

1	C O N T E N T S	
2	ORAL ARGUMENT OF	PAGE
3	SETH P. WAXMAN, ESQ.	
4	On behalf of the Petitioner	3
5	EDWIN S. KNEEDLER, ESQ.	
6	On behalf of the United States, as amicus	
7	curiae, supporting the Petitioner	14
8	DAVID C. FREDERICK, ESQ.	
9	On behalf of the Respondent	24
10	REBUTTAL ARGUMENT OF	
11	SETH P. WAXMAN, ESQ.	
12	On behalf of the Petitioner	51
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		

1 P R O C E E D I N G S

2 (10:06 a.m.)

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

5 Mr. Waxman.

6 ORAL ARGUMENT OF SETH P. WAXMAN

7 ON BEHALF OF THE PETITIONER

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

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

20 JUSTICE KENNEDY: Just at the outset, I'll
21 just make one comment. You argue that it's impossible
22 for Wyeth to comply with the State law and at the same
23 time the Federal label. As a textual matter, as a
24 logical matter, I just -- I don't understand that. I
25 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 discreetly 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 reference 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 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 to allow medical
25 professionals to make their judgments, 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 what the relevant risks are is, is
6 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 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? In other words, are they
10 saying you must have done so, or are they saying because
11 you could have done so and didn't you did not conform to
12 the 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 this 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 --

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 a certain number
9 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, 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 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 -- 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 KENNEDY: 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 KENNEDY: -- showing increased
11 frequency or increased severity?

12 MR. KNEEDLER: That's correct.

13 JUSTICE KENNEDY: Right?

14 And supposedly, it was burden of the drug
15 company to show --

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 JUSTICE KENNEDY: 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, 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 if 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 comes wrong. That's
25 having the effect, as our case has established, 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's 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 that 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 -- 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 risk or reassessing the risk, 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 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 developed 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: In other words, 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 liability.

25 MR. FREDERICK: Well, if --

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 do 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 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 -- 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 permitted. 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 which 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, the case was submitted.)
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able 7:24 44:9 47:8 48:18 above-entitled 1:11 absence 11:16 11:17 13:15 47:18 absent 40:20 absolutely 34:20 50:10 accept 33:7 account 21:4 accrual 33:9 acknowledge 42:11 act 10:4,6,8 11:2 11:3 18:19 21:20 33:13 acted 17:20 18:5 26:19 27:5 action 18:4 23:14 actions 10:8,11 10:14 add 35:7 49:11 49:12 added 49:8 addendum 24:15 addition 38:6 address 7:14 9:10 10:10 19:9 21:3 42:3 48:12 50:2 addressed 7:12 22:21,23 25:10 25:19 addresses 42:1 adequacy 40:17 adequate 36:6,7 36:25 39:4 54:2 adjunct 15:9 administered 5:4 6:20 27:9 administering	26:23 administration 4:19 5:17 6:5,7 6:16 7:15,25 8:14 10:2 25:23 29:10 36:10 41:6 42:14 44:4,7 53:8 54:5 administrative 9:7 23:15 admit 39:9 adulteration 16:6 advance 13:16 21:22 adverse 19:3 28:4 adverse-event 52:12 advised 54:1 advisory 6:17,17 21:8 affect 11:18 agency 24:6 agree 4:6,8 22:19,20 40:24 ahead 29:23 50:8 al 28:16 33:18 Alito 6:23 7:4 25:2 33:23 34:11 40:24 allow 8:24 11:25 13:1 42:20 allowed 29:11 allows 44:17 alter 16:10 alteration 4:3 alterations 35:12 altogether 16:22 amend 34:24 amendment 19:16 amendments 18:19 19:5	amici 10:13 15:18 amicus 1:19 2:6 14:20 28:16 33:18 ample 8:9 amputation 7:19 47:12 amputations 31:3 46:5 analyses 13:15 analysis 11:21 33:17 43:7 50:23 52:13 analytically 34:16 analyzed 46:6 answer 7:17 25:2 37:23 39:17 41:17 53:15 anti 17:2 antinausea 31:2 Apart 43:7 apparent 30:19 30:22 apparently 21:13 APPEARAN... 1:14 appeared 46:12 appears 34:1 appendix 5:22 5:23 31:3 32:13 42:5 43:13 45:4 52:20 53:11 applicable 48:16 applicant 24:17 application 4:14 24:6 36:10 43:17,18 45:20 45:23 51:22 52:16,18 applications 52:21 applied 10:17	13:3 applies 36:11 apply 5:24 applying 11:21 approval 13:17 18:11 21:21 22:2 23:11 24:1,18 28:22 36:15 38:25 43:17 46:24 47:2 52:15 approve 21:25 approved 3:13 10:19 12:3,17 13:20 15:8 17:9 18:7,23 22:24 25:5 26:17 34:21 36:12 37:7,11 43:20 51:22 approves 27:22 37:24 approving 4:14 12:18 23:16 area 9:10,11,11 9:16 45:2 argue 3:21 argued 20:22,24 21:2,10 47:20 arguing 15:22 16:14 18:15 argument 1:12 2:2,10 3:3,6 12:22,22 13:6 13:12 14:18 24:10 33:12 34:11 42:23 44:16 45:21 50:6 51:11 arguments 34:2 48:18 arising 17:9 arose 45:16 arterial 6:13,18 8:12 22:22 41:15,20 54:3 artery 32:25	54:6 articulated 4:10 asked 6:17 11:23 14:4 31:11,15 41:9 53:2,23 asking 52:21 aspiration 6:9 asserted 48:21 asserting 47:19 assertion 38:17 assessing 34:19 assessment 37:3 association 24:20 25:8 attention 16:12 17:10,13,19 18:17 52:12,13 authority 18:23 18:25 authorized 17:20,22 automatically 34:24 available 8:22 29:14 46:23 aware 5:2,16 25:22 a.m 1:13 3:2
				B
				B 14:2 back 10:13 12:5 12:13 14:4 17:16 31:10 32:23 43:12 background 10:7,11 bag 5:4 bags 42:10 balance 11:6 14:15 21:23,24 22:5 balancing 9:22 9:25 35:21 39:2 41:8 based 12:6

