

SUPREME COURT OF THE UNITED STATES

IN THE SUPREME COURT OF THE UNITED STATES

MONSANTO COMPANY,)
)
 Petitioner,)
)
 v.) No. 24-1068
)
 JOHN L. DURNELL,)
)
 Respondent.)

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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

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

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

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

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

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

6 I welcome the Court's questions.

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

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

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

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

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

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

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

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

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

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

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

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

1 JUSTICE JACKSON: So you mean they
2 just don't follow the process. But are you
3 saying that if new information comes out in the
4 15-year interregnum between registration and
5 reregistration that casts doubt on the efficacy
6 or the safety of this product, you could have a
7 product that is misbranded even though it has
8 been registered and initially labeled properly,
9 correct?

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

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

19 JUSTICE JACKSON: Yeah.

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

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

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

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

16 MR. CLEMENT: So I disagree with that.

17 JUSTICE JACKSON: Okay.

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

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

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

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

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

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

21 JUSTICE GORSUCH: Right. Can never be
22 misbranded?

23 MR. CLEMENT: -- is not misbranded.

24 JUSTICE GORSUCH: Can never be
25 misbranded?

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

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

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

8 JUSTICE GORSUCH: Yeah.

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

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

14 MR. CLEMENT: Yeah.

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

17 MR. CLEMENT: I'm sorry.

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

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

24 JUSTICE BARRETT: Okay.

25 MR. CLEMENT: It would be a criminal

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

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

20 JUSTICE JACKSON: But -- but --

21 CHIEF JUSTICE ROBERTS: What if --

22 JUSTICE JACKSON: Go ahead.

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

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

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

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

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

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

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

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

17 CHIEF JUSTICE ROBERTS: Well, I mean,
18 how does that -- how is that consistent with
19 136a(f)(2)? It seems to me when you're saying,
20 well, the state can't do anything about it,
21 it's because you're relying on the
22 registration.

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

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

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

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

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

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

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

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

16 JUSTICE GORSUCH: Assuming it's the
17 same.

18 MR. CLEMENT: So, even if you assume
19 that it's the same, I think that you have a
20 problem here, which is the idea would be that
21 the state requirement would be to add something
22 to the label. And under the plain text of
23 (f)(1) and the relevant regulations, 40 C.F.R.
24 156.70(c) and 152.44(a), those provisions say
25 that the registrant cannot change the label

1 with respect to state laws.

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

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

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

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

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

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

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

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

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

10 JUSTICE GORSUCH: I spot you that.

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

17 And I think those are worth looking at
18 carefully because they are unambiguous, I mean,
19 40 C.F.R. 144(a) and 156.70(c), and that one is
20 just absolutely unambiguous. You as a
21 registrant cannot change your safety warning,
22 full stop.

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

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

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

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

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

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

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

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

15 CHIEF JUSTICE ROBERTS: Thank you,
16 counsel.

17 Justice Thomas?

18 Justice Alito?

19 Justice Sotomayor?

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

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

6 MR. CLEMENT: Correct.

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

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

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

4 JUSTICE SOTOMAYOR: I think the
5 government -- yeah.

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

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

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

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

25 So, if you have a hypothetical

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

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

18 JUSTICE SOTOMAYOR: How do you --

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

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

1 about the manufacturer who added the California
2 50 proposition information without FDA -- FDA
3 approval, doesn't that defeat your
4 impossibility argument? It doesn't defeat your
5 other arguments, but why doesn't it?

6 Because --

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

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

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

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

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

5 JUSTICE SOTOMAYOR: Thank you.

6 CHIEF JUSTICE ROBERTS: Justice Kagan?

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

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

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

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

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

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

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

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

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

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

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

4 CHIEF JUSTICE ROBERTS: Justice
5 Gorsuch?

6 Justice Kavanaugh?

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

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

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

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

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

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

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

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

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

16 JUSTICE KAVANAUGH: Thank you.

17 CHIEF JUSTICE ROBERTS: Justice
18 Barrett?

19 JUSTICE BARRETT: Are design defect
20 claims preempted?

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

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

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

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

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

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

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

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

13 JUSTICE BARRETT: Mm-hmm.

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

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

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

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

15 MR. CLEMENT: Yeah.

16 JUSTICE BARRETT: Yeah.

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

24 JUSTICE BARRETT: Mm-hmm.

25 MR. CLEMENT: EPA looked at that and

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

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

13 So, here, they end up --

14 JUSTICE BARRETT: There is a
15 difference.

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

1 JUSTICE BARRETT: Thanks.

2 CHIEF JUSTICE ROBERTS: Justice
3 Jackson?

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

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

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

1 interregnum.

