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 FORMER FDA COMMISSIONER DR. DONALD KENNEDY AS *AMICUS CURIAE* SUPPORTING PETITIONER

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BATEMAN & SLADE, INC. BOSTON, MASSACHUSETTS

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INTEREST OF *AMICUS*

Dr. Donald Kennedy is a former Commissioner of Food and Drugs at the Food and Drug Administration (FDA) (1977-1979).[1] After serving as FDA Commissioner, Dr. Kennedy returned to Stanford University, where he had previously been a member of the faculty. From 1980 to 1992, Dr. Kennedy served as President of Stanford University. When he stepped down, he returned to the faculty and is currently a professor emeritus. From 2000 until 2008, Dr. Kennedy also served as editor-in-chief of SCIENCE, the weekly magazine published by the American Association for the Advancement of Science.

Amicus previously expressed his views on the proper interpretation of the Food, Drug, and Cosmetic Act in *Wyeth v. Levine*, 555 U.S. 555 (2009), in a brief filed with Dr. David Kessler, another former FDA Commissioner. That brief was cited by this Court in its opinion in *Wyeth*. *See* 555 U.S. at 579 n.12.

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[1] This brief has been filed with the written consent of the parties, which is on file with the Clerk of 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.

SUMMARY OF ARGUMENT

A private party may bring a Lanham Act challenge to a food product label regulated by the FDA under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. (FDCA). This Court can and should give effect to both the FDCA and the Lanham Act, because the requirements of both statutory schemes are complementary in this case.

The FDCA merely sets a "floor" for regulation of labels on which other laws can build. *Wyeth v. Levine*, 555 U.S. 555, 577-78 (2009). There is no conflict between the Lanham Act and FDCA – let alone an "irreconcilable" one. Here, Coca-Cola could have complied with both the FDCA's labeling regulations and the Lanham Act's ban on misleading advertising.

The Ninth Circuit erred in concluding that a Lanham Act challenge is foreclosed simply because the FDA has regulatory authority over food labeling. Such a conclusion would eliminate an important mechanism for preventing harm to consumers and competitors from false or misleading food labeling. If the FDA's regulatory authority were permitted to trump the Lanham Act, then competitors would be left without a federal remedy for false advertising that directly and substantially injures them. Such a result would run counter to congressional intent.

Moreover, the Ninth Circuit's approach would unwisely place complete responsibility for regulating food labels entirely in the hands of the FDA, which lacks the resources to perform such a daunting task. The FDA has an extremely wide range of regulatory duties, and justifiably the FDA's primary focus has been on pharmaceuticals and medical devices, not

food labels. Food labeling has traditionally been viewed as less critical to the FDA's mission than other activities.

Accordingly, it would be a mistake to read the FDCA as withdrawing the Lanham Act remedy. The two federal statutes – the FDCA and the Lanham Act, 15 U.S.C. § 1051 *et seq*. – should be interpreted as working together, not as being at odds with one another. The judgment below should be reversed.

ARGUMENT

I. The FDCA Does Not Displace The Lanham Act.

This Court has instructed that, in reconciling potentially overlapping federal statutes, courts must give full effect to both statutes unless they are in "'irreconcilable conflict.'" *Branch v. Smith*, 538 U.S. 254, 273 (2003) (quoting *Posadas v. National City Bank*, 296 U.S. 497, 503 (1936)). "[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).

That task is readily accomplished here. This Court can and should give effect to both the FDCA and the Lanham Act, because this is a false advertising case in which the requirements of both statutory schemes are complementary.

Coca-Cola seeks to sell a juice product with a label that prominently displays the words "Pomegranate Blueberry." The product label also contains a large picture of a pomegranate (among

other fruits). In fact, Coca-Cola's product actually contains merely 0.3% pomegranate juice and 0.2% blueberry juice. Over 99% of the Coca-Cola product is composed of less expensive apple and grape juices.

Pom challenged Coca-Cola's labeling as misleading under the Lanham Act and California state law. Pom produced survey evidence showing that consumers are misled by Coca-Cola's label. Consumers who discovered the true composition of the Coca-Cola product complained directly to the company in substantial numbers. The federal district court noted that Coca-Cola's own internal documents reveal that the company decided it was "willing to assume the risk" of "misleading" consumers about the fact that "the product has less than 0.5% of pomegranate and blueberry juices." Pet. App. 34a-35a.