14:25 16:24 17:15 27:6 38:1 39:8 44:9 47:5 48:14 basis 27:23 31:19 34:8,18 36:18 38:14,24 38:24,25 44:22 45:7,11 46:11 46:20 47:7,9 47:12,15 bearing 27:13 27:15 28:19 bears 36:6 beef 32:1 behalf 1:15,18 1:21 2:4,6,9,12 3:7 14:19 24:11 51:12 believe 10:22 35:20 50:5 benefit 6:25 7:19,20 8:4 26:13 benefited 35:25 benefiting 36:1 benefits 8:1 9:25 21:23 22:21 28:20 29:12 32:6 35:21 42:16,21 better 9:1,2 beyond 38:9 blood 6:9,13 8:12 board 4:25 boil 46:22 borne 48:9 box 16:7 breach 47:24 Breyer 19:11,17 19:20 20:4,8 20:13,23 21:7 21:17 49:3 50:2,4,12,20 brief 5:9,9,24 7:13 9:21	24:15 28:16 31:21 33:18 36:23 briefs 15:6 bright 6:10 bring 16:11 39:20 46:16 52:11 broad 11:21 39:16 brought 10:14 17:10,13,19 18:17 20:14,15 22:8 Brown 21:24 Budhwani 28:16 33:18 burden 20:16 21:12 22:14 28:14 47:18 48:3 50:13 C C 1:21 2:1,8 3:1 24:10 call 29:1,1 called 31:2 52:22 calls 36:5 candle 26:8 care 14:12 27:5 30:14 42:22 45:10 46:19 49:5 cascading 8:13 case 3:4,10 5:20 6:6,12 7:5 9:7 9:17 10:17 11:22 12:15 14:2 15:6 20:12 21:8,9 21:12,14 23:2 29:20,25 30:8 31:10 32:19 35:4 40:15,25 41:1,8 44:15 48:7,9 51:3,20	52:10,19,25 53:1 54:8,9 cases 10:13,15 10:22,24,25 11:9 20:9 26:8 31:4 catastrophic 25:25 26:12 29:8 42:18 causal 24:21 cause 33:1 caused 31:3 46:1 cautions 6:8 44:3 CEE 33:22 ceiling 37:11 Center 19:8 central 15:5 certain 5:2 19:12 20:8,19 21:9 35:24 certainly 8:6 21:5 25:22 46:1,4 chances 35:4 change 13:16 14:1 15:7,13 15:16 17:6,11 17:20 18:13,24 20:3 22:4 23:4 23:25,25 30:3 30:18,22 31:7 31:22 33:22 34:18 35:10 46:16 50:8 53:22,23 changed 12:8 14:6 44:19 changes 19:15 31:23 48:25 53:25 changing 18:1 23:17,22,22 45:8 Chief 3:3,8 9:9 9:15 10:3 14:16,22 24:7	24:12 25:17 26:1,10 29:9 29:16,22 30:3 30:8,13 31:8 41:13,23,24 51:9,13 53:16 54:7 children 36:8 Cipollone 10:23 circumstances 7:6,14 9:8 26:3 40:8 citations 7:11 cite 5:6 36:22 cited 7:13 claim 5:1 16:24 20:10,11 29:18 34:5,5,10,13 39:20 40:13 46:23 49:6,7 50:7 claims 14:25 clarify 15:5 class 9:19 clause 3:11 9:12 10:12 11:15,17 clauses 11:16 clear 5:8 25:16 26:23 28:13 33:7 34:17,20 38:13 45:6 46:8 clearly 33:24 43:4 44:11 client 27:1 client's 27:2 clinical 19:1,6 27:23 clinicians 8:8 close 40:15 closing 4:18 53:6 come 11:1,1 17:2 30:4 33:3 34:17 42:25 43:1,8 51:19 comes 29:20,24	49:5 comment 3:21 31:19 committee 6:17 common 11:8 23:19 communicating 42:6 communicatio... 42:5 43:11,16 company 12:5 22:15,16 43:12 comparative 25:15 42:16,24 43:24 45:7 compare 29:5 compared 26:13 comparison 32:15 46:10 complaint 4:17 completely 3:25 compliance 48:13,19 complicated 20:19 complied 48:16 comply 3:22 4:11 46:3,18 complying 50:25 51:5 comprehended 6:14 concentrate 40:23 concentration 32:25 concept 40:8 concerned 8:4 11:20 concerning 24:25 concerns 3:10 conclude 11:24 44:14 47:16 concluded 6:24 33:25 conclusion
--	--	---	--	--

10:21 conditions 3:14 10:1 15:2 28:2 36:8 conduct 11:11 conducts 35:9 confess 50:2 conflict 3:10,11 11:18,22 12:14 12:23 13:1,7 13:11,14,18 15:1 16:4 17:11,17 31:18 conform 14:11 Congress 11:2 18:19 21:21 35:22 36:3 39:1 connect 46:14 consequence 39:24 consider 5:3 30:11 38:14 43:2,4,9 47:17 48:7 consideration 26:3 41:4,5,14 considered 3:17 16:10 25:9,11 25:14,20,24 28:9 33:24 34:8 41:19 42:9,24 considering 18:9 consistent 4:1 constellation 8:1 11:8 constitutes 33:15 Constitution 11:19 consumers 15:10 contain 23:7 context 6:11,12 7:10	continuing 50:24 contra 4:20 49:13 53:3 contradicting 26:16 contraindicated 33:25 contraindicati... 19:23 contrary 36:3 contrast 9:13 contra-indicate 4:20 correct 22:12 34:25 40:5 43:25 correspondence 7:9 43:23 corresponding 42:21 costs 35:21 counsel 14:16 51:9 54:7 count 10:24 couple 27:24 course 9:12 49:21 court 1:1,12 3:9 9:18 10:17,20 11:20 14:23 20:25 21:3,23 23:8 29:21 32:12 41:23,25 45:3 48:19 50:6 51:25 courts 27:19 47:21 50:6 court's 29:4 44:23 45:1 cover 16:14 create 42:21 created 31:17 creating 29:7 criminal 51:16 51:20 criterion 44:15	crucial 32:9 42:17 curiae 1:19 2:7 14:20 current 51:6 D D 3:1 danger 38:1 dangerous 3:19 28:12,13 36:8 dark 6:10 data 9:23 12:7 19:2 33:17 DAVID 1:21 2:8 24:10 day 13:23 22:3 34:3 37:24 decades 52:6 decide 8:7 9:3 14:4 47:25 52:8,9 decided 10:25 13:19 21:14 53:15,17,18 deciding 21:8 42:16 44:15 decision 5:12 deemed 31:22 defense 16:23 47:20 48:13,14 48:14,21 demonstrate 5:7 denied 31:17 Department 1:18 dependent 30:12,13 depends 30:8 33:9 depressant 17:3 Deputy 1:17 described 3:14 54:6 design 3:25 desperate 35:25 determination	9:19 15:1 23:15 26:11,18 36:3 42:20 44:10 45:25 47:24 determinations 35:18 determine 7:24 26:2,7 41:21 50:24 determined 3:17 4:16 39:7 determines 26:9 determining 30:9 developed 37:10 device 9:10,11 9:16 10:8 23:1 devices 9:24 Diana 1:6 44:12 difference 9:16 10:12 13:10 46:1 different 10:21 23:19 25:22 28:2 29:5 32:4 32:5 41:7 45:8 45:14 differently 43:1 43:1,9 difficulties 18:20 dilution 54:2 direct 6:2 7:6 18:23 52:22 directed 7:22,23 directions 36:6 directly 6:22 9:18 disagreed 5:18 disapproval 34:22 disapproves 35:9 disclose 15:11 discolors 6:13 discovered 38:7	discovery 47:21 48:1,18 discreetly 5:3 discretely 42:9 discusses 44:2 dispute 33:14 disputed 27:18 disputes 29:4 distinct 41:6 43:14 distinction 9:10 distinctions 21:11 distinguish 44:7 44:10 distinguishes 41:1 distribute 13:24 distributing 51:21 distribution 11:6 doctor 27:5 doctors 35:17 doctrine 23:15 doing 39:2,3 40:19 dosage 36:9 dots 46:14 doubt 42:13 Dr 27:18 28:16 32:20 33:18 44:8 47:11 drafted 53:25 dramatic 42:19 draw 44:19 drip 5:4 6:4,5 25:15 32:7,21 42:10,17 44:7 44:13 52:23 drug 6:19 7:1,1 8:11,17 9:11 10:1,4,6 11:6 12:1 13:24 17:3,9 18:22 19:8,22 21:22 22:14,16 23:3
--	---	--	---	---

