No. 12-761

In the Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* STATES OF ALASKA, HAWAII, INDIANA, MAINE, MASSACHUSETTS, MISSOURI, NEVADA, NEW HAMPSHIRE, OREGON, AND TENNESSEE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the Food, Drug, and Cosmetic Act (FDCA).

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INTEREST OF *AMICI CURIAE*

The amici States take no position on the merits of petitioner Pom's underlying Lanham Act claim against Coca-Cola, nor do they suggest that Pom is itself beyond reproach from a consumer protection standpoint. *See, e.g., Pom Wonderful LLC v. Federal Trade Comm'n*, No. 13-1060 (D.C. Cir.) (pending petition for review of Federal Trade Commission false advertising action against Pom). But the amici States disagree with the apparent conclusion of the Ninth Circuit that even assuming Coca-Cola's juice labeling and marketing is misleading to consumers, the only entity that can do anything about it is the Food and Drug Administration (FDA). This holding implicates two important state interests.

First, the amici States have a strong interest in protecting consumers from deception and businesses from unfair competition. To that end, the amici States have a long history of exercising their traditional police powers to enact laws protecting citizens from unfair and deceptive business practices. These laws cover a wide range of commercial activity ranging from advertising to product safety and labeling and are enforced both through public actions by state attorneys general and through private rights of action. Federal laws that complement these state consumer protection laws—like the FDCA, the Federal Trade Commission Act, and the Lanham Act—help further the state interest in comprehensive enforcement. By creating a private right of action for those harmed by deceptive business practices, the federal Lanham Act allows private parties to supplement the efforts of the amici States and federal authorities to combat such practices. The amici

States therefore have an interest in ensuring that this federal remedy remains available.

Second, the amici States have a direct interest in how the Court analyzes the relationship between the FDCA and FDA regulations and other laws, particularly if the Court accepts Pom's invitation to draw on federal–state preemption principles and *Wyeth v. Levine*, 555 U.S. 555 (2009). Pet. Br. 16-17, 24-25, 28, 32-42. As separate sovereigns, the amici States want to ensure that their state laws—including consumer protection laws—remain effective when not expressly preempted, and that courts do not lightly infer that one law implicitly overrides another when both can be given full effect.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Ninth Circuit erred in concluding that, even if Coca-Cola's "Pomegranate Blueberry" juice labeling and marketing misleads consumers, only the FDA can take corrective action. Pet. App. 11a [679 F.3d at 1177] ("If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act. But, under our precedent, for a court to act when the FDA has not—despite regulating extensively in this area—would risk undercutting the FDA's expert judgments and authority.") FDA action need not, and should not, be the only available option to combat deceptive conduct, especially given the agency's limited resources and other priorities. The FDCA and FDA regulations leave room for a Lanham Act claim challenging aspects of a label that are not mandatory. Courts should not be so quick to find that one law implicitly cancels out another where, as here, the

two can coexist and work in tandem to further complementary goals.

Although this case involves an asserted conflict between federal laws, rather than between federal and state law, both Pom and the United States draw an analogy to federal–state implied preemption principles. Pet. Br. 32-42; U.S. Cert. Br. 10. These principles are not directly applicable here, and federal displacement of state law in an area of traditional state authority implicates federalism concerns not implicated in this case. Nonetheless, as the United States notes, federal–state implied preemption principles "are calculated to identify laws that cannot co-exist." U.S. Cert. Br. 10. Applying these principles to this case thus helps demonstrate that the FDCA and the Lanham Act can indeed coexist and both have full effect.

First, drawing an analogy to "field" preemption demonstrates that the FDCA does not "occupy the field" of food and drink labeling to the exclusion of all other laws. Rather, the FDCA explicitly allows other mechanisms such as state law to operate. In light of the long history of States' enforcement of consumer protection laws that touch on food and drink labeling and advertising, the Ninth Circuit's apparent conclusion that the FDA alone must police this entire field is both novel and extreme.

