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P R O C E E D I N G S

(10:06 a.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument first this morning in Case 06-1249, Wyeth v. Levine.

Mr. Waxman.

ORAL ARGUMENT OF SETH P. WAXMAN

ON BEHALF OF THE PETITIONER

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

This case concerns conflict pre-emption under the Supremacy Clause, and the conflict presented here is stark. Repeatedly over the years, the FDA approved Phenergan injection as safe and effective under all the conditions and methods of use described in the labeling, including what is referred to as "IV push" injection. Yet a State jury, evaluating the same risk that the FDA had considered, determined that the precise labeling that FDA had required Wyeth to use in fact rendered Phenergan "unreasonably dangerous." That --

JUSTICE KENNEDY: Just at the outset, I'll just make one comment. You argue that it's impossible for Wyeth to comply with the State law and at the same time the Federal label. As a textual matter, as a logical matter, I just don't understand that. I think I could design a label that's completely

1 consistent and that meets the requirements that the  
2 Respondents wish to urge.

3 Now, if you want to say that any alteration  
4 of the label violates Federal law, that's something  
5 else. But as a textual matter, as a logical matter, as  
6 a semantic matter, I don't agree with it.

7 MR. WAXMAN: Well, let me make sure, because  
8 I do think we do agree, and I want to make sure that I'm  
9 understood, Justice Kennedy. I think what you've  
10 articulated is the test which is, is it possible for a  
11 regulated party to comply at the same time with both  
12 Federal law and State law? In other words, could they  
13 use, as they were required by Federal law to do, to use  
14 the precise label that in approving the application in  
15 1998 the FDA required Wyeth to use, and also use the  
16 label that the Vermont jury determined should be used,  
17 and that was stated in the complaint and in the opening  
18 and the closing, a statement that you may not, should not  
19 use IV administration or IV push, in other words that  
20 you should contra -- the label should contra-indicate  
21 something --

22 JUSTICE GINSBURG: Mr. Waxman --

23 MR. WAXMAN: -- that --

24 JUSTICE GINSBURG: It didn't say -- it  
25 didn't say IV across the board. It said IV push is the

1 claim, and that was -- as I understand this, the FDA was  
2 aware of the IV use and a certain risk. But did it  
3 ever, ever discretely consider IV push versus IV  
4 administered the usual way by a drip bag?

5 MR. WAXMAN: Yes it did, Justice Ginsburg,  
6 and I want to cite you to the portions of the record  
7 that demonstrate that it did. But before I do so, I  
8 just want to underscore a point that I think is clear  
9 from both our brief and the Solicitor General's brief,  
10 which is that isn't the test of preemption in any event.  
11 The question is what did the labeling say and upon what  
12 information was the labeling decision made.

13 But as to your particular question, there  
14 are -- first of all, there was testimony in the record  
15 from multiple parties, including experts from both  
16 sides, that the FDA was aware of all of the forms of  
17 administration and the risk, including IV push. Their  
18 experts simply disagreed with the judgment that the  
19 labeling requires. But most saliently, the labeling in  
20 this case, which is reproduced, in sort of microscopic  
21 size unfortunately, on the last two pages of the  
22 petitioner appendix and the last two pages of the joint  
23 appendix, have four separate references that, as we  
24 explained in footnote 11 of our reply brief, only apply  
25 to IV push.

1           There is a reference to the use of the Tubex  
2 system. That is a direct IV push system. There is a  
3 reference to rigid plungers and small-bore needles.  
4 Again nothing to do with drip. There is a reference to  
5 a maximum rate of administration. Drip is gravity. The  
6 testimony in the case was that an instruction that a  
7 particular rate of administration not be exceeded only  
8 referred to IV push. And finally, there are cautions on  
9 the label about how the ordinary aspiration of blood to  
10 see if its bright or dark, which is only done in the  
11 context of a needle that is being used to push something  
12 into a vein, is not reliable in the context of this case  
13 because Phenergan discolors arterial blood immediately.

14           So the labeling plainly comprehended and  
15 warned about the specific risks of IV push  
16 administration, and that's not all. There is an  
17 advisory -- an advisory committee in 1976 was asked to  
18 look at precisely the risk of arterial exposure to  
19 Phenergan injection or any other irritant drug that is  
20 administered intravenously and it made specific  
21 recommendations, including recommendations that go  
22 directly to IV push.

23           JUSTICE ALITO: How could the -- how could  
24 the FDA have concluded that IV push was safe and effective  
25 when on the benefit side of this you don't have a

1 life-saving drug, you have a drug that relieves nausea,  
2 and on the risk side you have the risk of gangrene?

3 MR. WAXMAN: I mean, there was testimony --  
4 Justice Alito, I can go over the testimony, but there  
5 is -- there was testimony in this very case about those  
6 very circumstances in which direct IV injection is  
7 indicated. And there is also test -- there is also  
8 evidence in the FDA record, including if you look at the  
9 1987 correspondence that the FDA sent to Wyeth in the  
10 context of talking about what warnings had to be  
11 provided. The FDA provided Wyeth 20 citations to 20  
12 medical journals that addressed this problem, and in  
13 footnote 13 of our reply brief we've cited the ones that  
14 specifically address the circumstances in which IV push  
15 administration is an important tool. The point here is,  
16 I think, that --

17 JUSTICE GINSBURG: But that doesn't answer  
18 the question of was it -- the risk of gangrene and  
19 amputation is there. No matter what benefit there was,  
20 how could the benefit outweigh that substantial risk?

21 MR. WAXMAN: Justice Ginsburg, this is  
22 labeling that is directed at medical professionals. It  
23 is labeling that is directed at physicians, who have to  
24 be able to determine what method -- what pharmaceutical  
25 and what method of administration to use, given the

1 constellation of risks and benefits that a particular  
2 patient --

3 JUSTICE KENNEDY: The FDA was never  
4 concerned with risks versus benefit?

5 MR. WAXMAN: The FDA -- well, the FDA  
6 certainly is. And the issue, Justice Kennedy, here is  
7 the FDA has to decide what information to provide to  
8 clinicians so that they can make judgments about what to  
9 use. And it -- what it did here is it provided ample,  
10 lavish warnings about the risk of intra-arterial  
11 injection and exposure of an irritant drug like  
12 Phenergan to arterial blood. It provided in the  
13 labeling to the physicians a cascading hierarchy of  
14 methods of administration. It said intramuscular  
15 injection is the preferred method. It then said with  
16 respect to intravenous injection that it is, as with any  
17 irritant drug, it is usually preferable to inject it  
18 into an IV infusion set that is known to be running  
19 properly, in other words where a line has already been  
20 established into the vein and the IV push occurs into  
21 the line that's already established.

22 All that information was available to  
23 physicians and the FDA has to understand and does  
24 understand that in labeling for -- to allow medical  
25 professionals to make their judgment, taking options

1 away from physicians is not always better. It may  
2 not -- it may not even often be better. What the FDA  
3 has to decide in terms of telling physicians what's on  
4 the table and what's off the table and in terms of  
5 what's on the table and what the relevant risks are is,  
6 is this ever -- would this ever be medically warranted?  
7 The testimony in this case and in the administrative  
8 record was yes, there are circumstances --

9 CHIEF JUSTICE ROBERTS: I'd like you to  
10 address the distinction between the medical device area  
11 and the drug area because in the medical device area, of  
12 course, you have an express pre-emption clause, while  
13 here in contrast you don't.

