No. 07-1327

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 SUPREME COURT OF CALIFORNIA

## BRIEF IN OPPOSITION

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**STATUTES**

## STATEMENT

1. ***Plaintiffs' Allegations.*** Petitioners are large grocery store chains (hereinafter Grocery Stores). Respondents are consumers (hereinafter Plaintiffs) who allege that the Grocery Stores violated California law by failing to disclose that their farm-raised salmon was artificially colored. Plaintiffs state four causes of action: (1) violation of California's unfair competition law, Bus. & Prof. Code, § 17200 *et seq.*; (2) violation of California's Consumers Legal Remedies Act, Civ. Code, § 1750 *et seq.*; (3) violation of California's false advertising law, Bus. & Prof. Code, § 17500 *et seq.*; and (4) negligent misrepresentation under California law.

2. ***Proceedings in California Superior Court.*** Plaintiffs filed their actions in the California Superior Court. The Grocery Stores sought dismissal of Plaintiffs' consolidated complaint on the ground that § 337(a) of the FDCA preempts Plaintiffs' state law claims. The Superior Court agreed and dismissed the complaint. The Superior Court also dismissed the complaint on other grounds not at issue before this Court.

3. ***Proceedings in California Court of Appeal.*** The California Court of Appeal held that § 337(a) impliedly preempts all of Plaintiffs' claims. The Court of Appeal did not reach the other grounds for dismissal asserted by the Grocery Stores.

4. ***Proceedings in California Supreme Court.*** The California Supreme Court reversed the Court of Appeal's decision, unanimously holding that the FDCA does not preempt Plaintiffs' claims.

**Relevant Federal and State Laws**

a. The Supreme Court explained that § 343(k) of the FDCA requires disclosure of the use of color additives in food. Pet. App. 7-8. The Court also explained that FDA regulations permit the use of the chemical substances astaxanthin and canthaxanthin to color the flesh of salmon, but "the chemicals' presence must be declared as prescribed by the FDA . . . ." *Id.*

b. The Court next stated that Congress amended the FDCA with the Nutrition Labeling and Education Act of 1990 (Nutrition Labeling Act), Pub. L. No. 101-535 (Nov. 8, 1990), 104 Stat. 2353. The Court noted that the Nutrition Labeling Act "included an explicit preemption provision in the form of section 343-1(a) . . . ." Pet. App. 8. In particular, § 343-1(a)(3) provides that "no State or political subdivision or 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(k) of this title that is not identical to the requirements of such section . . . ."

The Court then explained that § 343-1 of the FDCA permits States to adopt or continue in effect labeling requirements so long as they are identical to federal requirements:

> "Although section 343-1 speaks in terms of what states may *not* do, by negative implication, section 343-1 also expresses what states *may* do, *i.e.*, states *may* establish their own requirements pertaining to the labeling

> of artificially colored food so long as their requirements are identical to those contained in the FDCA in section 343(k). (60 Fed.Reg. 57120 (Nov. 13, 1995) [under FDA regulations, 'if the State requirement is identical to Federal law, there is no issue of preemption . . .'] . . . .)"

Pet. App. 9.

c. Next, the Court stated that California's Sherman Food, Drug, and Cosmetic Law, Health & Saf. Code, § 109875 *et seq.* (hereinafter Sherman Law), prohibits the misbranding of food. Pet. App. 10. The Court explained that "the Sherman Law uses language 'identical to' section 343(k) to provide that food is misbranded 'if it bears or contains any . . . artificial coloring . . . unless its labeling states that fact.' (Health & Saf. Code § 110740.)" *Id.* The Court then noted that "California has adopted as its own the FDA regulations regarding the use of (and disclosure of the use of) astaxanthin and canthaxanthin in the feeding of farmed salmon . . . ." *Id.*

d. The Court then explained that FDCA § 337 is a "standing provision, providing that 'all such proceedings for the enforcement, or to restrain violations, *of* [*the FDCA*] shall be by and in the name of the United States . . . .'" Pet. App. 11. The Court explained that § 337 "precludes private enforcement of the FDCA . . . and limits the circumstances under which states may seek to enforce the FDCA in federal court (§ 337(b)). Whether or not section 337 also precludes private claims predicated on state law is the crux of the present litigation . . . ." *Id.*

**Presumption Against Preemption**

e. The Court next noted that a "strong presumption against preemption" applies. Pet. App. 12. The Court stated that "[t]here can be no doubt that the presumption applies with particular force here . . . . Indeed, as early as the 1860's, California was enacting laws regulating food marketing." *Id.* at 13-14.

