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

REPLY BRIEF FOR PETITIONER

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RULE 29.6 STATEMENT

The Rule 29.6 statement included in Pom Wonderful LLC's opening brief remains correct.

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Because Pom's Lanham Act claim was dismissed as a matter of law, this case comes to the Court on a limited record. But the complaint and record evidence show that Coca-Cola is willfully misleading consumers in order to take market share from Pom. Coca-Cola sells and markets as "POMEGRANATE BLUEBERRY" a product that contains only 0.3% pomegranate juice and 0.2% blueberry juice. There is no way consumers can know that Coca-Cola's product contains almost no pomegranate or blueberry juice, and consumers are, in fact, misled—a risk Coca-Cola was "willing to assume." Pet. App. 32a-35a.

Against this backdrop, Coca-Cola urges the Court to deny Pom the remedy Congress expressly provided businesses against competitors who misappropriate market share by intentionally misleading consumers about the product they sell. But Coca-Cola provides no colorable support for that extraordinary request. It concedes that no provision of the Food, Drug and Cosmetic Act ("FDCA") or the Nutrition Labeling and Education Act of 1990 ("NLEA") expressly displaces the Lanham Act. And it does not even attempt to show that the Lanham Act irreconcilably conflicts with the FDCA or the NLEA.

Instead, Coca-Cola asks this Court to divine an unspoken congressional intent in the NLEA to displace the Lanham Act in order to achieve "national uniformity"—a phrase Coca-Cola recites scores of times. The substantive provisions of the NLEA, however, established rules governing nutritional information and health claims on food labeling, which are not at issue here. Thus, all Coca-Cola can point to is the NLEA's express preemption clause, which displaces only state law—not federal law—and even then does so only partially. The fact that Congress preempted some state laws governing food labeling but did not displace the Lanham Act bolsters the case *against* preclusion. It is a non sequitur to argue, as Coca-Cola does, that a federal interest in uniformity compels the conclusion that Congress, without saying so, intended to limit application of the *nationally uniform federal* Lanham Act. Application of that law by judges and juries on a case-by-case basis is no more at odds with uniformity than application of the federal securities laws, the Patent Act, or any other federal law.

The United States agrees that the judgment should be reversed, and it correctly urges the Court to permit

Pom's challenge to Coca-Cola's label as a whole to proceed. But the United States errs in contending that the *name* of Coca-Cola's product is immune from challenge if it is in compliance with FDA's juice-naming regulation (a question the United States recognizes cannot be resolved on the limited, existing factual record). That position cannot be reconciled with *Wyeth* v. *Levine*. Even more so than the drug-labeling regime at issue in *Wyeth*, which required FDA to approve the specific label later challenged in state-court litigation, FDA's juice regulations do not set a "ceiling." A company may avoid FDA enforcement action to the extent it complies with FDA's rules, but that does not confer immunity for misleading consumers and unfairly acquiring market share. Nothing in the regulations prevented Coca-Cola from using a label (and a name) that would not mislead consumers. Coca-Cola chose a markedly different path, and it is responsible for defending that choice under the Lanham Act.

I. THE LANHAM ACT CANNOT BE SET ASIDE ABSENT AN IRRECONCILABLE CONFLICT

Coca-Cola argues (18-21) that a subsequently enacted "specific" federal law can nullify a more "general" law even in the absence of an irreconcilable conflict. It thus contends (21-22) that the Lanham Act can be rendered inapplicable if the Court is able to discern an unarticulated congressional intent to do so in the 1990 NLEA. Coca-Cola's invitation to re-write the Lanham Act in the guise of clarifying it should be rejected.

As the Solicitor General points out (3 n.2, 17), the substantive statutory provisions at issue derive from the 1938 FDCA—not from the NLEA, which added provisions directed to *nutritional* information not at issue in this case. *See infra* pp. 10-11. The only NLEA

provision remotely relevant is a partial *state-law* preemption provision that by its terms does not apply to Pom's Lanham Act claim. *See infra* pp. 7-14. This alone disposes of Coca-Cola's contention that the NLEA implicitly narrows the scope of the Lanham Act.

Moreover, the "general/specific" canon applies only where "a general permission or prohibition is contradicted by a specific prohibition or permission" or where the specific provision would be rendered superfluous by the general one. *RadLAX Gateway Hotel, LLC* v. *Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012). There is no "contradict[ion]" or "superflu[ity]" here. *Id.* The FDCA "prohibit[s]" misbranding, 21 U.S.C. §§331, 343, and subjects violators to criminal and regulatory penalties, *id.* §§333(a), 334(a)(1). The Lanham Act bars "false or misleading" statements in commercial advertising and provides civil remedies to injured competitors. 15 U.S.C. §§1125(a)(1), 1117-1118. No one disputes that compliance with both prohibitions is possible.