14 MR. WAXMAN: Yes. I mean, I think,  
15 Mr. Chief Justice, you've identified the respect in  
16 which this is difference than the medical device area.  
17 But for the salient purposes, I think the Riegel case  
18 is -- directly points the Court to the nature of the  
19 determination that the FDA makes with respect to class 3  
20 drugs. It goes through the same preclearance process.  
21 As we pointed out in our brief and as I think Justice  
22 Scalia's opinion in Riegel points out, the balancing  
23 time-intensive, data-intensive inquiry for medical  
24 devices was patterned after what is done for drugs, and  
25 it reflects a balancing of risks and benefits of the

1 particular drug in light of the conditions and methods  
2 of administration prescribed in the labeling.

3 CHIEF JUSTICE ROBERTS: If that's true you  
4 would have expected the Federal Drug Act to have a  
5 similar express pre-emption provision. And one reason  
6 perhaps that it didn't is that when the Drug Act was  
7 passed you had an established background of State  
8 actions; when the Medical Device Act was passed you  
9 didn't.

10 MR. WAXMAN: Well, let me address both the  
11 established background of State actions and then the  
12 pre-emption clause difference, if I may. The Respondent  
13 and her amici have identified 97 cases going back 150  
14 years in which tort actions have been brought with  
15 respect to pharmaceuticals. Very few of those cases --  
16 and they are recent -- are implicated by the rule that  
17 the Vermont Supreme Court applied in this case, which is  
18 where a fully informed FDA, informed of all the  
19 information that Wyeth had, approved a labeling  
20 standard, but a court looking at the same evidence can  
21 reach a different conclusion about what is on the label.  
22 The most -- those cases I believe all post-date  
23 Cipollone. Many of them postdate Geier. And by my  
24 count, there are fewer than 20 such cases out of all of  
25 the cases that have been decided and those issues --

1 that issue had never come up and never could have come  
2 up when Congress enacted the 1938 Act, because it was  
3 only the 1938 Act that established a drug-specific,  
4 preclearance regime, and really in 1962, in which the  
5 FDA was required not just to evaluate safety in terms of  
6 licensing the distribution of the drug, but to balance  
7 safety against effectiveness.

8           And so the -- the constellation of common  
9 law cases -- I mean, let me just say we are -- we are  
10 not seeking here a rule of field preemption. We are not  
11 seeking to preclude tort remedies for conduct that  
12 violates Federal law.

13           What we are saying here is -- and this goes,  
14 I think, finally to your point about the express  
15 pre-emption clause -- the presence of expressed  
16 pre-emption clauses or the absence, the presence of a  
17 savings clause or the absence, does not and cannot  
18 affect the operation of conflict pre-emption under the  
19 Federal Constitution.

20           Now, members of this Court are concerned  
21 about applying a broad, vague, or free-wheeling analysis  
22 of implied conflict pre-emption, but this case is  
23 heartland. A jury was asked to look at the same  
24 information and conclude that the precise language that  
25 the FDA just didn't allow, the FDA required Wyeth to

1 use, rendered that drug unreasonably unsafe.

2 JUSTICE SOUTER: Well, it required it  
3 because that is what the FDA had approved as a label.  
4 But as -- excuse me -- as I understand it, the -- the  
5 company, Wyeth, could have gone back to the FDA at any  
6 time and said, either based on experience or just our  
7 rethinking of the data that we have, we think the label  
8 ought to be changed to say "Don't use IV push." Wyeth  
9 could have done that at any time, and it simply didn't  
10 do it.

11 And the -- the reason I raise this is  
12 because it could have done it at any time, where, going  
13 back to Justice Kennedy's first question, where is the  
14 conflict?

15 MR. WAXMAN: The liability in this case was  
16 not predicated on the fact that Wyeth didn't go to the  
17 -- remember, the FDA had approved this label two years  
18 before Miss Levine was injured. In approving the label,  
19 it rejected stronger proposed language that Wyeth had  
20 presented. There was nothing that was -- Wyeth was --

21 JUSTICE SOUTER: But as I understand it,  
22 Wyeth's argument is not this argument. Wyeth is not  
23 saying the reason there is a conflict here is that we  
24 tried to give the kind of warning that the Vermont jury,  
25 in effect, says we should have given and the FDA didn't

1 allow us to do it, so that, in fact, there is a conflict  
2 between a specific rejection by the FDA of the Vermont  
3 rule and the rule that the Vermont jury applied.

4 MR. WAXMAN: Right.

5 JUSTICE SOUTER: As I understand it, Wyeth's  
6 argument is: Whatever is on the label, in fact, is the  
7 standard of conflict. It doesn't matter whether we  
8 tried or could have tried or didn't try. You simply  
9 look at the label and you look at what the Vermont jury  
10 did; and if there is a -- if there is a difference  
11 between them, there is a conflict. Am I right about  
12 your argument?

13 MR. WAXMAN: Yes, you are right. We -- we  
14 have both an impossibility form of conflict because, in  
15 the absence of any new information or new analyses of  
16 old information, we could not make the change in advance  
17 of getting approval. And we also have an -- an  
18 objects-and-purposes form of conflict pre-emption  
19 because the Vermont jury decided on the same information  
20 that the labeling that the FDA had approved and required  
21 was unreasonably unsafe.

22 And we cannot have a world in which the very  
23 day after an intensive process -- the FDA says you may  
24 distribute this drug, but you must use this specific  
25 language -- either, A, manufacturers can just run in and

1 change the label and ask for permission down the road;  
2 or, B, that a State jury -- let's take the easier case  
3 -- a State legislature or 50 State legislatures can  
4 decide: Because you could have gone back and asked, we  
5 can impose an obligation on you that you must have done  
6 so or must have changed the labeling. That just is  
7 inconsistent with --

8 JUSTICE SOUTER: Well, is it -- is it strict  
9 liability or negligence? Let's say -- are they saying you  
10 must have done so, or are they saying because you could  
11 have done so and didn't you did not conform to the  
12 standard of care?

13 MR. WAXMAN: Either a negligence theory or a  
14 strict-liability theory would be pre-empted.

15 May I reserve the balance of my time.

16 CHIEF JUSTICE ROBERTS: Thank you, counsel.

17 Mr. Kneedler.

18 ORAL ARGUMENT OF EDWIN S. KNEEDLER

19 ON BEHALF OF THE UNITED STATES,

20 AS AMICUS CURIAE,

21 SUPPORTING THE PETITIONER

22 MR. KNEEDLER: Mr. Chief Justice, and may it  
23 please the Court:

24 The State law duties on which Respondent's  
25 tort claims are based are pre-empted because they

1 conflict with the FDA's determination that Phenergan  
2 injection is safe and effective under the conditions of  
3 use recommended or suggested in the labeling.

4 JUSTICE GINSBURG: Mr. Kneedler, at the  
5 outset, would you clarify something that is central, I  
6 think, to this case? Some of the briefs tell us that  
7 this represents a change of policy on the part of the  
8 FDA, that in fact the FDA once approved and said torts  
9 were -- tort suits were a helpful adjunct to the FDA's  
10 own efforts to protect consumers. They helped because  
11 they prodded manufacturers to -- to disclose risks that  
12 were either unknown or under-evaluated. Was that once  
13 the FDA's policy; and, if so, when did it change?

14 MR. KNEEDLER: The -- the FDA, to my  
15 knowledge, has never taken the position that -- that, as  
16 a general matter, a manufacturer may change a label  
17 without -- without the existence of new information that  
18 justifies a revision. The Respondents and the amici  
19 relied primarily on some snippets of rule-making  
20 proceedings and things like that in which FDA has  
21 referred to the existence of tort remedies. But we are  
22 not arguing for the proposition that tort remedies are  
23 -- are pre-empted as a general matter.

