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 DR. MICHAEL FRIEDMAN, FORMER ACTING COMMISSIONER AND LEAD DEPUTY COMMISSIONER FOR THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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Dated: April 2, 2014

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INTEREST OF *AMICUS*

Dr. Michael Friedman has spent his career as an advocate for science in the service of the public health and welfare.[1] He is a former Acting Commissioner and Lead Deputy Commissioner at the United States Food and Drug Administration ("FDA") (1997-1998). Prior to his service with the FDA, Dr. Friedman, a board-certified medical oncologist, worked at the National Cancer Institute in various capacities for over a decade, before which he was on the faculty at the University of California, San Francisco Medical School, leading the institution's research on cancer treatment and education. From 2003 until January 2014, when he assumed emeritus status, Dr. Friedman was President and Chief Executive Officer of City of Hope, a comprehensive cancer research and treatment center. He was a Rear Admiral and served as Assistant Surgeon General in the U.S. Public Health Service. He has received numerous awards and citations throughout his career of public service, including the Surgeon General's Medallion, the DHHS Award for Superior Service, and the PHS Distinguished Service Medal.

Dr. Friedman participates in the editorial boards of many peer-reviewed journals, and he has also published 99 scholarly articles and authored 57 book chapters. He has been appointed to numerous boards of directors and advisory boards, including the Board of Trustees of

1. This brief has been filed with the written consent of the parties, which is on file with the Clerk of the Court. Pursuant to Rule 37.6, counsel for amicus affirms that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than amicus or his counsel, make a monetary contribution to the preparation or submission of this brief.

Tulane University; the Board of Governors of the Armed Forces Institute of Pathology; the Boards of Directors of Smith & Nephew Corporation, the Celgene Corporation, the Mannkind Corporation and the Independent Citizens' Oversight Committee of the California Stem Cell Initiative; the Harvard Medical School Industry Advisory Board; and the Harvard University John F. Kennedy School of Government Dean's Council.

SUMMARY OF ARGUMENT

In areas where the FDA has engaged in formal notice-and-comment rulemaking, carefully balancing the interests of consumers, regulators, scientists, and industry, private litigation should not be permitted to upset the FDA's detailed regulatory scheme and create a patchwork of inconsistent rules and precedents. In this action, the Ninth Circuit and the Central District of California correctly held that a private litigant's Lanham Act claim, impermissibly challenging the labeling of a juice product that complied with the FDA regulations permitting that labeling, should be barred. The FDA's regulatory scheme, which balances competing interests and is informed by scientific research and consumer expectations, is entitled to deference, and this Court should not enable private litigants to undermine the agency's considered judgments and actions.

Before the enactment of the Nutrition Labeling and Education Act of 1990 ("NLEA")[2], food and beverage labeling was a confusing hodgepodge that served neither

2. The NLEA amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*

consumers nor manufacturers. In passing the NLEA, Congress sought to bring order to this chaos by tasking the FDA with the creation of a national labeling standard. Pursuant to this statutory grant of authority, the FDA embarked on a formal notice and comment procedure that resulted in a detailed regulatory scheme embodying the FDA's judgment as to what would, and would not, mislead consumers.

Private litigation, substituting the judgment of self-interested commercial competitors for that of the FDA in a myriad of private lawsuits, and the judicial decisions arising from those individual actions, would lead to standards more likely to mislead consumers than the FDA's uniform regulations. Those regulations, based on scientific expertise and substantial public comment, permit industry and consumers to rely on settled expectations in creating and reading food labels, just as Congress intended in enacting the NLEA. The FDA's continuing enforcement actions on food labeling are taken seriously by industry and by consumers, and have caused manufacturers to make changes to misleading labels. In areas where the FDA has chosen to promulgate such rules and take such actions, the application of consistent, clear, objective, and scientific standards best serves the public interest. For these reasons, the judgment below should be affirmed.

ARGUMENT

I. THE FDA'S CONCLUSION THAT CERTAIN FOOD LABELING IS NOT MISLEADING IS ENTITLED TO DEFERENCE

This Court has long recognized that formal rulemaking relying on agency expertise, in making policy in the gaps purposely left by Congress in an enabling statute, is fundamentally entitled to respect. *See*, *e.g.*, *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 165 (2007) ("The subject matter of the regulation in question concerns a matter in respect to which the agency is expert, and it concerns an interstitial matter, . . . the details of which, as we said, Congress entrusted the agency to work out. The Department focused fully upon the matter in question. It gave notice, it proposed regulations, it received public comment, and it issued final regulations in light of that comment.") (citing *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)); *see also Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984); *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 981 (1986) (holding that FDA's interpretation of FDCA provision was "sufficiently rational to preclude a court from substituting its judgment for that of the FDA").

