IN THE SUPREME COURT OF THE UNITED STATES

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DENNIS BATES, ET AL., :

Petitioners :

v. : No. 03-388

DOW AGROSCIENCES, LLC. :

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Washington, D.C.

Monday, January 10, 2005

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 11:03 a.m.

APPEARANCES:

DAVID C. FREDERICK, ESQ., Washington, D.C.; on behalf of the Petitioners.

SETH P. WAXMAN, ESQ., Washington, D.C.; on behalf of the Respondent.

LISA S. BLATT, ESQ., Assistant to the Solicitor General, Department of Justice, Washington, D.C.; on behalf of the United States, as amicus curiae, supporting the Respondent.

C O N T E N T S

P R O C E E D I N G S

(11:03 a.m.)

JUSTICE STEVENS: We'll hear argument in Bates against Dow AgroSciences.

Mr. Frederick.

ORAL ARGUMENT OF DAVID C. FREDERICK

ON BEHALF OF THE PETITIONERS

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

Pesticides are economic poisons designed to kill living things. Sometimes they do not work as designed.

For more than a century until the 1990's, courts routinely permitted farmers to bring claims against pesticide manufacturers for crop damage caused by pesticides. In enacting amendments to FIFRA in 1972, Congress did not intend to displace those preexisting State law remedies.

The farmers here allege claims for defective design, defective manufacturing, fraud, breach of warranty, and failure to warn for a brand new product that severely damaged their peanut crops. I'd like to start with our narrowest theories for reversal and demonstrate for three reasons why those claims survive preemption.

The defective design and manufacturing claims challenge the product's composition, not its label. The

fraud, warranty, and negligence claims involve general legal duties, not pesticide-specific requirements, and the failure to warn and fraud claims are not different from or in addition to FIFRA requirements.

Now, with respect to the first point, Dow concedes at pages 43 and 49 of its brief that defective design and manufacturing claims generally are not preempted. That concession warrants a remand here, as this case was decided before discovery, enable the farmers to develop their claims.

JUSTICE GINSBURG: But couldn't you make every failure to warn claim a defective design claim? That is, they didn't warn about the effects, but those effects would not have been present if the product had been designed to assure that there wouldn't be any adverse effect on the peanut crop.

MR. FREDERICK: Justice Ginsburg, the way the Restatement of Torts and Product Liability in sections 1 and 2 describe, there are basically three theories that products liability claims can proceed on: a defective design, defective manufacturing, and defective warnings. The restatement explains that they are distinct legal theories that go to different problems that the manufacturer has caused with respect to the product. A defective design claim asserts that the composition was

inadequate and that a properly designed product could have been put on the market that would not cause the harm.

JUSTICE O'CONNOR: Mr. Frederick, on the defective design claim, presumably that's based on a factual theory that Dow could have reasonably designed Strongarm to be safe for growing peanuts in high-acid soil.

MR. FREDERICK: Correct.

JUSTICE O'CONNOR: But doesn't that mean your client should have to put forward some evidence establishing a material issue of disputed fact on that point?

MR. FREDERICK: Certainly, but here --

JUSTICE O'CONNOR: And it didn't do that.

MR. FREDERICK: Well here, Your Honor, the motion for summary judgment that Dow filed was not based on the merits of the claims. It was based on them being preempted, displaced as a matter of Federal law. They also asserted a limitation of -- of remedy provision.

But we never had discovery in this case. The District Court, after finding jurisdiction, considered Dow's motion for summary judgment on preemption and locked us out of the courthouse door before we ever had a chance to prove that a safer design for the product could have been made. And that's where we think the court's decision

below was overbroad and should be reversed.

JUSTICE KENNEDY: The -- the problem I have with -- with the Government's case and with the respondent's case is that -- it's really the obverse of what Justice Ginsburg said. Their problem is that they would recast everything as a warning.

MR. FREDERICK: That's absolutely correct.

JUSTICE KENNEDY: Does the restatement have some specific provisions that say no matter how good the warning is, you're still entitled to proceed when there's a -- I don't know -- dangerous product or defective product or something?

MR. FREDERICK: Yes. Restatement sections 1 and 2 address this, and what the restatement says is that if you can show that the product could have been reformulated to be properly designed, then the existence of a warning that might go to certain of its uses would not negate a defective design claim. The Texas Supreme Court --

JUSTICE KENNEDY: Even -- even if the warning specifically covered that design defect?

MR. FREDERICK: That -- that's -- that's correct. And what the restatement --

JUSTICE KENNEDY: So even if this product said, warning: may not be effective in high pH soils, that's not good enough?

MR. FREDERICK: Under the restatement rule, which Texas has adopted in the Uniroyal case, which we've cited in our brief I think at page 47, that is true because the restatement explains that there are certain warnings that could be ignored or not observed or not understood properly and that if it can be proved that a properly designed product would be on the market, there are public policy reasons why that's what we want to encourage manufacturers to do. I mean, under --

JUSTICE SCALIA: At any cost? I mean, what if it -- you know, yes, I can -- I can sell you stuff that will -- that will work in high pH soil, but it's going to be three times as effective. Do I have to sell it?

MR. FREDERICK: Well, the --

JUSTICE SCALIA: Can't I just sell it for those people who don't need it for -- for high pH soil at a third the price with a warning that says, hey, by the way, don't use this in high pH soil? It's crazy to say you can't do that.

MR. FREDERICK: Justice Scalia, to answer your question in several ways, that's a jury determination to -- to ascertain the reasonableness of the alternate design that the manufacturer would be asked to -- to do or to market a separate product that was separately designed for high-acid soils.

JUSTICE KENNEDY: But it's never a question of the reasonableness or the adequacy of the warning?

MR. FREDERICK: I don't think it's a question of warning in this sense, Justice Kennedy. If you take their theory, which is that a defective design claim always collapses to a failure to warn, they can put out a defectively designed product that admittedly causes harm, and all they have to do is change the label and say, if used in these particular circumstances, it may cause harm, because that would necessitate a change to the label --

JUSTICE BREYER: Oh, not necessarily. It wouldn't be always either way. I would think that if in fact you have a product and the product causes harm in a subset of cases, which you could warn against, then a jury could decide whether the unreasonableness consists of not having designed the super-safe product or the unreasonableness consists of not having had a different label.