**Rejection of Grocery Stores' Preemption Argument**

f. The Court then explained that § 343-1 of the FDCA undermines the Grocery Stores' preemption argument. As the Court stated, the "words of section 343-1 clearly and unmistakably evince Congress's intent to authorize states to establish laws that are 'identical to' federal law." Pet. App. 17. The Court stated that

> "[i]f Congress intended to permit states to enact identical laws on the one hand, but preclude states from providing private remedies for violations of those laws on the other hand, 'its failure even to hint at it is spectacularly odd.' (*Medtronic, supra*, 518 U.S. at p. 491 (plur. opn. of Stevens, J.).)"

Pet. App. 19.

The Court then explained that the Nutrition Labeling Act (also known as the NLEA) includes a preemption provision:

> "Congress made clear that the preemptive scope of section 343-1 was to sweep no further

> than the plain language of the statute itself. In NLEA section 6(c)(1) (an uncodified provision), Congress provided that '[t]he [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [section 343-1] of the [FDCA].' (Pub.L. No. 101-535, § 6(c)(1) (Nov. 8, 1990), 104 Stat. 2364.) Thus, Congress's decision not to expressly supplant private claims based on those state laws authorized by section 343-1 should be interpreted as its considered decision to continue to allow states to provide such private remedies."

Pet. App. 20.

g. The Court further explained that two decisions by this Court mandate the conclusion that § 343-1 permits Plaintiffs' action. Pet. App. 27. The Court first discussed *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), in which this Court addressed the preemptive effect of § 360k(a) of the FDCA, under which "no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement – [¶] (1) which is different from, or in addition to, any requirement applicable under this chapter to the device . . . ." The California Supreme Court noted that in *Medtronic*, this Court "concluded that Congress did not intend to preempt 'state rules that merely duplicate some or all of [the] federal requirements.' (*Medtronic, supra*, at p. 492.) The high court further reasoned that because Congress authorized states to adopt identical requirements,

states were also free to provide for private remedies for violations of those requirements." Pet. App. 25.

The California Supreme Court then discussed *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005), in which this Court held that the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) does not preempt "tort claims that parallel FIFRA's misbranding requirements." The Supreme Court of California noted that

> "[l]ike the provision at issue in *Medtronic*, FIFRA contains a preemption provision similar to section 343-1, which provides that states 'shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter' (7 U.S.C. § 136v(b); *see Bates, supra*, 544 U.S. at p. 436)."

Pet. App. 26. The Court further explained that "although FIFRA did not provide a federal remedy to the plaintiffs [for misbranding], the high court concluded that 'nothing in [7 U.S.C.] § 136v(b) precludes States from providing such a remedy.' (*Bates, supra*, 544 U.S. at p. 448.)" Pet. App. 26-27.

The California Supreme Court then reached the following conclusion regarding § 343-1:

> "[I]n light of the plain statutory language of section 343-1, and the high court's construction of similar preemption language, we conclude that Congress intended to allow

> states to establish their own requirements so long as they are identical to those contained in section 343(k), which California has done in the form of the Sherman Law. We further conclude that nothing in the text of section 343-1 or its legislative history supports the assertion that Congress intended to limit the scope of remedies states might choose to provide for the violations of those state laws."

Pet. App. 27.

h. The Court then rejected the argument by the Grocery Stores that § 337 impliedly preempts Plaintiffs' claims. The Court first established that the premise of the Grocery Stores' argument is invalid. The Court stated:

> "The crux of defendants' preemption argument is that plaintiffs' private state claims are precluded because they improperly seek to enforce the FDCA in violation of section 337(a). Defendants' starting assumption is incorrect. Plaintiffs do not seek to enforce the FDCA; rather, their deceptive marketing claims are predicated on violations of obligations imposed by the Sherman Law, something that state law undisputedly allows . . . ."

Pet. App. 28.

