No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

On Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

BRIEF OF AMICI CURIAE PUBLIC CITIZEN, INC., AARP, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, CONSUMER FEDERATION OF AMERICA, AND CONSUMERS UNION OF THE UNITED STATES, INC. IN SUPPORT OF PETITIONER

ALLISON M. ZIEVE
Counsel of Record
SCOTT L. NELSON
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
azieve@citizen.org
Attorneys for Amici Curiae

March 2014

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Statutes

Legislative Materials

Regulatory Materials

Miscellaneous

INTEREST OF AMICI CURIAE[1]

Amici curiae are five consumer advocacy organizations concerned about the effects of false and misleading advertising on consumers' choices, consumers' health, and consumers' pocketbooks. Amici submit this brief because the Ninth Circuit decision finding Lanham Act claims barred by the Nutrition Labeling and Education Act poses a significant obstacle to protecting against deceptive statements in advertising.

Public Citizen is a membership organization devoted to research, advocacy, and education on a wide range of public health and consumer safety issues. Public Citizen has a longstanding interest in fighting exaggerated claims that federal regulation impliedly bars private remedies for unlawful conduct, and its lawyers have represented parties and amici in significant federal preemption cases involving the Food, Drug, and Cosmetic Act. *E.g.*, *Warner-Lambert v. Kent*, 552 U.S. 440 (2008) (Mem.); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009); *Lockwood v. ConAgra Foods*, 597 F. Supp. 2d 1028 (N.D. Cal. 2009). Public Citizen has also worked to defend consumers' access to accurate information affecting their health. *See*, *e.g.*, *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976); *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 509 F. Supp. 2d 351, 355 (S.D.N.Y. 2007).

---

[1] Pursuant to Rule 37.6 of this Court, amici curiae state that this brief was not written in whole or in part by counsel for a party and that no one other than amici curiae or their counsel made a monetary contribution to the preparation or submission of this brief. Letters from both parties consenting to the filing of this amicus brief are being submitted concurrently with this brief.

AARP is a non-profit, non-partisan membership organization that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families—such as healthcare, employment and income security, retirement planning, affordable utilities, and protection from financial abuse. As the leading organization representing the interests of people aged fifty and older, AARP seeks to protect the financial security and safety of older people, which is threatened by deceptive labeling and marketing. Consumers benefit when individuals and businesses enforce prohibitions on deceptive labeling and advertising. AARP has filed numerous amicus briefs advocating against unwarranted preemption of state laws and supporting private enforcement as essential to protect consumers, especially where the federal government does not have the resources to monitor an increasingly sophisticated barrage of marketing and labeling.

Center for Science in the Public Interest (CSPI) is a national, non-profit advocacy organization for nutrition and health, food safety, and sound science. At congressional hearings in 1989, CSPI testified in support of passage of the Nutrition Labeling and Education Act. In the 25 years since, CSPI has tirelessly advocated for effective FDA enforcement of the statute. At the same time, CSPI has used litigation under state consumer protection laws to protect consumers from misleading food and beverage labeling.

The Consumer Federation of America (CFA), an association of non-profit consumer organizations, was established in 1968 to advance the consumer interest through research, advocacy, and education. Today, nearly 300 of these groups participate in the federation. As a research organization, CFA researches consumer issues and publishes its findings in reports that assist consumer

advocates, policymakers, and individuals. As an advocacy organization, CFA works to advance pro-consumer policies on a variety of issues before Congress, the White House, regulatory agencies, state legislatures, and the courts. As an education organization, CFA disseminates information on consumer issues to the public, news media, policymakers, and other public interest advocates. CFA's Food Policy Institute was established in 1999 to promote a safer, healthier, and more affordable food supply. The Institute supports reform of federal food safety programs, changes in federal food regulations to encourage production and marketing of healthier foods, and policies to ensure consumers have adequate and accurate information to make informed choices in the marketplace.

