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 THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE GROCERY MANUFACTURERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

KATE COMERFORD TODD
TYLER R. GREEN
NATIONAL CHAMBER LITIGATION CENTER, INC.
1615 H Street NW
Washington, DC 20062
(202) 463-5337

KARIN F.R. MOORE
GROCERY MANUFACTURERS ASSOCIATION
1350 I Street NW, #300
Washington, DC 20005
(202) 639-5900

BERT W. REIN
Counsel of Record
WILLIAM S. CONSOVOY
SAMUEL B. GEDGE
WILEY REIN LLP
1776 K Street NW
Washington, DC 20006
(202) 719-7000
brein@wileyrein.com

Counsel for Amici Curiae

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TABLE OF CONTENTS

TABLE OF CITED AUTHORITIES

Page

CASES

Page

Page

STATUTES AND AUTHORITIES

Cited Authorities

Page

Cited Authorities

Page

INTEREST OF AMICI CURIAE[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the nation. The Chamber advocates its members' interests before Congress, the executive branch, and the courts, and it regularly files amicus curiae briefs in cases raising issues of vital concern to the business community.

The Grocery Manufacturers Association ("GMA") is a trade association of food and beverage companies. Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and products consumers rely on every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions.

The Chamber's and GMA's member companies do business in highly regulated sectors, including the food industry. For their business practices to be efficient, predictability and uniformity are key; fragmented

1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person, other than amici curiae, their members, or their counsel, made a monetary contribution that was intended to fund preparing or submitting this brief. The parties have consented to the filing of this brief.

regulatory authority invites duplicative, burdensome regimes that increase production costs and the prices consumers must pay. Thus, both the Chamber and GMA have an acute interest in preserving unitary regulatory frameworks, particularly those—like the Food, Drug, and Cosmetic Act—that provide a balanced, nationwide business environment.

SUMMARY OF THE ARGUMENT

Permitting Pom to go forward with its Lanham Act challenge to Coca-Cola's labeling of its Pomegranate Blueberry Flavored Blend of Five Juices would defeat Congress's goals in delegating comprehensive, nationwide food-labeling authority to the Food and Drug Administration ("FDA") under the Federal Food Drug and Cosmetic Act of 1938 ("FDCA"). Since 1938, FDA has exercised broad prescriptive food-labeling authority for the benefit of consumers. Concomitantly, Congress has ensured that food manufacturers can rely on compliance with FDA regulations to market their products free from challenge under state law or other private actions that seek to enforce, directly or indirectly, the misbranding standards of the FDCA by imposing judicial interpretations that differ from FDA's regulatory positions.

But defeating Congress's assurance of national uniformity is Pom's precise aim. Pom would have Lanham Act juries throughout the country reach differing judgments about whether Coca-Cola's label is misleading and would in turn impose conflicting remedies. Coca-Cola might need to call its product "Apple Grape Blend of Five Juices" in Arkansas, "Apple, Grape, Pomegranate,

Blueberry, Raspberry Juice" in Maine, and "Five Juice Blend" in Washington. And it might need to convey that name in one font size in California, another font size in Minnesota, and yet another font size in New York. Avoiding such variation is why Congress granted FDA unified food-labeling authority, banned private rights of action to enforce the FDCA, and expressly preempted states from enforcing any food-labeling requirement not "identical" to the FDCA and FDA regulations. This is a comprehensive federal food-labeling regime.

Pom's Lanham Act claim is thus precluded, and cannot be resurrected under *Wyeth v. Levine*, 555 U.S. 555 (2009). *Levine* addressed a state-law verdict arising from Wyeth's failure to satisfy its FDCA duty to accommodate new post-approval safety information by modifying its label warnings; it was a *parallel* state-law proceeding. Pom's challenge is more properly analogized to *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), which sustained preemption under the FDCA of a claim against an FDA-compliant manufacturer despite the availability of means by which the manufacturer could have prevented the injury to the plaintiff. "[I]f federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior." *Levine*, 555 U.S. at 590 (Thomas, J., concurring in the judgment). Prohibitions arising from the general legal standard of the Lanham Act clearly fall within the same analysis.

The government's middle-ground position—in which FDA's "affirmative" regulations are preclusive but its

decision to afford labeling flexibility in other areas is not—is equally indefensible. FDA's conscious decision not to constrain certain aspects of the product's labeling reflects its considered judgment just as much as the agency's decision to afford manufacturers some latitude in choosing, for example, the product's name. Like Pom, moreover, the government would give business competitors greater rights under the Lanham Act than consumers hold under state law given the FDCA's express preemption of non-identical state-law claims. Indeed, FDA regulations acknowledge that the very kinds of labeling claims that would not be precluded under the government's theory would still be expressly preempted because they impose requirements different from those promulgated by the agency. Nothing in the FDCA's history suggests that Congress intended to wipe out non-identical state claims expressly only to see national uniformity demolished through the Lanham Act.

At most, then, Lanham Act claims challenging food labeling should be sustained only if they parallel FDA regulations. But Pom cannot prevail even under this forgiving method of reconciling the two laws. Pom's claim with regard to the juice product's name affirmatively contradicts FDA's regulation allowing the use of the name Coca-Cola chose. And Pom's claim regarding the "prominence" of certain words on the label, as well as its challenge to the size of certain graphics on the label's "vignette," likewise seek to impose requirements different from and in addition to FDA regulations. Accordingly, the decision below should be affirmed.

ARGUMENT

I. The FDCA Comprehensively Regulates Food Labeling To Educate Consumers And Ensure National Uniformity.

Seeking to justify an interpretation of federal law that would grant it an unrestricted right to bring Lanham Act claims against food labeling, Pom argues that the Lanham Act claims it presses are fully compatible with the FDCA because "the FDCA's misbranding provisions seek principally to protect public health and safety," while the "Lanham Act is intended to protect against unfair competition." Pet. Br. 6-7. But that self-serving description of the FDCA's purpose and scope is patently underinclusive. It grossly mischaracterizes FDA's longstanding consumer-protection mandate under the FDCA.

