SUPREME COURT
OF THE UNITED STATES

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MONSANTO COMPANY,)

Petitioner,)

v.) No. 24-1068

JOHN L. DURNELL,)

Respondent.)

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Washington, D.C.

Monday, April 27, 2026

The above-entitled matter came on for oral argument before the Supreme Court of the United States at 12:07 p.m.

APPEARANCES:

PAUL D. CLEMENT, ESQUIRE, Alexandria, Virginia; on behalf of the Petitioner.

SARAH M. HARRIS, Principal Deputy Solicitor General, Department of Justice, Washington, D.C.; for the United States, as amicus curiae, supporting the Petitioner.

ASHLEY C. KELLER, ESQUIRE, Chicago, Illinois; on behalf of the Respondent.

C O N T E N T S

P R O C E E D I N G S

(12:07 p.m.)

CHIEF JUSTICE ROBERTS: We'll hear argument next in Case 24-1068, Monsanto Company versus Durnell.

Mr. Clement.

ORAL ARGUMENT OF PAUL D. CLEMENT

ON BEHALF OF THE PETITIONER

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

Respondent's label-based failure-to-warn claim is preempted twice over. First, it is preempted by the express terms of FIFRA's express preemption clause, which forecloses state labeling claims that are in addition to or different from those imposed under FIFRA. Here, a Missouri jury imposed a cancer warning requirement that the EPA does not require. That additional requirement is preempted.

Now Respondent concedes, as he must, that the state tort law is a labeling requirement for purposes of the preemption clause. Bates held as much. Nonetheless, he insists that unless Congress expressly directs

the agency to bind the judiciary, then the requirements that are imposed on a particular pesticide in the registration process and backed by criminal penalties are not federal requirements.

That defies common sense, the statutory text, and this Court's precedents, in particular, this Court's 8-to-1 decision in Riegel, where this Court held that similar agency-imposed requirements on a particular device are federal requirements for preemption purposes.

The same result follows from principles of impossibility preemption. The EPA regulation and the government's brief here makes crystal-clear that a registrant cannot change the safety warnings on a pesticide label without approval of the agency. Thus, Missouri law here requires something that not only is not required by federal law but that federal law doesn't even allow.

Either way you come to it, either via express preemption or impossibility preemption, the result here is clear. Congress plainly wanted uniformity when it came to the safety

warnings on a pesticide's label. Ignoring Congress's clear direction here would open the door for crippling liability and undermine the interest of farmers who depend on federally registered pesticides for their livelihood.

I welcome the Court's questions.

JUSTICE THOMAS: Mr. Clement, just for clarification, you seem to focus more on the label requirement in -- in your brief and your argument, and Respondent seems to focus more on the underlying statute, FIFRA.

I could be wrong on that. Would you clarify -- would you comment on that?

MR. CLEMENT: Well, I guess, Justice Thomas, I think about it as a level of generality debate. And I don't want to put words in my friend's mouth, but I think he says, well, you know, what's the conflict here? State law looks to whether it's misbranded. Federal law looks to whether it's misbranded.

And I think that actually mistakes the inquiry both on the state level and on the federal level. I mean, state law, at least the applicable state law here, really doesn't address labeling of pesticides. It's a

negligence, duty of good care or due care. The way that you get to actual pesticide labeling is a jury applies that general tort law to a specific device and then decides a particular warning is necessary.

In the same way, on the federal level, you don't look just to misbranding in the abstract, but there's a process to take that down to the concrete. And that process at the federal level is the registration process, where the agency can't even register the pesticide unless it makes a determination that the label complies with the statute.

JUSTICE THOMAS: Well, I think my point is, first of all, this is a herbicide. The -- not a pesticide. But the -- I think my point is that what is the operative federal statute or regulation that has the preemptive effect? Is it the regulation, is it the labeling requirement, or is it FIFRA?

MR. CLEMENT: So it's all of the above, but to give you a textual answer, it's the federal requirements under FIFRA. And that word "under" -- I mean, I know the other side sort of mocks us for focusing on a preposition,

but the word "under" is important here because, if the statute just said the preemption clause in particular, 136v(b), if that provision said "by FIFRA," there might be something to my friend's arguments.

But the language of FIFRA's preemption provision, just like the language of the preemption provision for the medical device amendments that were at issue in the Riegel case, both of those uses the word "under," and I think that word textually captures the various requirements that are imposed at a device-specific level or a herbicide-specific level in the context of the registration process here.

JUSTICE JACKSON: But, Mr. -- Mr. Clement, you -- you don't dispute that a product that has been registered can become misbranded, right?

MR. CLEMENT: Sure. And the -- and the -- and the clearest way for a registered pesticide or herbicide to become misbranded is to omit something from the label that is required by EPA in the registration process. And that's --

JUSTICE JACKSON: So you mean they just don't follow the process. But are you saying that if new information comes out in the 15-year interregnum between registration and reregistration that casts doubt on the efficacy or the safety of this product, you could have a product that is misbranded even though it has been registered and initially labeled properly, correct?

MR. CLEMENT: So I would take issue with that with respect to safety. Efficacy, as I think you know, is different, and that's why I think the Bates case is quite distinguishable because the agency actually doesn't have to evaluate efficacy.

But, as to safety, I think the process, if there's some new information that comes out -- I mean --

JUSTICE JACKSON: Yeah.

MR. CLEMENT: -- first of all, the -- the registrant has a statutory requirement, backed by criminal penalties, to bring adverse information to the agency's --

JUSTICE JACKSON: No, I understand how it is brought to the agency's attention under

the statute. What I'm asking is, could we have a world in which a product that has been registered, the label is consistent with what the agency has said is appropriate at the time of registration, but let's say a new research study comes out at some point between when the EPA is statutorily required to look at it again that casts doubt on the safety of this product?

So I -- my understanding is that under Bates and the way the statute reads in saying that registration is not a defense to -- to the offense of misbranding, that you could have a product that is registered that becomes misbranded. That's my only -- am I right about that?

MR. CLEMENT: So I disagree with that.

JUSTICE JACKSON: Okay.

MR. CLEMENT: You know, the government may have a different view. I think the way that you deal with that and the way the agency deals with that is either through some amended registration or some cancellation process which could be subject to judicial review. But what you don't just do is to say, well, like, there's been label drift here.

JUSTICE JACKSON: No, no, no. I'm just asking you whether it can be -- whether misbranding and registration are two separate things.

MR. CLEMENT: They are two separate things, but I -- but I guess what I'm resisting is the idea that because of some subsequent development, a registrant who uses the F -- the EPA-approved label could somehow have just like kind of drifted into a misbranding violation. I don't think that's the case.

JUSTICE GORSUCH: So -- so just to put a pin on that, I do want to just make sure I understand where you're coming from.

So you're saying a properly -- a registered product can never be misbranded?

MR. CLEMENT: I'd say -- no, I -- I wouldn't say that. What I would say is a registered product that is marketed as labeled and approved by the agency is --

JUSTICE GORSUCH: Right. Can never be misbranded?

MR. CLEMENT: -- is not misbranded.

JUSTICE GORSUCH: Can never be misbranded?

MR. CLEMENT: Well, I -- I mean, right. But -- but, of course, the easiest way to --

JUSTICE GORSUCH: Okay. No, no, I just want to make sure I understood --

MR. CLEMENT: Yeah, yeah. I mean, that is my position. But I --

JUSTICE GORSUCH: Yeah.

MR. CLEMENT: -- I do want to say it's -- it's not that registration somehow makes misbranding impossible because you can deviate from the agency-approved label.

JUSTICE GORSUCH: I -- that wasn't --

MR. CLEMENT: Yeah.

JUSTICE GORSUCH: -- that wasn't my question.

MR. CLEMENT: I'm sorry.

JUSTICE BARRETT: But could the agency come after you for misbranding if you didn't comply with your statutory obligation to give the updated information to the EPA?

MR. CLEMENT: Absolutely. But it wouldn't be a misbranding action.

JUSTICE BARRETT: Okay.

MR. CLEMENT: It would be a criminal

action or a civil action for violating your specific requirement under 136d I think it is to keep the agency updated.

