impossibility preemption, there'd be no reason to do the analysis --

CHIEF JUSTICE ROBERTS: Well, but it's a little different. Our cases are focused on the concern that the State is going to impose on the manufacturer a different duty than the Federal government.

That's not what's going on in a strict liability regime. They're saying, we're not saying you

should have a different structure, we're not saying anything about warning, we're saying if you do this, you're going to have to pay for the damage. It's not -- it's not a different duty. And I think that's what's underlying the argument that, well, you can just stop selling because you don't have to adjust how you're going to make the drug. You understand that it's going to be the same as the Federal drug, but our system is, you pay for the damage.

MR. YANG: There are two, I think, arguments embedded within that. There is a question of whether State tort law, whether by negligence or strict liability, imposes a duty that might conflict with the Federal obligation. And the second argument, I think, which is distinct, is that if you could simply stop selling, that would be a way of -- of cancelling impossibility preemption if there were in fact a conflict between the two standards.

JUSTICE KENNEDY: How would you define the duty that New Hampshire imposed here according to the First Circuit and according to the Respondent?

MR. YANG: The duty is that one cannot market an unreasonably dangerous drug in light of the warnings -- that's unreasonably dangerous in light of the warnings. And what that means is that a

manufacturer will have to pay money in the liability suit if he doesn't meet that standard.

And as this Court recognized in Riegel and in earlier -- in Cipollone, that this type of tort obligation, when you contingent -- make an obligation to pay tort liability based on meeting a standard under State law, that is a duty that could conflict with a Federal duty. And the Federal duty here --

CHIEF JUSTICE ROBERTS: But is that meeting a standard under State law that your friend's argument says, that's not what we're talking about here. The standard is the same. It's just a question under strict liability that if you follow the same Federal standard and market this in our State, you're going to pay the compensation for the reason of -- you know, spreading the costs.

We don't want you to do something different. We just want to say that you want to do the same thing as the Federal government, and then you're going to have to pay. It's different than the -- at least that's how I understand their argument, which is that it's different where the situation says, yes, you can market it and avoid payment, but only if you do it our way. That's a different duty for the manufacturer.

MR. YANG: Well, with respect to the

question of stop selling, which I think is what your question goes to, that you can always escape liability if you simply stop selling and don't have the market. It's not clear to me, first, that Respondent is, in fact, adopting the government's position because in our view, the obligation to change the labeling to make it safer and therefore escape liability under design-defect law in New Hampshire falls within the Court's decision in PLIVA v. Mensing.

The only distinguishing factor we think that is material here would be whether the ability to stop selling means that there's really not a conflicting obligation. And as that would have been true in Mensing, it would have been true also in Levine, and would not have necessitated any impossibility analysis.

And I think this, as my brother was just explaining, traces back to Florida Lime and Avocado Growers. The court framed the impossibility preemption inquiry there -- and I think this is important -- at the top of page 143. It says, the question is whether compliance with Federal and State regulation is a physical impossibility for one engaged in interstate commerce. That was the -- the formulation.

So the idea is if you are an avocado grower in Florida and the Federal government said you have to

pick your avocados before they're at 7 percent oil and then California says, you can't sell in our State unless it's 8 percent oil, it's impossible to be a person engaged in interstate commerce there unless you violate one of those obligations. And when you have to violate one of those obligations, it's the State law that -- that falls. And I think, Justice Kagan, you were explaining --

JUSTICE KAGAN: I mean, that suggests that there is an obligation of the Federal government. If there is one, yes, there's a conflict and yes, there's an impossibility defense. But if there's no obligation, if all there is, is permission from the Federal government, where do you get the impossibility from?

MR. YANG: Let me draw a distinction if -- that I think might help.

When the Federal government were to say -- let's go -- stay with avocados -- that avocados must have at least 7 percent oil. And the State says, you know what, we think it actually needs 8 percent oil. It's not impossible to comply there. But what we have here is a comprehensive regulatory scheme, where an expert agency with the relevant information makes an expert judgment based on sound -- sound scientific evidence that this drug is, in fact, safe and effective

and --

JUSTICE KAGAN: Well, I take that point, Mr. Yang. I take that point, Mr. Yang, but I think then you're -- you're saying something quite deep about the FDCA, which is that the FDCA should not be thought of as merely authorizing drug sales.

You're saying essentially that when the -- when the FDA does what it does, it's saying not just -- you know, you can do this if you want to, but you can do this and we really think this drug ought to be marketed. So that when States take action as against that -- you know, it's -- it's a conflict.