MR. FREDERICK: And that -- there are -- that's why the restatement makes clear that there are distinctive theories for defect --

JUSTICE BREYER: And you're arguing that in this case you have the first.

MR. FREDERICK: That's correct.

JUSTICE BREYER: It seems implausible on -- you

know, --

MR. FREDERICK: Well, we have both actually.

JUSTICE BREYER: -- because all they'd have to do is don't use it in pH soil.

MR. FREDERICK: No. We have defective warning too, and -- and if I can address that as well. The statute here prohibits in section 136q(1) any false or misleading statement in the label as to any particular. Our position is that the 2000 label said, suitable for peanut-growing areas in all places where peanuts are grown. That was false. Under the statute, that is a misbranding, and that is actionable as -- both as a failure to warn, as a fraud claim, and as a breach of warranty.

Now, the Medtronic majority made absolutely clear that that kind of claim is not preempted, and in fact all nine Justices agreed that when the State law claim is parallel to the Federal requirements, the existence of a State law remedy is not an additional requirement.

JUSTICE KENNEDY: So on -- on that aspect of the case, you put in your pleadings that this was a violation of FIFRA.

MR. FREDERICK: We don't necessarily need to say a violation of FIFRA is -- so long as the requirement is

the same, although we can certainly --

JUSTICE KENNEDY: Well, that's a -- that's a bit different. You were -- you were asserting a moment ago I thought -- please correct me if I'm wrong -- that this was a violation of FIFRA because it was misbranded.

MR. FREDERICK: I --

JUSTICE KENNEDY: It seems to me that you then have a suit under FIFRA, but I don't think that was the theory of your complaint.

MR. FREDERICK: No. The theory of our complaint was a failure to warn both for negligence and as a defective product.

JUSTICE SOUTER: But the reason for that, I take it, is that FIFRA does not -- I mean, I think you agree FIFRA does not provide an independent private right of action.

MR. FREDERICK: That's correct.

JUSTICE SOUTER: So you've got to sue under State law, but you would -- you would kind of have a slam dunk for your position, I suppose, if your pleading said, the failure to warn only to the extent that in fact the -- the warning given in compliance with FIFRA was an inadequate warning. That would -- that would keep you within the -- the -- in effect, the -- the Federal limit, and it would also make clear that you had a State law

cause of action, not a Federal cause of action.

MR. FREDERICK: That's correct, and because --

JUSTICE SOUTER: And -- and that's in effect what you're arguing.

MR. FREDERICK: Yes. And -- and because of the preliminary of this suit, Justice Kennedy, we certainly should have the opportunity to amend our complaint. There are counterclaims that this is done at the motion for declaratory judgment.

JUSTICE BREYER: In your view -- in your -- your opinion, if you were to follow that, would EPA -- suppose EPA does the following. EPA looks into this and they publish a reg that says in this case or in this subset of cases, or some kind of description that fits yours, we think that the labeling should be thus and so and we think that State tort suits will interfere with our ability to promote the uniform labeling and therefore they're preempted. Can the EPA do that on your theory?

MR. FREDERICK: Yes, it can and the -- the interesting aspect of this, Justice Breyer, is that of course EPA hasn't done that. EPA has made very clear it never tested for efficacy. It never even gave notice and comment so that --

JUSTICE O'CONNOR: Well, EPA has -- has waived efficacy data requirements. Right?

MR. FREDERICK: Yes.

JUSTICE O'CONNOR: Now, is it your position that a State can pass a law requiring labels to have efficacy claims?

MR. FREDERICK: They have to do it pursuant to their powers under 136v(a) which is the regulation of sale or use or under 136v(c) which says that when a State designates a particular locality requirement and a special need, it can impose a label -- it can impose requirements that the manufacturer has to comply with.

Now, the EPA importantly -- and this is in their regulations at 163.152 -- has specifically said that States have labeling authority. The States can impose labeling requirements. Now, there's no reason why --

JUSTICE O'CONNOR: But you're not relying on that in this cause of action.

MR. FREDERICK: No, Justice -- no, Justice O'Connor, except to the extent that if the State can affirmatively do it through a positive regulation, their theory has to be wrong that the -- that any incidental effect that induces a change to label is preempted. That theory has to be wrong, and that's what the Fifth Circuit relied on.

JUSTICE O'CONNOR: Well, does -- does FIFRA require the manufacturer to say on the label what the item

can be used for?

MR. FREDERICK: Yes, but I want to address --

JUSTICE O'CONNOR: So how -- how does an express warranty claim escape preemption --

MR. FREDERICK: As the --

JUSTICE O'CONNOR: -- where -- where Dow just says the federally mandated statement is included on my label and it's true?

MR. FREDERICK: A warranty claim, Justice O'Connor, as this Court made clear in the Cipollone case, is not a requirement under State law because it's a voluntary contractual arrangement between the parties. The Court I think has made clear that what has to be ascertained here is does the State cause of action or the State law create a requirement. That's not true in the warranty case because FIFRA doesn't speak to requirements in -- as to warranties. It speaks to requirements in other ways.

So what Dow did here with its warranty was completely voluntary, and the fact that it breached that warranty by putting on the market a product that was not suitable for the use in all areas where peanuts are grown is a breach of a warranty that it voluntarily undertook. Breach of that is not a requirement imposed under State law. And that has been, I think, verified by seven

Justices of this Court in the -- in the Cipollone case.

Now, if I could speak to the fraud claim, it is important to understand that in both Cipollone and in a footnote in Medtronic, the Court made clear that where there are general legal duties that are not observed by the manufacturer that don't go to the specific product itself, those claims are not preempted.

Here our assertion is that Dow put on the market a -- a product that was mislabeled and that they went out and told people fraudulently was suitable for their uses. We acted in reliance on that and we suffered damages. Those are general legal duties, not pesticide-specific ones. And the existence of the preemption clause of 136v(b) does not displace us from the opportunity to try to prove to a court that fraud was committed here.