The Court then explained that Plaintiffs do not seek to enforce the FDCA:

> "That the Sherman Law imposes obligations identical to those imposed by the FDCA, as it must under section 343-1, does not substantively transform plaintiffs' action into one seeking to enforce federal law. Rather, it merely reflects Congress's considered judgment that states should uniformly regulate food labeling using identical standards. Indeed, while the high court in *Medtronic* did not expressly consider the impact of section 337 on the private state action at issue there, it held that those plaintiffs' private actions were permitted *because* they were identical to the FDCA. (*Medtronic, supra*, 518 U.S. at p. 495.) It is difficult to believe the high court would have so held if section 337 expressed a '"clear and manifest"' intent (*Medtronic*, at p. 485) to preclude private actions based on state laws explicitly authorized by the FDCA in section 343-1."

Pet. App. 28-29.

As a result, the California Supreme Court held that "[s]ection 337 does not apply to the state law claims presented here. The statute, by its very terms, only implicates efforts to enforce *federal* law. What section 337 does *not* do is limit, prohibit, or affect private claims predicated on *state* laws." Pet. App. 29.

i. Having rejected the Grocery Stores' arguments, the Court reversed the judgment of the Court of Appeal. The Grocery Stores now ask this Court to grant their petition for a writ of certiorari.

## REASONS FOR DENYING THE PETITION

The Petition should be denied. First, the question presented by the Grocery Stores is not at issue in this case. The Grocery Stores contend that the question for this Court is whether Plaintiffs may enforce FDCA requirements, even though Plaintiffs seek only to enforce state law requirements, as the California Supreme Court recognized. Second, the decision by the California Supreme Court (hereinafter Decision) does not conflict with any of this Court's precedents. To the contrary, consistent with this Court's decisions, the California Supreme Court held that private citizens may sue to enforce state labeling requirements that are identical to FDCA requirements. Third, the Decision does not conflict with any decision of another state court of last resort or United States court of appeals.

### A. The Question Presented By The Grocery Stores Is Not At Issue, Because Plaintiffs Do Not Seek To Enforce The FDCA Or Any FDA Regulation.

The question presented by the Grocery Stores is not at issue in this litigation. The question presented by the Grocery Stores is whether "private parties' state law claims to enforce FDCA requirements [are] preempted by Congress' mandate that the Act be enforced only by the federal or state governments." Petition at p. i. The Grocery Stores base that question

on the incorrect premise that the California Supreme Court "held that Respondents, private citizens, could bring a class action to enforce the FDCA under the aegis of state law." *Id.* To the contrary, the Court recognized that "plaintiffs do not seek to enforce the FDCA. Their action is based on the violation of *state law* – albeit state law that is, in compliance with section 343-1, identical to FDCA provisions." Pet. App. 24. Therefore, the Court did not address, and had no reason to address, whether Plaintiffs can sue to enforce the FDCA.

Moreover, the preemption issue decided by the California Supreme Court is not fairly included in the question presented by the Grocery Stores. Supreme Court Rule 14.1(a) states that "[o]nly the questions set out in the petition, or fairly included therein, will be considered by the Court." In *Yee v. City of Escondido*, 503 U.S. 519 (1992), this Court declined to consider a question that was not fairly included in the question presented. As this Court explained,

> "Whether or not the ordinance effects a regulatory taking is a question *related* to the one petitioners presented, and perhaps *complementary* to the one petitioners presented, but it is not 'fairly included therein.' Consideration of whether a regulatory taking occurred would not assist in resolving whether a physical taking occurred as well; neither of the two questions is subsidiary to the other."

*Id.* at 537. Therefore, this Court held that Rule 14.1(a) barred consideration of the regulatory taking question. *Id.* at 521.

Similarly, the preemption issue decided by the California Supreme Court is not fairly included in the question presented by the Grocery Stores to this Court. Specifically, consideration of whether Plaintiffs' state law claims to enforce state laws are preempted would not assist in resolving whether private parties may sue to enforce FDCA requirements. Conversely, deciding the question presented by the Grocery Stores would be an academic exercise, because it would not resolve whether Plaintiffs may sue under state law based on state labeling requirements. Thus, review is not warranted.

### B. The Decision Correctly Follows This Court's Precedents.

#### 1. Section 337 Does Not Show That Congress Clearly And Manifestly Intended To Preempt Plaintiffs' State-Law Remedies.