In 1990, Congress passed the NLEA, to regulate the nutrition labeling of food and beverages under the FDCA. *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990). The FDCA prohibits misbranded foods. *See* 21 U.S.C. §§ 331, 343.[3] When

3. Misbranded food includes: (1) labels which are "false or misleading" (21 U.S.C. § 343(a)); (2) labels on which required

Congress passed the NLEA, it elaborated two goals: First, to "make sense of the confusing array of nutrition labels" confronting consumers (*see* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Waxman)); and second, to ease the burden on manufacturers by creating a uniform regulatory scheme (*see* 136 Cong. Rec. S16607-02 (Oct. 24, 1990) (statement of Sen. Hatch)).

Pursuant to the NLEA, in July 1991, the FDA issued proposed rules regarding the naming and labeling of multi-juice beverages and sought comments. 56 Fed. Reg. 30452-01 (July 2, 1991). As the District Court noted, the FDA was particularly sensitive to the question of how best to label multiple-juice beverages which often "contain only a small amount of a highly flavored, expensive juice." Pet. App. 45a (quoting 56 Fed. Reg. 30452-01, 30455 (July 2, 1991)). Indeed, the FDA explained that "the very nature of these 'blends,' mixtures of several juices, with only one or two minor juices giving them flavor, makes them difficult to label." 56 Fed. Reg. 30452-01 at 30462. In January 1993, the FDA issued its final rules on the basis of "over 200 responses," each containing one or more comments, from "a wide range of sources, including consumers, consumer organizations, professional associations, State and local government agencies, manufacturers, and trade associations." 58 Fed. Reg. 2897-01, 2897 (Jan. 6, 1993). This deliberate rulemaking embodied the FDA's expert judgment on how best to create a uniform national standard that would "prevent misleading labels on multiple-juice beverages." *Id.* at 2920.

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statements are not prominently and conspicuously placed as to render it likely to be read and understood by ordinary individuals under customary conditions (21 U.S.C. § 343(f)); and (3) labeling that fails to disclose "the common or usual name of the food", if one exists (21 U.S.C. § 343(i)).

As federal courts consistently acknowledge, the FDA is uniquely qualified to make these determinations. *See, e.g.*, *Schering-Plough Healthcare Products, Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 509 (7th Cir. 2009) (noting that FDA "has more experience with consumers' understanding of drug labels than judges do"); *see also Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) ("We decline to find and do not believe that the district court had to find, either 'as a matter of common sense' or 'normal English,' that which the FDA, with all of its scientific expertise, has yet to determine."). The FDA's rules sought to achieve a careful balance among various competing stakeholders. *See* 58 Fed. Reg. 2897-01 at 2920 ("These provisions are intended to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the product.").

In this private litigation, Petitioner Pom Wonderful LLC ("Pom") asserted a claim against The Coca Cola Company ("Coca Cola") under the Lanham Act (15 U.S.C. §§ 1051 *et seq.*), asserting that the name and labeling of Coca Cola's "Pomegranate Blueberry Flavored Blend of 5 Juices" were misleading because, although flavored with pomegranate and blueberry, the juice was allegedly predominantly composed of apple and grape juice. Pet. App. 3a. The District Court and the Ninth Circuit both held that the beverage's name and labeling were permitted by FDA regulations. Pet. App. 9a, 12a, 62a, 64a. As the Ninth Circuit recognized, permitting Pom's Lanham Act claim to proceed would thus "undermine the FDA's regulations and expert judgments." Pet. App. 10a. Noting that regulation of juice labeling has been entrusted to the FDA by Congress, the Ninth Circuit observed that "the

FDA has apparently not taken a view on whether Coca-Cola's labeling misleads consumers – even though it has acted extensively and carefully in this field." Pet. App. 11a-12a. Under these circumstances, where the FDA has promulgated detailed regulations specifically addressing the question whether a multi-juice beverage's name and label are false or misleading, the lower courts properly decided not to second-guess the FDA's judgment.

The FDA's deliberative process in arriving at its detailed multi-fruit beverage labeling regulatory scheme, through formal notice-and-comment rulemaking, reveals the flaw in the argument of Petitioner's amicus Dr. Donald Kennedy, when he contends, "The FDCA merely sets a 'floor' for regulation of labels on which other laws can build." Kennedy Br. 2, 4 (citing *Wyeth v. Levine*, 555 U.S. 555, 577-78 (2009)). Respectfully, Dr. Kennedy's reliance on *Wyeth*'s state-law preemption analysis is misplaced.

