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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 level 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 is 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. And I think those are  
17 worth looking at carefully because they are  
18 unambiguous.

19 I mean, 40 C.F.R. 144(a) and  
20 156.70(c), and that one is just absolutely  
21 unambiguous. You as a registrant cannot change  
22 your safety warning, 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 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     You can sort of think about this like Riegel  
8     was an express preemption case, and just an  
9     express preemption case. But of course when  
10    Justice Scalia decided Riegel he deposit have  
11    the benefit of PLIVA and Bartlett which come  
12    later. And so if he did, you know, he might  
13    have said in Riegel, well, this is both an  
14    express preemption case and impossibility case.  
15    So I think both roads sort of lead there.

16            At the end of the day though I kind of  
17    like text. And I do think we get there on the  
18    express preemption provision and I do think  
19    that, you know, in some hypothetical case,  
20    maybe not under this particular REG or this  
21    particular provision, but it's going to matter  
22    that the words in addition to are there because  
23    that is at least in theory -- it doesn't really  
24    require a conflict at all for a state  
25    requirement to be preempted as long as it's an

1 additional requirement. That's textually  
2 enough for it to be preempted.

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

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

18 EPA looked at that and made it  
19 concrete in terms of this particular herbicide  
20 by saying here's what you need on your label.  
21 A Missouri jury did the same process, took a  
22 broad standard, made it concrete to the same  
23 herbicide and said you need a cancer warning.

24 And so under Missouri law, a cancer  
25 warning is required. Under federal law, a

1 cancer warning is not required. That is a  
2 requirement that is in addition to the federal  
3 requirement. And that would be true even if we  
4 could change the label.

5 So here they end up --

6 JUSTICE BARRETT: There is a  
7 difference.

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

18 JUSTICE BARRETT: Thanks.

19 CHIEF JUSTICE ROBERTS: Justice  
20 Jackson?

21 JUSTICE JACKSON: So I guess I'm not  
22 sure that retroactivity in the questions that  
23 you explored with Justice Kavanaugh necessarily  
24 captures all that's going on here. And I worry  
25 a little bit about the way in which you are

1 describing this and its seeming inconsistency  
2 with what we said in Bates.

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

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

18           So I mean, I -- I think in Bates we  
19 said that FIFRA complaint -- contemplates that  
20 pesticide labels will evolve over time. And we  
21 said "tort suits can serve as a catalyst in  
22 this process."

23           And you can see how that happens,  
24 right? When new information comes in in that  
25 15 years, the threat of tort liability is one

1 thing that spurs the manufacturer to go to the  
2 EPA and make sure that they're giving them the  
3 information. But it also enforces the no  
4 misbranding requirement.

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

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

13 So the one thing Bates was clearest  
14 about is -- kind of the clearest example anyway  
15 is that Bates contemplated of a conflict that  
16 would trigger the express preemption provision  
17 is federal law says for this particular  
18 pesticide, all you need is a caution label.

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

25 They do that in the registration

1 process by examining the toxicity of the  
2 substance. And then they say, all right, this  
3 is sufficiently non-toxic that it just requires  
4 a caution label.

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

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

16 JUSTICE JACKSON: Well, I understand.  
17 But -- but -- but isn't there a world in which  
18 that is a different circumstance because the  
19 EPA has not yet considered that information?  
20 So you're not actually conflicting with --  
21 you're not doing anything different or in  
22 addition to the determination that the EPA had  
23 made based on the information that was before  
24 it.

25 I guess I just -- I see that -- I mean

1 it's nuanced, for sure. I mean, the way you're  
2 saying it is pretty straightforward. But  
3 you're reading the express preemption statute  
4 as though it says such state shall not impose  
5 or continue in effect any requirements for  
6 labeling or packaging, period.

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

11 MR. CLEMENT: Well, I guess I would  
12 answer by saying only a completely parallel  
13 regime. So if they want to say that, you know,  
14 if -- if my client omits something that EPA has  
15 said must be on the label, and somebody gets  
16 hurt because that warning's not on the label,  
17 then you can have a tort claim that's a failure  
18 to warn claim that basically is a negligence  
19 per se claim.

