No. 12-

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

PETITION FOR A WRIT OF CERTIORARI

SETH P. WAXMAN
Counsel of Record
RANDOLPH D. MOSS
BRIAN M. BOYNTON
FELICIA H. ELLSWORTH
NICOLE RIES FOX*
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., N.W.
Washington, D.C. 20006
(202) 663-6000
seth.waxman@wilmerhale.com

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.

PARTIES TO THE PROCEEDING

Petitioner Pom Wonderful LLC was the plaintiff in the district court and the appellant in the court of appeals.

Respondent The Coca-Cola Company was the defendant in the district court and the appellee in the court of appeals.

RULE 29.6 DISCLOSURE

Pom Wonderful LLC is directly owned by Roll Global LLC and ultimately owned by Stewart and Lynda Resnick as trustees of the Stewart & Lynda Resnick Revocable Trust. No publicly held company holds any interest in the Stewart & Lynda Resnick Revocable Trust.

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Pom Wonderful LLC ("Pom") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-14a) is reported at 679 F.3d 1170. The opinion of the district court granting in part and denying in part the parties' motions for summary judgment (App. 21a-73a) is reported at 727 F. Supp. 2d 849. The district court's relevant prior orders in the case (App. 75a-101a) are unreported.

JURISDICTION

The court of appeals entered judgment on May 17, 2012. The court denied Pom's petition for rehearing and rehearing en banc on August 8, 2012. *See* App. 15a-16a. On October 31, 2012, Justice Kennedy extended the time within which to file a petition for a writ of certiorari to and including December 21, 2012. This Court has jurisdiction under 28 U.S.C. § 1254(1).

RELEVANT STATUTORY PROVISIONS

The relevant provisions of the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, are reproduced at App. 103a-111a.

INTRODUCTION

The Coca-Cola Company ("Coca-Cola") sells a "Pomegranate Blueberry" juice product that consists of only 0.3% pomegranate juice and 0.2% blueberry juice. Pom brought suit under the Lanham Act to challenge Coca-Cola's deceptive labeling and advertising of this product. In support of its claim, Pom presented evidence that Coca-Cola's label actually misleads consumers regarding the amount of pomegranate and blueberry juice the product contains and that Coca-Cola knew the label would have this misleading effect. Without considering this evidence, the district court rejected Pom's Lanham Act claim on the ground that it was implicitly barred by the FDCA. The court of appeals affirmed, also concluding that the Lanham Act had been silently displaced by the FDCA.

The court of appeals did not rely on any actual provision of statutory text—either in the Lanham Act or the FDCA—to support its conclusion that Pom's Lan-

ham Act claim could not proceed. Rather, it held that Pom's Lanham Act claim was foreclosed merely because Coca-Cola's misleading label is subject to assertedly "comprehensive" regulation by the Food and Drug Administration ("FDA") under the FDCA and, "as best [the court] c[ould] tell," the FDA had not prohibited Coca-Cola's labeling. The court of appeals' ruling conflicts with this Court's precedents governing how courts should reconcile potentially overlapping federal statutes and creates a conflict among the courts of appeals on the important question of whether false labeling claims are actionable under the Lanham Act notwithstanding regulation by the FDA under the FDCA.

As an initial matter, the decision below disregards this Court's repeated instruction that courts must give full effect to allegedly competing federal statutes unless they are in "irreconcilable conflict." That standard is dictated by principles of separation of powers and requires that a court adhere to the statutes Congress enacts—even where the court believes that it would be sensible to give one statute priority over another—unless a direct conflict prevents it from doing so. Here, the Lanham Act and the FDCA are not in irreconcilable conflict and, as a result, can both be given full effect.

As this Court made clear in *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the FDCA sets a floor for regulation upon which other laws can build, not a ceiling. The FDA's authority to make decisions under the FDCA does not reach so far as to preempt all parallel regimes. The Lanham Act, like the state tort regime at issue in *Wyeth*, simply provides an additional layer of protection that the FDCA does not address. Yet, rather than ask whether the Lanham Act and the FDCA are in "irreconcilable conflict," the court of appeals displaced the Lanham Act based on the FDA's supposed "compre-

hensive" regulation of juice labeling and the court's apparent conclusion that Coca-Cola's product complied with that regulation. That holding cannot be squared with the plain terms of the FDCA and the Lanham Act or with this Court's precedents, including *Wyeth*.

The decision below also conflicts with decisions of the Third, Eighth, and Tenth Circuits. Those courts have all held that false labeling or advertising claims are actionable under the Lanham Act notwithstanding federal regulation of the labeling or advertising. Under those circuits' precedents, Pom's claim that Coca-Cola's label misleads consumers would not be barred because it is not an attempt by a private party to *enforce* the FDCA, which is prohibited by the plain text of the statute. The Ninth Circuit had previously applied the same rule, but it abandoned that test in this case in favor of its "comprehensive regulation" inquiry. The resulting circuit split means that Lanham Act suits like Pom's may proceed in the Third, Eighth, and Tenth Circuits, but will be barred in the Ninth Circuit.

