No. 12-761

In the Supreme Court of the United States

POM WONDERFUL LLC, PETITIONER

v.

THE COCA-COLA COMPANY

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether and to what extent the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and regulations promulgated under that Act preclude a food manufacturer from challenging the label of its competitor's product under Lanham Act § 43(a), 15 U.S.C. 1125(a), which provides a cause of action against anyone who, *inter alia*, "uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, [or] qualities * * * of his * * * goods." 15 U.S.C. 1125(a)(1) and (B).

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This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. "Congress has regulated food and beverage labeling for more than 100 years." *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009). It did so first in the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, then in the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, and later through amendments to the FDCA. Congress amended the FDCA in 1990 to address nutrition labeling for nearly all food products for human consumption, including juices. Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353. Throughout those efforts, "[m]isbranding was one of the

chief evils Congress sought to stop." *62 Cases of Jam* v. *United States,* 340 U.S. 593, 596 (1951).

The FDCA bans the introduction into or receipt in commerce of "misbranded" foods. 21 U.S.C. 331(a) and (c). "Food" includes any "article[] used for food or drink for man." 21 U.S.C. 321(f). Of relevance here, a food is misbranded if "its labeling is false or misleading in any particular," if required information is not sufficiently prominent and conspicuous on the label or labeling, or if its label fails to bear "the common or usual name of the food, if any there be, and * * * in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient." 21 U.S.C. 343(a), (f) and (i).[1]

To implement those provisions and provisions of the NLEA, and to "promote honesty and fair dealing in the interest of consumers," 21 U.S.C. 341, the Food and Drug Administration (FDA) has regulated many aspects of the naming and labeling of juice beverages. See 58 Fed. Reg. 2897-2926 (Jan. 6, 1993) (removing and promulgating scattered Sections of 21 C.F.R. Pts. 101, 102). Particularly relevant here are three provisions of 21 C.F.R. 102.33 addressing aspects of the naming and labeling of multi-juice beverages:

- Under Section 102.33(b), juices identified by name on the label (and not just listed in the ingredient statement)—"named juices" for short—"must be [named] in descending order of predominance by

[1] The Federal Trade Commission (FTC) shares with the Food and Drug Administration enforcement authority over deceptive food labeling, advertising, and promotion. See 15 U.S.C. 45(a)(2), 52(a); 36 Fed. Reg. 18,539 (Sept. 16, 1971) (memorandum of understanding). The parties do not contend that the FTC's authority bears on the viability of petitioner's claim.

volume unless the name specifically shows that [a nonpredominant] juice [supplying a] represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink)."

- Under Section 102.33(c), if a named juice is not the only juice present, "then the common or usual name for the product shall indicate that the [named] juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')."
- Under Section 102.33(d), if a named juice is neither the only juice present nor the predominant juice, then the "common or usual name for the product shall" either "[i]ndicate that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)" or "[i]nclude the amount of the named juice, declared in a 5-percent range."

The foregoing requirements under the FDCA as amended by the NLEA are not, as such, privately enforceable. See 21 U.S.C. 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States."); cf. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance."). In addition, the NLEA prohibits any State from "directly or indirectly" establishing any requirement "that is not identical" to certain food-labeling requirements under the FDCA. 21 U.S.C. 343-1(a). But the NLEA does not expressly address its relationship to other federal laws.

b. The Trademark (Lanham) Act of 1946, ch. 540, 60 Stat. 427, amended existing trademark law to make "actionable the deceptive and misleading use of marks" in interstate commerce, to "protect persons engaged in such commerce against unfair competition," and to "provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations." 15 U.S.C. 1127. As amended, Section 43(a) of the Lanham Act creates a private civil action against

> [a]ny person who, on or in connection with * * * any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, [or] qualities * * * of his * * * goods.

15 U.S.C. 1125(a)(1) and (B). Such an action may be brought "by any person who believes that he or she is or is likely to be damaged by such act." 15 U.S.C. 1125(a)(1).