MR. YANG: Our -- our position is --

JUSTICE KAGAN: And that's --

MR. YANG: -- a little narrower.

JUSTICE KAGAN: -- and that's something I don't think we've really ever said.

MR. YANG: I don't think the Court has addressed this question expressly. That is -- that's true. But I think our position is a little -- little tighter than that. Which is, when the State is imposing an obligation, they do it based on a safety standard -- that is in fact second-guessing the FDA -- that is preemptive.

Not simply because the FDA has set the

standard, but the FDCA also has within it the judgment that safety is best effectuated not only by having the FDA set the standard, but by forbidding any manufacturer from deviating from that once it's been approved by the FDA.

When we're talking about a drug's formulation, the manufacturer cannot change it. And that's what brings this within the ambit of PLIVA v. Mensing. And it also, I think, reflects why the Florida Lime example is -- is relevant because when --

JUSTICE SOTOMAYOR: So without the preemption clause, actually, with an express saving clause, you're arguing essentially complete field preemption. You're basically saying the minute that the FDA gives you permission to sell, it's a right to sell. And -- and it can't be altered by any State police power.

MR. YANG: No, we're -- we're actually not saying that.

JUSTICE SOTOMAYOR: Well, I don't see how you're not saying that.

MR. YANG: Well, no, with respect to the design-defect claims that -- and failure to warn, with respect to generics -- remember, this is exactly what

the Court said in Mensing -- we're saying the result in Mensing controls here.

Now, if we go to the pure design-defect claim -- and a pure claim, in our view, is one in which carves out the failure to warn issue, and it hypothesizes a reasonable physician that knows all the -- the health benefits and risks --

JUSTICE SOTOMAYOR: But that's your -- you're telling me that's exactly what the FDA is saying. You're saying there is no such thing.

MR. YANG: No, but we -- in that --

JUSTICE SOTOMAYOR: And there's no strict liability that a State could impose.

MR. YANG: If I might just finish.

JUSTICE SCALIA: I would like to hear your answer.

MR. YANG: Yes. When that pure design-defect standard has been satisfied, it means that no physician would prescribe the drug for any person, which means that drug, regardless of how you might improve the warnings -- it just doesn't matter because they know all -- all the adverse and positive benefits of the drug. It should not be marketed because it should never be prescribed.

And when it should not be marketed and it

complies with the Federal government's misbranding standard, about dangerous to health when used as instructed, and it honors the FDA's rule by requiring new and scientifically significant information that was not previously before the FDA, that would not be preemptive. That is not this case.

And so what we are trying to do is preserve the FDA's role here, not have juries second-guess on a case-by-case and State-by-State basis imposing different safety obligations on manufacturers when the Congress has established a regime for FDA to control this.

Now, we're not saying the FDA's decision is forever binding. If there is new and scientifically significant evidence that hasn't been considered by the FDA -- and this is analogous to what the Court already did in Wyeth v. Levine -- because there, in the impossibility preemption, the Court looked to whether or not there would be newly acquired information that would allow a manufacturer to go within the changes being effected regulation in order to change the labeling.

So what we're doing is just like what the Court required to be done in Wyeth, that in that context, if you meet the Federal misbranding standard, and you avoid the problem of PLIVA -- because you don't have --

JUSTICE SOTOMAYOR: This applies to everything that requires FDA approval, or is this a prescription drug-only rule?

MR. YANG: May I answer?

CHIEF JUSTICE ROBERTS: Briefly.

MR. YANG: With respect to failure to warn, you can -- prescription drugs can be sued, generics cannot. With respect to pure design-defect claims, our view applies to both.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Frederick?

ORAL ARGUMENT OF DAVID C. FREDERICK

ON BEHALF OF THE RESPONDENT

MR. FREDERICK: Thank you, Mr. Chief Justice, and may it please the Court:

I'd like to start with the questions that you and Justice Alito posed about State law because it's important to understand, before you have impossibility conflict preemption, to understand what the State duty is here.

I think it was conceded that it would not be impossible to have an absolute liability regime. So the question here is because New Hampshire actually makes it somewhat easier for manufacturers to evade liability, that that somehow creates a different kind of preemption

problem. We would submit that it doesn't.

What the State law is seeking to do here, Mr. Chief Justice, is to impose liability where there is proof of an unreasonably dangerous product.

That unreasonable danger entails evidence of a risk/benefit analysis that looks at the overall risks to the population against the overall benefits that are provided to the drug.

JUSTICE SCALIA: The jury decides all of this, right?

MR. FREDERICK: That's correct.