Now, if I could briefly address two points. One is that the inducement to change theory should be rejected. That was the basis on which the Fifth Circuit decided this case and it is an overly broad theory for several reasons.

First, it's not supported by the text of 136v(b) which says requirements for labeling. It doesn't say requirements that induce a change to the label. And that's how many of the courts have gone off track since the Cipollone decision was announced by this Court. They

have read FIFRA as saying just because the word requirements is 136v(b), thereby any State law claim that imposes a requirement that might induce a manufacturer to change the label is thereby preempted. We think that's overly broad because it confers way too much discretion on manufacturers to decide what to put on labels, and they can claim immunity for any overly broad claim of efficacy so long as when they are sued, they can say we're induced to change the label.

Because EPA does not evaluate the specific contents with respect to efficacy or the claims that are made on -- on a label, if a manufacturer makes an overly ambitious statement as to efficacy, all the manufacturer has to do under the inducement to change theory is go to court and say we would have to change the label and thereby 136v(b) preempts it.

Now, I'd also like to stress that the other side's theory creates a huge regulatory gap. As your question, Justice O'Connor, noted, the EPA does not evaluate efficacy on the front end. And in fact, the history behind these provisions is that EPA understood from the very beginning that common law claims would serve an important incidental regulatory effect.

If we could review the history for a moment. Prior to the 1972 changes to FIFRA, for decades farmers

had brought claims against manufacturers for design defect, for failure to warn, for the kinds of common law claims that we have asserted in this case. It was so well established by 1972 that there was a huge section in the American Law Reports that annotated all the cases and explained what the common law duties of pesticide manufacturers were. Yet, notwithstanding that, when Congress enacted the 1972 act, despite thousands of pages of hearings, committee reports, legislative debates, there is not one mention of any effort to displace those preexisting common law claims.

And when EPA, in discharging its responsibilities under the 1972 act, got overwhelmed by the requirement that it re-register products that were already out on the market, pursuant to the 1972 act's standards, it very promptly went to Congress and said, you should waive efficacy requirements because we simply can't do this. Congress responded, but importantly in the administrations on both sides, EPA has always understood except until just a couple of years ago when the Solicitor General changed the position of the Government, that these kinds of incidental common law suits would have an important regulatory effect.

If we could just take the case of DDT. For 30 years, manufacturers were sued for DDT and awarded damages

until it became clear that the groundswell over the course of decades that DDT needed to be banned, and it was only at the back end that the expert agency regulators determined that in fact the product needed to be banned, but that was only after a very long history in which common law suits had provided remedies to farmers and others who were harmed by that product.

Now, in 1982, the Reagan administration's EPA expanded the efficacy waiver and it included far greater products than had been done in the Carter administration in 1979. And in the Federal Register notice announcing that it was intending to expand that efficacy waiver, the EPA in 1982 said the reason why we think this can be done is because suits can be brought against manufacturers who put on the market ineffective products. We cited that on page 31 of our brief.

JUSTICE KENNEDY: But do you take the position that juries can do what a State regulation cannot do, or are they much -- are they on a par?

MR. FREDERICK: Well, our broadest theory, Justice Kennedy, is that the word requirements in 136v(b) doesn't include common law claims at all.

JUSTICE KENNEDY: Suppose we disagree with that.

MR. FREDERICK: If you disagree with that, then they would have to be the same, and that's why our point

about the existence of the parallel requirements is the same.

I want to address the point of the discordance between what State juries can decide and what State regulators can decide because Dow and the Government have featured that in their case. The Government in the Medtronic case at page 27 of its amicus brief there said there was no problem to be had with juries rendering supposedly inconsistent decisions so long as they were following one Federal standard. The Federal standard here is clear: falsity. Tell the truth. That's what manufacturers are obliged to do under the statute and under the regulations.

JUSTICE BREYER: Well, that's their strong point. So what is the response to that? Because you can easily get two juries in different parts of the country to decide absolutely opposite things as to what the label should say, and in those circumstances, they say, well, they're in an impossible situation and that's why Congress passed this statute, to be sure it would be EPA and not two juries in different places.

MR. FREDERICK: First, the juries -- unlike a -- a declaratory judgment or an injunctive type remedy, Justice Breyer, a jury for a common law damages claim is not saying what affirmatively should be on the labels.

JUSTICE BREYER: I'm speaking practically. And I don't have to go into all the argument.

MR. FREDERICK: Sure.

JUSTICE BREYER: You know the argument. It's a very familiar argument.

MR. FREDERICK: Sure. The answer is that -- that Congress was prepared to accept a certain level of disuniformity when it enacted 136v because it made very clear in sandwiching the preemption provision of 136b -- surround -- by (a) and (c) that it was prepared to allow States to depart in significant respects from what was nationally uniform. And the way it did so was to say States can regulate sale or use and they can also impose extra requirements for special locations.

Now, what Dow did here I think illustrates the way the system is supposed to work, which is that when a problem was identified with their product in the States of Texas, Oklahoma, and New Mexico, within 7 months it petitioned the EPA to append to its national uniform label a supplemental label. And that supplemental label says it is for distribution in those three States only and it provided 10 important changes to the label that it otherwise had as a nationally uniform label. That's how the system is supposed to work. If the incidental regulatory effect of jury verdicts or common law claims

induces or causes some kind of change to the label, that can be done without an adverse effect to national uniformity through the supplemental labeling process. And what Dow did here was it has its label and then it attaches the supplemental label that addresses the particular conditions that exist in the State.

And the EPA has recognized that as a perfectly appropriate and valid way to address the geographic, environmental, and climatic conditions that exist in the different regions of the country that engage in agriculture. There's nothing that is uncertain about that if you accept the premise of the Government's argument in Medtronic, which is that juries can be properly instructed, if it came to that, so that they could follow the appropriate Federal standard.

Now, I would like to turn -- sorry. Did you -- no, go ahead.

I would like to turn briefly to the -- the requirements aspect of the case because we do think that, under our broadest theory, this is a different situation than Medtronic and Cipollone, and because of the important statutory indications that are in the provision 136v. Unlike in Medtronic, there is an explicit provision that is a non-preempted provision, and that is different from Medtronic. Where in Medtronic there was a provision that

allowed the FDA to impose its own decisions as to requirements and whether or not the States should be displaced, here Congress made the determination in 136v(a) and in (c) that those kinds of requirements can be imposed. They're in addition to what the Federal standard is. That means that you have to look at requirements in a somewhat different way because the States have this authority that they did not have under the Medical Device Amendments.