As early as 1906, Congress made clear that food labeling presents unique problems calling for a national legislative response. The Pure Food and Drug Act of 1906 ("1906 Act") prohibited the manufacture and interstate shipment of "any article of food or drugs which is adulterated or misbranded." Pub. L. No. 59-384, 34 Stat. 768, §§ 1-2 (1906). The law was a consumer-protection measure aiming "to enable purchasers to buy food for what it really is." *United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar*, 265 U.S. 438, 443 (1924). But the 1906 Act defined "misbranding" in general terms suited to *ex post* review. A food would be misbranded, for example, if it were "labeled or branded so as to deceive or mislead the purchaser" or if its label bore a false or misleading "statement, design, or device

regarding … the ingredients or substances contained therein." 34 Stat. 770, § 8. The sole affirmative labeling condition required that packages that state their contents "in terms of weight or measure" do so "plainly and correctly." *Id.*

"One of the principal objects of a national pure-food law is to obtain uniformity of food standards among the States." H.R. Rep. No. 59-2118, pt. 1 at 4 (1906). But the 1906 Act's potential was capped by its prohibitory terms and its ill-defined grant of power to implementing agencies. The law empowered the Secretary of Agriculture, among others, to make "uniform rules and regulations," 34 Stat. 768, § 3, but it was mostly "negative in character," *Hearings on H.R. 6906, H.R. 8805, H.R. 8941, and S. 5 before the House Subcomm. of the Comm. on Interstate and Foreign Commerce*, 74th Cong., 1st Session, at 44 (1935) (Statement of W.G. Campbell). Instead of prescribing what information food labels must convey, it spoke mainly to what manufacturers could *not* say. In the words of Walter G. Campbell, FDA chief in the 1930s, these early provisions "say you must not make a statement that is false or misleading, but they do not require you to make affirmatively a statement that is informing." *Id.* Thus, the Bureau of Chemistry, FDA's predecessor agency, could police misbranding violations, 34 Stat. 769, § 4, but lacked authority to implement its own prescriptive labeling regulations, F.D. No. 1, Reg. 14; FDA, *The Story of the Laws Behind the Labels*, Part II (1981) ("[The 1906 Act] enabled the Government to go to court against illegal products but lacked affirmative requirements to guide compliance.").[2]

2. http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

By the 1930s, the 1906 Act was viewed as insufficiently "broad in its scope to meet the requirements of consumer protection under modern conditions." H.R. Rep. No. 75-2139, pt. 1, at 1 (1938). To overcome these shortcomings, the Food Drug and Cosmetic Act of 1938 took a different approach. Like its predecessor, the FDCA was "primarily … a consumers' measure," S. Rep. No. 74-361, pt. 1, at 3 (1935), designed to "safeguard[] the public health" and "prevent[] deceit upon the purchasing public," H.R. Rep. No. 75-2139, pt. 1, at 1 (1938). But the FDCA "strengthen[ed] and extend[ed]" federal power in important ways. S. Rep. No. 74-361, pt. 1, at 1 (1935). Requiring "[i]nformative labeling of foods as to quality and composition … for the information and guidance of consumers" was a much-needed "improvement[] over existing law." H.R. Rep. No. 75-2139, pt. 1, at 2 (1938). The FDCA added a series of affirmative labeling requirements manufacturers now needed to honor to avoid misbranding. Pub. L. No. 75-717, 52 Stat. 1047, § 403 (codified as amended at 21 U.S.C. § 343); Statement of W.G. Campbell at 45 (S.B. 5 "offer[s] requirements for affirmative labeling which will make possible the purchase more intelligently and therefore more discriminatingly of food and drug products").

Congress further granted unprecedented power to FDA to "promote honesty and fair dealing in the interest of consumers." 52 Stat. 1046, § 401 (codified as amended at 21 U.S.C. § 341); *see also* 21 U.S.C. § 393(b)(2). In a calculated departure from the 1906 Act, Congress gave FDA prescriptive power to require labeling of foods. This delegation enhanced the 1906 Act, under which "[t]he government [lacked] authority and procedures for setting standards that would have the force of law." Oscar E. Anderson Jr., *Pioneer Statute: The Pure Food and Drugs*

Act of 1906, 13 J. Pub. L. 189, 195 (1964). Federal standards were "absolutely essential" to FDA's consumer-protection mission. Statement of W.G. Campbell at 45.

After 1938, FDA could condition food marketing on compliance with positive rules designed to enable consumers to make informed choices and compare commonly named items. 83 Cong. Rec. 7,774 (1938) (Statement of Rep. Lea) (FDA "is clothed with very broad authority for the purpose of enforcement, to make regulations to carry out the law that is proposed."). And to fortify FDA's new role, the FDCA assigned enforcement power exclusively to FDA. "All … proceedings for the enforcement, or to restrain violations of, th[e] Act" could be brought only "in the name of the United States." 52 Stat. 1046, § 307 (codified as amended at 21 U.S.C. § 337). Thus, FDA could harmonize interpretation and application of the FDCA and its regulations, avoiding the risk that private, regulation-based lawsuits would impose disjointed commands on food manufacturers.

National uniformity was as much an object in 1938 as it had been in 1906. Like the framers of the 1906 Act—who expressed concern that interstate commerce had been "largely nullified as to food products by the varying requirements as to standards and labels in different States"—lawmakers in the 1930s saw a need for "[g]reater uniformity" in food-industry oversight. H.R. Rep. No. 59-2118, pt. 1, at 4 (1906); S. Rep. No. 74-361, pt. 1, at 3 (1935) ("The States have unanimously urged the Federal Government to take leadership in modernizing existing law.").

In enacting the most recent food-labeling legislation—the Nutrition Labeling and Education Act of 1990 ("NLEA")—national uniformity was a central concern. Whereas the framers of the 1906 Act thought to "invite" the states "to adopt the same standard," 40 Cong. Rec. 8,961 (1906) (Statement of Rep. Richardson), the NLEA mandated it. While prescribing detailed nutrition-labeling requirements, the NLEA added an express preemption provision to the FDCA barring States from "directly or indirectly establish[ing] ... any requirement for the labeling of food of the type required by" a range of FDCA provisions unless it is "identical to" the federal counterpart. 21 U.S.C. § 343-1(a)(2).

