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 *AMICUS CURIAE* AMERICAN BEVERAGE ASSOCIATION IN SUPPORT OF RESPONDENT


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## INTEREST OF *AMICUS CURIAE* [1]

*Amicus curiae* the American Beverage Association ("ABA") is the trade association representing the broad spectrum of companies that manufacture and distribute non-alcoholic beverages in the United States, including regular and diet soft drinks, bottled water and water beverages, 100-percent juice and juice drinks, sports drinks, energy drinks, and ready-to-drink teas. Founded in 1919, the ABA represents hundreds of beverage producers, distributors, bottlers, franchise companies, and support industries. ABA's members employ more than 233,000 workers nationwide, generate U.S. sales in excess of $140 billion per year, and participate in food safety initiatives as they apply to and impact beverages. ABA has a substantial interest in ensuring that any regulations to which its members are subject are applied in a clear, efficient, and nationally uniform manner. To this end, ABA regularly represents its member companies in federal rulemaking proceedings and litigation when the issues presented will broadly affect the industry.

Pursuant to its express statutory authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") and Nutritional Labeling and Education Act ("NLEA"), the Food and Drug Administration ("FDA") has promulgated comprehensive regulations regarding the labeling of multi-juice beverages. The

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[1] This brief was not written in whole or in part by counsel for any party, and no person or entity other than *amici* and their counsel has made a monetary contribution to the preparation and submission of this brief. The parties have consented to the filing of this brief.

FDA has provided clear guidance about how to comply with the regulations regarding misbranding, and has given beverage manufacturers multiple options for how to prepare a compliant label.

POM's Lanham Act claims would fundamentally upend this regulatory regime. The FDA's expert policy judgments about how products can be labeled in a non-misleading manner would be rendered largely meaningless if beverage manufacturers could be subject to Lanham Act claims for "misleading" labels even where those labels fully comply with the FDA's regulations. Worse still, Lanham Act claims brought by competitors would eviscerate the uniformity and regulatory certainty that the FDA's regulations were designed to provide. ABA and its members thus have a powerful interest in ensuring that the FDA's regulations remain the exclusive means through which beverage labels are regulated.

## SUMMARY OF ARGUMENT

**I.** POM's core argument is that the name or label of a multi-juice beverage is "misleading" unless it prominently displays the constituent juices *by volume*. But the expert agency that Congress tasked with overseeing food labels has reached a different conclusion. Based on several unique characteristics of the beverage industry, the FDA concluded that it is not misleading for manufacturers to use labels that focus on the *flavor* of a multi-juice beverage rather than its ingredients by volume.

That conclusion was well-grounded in both the agency's extensive rulemaking record and common sense. Some fruit and vegetable juices have much stronger flavors than others, and a small amount of a

distinctly-flavored juice can go a long way in altering the taste of a blended beverage. Moreover, although POM seems to favor a rule that requires prominent disclosure of the exact percentages of each ingredient in a multi-juice blend, the FDA has rejected that *exact* proposal as unworkable. There is often some degree of variation in the makeup of multi-juice blends due to changes in the price or availability of ingredients, and beverage companies must have the flexibility to make those changes without having to constantly re-design their labels. A full-disclosure-at-all-costs rule would also threaten intellectual property rights by forcing companies to divulge beverage recipes that constitute some of their most valuable trade secrets.

POM's theory of Lanham Act liability would severely undermine the FDA's expert judgments and uniform national standards regarding beverage labeling. And beverage companies would be deprived of clear guidance about how to design labels that comply with the law. Rather than being subject to one set of comprehensive national standards, beverage companies would be subject to the whims of juries across the country under an amorphous totality-of-the-circumstances test. It is complicated and expensive to change the label on a nationally-distributed product, and POM's theory of Lanham Act liability would ensure that manufacturers *never* have certainty that their labels comply with the law.

**II.** When Congress enacted the FDCA in 1938, it made clear that only the government—not private parties—may enforce the prohibitions on misbranding. The FDCA's lack of a private right of

action was not an accident or oversight. It was instead a reasoned policy decision that expert regulators should decide when and how to enforce the FDCA. Congress recognized that the FDA should have broad discretion to choose when to exercise its enforcement authority, and to address issues one step at a time through a deliberative rulemaking process. The FDA's enforcement discretion and expert judgment would be undermined if private parties could bring their own claims challenging a label as "misleading" even when the FDA has made a reasoned decision that it is not.

POM's Lanham Act claims are just the most recent in a long line of attempts by plaintiffs to evade Congress' prohibition on private suits to enforce the FDCA. Although POM asserts that its Lanham Act claims are wholly distinct from the requirements of the FDCA, there is no question that its claims address matters within the heartland of the FDA's exclusive authority—namely, whether the manner in which a beverage label depicts ingredients is "misleading." POM's Lanham Act claims will interfere with the FDA's discretion and enforcement authority every bit as much as a private claim brought directly under the FDCA. If POM is dissatisfied with how the FDA has regulated multi-juice beverages, the proper remedy is to ask the FDA to change its rules, not to make an end-run around the statutory prohibition on private claims to enforce the FDCA.