There's a textual indicator under (b) also which refers to (a) in the sense that (b) says such State that shall issue these requirements. Such -- the meaning of it in Webster's means what has been already described -- is in (a), and in (a) the States are authorized to promulgate regulations. So we think that there is a textual basis for distinguishing the word requirements that this Court -- five Justices in this Court in Medtronic said would encompass common law claims.

If there are no further questions at this time, I'd like to reserve the balance --

JUSTICE BREYER: Let me ask one because I think you'll hear some variation of this, and you have a minute, which is the -- the statute sets up a perfectly good way of keeping this branded stuff off the market. All any complaining farmer has to do is to go to EPA and ask them

to pull it, and pulling it is an unbelievable sanction. It's like the atomic bomb on the company. And so that's very strong.

And the only thing that leaves out is the possibility of damage remedies, but if you want your damage remedy, just go to EPA and tell them to give it to you because they can write the rule the other way that I was suggesting.

MR. FREDERICK: Well, I don't think that EPA could write a rule requiring damages to be done. It doesn't have the statutory authority --

JUSTICE BREYER: They would just say it doesn't preempt.

MR. FREDERICK: Well, there's no indication here that EPA can do that kind of thing. In FIFRA, it certainly doesn't have that kind of provision. I mean, certainly there are different ways that the statute could have been written. That isn't the choice that Congress made.

Thank you.

JUSTICE STEVENS: Mr. Waxman.

ORAL ARGUMENT OF SETH P. WAXMAN

ON BEHALF OF THE RESPONDENT

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

FIFRA's preemption provision, which Congress specifically amended in 1978 to add the title uniformity, preempts by its terms, quote, requirements for labeling different from those required under FIFRA.

JUSTICE SOUTER: Why -- why doesn't the other amendment limit your argument? Because Congress has also passed an amendment to the effect that unless EPA chooses to get in to the business of -- of passing on efficacy, it -- it need not do so. And in fact we know it is not doing so. Why, therefore, doesn't the uniformity argument go to those subjects that EPA does review for and why doesn't the subject of efficacy, in effect, drop out of -- of the -- the whole preemption claim?

MR. WAXMAN: There are -- there are two fundamental reasons. The first is that it is a principal requirement of FIFRA, and has been since 1972 and remains, that a manufacturer may only sell a registered pesticide with the precise labeling to the word and font size that EPA has approved, and that requirement applies whether the wording relates to human safety, environmental protection, or efficacy.

Now, the specific amendment in 1978 was, as Mr. Frederick indicated, represented a representation by EPA to Congress -- and Congress' -- the -- the committee report plainly indicates this -- that the EPA was not

saying we are no longer regulating efficacy, we are no longer concerned with efficacy. What they said was because the Department of Agriculture and the extension services and the State universities are all involved in this and, in particular, are involved in the statutory requirement that before a manufacturer can even apply for registration, even submit a registration application, the manufacturer must do extensive, rigorous efficacy testing, which Congress has indicated correctly is very expensive --

JUSTICE GINSBURG: But it's not monitored at all. The -- the manufacturer can say -- make up reports and EPA is never going to look at it.

MR. WAXMAN: If the manufacturer makes up reports, it has committed a felony. EPA can enforce it. It can refer it to the Attorney General. It's just like the --

JUSTICE O'CONNOR: But maybe it isn't a labeling violation. I mean, there are claims made here that I have trouble shoehorning into your theory. For instance, why does a claim that Dow negligently failed to field test its product on peanuts on acid soil impose a label requirement?

MR. WAXMAN: Justice --

JUSTICE O'CONNOR: I -- I just don't understand

that.

MR. WAXMAN: Justice O'Connor, I think -- I will address the negligent testing and, of course, the design defect --

JUSTICE O'CONNOR: Yes.

MR. WAXMAN: -- discussion that's figured so prominently in my colleague's argument.

It's very, very important to understand that unlike in Sprietsma and Medtronic and so many of the -- and, for that matter, with respect to the preempted claims in Cipollone, the claims that were preempted below, we didn't file a rule 12 motion to dismiss. We couldn't have with respect to at least one of those two claims. We filed a motion for summary judgment that said with respect to -- let me take design defect first. With respect to design defect, it is possible under Texas State law to state a claim for products liability under defective design without impeaching the labeling.

And there is a brief filed in this case by Dean Powers, the University of Texas Law School, for the -- the Texas Chemistry Council who's an expert on Texas tort law, and he goes through the Texas torts in detail to show why they are all preempted and all invalid under independent and adequate State grounds.

But what we did is we didn't move to dismiss.

We filed a motion for summary judgment, and in that motion for summary judgment, we pointed the respondents in this case to this Court's decision in Celotex v. Catrett, and we said, in effect, we know that you can allege a design defect claim without impeaching the labeling, but we think that what you are complaining about does impeach the labeling. Therefore, show us what you have.

Now, under rule 56, they had two alternatives. They could have filed an affidavit or a request under rule 56(f), as this Court referenced in Anderson v. Liberty Lobby, and said, hey, we don't know how this was made. We don't know how this was tested. We don't know how this was manufactured. We're entitled to discovery, and district courts recognize that all the time. What they did --

JUSTICE O'CONNOR: And they didn't do that?

MR. WAXMAN: They did not do that, and what they did was to submit affidavits and documentary evidence, including expert affidavits.

JUSTICE STEVENS: Mr. -- Mr. Waxman, you said they didn't file a motion to dismiss. I thought you brought the lawsuit.

MR. WAXMAN: We brought the lawsuit and we --

JUSTICE STEVENS: But then they couldn't file --

MR. WAXMAN: No, no, no. I said we didn't file

a motion to dismiss --

JUSTICE STEVENS: You didn't file a motion to dismiss your own complaint?

MR. WAXMAN: No, no. Their counterclaims.

