No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

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

SUPPLEMENTAL BRIEF FOR PETITIONER

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Most of the United States' brief is devoted to explaining why the Ninth Circuit's reasoning is both wrong and in conflict with precedents of this Court. And the Solicitor General does not dispute the importance of the question presented. The government nonetheless suggests that the Court deny the petition. But the United States' limited arguments for denying review are unpersuasive.

I. THE UNITED STATES CONFIRMS THAT THE NINTH CIRCUIT'S DECISION RESTS ON THE FDA'S MERE REGULATORY AUTHORITY OVER FOOD LABELING

The United States' brief confirms that Coca-Cola's opposition to certiorari rests on a misunderstanding of the Ninth Circuit's decision rejecting Pom's Lanham Act challenge to Coca-Cola's label. Contrary to Coca-Cola's contention, the Ninth Circuit's decision did not rest on the FDA's asserted approval of Coca-Cola's label but rather on the FDA's mere regulatory authority in this area.

This is a classic false advertising case. Pom and Coca-Cola compete directly in the market for pomegranate juices. Pom sells juices that—as purchasers would naturally expect—overwhelmingly contain actual pomegranate juice, which is sought by health-conscious consumers. Pom's products include a pomegranate-blueberry juice. Coca-Cola sells and aggressively markets its competing "POMEGRANATE BLUEBERRY" juice, which it colors a deep purple and sells with a label containing a large image of each fruit. *See* Pet. 6-7. Coca-Cola's misleading label causes consumers to believe that the juice actually contains significant amounts of those fruits when in fact it contains only trivial amounts: 0.3% pomegranate juice and 0.2% blueberry juice.

Pom introduced survey evidence showing that consumers are in fact seriously misled. Pet. App. 32a-33a. Additionally, consumers who have discovered the false labeling have complained directly to Coca-Cola in record numbers. *Id.* 31a-32a. Coca-Cola's own documents produced in discovery state that the company decided that it was "willing to assume the risk" of "misleading" consumers about the fact that "the product has less

than 0.5% of pomegranate and blueberry juices." *Id.* 34a-35a.

Believing that it was losing sales of its pomegranate juices because of Coca-Cola's deceptive label, Pom brought this lawsuit under the Lanham Act. Pet. App. 3a. As is relevant here, that statute creates a private right of action against a person who uses a "false or misleading" description or representation "in connection with any goods" or "container for goods" that "misrepresents the nature, characteristics, [or] qualities" of those goods in commercial advertising or promotion. 15 U.S.C. § 1125(a)(1). Despite this unequivocal statutory text, the Ninth Circuit sweepingly held that no Lanham Act suit may be brought challenging the label of a product regulated under the Food, Drug, and Cosmetic Act ("FDCA"). Pet. App. 12a. The Ninth Circuit deemed it dispositive that the FDCA permits the FDA to determine that the juice is "misbranded" and forbid Coca-Cola from using a particular label. *Id.* 6a, 12a.

When Pom sought review in this Court, Coca-Cola's principal argument against certiorari was to try to recast the ruling below as if it forbids Lanham Act claims only with respect to a label that is "specifically authorized" by the FDA. Opp. 1, 4. According to Coca-Cola, the Ninth Circuit merely held "that the FDA's specific determination … that juice labels like Coca-Cola's are not misleading precludes a private party from advancing the opposite position … under the Lanham Act." *Id.* 10.

The invitation brief of the United States demonstrates that Coca-Cola's reading mischaracterizes the ruling below: "In short, the court's decision rested on what it perceived as 'Congress's decision to entrust matters of juice beverage labeling to the FDA and * * *

the FDA's comprehensive regulation of that labeling.'" U.S. Br. 10 (quoting Pet. App. 12a). Thus, "the court of appeals held that FDA's food-misbranding *authority* under the FDCA occupies the relevant field here to the *total exclusion* of" the Lanham Act. *Id.* 11 (emphasis added).

II. THE UNITED STATES AGREES WITH POM THAT THE NINTH CIRCUIT ERRED

The brief of the United States also explains that the Ninth Circuit's holding misinterprets the FDCA and conflicts with this Court's precedents.