JUSTICE SCALIA: That's wonderful.

Twelve -- twelve tried men and few -- and true decide for the whole State what the -- what the cost/benefit analysis is for a -- a very novel drug that unquestionably has some deleterious effects, but also can save some lives.

And the jury's going to decide that?

MR. FREDERICK: Yes, it is.

And notably, the FDCA doesn't preclude that. Wyeth v. Levine affirms that principle. And what's important here is that under State law, there's not a duty to change the design or to change the label. It is, Justice -- Mr. Chief Justice, exactly as you postulated, that if there is an unreasonably dangerous

drug, that the people that are harmed egregiously, like Karen Bartlett, will have an opportunity to compensation --

CHIEF JUSTICE ROBERTS: I'm not so sure -- I'm not so sure it works that way because of the jury point. They didn't say that yes, you can market this drug, it benefits -- you know, 99.9 percent of the people, but there is that 0.1 percent, and you're going to have to compensate that person.

They said the risks outweigh the benefits, period. So you should not market this at all. And it does seem inconsistent with the -- the Federal regime.

MR. FREDERICK: Well, of course, Mr. Chief Justice, Mutual put in their defense in this case -- they rested after the plaintiffs put in their case. So it's not to say that in another case, they wouldn't have an opportunity to prove that there is some benefit of their drug.

CHIEF JUSTICE ROBERTS: Well, what do you in that case? You've got one jury saying the risks outweigh the benefits, can't do it. And then you're saying well, later, there might be another jury saying yes, you can.

MR. FREDERICK: Well, there's no claim preclusion effect of a jury verdict, and that is why

there is no offensive collateral estoppel that would be applied, Mutual can adopt a different trial strategy. It is often the case, Mr. Chief Justice, that in these kinds of cases, the defense applies different tactics to how they defend this case.

In this particular case, they chose to waive their comment k affirmative defense. They chose not to put in any affirmative evidence itself. They chose after the trial in their Rule 50 motion for judgment as a matter of law not to challenge the warning instructions that were given to the jury -- as Judge Boudin noted and as the district court noted -- they had waived their preemption warning argument.

And so what they seek to do here after not being able to show, which they cannot show under New Hampshire Supreme Court precedent, Vautour and Kelleher, cases that we cited in our brief, that New Hampshire imposes any duty to change any conduct by the manufacturer whatsoever.

JUSTICE KAGAN: Mr. Frederick, it -- it does seem to me, and I understand that there's a waiver argument floating around here, but it does seem to me that this case was litigated such that the adequacy of the warning is really all over this case. There was expert testimony about the adequacy of the warning,

there were jury instructions about the adequacy of the warning.

In the closing statements that the lawyer gave, it was -- there was a lot of talk about -- that the FDA's decision to change the label, to show that the label was ineffective before. So there is just all over this stuff about adequacy of the warning, which does suggest that this is sort of within the four corners of Mensing.

MR. FREDERICK: Let me address that because I think that's the hardest part of this case to understand, and why this is different from Mensing. In a strict liability case in New Hampshire, the warning is not relevant as a -- as an element of the claim. What the jury is required as an element of the claim is to prove unreasonable dangerousness.

And District Judge La Plant, who presided over this very complex and difficult trial with a lot of skill, understood the difference between the concept of adequacy of a warning which describes the risks and efficacy of the warning which limits or minimizes the risks.

And all over the pretrial instructions, he made very clear to the counsel, you are not to argue about adequacy of the warning because that goes to the

comment k defense that they waived on the eve of trial. Instead, once the jury finds that the drug is unreasonably dangerous, it may use the warning as a way to limit or minimize the risk.

In other words, the warning could only benefit Mutual because liability was going to be found in spite of the warning and not because of the warning.

JUSTICE BREYER: I see that. But I don't understand why that matters. That is, the -- I mean, I was thinking just what you said. I was thinking well, I -- I dissented in the other case, but I lost, okay? So I lost, I lost. The -- the -- the point is that -- that you have a drug, and you say to the jury, well, if there were no warning here at all, then it would be unreasonably dangerous.

I think, yes, that probably applies to chemotherapy, it probably applies to Parkinson's, it probably applies to all kind, but you see, says the defense, there is a warning here and it says how to use it. And as you say, that would be not -- it would be despite or whatever it is, despite, not because.

But it seems to me in terms of -- it comes for the same thing, lots of drugs would be dangerous, too dangerous, unreasonably so without a warning. Chemotherapy is what I'm thinking of. But properly

labeled they're not, and so that seems to be your case.