If allowed to stand, the Ninth Circuit's opinion would have far-reaching consequences. The decision forecloses challenges to misleading labels by private parties under the Lanham Act, leaving regulation of food and beverage labels almost entirely to the FDA. Yet, as the Government Accountability Office ("GAO") explained in a 2008 report, the FDA's efforts to regulate food labeling leave significant gaps. The GAO concluded that the FDA was understaffed and underfunded and that it was not aggressively policing food labeling. Most critically, the GAO noted that the FDA itself had conceded that the "agency generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need

to legally demonstrate that a label is misleading." The court of appeals' decision is thus not merely wrong but also highly detrimental; it leaves no effective means of preventing all but a small portion of the misleading labeling of food and beverages.

The court of appeals' expansive reasoning would also extend beyond juice labeling to food and other products whose labels are subject to regulation by the FDA or even other agencies. In fact, the decision has already been applied to bar a Lanham Act challenge to a product label regulated by the U.S. Department of Agriculture. The Ninth Circuit's decision also calls into question other statutory regimes in which Congress has authorized private parties to enforce a statute alongside federal regulators. Under the Ninth Circuit's reasoning, any time an agency has broad authority to regulate in a given sphere, that regulation could preclude private actions under entirely different statutes.

The Ninth Circuit's decision thus not only conflicts with decisions of this Court and other courts of appeals, but also raises a question of exceptional importance. This Court should grant the petition for a writ of certiorari.

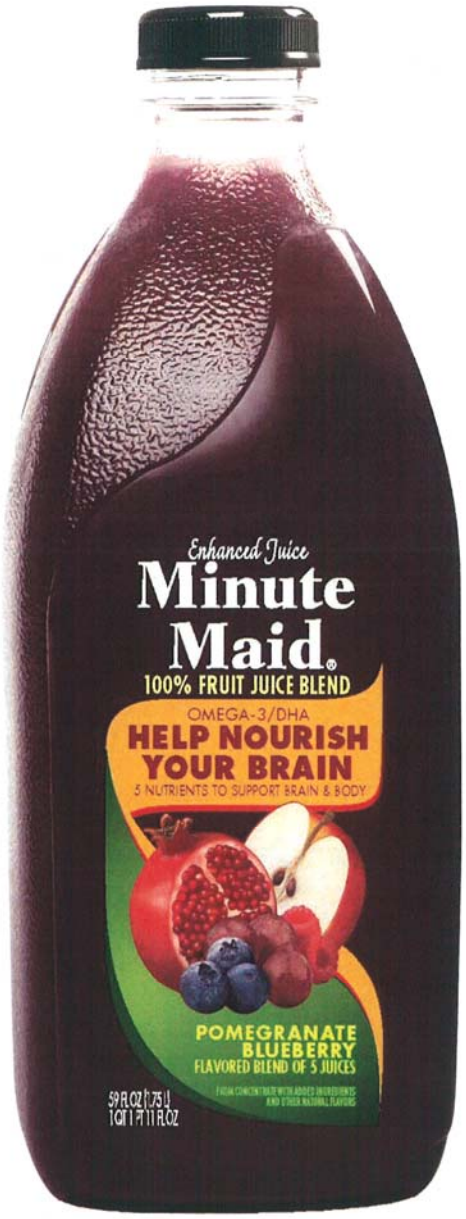
STATEMENT OF THE CASE

1. The Lanham Act creates a private right of action against anyone who uses a "false or misleading" description or representation "in connection with any goods or services" or who, "in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a). The Act's purpose is to prevent unfair competition. *See id.* § 1127 (noting that the

"intent" of the Lanham Act includes protection "against unfair competition"). In addition to protecting consumers from being misled, the Act protects businesses from unfair competitive acts by providing a private cause of action to a commercial plaintiff that has been harmed by a competitor's false advertising. Any person "who believes that he or she is or is likely to be damaged by" the use of a false description or misrepresentation may bring a lawsuit under the Lanham Act. *Id.* § 1125(a).

The FDCA, in contrast, regulates food and beverage labeling and provides that food is "deemed to be misbranded" in a variety of circumstances. 21 U.S.C. § 343. The statute serves a purpose that is distinct from, but complementary to, the purposes of the Lanham Act: It was enacted to protect public health and safety by ensuring that food and beverages are not misbranded. The FDA has promulgated regulations—relied upon by Coca-Cola for its defense in this action—that address various aspects of food labeling, including labeling of juice products. *See, e.g.*, 21 C.F.R. § 102.33(c)-(d). Only the federal government may enforce the FDCA, 21 U.S.C. § 337(a); the FDCA contains no private cause of action.

2. Pom produces, markets, and sells POM WONDERFUL® brand bottled pomegranate juice and various pomegranate juice blends, including a pomegranate blueberry juice blend. App. 1a. Coca-Cola markets and sells bottled juices and juice blends under the Minute Maid brand. *Id.* In September 2007, Coca-Cola announced the launch of a new "Pomegranate Blueberry" product. *Id.* An image of the front label of Coca-Cola's product is set forth below.


