No. 07-_____ 071327 APR 18 2008

In The
Supreme Court of the United States

ALBERTSON'S, INC., *et al.*,

Petitioners,

v.

JENNIFER KANTER, *et al.*,

Respondents.

On Petition For A Writ Of Certiorari To The California Supreme Court

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Seventy years ago, Congress decided that "all . . . proceedings for the enforcement, or to restrain violations, of [the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act")] shall be by and in the name of the United States." 21 U.S.C. § 337(a). In 1990 amendments to the FDCA, Congress created a narrow, secondary enforcement role for state governments. It allowed states to enact laws identical to specified portions of the FDCA, *id.*, § 343-1, and also permitted state governments to enforce certain FDCA provisions in federal court under certain conditions, *id.*, § 337(b). Congress, however, has never permitted the private enforcement of FDCA requirements. The California Supreme Court nonetheless held that Respondents, private plaintiffs, could bring a class action to enforce the FDCA under the aegis of state law.

The question presented is: Are private parties' state law claims to enforce FDCA requirements preempted by Congress' mandate that the Act be enforced only by the federal or state governments?

PARTIES TO THE PROCEEDING

Petitioners are Albertson's, Inc., Safeway Inc., The Kroger Co., T.A.C.T. Holding, Inc., Trader Joe's Company, Bristol Farms, Inc., Ocean Beauty Seafoods, Inc., Whole Foods Market California, Inc., and Mrs. Gooch's Natural Foods Market, Inc.

Respondents are Jennifer Kanter, Ben Betts, Ellyn Gerson, David Matsumoto, Lyta Jocum, Julian Carroll, Arleen Rovere, Monique Gauthier, Ivania Lourdes Flores, Sheila Malone, Pastor Romney Bernadette Darkin, and Cesar Tercero Alonzo.

RULE 29.6 STATEMENT

SUPERVALU INC., a publicly traded company, is the parent and owns the stock of New Albertson's, Inc. which consists of the core supermarket businesses owned by Albertson's, Inc. at the time this lawsuit was filed. New Albertsons, Inc. is an active corporation and a wholly owned subsidiary of SUPERVALU INC. No publicly held company owns 10% or more of the stock of SUPERVALU INC.

SUPERVALU INC. is also the parent and owns the stock of New Bristol Farms, Inc., which consists of the core supermarket businesses owned by Bristol Farms, Inc. at the time this lawsuit was filed. When New Bristol Farms, Inc. was an active corporation, it was a wholly owned subsidiary of SUPERVALU INC. SUPERVALU INC. is currently the parent and owns the stock of Bristol Farms, Inc.

RULE 29.6 STATEMENT – Continued

Safeway Inc. ("Safeway") is a publicly traded company. AXA Assurances I.A.R.D. Mutuelle (a French mutual insurance company), AXA Assurances Vie Mutuelle (a French mutual insurance company), AXA Courtage Assurance Mutuelle (a French mutual insurance company, and along with the first two acting as a parent holding company), AXA (a French company and parent holding company), and AXA Financial, Inc. (a Delaware corporation and parent holding company) beneficially owned 77,820,579 shares of Safeway common stock as of August 31, 2007, representing 17.7% of Safeway's outstanding shares. AllianceBernstein L.P. (a subsidiary of AXA Financial, Inc. organized under the laws of the State of Delaware) is deemed to have sole dispositive power over 77,258,207 of those shares.

The Kroger Co. is a publicly traded company. No publicly held company owns 10% or more of its stock.

Trader Joe's Company is owned entirely by T.A.C.T. Holding, Inc., a privately held company. There are no parent corporations of T.A.C.T. Holding, Inc. and no publicly held company owns more than 10% of T.A.C.T. Holding, Inc.

Mrs. Gooch's Natural Foods Market, Inc. and Whole Foods Market California, Inc. are 100% wholly owned subsidiaries of Whole Foods Market, Inc., which is a publicly traded company. No publicly held company owns 10% or more of its stock.

RULE 29.6 STATEMENT – Continued

Ocean Beauty Seafoods LLC is an Alaska limited liability company owned 50% by Ocean Beauty Holdings, Inc., a Washington corporation formerly known as Ocean Beauty Seafoods, Inc., and 50% by Bristol Bay Economic Development Corporation, an Alaska nonprofit corporation.

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The opinion of the California Supreme Court (Pet. App. 1) is reported at 42 Cal. 4th 1077, 175 P.3d 1170 (2008). The opinion of the California Court of Appeal (Pet. App. 36) is reported at 142 Cal. App. 4th 805 (2006). The opinion of the trial court (Pet. App. 51) is unreported.