**III.** Finally, although this case is cloaked in issues of statutory interpretation, it is still, at bottom, a case about restricting speech that

implicates the First Amendment. A product's name and label have a significant expressive component, as they are one of the most important ways in which a company communicates with its customers.

The FDA's comprehensive labeling regulations certainly burden protected expression, but they also contain several important safeguards to ensure that no more speech is chilled than necessary to advance the FDA's goals of preventing deception and promoting informed consumer choice. For example, the regulations provide clear and specific guidance about what companies must do in order to comply with the law, and the FDCA's ban on private suits prevents over-enforcement in borderline cases. The Lanham Act, in contrast, contains no such safeguards. Lanham Act claims are evaluated under an amorphous totality-of-the-circumstances test, and plaintiffs (*i.e.*, competitors) have no incentive whatsoever to exercise restraint in bringing such claims.

When it comes to expressive speech protected by the First Amendment, one layer of comprehensive and detailed regulation is more than enough. Given that beverage manufacturers' speech is already carefully regulated by a federal agency, it simply goes too far to then subject that speech to *another* level of regulation through case-by-case Lanham Act claims by any private plaintiff with a beef. There is a far greater risk to First Amendment freedoms when any private plaintiff can attack commercial speech, as opposed to allowing a single regulator to address labeling subject to uniform rules and without private enforcement. POM's approach poses a serious risk of

chilling protected expression, and the Lanham Act should be interpreted to avoid that constitutionally dubious result.

## ARGUMENT

### I. POM's Lanham Act Claims Would Severely Undermine The Flexible National Standards That Are Central To The FDA's Regulatory Regime.

Throughout its brief, POM suggests that the FDA's detailed and comprehensive labeling regulations merely establish a "floor" that can be supplemented on a case-by-case basis through Lanham Act suits. Those arguments misconstrue the FDA's regulations and wholly ignore the unique features of the beverage industry that were central to the FDA's policy decisions. The FDA's regulations were designed to ensure that consumers have all the information they need to make informed choices, while also providing beverage manufacturers with significant *flexibility* in naming and labeling their products. POM's Lanham Act claims would upend that scheme and allow labeling decisions to be made on an *ad hoc* basis by juries, rather than on a uniform national basis by the expert administrative agency.

#### A. Any Rules Regarding Naming and Labeling of Juices Must Take into Account the Unique Features of the Food and Beverage Industry.

The FDA's regulations regarding the naming and labeling of multi-juice blends were carefully crafted to accommodate several unique characteristics of the beverage industry.

*First*, it is extremely costly and complicated for food and beverage producers to change the labels on their products. Labels are one of the key ways in which a company interacts with its customers, and they are subject to exhaustive reviews within the company before being approved. Changing a label not only undermines the company's branding efforts but also poses a logistical nightmare. In order to change all of its labels at once, the company would have to recall millions of existing products, potentially resulting in a massive waste of perishable merchandise. Alternatively, the company could change the labels only for newly produced products, but that could lead to customer confusion as products with both the new label and old label are simultaneously in circulation. It is thus critical for any regulation of labels to provide clear standards for compliance that will minimize the need for costly changes.

*Second*, as all consumers know, some ingredients have much stronger flavors than others. A seemingly miniscule amount of jalapeño pepper can completely change the flavor of a food product. And one squeeze of lemon or lime can significantly alter the taste of a drink, even if the beverage is largely comprised of other ingredients. Beverage manufacturers offer countless products in which small amounts of distinctly-flavored juices—such as cranberry, pomegranate, blueberry, mango, and acai—are used to enhance the flavor of more "conventional" juices such as apple and grape. Relatedly, some juices are denser than others, and denser juices will typically have a stronger flavor than less-concentrated juices. Thus, there is often a substantial disconnect between

the predominant *flavors* in a beverage and the predominant *ingredients* as measured by volume.

In ABA's experience, consumers typically choose a juice product based on its characterizing flavor; unsurprisingly, taste is also a critical determinant of customer satisfaction.[2] When one ingredient is responsible for a significant portion of a beverage's flavor profile, it is entirely reasonable for the product name to prominently feature that ingredient, even if it comprises only a small percentage of the total volume. Indeed, under those circumstances, it can be *affirmatively misleading* to name a product based on its primary ingredients rather than its characterizing flavor.[3] Here, for example, if Coke had named its product "Apple-Grape Blend of Five Juices," many consumers would have been quite surprised to learn that the beverage tasted like a mix of blueberries and pomegranate and did not taste like either apple or grape juice.

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[2] *See*, *e.g.*, Nat'l Soft Drink Ass'n Comments at 7, Docket No. 80N-0140 (FDA Aug. 1, 1991) ("NSDA Comments") ("Consumers generally are more concerned with taste, quality, value, and total juice content than with the individual amounts of each component juice in a blend"). The National Soft Drink Association changed its name to the American Beverage Association in 2004.