JUSTICE STEVENS: Oh, okay.

MR. WAXMAN: In other words, this wasn't decided -- Mr. Frederick's reply brief talks over and over and over again about how this was decided on the pleadings, and you know, there was no discovery allowed. Under rule 56, they could have asked for discovery when we basically said, okay, let's show our hands. We got two jacks. What do you got? And what their expert said and what their response said was if the 2001 amended label had been on it, we wouldn't have been injured.

Now, rule 56(c) says that when you oppose a summary judgment motion with affidavit evidence, the burden is on the adverse -- the adverse party must by affidavits, or otherwise provided in this rule, set forth specific facts showing that there is a genuine issue for trial, and they didn't do that.

Now, the classic design defect -- let me -- let me give you an example.

JUSTICE O'CONNOR: Well, let's just try to boil it down a little bit for my purposes. Do you concede that there could be a claim based on no testing --

MR. WAXMAN: Well --

JUSTICE O'CONNOR: -- that there could be a claim based on design defect, that there could be a claim saying there were off-label oral statements made that amounted to fraud or misleading --

MR. WAXMAN: I'll take them in your precise order.

JUSTICE O'CONNOR: Okay.

MR. WAXMAN: Under Texas law -- and the Court of Appeals opinion, the Grinnell opinion cited by the Court of Appeals opinion, says this, as does Dean Powers. Under Texas law, negligent testing is not an independent tort. It is of necessity a subset of inadequate warnings. It is an element of a -- the tort -- the claim of product defect related to warnings. And so it is not possible under Texas law, settled Texas law. Other States are different, but Texas in its sovereign capacity has chosen to make claims of negligent testing an element of the tort of defective product by failure to warn, and that --

JUSTICE GINSBURG: And the way you proceeded in this case, you made it clear that it would be impossible for the Texas court itself to weigh in on this because you jumped the gun. They wanted to proceed in Texas court, and then we would have known what Texas law was on these subjects. You said, no, we want to be in the Federal

forum.

MR. WAXMAN: We want -- as the -- as the Fifth Circuit found and the District Court found, we filed a declaratory judgment in Texas after we received their demand letters because we wanted this to be adjudicated in a single forum, which the Texas venue rules would not have allowed, and we -- we actually filed this in Lubbock, Texas, which is the geographic center of where these 29 farmers operate.

Now, with respect to defective design, yes, under Texas law if they had a -- they have to allege and they have to prove that there is a safer alternative design for this product, which they never even introduced one quantum of evidence about. But --

JUSTICE STEVENS: It seems to me you're -- you're arguing the merits of the tort claims rather than the preemption issue.

MR. WAXMAN: Well, what we said was your claims are preempted if they impeach the labeling that we are required by Federal law to use.

JUSTICE O'CONNOR: But they now say they don't. They ought to be able to proceed on those claims. What do we do with that?

MR. WAXMAN: Well, what this -- what -- what happens under rule 56 --

JUSTICE O'CONNOR: And also the -- also the claims of false, misleading statements outside the label.

MR. WAXMAN: Yes. I'm going to get to the false and misleading statements outside the labeling in a minute, but just to finish the design defect point, they filed a complaint -- a counterclaim which had as a count this was defectively designed. It is possible under Texas law to prove that something is defectively designed. If they had come in and said, but we filed a motion for summary judgment that says here's our evidence and we don't think that you can satisfy -- that you are, in fact, complaining about a defective design --

JUSTICE STEVENS: But if they did allege a defective design claim under Texas law, would that have been preempted?

MR. WAXMAN: No. If -- if they had said, look, the problem with this, which as footnote 9 of our brief indicates, it's not a --

JUSTICE STEVENS: It seems to me your argument is not whether there's preemption. It's whether there's a State cause of -- State law cause of action.

MR. WAXMAN: No, no, no. It's -- it's both. With respect to defective design, what we said is, your claim is preempted because you aren't going to go to the jury on defective design without impeaching the label. If

we're wrong, prove it in response to our summary judgment submission.

JUSTICE SOUTER: But you can --

JUSTICE SCALIA: Is that their burden?

MR. WAXMAN: It is --

JUSTICE SCALIA: Is that their burden or is your burden to show --

MR. WAXMAN: It is -- it is absolutely their burden in -- as the responding party to a motion for summary judgment, to show that there are material facts that are either in dispute or there are material facts that would allow them to go to the jury.

JUSTICE SOUTER: But on your theory there is no material fact, it seems to me, because your -- what you say they cannot make good on that claim without impeaching the label.

MR. WAXMAN: And they --

JUSTICE SOUTER: Every time they sue on the -- on the ground that -- let's say, that -- that the -- the actual use was inconsistent with what the label described, you could say, gee, if their theory is correct, we'd have to change our label to say that what's on the label now is in fact not properly descriptive of the product. So it's not a -- a question of needing more fact. On your theory, whenever they, in effect, sue on the basis of what you

say, your response is going to be, as a matter of law, well, if they're correct, we'd have to say something else. That impeaches the label. Therefore, preemption.

MR. WAXMAN: That is exactly right. What they could have done in response to our motion for summary judgment is to say this product assertedly harms -- when it is applied before the seed is planted, will harm the product it is -- the plant that it's supposed to protect if the soil pH is too high. They could have easily have come back and said if they had a -- a design defect claim that didn't impeach the label to say you should have -- there was a way to manufacture this product. You could have it in pellet form rather than in the soluble form or if the problem was the alkalinity of the soil, there is a way to design this so that it is dissolved in a more acidic solution.

The classic case, which is referenced in the NRDC brief, which has many, many examples of true design defect claims that don't impeach labels, is a case involving rat poison. It's a case called Banks v. ICI America. It's a Georgia Supreme Court --

JUSTICE BREYER: So you quite clearly have both. I understand that.

Let me ask you a question about the -- the preemption point because what I think they're saying is go

read the red brief, your brief, pages 6 and 7, and there you see a statutory requirement and you see regulatory requirements, regulation. And I think one of their claims is we are arguing that that statutory requirement, without any change in the regulatory, that -- that it was violated. These are false. They're misbranded. So we are not imposing a requirement different from or in addition to the requirement of Federal law. We are enforcing a requirement that is the same as the requirement of Federal law, and if, by the way, the EPA were to think that tort suits in those circumstances in practice are too disuniform, let them promulgate a regulation to that effect. But they haven't.