Enhanced Juice
Minute Maid
100% FRUIT JUICE BLEND
OMEGA-3/DHA
HELP NOURISH YOUR BRAIN
5 NUTRIENTS TO SUPPORT BRAIN & BODY
POMEGRANATE BLUEBERRY
FLAVORED BLEND OF 5 JUICES

The product's emphasis on pomegranate and blueberry juice is unmistakable—the name "Pomegranate Blueberry" appears in large font with the words "Flavored Blend of 5 Juices" appearing only in smaller font below the name; the vignette on the bottle displays a pomegranate and blueberries as prominently as an apple and grapes; and the juice inside the bottle is artificially colored a deep purple that resembles the color of pomegranate juice. Yet Coca-Cola's "Pomegranate Blueberry" product contains only 0.3% pomegranate juice and 0.2% blueberry juice; it consists primarily of (less expensive and less desirable) apple and grape juices, which amount to over 99% of the juice. App. 2a. Nowhere on Coca-Cola's label are these percentages disclosed.

Unsurprisingly, Coca-Cola's "Pomegranate Blueberry" product is, in fact, misleading to consumers. A consumer survey revealed that

> a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that [Coca-Cola's juice] mainly contains pomegranate and blueberry juice (and not other types of fruit juice) due to the packaging (the words "pomegranate blueberry" on the front of the bottle and in the product name on the back of the bottle).

App. 32a-33a (quoting survey report) (internal quotation marks omitted). Indeed, 36% of consumers that were shown the juice's bottle label believed that the juice contains mainly pomegranate and blueberry juice. *See id.* n.8.

Coca-Cola "has received a record number of complaints" regarding its "Pomegranate Blueberry" product. App. 31a. A 14-year employee of Coca-Cola who

has "field[ed] consumer complaints about many products" admitted that "there have been no Minute Maid products about which consumers have complained more." *Id.* (internal quotation marks omitted). One such consumer, for example, complained:

> Today I made the mistake of buying [the] Minute Maid product that you call "Pomegranate Blueberry[.]" What a crock. It's nothing but fancy apple grape juice. You people are scumbags for mislabeling your products. I'll never buy this product again. I'll never buy Minute Maid products again. And I'll tell all of my friends about this fraud. Thanks for wasting my time and money[.]

Id. 31a-32a (alterations and omission in original) (footnote omitted).

None of this should have surprised Coca-Cola. Prior to the launch of its "Pomegranate Blueberry" product, Coca-Cola's Director of Scientific and Regulatory Affairs sent an internal email stating:

> As discussed here is a copy of the front label for the new MM Enhanced Juice Pomegran[a]te Blueberry product. The product has a blend of apple, grape, pomegranate, blueberry & raspberry juices from conc. We are in compliance with the FDA regs related to the naming of juice containing products. *There is a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices.* [The President and General Manager of Minute Maid] is aware of this issue & is willing to assume the risk.

App. 34a-35a (emphasis added).

3. In September 2008, Pom sued Coca-Cola under the Lanham Act and California law, alleging that Coca-Cola's labeling, marketing, and advertising misled consumers to believe that Coca-Cola's "Pomegranate Blueberry" product consists primarily of pomegranate and blueberry juices, when in fact it consists almost entirely of the less expensive apple and grape juices. App. 3a.

Coca-Cola moved to dismiss Pom's Lanham Act suit on the ground that Coca-Cola's label complied with juice-naming regulations the FDA promulgated under the FDCA, which permit a beverage to be named after a non-predominant juice in certain circumstances. The district court partially granted Coca-Cola's motion to dismiss. App. 83a. The court concluded that Pom's Lanham Act challenge to the name and label of Coca-Cola's "Pomegranate Blueberry" product was barred because Pom's claim "may be construed as impermissibly challenging" the FDA juice-naming regulations. *Id.* 90a. Pom subsequently filed a First Amended Complaint, and, after the district court denied Coca-Cola's subsequent motion to dismiss, the parties conducted discovery. *Id.* 37a, 75a-81a.

The parties then cross-moved for summary judgment. App. 37a. The district court granted partial summary judgment to Coca-Cola, finding that Pom's Lanham Act challenge to Coca-Cola's label was barred by the FDA's regulations because the label "sufficiently comports with the requirements" of those regulations and because any determination with respect to the effect of that labeling should be made by the FDA. *Id.* 62a. Pom appealed the district court's rejection of its challenges to the label.