And I think that's important, of course, because that would be the federal government essentially making sure that its registrants are continuing with their ongoing obligations, and that would sort of be more consistent with the thrust of Buckman, where is -- you know, if you have a situation where your concern is that somehow the registrant hasn't done something they're supposed to do vis- -vis the agency, you give the agency the ability to take care of that. You don't say somehow you're going to put that all in front of a jury and the jury is going to determine not just how this should be branded but also whether or not the registrant kept the agency sufficiently up to date.

JUSTICE JACKSON: But -- but --

CHIEF JUSTICE ROBERTS: What if --

JUSTICE JACKSON: Go ahead.

CHIEF JUSTICE ROBERTS: What if the agency, EPA, says we've got this new information and we're viewing it, we're

reviewing it. You know, as soon as we get to a point where we feel comfortable recommending something, we will.

In that situation, the state can't make a determination that, well, we have this new information so that it's perhaps the EPA's determination of the label shouldn't be given such determinative effect?

In other words, it's not necessarily the case that they're doing something inconsistent with what EPA would do. It's simply a fact that they're responsive to the new information more quickly than the federal government is.

MR. CLEMENT: Well, if they're more responsive than the federal government and the way they sort of manifest their responsiveness is to mandate an additional or a different labeling requirement, I think that walks them in directly to the plain text of the express preemption in FIFRA.

And I don't think the situation's any different for purposes of medical device amendments in this Court's decision in Riegel. You could have the same situation where there's

additional information that comes to light, and there are processes for getting all of that in front of the agency. If the agency takes its time and it might want to take its time because it has -- it's charged with the responsibility of looking not just at sort of how the new information affects hazards and the like but also how it affects the alternative pesticides, how it affects the overall dynamic and -- and the rest, I think you want to give the agency the time to do that.

And I think, in that respect, it's important that when -- you know, the real way to deal with this, I think, would be, if you think the agency's not being responsive enough, is to initiate a cancellation proceeding.

CHIEF JUSTICE ROBERTS: Well, I mean, how does that -- how is that consistent with 136a(f)(2)? It seems to me when you're saying, well, the state can't do anything about it, it's because you're relying on the registration.

MR. CLEMENT: Well, no, I -- I don't think so. I think you're relying on the entire registration process. But I do think, with

respect to (f)(2) in particular, I mean, first of all, I think the first problem with relying on (f)(2) to be a game changer here is that (f)(2) actually as written really, as I read it, is only limited to EPA enforcement actions because what it talks about is that the registration is in no event a -- a defense for the commission of any offense under the subchapter, and that offense under the subchapter, I think, does talk about an EPA enforcement action.

And I don't think even a non-preempted state tort suit is an offense under the subchapter. So, with all respect, I think (f)(2) is a bit of a red herring here. I do think, though, you know, as long as we're looking at (f), (f)(1) is actually the more relevant provision here because that's the statutory provision that tells a registrant that they can't change the label without the agency's approval.

JUSTICE GORSUCH: Well, before we leave (f)(2), if -- just supposing that EPA can bring a -- a -- a claim against you for misbranding and seek criminal and civil

penalties despite a properly registered item, how would it be inconsistent with FIFRA to allow state tort suits to do the same thing?

MR. CLEMENT: So it would still be inconsistent with FIFRA and the plain text of the statute to allow a state tort suit to do the same thing. And if you imagine a situation --

JUSTICE GORSUCH: Yes. I -- I -- I -- why is the question.

MR. CLEMENT: So why is because there would be a grave risk, and I think it is manifested in this case, that the state requirement would be different from or in addition to --

JUSTICE GORSUCH: Assuming it's the same.

MR. CLEMENT: So, even if you assume that it's the same, I think that you have a problem here, which is the idea would be that the state requirement would be to add something to the label. And under the plain text of (f)(1) and the relevant regulations, 40 C.F.R. 156.70(c) and 152.44(a), those provisions say that the registrant cannot change the label

with respect to state laws.

JUSTICE GORSUCH: So that's -- that's really what it boils down to then for you. It's not that -- that -- you -- you can, in fact, have misbranded but registered items, and EPA can seek remedies against you. You're just saying nobody else can do the same even if it's the parallel -- parallel proceeding, you know, no -- no additional requirements, because you have to go through processes to amend the label.

So is it kind of the -- this really boils down to the impossibility argument then, doesn't it?

MR. CLEMENT: Well, I -- I mean, I think they're closely related. I think they're slightly different. I mean, you know, part of it is like you've asked me to assume something, which is that the FDA -- the EPA, rather, would go after us for misbranding.

I don't think the EPA would ever go after a registrant for a misbranding that was based on the failure to include something on the label that EPA itself says that they can't unilaterally add to the label.

So I just, like -- you know, so maybe EPA would go after a registrant in the context of some efficacy claim or something like that, where EPA's position is the registrant is perfectly free to change the label, but where the -- where the arguments sort of come together is because EPA quite clearly takes the position that as to the safety warnings and the hazard warnings, those are things that the registrant can't change on their own.

JUSTICE GORSUCH: Well, with respect to that, if it all does boil down to the impossibility idea that it's hard to add to these labels without EPA's permission, what do we do about the fact that at least as the briefs before us suggest that registrants have added cancer warnings to their labels without EPA permission or objection?

MR. CLEMENT: So I -- I think those are, you know, essentially just a couple of episodic things that the EPA itself addresses in their brief and says were essentially implementation mistakes. I mean, you know, there may -- there may be slight quibbles about kind of each one of them and how they came to

pass. One of them I don't think was actually construed by the agency as -- as a hazard warning, so maybe they thought that something, you know, was more of a controversy warning about Prop 65 or something like that.

And, of course, in fairness, this is not a situation where the EPA has always had exactly the same interpretation across administrations, but --

JUSTICE GORSUCH: I spot you that.

MR. CLEMENT: Yeah. No, exactly. But I do think, you know, that my short answer to your question is, to the extent that was ever allowed, it's actually flatly inconsistent with the EPA's regulations that haven't changed across administrations.

And I think those are worth looking at carefully because they are unambiguous, I mean, 40 C.F.R. 144(a) and 156.70(c), and that one is just absolutely unambiguous. You as a registrant cannot change your safety warning, full stop.

JUSTICE KAVANAUGH: If -- if EPA came after someone for the label after telling you what must be on the label and saying you can't

change the label legally, I mean, that would seem like a due process problem or something where the agency says you have to do this and then sues you for doing what they told you to do. There's --

MR. CLEMENT: I -- I -- I completely agree, which is why I resist the idea that you could have a pure misbranding claim brought by the agency against a registrant for marketing the product with the EPA-approved label that EPA tells you you can't change. I mean --

JUSTICE JACKSON: Even -- even in a new evidence circumstance, I -- I feel like I understand your argument with respect to the T1 registration, EPA's looking at the label, it makes a determination on existing evidence.

But there's a 15-year window between when that product has to be reregistered again, and lots of things can happen in science in terms of developments about the product. So, if the product can become misbranded because of new information, I guess I'm just wondering why you think that you couldn't have a situation where it would be perfectly rational for either the EPA or the states to bring to the attention

of that manufacturer this new information and -- and -- and process a claim related to it.

MR. CLEMENT: All of that can happen, but it doesn't become misbranding. What happens is that information, first, the -- the registrant has a statutory obligation backed by criminal penalties to bring it to the attention of the agency.

And then, second, anybody can initiate a cancellation provision and get judicial review under 136n, and the government has taken the position here that that's subject to judicial review.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Justice Thomas?

Justice Alito?

Justice Sotomayor?

JUSTICE SOTOMAYOR: I -- I just want to pin down the area of dispute because I too believed that misbranding and registration were not inconsistent. A claim by FIFRA that someone has misbranded can come -- can come even when registered.

You're taking the position, I think, that misbranding would be limited to things that are not covered by the registration, meaning you change the label, you add something to it, you change it in some way, correct?

MR. CLEMENT: Correct.

JUSTICE SOTOMAYOR: You are, I think, answering Justice Jackson and Justice Kavanaugh, I think, by saying, if it's a failure to warn of something you should be warning, that would not be a misbranding claim; it would be a violation of a FIFRA obligation to disclose that information and ask for a change.