A. The government agrees with Pom that the court of appeals erred in holding that a Lanham Act claim is precluded whenever the "FDA had not (but could have) regulated the aspects of the label about which petitioner complained." U.S. Br. 8-9. That is so because "the FDCA does not occupy the juice-labeling field." *Id.* 10. "[N]othing in the FDCA, the [Nutrition Labeling and Education Act of 1990], FDA's regulations, or the preambles to those regulations suggests that FDA has marked the metes and bounds of all possible misleading materials on juice labels, or that its authority must be deemed exclusive even as to matters the agency has never specifically addressed." *Id.* 11-12. The FDCA requires that a label contain a product's "common or usual name." 21 U.S.C. § 343(i). In turn, FDA regulations provide that it is consistent with the statute to name a product after a non-predominant juice if the product name identifies the juice as a "blend" and states that it is "flavored" with the non-predominant juice. 21 C.F.R. § 102.33(c)-(d). But the agency does not view it as its mission—and in any event it does not have the resources—to police the details of many thousands of juice labels to determine

which ones mislead consumers into making purchases without presenting any public health threat. Pet. 25-26.

As the government emphasizes, Congress did not intend that the subject matter of petitioner's suit would be exclusively regulated by the FDA, to the exclusion of the Lanham Act's unqualified remedy:

> Most fundamentally, petitioner's claim arises under the Lanham Act, and it does not rely for its success on FDA's regulations (or, therefore, on FDA's application of those regulations). FDA does not administer the Lanham Act, and it has no authority to resolve a competitor's claim of competitive injury due to a misleading label.

U.S. Br. 14. Further, the "FDA does not approve juice labels, and its failure to initiate an enforcement action cannot be construed as such an approval." *Id.* 16. "In short, FDA's expertise in this field is not deployed in a way that justifies categorically depriving petitioner of a cause of action under Section 43(a) of the Lanham Act." *Id.* 15.[1]

B. The United States further agrees with Pom that, for those reasons, the ruling below cannot be reconciled with this Court's precedents. Absent clearly expressed congressional intent to the contrary, one federal statute does not displace another if the two are "'capable of coexistence.'" U.S. Br. 9 (quoting *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S.

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[1] The government also notes that the ruling below creates the "implausible" result that the FDCA precludes an action under the Lanham Act while preserving parallel state remedies. U.S. Br. 11 (citing 21 U.S.C. § 343-1).

124, 143 (2001)). The Court's precedents provide—and Congress legislates against the settled understanding—that two statutes will be given effect unless they are in "'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as a substitute.'" *Branch* v. *Smith*, 538 U.S. 254, 273 (2003) (quoting *Posadas* v. *National City Bank*, 296 U.S. 497, 503 (1936)). No such conflict exists here. *See* U.S. Br. 10-15. The United States confirms that "Congress has repeatedly amended both" the FDCA and the Lanham Act, never suggesting that the former limits the latter. *Id.* 13. "If Congress intended to foreclose such suits, it could easily have done so." *Id.*

It is uncontested—and dispositive—that Coca-Cola can easily comply with the Lanham Act by not using a label that misleads consumers while also employing the juice's "usual or common name" under the FDCA and the FDA's regulations. As this Court has held (in a decision the Ninth Circuit failed to cite), the FDCA sets a "floor"—not a ceiling—on federal regulation of labels. *Wyeth* v. *Levine*, 555 U.S. 555, 577-578 (2009). Indeed, the FDA indicated that it "encourages" manufacturers to declare "each juice in a beverage … in the name of the product." 58 Fed. Reg. 2897, 2919 (Jan. 6, 1993). It has also rejected the proposition that compliance with the requirements of one portion of its regulations insulates a label from review.[2]

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[2] *See* Warning Letter from Roberta F. Wagner, FDA, to Brad Alford, Nestle U.S.A., Dec. 4, 2009, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm (asserting that juice blend labels similar to Coca-Cola's were "misleading" because of the large prominent font used for the non-predominant juice, the proximity of the juice name to the words

C. Coca-Cola can take no solace from the fact that the government believes the Ninth Circuit's erroneous reasoning reached the correct result in one respect. The United States agrees with Pom that the Ninth Circuit erred in forbidding Pom from "challeng[ing] aspects of respondent's juice label that are not specifically addressed by the FDCA or FDA's regulations," including "'*how* [respondent] presents the words "Pomegranate Blueberry" and "Flavored Blend of 5 Juices" on the product's label.'" U.S. Br. 18-19 (emphasis added) (quoting Pet. App. 10a). On the other hand, the government contends that Pom's Lanham Act claim is impliedly precluded with respect to "the common name of respondent's juice"—*i.e.*, "Pomegranate Blueberry"—"because that claim sought to impose liability for what FDA's regulations under the FDCA had specifically permitted." *Id.* 8.