The Court of Appeals for the Ninth Circuit affirmed, holding that "the FDCA and its regulations bar pursuit of" Pom's Lanham Act claims. App. 9a. The court initially suggested that the suit was barred because "as best [the court] can tell, FDA regulations authorize the name Coca-Cola has chosen." *Id.* Thus, the court of appeals surmised that Pom's challenge "would require [the court] to undermine the FDA's apparent determination that so naming the product is not misleading." *Id.*

But the court of appeals then shifted course, indicating that it did "not suggest that mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability." App. 12a. It explained instead: "We are primarily guided in our decision not by Coca-Cola's apparent compliance with FDA regulations but by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* The court of appeals concluded that the FDA had sole authority to prevent deceptive labeling: "If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act." *Id.* 11a.

The court of appeals reached its conclusion that the FDCA barred Pom's Lanham Act claim without identifying a single provision of the FDCA that purports to displace the Lanham Act or even conflicts with it. The court did not cite or adhere to precedents of this Court mandating that potentially competing federal statutes both be given effect absent an irreconcilable conflict between them. Nor did the court identify any basis for distinguishing this Court's decision in *Wyeth*.

Pom petitioned for rehearing and rehearing en banc on June 29, 2012. The Ninth Circuit denied the petition on August 8, 2012.

REASONS FOR GRANTING THE WRIT

I. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S PRECEDENTS GOVERNING HOW COURTS SHOULD RECONCILE POTENTIALLY OVERLAPPING FEDERAL STATUTES

The court of appeals' conclusion that the FDCA implicitly displaces the Lanham Act disregards this Court's precedents. The interpretation of a statute "begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC* v. *United States*, 541 U.S. 176, 183 (2004) (plurality). By its plain terms, the Lanham Act applies to Coca-Cola's label and mandates that it not be misleading. Although the Lanham Act contains express exceptions that limit its reach in some circumstances, *see, e.g.*, 15 U.S.C. § 1125(c) (excluding certain trademark dilution claims that "shall not be actionable … under this subsection"), Congress included no such exception for challenges involving labels regulated in certain respects by the FDA. Similarly, nothing in the FDCA exempts activities that are governed by the FDCA from the Lanham Act's reach. The FDCA sets forth standards with which labels must comply, but it nowhere purports to displace the Lanham Act in all cases involving allegations of misleading juice labeling. Nor do the regulations implementing the FDCA contain any provision barring Lanham Act claims.

Nonetheless, the court of appeals held that "the FDCA and its regulations bar pursuit" of Pom's Lanham Act claim. App. 9a. In reaching that conclusion,

the court of appeals failed to apply this Court's precedents setting forth the standard for determining whether one federal statute implicitly displaces another as well as this Court's guidance in *Wyeth* v. *Levine*, 555 U.S. 555 (2009).

A. The Ninth Circuit Failed To Apply This Court's Irreconcilable Conflict Standard

This Court has repeatedly instructed that courts must give full effect to allegedly competing federal statutes unless they are in "'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as substitute.'" *Branch* v. *Smith*, 538 U.S. 254, 273 (2003) (quoting *Posadas* v. *National City Bank*, 296 U.S. 497, 503 (1936)). When asked to reconcile two federal statutes, courts have a duty to "regard each as effective" if they "are capable of co-existence." *Morton* v. *Mancari*, 417 U.S. 535, 551 (1974). Courts are "not at liberty to pick and choose among congressional enactments." *Id.* Even statutes that "overlap" or may appear to be somewhat "redundan[t]" can be "fully capable of coexisting." *United States* v. *Batchelder*, 442 U.S. 114, 118, 122 (1979).

The Ninth Circuit did not apply this standard and made no effort to reconcile the Lanham Act with the FDCA. Instead, the Ninth Circuit presumed that Coca-Cola's label complies with the FDCA and the FDA's implementing regulations and concluded that this alone precluded federal courts from considering Pom's Lanham Act claim. The court of appeals thus allowed the FDA's mere *authority to regulate* juice labeling to bar application of the Lanham Act to any label falling within that authority. That approach cannot be squared with this Court's precedents.

Had the Ninth Circuit applied this Court's prescribed framework, it would have reached a contrary conclusion. The Lanham Act does not irreconcilably conflict with the FDCA; both statutes can and should be given binding effect.

First, the FDCA and the Lanham Act are "fully capable of coexisting," *Batchelder*, 442 U.S. at 122, because a party generally can comply with both the FDCA's regulation of labeling for health and safety purposes and the Lanham Act's prohibition on misleading advertising. The two statutes can and do coexist because, as this Court has previously explained in a related context, the FDCA merely sets a "floor" for regulation of labels on which other laws can build. *See Wyeth*, 555 U.S. at 577-578. The FDCA requires that a label contain certain information, including "the common or usual name" of the product. 21 U.S.C. § 343(i). FDA regulations specify ways in which this requirement can be satisfied for beverages containing multiple juices. For example, the regulations permit a product containing multiple juices to be labeled using the name of a non-predominant juice so long as the label indicates that the product is a "blend" of juices and is "flavored" with the non-predominant juice. *See* 21 C.F.R. § 102.33(c), (d). Alternatively, the manufacturer may instead indicate on the label the percentage of the drink the non-predominant juice comprises. *Id.* § 102.33(d)(2).