2. Petitioner "produces, markets and sells bottled pomegranate juice and pomegranate juice blends, including a pomegranate blueberry juice blend." Pet. App. 1a. Respondent, doing business "under the brand Minute Maid, is one of [petitioner's] primary competitors in the bottled pomegranate juice market." *Id.* at 84a. In September 2007, respondent announced a new product called "Pomegranate Blueberry" or "Pomegranate Blueberry Flavored Blend of 5 Juices," consisting of "99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice." *Id.* at 1a-2a. The product's front label displays a graphic vignette depicting grapes, blueberries, and raspberries in front of

a halved pomegranate and a halved apple. Below the graphic vignette appear the words "Pomegranate Blueberry," and below those, in smaller type, the words "Flavored Blend of 5 Juices." See *id.* at 2a (reproducing label).

3. In September 2008, petitioner sued respondent under Section 43(a) of the Lanham Act.[2] Pet. App. 3a. Petitioner challenged the name, label, marketing, and advertising of respondent's juice, alleging that respondent misled consumers to believe that respondent's juice consists predominantly of pomegranate and blueberry juices when it in fact consists predominantly of less expensive apple and grape juices, thereby injuring both consumers and petitioner. *Id.* at 84a-85a. Petitioner described respondent's juice's label as containing "many misleading elements not required by federal or state regulation." First Am. Compl. ¶ 20. Petitioner alleged injury to its "business, reputation, and goodwill," and it sought damages, recovery of respondent's profits, and an injunction barring further false advertising of respondent's juice. *Id.* ¶¶ 33-35, Prayer for Relief.

The district court granted partial summary judgment to respondent on the Lanham Act challenge to the text displayed on the juice's label. Pet. App. 21a-73a. The court believed that "FDA has directly spoken on the issues that form the basis of" petitioner's claim in 21 C.F.R. 102.33(c) and (d). Pet. App. 62a. It further noted that 21 U.S.C. 343(f) requires only that respondent "prominently place the label on the Juice's bottle," which

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[2] Petitioner also brought claims under various California laws. Those claims are not at issue in this Court. See Pet. i. The district court granted summary judgment to respondent on those claims, No. 08-cv-6237, 2013 WL 543361 (C.D. Cal. Feb. 13, 2013), and petitioner's appeal is pending, No. 13-55770 (9th Cir.).

respondent "does sufficiently." Pet. App. 63a-64a. The court concluded that petitioner's claim failed because the common name for respondent's juice—"Pomegranate Blueberry Flavored Blend of 5 Juices"—"is expressly permitted (required here) by the FDA." *Id.* at 65a. Although the court found triable issues of fact on petitioner's advertising and marketing claims, *id.* at 72a, petitioner later stipulated that it could not carry its burden of proof on those claims in light of the court's order, and the court accordingly entered final judgment for respondent on all claims. *Id.* at 17a-19a. Accordingly, subsequent proceedings on petitioner's Lanham Act claim have been limited to material on the juice's label.

4. The court of appeals affirmed the district court's grant of summary judgment to respondent on petitioner's label-based Lanham Act claim. Pet. App. 1a-14a. It began by describing the FDCA as "comprehensively regulat[ing] food and beverage labeling." *Id.* at 6a. Next, acknowledging that "the Lanham Act and the FDCA can conflict with each other" but should each be given "as much effect * * * as possible," the court identified several scenarios in which, in its view, "the FDCA limits claims under the Lanham Act." *Id.* at 6a-7a (internal quotation marks and citation omitted). "A plaintiff may not, for example, sue under the Lanham Act to enforce the FDCA or its regulations," or "maintain a Lanham Act claim that would require a court originally to interpret ambiguous FDA regulations," or pursue a Lanham Act "claim [that] would require litigating whether [certain] conduct violates the FDCA." *Id.* at 7a (citing cases illustrating those principles). On the whole, the court concluded that generally, "the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority," but a court must still "focus

on the circumstances before it to strike a balance that disrupts the two statutory schemes as little as it can." *Id.* at 8a.

Applying those principles, the court of appeals concluded that "the FDCA and its regulations bar pursuit of both the name and labeling aspects of [petitioner's] Lanham Act claim." Pet. App. 9a. With respect to the juice's common name, the court explained that, because 21 C.F.R. 102.33(d) permits a manufacturer to name a beverage using the name of a flavoring juice that is not predominant, "as best we can tell, FDA regulations authorize the name [respondent] has chosen." Pet. App. 9a. Thus, the court reasoned, petitioner's challenge to the common name "'Pomegranate Blueberry Flavored Blend of 5 Juices' would create a conflict with FDA regulations and would require [the court] to undermine the FDA's apparent determination that so naming the product is not misleading." *Ibid.*