20 At that level of generality, that says  
21 you're liable because you didn't follow the  
22 federal requirement and we are going to give  
23 you a state remedy. That's why it is in  
24 addition to or different from. It's not --  
25 we're not striking those words from the

1 statute.

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

12           So even in Bates, there's a  
13 recognition that there is not this unilateral  
14 ability to change the label, at least with  
15 respect to safety and warnings. And I would  
16 say this is where my answer that you can still  
17 have design defect claims is important because  
18 that could be part of the process where  
19 additional information is generated and  
20 ultimately brought to the -- the attention of  
21 the agency.

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

1 preempted.

2 JUSTICE JACKSON: Thank you.

3 CHIEF JUSTICE ROBERTS: Thank you,  
4 counsel.

5 Ms. Harris.

6 ORAL ARGUMENT OF SARAH M. HARRIS  
7 FOR THE UNITED STATES, AS AMICUS CURIAE,  
8 SUPPORTING THE PETITIONER

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

11 Many paths lead to preemption here.  
12 The simplest is that states unfettered law  
13 imposed different and indeed conflicting  
14 labeling requirements for Roundup. Missouri  
15 forces Petitioner to add cancer warnings or  
16 face tort liability. But federal law requires  
17 Petitioner to stick with the label EPA approved  
18 in registering the product, unless EPA approves  
19 a change.

20 EPA registers pesticides only if EPA  
21 approves their labels as adequate to protect  
22 health. Federal law then requires  
23 manufacturers to keep using that label.  
24 Manufacturers must apply to amend registration  
25 to change the label. Indeed, registrations

1 provide specific statements pertaining to the  
2 hazards of the product must be approved by the  
3 agency. That's 40 CFR 156.70.

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

9 I welcome the Court's questions.

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

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

15 MS. HARRIS: We disagree with -- it's  
16 true we're focusing on different things. I  
17 would say we are focusing on the text and both  
18 the text of the statute and the regulations  
19 specific to how the misbranding mandate is  
20 implemented.

21 So the text from which we are getting  
22 the "do not change the label" requirement,  
23 which I agree with some of the questions is  
24 central to the case, starts off with 136a(f)(1)  
25 of FIFRA, which says, if you want to change

1 your label, go amend it, you have to get EPA's  
2 approval. EPA has to confirm it's not  
3 misbranded.

4           And then, for other federal  
5 requirements, in Bates's framing, I -- I -- I  
6 would turn you to the regulations, which are  
7 not specific just to registration. They talk  
8 about how do you change your label. And so  
9 156.70 is the clearest. It says, for hazards  
10 like cancer, you have to ask for EPA's  
11 approval. And then there's a whole welter of  
12 other ones that reinforce that. And that makes  
13 sense because EPA deals with misbranding both  
14 to prevent misbranding in what it actually has  
15 before it and to protect against people who  
16 might be -- state requirements that might be  
17 adding things that are misbranded, by saying,  
18 no, it's all up to EPA. EPA has to review  
19 changes to make sure they don't confuse people.  
20 You really have to stick with your label to  
21 safely use the product.

22           JUSTICE KAGAN: So do you agree with  
23 everything that Mr. Clement said about how this  
24 regulatory scheme operates? And even putting  
25 aside the preemption question, is everything he

1 said your understanding of how the agency  
2 works?

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

11 But, two, not only was Mr. Clement  
12 correct in talking about cancellation  
13 proceedings. If new evidence does come to  
14 EPA's attention -- and, again, we don't think  
15 this is a new information case because of the  
16 time periods involved -- even if it were, what  
17 EPA normally does, let's say EPA -- it came to  
18 EPA's attention we think this product might  
19 cause cancer. The requirements for dealing  
20 with that under federal law are completely  
21 different from a state just saying slap a  
22 cancer warning on the product.

23 What EPA does -- and this is at  
24 136a(d)(1) of the statute and then a whole  
25 bunch of regulations at 152.170 of the

1 regulations -- EPA first says, what's the  
2 exposure risk for cancer? Then EPA next asks,  
3 are there different forms of labeling that you  
4 could use for protective gear that would  
5 mitigate the exposure?