Neither the FDCA nor the FDA's implementing regulations require any of the features Coca-Cola elected to use in its label. They do not *mandate* that Coca-Cola name its product after an ingredient found in only trace amounts and feature that trace ingredient in large font and with a prominent pomegranate graphic on its label. And the regulations certainly do not au-

thorize actual consumer confusion of the type shown by the evidence here, particularly where the defendant knew that it "risk[ed]" misleading consumers but opted "to assume th[at] risk." *See* App. 35a.

Coca-Cola easily could have complied with the FDA's requirements, for example, by declining to emphasize pomegranate and blueberry juice more prominently than the juices making up almost all of the product or disclosing the actual percentage of pomegranate and blueberry juice actually contained in the product. If Coca-Cola had done so, it could have both complied with the FDCA and FDA regulations *and* marketed a product that was not misleading under the Lanham Act. Where, as here, a party can comply with two laws, there is no irreconcilable conflict between those laws. *See, e.g.*, *FTC* v. *A.P.W. Paper Co.*, 328 U.S. 193, 202 (1946).

Second, the Lanham Act and the FDCA have distinct requirements and serve distinct purposes. *Cf. J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) (explaining that when two laws have "different requirements and protections," each should be regarded as effective). The Lanham Act is meant to prevent "unfair competition." 15 U.S.C. § 1127. Its focus is not just on protecting consumers from being misled; it is intended to protect businesses from unfair competitive acts by providing a private cause of action to a commercial plaintiff that has been harmed by a competitor's false advertising. *See Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990).

The FDCA, by contrast, serves a different (though complementary) purpose. It protects public health and safety by ensuring that food and beverages are not

misbranded. *See, e.g.*, *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331-332 (3d Cir. 2009). The FDCA's food and beverage labeling requirements as amended by the Nutrition Labeling and Education Act ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (1990), require nutritional labeling for most food products and provide ingredient standards for labels. *See Holk*, 575 F.3d at 332. The FDA's regulations further the NLEA's purpose of ensuring that food and beverage labels contain appropriate nutritional information. Congress has not authorized private parties to enforce the FDCA or the FDA's regulations; sole enforcement responsibility lies with the United States. 21 U.S.C. § 337(a).

The FDCA and the Lanham Act are not in conflict. FDA enforcement of the FDCA's public health goals is not undermined by a private plaintiff's effort to prevent unfair competition through the Lanham Act. If anything, the statutes' requirements work in tandem to ensure that labels are marketed in ways that are *both* safe for consumers and not misleading. The statutes complement each other to ensure that consumers have accurate information about food products so that they can make safe, healthy choices. Where, as here, there is no reason that Coca-Cola could not have satisfied both statutes, allowing Pom's Lanham Act suit to proceed does not create an irreconcilable conflict with the FDCA.

B. The Ninth Circuit's Decision Conflicts With This Court's Decision In *Wyeth* v. *Levine*

In *Wyeth* v. *Levine*, 555 U.S. 555 (2009), this Court held that the FDA's approval of a specific warning label placed on a drug was not a defense to state tort failure-to-warn claims against a drug manufacturer alleging that certain information was omitted from the label.

See id. at 558. The Court reviewed the history of federal regulation of drugs and drug labeling in order to discern the "purpose of Congress" in enacting the FDCA. *Id.* at 566. The Court then rejected the petitioner's contention that permitting a state-law cause of action would obstruct the purposes and objectives of the FDCA, finding that this argument relied on "an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* at 573. The Court further concluded that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. "To the contrary, it cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims." *Id.* at 577-578.

Although *Wyeth* involved preemption, the teachings of *Wyeth* apply with equal force here. *Wyeth*'s reasoning and interpretation of the FDCA's preemptive effect on state law in the drug labeling context guides the analysis of that statute's preclusive effect on other *federal* laws. The conflict preemption standard[1] applied in *Wyeth* asks whether state law "creates an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" 555 U.S. at 563-564 (quoting *Hines* v. *Davidowitz*, 312 U.S.

[1] State-law preemption analysis in the food and beverage labeling context differs from that in *Wyeth* because the FDCA contains an express preemption provision applicable to regulation of food and beverage labeling, *see* 21 U.S.C. § 343-1, and the NLEA provides that the Act "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1] of the [FDCA]." Pub. L. No. 101-535 § 6(c), 104 Stat. 2353, 2364 (1990) (21 U.S.C. § 343-1 note).

52, 67 (1941)). For the very same reason state-law failure-to-warn claims do not create an "obstacle" to Congress's purposes and objectives in the FDCA, federal Lanham Act false advertising claims do not create an "irreconcilable conflict" with the FDCA. Just as the FDCA does not set a ceiling that precludes application of state laws in the drug context, it does not preclude application of another federal law in the food and beverage labeling context. In this case, for example, there is no doubt that Coca-Cola could have complied with both the FDCA and the Lanham Act.