24 JUSTICE SCALIA: But when -- when would  
25 there be a tort remedy? What -- what situation would

1 you envision?

2 MR. KNEEDLER: As Mr. Waxman mentioned, if  
3 -- if the State standard was the same as the Federal  
4 standard, there wouldn't be any conflict. And, for  
5 example, if -- and not to mention the fact if there was  
6 adulteration of -- of the product or if the -- if the  
7 product in the box was not the same --

8 JUSTICE SCALIA: What if they found out  
9 about new information which would, if properly  
10 considered, alter what the labeling ought to be? Would  
11 there be a tort remedy for the failure to bring that new  
12 information to the attention of --

13 MR. KNEEDLER: Well, the position we are  
14 arguing for here would not cover that situation, but --  
15 but there could be a further situation of pre-emption,  
16 if I could just explain why. I think --

17 JUSTICE SCALIA: You mean if you failed to  
18 provide the FDA the new information that you think  
19 negates the provisions on the -- on the label, you still  
20 couldn't be sued?

21 MR. KNEEDLER: No. If you -- if you failed  
22 to provide it altogether, there would not be a -- a  
23 pre-emption defense if there were -- if your  
24 failure-to-warn claim was based on the new information  
25 that you didn't furnish.

1 I was -- I was going to identify the  
2 situation where -- and this has come up in the anti-  
3 depressant drug situation, for example, where there is  
4 evolving information. There has been a rule- making  
5 petition, in fact several over the years, to the FDA to  
6 change the labeling to warn against -- to warn about the  
7 possibility of suicidal ideation. And FDA has  
8 rejected that even though it's -- it's new information  
9 arising after the drug was approved. If the information  
10 is brought to the FDA's attention and FDA rejects the  
11 proposed change, then you would you have conflict  
12 pre-emption again. But if the information was never  
13 brought to the FDA's attention in the first place, then  
14 -- then there would -- it would be not inconsistent with  
15 Federal law to have a tort suit based on that. If it's  
16 -- if it's been proposed and rejected, then you're back  
17 with a conflict.

18 JUSTICE SCALIA: What if -- what if you  
19 brought it to the FDA's attention and the FDA just  
20 hasn't acted on it? You would be authorized to change  
21 the label on your own.

22 MR. KNEEDLER: You would be authorized, but  
23 if FDA then rejects -- rejects the labeling --

24 JUSTICE SCALIA: I understand, but in the  
25 interim, you could -- could you be subject to a State

1 tort suit for not changing the label when -- when you  
2 had the power to do so?

3 MR. KNEEDLER: I -- if -- if FDA has taken  
4 no action at all, then I think you -- you could be. I  
5 think it's very likely that FDA would have acted by the  
6 -- by the time that -- I mean, I suppose there could be  
7 a window in there before it was approved.

8 JUSTICE GINSBURG: But why is that -- why is  
9 that likely, considering the huge number of drugs? I  
10 mean, one figure said that there are 11,000 drugs that  
11 have this approval. Is the FDA really monitoring every  
12 one of those to see if there is some new information  
13 that should change the label?

14 MR. KNEEDLER: If I could make two points  
15 about that: The first is, as I said, we are not arguing  
16 that there is pre-emption in a situation where there is  
17 new information that is not brought to FDA's attention.

18 But the second point is that in the 2007  
19 amendments to the Act, Congress recognized the  
20 difficulties with this and gave FDA important new  
21 enforcement tools and resources to go after the problem  
22 of things that arise after a drug is improved --  
23 approved, that has given FDA the authority to direct a  
24 change in the label, which it did not have before.

25 It has given the FDA the authority to order

1 new clinical studies, and it has ordered FDA to set up a  
2 data system where it will get electronic notification of  
3 -- of adverse events.

4 I -- I should point out in the -- in the one  
5 year since these amendments were passed, FDA has, I -- I  
6 think, in 21 instances ordered clinical trials. In four  
7 instances it has ordered a revision of labeling. It has  
8 hired 430 new employees in the Center for Drug  
9 Evaluation and Research to address the post-marketing  
10 situation.

11 JUSTICE BREYER: Why isn't -- why isn't the  
12 fact that some certain number of people are getting  
13 gangrene, why isn't that new information?

14 MR. KNEEDLER: The risk -- the way FDA --  
15 and this is set forth in the changes being affected  
16 regulation amendment that was adopted --

17 JUSTICE BREYER: That was all passed long  
18 after the events here took place, I think.

19 MR. KNEEDLER: But -- but --

20 JUSTICE BREYER: So at the time, you read  
21 the regulation, I think a person would think that he was  
22 free drug manufacturer if he learned something new to  
23 strengthen -- strengthens the contraindication, put it  
24 in.

25 MR. KNEEDLER: As FDA explained in 2008,

1 when it promulgated this regulation, it's been FDA's  
2 long-standing interpretation that only new information  
3 would justify a change.

4 JUSTICE BREYER: Why wouldn't that be new?

5 MR. KNEEDLER: New information means new  
6 information about a risk that is greater in severity or  
7 frequency. If you have --

8 JUSTICE BREYER: If you get -- if you get --  
9 if you get a number of cases.

10 MR. KNEEDLER: There is no claim -- there is  
11 no claim here that either of those -- in the record in  
12 this case, that either of those was true.

13 JUSTICE BREYER: That's because nobody  
14 brought up this new information point. So if nobody  
15 brought up the new information point at the trial and if  
16 the burden is on the manufacturer to show that it's  
17 pre-empted, then isn't that the manufacturer's fault, because  
18 if you simply read the regulation, you wouldn't find any  
19 of all this complicated stuff about certain kinds of new  
20 information.

21 MR. KNEEDLER: That's a legal question not a  
22 factual. And it was argued to the Vermont --

23 JUSTICE BREYER: Yes it's a legal question.

24 MR. KNEEDLER: It was argued to the Vermont  
25 Supreme Court, and I don't think -- I don't think that

1 Respondent -- Respondent has noted that it wasn't  
2 raised, but I don't think it's argued that it's waived.  
3 And I think for the Court to fully address this  
4 situation, I think it would be good to take into account  
5 FDA's -- certainly going forward that is the regulatory  
6 regime --

7 JUSTICE BREYER: But we are not making an  
8 advisory opinion. We are deciding this case. And this  
9 case here you say new information of a certain kind  
10 would be okay, nobody argued it. You read the reg, and  
11 it doesn't seem to make all these distinctions end of  
12 case. Since the manufacturer has the burden of going  
13 into this, which apparently it didn't do. So, now we  
14 have decided this case, and we can go on to the next one.

15 MR. KNEEDLER: Okay. If I could make just  
16 one further --

17 JUSTICE BREYER: What's your response to  
18 that?

19 MR. KNEEDLER: If I could make one further  
20 point about that. And that is the -- this act sets up a  
21 prior approval situation. In other words, Congress  
22 wanted the FDA to look at the drug in advance,  
23 balance risks against benefits as this Court said in  
24 Rutherford, and -- Brown & Williamson, strike a balance  
25 and approve it.

1           It would be fundamentally inconsistent with  
2 a prior approval system to have a regime in which the  
3 very next day State law could require the manufacturer  
4 to change the very labeling that FDA has struck a  
5 balance --

6           JUSTICE SCALIA: I don't understand what  
7 we're talking about here. The new information was not  
8 brought up by either side --

9           MR. KNEEDLER: Right.

10          JUSTICE SCALIA: -- showing increased  
11 frequency or increased severity?

12          MR. KNEEDLER: That's correct.

13          JUSTICE SCALIA: Right?

14          And supposedly, it was burden of the drug  
15 company to show that there was no --

16          MR. KNEEDLER: No. The drug company says  
17 it's pre-empted, and the only escape hatch from the  
18 preemption is new information.