Consumers Union of the United States, Inc. is a nonprofit organization based in Yonkers, New York that does business as Consumer Reports. The country's largest consumer research, testing, and advocacy organization, Consumer Reports was founded in 1936 with the mission of promoting a fair, just, and safe marketplace for all consumers and empowering consumers to protect themselves. The organization has a citizen activist base of more than 1 million people, and its various print and digital publications have a combined subscribership of more than 8 million people. Consumer Reports employs policy experts, lobbyists, grassroots organizers, and outreach specialists who work with the organization's grassroots activists to change legislation and the marketplace in favor of the consumer interest. Since its inception, Consumer Reports has engaged in research, advocacy, and public education with the goal of exposing and countering misleading advertising and claims. To that end it has focused on food safety and truth in labeling, and has

lobbied and litigated against federal preemption of pro-consumer laws in this area.

STATEMENT

A. Regulation of Food Labeling Under the NLEA

Under the Food, Drug, and Cosmetic Act (FDCA), the Food and Drug Administration (FDA) regulates certain aspects of food safety and labeling. In 1990, Congress enacted the Nutrition Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2353, 2364 (1990) (NLEA), codified as part of the FDCA, to augment the FDA's authority over food labeling. Among other things, the NLEA requires that nutrition labeling be placed on most packaged food, prohibits the use of terms that characterize the level of nutrients in a food unless they conform to definitions established by the FDA, and ensures that claims about the relationship between nutrients and health conditions are supported by significant scientific agreement.

The FDA can address violations of NLEA requirements by exercising its power under the FDCA to initiate enforcement proceedings against manufacturers of misbranded food. 21 U.S.C. §§ 332-334; *see id.* § 343 (defining "misbranded"). A food labeled in violation of FDCA or NLEA requirements may be deemed misbranded because its labeling is "false or misleading in any particular," *id.* § 343(a)(1), or because its label does not contain required nutrition information (such as serving size, number of servings per container, or total number of calories). *Id.* § 343(q).

Although neither the NLEA nor the FDA regulations implementing it require prior approval of juice names or labeling, they address a few discrete aspects of mixed-juice products. The NLEA provides that, if a beverage purports to contain fruit juice—including by using the

name of a fruit in the product name—the label must disclose the percentage of the named fruit contained in the product. 21 U.S.C. § 343(i); *see* 21 C.F.R. § 101.30. A beverage labeled as a juice must state the "common or usual name" of the beverage, *id.*, which "shall be a descriptive name" that "shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food and its characterizing ingredients." *Id.* § 102.5. Fruit juices identified on the label (other than in the ingredient statement) must be listed in descending order of predominance. *Id.* § 102.33(b). Generally, if the product contains only minor amounts of fruit juice for flavoring and the label uses a descriptive word such as "flavoring," these requirements do not apply. *Id.* §§ 101.30(c), 102.33(b). If, however, "the proportion of [a characterizing ingredient] in a food has a material bearing on price or consumer acceptance, or when the label or labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient[] ... is present in an amount greater than is actually the case," the percentage of the ingredient "shall be declared" as a part of the common or usual name of the food. *Id.* § 102.5(b); 58 Fed. Reg. 2897, 2920 (1993) (final rule).

The statutory provision and the implementing regulations regarding disclosure of juice content were motivated by concern that beverage labels referring to or depicting fruits were misleading to consumers with regard to the overall juice content and the healthiness of the product. *See generally* 58 Fed. Reg. 2897; 56 Fed. Reg. 30452 (1991) (proposed rule).

B. The NLEA's Preemption Provision

In enacting the NLEA, Congress did not address preclusion of other federal laws, such as the Lanham Act. It did, however, devote careful attention to the related

subject of the extent to which the legislation would preempt state laws. *See* Laura Sims, *The Politics of Fat: Food and Nutrition Policy in America* 199 (1998) ("The preemption issue remained a key area of dispute throughout consideration of the food labeling bill, with the basic issue being how far the legislation should go in setting uniform food labeling regulations that preempt state laws."). In the final moments of the floor debate before the NLEA was passed in the House of Representatives, Representative Waxman explained that a narrow preemption provision had been added to the bill to induce the food industry to support the legislation. 136 Cong. Rec. H12951-02, H12954 (Oct. 26, 1990) ("[I]t was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them some types of preemption of some burdensome State laws that interfered with their ability to do business in all 50 States."). The leading proponent of stronger federal preemption, Senator Orrin Hatch, agreed that "the carefully crafted uniformity section of this legislation is limited in scope." 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990).