The court of appeals likewise concluded that petitioner's Lanham Act claim was precluded with respect to the label's presentation of the words "Pomegranate Blueberry" in "larger, more conspicuous type" than the words "Flavored Blend of 5 Juices" appearing below them. Pet. App. 10a. The court found that the FDCA and its implementing regulations "have specified how prominently and conspicuously those words and statements must appear." *Ibid.* (citing 21 U.S.C. 343(f) and (i); 21 C.F.R. 102.33(c) and (d)). "Congress and the FDA have thus considered and spoken to what content a label must bear, and the relative sizes in which the label must bear it, so as not to deceive," but "ha[ve] not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size." *Ibid.* The court observed that "[i]f the FDA believes more should be

done to prevent deception, or that [respondent's] label misleads consumers, it can act." *Id.* at 11a.

The court of appeals emphasized that it was not "hold[ing] that [respondent's] label is non-deceptive," or that "mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability." Pet. App. 11a-12a. Rather, the court stated that it was guided by what it understood to be "Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* at 12a. "In the circumstances here," the court concluded, "'the appropriate forum for [petitioner's] complaints is the [FDA].'" *Ibid.* (quoting *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919, 929 (9th Cir. 2010)) (second set of brackets in original).

DISCUSSION

This case concerns the interplay of two federal statutes that apply to the label of a food product in commerce. The court of appeals correctly recognized that its task was to give maximum effect to each while respecting the other. Applying that principle, the court's rejection of petitioner's challenge under Section 43(a) of the Lanham Act to the common name of respondent's juice was sound, because that claim sought to impose liability for what FDA's regulations under the FDCA had specifically permitted. But the court of appeals should have permitted petitioner's Lanham Act challenge to proceed insofar as it concerns features of the juice's label that are not specifically addressed by the FDCA or FDA's regulations. The court concluded otherwise based on its observation that FDA had not (but could have) regulated the aspects of the label about which petitioner com-

plained. That reasoning endowed the FDCA's food-labeling provisions with too broad a preclusive reach.

Notwithstanding the court of appeals' error, further review is not warranted in this case. Because the court misinterpreted the preclusive reach of FDCA provisions that apply to food, the decision below does not conflict with the decisions petitioner identifies from this Court and other courts of appeals, each of which is distinguishable because (among other things) each concerned the preclusive effect of provisions of the FDCA that apply to a product other than food (or provisions of a statute other than the FDCA). Moreover, some doubt exists as to whether the summary-judgment record here properly presents the product-name/product-label dichotomy necessary for a sound treatment of the question presented.

A. The Court Of Appeals Erred By Giving The Federal Food, Drug, And Cosmetic Act Too Expansive A Preclusive Effect Over Claims Under Section 43(a) Of The Lanham Act

"[W]hen two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *J. E. M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001) (citation omitted). Here, although Section 43(a) of the Lanham Act and the FDCA overlap in that each applies to the label of respondent's juice, each can be given effect, except where the Lanham Act would undo what Congress or FDA specifically required or permitted under the FDCA.

1. The court of appeals reasoned that, because FDA regulations appear to authorize the common name of respondent's juice, and because the FDCA and FDA's regulations generally address "what content a label must bear, and the relative sizes in which the label must bear

it, so as not to deceive," entertaining petitioner's Lanham Act challenge to the label on respondent's juice "would risk undercutting the FDA's expert judgments and authority." Pet. App. 9a-11a. In short, the court's decision rested on what it perceived as "Congress's decision to entrust matters of juice beverage labeling to the FDA and * * * the FDA's comprehensive regulation of that labeling." *Id.* at 12a.

That reasoning is too broad. In holding that Congress intended FDA to regulate juice labeling under the FDCA to the exclusion of the remedy under Section 43(a) of the Lanham Act, the court of appeals' analysis parallels that used in "so-called field pre-emption" cases, where "'the scope of a [federal] statute indicates that Congress intended federal law to occupy a field exclusively.'" *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1266 (2012) (brackets in original) (quoting *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995)). Although federal-state preemption principles do not control the inquiry into whether "two [federal] statutes are capable of co-existence," *J. E. M. Ag Supply*, 534 U.S. at 143 (citation omitted), those principles may nonetheless be useful guides because they are calculated to identify laws that cannot co-exist. See Pet. 17-18. Moreover, circumstances that would not themselves support a finding of FDCA preemption of *state* remedies are unlikely to be a sufficient indication of Congress's intent to preclude an existing *federal* remedy. Here, a number of considerations, some borrowed by analogy from the preemption context, show that the FDCA does not occupy the juice-labeling field.