The cases Coca-Cola relies on (18-20) do not support its position. The very passage Coca-Cola quotes from *United States* v. *Fausto*, 484 U.S. 439 (1988), underscores the important difference between implying preclusion of "express statutory text" (*id.* at 453)—which is exactly what Coca-Cola advocates here—and reading a subsequent statute, enacted to "comprehensively overhaul[]" (*id.* at 443) an "outdated patchwork of … rules" (*id.* at 444), sensibly to reject "the implication" of a remedy under the *ancien regime* (*id.* at 453). *See also id.* ("All that we find to have been 'repealed' by the CSRA is the judicial interpretation of the Back Pay Act"). When the former is at stake, as here, *Fausto* reaffirms that "it can be strongly presumed that Congress will specifically address language on the statute books that it wishes to change." *Id.*

Elgin v. *Department of Treasury*, 132 S. Ct. 2126, 2133 (2012), is even more inapposite. It falls under this Court's precedents addressing laws that "simply channel[] judicial review of a constitutional claim to a particular court." *Id.* at 2132. In such cases, the only question is whether the same claim can be brought in multiple fora. In answering that question, the Court understandably does not require Congress to recite the obvious: that it intends to avoid "duplicative judicial review." *Id.* at 2135, 2133-2136.

Coca-Cola also invokes *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), and *Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003), for the principle that, where a statute has a "range of plausible meanings" when enacted, "subsequent acts can shape or focus *those* meanings." Resp. Br. 20 (quoting *Brown & Williamson*, 529 U.S. at 143) (emphasis added). Neither of those cases (or the other two Coca-Cola cites)[1] creates a judicial license to venture outside a statute's "range of plausible meanings" absent an irreconcilable conflict. *Brown & Williamson*, 529 U.S. at 143.

Here, Coca-Cola struggles even to articulate which language in the Lanham Act it purports to interpret.

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[1] In *United States* v. *Estate of Romani*, the Court found a "'plain inconsistency'" between the two relevant statutes. 523 U.S. 517, 533 (1998). In *Brotherhood of Railroad Trainmen* v. *Chicago River & Indiana Railroad Co.*, the Court held that the plain terms of the Railway Labor Act ("RLA") "should be literally applied in the absence of a clear showing of a contrary or qualified intention of Congress." 353 U.S. 30, 35 (1957); *see also id.* at 41 ("'[T]he Norris-LaGuardia Act can affect the present decree only so far as its provisions are found not to conflict with those of [the RLA]....'").

In a footnote (20-21 n.10), Coca-Cola contends that the Lanham Act's phrase "false or misleading" should be construed to mean false or misleading unless the deception involves "aspects of a nationally-uniform juice label that have been chosen in compliance with the FDCA and the FDA's regulations." That is not *interpretation* of statutory text; it is statutory *revision* that must be rejected absent an irreconcilable conflict.

II. UNDER ANY FRAMEWORK, THE NLEA AND THE FDCA DO NOT DISPLACE THE LANHAM ACT

In any event, under any framework, Coca-Coca's argument that the NLEA and the FDCA *sub silentio* displace the Lanham Act fails. There is no indication Congress intended such displacement.

A. There Is No Irreconcilable Conflict

Coca-Cola does not contest that it "can easily satisfy both [statutory] mandates." *Department of Transp.* v. *Public Citizen*, 541 U.S. 752, 767 (2004). It claims (48) that the Lanham Act and the FDCA are in "tension" because they both apply to the "same thing" in "non-identical" ways. But this "tension" merely reflects the statutes' distinct purposes. "[A] typical false-advertising case … implicate[s] *only* the [Lanham] Act's goal of 'protect[ing] persons engaged in [commerce within the control of Congress] against unfair competition'"—not consumer protection. *Lexmark Int'l, Inc.* v. *Static Control Components, Inc.*, 572 U.S. __ (2014) (slip op. 12) (last alteration in original; emphasis added). In contrast, the FDCA's misbranding provisions protect the public's health and safety through

criminal and regulatory penalties. Pet. Br. 26-27; 21 U.S.C. §393 (b)(2)(A).[2] In any event, "tension" does not establish an "irreconcilable conflict." *Public Citizen*, 541 U.S. at 766-767.[3]

B. The NLEA's Preemption Provision Does Not Support Coca-Cola

Coca-Cola's position (16, 24-36) rests almost entirely on the argument that the NLEA's state-law preemption provision sought to achieve "national uniformity" and thus shows that Congress must have also "intended to preclude a Lanham Act claim." There is no support for that novel contention, which disregards the NLEA's

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[2] Coca-Cola suggests (4, 48) that the FDCA provisions at issue are a form of economic consumer protection, but the provision Coca-Cola cites (21 U.S.C. §341) is irrelevant to the issues in this case.