[3] *See* Welch Foods Inc.'s Comments at 4, Docket No. 80N-0140 (FDA July 30, 1991) ("The flavor of a juice product is probably the single greatest determinant of product satisfaction and can only be evaluated by tasting. Consequently, the idea that the consumer can determine 'value' … by knowing the percentage of each juice in the product is not supportable, but may, in itself cause misjudgment and confusion.").

*Third*, the prices and availability of fruits and vegetables can be extremely volatile. Nearly all fruits and vegetables have some degree of seasonal price variation, and prices are also affected by weather patterns, global supply and demand, and international trade conditions. As a result, beverage manufacturers often adjust the proportions of ingredients in their products in response to changes in cost or availability. And, for a company that has multiple manufacturing facilities, there may be slight variations among the products produced at different facilities. In short, it is impossible to have an entirely standardized food or beverage product, and any labeling regulations must be flexible enough to accommodate the inherent variations in such products. *See* NSDA Comments at 7 (declaration of the specific percentages of each ingredient could "deprive producers of the flexibility to make minor adjustments in component juices").

*Fourth*, recipes are often a food or beverage company's most valuable trade secrets. Even though the same "basic ingredients" are used in many recipes, the "combination in which those ingredients are used" and the manner in which they are prepared are routinely deemed to be trade secrets. *Peggy Lawton Kitchens, Inc. v. Hogan*, 466 N.E.2d 138, 139-40 (Mass. App. Ct. 1984); *see also Magistro v. J. Lou, Inc.*, 703 N.W.2d 887, 890-91 (Neb. 2005) (pizza dough recipes were trade secrets); *Uncle B's Bakery, Inc. v. O'Rourke*, 920 F. Supp. 1405, 1428-29 (N.D. Iowa 1996) (bagel company's "recipes, manufacturing, and packaging processes" were all trade secrets). A regulatory regime that required disclosure of the exact amount of each ingredient in a

food or beverage would jeopardize proprietary recipes and, indeed, would risk being a taking of manufacturers' intellectual property. *Cf. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) (applying regulatory takings doctrine to government-mandated disclosure of proprietary information). Needless to say, one does not need to look beyond the named parties to this litigation to understand the salience of this point. Perhaps the Nation's most famous secret formula would not be a secret if Respondent had to display on its label precisely what flavors went into making a Coke a Coke.

### B. The FDA's Regulations Were Carefully Designed To Accommodate the Competing Interests at Stake While Providing Regulated Parties Flexibility in Labeling Juice Blends.

Based on these characteristics of the industry, the FDA made an eminently reasonable policy judgment that beverage manufacturers should have flexibility in how they name and label multi-juice blends.

The FDA has been studying the question of how to label multi-juice beverages for decades. Throughout the 1980s, the FDA initiated multiple rulemaking proceedings on this topic and considered several citizen petitions seeking specific regulations regarding multi-juice beverages. *See* 56 Fed. Reg. 30,452, 30,455 (July 2, 1991) (summarizing regulatory history). After the NLEA was enacted in 1990, the FDA again sought public comment on "how to represent accurately the contents of juice blends and diluted multiple-juice beverages containing one

or more characterizing flavors." *Id.* at 30,452; *see id.* (requesting comment on "whether the percentage of characterizing juices should be labeled"). Those proceedings resulted in a comprehensive rulemaking record that included comments from all interested stakeholders, including consumer groups, agricultural interests, beverage manufacturers, States, and individual citizens.

Several of the comments filed during the rulemaking process were strikingly similar to the arguments POM has raised in this case. For example, one commenter complained that "some juice beverages have misleading labels in that high cost/value or intense flavor juices are given greatest label prominence but are present in minor amounts." 58 Fed. Reg. 2,897, 2,900 (Jan. 6, 1993); *compare* POM Br. 2 ("every aspect of the product's appearance is tailored to convince consumers that it contains significant amounts of pomegranate and blueberry juice"). And other groups sought detailed regulation of illustrations on product labels (also known as "vignettes"), arguing that any vignette should "accurately reflect the quantity of fruit present." 58 Fed. Reg. at 2,922; *compare* POM Br. 52 (complaining that Coke's vignette "features outsized blueberries" and "prominently features a large pomegranate").

The FDA carefully considered those proposals, but ultimately rejected them as unnecessary or unworkable. As the agency explained, "it is not necessary to require that each juice in a beverage be named to ensure that the label is not [] misleading." 58 Fed. Reg. at 2,919. The "basic nature of the product can be described in various ways, *e.g.*, as a

blend of five juices, with a declaration of the name of the juice or juices that provide the characterizing flavor, as long as it is clear from the name that other juices are present." *Id*.

The FDA stated in no uncertain terms that the "name of the characterizing juice may [] be declared first *although it is not the predominant juice*." *Id.* at 2,920 (emphasis added). That is, the agency recognized that it is entirely appropriate to name a multi-juice blend based on its "characterizing flavor," even if the characterizing juice comprises only a small percentage of the overall volume. A label that describes the characterizing juice as a "flavor"—like Coca-Cola's label here—"will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case." *Id.* at 2,921.

