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IN THE SUPREME COURT OF THE UNITED STATES

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RUSSELL BRUESEWITZ, ET AL., :
Petitioners :
v. : No. 09-152
WYETH, INC., FKA WYETH :
LABORATORIES, ET AL. :
- - - - - x

Washington, D.C.
Tuesday, October 12, 2010

The above-entitled matter came on for oral
argument before the Supreme Court of the United States
at 1:00 p.m.

APPEARANCES:
DAVID C. FREDERICK, ESQ., Washington, D.C.; on behalf of
Petitioners.
KATHLEEN M. SULLIVAN, ESQ., New York, New York; on
behalf of Respondents.
BENJAMIN J. HORWICH, ESQ., Assistant to the Solicitor
General, Department of Justice, Washington, D.C.; for
United States, as Amicus Curiae, Supporting
Respondents.

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P R O C E E D I N G S

(1:00 p.m.)

CHIEF JUSTICE ROBERTS: We will hear argument this afternoon in Case 09-152, Bruesewitz v. Wyeth.

Mr. Frederick.

ORAL ARGUMENT OF DAVID C. FREDERICK

ON BEHALF OF THE PETITIONERS

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

This case involves a vaccine designed in the 1940s that was administered to Hannah Bruesewitz in 1992, some 30 years after scientists discovered a safer way to design the pertussis component of the DTP vaccine. The Third Circuit held that the Bruesewitzes could not pursue a design defect claim under State law invoking the preemption principle in claiming that the Vaccine Act of 1986 preempted the Bruesewitz's State claim. That holding is in error for three reasons.

First, the court overlooked the numerous provisions of the Act protecting manufacturers from liability, but it did not expressly preempt design defect claims.

Second, the court misconstrued the word "unavoidable" in section 22(b)(1)'s Federal law defense.

1 And third, the court adopted a policy that
2 exposes children to unnecessary safety risks.

3 With respect to the first reason, in the
4 1986 Act Congress created a program, the vaccine
5 program, that was funded by surcharges on the vaccines
6 that users used, and out of that fund designed a program
7 to pay compensation to persons who were injured by
8 vaccine-related acts.

9 Congress also provided a mechanism for
10 exhaustion through the vaccine court program before a
11 person claiming injury could pursue a State law cause of
12 action. In creating Federal law defenses to the State
13 law that was designed to govern such actions, Congress
14 established certain defenses, but all of those defenses
15 apply on a case-by-case basis. There are no absolute
16 provisions that preclude a State law claim. The Third
17 Circuit misunderstood that basic principle.

18 The defenses that the Vaccine Act created
19 for manufacturers includes such things as a regulatory
20 compliance defense for failure to warrant claims, a
21 learned intermediary doctrine that is instituted at a
22 national level, the imposition of comment k --

23 CHIEF JUSTICE ROBERTS: What is -- I'm
24 sorry, Mr. Frederick. What's the point that you are
25 trying to make? That because there are a whole bunch of

1 provisions designed to help manufacturers, that this one
2 can't possibly also be designed to help manufacturers?

3 MR. FREDERICK: My point is that when one
4 looks at the specific language of 22(b)(1) against the
5 backdrop of these other provisions, it's clear what
6 Congress was intending was to enact a national defense,
7 but not to displace State law completely. And the
8 question presented is whether, on a case-by-case basis,
9 the design defect claims that had been brought by the
10 Bruesewitzes are displaced as a matter of law.

11 CHIEF JUSTICE ROBERTS: I would have thought
12 the argument would go the other way: That because they
13 set up a compensation scheme, that was a good sign that
14 they didn't want to allow State law claims.

15 MR. FREDERICK: And if one looks,
16 Mr. Chief Justice, at sections 21, 22, and 23 of the
17 Act, what 21 provides is that the Claimant can elect not
18 to accept the vaccine court judgment. Section 22
19 provides the standards of responsibility, and section 23
20 provides the mechanisms for trial of the State law
21 claim. And 23(e) provides that the evidence of the
22 vaccine table and what happens in the vaccine court
23 shall not be admissible in the State law claim.

24 JUSTICE ALITO: Section 22(b)(1) refers to
25 side effects that were unavoidable even though the

1 vaccine was properly prepared and was accompanied by
2 proper directions and warnings.

3 If the term "unavoidable" was intended to
4 carry its ordinary meaning, what need was there for the
5 rest of that language: "Even though the vaccine was
6 properly prepared and was accompanied by proper
7 directions and warnings"? If it was improperly prepared
8 or didn't have the proper directions and warnings, then
9 the side effects are avoidable. So that language is
10 surplus, isn't it, if "unavoidable" really means
11 unavoidable?

12 MR. FREDERICK: What Congress was intending
13 to do, Justice Alito, was, with the word "unavoidable,"
14 to use a word that had a settled meaning in the common
15 law. And that settled meaning referred to the design of
16 the product in light of the current state of scientific
17 knowledge. That grew directly from comment k, the
18 section 402A of the restatement of torts.

19 And in comment k, which tracked the
20 structure of the restatement provision itself, the
21 general rule for the restatement was strict liability
22 for dangerous products, quote, "although the drug is
23 properly manufactured or properly warned against."

24 JUSTICE ALITO: But isn't it true that at
25 the time, there was a distinct minority view that you

1 could not recover for design defects for vaccines?

2 MR. FREDERICK: There certainly was a
3 debate. The majority view, however, was to adopt
4 comment k as a defense to strict liability claims on a
5 case-by-case basis. And the cases that we've set forth,
6 I think, illustrate that, even the cases that the other
7 side cites. Several of them had been overruled by the
8 time the 1986 act took effect and there was a decided
9 shift in favor in the case-by-case application of
10 comment k. And in the 1987 report, Congress made very
11 clear it intended to preserve that case-by-case
12 approach. That is set forth at page 50 of our brief,
13 Justice Alito.

14 So when one looks at both the words that
15 Congress used in 22(b)(1), the debates that occurred,
16 and the committee reports that explained what Congress
17 is intending here, we believe the intent is unmistakably
18 clear to adopt comment k as a defense to --

19 JUSTICE SCALIA: But you haven't really
20 answered Justice Alito's question as to why the later
21 language is not surplus. If indeed it bears the
22 technical meaning you say that it -- that it bears, that
23 later language is surplus.

24 MR. FREDERICK: It is not surplus if one
25 reads comment k and understands what the drafters there

1 were intending to get at, which was: If, based on
2 current scientific knowledge, the risks are unavoidably
3 unsafe, meaning there is no way in science we can design
4 a safer product, there will be a defense to a claim of
5 strict liability unless or provided that the product is
6 properly manufactured and warned against. This was a
7 proviso that was intended to ensure that the focus be
8 kept on the unavoidable, unsafe aspects of the design of
9 the vaccine.

10 Now, the other side's view takes other words
11 of 22(b)(1) and renders them surplusage. And I am
12 looking now at page 19A of our reply brief, where we set
13 forth the statutory language, if you want to follow
14 along here. What the other side's view is that after
15 the word "if" following the date of October 1, 1988 -- I
16 am at page 19A of the reply brief, the addendum.

17 Under their view, all of the words that
18 follow the word "if" and through "even though" becomes
19 surplusage, because under their reading the manufacturer
20 is relieved of all liability if, quote, "the vaccine was
21 properly prepared and was accompanied by proper
22 directions and warnings," and renders the entire concept
23 of unavoidability surplusage. So our view is that what
24 these --

25 JUSTICE SCALIA: Say that again. I don't

1 follow it. Tell me that again.

2 MR. FREDERICK: Under their --
3 Justice Scalia, looking at (b)(1) on page 19A following
4 the date October 1, 1988.

5 JUSTICE SCALIA: Right.

6 MR. FREDERICK: Under their view, after the
7 word "if," the phrase "the injury or death resulted from
8 side effects that were unavoidable even though" is
9 surplusage, because in their view of the statute
10 Congress created a complete exoneration from liability
11 if the vaccine was properly prepared and was accompanied
12 by proper warnings. They took the concept of
13 unavoidability completely out of the statute.