19          CHIEF JUSTICE ROBERTS: You agree with -- you  
20 agree with Mr. Waxman that the FDA specifically  
21 addressed the risks and benefits of IV push as opposed  
22 to the risks of arterial exposures?

23          MR. KNEEDLER: It specifically addressed in  
24 the labeling that the FDA approved, and I think that's  
25 all that needs to be looked at in -- it's just as in

1 Riegle, where the preemption turns on that device, in  
2 that case, and the labeling that was presented. Here  
3 the preemption turns on the labeling and the drug that  
4 was presented. And FDA regulations prohibit the change  
5 unless there is new information.

6           If I could make one other point about  
7 Riegle. Riegle does contain an FDA -- an expressed  
8 preemption provision. But the reason why this Court  
9 found preemption in Riegle under that provision is very  
10 instructive here, because as Mr. Waxman pointed out, the  
11 premarket approval process in the two situations are  
12 essentially the same.

13           And what you had on the one hand was Federal  
14 action having the force of law like under the file rate  
15 doctrine or some administrative determination having the  
16 force of law approving a license or -- or a drug, a  
17 legal prohibition against changing that without new  
18 information. And on the state side, you have a rule of  
19 law under the common law of torts imposing a different  
20 obligation. Those are squarely termed --

21           JUSTICE KENNEDY: You're talking about  
22 changing but you can supplement without changing the  
23 label.

24           MR. KNEEDLER: No -- no, you cannot. Any --  
25 any change in the wording of -- of the label is a change

1 that requires FDA approval unless it is --

2 JUSTICE SCALIA: You can supplement only  
3 when there is new information?

4 MR. KNEEDLER: When there is new information  
5 and even then, it has to be in the form of a new drug --  
6 a supplemental drug application to the agency.

7 CHIEF JUSTICE ROBERTS: Thank you,  
8 Mr. Kneedler.

9 Mr. Frederick.

10 ORAL ARGUMENT OF DAVID C. FREDERICK

11 ON BEHALF OF THE RESPONDENT

12 MR. FREDERICK: Thank you, Mr. Chief  
13 Justice.

14 I'd like to start with regulation 201.80,  
15 which is set forth in an addendum to our brief at 19-A.  
16 The second sentence of which reads: "The labeling shall  
17 be revised -- this is after an applicant, a sponsor has  
18 obtained approval of the drug label -- "it shall be  
19 revised to include a warning as soon as there is  
20 reasonable evidence of an association of a serious risk  
21 with a drug. A causal relationship need not have been  
22 proved."

23 The testimony at trial established that  
24 Wyeth knew or should have known from at least the '70s  
25 that there was a significance issue concerning IV push

1 risks.

2 And, Justice Alito, in answer to your  
3 question --

4 JUSTICE SCALIA: Excuse me. Those -- those  
5 risks were set forth on the labeling approved by the  
6 FDA. Surely that sentence means it shall be revised to  
7 include a warning as soon -- as soon as there is  
8 reasonable evidence of an association of a serious  
9 hazard that the FDA has not considered. And that is not  
10 already addressed on the labeling. I mean to read it  
11 as -- as opening up stuff that's already been considered  
12 by the FDA would -- would -- would make a -- a mush out  
13 of it.

14 MR. FREDERICK: FDA never considered any  
15 comparative risks of IV push versus IV drip. The  
16 evidence on this was clear. Wyeth had a --

17 CHIEF JUSTICE ROBERTS: What about the  
18 various portions of the label in the record that  
19 Mr. Waxman addressed and Mr. Kneedler, representing the  
20 FDA, said they specifically considered IV push risks?

21 MR. FREDERICK: What the evidence showed was  
22 that FDA certainly was aware that there are different  
23 forms of intravenous administration of drugs, but it  
24 never considered that the risk of IV push so greatly  
25 increased the risks of a catastrophic injury --

1                   CHIEF JUSTICE ROBERTS: Well, they have to.  
2 When they determine that it's safe to use it under those  
3 circumstances that necessarily includes a consideration  
4 of the risk. People can say it's safe for you to walk  
5 down the sidewalk. That doesn't mean there is no risk  
6 that you get hit by lightning or something else. It  
7 just means in evaluating them together, they determine  
8 that it's worth the candle in particular cases where a  
9 physician determines that that's the indicated method.

10                   MR. FREDERICK: Mr. Chief Justice, here  
11 there was no way FDA could have made this determination  
12 because the risks of IV push are so catastrophic  
13 compared to the benefit which the testimony at trial  
14 showed --

15                   JUSTICE SCALIA: Well, you're just  
16 contradicting the label. The fact is they could not  
17 have approved that label unless they made that  
18 determination.

19                   Now, if you're telling me the FDA acted  
20 irresponsible -- irresponsibly, then sue the FDA.

21                   MR. FREDERICK: No.

22                   JUSTICE SCALIA: But the labeling made it  
23 very clear that the preferred method of administering  
24 this medicine was -- was -- was muscular and -- and that  
25 there were serious risks involved in -- in the IV push.

1           Moreover, your client didn't follow the  
2 labeling or your client's physician didn't follow the  
3 labeling prescription for IV push, did he?

4           MR. FREDERICK: The testimony at trial  
5 showed that the doctor acted with a standard of care  
6 that was not negligent, and that was based on expert  
7 testimony.

8           JUSTICE SCALIA: No. No. Wait, wait. He  
9 administered a -- a level of the drug that was vastly in  
10 excess of -- of -- of what the labeling said could  
11 safely be used for IV push.

12          MR. FREDERICK: And the testimony at trial  
13 showed that that had no bearing on her injury,  
14 because --

15          JUSTICE SCALIA: Had no bearing. Are you  
16 serious?

17          MR. FREDERICK: Yes. It did. The testimony  
18 at trial from Dr. Green disputed that point. Both  
19 courts below rejected that notion.

20                 But the idea that a label is set in stone  
21 for all time misunderstands the way the process works.  
22 When FDA approves a drug with a drug label, it does so  
23 on the basis of small clinical trials with very few,  
24 sometimes as few as a thousand or a couple of thousand  
25 people. And when the drug is marketed and goes to lots

1 and lots of people that are not healthy, that are in  
2 different conditions, new problems arise. That's why  
3 the general -- the GAO found that over 51 percent of  
4 drugs have adverse drug events not known.

5 JUSTICE SCALIA: You established that there  
6 were new problems? I mean, if there were new problems,  
7 then -- then they could have simply supplemented the  
8 labeling. But did you establish that there were  
9 problems that had not been considered already by the  
10 FDA?

11 I mean, the labeling says, you know, that  
12 this is dangerous to use -- use IV push. It made it  
13 very clear that it's dangerous.

14 MR. FREDERICK: That was not our burden and  
15 that was not how the testimony came in at trial. But as  
16 the amicus brief by Dr. Budhwani, et al. at pages 54  
17 establishes, had Wyeth been a reasonably prudent  
18 manufacturer over the years, it would have known that  
19 the risks of IV push so far outweigh any bearing  
20 negligible benefits, that it would have offered a  
21 stronger instruction, it would have moved to revise its  
22 label either with FDA approval or --

23 JUSTICE SCALIA: It proposed a more  
24 restrictive label to the FDA, didn't it? And the FDA  
25 said, no, you use this label. In other words, it's --

1 what you're saying was not its call. It was the call of  
2 the FDA.

