

1 IN THE SUPREME COURT OF THE UNITED STATES

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3 POM WONDERFUL LLC, :  
4 Petitioner : No. 12-761

5 v. :

6 THE COCA-COLA COMPANY. :

7 - - - - - x

8 Washington, D.C.

9 Monday, April 21, 2014

10

11 The above-entitled matter came on for oral  
12 argument before the Supreme Court of the United States  
13 at 11:06 a.m.

14 APPEARANCES:

15 SETH P. WAXMAN, ESQ., Washington, D.C.; on behalf of  
16 Petitioner.

17 MELISSA ARBUS SHERRY, ESQ., Assistant to the Solicitor  
18 General, Department of Justice, Washington, D.C.; on  
19 behalf of United States, as amicus curiae, supporting  
20 neither party.

21 KATHLEEN M. SULLIVAN, ESQ., New York, New York; on  
22 behalf of Respondent.

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1 P R O C E E D I N G S

2 (11:06 a.m.)

3 CHIEF JUSTICE ROBERTS: We'll hear argument  
4 next in Case No. 12-761, POM Wonderful v. The Coca-Cola  
5 Company.

6 Mr. Waxman?

7 ORAL ARGUMENT OF SETH P. WAXMAN

8 ON BEHALF OF THE PETITIONER

9 MR. WAXMAN: Mr. Chief Justice, and may it  
10 please the Court:

11 The Lanham Act provides a remedy for  
12 businesses whose market is misappropriated by  
13 competitors that misrepresent the character of the goods  
14 they sell. This case presents an egregious violation of  
15 the law. Coca-Cola's label grossly misleads customers,  
16 as Coke anticipated, but Coke says that it need not  
17 answer under the Lanham Act because its label is  
18 authorized by FDA regulations. The label is not, in  
19 fact, authorized for reasons we explain and with which  
20 the United States largely agrees, but even if it were  
21 consistent with FDA regulations that would not strip POM  
22 of its right to prove a willful Lanham Act violation.

23 Courts are obligated to give full effect to  
24 Congressional enactments wherever possible. Here  
25 Congress has never precluded or conditioned enforcement

1 of the Lanham Act in food labeling cases, and it is  
2 entirely possible, in fact, entirely easy for Coke to  
3 comply with both statutory obligations.

4 JUSTICE SOTOMAYOR: If there is no private  
5 cause of action to enforce the FDA label standards, only  
6 the FDA can bring a proceeding to say that an ad  
7 violates its regulations, how does a Court below,  
8 without interpreting the regulations, go about deciding  
9 whether or not a particular ad doesn't comport with the  
10 regulations and hence would be subject to the Lanham  
11 Act?

12 MR. WAXMAN: Justice --

13 JUSTICE SOTOMAYOR: Maybe that's a better  
14 question for the SG, but I'm trying to figure out --

15 MR. WAXMAN: Well, let me take a shot at it  
16 and, you know, the SG can and Ms. Sullivan can, as well.

17 There's no question under -- as this Court  
18 explained in *Buckman*, that there is no private cause of  
19 action to enforce provisions of the FDCA. Now, this  
20 Court in *Buckman* distinguished *Medtronic v. Lohr*, which  
21 provided and held -- and did not save from preemption a  
22 state law that imposed parallel requirements, and in  
23 that instance, and this is not a case involving an  
24 attempt to enforce parallel requirements under state law  
25 or any other law. In those circumstances, as the

1 government explains, of course a court is going to be  
2 required to ascertain what those parallel requirements  
3 are, and whether they were or were not complied with.

4 But this is a case involving a different  
5 statute. Our submission is that it is entirely  
6 irrelevant whether or not the Coke label, in any  
7 particular, is consistent with a regulation that  
8 implements criminal prohibitions by announcing when and  
9 under what limited circumstances the FDA will forebear  
10 from exercising its criminal and regulatory penalties.  
11 Even in that instance, with respect, Your Honor, as this  
12 Court explained in Wyeth, misbranding provisions are, in  
13 fact, adjudicated by courts even under the FDCA.

14 JUSTICE KENNEDY: And so do you concede that  
15 under the Lanham Act, plaintiff could not challenge  
16 aspects of the a food label that the FDA said is  
17 required?

18 MR. WAXMAN: Well, Justice Kennedy --

19 JUSTICE KENNEDY: I know that's not this  
20 case.

21 MR. WAXMAN: Thank you.

22 Let me just say, not only is that not this  
23 case because the FDA has never examined --

24 JUSTICE KENNEDY: I want you to answer the  
25 question, though.

1           MR. WAXMAN:           My answer to the question would  
2 be, under Wyeth, under this Court's decision in Wyeth,  
3 the FDCA and the FDA's regulations interpreting it and  
4 applying it, supply a floor and not a ceiling. And the  
5 FDA would have no authority -- if the FDA said, This  
6 label is fine and you are required to use this label,  
7 the question would be, does it have the statutory  
8 authority to essentially create an immunity from  
9 enforcement of another federal statute that protects a  
10 different purpose and a different class of victims? The  
11 answer would be no.

12           JUSTICE KAGAN:           Justice Kennedy's question,  
13 I think, was different. He said, suppose that it said  
14 you are required to use this label and only this label,  
15 then you would acknowledge that there is an  
16 impossibility issue; is that right?

17           MR. WAXMAN:           Yes. Unless, as in Wyeth,  
18 there was, in fact, some possibility to change the  
19 label, but if -- and I apologize if I didn't understand  
20 the question. If the FDA said, counterfactually, we've  
21 examined this label, you are not only permitted to use  
22 it but you are required to use it, and unlike what we do  
23 with respect to pharmaceuticals, you are not allowed to  
24 make any changes. In that instance, there would be an  
25 irreconcilable conflict and a Court would have to decide

1 which of two opposite-facing canons of construction to  
2 give primacy to, but that would be impossibility.

3 JUSTICE KAGAN: Why isn't there a different  
4 kind of conflict here? Let's just focus on the name,  
5 which is what the solicitor general says the FDA has  
6 considered and has specifically permitted. They went  
7 through this very long and involved process, and they  
8 decided exactly what kind of names were permitted for  
9 this kind of product and what were not permitted,  
10 because they constituted misbranding. And essentially  
11 the FDA has said, This is what counts as misbranding,  
12 nothing else counts as misbranding. And now you're  
13 coming in and under a Lanham Act claim saying, no, the  
14 FDA is wrong. This is misbranding. That seems -- why  
15 isn't that a problem?

16 MR. WAXMAN: Why isn't that a problem?

17 JUSTICE KAGAN: Yeah. That the FDA said  
18 it's not misbranding, you're saying it is misbranding.  
19 That seems a quite direct conflict as to what the FDA  
20 says versus what you are alleging under the Lanham Act.

21 MR. WAXMAN: So we know that that is not, in  
22 fact, how the FDA construes its regulation, and we know  
23 that because just by examining the FDA's own limited  
24 enforcement history, all the parties have cited the  
25 Court --

1 JUSTICE KAGAN: Well, just hypothetically,  
2 let's say that the FDA said that this name was not  
3 misbranding, that this name was fine under their  
4 regulations, that they did not count as misbranding.

5 MR. WAXMAN: So we're challenging the label  
6 as a whole, which is covered by -- under the --

7 JUSTICE KAGAN: Right. So I understand  
8 that, you would have some claims about different parts  
9 of the label. But I'm only asking about your  
10 claiming as -- your claim as to the specific thing that  
11 the FDA ruled on.