First, the court of appeals relied heavily on the existence of FDA regulations and the agency's ability to regulate further if it saw fit. But in the preemption

context, this Court has cautioned that "the mere existence of a federal regulatory or enforcement scheme," even a particularly detailed one, "does not by itself imply pre-emption of state remedies." *English* v. *General Elec. Co.*, 496 U.S. 72, 87 (1990). To hold otherwise would be "tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." *Hillsborough Cnty.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985). Likewise here, the court below was too quick to regard the commitment of authority to FDA as exclusive.

Second, the NLEA specifically disclaims federal occupation of the food-labeling field "unless such provision is expressly preempted" by 21 U.S.C. 343-1(a), which in turn forbids States from "directly or indirectly" establishing any requirement "that is not identical" to certain requirements under the FDCA. 21 U.S.C. 343-1(a) & note. That arrangement thus permits some state law unfair competition claims and bars others. By contrast, the court of appeals held that FDA's food-misbranding authority under the FDCA occupies the relevant field here to the total exclusion of the federal unfair-competition claim under Section 43(a) of the Lanham Act. It is counterintuitive to conclude that Congress intended a total displacement of a federal remedy but only a partial displacement of state remedies of a similar nature. And here in particular, it is implausible to think Congress meant to *favor* state remedies over a federal remedy, given that the NLEA was designed to promote "[n]ational[ly] uniform nutrition labeling," 21 U.S.C. 343-1.

Third, nothing in the FDCA, the NLEA, FDA's regulations, or the preambles to those regulations suggests that FDA has marked the metes and bounds of all possi-

ble misleading material on juice labels, or that its authority must be deemed exclusive even as to matters the agency has never specifically addressed. To the contrary, the preamble to the final juice-labeling rule makes clear that even when a manufacturer complies with 21 C.F.R. 102.33, there remains considerable potential for particular labels to prove misleading.[3] And as to unexercised regulatory authority, although the court of appeals professed to limit its holding to "matters of juice beverage labeling," Pet. App. 12a, its deference to FDA's available but unexercised authority would arguably preclude a Lanham Act challenge to the label of *any* food. Such reasoning could reach even the many foods that FDA's regulations do not specifically address at all. See generally 21 C.F.R. Subchap. B (regulating certain aspects of the labeling of food for human consumption, and defining common names of certain standardized foods).

Fourth, petitioner's use of the Lanham Act to challenge a food label is not novel. Congress first provided a private right of action in the Lanham Act eight years

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[3] For example, although 21 C.F.R. 102.33(b) permits the primary declaration of a characterizing juice even if "it is not the most predominant juice," FDA cautioned that "there is great potential for [such a] label to misrepresent the contribution of the named juice to the product" and that "this provision does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner." 58 Fed. Reg. 2920 (Jan. 6, 1993). Likewise, the use of vignettes on an otherwise-appropriate label can raise misbranding concerns. See *id.* at 2922 ("[F]or a beverage label to not be misleading, it is necessary that the vignette and other label statements on the beverage not conflict in any way."); *ibid.* ("[FDA] will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information or for other reasons.").

after giving FDA authority in the FDCA to regulate the misbranding of food products. See 21 U.S.C. 331-334, 343, 371 (Supp. IV 1938); 15 U.S.C. 1125 (1946). Congress has repeatedly amended both laws without addressing their overlap. In that time, food labels have been challenged under Section 43(a) of the Lanham Act. *E.g., Hesmer Foods, Inc.* v. *Campbell Soup Co.*, 346 F.2d 356, 359 (7th Cir.) (naming a product "Barbecue Beans" despite the fact it neither contains meat nor was cooked over an open fire), cert. denied, 382 U.S. 839 (1965); *Potato Chip Inst.* v. *General Mills, Inc.*, 333 F. Supp. 173 (D. Neb. 1971) (addressing challenge to package label describing dehydrated potato product "CHIPOS" as potato chips), aff'd, 461 F.2d 1088 (8th Cir. 1972) (per curiam). If Congress intended to foreclose such suits, it could easily have done so in the NLEA or otherwise. See *Hagen* v. *Utah*, 510 U.S. 399, 416 (1994); cf. *Wyeth* v. *Levine*, 555 U.S. 555, 574 (2009) ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history."). The fact that Congress has not expressly addressed the application of Section 43(a) of the Lanham Act to food labels therefore casts doubt on the seemingly categorical breadth of the court of appeals' reasoning.