In the same way that state laws offer "an additional, and important, layer of consumer protection that complements FDA regulation," *Wyeth*, 555 U.S. at 579, the Lanham Act provides a layer of consumer and competitor protection that the FDCA does not address. The FDA's authority to regulate labeling does not preempt all parallel regimes. *See id.* at 573. As the Third Circuit has recognized, "the FDA has stated that it does not intend to occupy the field of food and beverage labeling, even with regard to regulations affecting juice products." *Holk*, 575 F.3d at 338. And as this Court emphasized in *Wyeth*, it is "manufacturers, not the FDA, [who] bear primary responsibility for their drug labeling at all times." 555 U.S. at 579. Like state-law failure-to-warn claims in the drug context, the Lanham Act "complements FDA regulation," *id.*, by permitting an aggrieved party to bring suit challenging deceptive labeling even where the label might not separately violate the FDA's food and beverage labeling regulations.

The decision below did not address this Court's decision in *Wyeth*. Instead, the Ninth Circuit concluded that Pom's Lanham Act claim was barred simply because the FDA regulates Coca-Cola's label. That is

precisely what this Court declined to do in *Wyeth*. This Court should grant review to correct the Ninth Circuit's failure to adhere to this Court's precedents.

II. THE NINTH CIRCUIT'S DECISION CREATES A CONFLICT AMONG THE COURTS OF APPEALS

Review by this Court is also necessary to address a conflict among the circuits. The Ninth Circuit's decision conflicts with decisions of three different courts of appeals that found false labeling or advertising claims actionable under the Lanham Act notwithstanding federal regulation and that applied a fundamentally different approach to determining whether Lanham Act claims are precluded.

1. The Ninth Circuit's decision conflicts with the Eighth Circuit's decision in *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005). In *Alpharma*, the plaintiff brought suit under the Lanham Act alleging that the defendant falsely advertised that the FDA had approved its product. The defendant argued that the Lanham Act claims were precluded because "Congress did not intend for the Lanham Act to be a vehicle for enforcing the provisions [of the FDCA] indirectly, and the area is within the expertise of the FDA." *Id.* at 939. In rejecting that argument, the Eighth Circuit drew on prior circuit precedent that had "confirmed the viability of Lanham Act claims concerning representations of FDA approval" and held that because the plaintiff's Lanham Act claim did not require a determination by the court of how the FDA would interpret and enforce its own regulations, the FDCA did not bar that claim. *Id.* at 941.

Prior to the decision below, the Ninth Circuit had employed a standard similar to that applied in *Alphar-*

ma. It had held that a Lanham Act claim is foreclosed only when it "would require [the court] to usurp [the FDA's] responsibility for interpreting and enforcing" the FDCA. *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919, 930 (9th Cir. 2010) (quoting *Sandoz*, 902 F.2d at 231 (internal quotation marks omitted)). As the Ninth Circuit acknowledged in *PhotoMedex*, however, that rule does not apply where "the claim would *not* require a preemptive interpretation by the court of FDA regulations." 601 F.3d at 929-930 (emphasis added).

In this case, the Ninth Circuit reversed course and ignored this distinction altogether. Pom seeks to enforce its rights under the Lanham Act entirely independent of the FDCA and does not seek to enforce the FDCA at all. Pom's claim does not rely upon the FDCA or FDA regulations to prove that Coca-Cola's label is likely to mislead consumers. To the contrary, as the Lanham Act requires, Pom has tendered independent evidence that Coca-Cola's label is likely to deceive consumers notwithstanding the label's purported compliance with the requirements of the FDCA. *See* App. 30a-35a (discussing Pom's evidence of consumer survey data, consumer complaints, and admissions by Coca-Cola's own senior employees who developed the product). Pom's claim also does not require any judicial interpretations of the FDCA or the FDA's regulations; those regulations are immaterial to Pom's allegations. Yet rather than follow the rule it had previously recognized in *PhotoMedex* and that the Eighth Circuit applied in *Alpharma*, the Ninth Circuit has now precluded *all* Lanham Act claims touching on food and beverage labeling irrespective of whether those claims require interpretation of FDA regulations. *See* App. 12a (finding preclusion based on asserted compliance and "comprehensive regulation").

2. The Ninth Circuit's holding that the FDA's mere regulation of food and beverage labeling bars Pom's Lanham Act claim also conflicts with the Third Circuit's decision in *Sandoz*, 902 F.2d 222, which permitted a Lanham Act challenge to drug advertising to proceed despite overlapping federal regulation and foreclosed the plaintiff's Lanham Act challenge to the drug's label only because it would have required the court to interpret and enforce regulations promulgated by the FDA. The Third Circuit first considered what a plaintiff needs to show when raising a false advertising claim under the Lanham Act. The court concluded that a plaintiff cannot meet its burden under the Lanham Act simply by demonstrating that the defendant's advertising claims about a drug's effectiveness "are inadequately substantiated under FDA guidelines." *Id.* at 229. Instead, "the plaintiff must *also* show that the claims are literally false or misleading to the public." *Id.* (emphasis added). The court thus permitted the Lanham Act false advertising claim to proceed despite the authority of the FDA and the Federal Trade Commission to regulate the advertising because—like Pom's claim here—it did not implicate the relevant regulations. By contrast, the *Sandoz* court held that the plaintiff's labeling claim—which (unlike Pom's claim) expressly turned on the definition of the term "active ingredient" set forth in an FDA regulation—was barred because that claim would have required the court to "usurp" the FDA's responsibility for "interpreting and enforcing potentially ambiguous regulations." *Id.* at 231.