14 And the word "unavoidable" had a settled
15 meaning. There were numerous cases that had construed
16 that meaning in light of the 20-year history of
17 Restatement section 402A. So --

18 JUSTICE GINSBURG: I take it that the
19 government is urging that "unavoidable" means
20 unavoidable in the vaccine that has gained FDA approval.

21 MR. FREDERICK: Justice Ginsburg, that
22 position is incorrect. And there is empirical evidence
23 indicating that the manufacturers, Lederle's Mr.
24 Johnson, testified that the problem with the '86 version
25 of the statute was that it allowed for design defects to

1 go forward. And he urged there to be a regulatory
2 compliance defense.

3 CHIEF JUSTICE ROBERTS: So you are asking us
4 to interpret this statute in light of his testimony at a
5 hearing?

6 MR. FREDERICK: What I'm saying is that
7 Congress had choices, and one of the choices was to
8 adopt a regulatory compliance defense for design defect
9 claims, and it chose not to do that.

10 CHIEF JUSTICE ROBERTS: It seems to me the
11 language supports the reading Justice Ginsburg has just
12 suggested, or the government has just suggested, with
13 the use of the word "the." It says the effects of the
14 vaccine were unavoidable, even though the vaccine was
15 properly prepared. Your position is, well -- the
16 question is whether it was unavoidable if you could have
17 prepared a different vaccine. But this says
18 "unavoidable, even though the vaccine."

19 MR. FREDERICK: Right. And it is preceded
20 by the word "if," Mr. Chief Justice. And if --

21 CHIEF JUSTICE ROBERTS: I don't see the word
22 "if."

23 MR. FREDERICK: It's right after the date,
24 1988. If the injury resulted from side effects.

25 So it is looking on a case-by-case basis in

1 that context, whether the vaccine created the injury or
2 side effect that is being complained of.

3 JUSTICE SCALIA: Mr. Frederick, I have this
4 problem with -- with your interpretation. As -- as has
5 been said, the government interprets "unavoidable" to
6 mean unavoidable with respect to the vaccine that has
7 been approved.

8 If it doesn't mean that, if it simply means
9 unavoidable with some other vaccine, you could always
10 avoid them if you have a vaccine that is significantly
11 less effective. I mean, what other vaccine are you
12 comparing it with?

13 MR. FREDERICK: Justice Scalia, let me try
14 to clear this up in this way. All of these vaccines are
15 approved by the FDA. And the question is whether you
16 give a presumption of design correctness for all time
17 based on the FDA's approval of that vaccine. This
18 vaccine was approved in --

19 JUSTICE SCALIA: I understand that, but the
20 plaintiff comes in and says, Look, you could have
21 eliminated this, this, and this, and these side effects
22 would not occur. Of course the vaccine would only be
23 effective in 75% of the cases, but nonetheless, it was
24 avoidable.

25 MR. FREDERICK: And that's why the concept

1 of unavailability as a defense always rested on the
2 current State of scientific knowledge. In the 1960s,
3 Lederle signed --

4 JUSTICE SCALIA: Well, that doesn't answer
5 my question. I acknowledge it rests on current
6 scientific knowledge, but current scientific knowledge
7 would enable you to design a drug that does not have
8 these side effects even though it's significantly less
9 effective, and there is no criterion as to how much less
10 effective it has to be to qualify and so forth, whereas
11 the government's interpretation of the word ties it to
12 a -- to a particular vaccine.

13 MR. FREDERICK: Justice Scalia, the way
14 these cases were construed, and we have cited them in
15 our reply brief, the standard was whether or not it was
16 as safe as a feasible alternative but was -- sorry, as
17 efficacious but safer as a feasible alternative. That's
18 how the courts -- the State court --

19 JUSTICE SCALIA: It has to be just as
20 effective?

21 MR. FREDERICK: It has to be efficacious.

22 JUSTICE SCALIA: Just as effective?

23 MR. FREDERICK: Sure. I will concede that
24 point.

25 The problem here was that an efficacious

1 design existed as of the 1960s and the internal
2 documents indicated that Lederle --

3 JUSTICE SOTOMAYOR: You keep saying that.
4 But didn't I understand correctly that that drug was
5 withdrawn from the Japanese market in which it had
6 originally been --

7 MR. FREDERICK: No. Let me clarify.

8 There are two theories by which there was a
9 design defect claim. One concerned a product by Eli
10 Lilly called Tri-Solgen. That was a split cell vaccine
11 that was developed and sold in the 1960s. It was
12 demonstrated to have far less serious effects for
13 encephalopathy and other residual seizure disorders and
14 problems.

15 JUSTICE SOTOMAYOR: Was it proven that it
16 was as effective?

17 MR. FREDERICK: Yes, it was, and it had 65%
18 of the market.

19 JUSTICE GINSBURG: And could it be used for
20 all five -- there are five inoculations in this series.

21 MR. FREDERICK: That's correct.

22 JUSTICE GINSBURG: And only one of them was
23 not approved for the first three.

24 MR. FREDERICK: That's the second one for
25 Justice Sotomayor. This was an acellular technique that

1 had been studied in the United States in the 1950s and
2 eventually was developed by the Japanese in the 1980s.
3 That acellular technique was eventually approved by the
4 FDA in the mid-1990s and is now common in all of the
5 three-part VDAP vaccines that are currently on the
6 market.

7 Our point is that the scientists literally
8 knew about that acellular technique. They were
9 beginning to do tests, but they didn't aggressively do
10 it for economic reasons. And that has never been --

11 JUSTICE GINSBURG: If there is a safer
12 alternative, it must be pursued regardless of cost?

13 MR. FREDERICK: No, there is a
14 reasonableness standard. The standard of due care that
15 State law and tort has always had is: What does a
16 reasonable manufacturer do in the same or similar
17 circumstances? But that is a question, ultimately, of
18 fact, whether or not the economics --

19 JUSTICE KENNEDY: In a question of fact in a
20 case-by-case determination in every State, the
21 manufacturers would probably be worse off under your
22 approach than if they didn't have the law at all,
23 because the law seems to at least qualify section --
24 comment k.

25 MR. FREDERICK: Justice Kennedy, that was

1 the whole design of the vaccine program, because if you
2 channelled most claims into something that the
3 manufacturers didn't have to defend against or pay the
4 judgments of, the thought was that the vast, vast
5 majority of people would never go to State court. And
6 it would only be in those rare circumstances like the
7 problem we have here where the vaccine court awards
8 nothing that the Bruesewitzes even had to go to State
9 court.

10 Had they filed their claim a month earlier
11 when residual seizure disorder was still on the vaccine
12 table, we wouldn't be here.

13 JUSTICE GINSBURG: Why was it taken off?

14 MR. FREDERICK: There was a debate in the
15 scientific community. The Institute of Medicine
16 believed that residual seizure disorder was medically
17 proved to be a causative factor from the pertussis
18 component of the DTP. There was a disagreement of -- by
19 folks in the Secretary of Health and Human Services as
20 to whether or not that was sufficient to justify legal
21 cause.

22 JUSTICE GINSBURG: And so didn't the special
23 master find what -- in the compensation proceeding that
24 causation had not been proved?

25 MR. FREDERICK: Yes. And it was a

1 proceeding, Justice Ginsburg, that had allowed for no
2 discovery against the drug manufacturer.

3 JUSTICE GINSBURG: Well, you -- you say that
4 in court you could prove causation, since you had
5 discovery, although you couldn't prove it before the
6 special master because discovery was very limited?

7 MR. FREDERICK: That's our submission. And
8 that was the design that Congress intended. That's why
9 what happens in the vaccine court under section 23(e),
10 as a matter of law, is inadmissible in a subsequent
11 State court action.

12 JUSTICE BREYER: And can you -- maybe this
13 is a good point, but I would like to know what your
14 response is. I'm not asking you in either a hostile nor
15 friendly way.