JURISDICTION

The opinion of the California Supreme Court was issued on February 11, 2008. (Pet. App. 1.) The jurisdiction of this Court is invoked pursuant to 28 U.S.C. § 1257.

STATUTORY PROVISIONS INVOLVED

The FDCA provides, in relevant part:

> (a) Except as provided under subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. . . . .
>
> (b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is

the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1) –

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

21 U.S.C. § 337.

The FDCA further provides, in relevant part:

(a) 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)(3).

STATEMENT OF THE CASE

This case concerns whether FDCA requirements will be enforced exclusively by the federal and state governments, or by private parties as well. When Congress enacted the FDCA in 1938, it deliberately and consciously rejected the possibility of private enforcement in favor of exclusive federal enforcement. When Congress amended the Act in 1990, it carved out a limited exception to exclusive federal enforcement, allowing state governments to enforce certain FDCA violations under specified conditions. Congress, however, never altered its long-standing prohibition against private enforcement actions.

The California Supreme Court nevertheless held that Respondents, private plaintiffs, are entitled to enforce FDCA requirements governing the use of artificial color in farm-raised salmon under identical state laws. Its decision cannot be reconciled with Congress' government enforcement scheme, or with the decisions of this Court and many lower courts reinforcing the Congressional ban on private FDCA enforcement.

A. The Federal Statutory Scheme

1. Congress' Original Plan Mandated Exclusive Federal Enforcement and Unequivocally Prohibited Private Enforcement.

From its inception in 1938, the FDCA was intended to be enforced by the federal government – and not by private parties. In fact, Congress considered and rejected a version of the statute that would have allowed a private right of action. *National Women's Health Network, Inc. v. A. H. Robins Co.*, 545 F. Supp. 1177, 1179-80 (D. Mass. 1982) (citing Hearings on S. 1944 (Subcommittee of Committee on Commerce 73d Cong., 2d Sess. (1933)). It opted instead for a provision mandating that "all" proceedings "for the enforcement, or to restrain violations" of the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337.

In keeping with its plan of exclusive federal enforcement, Congress afforded the Food and Drug Administration ("FDA"), the responsible federal agency, a wide range of enforcement options. It authorized the FDA to bring civil actions to seize misbranded or adulterated goods, to restrain violations of the FDCA, and to seek civil and criminal penalties for such violations. 21 U.S.C. §§ 332-334.

As part of its careful design, Congress also gave the FDA the power *not* to prosecute "minor violations of [the Act] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. Congress

thus ensured that the federal government would decide whether and how to enforce the law.

Courts interpreting the FDCA's enforcement framework before it was amended in 1990 held that Congress had deliberately excluded private claims by placing enforcement exclusively in the hands of the federal government, *see, e.g.*, *Pacific Trading Co. v. Wilson & Co., Inc.*, 547 F.2d 367, 370 (7th Cir. 1976) ("[T]he statute does not provide a cause of action for private parties suing for civil damages."), even those claims brought under state law, *see, e.g.*, *National Women's Health*, 545 F. Supp. at 1181 (holding that a private right of action to enforce FDCA standards is "inconsistent with the federal regulatory scheme, whether the right is based in federal or state law"); *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986) (same).

2. Congress' 1990 Amendments Created A Limited Role For State Governments, But None For Private Parties.

Cognizant of the uniform case law prohibiting private enforcement, Congress enacted the Nutrition Labeling and Education Act of 1990 ("NLEA"), which amended the FDCA to require nutrition labeling on certain foods and to permit state government enforcement of specified labeling requirements. Two provisions of the NLEA pertain to the state enforcement of

federal labeling requirements: sections 343-1 and 337(b).

Section 343-1 allows states to enact laws with requirements "identical" to certain FDCA labeling requirements. 21 U.S.C. § 343-1. One of the FDCA provisions that section 343-1 permits states to replicate is section 343(k), the provision on which Respondents' claims are based, which deems any food containing artificial coloring to be misbranded "unless it bears labeling stating that fact," *id.*, § 343(k). Although section 343-1 is silent on the issue of enforcement, the House Report indicates that state laws enacted pursuant to section 343-1 may only be enforced by "governmental entities":

> The bill . . . contains a provision that would prevent State and local governments from adopting inconsistent requirements with respect to the labeling of nutrients or with respect to the claims that may be made about the nutrients in foods. However, these *governmental entities are explicitly permitted to enforce Federal requirements with respect to nutrition labeling.*

(Pet. App. 74 (H.R. Rep. No. 101-538, 2d Sess., p. 8 (1990) (emphasis added)).)