FDA has responded by proactively regulating food labels to enhance consumer choice. Juice producers, in particular, must comply with a unique layer of rules on top of the baseline scheme governing foods generally. Like all food labels, the "principal display panel" of every juice container must bear "as one of its principal features a statement of the identity of the commodity." 21 C.F.R. § 101.3(a). For "[b]everages that contain fruit or vegetable juice," the FDA prescribes the "common or usual name" with great specificity. *Id.* § 102.33; 21 U.S.C. § 343(i). If a beverage is a "blend of single-strength juices" and the display label names more than one juice, "the names of those juices ... must be in descending order of predominance by volume." 21 C.F.R. § 102.33(b). If a blend contains juices that are not named on the display label, "the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')." *Id.* § 102.33(c).

Notably, FDA has concluded that a juice blend's common or usual name may reflect a juice that "is not the predominant juice" if the name either "[i]ndicate[s] that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)" or "[i]nclude[s] the amount of the named juice, declared in a 5-percent range …." *Id.* § 102.33(d). Coca-Cola chose the former. *Infra* 30.

Other information also is required. Along with the statement of identity, for example, the principal display panel must reflect a net quantity declaration. 21 U.S.C. § 343(e). Any beverage that "purports to … contain[] vegetable or fruit juice" must also bear a declaration of the total percentage of juice. *Id.* § 343(i)(2); 21 C.F.R. § 101.30(e). Juice containers, like other foods, must further identify component ingredients, listed in descending order of predominance by weight. 21 C.F.R. § 101.4(a)(1). And the information panel must bear a "Nutrition Facts" label, which, in turn, can disclose "[o]nly those nutrients listed in FDA's nutrition regulations, as mandatory or voluntary components of the nutrition label." FDA, *A Food Labeling Guide: Guidance for Industry*, at 25, 27 (rev. Jan. 2013).

Presentation is as much controlled as content. Under the FDCA, a food is misbranded

> [i]f any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and

> understood by the ordinary individual under customary conditions of purchase and use.

21 U.S.C. § 343(f). FDA has defined ways in which "[a] word, statement, or other information required by or under authority of the act" may lack "prominence and conspicuousness." 21 C.F.R. § 101.15(a).

For many labeling components, FDA also overlays its general prominence regulations with specific rules. A food's statement of identity must, *inter alia*, "be presented in bold type on the principal display panel, [and must] be in a size reasonably related to the most prominent printed matter on such panel …." *Id.* § 101.3(d). On the information panel, a juice's percentage-juice declaration must be placed "[n]ear the top ... with no other printed label information appearing above the statement except the brand name, product name, logo, or universal product code." *Id.* § 101.30(e) (detailing declaration size and typeface). For the neighboring Nutrition Fact label, FDA regulations specify the content, relative type-sizes, and arrangement of the required data. *Id.* § 101.9. "In the interest of uniformity of presentation" FDA even urges manufacturers to comply with other, permissive specifications. *Id.* § 101.9(d).

Collectively, the 1906 Act, the FDCA, and the NLEA amendments constitute nearly a century of congressional effort to empower consumer choice through labeling regulation. The comprehensive end-result vindicates two related interests: protecting consumers from deceptive trade practices and "provid[ing] national uniformity where it is most necessary … ." 136 Cong. Rec. 33,427 (1990) (Statement of Sen. Mitchell); 58 Fed. Reg. 2462,

2462 (Jan. 6, 1993). Congress has long understood that "consistent, enforceable rules," H.R. Rep. No. 101-538, at 3338 (1990), ensure that "the food industry can market its products efficiently in all 50 States in a cost-effective manner," 58 Fed. Reg. at 2462. "A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws." 136 Cong. Rec. 20,418 (1990) (Statement of Rep. Waxman). Thus, federal labeling legislation has aimed to "provid[e] complete and meaningful information to consumers without being overly burdensome on industry." 136 Cong. Rec. 35,095 (1990) (Statement of Rep. Madigan); *id.* ("[T]he bill provides industry with uniformity of law in a number of important areas … that will permit them to conduct their business in an efficient and cost-effective manner."); 136 Cong. Rec. 20,418 (1990) (Statement of Rep. Waxman) (this point "has particular appeal with respect to food labels").

National uniformity also reflects Congress's desire to convey "certain items of information deemed essential to the consumer." Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 Food & Drug L.J. 49, 51 (1997). "[L]imits are necessary so that the emphasis is on the required information, and that the additional information does not clutter the food label or mislead or confuse the consumer." 58 Fed. Reg. at 2081.

In sum, the FDCA "has been carefully crafted to limit the amount of information that can be required to appear on the food label." Degnan, *supra*, at 50. Rather than police malpractices, FDA has exercised its power to determine what reasonable consumers should know when making purchases. Juice manufacturers, in turn,

can market their products only if their labels comply. Against this backdrop, "[i]t does not help the [FDA] … to have myriad state labeling laws with each trying to 'go one better' than the FDA." 2 James T. O'Reilly, Food and Drug Administration § 25.30. Nor are the FDCA's goals advanced by independent, and potentially conflicting, Lanham Act determinations whether food labels are misleading.

II. Food-Labeling Requirements That Are Not "Identical" To Those Imposed Under The FDCA Are Precluded.

A. Pom's Assertion That The FDCA Merely Establishes A "Floor" Is Contrary To The Statute And This Court's Decisions.

The parties agree that the FDCA and Lanham Act must be reconciled, Pet. Br. 19-20; Resp. Br. 18; *see also* U.S. Br. 11, 18; and there can be no question that the FDCA controls where the two overlap, as a specific law takes precedence over a general one, Resp. Br. 18-21; U.S. Br. 17-18; *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992); *Nw., Inc. v. Ginsberg*, 572 U.S. __ (2014) (Slip Op. at 8). That interpretive canon has special force when, as here, "Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012) (citation and quotations omitted).