Even assuming that the Grocery Stores presented the correct preemption issue to this Court, the Petition should be denied. The Grocery Stores argue that § 337, which bars private rights of action to enforce the FDCA, also impliedly preempts all private actions to enforce state requirements that parallel FDCA requirements. That argument overlooks the presumption that the FDCA does not preempt historic police powers of the States unless that was the clear and manifest purpose of Congress. *See Medtronic,* 518 U.S. at 485. Laws regulating the marketing of food are within States' historic police powers. *Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 144 (1963) ("States have always possessed a legitimate interest in 'the

protection of . . . [their] people against fraud and deception in the sale of food products' at retail markets within their borders.") (internal citation omitted). Therefore, the presumption applies.

Moreover, § 337 does not clearly and manifestly indicate that Congress intended the FDCA to preempt all private actions to enforce state requirements that parallel FDCA requirements. To the contrary, the lack of a private right of action undermines the Grocery Stores' argument. In *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984), this Court stated that

> "there is no indication that Congress even seriously considered precluding the use of [state] remedies either when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959. This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct. It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."

Similarly, Congress' decision not to create a federal cause of action for violation of the FDCA does not demonstrate that Congress silently intended to bar private remedies for violation of parallel state laws. To the contrary, as in *Silkwood*, the lack of a private right of action under the FDCA undermines the Grocery Stores' argument that Congress silently removed all means of judicial recourse for consumers injured by illegal conduct. *Accord, Bates*, 544 U.S. at 448 ("although

FIFRA does not provide a federal remedy to farmers and others who are injured as a result of a manufacturer's violation of FIFRA's labeling requirements, nothing in § 136v(b) precludes States from providing such a remedy").

### 2. The Decision Is Consistent With *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

The Grocery Stores erroneously argue that the Decision conflicts with this Court's holding in *Buckman*. Contrary to the Grocery Stores' argument, *Buckman* does not stand for the proposition that § 337 precludes "state law claims to enforce requirements substantively identical to federal law" (Petition at 15). Instead, this Court recognized in *Buckman* that section 337 does *not* preclude state law claims that parallel federal requirements and that predate the FDCA.

The holding in *Buckman* was far narrower than the Grocery Stores assert. The plaintiffs in *Buckman* alleged that the defendant defrauded the FDA as to the intended use of its bone screws. The plaintiffs further alleged that "[h]ad the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." 531 U.S. at 343. This Court held that the FDCA preempted the plaintiffs' claim. This Court first explained that "policing fraud against federal agencies is hardly a field which the States have traditionally occupied such as to warrant a presumption against finding federal pre-emption of a

state-law cause of action." *Id.* at 347 (citation and internal quotations omitted). This Court concluded that

> "were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme."

*Id.* at 353.

Thus, this Court did not hold that the FDCA precludes private enforcement of state requirements that predate the FDCA and that concern a field that States have traditionally occupied. Instead, this Court held that the FDCA preempted the plaintiffs' claims because: (1) the plaintiffs did not rely on traditional state requirements that predate the FDCA; (2) policing fraud on the FDA is not a field traditionally occupied by the States; and (3) the existence of federal requirements was a critical element of the plaintiffs' case.

Under *Buckman*, the FDCA does not preempt Plaintiffs' claims in this action. First, California's requirement that artificially-colored food be labeled as such predates the enactment of the FDCA. *See* 1907 California Pure Food Act, § 6 ("Food and liquor shall be deemed mislabeled or misbranded within the meaning

of this act in any of the following cases: . . . If it be labeled or branded or colored so as to deceive or mislead, or tend to deceive or mislead the purchaser . . . ."). Second, the regulation of mislabeled food is a field traditionally occupied by the States. Third, the existence of the federal requirements regarding the labeling of foods is not an element of Plaintiffs' case, let alone a critical element.

The differences between this case and *Buckman* are reflected in this Court's explanation of the differences between *Buckman* and *Medtronic*. This Court stated in *Buckman* that

> "petitioner's dealings with the FDA were prompted by the [Medical Devices Act], and the very subject matter of petitioner's statements were dictated by that statute's provisions. Accordingly — and in contrast to situations implicating 'federalism concerns and the historic primacy of state regulation of matters of health and safety,' *Medtronic*, 518 U.S. at 485 — no presumption against preemption obtains in this case."

531 U.S. at 347-48. Moreover, this Court stated:

> [T]he *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. *See* 518 U.S. at 481. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure

> requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

*Id.* at 352-53. Here, Plaintiffs' claims do not rest on any violation of the FDCA but instead rest on state requirements that predate the FDCA and that are within the traditional police powers of the states. Therefore, they are not preempted.