The express preemption provision of the NLEA, codified at 21 U.S.C. § 343-1(a), carefully specifies and limits the subjects on which federal standards will preclude enforcement of non-identical state laws. Under that section, state "requirements" that are "not identical" to federal requirements addressing twelve specified topics are preempted. For example, states may not impose a "standard of identity" on a food subject to an FDA standard of identity, unless the state standard is identi-

cal to the federal standard. *Id.* § 343-1(a)(1).[2] And states may not impose requirements related to nutrition labeling (the statement of serving size, calories, etc., required on food packages) or requirements regarding labeling that characterizes the level of nutrients or makes health claims related to nutrients, unless those state requirements are identical to federal requirements. *Id.* § 343-1(a)(4)-(5).

The only provision of the express preemption provision, § 343-1(a), that specifically addresses fruit juice is paragraph 2, which provides that states may not impose non-identical "requirement[s] for the labeling of food of the type required by" § 343(i)(2). That provision in turn provides that beverages purporting to contain fruit juice must prominently disclose the percentage of juice contained in the beverage. The provision is not implicated here, as none of the claims seek to enforce requirements for listing percentages of juices (although listing the tiny percentages of pomegranate and blueberry juices in the product is one way in which Coca-Cola could have ameliorated the misleading nature of the label at issue here).

In addition, paragraph 3 of the express preemption provision provides that states may not impose any non-identical "requirement for the labeling of food of the type required by" § 343(i)(1). That provision in turn provides that a food label must bear the common or usual name of the food (or beverage). The provision would be informative here, although not dispositive, if POM's challenge were limited to the propriety of a name that complied

[2] A standard of identity is a regulatory definition of what ingredients are required to be or prohibited to be in a food product that is sold under a particular name. *See, e.g.*, 21 C.F.R. § 139.110 (setting standard of identity for macaroni products).

with § 343(i)(1) and related regulations. *See also* 58 Fed. Reg. at 2920 (regulation concerning naming of juice "does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner").

Notably, § 343(a)(1), which prohibits food labeling that "is false or misleading in any particular" is not among the types of requirements listed as having preemptive effect in § 343-1(a). Thus, the express preemption provision does not bar the enforcement of state laws imposing requirements of that type—that is, requirements addressing false or misleading labels.

The NLEA's very specific limitations on the types of requirements that displace state laws reflect an effort to satisfy industry concerns while remaining "sensitive to the regulatory roles played by the States." 136 Cong. Rec. at S16609 (Sen. Mitchell). The preemption provision was "refined to provide national uniformity where it is most necessary, while otherwise preserving State regulatory authority where it is appropriate." *Id.*; *see also* 136 Cong. Rec. at S16611 (Sen. Hatch) ("[T]he compromise makes clear that the national uniformity in food labeling that is set forth in the legislation has absolutely no effect on preemption of State or local requirements that relate to such things as warnings about foods or components of food.").

To make clear that, aside from § 343-1(a), the new labeling laws would, as Senator Mitchell said, "otherwise preserv[e] State regulatory authority," Congress added § 6(c) of the NLEA. Section 6(c) precludes implied preemption of state laws by limiting the scope of preemption to the areas specified in the express preemption provision:

> The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. § 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

Pub. L. No. 101-535, § 6(c), 104 Stat. at 2364 (21 U.S.C. § 343-1 note).

Section 6(c) makes explicit that the NLEA does not preempt, either expressly or impliedly, state requirements concerning aspects of fruit juice labeling not specified in § 343-1(a). And nothing in the NLEA addresses preclusion of claims that might be otherwise available under federal law.

SUMMARY OF ARGUMENT

POM Wonderful LLC (POM) brought this action against the Coca-Cola Company, stating a false-advertising claim under the Lanham Act and claims under California's Unfair Competition Law and False Advertising Law. At issue here is the claim that Coca-Cola's advertising, name, and labeling of its Minute Maid "Pomegranate Blueberry" juice are false or misleading, in violation of the Lanham Act, 15 U.S.C. § 1125(a).

The court below held that POM's Lanham Act claim is barred by the FDA's "comprehensive" regulation of beverage labeling. The court did not suggest that the product's label was not misleading to consumers. Instead, the court held that the Lanham Act claim "would risk undercutting the FDA's expert judgment and authority." Pet. App. 11a, 12a.