In *Wyeth*, this Court affirmed a state-law tort judgment, rejecting petitioner's implied preemption arguments, notwithstanding the FDA's approval of a specific pharmaceutical manufacturer's warning label for a specific medication, but the Court expressly distinguished the FDA's approval of a specific prescription drug's warning label from the agency's formal regulations. *See Wyeth v. Levine*, 555 U.S. 555, 580 (2009) ("By contrast, we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law."). Indeed, Justice Breyer's concurring opinion in *Wyeth* noted this distinction, and recognized that the FDA "may seek to embody those determinations in lawful specific regulations describing, for example, when labeling requirements serve as a ceiling as well as

a floor." *See Wyeth*, 555 U.S. at 582 ("And it is possible that such determinations would have pre-emptive effect.") (Breyer, J., concurring).[4] The District Court below adopted a similar analysis. *See* Pet. App. 62a ("The FDA has directly spoken on the issues that form the basis of Pom's Lanham Act claim against the naming and labeling of the Juice, and has therefore, reached a conclusion as to what is permissible. *See* 21 C.F.R. §§ 102.33(c), (d).").

II. THE PUBLIC GOOD IS BEST SERVED BY CONSISTENT, SCIENTIFIC STANDARDS, UNIFORMLY ENFORCED BY THE FDA.

As Congress recognized in passing the NLEA, the public good is best served by a consistent, clear, rigorous, scientific standard of food and beverage labeling, uniformly enforced by the FDA. Permitting ad hoc challenges by competitors would result in just the opposite. Moreover, allowing rules to be determined by the adjudication of private claims among commercially-motivated parties could very easily result in a system that is actually more misleading to consumers. Not surprisingly, Congress has provided for no private cause of action under the FDCA, reserving enforcement powers exclusively to the United States government. *See* 21 U.S.C. § 337(a).

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4. Of course, unlike in *Wyeth*, the instant appeal does not implicate state law preemption, and in any event Congress expressly preempted inconsistent state law when it enacted the NLEA. *See* NLEA § 6(a)(3) (codified in part at 21 U.S.C. § 343-1(a)(3)). By contrast, as this Court noted in *Wyeth*, Congress expressly declined to enact an express state-law preemption provision for prescription drug labeling. *See* 555 U.S. at 574-75.

Private litigation would disrupt the very uniformity sought by Congress in enacting the NLEA and subject manufacturers to an inefficient hodgepodge of judge-made rules across the fifty states. *See* 136 Cong. Rec. S16607-02 (Oct. 24, 1990) (statement of Sen. Hatch) ("[I]t is wrong to burden the manufacturer with the fear of potentially 50 different lawsuits from 50 different State attorneys general, even if similar cases have been dismissed or settled."). Here, permitting private Lanham Act claims against food labels that comply with the FDA's specific labeling requirements would frustrate Congress's stated intention to create a national, uniform standard. A lack of uniformity would also be detrimental to consumers, whose ability to comprehend product names and labeling is facilitated through the use of standardized conventions, such as the specific meaning of the word "flavored" here, *see* 21 C.F.R. § 102.33(b), (d),[5] and to industry, who require bright-line rules in making food and beverage product investment and marketing decisions as well as formulating labels. *See* 58 Fed. Reg. 2462-01, 2462 (Jan. 6, 1993) ("FDA acknowledges that some stringent State laws will be preempted by less restrictive Federal regulations. However, one of the goals of the 1990 [NLEA] is national uniformity in certain aspects of food labeling, so that the

5. *See* 58 Fed. Reg. 2897-01 at 2921 ("The agency believes that using the 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 but will not imply that the content of that juice is greater than is actually the case."). The FDA's decision to adopt such standardized terminology, after it carefully considered over 200 public comments, is itself subject to deference. *See id.* at 2900 ("The agency believes that this approach will adequately deal with the kinds of misleading labeling discussed in the comments from consumer groups.").

food industry can market its products efficiently in all 50 States in a cost-effective manner.") (citation omitted); *cf.* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Bruce) (noting the high cost "to accommodate any one State with unique food labeling requirements").

Moreover, business competitors striving for commercial advantage lack the FDA's dispassionate scientific expertise or consideration for the consumer, and are not better positioned than the FDA to police food and beverage labeling. It is simply wishful thinking to assume that private enforcement by competitors focused on their own pocketbook — not on consumers' best interests — will result in a scheme that is beneficial to consumers. Indeed, the present case is instructive. Pom has asserted that Coca Cola ought to have named its product "Apple Grape" (*see* Pet. App. 60a), but naming a beverage for certain fruits, when it has the flavoring of, and tastes like, different fruits, would clearly be misleading and confusing to consumers. The FDA's regulations in this context specifically resolve this problem, permitting manufacturers to use a product name that "identifies the juice that provides the characterizing flavor and specifically shows that that juice is used to flavor the product." 58 Fed. Reg. 2897-01 at 2921.