2. Nor can the breadth of the court of appeals' decision be justified on other grounds.

a. In *Schering-Plough Healthcare Products, Inc.* v. *Schwarz Pharma, Inc.*, 586 F.3d 500, 505-509 (2009), the Seventh Circuit held that an ongoing FDA proceeding about alleged misbranding of the subject drug made an action under Section 43(a) of the Lanham Act against the drug's manufacturer unripe and unsuitable for resolution on summary judgment. In that court's view, "FDA

should be given a chance to opine on the proper labeling before a Lanham Act suit is filed, * * * since it has more experience with consumers' understanding of drug labels than judges do." *Id.* at 508-509. The court of appeals below similarly expressed the view that the resolution of petitioner's claim fell within FDA's special competence, and it suggested that petitioner bring its complaints directly to FDA. Pet. App. 12a.

Such considerations—which mirror those underlying the doctrine of primary jurisdiction, see *Reiter* v. *Cooper*, 507 U.S. 258, 268-269 (1993)—lack force here. Most fundamentally, petitioner's claim arises under the Lanham Act, and it does not rely for its success on FDA's regulations (or, therefore, on FDA's application of those regulations). FDA does not administer the Lanham Act, and it has no authority to resolve a competitor's claim of competitive injury due to a misleading label.[4]

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[4] The FDCA's food misbranding provision makes one reference to "unfair competition" in connection with ingredient disclosure, but it is not relevant here: "To the extent that compliance with the requirement[] [to disclose all ingredients in foods with two or more ingredients] * * * results in deception or unfair competition, exemptions shall be established by regulations." 21 U.S.C. 343(i). FDA has promulgated such exemptions, which are now codified at 21 C.F.R. Pt. 101, Subpt. G. FDA elucidated the statutory reference to "unfair competition" when it promulgated the predecessors to those exemption regulations:

> [Because] there may be no feasible way to determine whether nonfunctional trace amounts of some particular substances remain in particular lots of a finished food, * * * label declaration of such ingredients would be false and misleading for those lots which do not contain any remaining traces of such incidental substances. Furthermore, to require lengthy listings of such substances might cause consumers to give undue attention to the essentially meaningless compilations resulting in deception and unfair competition from competing products whose manufactur-

Moreover, the application of primary-jurisdiction-like principles presupposes that the parties may "apply to the [agency] for a ruling." *Reiter*, 507 U.S. at 268 n.3 (citation omitted). But FDA does not accept formal petitions to take a discretionary enforcement action (see 21 C.F.R. 10.30(k)), and its discretionary decision whether to initiate an enforcement action would not be subject to judicial review (see *Heckler* v. *Chaney*, 470 U.S. 821, 837-838 (1985)). Cf. *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (concluding that Lanham Act Section 43(a) plaintiff did not need to exhaust administrative remedies because the FDCA creates no administrative procedure for resolving claims of false advertising of animal drugs and because FDA lacks "authority to award the compensatory and punitive damages sought by [the plaintiff]"). Petitioner could petition FDA to undertake a rulemaking to revise its labeling regulations for juice mixtures (21 U.S.C. 371(e)(1)(B); 21 C.F.R. 102.19(a)), but such a rule would not itself redress petitioner's competitive injury. In short, FDA's expertise in this field is not deployed in a way that justifies categorically depriving petitioner of a cause of action under Section 43(a) of the Lanham Act.

b. The court of appeals also treated the absence of an FDA enforcement action against respondent as an affirmative signal that no Lanham Act claim was available.

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ers fail to do as thorough a job of imagining all possible substances which may be present in some trace amount.

38 Fed. Reg. 20,705 (Aug. 2, 1973). The statute thus reflects a narrow concern that FDA should be able to temper label requirements that would otherwise compel manufacturers to put themselves at an unwarranted competitive disadvantage; it is not a broader mandate that FDA police all matters of unfair competition in food labeling.