16 The -- assume for the moment that the
17 language, I cannot find clear one way or the other. So
18 I think it's ambiguous. At that point, what is your
19 response, on that assumption that this brief on the
20 other side from the American Academy of Pediatrics and
21 21 other physician and public health organizations --
22 what the pediatricians here say is that, if you win,
23 we're turning this over to judges and juries instead of
24 the FDA and other specialized agencies, that the result
25 could well be driving certain vaccines from the market,

1 and basically, a lot of children will die. And that --
2 that's their claim.

3 And I think that their legal argument there
4 is that wasn't Congress's purpose. Congress's purpose
5 was the contrary.

6 So leaving the language out of it, I would
7 like you to respond to what I would call that
8 purpose-related, fact-related argument by these
9 particular people.

10 MR. FREDERICK: If I may, let me make two
11 points, Justice Breyer, the legal point and the policy
12 point.

13 The legal point is: This Court's cases make
14 clear that there is a clear statement principle. Before
15 Congress is presumed to have displaced State law, it
16 must act with a clear statement. And that is true in
17 the Eleventh Amendment context as well as the preemption
18 context. So if you conclude there is ambiguity, we
19 should win --

20 JUSTICE BREYER: Well, there is another case
21 on that where we are going to have to go into -- which
22 is, does that mean every bit of it has to be clear?
23 Does it mean the intent has to be clear? That's a
24 complicated area. But I will put that aside for the
25 moment.

1 MR. FREDERICK: Here, 22(a) answers that
2 question as a matter of law, because it says the State
3 law provides the general rule.

4 JUSTICE BREYER: Right. I've got --

5 MR. FREDERICK: Now, that's the legal point.
6 The policy point is that by channelling the vast
7 majority -- and the SG's brief says 99 percent of the
8 people who go through vaccine court accept the judgment
9 of the vaccine court.

10 And on the First Circuit, the Schaefer
11 decision -- which you wrote, Justice Breyer -- said that
12 even in the instances in which people lose in the
13 vaccine court, they may regard the hurdles and obstacles
14 of the State court process to be so great that they
15 don't bother to try. It's difficult to win these kinds
16 of cases in State court.

17 JUSTICE SOTOMAYOR: Explain why.

18 MR. FREDERICK: Because proving causation
19 and proving the availability, based on science, of an
20 alternative design is not something that is a relatively
21 easy thing to do.

22 JUSTICE BREYER: But that's -- that's why I
23 asked the question. Frankly, if I see the Academy of
24 Pediatrics telling me one thing, and I in an earlier
25 case wrote the other thing, I do tend to think I could

1 have been wrong.

2 (Laughter.)

3 JUSTICE BREYER: And that's -- that's why I
4 am asking you: Is that the best you can find on the
5 other side, namely something I once wrote in a case? Or
6 are there other -- are there other things?

7 (Laughter.)

8 MR. FREDERICK: It happened in the moment to
9 come to mind, Justice Breyer.

10 (Laughter.)

11 MR. FREDERICK: The point that I want to
12 make is that the threat of liability is only a realistic
13 one if there is a threat that there's actually going to
14 be payment at the end. And Plaintiffs do not bring
15 cases to lose; they bring cases if they have a
16 reasonable prospect of winning based on what the
17 evidence would show a design defect to be.

18 And so when Congress set up this system and
19 it exonerated the vaccine makers of 99 percent of all
20 cases that are going to go through this system claiming
21 defects or problems, if you ask manufacturers around the
22 country that you get a special defense against punitive
23 damages, you get a regulatory compliance defense for
24 failure to warn, you have to have a trifurcated
25 proceeding, and you are not going to have to pay damages

1 or defend the actions 99 percent of the time, most
2 manufacturers in the United States would take that
3 bargain.

4 And so the question --

5 CHIEF JUSTICE ROBERTS: It would depend, I
6 suppose, on what they thought the judgments were going
7 to be in the 1 percent of the time.

8 MR. FREDERICK: And --

9 CHIEF JUSTICE ROBERTS: It doesn't take too
10 many \$60 million verdicts to make you come out on the
11 other side of your calculus.

12 MR. FREDERICK: And that's why, going back
13 to the wording of the statute, Mr. Chief Justice, in
14 section 23, where Congress said for someone who had
15 elected not to accept the judgment in 21, you get to go
16 to State court and try to prove your claim.

17 JUSTICE GINSBURG: Anyone could go to the
18 State -- I mean, somebody who won in the vaccine court
19 could go to court on the argument that the amount was
20 insufficient, the amount of compensation.

21 There is -- there is no foreclosure of
22 anyone to come to court; is that right?

23 MR. FREDERICK: That's correct. But you
24 have to fight through the defenses that Congress erected
25 in 22(b)(1), (b)(2), and (c), which are quite difficult

1 defenses.

2 JUSTICE ALITO: What would happen if a drug
3 manufacturer sought FDA approval of an alternative
4 vaccine and the injury occurred during the period while
5 that was under consideration by the FDA? That's --
6 that's just too bad?

7 MR. FREDERICK: A harder case, but not one
8 that couldn't be proved under State law. The negligence
9 inquiry would look into whether or not a reasonable
10 manufacturer would have tried earlier and more
11 aggressively to obtain FDA approval.

12 Here, we think we can meet that standard,
13 because we had a drug that was on the market, the split
14 cells Tri-Solgen, that was proved to be safer and just
15 as efficacious, and it had been on the market until
16 Wyeth took it off, after Wyeth concluded that when it
17 purchased the rights from Eli Lilly it couldn't
18 manufacture the vaccine Tri-Solgen in a way that it
19 would get it the profit stream that it wanted.

20 JUSTICE GINSBURG: In the -- when it was --
21 when Tri-Solgen was owned by Lilly and you said that it
22 was approved and marketed, was that one available for
23 all five inoculations?

24 MR. FREDERICK: Yes. Yes, Justice Ginsburg.
25 That was used for all through the series for children's

1 vaccination for DTP.

2 And the problem here with the other side's
3 approach, fundamentally, is that not only does it render
4 part of 22(b)(1) surplusage, and not only does it ignore
5 the many benefits that manufacturers got, but at the end
6 of the day it allows for an exoneration from liability,
7 even for manufacturers who know there is a safer design
8 available.

9 And that fundamentally is something Congress
10 never would have imagined, that manufacturers would
11 invoke an immunity from suit, even when they knew --

12 JUSTICE KENNEDY: Does the secretary -- does
13 the secretary have the authority to -- to withdraw
14 certification on the ground that it is no longer safe,
15 fair, and potent?

16 MR. FREDERICK: Yes, Justice Kennedy. There
17 is --

18 JUSTICE KENNEDY: You are assuming that the
19 manufacturer knows something that the secretary doesn't?

20 MR. FREDERICK: No. Our submission,
21 Justice Kennedy, is that for many vaccines there is no
22 safer alternative, and there could be no design defect
23 claim. But for those instances in which there is a
24 safer alternative, the burden under State law is for the
25 manufacturer to act reasonably in pursuing the safer

1 design, if that is available.

2 It's not -- there is no provision in the FDA
3 regulations or under statute for the FDA to engage in a
4 comparative safety analysis.

5 CHIEF JUSTICE ROBERTS: If the language --

6 JUSTICE SOTOMAYOR: Is there any provision
7 in the regulations that require a manufacturer to
8 withdraw a drug earlier than when the FDA tells them to?

9 MR. FREDERICK: Not that I'm aware of.

10 JUSTICE SOTOMAYOR: So this immunity would
11 come along until they go to the FDA and say, Well, we've
12 gotten enough incidents to prove --

13 MR. FREDERICK: That's correct. And this
14 very vaccine, Justice Sotomayor, was taken off the
15 market in 1998. And the product that Wyeth used as the
16 substitute for it says in its package insert, this is a
17 safer vaccine than the Tri-Immunol that we have taken
18 off the market.

19 CHIEF JUSTICE ROBERTS: But I'm not sure
20 that in most cases you are going to be able to tell
21 immediately -- you are marketing one vaccine and
22 something else is being tested or about to be approved,
23 or it's on the market -- that that's safer.

24 Particularly since you have to look not only at --
25 whatever -- injury and mortality rates, but also

1 efficaciousness -- or efficiency, I guess -- in terms of
2 the vaccine.