12 MR. WAXMAN: Right. And the question is  
13 whether Congress gave any indication and it would have  
14 to, in this context where the Lanham Act is an express  
15 statutory enactment that Congress was well aware of when  
16 it enacted the Nutrition Labeling Act and, in fact, was  
17 told, not just by the industry, but by OBM, in  
18 testimony, that the Lanham Act was being used to police  
19 misrepresentations of the character of food products,  
20 you would have to conclude that Congress intended to  
21 allow the FDA to supply, if you will, the substantive  
22 rule of decision under a different statute that uses  
23 different words and -- and protects a different class of  
24 people when -- and here again, I think it's an important  
25 indicator why Congress didn't mean that. The FDA, the



1 misbranding provisions of the FDCA are prohibitions.  
2 They are not permissions. And the rules that the FDA  
3 has promulgated announce essentially an enforcement  
4 forbearance. They don't represent a judgment and the  
5 Federal Register provisions that we've cited that  
6 accompanied the promulgation of the juice naming  
7 regulations make this as clear as day. They do not  
8 represent a pronouncement that for all purposes, for all  
9 statutes, the name on -- the name ascribed to the  
10 product is okay. In fact, they say although for  
11 purposes of our forbearance under our government  
12 enforcement authority, we will allow you to do one or  
13 the other -- and this is 2919 and 2920 of Federal  
14 Register 58, We warn manufacturers that even compliance  
15 with this, where there is a small amount of the  
16 non-predominant juice name has great capacity to mislead  
17 and we encourage -- twice in the rulemaking, we  
18 encourage manufacturers, nonetheless, to name the juices  
19 in the product. Under those circumstances, the notion  
20 that Congress intended this type of regulation to  
21 preclude a case in which -- and these are the facts as  
22 the Court -- as they come to the Court -- Coke well knew  
23 and intentionally designed a label that, in fact,  
24 grossly misleads consumers to the economic disadvantage  
25 of the company that, in large part, created the market.

1 And the notion that Congress wanted to allow the FDA to  
2 apply substantive rules of decision in that very  
3 different inquiry using very different language in a  
4 different statute, I think, is completely unsupported.  
5 I mean --

6 JUSTICE GINSBURG: What would be the  
7 components of the injunctive relief that you would seek?  
8 Assuming you have a Lanham Act claim, what should Coke  
9 have done to make its product non-misleading?

10 MR. WAXMAN: Well, we have in -- in the  
11 course of our complaint, we didn't specify -- I mean,  
12 the injunction that we would seek is ceasing to use the  
13 label as it currently exists, and of course --

14 JUSTICE GINSBURG: Without saying what label  
15 would be lawful?

16 MR. WAXMAN: That's correct. It's just as  
17 in criminal actions under the FDCA and civil actions  
18 under parallel state laws and actions under the Lanham  
19 Act, juries aren't required or permitted to give  
20 prescriptive judgments. All that they may -- all they  
21 do is make a judgment about whether or not on balance,  
22 there is substantial evidence that to the harm of the  
23 competitor, a substantial number of consumers are  
24 misled, and if so, was it willful. And that is no more  
25 of a problem in this particular case than it is in any

1 of these cases, whether they involve food or anything  
2 else. In Wyeth versus Levine, the plaintiff had all  
3 sorts of reasons -- all sorts of different theories  
4 about what the warning label should or shouldn't say.  
5 The jury simply decided that it violated the common law  
6 of the state of Vermont to use that particular label.  
7 And the FD -- I'm sorry.

8 JUSTICE ALITO: Suppose the percentage were  
9 a lot higher. Suppose it was 50 percent pomegranate and  
10 blueberry.

11 MR. WAXMAN: It's hard to see how we  
12 would have a -- it's hard to see how we would have a --  
13 could possibly prevail in a Lanham Act case. I mean, we  
14 have to come up with -- we have to adduce, it's our  
15 burden, substantial evidence to show that a substantial  
16 number of competitors -- of consumers are not only  
17 misled, but misled to the detriment of our product. I  
18 don't think we could establish it. But Coke's argument,  
19 and for that matter the government's argument, with  
20 respect to the name itself, would apply if, unlike the  
21 eyedropper's worth of pomegranate juice that's in the  
22 half-gallon bottle, there were two microns. I mean,  
23 this -- the question simply is whether a manufacturer  
24 like Coca-Cola can design something that it knows runs a  
25 substantial risk, quote, "from a misleading

1 perspective." And the evidence shows that over a third  
2 of consumers who look at this label believe that  
3 pomegranate and blueberry juice, in fact, are the  
4 majority juices.

5 JUSTICE ALITO: What if it were the -- what  
6 if it were the case that there were very small number of  
7 people who were allergic to one of these ingredients?  
8 I'm not suggesting it's true. For all I know, it's not.  
9 But let's say there are a few people who are very  
10 allergic to pomegranate juice or blueberry juice. And  
11 so the FDA says, if you put even an eyedropper full of  
12 that in your blend, you have to put that prominently on  
13 the bottle so that these people will not inadvertently  
14 get an allergic reaction. Could you have a Lanham Act  
15 claim then?

16 MR. WAXMAN: Well, of course, pome -- the  
17 only thing that consumers know is that -- from the front  
18 label is that there is pomegranate -- arguably  
19 pomegranate juice and blueberry juice in here. So the  
20 question would be whether they had to disclose on the  
21 label whether there was also .01 percent strawberry  
22 juice or 99.4 percent apple and grape juice. That's the  
23 kind of judgment that we want the FDA to make, because  
24 the purpose of the FDCA is protect public health and  
25 safety.

1           What the FDA doesn't do, particularly given  
2 the criminal nature of its sanctions, is regulate or  
3 interpret, apply its forbearance authority with an eye  
4 toward, well, what kinds of things are going to so  
5 mislead consumers that they think there is going to be a  
6 substitute in the marketplace where there isn't.

7           JUSTICE ALITO:           Well, what I'm saying is  
8 suppose it's the case that for 99.999 percent of the  
9 population, the more pomegranate juice, the better, you  
10 just can't drink enough of it. The more you drink, the  
11 healthier you are. But for this tiny percentage of the  
12 population, it could produce an allergic reaction. And  
13 so the FDA says, you've got to put that on there even if  
14 there is just a tincture of pomegranate juice. Could  
15 you have a Lanham Act claim on the ground for the vast  
16 majority of your potential customers, they are going to  
17 be misled, because they want pomegranate juice and they  
18 are buying this stuff that just has a little bit of it  
19 in it?

20           MR. WAXMAN:           Well, I think the vast --  
21 presumably, and we're talking about a hypothetical  
22 regulation, presumably the FDA would promulgate a  
23 requirement that, in fact, you must name each of the --  
24 each of the constituent juices in case there is an  
25 allergy. I mean, we wouldn't have an objection -- the

1 argument wouldn't be that consumers are misled by that  
2 fact alone. What's misleading consumers here is they  
3 have no way on God's green earth of telling that the  
4 total amount of blueberry and pomegranate juice in this  
5 product can be dispensed with a single eyedropper. It  
6 amounts to a teaspoon in a half gallon. And the FDA  
7 has -- the FDA has explained in this case that it has no  
8 expertise, it has no warrant to interpret or understand  
9 or apply judgments about what kind of words and symbols  
10 and the combination thereof, to use the language of the  
11 Lanham Act, will have a tendency to misrepresent the  
12 nature or quality of the goods from the perspective of  
13 the competitor. And that's --

14 JUSTICE KENNEDY: Do you agree that if you  
15 brought this suit under state law, it would be  
16 preempted?

17 MR. WAXMAN: I think it certainly would not  
18 be preempted under state law. The state law provision,  
19 Justice Kennedy, is Section 110660 of the California  
20 Health and Safety Code, which -- the language of which  
21 is in haec verba with the very first subsection of the  
22 misbranding statute 343(A), which declares misbranded  
23 any label which is false in particular -- false and  
24 misleading in any particular. That subsection is not  
25 even the subject -- it's excluded from the limited

1   preemption provisions of the NLEA. So it certainly  
2   wouldn't be preempted. There might be an open question  
3   if one of the things that we were challenging in the  
4   course of that state lawsuit was the name itself, and  
5   the question then would be is this name, in fact,  
6   compliant with the FDA regulation?