3 MR. FREDERICK: Footnote one of the Vermont  
4 Supreme Court's opinion disputes that point, because it  
5 says the label was different. And if you compare what  
6 was submitted to FDA versus what FDA looked at, there  
7 was no reference to IV push risks creating the risk of  
8 catastrophic harm versus negligible benefits, Justice Scalia.

9 CHIEF JUSTICE ROBERTS: I thought your -- I  
10 thought your theory was that this type of administration  
11 of the drug should not be allowed. The label should not  
12 say here are the risks, here are the benefits. You --  
13 your jury theory was you cannot suggest in the labeling  
14 that physicians should have this available.

15 MR. FREDERICK: Well, as the jury was  
16 instructed, Mr. Chief Justice, and the evidence came in  
17 at trial, it was -- it was somewhat larger than that in  
18 the sense that a State failure to warn claim doesn't  
19 prescribe particular wording. It simply says that the  
20 existing wording is inadequate. And as the case comes  
21 to this Court --

22 CHIEF JUSTICE ROBERTS: Well, it simply says  
23 that if you go ahead with the label like this, you don't  
24 have to pay \$10 million whenever it goes wrong. That's  
25 having the effect, as our case has established, of imposing

1 a limitation on the label.

2 MR. FREDERICK: But the label itself is not  
3 set in stone, Mr. Chief Justice. Manufacturers change  
4 their labels all the time as new drug risks come in.  
5 And the regulations provide that the manufacturer is  
6 responsible not only for the label, but for monitoring  
7 post-market information.

8 CHIEF JUSTICE ROBERTS: So your case depends  
9 upon us determining that the risk at issue here that was  
10 presented to the jury was a new risk that the FDA did  
11 not consider?

12 MR. FREDERICK: No. It is not dependent on  
13 that at all, Mr. Chief Justice. It is dependent on a  
14 finding that the manufacturer had a duty of due care and  
15 it didn't live up to that.

16 JUSTICE SCALIA: What if it referred to new  
17 drug risks, then, in your preceding sentence, where you  
18 are saying manufacturers change it all the time as new  
19 drug risks become apparent?

20 MR. FREDERICK: The testimony --

21 JUSTICE SCALIA: What you mean is whether or  
22 not new drug risks become apparent, they have to change,  
23 right?

24 MR. FREDERICK: The question is what does  
25 the manufacturer know and when did this manufacturer

1 know it? And here, the testimony at trial showed that  
2 an antinausea drug called Vistrol -- this is at page 79  
3 of the joint appendix -- caused amputations in two  
4 cases. Pfizer voluntarily removed IV push injection for  
5 that drug. This was information in Wyeth's files; Wyeth  
6 knew this from the 1970s; and yet it did nothing to  
7 change the Phenergan label.

8 CHIEF JUSTICE ROBERTS: Suppose --

9 JUSTICE SOUTER: With respect to the  
10 obligation in this case, may I go back to an earlier  
11 question that Justice Scalia asked you? And I -- I --  
12 if you responded to this particular point, I didn't get  
13 it.

14 He said that he understood that Wyeth had in  
15 fact asked the FDA to modify the label, at least to  
16 strengthen the warning against IV push, and that request  
17 was -- was denied, so that in fact that -- that created  
18 the conflict. What is your response to -- to the  
19 factual basis for that -- for that comment?

20 MR. FREDERICK: Well, the FDA itself said in  
21 the Solicitor General's brief at page 25 that it was  
22 deemed to be a nonsubstantive change. These were  
23 changes that were being made --

24 JUSTICE SOUTER: Well, regardless of what  
25 their -- their semantic label was, was there a request at

1 least to -- to beef up the warning against using IV  
2 push? And if so, did the -- did the FDA reject it and  
3 say no, you can't do that.

4 MR. FREDERICK: It was a different label and  
5 it was a different strength of warning, but it didn't  
6 have to do with the relative risks and benefits of IV  
7 push versus IV drip.

8 JUSTICE SOUTER: What would it --

9 MR. FREDERICK: That was the crucial point.

10 JUSTICE SOUTER: What would it have said?

11 MR. FREDERICK: This is set out at footnote  
12 1 of the Vermont Supreme Court opinion, which is set out  
13 in the joint -- in the petition appendix at pages 4a to  
14 5a, and it goes on for two pages. But essentially what  
15 the -- what the comparison was was talking about the  
16 preferability of injecting it through the tubing of an  
17 intravenous infusion set that is known to be functioning  
18 satisfactorily, which would suggest to most medical  
19 practitioners and was it the case in the trial testimony  
20 given by Dr. Green below, that that would suggest an IV  
21 drip, not IV push.

22 When FDA then rejected it for -- for  
23 nonsubstantive reasons, it went back to the prior  
24 verbiage which is set out at 5a, which simply says if  
25 you put this drug in an artery the concentration can be

1 such that it will -- it will cause harm.

2 But our point is that these kinds of risks  
3 come to light frequently with drugs that are on the  
4 market and the need to revise these labels is the duty  
5 of the manufacturer. Section 314. --

6 JUSTICE SOUTER: But you -- you also, to be  
7 clear on it, as I understand it, you do not accept the  
8 position that the FDA puts forward, that the obligation  
9 depends upon the accrual of new information.

10 MR. FREDERICK: Well, how you --

11 JUSTICE SOUTER: Any information, new or  
12 old, as I understand it, on your argument raises this  
13 obligation to -- to act.

14 MR. FREDERICK: I think that the dispute is  
15 -- is what constitutes new information, because we don't  
16 take issue with the notion that new information can be  
17 new analysis of prior submitted data; and what the  
18 amicus brief by Dr. Budhwani et al. points out is that  
19 there was a lot of unpublished information about the  
20 harms of Phenergan that was known to Wyeth or should  
21 have been known to Wyeth in the '80s and '90s, it would  
22 have justified a change under the CEE regulations.

23 JUSTICE ALITO: Well, suppose the record  
24 showed that the FDA clearly considered whether IV push  
25 should be contraindicated and concluded it should not be

1 and prescribed the label that now appears on the drug;  
2 and then, as some of the other arguments have  
3 referenced, the very day after the FDA made that ruling,  
4 Ms. Levine was injured. Would you still -- would she  
5 still have a claim in your view, a non-pre-empted claim?

6 MR. FREDERICK: That be pre-empted. And the  
7 reason it would be pre-empted is because the FDA would  
8 have considered and rejected on the basis of the same  
9 information or similar information the very duty that  
10 underlies the State claim.

11 JUSTICE ALITO: So your argument is -- is  
12 predicated on the existence of new information. If  
13 there was no new information, then the claim is  
14 pre-empted?

15 MR. FREDERICK: No, it's not -- well, it is  
16 not -- I think there are two things to keep analytically  
17 clear. One is can the manufacturer come forward with a  
18 label change on the basis of -- of information that is  
19 assessing the risks or reassessing the risks, and under  
20 the -- under the regulations it's absolutely clear it  
21 can do that before FDA has approved it. It is subject  
22 to FDA disapproval.

23 JUSTICE SCALIA: And -- and is entitled to  
24 amend the labeling automatically.

25 MR. FREDERICK: That's correct.

1 JUSTICE SCALIA: I envision a -- a scheme  
2 under which manufacturers who are worried about jury  
3 liability of -- of the magnitude that occurred in this  
4 case saying, gee, why should we take chances? And every  
5 time there is a jury verdict on some -- on some other --  
6 some other ground not -- not prohibited by the label,  
7 they just add that to the label; and they submit it  
8 to -- to the FDA and the -- and until -- unless and  
9 until the FDA conducts an investigation and disapproves  
10 that label, that labeling change occurs.