MR. CLEMENT: Absolutely. And I think that way of looking at the world makes the whole regime, A, mirror the medical device amendments regime but also makes it work a lot more sensibly because, otherwise, what you're basically telling a registrant is they can go through this whole process, which exhaustively considers not just the -- the -- the product and its active ingredient but all in conjunction with the label to make sure that it's safe and effective as used and has, like,

a danger label if it needs it or a caution label if it needs it, they go through all that process, and then the next day --

JUSTICE SOTOMAYOR: I think the government -- yeah.

MR. CLEMENT: -- they market it as labeled and they could have that all be subject to a misbranding claim.

JUSTICE SOTOMAYOR: I think the problem is 136a(f)(2) because it also says a valid registration, however, is prima facie evidence that the pesticide's labeling and packaging comply with the registration provisions of FIFRA. But it's prima facie. It's not presumptive.

And so it seems to me, if it's prima facie, it could be rebutted, that you -- that FIFRA could come in and say you misbranded because you failed to tell us about this risk.

MR. CLEMENT: So misbranding isn't the only offense under the statute, and there's a specific criminal penalty for failing to comply with your obligations as a registrant under that.

So, if you have a hypothetical

registrant who has some terrible information that comes out that they're obligated under the statute to give to the agency and they -- and they withhold it, they are certainly subject to criminal penalties. But it's not a misbranding claim.

And -- and I think it's a mistake to think all the different ways that a registrant can violate FIFRA all come down to misbranding. I mean, misbranding is just one species. And, of course, the most obvious violation -- and this is why there isn't this inconsistency between registration and misbranding -- the most obvious way to commit a misbranding violation is to omit something from the label that -- that you were told you had to put on it in the registration process.

JUSTICE SOTOMAYOR: How do you --

MR. CLEMENT: That's a misbranding claim. And -- and, of course, it would only be prima facie evidence because you -- you -- you blew it. You misbranded.

JUSTICE SOTOMAYOR: We have two lines of impossibility defense. PLIVA and Wyeth are also there. Doesn't the history we're showed

about the manufacturer who added the California 50 proposition information without FDA -- FDA approval, doesn't that defeat your impossibility argument? It doesn't defeat your other arguments, but why doesn't it?

Because --

MR. CLEMENT: Because, I mean -- sorry.

JUSTICE SOTOMAYOR: -- the agency has, you've said by error -- whether it's error or not, they've permitted this to be done.

MR. CLEMENT: So I don't think -- my answer to that would be I don't think PLIVA and Bartlett come out differently if you could point to a couple of generic manufacturers who, ultra vires and in a way that they actually weren't allowed to, tried to change the label on the -- their generic pharmaceutical. I think that would have actually made those generic pharmaceuticals mislabeled if I understand that regime, which is why it didn't happen.

But I think you look to the law. You don't look to whether somebody essentially did something that was ultra vires. And if you

look to the law here, this is -- and the government flat-out says this in their brief. This is really analogous to the generic labeling regime, not the branded regime.

JUSTICE SOTOMAYOR: Thank you.

CHIEF JUSTICE ROBERTS: Justice Kagan?

JUSTICE KAGAN: And, Mr. Clement, not -- not to say you're wrong about your view of the scope of the misbranding actions, but if you were wrong, how would it matter? Could you still win if misbranding actions were more expansive than what you're arguing?

MR. CLEMENT: I mean, I suppose I could, and I suppose, like, you could, you know, kind of just go with impossibility preemption and make this, like, very simple because I just think you look at those regulations and it makes it clear we can't change the -- we can't change the label.

The reason I'm sort of, you know, fighting on this and the reason I think I'm not wrong is because I think that there -- as I said, you know, when it comes to misbranding, that's very specific. The easiest way to commit a misbranding offense is to omit

something that you're required in the registration process to put on the label, if you take it -- if you omit something.

And if, of course, the state thinks you need to add something that EPA is not requiring you to put on the label, I mean, that just walks squarely into the text of the express preemption clause.

And -- and part of the reason I'm kind of, like, resistant to put all the weight on impossibility preemption is because, you know, in some respects, the express preemption clause is even broader because it doesn't require an actual conflict. You know, if the state imposes a labeling requirement that's different from or in addition to, that's still preempted by the plain text of the statute without really regard to whether it's misbranded.

And it seems to me that if -- EPA, once you go through the registration process, they tell you what's required to be on your label. And there's really no way to look at this case and not come to the conclusion that a Missouri jury has told us that a cancer warning that EPA hasn't required us to put on the label

is required to put on that label. And that just seems like a requirement in addition to what's required by the EPA.

And if you can get there without saying the word "misbranding" or thinking that, you know, I have to be right about that, I'm -- you know, I'm totally fine with that. I just happen to think that from the perspective of my client -- I mean, I guess what I would say is this: We go through that entire registration process. The way I would understand that is the agency is giving us a green light that we can then go forward and mark it a pesticide or a herbicide as labeled and not have to worry about a misbranding offense. We don't respond to all the other statutory requirements.

And, again, that's exactly parallel to what happens in the medical devices amendments case. Once you get that device and it's approved with labeling, I mean, you can't deviate from that labeling. And if there's additional science that comes along, you've got to get the agency apprised of that. But you can't be held liable in state court for marketing a medical device that's labeled

exactly like the FDA told you to label it. And I think the same thing should apply under this statute.

CHIEF JUSTICE ROBERTS: Justice Gorsuch?

Justice Kavanaugh?

JUSTICE KAVANAUGH: Just on that, there are ways, I think you're saying, that EPA can change requirements going forward, but if it tries to say you were misbranding when you did what they told you to do, that's a retroactivity problem of sorts in the sense that they're penalizing you retroactively for something they're saying is now required that they didn't say was required before, in fact, was prohibited before.

MR. CLEMENT: Yes. And I actually think the retroactivity frame is a helpful one because, if you look at the statutory scheme, the real way you sort of change warnings or take a pesticide off the market is through the cancellation proceedings.

And when the agency actually goes through the cancellation proceedings, there are requirements. They're supposed to allow the

manufacturer, except in extraordinary cases, to continue to sell the existing stock. They're supposed to make a specific analysis that takes into account the reliance interest of farmers and other users. And all of that kind of makes sense, that if you're going to, like, sort of prospectively take something off the market, you go through an orderly process.

And one of the anomalies of allowing a state tort remedy to be essentially a requirement is it does have this kind of retroactive effect to it. And I think that's what makes it particularly problematic here.

JUSTICE KAVANAUGH: And I think you just covered this in part, but to Justice Jackson's good point about new science, you're saying the way you account for new science is on a process that changes the requirements going forward, not on a process that retroactively tells you that what you did yesterday as ordered by EPA is somehow illegal.

MR. CLEMENT: Absolutely. And it's an agency process that takes into account all of the various factors, costs and benefits. And, of course, the agency has incredible resources

at its command, including peer-reviewed panels, cancer review, and -- and the like.

And that -- this case provides a perfect example of that. It's not like when this IARC study came out and said that, you know, glyphosate, like hot beverages, is a -- is a cancer risk. It's not like the agency said we don't want to hear about it. They exhaustively studied it and they actually did peer review that IARC doesn't do. They looked at more sources than IARC did. And then they came to a conclusion that's shared by regulators around the globe that glyphosate doesn't have a cancer risk, it's not -- not carcinogenic.

JUSTICE KAVANAUGH: Thank you.

CHIEF JUSTICE ROBERTS: Justice Barrett?

JUSTICE BARRETT: Are design defect claims preempted?

MR. CLEMENT: They're only preempted if they are disguised failure-to-warn claims. But the -- that's -- that is an important difference from this context and the medical device amendments context, which is, although

they're worded similarly, the preemption clause in the medical device amendments sweeps in design defect claims. And, here, it's really just on the labeling.

But, you know, the only reason I do hesitate is because it's obviously tempting in a world where you can bring design defect claims but not failure-to-warn claims that you try to make a design defect. Well, the design problem here is the way you designed your label or that you failed to warn. So, with that caveat, design defect claims are not preempted.

JUSTICE BARRETT: Okay. And then, you know, you put most of your weight on express preemption, but, obviously, you do make the impossibility argument as well.