Pom seeks to evade reconciliation by incorrectly labeling the FDCA regulation "a floor—but not a ceiling—on the adequacy of labeling." Pet. Br. 32. The 85-year course of federal food-labeling law reflects Congress's

abiding intent to aid consumers and manufacturers alike by framing a comprehensive unitary regime. Congress first barred misbranding generally, then imposed affirmative labeling requirements, vested FDA with supervening regulatory power, and secured to the federal government exclusive enforcement authority. Later still, it gave the FDCA's core food-labeling requirements express preemptive force. Consistently, Congress has sought to "obtain uniformity of food standards among the States." H.R. Rep. No. 59-2118, pt. 1, at 4 (1906). In light of this history, Pom's claim that Congress merely created a minimum standard to be supplemented by private actions is unsustainable.

According to Pom, *Levine* nevertheless confirms its interpretation of the FDCA because the Court "held that despite FDA's specific approval of the precise label being challenged, the plaintiff's tort claim was not preempted." Pet. Br. 32. But *Levine* arose from circumstances quite different from the present case. Resp. Br. 29-30; U.S. Br. 20-21. The question in *Levine* was whether the FDCA's new drug-approval process impliedly preempted State law. 555 U.S. at 565-66. Here, however, the Court must reconcile two *federal* statutes in a way that ensures consistency with the FDCA's centralization of federal authority in the FDA and broad *express* preemption clause. Both distinctions are crucial. Implied preemption of Levine's state failure-to-warn claim threatened to trench on the historic powers of the states in a way this dispute does not. *Levine*, 555 U.S. at 587-88 (Thomas, J., concurring in the judgment). And Congress's failure to include an express preemption clause was considered "powerful evidence" that it "did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," *id.* at 575, an inference that cannot be drawn here, U.S. Br. 20.

The new drug-approval regime reviewed in *Levine* and the food-labeling regime at issue here function very differently. "[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Levine*, 555 U.S. at 570-71. The new drug-approval labeling regime is a bottom-up process in which the manufacturer "is charged both with crafting an adequate label and with *ensuring that its warnings remain adequate as long as the drug is on the market*." *Id.* at 571 (emphasis added). Accordingly, the *Levine* Court was addressing an FDA labeling regime where drug manufacturers were required to modify their labels as experience accumulated.

By contrast, FDA's food-labeling regime prescribes essential elements of food labeling to which manufacturers must conform without deviation. The elements of Coca-Cola's labeling that Pom attacks were not crafted by Coca-Cola and then submitted for approval to an overburdened federal agency. FDA's top-down prescriptive regulations specify almost every detail of the label's content and appearance. The continuing duty that led the Court to conclude there was no direct conflict between the FDCA's new drug-approval regime and Levine's state-law claim is absent here.

Moreover, *Levine* undermines Pom's position that the FDCA is a "floor" *even in the drug-labeling setting*. *Levine* did not question the pre-emptive effect of FDA's labeling approval when originally issued. But as the holder of an approved New Drug Application (NDA), Wyeth was required under the FDCA to monitor the safety of its product in use and to take corrective action if experience disclosed a serious risk of unexpected injury. *Id.* at 570-

51. FDA regulations consequently "permitted Wyeth to unilaterally strengthen its warning" without prior FDA approval if new evidence warranted such action. *Id.* at 573. *Levine* held that states could supplement FDA enforcement of an NDA holder's continuing monitoring responsibility by permitting injured plaintiffs to recover when approved drug labeling had not been properly updated.

The Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), confirms that the FDCA is not a floor. There, the plaintiffs brought state-law claims analogous to those successfully pursued in *Levine*; the plaintiffs' injuries, however, were caused by a generic drug—marketed pursuant to an ANDA approval. *Id.* at 2574-75. That distinction proved decisive, for while "[a] brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label," a generic manufacturer only "is responsible for ensuring that its warning label is the same as the brand name's." *Id.* at 2574. Unlike brand name labels, the FDCA required "changes to generic drug labels only … to match an updated brand-name label or to follow the FDA's instructions." *Id.* at 2575. Had the generic manufacturers "independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 2578. Mensing's state-law claims thus were preempted.

If, as Pom contends, FDCA labeling requirements were a "floor," *Mensing* would have presented immense difficulty. States would be free to impose damages awards on generic manufacturers who were acting in compliance with federal law and subject to FDA enforcement for unilaterally modifying their labels. The Court resolved

this difficulty by holding that compliance with the FDCA by generic manufacturers preempted state-law claims based on failure to label above the alleged federal floor. *Id.* at 2581 n.8.

Pom responds that this case is not like *Mensing* because "nothing in the FDCA or FDA's regulations prevented Coca-Cola from making its label … compliant with the Lanham Act." Pet. Br. 24; Pet. Br. 22 (claiming that "Coca-Cola was not required" under the FDCA "to use the misleading name it selected for its product"). But that argument is foreclosed by this Court's decision in *Bartlett*. There, the plaintiffs attempted to circumvent *Mensing* by arguing that the generic drug manufacturer could respond to inadequate labeling consistently with the FDCA and New Hampshire law by ceasing to sell its product. *Bartlett*, 133 S. Ct. at 2477. The Court held that preemption could not be so easily defeated. The FDCA granted the manufacturer the federal right to distribute its generic drug in interstate commerce so long as it complied with the FDCA, FDA's regulations, and any parallel state-law duties. *Id.* at 2471; 21 U.S.C. § 355(a). States could not condition that right on compliance with additional state-imposed labeling requirements. 133 S. Ct. at 2478 n.5. Similarly, Coca-Cola's right to distribute its juice in compliance with the FDCA and FDA regulations cannot be conditioned on added labeling requirements imposed by state law or the Lanham Act.

Bartlett thus defeats Pom's claim that Coca-Cola's ability to comply with the FDCA and different duties under state law or the Lanham Act avoids preemption and preclusion. Invoking its unchallenged Article I authority to regulate the interstate sale of food, Congress

determined that Coca-Cola was entitled to distribute its juice product so long as its label complied with FDA regulations. There is no support for Pom's contention that Congress further conditioned that right on Lanham Act compliance. Strict compliance with FDA's many labeling requirements "would be 'all but meaningless'" if it did not provide insulation from liability for lack of compliance with conflicting legal regimes. *Id.* at 2477 (quoting *Mensing*, 131 S. Ct. at 2579).