3 So you don't know right away. Somebody
4 comes in and says, Here's a different vaccine; your
5 vaccine causes one death every 10,000 doses, or whatever
6 it is. And the other says, This is better; it's one
7 death every 12,000 doses. You say, Well, but ours is
8 more efficient in stopping the vaccine.

9 Well, how much more efficient? Well, it
10 depends on the judgment of a jury.

11 MR. FREDERICK: And the manufacturers win
12 that case, probably, Mr. Chief Justice.

13 JUSTICE KENNEDY: But -- but you assume that
14 there is no clause or burden to the manufacturers who
15 defend these suits to assess settlement offers. This is
16 a -- this is a tremendous expense.

17 MR. FREDERICK: Only if you accept the --

18 JUSTICE KENNEDY: It -- it may well be that
19 the manufacturer has to settle a meritorious case; we
20 all know that.

21 MR. FREDERICK: Yes. But, Justice Kennedy,
22 that's after an exhaustive process through which they
23 have gone through the vaccine program and the person is
24 dissatisfied with the remedy that's provided.

25 So in these vast majority of cases, unlike

1 drug cases where there is no channeling mechanism, here
2 the vaccine fund is designed to take care of the vast,
3 vast, vast majority of those kinds of claims. And it's
4 only in those rare circumstances where there would be a
5 State lawsuit.

6 If I could reserve the balance of my time.

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

9 Ms. Sullivan.

10 ORAL ARGUMENT OF KATHLEEN M. SULLIVAN

11 ON BEHALF OF THE RESPONDENTS

12 MS. SULLIVAN: Mr. Chief Justice, and may it
13 please the Court:

14 Congress enacted the National Childhood
15 Vaccine Injury Act against the backdrop of a wave of
16 tort litigation that threatened to drive manufacturers
17 out of the business of providing the vaccine --

18 JUSTICE SOTOMAYOR: So why didn't they make
19 the vaccine court exclusive? There is plenty of
20 administrative systems that make -- preclude State law
21 actions altogether and place you in administrative
22 proceedings. So if their intent was to drive out State
23 lawsuits, why not do that?

24 MS. SULLIVAN: Because, Justice Sotomayor,
25 the kind of lawsuits that caused Congress concern were

1 the very kind of lawsuits that are expressly preempted
2 by 22(b)(1), and that is design defect claims, which
3 have the exact problem that was just being discussed.

4 For a design defect claim, as Justice Scalia
5 pointed out, the challenge that is brought to the
6 vaccine that was approved by the FDA can be challenged
7 as less safe than some alternative vaccine, bounded only
8 by the imagination of the experts. It was those design
9 defect claims that were the problem. Congress
10 preserved --

11 JUSTICE SOTOMAYOR: So, how -- couldn't they
12 have taken care of that with Daubert? I mean, won't
13 most of these cases get resolved on a motion for summary
14 judgment?

15 MS. SULLIVAN: Not design defect claims,
16 Your Honor. Just to go back to 1986 and what the crisis
17 was. As the 1986 House report makes clear, the
18 manufacturers were being driven out of the vaccine
19 business, imperiling the nation's design -- vaccine
20 supply by design defect claims that did survive summary
21 judgment. And that did lead to the danger, as
22 Justice Kennedy pointed out, of settlements. The key
23 point about protection --

24 JUSTICE SOTOMAYOR: Point me to the FDA
25 regulations or law where the FDA, in giving a license to

1 or permitting a new vaccine, actually looks at whether
2 that vaccine is the most efficacious way with the least
3 serious harm to the population. Is there a regulation
4 that requires that judgment by them before they issue
5 permission to market?

6 MS. SULLIVAN: There is not, Justice
7 Sotomayor. What the FDA is empowered by regulation to
8 decide under the Food, Drug, and Cosmetic Act is whether
9 the vaccine is safe and efficacious. Once approved --

10 JUSTICE SOTOMAYOR: All right. What is the
11 motivation? If there is no -- there's no approval
12 mechanism for the FDA to look at that issue, what is the
13 motivation for manufacturers to voluntarily remove a
14 drug that is causing harm to the public before the FDA
15 acts?

16 If they are completely immune under your
17 reading of this preemption statute, what motivates them
18 to act more quickly?

19 MS. SULLIVAN: The Act itself. But
20 section 27 of the Act -- let me just go back and
21 describe what Congress did in 1986. It said, We have a
22 crisis, and it created three things to solve the crisis:
23 A preemption provision that said, Let's end the design
24 defect claims that are causing the problem. Let's
25 provide --

1 JUSTICE GINSBURG: Ms. Sullivan --
2 Ms. Sullivan, if Congress had wanted to do that, they
3 could have said simply that no vaccine manufacturer may
4 be held civilly liable if the vaccine is properly
5 prepared and accompanied by proper directions and
6 adequate warnings. That would have been the simplest
7 statement.

8 Congress didn't make that statement. They
9 were asked to amend the statute to make that statement,
10 and they didn't. I mean, if you wanted to make it clear
11 that there is no design defect liability, then say that:
12 No civil liability unless inadequately -- improperly
13 prepared, improper directions, or warnings.

14 What they -- the language that they used is
15 certainly, to say the least, confusing. This
16 unavoidable -- these side effects that were unavoidable.
17 Well, why did they need to put that in there if what
18 they were concerned with was to cut out liability for
19 design defects?

20 MS. SULLIVAN: Justice Ginsburg, let's go
21 back to the text and put -- read the two clauses
22 together. And our main point here is, as Justice Alito
23 and Justice Scalia have already pointed out, the
24 Petitioners render the "even though" clause surplusage.

25 We read the two clauses together. And let's

1 read them together against the backdrop of the three
2 kinds of product liability claims that could be brought:
3 Design defect, manufacturing defect, and failure to
4 warn.

5 The -- the statute references two out of the
6 three. And we -- we believe that -- and the Government
7 believes that the reason that was done was to say that
8 the third omitted kind of claim, design defect claims,
9 were preempted. The two that were allowed -- and,
10 Justice Sotomayor, this is what makes it different from
11 straight pure administrative schemes -- this does
12 preempt defect claims, the omitted claim. It allows
13 manufacturing defect claims and it allows warning claims
14 subject to the presumption in 22(b)(2). Limited --

15 JUSTICE KENNEDY: Under your view, when does
16 the manufacturer have to come forward and acknowledge
17 that there is a defect in the design?

18 MS. SULLIVAN: Well, Justice Kennedy, the
19 manufacturer is subject to ongoing reporting
20 requirements under section 28 of the statute. And I
21 think that if you think there is ambiguity in the text,
22 as Justice Breyer suggests, we can go to the structure
23 of the statute. And let me just mention a number of
24 features of the statute --

25 JUSTICE SOTOMAYOR: Could you please just

1 answer that question? What is the motivation for the
2 manufacturer to either continue the testing of their
3 product and voluntarily stopping it if a better design
4 has been found by someone else or even an inducement for
5 them to find a better design if a competitor comes
6 around?

7 Because I don't see why they should stop
8 until they have caused as many injuries as they need to
9 before the FDA says stop.

10 MS. SULLIVAN: Well, Justice --

11 JUSTICE SOTOMAYOR: What is the inducement
12 for them to do it voluntarily?

13 MS. SULLIVAN: Yes. First of all, Justice
14 Sotomayor, Justice Kennedy is correct, the FDA can order
15 removal from the market.

16 JUSTICE SOTOMAYOR: I am not asking about
17 the FDA.

18 MS. SULLIVAN: But the reason why --

19 JUSTICE SOTOMAYOR: I said the
20 manufacturers' motivations.

21 MS. SULLIVAN: And -- and, Justice
22 Sotomayor, the reason why the FDA has never had to use
23 that nuclear option is that it -- it works closely with
24 manufacturers long before it needs to be used, and
25 that's because of the rest of the structure of the Act.

1 I would like to focus on what Congress did
2 in 1986 in addition to --

3 CHIEF JUSTICE ROBERTS: Before you get to
4 that, I think your answer to Justice Sotomayor's
5 question is: Nothing; the manufacturers have no reason
6 to take the vaccine off the market until the FDA tells
7 them to.