Now, what -- what is the answer to that argument?

MR. WAXMAN: The answer is threefold. Number one, a challenge to a -- the wording of a statement on the label on the grounds that it is false and misleading is -- does impose a requirement different than Federal law, not the requirement that -- that labeling not be false and misleading, but the fundamental requirement that a -- unless and until the EPA says otherwise, the manufacturer can only sell this product with the precise labeling that EPA has approved. And it -- if you look at page 63a --

JUSTICE GINSBURG: Mr. Waxman, do I --

MR. WAXMAN: -- of the joint appendix --

JUSTICE GINSBURG: Mr. Waxman, do I take it from what you have just said that there is no -- even though the statute prohibits misbranding, that there is no way that that can be privately enforced, that misbranding is something strictly for EPA to deal with, that the statute has a prohibition on misbranding? I can see the argument that all we're doing is enforcing the provision that says no misbranding. So is EPA the only the player in the misbranding --

MR. WAXMAN: Insofar as labeling is concerned, the answer is yes, and that's because the statute -- the statute has many, many instances in which it makes it clear that in service of the objective of a nationally uniform label, the expert agency that approves and dictates the language of that label be the one to decide what is or isn't --

JUSTICE STEVENS: Mr. Waxman --

JUSTICE BREYER: Where does it say that?

JUSTICE STEVENS: -- can I ask you one question here?

JUSTICE BREYER: Because you were just going to point out where it says that --

JUSTICE STEVENS: It goes to your --

JUSTICE BREYER: -- which I think is --

JUSTICE STEVENS: Excuse me.

JUSTICE BREYER: I'm sorry.

JUSTICE STEVENS: Just let me ask this one question. Supposing the label says, this product contains vitamin A. Period. And it doesn't contain vitamin A, and they prove that in court. And you say you would have to change the label. I suggest you could change the product by putting vitamin A in it.

MR. WAXMAN: Well, you can -- you're --

JUSTICE STEVENS: Why isn't that an answer to the misbranding? You change the product not necessarily the label.

MR. WAXMAN: Because the difference between a -- that would be a -- a manufacturing defect, which are cases that have been decided --

JUSTICE STEVENS: It would be a false statement in the label. The label happened to be false, a misrepresentation in it.

MR. WAXMAN: If -- if the -- if it contains -- I'm sorry. Was it vitamin A? If it contains vitamin A because that's what the manufacturer intended and that's what the manufacturer produced --

JUSTICE STEVENS: No. The manufacturer knew it didn't contain it. He falsely put that in the statement --

MR. WAXMAN: Oh, I see. Said that --

JUSTICE STEVENS: -- and -- and it's -- it's a misbranded, false statement. Now, does he have to change the label or could he change the product?

MR. WAXMAN: Well, I believe that you have -- you would have to -- I mean, would it be efficacious with vitamin A? I don't know, but if it -- if it requires a change in the label, it has to be done by EPA because the manufacturer commits a Federal law violation if it sells the product with any different label. If you -- if I can just direct the Court's attention to --

JUSTICE STEVENS: No, but I'm suggesting he could sell the product with the same label if he just changed the product to correct the misstatement.

MR. WAXMAN: Well, the test, as the Fifth Circuit stated, Justice Stevens, is whether a judgment against Dow -- I'm quoting. Quote: whether a judgment against Dow would cause it to need to alter the Strongarm label. I'm -- and that's the -- those are -- that's the test that was applied here and is always applied.

JUSTICE SOUTER: Okay, but why --

MR. WAXMAN: That is, does the State law cause of action -- is it premised on a State law duty that there -- that different labeling be used --

JUSTICE SOUTER: No, but neither --

MR. WAXMAN: -- that is, a little bit different than what Federal law requires.

JUSTICE SOUTER: The problem that I think some of -- several of us are having is that both the -- as I understand it, the Fifth Circuit test in your argument draws no distinction between the two following kinds of situations. Situation A: there's something that the manufacturer should have told you, should have put on the label, but the manufacturer didn't. Situation B: the manufacturer puts something on the label which in fact is wrong and in Justice Stevens' example is in fact false and it causes harm.

It makes sense, it seems to me, for preemption purposes to say if the person who sues sues simply on the ground that I bought it in reliance on the label, the label was false, I should get damages for -- for whatever harm was caused, that situation should be dealt with for preemption purposes differently from the situation in which the -- the manufacturer made no false statement. He simply should have said more. And if -- if you don't distinguish between those two situations, then the -- the prohibition against mislabeling means absolutely nothing because -- because it can never be enforced, in effect, except with respect to some prospective user. It can never be enforced with respect to the actual user.

MR. WAXMAN: Justice Souter, that is a choice that Congress could have made. It is plainly not a choice that Congress did make because it applied the preemption provision to requirements that are either in addition to or different than. And whether a label is assertedly misleading because it fails to include something on the EPA-approved label or --

JUSTICE SCALIA: Requirements for labeling or packaging --

MR. WAXMAN: Yes.

JUSTICE SCALIA: -- that are in addition to or different.

MR. WAXMAN: Yes. I -- I --

JUSTICE SCALIA: Requirements for labeling or packaging.

MR. WAXMAN: Yes, and -- and if it -- if the --

JUSTICE SOUTER: Yes, and the argument that's being made is that we ought to -- we ought to read -- we ought to read the limitation, which Justice Scalia has just described, with respect to labeling and packaging, in a relatively narrow way to allow the suit to go forward and, therefore, we ought to make a distinction between the two kinds of situations.

MR. WAXMAN: The allegation in this suit -- the claims in this suit -- and I -- I see that my time has

expired.

JUSTICE STEVENS: Ms. Blatt.

ORAL ARGUMENT OF LISA S. BLATT

ON BEHALF OF THE UNITED STATES,

AS AMICUS CURIAE, SUPPORTING THE RESPONDENT

MS. BLATT: Thank you, Justice Stevens, and may it please the Court:

It would entirely destroy the uniformity contemplated by -- contemplated by the statute if the EPA-approved and mandated label were subject to jury-by-jury invalidation based on a jury's determination of whether a label is false.