Whatever the merit of the theoretical distinction between the product's name and its label, that distinction has no practical consequence. Consumers see the entire product label (or product advertisement), not merely the product's name. In the context of a false advertising claim, it is meaningless to say that the name "Pomegranate-Blueberry" juice is not misleading without accounting for how that name is depicted along with, for example, images of those fruits and the fact that the label describes the juice as a "blend" only in a much smaller font. As the Solicitor General elsewhere

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"All Natural 100% Juice," and the fact that the "flavored" and "blend" caveats were at the bottom of the labels in small, white font); *see also, e.g.*, 21 C.F.R. § 102.5(b) (imposing limitations on the ability to use juice names like that chosen by Coca-Cola).

emphasizes, the "FDA specifically cautioned manufacturers who would take advantage of 21 C.F.R. 102.33(b)-(d) about the potential for their labels to mislead." U.S. Br. 19.

D. To the extent the distinction drawn by the Solicitor General might have any force, it only highlights that this case is an ideal vehicle to decide the question presented. As the government recognizes, Pom challenges the label of Coca-Cola's product with respect to both the product's name (a claim the government says is precluded) and the way the label is presented (which it says is not precluded). U.S. Br. 8, 17-19. This case accordingly provides this Court an excellent opportunity to explore the potential preclusive effect of the FDCA and the FDA's regulations with respect to both allegations and their relationship to each other. Later cases, by contrast, may present only one allegation or the other.

The government's contrary argument that this case may not present an ideal vehicle to decide the question presented lacks merit. The government says that one aspect of petitioner's *proof* of its Lanham Act claim—a consumer survey—found that Coca-Cola's label was misleading, without distinguishing those two features of the label. U.S. Br. 21. The obvious answer is that the question presented does not ask this Court to evaluate the evidence that could be cited on remand in support of Pom's claim. It is asking the Court to hold that Pom's suit under the Lanham Act may proceed, in whole or in part. Pom's challenges to the name and label of Coca-Cola's product were rejected as a matter of law at the motion to dismiss stage. *See* Pet. App. 85a-92a. That rejection was then confirmed—again as a matter of law—at the summary judgment stage. *See id.* 60a-65a. The legal question presented by the peti-

tion does not turn on whether Pom's consumer survey anticipated the distinction the government now draws regarding which types of Lanham Act claims would proceed. Put another way, the government cannot and does not explain how this Court's interpretation of the Lanham Act, the FDCA, or the FDA's regulations turns on which question Pom's expert asked consumers.

III. There Is No Merit To The United States' Attempt To Minimize The Circuit Conflict On This Important Question

A. The petition demonstrates that the ruling below creates a square conflict with decisions of the Third, Eighth, and Tenth Circuits. Pet. 19-24. Coca-Cola itself acknowledges that those other courts broadly hold "that false or misleading product labels are actionable under the Lanham Act even though they are regulated by FDA." Opp. 16. The government recognizes the "tension" between the ruling below and those decisions. U.S. Br. 20. It also makes the important point that the ruling below disrupts the previously uniform understanding that competitors may bring "challenges to food labels under Section 43(a) of the Lanham Act." *Id.* (citing decisions of the Fourth, Seventh, and Eighth Circuits).

