

1                   IN THE SUPREME COURT OF THE UNITED STATES

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3   MUTUAL PHARMACEUTICAL                   :

4   COMPANY, INC.,                           :

5                           Petitioner                   :   No. 12-142

6                           v.   :

7   KAREN L. BARTLETT                       :

8   - - - - - x

9   Washington, D.C.

10    Tuesday, March 19, 2013

11

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

15 APPEARANCES:

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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

1 dealing with brand-named drugs.

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

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

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

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

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

12 JUSTICE KAGAN: Just about how you make the  
13 drug?

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

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

23 MR. LEFKOWITZ: Your Honor --

24 JUSTICE KAGAN: So I'm asking you.

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

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

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

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

25 We have a case here that is directly

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

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

14 MR. LEFKOWITZ: Absolutely not,  
15 Justice Sotomayor.

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

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

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

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

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

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

18 Because your adversary basically took that  
19 position at trial.

20 MR. LEFKOWITZ: Well --

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

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

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

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

12 MR. LEFKOWITZ: Absolutely not --

13 JUSTICE SOTOMAYOR: -- because the FDA  
14 approved it.

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

18 JUSTICE SOTOMAYOR: So what tort claim could  
19 they bring?

20 MR. LEFKOWITZ: Well, they could bring --

21 JUSTICE SOTOMAYOR: Both, again, the brand  
22 could manufacture and the generic.

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

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

5 JUSTICE SOTOMAYOR: How? The FDA approved  
6 the design.

7 MR. LEFKOWITZ: Because the design defect  
8 claim --

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

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

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

23 CHIEF JUSTICE ROBERTS: One of our cases --

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

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

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

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

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

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

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

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

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

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

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

24 MR. LEFKOWITZ: Sure.

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

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

4 MR. LEFKOWITZ: Well --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

25 CHIEF JUSTICE ROBERTS: Thank you, counsel.

1 Mr. Yang?

2 ORAL ARGUMENT OF ANTHONY A. YANG,  
3 FOR UNITED STATES, AS AMICUS CURIAE,  
4 SUPPORTING THE PETITIONER

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

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

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

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

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

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

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

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

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

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

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

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

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

25 MR. YANG: Well, with respect to the

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

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

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

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

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

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

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

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

1 and --

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

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

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

14 JUSTICE KAGAN: And that's --

15 MR. YANG: -- a little narrower.

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

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

25 Not simply because the FDA has set the

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

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

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

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

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

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

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

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

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

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

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

14 MR. YANG: If I might just finish.

15 JUSTICE SCALIA: I would like to hear your  
16 answer.

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

25 And when it should not be marketed and it

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

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

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

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

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

4 MR. YANG: May I answer?

5 CHIEF JUSTICE ROBERTS: Briefly.

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

10 CHIEF JUSTICE ROBERTS: Thank you, counsel.

11 Mr. Frederick?

12 ORAL ARGUMENT OF DAVID C. FREDERICK

13 ON BEHALF OF THE RESPONDENT

14 MR. FREDERICK: Thank you,

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

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

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

1 problem. We would submit that it doesn't.

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

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

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

11 MR. FREDERICK: That's correct.

12 JUSTICE SCALIA: That's wonderful.

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

18 And the jury's going to decide that?

19 MR. FREDERICK: Yes, it is.

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

1 drug, that the people that are harmed egregiously, like  
2 Karen Bartlett, will have an opportunity to compensation  
3 --

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

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

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

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

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

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

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

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

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

1 there were jury instructions about the adequacy of the  
2 warning.

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

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

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

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

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

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

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

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

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

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

2 MR. FREDERICK: It is not.

3 JUSTICE BREYER: Because -- why?

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

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

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

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

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

1 what the risks are, complete immunity from suit.

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

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

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

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

24           MR. FREDERICK: Yes.

25           JUSTICE BREYER: Okay. Now what you're

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

6 MR. FREDERICK: Where is it in the record?

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

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

15 JUSTICE BREYER: How do I discover that?

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

25 He then goes further to explain that "You

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

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

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

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

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

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

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

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

25 JUSTICE ALITO: But isn't it true that when

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

3 MR. FREDERICK: That is true, but what the  
4 FDA did not take into account, and this is what the  
5 district judge instructed the jury on September 22nd,  
6 2010, I think it's page 108 in the charging colloquy, is  
7 the evidence in this case was that the FDA did not have  
8 that evidence.

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

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

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

1 rulemaking.

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

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

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

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

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

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

24 MR. FREDERICK: And Justice Kennedy --

25 JUSTICE KENNEDY: I mean, which does -- was

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 MR. FREDERICK: Yes.

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

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

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

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

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

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

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

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

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

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

3 MR. FREDERICK: Yes.

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

6 MR. FREDERICK: It would be very dangerous.

7 JUSTICE ALITO: Not to drive at all?

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

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

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

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

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

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

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

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

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

25 JUSTICE BREYER: But even the compensation,

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

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

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

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

1 nullify State law, which is a rather sweeping  
2 proposition.

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

5 MR. FREDERICK: Granted --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

24           Number 4, if they are only making  
25 \$7 million, they ought to withdraw from the market

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

3 Thank you.

4 CHIEF JUSTICE ROBERTS: Thank you, counsel.

5 Mr. Lefkowitz, you have three minutes  
6 remaining.

7 REBUTTAL ARGUMENT OF JAY P. LEFKOWITZ

8 ON BEHALF OF THE PETITIONER

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

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

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

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

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

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

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

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

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

25           JUSTICE GINSBURG: How -- how did the Court

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

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

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

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

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

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

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

5                   CHIEF JUSTICE ROBERTS: Thank you, counsel.  
6 Counsel.

7                   The case is submitted.

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

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