7           Now, we've explained in our brief that there  
8   are three reasons why it is not compliant. And the  
9   United States agrees that a remand would be appropriate  
10  in any case to determine whether it is compliant. But  
11  generally speaking, our state law claim wouldn't be  
12  preempted at all. Not only is it parallel to the  
13  misbranding provision, but the provision that it's  
14  parallel to is not preempted.

15           Unless the Court has further questions, I  
16  would like to reserve the balance of my time.

17           CHIEF JUSTICE ROBERTS:           Thank you, Counsel.  
18           Ms. Sherry.

19           ORAL ARGUMENT OF MELISSA ARBUS SHERRY,  
20           FOR UNITED STATES, AS AMICUS CURIAE,  
21           SUPPORTING NEITHER PARTY

22           MS. SHERRY:           Mr. Chief Justice, and may it  
23  please the Court:

24           If I could start with the naming aspect of  
25  the case. Justice Kagan, you are exactly right. We

1 have a circumstance here where we have two Federal  
2 statutes that cover the same subject matter that apply  
3 functionally the same standard to the same words on the  
4 same product label.

5 Under the FDCA, we have an authoritative  
6 interpretation of that language by the FDA. 102.33 is a  
7 regulation that was reached after extensive rule-making  
8 proceedings over the course of 25 years. The FDA  
9 considered the exact same question that is being raised  
10 here. It looked to figure out what an appropriate  
11 common or unusual name was for a juice blend that had a  
12 small amount of a highly flavorful and expensive juice  
13 in order to allow consumers to know -- in order to  
14 prevent consumers from being misled as to the juice  
15 content of that particular product.

16 JUSTICE ALITO: What public health benefit  
17 is served by this regulation? This is what puzzles me  
18 about it.

19 MS. SHERRY: The regulations comes under the  
20 misbranding provisions of the FDCA. So 343 focuses on  
21 misbranding. It has a number of subsections, one of  
22 which gives the FDA authority to establish common or  
23 usual names of products. And the purpose of that is to  
24 have some form of standardization so that when a  
25 consumer goes to a marketplace to purchase a particular



1 product, it knows what is going to be in the product.  
2 And, in fact, that was the purpose of the very  
3 regulation at issue here, the idea being by allowing  
4 manufacturers to choose to name their juice product  
5 based on the juice that flavors the product as opposed  
6 to based on the juice that is predominant by volume,  
7 that consumers will come to understand that when a juice  
8 says pomegranate and blueberry flavored, what it means  
9 is that the juice is present as a flavor.

10 JUSTICE SOTOMAYOR: Excuse me. I'm not sure  
11 that -- I mean, the argument is you can't even taste  
12 these flavors. That's their point. And you are taking  
13 a contrary point, that the flavor doesn't mean what you  
14 taste, flavor means something else.

15 MS. SHERRY: No, no. The point is -- and I  
16 think the argument that Petitioner is making has to do  
17 with the particular facts of this case. The argument is  
18 because there is only 0.3 percent of pomegranate juice,  
19 that it is not actually enough to flavor the beverage.  
20 And that's a factual question that could be resolved on  
21 remand. But Petitioner's argument with respect to the  
22 name would be exactly the same, Justice Alito, if there  
23 were 10 percent of pomegranate juice in this product or  
24 there was 15 percent. In Petitioner's view, a Lanham  
25 Act claim could still go forward in those circumstances

1 because there would be no irreconcilable conflict.

2 JUSTICE SOTOMAYOR: Then, Ms. Sherry, you --  
3 the government is taking the position that it's okay for  
4 District Courts to determine whether labels, in fact,  
5 comply or don't comply with FDA regulations?

6 MS. SHERRY: Yes.

7 JUSTICE SOTOMAYOR: And if they decide they  
8 don't comply, that's when they can could permit a Lanham  
9 Act claim?

10 MS. SHERRY: That's correct. And let me try  
11 to explain why I don't think that is inconsistent with  
12 the notion of the FDA having exclusive enforcement  
13 authority with respect to the FDCA. This is still a  
14 Lanham Act claim. So the only thing that is being  
15 enforced is the Lanham Act. The FDCA and the FDA  
16 regulations come up by virtue of the preclusion defense  
17 that is being raised by Respondents here. And so in the  
18 course of adjudicating that defense, we agree that  
19 district courts can look to the FDA regulations to  
20 determine compliance, of course, by applying all the  
21 normal rules of deference that would otherwise apply in  
22 those circumstances. And as my colleague --

23 JUSTICE KENNEDY: Do I understand your  
24 position to be that then if the label is specifically  
25 authorized, then the Lanham Act is precluded, but if the

1 FDCA has just simply failed to forbid it then it's not?  
2 Is that your distinction that you draw.

3 MS. SHERRY: I think so. If I could just  
4 articulate it --

5 JUSTICE KENNEDY: Because if it is, I think  
6 it's very hard to work with.

7 MS. SHERRY: And I will try to articulate it  
8 slightly differently and explain why we don't think it  
9 is difficult to work with. What we're saying is that if  
10 the FDA or the FDCA provisions have specifically  
11 permitted something here, they've specifically permitted  
12 this type of name in certain circumstances, that that is  
13 something that should preclude a Lanham Act claim. To  
14 the extent the FDCA or the FDA has not spoken to the  
15 particular issue with any degree of specificity, we  
16 don't see a problem with the Lanham Act claim going  
17 forward, because in that case you're not really second-  
18 guessing any judgment --

19 JUSTICE GINSBURG: But, Ms. Sherry, applied  
20 to this case, so we have -- you said the name is okay,  
21 pomegranate and blueberry flavored, but you say the  
22 label is something different from the name and the  
23 Lanham Act can apply to the label. So what parts of the  
24 label are you saying are not touched -- are not  
25 preempted by the FDA laws?

1 MS. SHERRY: We're drawing a distinction --  
2 when we say the name, we mean the actual words  
3 themselves, "pomegranate blueberry flavored blendified  
4 juices." When we talk about the label more generally,  
5 we mean how those words are presented on the label and  
6 other aspects of the label.

7 And if I could point the Court to the Nestle  
8 warning letter, it's discussed in a number of the  
9 different briefs and it's cited at footnote 7 of our  
10 brief. I think my colleague was going to bring it up  
11 earlier. I actually think this letter proves the very  
12 distinction that we're trying to make. What the FDA  
13 said in that letter was that the juice labels at issue  
14 there were misleading, not because of the name, but  
15 because how the words of the name were displayed on the  
16 label, because the words "orange tangerine," for  
17 example, were placed next to the picture of an orange,  
18 because they were in close proximity to "100 percent" --

19 CHIEF JUSTICE ROBERTS: What if the label  
20 just had the name on it, nothing else? Could they still  
21 sue on the ground that the label was misleading?

22 MS. SHERRY: Not unless they are able to  
23 point to something else on the label that was misleading  
24 aside from the actual words in the name. The difficulty  
25 we have with the naming aspect of the Lanham Act claim

1 here is the arguments that Petitioner is making that  
2 they should have instead named this "apple grape juice,"  
3 that they should have instead included the percentage  
4 declarations, are arguments that the FDA  
5 specifically considered when it adopted this rule and it  
6 ultimately objected.

