IN THE SUPREME COURT OF THE UNITED STATES

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POM WONDERFUL LLC, :

Petitioner : No. 12-761

v. :

THE COCA-COLA COMPANY. :

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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.

C O N T E N T S

P R O C E E D I N G S

(11:06 a.m.)

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

Mr. Waxman?

ORAL ARGUMENT OF SETH P. WAXMAN

ON BEHALF OF THE PETITIONER

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

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

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

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

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

MR. WAXMAN: Justice --

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

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

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

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

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

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

MR. WAXMAN: Well, Justice Kennedy --

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

MR. WAXMAN: Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE GINSBURG: Without saying what label would be lawful?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, Counsel.

Ms. Sherry.

ORAL ARGUMENT OF MELISSA ARBUS SHERRY,

FOR UNITED STATES, AS AMICUS CURIAE,

SUPPORTING NEITHER PARTY

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

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

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

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

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

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

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

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

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

because there would be no irreconcilable conflict.

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

MS. SHERRY: Yes.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

JUSTICE ALITO: You don't think there are a

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

MS. SHERRY: And I think --

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

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

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

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

Ms. Sullivan.

ORAL ARGUMENT OF KATHLEEN M. SULLIVAN

ON BEHALF OF THE RESPONDENT

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

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

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

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

MS. SULLIVAN: That's correct, Justice

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

we're talking here about labeling so that

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

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

MS. SULLIVAN: It's an authorization.

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

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

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

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

MS. SULLIVAN: Well, Your Honor --

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

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

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

JUSTICE SOTOMAYOR: You basically are talking about field preemption.

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

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

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

juice.

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

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

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

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

CHIEF JUSTICE ROBERTS: Okay.

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

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

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

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

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

than the general misrepresentation provisions of the Lanham Act.

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

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

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

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

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

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

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

MS. SULLIVAN: Correct, Your Honor.

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

MS. SULLIVAN: Correct, Your Honor.

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

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

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

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

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

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

MS. SULLIVAN: Correct, Your Honor, but the

falsity standard --

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

MS. SULLIVAN: We do, Your Honor.

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

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

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

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

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

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

MS. SULLIVAN: Justice --

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

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

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

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

(Laughter.)

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

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

(Laughter.)

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

JUSTICE SOTOMAYOR: How do we square this with Wyeth?

MS. SULLIVAN: Your Honor --

JUSTICE SOTOMAYOR: Wyeth, the FDA actually

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHIEF JUSTICE ROBERTS: Yes.

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

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

CHIEF JUSTICE ROBERTS: Thank you, counsel.

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

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

REBUTTAL ARGUMENT OF SETH P. WAXMAN

ON BEHALF OF THE PETITIONER

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

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

objectives were.

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

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

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

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

JUSTICE KENNEDY: Thank you.

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

because it was concerned about this.

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

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

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

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

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

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

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

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

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

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

is not what the FDCA is about.

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

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

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

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

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

JUSTICE KENNEDY: Any authority that the FDA

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

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

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

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

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

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

Thank you.

CHIEF JUSTICE ROBERTS: Thank you, Counsel.

The case is submitted.

(Whereupon, at 12:07, the case in the above-entitled matter was submitted.

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