[3] In a footnote (21-22 n.11), Coca-Cola cites *Credit Suisse Securities (USA) LLC* v. *Billing*, 551 U.S. 264 (2007), which applied the unique doctrine of antitrust immunity. *See, e.g.*, *Branch* v. *Smith*, 538 U.S. 254, 293 (2003) (O'Connor, J., concurring in part) ("[O]utside the antitrust context, we appear not to have found an implied repeal of a statute since 1917."). But here, Pom's claim poses *no* risk of a "'chilling effect' on 'lawful joint activities … of tremendous importance to the economy of the country.'" 551 U.S. at 283. Quite the contrary, FDA has "*encouraged*" manufacturers to declare "each juice in a beverage … in the name of the product." 58 Fed. Reg. 2897, 2919 (Jan. 6, 1993) (emphasis added). Further, unlike the SEC in *Credit Suisse*, FDA has not "actively enforce[d] the rules and regulations that forb[ade] the conduct in question." *Compare* 551 U.S. at 283, *with* Pet. Br. 52-56; *infra* pp. 22-23. And FDA has no statutory obligation to address the concerns underpinning the purportedly conflicting statute. *Compare* 551 U.S. at 283, *with* U.S. Pet. Br. 14 (FDA lacks "authority to resolve a competitor's claim of competitive injury due to a misleading label.").

text, misconstrues its purpose, lacks foundation in this Court's precedents, and fails even on its own terms.

1. When Congress wants to preclude both state and federal law, it does so explicitly—including in the context of product labeling. *See, e.g.*, 15 U.S.C. §1334(a) ("[N]o statement relating to smoking and health, other than the statement required by [15 U.S.C. §1333], shall be required on any cigarette package."); *cf.* 49 U.S.C. §10501 ("[R]emedies provided under [Surface Transportation Board statute] are exclusive and preempt the remedies provided under Federal or State law."). In §343-1, Congress did the opposite: It expressly preempted only certain state requirements, disavowed any implied preemption, and never mentioned federal law.

Coca-Cola questions (31-32 & n.20) whether Congress was really aware that the Lanham Act applied to misleading food labels. But this Court presumes Congress' knowledge of the law, *see Cannon* v. *University of Chi.*, 441 U.S. 677, 697-698 (1979), and the decisions and hearings cited by Pom (29-30) underscore that there is no basis to discard that presumption here. The pendency of Lanham Act suits against misleading juice labels just as Congress was considering the NLEA confirms as much. *See, e.g.*, *Grove Fresh Distribs., Inc.* v. *Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 715 (N.D. Ill. 1989) ("Flavor Fresh 100% Orange Juice from Concentrate").

2. Nor can Coca-Cola justify its atextual interpretation based on an asserted need for "national uniformity." As Pom previously explained (31), laws that prohibit false or misleading labeling do apply a "'single, uniform'" standard. *Altria Group, Inc.* v. *Good*, 555 U.S. 70, 79-80 (2008); *see also id.* at 82. That is true, a

fortiori, where the relevant standard is set out in a *federal* statute. Congress has long recognized private rights of action under federal laws even in areas where the need for national uniformity has constitutional pedigree. *See Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) ("[O]ne of the fundamental purposes behind the Patent … Clause[] … was to promote national uniformity in the realm of intellectual property."); 35 U.S.C. §281 (private right of action for patent infringement).

Coca-Cola's and its amici's concern with inconsistent jury determinations is similarly unfounded. *See* Resp. Br. 2, 25, 29; GPhA Br. 12; Am. Bev. Ass'n Br. 6, 15; Chamber of Commerce et al. Br. 27. The FDCA specifically "contemplates that federal juries will resolve most misbranding claims." *Wyeth* v. *Levine*, 555 U.S. 555, 570 (2009). "[L]ay juries," therefore, "are in no sense anathema to [the FDCA's] scheme." *Bates* v. *Dow AgroSciences LLC*, 544 U.S. 431, 452 (2005) ("[T]here is no reason to think [inconsistent verdicts] would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that every day bear the risk of conflicting jury verdicts."). Nor can Coca-Cola or its amici point to a single instance of such inconsistent determinations, despite the longstanding availability of Lanham Act claims in this area. *See* Pet. Br. 29.[4] This

[4] Fearmongering by Coca-Cola and its amici that one jury will require one thing and another will mandate something different is no more persuasive here than it was in *Wyeth*. Juries do not prescribe the contents of labels: They decide only whether, on the evidence presented, a challenged label is false or misleading and, if so, whether the manufacturer acted willfully.

case confirms that juice manufacturers—like all other participants in the national economy, who are undisputedly subject to the Lanham Act—can readily ascertain when their products pose a "'risk from a misleading standpoint.'" Pet. App. 35a.