11 How many -- how many -- you mentioned a  
12 number of -- of times that -- that label alterations  
13 are -- are proposed. I mean, this is going to be a  
14 massive operation for the FDA.

15 MR. FREDERICK: Justice Scalia, that would  
16 promote public safety, because it puts into the hands of  
17 doctors the information that enables them to make  
18 individualized risk determinations.

19 JUSTICE SCALIA: It would not promote public  
20 safety if you believe that the name of this game is  
21 balancing benefits and costs.

22 MR. FREDERICK: And Congress said --

23 JUSTICE SCALIA: And if you are simply  
24 eliminating certain drugs which people who -- who have  
25 real desperate need for could -- could be benefited by,

1 you're not benefiting the public.

2 MR. FREDERICK: No, and in fact that's  
3 contrary to the policy determination Congress made. In  
4 the misbranding provision, which is Section 352(f), it  
5 requires -- it calls that the label is misbranded unless its  
6 labeling bears adequate directions for use and such  
7 adequate warnings against use in those pathological  
8 conditions or by children where its use may be dangerous  
9 to health or against unsafe dosage or methods or  
10 duration of administration or application.

11 JUSTICE SCALIA: And that applies even if  
12 it's approved by the FDA?

13 MR. FREDERICK: Yes. It's misbranded. And  
14 in the 1979 --

15 JUSTICE SCALIA: You're saying FDA approval  
16 doesn't -- doesn't give you any protection at all?

17 MR. FREDERICK: It -- it provides you a  
18 basis for marketing your --- your product.

19 JUSTICE SCALIA: But -- but -- but the  
20 marketing may be a misbranding?

21 MR. FREDERICK: In -- the FDA itself said so  
22 in 1979 in 44 Federal Register, which we cite in our  
23 brief, that even an original label may be misbranded if  
24 the drug manufacturer subsequently learns that it was  
25 not adequate for the safe use of the drug.

1 JUSTICE SCALIA: Well then, gee, then all of  
2 the qualifications you were making earlier about whether  
3 it's new information or a new assessment, that's  
4 irrelevant.

5 MR. FREDERICK: No, it's --

6 JUSTICE SCALIA: You're saying whenever it's  
7 unsafe, whatever the FDA has approved, you have a  
8 lawsuit.

9 MR. FREDERICK: No. What I'm saying is that  
10 the information develops after the original label is  
11 approved, and it is not a floor and a ceiling --

12 JUSTICE SCALIA: There -- there was nothing  
13 about new information in what you just said. You said  
14 it's misbranded if it's not safe, new information or  
15 not.

16 MR. FREDERICK: And that's --

17 JUSTICE SCALIA: Is that -- is that -- is  
18 that your position?

19 MR. FREDERICK: Our position is that the  
20 duty is on the manufacturer to make a safe label, and if  
21 the label is --

22 JUSTICE SOUTER: But getting to Justice  
23 Scalia's point, as I understand your answer to an  
24 earlier question, on the day that the FDA approves the  
25 label, if there is no further information indicating

1 danger, then any liability that is based upon what the  
2 -- the kind of information that the FDA knew would be  
3 pre-empted. The only time -- you're saying pre-emption  
4 does not occur when there is -- forget the word "new"  
5 for a moment -- when there is further information,  
6 information in addition to what the FDA was told,  
7 whether it's 1,000 years old or discovered yesterday;  
8 and if there is liability predicated on further  
9 information beyond what the FDA was told, then there is  
10 not pre-emption.

11 Is that a fair statement of your position?

12 MR. FREDERICK: That's fair, but let me just  
13 make clear that our test would require the FDA to  
14 consider and reject the specific basis on which the  
15 State law --

16 JUSTICE SCALIA: If that's a fair statement  
17 then you have to retract your -- your earlier assertion  
18 that whenever it's not safe it's misbranded. I mean --

19 MR. FREDERICK: I'm not going to retract  
20 that, Justice Scalia.

21 JUSTICE SCALIA: -- which is it? Whenever  
22 it's not safe, it's misbranded, or what you just  
23 responded to Justice Souter?

24 MR. FREDERICK: The basis -- the basis of  
25 the FDA's approval is on the basis of limited

1 information, which Congress has said for public safety  
2 reasons -- we are not doing a balancing here; we are  
3 doing this for public safety --

4 And if the label is not adequate for public  
5 safety it is a misbranded drug.

6 JUSTICE SOUTER: Okay, but if -- if the  
7 so-called misbranding is determined to be misbranding,  
8 based upon information which was given to the FDA, as I  
9 understand your position, you would admit that there was  
10 pre-emption.

11 MR. FREDERICK: I -- I think there is  
12 pre-emption, but that does not mean --

13 JUSTICE SOUTER: Okay. So there --

14 MR. FREDERICK: Maybe there is no --

15 JUSTICE SOUTER: There is -- there is  
16 that one exception at least to the broad statement that  
17 you gave in answer to Justice Scalia?

18 MR. FREDERICK: Let me try to untangle it  
19 this way. The fact that there is pre-emption and you  
20 cannot bring as State law failure-to-warn claim doesn't  
21 mean that the drug isn't misbranded under the Federal  
22 standard the FDA --

23 JUSTICE SOUTER: But the -- but the  
24 misbranding is of no consequence to what liability?

25 MR. FREDERICK: Well, it's --

1 JUSTICE SOUTER: In other words, I think  
2 you're saying if there -- if there would be pre-emption  
3 it may be misbranded, but there cannot be any recovery  
4 in a State tort suit.

5 MR. FREDERICK: That's correct. The -- the  
6 point --

7 JUSTICE SOUTER: Okay. So misbranding under  
8 those circumstances is a purely theoretical concept.

9 MR. FREDERICK: In that very hypothetical,  
10 yes.

11 JUSTICE SOUTER: Okay.

12 MR. FREDERICK: But the point is that the  
13 failure is that the failure-to-warn claim tracks the  
14 misbranding provision; and if you look at the jury  
15 instructions in this case, the wording is very close to  
16 the wording of the misbranding provision in terms of the  
17 adequacy of the warning that must be provided.

18 JUSTICE STEVENS: Mr. Frederick --

19 MR. FREDERICK: All State law is doing is  
20 providing a remedy that is absent from Federal law.

21 JUSTICE STEVENS: Mr. Frederick, I'd like to  
22 put the misbranding point to one side and just  
23 concentrate on pre-emption. And I understood you to  
24 agree with Justice Alito that there is a hypothetical  
25 case in which there would be pre-emption, and would you

1 tell me what particular fact distinguishes your case  
2 from his hypothetical?

3 MR. FREDERICK: The fact is there was no  
4 consideration and rejection of a stronger IV push  
5 warning. There was no consideration by the FDA of IV  
6 push as a means of administration distinct from other  
7 intravenous forms that would lead to a different kind of  
8 risk-benefit balancing. So with the -- in the case  
9 where there would be pre-emption, FDA would be asked, we  
10 -- we want to put a stronger warning as against this --  
11 FDA says: We don't think there is scientific evidence.  
12 Do not put that warning on the label.

13 CHIEF JUSTICE ROBERTS: So now, your friends  
14 on the other side said there was specific consideration  
15 of IV push as opposed to simply arterial exposure, and  
16 that that is laid forth in the labeling. So, as I  
17 understood your answer to be, all we have to do is  
18 simply look at the record, and if we think the FDA  
19 considered specifically IV push risks as opposed to  
20 general arterial exposure, then you lose, and if we  
21 determine that they did not, then they lose.