Second, drawing an analogy to "conflict" preemption demonstrates that Pom's Lanham Act claim can readily coexist with the FDCA. In preemption cases, this Court has held that a state law impliedly conflicts with a federal law, and therefore is displaced, if it is impossible to comply with both laws or the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Hines v. Davidowitz, 312 U.S. 52, 67 (1941). Neither type of conflict is present here. A manufacturer can both comply with FDA's labeling requirements *and* refrain from misleading consumers in ways that create Lanham Act liability. And recognizing a concurrent Lanham Act obligation not to mislead does not pose an obstacle to the health, safety, and consumer protection purposes underlying the FDCA. On the contrary, allowing the Lanham Act and the FDCA to operate in tandem to protect consumers is more consistent with congressional objectives than leaving businesses free to use their labeling flexibility under the FDCA to mislead consumers and harm competitors with impunity.

Because Pom's Lanham Act claim can coexist with—and complement—the FDCA and the FDA's juice labeling regulations, the judgment of the Ninth Circuit should be reversed.

ARGUMENT

I. Implied preemption principles, although not controlling, help demonstrate that the Lanham Act and the FDCA can coexist.

This case does not raise a potential conflict between state and federal law, but rather a potential conflict between two federal laws. Applying an analogy to federal–state preemption cases nonetheless helps demonstrate that the Lanham Act and the FDCA can easily coexist. Although this analogy is analytically useful, the amici States caution that the outcome in this case would not be dispositive in a federal–state preemption case, which would involve additional federalism considerations.

If this were a federal–state preemption case, Coca-Cola would be required to overcome the strong presumption against preemption of state law in areas traditionally regulated by the States. *Wyeth*, 555 U.S. at 565. The Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *see also Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894) ("If there be any subject over which it would seem the states ought to have plenary control, and the power to legislate in respect to which, it ought not to be supposed, was intended to be surrendered to the general government, it is the protection of the people against fraud and deception in the sale of food products."). Courts should be especially reluctant to find that federal law overrides state law in an area like consumer protection absent an express statement by Congress or a direct and unavoidable conflict between state and federal law. The presumption against preemption of state law reflects important federalism concerns that are not implicated when two federal statutes are alleged to be in conflict.

There are nonetheless some similarities between cases addressing an alleged conflict between state law and federal law and cases addressing an alleged conflict between two federal laws. In both types of cases, courts try to give effect to both laws. In federal–federal preclusion cases, courts start with the principle that two federal laws on the same subject should be given effect to the maximum extent possible. *United States v. Borden Co.*, 308 U.S. 188, 198 (1939). "Indeed 'when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional

intention to the contrary, to regard each as effective.' . . . [T]his Court has not hesitated to give effect to two statutes that overlap, so long as each reaches some distinct cases." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001) (internal citations omitted). The preclusion and preemption analyses are also similar in that their resolution depends upon whether Congress really intended for one law to displace another. *Wyeth*, 555 U.S. at 565 ("[T]he purpose of Congress is the ultimate touchstone in every pre-emption case.") (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1995)); *see also New York Tel. Co. v. New York State Dep't of Labor*, 440 U.S. 519, 540 n.32 (1979) ("[H]owever the conflict is viewed, its ultimate resolution depends on an analysis of congressional intent.").

Thus, although this case does not call into question the preemption of state consumer protection laws—laws presumptively not preempted by the FDCA—it is nonetheless useful to borrow from federal–state preemption cases in analyzing whether the relevant provisions of the Lanham Act and the FDCA can coexist. These cases help show that no matter how one conceptualizes the alleged tension between the laws, the Court can easily give full effect to both of them.

In federal–state preemption cases, absent an express statement by Congress that it intends to preempt state law, courts rely on two general bases to find that state law is implicitly preempted. First, when Congress intends federal law to completely occupy a given field, state law in that field may be preempted. *California v. ARC America Corp.*, 490 U.S. 93, 100 (1989) (citing *Pacific Gas & Electric Co. v. State Energy Resources Conservation and Dev. Comm'n*, 461 U.S. 190, 212-13

(1983)). Second, even if Congress has not completely occupied a field, state law may be preempted to the extent it actually conflicts with federal law. Courts have recognized two subtypes of conflict preemption: "impossibility" preemption occurs when compliance with both state and federal law is impossible; and "obstacle" preemption occurs when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *ARC Am. Corp.*, 490 U.S. at 100-101 (quoting *Hines*, 312 U.S. at 67). None of these types of preemption—applied to this case by analogy—supports the conclusion that the FDCA and the Lanham Act cannot coexist here.