The other amendment was the addition of section 337(b) to the original section 337 (which was renumbered as section 337(a)). It carved out a narrow exception to exclusive federal enforcement, but only for state governments. Section 337(b) permits state

governments to enforce certain sections of the FDCA in federal court after giving the FDA notice and the opportunity to preempt any state government action with an action of its own. 21 U.S.C. § 337(b).

Together, sections 337(b) and 343-1 were intended to give states the option of enforcing federal labeling requirements under the mantle of federal or state law, in either federal or state court. Under section 337, "[a] State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of" the FDCA in federal court. (21 U.S.C. § 337(b)(1); Pet. App. 75 (H.R. Rep. No. 101-538, 101st Cong., 2d Sess., p. 23 (1990) ("The proceedings [under section 337(b)] would be brought in Federal court and would supplement the FDA's enforcement capabilities.")).) Under section 343-1, states can enforce those same FDCA requirements under identical state law in state court. As Representative Henry Waxman, who originally introduced the bill in the House, explained:

> *H.R. 3562 recognizes the importance of the State role*: by allowing *States* to adopt standards that are identical to the Federal standard, which may be enforced in State court; by allowing the *States* to enforce the Federal standard in Federal court.

(Pet. App. 70 (House Debate on H.R. No. 3562, 101st Cong., 2d Sess., 136 Cong. Rec. 1539 (daily ed. July 30, 1990) (emphasis added)).) By way of both sections 337(b) and 343-1, the NLEA allowed state enforcement of certain federal labeling requirements, but

never granted private parties any enforcement rights whatsoever.

B. Procedural History

Respondents brought this class action claiming that Petitioner supermarkets violated FDCA section 343(k) and its implementing regulations by failing to disclose that farm-raised salmon they sold contained artificial coloring. (JA 162-64 (Consolidated Amended Class Action and Representative Action Complaint ("Complaint")).) Although claims are stated under numerous state laws, including the Unfair Competition Law ("UCL"), Cal. Bus. and Prof. Code § 17200 *et seq.*, the Consumers Legal Remedies Act ("CLRA"), Cal. Civ. Code § 1750 *et seq.*, and the False and Misleading Advertising Law, Cal. Bus. and Prof. Code § 17500, the predicate for each claim is identical: the violation of FDA regulations and "equivalent provisions of California law" governing the use of color additives in farm-raised salmon.[1] (JA 169-72 (Complaint).)

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[1] California's UCL proscribes any "unlawful business activity," which includes "anything that can properly be called a business practice and that at the same time is forbidden by law." *Barquis v. Merchants Collection Assn.*, 7 Cal. 3d 94, 113 (1972). Respondents' UCL claims are predicated on violations of the color additive provisions of California's Health and Safety Code – provisions that replicate the FDA's color additive regulations *in toto*, *see* Cal. Health & Saf. Code § 110090. When the California Legislature enacted its "little FDCA," called the Sherman Law, it did not include an express private right of action. *See id.*, § 111840.

Respondents seek restitution, compensatory damages, and an injunction "to permanently halt [Petitioners'] misbranding" in violation of federal and identical state law. (JA 172-73.)

1. The Trial Court's Decision Dismissing Respondents' Case On Federal Preemption Grounds

Petitioners demurred to Respondents' Complaint on federal preemption grounds, arguing that Respondents' claims – all of which are based on violations of the FDCA and its implementing regulations – are barred by the FDCA's express prohibition on private rights of action. (JA 193-241.)

The trial court sustained Petitioners' demurrer and dismissed Respondents' case in its entirety. (Pet. App. 64.) It recognized that Respondents' Complaint does not allege any wrongful conduct beyond the federal violations, and that "[r]esolving [Respondents'] claims will have to turn on [Petitioners'] compliance with the FDA's regulations." (Pet. App. 58.) The trial court concluded that a private state law action that "seeks to borrow FDCA standards is barred by § 337(a) of the FDCA." (Pet. App. 55.)

2. The California Court Of Appeal's Decision Unanimously Affirming The Trial Court's Dismissal On Federal Preemption Grounds

In a published decision, the Court of Appeal unanimously affirmed the trial court's federal preemption decision. (Pet. App. 36.) Relying on this Court's opinion in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court of Appeal held that FDCA section 337 "precludes a private right of action to enforce the FDCA." (Pet. App. 45.) It reasoned that "[b]y providing that only the federal government and, in some limited circumstances and only after giving notice to the federal government, a state may commence an action to enforce the FDCA, *Congress reserved for the federal government and the states the discretion to enforce or not enforce the FDCA in any particular set of circumstances and afforded the federal government a degree of oversight of the enforcement of the act.*" (Pet. App. 46-47 (emphasis added).)