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

13           And at the end of all that, if EPA  
14 thinks that there needs to be a change in the  
15 label because it wasn't initially adequate to  
16 protect against that exposure risk, whether  
17 it's cancer, whether it's something else, but  
18 it can be solved for with these restrictions,  
19 what EPA does is not go after the manufacturer  
20 and say you're in big trouble now. EPA has a  
21 default 120-day grace period to change the  
22 label.

23           Now, if there's an emergency, EPA can  
24 shorten that significantly with their  
25 suspension powers. But EPA -- and this is --

1 this is at 152.167 of the regulations -- has  
2 the flexibility to say when your label changes.

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

15 JUSTICE BARRETT: What if the --

16 CHIEF JUSTICE ROBERTS: Well, and  
17 throughout that long process in response to  
18 information that suggests there is a risk  
19 that's not on the label, the states cannot do  
20 anything?

21 MS. HARRIS: The states can do things  
22 that add additional penalties, as Mr. Clement  
23 said, but what they can't do is try to sort of  
24 second-guess or undermine this process. And I  
25 think that makes a lot of sense. Again, EPA is

1 getting new information. EPA is the one with  
2 suspension power.

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

11 CHIEF JUSTICE ROBERTS: Well, it does  
12 undermine the uniformity. I appreciate that.  
13 On the other hand, if it turns out that they  
14 were right, it might have been good if they had  
15 an opportunity to do something to call this  
16 danger to the attention of the people while the  
17 federal government was going through its -- its  
18 process.

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

24 What FIFRA does not allow is throwing  
25 preemption out the window, throwing express

1     preemption clause out the window, and saying  
2     states are perfectly fine to have a  
3     free-for-all because, again, FIFRA is designed  
4     to guard against both sides of the risk.

5             JUSTICE KAVANAUGH:   How does --

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

11            MS. HARRIS:   If I'm understanding the  
12    correct -- the question correctly, states, with  
13    respect to labeling, cannot propose their own  
14    labeling.   States, of course, remain free to  
15    restrict the use of the pesticides under  
16    136v(a).   So, if a state said, look, within my  
17    borders, I just don't think this pesticide is  
18    safe, don't use it, they're free to do that.  
19    What you can't do is --

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

23            MS. HARRIS:   Because --

24            JUSTICE GORSUCH:   That greater power  
25    exists.   Why doesn't the lesser power, without

1 saying the label -- we know we can't change the  
2 label?

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

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

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

14 JUSTICE GORSUCH: If we say it's so  
15 hazardous we can ban it, why can't we say it's  
16 so hazardous that -- that there can be tort  
17 recoveries for it?

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

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

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

1 JUSTICE GORSUCH: So those would be  
2 fine.

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

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

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

14 JUSTICE KAVANAUGH: People including  
15 states?

16 MS. HARRIS: Sorry. People I believe  
17 including states. There have been many brought  
18 by environmental groups --

19 JUSTICE KAVANAUGH: Mm-hmm.

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

23 JUSTICE KAVANAUGH: Cancel the  
24 registration?

25 MS. HARRIS: Cancel the registration.

1 It then gets litigated out. There's judicial  
2 review of this process specified both in the  
3 specific cancellation provisions and more  
4 broadly in 136n of FIFRA. And so --

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

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

18 JUSTICE KAVANAUGH: Right.

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

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

23 MS. HARRIS: Of a denied petition for  
24 cancellation?

25 JUSTICE KAVANAUGH: Mm-hmm.

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

7           And on top of that, I just want to  
8 correct some sort of -- any misimpression that  
9 EPA is just sort of sitting on its hands, like  
10 every 15 years it springs into action. EPA  
11 itself does monitor new information whenever it  
12 came -- comes to light. It often calls for  
13 information from manufacturers. Dacthal is a  
14 great example of that. That is a pesticide  
15 where EPA became aware of possible thyroid  
16 risks in unborn babies. EPA asked the  
17 manufacturer for information. The manufacturer  
18 was dragging its feet. EPA threatened to  
19 suspend the registration. The manufacturer  
20 supplied the data. EPA wasn't satisfied and  
21 said it was going to cancel the pesticide.  
22 It's now off the market.

23           So I don't think this is a situation  
24 where there aren't sort of means by which  
25 people can bring information to EPA's

1 attention. The whole point of the registration  
2 process and why it takes long is, throughout,  
3 like, that -- that process, EPA is often  
4 soliciting information from people to comment  
5 on interim steps in the decision, and so that's  
6 one reason it takes a while, honestly.

