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IN THE SUPREME COURT OF THE UNITED STATES

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POM WONDERFUL LLC, :

Petitioner : No. 12-761

v. :

THE COCA-COLA COMPANY. :

- - - - - x

Washington, D.C.

Monday, April 21, 2014

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

APPEARANCES:

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

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

KATHLEEN M. SULLIVAN, ESQ., New York, New York; on 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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