The Court of Appeal concluded:

> To allow a private person to prosecute a state law private right of action *based on a violation of the FDCA* would interfere with that governmental prosecutorial discretion and federal government oversight and conflict with the clear congressional intent to provide for a comprehensive and exclusive governmental enforcement scheme.

(Pet. App. 47 (original emphasis).) Because all of Respondents' claims are admittedly "based on a violation of the FDCA," the Court of Appeal held that allowing private parties to pursue them would "frustrate the purposes of exclusive federal and state governmental prosecution of the act." (Pet. App. 37-38.) It affirmed the trial court's dismissal on the ground that "section 337(a) impliedly preempts all of [Respondents'] causes of action." (Pet. App. 38.)

3. The California Supreme Court's Decision Allowing Respondents' Private FDCA Claims To Proceed.

The California Supreme Court reversed. (Pet. App. 35.) Its decision begins and ends with the "strong presumption against preemption" (Pet. App. 12, 35), which it applied with "particular force" because consumer protection laws and laws regulating the proper marketing of food "are within the states' historic police powers" (Pet. App. 13).

The court held that Respondents' claims were not preempted because they had sued not under the FDCA itself, but rather under state laws identical to federal standards – laws that FDCA section 343-1 authorized states to enact. (Pet. App. 24.) Acknowledging that Congress "said absolutely nothing" about the private enforcement of such identical state laws (Pet. App. 18), the court nevertheless presumed that Congress "made a conscious choice" not to "preclude

states from providing private remedies for violations of those laws" (Pet. App. 34, 19).

The California Supreme Court further held that section 337 is not a valid source of preemption because Respondents' claims "arise out of violations of [identical state law], not out of the FDCA itself." (Pet. App. 31.) It distinguished, for example, a case in which "the complaint alleged defendant violated the FDCA, misbranded its food in violation of federal regulations, and made actionable health claims in violation of federal regulations." (Pet. App. 32 (discussing *Fraker v. KFC Corp.*, No. 06-CV-01284, 2007 WL 1296571 (S.D. Cal. Apr. 30, 2007)).) The California Supreme Court did not discuss Respondents' allegations that Petitioners violated the FDCA and misbranded their salmon in violation of FDA regulations (JA 163-64) – allegations that serve as the factual predicate for all of their state causes of action (JA 169-72).

REASONS FOR GRANTING THE PETITION

At stake in this case is whether the FDCA will continue to be enforced by government entities – as it has been for seventy years – or whether the door is now open to private class action attorneys to decide whether and how to enforce the federal Act. The California Supreme Court's decision approving Respondents' private FDCA enforcement claims thwarts Congress' exclusively public enforcement plan and

conflicts with this Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001), which recognizes the Congressional prohibition against private FDCA enforcement actions.

The California Supreme Court's decision is also an open invitation to private plaintiffs nationwide to bring class actions alleging FDCA violations. The decision below will wreck Congress' exclusive government enforcement scheme and all its built-in advantages. Because of the broad jurisprudential and practical significance of the ruling below on federal enforcement of the FDCA, Petitioners respectfully request that this Court obtain and consider the views of the Solicitor General before deciding whether to grant review.

I. THE CALIFORNIA SUPREME COURT'S DECISION CONFLICTS WITH CONGRESS' PROHIBITION AGAINST PRIVATE FDCA ENFORCEMENT ACTIONS AND THIS COURT'S DECISION IN *BUCKMAN* UPHOLDING THAT PROHIBITION.

A. FDCA Section 337 Reflects Congress' Unmistakable Intent To Preclude *All* Private Enforcement Actions, As This Court And Many Lower Courts Have Recognized.

Section 337 of the original FDCA mandated that only the federal government could enforce the Act, 21 U.S.C. § 337(a), and all courts interpreting section

337 before it was amended in 1990 understood that Congress had erected a barrier against private rights of action, whether grounded in federal or state law, *see, e.g.*, *Pacific Trading*, 547 F.2d at 370; *National Women's Health*, 545 F. Supp. at 1181; *Animal Legal Defense Fund*, 626 F. Supp. at 283. When Congress amended section 337 in 1990 to allow certain limited actions by state governments, it was undoubtedly aware of that uniform case law. *Keene Corp. v. United States*, 508 U.S. 200, 212 (1993) (holding that when Congress reenacts statutory language that has been consistently interpreted by the courts, "the presumption that Congress was aware of the[ ] earlier judicial interpretations and, in effect, adopted them" applies). While Congress expressly decided to authorize state enforcement, it made no change in the proscription of private enforcement under section 337. *Bailey v. Johnson*, 48 F.3d 965, 967 n.1 (6th Cir. 1995) (acknowledging, while dismissing a private cause of action to enforce the FDCA, that when Congress amended section 337 in 1990 to allow for certain enforcement actions by state governments, it "made no change respecting private actions").