MR. FREDERICK: It is not.

JUSTICE BREYER: Because -- why?

MR. FREDERICK: No, absolutely not, Justice Breyer. The evidence here was clear. No warning would have made any difference to lessening the risk. And that is because, and this is on --

JUSTICE BREYER: In other words, in this case, they have to find that -- that no warning -- there is no such warning that could make a difference, that's what they're asked to find?

MR. FREDERICK: All that they -- in terms of minimizing the risk. Justice Breyer, here --

JUSTICE KAGAN: Well, how can that be, Mr. Frederick, because the plaintiff really spent a large portion of their case trying to show this, that the warning was inadequate. So the plaintiff must have thought that there was a possibility that if the warning was adequate, the jury would find one thing, but if the warning was not adequate, liability would follow.

MR. FREDERICK: The case as it was litigated up until the day before the trial was with a comment k defense, which allows as an affirmative defense the defendant to say if the drug is unavoidably unsafe and it has an adequate warning, i.e. it adequately describes

what the risks are, complete immunity from suit.

They abandoned that comment k defense on the eve of trial. And so as the judge understood and instructed the jury, the only role that the warning actually played was whether it could lessen the risk to patients who took the drug, i.e. in the risk/benefit analysis, it's somewhat less risky in weighing it against the benefits.

JUSTICE GINSBURG: The failure -- the failure to warn defense was -- the -- the judge struck that out. So there was no failure to warn defense in the case.

MR. FREDERICK: That's correct, that's correct. And as the Le Blanc case held in the New Hampshire Supreme Court, the New Hampshire law treats failure to warn cases as distinct from design-defect cases. Here, no words would have made any difference because the scientific --

JUSTICE BREYER: Where is that? That's -- I do see that distinction. If, what you're -- but look, the complaint's filled with words about adequate warning, no adequate warning, no adequate warning, da, da, da.

MR. FREDERICK: Yes.

JUSTICE BREYER: Okay. Now what you're

saying is, is really what the jury found, nothing to do with adequate. There is no warning in the world that anybody could have invented that would have made a difference. I'll have to think about that one. But in the meantime, where is it that that's what they said?

MR. FREDERICK: Where is it in the record?

JUSTICE BREYER: Yes. How do I discover that you're right about this? Because everything in the -- in the complaint that I've read so far seems to talk about the adequacy of warnings, not that there is no warning in the universe could possibly have made a difference.

MR. FREDERICK: Well, I would direct you to two --

JUSTICE BREYER: How do I discover that?

MR. FREDERICK: -- two pieces. The JMOL order that the judge issued, which is in the petition appendix, goes through this very clearly. And Judge Le Plant understood how the different roles of warning apply, and he instructed the jury, and this is in the pre-formal colloquy that he's giving to the jury orally, you can find this at 496 of the Joint Appendix where he says, "Adequacy is not an issue for -- the adequacy of the warning is not an issue for you to decide."

He then goes further to explain that "You

will only consider the warning after you have considered the unreasonable danger" -- that's at 513 to 514, and then on page 516 of the Joint Appendix, he says, "You only consider the warning to minimize the risk," i.e. to benefit Mutual in the assessment of whether or not in a risk/benefit analysis this drug has greater risks than --

JUSTICE BREYER: The second point is a different point. The second point is, look, I have chemotherapy, it saves 100 and it kills 10. All right. If you have no label at all, a jury might find it was unreasonably dangerous, but once you put in the label explaining the whole thing, it doesn't. It isn't unreasonably dangerous because of the situation, and they could perhaps wouldn't find it.

All right. Now, you can call that diminishing or you could call it adequacy. Call it what you want, but that seems to me to come to the same thing and is different from saying, no label in the universe would say it.

MR. FREDERICK: Justice Breyer, a chemotherapy drug has got a huge benefit. It potentially saves you from cancer. A nonsteroidal antiinflammatory drug, of which there were 16 other types, is not at all analogous to a chemotherapy drug.

JUSTICE BREYER: We're talking about what juries could find and that's what -- and I don't know about Parkinson's -- I don't know what these drugs are. That's why I said let the FDA say it.

MR. FREDERICK: But that's why when the jury gets evidence that aspirin and acetaminophen, Tylenol produce the same kind of pain relief, but they do not produce the kind of SJS/TEN that Ms. Bartlett -- that caused 60 percent of her body to burn. I mean, that gives you a very clear contrast.

JUSTICE ALITO: If that's correct, and maybe it is, doesn't that mean the drug should never have been approved?