24:18,21 27:9 27:22,22,25 28:4 29:11 30:4,17,19,22 31:2,5 32:25 34:1 36:24,25 39:5,21 42:20 43:20 44:12 45:20 46:3,15 47:22,24 48:24 49:1 52:17 drugs 9:20,24 18:9,10 25:23 28:4 33:3 35:24 45:24 50:24 51:7,21 drug-specific 11:3 due 30:14 45:10 46:19 duration 36:10 duties 14:24 duty 30:14 33:4 34:9 37:20 44:17 45:10,14 47:24 50:19 51:1,5 D.C 1:8,15,18 1:21	13:25 14:13 15:12 20:11,12 22:8 28:22 42:1,3 47:4 elaborately 45:5 electronic 19:2 eliminating 35:24 emphatic 41:23 41:25 42:2 46:7 employees 19:8 enables 35:17 enacted 11:2 enforcement 18:21 ensure 51:5 54:2 entitled 34:23 envision 16:1 35:1 escape 22:17 ESQ 1:15,17,21 2:3,5,8,11 essentially 23:12 32:14 establish 28:8 47:8 50:21 established 8:20 8:21 10:7,11 11:3 24:23 28:5 29:25 establishes 28:17 et 28:16 33:18 evaluate 11:5 52:3 evaluated 15:12 evaluating 3:16 26:7 Evaluation 19:9 event 5:10 events 19:3,18 28:4 evidence 7:8 10:20 24:20 25:8,16,21 29:16 41:11	45:24 53:19 evolving 17:4 exactly 42:21 53:5 example 16:5 17:3 exceeded 6:7 exception 39:16 excess 27:10 excuse 12:4 25:4 existence 15:17 15:21 34:12 49:11 existing 29:20 expected 10:4 experience 12:6 expert 27:6 experts 5:15,18 46:9 52:4 explain 16:16 explained 5:24 19:25 exposure 6:18 8:11 41:15,20 exposures 22:22 express 9:12 10:5 11:14 expressed 11:15 23:7 extant 43:23 extensive 52:18	29:18 40:13 46:17 failure-to-warn 16:24 39:20 40:13 fair 38:11,12,16 fall 47:19 false 51:19 far 28:19 fault 20:17 FDA 3:12,17,18 4:15 5:1,16 6:24 7:8,9,11 8:3,5,5,7,23 9:2,19 10:18 11:5,25,25 12:3,5,17,25 13:2,20,23 15:8,8,14,20 16:18 17:5,7 17:10,19,23 18:3,5,11,20 18:23,25 19:1 19:5,14,25 21:22 22:4,20 22:24 23:4,7 24:1 25:6,9,12 25:14,20,22 26:11,19,20 27:22 28:10,22 28:24,24 29:2 29:6,6 30:10 31:15,20 32:2 32:22 33:8,24 34:3,7,21,22 35:8,9,14 36:12,15,21 37:7,24 38:2,6 38:9,13 39:8 39:22 41:5,9 41:11,18 42:1 42:2,6,13,15 45:8 46:13 48:7,23 49:8 49:17 51:18 52:2,4,8 FDA's 15:1,9,13	17:10,13,19 18:17 20:1 21:5 38:25 50:7 52:12,13 FDA-labeling 53:4 Federal 3:23 4:4 4:12,13 10:4 11:12,19 16:3 17:15 23:13 36:22 39:21 40:20 45:10 48:21 51:1 fewer 10:24 field 11:10 figure 18:10 49:4 50:13 file 23:14 filed 52:19 files 31:5 43:19 46:6 47:23 finally 6:8 11:14 find 20:18 finding 30:14 finds 51:18 finish 53:15 first 3:4 5:14 12:13 17:13 18:15 49:19 five 52:19,20 flat 52:3 floor 37:11 follow 27:1,2 followed 54:4 following 49:25 footnote 5:24 7:13 29:3 32:11 force 23:14,16 48:25 49:1 forget 38:4 form 13:14,18 24:5 forms 5:16 25:23 41:7 forth 19:15 24:15 25:5
E				
E 2:1 3:1,1 earlier 31:10 37:2,24 38:17 early 45:17 easier 14:2 EDWIN 1:17 2:5 14:18 effect 12:25 29:25 51:6 effective 3:13 6:24 15:2 51:22 effectiveness 11:7 efforts 15:10 either 12:6				
		F		
		fact 3:18 12:16 13:1,6 15:8 16:5 17:5 19:12 26:16 31:15,17 36:2 39:19 41:1,3 48:15 49:14 52:24 factual 20:22 31:19 failed 16:17,21 52:11 fails 43:24 failure 16:11		