Justice Thomas's *Levine* concurrence anticipated this point; he recognized there was no "'direct conflict'" between the FDCA and the state-law duty to strengthen the label's warning because "FDA regulations require a drug manufacturer—after initial federal approval of a drug's label—to revise the federally approved label 'to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.'" 555 U.S. at 592 (quoting 21 C.F.R. § 201.80(e)). Accordingly, "nothing in the text of the statutory or regulatory scheme necessarily insulat[ed] Wyeth from liability under state law simply because the FDA has approved a particular label." *Id* at 593.

But Justice Thomas distinguished the situation confronting Wyeth from one in which state law imposed duties beyond what is required to secure and maintain federal approval. As he explained, and *Bartlett* eventually confirmed, "if federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior." *Id.* at 590; Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 261 (2000)

("Imagine, for instance, that a valid rule of federal law gives workers the right to join a labor union (subject to certain qualifications), while state law purports to prohibit all union membership. It is physically possible for workers to comply with both laws by refraining from joining a union. But … the state law is preempted: A court that enforced the state-law prohibition would be ignoring the federal-law right."); *Gordon v. New York Stock Exchange, Inc.*, 422 U.S. 659, 689-90 (1975).

That is the situation here. Manufacturers of blended juices are not charged under the FDCA or FDA regulations with a continuing duty to "analyze[] … accumulating data and add[] a stronger warning" concerning the product's safety if the new information warrants that step. *Levine*, 555 U.S. at 570. Thus, Pom does not seek to use the Lanham Act to enforce a standard paralleling the FDCA's labeling regime. Pom instead seeks to constrain Coca-Cola's federal right to sell blended juice in interstate commerce under the approved federal label by imposing a more restrictive rule under the Lanham Act. The fact that Coca-Cola could comply with both does not negate the direct conflict.

B. The Government's Acknowledgement of Preclusion Under The FDCA Is Unduly Constrained.

The government correctly rejects Pom's "floor" argument with regard to FDA's juice-labeling regulation. U.S. Br. 16-21. FDA's regulation authorized the product name Coca-Cola chose, *infra* 29-31, and "'[t]he conflict' between the changes petitioner seeks to impose under the Lanham Act and FDA's juice-naming regulation 'does

not evaporate' because the 'regulation simply permits, but does not compel,' the name respondent chose," U.S. Br. 18 (alteration in original) (quoting *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 155 (1982)). Allowing Pom's challenge to "the naming aspect of petitioner's claim to proceed … would not supplement FDA's enforcement resources; it would supplant FDA's regulatory judgment." U.S. Br. 19 (citation omitted).

The government's conclusion with respect to naming follows directly from the legal principles set forth above: even though Coca-Cola could have refrained from using pomegranate or blueberry in its product name "without running afoul of [FDA's] regulations," U.S. Br. 18, a "successful challenge to a name that complies with FDA's juice-naming regulation" would *still* conflict with a right afforded to the manufacturer under the FDCA, U.S. Br. 20. Accordingly, the government correctly concludes that "the Lanham Act must give way." U.S. Br. 20.

But the government attempts to limit this interpretation to when "the FDCA or its implementing regulations affirmatively authorizes [a] labeling decision or embodies a determination by FDA that it is not misleading." U.S. Br. 23. That position is too narrow for several reasons.[3]

First, the complete overlap of the Lanham Act's general prohibition of commercial practices that "misrepresent[] the nature, characteristics, [or] qualities … of [a seller's]

3. The government's interpretation of the FDCA's preclusive force, unlike its interpretation of FDA's labeling regulations, is not entitled to judicial deference. *Mensing*, 131 S. Ct. at 2575 n.3 (citing *Levine*, 555 U.S. at 576).

or another person's goods," 15 U.S.C. § 1125(a)(1)(B), and the FDCA's specific prohibition on marketing goods whose "labeling is false or misleading," 21 U.S.C. § 343(a)(1), must be reconciled to respect Congress's decision to restrict FDCA enforcement to FDA, acting "in the name of the United States." *Id.* § 337(a). Any contention that FDA's labeling regulation was or is inadequate must be addressed to the agency rather than through an *ad hoc* judicial process under the Lanham Act. Pet. App. 12a.[4] Tellingly, Congress allowed non-FDA enforcement actions under the FDCA—*but only by States*. 21 U.S.C. § 337(b)(1) ("A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.").

Second, FDA's decision *not* to regulate is as significant as its affirmative commands. FDA's regulatory mandate goes beyond dealing with discrete labeling elements; the agency is charged with ensuring that the label in its entirety enables informed consumer choice. *Id.* §§ 341, 393(b). By establishing which labeling elements should be mandatory and which should be subject to manufacturer discretion, FDA necessarily determines that conforming labels accord with its statutory mission. That FDA allows food manufacturers to exercise some marketing discretion does not undermine its consumer-protection

4. This does not mean that the Lanham Act is inapplicable to food manufacturers. Resp. Br. 52-53. It would still apply, for example, to matters not addressed by the FDCA, such as trademark violations and fraudulent product endorsements.

regime. The FDCA "ensure[s] that the label communicates essential information to consumers" consistent with FDA's expert judgment, while also giving businesses flexibility to differentiate their product and compete in the marketplace. 58 Fed. Reg. at 2920.

Third, and decisively, the government incongruously advocates far greater rights under the Lanham Act for competitors than consumers invoking state law. The NLEA 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 commerce … any requirement for the labeling of food of the type required by" Sections 343(f) and (i), among other provisions, "that is not *identical* to the requirement of such section …." 21 U.S.C. § 343-1(a)(3) (emphasis added). The ordinary meaning of "identical" is "[t]he same; not different or other," or "exactly alike or equal." Webster's New Int'l Dictionary 1236 (2d ed. 1936). FDA has thus concluded that, within its compass, Section 343-1(a)'s "preemptive effect is quite broad." 58 Fed. Reg. at 2471. It makes no difference whether a state requirement affirmatively conflicts with the FDCA or FDA regulation. Section 343-1(a) preempts any state requirement, regardless of its "specific words," that "directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food" that are not "imposed by or contained in" the relevant FDCA provision or FDA regulation. 21 C.F.R. § 100.1(c)(4).