MR. FREDERICK: No, because the evidence at the time of approval had not yet been ascertained. What was clear from the unpublished Pharmacia report that went into evidence in this case was that between the time of 1980 and 1997, the adjusted reporting rate of these adverse incidents went very high, and it was of a rate that was comparable to Bextra, which went on the market several years after that study ended, in which the FDA, in looking at a comparable adjusted adverse reporting rate, concluded should be taken off the market.

JUSTICE ALITO: But isn't it true that when

the -- the FDA reviewed this whole class of drugs, they decided to pull Bextra, but not this drug?

MR. FREDERICK: That is true, but what the FDA did not take into account, and this is what the district judge instructed the jury on September 22nd, 2010, I think it's page 108 in the charging colloquy, is the evidence in this case was that the FDA did not have that evidence.

So what the Solicitor General seeks to argue here is evidence that was not in the record and in which Mutual's own expert who created this evidence testified in deposition he didn't give it to the FDA. And then Mutual never put him on the stand to be cross examined. And so now what we have is a trial record that shows this evidence was not given to the FDA at all.

JUSTICE ALITO: The -- the SG says that the FDA did have this right, did have it and did consider it, and that's incorrect?

MR. FREDERICK: That is incorrect. That the FDA, if it considered it, there is no record of it doing so because in the response to the 2005 citizen petition and in a later memorandum, it never mentions sulindac. So if you are to take any kind of regulatory preemption here, it surely has to be on the basis of a considered action that the FDA takes after notice and comment

rulemaking.

That was the kind of standard that was advocated in the concurring opinion in Wyeth v. Levine, that is absent here. And, in fact, this case has even a weaker case for that kind of considered and rejected than in Levine itself where there was evidence that Phenergan had caused some arterial exposure.

JUSTICE KENNEDY: Do you want me to write down in this case, from my understanding, that under New Hampshire law, strict liability is determined quite without reference to the adequacy of warning?

MR. FREDERICK: You can do that. Yes, Justice Kennedy, you can do that. It is a factor for the jury to consider. It is not an element of the claim. And what PLIVA makes clear --

JUSTICE KENNEDY: Now wait. What's -- what's a factor? The warning is or is not a factor?

MR. FREDERICK: The warning can be a factor. What that --

JUSTICE KENNEDY: Well, but that's -- that's not the thrust of your argument. And I think it was a factor here for some of the reasons Justice Kagan has suggested.

MR. FREDERICK: And Justice Kennedy --

JUSTICE KENNEDY: I mean, which does -- was

the warning relevant or not relevant to the determination of strict liability?

MR. FREDERICK: Yes, it was relevant as in this case. But, Justice Kennedy, if you were to take the position that mere evidence that is a factor for the jury to consider, even though there is no need to change any legal duty, you would be adopting field preemption under this statute because the whole thrust of PLIVA --

JUSTICE KENNEDY: I'm talking about the definition of the duty. Was it permissible for the jury to define the duty here and the breach of the duty in part by -- by reference to the adequacy of the warning? And I -- I now understand your answer to be yes.

MR. FREDERICK: No. And let's be clear on our nomenclature here. A duty is a legal requirement imposed under State common law, a duty to use due care, a duty to change the label, which is what was conceded in PLIVA and Mensing. Here New Hampshire law does not require a duty to change the label or to change the design. All it does, Justice Kennedy, is to say, if the jury finds that the risks outweigh the benefits, it may consider whether the warning would have lessened the risk.

CHIEF JUSTICE ROBERTS: So you are saying there is a huge difference between saying you didn't put

the warning in, so you are liable for $9 million, and saying, you are liable for $15 million, but if you put the warning in, you are only liable for 9 million?

MR. FREDERICK: Well, when there is a comment k defense, Mr. Chief Justice, you may be off completely. And that's why the role of comment k is so critical in these strict liability claims. All --

CHIEF JUSTICE ROBERTS: But -- but just to get back to my -- to my question. You say there is a difference between saying, you have to put on warning and you are going to be liable if you don't, and saying, you are liable no matter no matter what because it's strict liability, but if you put on a warning it's reduced. If you are a drug manufacturer, you are supposed to see a difference in those two situations?

MR. FREDERICK: There is a difference, and the difference is this, assume in the Diana Levine case there had been a strict liability claim that went all the way through. The question under a strict liability law would be would a -- would -- did the warning lessen the risk that she would have had gangrene and amputation of her arm? The adequacy of the warning under a strict liability law simply goes to did the manufacturer adequately describe the risks that the patient might incur.