This Court thus held in 2001 that "[t]he FDCA leaves no doubt" that "private litigants" cannot bring suits for noncompliance with the FDCA. *Buckman*, 531 U.S. at 349 n.4 (citing 21 U.S.C. § 337(a)).[2]

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[2] Federal appellate courts are in accord. *See, e.g., In re Orthopedic Bone Screw Products Liability Litig.*, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well-settled . . . that the FDCA creates

(Continued on following page)

Although *Buckman*, this Court's only decision addressing section 337, involved state law fraud-on-the-FDA claims that were preempted for reasons largely unique to those claims, numerous lower courts have recognized that Congress' mandate of no private enforcement extends to state law claims to enforce requirements substantively identical to federal law, *see, e.g., Fraker,* 2007 WL 1296571, at *4 ("[T]o the extent Plaintiff contends that alleged violations of the FDCA and [identical California law] give rise to viable state law claims, such claims are impliedly preempted by the FDCA."); *Summit Tech., Inc. v. High-Line Medical Instruments Co.*, 922 F. Supp. 299, 306, 316 (C.D. Cal. 1996) (dismissing state law claims that did not involve "any additional theories" beyond purported FDCA violations as attempts to "circumvent 21 U.S.C. § 337(a)'s denial of a private right of action"); *Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001) (dismissing on federal preemption grounds state law claims "involv[ing] all the facts and arguments to be determined in a misbranding enforcement action, matters within the sole jurisdiction of the FDA"); *Autin v. Solvay Pharmaceuticals, Inc.*, No. 05-2213, 2006 WL 889423, at *4 (W.D. Tenn. Mar. 31, 2006) (holding that state law claims "based on an alleged violation of

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no private right of action."); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (holding that "no . . . private right of action exists" under the FDCA); *Bailey*, 48 F.3d at 968 ("Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA.").

the FDCA" are preempted by section 337(a)); *Ethex Corp. v. First Horizon Pharmaceutical Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (dismissing defendant's false advertising counterclaim where the "touchstone" of defendant's argument was an FDCA violation); *Anthony v. Country Life Mfg., L.L.C.*, No. 02C1601, 2002 WL 31269621, at *1 (N.D. Ill. Oct. 9, 2002) (granting defendant's motion to dismiss state consumer fraud claims on the ground that they "amount[ed] to nothing other than an attempt to enforce the FDCA"); *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, No. 96-2459, 1997 WL 94237, at *7 (D. Kan. Feb. 26, 1997) (dismissing plaintiff's unfair competition claim on federal preemption grounds when the "crux" of the claim was an FDCA violation).

Although the California Supreme Court sought to distinguish those cases because "[t]hey invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA" (Pet. App. 31), that is no less true here. The factual allegations that support Respondents' state law claims are the very same factual allegations that would support an FDCA claim. (JA 153-173.) As the Court of Appeal recognized, the correct litmus test is not whether claims are labeled state or federal, but "what facts the plaintiffs will be required to prove under the allegations of their complaint":

> If those facts demonstrate violations of the FDCA, then preemption will apply irrespective of the particular state law theories of recovery relied upon by the plaintiffs. To hold

> otherwise would sanction a patent evasion of section 337(a) and would permit the plaintiffs to do the very thing that adherence to federal law would preclude.

(Pet. App. 50.) The California Court of Appeal's decision was but the latest in a long line of cases to hold that state law claims "involv[ing] all the facts and arguments to be determined in a misbranding enforcement action" under the FDCA are preempted. *Healthpoint*, 273 F. Supp. 2d at 838.

The California Supreme Court nevertheless insisted that FDCA section 337 "only implicates efforts to enforce *federal* law," and does not "limit, prohibit, or affect private claims predicated on *state* laws." (Pet. App. 29.)[3] Its opinion ignores the fact that when Congress amended section 337 in 1990, it knew that the provision had been consistently interpreted to preclude private actions brought under *both* federal and identical state law. Had Congress actually intended to allow private state law actions, section 343-1 presented the perfect opportunity. While permitting states to enact laws identical to certain FDCA provisions, Congress easily could have told the courts

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[3] Although not cited by the California Supreme Court, two federal district courts earlier reached the same conclusion. *Vermont Pure Holdings, Ltd. v. Nestle Waters North America, Inc.*, No. Civ.A. 03-11465, 2006 WL 839486, at *6 & n.5 (D. Mass. Mar. 28, 2006); *Reyes v. McDonald's Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579, at *6 (N.D. Ill. Nov. 8, 2006). They are discussed below. (*See* section II, *infra*.)

that – contrary to what they had held – private claims to enforce state replicas of FDCA provisions were to be permissible in the future.