JUSTICE SCALIA: This is a new position for the Government, isn't it?

MS. BLATT: Yes, we have --

JUSTICE SCALIA: You used to take the opposite position.

MS. BLATT: That's right.

JUSTICE SCALIA: And we're dealing here, as -- nobody has mentioned it, but there -- there's a clear statement rule for preemption, isn't there? Doesn't the preemption of -- of traditional State powers have to be clear in the statute?

MS. BLATT: We -- we think subsection (b) is unambiguous in preempting any statement.

JUSTICE SCALIA: It's -- it's ambiguous enough that the Government -- the -- the chief beneficiary of the -- of the supposed preemption didn't see it. It used to come out the other way. How can you possibly say it's clear?

MS. BLATT: Well, the agency is allowed to change its position and we realize --

JUSTICE SCALIA: I understand. It's -- it's welcome to change it, but it -- it's one thing to change it. It's another thing to change it and come in to say that the question is clear.

MS. BLATT: Well, we think that -- we realize that our position was inconsistent with not only the Court's decision in Cipollone and in Medtronic that recognizes that requirement extends to common law duties. But more importantly, a system where a jury-by-jury on the same facts could come up with completely different reasons why a label is false --

JUSTICE BREYER: So -- so if you have one administration thinking the one thing and the other thinking the other thing, why isn't the answer that the agency can promulgate the reg it wants? And therefore if the reg -- if the agency comes to that conclusion, let them promulgate that reg. And if a different one thinks it can work with the tort suits, let them promulgate that

reg.

MS. BLATT: Well, unlike Medtronic where preemption occurred by virtue of the FDA's regulation, under FIFRA there's preemption by virtue of the statute itself. And I just want to give one --

JUSTICE SOUTER: Yes, but why isn't there a big difference, for purposes of your argument, between the Medtronic situation and this one for the simple reason in this case you've got a statute that authorizes EPA to do absolutely nothing on the subject of efficacy? And EPA does nothing on the subject of efficacy.

MS. BLATT: Well, that's just not true, with all due respect. I mean, they -- the -- we don't verify the accuracy of the efficacy labeling, but the requirement, both in the preemption provision and in the requirement to use the EPA label, clearly extends to efficacy.

And you can have disuniform context whether it's safety or efficacy. Imagine a label that directs a product to be mixed for 20 minutes. One jury could find the label was false because the product should have only been mixed for 10 minutes. Another jury in the same courthouse could find the label was false because the product should have been mixed for at least 30 minutes.

And this case is another really good example. Now the petitioners are saying the label says that the

soil only should be a 7.2 level. Their expert says --

JUSTICE STEVENS: Yes, but the remedy to that would not necessarily be to change the label. It might be to change the quality of the product that requires how much time for mixing.

MS. BLATT: And we think it's critical that our position is that this statute only operates in the area of labeling, and it preempts only those State labeling requirements --

JUSTICE STEVENS: What do you say about my vitamin A example?

MS. BLATT: I think your vitamin A example is an excellent example of a non-preempted claim. If a manufacturer says that this is a pesticide and he puts Clorox in the bottle, the plaintiff wants to get to the jury on the theory that a reasonable manufacturer would not have used Clorox. He would have used the pesticide. If the argument, on the other hand, is Clorox was fine. I don't have a problem with Clorox, I just wish I would have been given a warning, but that's not the way a plaintiff would frame his complaint.

We think it's critical that our theory is if the plaintiff's theory of recovery is necessarily -- necessarily predicated on a requirement that the manufacturer used a label different than the EPA-approved

label the Federal law required it use --

JUSTICE O'CONNOR: Well, let's -- let's be specific here. If it's a failure to test, if it's a -- a design defect requirement, if it's an off-labeled, false misrepresentation, why are they preempted?

MS. BLATT: On the face of the complaint, we agree that they're not preempted. Our only position is by the time it got to summary judgment, the courts decided that they had no evidence on what would have been non-preempted claims. If another farmer wants to bring an expert that says Strongarm can be manufactured --

JUSTICE STEVENS: But then do you endorse the theory of the Court of Appeals in this case?

MS. BLATT: Well, we think the Court of Appeals took it claim by claim and read the affidavit -- or at least the District Court did --

JUSTICE STEVENS: And you think just mere inducement to change a label is sufficient to create preemption.

MS. BLATT: Mere inducement only to the extent that that's a shorthand way of saying the label was -- necessarily had to be required. Let me give you an example.

JUSTICE SCALIA: If Congress wanted that, surely it could have stated it more clearly than simply saying

the State shall not impose or continue in effect any requirements for labeling or packaging. A tort suit because of -- of mislabeling is not a requirement for labeling or packaging.

MS. BLATT: If the --

JUSTICE SCALIA: And if Congress wanted to say that, they could have said it.

MS. BLATT: Well, I think they did say if a common law duty is necessarily premised on the requirement that the manufacturer used a different label than Federal law required him to use. In this case, the common law duty of a failure to warn is saying the manufacturer should have put something on --

JUSTICE SCALIA: You have -- you have that provision which talks about requirements for labeling or packaging in conjunction with another provision that authorizes the State to regulate the sale or use.

MS. BLATT: The --

JUSTICE SCALIA: I mean, you -- you have to make sense of the two.

MS. BLATT: Right, and that's --

JUSTICE SCALIA: And it seems to me that means the State can impose certain requirements upon the seller to the consumer --

MS. BLATT: Not on labeling. Justice Scalia,

every day --

JUSTICE SCALIA: Well, every change -- virtually every change -- virtually everyone -- if -- if you believe the respondent's theory, virtually any State regulation of the substance of the sale will require a change in the label.

MS. BLATT: That's just not true. Every day States and localities around the country are imposing use restrictions. They tell -- they tell applicators and users when and where to apply the pesticide and what types of --

JUSTICE SCALIA: Sale -- sale or use is what it says.

MS. BLATT: That's right and they --

JUSTICE SCALIA: Say -- if they regulate the sale or use.