The FDA also rejected a proposal that would have required all constituent juices in a blend to be disclosed in 1%-increments, finding that such a rule was "not practicable." *Id.* The agency emphasized that beverage producers "need to have flexibility in the formulation of the beverage to accommodate variations in raw material juices and price changes." *Id.* The FDA thus allowed beverage makers to comply with its naming rules for multi-juice blends by *either* stating that a named characterizing juice is present only as a "flavoring" *or* disclosing the amount of the named juice in a 5-percent range. *See* 21 C.F.R. § 102.33(d).

Finally, the FDA also rejected the detailed regulation of vignettes that several commentators

had sought. The agency concluded that a vignette that depicts the fruits used to flavor a multi-juice blend "would not be misleading," even if some of those juices were present only in small amounts. 58 Fed. Reg. at 2,921. The FDA also flatly rejected proposals that would have required fruits on a vignette to be "depicted in proportion to the amount of each juice present." *Id.* at 2,922. Such a rule would be too "difficult" for manufacturers to implement, and would be of little benefit to consumers. *Id.*

### C. POM's Lanham Act Claims Would Disrupt the FDA's Regulatory Regime and Lead to Significant Uncertainty and Practical Problems.

If accepted by this Court, POM's theory of Lanham Act liability would fundamentally upend the FDA's regulatory regime, and would lead to serious practical problems for beverage manufacturers.

Most important, POM's Lanham Act claims would severely undermine the FDA's flexible and nationally uniform approach to beverage labeling. One of the FDA's primary goals in its misbranding regulations was to promote "national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 States in a cost-effective manner." 58 Fed. Reg. 2,462, 2,462 (Jan. 6, 1993). The agency determined that "the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur" if labels are not subject to case-by-case litigation. *Id.*

POM, in contrast, argues that—in addition to the FDA's detailed regulations—every juice label is also potentially subject to an amorphous, totality-of-the-circumstances inquiry under the Lanham Act. Tellingly, POM never specifies exactly what it thinks Coke *should have done* to make its label non-misleading. At some points in its brief, POM suggests that Coke was obligated to disclose the exact percentages of each juice in its blend, an obligation specifically considered and affirmatively rejected by the FDA in its labeling rules. *Compare* 58 Fed. Reg. at 2,920 ("declaration of percentage of individual juices represented on the label is not required") *with* POM Br. 51-52 ("Coca-Cola's label does not include—or even hint at—the trivial percentage of pomegranate and blueberry juice in the product."). At other points, POM suggests that Coke should have given its product a different name or included more information on the front of the label. *See id.* at 10 ("Coca-Cola's front label does not even mention the product's overwhelmingly dominant ingredients—apple juice or grape juice—by name.").[4] And POM argues elsewhere that the vignette on the label depicting the constituent fruits should have been crafted differently by, for example, shrinking the "outsized blueberries." *Id.* at 52.

It is anyone's guess when a label rises to the level of "misleading" under POM's totality-of-the-

[4] It is unsurprising that POM limits its challenge to the front of the label, given that other FDA regulations require all ingredients to be listed "in descending order of predominance by weight" in the statement of ingredients on the back of the label. *See* 21 C.F.R. § 101.4(a)(1).

circumstances inquiry. What if the "outsized blueberries" in the vignette were shrunk to what POM deems an appropriate size? What if the statement "flavored blend of five juices" was listed in the same font as "Pomegranate Blueberry" on the front label? Or what if Coca-Cola had named its product "Blueberry/Apple/Pomegranate/Grape Juice"? POM does not even attempt to explain which aspects of the label are dispositive under its theory; it merely asserts that all of this somehow adds up to a Lanham Act violation, or at least a Lanham Act claim that a jury could sort out. And, of course, another competitor might have different theories about why the same label is "misleading."

Food and beverage companies sell their products into a nationwide marketplace. It is wholly untenable for each label to be subject to the FDA's comprehensive regulatory scheme *plus* an amorphous, totality-of-the-circumstances inquiry that will vary from court to court and will ultimately be resolved by juries that may not possess the expertise required to interpret FDA regulations. *See Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 509 (7th Cir. 2009) (FDA "has more experience with consumers' understanding of drug labels than judges do"). The FDA can consider labeling issues comprehensively and strike a reasonable balance among the many competing interests at stake. A jury, in contrast, will focus on a single label in isolation, while disregarding the broader policy interests that might be undermined if such labels were prohibited. *Cf. Riegel v. Medtronic*, 552 U.S. 312, 325 (2008) ("A jury … sees only the cost

of a more dangerous design, and is not concerned with its benefits.").

Indeed, POM's theory of Lanham Act liability would effectively nullify one of the two options provided by the FDA for labeling multi-juice beverages. The regulations provide two alternatives for how a multi-juice beverage can comply with the misbranding rules, and provide clear, uniform guidance about the requirements for each alternative. *See* 21 C.F.R. § 102.33(d)(1) (manufacturer can indicate that a non-predominant juice is "present as a flavor or flavoring"); *id.* § 102.33(d)(2) (manufacturer can identify the amount of a non-predominant juice within a 5-percent range). When a juice blend has a "characterizing flavor," the FDA has concluded that "*it is not necessary* to require that each juice in a beverage be named to ensure that the label is not [] misleading." 58 Fed. Reg. at 2,919 (emphasis added). POM, however, argues that it *is* "misleading" under the Lanham Act to name and label a juice blend based on its characterizing flavor rather than its predominant ingredients by volume.