41:16 43:12 44:3 forward 21:5 33:8 34:17 found 16:8 23:9 28:3 four 5:23 19:6 Frederick 1:21 2:8 24:9,10,12 25:14,21 26:10 26:21 27:4,12 27:17 28:14 29:3,15 30:2 30:12,20,24 31:20 32:4,9 32:11 33:10,14 34:6,15,25 35:15,22 36:2 36:13,17,21 37:5,9,16,19 38:12,19,24 39:11,14,18,25 40:5,9,12,18 40:19,21 41:3 41:22 42:4,11 43:3,6,11,18 43:25 44:5,21 44:25 45:16,21 47:1,7 48:11 50:1,10,19 52:24 free 19:22 free-flowing 54:1 free-wheeling 11:21 frequency 20:7 22:11 frequently 33:3 friends 41:13 fully 10:18 21:3 functioning 32:17 fundamentally 22:1 furnish 16:25 further 16:15	21:16,19 37:25 38:5,8 G G 3:1 game 35:20 gangrene 7:2,18 19:13 GAO 28:3 gee 35:4 37:1 Geier 10:23 general 1:17 15:16,23 28:3 41:20 General's 5:9 31:21 getting 13:17 19:12 37:22 Ginsburg 4:22 4:24 5:5 7:17 7:21 15:4 18:8 42:7 give 12:24 36:16 given 7:25 12:25 18:23,25 32:20 39:8 44:12 go 6:21 7:4 12:16 18:21 21:14 29:23 31:10 45:2 49:11,12 50:8 51:14 goes 9:20 11:13 27:25 32:14 48:12 going 10:13 12:12 17:1 21:5,12 35:13 38:19 47:15,18 48:18 50:20 good 21:4 gravity 6:5 52:24 greater 20:6 greatly 25:24 Green 27:18 32:20 47:11	ground 35:6 guess 49:14 H hand 23:13 hands 35:16 happened 48:9 49:19 50:5 happening 49:15 happens 49:20 50:5 harm 29:8 33:1 harms 33:20 hatch 22:17 hazard 25:9 health 36:9 46:20 healthy 28:1 hear 3:3 heartland 11:23 helped 15:10 helpful 15:9 hierarchy 8:13 high 44:2 hired 19:8 hit 26:6 horrible 49:15 huge 18:9 hypothetical 40:9,24 41:2 I idea 27:20 ideation 17:7 identified 9:15 10:13 identify 17:1 immediately 6:13 implicated 10:16 implied 11:22 important 7:15 18:20 47:14 impose 14:5 imposing 23:19	29:25 impossibility 13:14 impossible 3:21 improved 18:22 54:4 inadequate 29:20 inadvertent 54:5 incident 45:18 incidents 52:2 include 24:19 25:7 includes 26:3 including 3:15 5:15,17 6:21 7:8 inconsistent 14:7 17:14 22:1 48:4,6 increased 22:10 22:11 25:25 indicate 53:3 indicated 7:7 26:9 indicating 37:25 indication 49:13 individualized 35:18 infer 43:2 information 5:12 8:7,22 10:19 11:24 13:15,16,19 15:17 16:9,12 16:18,24 17:4 17:8,9,12 18:12,17 19:13 20:2,5,6,14,15 20:20 21:9 22:7,18 23:5 23:18 24:3,4 30:7 31:5 33:9 33:11,15,16,19 34:9,9,12,13 34:18 35:17	37:3,10,13,14 37:25 38:2,5,6 38:9 39:1,8 44:11,15,18 46:20,23 47:5 47:6,10,15,18 47:22 48:2,22 49:18 50:8,16 50:18 51:6 52:1 53:21 informed 10:18 10:18 infusion 8:18 32:17 inject 8:17 injectia 54:3 injecting 32:16 injection 3:13 3:16 6:19 7:6 8:11,15,16 15:2 31:4 52:22,23 injured 12:18 34:4 injuries 46:11 injury 25:25 27:13 inquiry 9:23 instances 19:6,7 42:12 instructed 29:16 instruction 6:6 28:21 54:4 instructions 40:15 48:6 instructive 23:10 intensive 9:23 13:23 interested 42:2 interim 17:25 interpretation 20:2 intramuscular 8:14 intravenous 8:16 25:23
---	--	--	--	---