See Pet. App. 10a-12a. To be sure, affirmative FDA *approval* of specific labeling—as in the prescription drug context, for example, see 21 U.S.C. 355(d)—would preclude a claim under Section 43(a) of the Lanham Act, if that claim rested on grounds that would conflict with a determination underlying the agency's approval. Cf. pp. 17-18, *infra*. But FDA does not approve juice labels, and its failure to initiate an enforcement action cannot be construed as such an approval. See *Chaney*, 470 U.S. at 831 (observing that an agency contemplating enforcement action "must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all").

c. Finally, courts have rejected private suits seeking enforcement of agency-administered statutes and regulations "dressed up as a Lanham Act claim." See, *e.g.*, *Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248, 1254-1255 (10th Cir. 1999) (rejecting as precluded plaintiff's claim that because defendant's advertising allegedly violated the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and regulations thereunder, such advertising was actionable under the Lanham Act). Those courts have concluded that the private right of action under Section 43(a) of the Lanham Act cannot be used to circumvent Congress's determination that provisions of another statute or agency regulations should not, as such, be privately enforceable. Whatever the force of that reasoning, it does not apply here. As we understand it, petitioner does not seek to prove its Lanham Act claim by showing that respond-

ent's juice's label violates the FDCA or FDA's regulations; rather, it seeks to show that the label bears a misrepresentation independently made actionable by the Lanham Act irrespective of the FDCA. Cf. *Cottrell*, 191 F.3d at 1255-1257 (allowing plaintiff to pursue theories on which it had "alleged sufficient facts to support a Lanham Act claim independent of FIFRA").[5]

3. a. Although the court of appeals' preclusion reasoning was too broad, it was correct to recognize that FDA's regulations preclude a Lanham Act challenge to the common name of respondent's juice. The parties do not seriously contest that 21 C.F.R. 102.33 envisions that a blend of juices characterized by flavors of pomegranate and blueberry may be represented as "Pomegranate Blueberry Flavored" (see 21 C.F.R. 102.33(b) and (d)), so long as the common name indicates the presence of other juices by further describing the product as, for example, a "Blend of 5 Juices" (see 21 C.F.R. 102.33(c)). Indeed, the common name of respondent's juice closely parallels examples that FDA's regulations offer as permissible common names for juice mixtures. See pp. 2-3, *supra*.

FDA explained that those naming regulations were calculated "to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the

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[5] In the preemption context, this Court has recognized, analogously, that although a State may not supply a private cause of action based solely on a violation of federal statutes that are not privately enforceable, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (Medical Device Amendments to the FDCA), a State is permitted to adopt its own regulatory or tort duties that "parallel" (*i.e.*, are the same as) duties under such federal statutes, see, *e.g.*, *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (Medical Device Amendments to the FDCA); *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 447-448 (2005) (FIFRA).

product." 58 Fed. Reg. 2920 (Jan. 6, 1993). The agency noted its "aware[ness] of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount." *Ibid.* Yet FDA discussed at length why it would not be misleading to describe such a beverage as "flavored" with a non-predominant juice, even while not listing by name or percentage the other juices present. *Id.* at 2918-2921.

Within their limited reach, those naming regulations reflect the agency's balance of competing considerations in a specific setting that could be easily upset by the intrusion of a general private remedy such as that provided under Section 43(a) of the Lanham Act. Cf. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 874-886 (2000) (explaining how, in that case, imposition of a general tort duty would frustrate a delicately crafted motor vehicle safety regulation). Success on petitioner's claim that the common name of respondent's juice was misleading would undo what the parties seemingly accept as FDA's regulations' specific pronouncement on that very subject. Accordingly, invocation of the general remedy under Section 43(a) of the Lanham Act specifically for the claim regarding the common name of respondent's juice is not "capable of coexistence" with those regulations, *J. E. M. Ag Supply*, 534 U.S. at 143 (citation omitted), and must give way. Indeed, the clash is particularly acute here because the content of FDA's naming regulations derives largely from the agency's answer to the question of what will and will not mislead juice consumers—essentially the question posed by petitioner's Lanham Act claim.

b. By contrast, petitioner should be free to challenge aspects of respondent's juice's label that are not specifi-

cally addressed by the FDCA or FDA's regulations. In particular, the FDCA and FDA have not specifically addressed "how [respondent] presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label." Pet. App. 10a. Petitioner appears to contend that the prominence of the former words relative to the latter obscures the message that FDA believed would be conveyed by designating a characterizing juice as a "flavor." See Pet. 8.