Where two federal statutes pose no irreconcilable conflict and Congress has not stated its intent to oust operation of either, this Court presumes both to be effective. Here, both the NLEA and the Lanham Act easily

can co-exist, and, therefore, the decision below was incorrect. Congress's unusually clear instruction in 21 U.S.C. § 343-1(a) and § 6(c) of the NLEA as to the preemptive scope of the NLEA with regard to state law reinforces this conclusion. Through those provisions, Congress specified that a state-law claim that is substantially similar to POM's Lanham Act claim is not preempted. Congress thus specified that such challenges pose no threat to FDA regulation. If enforcement of state laws on these subjects is not inconsistent with the NLEA, it follows that enforcement of other federal laws that address these subjects also is not inconsistent with the NLEA. Likewise, Congress's careful delineation of the preemptive scope of the NLEA belies the notion that the FDA occupies the field so as to bar Lanham Act claims.

In addition, "Congress enacted the FDCA to bolster consumer protection against harmful products." *Wyeth v. Levine*, 555 U.S. 555, 574 (2009). Just as in the context of prescription drugs, reading the statute broadly to bar private rights of action with respect to food labeling "is at odds with what evidence we have of Congress' purposes." *Id.* at 577. And just as in the context of prescription drugs, private rights of action challenging aspects of food labeling over which manufacturers exercise control are not barred by the FDCA and FDA regulation under it.

Finally, the FDA has acknowledged that it does not have the resources to address and does not address misleading food and beverage labeling. Private enforcement is therefore the only existing mechanism for deterring and addressing misleading food labeling.

ARGUMENT

I. The NLEA's Disavowal of Implied Preemption of State-Law Claims Shows That Federal Lanham Act Claims Likewise Are Not Impliedly Barred.

A. The NLEA Devotes Careful Attention to Preemption but Includes No Provision Suggesting That Lanham Act Claims Are Barred.

In the NLEA, Congress set forth, in unusually specific fashion, which federal requirements would preempt non-identical state requirements, and foreclosed any attempt to give the statute a broader preemptive reading. 21 U.S.C. § 343-1(a) & note (§ 6(c)). Two aspects of § 343-1(a) are significant here. First, the provision preserves laws that would impose requirements "identical" to the specified federal requirements and, therefore, does not preempt private remedies for violations of those requirements. Thus, the NLEA does not preempt a challenge to a juice name where the name does not comply with federal requirements, or where the challenge is based on advertising, rather than labeling. *See id.* § 343-1(a)(3). Second, the preemption provision does not reach the descriptive content of beverage labeling or advertising.[3] Accordingly, state-law claims challenging the descriptive labeling of a juice beverage are not preempted: "The NLEA explicitly forecloses the possibility that state law would be impliedly preempted." *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 509 F. Supp. 2d 351, 355 (S.D.N.Y. 2007) (citing NLEA § 6(c), 21 U.S.C.

[3] As used here, "descriptive content" refers to aspects of labeling other than the nutrition panel, ingredient lists, common name, and percentage-of-juice statements that are specified as preemptive requirements in § 343-1(a).

§ 343-1 note). *Accord Holk v. Snapple Bev. Corp.*, 575 F.3d 329, 337 (3d Cir. 2009); *Lockwood v. ConAgra Foods*, 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009); *see also Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 957 (N.D. Cal. 2013).

As the FDA has explained, § 6(c) of the NLEA "clearly manifests Congress's intention" that the NLEA not preempt state law beyond the NLEA's express terms: "If there is no applicable Federal requirement that has been given preemptive status by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under the 1990 amendments for Federal preemption." 56 Fed. Reg. 60528, 60530 (1991).

Thus, Congress has directed and the FDA has recognized that "the *only* State requirements that are subject to preemption are those that are affirmatively different on matters that are covered by section [343-1] of the act." 58 Fed. Reg. 2462 (1993) (emphasis added). In this respect, the NLEA's preemption provisions are "somewhat unusual," in that, when considering state-law claims, "[t]he NLEA can be analyzed only in terms of express preemption, because its express provisions prohibit any implied preemption under the statute." Burk, *The Milk-Free Zone: Federal and Local Interests*, 22 Colum. J. Envt'l L. 227, 259 (1997); *accord In re Farm Raised Salmon*, 175 P.2d 1170, 1179 (Cal. 2008).