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

7 And you can see how that happens,
8 right? When new information comes in in that
9 15 years, the threat of tort liability is one
10 thing that spurs the manufacturer to go to the
11 EPA and make sure that they're giving them the
12 information, but it also enforces the no
13 misbranding requirement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 JUSTICE JACKSON: Thank you.

12 CHIEF JUSTICE ROBERTS: Thank you,
13 counsel.

14 Ms. Harris.

15 ORAL ARGUMENT OF SARAH M. HARRIS
16 FOR THE UNITED STATES, AS AMICUS CURIAE,
17 SUPPORTING THE PETITIONER

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

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

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

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

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

18 I welcome the Court's questions.

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

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

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

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

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

13 And then, for other federal
14 requirements, in Bates's framing, I -- I -- I
15 would turn you to the regulations, which are
16 not specific just to registration. They talk
17 about how do you change your label. And so
18 156.70 is the clearest. It says, for hazards
19 like cancer, you have to ask for EPA's
20 approval. And then there's a whole welter of
21 other ones that reinforce that. And that makes
22 sense because EPA deals with misbranding both
23 to prevent misbranding in what it actually has
24 before it and to protect against people who
25 might be -- state requirements that might be

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

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

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

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

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

7 What EPA does -- and this is at
8 136a(d)(1) of the statute and then a whole
9 bunch of regulations at 152.170 of the
10 regulations -- EPA first says, what's the
11 exposure risk for cancer? Then EPA next asks,
12 are there different forms of labeling that you
13 could use for protective gear that would
14 mitigate the exposure?

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

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

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

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

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

24 JUSTICE BARRETT: What if the --

25 CHIEF JUSTICE ROBERTS: Well, and

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

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

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

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

1 federal government was going through its -- its
2 process.

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

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

14 JUSTICE KAVANAUGH: How does --

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

20 MS. HARRIS: If I'm understanding the
21 correct -- the question correctly, states, with
22 respect to labeling, cannot propose their own
23 labeling. States, of course, remain free to
24 restrict the use of the pesticides under
25 136v(a). So, if a state said, look, within my

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

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

7 MS. HARRIS: Because --

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

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

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

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

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

1 recoveries for it?

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

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

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

10 JUSTICE GORSUCH: So those would be
11 fine?

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

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

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

23 JUSTICE KAVANAUGH: People including
24 states?

25 MS. HARRIS: Sorry. People I believe

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

3 JUSTICE KAVANAUGH: Mm-hmm.

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

7 JUSTICE KAVANAUGH: Cancel the
8 registration?

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

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

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

1 change it?

2 JUSTICE KAVANAUGH: Right.

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

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

7 MS. HARRIS: Of a denied petition for
8 cancellation?

9 JUSTICE KAVANAUGH: Mm-hmm.

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

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

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

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

16 CHIEF JUSTICE ROBERTS: Thank you,
17 counsel.

18 Justice Thomas, anything?

19 Justice Alito?

20 Justice Sotomayor?

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

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

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

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

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

25 MS. HARRIS: Respectfully, that's from

1 2012, and that is a different --

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

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

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

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

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

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

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

13 JUSTICE SOTOMAYOR: Thank you.

14 CHIEF JUSTICE ROBERTS: Justice Kagan?

15 Justice Gorsuch?

16 Justice Kavanaugh?

17 Justice Barrett?

18 Justice Jackson?

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

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

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

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

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

25 MS. HARRIS: Respectfully, I don't

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

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

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

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

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

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

4 JUSTICE JACKSON: Thank you.

5 CHIEF JUSTICE ROBERTS: Thank you,
6 counsel.

7 Mr. Keller.

8 ORAL ARGUMENT OF ASHLEY C. KELLER

9 ON BEHALF OF THE RESPONDENT

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

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

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

1 repudiates that proposition in no uncertain
2 terms.

3 136a(f)(2) is an anti-delegation
4 clause. It says that the agency's findings at
5 registration are nothing more than prima facie
6 evidence of compliance with the labeling
7 requirements. Prima facie evidence is not a
8 law of the United States made in pursuance of
9 the Constitution. It is a thumb on the
10 evidentiary scales that can be rebutted. And a
11 reasonable jury has rejected that evidence.

12 With no satisfactory response to
13 136a(f)(2), Monsanto changes the subject,
14 making the totally uncontested point that the
15 express preemption clause talks about
16 requirements under FIFRA.