For state labeling requirements "of the type" imposed under Sections 343(f) and (i), then, "consistency is not the test; identity is." *Turek v. Gen. Mills, Inc.*, 662 F.3d

423, 426-27 (7th Cir. 2011). States are not free to add labeling requirements merely "consistent with [those] imposed by the [FDCA]." *Id.* at 427. "State laws that impose affirmatively different labeling requirements from federal law in these areas will be preempted." *Koenig v. Boulder Brands, Inc.*, --- F. Supp. 2d ----, 2014 WL 349706, at *5 (S.D.N.Y. Jan. 31, 2014). Put simply, state labeling requirements must parallel federal labeling requirements. *In re PepsiCo, Inc., Bottled Water Mktg. and Sales Practice Litig.*, 588 F. Supp. 2d 527, 538-39 (S.D.N.Y. 2008) (explaining that to "permit[] state requirements [to] go beyond federal law as long as federal law does not expressly prohibit or permit the specific labeling at issue" would contravene the "plain meaning" of Section 343-1).

The Seventh Circuit's *Turek* decision illustrates the point. There, a consumer brought state deceptive-trade-practices claims alleging that a "chewy bar" food label should have contained disclaimers about the bar's fiber content beyond what FDA had required. *Turek*, 662 F.3d at 425-26. Nutrient-content labeling is governed by Section 343(r)(1), which has preemptive force under the NLEA. 21 U.S.C. § 343-1(a)(5). Because "[t]he information required by federal law [did] not include" the disclaimers sought by the consumer, the state-law requirements were "not identical to the labeling requirements imposed … by federal law" and gave way. *Turek*,662 F.3d at 427. Whether the added information would be "a good thing" or "consistent" with the FDCA was "irrelevant." *Id.* What mattered was the lack of identity.

This Court's interpretation of the preemptive force of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") is also instructive. Express preemption under

Section 343-1 of the FDCA is equal to (if not broader than) preemption under the FIFRA, which prohibits states from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging *in addition to or different from* those required under [the FIFRA]." 7 U.S.C. § 136v(b) (emphasis added); *Turek v. Gen. Mills, Inc.*, 754 F. Supp. 2d 956, 959 (N.D. Ill. 2010) ("[S]everal courts have used the *Bates* test to determine the preemptive effect of [the FDCA]."), *aff'd as modified* 662 F.3d 423; *In re PepsiCo.*, 588 F. Supp. 2d at 533 (characterizing this Court's analysis of the FIFRA as "strikingly similar" to the proper framework for analyzing the FDCA); *cf. Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 108 (D.D.C. 2006) ("The scope of FDCA's preemption clause is much broader than FIFRA's.").

To survive express preemption under the FIFRA, a state requirement must be "equivalent to, and fully consistent with, the FIFRA's misbranding provisions." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005). In other words, the state law must be strictly "parallel." *Id.*; *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (applying similar reasoning to Medical Device Amendments of 1976). "[N]ominally equivalent labeling requirements" are not enough; the state laws must be "*genuinely* equivalent" to the federal rule, *Bates*, 544 U.S. at 454, or, in the words of the FDCA, "identical." "[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA." *Id.*

Accordingly, legislative or judicial state requirements imposing nutritional labeling rules "of the type" required by applicable FDCA provisions survive preemption under

Section 343-1(a) only if they are "identical to," "fully consistent with," and "genuinely equivalent" to the federal regime. Requirements to supplement an FDA-authorized use of "blend of juices" with percentage specifications or to make inflexible the prominence required of FDA-authorized terms like "Blend" are foreclosed to states.

Indeed, any other construction of Section 343-1(a) would render Section 343-1(b)(3) surplusage. *Duncan v. Walker* 533 U.S. 167, 174 (2001) ("It is our duty to give effect, if possible, to every clause and word of a statute."(internal quotations and citations omitted)). Under Section 343-1(b):

> Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a) of this section, under such conditions as may be prescribed by regulation, any State or local requirement that—
>
> > (1) would not cause any food to be in violation of any applicable requirement under Federal law,
> >
> > (2) would not unduly burden interstate commerce, and
> >
> > (3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

21 U.S.C. § 343-1(b).

If the labeling requirements given preemptive effect by Section 343-1(a) could be freely supplemented under state law, as Pom argues, Section 343-1(b) would be surplusage. And, if express preemption were limited only to those subjects affirmatively addressed by FDA, as the government claims, there would have been no need for subsection (3) since an informational need "not met by" the FDCA's labeling requirements already could be pursued under state law. Congressional authorization of state petitions to FDA reinforces Congress's determination to make the FDCA requirements exclusive absent an approved state-specific request.[5]

The government conveniently ignores the gap its interpretation creates between Lanham Act and state-law claims and the superior litigation rights it proposes to afford business competitors. U.S. Br. 25 & n.10. But there is no basis for permitting more extensive disruption of the FDCA labeling regime by competitor actions under the Lanham Act than consumer actions under state law. FDCA is designed to ensure "national uniformity" for covered labeling requirements. *See* Pet. Br. 31; U.S. Br. 25; U.S. Br. in Opp. to Cert. 11 (explaining that the NLEA "was designed to promote '[n]ational[ly] uniform nutrition labeling'"). The NLEA and Section 337(a) conclusively balance disclosure and uniformity interests, and this Court should honor that balance.

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5. It is no answer to say, as Pom does, that a state-law claim is insulated from preemption if framed in the general terms of Section 343(a). Pet. Br. 31. Congress's omission of this subsection from the FDCA's express preemption provision does not have the significance Pom ascribes to it. Section 343(a) enables parallel state actions but does not permit departing from identity limitations under Sections 343(f) and (i).