In the Levine case it very well might have been that the warning adequately describes that there's a possibility of gangrene, but it didn't do enough to lessen the risk that she would sustain. And because there was a way to change the label to lessen that risk, she got a judgment for a failure to warn. Because the manufacturer's conduct was such that it could have improved the label.

Here we acknowledge and the evidence shows there is no way to change the label here. Some -- some -- some number of people, maybe some in this room, might take sulindac and get SJS/TEN. We don't know who they are, and we can't write words that would tell anyone in this room, you have a lesser chance of getting that horrible disease.

JUSTICE BREYER: Well, but then if you apply this -- what is deeply bothering me in all these cases, and it's why I came up and said, the FDA has to tell us -- you know. Because just what you said before; what you say applies to sulindac also applies to 12 people who will tell the Mary Hitchcock Hospital up in Dartmouth that they can't use a certain kind of chemotherapy.

You see, you could in certain horrible cases find a very sympathetic plaintiff who really did suffer

terribly. And -- and -- and you are getting 12 people rather than the FDA. So my solution to it, which you know because you read Medtronics, may not work, but it's the best I can think of.

Now, what -- what -- you can tell me if you want, no, there is some totally different thing. But what you are saying at the moment, what I do in my mind is I say, beware because it's also true potentially of some of these life-saving drugs and that's what's worrying me.

MR. FREDERICK: Let's be clear, Justice Breyer. There is a difference between the application of impossibility preemption, which I don't think anybody here can argue with a straight face that simply paying a judgment in strict liability is impossible in light of the Federal regime, an obstacle preemption.

Now, it may well be that there could be cases out there like your life-saving type drug, which by the way has a special regulation under a special statute to ensure that that is on the market, and some other drug where the risk/benefit equation is -- is such.

But surely in our system we have to trust district judges to be able to grant or deny judgments as

a matter of law, where they conclude that the evidence would not be sufficient to show that the risk outweighed the benefit.

And here, the judge made very clear that because Mutual had not put in any evidence of the benefit of its drug at all and arguably couldn't have done so because this drug is like aspirin -- except that it causes these horrific injuries -- it's reasonable to suppose that a jury which can decide misbranding actions under the FDCA, and that has been acknowledged by the majority in Wyeth v. Levine, can make the very same risk/benefit safety determination that Justice Thomas in his concurring opinion said also is -- enabled the States to make. The States are not precluded under the FDCA from making that kind of judgment.

So in the hard case, Justice Breyer, there is a mechanism for preemption. The FDA has to act. It has to act pursuant to notice and comment rulemaking. It has to identify which drugs it thinks would not be subject to these kinds of strict liability claims, but it hasn't done that here.

All it's done is to say, we happen to have some evidence in our files, ergo preemption. Well, preemption doesn't work like that under the Supremacy Clause.

JUSTICE SOTOMAYOR: Just -- just to -- because my memory is failing me, is this drug still on the market?

MR. FREDERICK: Yes.

JUSTICE SOTOMAYOR: All right. And is it on the market with a different label?

MR. FREDERICK: It is. The label changed after Karen Bartlett sustained the injuries that she did in this case. In fact, that was one of the arguments that -- that at the time, this was before PLIVA, okay? So there was a lot of failure to warn being argued because the regime, as the case came into trial was under Wyeth v. Levine, it was not under the PLIVA v. Mensing case.

So Justice Kagan, that's why it's perfectly reasonable for the trial lawyers here to think that the warning is an appropriate thing because this Court's case that had just been decided made that perfectly clear. But what was interesting here was that Judge La Plant made a very clear distinction between the role that the warning would play, appropriately so, under a strict liability regime.

Now, I would like to note that the avocado case is one that did not entail the State banning avocado sales. Judge Boudin is absolutely right when he

says that there is nothing under the FDCA to preclude the State from making a reasonable safety determination that might lead to the withdrawal of the drug. Now, admittedly, that is a rare circumstance.

And that is not what New Hampshire is doing here, and in his post-trial orders Judge La Plant made clear that is not what New Hampshire is imposing here. All New Hampshire is imposing here is a duty to pay compensation if your unreasonably dangerous product harms a patient.

JUSTICE ALITO: This argument about stopping the sale of the drug completely seems to me to eliminate the impossibility -- impossibility preemption, doesn't it?

MR. FREDERICK: No, because the -- the duty here, if there is any duty to stop selling under New Hampshire law, it can be complied with by not selling the drug. There's nothing in Federal law that requires or mandates the sale of these drugs.