22 MR. FREDERICK: And the Vermont Supreme  
23 Court was quite emphatic about this, Mr. Chief Justice.

24 CHIEF JUSTICE ROBERTS: Well, I don't know  
25 if the Vermont Supreme Court was emphatic about it. I

1 mean, the record is either -- addresses the FDA -- I'm  
2 more interested in what the FDA was emphatic about, and  
3 they either address IV push separately or they don't.

4 MR. FREDERICK: And you search in the joint  
5 appendix in vain for communications between Wyeth and  
6 FDA communicating about the particular risks of IV push.

7 JUSTICE GINSBURG: What -- can you turn to  
8 the references that Mr. Waxman and Mr. Kneedler made?  
9 They said oh, yes, IV push was considered discretely  
10 from IV drip bags.

11 MR. FREDERICK: I will acknowledge that the  
12 references in some instances suggest IV push. There is  
13 no doubt that the FDA knew that IV push was a method of  
14 intravenous administration, but our point is a starker  
15 one, and that is that the FDA never was put to the test  
16 of deciding comparative risks and benefits of IV push  
17 versus IV drip. And it's that point that is crucial,  
18 because the catastrophic risks of IV push are so  
19 dramatic, no reasonable person could have made a safety  
20 determination to allow this drug with its risks when  
21 there are corresponding benefits that create exactly the  
22 same kind of treatment of care for the patient.

23 JUSTICE SOUTER: Well, is your argument that  
24 they couldn't have considered these comparative risks,  
25 because if they had, they would have come out

1 differently; because they didn't come out differently,  
2 we have to infer that they didn't consider it?

3 MR. FREDERICK: It's two things: One, they  
4 didn't consider it and that's clearly --

5 JUSTICE SOUTER: No, I --

6 MR. FREDERICK: Second,

7 JUSTICE SOUTER: Apart from your analysis  
8 that they couldn't have or they would have come out  
9 differently, how did we know that they didn't consider  
10 it?

11 MR. FREDERICK: There are communications  
12 that went back and forth between the company. These are  
13 set out in the joint appendix. They make no reference  
14 to IV push risks as distinct from --

15 JUSTICE SOUTER: And are these -- when you  
16 say "communications," do you mean starting with the  
17 original application for approval of the label?

18 MR. FREDERICK: The original application  
19 actually is not known. It wasn't in Wyeth's files.  
20 This drug was approved in 1955. We don't know where the  
21 original label was, Justice Souter.

22 JUSTICE SOUTER: So, you are saying all the  
23 correspondence that we do know about, that is extant,  
24 fails to mention the comparative risk.

25 MR. FREDERICK: That's correct. And --

1 JUSTICE SCALIA: But the label doesn't. I  
2 mean, the label ask discusses the high risk from IV push  
3 and sets forth particular cautions for that -- for that  
4 specific means of administration.

5 MR. FREDERICK: It does not, Justice Scalia.  
6 The label says -- it's talking about intravenous  
7 administration. It does not distinguish between IV drip  
8 and IV push. And Dr. Matthew testified at trial that,  
9 based on the label, he would not have been able to make  
10 a treatment determination to distinguish between the  
11 two, and that had he had that information, he clearly  
12 would have given this drug to Diana Levine through the  
13 intravenous drip method. The label simply didn't --

14 JUSTICE KENNEDY: If we conclude that new  
15 information is the criterion for deciding this case, if  
16 we reject the argument that misbranding at the outset  
17 allows State law to supplement the duty, but that if  
18 there's new information, then the label has to be  
19 changed -- if it that's the line we draw, can this  
20 verdict be sustained?

21 MR. FREDERICK: Yes, I think it can be  
22 sustained on the basis of --

23 JUSTICE KENNEDY: And the Vermont court's  
24 opinion?

25 MR. FREDERICK: I don't think that the

1 Vermont Supreme Court's opinion totally, because it does  
2 go into the area that you're talking about, Justice  
3 Kennedy, but if I could refer the Court to trial record  
4 testimony, which is set out in the joint appendix and  
5 more elaborately in the trial record itself, which makes  
6 clear that Wyeth knew or should have known about these  
7 comparative risks. It should have had a basis for  
8 changing its label or proposing to FDA a different  
9 label, and that would be sufficient to satisfy the  
10 Federal standards as well as the State duty of due care.  
11 And we think the judgment on that basis could be  
12 sustained.

13 JUSTICE STEVENS: May I ask this: When did  
14 the duty on the part of Wyeth to have a different label  
15 arise, in your view?

16 MR. FREDERICK: I think it probably arose in  
17 the early '70s when a -- when there was a published --  
18 or there was an incident --

19 JUSTICE STEVENS: Did it arise before or  
20 after submitting the original drug application?

21 MR. FREDERICK: A strong argument can be  
22 made that it would have been before the 1970s  
23 application when they were reformatting. These are old  
24 drugs. We don't have evidence from the 1950s that would  
25 have suggested that the original label determination in

1 1955 would have caused a difference but certainly by the  
2 1970s when -- when Wyeth was reformatting this as an old  
3 drug to comply with new standards, it should have known  
4 and it certainly should have known by the 1990s when  
5 several amputations had occurred from IV push Phenergan,  
6 which were in Wyeth's files. The people who analyzed  
7 these records, you know, were emphatic that Wyeth knew  
8 or should have known by the 1990s. And that was clear  
9 by the testimony of experts that said -- that showed the  
10 comparison between Vistrol and Phenergan and on the  
11 basis of the IV push injuries that had occurred that  
12 were nonpublished. They appeared to have been reported  
13 to FDA, but Wyeth never took the trouble to do the  
14 synthesis, to connect the dots between these very  
15 terrible tragedies that had occurred from its drug, to  
16 bring about a labeling change or a modification that  
17 would have saved lives. And that is a failure on the  
18 part of the manufacturer not to comply with its  
19 standards of due care and with the regulations which  
20 require health risk information to be the basis of  
21 modifications to the labeling.

22 JUSTICE STEVENS: Does that boil down to a  
23 claim that there was new information that was available  
24 between the original approval and the time of the  
25 lawsuit?

1                   MR. FREDERICK: Well, by "original  
2 approval," do you mean 1955 or do you mean in 1998 and  
3 2000?

4                   JUSTICE STEVENS: Either one. But is your  
5 theory really a theory based on new information or new  
6 judgment about old information?

7                   MR. FREDERICK: It would be on the basis, I  
8 think, of both. I think we would be able to establish  
9 that there was a justification on the basis of  
10 information before the reformatted labeling took place,  
11 and that was testimony by Dr. Green at trial on the  
12 basis of Vistrol, the other amputation that had occurred  
13 with Phenergan in 1965.

14                   And the -- the important point here is that  
15 on the basis of new information, if you are going to  
16 conclude that there is a standard that has to be met, I  
17 would urge you to consider two things: One is that the  
18 burden of showing absence of new information is going to  
19 fall on the manufacturer because it is asserting a  
20 pre-emption defense, but the way pre-emption gets argued  
21 in the courts, it is done oftentimes before discovery is  
22 committed. So, if there is information in the drug  
23 manufacturer's files that would be relevant to a  
24 determination of the breach of duty by the drug  
25 manufacturer, if you decide pre-emption has to be done

1 before discovery can be done, there would be no way to  
2 get that information.