7 CHIEF JUSTICE ROBERTS: Does the FDA -- does  
8 the FDA take into account purely commercial confusion  
9 when it issues -- when it issued its regulations  
10 governing the label? Or is it limited solely to the,  
11 what I would expect, you know, the health and well-being  
12 concerns?

13 MS. SHERRY: It absolutely took into account  
14 -- into account consumer confusion. There were comments  
15 with respect to this particular regulation, and the  
16 commenters were consumers saying that they were  
17 concerned that they were being misled with respect to  
18 the juice content.

19 CHIEF JUSTICE ROBERTS: What does the FDA  
20 know about that? I mean, I would understand if it was  
21 the FTC or something like that, but I don't know that  
22 the FDA has any expertise in terms of consumer confusion  
23 apart from any health issues.

24 MS. SHERRY: I'm not sure that is right.  
25 The misbranding provisions, 343(a)(1), speak generally

1 about labels that are false or misleading in any  
2 particular. And in adopting the common or usual name  
3 here, that is something that the FDA was specifically  
4 focused on.

5 The other point I would make is, in  
6 the court of appeals in the reply brief at page 23, the  
7 Petitioner acknowledges and argues that the misleading  
8 standard for the Lanham Act and for the FDCA are not  
9 materially different from one another.

10 Another point I would make with respect  
11 to the regulation --

12 JUSTICE KAGAN: Ms. Sherry, you know, there  
13 is no irreconcilable conflict if we view what the FDA  
14 has done as just setting a floor. And you talk a lot  
15 about how, oh, the FDA specifically considered this and  
16 it decided not to do this. You put a lot of emphasis on  
17 process.

18 And I guess my question to you is, is that  
19 the way you are saying we should know whether the FDA  
20 has only set a floor or instead has also set a ceiling,  
21 that we're supposed to look to the process and figure  
22 out whether the FDA specifically rejected a more  
23 extensive proposal, a more aggressive proposal?

24 MS. SHERRY: No. I think you look to  
25 whether or not allowing the claim to go forward would

1 complement what the agency has done or would actually  
2 conflict with what the agency has done. And here, we  
3 think there is a real conflict. We're not talking about  
4 supplementing the agency's enforcement resources. We're  
5 talking about supplanting their regulatory judgment in  
6 the area.

7 JUSTICE KAGAN: Well, I guess I don't  
8 understand that. Why wouldn't it complement? You've  
9 said here is the floor to make it not misleading, but,  
10 you know, we are not saying that there are some things  
11 that, you know, wouldn't mislead a lot of consumers  
12 anyway, and then the Lanham Act can come in and  
13 supplement that and really put us in a position where  
14 nothing is misleading at all.

15 MS. SHERRY: Oh, for two reasons. Number  
16 one, because the agency considered why manufacturers  
17 would want to actually name their product based on the  
18 flavor, because consumers actually do care about the  
19 flavor and they care about the taste. If the product  
20 had the name "apple grape juice," for example, and it in  
21 fact tasted like pomegranate blueberry juice, a consumer  
22 might be very surprised when he came home and had a sip  
23 of that juice and realized it tasted like something very  
24 different than what he expected.

25 JUSTICE ALITO: You don't think there are a

1 lot of people who buy pomegranate juice because of --  
2 they think it has health benefits and they would be very  
3 surprised to find when they bring home this bottle  
4 that's got a big picture of a pomegranate on it and it  
5 says "pomegranate" on it, that it is -- what is it, less  
6 than one-half of one percent pomegranate juice?

7 MS. SHERRY: And I think --

8 JUSTICE ALITO: The FDA didn't think that  
9 would mislead consumers?

10 MS. SHERRY: I think -- I think there is a  
11 reasonable argument that it may. And if I could just go  
12 to the second part of my argument here. We've been  
13 talking all about the naming part of the claim at issue  
14 here. We agree with Petitioners that the remainder of  
15 the Lanham Act claim shouldn't be allowed to proceed,  
16 that it is complementary. We agree with Petitioners  
17 that the Ninth Circuit decision here adopted an overly  
18 broad understanding of preclusion.

19 Respondent suggests it doesn't defend the  
20 Ninth th Circuit's decision here in footnote 5 of their  
21 brief, but it's a little bit hard to see what daylight  
22 there actually is between the Ninth th Circuit's  
23 approach and that of Respondent. Respondent relies on  
24 the express preemption clause here, but the express  
25 preemption clause applies only to State or local law.



1 By its terms, it doesn't apply to Federal law and it  
2 doesn't apply to the Lanham Act.

3 CHIEF JUSTICE ROBERTS: Thank you, counsel.

4 Ms. Sullivan.

5 ORAL ARGUMENT OF KATHLEEN M. SULLIVAN

6 ON BEHALF OF THE RESPONDENT

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

9 The FDCA does not deal just with health.  
10 Section 341 makes clear that it also and with respect to  
11 the labeling requirements at issue here, quote,  
12 "promotes honesty and fair dealing in the interest of  
13 consumers." And here, the most important data we have  
14 about what Congress did that's barely been mentioned by  
15 POM or the government, is the enactment in 1990 of the  
16 NLEA, the Nutrition Labeling and Education Act, and its  
17 express preemption provision.

18 Now, Justice Kennedy, our position is that  
19 if POM's suit had been brought as a State law lawsuit,  
20 it would be precisely preempted by the terms of that  
21 express preemption provision.

22 JUSTICE GINSBURG: But the NLEA provision  
23 doesn't preempt all State law claims, only some State  
24 law claims.

25 MS. SULLIVAN: That's correct, Justice

1 Ginsburg. And it preempts precisely these claims if  
2 they had been brought As state law claims, because let's  
3 look at the language of the express preemption  
4 provision. To be clear, Coca-Cola's position is very  
5 narrow. Our position is that were these claims that POM  
6 is making brought as State law claims, they would be  
7 expressly preempted, and it cannot be that Congress  
8 meant to preempt these claims if brought as State law  
9 claims designed to go above the Federal floor, but  
10 meant to say never mind --

11 JUSTICE KAGAN: Well, why can't it be? I  
12 mean, there are plenty of statutes which say you can't  
13 bring State law or Federal law claims. Congress knows  
14 how to do that. And instead, it said you can only  
15 not bring State law claims.

16 MS. SULLIVAN: In fact, Justice Kagan, it's  
17 very rare that Congress actually says no State or  
18 Federal claims.

19 JUSTICE KAGAN: They just say no claims or  
20 no -- notwithstanding any law to the contrary.

21 MS. SULLIVAN: Fair enough, Your Honor. But  
22 you have said in numerous cases in which you have found  
23 a prior or more general law narrowed by a subsequent or  
24 more specific law, you have said Congress should not be  
25 put to the burden every time it enacts a statute of

1 looking to the four corners of the U.S. Code and  
2 figuring out what it might displace. And there is no  
3 reason --

4 JUSTICE GINSBURG: Do you have an example,  
5 Ms. Sullivan, of a case where Congress precluded some  
6 State claims and said nothing at all about Federal laws  
7 in which this Court has held that the express preclusion  
8 of State law claims implicitly precluded Federal claims?