II. The FDA's authority over juice labeling is not so comprehensive as to "occupy the field" of food labeling and shut out complementary enforcement efforts.

Coca-Cola maintains that Congress intended the FDCA and FDA regulations to be the "exclusive body of regulation to which food and beverage labels would be subject." Br. in Opp. 14. The Ninth Circuit agreed, concluding that the FDA's authority over juice labeling is so "comprehensive" that it shuts out even claims touching on topics the regulations do not address, such as the use of different font sizes for words within a product name. Pet. App. 12a [679 F.3d at 1178]. As the United States notes, this analysis is similar to that used in federal–state "field" preemption cases. U.S. Cert. Br. 10.

Field preemption occurs "when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). But the Court long ago

established that courts should not lightly infer field preemption. "[F]ederal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963). Consistent with that principle, this Court rarely finds implied field preemption of state law based solely on the complex or comprehensive character of federal regulation. *See Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 617 (1997) (Thomas, J., dissenting) ("[O]ur recent cases have frequently rejected field pre-emption in the absence of statutory language expressly requiring it."); *New York Dep't of Social Services v. Dublino,* 413 U.S. 405, 415 (1973) (rejecting "the contention that pre-emption is to be inferred merely from the comprehensive character of the federal [legislation]"). Although federalism considerations make arguments against implied field preemption even stronger in federal–state preemption cases, courts should likewise be reluctant to find that one federal law implicitly shuts out all others that might operate in the same field.

The FDCA does not "occupy the field" of food and drink labeling, conferring exclusive responsibility and authority on the FDA. This is clear because state consumer protection and food labeling laws remain effective except in a few respects where expressly preempted under 21 U.S.C. §343-1.[1] In crafting §343-1,

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[1] 21 U.S.C. §343-1 provides that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate com-

Congress painstakingly listed each specific statutory subsection under which state law would be preempted. And even on the topics included in §343-1, state law is not preempted completely—States may enact requirements that are identical to federal requirements and may provide their own enforcement mechanisms and remedies. The carefully constructed preemption provision in §343-1 would be superfluous if the FDCA were intended to completely occupy the field of food and beverage regulation to the exclusion of all other laws.

Moreover, the Ninth Circuit's view of the law would place a considerable burden on the FDA by making it the sole regulator, police officer, judge, and jury responsible for dealing with a wide range of potential business misconduct. Under the Ninth Circuit's expansive reasoning, even if a food or drink label contains deliberate, literal falsehoods, apparently only the FDA can act to stop it. The FDA does not have the resources to police the marketplace in this way. *Cf. Wyeth*, 555 U.S. at 578 (noting the FDA's "limited resources to monitor the 11,000 drugs on the market"). Moreover, consumers and businesses injured by deception in food and drink labeling would have no remedy because, as the United States explains, the FDA "has no authority to resolve a competitor's claim of competitive injury due to a misleading label." U.S. Cert. Br. 14.

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merce" any of 14 different specified types of requirements "that is not identical to" the corresponding FDCA requirement. For example, under §343-1(2), a State may not adopt a requirement about labeling imitation foods that is not identical to the FDCA's requirement under 21 U.S.C. §343(c) that such labels "bear[], in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated."

Rather than giving the FDA exclusive responsibility to police the entire field of food and drink labeling, the FDCA contemplates that multiple sources of law and enforcement mechanisms can operate in tandem to protect consumers.

III. The Lanham Act does not directly conflict with the FDA's juice labeling regulations because it is possible to comply with both.

In federal–state preemption cases, federal law overrides state law when compliance with both "is a physical impossibility." *Fla. Lime & Avocado Growers,* 373 U.S. at 142-43. By analogy here, the FDA labeling regulations might override a Lanham Act claim that sought to prohibit something the regulations require or require something the regulations prohibit.

