No. 12-761

In the Supreme Court of the United States

POM WONDERFUL LLC,
Petitioner,

v.

THE COCA-COLA COMPANY,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICUS CURIAE* DRI – THE VOICE OF THE DEFENSE BAR IN SUPPORT OF RESPONDENT

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QUESTION PRESENTED

Whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the Food, Drug, and Cosmetic Act?

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae DRI—the Voice of the Defense Bar, is a 22,500-member international association of defense lawyers who represent individuals, corporations, insurance carriers, and local governments involved in civil litigation. DRI has long been a voice for a fair and just system of civil litigation, seeking to ensure that it operates to effectively, expeditiously, and economically resolve disputes for litigants. To that end, DRI participates as amicus curiae in cases that raise issues of importance to its membership and to the judicial system. This is such a case.

DRI's interest here stems from its members' need to advise clients when to bring or defend against suits under the false advertising provision of the Lanham Act (15 U.S.C. § 1125(a)(1)(B)) and from their representation of clients whose products are subject to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. (FDCA). DRI believes it is critical for this Court to preserve Congress's uniform national regulatory scheme with respect to food labeling created by the FDCA and the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343-1 (NLEA). The system does not permit private rights of action to enforce the FDCA or state law requirements for food labels that differ from the NLEA. DRI members' extensive litigation experience counsels that, when the category of

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[1] Pursuant to Rule 37.6, amicus certifies that no counsel for a party authored this brief in whole or in part and that no person or entity, other than amicus, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief. The parties have filed written consent to the filing of amicus briefs pursuant to Rule 37.

plaintiffs is expanded – here by potentially allowing private parties to bring claims under the Lanham Act, 15 U.S.C. § 1051 *et seq*., for labels that are authorized by the FDCA – the job of advising or defending clients increases in difficulty; a difficulty that will be compounded by the lack of a uniform predictable standard. Unless this framework is preserved by precluding private parties from bringing Lanham Act claims, the practical, real world ramifications of private party suits that urge disparate and potentially mutually exclusive labeling requirements will undermine the regulatory approach Congress envisioned. The potential for multiple plaintiffs means that DRI members will be defending against myriad suits, each potentially insisting on a different label. This will result in conflicting standards impossible to know in advance. DRI's members and their food-and-beverage-manufacturer clients will be unable to create an acceptable label, thus thwarting any semblance of a regulatory safe harbor.

In addition to providing consumer information, labels have a branding aspect and manufacturers expend vast resources developing a label that is authorized under the law. If a label can be constantly attacked by competitors through litigation, it will undermine marketing efforts and become a costly drag on the market. Congress intended the regulatory scheme created by the FDCA and NLEA to allow manufacturers in the food industry to effectively and efficiently market their products nationwide. Senator Hatch emphasized amicus DRI's concern that any system that does not ensure uniformity burdens manufacturers by increasing the likelihood of litigation: "it 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." 136 Cong. Rec. S16607-02, 1990 WL 206648 (October 24, 1990). The situation would only be magnified if manufacturers were subjected to the whims of an infinite number of private parties enforcing their own notions of what constitutes an appropriate label. Amicus curiae DRI urges this Court to rule that the FDCA and NLEA establish a single nationwide standard that is enforced exclusively by the FDA. Accordingly, this Court should affirm the Ninth Circuit's decision here, which held that a private party cannot bring a Lanham Act claim challenging a product label that is authorized by the FDCA.

SUMMARY OF ARGUMENT

The decision of the court of appeals should be affirmed and this Court should hold that a private party cannot bring a claim under the general provisions of the Lanham Act to challenge a product label that is authorized under the specific requirements of the FDCA and NLEA, through which Congress intended to create a system of national uniformity in food labeling. When statutes seemingly conflict, as do the Lanham Act and FDCA here, courts must read them consistently whenever possible, *Kremer v. Chem. Const. Corp*., 456 U.S. 461, 468 (1982), and give precedence to the more specific statute, *Busic v. U.S*., 446 U.S. 398, 406 (1980).