3 JUSTICE KENNEDY: Well, to put the burden on  
4 the manufacturer seems to me inconsistent with what 10  
5 States have said, that there is a rebuttable presumption  
6 and inconsistent also with the instructions the jury  
7 received in this case, that you can consider the FDA  
8 label. So, I think, to me, what you say there is not  
9 borne out by what happened in this case or by those  
10 other States' --

11 MR. FREDERICK: Well, let me -- let me  
12 address that question because your question goes to the  
13 regulatory compliance defense and that is not a  
14 pre-emption defense. It is a defense based on State law  
15 that the manufacturer in fact was not negligent because  
16 it complied with the applicable regulations. In that --  
17 under that scenario, Justice Kennedy, the plaintiff is  
18 going to be able to obtain discovery and make arguments  
19 to the trial court about whether or not that compliance  
20 negated or did not negate negligence. But pre-emption  
21 is a Federal defense that would be asserted typically at  
22 the outset of the lawsuit before information is  
23 obtained. And notably, before 2000, FDA did not have  
24 subpoena power of drug manufacturers. It did not have  
25 the power to force labeling changes. It didn't even

1 have the power to force drug manufacturers to make  
2 post-marketing studies.

3 JUSTICE BREYER: The --the part I'm trying  
4 to figure out is this: Suppose it was before trial. I  
5 don't care, before or after. The plaintiff comes in  
6 with a claim. All right. Manufacturer: That's  
7 pre-empted. The claim is that you should have told the  
8 FDA and added something to your label.  
9 Manufacturer: That's preempted. Plaintiff: Well, you  
10 haven't read this reg here. The reg here which has been  
11 in existence since 1965 says that we can go and add  
12 something. I mean you can go and add something to show  
13 a contra indication, and that's the end of it.

14 Now, in fact, 30 years later, I guess,  
15 without the horrible things happening that Justice  
16 Scalia mentioned, or maybe they did -- I don't know.  
17 But 30 years later the FDA makes another mention of new  
18 information. I take it that's in 1982. That's the  
19 first time that happened.

20 Now, if I'm right about that, what happens  
21 when no one says a word about that? Of course, if the  
22 manufacturer had said something about that, then maybe  
23 the plaintiff would have said: And it was new. It was  
24 new, but the manufacturer doesn't say a word. Are you  
25 following what I'm saying?

1           MR. FREDERICK: I'm not totally, Justice  
2 Breyer, I confess, but let me try to address it this  
3 way.

4           JUSTICE BREYER: I mean, I'm wondering still  
5 what happens. I believe what happened here is that in  
6 the argument in the lower courts, in the trial court,  
7 nobody said anything about the FDA's claim that the  
8 information necessary to just go ahead and change the  
9 label had to be new. Am I right about that?

10          MR. FREDERICK: You are absolutely right  
11 about that.

12          JUSTICE BREYER: So what I'm trying to  
13 figure out -- and I don't know if "burden of proof" is  
14 the right word -- where nobody says a word about it, who  
15 wins? If they had said a word about it, you need new  
16 information, maybe the manufacturer -- the plaintiff  
17 could have shown that the manufacturer had new  
18 information.

19          MR. FREDERICK: I think the duty is always  
20 going to be on the manufacturer, Justice Breyer. The  
21 regulations at 314.80(b) establish that the -- that the  
22 manufacturer has the responsibility to do post-  
23 marketing analysis and post-marketing surveys to  
24 determine the continuing safety of its drugs. If the  
25 manufacturer doesn't do that, it isn't complying with

1 the Federal regulations which have an ongoing duty on  
2 them.

3 And so in the case where there is silence, I  
4 would respectfully submit the manufacturer is not  
5 complying with its regulatory duty to ensure that there  
6 is current information about all of the side-effect  
7 risks of its drugs.

8 Thank you.

9 CHIEF JUSTICE ROBERTS: Thank you, counsel.  
10 Mr. Waxman, you have three minutes remaining.

11 REBUTTAL ARGUMENT OF SETH P. WAXMAN

12 ON BEHALF OF THE PETITIONER

13 MR. WAXMAN: Thank you, Mr. Chief Justice.

14 I want to make -- I do want to go to -- make a  
15 preliminary point about all the talk about misbranding  
16 here. The statute has two criminal prohibitions. One  
17 is misbranding, which is the original 1906 reactive  
18 penalty. If the FDA subsequently finds that something  
19 is false or misleading, it can come after you for  
20 misbranding. But this case involves the criminal  
21 prohibition against distributing drugs for which there  
22 is not an approved, effective application. And that's  
23 what's at stake here.

24 Now, the notion that there was any -- any  
25 misunderstanding in the trial court about whether there

1 was new information or whether there was -- there were  
2 incidents that the FDA didn't know about, or it didn't  
3 evaluate the risk, is just flat wrong. The plaintiff  
4 tried this -- the plaintiff's experts said the FDA knew  
5 about this risk. Wyeth knew about this risk for  
6 decades.

7           That is what is so wrong. That is why he  
8 stood up and said the FDA doesn't decide this question.  
9 You decide this question. And there was never, ever a  
10 suggestion in the record in this case, nor could there  
11 have been, that Wyeth ever failed to bring every single  
12 adverse-event report to the FDA's attention, every  
13 analysis that it did to the FDA's attention.

14           And what the record does show is that after  
15 -- between the time of the 1955 approval of the new-drug  
16 application and the 1998 rejection of the SDNA, the  
17 Supplemental New -- SNDA, the Supplemental New Drug  
18 Application, that did have more extensive, stronger  
19 warnings in this case, Wyeth filed five -- and these are  
20 all in the joint appendix -- five supplemental, new-drug  
21 applications, each one asking for more language, more  
22 warnings, about direct IV injection. It's not called  
23 "push." It's IV injection versus drip, which is a  
24 gravity method. And, in fact, Mr. Frederick  
25 says: Well, you know, in this case there could have

1 been stronger warnings, and that -- and this case wasn't  
2 really about -- the jury wasn't really asked to -- it  
3 didn't really say that the label had to contra indicate  
4 something that the FDA-labeling required.

5 That is exactly the opposite of what the  
6 trial lawyer told the jury at opening and at closing.  
7 What he said is this was unreasonably unsafe because it  
8 didn't say: Do not use by intravenous administration.

9 With respect to whether or not the warning  
10 -- the last SNDA that we submitted, which was in 1987  
11 and is reprinted in the joint appendix -- not only is it  
12 an original, but there is a typewritten version that  
13 actually has the text in the type size that one can  
14 actually read. At the summary-judgment stage that the  
15 pre-emption issue was decided -- may I finish my answer?

16 CHIEF JUSTICE ROBERTS: Sure.

17 MR. WAXMAN: Summary judgment was decided at  
18 the -- pre-emption was decided at summary judgment  
19 before trial. So there was no evidence about what was  
20 new or wasn't new. In Ms. Levine's motion for summary  
21 judgment, she uses the word "new" information about  
22 labeling change. And, with respect to the proposed 1987  
23 language, the '88 change that we asked for, she said --  
24 and I'm reading from page 24 of her motion for summary  
25 judgment -- "In 1988, Wyeth drafted changes to the

1 warning which advised that the use of a free-flowing IV  
2 would ensure adequate dilution and reduce the risk of  
3 arterial injectia. Although not strong enough, this  
4 improved the labeling instruction; if followed, would  
5 have prevented the inadvertent administration of  
6 Phenergan into an artery for the reasons described."

7 CHIEF JUSTICE ROBERTS: Thank you, counsel.  
8 The case is submitted.

9 (Whereupon, at 11:08 a.m., the case in the  
10 above-entitled matter was submitted.)

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