The structure of §343-1 squarely refutes Coca-Cola's argument that Congress intended absolute "national uniformity." Certain FDCA misbranding requirements *never* preempt state laws—most significantly, the FDCA's prohibition on false or misleading labels, §343(a)(1). Resp. Br. 33, 52; U.S. Br. 25. States, moreover, can petition for exemptions from preemption (§343-1(b)), and may directly enforce certain misbranding provisions when FDA does not (§337(b)). And courts and juries necessarily interpret the FDCA and FDA regulations when adjudicating state-law claims that are "identical" to the FDCA and thus not preempted. *See* 21 U.S.C. §343-1(a)(1)-(5); U.S. Br. 27.[5] The NLEA thus reflects a compromise between even *state-by-state* regulation and "national uniformity"—not complete abdication to FDA.

To the extent the NLEA expresses any heightened desire for uniformity, it is with respect to nutritional information. Congress's purpose in enacting the *Nutrition* Labeling and Education Act was "to make sense of the confusing array of nutrition labels" then prevailing. 136 Cong. Rec. H5840 (July 30, 1990) (Rep. Waxman). To accomplish this goal, the NLEA required "[n]utrition [l]abeling" in most food products—i.e., the

[5] Coca-Cola takes the extreme position (33 n.23) that even claims under "identical" state laws cannot proceed. That contention is foreclosed by the plain terms of §343-1.

now-ubiquitous "Nutrition Facts" panel. *See* Pub. L. No. 101-535, §2, 104 Stat. 2353 (21 U.S.C. §343(q) ("Nutrition Labeling")). NLEA thus created a "uniform nutrition label that would disclose the amount of calories, fat, salt, and other nutrients." 136 Cong. Rec. at H5840.[6] Indeed, the section title upon which Coca-Cola so heavily relies (1, 7, 24, 51 n.40) refers to "National Uniform *Nutrition* Labeling." 21 U.S.C. §343-1 (emphasis added).

3. There is also no support in this Court's precedents for Coca-Cola's contention that NLEA's selective preemption of state law can be extended to preclude claims under federal law. Coca-Cola cites *Fausto* and *Elgin* (24), but those cases—both of which arise in the context of the Civil Service Reform Act and neither of which involves a preemption provision—are wholly inapposite. The "leading purpose" of the statute was "to replace the haphazard arrangements for administrative and judicial review of personnel action" for federal employees, *Fausto*, 484 U.S. at 444, with a comprehensive, integrated system of review that would remove the risk of inconsistent "fact-finding as well as interpretation of law" by different courts with concurrent jurisdiction, *id.* at 451. *See Elgin*, 132 S. Ct. at 2135 (similar). In contrast, nothing in the NLEA suggests that

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[6] *See also id.* at H5843 ("The main features of the bill require mandatory nutrition labeling for most foods that will be uniform throughout the country.") (Sen. Madigan); 136 Cong. Rec. S16607, S16609 (Oct. 24, 1990) ("The elements of this bill will help all consumers to better understand and improve their eating habits by providing uniform nutritional information in a coherent and understandable format.") (Sen. Mitchell); *id.* at S16610 (NLEA "will mandate that all processed package foods have uniform nutritional labels") (Sen. Hatch).

Congress was interested in concentrating adjudications in any particular forum. The NLEA left district courts in charge of resolving charges of misbranding, continued to permit parallel state-court proceedings under state law, and actually created a vehicle for state authorities to bring their own FDCA enforcement proceedings (presumably in state courts) when FDA does not. Pub. L. No. 101-535, §4, 104 Stat. 2353 (21 U.S.C. §337(b)).[7] The NLEA was intended only to avoid state-by-state variations in substantive standards. That interest is not implicated by permitting enforcement of a federal statute that applies equally in all 50 States.

Coca-Cola also cites (25-26) three lower-court decisions addressing the interplay between the Federal Employers' Liability Act ("FELA"), which provides a negligence remedy for railroad employees, and the Federal Railroad Safety Act ("FRSA"), which requires the Secretary of Transportation to promulgate standards for the safe operation of railroads that expressly preempt state law. The cited cases, which represent one side of a developing split,[8] lack analogic force. Pre-

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[7] *Keogh* v. *Chicago & Northwestern Railway Co.*, 260 U.S. 156 (1922), is even farther afield. *Keogh* held that the filed-tariff doctrine precluded damages under the Sherman Act because such damages "might, like a rebate, operate to give … a preference [to the plaintiff] over his trade competitors." *Id.* at 163. Nothing of the sort is at issue here.