8 MS. SULLIVAN: That's not correct, Your
9 Honor. So the -- section 27. Section 27 distinguishes
10 vaccines from other drugs. Section 27 says that the
11 Secretary of Health and Human Services shall -- shall
12 have an affirmative mandate to promote safer vaccines
13 and to reduce the number of side effects.

14 And the Vaccine Act didn't just eliminate
15 design defects --

16 JUSTICE KENNEDY: But if the manufacturer is
17 slow or remiss or negligent or willful in not giving the
18 information to the Government, there is nothing the
19 injured person can do. There is still complete
20 preemption, under your view?

21 MS. SULLIVAN: Of design defect claims,
22 Justice Kennedy, but not of warning claims. And it
23 will -- there are grave consequences if a manufacturer
24 withholds knowledge of adverse effects from the FDA.
25 Section 22(b)(2) --

1 JUSTICE SOTOMAYOR: Does the victim of that
2 withholding have a private cause of action? I don't see
3 anything in this that would give them --

4 MS. SULLIVAN: There is not a freestanding
5 cause of action. But if you look at 22(b)(2), you see
6 that the manufacturer will lose his -- lose its
7 presumption that its warnings were correct. It will be
8 subject to warnings suits in State court if it withholds
9 information from the FDA without the benefit of the
10 presumption.

11 JUSTICE GINSBURG: The warning --

12 MS. SULLIVAN: And if you look at --

13 JUSTICE GINSBURG: The warning -- the
14 warning claims, the manufacturing claims, those are
15 always avoidable.

16 MS. SULLIVAN: Always avoidable. Exactly,
17 Your Honor.

18 JUSTICE GINSBURG: But -- so what can be --
19 the only thing that can be unavoidable is the design
20 defect.

21 MS. SULLIVAN: That's exactly right, Your
22 Honor. And that's how the text makes sense.

23 To go back to the text, the text says there
24 are two kinds of avoidable side effects: Side effects
25 that come from improper preparation -- well, of course

1 the manufacturer can avoid those; it can prepare the
2 vaccine better without contaminants -- and it can avoid
3 warning defects by changing the warning.

4 JUSTICE KENNEDY: The warning doesn't have
5 to say, "Warning: We could make something better if we
6 wanted to."

7 (Laughter.)

8 MS. SULLIVAN: It does not. That's correct,
9 Your Honor. And that's because --

10 JUSTICE SOTOMAYOR: Or there is something
11 better on the market than this that won't cause that.

12 MS. SULLIVAN: But look. Mr. Frederick has
13 told a story that perhaps has misled the Court into
14 thinking there was a safer vaccine in the 1980s. There
15 was not.

16 And just to be -- just to tell the story of
17 a success in the way that FDA worked with the scientific
18 community and the national Government worked with
19 manufacturers to produce a safer vaccine, it was the
20 Federal --

21 JUSTICE GINSBURG: Well, can you -- can we
22 be concrete and concentrate on this Tri-Solgen, which,
23 according to Mr. Frederick --

24 MS. SULLIVAN: Yes.

25 JUSTICE GINSBURG: -- Eli was producing, and

1 it was available for all five inoculations. And then
2 Wyeth bought it, and then --

3 MS. SULLIVAN: Justice Ginsburg, Tri-Solgen
4 was a split cell vaccine. It was manufactured and
5 produced by Lily in the 60s and withdrawn in the 70s.
6 But Mr. Frederick was incorrect that the Government ever
7 deemed it as effective and safer than the wholesale
8 vaccine, Tri-Immunol, that was administered in this
9 case.

10 If I could refer Your Honor to page 19 of
11 the Respondent's brief, we cite to 50 -- Federal
12 Register 51051 and 52. That's where the FDA
13 specifically determined that Tri-Solgen was not safer,
14 was not safer, than Tri-Immunol with respect to seizure
15 disorders or other severe effects. It simply may have
16 involved less local effects like fevers and rashes.

17 So there was never any government
18 determination that Tri-Solgen was safer. In fact,
19 Tri-Solgen came off the market. Why? Because the
20 section 27 worked, the Federal Government worked to
21 promote safer vaccines.

22 JUSTICE BREYER: How does it do that? Look,
23 I think a difficulty I have is this. Imagine vaccine X
24 saves 10,000 lives, but inevitably 20 children will be
25 killed. That's inevitable. Time period one.

1 Five years passes. The manufacturer now
2 realizes he could save three of those five people. All
3 right. Is there anything in the law that requires him
4 to tell the FDA that that is so?

5 MS. SULLIVAN: There is not anything that
6 requires him to tell the FDA that is so.

7 JUSTICE BREYER: All right. If there is
8 nothing that requires him to tell the FDA what comes
9 along, what I think your opponent is saying is at that
10 moment, it is no longer an unavoidable harm and there is
11 nothing in this statute that says that unavoidable
12 harms -- that avoidable harms are taken away from the
13 courts.

14 So what is your response to -- what is your
15 response to that? He's saying all the unavoidable ones
16 are taken away, but not the avoidable ones. And now we
17 have an example. So what is your response to that?

18 MS. SULLIVAN: That "unavoidable" in the
19 statute is a term of art. And to the extent that
20 comment k is relevant at all, Mr. Frederick says, "Oh,
21 Congress was adopting comment k, the majority view."
22 Well, first, there was not a majority view.

23 JUSTICE BREYER: If you want to read it
24 especially to mean unavoidable and avoidable. Let's
25 assume you are right about that, or let's assume it is

1 at least ambiguous. If that's so, then what is your
2 response to the question I raised before, that is: That
3 he says that if you allow judges and juries to decide
4 only the question of avoidability, there will not be the
5 harms that the childhood pediatricians thought there
6 would be, because most people will go to the courts --
7 to the vaccine court anyway. There are very few such
8 cases, and there will not be enough liability to drive
9 manufacturers from the market.

10 You heard him respond to that. What is your
11 response to that?

12 MS. SULLIVAN: First, there will be enough
13 liability to drive manufacturers from the market. Let
14 me correct some things that Mr. Frederick said that were
15 not true.

16 The vaccine court, 99 percent of those who
17 receive monetary judgments in vaccine court, the
18 administrative no fault system, do accept their award,
19 but what Congress was concerned about was those who lose
20 in the administrative system and then go take their
21 second bite at the apple in State court, whereas, as has
22 been mentioned, they are not bound by any findings in
23 the vaccine court. 23(b) says --

24 JUSTICE BREYER: That's a minor point, but I
25 thought if you went into the vaccine court you had to

1 sign something saying you weren't going to go into a
2 tort case. I'm wrong about that?

3 MS. SULLIVAN: No. You go into a vaccine
4 court and there is an exhaustion requirement. 22(b)(1)
5 must add something to the exhaustion requirement. We
6 say it adds an exemption preemption provision, but you
7 can elect at the end to take the judgement or not.
8 Those who get money in vaccine court, 99 percent take
9 it. What we are worried about is the 64 percent who
10 lose in vaccine court.

11 JUSTICE SOTOMAYOR: What do those 64 percent
12 do now? What is the percentage of those people who
13 actually go into court now?

14 MS. SULLIVAN: I can't answer that, Your
15 Honor.

16 JUSTICE SOTOMAYOR: Is that because whatever
17 the percentage is, proving causation is never easy --

18 MS. SULLIVAN: That's true, Your Honor.

19 JUSTICE SOTOMAYOR: -- for non-listed --

20 MS. SULLIVAN: But there are 5,000 claimants
21 in vaccine court now who claim there is a relationship
22 between the mumps, measles, and rubella vaccine and
23 autism. They have lost all six test cases and when the
24 individual cases are resolved, that is 5,000 potential
25 claimants in State court.