32:17 41:7 42:14 44:6,13 53:8 intravenously 6:20 intra-arterial 8:10 investigation 35:9 involved 26:25 involves 51:20 irrelevant 37:4 irresponsible 26:20 irresponsibly 26:20 irritant 6:19 8:11,17 issue 8:6 11:1 24:25 30:9 33:16 53:15 issues 10:25 IV 3:15 4:19,19 4:25,25 5:2,3,3 5:17,25 6:2,8 6:15,22,24 7:6 7:14 8:18,20 12:8 22:21 24:25 25:15,15 25:20,24 26:12 26:25 27:3,11 28:12,19 29:7 31:4,16 32:1,6 32:7,20,21 33:24 41:4,5 41:15,19 42:3 42:6,9,10,12 42:13,16,17,18 43:14 44:2,7,8 46:5,11 52:22 52:23 54:1	journals 7:12 judgment 5:18 45:11 47:6 53:17,18,21,25 judgments 8:8 8:25 jury 3:16 4:16 11:23 12:24 13:3,9,19 14:2 29:13,15 30:10 35:2,5 40:14 48:6 53:2,6 Justice 1:18 3:3 3:8,20 4:9,22 4:24 5:5 6:23 7:4,17,21 8:3,6 9:9,15,21 10:3 12:2,13,21 13:5 14:8,16 14:22 15:4,24 16:8,17 17:18 17:24 18:8 19:11,17,20 20:4,8,13,23 21:7,17 22:6 22:10,13,19 23:21 24:2,7 24:13 25:2,4 25:17 26:1,10 26:15,22 27:8 27:15 28:5,23 29:8,9,16,22 30:3,8,13,16 30:21 31:8,9 31:11,24 32:8 32:10 33:6,11 33:23 34:11,23 35:1,15,19,23 36:11,15,19 37:1,6,12,17 37:22,22 38:16 38:20,21,23 39:6,13,15,17 39:23 40:1,7 40:11,18,21,24 41:13,23,24 42:7,23 43:5,7	43:15,21,22 44:1,5,14,23 45:2,13,19 46:22 47:4 48:3,17 49:3 49:15 50:1,4 50:12,20 51:9 51:13 53:16 54:7 justification 47:9 justified 33:22 justifies 15:18 justify 20:3	49:16 50:13 52:2,25 knowledge 15:15 known 8:18 24:24 28:4,18 32:17 33:20,21 43:19 45:6 46:3,4,8	34:24 35:10 36:6 41:16 46:16,21 47:10 48:25 53:22 54:4 labels 30:4 33:4 laid 41:16 language 11:24 12:19 13:25 52:21 53:23 larger 29:17 lavish 8:10 law 3:22 4:4,12 4:12,13 11:9 11:12 14:24 17:15 22:3 23:14,16,19,19 38:15 39:20 40:19,20 44:17 48:14 lawsuit 37:8 46:25 48:22 lawyer 53:6 lead 41:7 learned 19:22 learns 36:24 legal 20:21,23 23:17 legislature 14:3 legislatures 14:3 let's 14:2 level 27:9 Levine 1:6 3:4 12:18 34:4 44:12 Levine's 53:20 liability 12:15 14:9 35:3 38:1 38:8 39:24 license 23:16 licensing 11:6 life-saving 7:1 light 10:1 33:3 lightning 26:6 limitation 30:1 limited 38:25 line 8:19,21
J joint 5:22 31:3 32:13 42:4 43:13 45:4 52:20 53:11		K keep 34:16 Kennedy 3:20 4:9 8:3,6 22:6 22:10,13,19 23:21 44:14,23 45:3 48:3,17 Kennedy's 12:13 kind 12:24 21:9 38:2 41:7 42:22 kinds 20:19 33:2 Kneedler 1:17 2:5 14:17,18 14:22 15:4,14 16:2,13,21 17:22 18:3,14 19:14,19,25 20:5,10,21,24 21:15,19 22:9 22:12,16,23 23:24 24:4,8 25:19 42:8 knew 24:24 31:6 38:2 42:13 45:6 46:7 52:4 52:5 know 28:11 30:25 31:1 41:24 43:9,20 43:23 46:7	L label 3:23,25 4:4 4:14,16,20 6:9 10:21 12:3,7 12:17,18 13:6 13:9 14:1 15:16 16:19 17:21 18:1,13 18:24 23:23,25 24:18 25:18 26:16,17 27:20 27:22 28:22,24 28:25 29:5,11 29:23 30:1,2,6 31:7,15,25 32:4 34:1,18 35:6,7,10,12 36:5,23 37:10 37:20,21,25 39:4 41:12 43:17,21 44:1 44:2,6,9,13,18 45:8,9,14,25 48:8 49:8 50:9 53:3 labeling 3:15,18 5:11,12,19,19 6:14 7:22,23 8:13,24 10:2 10:19 13:20 14:6 15:3 16:10 17:6,23 19:7 22:4,24 23:2,3 24:16 25:5,10 26:22 27:2,3,10 28:8 28:11 29:13	

44:19 live 30:15 lives 46:17 logical 3:24 4:5 long 19:17 long-standing 20:2 look 6:18 7:8 11:23 13:9,9 21:22 40:14 41:18 looked 22:25 29:6 looking 10:20 lose 41:20,21 lot 33:19 lots 27:25 28:1 lower 50:6	3:24 4:5,5,6 7:19 13:7 15:16,23 Matthew 44:8 maximum 6:5 mean 7:3 9:14 11:9 16:17 18:6,10 25:10 26:5 28:6,11 30:21 35:13 38:18 39:12,21 42:1 43:16 44:2 47:2,2 49:12 50:4 means 20:5 25:6 26:7 41:6 44:4 medical 7:12,22 8:24 9:10,11 9:16,23 10:8 32:18 medically 9:6 medicine 26:24 meets 4:1 members 11:20 mention 16:5 43:24 49:17 mentioned 16:2 35:11 49:16 met 47:16 method 7:24,25 8:15 26:9,23 42:13 44:13 52:24 methods 3:14 8:14 10:1 36:9 microscopic 5:20 million 29:24 minutes 51:10 misbranded 36:5,13,23 37:14 38:18,22 39:5,21 40:3 misbranding 36:4,20 39:7,7 39:24 40:7,14 40:16,22 44:16	51:15,17,20 misleading 51:19 misunderstan... 51:25 misunderstands 27:21 modification 46:16 modifications 46:21 modify 31:15 moment 38:5 Monday 1:9 monitoring 18:11 30:6 morning 3:4 motion 53:20,24 moved 28:21 multiple 5:15 muscular 26:24 mush 25:12	46:13 52:9 new 13:15,15 15:17 16:9,11 16:18,24 17:8 18:12,17,20 19:1,8,13,22 20:2,4,5,5,14 20:15,19 21:9 22:7,18 23:5 23:17 24:3,4,5 28:2,6,6 30:4 30:10,16,18,22 33:9,11,15,16 33:17 34:12,13 37:3,3,13,14 38:4 44:14,18 46:3,23 47:5,5 47:15,18 49:17 49:23,24 50:9 50:15,17 52:1 52:17,17 53:20 53:20,21 new-drug 52:15 52:20 nonpublished 46:12 nonsubstantive 31:22 32:23 non-pre-empted 34:5 notably 48:23 noted 21:1 notification 19:2 33:16 51:24 November 1:9 number 18:9 19:12 20:8 35:12	obtain 48:18 obtained 24:18 48:23 occur 38:4 occurred 35:3 46:5,11,15 47:12 occurs 8:20 35:10 offered 28:20 oftentimes 47:21 oh 42:9 okay 21:10,15 39:6,13 40:7 40:11 old 13:16 33:12 38:7 45:23 46:2 47:6 once 15:8,12 ones 7:13 ongoing 51:1 opening 4:17 25:11 53:6 operation 11:18 35:14 opinion 9:22 21:8 29:4 32:12 44:24 45:1 opposed 22:21 41:15,19 opposite 53:5 options 8:25 oral 1:11 2:2 3:6 14:18 24:10 order 18:25 ordered 19:1,6,7 ordinary 6:9 original 36:23 37:10 43:17,18 43:21 45:20,25 46:24 47:1 51:17 53:12 ought 12:8 16:10 outset 3:20 15:5
M magnitude 35:3 making 17:4 21:7 37:2 manufacturer 15:16 19:22 20:16 21:12 22:3 28:18 30:5,14,25,25 33:5 34:17 36:24 37:20 46:18 47:19,25 48:4,15 49:6,9 49:22,24 50:16 50:17,20,22,25 51:4 manufacturers 13:25 15:11 30:3,18 35:2 48:24 49:1 manufacturer's 20:17 47:23 market 33:4 marketed 27:25 marketing 36:18,20 50:23 massive 35:14 matter 1:11 3:23		N N 2:1,1 3:1 name 35:20 nature 9:18 nausea 7:1 necessarily 26:3 necessary 50:8 need 24:21 33:4 35:25 50:15 needle 6:11 needles 6:3 needs 22:25 negate 48:20 negated 48:20 negates 16:19 negligence 14:9 14:13 48:20 negligent 27:6 48:15 negligible 28:20 29:8 never 8:3 11:1,1 15:15 17:12 25:14,24 42:15	O O 2:1 3:1 objects-and-p... 13:18 obligation 14:5 23:20 31:10 33:8,13	