Instead, Congress gave no signal that it intended to authorize private enforcement when it enacted an unambiguous, highly detailed provision for state enforcement. It is hard to believe that Congress legislated about enforcement and only changed the law as to state enforcement, but actually intended to permit both state *and* private enforcement, without mentioning private enforcement at all. *See Monessen Southwestern Ry. Co. v. Morgan*, 486 U.S. 330, 336-38 (1988) (where Congress had amended a statute and "dispensed with [certain] doctrines," but had not addressed the specific doctrine at issue, this Court considered "Congress' silence on this matter in the appropriate historical context" and was "unpersuaded that Congress intended to abrogate that doctrine *sub silentio*"). The NLEA's legislative history, which discusses the "importance of the state role" (Pet. App. 70) and refers to enforcement by "governmental entities" (Pet. App. 74), makes the lower court's theory that Congress somehow intended to allow private enforcement without ever mentioning it even more implausible. Ultimately, it is inconceivable that Congress by its silence changed the law to allow the private enforcement of state laws *identical* to the FDCA – when it had consistently and unequivocally prohibited the private enforcement of the federal law itself.

B. Congress' Longstanding Ban On Private Enforcement Actions Was Unaffected By FDCA Section 343-1.

The California Supreme Court largely justified its decision by pointing to FDCA section 343-1, which not only allows states to adopt laws identical to certain federal labeling requirements, but also in its view permits private parties to enforce those identical state laws. (Pet. App. 27.) Acknowledging that Congress "said absolutely nothing" about private enforcement when it enacted section 343-1 in 1990 (Pet. App. 18), the court nevertheless presumed that Congress "did not intend to alter the status quo, i.e., states may choose to permit their residents to file unfair competition or other claims based on the violation of state laws." (Pet. App. 19.) The court, however, failed to acknowledge that the "status quo" was Congress' longstanding ban on private enforcement actions in FDCA section 337.

In reaching its decision, the California Supreme Court leaned heavily on the "strong presumption against preemption" (Pet. App. 12, 35), which it claimed "applies with particular force here" (Pet. App. 13). While it is true that courts always "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," *California v. ARC America Corp.*, 490 U.S. 93, 101 (1989) (internal quotations and citation omitted), the court below overlooked the fact that preemption *was* the "clear and manifest purpose of

Congress." Section 337 of the original Act is as plain as enforcement provisions come, commanding that "all" proceedings to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a); *Buckman*, 531 U.S. at 349 n.4. That statutory mandate was born of Congress' decision to reject a version that would have allowed a private right of action, *National Women's Health*, 545 F. Supp. at 1179-80, and was intended to exclude private litigants from the Act's enforcement scheme, *Buckman*, 531 U.S. at 349 n.4.

Thus, when Congress in 1990 allowed states to enact laws identical to the FDCA, it was legislating in an area in which the presumption against preemption had already been overcome by its own more than fifty-year ban on private enforcement. The California Supreme Court's theory that Congress silently obliterated its more than fifty-year-old regime of exclusive government enforcement is untenable. In 1990, Congress intended to allow state *governments* – the same parties that were simultaneously permitted to bring certain enforcement actions in federal court, 21 U.S.C. § 337(b) – to enforce in state court the "little FDCA" provisions that section 343-1 allowed states to enact, but it never intended to allow private enforcement.[4]

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[4] While the court below suggested that this Court's opinions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) and *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), somehow support its decision (Pet. App. 24-26), those cases have no relevance here.

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The proper construction of this key federal statute should be settled by this Court. *See, e.g.*, *United States v. Donovan*, 429 U.S. 413, 422 (1977) ("We granted certiorari to resolve these issues, which concern the construction of a major federal statute. . . ."); *Reliance Electric Co. v. Emerson Electric Co.*, 404 U.S. 418, 421-22 (1972) (granting certiorari petition "in order to consider an unresolved question under an important federal statute").