[8] *See, e.g.*, *Cowden* v. *BNSF Ry. Co.*, 690 F.3d 884, 892 (8th Cir. 2012) (deciding appeal on other grounds to avoid "creat[ing] a circuit split on this issue"); *Infermo* v. *New Jersey Transit Rail Operations, Inc.*, No. 10-2498, 2012 WL 209359, at *6 (D.N.J. Jan. 24, 2012) (preclusion of FELA "very problematic"); *Earwood* v. *Norfolk S. Ry. Co.*, 845 F. Supp. 880, 891 (N.D. Ga. 1993) (rejecting FELA preclusion).

clusion of FELA claims might be justified by the need to avoid disparate treatment of accident victims who differ only with respect to their status as railroad employees or non-employees. *See Lane* v. *R.A. Sims, Jr., Inc.*, 241 F.3d 439, 442 (5th Cir. 2001). By contrast, here, *all* plaintiffs suffering an "injury to a commercial interest" are able to sue. *Lexmark* (slip op. at 13). Any "disparity" between commercial plaintiffs (who have a federal remedy under the Lanham Act) and consumers (who have rights under state law) would merely reflect Congress' judgment that commercial plaintiffs suffer different types of harm. *See id.*

4. Even assuming §343-1 could somehow affect other federal laws, Pom's Lanham Act claim would still proceed. Coca-Cola strives (28-29) to link each allegation underlying Pom's claim to a subsection of §343. But if Pom's Lanham Act challenge is "of the type" of any section of the FDCA, it would be §343(a)(1)—the FDCA's prohibition on misleading labeling. *Cf. Altria*, 555 U.S. at 84 (prohibition on deceptive practices "is a general rule that creates a duty not to deceive" and is not "'based on'" the specific subject matter addressed by the preempting provision). State-law claims that parallel §343(a)(1) are not preempted under the NLEA. *See* 21 U.SC. § 343-1 & note (saving clause).[9]

Coca-Cola's only response (32) is that Congress "cannot have contemplated" that §343(a)(1) would

[9] Several courts have found that state-law claims challenging labels as misleading are not preempted. *See, e.g.*, *Chavez* v. *Blue Sky Natural Beverage Co.*, 268 F.R.D. 365, 370 (N.D. Cal. 2010); *Pom Wonderful LLC* v. *Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1122 (C.D. Cal. 2009). The district court in this case disagreed, but Pom's appeal is pending.

"cover" circumstances where other §343 subsections might also be relevant. But, again, Coca-Cola is asking the Court to imagine carve-outs in the statutory text (this time, in §343) that Congress never enacted. In fact, Coca-Cola acknowledges (33 n.22) that FDA has used §343(a)(1) precisely to address misleading labels "covered" in part by other subsections of §343.[10] *See* U.S. Br. 19 (compliance with specific FDA regulations does not make label non-misleading).

C. FDA's Juice-Naming Regulations Do Not Displace The Lanham Act

Coca-Cola and the government argue that FDA's regulations displace the Lanham Act where they specifically "permit" the challenged aspects of a label. This argument fails in multiple respects.

As a threshold matter, the government's analysis of the juice-naming regulations (18-20) relies on "obstacle" preemption cases. The "irreconcilable conflict" standard, however, is markedly more demanding—courts must strive, wherever possible, to give full effect to all congressional enactments. *See* Pet. Br. 20-21. Moreover, while federal regulations can preempt state laws, federal regulations cannot trump a federal statute. Thus, whatever may be said about "obstacle" preemption, *see Wyeth*, 555 U.S. at 594 (Thomas, J., concurring in the judgment), analogies to that doctrine here are a

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[10] *See also* Institute of Medicine, *Food Labeling: Toward National Uniformity* 77 (1992) (noting "interrelationship" of § 343(a)(1) with other subsections and that, "when the Committee reviewed the enforcement history of regulatory actions taken by FDA, it invariably encountered charges under multiple sections of FDCA").

one-way street: They can (and, in this case, do) prove that a federal statute is not impliedly precluded, but not vice versa.

In any event, the government's preemption analysis is flawed. As in *Wyeth*, FDA's juice-labeling regulations constitute merely a "floor," not a "ceiling." The government attempts (20) to distinguish *Wyeth*, but the purported distinctions it draws bolster the case *against* preclusion. The government first notes the absence of an express state-law preemption provision in *Wyeth*. But the government elsewhere acknowledges (25 n.10) that "[t]here is … little reason to think Congress intended to preclude federal Lanham Act claims to the same extent state-law claims are expressly preempted." The government also notes that *Wyeth* relied in part on statements previously made by FDA disclaiming preemption. But the Court relied on those statements to reject FDA's "dramatic change in position." 555 US. at 579. Finally, the government observes that, in *Wyeth*, FDA had not "consider[ed] and reject[ed] a stronger warning." Here, however, FDA has never reviewed Coca-Cola's label much less rejected any proposal to make that label less misleading. *See* U.S. Br. 29 n.12.