It is difficult to imagine a more clear-cut example of a private party seeking to second-guess and override the policy determinations of an expert agency. POM effectively seeks to use the Lanham Act to *prohibit* labels that are expressly *authorized* by the FDA's regulations. Needless to say, the choice provided by the FDA will be rendered meaningless if choosing the "wrong" option can lead to Lanham Act liability. When a federal agency has provided regulated entities with a "range of choices" for compliance with a regulation, any attempt to nullify

that choice through private tort claims stands as an obstacle to the federal policy and must yield to the agency's regulations. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 874-86 (2000).

## II. Congress' Express Refusal To Include A Private Right Of Action In The FDCA Must Be Given Effect.

POM asserts (at 32, 37) that it is not seeking to enforce the FDCA or the FDA's regulations, but is instead attempting to use the Lanham Act to *supplement* the FDCA. This Court should reject that maneuver for all of the reasons set forth in Coke's brief. But even if POM were merely attempting to *enforce* the requirements of the FDCA through the Lanham Act, its claims would still fail.

**A.** The FDCA's text and legislative history make clear that Congress intended the government, not private parties, to have exclusive responsibility for enforcing the prohibition on misbranding. Since its enactment in 1938, the FDCA has provided that "all … proceedings for the enforcement, or to restrain violations, of this chapter *shall be by and in the name of the United States*." 21 U.S.C. § 337(a) (emphasis added). During the debates over the FDCA, Congress considered—and rejected—a version of the bill that would have allowed a private right of action for damages. *See National Women's Health Network v. A.H. Robins Co.*, 545 F. Supp. 1177, 1179-80 (D. Mass. 1982) (summarizing legislative history).

Courts have consistently honored this congressional judgment. Thus, there is no need for courts to distinguish between the "bad old days" of implied causes of action, *see Alexander v. Sandoval*,

532 U.S. 275, 286-88 (2001), and the modern reluctance to infer such actions from congressional silence, *id.* When it comes to the FDCA, there is "no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001).[5]

Congress granted the FDA sweeping authority to enforce the FDCA. The FDA can seek an injunction to restrain violations, 21 U.S.C. § 332, impose civil *and criminal* penalties, *id.* § 333, and seize adulterated or misbranded products, *id.* § 334.[6] Critically, however, the statute also grants the FDA authority *not* to enforce the Act to its fullest possible extent. Section 336 provides that "[n]othing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of [] injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning." *Id.* § 336.

That is, Congress recognized that it is not necessarily in the public interest to have the FDCA

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[5] In 1990, the NLEA carved out a narrow exception to exclusive federal enforcement for suits brought by a State "*in its own name*" to enforce certain provisions of the FDCA. 21 U.S.C. § 337(b)(1) (emphasis added). But those amendments did not in any way authorize enforcement by private parties.

[6] The FDA has not hesitated to use those far-reaching powers when it deems appropriate. *See* Warren Leary, *Citing Labels, U.S. Seizes Orange Juice*, New York Times (Apr. 25, 1991) (FDA inspectors seized 2,000 cases of orange juice made from frozen concentrate that was falsely labeled as "fresh").

enforced to its fullest possible extent in all circumstances. Taken together, Sections 336 and 337 make clear that the federal government has exclusive authority to both enforce and *decline to enforce* the federal requirements regarding misbranding. *See United States v. Sullivan*, 332 U.S. 689, 694 (1948) (under Section 336, agency need not bring enforcement actions for "technical infractions of law").

For example, the FDA has concluded that a product may be labeled as "calorie free" or "zero calories" as long as it has "less than 5 calories per reference amount customarily consumed." 21 C.F.R. § 101.60(b)(1). Similarly, a "nonfat" or "fat free product" is not deemed misbranded if it has "less than 0.5 g[rams] of fat per labeled serving." *Id.* § 101.62(b)(1). Some consumers might be surprised to learn that a product labeled "fat free" actually has small amounts of fat, and class actions have been filed over equally trivial variances.[7] But the FDA concluded based on an extensive rulemaking record that the 0.5 gram threshold is "appropriate because it is the reliable limit of detection of fat in all types of foods, and thus analytically equates it to zero." 58 Fed. Reg. 2,302, 2,328 (Jan. 6, 1993). The FDA's

[7] ConAgra Foods has been sued by class-action plaintiffs alleging that its "Parkay Spray" product—which contains small amounts of fat per serving—"is deceptively labeled, marketed and sold to … consumers as having '0 fat' and '0 calories.'" Class Action Complaint at 1, *Allen v. ConAgra Foods, Inc.*, No. 3:13-cv-1279 (N.D. Cal. Mar. 21, 2013); *see also The Non-Fat Yogurt*, Seinfeld (NBC, Nov. 4, 1993) ("I promise you, my fellow New Yorkers, that Mayor Giuliani will do everything possible to cleanse this city of this falsified non-fat yogurt.").

enforcement discretion and expert judgment would be rendered meaningless if private parties could bring their own claims challenging a label as misleading even when the FDA has made a reasoned decision not to act.