7 CHIEF JUSTICE ROBERTS: Thank you,  
8 counsel.

9 Justice Thomas, anything?

10 Justice Alito?

11 Justice Sotomayor?

12 JUSTICE SOTOMAYOR: If I understood  
13 Mr. Clement, he was saying that even if the law  
14 permitted the manufacturer to choose to add a  
15 cancer warning, it would still be express  
16 preemption because the state would require it,  
17 as opposed to giving the manufacturer a choice.  
18 Is that your position as well?

19 MS. HARRIS: I would just put a little  
20 refinement on that. I think that's probably  
21 correct as a conceptual matter, but one reason  
22 why it would -- one -- one reason backstopping  
23 it is the process I described where, if EPA  
24 identifies a risk, it has a completely  
25 different process and sort of mitigation

1 procedure for figuring out what kinds of  
2 warnings are adequate to guard against the  
3 risks.

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

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

16 MS. HARRIS: Respectfully, that's from  
17 2012. And that is a different --

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

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

24 More relevant are two things, one law,  
25 one facts. On the law Mr. Clement is correct

1 that the label regulations, like, could not be  
2 clearer, if you were doing something like a  
3 hazard warning, which I don't see any way of  
4 describing a cancer warning as anything other  
5 than that, you must get agency approval.  
6 That's what it says. That's 156.70.

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

15 So even that universe of Prop 65  
16 warnings, which, again, are just saying  
17 California thinks that might cause cancer, not  
18 this causes cancer, even those, went through  
19 the amended registration process requiring EPA  
20 approval.

21 Now, the first Trump administration  
22 said that's misbranding, don't do that at all.  
23 And there's a lot of water under the bridge at  
24 this point because those specific warnings were  
25 invalidated on First Amendment grounds by the

1 Ninth Circuit, but I don't think Prop 65 can  
2 possibly get Respondent anywhere either on law  
3 or facts for those reasons.

4 JUSTICE SOTOMAYOR: Thank you.

5 CHIEF JUSTICE ROBERTS: Justice Kagan?

6 Justice Gorsuch?

7 Justice Kavanaugh?

8 Justice Barrett?

9 Justice Jackson?

10 JUSTICE JACKSON: Can I just quickly  
11 ask you about doesn't the statute contemplate  
12 that the EPA will approval label changes, if  
13 they're consistent with FIFRA? So we're not  
14 talking about a -- a -- an arduous process  
15 here.

16 If the manufacturer proposes a label  
17 change, I think the language of the statute  
18 says the registration shall be amended to  
19 reflect such a change.

20 MS. HARRIS: But, respectfully, it is  
21 very arduous because, as part of that process,  
22 and if you look at the regulations at 156 --  
23 it's the regulations at 156 onwards, what they  
24 say is you have to also submit data adequate to  
25 support the change, so that the agency can go

1 through and make sure whatever label change  
2 you're proposing, especially if it's a cancer  
3 or other hazard warning, is not itself  
4 misbranding, is consistent with FIFRA.

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

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

16 MS. HARRIS: Respectfully, I don't  
17 think the idea that just because you might  
18 think approval is easy in certain situations is  
19 enough. I think that would be directly  
20 contrary to PLIVA and Bartlett where the Court  
21 said --

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

24 MS. HARRIS: No, it's completely  
25 different from Wyeth. It's a very stark

1 contrast. For the changes to be affected for  
2 the FDA for brand manufacturers in Wyeth, it  
3 really was you, brand manufacturer, out loud,  
4 unilaterally to change your label for this  
5 period of time, FDA will then tell you if it  
6 disagrees.

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

11 And that is in the heartland of what  
12 PLIVA and Bartlett said, which is if your  
13 action depends on the approval of a federal  
14 agency in order to do it, then you are not able  
15 to unilaterally act for purposes of federal  
16 law. And when state law is telling you you  
17 better change that warning, that is a direct  
18 conflict, or in the words of Bates relevant  
19 here, that would be different from state law.