Fidelity Federal Savings & Loan Ass'n v. *de la Cuesta*, 458 U.S. 141 (1982), which did not involve displacement of a federal statute, highlights why FDA's juice-naming regulation is a particularly poor candidate for implied preclusion. In *de la Cuesta*, the Court found preemption because there was a clear conflict between an agency's affirmative grant of "power" to the regulated entities and a state law restricting that "power." *Id.* at 141, 146-147, 154. In contrast, the FDCA's food misbranding provisions (and, thus, FDA's regulations) do not authorize conduct. They establish what the FDCA forbids manufacturers from doing lest their

products be considered misbranded and they be subject to government enforcement. *See* 21 U.S.C. §331(a) ("prohibit[ing]" misbranding); *id.* §343 (giving content to "misbranding").

Geier v. *American Honda Motor Co.*, 529 U.S. 861 (2000), is likewise inapposite. *Geier* holds that where an agency acts to *encourage* the conduct being challenged in order to advance the statute's regulatory purpose, state laws cannot undermine that judgment. *Id.* at 881. But here, FDA has not encouraged manufacturers to obscure the contents of their products as Coca-Cola has done. FDA has "*encouraged*" manufacturers to declare "each juice in a beverage … in the name of the product." 58 Fed. Reg. 2897, 2919 (Jan. 6, 1993). The government hints (19) at an undefined interest in manufacturer "'flexibility'" in this case. The Court, however, has rejected flexibility for flexibility's sake as a "significant regulatory objective" entitled to preemptive effect. *Williamson* v. *Mazda Motor of Am.*, 131 S. Ct. 1131, 1137 (2011). "[T]o infer from the mere existence of … cost-effectiveness judgment that the federal agency intends to bar States from imposing stricter standards would treat all … federal standards as if they were *maximum* standards." *Id.* at 1139.

D. Section 337 Does Not Displace The Lanham Act

There is no support for Coca-Cola's contention (23, 33 n.23, 39 n.29) that §337(a) precludes Lanham Act claims for misleading juice labels. Section 337(a) makes the government the exclusive enforcer of the FDCA, not the Lanham Act. Nor can Coca-Cola's argument be reconciled with *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 494-497 (1996), and *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 330 (2008), where the Court allowed state-law

claims "parallel" to the FDCA's provisions to proceed. *Cf. Bates*, 544 U.S. at 447-448 (FIFRA); *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341, 352-353 (2001) (distinguishing state-law claims in *Lohr* because they did not arise "solely from the violation of FDCA requirements").

III. COCA-COLA'S MISLEADING LABEL DOES NOT COMPLY WITH THE FDCA AND FDA'S REGULATIONS

For the foregoing reasons, Pom's Lanham Act claim should be allowed to proceed regardless of Coca-Cola's alleged regulatory compliance. Pom's challenge does not depend on the FDCA or FDA's regulations; it is Coca-Cola's theory that would "inject[] FDCA compliance questions into the case." U.S. Br. 28; *see* JA53a ("Thirty-Second Affirmative Defense."). In any event, Coca-Cola's compliance theory is deeply flawed.

Label as a Whole. No FDA regulation forecloses Pom's challenge to Coca-Cola's label as a whole. The government recognizes (19) that compliance with FDA's juice-naming regulation does not "render a juice *label* non-misleading" (emphasis added). Pom is thus entitled to proceed with its challenge to Coca-Cola's product and have a jury decide whether the label in its totality—including the name—is misleading. That is precisely the approach FDA took in the 2009 Warning Letter cited in Pom's opening brief (37 & n.6). In deeming the juice labels "misleading" under §343(a)(1), FDA relied principally on the juice names:

> The principal display panels identify the products as "Orange Tangerine" and "Grape," respectively, in large, bold lettering outlined in black; however, neither orange/tangerine juice

> nor grape juice is the predominant juice in the products.[11]

It noted other factors only as subsidiary considerations. *Id.* Just as FDA's finding of deception in that case was not "based on" the juice names, U.S. Br. 19 n.7, so too Pom would be permitted to argue to the jury, among other things, that Coca-Cola's label is misleading for displaying the words "Pomegranate Blueberry" in "large, bold lettering."