Thus, this case is precisely the kind of false advertising case traditionally covered by the Lanham Act. Nothing about the FDCA changes that conclusion. As this Court explained in a related context, the FDCA merely sets a "floor" for regulation of labels on which other laws can build. *Wyeth v. Levine*, 555 U.S. 555, 577-78 (2009). There, this Court held that the FDA's approval of a specific drug warning label did not bar state tort failure-to-warn claims based on the omission of certain information from the label. This Court observed that "Congress enacted the FDCA to bolster consumer protection against harmful products" and "did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 574, 575. That reasoning is even more persuasive in the present context, which involves the harmonization of two federal statutes rather than

the preemption of state law. *E.g.*, *Branch v. Smith*, 538 U.S. 254, 273 (2003); *J.E.M. AG Supply*, 534 U.S. at 141-44; *N.Y. Tel. Co. v. N.Y. State Dep't of Labor*, 440 U.S. 519, 540 n. 32 (1979) (plurality opinion).

There is no conflict between the Lanham Act and FDCA – let alone an "irreconcilable" one. Coca-Cola could have complied with both the FDCA's labeling regulations and the Lanham Act's ban on misleading advertising. In particular, 21 C.F.R. § 102.5(b) provides:

> The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case.

FDA rules located in 21 C.F.R. § 102.33 also address the naming and labeling of multi-juice beverages.

Coca-Cola could have complied with these rules by disclosing the amount of pomegranate juice in its product. Indeed, the regulations arguably compelled Coca-Cola to do so. For example, under 21 C.F.R. § 102.5(b), the proportion of ingredients "has a material bearing on price or consumer acceptance" of the product, and "the labeling or the appearance of" Coca-Cola's dyed-purple product "may otherwise create an erroneous impression" that pomegranate

juice "is present in an amount greater than is actually the case."

Hence, the Lanham Act and the FDCA can and do coexist. The underlying goal of the FDCA is "to protect consumers," *United States v. Sullivan*, 332 U.S. 689, 696 (1948), not to leave them vulnerable to misbranded or dangerous products. The Lanham Act was enacted "to protect persons engaged in . . . commerce against unfair competition." 15 U.S.C. § 1127; *see also Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 29 (2003). Both statutes can be given full effect.

Regulation by the FDA to ensure that food is not "misbranded" is not a substitute for Lanham Act suits. While the Lanham gives private parties a right to bring suit, the FDCA does not create a private cause of action. *See* 21 U.S.C. § 337(a). If the FDA's regulatory authority were permitted to trump the Lanham Act, then competitors would be left without a federal remedy for false advertising that directly and substantially injures them. Such a result would run counter to congressional intent.

Indeed, even in the context of preemption of *state* law, this Court has acknowledged that a federal statute will not ordinarily be construed to withdraw an available remedy to victims of an injury. In *Bates v. Dow Agrosciences LLC,* 544 U.S. 431 (2005), for example, this Court reasoned that "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.* at 449; *see also Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238, 251 (1984) (similar reasoning with respect to Atomic Energy Act).

That principle is squarely applicable here and demonstrates that the FDCA should not be construed as displacing the Lanham Act remedy.

II. The FDA Is Not Equipped To Exercise Exclusive Responsibility For Policing False Food Labels.

In many areas of the law, Congress has relied on private suits to supplement federal agency enforcement efforts. False advertising under the Lanham Act is one such example. Eliminating private enforcement efforts would have profoundly negative implications for consumers of food products and beverages throughout the Nation.

Under the Ninth Circuit's view, the task of policing false labeling would be left exclusively to the FDA. However, the FDA is in no position to address the problem of false and misleading food labeling on its own. As this Court has noted, the FDA faces severe resource constraints. *Wyeth v. Levine*, 555 U.S. at 578 n.11.