1 Congress was worried about episodic waves of
2 fear about vaccines leading to future litigation. They
3 took care of existing Claimants with vaccine injuries
4 back in 1986 with the compensation system. The reason
5 they put in 22(b)(1) was to prevent future litigation in
6 State court where manufacturers could be driven from the
7 market by the fear of liability that had in 1986
8 involved the withdrawal of insurance, the escalation of
9 insurance costs, the withdrawal of one manufacturer from
10 the vaccine market.

11 And today there are very few vaccine
12 manufacturers and the risk of the vaccine supply on
13 which the nation's protection from contagious disease
14 depends, it depends upon the existence of that stable
15 supply of vaccines.

16 JUSTICE GINSBURG: If Congress were so
17 clear, as you are describing it, then why didn't it
18 adopt the provision that said failure to develop a safer
19 vaccine would not be grounds for liability?

20 MS. SULLIVAN: Your Honor, Justice Ginsburg,
21 I think you have to look to the rest of the structure of
22 the Acts to see what Congress did here. It did three
23 things.

24 It made vaccines quite different from other
25 drugs. And this is not a situation where the FDA has to

1 monitor 11,000 drugs, of which it wouldn't even care if
2 they came off the market. The government doesn't care
3 if --

4 JUSTICE GINSBURG: But it also was directed
5 to vaccines.

6 MS. SULLIVAN: That's right --

7 JUSTICE GINSBURG: The failure to develop a
8 safer vaccine would not be grounds for liability, and
9 Congress didn't enact that.

10 MS. SULLIVAN: Your Honor, Congress enacted
11 a preemption provision that we think it was in the four
12 corners of the provision of 22(b)(1), "preempts design
13 defects." It has a carveout for the two kinds of suits
14 that are allowed, manufacturer and warning defects. The
15 clear holding of the rest of the text is that design
16 defect claims are precluded. Compensation makes sure
17 that people who do have injuries from vaccines are taken
18 care of.

19 The rest of the structure of the Act injects
20 the Federal Government into driving the vaccine
21 development process in a way that it does not for other
22 drugs. Congress wants people to take vaccines. It
23 wants us to inoculate all our children. It wants us to
24 have compensation to ensure people who are injured that
25 they can get some money to take care of their children's

1 disabilities.

2 But Congress wanted to make sure that it was
3 driving, that the Federal Government, the FDA, the
4 Centers For Disease Control, together with the AMA,
5 together with task forces, were driving research to make
6 safer vaccines.

7 JUSTICE SOTOMAYOR: You are making an
8 assumption that has a flawed premise, which is that
9 their only concern was protecting the manufacturers.

10 MS. SULLIVAN: Not at all, Your Honor.

11 JUSTICE SOTOMAYOR: It couldn't have been.

12 MS. SULLIVAN: They compensate the victims.

13 JUSTICE SOTOMAYOR: Not only do they
14 compensate victims, but they permitted victims to go
15 into State court.

16 MS. SULLIVAN: For manufacturing and warning
17 claims. For manufacturing and warning claims.

18 JUSTICE SOTOMAYOR: No, no, no. That's your
19 assumption. My point is that if we are talking about
20 what the purpose was, you can't assume that --

21 MS. SULLIVAN: Two purposes: Compensation
22 and the protection of the vaccine supply. Justice
23 Sotomayor, the clearest way that I --

24 JUSTICE SOTOMAYOR: So what you are
25 suggesting is there is no compensation for an injury

1 that was avoidable in its normal sense, which is --

2 MS. SULLIVAN: No --

3 JUSTICE SOTOMAYOR: If this drug had not
4 been sold and another drug had been used the person
5 would have avoided their injury.

6 MS. SULLIVAN: Well, there is no such drug
7 here. Acellular vaccine was not approved by the FDA for
8 use in infants under two until 1996. It was approved
9 for children over two in 1991. That's because in this
10 country, we require clinical studies that weren't
11 required in Japan a decade earlier to make sure that --

12 JUSTICE SOTOMAYOR: It sounds to me that
13 you're going to win on non-summary judgment. I don't
14 see -- I do understand the cost of litigation. It can
15 be very, very onerous. So I'm not trying to minimize
16 it, but I do think that there's a whole lot of hurdles
17 in place before a plaintiff wins on one of these claims.

18 MS. SULLIVAN: Justice Sotomayor,
19 manufacturing claims and warning claims are susceptible
20 to summary judgment. Design defect claims are not in
21 the same way. You are shadowboxing against an infinite
22 number of theories about how there could have been a
23 safer vaccine.

24 But the clearest way I can say why
25 Mr. Frederick's interpretation can't be right is: If

1 you concede at least one purpose was to protect
2 manufacturers, to protect the vaccine supply, in
3 addition to compensating the victims, Mr. Frederick's
4 reading of 22(b)(1) does not serve that purpose. He
5 reads 22(b)(1) to leave manufacturers in the exact same
6 place after the Act that they were before. Go to State
7 court. Try to show that there was --

8 JUSTICE GINSBURG: They set up this whole
9 compensation scheme where everybody agrees -- I mean,
10 the manufacturers got this compensation scheme which
11 took most of the cases out of State court.

12 So to say they were left just like they were
13 before, before they were exposed to all these claims --
14 now it's only to a very small part of them.

15 MS. SULLIVAN: That's not quite right,
16 Justice Ginsburg. The Act allows all losers in vaccine
17 court to go to State court. There are 5,000 --

18 JUSTICE GINSBURG: Yes, yes. I got that
19 answer from Mr. Frederick before. But most of them
20 don't, because it's cheaper, faster, and working well.

21 MS. SULLIVAN: For vaccine court winners,
22 that's true. For vaccine court losers, the fear was
23 that these lawsuits would drive manufacturers out of the
24 market, even if the manufacturers could win in the end.

25 For a preemption provision to do any work,

1 it needs to attach at the beginning of the claim.
2 22(e), for example, refers to bringing an action.
3 22(b)(1), to do any work to protect manufacturers, has
4 to attach to prevent the cause of action from being
5 brought.

6 JUSTICE KENNEDY: I'm still not clear -- I'm
7 still not clear what answer you gave to
8 Justice Ginsburg's question, saying: Why didn't
9 Congress put this out in plain words: There should be
10 no liability for design? Is the answer sloppy drafting?
11 Are you reluctant to give that answer?

12 MS. SULLIVAN: Well, Justice Kennedy, it
13 could have been drafted a different way and it would
14 have meant the same thing. We think the best way to
15 read the two clauses together "unavoidable," "even
16 though," is to refer to what comment k meant. Now,
17 comment k used the term "unavoidable." We know Congress
18 was thinking about the term unavoidable. We know that
19 because in the 1986 House report the congressional
20 committee say we would like to enact the principle of
21 comment K.

22 Well, what is the principle of comment K?
23 The principle of comment k is there are so products so
24 useful that we want them to stay on the market without
25 design defect liability. They can only be sued for

1 manufacturing or warning defects. Those are the only
2 two kinds of suits you can bring.

3 In our view, comment k was Congress's
4 denomination of vaccines as comment -- sorry, 22.1 was
5 the denomination of --

6 CHIEF JUSTICE ROBERTS: Thank you,
7 Ms. Sullivan.

8 MS. SULLIVAN: -- as a comment k product.
9 Thank you.

10 CHIEF JUSTICE ROBERTS: Mr. Horwich.

11 ORAL ARGUMENT OF BENJAMIN J. HORWICH,
12 FOR UNITED STATES, AS AMICUS CURIAE,
13 SUPPORTING THE RESPONDENTS

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

16 I think the Court finds itself actually
17 three-quarters of the way through the argument without
18 actually hearing about the most important federal agency
19 that is involved with this, which is arguably not the
20 Food and Drug Administration but the Centers for Disease
21 Control and Prevention.

22 And so with respect to the question about
23 what is it that is governing whether the -- whether
24 the -- the - a given vaccine is subject to the Act and
25 what are the incentives and who is actually making the

1 decision and who is trying to determine if there's
2 something better that's out there that we should be
3 pursuing -- that is the mission of the Centers for
4 Disease Control and Prevention.

5 That is why Congress took the original
6 table -- the vaccines that are on the original table in
7 this statute were taken from CDC's recommendations that
8 reflect CDC's expert scientific judgment, based on the
9 input from the medical and scientific community, of what
10 vaccines do we have that are the ones we should use to
11 protect the public health?