44:16 48:22 outweigh 7:20 28:19	pharmaceutic... 10:15 Phenergan 3:13 3:19 6:13,19 8:12 15:1 31:7 33:20 46:5,10 47:13 54:6 physician 26:9 27:2 physicians 7:23 8:13,23 9:1,3 29:14 place 17:13 19:18 47:10 plainly 6:14 plaintiff 48:17 49:5,9,23 50:16 52:3 plaintiff's 52:4 please 3:9 14:23 plungers 6:3 point 5:8 7:15 11:14 18:18 19:4 20:14,15 21:20 23:6 27:18 29:4 31:12 32:9 33:2 37:23 40:6,12,22 42:14,17 47:14 51:15 pointed 9:21 23:10 points 9:18,22 18:14 33:18 policy 15:7,13 36:3 portions 5:6 25:18 position 15:15 16:13 33:8 37:18,19 38:11 39:9 possibility 17:7 possible 4:10 post 50:22 postdate 10:23	post-date 10:22 post-market 30:7 post-marketing 19:9 49:2 50:23 power 18:2 48:24,25 49:1 practitioners 32:19 preceding 30:17 precise 3:17 4:14 11:24 precisely 6:18 preclearance 9:20 11:4 preclude 11:11 predicated 12:16 34:12 38:8 preempted 49:9 preemption 5:10 11:10 22:18 23:1,3,8 23:9 preferability 32:16 preferable 8:17 preferred 8:15 26:23 preliminary 51:15 premarket 23:11 prescribe 29:19 prescribed 10:2 34:1 prescription 27:3 presence 11:15 11:16 presented 3:11 12:20 23:2,4 30:10 presumption 48:5 prevented 54:5	pre-empted 14:14,25 15:23 20:17 22:17 34:6,7,14 38:3 49:7 pre-emption 3:10 9:12 10:5 10:12 11:15,16 11:18,22 13:18 16:15,23 17:12 18:16 38:3,10 39:10,12,19 40:2,23,25 41:9 47:20,20 47:25 48:14,20 53:15,18 primarily 15:19 prior 21:21 22:2 32:23 33:17 probably 45:16 problem 7:12 18:21 problems 28:2,6 28:6,9 proceedings 15:20 process 9:20 13:23 23:11 27:21 prodged 15:11 product 16:6,7 36:18 professionals 7:22 8:25 prohibit 23:4 prohibited 35:6 prohibition 23:17 51:21 prohibitions 51:16 promote 35:16 35:19 promulgated 20:1 proof 50:13 properly 8:19 16:9	proposed 12:19 17:11,16 28:23 35:13 53:22 proposing 45:8 proposition 15:22 protect 15:10 protection 36:16 proved 24:22 provide 8:7 16:18,22 30:5 provided 7:11 7:11 8:9,12 40:17 provides 36:17 providing 40:20 provision 10:5 23:8,9 36:4 40:14,16 provisions 16:19 prudent 28:17 public 35:16,19 36:1 39:1,3,4 published 45:17 purely 40:8 purposes 9:17 push 3:15 4:19 4:25 5:3,17,25 6:2,8,11,15,22 6:24 7:14 8:20 12:8 22:21 24:25 25:15,20 25:24 26:12,25 27:3,11 28:12 28:19 29:7 31:4,16 32:2,7 32:21 33:24 41:4,6,15,19 42:3,6,9,12,13 42:16,18 43:14 44:2,8 46:5,11 52:23 put 19:23 32:25 40:22 41:10,12 42:15 48:3 puts 33:8 35:16
--	---	--	---	--