How do you think about implied preemption when there is an express preemption clause present? It seems odd to move on to implied preemption. Wouldn't it all be governed just by the express preemption clause?

MR. CLEMENT: Well, this Court has been very clear, and this is critical, that you don't sort of say, well, there's an express preemption clause, and so that's the only

preemption we're going to do here. We're not going to do any kind of implied preemption analysis or impossibility analysis.

You've squarely rejected that, and I think you should do it here too. I don't think there's a huge difference between the two here. I think you can sort of think about this like Riegel was an express preemption case and just an express preemption case. But, of course, when Justice Scalia decided Riegel, he didn't have the benefit of PLIVA and Bartlett, which come later.

JUSTICE BARRETT: Mm-hmm.

MR. CLEMENT: And so, if he did, you know, he might have said in Riegel, well, this is both an express preemption case and an impossibility case. So I think both roads sort of lead there.

At the end of the day, though, you know, I kind of like text. And I do think we get there on the express preemption provision and I do think that, you know, in some hypothetical case, maybe not under this particular reg or this particular provision, but it's going to matter that the words "in

addition to" are there because that is at least in theory -- it doesn't actually require a conflict at all for a state requirement to be preempted. As long as it's an additional requirement, that's textually enough for it to be preempted.

JUSTICE BARRETT: Well, yeah. I mean, it seems to me that your impossibility argument is kind of wrapped up into the express preemption argument because the whole reason it's impossible is that you are required to do that. You can't -- you can't change it. And the state is prohibited from requiring anything in addition to or less than.

MR. CLEMENT: Yeah.

JUSTICE BARRETT: Yeah.

MR. CLEMENT: I guess here's the difference, though. Like, even if in theory we could change the label, I mean, we're still not required to in the registration process. And I still think the way I understand this is, like, look, there's a broad general standard of misbranding.

JUSTICE BARRETT: Mm-hmm.

MR. CLEMENT: EPA looked at that and

made it concrete in terms of this particular herbicide by saying here's what you need on your label. A Missouri jury did the same process, took a broad standard, made it concrete to the same herbicide and said you need a cancer warning.

And so, under Missouri law, a cancer warning is required. Under federal law, a cancer warning is not required. That is a requirement that is in addition to the federal requirement. And that would be true even if we could change the label.

So, here, they end up --

JUSTICE BARRETT: There is a difference.

MR. CLEMENT: -- kind of being coextensive, but -- but I can imagine a world where they're not. In some respects, if you're concerned about the one or two outlying examples where somebody was allowed to do a warning, I mean, the express preemption clause may be a little bit more impervious to that objection, but, again, I -- I -- as I say, we're happy to win either way, but it's hard not to like the text.

JUSTICE BARRETT: Thanks.

CHIEF JUSTICE ROBERTS: Justice Jackson?

JUSTICE JACKSON: So I guess I'm not sure that retroactivity in the questions that you explored with Justice Kavanaugh necessarily captures all that's going on here. And I worry a little bit about the way in which you are describing this and its seeming inconsistency with what we said in Bates.

So I -- I think that one way to understand this scheme, the -- the statute's scheme, is that there's a registration requirement and there's a no misbranding requirement, and every 15 years, EPA makes a registration decision that sets the requirements for a pesticide's label based on the information that EPA has considered at that time.

But, in the years between registrations, the company still has to comply with the no misbranding requirement. And I guess I'm trying to understand why it couldn't be that both the EPA and state tort law can enforce the misbranding requirement in the

interregnum.

So, I mean, I -- I think, in Bates, we said that FIFRA complaint -- contemplates that pesticide labels will evolve over time. And we said: "Tort suits can serve as a catalyst in this process."

And you can see how that happens, right? When new information comes in in that 15 years, the threat of tort liability is one thing that spurs the manufacturer to go to the EPA and make sure that they're giving them the information, but it also enforces the no misbranding requirement.

So why isn't the kind of concept of the way the scheme works as we laid it out in Bates how we should be thinking about it? It's -- it's proact -- it's -- it's prospective, not retrospective, in that sense.

MR. CLEMENT: So let me try to use Bates as an example of -- in answering your question.

So the one thing I think Bates was clearest about is -- kind of the clearest example anyway is that Bates contemplated of a conflict that would trigger the express

preemption provision is federal law says, for this particular pesticide, all you need is a caution label.

And state law comes in and says no, for that pesticide, you need a danger label. Bates says that's a clear, clear conflict. Well, how does EPA decide that a particular pesticide needs just a caution label and not the more serious danger level?

They do that in the registration process by examining the toxicity of the substance, and then they say, all right, this is sufficiently non-toxic that it just requires a caution label.

Now let's say five years goes on and somebody with some new science goes in before a state court jury and says: Actually, EPA got it wrong, this thing is more toxic than they thought, and so, under Missouri law, you need a danger label.

I think that would still be clearly, clearly preempted by Bates. And the fact that you could tell the jury you need the danger label in order for the product to be not misbranded would not change anything.

JUSTICE JACKSON: No, I understand. But -- but -- but isn't there a world in which that is a different circumstance because the EPA has not yet considered that information? So you're not actually conflicting with -- you're not doing anything different or in addition to the determination that the EPA had -- had made based on the information that was before it.

I guess I just -- I see that -- I mean, it's nuanced, for sure. I mean, the way you're saying it is pretty straightforward. But you're reading the express preemption statute as though it says such state shall not impose or continue in effect any requirements for labeling or packaging, period.

And this says in addition to or different, which suggests that there could be a parallel state enforcement proceeding happening.

MR. CLEMENT: Well, I guess I would answer by saying only a completely parallel regime. So, if they want to say that, you know, if -- if my client omits something that EPA has said must be on the label and somebody

gets hurt because that warning's not on the label, then you can have a tort claim that's a failure-to-warn claim that basically is a negligence per se claim at that level of generality that says you're liable because you didn't follow the federal requirement and we are going to give you a state remedy.

That's why it is in addition to or different from. It's not -- we're not striking those words from the statute.

And the one thing I would say is, if you read Bates carefully, at the end of the opinion on this point about tort suits can get information, there's a block quote from a court of appeals opinion, and if you actually read it carefully, what the Court says by quoting that is these -- these tort suits could generate information and then people could go and ask EPA to allow the registrant to change the label.

So even in Bates, there's a recognition that there is not this unilateral ability to change the label at least with respect to safety and warnings. And I would say this is where my answer that you can still

have design defect claims is important because that could be part of the process where additional information is generated and ultimately brought to the -- the attention of the agency.

This is a -- this is a narrow but critically important preemption clause. It focuses on label-based failure-to-warn claims. And that's exactly what this is and should be preempted.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Ms. Harris.

ORAL ARGUMENT OF SARAH M. HARRIS

FOR THE UNITED STATES, AS AMICUS CURIAE, SUPPORTING THE PETITIONER

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

Many paths lead to preemption here. The simplest is that state and federal law impose different and, indeed, conflicting labeling requirements for Roundup. Missouri forces Petitioner to add cancer warnings or face tort liability. But federal law requires

Petitioner to stick with the label EPA approved in registering the product unless EPA approves a change.

EPA registers pesticides only if EPA approves their labels as adequate to protect health. Federal law then requires manufacturers to keep using that label. Manufacturers must apply to amend registration to change the label. Indeed, regulations provide specific statements pertaining to the hazards of the product must be approved by the agency. That's 40 C.F.R. 156.70.

Missouri thus requires adding cancer warnings, but federal law requires EPA to approve new warnings and tasks EPA with deciding what label changes would mitigate any health risks. State law must give way.

I welcome the Court's questions.

JUSTICE THOMAS: Ms. Harris, I -- I'll ask you the same question as I asked Mr. Clement.

It seems as though you are focusing on different things from the Respondent.

MS. HARRIS: We disagree with -- it's true we're focusing on different things. I

would say we are focusing on the text and both the text of the statute and the regulations specific to how the miss -- misbranding mandate is implemented.

So the text from which we are getting the "do not change the label" requirement, which I agree with some of the questions is central to the case, starts off with 136a(f)(1) of FIFRA, which says, if you want to change your label, go amend it, you have to get EPA's approval, EPA has to confirm it's not misbranded.