**B.** Plaintiffs have been trying for decades to evade Section 337's ban on private actions to enforce the FDCA. Plaintiffs' lawyers initially tried to convince courts to invent an implied right of action for private parties to enforce the FDCA directly. But, as noted, the courts resisted any effort to infer a cause of action under the FDCA. The lower courts have uniformly held that "Congress did not intend, either expressly *or by implication*, to create a private cause of action under the FDCA." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (emphasis added); *see also PDK Labs v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) ("no … private right of action exists" under the FDCA"); *In re Orthopedic Bone Screw Products Liability Litig.*, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well-settled … that the FDCA creates no private right of action.").

After those theories were rejected, plaintiffs tried a variety of different maneuvers to evade the FDA's exclusive enforcement authority under Section 337. Some plaintiffs sought to evade Section 337 by cloaking their misbranding claims in state-law causes of action. Although there is some tension among the lower courts on this issue, the far better view is that such claims cannot be brought because they stand as a direct obstacle to the policy of exclusive government enforcement embodied in Section 337. It would have made no sense at all for

Congress to have prohibited private actions to enforce the FDCA while simultaneously allowing private misbranding claims to be brought under state law. A private right of action "is equally inconsistent with the federal regulatory scheme, whether the right is based in federal or state law." *National Women's Health Network*, 545 F. Supp. at 1181.

For example, in *Fraker v. KFC Corp.*, No. 06-cv-1284, 2007 WL 1296571 (S.D. Cal. Apr. 30, 2007), the court found that state-law challenges to health claims made by a fast-food company were impliedly preempted by the FDCA. As the court explained, "[t]o overlay the state law tort system over the FDCA would significantly increase the burdens on the FDA to ensure uniform enforcement of its administrative duties." *Id.* at *4. Thus, the plaintiffs' state-law claims were barred by federal law to the extent they depended on "alleged violations of the FDCA." *Id.*

Another court similarly held that "Massachusetts cannot confer on private persons the power to enforce a federal statute whose enforcement Congress left to federal administrative agencies." *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986). Even though the complaint was ostensibly brought under the "Massachusetts consumer protection statute," the court nonetheless found that it was "preempted by the FDCA." *Id.* That is, plaintiffs may not evade the prohibition on private actions under the FDCA through a state "statute which parallels the FDCA." *Id.*; *see also Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001) (plaintiffs cannot bring claims under state law

that "involve[] all the facts and arguments to be determined in a misbranding enforcement action, matters within the sole jurisdiction of the FDA").[8]

**C.** POM's Lanham Act claims are just the most recent attempt to do indirectly what Section 337 bars private parties from doing directly. POM asserts (at 25-28) that its Lanham Act claims are wholly distinct from the FDCA and that its claims can "easily coexist" with the FDA's exclusive authority to enforce the FDCA. But, tellingly, POM makes no attempt to compare the *text* of the two statutes. The FDCA provides that food is impermissibly misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 343(a)(1). Using nearly identical language, the Lanham Act prohibits a "false or misleading description of fact, or false or misleading representation of fact" in connection with the sale of goods or service. 15 U.S.C. § 1125(a)(1).

Thus, although POM is nominally seeking relief under the Lanham Act, it is also accusing a beverage company of using a "misleading" label—which is precisely the type of issue that Congress has committed to the FDA's expert discretion. POM's

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[8] *But see In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1181-84 (Cal. 2008) (holding that Section 337 does not preempt private claims under state misbranding law that was "identical" to the FDCA). A pending petition for certiorari—in which this Court has called for the views of the Solicitor General—challenges a similar decision from the California Supreme Court holding that private parties could use the California unfair competition law to enforce the requirements of a federal law that did not include a private right of action for damages. *See Rose v. Bank of America*, 304 P.3d 181 (Cal. 2013), *petition for cert. filed* No. 13-662 (U.S. Nov. 27, 2013).

Lanham Act claims will interfere with the FDA's policy judgments every bit as much as private claims brought directly under the FDCA. Indeed, the enhanced remedies available under the Lanham Act—such as disgorgement of profits and recovery of attorneys' fees, *see* 15 U.S.C. § 1117—would make such claims particularly attractive to plaintiffs and particularly inconsistent with Congress' decision to assign such judgments to the expert agency.

The fact that there is some play in the joints about how a company can comply with the FDA's regulations does not mean that there is a vacuum to be filled by *ad hoc* Lanham Act claims. It instead reflects the reasoned judgment of the expert agency about how best to balance and accommodate the many competing interests at stake. Some percentage of consumers may feel "confused" or "misled" by nearly any statement a company makes about a food or beverage. Sections 336 and 337 ensure that the FDA has authority to prohibit statements that are *actually* misleading while also preventing the harm to the industry that would result from over-enforcement of labeling rules based on trivial or *de minimis* allegations of misbranding.