This type of conflict preemption necessitates careful analyses of what the two purportedly conflicting laws actually require. For example, in *Wyeth* a drug manufacturer argued for "impossibility" preemption of a state tort claim on the theory that federal law prohibited it from changing its drug label and the tort claim would have required it to do so. 555 U.S. at 568. The Court declined to find impossibility preemption because it rejected the manufacturer's interpretation of federal law, holding that the manufacturer did indeed have flexibility to change its label. *Id*. at 573. By contrast, in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)—a similar drug label case involving different federal regulations—the Court concluded that the drug manufacturer did not have flexibility to change its label and thus found impossibility preemption. *Id*. at 2578. These cases illustrate that two laws do not di-

rectly conflict when they give regulated parties flexibility to comply with both.

Here, the laws give Coca-Cola substantial flexibility. Unlike the manufacturer in *PLIVA*, Coca-Cola is free to change its juice label at any time. And Coca-Cola can vary much of the information, design, and presentation of its label without running afoul of the FDCA or any FDA regulations. Although the FDA regulations address how multi-juice beverages can be named, the regulations neither mandate the specific name Coca-Cola has chosen for its juice nor dictate every aspect of how that name is presented. *See* 21 C.F.R. §102.33. The regulations do not appear to prohibit Coca-Cola's chosen name, "Pomegranate Blueberry Flavored Blend of 5 Juices." *Id.* But the regulations also do not *require* that Coca-Cola use this particular name for this product. Nor do the regulations mandate *how* Coca-Cola presents this name in conjunction with other labeling elements and the way it uses this name it its marketing materials.

For example, the regulations neither condone nor prohibit displaying part of this name in a smaller font on the label, as Coca-Cola has chosen to do.[2] Nor

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[2] Coca-Cola asserts that it has complied with a regulation requiring that the words "Flavored Blend of 5 Juices" appear in a font that is at least half the size of the words "Pomegranate Blueberry." Resp. Supp. 3 (citing 21 C.F.R. §101.22(i)(1)(i)). But the regulation Coca-Cola cites is inapposite because it has to do with the font size for required label information other than the product name—it does not speak to the questionable practice of using different font sizes *within* the product name in a manner that obscures the actual name. The FDA commentary makes clear that the requirement in §101.33(d)(1) that the word "flavored" appear in the product name is separate from the requirement in §101.22(i) that flavors be declared on the label in a certain way.

do they mandate the line break Coca-Cola has chosen to insert in the middle of the name, which makes it less likely that a consumer would realize that the word "Flavored" should be read together with the words "Pomegranate Blueberry" as a compound modifier for the noun "Blend." The result of Coca-Cola's voluntary formatting choices—together with its voluntary selection of a vignette dominated by a large pomegranate—is that a consumer may perceive the product name to be "Pomegranate Blueberry," conveying the impression that the product contains more than trace amounts of these juices.

A conflict between the Lanham Act and the FDCA might exist if Pom's claim challenged a specific labeling element that is actually *required* by the FDA regulations. For example, a hypothetical Lanham Act claim alleging that declaring that a juice is "from concentrate" is somehow misleading might be precluded by the regulation explicitly requiring that declaration. *See* 21 C.F.R. §102.33(g). But a Lanham Act claim challenging the many voluntary aspects of a label that includes a "from concentrate" declaration—including the manner in which the required declaration is displayed relative to other labeling elements—would not conflict with any regulations. The fact that a business must include certain information on its label does not insulate from challenge its voluntary choices about how to present that information.

See 58 Fed. Reg. 2897-01, 2920 (Jan. 6, 1993) ("[B]oth §§101.22 and 102.33 are intended to ensure that the label communicates essential information to consumers. . . . One type of information informs the consumer when flavoring substances have been added to the product. The other type describes other aspects of the basic nature of the product.").

Pom's Lanham Act complaint creates no conflict because it challenges only the *voluntary* labeling choices Coca-Cola has made, alleging that Coca-Cola's label contains "many misleading elements not required by federal or state regulation." First Am. Compl. ¶ 20. The FDCA and FDA regulations leave room for this kind of challenge because they do not exhaustively cover every aspect of labeling. Manufacturers retain substantial freedom to vary many elements of their labels, just as the manufacturer in *Wyeth* had the freedom to change its drug label. 555 U.S. at 568. And wherever manufacturers have this freedom to maneuver, the Lanham Act can—without creating a direct conflict—task them with the responsibility not to use their freedom in ways that mislead consumers.