As relevant here, under the NLEA, a *state-law* claim challenging the "common or usual name" of a juice beverage would be expressly preempted if that name complied with 21 C.F.R. §§ 102.5 and 102.33—the FDA regulations that address "common or usual names" generally and for fruit juices. The product name "Pomegranate Blueberry," however, does not seem to comply with those regulations because the name does not include

"blend," "flavored," or other such qualifiers, and does not state the percentage of the "characterizing ingredients," pomegranate and blueberry. A *state-law* claim challenging that name as misleading would therefore not be barred to the extent that it sought to enforce a requirement identical to these federal requirements.[4] Moreover, because the applicable paragraph of the NLEA's preemption provision applies only to requirements for "the labeling" of food, it likewise does not bar a state-law claim premised on misleading use of a name in advertising.

Similarly, a state-law claim challenging a juice beverage label as a whole (as opposed to the name in particular) as misleading—for example, because the label highlights pomegranate and blueberry when the beverage in fact it contains only 0.3% pomegranate and 0.2% blueberry juice (particularly if the percentages are not disclosed on the label)—is not barred. To the contrary, because the claim does not fall under any paragraph of § 343-1(a), which defines the express preemptive scope of the NLEA, and because Congress has specified that the

---

[4] The parties apparently disagree about whether the name of Coca-Cola's product as displayed on its label is "Pomegranate Blueberry," as POM contends, or "Pomegranate Blueberry Flavored Blend of 5 Juices," as Coca-Cola argues. Pet. App. 1a-2a. That dispute turns on whether additional words placed in smaller print on a different line of the label are part of the name. The disagreement is noted in the opinion below, and although the court stated that it took "no view" on the disagreement, *id.* 2a, the court in reaching its holding seemed to assume that the name was "Pomegranate Blueberry Blend of 5 Juices." *Id.* 9a. Resolution of this dispute would not determine whether the NLEA would expressly preempt a state-law claim challenging that name, as the dispute does not address the requirements of 21 C.F.R. § 102.5(b), concerning the treatment of characterizing ingredients in the product's common or usual name.

NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted" under § 343-1(a), such a state-law claim is expressly *not* preempted.

The NLEA's state-law preemption provisions (including § 6(c), the no-implied-preemption provision) weigh strongly against reading the statute to bar Lanham Act claims: A Congress so concerned with precisely defining the types of laws displaced by the NLEA surely would have mentioned the Lanham Act or other federal laws had it intended to foreclose their application.

Further, the Lanham Act creates a private right of action against any person who makes false and deceptive statements in a commercial advertisement about its product or on the product container. 15 U.S.C. § 1125(a). POM's claim thus has much in common with claims under the unfair and deceptive acts and practices statutes of the 50 states. *See*, *e.g.*, Cal. Bus. & Prof'l Code § 17200 (creating a cause of action against unfair or fraudulent business acts or practices and unfair, deceptive, untrue, or misleading advertising). Given that a state-law claim substantially similar to POM's Lanham Act claim is not preempted—because Congress has expressly so stated—Coca-Cola's position would create the odd scenario in which one federal law would be deemed to bar operation of another, but to leave a similar state law untouched.

This illogical outcome reveals the flaw in the decision below. The purported justification for barring Lanham Act claims is refuted by Congress's decision *not* to bar substantially similar state-law claims. As in the context of preemption of state law, "[i]f there is no Federal requirement to be given preemptive effect, preemption [or

here, preclusion] does not occur." 60 Fed Reg. 57076, 57120 (1995) (FDA statement).[5] And "when two [federal] statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Morton v. Mancari*, 417 U.S. 535, 551-52 (1974) ("When there are two acts upon the same subject, the rule is to give effect to both if possible . . . . The intention of the legislature to repeal 'must be clear and manifest.'" (quoting *United States v. Borden Co.*, 308 U.S. 188, 198 (1939))); *see Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 662-63 (2007). If state requirements can coexist with the NLEA, it necessarily follows that similar requirements imposed by other *federal* laws can likewise coexist.