And then, for other federal requirements, in Bates's framing, I -- I -- I would turn you to the regulations, which are not specific just to registration. They talk about how do you change your label. And so 156.70 is the clearest. It says, for hazards like cancer, you have to ask for EPA's approval. And then there's a whole welter of other ones that reinforce that. And that makes sense because EPA deals with misbranding both to prevent misbranding in what it actually has before it and to protect against people who might be -- state requirements that might be

adding things that are misbranded, by saying, no, it's all up to EPA. EPA has to review changes to make sure they don't confuse people. You really have to stick with your label to safely use the product.

JUSTICE KAGAN: So do you agree with everything that Mr. Clement said about how this regulatory scheme operates? And even putting aside the preemption question, is everything he said your understanding of how the agency works?

MS. HARRIS: I agree with him. I would just add two refinements. One, he is correct that EPA doesn't go after people for, in a hypothetical world, if things change, would you have been in trouble for not changing your label even though EPA doesn't let you? That's right. We don't bring that kind of enforcement action.

But, two, not only was Mr. Clement correct in talking about cancellation proceedings, if new evidence does come to EPA's attention -- and, again, we don't think this is a new information case because of the time periods involved -- even if it were, what EPA

normally does -- let's say EPA -- it came to EPA's attention we think this product might cause cancer. The requirements for dealing with that under federal law are completely different from a state just saying slap a cancer warning on the product.

What EPA does -- and this is at 136a(d)(1) of the statute and then a whole bunch of regulations at 152.170 of the regulations -- EPA first says, what's the exposure risk for cancer? Then EPA next asks, are there different forms of labeling that you could use for protective gear that would mitigate the exposure?

And then, if that doesn't work, EPA says, are there different things we can do to the label to restrict the use to particular crops or say that only professional applicators can use the product? All of that again very different from the way that state law is processing it.

And at the end of all that, if EPA thinks that there needs to be a change in the label because it wasn't initially adequate to protect against that exposure risk, whether

it's cancer, whether it's something else, but it can be solved for with these restrictions, what EPA does is not go after the manufacturer and say you're in big trouble now. EPA has a default 120-day grace period to change the label.

Now, if there's an emergency, EPA can shorten that significantly with their suspension powers. But EPA -- and this is -- this is at 152.167 of the regulations -- has the flexibility to say when your label changes.

So, in all of those particulars, not only is this a situation where EPA is controlling how to respond to a risk or new information that might change the calculus about what happens. EPA is doing so in a completely different way than just saying slap on a cancer warning and assume that that will sort of solve for the issue, because EPA is looking holistically not only at someone who might read the label and be exposed but also at other people in the process and endangered species.

JUSTICE BARRETT: What if the --

CHIEF JUSTICE ROBERTS: Well, and

throughout that long process in response to information that suggests there is a risk that's not on the label, the states cannot do anything?

MS. HARRIS: The states can do things that add additional penalties, as Mr. Clement said, but what they can't do is try to sort of second-guess or undermine this process. And I think that makes a lot of sense. Again, EPA is getting new information. EPA is the one with suspension power.

If you had 50 different states that are just, like, jumping the gun, Iowa says maybe this causes cancer, California says absolutely it causes cancer, some other state says this doesn't cause cancer at all, so put that on your label too, it completely undermines the uniformity of the labeling scheme and causes confusion.

CHIEF JUSTICE ROBERTS: Well, it does undermine the uniformity. I appreciate that. On the other hand, if it turns out that they were right, it might have been good if they had an opportunity to do something to call this danger to the attention of the people while the

federal government was going through its -- its process.

MS. HARRIS: But what they have the power to do is to bring suits to -- you can petition for cancellation or find many other mechanisms of saying EPA currently has it wrong, spur EPA to action.

What FIFRA does not allow is throwing preemption out the window, throwing express preemption clause out the window, and saying states are perfectly fine to have a free-for-all because, again, FIFRA is designed to guard against both sides of the risk.

JUSTICE KAVANAUGH: How does --

CHIEF JUSTICE ROBERTS: So the only thing that we need to worry about is the labeling, but the states can do anything else with respect to the particular cancer that they would like?

MS. HARRIS: If I'm understanding the correct -- the question correctly, states, with respect to labeling, cannot propose their own labeling. States, of course, remain free to restrict the use of the pesticides under 136v(a). So, if a state said, look, within my

borders, I just don't think this pesticide is safe, don't use it, they're free to do that. What you can't do is --

JUSTICE GORSUCH: Why -- why can't they impose tort liability then if they can stop the product from being sold at all?

MS. HARRIS: Because --

JUSTICE GORSUCH: If that greater power exists, why doesn't the lesser power, without saying the label -- we know we can't change the label?

MS. HARRIS: Well, again, you could say you can't sell the product. What you can't do is countermand the judgment Congress put in not --

JUSTICE GORSUCH: How about the label? You can label -- you can put whatever label you want on it.

MS. HARRIS: Then your -- is -- is the premise of it just a design defect claim? I'm sorry not to follow the question. But what states can do is say --

JUSTICE GORSUCH: If we say it's so hazardous we can ban it, why can't we say it's so hazardous that -- that there can be tort

recoveries for it?

MS. HARRIS: I think that would just be a sort of defective -- defective design suit, and it would go into what Mr. Clement said.

JUSTICE GORSUCH: Well, if -- is -- is it --

MS. HARRIS: Those are fine under Bates as long as it's not a label claim.

JUSTICE GORSUCH: So those would be fine?

MS. HARRIS: A design defect claim that is not masquerading as a failure-to-warn claim is permissible under Bates for the reasons Mr. Clement said and the reasons that Bates itself recognizes.

JUSTICE KAVANAUGH: How -- how does that petition for cancellation process work that you described to the Chief Justice? Can you lay that out?

MS. HARRIS: Sure. People can bring petitions --

JUSTICE KAVANAUGH: People including states?

MS. HARRIS: Sorry. People I believe

including states. There have been many brought by environmental groups --

JUSTICE KAVANAUGH: Mm-hmm.

MS. HARRIS: -- any other interested group. You petition to EPA to cancel. It's a way to test, you know, is EPA --

JUSTICE KAVANAUGH: Cancel the registration?

MS. HARRIS: Cancel the registration. It then gets litigated out. There's judicial review of this process specified both in the specific cancellation provisions and more broadly in 136n of FIFRA. And so --

JUSTICE KAVANAUGH: Does that encompass a petition to change the label?

MS. HARRIS: It could in theory be because you think that -- to cancel it, you could say it shouldn't have been registered at all because it's misbranded for whatever reason. Again, if EPA also thought that there was some sort of misbranding risk, like, as a practical matter, what happens is EPA gets information and might ask the manufacturer, like, can you please change -- you know, can you please try to amend your registration and

change it?

JUSTICE KAVANAUGH: Right.

MS. HARRIS: And if they don't, at that point, you might have misbranding.

JUSTICE KAVANAUGH: Is there any judicial review of a denied petition?

MS. HARRIS: Of a denied petition for cancellation?

JUSTICE KAVANAUGH: Mm-hmm.

MS. HARRIS: Yes. There -- the whole process is set off in 136n. It's the petition -- petition process similar to denials of registration. The whole -- any final EPA action under 136n is judicially reviewable. It's a very prescribed process.

And on top of that, I just want to correct some sort of -- any misimpression that EPA is just sort of sitting on its hands, like every 15 years it springs into action. EPA itself does monitor new information whenever it came -- comes to light. It often calls for information from manufacturers. Dacthal is a great example of that. That is a pesticide where EPA became aware of possible thyroid risks in unborn babies. EPA asked the

manufacturer for information. The manufacturer was dragging its feet. EPA threatened to suspend the registration. The manufacturer supplied the data. EPA wasn't satisfied and said it was going to cancel the pesticide. It's now off the market.

So I don't think this is a situation where there aren't sort of means by which people can bring information to EPA's attention. The whole point of the registration process and why it takes long is, throughout, like, that -- that process, EPA is often soliciting information from people to comment on interim steps in the decision, and so that's one reason it takes a while, honestly.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Justice Thomas, anything?

Justice Alito?

Justice Sotomayor?