### 3. The Decision Properly Follows This Court's Precedents Construing Statutes That Permit States To Adopt Requirements That Parallel Federal Requirements.

This Court has held three times that statutes such as § 343-1(a)(3) permit private causes of action to enforce state requirements that parallel federal requirements. First, in *Medtronic*, this Court construed § 360k of the FDCA, which bars States from establishing standards that are "different from, or in addition to," specified federal standards. This Court held that "[n]othing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." 518 U.S. at 495. This Court explained that a damages remedy under state law "merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Id.*

The Grocery Stores argue that this Court did not consider in *Medtronic* whether § 337 impliedly preempts state-law claims to enforce state requirements that parallel federal requirements. The Grocery Stores, however, cannot explain why this Court would hold that private remedies for the violation of parallel state laws are not preempted if Congress clearly and manifestly intended to bar such claims by means of § 337. The plain answer is that § 337 does not preempt any such claims.

Second, this Court held in *Bates* that private citizens may enforce state law duties that parallel FIFRA requirements, even though FIFRA does not provide for a private right of action. This Court discussed the preemptive effect of § 136v(b) of FIFRA, which provides that States "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." *Bates*, 544 U.S. at 431. This Court held that "a state-law labeling requirement is not pre-empted by § 136v(b) if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." *Id.* at 447. This Court further held that § 136v(b) allows States to provide private remedies for violation of parallel state labeling requirements. *Id.* at 448. Similarly, § 343-1(a)(3) of the FDCA permits states to adopt labeling requirements that are identical to federal requirements and to provide private remedies for violation of those requirements. As a result, the Grocery Stores' implied preemption argument under § 337 misses the mark. *See Bates*, 544 U.S. at 458 ("Because we need only determine the ordinary meaning of § 136v(b), the majority rightly declines to address respondent's argument that

petitioners' claims are subject to other types of pre-emption.") (Thomas, J., concurring in part and dissenting in part).

Third, in *Riegel v. Medtronic, Inc.*, __ U.S. __, __, 128 S. Ct. 999, 1011 (2008), this Court explained that § 360k of the FDCA

> "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements. *Lohr*, 518 U.S., at 495; *see also id.*, at 513 (O'Connor, J., concurring in part and dissenting in part). The District Court in this case recognized that parallel claims would not be pre-empted . . . ."

The Grocery Stores cannot explain why this Court held in *Riegel* that parallel claims are *not* preempted if § 337 plainly preempts such claims, as the Grocery Stores argue.

### C. There Is No Conflict With Any Decision Of Another State Court Of Last Resort Or Of A United States Court Of Appeals.

The Grocery Stores do not cite a single decision by a state court of last resort or of a United States court of appeals that conflicts with the decision by the California Supreme Court. None of the cases cited by the Grocery Stores holds that § 337 impliedly preempts all parallel state-law claims. To the contrary, each case involved an attempt to enforce FDCA requirements in federal court.

For example, in *Pacific Trading Co. v. Wilson & Co.*, 547 F.2d 367 (7th Cir. 1976), the plaintiffs claimed that the defendants violated the FDCA. The Seventh Circuit affirmed dismissal of the claim, which was predicated on federal question jurisdiction, because the FDCA "does not provide a cause of action for private parties suing for civil damages." *Id.* at 370. The Seventh Circuit did not address whether the FDCA preempts state-law claims to enforce state requirements that parallel federal requirements.

The other cases cited by the Grocery Stores are similarly inapposite. In *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781 (3d Cir. 1999), the plaintiffs alleged a conspiracy to violate the FDCA. The court held that "[b]ecause plaintiffs here could not sue an individual defendant for an alleged violation of the FDCA, it follows that they cannot invoke the mantle of conspiracy to pursue the same cause of action against a group of defendants." *Id.* at 789-90. Similarly, in *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997), the Court stated that "Friedlander's dogged insistence that PDK's products are sold without proper FDA approval suggests — as the district court observed in the Georgia action — that Friedlander's true goal is to privately enforce alleged violations of the FDCA .... However, no such private right of action exists." *See also Bailey v. Johnson*, 48 F.3d 965, 966 (6th Cir. 1995) ("The defendants bring this interlocutory appeal of the district court's denial of their motion to dismiss for lack of federal jurisdiction. Because we conclude that Congress did not intend to create a private cause of action when it enacted the FDCA, we reverse.").