9 MS. SULLIVAN: I cannot, Justice Ginsburg,  
10 though I can cite to you the most relevant and unbroken  
11 line of court of appeals authority, which are the  
12 Federal Railroad Safety Act cases. The Federal Railroad  
13 Safety Act expressly preempted State law negligence  
14 claims, and the Fifth, Sixth and Seventh Circuits have  
15 held, without a competing circuit, that therefore,  
16 Federal FLEA negligence claims must be deemed to be  
17 precluded, because otherwise, the national scheme of  
18 uniformity in Federal railroad safety would be  
19 undermined. So, too, here.

20 And if I could just go back, Justice  
21 Ginsburg, to make sure I answer the question. The  
22 passage of the NLEA and its express preemption provision  
23 in 1990 was all about national uniformity. In fact,  
24 what Congress aimed at in passing that statute was  
25 the --

1 JUSTICE KENNEDY: Is it part of Coke's  
2 narrow position that national uniformity consists in  
3 labels that cheat the consumers like this one did?

4 MS. SULLIVAN: Justice Kennedy, you have  
5 perhaps succumbed to Mr. Waxman's attempts to argue his  
6 jury argument here. We're on a motion to dismiss.  
7 There is no record. We've put in a brief --

8 JUSTICE KENNEDY: I think it's important for  
9 us to know how the statutes work. And if the statute  
10 works in the way you say it does and that Coca-Cola  
11 stands behind this label as being fair to consumers,  
12 then I think you have a very difficult case to make. I  
13 think it's relevant for us to ask whether people are  
14 cheated in buying this product. Because Coca-Cola's  
15 position is to say even if they are, there's nothing we  
16 can do about it. Do you still have this -- do you still  
17 have this label?

18 MS. SULLIVAN: Yes, Your Honor. It's  
19 changed in non-material aspects. There is no aspect  
20 covered by the claims here that has changed.

21 But I just want to be very, very clear on  
22 what POM is arguing here. POM is arguing -- and,  
23 Justice Sotomayor, they are not arguing your  
24 hypothetical. POM is arguing here that it may challenge  
25 Coca-Cola's name and label under the Lanham Act even if

1 that name and label complies with the FDCA and all the  
2 relevant implementing regulations. So, Justice Kagan,  
3 this is exactly your case, where POM said it can say  
4 misbranded under the Lanham Act, even where Coca-Cola  
5 has complied with all of the authorizations set forth in  
6 the FDA.

7 JUSTICE GINSBURG: But maybe the two acts  
8 are serving different purposes, Ms. Sullivan. The law  
9 that you are relying on is supposed to be concerned with  
10 nutritional information and health claims, not a  
11 competitor is a competitor losing out because of the  
12 deception. The consumer is able to buy the Coke product  
13 much cheaper and the POM product costs more; the  
14 consumer thinks that they are both the same, so they'll  
15 buy the cheaper one.

16 MS. SULLIVAN: First, Justice Ginsburg, let  
17 me be clear: Safety is not at issue in this case.  
18 Safety warnings are especially carved out. Justice  
19 Alito, if there is a worry about allergies; Chief  
20 Justice Roberts, if there is a worry about health.  
21 That's not what we're about here. In fact, the NLEA  
22 especially -- expressly in 6(c)(2) carved out safety  
23 warnings from the preemption clause. We're not talking  
24 here about safety.

25 we're talking here about labeling so that

1 consumers have adequate information, at the same time as  
2 manufacturers are not put to the burdens and  
3 inefficiencies of having constantly shifting labeling  
4 standards imposed by juries, which ultimately will cost  
5 more to the consumer.

6 JUSTICE SOTOMAYOR: Well, let's -- let's  
7 assume the following. The FDA just wanted to know what  
8 the name should be. That's all they are regulating.  
9 That's the only requirement. And it's not even a  
10 requirement.

11 MS. SULLIVAN: It's an authorization.

12 JUSTICE SOTOMAYOR: It's an authorization.  
13 And that's where I'm having a little bit of difficulty,  
14 because it's not that you have to use this name, you're  
15 permitted to use this name under their regulations. But  
16 why are you permitted to use it in a misleading way?  
17 That's really the -- I think the government's position,  
18 which is, if you're using the name in combination with  
19 other factors in a misleading way that's not a subject  
20 to the regulation, just the name, then it's actionable  
21 under the Lanham Act.

22 MS. SULLIVAN: Justice Sotomayor and Justice  
23 Kennedy, I need to make very clear that we believe that  
24 under the FDCA and the FDA regulations, Coke's label is  
25 as a matter of law not misleading. And once we reach

1 that conclusion under FDCA and FDA, Lanham Act can't  
2 come in from the side and say, oh, yes, it is, because  
3 that would undermine the express preemption provision  
4 that was designed to create national uniformity.

5 JUSTICE SOTOMAYOR: Could the government --  
6 I think what the government is saying nothing about our  
7 permission goes to the size of the name on the label --

8 MS. SULLIVAN: Well, Your Honor --

9 JUSTICE SOTOMAYOR: -- that you can break up  
10 the name of the juice into two different sizes so that  
11 you are deemphasizing it. It also says that the  
12 vignette is misleading because it shows products that  
13 have potentially nothing in their regulations say  
14 anything about the -- and how they display them.  
15 It's -- nothing in the regulations talk about using  
16 purple instead of whatever that color is that the juice  
17 is, that blue, purple, whatever, instead of the color of  
18 apple juice. If you use the color of apple juice and  
19 grapes, it would be a white color.

20 MS. SULLIVAN: Justice Sotomayor, there are  
21 five different attacks that POM has made on our label,  
22 only two of which were addressed in the lower court.  
23 And we say that we comply with FDA regulations as to all  
24 five of them. But more important, compliance doesn't  
25 matter; what matters is are these of the type covered by

1 the provisions of the NLEA preemption provision --  
2 sorry. Are these of a type covered through the NLEA  
3 preemption provision?

4 JUSTICE SOTOMAYOR: You basically are  
5 talking about field preemption.

6 MS. SULLIVAN: Absolutely not, Your Honor.  
7 Let me make absolutely clear we do not argue for field  
8 preemption. We argue that where the NLEA express  
9 preemption provision would make POM's claims expressly  
10 preempted under State law, it follows as a matter of  
11 inference from the national uniform scheme that Congress  
12 set up, that Lanham Act claims are precluded to the  
13 extent and only to the extent the state claims would  
14 have been preempted under if they were brought as state  
15 law claims.

16 Now, Justice Sotomayor, all five of POM's  
17 issues here -- name, vignette, font size, multiple  
18 lines, and coloring -- name, vignette, font size,  
19 multiple lines, and coloring -- every one of those is of  
20 the type required by certain enumerated sections in the  
21 NLEA express preemption provision. And POM wants  
22 something that is not identical.

23 Justice Ginsburg, POM doesn't just want to  
24 enjoin our label. POM at JA61 said: You should have  
25 called it apple grape juice, not pomegranate blueberry



1 juice.

2 JUSTICE GINSBURG: Well, Mr. Waxman  
3 clarified that that's not what they are seeking. They  
4 just want to say your label is misleading. And is  
5 there -- what statute or regulation of the FDA says that  
6 compliance with the permissive regulation of the FDA  
7 necessarily renders the label non-misleading?

8 MS. SULLIVAN: Justice Ginsburg, every  
9 single aspect of their misleadingness claim is covered  
10 by specific provisions of the FDCA that have preemptive  
11 force. Under -- I just want you to focus, if on nothing  
12 else, because my colleagues on the other side haven't  
13 even mentioned it, on 21 USC 343(i)(a)(2) and (3), the  
14 express preemption provision. The express preemption  
15 provision says --

16 CHIEF JUSTICE ROBERTS: Where is that set  
17 forth in the --

18 MS. SULLIVAN: It's set forth, Mr. Chief  
19 Justice, in the red brief addendum at page 5A.

20 CHIEF JUSTICE ROBERTS: Okay.

21 MS. SULLIVAN: And if you look at the  
22 express preemption provision, which is notably called  
23 "National Uniform Nutrition Labeling," Section (2) and  
24 Section (3) on 5A over to 6A, set forth those portions  
25 of the FDCA that will and won't have preemptive force.