JUSTICE ALITO: But that's true -- isn't that true often in -- in these impossibility cases? Let me say Congress passes a law that says everywhere in the United States you must drive on the right side of the road, and New Hampshire is quirky, they say, in New Hampshire you have to drive on the left side of the

road. That would seem to me to be a very clear impossibility case, wouldn't it?

MR. FREDERICK: Yes.

JUSTICE ALITO: But you could comply with both rules by not driving.

MR. FREDERICK: It would be very dangerous.

JUSTICE ALITO: Not to drive at all?

MR. FREDERICK: Well, it would be dangerous to try comply with both at the same time. But certainly if --

JUSTICE ALITO: You decide -- if you decide to drive --

MR. FREDERICK: Yeah. If the difference -- right. But the difference, Justice Alito, is what is the content of the substantive duty. If the content of the substantive duty is you -- the State says to do one thing and the Feds say do the opposite, that's impossibility conflict.

JUSTICE SCALIA: The Feds didn't say to do the opposite. They said -- they didn't say you have to drive in New Hampshire. They say, you must drive on the right if you drive. They don't require you to drive in New Hampshire.

MR. FREDERICK: Right, but our position, Justice Scalia, is if you that follow PLIVA to what it

says in its logical extension, you look at the -- you look at the content of the duty there, the content of the duty was to change the label. What the majority opinion says is that Minnesota and Louisiana law said you must change the label and the Federal government says, you cannot change the label. So here --

CHIEF JUSTICE ROBERTS: Well, just -- I'm sorry to interrupt you. But your friend on the other side, of course, says PLIVA involves strict liability as well. So it did not say you must change the label.

MR. FREDERICK: Actually we dispute what they say, and we've got an -- an excursus about Mensing in our brief, and what is clear is that as the case came to this Court, the only duty that was being litigated was the duty concerning the warning label. There was not a strict liability claim in the sense of a design defect.

Mind you, there are strict liability claims in -- in failure to warn as well. That is essentially what comment k gets at. This case however, was tried as a design case only, and the State law duty made very clear there was no duty to change the design of the drug. And so therefore, under Mensing, there can't be impossibility because State law is not telling you --

JUSTICE BREYER: But even the compensation,

suppose you had strict liability that Florida Avocado Growers could -- what they have to do, all they have to do since they can just be fined and the money would go to pay the consumers of California who have the unfortunate mixup sometimes of eating Florida avocados. I mean, that would raise at least serious problems of -- commerce clause problems and preemption and so forth.

MR. FREDERICK: Justice Breyer, that's not an impossibility hypothetical. That's an obstacle hypothetical. And in Wyeth, I think six justices said there is no obstacle under the FDCA of having State law remedies to compensate injured patients.

So you know, the reason why it's important to keep these concepts of preemption distinct is that they ask you to grant cert on whether or not it is impossible to comply in light of PLIVA, which was an impossibility preemption case. That was not an obstacle preemption case.

Now, having -- you know, I think gotten a deeper view of what State law requires, they're seeking to shift the case into an obstacle case, and virtually all of the Federal government's arguments here are obstacle-type arguments. It is because the FDA is so expert that it has this information in its files and that that should therefore negate and displace and

nullify State law, which is a rather sweeping proposition.

JUSTICE SOTOMAYOR: Is your point in this case that obstacle preemption has been waived?

MR. FREDERICK: Granted --

JUSTICE SOTOMAYOR: Or were you granted cert just on impossibility?

MR. FREDERICK: Yes, yes. Our position, and we -- we -- we made this clear that all they were asking in the cert petition was for an impossibility look at PLIVA. The obstacle argument has been waived in our view of the way this Court ordinarily takes certiorari cases and then decides them. So -- and on the impossibility point, I think that our position is clear.

Now, Justice Kagan, the very first question out of the box was does this rule that they're advocating apply to brand name drugs and the answer unfortunately is yes. Because the premise of their argument is that simply because the FDA approved the drug and there would need to be some State law claim that would give rise to some alteration, that that necessarily would mean that it would be impossible to comply with.

And so that applies to brand name drugs as well as generic drugs. We don't see a principal

difference, unfortunately, to distinguish them. There may be some difference in certain State laws. I don't want to speak for all 50 States, but the basic gist of their argument is FDA approval über alles.

JUSTICE KAGAN: There is no such thing then as a brand name manufacturer can change some design features of the drug -- you know, without FDA approval or without going back to square one of the FDA, there's nothing like that?