20 JUSTICE JACKSON: Thank you.

21 CHIEF JUSTICE ROBERTS: Thank you,  
22 counsel.

23 Mr. Keller.

24

25

1 ORAL ARGUMENT OF ASHLEY C. KELLER

2 ON BEHALF OF THE RESPONDENT

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

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

14 After two briefs and a lot of podium  
15 time, Monsanto still hasn't pointed to one word  
16 in FIFRA's text that says the agency's factual  
17 findings at registration create a requirement  
18 for labeling. That's because the text  
19 repudiates that proposition in no uncertain  
20 terms.

21 136a(f)(2) is an anti-delegation  
22 clause. It says that the agency's findings at  
23 registration are nothing more than prima facie  
24 evidence of compliance with the labeling  
25 requirements. Prima facie evidence is not a

1 law of the United States made in pursuance of  
2 the Constitution. It is a thumb on the  
3 evidentiary scales that can be rebutted. And a  
4 reasonable jury has rejected that evidence.

5 With no satisfactory response to  
6 136a(f)(2), Monsanto changes the subject,  
7 making the totally uncontested point that the  
8 express preemption clause talks about  
9 requirements under FIFRA. We agree. We're  
10 good textualists. We don't ignore  
11 prepositions.

12 And we agree there are affirmative  
13 delegations of authority to the administrator  
14 to issue regulations that create labeling  
15 requirements. Monsanto's problem is they're  
16 not relying on any of those regulations. They  
17 are relying on registration and registration  
18 alone.

19 There is nothing in, by, under, or  
20 next to FIFRA that makes the registration  
21 decisions that EPA makes binding labeling  
22 requirements with preemptive force.

23 I welcome your questions.

24 JUSTICE THOMAS: Could you tease out  
25 your delegation argument and how that has --

1 the impact that has on preemption?

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

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

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

18 I think in the new Loper Bright  
19 regime, you would say point to text delegating  
20 that power to the agency directly. Well, they  
21 don't have that notice and comment rule. But  
22 they are trying to rely just on 136a, the  
23 registration process, to say whenever the EPA  
24 approves the label at registration, even if  
25 it's from 1974, that is the label. The label

1 is the law. It can't be anything other than  
2 that for purposes of misbranding.

3 But nothing in 136a says that.  
4 Everything that the administrator does under  
5 136a is textually linked to the administrator's  
6 power to register the pesticide. He shall  
7 register the pesticide or he shall not register  
8 the pesticide.

9 He's not liquidating the meaning of  
10 whether Roundup is misbranded for all purposes.  
11 He's expressing his opinion on the matter.

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

19 I think there are other problems with  
20 136a(f)(1). You heard my friend on the other  
21 side and my friend from the United States  
22 saying that that requires preclearance for a  
23 label. I don't agree with that proposition.  
24 Look at the text.

25 It says, if the labeling is changed,

1 past tense, then the administrator shall amend  
2 the registration. There's nothing that  
3 requires the manufacturer to wait for the  
4 amended registration. There's nothing that  
5 even requires the manufacturer, if the EPA says  
6 no, I'm not amending the registration, to walk  
7 back the label change.

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

19           You said in Mensing you're not going  
20 to play a mouse trap game to create  
21 impossibility. You're not going to benefit  
22 plaintiffs by saying: Well, you could have  
23 gone to the FDA and sought pre-permission or  
24 approval and they might have said yes.

25           You shouldn't play a mouse trap game

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

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

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

16 MR. KELLER: Yes.

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

20 MR. KELLER: No. I very respectfully  
21 think Mr. Clement has a pretty tortured reading  
22 of the first sentence of 136a(f)(2). It says,  
23 in no event shall this be a defense to any  
24 violation of FIFRA.

25 Obviously that includes any of the

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

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

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

20 If paragraph (E) were really meant to  
21 just be you can't sell a misbranded pesticide,  
22 and the definition is the label departs from  
23 the one in the registration statement, of  
24 course Congress would have used a parallel  
25 formulation, but it didn't. So I think

1 136a(f)(2)'s first sentence can't possibly bear  
2 the meaning that he's suggesting.