* * *

In sum, POM's approach would allow the Lanham Act to "stray[] too close to the exclusive enforcement domain of the FDA," and would "'usurp[] the FDA's discretionary role in the application and interpretation of its regulations.'" *Summit Technology, Inc. v. High-Line Medical Instruments*, 922 F. Supp. 299, 306 (C.D. Cal. 1996). Congress made a reasoned determination—embodied in

Sections 336 and 337 of the FDCA—that the FDA should be responsible for crafting and enforcing regulations regarding misbranding of food and beverages, and that private enforcement should play no role whatsoever in that scheme. If POM is dissatisfied with how the FDA has chosen to regulate beverage labels, this "is a problem to be addressed by the FDA and not by the courts in a Lanham Act suit." *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987).

## III. The Lanham Act Should Be Construed To Avoid The Serious First Amendment Concerns That Would Arise From Over-Regulation Of Protected Expression.

Finally, although the resolution of this case will turn largely on questions of statutory interpretation, this is still—at heart—a case about the regulation of speech that implicates important First Amendment interests. In reconciling and harmonizing the FDA's regulations and the Lanham Act, this Court should ensure that these First Amendment interests are protected, and that no more speech is chilled than necessary to serve the government's goals of preventing misbranding and promoting informed consumer choice. There is no question that the legal regime envisioned by POM would create a speaker-beware environment when it comes to beverage labels. In light of the FDA's ability to prevent misleading speech, there is no reason to adopt a rule that chills more speech than is necessary.

**A.** There is no question that the First Amendment applies to product names and labels. As a number of lower courts have recognized, "[p]roduct

labels, which are part of a firm's marketing plan to provide certain information to the consumer … constitute commercial speech." *Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1546 (10th Cir. 1991); *see also International Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 635 (6th Cir. 2010) ("composition claims" about a product, such as "antibiotic-free" and "pesticide-free," constitute commercial speech); *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) ("It is undisputed that FDA's restrictions on … health claims are evaluated under the commercial speech doctrine."); *Hornell Brewing Co. v. Brady*, 819 F. Supp. 1227, 1233 (E.D.N.Y. 1993) ("The Crazy Horse Malt Liquor label is indisputably commercial speech.").

Indeed, even if product names and labels are deemed to be "commercial speech," they are still fundamentally *expressive* in nature. Product names and labels are how companies differentiate their products in a competitive marketplace and build lasting relationships with consumers. "In today's world, branding is more important than ever," as product branding "convey[s] a uniform quality, credibility, and experience."[9] A brand is "a company's face to the world," and includes "the company's name, how that name is visually expressed through a logo, and …. how the company is perceived by its customers."[10]

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[9] Scott Goodson, *Why Brand Building Is Important*, Forbes (May 27, 2012), http://www.tinyurl.com/7b5w22r.

[10] *The Importance of Branding Your New Business*, New York Times (Mar. 18, 2009), http://www.tinyurl.com/78ntbme.

For example, Ben & Jerry's is well-known among consumers for its uniquely named ice cream flavors (*e.g.*, "Cherry Garcia," "Half Baked," "John Lennon's Imagine Whirled Peace"), and its labels often contain graphics or messages about political and social issues. Other companies similarly boast on their labels that their products are "fair trade" or "sustainably grown." These product names and labels are far more than just descriptive; they are important expressions about a company's values and the image it seeks to convey to the public.

**B.** Given the significant expressive component of product names and labels, any regulation of this speech must not be "more extensive than is necessary" to serve the government's interests in preventing deception and allowing consumers to make informed choices. *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 566 (1980). That is, any regulation of this type of speech must avoid unnecessarily chilling protected expression.

The FDA's regulations impose an exhaustive array of requirements on the names and labels of food and beverage products. The regulations provide detailed instructions about what manufacturers can name their products. *See* 21 C.F.R. §§ 102.5, 102.22-102.57. They commandeer a significant portion of product labels for government-mandated disclosures of ingredients and nutritional information. *Id.* §§ 101.1-101.5, 101.9. They restrict claims that can be made about nutrients and calorie content (*i.e.*, whether a product is "light," "low sodium," or a "good source of vitamins"). *Id.* §§ 101.54-101.69. They

provide extraordinarily detailed rules about the types of health claims that food and beverage manufacturers can make. *Id.* §§ 101.70-101.83. And an entire regulation is devoted to placing restrictions on when food and beverage companies can characterize their products as "fresh" or "frozen." *Id.* § 101.95.

Although these regulations certainly *burden* protected expression, they also contain built-in safeguards to ensure that speech is not restricted more than necessary to advance the FDA's policy goals. Most important, the FDA has minimized any potential chilling effect on protected speech by clearly specifying what a company needs to do to comply with the misbranding rules. The regulations provide a relatively clear picture of how to comply with the law, thus allowing food and beverage companies to utilize creative names or labels while still complying with the FDA's regulations.