MS. BLATT: That's right, and they do that every day without imposing labeling requirements. Imagine -- imagine --

JUSTICE SCALIA: Give me sale examples.

MS. BLATT: They require the manufacturer, in order to sell the product, be registered with the State, and they can impose whatever sale restrictions they want --

JUSTICE KENNEDY: And can they --

MS. BLATT: -- that don't go to the labeling.

JUSTICE KENNEDY: Can they do the same thing by -- through jury verdicts?

MS. BLATT: Absolutely not. It would be bad enough if a manufacturer had to shop his label around 50 States and had each --

JUSTICE KENNEDY: So now -- so now you say a State can do something by regulation that a jury can't do.

MS. BLATT: No. A State absolutely cannot impose labeling restrictions on a manufacturer.

JUSTICE KENNEDY: I'm asking if the -- if juries can do anything that the -- are -- are prohibited under your view from doing anything that the State could do by a State regulation.

MS. BLATT: Right. I'm sorry. Right. Under -- it -- the alternative theory would give more power to the jury to impose labeling restrictions than the State, and we don't think the State can do it. And it would be far more pernicious if a label were subject to jury-by-jury invalidation. No one would read the label, much less understand it.

JUSTICE GINSBURG: Ms. Blatt, there's a brief in this case -- there's a brief in this case that just shows hundreds, if not thousands, of crop damage claims. And your theory is that with this ambiguous provision Congress

wiped all that out. It's hard to believe.

MS. BLATT: No. Congress just wiped out labeling and only those labeling requirements --

JUSTICE GINSBURG: But everything becomes -- but every -- every time -- my crop was stunted. Okay. You have to change the label so you can't bring that suit.

MS. BLATT: Justice Ginsburg, it's just not true. The lower courts well understand this distinction, and they -- they let go all the time claims as not preempted that are true manufacturing defect or true design defect claims. This is not a complete immunity. This is a narrowly targeted one as to labeling.

There is a famous example of the Benlate --

JUSTICE GINSBURG: He says their claim is -- is very simple. You didn't tell us that using this in our kind of soil would stunt the crop and wouldn't kill the weeds.

MS. BLATT: Right.

JUSTICE GINSBURG: But you're saying that kind of claim can't be brought anymore.

MS. BLATT: It can be brought if there's State law and evidence to support the State law that doesn't attack the labeling. And our --

JUSTICE GINSBURG: I've described a set of facts which your position I think you have to say affects the

label. The -- the farmer says I bought this bottle. It said okay for all peanuts. My crop grew and it was stunted and the weeds stayed alive.

MS. BLATT: If they found an expert that said if you had manufactured this differently or if you had designed it differently and there was evidence to support that, our view is that those claims aren't preempted. And the alternative to let juries --

JUSTICE GINSBURG: No. I'm not giving you that case. I'm giving you exactly what happened.

MS. BLATT: This case -- they didn't have any evidence other than saying that the label was inaccurate. But the next -- another jury could rely on the respondent's evidence to say the label was inaccurate because it works better on high pH soil, and another jury could say, well, we need a margin of safety and the label should have said 6.8 instead of 7.0, which is what their expert says. And you can have this time and time again with how often the pesticide has to be applied, when it has to be applied. And to -- and the -- the whole point of section 136v(b) was to have reliability --

JUSTICE GINSBURG: Was that happening when EPA took the opposite view? Was there this tremendous disparity with juries going every which way --

MS. BLATT: Well, there's -- there's been

preemption at least since the late '80's, and I don't know of cases where juries -- or the theory for recovery was invalidating the label.

There are lots of cases that are true manufacturing defect claims, and I direct your attention to the Benlate where the manufacturer contaminated his product. If I'm the plaintiff, my theory -- the theory was you mismanufactured this product. A reasonable manufacturer would have taken practices to prevent contamination, and it destroyed a lot of crops and EPA actually took enforcement action against that manufacturer.

The rat poisoning example -- a 9-year-old kid died of rat poisoning because it tasted like a candy bar. The theory of recovery was all the manufacturer had to do was put a bittering agent in it that would have made the kid throw up and the rats still would have loved the poisoning. That has nothing to do with the label.

JUSTICE STEVENS: Thank you, Ms. Blatt.

You have about 4 minutes.

REBUTTAL ARGUMENT OF DAVID C. FREDERICK

ON BEHALF OF THE PETITIONERS

MR. FREDERICK: I just have two points to make.

With respect to the summary judgment posture of the case, the way this unfolded was that on one day the

District Court decided the motion for jurisdiction, that it had jurisdiction. On the very next day, Dow rushed into court with its motion for summary judgment. And what Mr. Waxman cites as the Celotex invocation merely says that on -- on this point it is neither unfair nor premature to require defendants to produce evidence in support of their claims now as the Celotex trilogy requires. I'm reading from their motion for summary judgment. That was filed before the counterclaims.

The only thing that they knew about was the deceptive trade practices notice letter that the farmers had filed pursuant to State law. So they didn't know what our claims were, and they were requiring or saying that the District Court could throw us out of court without giving us any opportunity to file counterclaims, much less try to develop evidence that would prove them.

Now, with respect to the disuniformity point, when Congress amended the statute in 1988 to add the word uniformity, it said in that public law that it was a technical amendment. We don't know why Congress put the word uniformity in. The legislative history is barren. It just says this is a technical amendment. It didn't change the substantive provisions that empowered States to impose regulations that would have the effect of disuniformity.

Now, at the end of the day, we've got claims that have been brought historically since the late 19th century. Until EPA had a sudden change of heart, there were decades in which juries made these decisions with respect to these kinds of products, and those preemption decisions really didn't take hold until after this Court announced Cipollone in 1992. And it was only at that point that the courts began to have preemption, but for the previous 2 decades, juries routinely decided these kinds of cases. The sky did not fall. EPA didn't come in and say there's labeling disuniformity as a result of this. There simply were no problems. But what did happen was that the farmers who used products were able to get compensation when pesticides damaged their crops.

Thank you.

JUSTICE STEVENS: The case is submitted.

(Whereupon, at 12:01 p.m., the case in the above-entitled matter was submitted.)