The Ninth Circuit's decision cannot be reconciled with either of *Sandoz*'s holdings. *Sandoz*'s first holding—requiring a private party suing under the Lanham Act to show more than mere noncompliance with

FDA's rules—necessarily means that mere federal regulatory authority does not preclude a Lanham Act claim altogether. If, as the Ninth Circuit held here, agency regulation precluded any private cause of action against a regulated defendant, then the Third Circuit's holding that a plaintiff must prove more than mere noncompliance with FDA guidelines would have been entirely unnecessary. The very fact that there were regulations with which the defendant was supposed to comply would have precluded the action altogether. The second holding of *Sandoz*—finding a Lanham Act challenge to a drug label barred because it would have required the court to interpret and enforce the FDCA—also conflicts with the decision of the court below. The court of appeals here foreclosed Pom's Lanham Act claim without considering whether it would have required interpretation of or was an attempt to enforce the FDA's regulations.

The resulting conflict means that in the Third Circuit, a Lanham Act plaintiff may bring a lawsuit that challenges a product governed by agency regulations, so long as (1) he proves "that the claims are literally false or misleading to the public," and (2) the claim does not require "original interpretation" of those regulations. *Sandoz*, 402 F.2d at 229-231. But in the Ninth Circuit, the mere fact that the product is subject to federal agency regulation would provide a defense to that very same lawsuit. Pom's claim, which was entirely independent of the FDCA and FDA regulations, would be permitted in the Third Circuit, but was barred in the Ninth Circuit.

3. Like the Eighth and the Third Circuits, the Tenth Circuit has also held—in conflict with the decision of the Ninth Circuit here—that false labeling challenges under the Lanham Act are actionable even if a

product is regulated by a federal enforcement agency. In *Cottrell, Ltd.* v. *Biotrol Intern., Inc.*, 191 F.3d 1248 (10th Cir. 1999), the court addressed a Lanham Act claim alleging that the defendants misleadingly represented that their hard surface cleaner had obtained clearance from the Environmental Protection Agency ("EPA"). *Id.* at 1250. The defendants argued that the plaintiff could not pursue its Lanham Act claim because the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") "is the exclusive federal law that regulates the labeling of pesticides." *Id.* at 1253. The Tenth Circuit rejected the defendants' argument, finding that the plaintiff could bring its Lanham Act suit because the plaintiff was "not attempting to enforce FIFRA, but rather to vindicate its rights under the Lanham Act *independent of FIFRA*." *Id.* at 1254 (emphasis added).

The Tenth Circuit looked to cases that considered the Lanham Act's relationship to the FDCA, finding them applicable to *Cottrell* because "the EPA stands in a similar enforcement relationship to FIFRA as the FDA does to the FDCA." 191 F.3d at 1255. The court gleaned from these cases the very proposition that the Ninth Circuit rejected here: "Affirmative misrepresentations … are generally actionable under the Lanham Act, *even if the product is regulated by the FDA*." *Id.* at 1254 (quoting *Braintree Labs., Inc.* v. *Nephro-Tech, Inc.*, No. 96-2459, 1997 WL 94237 (D. Kan. Feb. 26, 1997) (emphasis added)). The Tenth Circuit noted that the defendants "would have [the court] dismiss this case because [the plaintiff]'s Lanham Act claim touches on issues covered by FIFRA." *Id.* at 1256. Unlike the Ninth Circuit, the Tenth Circuit rejected that idea: "[B]ecause FIFRA nowhere explicitly precludes Lanham Act coverage, we refuse to limit the scope of the Lanham Act absent circumstances that inherently re-

quire interpretation of FIFRA regulations and/or EPA approvals." *Id.*

As explained above, Pom's claim did not require the court of appeals to interpret the FDCA or the FDA's implementing regulations. Yet the Ninth Circuit dismissed that claim simply because it "touche[d] on issues" covered by those regulations. *See* App. 12a ("Out of respect for the statutory and regulatory scheme before us, we decline to allow the FDA's judgments to be disturbed."). In so doing, the Ninth Circuit has parted ways with its sister circuits, creating an untenable conflict among the courts of appeals that only this Court can reconcile.

III. THE QUESTION PRESENTED IS IMPORTANT

This case involves an issue of significant importance with far-reaching implications. The court of appeals' decision would eliminate suits by private parties under the Lanham Act challenging the truthfulness of food and beverage labeling. The job of policing false labeling thus would be left to the FDA. The agency, however, is in no position to address the problem of false and misleading labeling on its own.