Q qualifications 37:2 question 5:11,13 7:18 12:13 20:21,23 25:3 30:24 31:11 37:24 48:12,12 52:8,9 quite 41:23	recommenda... 6:21,21 recommended 15:3 record 5:6,14 7:8 9:8 20:11 25:18 33:23 41:18 42:1 45:3,5 52:10 52:14 records 46:7 recovery 40:3 reduce 54:2 refer 45:3 reference 5:23 6:1,3,4 29:7 43:13 referenced 34:3 references 42:8 42:12 referred 3:15 6:8 15:21 30:16 reflects 9:25 reformatted 47:10 reformatting 45:23 46:2 reg 21:10 49:10 49:10 regardless 31:24 regime 11:4 21:6 22:2 Register 36:22 regulated 4:11 regulation 19:16 19:21 20:1,18 24:14 regulations 23:4 30:5 33:22 34:20 46:19 48:16 50:21 51:1 regulatory 21:5 48:13 51:5 reject 32:2 38:14 44:16	rejected 12:19 17:8,16 27:19 32:22 34:8 rejection 13:2 41:4 52:16 rejects 17:10,23 17:23 relationship 24:21 relative 32:6 relevant 9:5 47:23 reliable 6:12 relied 15:19 relieves 7:1 remaining 51:10 remedies 11:11 15:21,22 remedy 15:25 16:11 40:20 remember 12:17 removed 31:4 rendered 3:19 12:1 Repeatedly 3:12 reply 5:24 7:13 report 52:12 reported 46:12 representing 25:19 represents 15:7 reprinted 53:11 reproduced 5:20 request 31:16,25 require 22:3 38:13 46:20 required 3:18 4:13,15 11:5 11:25 12:2 13:20 53:4 requirements 4:1 requires 5:19 24:1 Research 19:9	reserve 14:15 resources 18:21 respect 8:16 9:15,19 10:15 31:9 53:9,22 respectfully 51:4 responded 31:12 38:23 Respondent 1:22 2:9 10:12 21:1,1 24:11 Respondents 4:2 15:18 Respondent's 14:24 response 21:17 31:18 responsibility 50:22 responsible 30:6 restrictive 28:24 rethinking 12:7 retract 38:17,19 revise 28:21 33:4 revised 24:17,19 25:6 revision 15:18 19:7 Riegel 9:17,22 Riegle 23:1,7,7,9 right 13:4,11,13 22:9,13 30:23 49:6,20 50:9 50:10,14 rigid 6:3 risk 3:16 5:2,17 6:18 7:2,2,18 7:20 8:10 19:14 20:6 24:20 25:24 26:4,5 29:7 30:9,10 34:19 34:19 35:18 43:24 44:2 46:20 52:3,5,5	54:2 risks 6:15 8:1,4 9:5,25 15:11 22:21,22 25:1 25:5,15,20,25 26:12,25 28:19 29:7,12 30:4 30:17,19,22 32:6 33:2 41:19 42:6,16 42:18,20,24 43:14 45:7 51:7 risk-benefit 41:8 road 14:1 ROBERTS 3:3 9:9 10:3 14:16 24:7 25:17 26:1 29:9,22 30:8 31:8 41:13,24 51:9 53:16 54:7 rule 10:16 11:10 13:3,3 17:4 23:18 rule-making 15:19 ruling 34:3 run 13:25 running 8:18 Rutherford 21:24
R R 3:1 raise 12:11 raised 21:2 raises 33:12 rate 6:5,7 23:14 reach 10:21 reactive 51:17 read 19:20 20:18 21:10 25:10 49:10 53:14 reading 53:24 reads 24:16 real 35:25 really 11:4 18:11 47:5 53:2,2,3 reason 10:5 12:11,23 23:8 34:7 reasonable 24:20 25:8 42:19 reasonably 28:17 reasons 32:23 39:2 54:6 reassessing 34:19 rebuttable 48:5 REBUTTAL 2:10 51:11 received 48:7 recognized 18:19				S S 1:17 2:1,5 3:1 14:18 safe 3:13 6:24 15:2 26:2,4 36:25 37:14,20 38:18,22 safely 27:11 safety 11:5,7 35:16,20 39:1 39:3,5 42:19 50:24 salient 9:17

saliently 5:19	31:25	situation 15:25	state 3:16,22	54:8,9
satisfactorily	sense 29:18	16:14,15 17:2	4:12 10:7,11	submitting
32:18	sent 7:9	17:3 18:16	14:2,3,3,24	45:20
satisfy 45:9	sentence 24:16	19:10 21:4,21	16:3 17:25	subpoena 48:24
saved 46:17	25:6 30:17	situations 23:11	22:3 23:18	subsequently
savings 11:17	separate 5:23	size 5:21 53:13	29:18 34:10	36:24 51:18
saying 11:13	separately 42:3	small 27:23	38:15 39:20	substantial 7:20
12:23 14:10,10	serious 24:20	small-bore 6:3	40:4,19 44:17	sue 26:20
29:1 30:18	25:8 26:25	SNDA 52:17	45:10 48:14	sued 16:20
35:4 36:15	27:16	53:10	stated 4:17	sufficient 45:9
37:6,9 38:3	set 8:18 19:1,15	snippets 15:19	statement 4:18	suggest 29:13
40:2 43:22	24:15 25:5	Solicitor 1:17	38:11,16 39:16	32:18,20 42:12
49:25	27:20 30:3	5:9 31:21	States 1:1,12,19	suggested 15:3
says 12:25 13:23	32:11,12,17,24	somewhat 29:17	2:6 14:19 48:5	45:25
22:16 28:11	43:13 45:4	soon 24:19 25:7	48:10	suggestion
29:5,19,22	SETH 1:15 2:3	25:7	statute 51:16	52:10
32:24 41:11	2:11 3:6 51:11	sort 5:20	STEVENS	suicidal 17:7
44:6 49:11,21	sets 21:20 44:3	Souter 12:2,21	40:18,21 45:13	suit 17:15 18:1
50:14 52:25	severity 20:6	13:5 14:8 31:9	45:19 46:22	40:4
Scalia 15:24	22:11	31:24 32:8,10	47:4	suits 15:9
16:8,17 17:18	show 20:16	33:6,11 37:22	stone 27:20 30:3	summary 53:17
17:24 24:2	22:15 49:12	38:23 39:6,13	stood 52:8	53:18,20,24
25:4 26:15,22	52:14	39:15,23 40:1	strength 32:5	summary-jud...
27:8,15 28:5	showed 25:21	40:7,11 42:23	strengthen	53:14
28:23 29:8	26:14 27:5,13	43:5,7,15,21	19:23 31:16	supplement
30:16,21 31:11	31:1 33:24	43:22	strengthens	23:22 24:2
34:23 35:1,15	46:9	so-called 39:7	19:23	44:17
35:19,23 36:11	showing 22:10	specific 6:15,20	strict 14:8	supplemental
36:15,19 37:1	47:18	13:2,24 38:14	strict-liability	24:6 52:17,17
37:6,12,17	shown 50:17	41:14 44:4	14:14	52:20
38:16,20,21	side 6:25 7:2	specifically 7:14	strike 21:24	supplemented
39:17 44:1,5	22:8 23:18	22:20,23 25:20	strong 45:21	28:7
49:16	40:22 41:14	41:19	54:3	supporting 1:19
Scalia's 9:22	51:6	sponsor 24:17	stronger 12:19	2:7 14:21
37:23	sides 5:16	squarely 23:20	28:21 41:4,10	suppose 18:6
scenario 48:17	sidewalk 26:5	stage 53:14	52:18 53:1	31:8 33:23
scheme 35:1	significance	stake 51:23	struck 22:4	49:4
scientific 41:11	24:25	standard 10:20	studies 19:1	supposedly
SDNA 52:16	silence 51:3	13:7 14:12	49:2	22:14
search 42:4	similar 10:5	16:3,4 27:5	stuff 20:19	Supremacy 3:11
second 18:18	34:9	39:22 47:16	25:11	Supreme 1:1,12
24:16 43:6	simply 5:18 12:9	standards 45:10	subject 17:25	10:17 20:25
Section 33:5	13:8 20:18	46:3,19	34:21	29:4 32:12
36:4	28:7 29:19,22	stark 3:12	submit 35:7	41:22,25 45:1
see 6:10 18:12	32:24 35:23	starker 42:14	51:4	sure 4:7,8 53:16
seeking 11:10,11	41:15,18 44:13	start 24:14	submitted 29:6	Surely 25:6
semantic 4:6	single 52:11	starting 43:16	33:17 53:10	surveys 50:23

