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. :

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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.

C O N T E N T S

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

could not recover for design defects for vaccines?

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

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

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

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

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

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

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

JUSTICE SCALIA: Say that again. I don't

follow it. Tell me that again.

MR. FREDERICK: Under their --

Justice Scalia, looking at (b)(1) on page 19A following the date October 1, 1988.

JUSTICE SCALIA: Right.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. FREDERICK: And that's why the concept

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

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

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

JUSTICE SCALIA: It has to be just as effective?

MR. FREDERICK: It has to be efficacious.

JUSTICE SCALIA: Just as effective?

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

The problem here was that an efficacious

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

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

MR. FREDERICK: No. Let me clarify.

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

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

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

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

MR. FREDERICK: That's correct.

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

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

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

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

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

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

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

MR. FREDERICK: Justice Kennedy, that was

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

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

JUSTICE GINSBURG: Why was it taken off?

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

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

MR. FREDERICK: Yes. And it was a

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE BREYER: Right. I've got --

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

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

JUSTICE SOTOMAYOR: Explain why.

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

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

have been wrong.

(Laughter.)

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

(Laughter.)

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

(Laughter.)

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

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

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

And so the question --

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

MR. FREDERICK: And --

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

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

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

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

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

defenses.

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

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

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

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

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

vaccination for DTP.

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

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

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

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

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

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

design, if that is available.

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

CHIEF JUSTICE ROBERTS: If the language --

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

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

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

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

CHIEF JUSTICE ROBERTS: But I'm not sure that in most cases you are going to be able to tell immediately -- you are marketing one vaccine and something else is being tested or about to be approved, or it's on the market -- that that's safer. Particularly since you have to look not only at -- whatever -- injury and mortality rates, but also

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

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

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

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

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

MR. FREDERICK: Only if you accept the --

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

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

So in these vast majority of cases, unlike

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

If I could reserve the balance of my time.

CHIEF JUSTICE ROBERTS: Thank you, Mr. Frederick.

Ms. Sullivan.

ORAL ARGUMENT OF KATHLEEN M. SULLIVAN

ON BEHALF OF THE RESPONDENTS

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We read the two clauses together. And let's

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

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

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

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

JUSTICE SOTOMAYOR: Could you please just

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

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

MS. SULLIVAN: Well, Justice --

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

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

JUSTICE SOTOMAYOR: I am not asking about the FDA.

MS. SULLIVAN: But the reason why --

JUSTICE SOTOMAYOR: I said the manufacturers' motivations.

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

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

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

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

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

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

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

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

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

JUSTICE GINSBURG: The warning --

MS. SULLIVAN: And if you look at --

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

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

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

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

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

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

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

(Laughter.)

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

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

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

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

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

MS. SULLIVAN: Yes.

JUSTICE GINSBURG: -- Eli was producing, and

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE SOTOMAYOR: -- for non-listed --

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

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

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

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

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

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

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

JUSTICE GINSBURG: But it also was directed to vaccines.

MS. SULLIVAN: That's right --

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

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

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

disabilities.

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

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

MS. SULLIVAN: Not at all, Your Honor.

JUSTICE SOTOMAYOR: It couldn't have been.

MS. SULLIVAN: They compensate the victims.

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

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

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

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

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

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

MS. SULLIVAN: No --

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

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

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

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

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

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

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

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

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

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

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

For a preemption provision to do any work,

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, Ms. Sullivan.

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

CHIEF JUSTICE ROBERTS: Mr. Horwich.

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

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

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

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

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

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

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

MR. HORWICH: Well --

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

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

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

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

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

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

What do I do about this word unavoidable?

MR. HORWICH: Well I think --

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

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

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

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

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

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

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

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

MR. HORWICH: Yes.

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

MR. HORWICH: CDC does not issue a license.

JUSTICE SOTOMAYOR: No --

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

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

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

MR. HORWICH: Yes. Yes.

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

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

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

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

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

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

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

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

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

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

MR. HORWICH: Yes, certainly.

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

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

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

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

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

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

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

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

MR. HORWICH: Yes.

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

MR. HORWICH: Correct.

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

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

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

MR. HORWICH: I'm sorry?

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

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

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

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

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

MR. HORWICH: If -- if I may?

CHIEF JUSTICE ROBERTS: Sure.

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

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

CHIEF JUSTICE ROBERTS: Mr. Frederick, take

five minutes.

REBUTTAL ARGUMENT OF DAVID C. FREDERICK

ON BEHALF OF THE PETITIONERS

MR. FREDERICK: Thank you.

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

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

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

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

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

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

MR. FREDERICK: Yes.

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

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

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

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

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

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

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

vaccines to the ones that are out in the market?

MR. FREDERICK: He cited no law.

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

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

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

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

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

MR. FREDERICK: Whether, I'm not.

CHIEF JUSTICE ROBERTS: You open up the weekly report.

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

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

vaccine than the one that is out there or not?

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

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

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

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