JUSTICE SOTOMAYOR: If I understood Mr. Clement, he was saying that even if the law permitted the manufacturer to choose to add a cancer warning, it would still be express preemption because the state would require it,

as opposed to giving the manufacturer a choice. Is that your position as well?

MS. HARRIS: I would just put a little refinement on that. I think that's probably correct as a conceptual matter, but one reason why it would -- one -- one reason backstopping it is the process I described where, if EPA identifies a risk, it has a completely different process and sort of mitigation procedure for figuring out what kinds of warnings are adequate to guard against the risks.

So EPA is very zealously saying not only yes or no, do you need a particular type of warning, but for that type of risk, what is the best way of making sure that not just the person using the product but people who might have secondary exposure to it or endangered species get the information they need to ideally mitigate the exposure risk.

JUSTICE SOTOMAYOR: So what do we make from their 2022 statement where they were approving the California Proposition 65 label? It hasn't been withdrawn, correct?

MS. HARRIS: Respectfully, that's from

2012, and that is a different --

JUSTICE SOTOMAYOR: I'm sorry, I misspoke on the date.

MS. HARRIS: It's okay. It's with respect to a different product. So I think you make absolutely nothing of it. We have said repeatedly ever since then that was an error.

More relevant are two things, one law, one facts. On the law, Mr. Clement is correct that the label regulations, like, could not be clearer, if you are doing something like a hazard warning, which I don't see any way of describing a cancer warning as anything other than that, you must get agency approval. That's what it says. That's 156.70.

Two, on the facts, I would say the even more relevant facts for Prop 65 would have to do with glyphosate itself. Whenever pre-first Trump administration people were using those warnings on glyphosate products, they were always submitting amended registration requests. The agency approved those.

So even that universe of Prop 65 warnings, which, again, are just saying

California thinks this might cause cancer, not this causes cancer, even those went through the amended registration process requiring EPA approval.

Now the first Trump administration said that's misbranding, don't do that at all. And there's a lot of water under the bridge at this point because those specific warnings were invalidated on First Amendment grounds by the Ninth Circuit, but I don't think Prop 65 can possibly get Respondent anywhere either on law or facts for those reasons.

JUSTICE SOTOMAYOR: Thank you.

CHIEF JUSTICE ROBERTS: Justice Kagan?

Justice Gorsuch?

Justice Kavanaugh?

Justice Barrett?

Justice Jackson?

JUSTICE JACKSON: Can I just quickly ask you about doesn't the statute contemplate that the EPA will approval label changes if they're consistent with FIFRA? So we're not talking about a -- a -- an arduous process here. If the manufacturer proposes a label change, I think the language of the statute

says the registration shall be amended to reflect such a change.

MS. HARRIS: But, respectfully, it is very arduous because, as part of that process, and if you look at the regulations at 156 -- it's the regulations at 156 onwards, what they say is you have to also submit data adequate to support the change so that the agency can go through and make sure whatever label change you're proposing, especially if it's a cancer or other hazard warning, is not itself misbranding, is consistent with FIFRA.

This is not just a, like, send me a quick letter, don't tell me why you want to change your label situation. Again -- and that reflects these are regulations that are trying to implement the mandate, not to have misbranded pesticides.

JUSTICE JACKSON: No, I understand. But it's -- the suggestion that, you know, we can't do it on our own, it looks as though you pretty much can if you send the relevant information, that the registration shall be amended.

MS. HARRIS: Respectfully, I don't

think the idea that just because you might think approval is easy in certain situations is enough. I think that would be directly contrary to PLIVA and Bartlett, where the Court said --

JUSTICE JACKSON: What about Wyeth? Is this like Wyeth?

MS. HARRIS: I -- no, it's completely different from Wyeth. There's a very stark contrast. For the changes to be affected regulations for the FDA for brand manufacturers in Wyeth, it really was you, brand manufacturer, out loud, unilaterally, to change your label for this period of time, FDA will then tell you if it disagrees.

Here, it's the opposite. It is do not change your label. Under no circumstances change your label if it's a hazard warning unless EPA says yes.

And that is in the heartland of what PLIVA and Bartlett said, which is, if your action depends on the approval of a federal agency in order to do it, then you are not able to unilaterally act for purposes of federal law. And when state law is telling you you

better change that warning, that is a direct conflict, or in the words of Bates relevant here, that would be different from state law.

JUSTICE JACKSON: Thank you.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Mr. Keller.

ORAL ARGUMENT OF ASHLEY C. KELLER

ON BEHALF OF THE RESPONDENT

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

You unanimously held in Bates that a pesticide can be registered and nevertheless misbranded even if it uses the label that EPA approved at registration. Yet Monsanto now asks you for the opposite holding, that Roundup cannot be misbranded as a matter of law because EPA found for the first time 50 years ago as a matter of fact that it is safe based on information Monsanto submitted.

After two briefs and a lot of podium time, Monsanto still hasn't pointed to one word in FIFRA's text that says the agency's factual findings at registration create a requirement for labeling. That's because the text

repudiates that proposition in no uncertain terms.

136a(f)(2) is an anti-delegation clause. It says that the agency's findings at registration are nothing more than prima facie evidence of compliance with the labeling requirements. Prima facie evidence is not a law of the United States made in pursuance of the Constitution. It is a thumb on the evidentiary scales that can be rebutted. And a reasonable jury has rejected that evidence.

With no satisfactory response to 136a(f)(2), Monsanto changes the subject, making the totally uncontested point that the express preemption clause talks about requirements under FIFRA.

We agree. We're good textualists. We don't ignore prepositions. And we agree there are affirmative delegations of authority to the Administrator to issue regulations that create labeling requirements. Monsanto's problem is they're not relying on any of those regulations. They're relying on registration and registration alone.

There is nothing in, by, under, or

next to FIFRA that makes the registration decisions that EPA makes binding labeling requirements with preemptive force.

I welcome your questions.

JUSTICE THOMAS: Could you tease out your delegation argument and how that has -- the impact that has on preemption?

MR. KELLER: Yes, I can, Justice Thomas.

I think a good example would be imagine if the EPA had promulgated a notice and comment rule. It went through an entirely formal process that in the Chevron regime would have unquestionably satisfied Mead, saying Roundup is perfectly safe, there's nothing wrong with glyphosate, if you put any type of warning on glyphosate, we, the EPA, determine that that would be misbranded.

In the old regime, I think you could say we're going to engage the fiction that Congress intended to delegate that power to EPA. We don't need some source of text saying that they can do that.

I think, in the new Loper Bright regime, you would say point to text delegating

that power to the agency directly. Well, they don't have that notice and comment rule. But they're trying to rely just on 136a, the registration process, to say whenever the EPA approves the label at registration, even if it's from 1974, that is the label. The label is the law. It can't be anything other than that for purposes of misbranding.

But nothing in 136a says that. Everything that the Administrator does under 136a is textually linked to the Administrator's power to register the pesticide. He shall register the pesticide or he shall not register the pesticide. He's not liquidating the meaning of whether Roundup is misbranded for all purposes. He's expressing his opinion on the matter.

You heard last week the FCC case, and it sounds like some of you might be willing to say, when the FCC issues an order saying pay hundreds of millions of dollars, that's just the FCC's opinion on the matter. It doesn't become actually the law until a jury finds the facts and enters a verdict.

I think there are other problems with

136a(f)(1). You heard my friend on the other side and my friend from the United States saying that that requires preclearance for a label. I don't agree with that proposition.

Look at the text. It says, if the labeling is changed, past tense, then the Administrator shall amend the registration. There's nothing that requires the manufacturer to wait for the amended registration. There's nothing that even requires the manufacturer, if the EPA says no, I'm not amending the registration, to walk back the label change.

The only thing that the EPA administrator could do in that sense is bring a civil penalties action, a criminal penalties action, whether it be a jury trial, right, or bring cancellation proceedings, where the manufacturer would get to defend itself in a formal adjudicatory process with cross-examination and calling live witnesses, the kinds of formality, again, even in the old regime that would have been required before you give agency action the force of law.

You said in Mensing you're not going to play a mouse trap game to create

impossibility. You're not going to benefit plaintiffs by saying: Well, you could have gone to the FDA and sought pre-permission or approval and they might have said yes.