Not only does the FDCA give manufacturers labeling flexibility, but the Lanham Act does as well. A Lanham Act judgment that Coca-Cola's label is misleading might require Coca-Cola to change and clarify its label, but Coca-Cola would have flexibility to decide how best to do so. Such a judgment would not require Coca-Cola to change any specific label element that is required by the FDCA or regulations. In *Wyeth*, the Court noted that a tort judgment finding a drug warning label inadequate did not "mandate a particular replacement warning"; rather, the manufacturer could strengthen its warning in "any number of ways." 555 U.S. at 565. Likewise here, if a Lanham Act claim against Coca-Cola's label were to succeed, Coca-Cola could redesign its label in "any number of ways" to make it less misleading. Unlike the manufacturer in *PLIVA*, Coca-Cola would not have to do anything that is prohibited by the FDCA or FDA regulations to revise its label in response to a Lanham Act judgment.

Coca-Cola asserts (Br. in Opp. 10-11) that the more specific provision—the FDA's multi-juice labeling regulation—must trump the more general one—the Lanham Act duty not to mislead consumers. But neither provision needs to "trump" the other where, as here, the two can coexist. Subjecting Coca-Cola's *voluntary* labeling and marketing choices to a Lanham Act challenge creates no direct conflict with any requirements of the FDA regulations.

IV. Lanham Act claims do not pose an "obstacle" to any congressional objective because enforcing an ongoing duty not to mislead consumers complements and supports the FDCA.

A state law that does not directly conflict with a federal law may nonetheless be held preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. Coca-Cola makes an analogous argument here, maintaining that Pom's Lanham Act claim is precluded because it poses an obstacle to congressional purposes. That argument is without merit.

Although the presumption against preemption that applies in federal–state cases does not apply here, the Court should still give effect to both the FDCA and the Lanham Act if possible. *See Morton v. Mancari*, 417 U.S. 535, 551 (1974) ("The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective."). Like the presumption against preemption, this principle weighs strongly against finding that Lanham

Act claims are disallowed in the absence of a direct conflict. So too does the fact that the FDCA expressly preempts some specifically identified state laws, but includes no similar provision expressly ousting Lanham Act claims or equivalent state law claims. 21 U.S.C. § 343-1. Congress's inclusion of an express provision excluding some laws suggests that Congress did not intend to exclude other laws that it did not mention. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 517 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.").

More generally, the Court has cautioned that a federal–state "obstacle" preemption analysis "does not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives'" because such an inquiry would intrude on congressional prerogatives. *Chamber of Commerce of U.S. v. Whiting*, 131 S. Ct. 1968, 1985 (2011) (quoting *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in judgment)). Similarly here, to avoid intruding on congressional prerogatives, the Court should avoid a "freewheeling judicial inquiry" into the various policy objectives that might arguably be obstructed if the Lanham Act is given full effect. Both the Lanham Act and the FDCA should be given full effect absent a clear and overwhelming contrary purpose. No such contrary purpose exists.

At the most basic level, the Lanham Act's prohibition on using "false or misleading" descriptions or representations in connection with goods complements, rather than obstructs, the FDCA, because the FDCA likewise prohibits food and drink labels that are "false

or misleading in any particular." *See* 15 U.S.C. §1125(a); 21 U.S.C. §343(a). To be sure, the FDA regulations impose various additional, more specific labeling requirements. *See* 21 C.F.R. §102.33. But these specific regulatory requirements neither replace the statutory obligation not to mislead consumers nor redefine the word "misleading." A label can comply with specific requirements—such as containing the words "from concentrate"—and nonetheless still be "misleading," as that word is commonly understood. Because the FDA regulations do not replace or redefine the FDCA statutory obligation not to mislead in 21 U.S.C. §343(a), they also need not supplant the separate, but complementary, Lanham Act statutory obligation not to mislead in 15 U.S.C. §1125(a), which creates a private cause of action for injured competitors. The Court will better harmonize the statutes by holding that manufacturers have *both* a Lanham Act obligation not to mislead consumers *and* an obligation to comply with the FDA's specific labeling requirements—rather than that they are free to use the flexibility granted by the FDCA to mislead consumers with impunity.