MR. FREDERICK: No, the FDA requires a -- a new drug or an abbreviated drug application, I get the terms of them sometimes confused, but if there was to be a tweak to the design, they'd need to go to the FDA to get approval for that.

I want to make one other point, which is that strict liability applies to distributors as well as to manufacturers. And so here it seems obvious that a distributor can't change the design and it cannot change the label.

But under normal principles of strict liability, the idea is that if you are a seller of the product in your normal course and it is a dangerous product that causes somebody to be injured, you can be held liable in strict liability. That principle is very well settled.

And so it would seem odd to suppose that the distributor who has no power to make any change in conduct that would make the product any safer also gets to be immunized from suit.

I have no further points unless the Court has further questions.

JUSTICE GINSBURG: How do you respond to the argument, Mutual's argument that they have -- in 2005, they made -- this drug produced $7 million. The jury verdict was 21 million. They said that 3 years of their earnings wiped out.

MR. FREDERICK: Justice Ginsburg, I've never been in a case in my time arguing before this Court where somebody in a reply brief at the merits put in evidence that they did not put in at trial and they sought to persuade you that that was somehow relevant.

Number 2, the issue here concerns sulindac manufactured by all the different manufacturers of sulindac, not just Mutual.

Number 3, we never have seen that information. It was never served on us. We have no way to test it. I have no idea whether it is accurate or not.

Number 4, if they are only making $7 million, they ought to withdraw from the market

because their -- their product causes such horrific injuries it ought not to be sold.

Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Lefkowitz, you have three minutes remaining.

REBUTTAL ARGUMENT OF JAY P. LEFKOWITZ

ON BEHALF OF THE PETITIONER

MR. LEFKOWITZ: Thank you. I'd like to just make three brief points.

It is rather incredible to hear counsel talk about how the warnings were not the issue in this case. From the opening statement of plaintiff's counsel, I'm quoting now, "The evidence will show you that sulindac was unreasonably dangerous and had an inadequate warning as well. One of the easiest ways to show you this will be to show you that they got a new and better warning about six months after respondent took the drug. The label got better.

And at CA App. 2761, we have the FDA letter explaining exactly why, in the FDA's view, the new warning was going to make the drug safer. What it said" --

JUSTICE GINSBURG: Did you get to the jury's -- to the instructions to the jury?

MR. LEFKOWITZ: Absolutely not. It was a proper instruction under New Hampshire law. It was an instruction that --

JUSTICE GINSBURG: So that's what the jury was supposed to apply, not what counsel said.

MR. LEFKOWITZ: The jury applied the instruction that the court gave it, which was to decide whether or not the jury was good enough -- the warning was good enough or not. And, in fact, as the First Circuit made very, very clear at PA 18A, it said, the label was relevant to the design defect. The lack of a clearer warning made the product itself more dangerous under the risk/benefit analysis of New Hampshire law.

JUSTICE GINSBURG: But you just said there was nothing wrong with the jury instructions, at least you didn't object.

MR. LEFKOWITZ: Your Honor, let me be clear. We objected at the very beginning of this case, we said this is all preempted. There is no ability to change the warnings. The warnings are acceptable as a matter of Federal law. And this Court, every Justice on the Court agreed in Mensing that we couldn't change the warnings. Once the Court rejected that, it was a fair statement of New Hampshire law.

JUSTICE GINSBURG: How -- how did the Court

reject it? They threw out the failure to warn claim.

MR. LEFKOWITZ: The trial judge rejected our summary judgment motion on preemption. We raised these issues.

JUSTICE BREYER: It says on page 5496, adequacy of the warning, I guess, the judge says, is not an issue before this jury. And that was the point.

MR. LEFKOWITZ: Well, he said that, but then he went and he instructed the jury and, again, as the First Circuit made clear, it was in fact -- the dangerousness was because of the arguable inadequacies of the warning, which the plaintiff said we could have changed, we should have changed.

I want to just finish with two brief points, if I may. On impossibility, look, this impossibility doctrine under preemption is premised on the fact that parties will engage in conduct. As Justice Breyer made clear in his opinion in the Geier case, he said, under ordinary obstacle principles, a State might be able to make you liable for using the Federally required windshield retention requirements.

Obviously, there is no Federal requirement to sell cars. It conditions that if you sell the car, you have a requirement. If you sell a drug, a generic drug, you have a particular requirement.

The distinction between strict liability and negligence, Cipollone, Riegel, make absolutely clear there is no basis whatsoever for a distinction under law.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Counsel.

The case is submitted.

(Whereupon, at 12:15 p.m., the case in the above-entitled matter was submitted.)

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