Section 43(a) of the Lanham Act is designed to combat false advertising of any product or service, thereby protecting business entities against unfair competition. See 15 U.S.C. § 1127. To have standing in

a suit for false advertising under § 1125(a), "a plaintiff must allege an injury to a commercial interest in reputation or sales." *Lexmark Int'l, Inc. v. Static Control Components, Inc*., 12-873, 2014 WL 1168967 (U.S. Mar. 25, 2014). Thus, competitors are likely to use the Lanham Act to avenge perceived wrongs. See *TrafficSchool.com, Inc. v. Edriver Inc*., 653 F.3d 820, 827 (9th Cir. 2011). Like the Lanham Act, the FDCA also addresses false statements. But the FDCA, in conjunction with the NLEA, is directed toward consumer protection as well as to ensuring efficiency in operations and marketing for manufacturers. The FDCA and NLEA are more specific that the Lanham Act in determining whether a statement on a beverage label is false.

In enacting the FDCA and NLEA, Congress intended to protect consumers and provide guidance to manufacturers by establishing a national uniform system in food labeling. Congress sought to allow the food industry to "market its products efficiently in all 50 States in a cost-effective manner." State Petitions Requesting Exemption from Federal Preemption, 58 Fed. Reg. 2462-01 (Jan. 6, 1993). This included freedom from the potential of "50 different lawsuits from 50 different State attorneys general." 136 Cong. Rec. S16607-02, 1990 WL 206648 (October 24, 1990). Thus, allowing private parties to use the general provisions of the Lanham Act to bring a claim against a product label that complies with the specific requirements of the FDCA and NLEA would undermine the system of uniformity created by Congress.

The Ninth Circuit here and other courts have determined that in a comprehensively regulated area where the FDA has clearly spoken, it is not proper for a private party to bring a Lanham Act claim. The reasoning in the opinions is characterized as deference to Congress's decision to entrust food and drug labeling decisions to the FDA – which in essence recognizes Congress's intent to create a system of national uniformity in labeling. The decisions also respect the fact that, while the Lanham Act and the FDCA both share the common purpose of preventing false statements, the FDCA is directed more specifically to what is false or misleading on a food or beverage label. This Court should affirm the Ninth Circuit's decision here and hold that a private party cannot bring a Lanham Act claim challenging a product label that complies with the FDCA.

ARGUMENT

The Ninth Circuit Correctly Held That A Lanham Act Claim Cannot Be Used to Challenge A Product Label That Is Authorized By The Food, Drug, And Cosmetic Act, And Relevant Food And Drug Administration Regulations.

The issue before this Court involves the interaction between the FDCA and the Lanham Act. DRI members' national and multinational clients in the food and beverage industry rely on the system of national uniformity in labeling established by the specific requirements of the FDCA and NLEA. Allowing competitors to wield the general provisions of the Lanham Act as a weapon eliminates this safe harbor, is contrary to Congressional intent, and disregards

established rules for resolving conflicts between federal statutes. Private party suits also make it difficult for DRI members to advise their clients who are governed by the FDCA because standards will be unknowable in advance. Moreover, in DRI's experience, expanding the class of available plaintiffs results in increased litigation and concomitant costs. This Court should affirm the Ninth Circuit's ruling that Congress intended to preclude a private party from bringing a Lanham Act claim where a label is authorized by the specific provisions of the FDCA and the NLEA.

A. The specific provisions of the FDCA and NLEA provide guidance to manufacturers in developing proper labels.

When two federal statutes seemingly conflict, here the Lanham Act and the FDCA, courts must read them consistently whenever possible, *Kremer*, 456 U.S. at 468, and give precedence to the more specific statute, regardless of their temporal sequence, *Busic*, 446 U.S. at 406. See e.g., *Morton v. Mancari*, 417 U.S. 535, 547 (1974) (holding that the Equal Employment Opportunity Act of 1972, 42 U.S.C. § 2000e *et seq*., did not negate employment preference for Indians expressly established by the Indian Reorganization Act of 1934, 25 U.S.C. § 461 *et seq*.). Similarly, the meaning of one statute may be affected by other acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. *Food & Drug Admin. v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 133 (2000).