The FDA recognized that its multi-juice labeling regulations would not replace the manufacturers' obligation not to mislead. For example, in its 1993 Final Rule, the FDA noted that although it had decided not to prohibit beverage names like Coca-Cola's that begin by listing non-predominant juices, the underlying obligation not to mislead consumers would remain:

> The name of the characterizing juice may . . . be declared first although it is not the most predominant juice. However, . . . this provision does not relieve the manu-

> facturer of the obligation to label the product in a truthful and nonmisleading manner. [58 Fed. Reg. 2897-01, 2920 (Jan. 6, 1993).]

The FDA cautioned that "beverage labels are clearly misleading if they misrepresent the contribution of one or more individual juices to the nature of the product," but also recognized that "there are several ways in which a multiple-juice beverage can be appropriately labeled." In short, the FDA concluded that rigid, across-the-board regulatory prescriptions are not always warranted, *id*. at 2919, and that it need not craft regulations exhaustively addressing every way in which a label might mislead consumers. Just as the Court recognized in *Wyeth* that drug manufacturers, rather than the FDA, bear responsibility for the content of their labels at all times, food and drink manufacturers likewise bear an ongoing responsibility to ensure that their own labels are not misleading. 555 U.S. at 570-71.

The multi-juice labeling regulations thus represent only the FDA's judgment that certain minimum requirements should be imposed on all beverages and will make labels clearer and more informative in general. An FDA decision not to resolve a labeling issue with an across-the-board requirement does not constitute a judgment that the issue could never lead to a misleading label in a specific case. *Cf. Sprietsma v. Mercury Marine, a Div. of Brunswick Corp*., 537 U.S. 51, 65-68 (2002) (rejecting the position that the Coast Guard's decision not to adopt a propeller guard regulation for boats represented a federal policy against propeller guards that would preempt a state tort suit alleging that a particular boat should have had a pro-

peller guard). For this reason, the fact that the regulations allow multi-juice beverage manufacturers to use the names of non-predominant juices (while remaining silent on Coca-Cola's formatting choices) does not mean that the FDA has determined that labels like Coca-Cola's cannot be misleading.

Nor do the gaps in the FDA's juice labeling regulations reflect a policy choice to keep those gaps open. Because the gaps are not themselves a policy choice, Lanham Act claims operating within the gaps pose no obstacle to any congressional objective. By contrast, in *Geier v. American Honda Motor Co.,* 529 U.S. 861 (2000), the Court observed that a federal agency had deliberately provided auto manufacturers with a range of different safety device choices in order to "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance." *Id*. at 875. The Court held that restricting those choices by requiring a specific safety device—an airbag—would have posed an obstacle to the deliberate policy decision to give manufacturers a range of choices. *Id*. at 886. Here, by contrast, the FDA regulations do not deliberately provide juice manufacturers with a range of labeling options for policy reasons that would be undermined if another law limited the options. No identifiable congressional policy is compromised if Coca-Cola is forced to revise and clarify its juice label in response to a Lanham Act claim. The FDCA and FDA regulations provide manufacturers with flexibility not for flexibility's sake—as in *Geier*—but because it would be unworkable to exhaustively dictate required labels for every food and drink product. *Cf. Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1137 (2011) ("Like the regulation in *Geier*, the regulation here leaves the manufacturer with a

choice. And, like the tort suit in *Geier*, the tort suit here would restrict that choice. But unlike *Geier*, we do not believe here that choice is a significant regulatory objective."); *Sprietsma*, 537 U.S. at 67-68 (distinguishing *Geier*).