II. THE CALIFORNIA SUPREME COURT'S DECISION WILL HAVE PROFOUNDLY NEGATIVE CONSEQUENCES THROUGHOUT THE COUNTRY.

Exclusive government enforcement has always been an integral component of the FDCA. Congress from the start eschewed the idea of private enforcement, *National Women's Health*, 545 F. Supp. at

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Both decisions addressed only whether the challenged state law claims fell within the scope of the express preemption provisions at issue, never addressing the possibility of conflict preemption. Thus, while the lower court was correct to note that in those cases "the high court considered the impact on assertions of federal preemption of provisions similar to section 343-1" (Pet. App. 24), neither case considered other types of preemption, *see Buckman,* 531 U.S. at 352 ("*Medtronic* did not squarely address the question of implied pre-emption."); *Bates*, 544 U.S. at 458 (conc. & dis. opn. of Thomas, J.) ("Because we need only determine the ordinary meaning of [the Federal Insecticide, Fungicide, and Rodenticide Act provision at issue], the majority rightly declines to address respondent's argument that petitioners' claims are subject to other types of pre-emption.").

1179-80, instead giving the FDA a panoply of enforcement options, 21 U.S.C. §§ 332-334. Importantly, Congress also bestowed upon the FDA the authority not to prosecute "minor violations of [the FDCA] whenever [it] believes that the public interest will be adequately served by a suitable written notice or warning." 21 U.S.C. § 336. By allowing the FDA the discretion to distinguish between minor violations and ones worthy of enforcement, Congress anticipated that the government would determine whether and how to enforce the law. *See, e.g.*, *United States v. Sullivan*, 332 U.S. 689, 694 (1948) (noting that FDCA section 336 grants the Secretary of Health and Human Services the ability to decide not to redress "technical infractions of law"); *United States v. Hunter Pharmacy, Inc.*, 213 F. Supp. 323, 324 (S.D.N.Y. 1963) ("The determination of whether a violation is of such a nature as not to require criminal prosecution to vindicate the public interest is entrusted to the judgment of the Secretary.").

Without this Court's intervention, Congress' government enforcement plan and all its inherent benefits will be lost. As the Sixth Circuit recognized in *Bailey v. Johnson*, a private cause of action under the FDCA would jeopardize the "major advantages" of government enforcement, "including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a uniform enforcement policy." 48 F.3d at 968. Under the California Supreme Court's decision, the enforcement of a vital federal statute and identical state statutes will

be left largely in the hands of class action counsel whose expertise is not in the FDCA, who have no ability to solicit comments on an enforcement policy, whose job is to represent private clients and not the public interest, and who have no ability to pursue a unitary enforcement policy.

If the California Supreme Court's decision allowing private enforcement of the FDCA stands, the reaction will be viral. The California Supreme Court is followed more frequently than any other state court, Dear & Jessen, *"Followed Rate" and Leading State Cases, 1940-2005*, 41 U.C. Davis L. Rev. 683, 693 (2007), so its decision is likely to be widely followed. Moreover, California is not the only state that would allow its unfair competition law to bring private class actions for violation of state laws identical to the FDCA. In fact, a violation of federal or state consumer protection-related statutes automatically constitutes a violation of the unfair competition laws of numerous states.[5]

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[5] *See, e.g., Cheshire Mortgage Service, Inc. v. Montes*, 612 A.2d 1130, 1143 (Conn. 1992) (holding that plaintiff's violation of the federal Truth in Lending Act and a Connecticut statute governing prepaid finance charges automatically resulted in violation of the state unfair trade practices act); *Tuckish v. Pompano Motor Co.*, 337 F. Supp. 2d 1313, 1319-20 (S.D. Fla. 2004) (holding that the violation of a Federal Trade Commission Act rule supported a cause of action under Florida's unfair trade practices act); *Ai v. Frank Huff Agency, Ltd.*, 607 P.2d 1304, 1311 (Haw. 1980), overruled on other grounds, *Robert's Hawaii School Bus, Inc. v. Laupahoehoe Transp. Co., Inc.*, 982 P.2d 853 (Haw.