In this case, the FDCA and NLEA are more specific that the Lanham Act in determining whether a statement on a beverage label is false. DRI members

rely on these provisions to counsel their clients on developing proper labels. Allowing competitors to use the general provisions of the Lanham Act to destroy this safe harbor and thwart otherwise lawful marketing efforts is contrary to Congress's intent to create a system of national uniformity.

Section 43(a) of the Lanham Act is designed to combat false advertising of any product or service. It provides:

> [a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action 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)(B).

The Lanham Act protects business entities against unfair competition. See 15 U.S.C. § 1127. Congress intended to allow false advertising suits by competitors "to stop the kind of unfair competition that consists of lying about goods or services, when it occurs in interstate commerce." *U-Haul Int'l, Inc. v. Jartran, Inc.*, 681 F.2d 1159, 1162 (9th Cir. 1982). See also *Proctor & Gamble Co. v. Haugen*, 222 F.3d 1262, 1272

(10th Cir. 2000), citing 5 McCarthy on Trademarks and Unfair Competition § 27:7 (4th ed.) ("As a general matter, the drafters and promoters of the original [Lanham Act], sought to create a general federal law of unfair competition to protect competing companies in the wake of the Supreme Court's decision in *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), which was thought to have eliminated the existing body of federal unfair competition law."). To have standing in a suit for false advertising under § 1125(a), "a plaintiff must allege an injury to a commercial interest in reputation or sales." *Lexmark*, 12-873, 2014 WL 1168967 at *9. Thus, competitors are likely to use the Lanham Act to avenge perceived wrongs. See *TrafficSchool.com,* 653 F.3d at 827 ("[c]ompetitors vie for the same dollars from the same consumer group, and a misleading ad can upset their relative competitive positions).

Like the Lanham Act, the FDCA addresses false statements. But the FDCA, in conjunction with the NLEA, is directed more specifically to what is false or misleading on a food or beverage label, with an eye toward consumer protection as well as to ensuring efficiency in operations and marketing for manufacturers. DRI members' clients in the food and beverage industry rely on the specific provisions of these statutes to develop appropriate labels.

Under the FDCA, "[a] food shall be deemed to be misbranded" if "its labeling is false or misleading in any particular," 21 U.S.C. § 343(a)(1), or "[i]f any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness . . . and in such terms as to render it

likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 343(f). A food is also misbranded unless it includes "the common or usual name of the food, if any there be." 21 U.S.C. § 343(i). FDA regulations further explicate specific rules for naming and labeling beverages that contain fruit or vegetable juice. See 21 C.F.R. § 102.33. Only the United States can bring an action to enforce these provisions, 21 U.S.C. § 337(a); the FDCA does not create a private right of action, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996).

Additionally, the NLEA preempts states from enacting different labeling requirements from those discussed above.

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . . (3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section . . . .

21 U.S.C. § 343-1(a).

B. Congress intended to create a uniform national system of food and beverage labeling.

Together, the FDCA and NLEA protect consumers and provide guidance to the food and beverage manufacturers that DRI members represent. The FDCA was intended to "touch phases of the lives and

health of people which . . . are largely beyond self-protection." *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951). "The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. . . . The statute . . . was enacted to enable purchasers to buy food for what it really is." *United States v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar*, 265 U.S. 438, 442-43 (1924). Misbranding, therefore, "was one of the chief evils Congress sought to stop." *62 Cases,* 340 U.S. at 596. It follows that the purpose of the labeling requirement is to inform and protect the ultimate consumer. *United States v. Kocmond*, 200 F.2d 370, 373-74 (7th Cir. 1952). See also 21 U.S.C § 341 (regulations are intended to "promote honesty and fair dealing in the interest of consumers").