Certainly, the FDCA touches on that issue by providing that a food is misbranded if required label material (such as a juice mixture's common name) "is not prominently placed [on the label] with such conspicuousness * * * as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase." 21 U.S.C. 343(f). But a suit under Section 43(a) of the Lanham Act successfully challenging an inconspicuous disclaimer would tend to *reinforce*, not undo, that requirement. And indeed, FDA specifically cautioned manufacturers who would take advantage of 21 C.F.R. 102.33(b)-(d) about the potential for their labels to mislead. See note 3, *supra*. Because the non-naming aspect of petitioner's Lanham Act claim can easily co-exist with the FDCA and FDA's regulations, the court of appeals erred in concluding it was precluded.

B. The Court Of Appeals' Error Implicates No Developed Circuit Conflict

1. Petitioner contends (Pet. 16-24; Pet. Reply Br. 5-10) that the decision below conflicts with decisions of other courts of appeals in Lanham Act cases. Any conflict is too oblique to justify review. None of the cases petitioner cites concerned the preclusive effect of the FDCA's regulation of food labels and labeling. See *Alpharma*, *supra* (antibiotic animal feed additive regulated

by FDCA's animal drug provisions and regulations thereunder); *Cottrell*, *supra* (cleaning product governed by FIFRA's pesticide provisions and regulations thereunder); *Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990) (cough syrup regulated by FDCA's over-the-counter drug provisions and regulations thereunder, and under the Federal Trade Commission's authority); cf. *Wyeth*, *supra* (addressing preemptive effect of FDCA's name-brand prescription drug provisions and regulations thereunder).

To be sure, some tension may exist between the reasoning in those cases and the reasoning of the decision below. But no square conflict is presented because, as explained (pp. 9-13, *supra*), the court of appeals' error traces principally to its misapprehension of the scope and purpose of the FDCA's food labeling provisions and particular FDA juice-labeling regulations.

2. As for challenges to food labels under Section 43(a) of the Lanham Act, other courts of appeals have proceeded to the merits of such claims. See *PBM Prods., LLC* v. *Mead Johnson & Co.*, 639 F.3d 111 (4th Cir. 2011) (infant formula); *American Italian Pasta Co.* v. *New World Pasta Co.*, 371 F.3d 387 (8th Cir. 2004) (pasta); *Mead Johnson & Co.* v. *Abbott Labs.*, 201 F.3d 883 (7th Cir.) (infant formula), cert. denied, 531 U.S. 917 (2000). But to our knowledge all have done so without addressing the question presented, presumably because that threshold question was not raised (and, indeed, may not have been implicated on the facts of those cases). If the question presented in this case is significant, then the opportunity for beneficial percolation in lower courts exists because claims like petitioner's can be expected to be brought in the future challenging food labels. At the present time, however, in the absence of a conflict of

appellate decisions addressing the availability of a remedy under Section 43(a) of the Lanham Act concerning food labels, the issue does not warrant this Court's review.

C. The Record In This Case Is Unclear Concerning The Nature Of Respondent's Alleged Misrepresentation

An additional feature of this case weighs against review. This case was resolved on summary judgment after full fact and expert discovery. Yet the summary judgment record may be equivocal on the precise misrepresentation that petitioner's Lanham Act claim challenges.

In particular, petitioner's expert testimony that the label of respondent's juice misleads consumers was based on an in-person consumer survey. See Doc. 152-2 Exh. 1 (petitioner's expert's report). That survey was conducted by comparing consumers' reactions to the actual product package with other consumers' reactions to a modified package that removed the words "Pomegranate Blueberry." See *id.* at 1-2. As respondent pointed out to the district court (*e.g.*, Doc. 150, at 2), that survey may simply reflect that some consumers are misled by the *common name* of the juice (which was altered on the modified package). Of course, it may be that the survey reflects that some consumers were misled by the *presentation* on the package of the otherwise non-misleading common name.

That ambiguity in what we take to be petitioner's key evidence is problematic. As explained (pp. 17-19, *supra*), the question of what feature of the label misleads consumers is material to the proper analysis of whether a claim under Section 43(a) of the Lanham Act is precluded. Yet the ambiguity in the record suggests that this case may not properly present the very distinction that

is required for a sound resolution of the question presented. That would be an additional, prudential reason to deny review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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