1 We are living in this case entirely within two sections  
2 that have preemptive force under this statute, and those  
3 are sections 343(i) and 343(f). "Name" is covered by  
4 343(i). "Vignette" is covered by 343(i) because, as the  
5 Federal Register makes clear, name and vignette were  
6 thought of together.

7 "Font size" is covered by 343(f), which goes  
8 to the presentation of the name and other printed matter  
9 on the label. "Multiple lines" is covered by 343(f),  
10 and "coloring" is covered by 343(i)(2).

11 JUSTICE KAGAN: Ms. Sullivan, can I ask --  
12 if this gets you away from the argument you want to  
13 make, I apologize for that. But suppose we thought that  
14 the preemption provision here was utterly irrelevant,  
15 that it applies to state law and not Federal law, and  
16 that you can't go around broadening the statute just  
17 because the purposes behind that statute might be  
18 thought to apply to something else. So suppose I just  
19 put that aside. Do you still have any kind of argument?

20 MS. SULLIVAN: Yes, Your Honor, we still win  
21 because of your more general approach to preclusion by  
22 one Federal statute of another, because the FDA  
23 regulations as to misbranding here are far more  
24 specific. Let me back up. The statute of the FDCA and  
25 the regulations promulgated thereunder are more specific

1 than the general misrepresentation provisions of the  
2 Lanham Act.

3 JUSTICE KENNEDY: But you say that even --  
4 I -- I take it I'm characterizing your position right.  
5 You say that even if there's a violation of the FDA  
6 regulations, they still couldn't sue under the Lanham  
7 Act because that's for the FDA.

8 MS. SULLIVAN: We do -- we do not take that  
9 position here, Your Honor, because it's not presented  
10 here. We said there might --

11 JUSTICE KENNEDY: I thought that was -- I  
12 thought that was at Page 39 in your brief in a footnote.

13 MS. SULLIVAN: Justice Kennedy, let me be  
14 clear. In this case we believe the Lanham Act claim is  
15 precluded because POM wants to go above the floor set by  
16 the FDCA and the FDA reg. POM has said repeatedly in  
17 this case, right through the reply brief -- right  
18 through its reply brief at Page 17, and I quote, and  
19 this has been their position the whole time, POM's  
20 challenge does not depend on the FDCA or FDA's  
21 regulation.

22 Justice Sotomayor, POM is not bringing your  
23 hypothetical suit where they come in to enforce the FDCA  
24 and the FDA. Had they done so, we think there might be  
25 a serious question for you to resolve another day about

1 whether that's an end run around 337(a)'s restriction of  
2 enforcement to the United States and prohibition of  
3 private lawsuits, but that's not this case.

4 JUSTICE GINSBURG: I understood them to say  
5 they were making a Lanham Act challenge. And there is  
6 no judicial review of the FDA regulations. There's no  
7 private right of action under the FDA.

8 MS. SULLIVAN: Correct, Your Honor.

9 JUSTICE GINSBURG: So they are not saying,  
10 We're bringing an action under the FDCA or the NLEA.  
11 They say, We're bringing a Lanham Act.

12 MS. SULLIVAN: Correct, Your Honor.

13 But what I'm trying to say here is, to the  
14 extent their Lanham Act claims seeks to say, as Justice  
15 Kagan said before, You are misbranded for  
16 misrepresentations under the Lanham Act, even though  
17 Coke has not been misbranded and has not made  
18 misrepresentations under FDCA and the FDA regulations,  
19 that is a conflict that should be resolved by this Court  
20 in the usual manner that statutory construction  
21 conflicts are resolved by making the statutes make sense  
22 together.

23 CHIEF JUSTICE ROBERTS: I don't know why --  
24 I don't know why it's impossible to have a label that  
25 fully complies with the FDA regulations and also happens

1 to be misleading on the entirely different question of  
2 commercial competition, consumer confusion that has  
3 nothing to do with health.

4 MS. SULLIVAN: Mr. Chief Justice, as I said  
5 before, the FTC in Section 341 as codified expressly  
6 refers to maintaining honesty for the consumer as well  
7 as health. But just let me suggest why there is still a  
8 conflict, and irreconcilable conflict is not the  
9 touchstone. You have never required irreconcilable  
10 conflict in -- in all the cases we have cited in our  
11 brief, Fausto and Elgin, Keogh, Romani, Daystar. You've  
12 never required irreconcilable conflict. You've  
13 recognized that one federal statute, if more specific,  
14 may narrow the scope of a more general statute where  
15 there is a conflict.

16 And there is a conflict here, Your Honor.  
17 Just to be clear, what Congress wanted was national  
18 uniformity so that a manufacturer could print one label  
19 and sell in the 50 states and not have its juice legal  
20 when you leave on the flight in California and  
21 illegal when you land in D.C. That national uniformity  
22 bill --

23 JUSTICE KENNEDY: Well, the Lanham -- the  
24 Lanham Act applies nationally.

25 MS. SULLIVAN: Correct, Your Honor, but the

1 falsity standard --

2 JUSTICE KENNEDY: So you're -- you used a  
3 state preemption and then say we should apply the same  
4 principles to two federal statutes --

5 MS. SULLIVAN: We do, Your Honor.

6 JUSTICE KENNEDY: -- but that's a quite  
7 different point.

8 MS. SULLIVAN: Here's what I'm saying,  
9 Justice Kennedy. I'm saying after the NLEA express  
10 preemption provision, a state cannot say that  
11 pomegranate-blueberry-flavored blend of five juices --  
12 which is perfectly consistent with the naming  
13 regulations, as the U.S. agrees. Why is that? Because  
14 the naming regulations, Justice Sotomayor, said, you can  
15 name your minority juice, your non-predominant juice in  
16 either of two ways. You, as a manufacturer, may either  
17 mention a percentage or --

18 JUSTICE KENNEDY: You want us to -- you want  
19 us to write an opinion that said that Congress enacted a  
20 statutory scheme because it intended that no matter how  
21 misleading or how deceptive a label it is, if it passes  
22 the FDA, it cannot -- it -- there can be no liability.  
23 That's what you want us to say?

24 MS. SULLIVAN: We do not, Your Honor. We  
25 would want you to say that what misleading is when it is

1 defined by FDA in specific regulations pursuant to a  
2 specific statute that specifically seeks national  
3 uniformity, in the sense that the manufacturer picks one  
4 label and doesn't, as the American Beverage Association  
5 brief says at Page 7, create a logistical nightmare that  
6 you have to change your label in response to every jury  
7 verdict. We're saying that once your --

8 JUSTICE GINSBURG: Let's suppose there were  
9 a consumer survey, as there was, but -- and -- and say  
10 it was a valid survey. And overwhelmingly, consumers  
11 said that they are misled, that they thought that they  
12 were getting pure pomegranate, and they were just  
13 astonished to find what they were getting was apple  
14 juice with, what Mr. Waxman told us, a dropper of  
15 blueberry.

16 MS. SULLIVAN: Justice --

17 JUSTICE GINSBURG: Suppose -- suppose the  
18 reality is that consumers are misled.

19 MS. SULLIVAN: If I suppose that, Your  
20 Honor, then the proper procedure for a consumer or a  
21 competitor is to go to the FDA and seek FDA's change of  
22 its rulemaking. Your Honor, in the red addendum -- red  
23 brief addendum at Page 17(a) over to 18(a), you'll see  
24 that in 21 CFR 102.33(d) FDA said, Your juice will not  
25 be misleading if it uses the word "flavored."