The lack of a private right of action in the FDCA also serves First Amendment values by preventing over-enforcement of the misbranding regulations. In selecting remedies for misbranding, the FDA has broad discretion to balance the public interest against the speaker's right of free expression. For example, the FDA may issue a warning letter before bringing a formal enforcement action, or may seek to remedy alleged misbranding on a *prospective* basis only rather than seeking penalties or damages for past conduct. Because the FDA has limited resources, it also has strong incentives to act through clear regulations and carefully targeted enforcement actions. In short, the FDA is likely to restrict

protected speech only where necessary, and its enforcement actions for misbranding will be taken only in circumstances where consumers are most likely to be harmed.[11]

Lanham Act claims, in contrast, have none of the speech-protecting features of the FDA's regulations. In contrast to the FDA's clear guidance about how to comply with the misbranding regulations, Lanham Act suits are necessarily *ad hoc* and based on an amorphous totality-of-the-circumstances test. *See supra* 13-16. This Court has repeatedly emphasized that vague or imprecise laws "raise[] special First Amendment concerns because of [their] obvious chilling effect on free speech." *Reno v. ACLU*, 521 U.S. 844, 871-72 (1997); *see also Citizens United v. FEC*, 558 U.S. 310, 324 (2010) (vague laws "chill speech" because regulated parties "'must necessarily guess at [the law's] meaning'"); *Pearson*, 164 F.3d at 661 ("it must be possible for the regulated class to perceive the principles which are guiding" a regulation of speech).

Moreover, there is no check whatsoever on private parties' ability to bring Lanham Act suits challenging a competing product's name or label. *See New York Times v. Sullivan*, 376 U.S. 254, 277 (1964) (safeguards for the defendant in a government

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[11] For example, after reviewing POM's websites in January 2010, the FDA found "serious violations" of the FDCA based on POM's claims that its juices can be used to treat medical conditions ranging from heart infections to erectile dysfunction. *See* Warning Letter from Roberta C. Wagner to POM Wonderful (Feb. 23, 2010), http://www.fda.gov/iceci/enforcementactions/warningletters/ucm202785.htm.

enforcement action "are not available to the defendant in a civil action"). Companies can face years of litigation as a result of Lanham Act claims initiated by their competitors, even if the FDA would not have deemed the case worthy of an enforcement action or warning letter. The Lanham Act's relatively unconstrained private cause of action thus poses a much greater threat to First Amendment values than circumscribed government enforcement actions.

**C.** This Court has long held that "[a] statute must be construed, if fairly possible, so as to avoid not only the conclusion that it is unconstitutional but also *grave doubts* upon that score." *United States v. Jin Fuey Moy*, 241 U.S. 394, 401 (1916) (emphasis added); *see FCC v. Fox Television Stations*, 556 U.S. 502, 516 (2009) ("ambiguous statutory language should be construed to avoid serious constitutional doubts"). The same principles should govern how to reconcile two competing federal statutes. When one statute already addresses First Amendment-protected activity in a way that specifically foreswears the chilling effect of private causes of action, courts should err on the side of caution and the First Amendment in not allowing a duplicative private cause of action.

In the course of harmonizing the FDA's regulations and the Lanham Act, the First Amendment interests at stake should tip the balance in favor of protected speech and against Lanham Act claims. There are few, if any, other industries in which it would be acceptable for a federal regulator to tell companies how they can name and label their

products, and what adjectives they can use to describe their products. To be sure, the FDA's regulations may be justified by the important government interests in preventing deception and promoting informed consumer choice. But that does not change the fact that these regulations impose significant speaker-based and content-based restrictions on protected expression. *Cf. Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2662 (2011).

Given that food and beverage manufacturers' speech about their products is *already* micro-managed by the FDA in countless ways, it raises serious First Amendments concerns to then subject that FDA-authorized speech to yet another layer of regulation through *ad hoc*, totality-of-the-circumstances Lanham Act claims. Once a company clears the many hurdles imposed by the primary regulator, the restrictions on protected speech should be at an end. POM's "prophylaxis-upon-prophylaxis approach to regulating expression," *see FEC v. Wisconsin Right to Life, Inc.*, 551 U.S. 449, 479 (2007) (plurality op.), must be rejected.

In this regard, it bears emphasis that there is an obvious alternative to more speech-chilling lawsuits—more speech. If POM believes it has a superior product, it is perfectly free—subject to FDA regulations—to go to the airwaves and trumpet what makes its product a better juice. That is clearly the remedy that First Amendment values favor. The choice between more speech and more speech-chilling private actions is not a close one.

* * *

When it comes to expressive speech protected by the First Amendment, one layer of comprehensive and detailed regulation is more than enough. This Court should construe the Lanham Act to avoid the serious constitutional concerns that would arise if speech that is already exhaustively regulated by the FDA were also subject to case-by-case adjudication under the amorphous standards of the Lanham Act.

## CONCLUSION

This Court should affirm the judgment of the Ninth Circuit.

Respectfully submitted,

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