The amicus brief of Rexall Sundown, Inc., cites yet another inapposite decision by a federal court of appeals. In *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990), the plaintiff sued for false advertising under the Lanham Act. Preemption of state-law claims was not at issue. Instead, the issue was "whether a Lanham Act false labeling claim exists against a manufacturer who lists an ingredient as 'inactive' when FDA standards seem to require that such an ingredient be labeled as 'active.'" *Id.* 230. The Third Circuit explained that the

> "FDA has not found conclusively that demulcents must be labelled as active or inactive ingredients within the meaning of 21 C.F.R. § 210.3(b)(7) . . . . Thus, we are unable to conclude that Vicks's labeling of Pediatric 44's demulcents as inactive is literally false, even if Vicks concurrently claims that these ingredients enable its medicine to work the instant it is swallowed."

*Id.* at 230-31. As a result, "Sandoz's position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations." *Id.* at 231.

*Sandoz* is inapposite for two reasons. First, it did not involve preemption. Second, there is nothing ambiguous about the federal and state regulations that require the Grocery Stores to label their farm raised salmon as artificially colored. This case has proceeded

for years without any suggestion by the Grocery Stores that either the FDA or California is reconsidering those requirements.[1]

Finally, the Grocery Stores rely on several district court decisions, even though conflicts with district court decisions provide no basis for review under Rule 10. In any event, those decisions do not conflict with the decision of the California Supreme Court. Instead, as the California Supreme Court explained, those cases "invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA." Pet. App. 31.[2] The Court also explained that "[b]y

[1] The amicus brief filed by The Food Marketing Institute, *et al.*, does not provide any support for the Petition. The policy reasons set out in that brief have no bearing on the question before this Court but instead should be addressed to Congress. Moreover, this Court has explained that a state-law damages remedy "merely provides another reason for [defendants] to comply with identical existing 'requirements' under federal law." *Medtronic*, 518 U.S. at 495.

[2] *See Fraker v. KFC Corp.*, 2007 U.S. Dist. Lexis 32041 (S.D. Cal. Apr. 30, 2007) (as the California Supreme Court explained below, the plaintiff in *Fraker* sought to enforce FDA food labeling regulations); *Autin v. Solvay Pharms., Inc.* 2006 U.S. Dist. Lexis 19507, at *11 (W.D. Tenn. Mar. 31, 2006) (section 337 preempted claim that drug was sold without FDA-approval, because courts "cannot usurp the FDA's power to evaluate the effectiveness of a drug or to approve a drug"); *Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1055 (E.D. Mo. 2002) (courts "have refused to allow plaintiffs to state a claim based on implicit representations of FDA approval"); *Anthony v. Country Life Mfg., L.L.C.*, 2002 U.S. Dist. Lexis 19445, at *8-9 (N.D. Ill. Oct. 7, 2002) (claim "premised solely upon a (Cont'd)

contrast, plaintiffs' claims in this case do not require referring to, or applying the FDCA. Plaintiffs' claims are based on violation of the Sherman Law and can be resolved with reference to state law alone." Pet. App. at 33. Thus, the district court cases cited by the Grocery Stores are inapposite.

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(Cont'd)
violation of the FDCA—that defendant sold nutrition bars containing ingredients that the FDA had not approved"); *Healthpoint, Ltd. v. Ethex Corp.* 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001) ("a party may not use the FDCA to establish a crucial element of a Lanham Act claim"); *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 U.S. Dist. Lexis 2372, at *21 (D. Kan. Feb. 26, 1997) ("even if it were determined in litigation that Calphron did not meet some independent, lay understanding of the term 'dietary supplement', defendants might not be able to remove the term from its label without violating the FDCA"); *Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 922 F. Supp. 299, 306 (C.D. Cal. 1996) (barring claim that defendant "has failed to disclose the fact of FDA non-approval, when the FDA has not yet determined whether or not the product in question has been approved"); *Animal Legal Defense Fund, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 286 (D. Mass. 1986) (plaintiff's claim was preempted because "states cannot impose different or additional affirmative requirements on meat and meat food products"); *National Women's Health Network, Inc. v. A.H. Robins Co.*, 545 F. Supp. 1177, 1180-81 (D. Mass. 1982)

> "No court has ever ordered a notification and recall campaign on the basis of state law. The vast majority of the state law cases cited by plaintiffs are ordinary duty to warn damage actions, a line of cases which is well established but not authority for the much broader form of relief sought in this case."

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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