A long series of investigations and expert reports has documented the daunting challenges that the FDA faces. As an FDA advisory panel observed, since 1938, when the FDCA was enacted, Congress has adopted "125 statutes that directly impact FDA's regulatory responsibilities," by requiring "the development of implementing regulations, guidance or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific

knowledge or expertise for the agency to address them."[2]

The report found that, despite the addition of all of these requirements, Congress has not provided "an appropriation of new personnel and increased funding designed to allow adequate implementation." *Id.* Indeed, during the past two decades, the agency's funding and staffing levels have remained static. For these and other reasons, the report concludes that "[t]his reality, combined with a burgeoning industry . . . has made it increasingly impossible for the FDA to maintain its historic public health mission." *Id.*

The report concluded that "[t]he scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the . . . regulatory system, and hence to the safety of the public." *Id.*, at § 1.1. The report found that the agency has "serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." *Id.* at pp. 2-3.

The Institute of Medicine has similarly warned that the FDA "lacks the resources needed to accomplish its large and complex mission."[3] As a former FDA chief counsel has observed, FDA suffers from "the hollow government syndrome—an agency with expanded responsibilities, stagnant resources,

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[2] FDA Science Board, FDA Science and Mission at Risk: A Report of the Subcommittee on Science and Technology § 2.1 (2007).

[3] The National Academies, Institute of Medicine, The Future of Drug Safety: Promoting and Protecting the Health of the Public 193 (2007).

and the consequent inability to implement or enforce its statutory mandates."[4]

Justifiably, the FDA's primary focus is on pharmaceuticals and medical devices, not food. Food labeling has traditionally been viewed as less critical to the FDA's mission than other activities. As one scholar has observed, "[t]he FDA does not have the resources to sufficiently address the current state of labeling, nor is there funding allocated to feasibly increase its enforcement power. . . . [T]he FDA has not utilized what little authority it does have to adequately address food misbranding or revise current regulations on permissible claims."[5] "Thus, the FDA's current system of enforcement is essentially based on voluntary compliance. The agency issues a Warning Letter to put a company on notice that it violated a regulation; this is typically the extent of its enforcement activity."[6]

In 2008, the GAO published an examination of the FDA's efforts to regulate food labeling.[7] Noting the FDA's severe resource constraints, GAO

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[4] Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 431 (2008).

[5] Jennifer L. Pomeranz, *A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J. LAW & MED. 617, 617 (2013).

[6] *Id.*

[7] *See* U.S. Gov't Accountability Office, GAO 08-597, Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods (2008), available at http://www.gao.gov/ assets/290/280466.pdf.

concluded that the "FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those prohibiting false or misleading labeling."[8] Indeed, GAO observed that the FDA has itself acknowledged that it "generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading."[9]

According to the GAO, as of 2007, over 65,000 firms were subject to FDA's food regulations.[10] These firms, of course, manufacture untold numbers of many different varieties of food products. In contrast, from 2005 to 2007, the portion of the FDA Office of Nutrition, Labeling, and Dietary Supplements "dedicated to food labeling activities" had an annual budget of only "$1.1 million to $1.3 million" and had only "from 9.0 to 10.5" full-time equivalent employees.[11]

In 2011, the GAO revisited the food label issue and again concluded that the FDA needs to reassess its approach to protecting consumers from false or misleading claims.[12] The GAO recited its earlier

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[8] *Id.* at 5.

[9] *Id.* at 30.

[10] *See id.* at 51.

[11] *Id.* at 7.

[12] *See* U.S. Gov't Accountability Office, GAO 11-102, Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims (2011), available at http://www.gao.gov/assets/320/314473.pdf.

finding that "FDA had little assurance that companies complied with food labeling laws and regulations for preventing false or misleading labeling, among things. We found weaknesses in FDA's oversight and use of data and resources."[13] The GAO added that the FDA has not "given its inspectors instructions for identifying potentially false or misleading information" in food labels with respect to certain kinds of claims and "does not have the ability to compel companies to turn over their substantiation documents."[14] The GAO described FDA label oversight as "minimal."[15]

These severe limitations mean that the FDA cannot serve as the exclusive entity with responsibility for food labeling. Thus, practical reasons, as well as the need to harmonize the FDCA and the Lanham Act, demonstrate that a private party should be allowed to bring a Lanham Act challenge to a food product label regulated by the FDA.

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[13] *Id.* at 8.

[14] *Id.* at i.

[15] *Id.* at 21.

CONCLUSION

The judgment below should be reversed.

Respectfully submitted,

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