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1999) (holding that a collection agency that failed to comply with state debt collection provisions also violated state's prohibition against unfair trade practices); *McCoy v. MTI Vacations, Inc.*, 650 N.E.2d 605, 607 (Ill. App. 1995) (holding that the state's consumer fraud act provides a private cause of action to persons damaged as a result of violations of Illinois' Travel Promotion Consumer Protection Act); *William Mushero, Inc. v. Hull*, 667 A.2d 853, 855 (Me. 1995) (holding that a violation of the Home Construction Contracts Act also creates liability under the state unfair trade practices act); *MacGillivary v. W. Dana Bartlett Ins. Agency of Lexington, Inc.*, 436 N.E.2d 964, 969 (Mass. App. 1982) (holding that negligent violation of a statute governing unlicensed insurers constituted violation of the state's unfair trade practices law); *Jacobs v. Rosemount Dodge-Winnebago South*, 310 N.W.2d 71, 79 (Minn. 1981) (holding that breach of an express warranty in violation of a Minnesota statute also amounts to violation of the state consumer protection act "[a]s a matter of law"); *State ex rel. Nixon v. Beer Nuts, Ltd.*, 29 S.W.3d 828, 837-38 (Mo. App. 2000) (holding that selling beer in violation of state liquor licensing requirements subjected defendant to liability under the state consumer protection statute); *Chroniak v. Golden Investment Corp.*, 983 F.2d 1140, 1147 (1st Cir. 1993) (holding that a lender's violation of New Hampshire's Second Mortgage Home Loans Act formed a predicate "unfair or deceptive practice or act" under New Hampshire's consumer protection act); *Morgan v. Air Brook Limousine, Inc.*, 510 A.2d 1197, 1205 (N.J. Super. 1986) (holding that a violation of the Federal Trade Commission rule dealing with unfair and deceptive franchising practices "constitutes a per se unconscionable commercial act or practice in violation" of the New Jersey consumer fraud act); *In re Scrimpsher*, 17 B.R. 999, 1015 (Bankr. N.D.N.Y. 1982) (holding that a violation of the federal Fair Debt Collection Practices Act subjected defendant to concurrent liability under the state consumer fraud act); *Pearce v. American Defender Life Ins. Co.*, 343 S.E.2d 174, 180 (N.C. 1986) (holding that insurer's representation in violation of state insurance law "as a matter of law constitutes an unfair or deceptive trade practice" under the state's unfair and deceptive trade practices act); *Ganson v. Vaughn*, 735 N.E.2d 483, 486 (Ohio App. 1999)

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This is not, in short, a problem that will be limited or is unique to California. In fact, federal district courts in Massachusetts and Illinois have already held that FDCA section 343-1 permits private actions under various state unfair competition laws for violation of FDCA requirements. *Vermont Pure Holdings, Ltd. v. Nestle Waters North America*, No. Civ.A. 03-11465, 2006 WL 839486, at *6 & n.5 (D. Mass. Mar. 28, 2006) (holding that plaintiff could pursue claims under the unfair competition laws of at least six different states, including Connecticut, Massachusetts, Maine, New Hampshire, New York, and Rhode Island, for violations of statutes in each of those states incorporating the FDA's definition of the term "spring water"); *Reyes v. McDonald's Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579, at *6 (N.D. Ill. Nov. 8, 2006) (allowing a claim under the state's consumer fraud act "seeking to enforce the exact terms of the NLEA").

The certain flood of private class actions nationwide will undermine federal and state governments' ability to enforce federal labeling requirements

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(holding that failure to comply with an administrative code provision regarding refund policies and deposits in consumer transactions constitutes an automatic violation of the state consumer sales practices act); *Salois v. Mutual of Omaha Ins. Co.*, 581 P.2d 1349, 1350 (Wash. 1978) (holding that insurer's breach of duty of good faith and fair dealing by refusing to pay insured's claim for benefits was unlawful and against public policy and therefore also a violation of the state consumer protection act).

"consistently with [their] judgment and objectives." *Buckman*, 531 U.S. at 350. The federal and state governments can certainly coordinate their enforcement efforts; the FDA has even declared its intent "to work with the States to attempt to ensure that State provisions that are identical to provisions in the act are interpreted by the States in a way that is as consistent as possible with the FDA's interpretation of the Federal provisions." 58 Fed. Reg. 2457-01, 2458 (1993). The FDA, however, cannot possibly work with countless plaintiffs' lawyers across the country to ensure that their class actions are "as consistent as possible with the FDA's interpretation of the Federal provisions." Instead, inconsistent lawsuits and inconsistent judgments will abound, throwing the enforcement of the Act and identical state laws into hopeless confusion.

The adverse impact of the California Supreme Court's decision cannot be overstated. Permitting private parties to enforce the FDCA and identical state statutes will frustrate Congress' intent to keep enforcement in the hands of experienced government entities capable of coordinating their enforcement efforts. If the decision remains, class action litigation concerning alleged violations of the FDCA and identical state statutes will explode nationwide, wrecking an enforcement regime that has remained in place for the last seventy years. Because the California Supreme Court's decision will have such a radical impact on governmental discretion, oversight, and enforcement, Petitioners respectfully request that

this Court call for the views of the Solicitor General in deciding whether review is appropriate.

CONCLUSION

Congress provided for an exclusive government enforcement scheme to avoid inconsistent judgments and to preserve the governmental discretion and oversight that it believed was necessary for the Act's effective enforcement. Had Congress intended to change that deliberate, longstanding regime, it would have clearly said so. The California Supreme Court's unilateral decision to demolish Congress' well-constructed enforcement framework necessitates this Court's review.

Respectfully submitted,

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