1           And in fact, over on 18(a), if you want to  
2 see the closest thing to an express authorization of our  
3 label here, it's the example that FDA gave on 18(a). It  
4 said, You can use either flavor or a percentage, and it  
5 won't be misleading. Why? Because we don't think that  
6 consumers are quite as unintelligent as POM must think  
7 they are. They know when something is a favored blend  
8 of five juices, non-min- -- the non-predominant juices  
9 are just a flavor.

10           JUSTICE KENNEDY:           Don't make me feel bad  
11 because I thought that this was pomegranate juice.

12           (Laughter.)

13           MS. SULLIVAN:           Justice Kennedy -- Justice  
14 Kennedy, it's pomegranate-blueberry-flavored blend of  
15 five juices. I've found that oftentimes -- well --

16           JUSTICE SCALIA:           He sometimes doesn't read  
17 closely enough.

18           (Laughter.)

19           MS. SULLIVAN:           Yeah,  
20 pomegranate-blueberry-flavored blend of five juices.  
21 And the key point here --

22           JUSTICE SOTOMAYOR:           How do we square this  
23 with Wyeth?

24           MS. SULLIVAN:           Your Honor --

25           JUSTICE SOTOMAYOR:           Wyeth, the FDA actually



1 approves, looks at the label and says, this one is okay.  
2 Not only is it not misleading, but it complies with all  
3 health requirements, and because the producers of drugs  
4 have the ability to change the label without FDA  
5 approval, there was -- we found no preemptions and no  
6 impossibility.

7           How is Wyeth any different?           The FDA here --  
8 it's even worse, this case. The FDA doesn't approve the  
9 labels. It never looks at them and says they are okay  
10 or not okay unless they decide to enforce the statute.  
11 How is this better than Wyeth?

12           MS. SULLIVAN:           Two important distinctions,  
13 Your Honor, but let me first disagree with the premise.  
14 It's true that FDA doesn't pre-approve the label, but  
15 they couldn't have gotten closer here, Justice Kennedy,  
16 than solving your difficulty by saying that  
17 ras-cranberry juice, it's okay if you call it  
18 raspberry-and-cranberry-flavored juice drink. You don't  
19 have to put the percentages in.

20           So this is -- it's not a preapproval  
21 requirement, but these regulations are very specific.

22           Justice Sotomayor, Wyeth, as you said, as  
23 this Court said, did not involve an express preemption  
24 provision. It is the express preemption provision here  
25 that says that Congress wanted nationally uniform

1 labeling regulations whereby a manufacturer could pick  
2 one label and stick with it. This is Guyer, not Wyeth.

3 JUSTICE SOTOMAYOR: You assume people would  
4 pick a label and stick with it. The Lanham Act would --  
5 if a Lanham Act claim is bought, and it's upheld, you  
6 change the label nationally.

7 MS. SULLIVAN: Oh, but, Your Honor, that's  
8 one thing if the FDA decides to adapt its rulemaking.  
9 Suppose Justice Ginsberg's consumers or competitors  
10 showed up and said, Excuse me, we don't think  
11 ras-cranberry is clear enough. Justice Kennedy said it  
12 wasn't. Please change your rulemaking.

13 When the FDA issues guidance or changes its  
14 rules or issues a new kind of interpretation, that's one  
15 agency speaking nationally. What Mr. Waxman wants to do  
16 is invite plaintiffs to walk into every court in the  
17 land under Lanham Act claims and create one jury saying,  
18 I think you should have called it apple-grape juice, and  
19 another saying you should have had the percentage.

20 JUSTICE GINSBURG: I would like you to  
21 respond to this question: In the real world, the FDA  
22 has a tremendous amount of things on its plate, and  
23 labels for juices are not really high on its list. It  
24 has very limited resources. You are asking us to take  
25 what it has said about juice as blessing this label,

1 saying it's not misbranding, when its regulations aren't  
2 reviewed by the Court, when there is no private right of  
3 action, and say that that overtakes the Lanham Act.  
4 It's -- it's really very hard to conceive that Congress  
5 would have done that.

6 MS. SULLIVAN: Justice Ginsburg, precisely  
7 for the reasons you say, you should affirm here and go  
8 with us in precluding the Lanham Act claims. And the  
9 reason is that Congress has authorized a very specific  
10 regulatory regime here. Of course you don't want the  
11 FDA deciding is pomegranate-blueberry or cranberry  
12 clear -- that's why they gave specific regulations. And  
13 contrary to what Mr. Waxman said, the FDA does not just  
14 have criminal jurisdiction. It has adjudicatory  
15 jurisdiction. It has civil authority. It can issue  
16 warning letters, which, as the amicus brief of  
17 Mr. Friedman points out, are very effective.

18 JUSTICE KENNEDY: But the point is that it  
19 is doubtful that FDA has sufficient resources to police  
20 food and beverage labeling. I think that was the thrust  
21 of Justice Ginsburg's question. I had the same concern.  
22 And this is relevant because we want to see what the  
23 likely intention of Congress was with reference to these  
24 two statutes.

25 MS. SULLIVAN: Justice Kennedy, the U.S.

1 position is unworkable, as you said before. And the  
2 U.S. hasn't said that they lack sufficient resources.  
3 What we would respectfully suggest you look at is not  
4 FDA's latest amicus brief through the U.S., but FDA's  
5 authoritative statement about whether its labeling  
6 regulations were being implemented.

7 In the red brief at Page 7, we cite to the  
8 rulemaking in which the FDA found after the three-year  
9 study -- remember the express preemption provision  
10 couldn't go into force until there was a three-year  
11 study by the OIM. And if you look at Page 7 of the red  
12 brief, three-quarters of the way down the page, you'll  
13 see FDA in its authoritative statement, irrespective of  
14 its amicus brief here, found that 343(f), the  
15 presentation regulation, and 343(i), the naming  
16 regulation, were being adequately implemented.

17 JUSTICE GINSBURG: So that's contrary to its  
18 current position, and I think we have to take it -- the  
19 FDA is -- is -- the government is representing the  
20 current FDA position.

21 MS. SULLIVAN: But, Your Honor, you don't  
22 give our deference to an amicus brief when there's an  
23 authoritative prior statement by FDA that these  
24 implementation -- for the very reason you suggest, the  
25 FDA has other things to do.

1 JUSTICE GINSBURG: Would that -- without  
2 regard to deference, we don't resurrect the statement  
3 that they no longer support.

4 MS. SULLIVAN: Well, Your Honor, they  
5 haven't disavowed that statement. We would respectfully  
6 suggest that just as it's too late for Mr. Waxman to  
7 change his theory, as you said in Riegel, to a -- we're  
8 enforcing the FDA theory -- and he doesn't purport to do  
9 it here -- it's -- the FDA, it's too late now to say in  
10 an amicus brief that they didn't mean it back in 1993.

11 JUSTICE KAGAN: Do you think, Ms. Sullivan,  
12 that there are any Lanham suits regarding food labels  
13 that are allowable?

14 MS. SULLIVAN: Yes, Your Honor. Putting  
15 aside the private enforcement 337(a) problem that  
16 Justice Sotomayor raised before, we believe that Lanham  
17 Act suits are not preempted -- would not be preempted as  
18 state law claims, and, therefore, are not precluded as  
19 Lanham Act claims, if they fall outside the specific  
20 provisions of FDCA that have preemptive force. So  
21 343(a) -- may I finish, your Honor?