Moreover, a Lanham Act claim would not second-guess any FDA determination because the FDA plainly has not, as Coca-Cola contends, approved Coca-Cola's label as "not misleading." Br. in Opp. 3, 7. Congress could have—but did not—create a scheme under which the FDA would have the responsibility to examine and pre-approve individual juice labels as "not misleading" before they can be used in the marketplace. As the United States explains, the FDA "does not approve juice labels, and its failure to initiate an enforcement action cannot be construed as such an approval." U.S. Cert. Br. 16. The FDA has many duties and enforcement priorities, and the fact that it has not actively prevented Coca-Cola from using this label—one out of many thousands in the marketplace—does not constitute a considered judgment that the label is acceptable, much less that it is unassailable. Because juice labels enter the marketplace without approval and are not closely monitored by the FDA, recognizing other means of policing their content—like private Lanham Act claims—helps protect consumers.

In fact, even if Congress *had* created a juice label pre-approval process and the FDA *had* approved Coca-Cola's label, a Lanham Act claim still would not necessarily be precluded. In *Wyeth*, this Court recognized that a tort claim challenging a drug label could coexist with the FDCA even though the FDA had examined and pre-approved the label. 555 U.S. at 558. The Court disagreed that recognizing the state tort

claim would pose an obstacle to "Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." *Id*. at 574.

The argument that private claims would upset the FDA's "precise balancing" carried more force in *Wyeth*—where it failed—than it does here. *Id*. at 575. *Wyeth* involved the context of drug regulation, which requires the FDA to use its expert scientific judgment and consider the important competing objectives of drug safety and effectiveness. The Court nonetheless rejected the position that "the agency must be presumed to have performed a precise balancing of risks and benefits," leaving no room for additional requirements. *Id*. Here, the FDA's juice labeling regulations do not even arguably involve any "precise balancing" of important competing objectives that could conceivably shut out other laws. The juice labeling regulations may roughly balance a desire for labeling clarity against a desire not to create heavy labeling burdens, but this balance is not so central to the FDCA that it should be deemed inviolate. Like the federal law in *Wyeth*, the juice labeling regulations create a regulatory "floor," not a "ceiling," and no policy balance is compromised by requiring more.

Coca-Cola contends that "lay judges and juries" lack the necessary expertise to figure out what does and does not mislead consumers in the context of food and drink labeling. Br. in Opp. 17. But "false" and "misleading" are not technical terms that can only be applied through the expertise of a federal agency; they are concepts well suited to a common-sense assessment. Judges and juries are fully capable of deciding claims of misleading labeling, false advertising, and

unfair competition. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) (upholding power of juries to apply the misbranding provision of the Federal Insecticide, Fungicide, and Rodenticide Act). Indeed, it is a simpler task than evaluating the failure-to-warn claim about a drug label that this Court permitted to go forward in *Wyeth*. 555 U.S. at 558.

Far from creating an obstacle, law suits establishing that specific food and drink labels are misleading consumers—such as Lanham Act suits based on consumer survey data—would both help inform the FDA in crafting new regulations and support its enforcement efforts. As the Court explained in *Wyeth*, "[s]tate tort suits uncover unknown . . . hazards and provide incentives for . . . manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." 555 U.S. at 579; *see also Bates*, 544 U.S. at 451 (explaining that private state law remedies "would seem to aid, rather than hinder" functioning of federal statute).

Nor would Lanham Act challenges to product labels create an undesirable patchwork of different labeling requirements; they would simply enforce the ongoing obligation not to use the flexibility granted by the FDA regulations to mislead consumers. Coca-Cola's emphasis on Congress's desire for labeling uniformity elevates one purported sub-goal of the FDCA over its larger purpose—to protect consumer health and safety with clear and accurate product labeling. Congress did want some uniformity, and thus acted to prevent States from enacting different, potentially conflicting, labeling laws about certain specific topics like nutrition facts. See 21 U.S.C. §343-1(a)(4). But this sub-goal of

the larger statutory scheme is insufficient to oust Lanham Act claims absent a direct conflict, given the presumption in favor of giving both laws full effect.

Allowing Lanham Act challenges to food and drink labels is more consistent with the FDCA's health, safety, and consumer protection goals than leaving businesses free to design their labels to mislead consumers unless the FDA intervenes. Lanham Act claims thus pose no "obstacle" to the accomplishment of congressional objectives.

CONCLUSION

The judgment of the Ninth Circuit should be reversed.

Respectfully submitted,

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