3 He also suggests, I believe, that  
4 136a(f)(2)'s first sentence is not in itself  
5 the thing that he's using as the defense. He  
6 says it's not registration alone; it's  
7 registration plus the EPA's findings of safety  
8 at registration. That doesn't make any  
9 analytical sense. He's saying that the EPA has  
10 to consider safety at registration. So he's  
11 saying it's -- it's no defense by itself; it's  
12 just a defense if the EPA does the job that he  
13 says they are statutorily required to do. And  
14 then it's a complete defense. That's adding a  
15 lot of words to the statute that I don't think  
16 bear the plain meaning.

17 CHIEF JUSTICE ROBERTS: Your friends  
18 on the other side rely heavily on Riegel, and  
19 they did in their opening briefs. In the reply  
20 brief, they say, well, you just mentioned it,  
21 you know, at pages 49 and 50 of your brief,  
22 kind of in passing.

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

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

5           So, first, there's nothing like  
6 136a(f)(2) in the medical device amendments.  
7 So that's a huge distinction. 136a(f)(2),  
8 again, I think is making very clear that  
9 registration doesn't have the effect that the  
10 medical device amendments do.

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

18           And then, finally, even then you  
19 preserved the option of a parallel claim. In  
20 the penultimate paragraph of the opinion, you  
21 said we're not going to address whether a  
22 misbranding claim could proceed here because  
23 there is an obligation under the Federal Food,  
24 Drug, and Cosmetic Act to not sell a  
25 misbranded device. Stop selling is the duty.

1 Ms. Riegel might have been able to pursue that  
2 sort of claim, but she raised it too late.  
3 We're a court of review, not first view, as  
4 you've said many times, so you're not going to  
5 address it. So you left open the question  
6 that's not open in FIFRA because you have  
7 Bates, and Riegel didn't overrule Bates sub  
8 silentio.

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

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

22 It does not require fact finders to  
23 find the facts the same way. So the law of the  
24 United States and the law of Missouri could be  
25 the same. One jury could say Monsanto didn't

1 do it, there's nothing wrong with this  
2 pesticide, glyphosate is totally safe, there's  
3 no breach of duty. That's not a preemption  
4 question. That's a question of breach of duty.  
5 And a different jury could come out the way  
6 Mr. Durnell's jury did.

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

14 JUSTICE KAVANAUGH: Do you --

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

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

20 MR. KELLER: I don't think each state  
21 can require different things. The law has to  
22 be uniform. So if Missouri law was in addition  
23 to a different thing --

24 JUSTICE KAVANAUGH: No. It's the  
25 label is illegal in one state and legal in

1 another state. That's uniformity?

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

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

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

17 JUSTICE KAVANAUGH: I'd agree with you  
18 absent a clause that says uniformity in federal  
19 law.

20 MR. KELLER: Well, it -- it says  
21 uniformity but uniformity is the caption. What  
22 does the actual text of the uniformity clause  
23 say? It says you can't have any requirements  
24 for labeling in addition to or different from  
25 those required under FIFRA.

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

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

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

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

23           Justice Thomas, you've talked about --

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

1 MR. KELLER: Apologies.

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

6 MR. KELLER: No. I think I win that  
7 three different ways. I don't think the  
8 statute prohibits a label change. Look at  
9 136j. There's a long laundry list of  
10 prohibited acts. Changing the label  
11 unilaterally is not on that list. We've  
12 already talked about 136a(f)(1). I don't think  
13 that there's anything there that --

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

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

21 Then they go to the regulations. They  
22 quickly jump to the regulations. What's the  
23 source of authority for those regulations? If  
24 you ask the EPA the source of authority for  
25 those regulations, I kid you not, it's 136 to

1 136y. They cite the entire statute. That's  
2 their source of authority.

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

10 JUSTICE ALITO: Well, Mr. Keller --

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

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

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

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

19 MR. KELLER: Well, I -- I agree with  
20 that. I think it is always a separation of  
21 powers issue if you're going to ask whether the  
22 executive branch gets to pronounce what the law  
23 is instead of the judiciary. And then, of  
24 course, that's relevant in the preemption  
25 context.

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

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

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

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

21 MR. KELLER: Well, I -- I think that  
22 that's what you meant in Loper Bright. You all  
23 know better than I do what you really meant in  
24 Loper Bright, but I think a rule that says the  
25 Loper Bright regime is cabined to separation of

1 powers cases and doesn't apply in preemption  
2 cases I don't think makes analytical sense.  
3 You could draw that line. You've drawn lines  
4 before that maybe previously didn't occur to me  
5 that subsequently emerged. So I'm not going to  
6 tell you you couldn't do it.