You shouldn't play a mouse trap game for the other side either. They shouldn't be allowed to say: Well, we didn't even try to amend our label, which we unilaterally could have done, but if we had, the EPA might have told us no, and they might have brought these cancellation proceedings and they might have then won those proceedings and it would have stuck in court. That's too many links in a causal chain for impossibility analysis to apply.

I also think we could talk about the regulations that my friend on the other side --

JUSTICE JACKSON: Before you do that, can you just speak to a(f)(2) and the clause that talks about not being a defense?

MR. KELLER: Yes.

JUSTICE JACKSON: Mr. Clement indicates that that's not a defense to an EPA action. Is that your understanding as well?

MR. KELLER: No. I very respectfully

think Mr. Clement has a pretty tortured reading of the first sentence of 136a(f)(2). It says, in no event shall this be a defense to any violation of FIFRA.

Obviously, that includes any of the definitions of misbranding. You can see the offense in 136j(a)(1)(E), which defines any misbranded sale as a violation of the statute.

He wants to reread 136j(a)(1)(E) to say any misbranded pesticide is really just a pesticide that doesn't use the label that EPA approved at registration. That is not a possible reading of "any misbranded pesticide," particularly given paragraphs (B) and (C). So, if you want to follow the statute, it's at page 40 of the red brief appendix.

Congress knew how to lock in place information from the registration statement. Paragraph (B) says you can't sell even a registered pesticide with claims made for it different than the registration statement. Paragraph (C) says you can't sell a registered pesticide with a composition different from the registration statement.

If paragraph (E) were really meant to

just be you can't sell a misbranded pesticide and the definition is the label departs from the one in the registration statement, of course, Congress would have used a parallel formulation, but it didn't. So I think 136a(f)(2)'s first sentence can't possibly bear the meaning that he's suggesting.

He also suggests, I believe, that 136a(f)(2)'s first sentence is not in itself the thing that he's using as the defense. He says it's not registration alone; it's registration plus the EPA's findings of safety at registration. That doesn't make any analytical sense. He's saying that the EPA has to consider safety at registration. So he's saying it's -- it's no defense by itself; it's just a defense if the EPA does the job that he says they are statutorily required to do. And then it's a complete defense. That's adding a lot of words to the statute that I don't think bear the plain meaning.

CHIEF JUSTICE ROBERTS: Your friends on the other side rely heavily on Riegel, and they did in their opening briefs. And in the reply brief, they say, well, you just mentioned

it, you know, at pages 49 and 50 of your brief kind of in passing.

I wonder if you want to give a fuller exposition about why your case is different than Riegel.

MR. KELLER: Of course, Mr. Chief Justice. I thought our three paragraphs at the end of the brief were persuasive, but let me hum a few more bars on that score.

So, first, there's nothing like 136a(f)(2) in the medical device amendments. So that's a huge distinction. 136a(f)(2), again, I think is making very clear that registration doesn't have the effect that the medical device amendments do.

Second, in Riegel, you found as a matter of the statute, not as a matter of regulation, we didn't have to ask a Loper Bright question, as a matter of the statute, that once the FDA approved the medical device, you couldn't depart from the label. So that's an obvious distinction.

And then, finally, even then, you preserved the option of a parallel claim. In the penultimate paragraph of the opinion, you

said we're not going to address whether a misbranding claim could proceed here because there is an obligation under the Federal Food, Drug, and Cosmetic Act to not sell a misbranded device. Stop selling is the duty. Ms. Riegel might have been able to pursue that sort of claim, but she raised it too late. We're a court of review, not first view, as you've said many times, so you're not going to address it. So you left open the question that's not open in FIFRA because you have Bates, and Riegel didn't overrule Bates sub silentio.

JUSTICE KAGAN: I mean, just to be simple-minded about this, Mr. Keller, you have a preemption provision that's labeled "uniformity" that's clearly designed to achieve uniformity in labeling. And what uniformity would your regime achieve?

MR. KELLER: Uniformity at law. So I believe that the express preemption clause is requiring uniformity in law. The law of Missouri and the law of the United States have to be the same. They can't be in addition to or different from each other. So it is truly requiring parallel law.

It does not require fact finders to find the facts the same way. So the law of the United States and the law of Missouri could be the same. One jury could say Monsanto didn't do it, there's nothing wrong with this pesticide, glyphosate is totally safe, there's no breach of duty. That's not a preemption question. That's a question of breach of duty. And a different jury could come out the way Mr. Durnell's jury did.

Congress could, of course, write a different express preemption clause. Monsanto is lobbying literally right now for Congress to do that. And if they are successful through the bicameralism and presentment process, we would begrudgingly concede that the state claims would be preempted.

JUSTICE KAVANAUGH: Do you think it's --

MR. KELLER: But that's not the law Congress wrote.

JUSTICE KAVANAUGH: Do you think it's uniformity when each state can require different things?

MR. KELLER: I don't think each state

can require different things. The law has to be uniform. So, if Missouri law was in addition to a different thing --

JUSTICE KAVANAUGH: No. It's the label's illegal in one state and legal in another state. That's uniformity?

MR. KELLER: I don't agree with that. The label is not illegal in one state and legal in a different state. A jury has found the facts to say --

JUSTICE KAVANAUGH: The label subjects you to liability in one state and does not subject you to liability in the other state. Is that uniformity?

MR. KELLER: I don't think it's state by state. I think it's jury by jury. You noted in Bates that despite the government's claim of a cacophony or a patchwork or a crazy quilt, that's just the consequence of our civil jury system, where you have individual cases or controversies --

JUSTICE KAVANAUGH: Well, I agree with you absent a clause that says uniformity in federal law.

MR. KELLER: Well, it -- it says

uniformity, but uniformity is the caption. What does the actual text of the uniformity clause say? It says you can't have any requirements for labeling in addition to or different from those required under FIFRA.

And the requirements for labeling are those supplied by the misbranding prohibitions defined by Congress in 136(q). So, as long as Missouri mirrors those requirements -- Bates says a requirement is a rule of law to be obeyed -- so, if Missouri law and federal law have the same requirements, it's not -- it's not in addition to or different from.

JUSTICE KAVANAUGH: If they -- if they change the label from what EPA had said, would they have been violating federal law?

MR. KELLER: So no. This goes more to impossibility. I agree with Justice Barrett. In this context, I don't see how impossibility and express preemption could come out differently.

You have cases like Geier, where you say you can still go on to implied preemption. But, here, it requires parallelism. It can't be in addition to or different from, so they

have to be the same.

Justice Thomas, you've talked about --

JUSTICE KAVANAUGH: This was just a -- just go to my question if you could.

MR. KELLER: Apologies.

JUSTICE KAVANAUGH: Under -- under federal law, if they do a different label than what EPA has approved, would they be violating federal law?

MR. KELLER: No. I think I win that three different ways. I don't think the statute prohibits a label change. Look at 136j. There's a long laundry list of prohibited acts. Changing the label unilaterally is not on that list. We've already talked about 136a(f)(1). I don't think that there's anything there that --

JUSTICE KAVANAUGH: So the Solicitor General was wrong about that?

MR. KELLER: Yeah. Very respectfully, yes, he is. And you don't give deference to the Solicitor General in interpreting FIFRA. You look at the words for yourself. So, yes, the United States is wrong about that.

Then they go to the regulations. They

quickly jump to the regulations. What's the source of authority for those regulations? If you ask the EPA the source of authority for those regulations, I kid you not, it's 136 to 136y. They cite the entire statute. That's their source of authority.

If you cite the entire statute as your source of authority, that's a pretty good indication that you don't really have a good textual source of authority. Again, maybe in the Chevron regime, we might have looked past that. But we're in the Loper Bright regime. I think you need affirmative text --

JUSTICE ALITO: Well, Mr. Keller --

MR. KELLER: -- for what they can regulate.

JUSTICE ALITO: -- did Loper Bright say one word about preemption?

MR. KELLER: No, it doesn't, but I --

JUSTICE ALITO: Loper Bright is about the relationship between two branches of the federal government, right?

MR. KELLER: Well, I -- I agree with that. I think it is always a separation of powers issue if you're going to ask whether the

executive branch gets to pronounce what the law is instead of the judiciary. And then, of course, that's relevant in the preemption context.