22 CHIEF JUSTICE ROBERTS: Yes.

23 MS. SULLIVAN: If there is something that is  
24 not covered -- name, vignette, font, multiplied are  
25 covered. If there's something else that's not

1 covered -- and I would refer Your Honor to --  
2 specifically to religious dietary labeling, bottle  
3 container deposit labeling -- those are things that the  
4 FDA said in its rulemaking, based on the Congressional  
5 record, are outside the specific provisions with  
6 preemptive force. Then, assuming there's no 337  
7 problem, you can have a Lanham Act claim. All we say is  
8 that --

9 CHIEF JUSTICE ROBERTS: Thank you, counsel.

10 MS. SULLIVAN: -- the preemption provision  
11 governs here. Thank you very much.

12 CHIEF JUSTICE ROBERTS: Mr. Waxman, you have  
13 seven minutes remaining.

14 REBUTTAL ARGUMENT OF SETH P. WAXMAN

15 ON BEHALF OF THE PETITIONER

16 MR. WAXMAN: Thank you, Mr. Chief Justice.

17 I need to correct a few misstatements by my  
18 colleague, Ms. Sullivan. First of all, this three-year  
19 study that she's referring to, as we pointed out in our  
20 brief, the IOM and the FDA made absolutely clear  
21 repeatedly in that study that they did not look at FDA's  
22 enforcement capabilities, its enforcement efforts. It  
23 had -- it simply was a judgment about whether the  
24 specific forbearance regulations that they promulgated,  
25 in fact, adequately accomplished what Congress's

1 objectives were.

2           Number two, we -- we are not saying that  
3 this is a misbranded product. We are not trying to  
4 enforce the FDCA. And the FD -- and the FDA itself has  
5 made clear, not only in its brief in this case and not  
6 only in its enforcement action in the Nestle case, but  
7 in the Federal Register discussion of the juice naming  
8 regulation, that the fact that the juice may comply --  
9 and here it probably doesn't -- may comply with the  
10 naming convention does not mean that it is misleading.

11           The FDA said over and over again in that  
12 rulemaking that we strongly caution manufacturers that,  
13 in fact, mere compliance with this does not mean that  
14 the label is misleading and -- and that manufacturers  
15 are under an obligation to ensure that the label is not  
16 misleading. Now, as to the question of --

17           JUSTICE KENNEDY:           Where -- where is that  
18 statement contained?

19           MR. WAXMAN:           That is in 58 -- the statements  
20 that I'm quoting are in 58 Federal Register, Pages 2900,  
21 2919, and 2920.

22           JUSTICE KENNEDY:           Thank you.

23           MR. WAXMAN:           And also, indeed said,  
24 nonetheless, we encourage manufacturers to name all of  
25 the juices in a multiple juice product specifically

1 because it was concerned about this.

2 Now, Ms. Sullivan says, well, you know, not  
3 all Lanham Act claims are preempt -- precluded. They  
4 wouldn't be precluded if the parallel cognate state law  
5 enforcement of an identical standard wouldn't be  
6 precluded.

7 This is -- the closest cognate here is  
8 343(a), which provides that a food is misbranded if it  
9 is false -- if the label is false and -- false or  
10 misleading at any particular. That isn't in this sort  
11 of Swiss cheese exception -- exemption-filled preemption  
12 provision of the NLEA. That one isn't preempted. There  
13 is nothing whatsoever that preempts any person from  
14 going into state court and enforcing a state law  
15 provision that recites in haec verba 343(a).

16 Now, Ms. Sullivan says, okay, we're not  
17 worried here. The FDA wasn't worried here about health  
18 or safety. That's not what's going on here.

19 That is the point. That is the point. It's  
20 because there were concerns about health and safety with  
21 this juice naming regulation that they said, in the  
22 exercise of our sovereign enforcement authority, we are  
23 not going to go after you for complying with this naming  
24 convention, because, as they've explained, we don't know  
25 anything about how to protect competitors. We don't



1 purport to know what is in the competitive marketplace.  
2 And we aren't about writing regulations under these  
3 criminal provisions.

4 And Ms. Sullivan is right. There are civil  
5 enforcement mechanisms, but they're all enforced by  
6 juries. We aren't going to go this way because this is  
7 not our job. It's not our expertise. And yet,  
8 interesting --

9 JUSTICE KAGAN: But, Mr. Waxman, I think  
10 Ms. Sherry said that the FDA views itself as having a  
11 job beyond health and safety, that they view themselves  
12 as least -- not thinking about competitors' welfare or  
13 lack thereof, but at least thinking about consumer  
14 understanding of labels.

15 So if that's the case, is the determination  
16 under the Lanham Act different from the determination  
17 under the FDCA?

18 MR. WAXMAN: Very definitely, and for -- for  
19 some of the reasons that this Court discussed in the  
20 Lexmark case, where you were talking about who can sue  
21 under the Lanham Act and who's protected. And the Court  
22 noted that, of course, consumer confusion itself can be  
23 the engine for a competitor harm.

24 But the former is not what the Lanham Act is  
25 about, and the latter, the FDA has made perfectly clear

1 is not what the FDCA is about.

2 And interestingly, even with respect to this  
3 naming provision, and, you know, we -- the government  
4 agrees with us far more than it disagrees with us, but  
5 our disagreement about the preclusive effect of their  
6 judgment is important.

7 You know, they say, okay, we -- we spent a  
8 lot of time on these regulations, and we are entitled to  
9 chevron deference. And we think they are entitled to  
10 Chevron deference with respect to interpreting the  
11 misbranding provisions that they are in fact -- that  
12 they do enforce.

13 They're asking as -- their submission here  
14 is not -- not -- not just in an FDA action, enforcement  
15 action in court, will we get chevron deference for our  
16 interpretation of what the meaning of 343(i)(1) is.

17 But in a Lanham Act case, we get chevron on  
18 steroids deference. We get to basically keep you out  
19 of court entire -- you're not even allowed to make that  
20 claim.

21 That is an astonishing proposition, and it  
22 is one that there is nothing whatsoever in the  
23 legislative history, the language of the statute,  
24 anything at all to indicate that Congress wanted --

25 JUSTICE KENNEDY: Any authority that the FDA

1 interpretation gets deference is presumed to be correct,  
2 or presumed to be not misleading? Has there ever been  
3 any scholarship or commentary or cases saying that?

4 MR. WAXMAN: Well, certainly not in the  
5 Lanham Act context. There's been no suggestion that  
6 they have anything whatsoever to say about the Lanham  
7 Act. Knowing the professoriate, I'm sure there must be  
8 some commentary about whether they do or don't get  
9 chevron deference. But Ms. Sullivan says that they  
10 don't and the government says that they do. And there  
11 must be a scholar at least on each side of that  
12 position, but I simply don't know. I will make one  
13 final point.

14 JUSTICE SCALIA: If there is a Lanham Act  
15 suit and the regulation is brought forward to prevent  
16 the suit, cannot the party against whom it's brought  
17 forward say the regulation is --

18 MR. WAXMAN: We certainly intend to say that  
19 if it becomes relevant, absolutely.

20 JUSTICE SCALIA: So it's not on steroids  
21 then. You can still apply --

22 MR. WAXMAN: Well, I -- right. I think that  
23 it doesn't apply at all. The government would take the  
24 position that it has preclusive authority.

25 Thank you.

1 CHIEF JUSTICE ROBERTS: Thank you, Counsel.

2 The case is submitted.

3 (Whereupon, at 12:07, the case in the

4 above-entitled matter was submitted.

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