B. The NLEA Does Not Occupy the Field of Beverage Labeling.

The decision below suggests that the FDA occupies the field of beverage labeling. Pet. App. 12a ("We are primarily guided in our decision … by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling."). Preemption or preclusion based on this theory applies, however, only when the "scheme of federal regulation" is "so pervasive as to make reasonable the inference that Congress left no room for the States [or other federal law] to supplement it." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) (citation omitted). No

[5] In other settings, courts have recognized that whether a federal law displaces another exercise of federal authority is governed by principles similar to federal-state preemption. *See, e.g., Chamber of Commerce v. Reich*, 74 F.3d 1322, 1334 (D.C. Cir. 1996).

such federal scheme exists here.[6] Rather, the NLEA itself makes plain that Congress did not intend to occupy the field of food labeling in general or beverage labeling in particular.

Section 343-1(a) identifies very specifically which statutory provisions preempt state law, and § 6(c) states unequivocally that state law outside the scope of § 343-1(a) is not preempted. "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted" under field preemption principles. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992); *see also Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 613 (1991) (express preemption provision would be "pure surplusage if Congress had intended to occupy the entire field"). Thus, even absent § 6(c), the statute's limited express preemption provision would impliedly foreclose the conclusion that Congress intended to occupy the field of food and beverage labeling. Here, where § 6(c) expressly disclaims any such intention, the conclusion is even clearer. The NLEA's limited express preemption provision and its anti-implied preemption provision manifest that Congress did not intend to displace all other law with regard to food labeling.

---

[6] *Cf. Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002) (no field preemption where Coast Guard authorized to regulate boat safety but statute "does not *require* the Coast Guard to promulgate comprehensive regulations covering every aspect of recreational boat safety and design") (emphasis in original).

II. The FDA Does Not Police the Type of Misleading Labeling Alleged Here.

A. Lanham Act Claims Do Not Challenge the FDA's Expert Determinations.

The court below held that, if POM were to succeed in its Lanham Act challenge to the product's name, the finding that the name was misleading "would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading." Pet. App. 9a. With respect to the presentation of the product's label, the court reached a similar conclusion, finding that the claim "would risk undercutting the FDA's expert judgments and authority." *Id.* 11a.

In addition to being incorrect in believing that POM's challenge to the name of Coca-Cola's beverage conflicted with the FDA's product-name regulations, the appellate court was wrong to worry that the Lanham Act claims would challenge the FDA's expert determination about beverage labeling. FDA regulations about fruit juice labeling set forth a small number of requirements for labeling of mixed-juice beverages. *See supra* p. 5. The regulations, however, give companies substantial autonomy in crafting labeling, and companies are free to go beyond the regulatory requirements. For example, no FDA regulation required Coca-Cola to make pomegranate or blueberries predominant images on the label. And Coca-Cola would not have run afoul of any FDA requirement by stating, for example, "a blend of 3 juices, with a splash of pomegranate and blueberry." That is, nothing in the NLEA or the applicable regulations precludes a company from *both* complying with FDA fruit-juice regulations *and* giving consumers a clear understanding of a product's juice content. *See also Morton*, 417 U.S. at 551

(overlapping statutes capable of co-existence should be regarded as effective, unless Congress clearly states otherwise). Under this regulatory scheme, for claims that do not implicate a topic specified in the express preemption provision, concern about infringing on the FDA's decisionmaking is misplaced.

Further, for matters beyond the scope of express preemption, there is no policy basis for precluding application of the Lanham Act because—even leaving aside that the NLEA specifies that it does not impliedly bar the application of other laws—there is no conflict that would support implied preemption here. Rather, the purpose of the pertinent FDA requirements is to ensure that beverages that purport (through names, descriptions, or pictures on labeling or advertising) to contain juice do not mislead consumers by creating a false impression about juice content. *See generally* 58 Fed. Reg. 2897 (discussing reasoning behind rule requiring percentage disclosure); *see also id.* at 2919 (explaining that 21 C.F.R. § 102.33 reflects an attempt to address the problem that "beverage labels are clearly misleading if they misrepresent the contribution of one or more individual juices to the nature of the product").

Lanham Act claims alleging misleading advertising or labeling are consistent with and pose no obstacle to the accomplishment of the purpose behind these federal requirements. Indeed, the objectives are the same—to prevent misleading labeling. Requirements of federal law generally do not preclude enforcement of other laws aimed at the same or consistent objectives. *Cf. Hillsborough County v. Auto. Med. Labs.*, 471 U.S. 707, 717 (1985) ("[M]erely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were

barred from identifying additional needs or imposing further requirements in the field.").