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

25 There is nothing in, by, under, or

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

4 I welcome your questions.

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

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

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

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

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

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

9 But nothing in 136a says that.
10 Everything that the Administrator does under
11 136a is textually linked to the Administrator's
12 power to register the pesticide. He shall
13 register the pesticide or he shall not register
14 the pesticide. He's not liquidating the
15 meaning of whether Roundup is misbranded for
16 all purposes. He's expressing his opinion on
17 the matter.

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

25 I think there are other problems with

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

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

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

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

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

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

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

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

21 MR. KELLER: Yes.

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

25 MR. KELLER: No. I very respectfully

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

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

9 He wants to reread 136j(a)(1)(E) to
10 say any misbranded pesticide is really just a
11 pesticide that doesn't use the label that EPA
12 approved at registration. That is not a
13 possible reading of "any misbranded pesticide,"
14 particularly given paragraphs (B) and (C). So,
15 if you want to follow the statute, it's at page
16 40 of the red brief appendix.

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

25 If paragraph (E) were really meant to

1 just be you can't sell a misbranded pesticide
2 and the definition is the label departs from
3 the one in the registration statement, of
4 course, Congress would have used a parallel
5 formulation, but it didn't. So I think
6 136a(f)(2)'s first sentence can't possibly bear
7 the meaning that he's suggesting.

8 He also suggests, I believe, that
9 136a(f)(2)'s first sentence is not in itself
10 the thing that he's using as the defense. He
11 says it's not registration alone; it's
12 registration plus the EPA's findings of safety
13 at registration. That doesn't make any
14 analytical sense. He's saying that the EPA has
15 to consider safety at registration. So he's
16 saying it's -- it's no defense by itself; it's
17 just a defense if the EPA does the job that he
18 says they are statutorily required to do. And
19 then it's a complete defense. That's adding a
20 lot of words to the statute that I don't think
21 bear the plain meaning.

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

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

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

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

10 So, first, there's nothing like
11 136a(f)(2) in the medical device amendments.
12 So that's a huge distinction. 136a(f)(2),
13 again, I think is making very clear that
14 registration doesn't have the effect that the
15 medical device amendments do.

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

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

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

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

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

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

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

18 JUSTICE KAVANAUGH: Do you think
19 it's --

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

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

25 MR. KELLER: I don't think each state

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

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

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

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

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

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

25 MR. KELLER: Well, it -- it says

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

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

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

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

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

1 have to be the same.

2 Justice Thomas, you've talked about --

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

5 MR. KELLER: Apologies.

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

10 MR. KELLER: No. I think I win that
11 three different ways. I don't think the
12 statute prohibits a label change. Look at
13 136j. There's a long laundry list of
14 prohibited acts. Changing the label
15 unilaterally is not on that list. We've
16 already talked about 136a(f)(1). I don't think
17 that there's anything there that --

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

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

25 Then they go to the regulations. They

1 quickly jump to the regulations. What's the
2 source of authority for those regulations? If
3 you ask the EPA the source of authority for
4 those regulations, I kid you not, it's 136 to
5 136y. They cite the entire statute. That's
6 their source of authority.

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

14 JUSTICE ALITO: Well, Mr. Keller --

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 MR. KELLER: I agree.

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

1 to EPA --

2 MR. KELLER: I agree.

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

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

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

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

1 take seriously further information that
2 industry gives you --

3 MR. KELLER: All true.

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

9 MR. KELLER: I completely agree with
10 you. FIFRA is structured in a way to maximally
11 protect the consumer. So selling an
12 unregistered pesticide is the first offense in
13 136j. But you also can't sell a misbranded
14 pesticide.

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

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

1 slip through the cracks with that agency.

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

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

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

1 MR. KELLER: Yeah.

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

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

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

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

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

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

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

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

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

1 JUSTICE JACKSON: Thank you.

2 MR. KELLER: I'm happy to cede back
3 time if --

4 CHIEF JUSTICE ROBERTS: Justice
5 Thomas?

6 Justice Alito?

7 Justice Jackson?

8 Okay. Thank you, counsel.

9 MR. KELLER: Thank you.

10 CHIEF JUSTICE ROBERTS: Mr. Clement.

11 REBUTTAL ARGUMENT OF PAUL D. CLEMENT

12 ON BEHALF OF THE PETITIONER

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

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

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

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

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

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

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

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

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

1 second-guess that judgment.

2 Thank you, Your Honors.

3 CHIEF JUSTICE ROBERTS: Thank you,
4 counsel.

5 The case is submitted.

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

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