Even more instructive, Pom has itself received a warning letter from the FDA regarding its product labeling, and it has been involved in protracted litigation with the Federal Trade Commission regarding claimed health benefits. *See In the Matter of Pom Wonderful LLC and Roll Int'l Corp.*, FTC File No. 082-3122, Docket No. 9344 (Jan. 16, 2013); *see also* Letter from Roberta C. Wagner, FDA Director of Compliance, to Matt

Tupper, President, Pom Wonderful LLC (Feb. 23, 2010), *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm202785.htm. Without any comment on the merits of those allegations, these circumstances show how any particular business competitor's interests may not always coincide with consumer welfare — and no one should expect otherwise.

By contrast, scientific research and investigation of food components and health factors is crucial to the FDA's mission. For example, the FDA is deeply committed to expanding its expertise in how consumers make sense of labels. In July 2013, the FDA proposed studies "designed to assist the agency in developing labeling information to help consumers make informed dietary decisions." *See* Proposed Data Collection Abstract, *Eye Tracking Experimental Studies to Explore Consumer Use of Food Labeling Information and Consumer Response to Online Surveys*, OMB Control No. 0910-0761 (Jul. 16, 2013), *available at* http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201307-0910-003#section2_anchor. These studies will use "state-of-the-art eye-tracking equipment and techniques" to "collect data on how consumers view and use labeling information." *Id.*[6] As available information and consumer habits change, the FDA updates the regulatory structure for food and beverage labeling. As recently as March 3, 2014, the FDA issued a proposed rule to amend its food labeling regulations to provide updated nutrition information. *See* 79 Fed. Reg. 11879, 11880 (March 3, 2014). This is

6. On March 17, 2017, FDA announced that the Office of Management and Budget had approved these studies. 79 Fed. Reg. 14713-03, 14713 (March 17, 2014).

hardly an area where Congress delegated authority and the agency failed to act.

Nor has the FDA neglected the enforcement imperative. For example, in February 2010, the FDA issued warning letters to 17 different companies, including Nestle, Gerber, and Pom itself. *See* Layton, L., *FDA Warns 17 Food Companies of Misleading Claims on Labels*, The Washington Post (March 4, 2010), *available at* http://www.washingtonpost.com/wp-dyn/content/article/2010/03/03/AR2010030303119_pf.html. In connection with these warning letters, Dr. Margaret A. Hamburg, Commissioner of Food and Drugs, released an open letter to the industry stating that "improving the scientific accuracy and usefulness of food labeling" was one of her priorities as Commissioner. Dr. Hamburg also noted the desire within the industry for a "level playing field" and her own belief that "FDA should provide as clear and consistent guidance as possible about food labeling claims." Letter from Dr. Margaret A. Hamburg, Commissioner of Food and Drugs, to Industry (March 3, 2010), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm202733.htm.

These warning letters are not trivial matters; companies take them seriously. For example, on February 22, 2010, the FDA issued a warning letter to Diamond Food, Inc. ("Diamond"), alleging that their walnuts were misbranded as a result of unauthorized health claims. *See* Letter from Roberta Wagner, FDA Director of Compliance, to Michael J. Mendes, President and Chief Executive, Diamond Food, Inc. (Feb. 22, 2010), *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm202825.htm. In response, Diamond

promptly issued a press release expressing its intent to work with the FDA and make any required changes "expeditiously and with minimal expense." Press Release, Diamond Foods, Inc., Statement from Diamond Foods (March 3, 2010), *available at* http://investor.diamondfoods.com/phoenix.zhtml?c=189398&p=irol-newsArticle&ID=1398458&highlight. In this case, and many others, the system worked fairly and efficiently, without the attendant costs to parties and strain on the already burdened court system that private litigation would have entailed. The FDA's warning letters' success in motivating voluntary compliance by manufacturers is a vital and real component of the FDA's enforcement arsenal.

Although it is true that the scope of Congress's delegation to the FDA is enormous, and the resources of the FDA are finite, those truths do not alter the fundamental public policy principle that the agency is the appropriate place for specific labeling regulations to be promulgated and enforced. While there may be resource constraints, enforcement responsibility should nevertheless rest with FDA — the agency, not private parties, is the only instrument for consistent, unbiased, fair, uniform enforcement based on scientific principles.

CONCLUSION

The judgment below should be affirmed.

Respectfully submitted,

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Dated: April 2, 2014