12 JUSTICE BREYER: Do they get the information
13 from the manufacturers? And -- I mean, would they find
14 out if in fact there had been a change --

15 MR. HORWICH: Well --

16 JUSTICE BREYER: -- and it was now -- there
17 is a safer alternative?

18 MR. HORWICH: Well, let me -- let me give --
19 kind of -- let me answer that in -- in two ways.

20 The -- the first is that the -- the nature
21 of vaccine research is not something that manufacturers
22 do in a cloistered laboratory somewhere. So it's
23 actually very unlikely to imagine that a manufacturer
24 somehow comes uniquely into possession of this
25 knowledge.

1 I mean in fact, the Federal Government
2 spends billions of dollars doing vaccine research that
3 government scientists themselves perform. The
4 government sets the agenda for what are our targets for
5 development. The -- the research agenda to pursue the
6 acellular pertussis vaccine was something driven by the
7 Federal Government.

8 Federal Government made a choice and said
9 we -- we don't want manufacturers and our scientists
10 pursuing the -- the Tri-Solgen approach and trying to
11 improve that. We don't understand that vaccine very
12 well. We know the ultimate target needs to be the
13 development of an acellular vaccine, and so that's the
14 research path that -- to go on.

15 JUSTICE BREYER: Suppose then that in --
16 suppose I look into this, which I will do, the CDC and
17 what they do. And suppose I become convinced you are
18 completely right, that this is a government agency that
19 is top of this and the chances of something going wrong
20 are very small and they will figure it all out, together
21 with the manufacturers. Suppose I conclude that.

22 What do I do about this word unavoidable?

23 MR. HORWICH: Well I think --

24 JUSTICE BREYER: Now I can't say that the
25 word unavoidable -- it's pretty hard to say that that

1 word unavoidable means avoidable; and I am in fact --
2 like to look to the purposes of this statute, that if
3 something says "day" I can't say it means "night." And
4 so -- so what -- what is it about this word that allows
5 us to say that it's avoidable?

6 MR. HORWICH: Well, I think the answer to
7 that actually came in a question that Justice Ginsburg
8 posed to Mr. Frederick, which is that unavoidable is
9 being used in the sense of okay; what are the vaccines
10 that FDA has approved that CDC has recommended for
11 routine administration to children, and that are the --
12 and that are the ones that the Federal Government has
13 determined are appropriate therefore to protect the
14 public health? And given that that is the state of
15 affairs that we are in, was this injury --

16 JUSTICE BREYER: To show that -- remember
17 they only want to say, because of special circumstances
18 this is an avoidable -- this is an avoidable injury. I
19 think I am right on that.

20 And -- and so the best place to look in your
21 opinion, for me to look, to show that this word
22 unavoidable includes that avoidable claim, is where?

23 MR. HORWICH: I think the way to understand
24 it is -- is to see that as the -- as the committee
25 report -- as the '86 committee report says, that what

1 Congress is trying to convey in using the word
2 unavoidable is it is -- it is respecting the principle
3 of comment k, which is the principle that socially
4 beneficial products that nonetheless have these adverse
5 effects ought to be on the market and we ought not to
6 allow tort law to push them off the market, which is
7 exactly what --

8 JUSTICE SOTOMAYOR: Excuse me -- going back
9 to the point you just started with --

10 MR. HORWICH: Yes.

11 JUSTICE SOTOMAYOR: -- which was is this --
12 is the Control -- Disease Center, is it making a
13 judgment before it approves a drug for licensing, that
14 it's the most efficacious drug on market?

15 MR. HORWICH: CDC does not issue a license.

16 JUSTICE SOTOMAYOR: No --

17 MR. HORWICH: But the way the statute works
18 is that the statute only covers, in its present form,
19 the way -- I'm referring now to the present version of
20 the provision in the statute that explains how vaccines
21 become subject to the Act, because not all vaccines are.
22 The provision is in 14(e) of the Act, which I believe
23 may not be reproduced in any of the papers, but it
24 basically says that two things have to happen. One is
25 that before the vaccine becomes subject to either the

1 compensation program or the preemption provision -- is
2 that CDC has to recommend it for routine administration.
3 And that is a judgment that CDC makes with the advice of
4 the Advisory Committee on Immunization Practices.

5 JUSTICE SOTOMAYOR: Where do I look at that?
6 At what documents do I look at to make a judgment that
7 in fact, CDC is doing what I ask, that it is looking at
8 the question of whether this is the most efficacious
9 drug with the least adverse effects? Is that a judgment
10 it's making?

11 MR. HORWICH: Yes. Yes.

12 JUSTICE SOTOMAYOR: We know the FDA is not.
13 Are you representing to us right now that CDC makes that
14 judgment?

15 MR. HORWICH: CDC makes that judgment and
16 announces it in a reasoned, published announcement in
17 its official journal which is the Morbidity and
18 Mortality Weekly Report.

19 And so for every drug -- or excuse me, for
20 every vaccine that it recommends for routine
21 administration, it publishes a notice in its journal
22 explaining, this is -- these are the products that we
23 are recommending for routine use, this is the -- the
24 studies, this is the development of them, this is our
25 basis for this determination. And so --

1 JUSTICE SOTOMAYOR: That would include
2 comparisons to other drugs on the market?

3 MR. HORWICH: Well, it -- there often won't
4 be other drugs actually on the market to compare it to,
5 but there will be -- there will be a vast body of
6 scientific literature that again is not exclusively
7 within the manufacturers' control, because it has been
8 produced by the Federal Government, by other countries'
9 public health agencies, by academic scientists, that CDC
10 will reference or its advisory committee will have
11 incorporated in its recommendation.

12 CHIEF JUSTICE ROBERTS: So it doesn't make a
13 determination that the one that they are listing in
14 their morbidity report is better than one that's out
15 there? This is a situation where there were two of them
16 out there.

17 MR. HORWICH: Well, there -- there were not
18 two out there, Mr. Chief Justice. At the time of this
19 there was -- there were two forms of the -- out there --
20 I'm sorry, if I can ask at what time you are referring
21 to?

22 CHIEF JUSTICE ROBERTS: Well, the comparison
23 between the vaccine that caused the harm and the one
24 that Mr. Frederick's client says was more efficacious
25 and therefore the harms were avoidable.

1 MR. HORWICH: Right, and I'm not --

2 CHIEF JUSTICE ROBERTS: There must be a
3 situation where the Centers for Disease Control approve,
4 alert people to the fact that there is a particular
5 vaccine that they think manufacturers should -- should
6 produce, and there is another vaccine addressed to the
7 same disease already on the market. That's never the
8 case? They must improve the vaccine --

9 MR. HORWICH: Yes, certainly.

10 CHIEF JUSTICE ROBERTS: -- or we wouldn't
11 have this case.

12 MR. HORWICH: Certainly they do. And I
13 mean, the Federal Government --

14 CHIEF JUSTICE ROBERTS: When they publish
15 that information in their weekly report, do they compare
16 it both with respect to losses or mortality and with
17 respect to efficiency, with -- to the other vaccines on
18 the market.

19 MR. HORWICH: Yes. Let me give you an
20 excellent example of that which is probably familiar to
21 the Court, that there are two types polio vaccines.
22 There is the Sabin vaccine, with is associated with
23 certain very rare but serious side effects but which is
24 extremely efficacious at protecting a population, and
25 then there is the Salk vaccine, which is not associated

1 with those same side effects, but is not as effective at
2 protecting the population.

3 Now CDC made a determination and this was a
4 determination in effect from the 1960s through the
5 1990s, that the Sabin vaccine -- the one that is, quote,
6 unquote, "less safe," was the appropriate one for use
7 because it better served the public health. Now as
8 polio -- now this is a dynamic process that CDC is
9 continually engaged in, and so as polio approached
10 global eradication and you are not as concerned about
11 actual control of disease running in the community, CDC
12 transitioned its recommendation to the Salk vaccine.