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

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

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

19 MR. KELLER: I agree.

20 JUSTICE KAGAN: And it seems here as  
21 though there's a pretty big delegation of power  
22 to EPA --

23 MR. KELLER: I agree.

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

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

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

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

24           MR. KELLER: All true.

25           JUSTICE KAGAN: -- after registration.

1 There just seems like a lot of stuff that the  
2 EPA does and is told by Congress to do to  
3 ensure the -- the appropriateness of a  
4 particular pesticide.

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

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

18 I agree the EPA has all of those  
19 obligations and though I think there are a lot  
20 of conscientious people working at that agency,  
21 I think we should also all agree that things  
22 slip through the cracks with that agency.

23 They were a decade behind schedule in  
24 they're reregistration of Roundup only to have  
25 their findings regarding human health vacated

1 by the Ninth Circuit, in a decision they don't  
2 challenge. So the last reregistration that we  
3 have is 30 years old; 1993.

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

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

22 MR. KELLER: Yeah.

23 JUSTICE KAVANAUGH: -- you're behind  
24 the times, everything you just said? I thought  
25 there is a process you can go to EPA but I want

1 you to address what you think that is.

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

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

14 MR. KELLER: Yes. Many. So  
15 136w(c)(2) is a good example of an interaction  
16 between what the agency does and labeling  
17 requirements. I think you can find that at  
18 page 48 of the red brief appendix.

19 So 136w(c)(2) invites the EPA by  
20 notice and comment rule-making to designate a  
21 pesticide highly toxic to man. That  
22 designation creates labeling requirements  
23 because a highly toxic pesticide is misbranded  
24 if it doesn't have the skull and cross bones on  
25 the label or if it doesn't have poison in reds

1 letters. That's 136(q)(2)(D).

2 So if Missouri law said put poison in  
3 purple letters it would be preempted. If  
4 Missouri law said don't scare consumers with  
5 the skull and cross bones, it would be  
6 preempted, and it would be preempted under  
7 FIFRA because it's the operation of the  
8 misbranding prohibition in conjunction with a  
9 valid delegation of authority.

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

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

22 JUSTICE JACKSON: Thank you.

23 MR. KELLER: I'm happy to cede back  
24 time.

25 CHIEF JUSTICE ROBERTS: Justice

1 Thomas?

2 Justice Alito?

3 Justice Jackson?

4 Okay. Thank you, counsel.

5 MR. KELLER: Thank you.

6 CHIEF JUSTICE ROBERTS: Mr. Clement.

7 REBUTTAL ARGUMENT OF PAUL D. CLEMENT

8 ON BEHALF OF THE PETITIONER

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

22 On Riegel itself, my friend offers two  
23 distinctions. I don't think either of them  
24 works. First he says there's no equivalent to  
25 (f)(2) but even without the equivalent of

1 (f)(2), nobody in Riegel thought that just  
2 because you got premarket approval, that didn't  
3 mean you couldn't possibly mislabel your device  
4 if you use labeling that was different from  
5 what was approved in the premarket approval  
6 process.

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

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

19 So Riegel really is parallel here.  
20 The possible difference is there's still more  
21 open in this regime because you can have design  
22 defect claims, you can have states -- if they  
23 really want to say you can't use it, states  
24 have options that they didn't have under the  
25 medical device amendments. So let me just

1 finish with uniformity and practicality.

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

8 Finally, just on the practicalities of  
9 this, if you tell any one of those juries that  
10 this fancy sounding international association  
11 and the research of cancer found a hazard  
12 warning for glyphosate, that sounds pretty bad.  
13 But every agency around the globe, New Zealand,  
14 Japan, Australia, the European Union, Canada,  
15 they've all looked at glyphosate. It's  
16 probably the most, like, studied herbicide in  
17 the history of man.

18 And they've all reached the conclusion  
19 based on more data and the kind of expert  
20 analysis they can do that there isn't a risk  
21 here. You shouldn't let a single Missouri jury  
22 second-guess that judgment.

23 Thank you, Your Honors.

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

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

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