Through the NLEA, Congress sought further to ensure a national uniform system in food labeling and was cognizant of the parallel benefit to manufacturers. Senator Mitchell observed that the amendment requires the FDA "to develop standardized nutrition labels for our foods . . . ." 136 Cong. Rec. S16607-02, 1990 WL 206648 (October 24, 1990). But this goal of national uniformity also allows the food industry to "market its products efficiently in all 50 States in a cost-effective manner." State Petitions Requesting Exemption from Federal Preemption, 58 Fed. Reg. 2462-01 (Jan. 6, 1993). Moreover, "the net benefits from national uniformity" ultimately help the consumer. *Id*.

Statements from other legislators emphasized national uniformity and recognized the benefit of such

a system to the twin goals of consumer protection and efficiency for manufactures. Rep Madigan explained that the NLEA "emphasizes disclosure of all valid and relevant information to the consumer, while providing the industry with uniformity of law in a number of important areas that will permit them to conduct their business of food distribution in an efficient and cost-effective manner." 136 Cong. Rec. H5836-01, 1990 WL 107635 (July 30, 1990). Senator Hatch agreed, and articulated amicus DRI's concern that any system that does not ensure uniformity burdens manufacturers by increasing the likelihood of litigation: "it is wrong to permit each of the 50 States to require manufacturers of 20,000 packaged food items to display different health and diet information on identical products sold throughout this country. And, it 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." 136 Cong. Rec. S16607-02, 1990 WL 206648 (October 24, 1990). Rep. Waxman's comments echoed these concerns: "A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws." 136 Cong. Rec. H5836-01, 1990 WL 107635 (July 30, 1990).

The situation would only be magnified if manufacturers were subjected to the whims of an infinite number of private parties enforcing their own notions of what constitutes an appropriate label. In DRI's experience, it is not out of the question for competitors to also use the Lanham act to thwart legitimate marketing efforts. DRI members' role in advising their clients as to an appropriate label thus

becomes more challenging and the potential for litigation increases exponentially. Litigation costs are ultimately passed on to the consumer and have ramifications on the economy as a whole. See e.g., Threat of Suits Spurs Hiring Cuts, Study Shows, 10 Alternatives to High Cost Litig. 74 (1992) ("State court decisions expanding employers' liability in wrongful termination cases are generating substantial costs beyond those directly related to litigation . . . . [A]ggregate employment has dropped by as much as five percent in states where the theories are most liberally applied."). Allowing private party suits where labels are authorized by the FDCA undermines the system of uniformity created by Congress because standards are unknowable in advance, leaving DRI members unable to properly advise their clients. See e.g., *Elgin v. Dep't of Treasury*, 132 S. Ct. 2126, 2130 (2012) (Undermining the integrated scheme of review created by the Civil Service Reform Act "would reintroduce the very potential for inconsistent decisionmaking and duplicative judicial review that the CSRA was designed to avoid."). See also *Holloway v. Bristol-Myers Corp*., 485 F.2d 986 (D.C. Cir. 1973) (Court held that private enforcement of the Trade Commission Act would be inconsistent with the legislative scheme established by Congress; the Federal Trade Commission's role in providing certainty and specificity to broad proscription of the Act would be endangered by private actions.)

C. Courts have recognized and upheld the system of uniformity intended by Congress.

DRI members' food and beverage manufacturer clients rely on the system of national uniformity for

food and beverage labeling created by the FDCA and NLEA. Lower courts have consistently recognized the safe harbor created by these statutes and have barred Lanham Act claims where labels and advertising are authorized by the specific provisions of the FDCA. The reasoning in the opinions is characterized as deference to Congress's decision to entrust food and drug labeling decisions to the FDA – which in essence recognizes Congress's intent to create a system of national uniformity in labeling.