Congress's goal of national uniformity would be ill-served by the jigsaw arrangement that the government advocates. Lanham Act litigation risks presenting labeling questions properly entrusted to FDA to federal juries time and again, and each time for consideration *de novo*. There would not be just a single "Lanham Act" labeling standard to compete with FDA's regime. Quite the opposite. The policy judgments and expert decision-making Congress delegated to FDA would be decided and re-decided anew by different judges and juries in each Lanham Act labeling case across the nation.

Consider, for example, the FDCA's "common or usual name" provision, under which a food is misbranded if its label does not "bear[] … the common or usual name of the food, if any there be … ." 21 U.S.C. § 343(i). Although FDA is authorized to define "common or usual names" by regulation, not all foods have been so named. Nonetheless, because Section 343(i) is given preemptive force, FDA has correctly concluded that states may not establish their own "common or usual" names "for a food for which there is no specific Federal common or usual name." 58 Fed. Reg. at 2471. Even if a state's name were in full "conformance with" FDA naming principles, it would still be preempted. *Id.* "It would be a requirement of the type required by section [34]3(i)(1) of the act, but it would not be identical to the provisions that FDA has adopted under that section." *Id.*

Still, the government would incongruously allow that same preempted state-law claim to proceed under the Lanham Act, as FDA would not have "affirmatively authorize[d]" the manufacturer's choice of a name for a product that had not been given a prescribed common

name. This cannot be what Congress intended in opting for uniformity through a unified regulatory regime. It would indeed be "counterintuitive" to conclude that Congress sought to achieve national uniformity by cabining state experimentation with one hand while, with the other, endorsing an equally disruptive federal regime. U.S. Br. 25; *cf. Waymire v. Norfolk & W. Ry. Co.*, 218 F.3d 773, 777 (7th Cir. 2000) ("To allow a plaintiff to argue adequacy of warning claims under [the Federal Employers' Liability Act] but not under state law would undermine the railroad safety uniformity intended by Congress ….").

Nothing in this Court's precedent or the FDCA's history supports such a result. For whether the rule of decision is state or federal, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." *Garner v. Teamsters Local Union No. 776*, 346 U.S. 485, 490-91 (1953). In either case, it "is wholly inconsistent with the administrative power conferred upon the [FDA], and with the duty, which the [FDCA] casts upon that body, of seeing to it that the statutory requirement as to uniformity" and clarity of labeling is observed. *Tex. & Pac. Ry. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 440-41 (1907).

III. Pom's Lanham Act Claim Cannot Proceed When Coca-Cola's Label Complies With The FDCA And Its Implementing Regulations.

Even if, contrary to Section 337, Lanham Act plaintiffs were permitted to bring a claim that seeks to enforce a requirement parallel to the FDCA and FDA's implementing

regulations, Pom's action still would be foreclosed.[6] Far from paralleling FDA's regulations, Pom's Lanham Act claim regarding the content and presentation of Coca-Cola's labeling seeks to impose labeling requirements that are different from or in addition to those imposed by FDA. Pet. Br. 44 (Coca-Cola's liability under the Lanham Act "is independent of the application or interpretation of the FDCA or FDA's regulations.").

Pom principally attacks Coca-Cola's naming its product "Pomegranate Blueberry Flavored Blend of 5 Juices." Pet. App. 9a-10a; Pet. Br. 49-52. Pom claims that this name misleads consumers into perceiving the product as primarily containing pomegranate and blueberry juices when apple and grape juices are, in fact, the primary ingredients. Pet. Br. 10. In Pom's view, Coca-Cola could have—and thus should have—named its product after "the two primary juices in its product," apple and grape. App. 61a. But Coca-Cola's product name is specifically authorized by FDA regulations. Resp. Br. 38-42; U.S. Br. 13-16.

For a multiple-juice blend, such as this product, FDA regulations provide that non-predominant juices may

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6. Separately, Pom's claim may well be foreclosed by the Court's recent holding that a plaintiff bringing a Lanham Act false advertising claim "must plead (and ultimately prove) an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. ___ (2014) (Slip. Op. at 25); *see* Pet. App. 5a (noting the district court's holding "that Pom lacked statutory standing to pursue its state law claims" because "Pom had not established the statutory standing prerequisite of 'lost money or property'").

be named on the principal display panel so long as "the common or usual name for the product" meets one of two requirements:

- It must "[i]ndicate that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)"; *or*

- It must "[i]nclude the amount of the named juice, declared in a 5-percent range."

21 C.F.R. § 102.33(d).

Coca-Cola follows the first of these alternatives. Resp. Br. 38-39; U.S. Br. 14. In FDA's considered judgment, complying with either command adequately "describe[s] the contribution of the named juice if it is not the predominant juice." 58 Fed. Reg. at 2921; *id.* ("FDA is providing in § 102.33(d)(1) that a multiple-juice beverage may use a product name that specifically shows that the named juice is used as a flavor.").[7] FDA has voiced confidence that "consistent use of" these terms will "help to reduce or remove consumer confusion." 56 Fed. Reg. 30,452-01, 30,461 (July 2, 1991). "Indicat[ing] that the named juice is present as a flavor or flavoring" ensures that the label "will not imply that the content of that juice is greater than is actually the case." 58 Fed. Reg. at 2921.

7. Pom argues, for the first time, that "Pomegranate Blueberry Flavored Blend of 5 Juices" is somehow *not* a permissible common or usual name under Section 343(i) and 21 C.F.R. § 102.33(d)(1). Pet. Br. 49-52. This new theory finds no support in the existing record. Resp. Br. 40-41; U.S. Br. 21-23.

Pom disagrees. "By name alone," it maintains, "one would expect that the primary ingredients in Coca-Cola's … Product are pomegranate and blueberry juice." App. 62a. To rectify this perceived shortcoming, Pom would have Coca-Cola name "the two primary juices in its product" on the principal display panel. App. 61a. But this is hardly "identical to" Section 343(i) and its implementing regulations. Pom's demand goes far beyond Section 343(i), and that alone should be enough to defeat the claim. Worse still, advocating a head-on collision with the policy judgments expressed in FDA regulations, U.S. Br. 16-21, Pom would invite precisely the kind of "conflicting and inconsistent" requirements that the FDCA is designed to foreclose.