Font Sizes. Coca-Cola's new contentions that certain FDA regulations bar Pom from challenging the misleading use of a diminutive font for the words "Flavored Blend Of 5 Juices" are meritless. In the court of appeals, Coca-Cola relied only on §343(f) and §101.2 and §101.3 of FDA's regulations. *See* Appellees Br. 16. In its supplemental brief opposing certiorari, Coca-Cola claimed (3) for the first time that an FDA regulation requiring disclosure of added flavorings, §101.22(i)(1)(i), authorizes its reduced font size for the words "Flavored Blend of 5 Juices." FDA not only disagrees with the applicability of that regulation, *see* U.S. Br. 31-32, but also has explained that the provision does not address the font size of the phrase "Blend Of 5 Juices," *id.* 33.

Coca-Cola now claims (44 n.33) that a different provision, §101.22(i)(1)(iii), excuses its font-size selection. But that provision governs only the phrase "With Other Natural Flavor." 21 C.F.R. §101.22(i)(1)(iii) ("the name of the food shall be immediately followed by the

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[11] Warning Letter from Roberta F. Wagner, FDA, to Brad Alford, Nestle U.S.A., Dec. 4, 2009, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm.

words 'with other natural flavor' in letters not less than" the font size of the juice's name); U.S. Br. 32 n.15.

The Product Name. Coca-Cola's admission (44 n.33) that §101.22(i)(1)(iii) "directly applies here" confirms that Coca-Cola's product name is not in compliance. Section 101.22(i)(1)(iii) requires that "the name of the food shall be *immediately followed* by the words 'with other natural flavor.'" (Emphasis added.) Attempting to satisfy this requirement, Coca-Cola now proclaims (44 n.33) for the very first time in this litigation (and likely ever) that the name of its product is actually, improbably, "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES FROM CONCENTRATE WITH ADDED INGREDIENTS." But that dubious contention cannot be squared with the label itself, Coca-Cola's prior assertions, or the regulations Coca-Cola invokes. *See* Br. in Opp. 4; Appellee Br. 17; 21 C.F.R. §102.33(g)(1) (if stated just once, "from concentrate" must be "adjacent to the product name"); §101.30(b)(3) (not a naming regulation).

Additionally, as Pom has explained (51-52), a separate FDA regulation, §102.5(b), mandates declaration of the percent content of ingredients when the information "has a material bearing on price or consumer acceptance" or its omission would "create an erroneous impression." Coca-Cola does not contest that the pomegranate and blueberry juices meet §102.5(b)'s definition. Coca-Cola merely contends (38 n.28) that §102.5(b) does not apply because it has been "'modified by a specific regulation.'" But the text of §102.5(b) makes crystal clear that only its technical presentation requirements set forth at §102.5(b)(1)-(2) may be so modified. *See* 21 C.F.R. §102.5(b) (stating *after setting forth the percent-declaration* requirement: "The *following* requirements

shall apply unless modified by a specific regulation in subpart B of this part" (emphasis added)).

Finally, FDA has now concluded that to determine compliance with §102.33(d)(1), a remand would be necessary to adjudicate an "unresolved factual dispute": whether pomegranate and blueberry juices are, in fact, "'present as … flavor[s] or flavoring[s]'" as required. U.S. Br. 22-23 & n.8. Coca-Cola argues (40-41) that a juice can be present "as a flavor" even though it is present only in trivial amounts that must be "reinforced by added flavors." But that position, which would allow mere microns of a juice to satisfy §102.33(d)(1), is contradicted by both the plain meaning of the word "flavor" and FDA's longstanding position."[12] This issue was by no means waived. Coca-Cola's non-compliance came to light only when Coca-Cola admitted to it by invoking §101.22(i)(1)(i) in its supplemental brief. Resp. Supp. Br. 3; Pet. Br. 49-50. Because Pom's challenge was dismissed at the pleading stage, Pet. App. 92a, Pom has not had the opportunity to develop an adequate record.

Vignette, Multiple Lines, and Color. As the government explains, "nothing in the FDCA or its implementing regulations precludes" a claim against Coca-Cola's "fruit vignette as misleading." U.S. Br. 30 n.14; *see also id.* (after considering whether to issue specific regulations, FDA "ultimately opted for a case-by-case assessment" of vignettes); 58 Fed. Reg. at 2922 (same).

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[12] *See* 58 Fed. Reg. at 2921 ("[T]he term 'flavor' with the name of the characterizing juice will inform the consumer that *the juice is present in an amount sufficient to flavor the beverage*." (emphasis added)); U.S. Br. 23. The FDA discussion of flavored *waters* (58 Fed. Reg. at 2921) Coca-Cola cites (40) is inapposite.