B. The Decision Below Is Inconsistent with *Wyeth v. Levine.*

Importantly, the FDA exercises far less careful oversight over beverage labeling than over drug labeling. Drug manufacturers must not only comply with general FDA regulations about labeling, they must also obtain FDA approval of the specific labeling they wish to use. 21 U.S.C. § 335(b); *see also* 21 C.F.R. § 314.50(c)(2)(i). Approval of the labeling is part of the approval required as a precondition to marketing the product at all, and all changes to labeling must be run past the FDA (either in advance or when made). 21 C.F.R. § 314.80. Yet, as this Court has confirmed, FDA approval of a drug's labeling does not preclude state-law claims challenging the adequacy of that labeling. *See Wyeth v. Levine*, 555 U.S. 555. Rather, the Court recognized that the approved labeling sets not a ceiling, but a floor, establishing minimum standards. State-law challenges to labeling "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 579; *see id.* at 583 (Thomas, J., concurring in the judgment) (agreeing that, in light of regulations allowing labeling changes, "federal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA").

FDA regulation of beverage labeling does not begin to approach the level of FDA regulation of drug labeling. Unlike the regulatory scheme applicable to drugs, the FDA does not approve beverage names or labeling, matters over which companies have significant freedom. For instance, although some FDA regulations are applicable

to beverage labeling generally, the FDA has never evaluated the name or labeling of the Minute Maid juice at issue, much less made a determination that the name and labeling are or are not misleading.

In short, the FDA's significantly greater regulation of drugs and this Court's recognition in *Wyeth* that claims challenging aspects of drug labeling are not barred directs the answer to the question presented here. Congress cannot have intended to create a scheme whereby claims challenging misleading drug labeling could go forward (as this Court has held) but claims about misleading beverage labeling are impliedly barred (as the lower court held).

C. Private Enforcement Is the Primary Mechanism for Addressing and Redressing Misleading Labeling.

Congress's decision to carefully limit the preemptive scope of the NLEA reflects a recognition that the FDA is not equipped to act as the sole monitor of the expansive marketplace for foods and beverages. The NLEA was enacted, in part, to address a sizable increase in "unfounded health claims … being made in the marketplace." H. Rep. No. 101-538, at 9 (1990) (quoting then-FDA Commissioner Sullivan). To find preclusion here would mean that, in seeking to expand oversight of misleading food labeling, Congress implicitly cut back on existing tools for doing so. This result is neither required by nor consistent with the NLEA.

The oversight role of competitors and consumers is particularly important because the FDA lacks the resources to handle the task alone. As the Government Accountability Office (GAO) reported in 2008, "FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those

prohibiting false or misleading labeling." GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods* 5, 13 (2008), *available at* www.gao.gov/new.items/d08597.pdf. In addition, the GAO stated that the "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." *Id.* at 6.

Perhaps most significant here, "according 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." *Id.* at 30. The FDA's online list of enforcement actions bears out this fact. From February 1, 2013, through February 1, 2014, the FDA sent only one warning letter concerning a food labeled in a misleading way. *See* Letter from FDA to John Stanger, dated July 26, 2013, *available at* www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm364729.htm (label inaccurately stated that products were "all natural" and contained cheddar cheese, among numerous other violations).

Although the FDA's Office of Food Safety and Applied Nutrition does take enforcement actions, its labeling-related actions are almost exclusively concerned with specific violations of specific statutory requirements: failure to properly format the nutrition labeling panel, a topic on which the FDA regulations are extremely specific, *see* 21 C.F.R. § 101.9; or labeling that includes drug claims, *see* 21 C.F.R. §§ 101.72-101.83. These FDA enforcement efforts are important. They do not obviate,

however, the problem of labeling that misleads consumers without violating a specific FDA requirement (aside from the general prohibition against misleading labeling). For that problem, private enforcement is the only mechanism for deterring, addressing, and redressing misleading labeling.

CONCLUSION

For the foregoing reasons, the decision below should be reversed insofar as it held POM's Lanham Act claims barred by the FDCA.

Respectfully submitted,

ALLISON M. ZIEVE
Counsel of Record
SCOTT L. NELSON
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
azieve@citizen.org
Attorneys for amici curiae

March 2014