Pom also challenges the prominence of the words "flavored Blend of Five Juices," which it claims enhances the misrepresentation caused by the product name. Pet. App. 10a-12a; Pet. Br. 10, 23-24. Within the common or usual name, Pom argues, the words "Pomegranate" and "Blueberry" wrongly "dwarf" the remainder of the product's name, "Flavored Blend of 5 Juices." Pet. Br. 2; Pet. App. 10a ("Pom focuses its labeling argument on how Coca-Cola presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label."). In other words, Pom seeks to introduce a type-size requirement into Coca-Cola's product name.

Again, however, Coca-Cola's choice of type size conforms to the FDCA's requirement that required label elements be sufficiently "prominent" to attract consumer attention. Under Section 343(f), a "statement … required by or under authority of [the FDCA] to appear on the label" must be "prominently placed thereon with such

conspicuousness … and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 343(f). While FDA "has not explicitly enunciated definitions of 'conspicuous' or 'prominent,'" it has fashioned a "strong standard" to give effect to Section 343(f). 58 Fed. Reg. at 2473. A food's statement of identity, for example, must "be presented in bold type on the principal display panel," must "be in a size reasonably related to the most prominent printed matter on such panel," and must "be in lines generally parallel to the base on which the package rests as it is designed to be displayed." 21 C.F.R. § 101.3(d). FDA also has set forth general factors that the agency may consider in evaluating whether a statement satisfies Section 343(f), *id.* § 101.15, and has adopted a specific regulation concerning the font size of the disputed labeling with which Coca-Cola fully complied, Resp. Br. 42-45.

Regardless, neither Section 343(f) nor any FDA regulation requires that a product's common or usual name be set in uniform type. Pet. Br. 47; U.S. Br. 28-29 & n.13. Pom therefore seeks to impose a prominence requirement under the Lanham Act as to the size of a common or usual name that is not "identical to" Section 343(f) or FDA regulations. At the very least, FDA has *not* specifically addressed "how [Coca-Cola should] present[] the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label." U.S. Br. in Opp. to Cert. 19 (citation and quotations omitted). By necessity, then, Pom's requirement is not identical to the existing FDCA regime. It was FDA's assessment that the specific requirement Pom seeks to impose here was not necessary to apprise consumers adequately of the product's contents. Permitting a court or jury to add type-size specificity

under the Lanham Act would impermissibly question FDA's regulatory judgment. Regardless, the type-size complaint cannot be separated from Pom's challenge to the product's name. Had Coca-Cola, as Pom demands, named its product "Apple Grape Blend of Five Juices," the type size of the words "Flavored Blend of Five Juices" would have no significance to Pom.

Finally, Pom belatedly takes issue with the "vignette" on Coca-Cola's label, which displays each of the five fruits represented in its product and, according to Pom, distorts the prominence of pomegranate and blueberry juices in the blend. Pet. Br. 52. Setting aside questions of waiver, Pet. App. 10a; Resp. Br. 45-46; U.S. Br. 30 n.14, Coca-Cola's vignette does not offend the FDCA regime. According to FDA, "it is not always necessary that the label of a multiple-juice beverage depict each juice in a vignette." 58 Fed. Reg. at 2921. Rather, "a vignette that pictures only some of the fruit … in the beverage *would not be misleading* where the name of the food adequately and appropriately describes the contribution of the pictured juice." *Id.* (emphasis added). Because Coca-Cola's product name fully specifies that pomegranate and blueberry juices are flavorings, *supra* 30, Coca-Cola could have used a vignette displaying *only* pomegranates and blueberries. Thus, any live claim Pom might have with regard to the vignette is precluded because it seeks to impose a requirement different from the FDCA and FDA's regulations.

More broadly, Pom's arguments ignore or seek to override FDA's determination that the use of the word "flavored" properly communicates to consumers that pomegranate and blueberry juices blend into the product

to provide characterizing flavor. Pom likewise ignores Coca-Cola's FDA-mandated nutrition label disclosure of all five juices in its blend in order of importance. That listing enables interested consumers to ascertain that apple and grape juices are principal components, with pomegranate and blueberry juices—as the labeling communicates—being used for characterizing flavor and raspberry juice being of even less significance.

Thus, Pom cannot salvage its Lanham Act claim by claiming that it just echoes the general labeling mandate set forth in Sections 343(f) and (i) as opposed to FDA's interpretation of those provisions via regulation. The label conveys all information required by Sections 343(f) and (i). As for the name, Coca-Cola uses "the term 'flavor'" to "inform the consumer that the juice is present in an amount sufficient to flavor the beverage but [without] imply[ing] that the content of that juice is greater than is actually the case." 58 Fed. Reg. at 2921. As for the type size, "the ordinary individual who is interested in discovering and learning" the full product name can do so with "minimum examination of the package." 58 Fed. Reg. at 2473. And, as for the vignette, the FDA has already found that unrepresentative—even incomplete—vignettes are "not ... misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice." 58 Fed. Reg. at 2921.

Pom's grievance thus is not that Coca-Cola has failed to comply with the FDCA or FDA's regulations. It is that FDA has not adequately prevented consumer misperception. Unlike in *Levine*, then, Pom does not seek to reinforce the federal standard through a parallel action. Rather, as in *Mensing* and *Bartlett*, Pom seeks to invoke

the Lanham Act to override FDA's judgment and defeat the labeling uniformity Congress mandated under the FDCA. That should be the end of the matter.

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

KATE COMERFORD TODD
TYLER R. GREEN
NATIONAL CHAMBER
LITIGATION CENTER, INC.
1615 H Street NW
Washington, DC 20062
(202) 463-5337

KARIN F.R. MOORE
GROCERY MANUFACTURERS
ASSOCIATION
1350 I Street NW, #300
Washington, DC 20005
(202) 639-5900

BERT W. REIN
Counsel of Record
WILLIAM S. CONSOVOY
SAMUEL B. GEDGE
WILEY REIN LLP
1776 K Street NW
Washington, DC 20006
(202) 719-7000
brein@wileyrein.com

Counsel for Amici Curiae

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