JUSTICE ALITO: Why is it relevant? Preemption involves the relationship between the federal government and the states.

MR. KELLER: It -- it does, and under the Supremacy Clause, federal law is the supreme law of the land, so what counts as federal law is relevant to every preemption inquiry.

I -- I would be surprised if Loper Bright were somehow cabined and not applied in preemption cases where a regulation is doing the work to create preemption. You have the separation of powers problem plus a federalism problem because you're letting the executive, not Congress, preempt valid state law. That should only be done pursuant to a valid delegation.

JUSTICE ALITO: Well, your -- your prescience about where the law might go is -- is interesting, but it's not there now, is it?

MR. KELLER: Well, I -- I think that

that's what you meant in Loper Bright. You all know better than I do what you really meant in Loper Bright, but I think a rule that says the Loper Bright regime is cabined to separation of powers cases and doesn't apply in preemption cases I don't think makes analytical sense. You could draw that line. You've drawn lines before that maybe previously didn't occur to me that subsequently emerged. So I'm not going to tell you you couldn't do it.

JUSTICE ALITO: You think that would be an irrational line to draw?

MR. KELLER: I do, yes, because Loper Bright is asking the same sort of question, who decides what the law is? Is it the judiciary or is it the executive branch? That is obviously relevant to preemption questions when we're trying to figure out what the law of the United States says.

JUSTICE KAGAN: Well, Loper Bright didn't suggest that Congress couldn't delegate power to agencies.

MR. KELLER: I agree.

JUSTICE KAGAN: And it seems here as though there's a pretty big delegation of power

to EPA --

MR. KELLER: I agree.

JUSTICE KAGAN: -- to figure all these matters out.

MR. KELLER: I agree there is an important set of delegated powers to EPA. And there are many that we haven't discussed that I do think would create labeling requirements. But the registration provision of 136a, which is where he and the government hang their hats, I do not think is this broad delegation to ultimately decide whether a pesticide is misbranded or not.

I agree with you, though, there are express delegations of authority that I do think could create labeling requirements. I can give you 136w(c)(2).

JUSTICE KAGAN: Well, I mean, if we just sort of think about this scheme, right, it says to EPA you have to do this big study, you have to weigh costs and benefits, you have to figure out on the basis of that whether to register a pesticide, you have to do that again every 15 years, you have to keep track of things in the interim, you have to, you know,

take seriously further information that industry gives you --

MR. KELLER: All true.

JUSTICE KAGAN: -- after registration. There just seems like a lot of stuff that the EPA does and is told by Congress to do to ensure the -- the appropriateness of a particular pesticide.

MR. KELLER: I completely agree with you. FIFRA is structured in a way to maximally protect the consumer. So selling an unregistered pesticide is the first offense in 136j. But you also can't sell a misbranded pesticide.

And so, regardless of what the EPA says, they are not a safe harbor. They don't get to announce for you by registration all of those other provisions to protect the consumer from these dangerous products, which by definition kill living organisms. They just don't have that blanket immunity.

I agree the EPA has all of those obligations, and though I think there are a lot of conscientious people working at that agency, I think we should also all agree that things

slip through the cracks with that agency.

They were a decade behind schedule in their reregistration of Roundup only to have their findings regarding human health vacated by the Ninth Circuit in a decision they don't challenge. So the last reregistration that we have is 30 years old, 1993.

It would also probably not surprise you if they're not constantly keeping abreast of all of the annual reports. You've said similar things in the Food, Drug and Cosmetic Act context, where there's a lot more rigorous upfront data because human data, phase 3 clinical trial data is given to the FDA, and even there, the FDA agrees that post-NDA application, post-approval, you can still have a misbranded drug. It shouldn't be less protective of consumers under the context of FIFRA, where the EPA is operating with less information.

JUSTICE KAVANAUGH: On those points, can you speak to the petition process that Ms. Harris was addressing, the petition to change the process where you go to EPA and say there's new science --

MR. KELLER: Yeah.

JUSTICE KAVANAUGH: -- you're behind the times, everything you just said? I thought there's a process you can go to EPA, but I want you to address what you think of that.

MR. KELLER: I actually think Ms. Harris said it exactly right. There is a process by which citizens, and I'll confess I don't know if states can as well, but I'll take her word for it that states can also go and say you shouldn't have reregistered this pesticide and there can be a formal process. The agency, of course, would get deference, but there is judicial review under I believe 136m.

JUSTICE JACKSON: Are there any labeling impacting requirements under this subchapter in your review?

MR. KELLER: Yes, many. So 136w(c)(2) is a good example of an interaction between what the agency does and labeling requirements. I think you can find that at page 48 of the red brief appendix.

So 136w(c)(2) invites the EPA by notice and comment rulemaking to designate a pesticide highly toxic to man. That

designation creates labeling requirements because a highly toxic pesticide is misbranded if it doesn't have the skull and crossbones on the label or if it doesn't have poison in red letters. That's 136(q)(2)(D).

So, if Missouri law said put poison in purple letters, it would be preempted. If Missouri law said don't scare consumers with the skull and crossbones, it would be preempted, and it would be preempted under FIFRA because it's the operation of the misbranding prohibition in conjunction with a valid delegation of authority.

Congress knew how to delegate authority. The danger caution example in Bates is another one. 136a(d) is where there's an express delegation to regulate to create signal words on restricted use pesticides.

So, even though Bates didn't go into a long discussion of where that source of authority was, again, we were in the Chevron era, so it didn't have to. There's an actual delegation. Congress knows how to delegate this authority. It did it through the registration process.

JUSTICE JACKSON: Thank you.
MR. KELLER: I'm happy to cede back time if --
CHIEF JUSTICE ROBERTS: Justice Thomas?
Justice Alito?
Justice Jackson?
Okay. Thank you, counsel.
MR. KELLER: Thank you.
CHIEF JUSTICE ROBERTS: Mr. Clement.

REBUTTAL ARGUMENT OF PAUL D. CLEMENT
ON BEHALF OF THE PETITIONER

MR. CLEMENT: Thank you, Mr. Chief Justice. Just a few quick points in rebuttal. My friends started with Bates. Bates really is distinguishable because it was mostly talking about efficacy and went out of its way to say safety is different. You can sort of think that in some respects Bates is like Lohr to Riegel. Lohr said 510(k)s, we really don't do a lot, so we're not focused on that much. There's nothing there to essentially have preemptive effect, but premarket approval in Riegel was different. I think it's the same with respect to efficacy and safety.

On Riegel itself, my friend offers two distinctions. I don't think either of them works. First, he says there's no equivalent to (f)(2), but even without the equivalent of (f)(2), nobody in Riegel thought that just because you got premarket approval, that didn't mean you couldn't possibly mislabel your device if you used labeling that was different from what was approved in the premarket approval process.

So (f)(2) really doesn't do anything that wasn't already implicit. And then he also pointed to, he said, well, there's a statutory provision there that said that you can't change the labeling.

If you look at the provision Justice Scalia cited there, you'll see that it's very analogous to the (f)(1) provision that basically says you can't change the label, and you have to read the whole sentence because, at the end, it says without the approval of the agency.

So Riegel really is parallel here. The possible difference is there's still more open in this regime because you can have design

defect claims, you can have states -- if they really want to say you can't use it, states have options that they didn't have under the medical device amendments.

So let me just finish with uniformity and practicality. On uniformity, it's worse than 50 states. It's every jury is a new day. And I checked. Uniformity is a title, but it went through bicameralism and -- and -- and presentment just like the rest of the statute. So I think you have to take that seriously.

Finally, just on the practicalities of this, if you tell any one of those juries that this fancy-sounding International Association on the Research of Cancer found a hazard warning for glyphosate, that sounds pretty bad.

But every agency around the globe -- New Zealand, Japan, Australia, the European Union, Canada -- they've all looked at glyphosate. It's probably the most, like, studied herbicide in the history of man. And they've all reached the conclusion based on more data and the kind of expert analysis they can do that there isn't a risk here. You shouldn't let a single Missouri jury

second-guess that judgment.

Thank you, Your Honors.

CHIEF JUSTICE ROBERTS: Thank you, counsel.

The case is submitted.

(Whereupon, at 1:21 p.m., the case was submitted.)

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