Coca-Cola would infer from FDA's approach a license to use misleading vignettes until FDA takes action. But FDA itself (30 n.14) has rejected that interpretation in this case. Nor do any FDA regulations address Coca-Cola's decision to divide its product's name into different lines, or color its juice, in a misleading manner.

Again, Coca-Cola resorts to arguing waiver (28 n.16, 38-49). But at every stage, Pom has challenged Coca-Cola's label *as a whole*, and it has specifically identified individually misleading aspects of Coca-Cola's label.[13] And, at every juncture, Coca-Cola has attempted to respond.[14] The Ninth Circuit acknowledged that Pom challenged Coca-Cola's "name, labeling, marketing, and advertising." Pet. App. 3a. It addressed both "Pom's challenge to the name" and "the labeling component of Pom's claim." *Id.* 9a-10a. Although the court incorrectly stated that Pom did not "meaningfully" challenge the label's vignette on appeal, *id.* 10a,[15] the court did *not* find that Pom waived that

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[13] *See, e.g.*, Appellant Br. 1 ("Coca-Cola's naming and labeling"); *id.* n.1 (font size and line breaks); *id.* 28 n.11 (label's "place[ment of] 'Pomegranate Blueberry' on a separate line and in a larger font" and Coca-Cola's misleading "fruit vignette"); Pet. for Reh'g and Reh'g En Banc 3 (listing "several factors [that] worked together to create th[e] misleading effect, including the juice's name and font size, the fruit vignette on the juice's front label …, and the juice's dark purple color").

[14] *See, e.g.*, Appellee Br. 5 (juice-naming and vignette); *id.* 16 (font size and line breaks); *id.* 24 (name and vignette); *id.* 43 ("Pom contends that the Juice's label violates the [FDCA]'s *general misbranding provisions*—and by extension, the Lanham Act." (emphasis added)).

[15] *See* Appellant Br. 28 n.11 ("[N]o FDA regulation mandated that Coca-Cola place the words 'Pomegranate Blueberry' on a sep-

argument. When the Ninth Circuit declares an argument waived, it does so explicitly. *E.g.*, *Cruz* v. *International Collection Corp.*, 673 F.3d 991, 998 (9th Cir. 2012).[16] To the extent the vignette, line breaks, and coloring have been discussed by the parties in less detail than other aspects of the label, that is a function of the way in which Coca-Cola has raised its alleged regulatory-compliance defense.

IV. COCA-COLA'S POSITION WOULD HAVE FAR-REACHING AND UNINTENDED CONSEQUENCES

FDA does not contest that it utterly lacks the resources to engage in meaningful oversight of food labels. *See* Pet. Br. 52-54. Coca-Cola demurs, relying (49-50) on FDA's 1993 certification that certain FDCA provisions were "adequately implemented." But in making that determination, FDA considered neither "the level of FDA enforcement" nor "the level of industry compliance." 58 Fed. Reg. 2470, 2471 (Jan. 6, 1993). FDA's certification thus says nothing about the agency's ability—or, more accurately, inability—to police false and misleading food labeling. The few warning letters issued by FDA in the context of food labeling cited by Coca-Cola and its amici pertain almost entirely to *nutrition* labeling and health claims. *See* Friedman

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arate line and in a larger font than the words 'Flavored Blend of 5 Juices' or use a fruit vignette on its label that features a disproportionately large pomegranate.").

[16] If anything was waived, it is Coca-Cola's meritless waiver arguments, which were nowhere advanced in its brief in opposition to certiorari. *See* Pet. 8, 14, 15 (challenge to Coca-Cola's entire label, including the product's coloring, vignette, name, and label structure); S. Ct. R. 15.2; *Knowles* v. *Iowa*, 525 U.S. 113, 116 n.2 (1998).

Br. 12 (16 of 17 warning letters related only to nutrition labeling and health claims); Resp. Br. 51 n.39 (only three warning letters in the last year relating to misleading food labels).

Coca-Cola and its industry supporters are asking for dispensation from the rules applicable to the rest of the national economy. Under their preferred regime, "'assum[ing] the risk'" of selling a knowingly misleading product—as Coca-Cola did here—would mean assuming no risk at all. Pet. App. 35a. Congress has never given the slightest indication that it intended such an exemption, and there is no valid reason why this one industry should be accorded one.[17]

CONCLUSION

The judgment should be reversed.

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[17] Attempting to downplay the reach of its theory, Coca-Cola points (53) to the FTC Act's saving clause, which expressly "saves" from preclusion "the antitrust Acts and the Acts to regulate commerce." 15 U.S.C. §51. But "Acts to regulate commerce" is a defined term that excludes the Lanham Act, *see id.* §44.

Respectfully submitted.

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