In this case, the Ninth Circuit sought to give "as much effect to both [the FDCA and Lanham Act] as possible." *Pom Wonderful LLC v. Coca-Cola Co.,* 679 F.3d 1170, 1176 (9th Cir. 2012), quoting *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009). The court determined that, where a label is authorized by the FDCA, it is not proper for a private party to bring a Lanham Act claim. "[C]ourts must generally prevent private parties from undermining, through private litigation, the FDA's considered judgments." *Id*. at 1178. As the Ninth Circuit recognized, the overriding consideration here is that Congress has entrusted the FDA with interpreting and enforcing the FDCA. *Id.* at 1175.

Other courts have articulated rules consistent with the Ninth Circuit's holding when construing the FDCA in conjunction with the Lanham Act, recognizing the safe harbor created by the FDCA. In the context of pharmaceuticals, "courts have generally rejected Lanham Act claims based on advertisements that merely repeat labeling information that has been approved by the FDA." *Mylan Pharm., Inc. v. Proctor*

& Gamble Co., 443 F. Supp. 2d 453, 460 (S.D.N.Y. 2006), citing *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F.Supp.2d 296, 301 (S.D.N.Y.1998) ("representations ... that comport substantively with statements approved as accurate by the FDA cannot supply the basis for [Lanham Act] claims") and *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharm. Co., Inc.*, 1996 WL 280810, *13 (S.D.N.Y. May 24, 1996) (denying injunction against defendant for advertising claims based on FDA-approved packaging and labeling).

In *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 937 (8th Cir. 2005), by contrast, the Court *allowed* a Lanham Act challenge asserting that the defendant falsely advertised that a product had been approved by the FDA for a number of uses for which it had not. This was plainly a false statement that was not relevant to whether the label otherwise complied with the specific requirements of the FDCA. The court thus found that deference to the FDA was not required in that case because the resolution of the issue did not require "expert consideration and uniformity of resolution." *Id.* at 939, citing *United States v. McDonnell Douglas Corp.*, 751 F.2d 220, 224 (8th Cir. 1984). Rather, a plainly false statement is actionable under the Lanham Act because it affects fairness in competition.

Courts have also recognized that barring private parties from bringing Lanham Act claims against a product label that complies with the FDCA respects the fact that, while the Lanham Act and the FDCA both share the common purpose of preventing false statements, the FDCA is directed more specifically to

what is false or misleading on a food or beverage label with an eye toward consumer protection. In *Am. Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135 (S.D.N.Y. 1987), the court found that FDA approval of a label used by the manufacturer of aspirin-containing products was a complete defense to a competitor's Lanham Act claim, which alleged that the defendant falsely advertised the superior safety and efficacy of its product but failed to warn of the risk of contracting Reye Syndrome. *Id*. at 144. The FDA had not required such a warning at the time. Thus the situation is analogous to Petitioner here demanding more or different regulations on how images and words must appear on the juice label.

In *Am. Home Products Corp.,* the plaintiff relied on several state law product liability cases which held that "a consumer who is injured as a result of using a dangerous product may recover damages against the manufacturer," even where a government agency had approved the products as safe. 672 F. Supp. at 142. But the court found that "[r]ulings in product liability cases are simply not controlling in a Lanham Act action," because the Lanham Act was not designed for consumer protection but rather the protection of " 'persons engaged in commerce against unfair competition.' "*Id*. at 143, quoting *Colligan v. Activities Club of New York, Ltd.*, 442 F.2d 686, 691-92 (2d Cir. 1971).

Accordingly, where the FDCA and NLEA are more specific that the Lanham Act in determining whether a statement on a beverage label is false, barring private parties from bringing Lanham Act claims against a product label that is authorized by the FDCA is

consistent with the purposes of the two federal statutes and with Congress's intent to create a national system of uniformity in labeling to protect consumers and allow manufactures to efficiently market in all 50 states. This Court should affirm the Ninth Circuit and hold that a private party cannot bring a Lanham Act claim challenging a product label that is authorized by the FDCA.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

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