13 So I -- I think that answers the question
14 that the CDC is making determinations in this regard in
15 a comparative way; and I think it would be extraordinary
16 then to have juries -- to have -- to imagine that
17 Congress set up a system in which juries would
18 effectively be second-guessing decisions like that,
19 because CDC has made --

20 CHIEF JUSTICE ROBERTS: It has not only
21 given that information; it has also said in its weekly
22 report that this is the one we want you to make.

23 MR. HORWICH: Yes.

24 JUSTICE BREYER: They are not lawyers; they
25 are scientists.

1 MR. HORWICH: Correct.

2 JUSTICE BREYER: So they may not use these
3 exact words, but you are saying whatever word they use,
4 what they have is an ongoing process to say this is the
5 best vaccine available; is that right?

6 MR. HORWICH: Yes. And part of the on going
7 process, as we described in our brief, is a unique
8 system of monitoring and following up when there are
9 adverse events. So that we gave the example of the --

10 JUSTICE BREYER: The committees have
11 manufacturers on them and Government scientists and
12 university people and others?

13 MR. HORWICH: I'm sorry?

14 JUSTICE BREYER: The committees have
15 manufacturers and Government scientists and university
16 professors and others?

17 MR. HORWICH: My understanding is actually
18 the manufacturers are -- are -- are relatively less
19 represented on these -- on these committees. In a sense
20 that the manufacturers are sometimes doing the
21 manufacturing, but a lot of the research agenda is
22 really driven by the Federal Government.

23 CHIEF JUSTICE ROBERTS: Thank you, counsel.

24 JUSTICE GINSBURG: Mr. Horwich, would you --
25 would you explain one feature of this, it was the

1 allegation that there were an unusual number of adverse
2 reactions to the particular lot that this child's third
3 vaccine came from, and that those adverse reactions were
4 not disclosed to the doctors. And the doctors -- the
5 child's doctor said if I had known about the unusual
6 number of adverse reactions, I never would have used
7 this vaccine.

8 Is there any actionable claim for that, for
9 not disclosing that there were a number of adverse -- an
10 unusual number of adverse reactions to this particular
11 lot.

12 MR. HORWICH: If -- if I may?

13 CHIEF JUSTICE ROBERTS: Sure.

14 MR. HORWICH: Yes, absolutely there is,
15 because that claim is either in the nature of a labeling
16 claim or in the nature of a manufacturing defect claim.
17 And the -- the district court here and the court of
18 appeals both treated that question not under preemption
19 but on the facts, summary judgment in this case was
20 granted purely on the absence of a disputed issue of
21 material fact --

22 CHIEF JUSTICE ROBERTS: Thank you, counsel.

23 MR. HORWICH: -- with respect to those
24 claims.

25 CHIEF JUSTICE ROBERTS: Mr. Frederick, take

1 five minutes.

2 REBUTTAL ARGUMENT OF DAVID C. FREDERICK

3 ON BEHALF OF THE PETITIONERS

4 MR. FREDERICK: Thank you.

5 The only law cited by the Government today
6 was section 14 of the Vaccine Act. It is not reproduced
7 in the materials, but it is -- the title of section 14
8 is a vaccine injury table. It's about recommendations
9 that the CDC makes as to which vaccines will be on the
10 vaccine table, so that when the person goes throughout
11 vaccine court process, you can look and determine
12 whether or not on a no-fault basis the vaccine is listed
13 on the table or not listed on the table.

14 JUSTICE ALITO: May I ask you this question
15 about something that Mr. Horwich said? Under your
16 understanding of this scheme, if a -- a person suffered
17 a very serious injury as a result of the Sabin vaccine
18 during the period when the CDC recommended that over the
19 Salk vaccine, would the -- would that injured person
20 have a claim for design defect if the person could --
21 could produce experts who said the CDC was wrong, that
22 they should never have made this recommendation?

23 MR. FREDERICK: It's not that the CDC would
24 be wrong, Justice Alito. There is a difference between
25 strict liability and a no-fault arrangement and where

1 negligence would be asserted that a reasonable
2 manufacturer would have come forward with information
3 about a safer design.

4 So what Congress explicitly rejected and
5 they voted this down in the Energy and Commerce
6 Committee was a regulatory compliance defense solely on
7 the basis that the FDA had approved at the time --

8 JUSTICE ALITO: Well, this may be -- this
9 may be what Congress wanted and may be the better
10 policy, but your answer to my question is that --

11 MR. FREDERICK: Yes.

12 JUSTICE ALITO: -- that would permit a lay
13 jury relying on experts produced in court, the CDC got
14 this wrong, the Salk vaccine was really the better one.

15 MR. FREDERICK: Yes, yes, that would be a
16 viable design defect claim. And let me give you an
17 example right out of the Joint Appendix in this case.
18 In 1965 Lederle's researchers determine that Lily, the
19 Tri-Solgen, had a "superior product," that's at page 245
20 of the Joint Appendix. That was in 1967. Eight years
21 later the internal scientists at Lederle wrote a memo to
22 the head of Lederle and said we recommend that we
23 approach Lily for its pertussis vaccine process and/or
24 continue to bid on foreign contracts for this product
25 line with the intent of increasing volume.

1 They had made the determination they were
2 not capable internally of doing a safer design and they
3 knew that for eight years and they nonetheless kept the
4 wholesale pertussis in its market and the documents in
5 this case indicate they did it for economic reasons.
6 And the whole idea behind having design defect claims is
7 to put manufacturers to the duty of putting out safest
8 possible products in light of what the science holds.

9 The CDC -- there are no regulations that the
10 Government cites in its brief or today saying that the
11 CDC does the kind of comparative analysis for safety
12 that is provided under State law design defect claims.

13 JUSTICE BREYER: Their argument is that the
14 CDC will do it better than juries. That's what I heard
15 him say.

16 MR. FREDERICK: And, Justice Breyer, there
17 are now six DTaP vaccines on the market that CDC doesn't
18 distinguish between them, but if it comes to pass that
19 the science would indicate that one of them was woefully
20 not as safe, and here, their argument is that the
21 vaccine industry is going to go out of business. This
22 vaccine that's at issue in this case was taken off the
23 market in 1998.

24 CHIEF JUSTICE ROBERTS: I thought
25 Mr. Horwich told me that the CDC does compare new

1 vaccines to the ones that are out in the market?

2 MR. FREDERICK: He cited no law.

3 CHIEF JUSTICE ROBERTS: You think he was
4 incorrect in that assertion. We can go back and look at
5 these weekly reports and they are either going to say
6 this is better than the one that's out there or they are
7 not.

8 MR. FREDERICK: Yes. And if you compare
9 that to what Congress wrote in the statute, our
10 submission is that Congress's words in section 22 take
11 precedence.

12 CHIEF JUSTICE ROBERTS: I'm just trying to
13 find out what your position is on that. Do they compare
14 it to existing vaccines or not?

15 MR. FREDERICK: We found no law that gives
16 the CDC the authority.

17 CHIEF JUSTICE ROBERTS: I'm not asking about
18 law, I'm asking matter of fact.

19 MR. FREDERICK: Whether, I'm not.

20 CHIEF JUSTICE ROBERTS: You open up the
21 weekly report.

22 MR. FREDERICK: I'm sorry,
23 Mr. Chief Justice.

24 CHIEF JUSTICE ROBERTS: When you open up the
25 weekly report and it says this new vaccine is better

1 vaccine than the one that is out there or not?

2 MR. FREDERICK: I'm not aware that the CDC
3 does the kind of granular comparisons that would go to
4 the level of safety that is at issue in this kind of
5 case. And that's what's important here. We are talking
6 about trying to eliminate some of the most horrifying
7 and horrible incidents of injury to vaccines that we
8 compel children to take.

9 And the whole idea behind Congress's scheme
10 was to balance having vaccine supply available with
11 providing a generous form of compensation to those
12 persons who would be injured.

13 CHIEF JUSTICE ROBERTS: Thank you, counsel.
14 The case is submitted.

15 (Whereupon, at 2:02 p.m., the case in the
16 above-entitled matter was submitted.)

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