sustained 44:20 44:22 45:12 synthesis 46:14 system 6:2,2 19:2 22:2	43:3 47:17 49:15 think 3:25 4:8,9 5:8 7:16 9:14 9:17,21 11:14 12:7 15:6 16:16,18 18:4 19:6,18,21,21 20:25,25 21:2 21:3,4 22:24 33:14 34:16 39:11 40:1 41:11,18 44:21 44:25 45:11,16 47:8,8 48:8 50:19 thought 29:9,10 thousand 27:24 27:24 three 51:10 time 3:23 4:11 12:6,9,12 14:15 18:6 19:20 27:21 30:4,18 35:5 38:3 46:24 49:19 52:15 times 35:12 time-intensive 9:23 told 38:6,9 49:7 53:6 tool 7:15 tools 18:21 tort 10:14 11:11 14:25 15:9,21 15:22,25 16:11 17:15 18:1 40:4 torts 15:8 23:19 totally 45:1 50:1 tracks 40:13 tragedies 46:15 treatment 42:22 44:10 trial 20:15 24:23 26:13 27:4,12	27:18 28:15 29:17 31:1 32:19 44:8 45:3,5 47:11 48:19 49:4 50:6 51:25 53:6,19 trials 19:6 27:23 tried 12:24 13:8 13:8 52:4 trouble 46:13 true 10:3 20:12 try 13:8 39:18 50:2 trying 49:3 50:12 Tubex 6:1 tubing 32:16 turn 42:7 turns 23:1,3 two 5:21,22 12:17 18:14 23:11 31:3 32:14 34:16 43:3 44:11 47:17 51:16 type 29:10 53:13 typewritten 53:12 typically 48:21	unknown 15:12 unpublished 33:19 unreasonably 3:19 12:1 13:21 53:7 unsafe 12:1 13:21 36:9 37:7 53:7 untangle 39:18 urge 4:2 47:17 use 3:14,18 4:13 4:13,15,15,19 5:2 6:1 7:25 8:9 12:1,8 13:24 15:3 26:2 28:12,12 28:25 36:6,7,8 36:25 53:8 54:1 uses 53:21 usual 5:4 usually 8:17	11:12 Vistrol 31:2 46:10 47:12 voluntarily 31:4
T			W	
T 2:1,1 table 9:4,4,5 take 14:2 21:4 33:16 35:4 49:18 taken 15:15 18:3 talk 51:15 talking 7:10 22:7 23:21 32:15 44:6 45:2 tell 15:6 41:1 telling 9:3 26:19 termed 23:20 terms 9:3,4 11:5 40:16 terrible 46:15 test 4:10 5:10 7:7 38:13 42:15 testified 44:8 testimony 5:14 6:6 7:3,4,5 9:7 24:23 26:13 27:4,7,12,17 28:15 30:20 31:1 32:19 45:4 46:9 47:11 text 53:13 textual 3:23 4:5 Thank 14:16 24:7,12 51:8,9 51:13 54:7 theoretical 40:8 theory 14:13,14 29:10,13 47:5 47:5 things 15:20 18:22 34:16			wait 27:8,8 waived 21:2 walk 26:4 want 4:3,8 5:6,8 41:10 51:14,14 wanted 21:22 warn 17:6,6 29:18 warned 6:15 warning 12:24 24:19 25:7 31:16 32:1,5 40:17 41:5,10 41:12 53:9 54:1 warnings 7:10 8:10 36:7 52:19,22 53:1 warranted 9:6 Washington 1:8 1:15,18,21 wasn't 21:1 43:19 53:1,2 53:20 Waxman 1:15 2:3,11 3:5,6,8 4:7,22,23 5:5 7:3,21 8:5 9:14 10:10 12:15 13:4,13 14:13 16:2 22:20 23:10 25:19 42:8 51:10,11 51:13 53:17 way 5:4 19:14 26:11 27:21 39:19 47:20 48:1 50:3 went 32:23 43:12 We'll 3:3	

we're 22:7	12:17 17:5	21 19:6		
we've 7:13	28:18 38:7	24 2:9 53:24		
Williamson	49:14,17	25 31:21		
21:24	yesterday 38:7			
window 18:7		3		
wins 50:15	\$	3 1:9 2:4 9:19		
wish 4:2	\$10 29:24	30 49:14,17		
wondering 50:4	0	314 33:5		
word 38:4 49:21	06-1249 1:5 3:4	314.80(b) 50:21		
49:24 50:14,14		352(f) 36:4		
50:15 53:21	1	4		
wording 23:25	1 32:12	4a 32:13		
29:19,20 40:15	1,000 38:7	430 19:8		
40:16	10 48:4	44 36:22		
words 4:12,19	10:06 1:13 3:2			
8:19 14:9	11 5:24	5		
21:21 28:25	11,000 18:10	5a 32:14,24		
39:15 40:1	13 7:13	50 14:3		
works 27:21	14 2:7	51 2:12 28:3		
world 13:22	150 10:13	54 28:16		
worried 35:2	19-A 24:15			
worth 26:8	1906 51:17	7		
wouldn't 16:4	1938 11:2,3	70s 24:24 45:17		
20:4,18	1950s 45:24	79 31:2		
wrong 29:24	1955 43:20 46:1			
52:3,7	47:2 52:15	8		
Wyeth 1:3 3:4	1962 11:4	80s 33:21		
3:18,22 4:15	1965 47:13	88 53:23		
7:9,11 10:19	49:11			
11:25 12:5,8	1970s 31:6 45:22	9		
12:16,19,20,22	46:2	90s 33:21		
24:24 25:16	1976 6:17	97 10:13		
28:17 31:5,14	1979 36:14,22			
33:20,21 42:5	1982 49:18			
45:6,14 46:2,7	1987 7:9 53:10			
46:13 52:5,11	53:22			
52:19 53:25	1988 53:25			
Wyeth's 12:22	1990s 46:4,8			
13:5 31:5	1998 4:15 47:2			
43:19 46:6	52:16			
X	2			
x 1:2,7	20 7:11,11 10:24			
Y	2000 47:3 48:23			
year 19:5	2007 18:18			
years 3:12 10:14	2008 1:9 19:25			
	201.80 24:14			