The Solicitor General nonetheless maintains that there is not a sufficiently "*[d]eveloped*" circuit conflict, U.S. Br. 19 (emphasis added), because the ruling below "misinterpreted the preclusive reach of the FDCA provisions that apply to food," whereas the cases in other courts of appeals involved products other than food, *id.* 9. The United States does not explain why that distinction makes a legal difference or why this Court should review seriatim numerous cases involving the preclu-

sive effect of distinct FDA regulatory schemes rather than providing the lower courts with guidance in this one, well-presented case. The government's position is that the FDCA precludes a Lanham Act suit when the FDA issues an on-point regulation, whereas the Lanham Act applies when the agency does not act in that fashion. That view has nothing to do with whether the subject matter of the agency's regulation is "food" or something else. Indeed, the lower courts have applied the "seemingly categorical breadth of the court of appeals' logic," *id.* 13, well beyond food labels regulated under the FDCA to other types of products. *See, e.g.*, *All One God Faith, Inc.* v. *Hain Celestial Grp., Inc.*, No. 09-3517, 2012 WL 3257660, at *1-11 (N.D. Cal. Aug. 8, 2012) (Lanham Act challenging false label of personal care and cosmetic products as "organic" barred by USDA's authority to regulate such products under the Organic Food Products Act of 1990).

Further, the regulatory schemes that other circuits did not find to be preclusive were no less comprehensive than the FDA's regulation of food products:

- *Sandoz Pharmaceuticals Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 226-227 (3d Cir. 1990), involved the FDA's and FTC's extensive regulatory authority with respect to over-the-counter drug advertising and labeling. *See* 15 U.S.C. §§ 45, 52; 21 C.F.R. §§ 201.1-201.26, 201.60-201.80.
- *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 935 (8th Cir. 2005), addressed FDA approval of new animal drugs, which are subject to extensive FDA regulation. *See* 21 U.S.C. § 360b; 21 C.F.R. §§ 500.23-589.2001.

- *Cottrell, Ltd.* v. *Biotrol International, Inc.*, 191 F.3d 1248 (10th Cir. 1999), involved the labeling and advertising of pesticides regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") in a manner similar to the FDA's regulation under the FDCA. *See id.* at 1250 & n.1 (noting that FIFRA provides "a detailed regulatory framework for registering pesticides … including provisions for approving pesticide labels and claims made therein."); *id.* at 1255 (noting similarity to FDA regulation); *see also* 7 U.S.C. §§ 136-136y; 40 C.F.R. §§ 152.1-152.500.

Because those decisions each involve the identical legal issue, they represent a coherent and recognized body of law that does not turn on the particular regulatory scheme at issue. The Ninth Circuit in this case purported to rely on *Sandoz* as well as its prior decision in *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919 (9th Cir. 2010), which addressed marketing of a medical device subject to FDA regulation. *See* Pet. App. 7a. *PhotoMedex*, in turn, relied on *Sandoz* and discussed *Alpharma*. *See* 601 F.3d at 928-930. *Cottrell* and *Alpharma* relied on *Sandoz*. *See* 191 F.3d at 1253; 411 F.3d at 938-940. In fact, in assessing whether the Ninth Circuit erred in this case, the United States relied upon *Alpharma* and *Cottrell* as well as *Schering-Plough Healthcare Products, Inc.* v. *Schwarz Pharma, Inc.*, 586 F.3d 500 (7th Cir. 2009), which involved an over-the-counter drug regulated by the FDA. *See* U.S. Br. 13, 15-16.

B. The United States does not dispute the importance of the question presented. Even if it were limited to food products, the ruling below grants tens of thousands of food and juice producers sweeping immun-

ity with respect to countless products from liability under the Lanham Act for even knowingly misleading consumers. *See* Pet. 26-27. The government recognizes that the court's "deference to FDA's available but unexercised authority would arguably preclude a Lanham Act challenge to the label of *any* food," including "the many foods that FDA's regulations do not specifically address at all." U.S. Br. 12. As the GAO has confirmed, the FDA "'generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions.'" Pet. 26 (quoting GAO Report 30). The Ninth Circuit's decision thus would upset a longstanding statutory scheme that permits both Lanham Act challenges to, and FDA regulation of, food and other product labels in favor of exclusive regulation by a governmental agency that acknowledges it lacks the resources for such a role. Under the Ninth Circuit's field-preemption holding, private enforcement of the Lanham Act would be precluded whenever there is allegedly "comprehensive" agency regulation. Pet. App. 12a. The United States does not dispute that such a holding would have significant consequences.

CONCLUSION

For the foregoing reasons, Pom's petition for a writ of certiorari should be granted.

Respectfully submitted.

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