The FDA is charged with a number of critical missions. According to the agency, it is responsible for:

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation

- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health[2]

As Congress has long understood, the FDA woefully lacks the resources necessary to perform each of these functions adequately. In *Wyeth*, this Court noted that the "FDA has limited resources" to conduct even what might be its most critical mission: to ensure the safety and effectiveness of pharmaceuticals. 555 U.S. at 578. For this reason, even in that area of significant scientific complexity, the FDA has "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 579.

In the area of food and beverage labeling, the agency's resources are even more markedly inadequate to its mission. In 2008, the GAO published a comprehensive analysis of the FDA's efforts to regulate food labeling. *See* U.S. Gov't Accountability Office, GAO 08-597, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods* (2008) ("GAO Report"), *available at* http://www.gao.gov/

[2] U.S. Food and Drug Administration, *What does FDA do?*, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm.

assets/290/280466.pdf. The Report's overall conclusion was summarized as follows: "FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those prohibiting false or misleading labeling." *Id.* at 5.

More specifically, the Report explained that: "FDA has reported that limited resources and authorities significantly challenge its efforts to carry out food safety responsibilities—challenges that also impact efforts to administer and enforce labeling requirements." GAO Report 6. In 2007, over 65,000 firms were subject to FDA's food regulations. *See id.* at 51. These firms, of course, manufacture countless numbers of different food products. But from 2005 to 2007, the portion of the FDA Office of Nutrition, Labeling, and Dietary Supplements "dedicated to food labeling activities" had an annual budget of only "$1.1 million to $1.3 million" and had only "from 9.0 to 10.5" full-time equivalent employees. *Id.* at 7. From 1998 through 2006, FDA obtained only *two* injunctions against firms for mislabeling. *See id.* at 22. For the most part, the agency simply issued warning letters. *See id.* at 18-21.

FDA has acknowledged that it generally does not even attempt to police misleading food labels:

> [A]ccording to FDA officials, the agency generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading ….

GAO Report 30.

Because the FDA lacks the resources effectively to regulate false labeling, the Ninth Circuit's decision pre-

cluding private parties from challenging food labels under the Lanham Act will have the practical effect of leaving food labels almost entirely unregulated.[3] There is no indication that Congress intended that extraordinary result.

The unbounded scope of the court of appeals' decision only magnifies its adverse impact. Under the Ninth Circuit's ruling, so long as products meet the FDA's minimum requirements, manufacturers can label them in any manner, without regard to whether their labeling deceives consumers. The ruling displaces even Lanham Act claims that allege that a manufacturer has *knowingly* used a label that is misleading. For example, in this case, Pom pointed to evidence that Coca-Cola knew that there was "a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices" but was "willing to assume the risk." App. 35a.

The Ninth Circuit's holding also reaches beyond food and beverage labeling potentially to any claim under the Lanham Act that targets a product regulated by the FDA or, indeed, other agencies. One court has already applied the Ninth Circuit's decision to preclude a Lanham Act claim challenging the labeling of personal care and cosmetic products as "organic" in light of the USDA's regulation of such products under the Organic Food Products Act of 1990. *See All One God Faith, Inc.* v. *Hain Celestial Grp., Inc.*, No. 09-3517,

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[3] Indeed, if taken to its logical extreme, the court of appeals' apparent conclusion that compliance with particular juice-naming regulations precludes a juice label from being misleading (*see* App. 9a-12a) might impair even the FDA's authority to take action against misleading labels.

2012 WL 3257660, at *1-11 (N.D. Cal. Aug. 8, 2012). And the reasoning of the Ninth Circuit's decision extends beyond the Lanham Act to other areas in which the federal government has regulatory authority but private parties are permitted to bring civil actions. A broad range of federal statutes afford individuals a private right of action while also providing for government enforcement. *See, e.g.*, 29 U.S.C. § 2617 (Family Medical Leave Act of 1993 ("FMLA")) (creating a private right of action "against any employer" who "interfere[s] with, restrain[s], or den[ies] the exercise of" FMLA rights); 15 U.S.C. § 26 (Clayton Act) (providing a private right of action "against threatened loss or damage by a violation of the antitrust laws"). The Ninth Circuit's reasoning in this case threatens the viability of such dual-enforcement regimes.

CONCLUSION

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

Respectfully submitted.

SETH P. WAXMAN
Counsel of Record
RANDOLPH D. MOSS
BRIAN M. BOYNTON
FELICIA H. ELLSWORTH
NICOLE RIES FOX*
WILMER CUTLER PICKERING
HALE AND DORR LLP
1875 Pennsylvania Ave., N.W.
Washington, D.C. 20006
(202) 663-6000
seth.waxman@wilmerhale.com

* *Admitted to practice in the State of California. Supervision by members of the firm who are members of the District of Columbia Bar.*

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