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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 California Supreme Court

REPLY TO BRIEF IN OPPOSITION

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INTRODUCTION

Respondents' Brief in Opposition is built entirely on the unsupportable idea that Congress deliberately reserved for the government the power to enforce the provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA"), but licensed private parties to enforce state laws *identical* to the FDCA and its implementing regulations via class actions. Respondents' theory pays no heed to the statutory framework that Congress carefully constructed, which places primary enforcement responsibility and oversight in the hands of the federal government – with a narrow, secondary role for state governments – while precluding *any* form of private enforcement. Their Opposition also ignores the inconvenient truth that the FDCA provides no private right of action, so permitting private state law claims to redress FDCA violations would be as destructive to Congress' government enforcement scheme as a private right to enforce the FDCA itself. Respondents, in sum, offer no way around the conflict between their private FDCA enforcement claims and section 337 of the FDCA, which unequivocally states 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 any event, Respondents' defense of the lower court's decision nowhere denies that the California Supreme Court "decided an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). Without question, the California Supreme Court has effected a radical

change in the enforcement of a critical federal statute, opening the door for private parties to decide when and how to redress violations of the FDCA via class actions – decisions that until now have been left to government entities as Congress intended. Without this Court's intervention, the public will no longer benefit from the federal government's judgment, expertise, and ability to maintain a uniform national enforcement policy in coordination with state governments. Petitioners thus respectfully request that this Court solicit the Solicitor General's views before deciding whether to grant review.

ARGUMENT

I. RESPONDENTS' OPPOSITION IS BASED ON THE FALSE PREMISE THAT CONGRESS PROHIBITED PRIVATE ACTIONS TO ENFORCE THE FDCA, BUT ALLOWED PRIVATE SUITS TO ENFORCE STATE LAWS *IDENTICAL* TO THE FDCA.

A. Congress' FDCA Enforcement Scheme Bars Private Actions, Whether Grounded In Federal Or State Law.

Respondents' Opposition is founded on the flimsy notion that their claims are not preempted because they "seek only to enforce state law requirements," not the FDCA itself. (Brief in Opposition ("Opp."), p. 9.) As a threshold matter, Respondents' insistence that their claims are based solely on violations of state law is belied by their own class action complaint, which explicitly alleges that Petitioners violated the FDCA and misbranded their salmon in violation of Food and Drug Administration ("FDA") regulations. (JA 163-164.) In fact, Respondents' claims concerning Petitioners' purported FDCA violations constitute the factual predicate for *all* of their causes of action. (JA 169-172.)[1]

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[1] Contrary to what Respondents suggest in their Opposition (Opp., p. 1), the California Court of Appeal *has* rejected the other grounds argued by Petitioners in support of their demurrer before the trial court. On remand from the California Supreme Court, the Court of Appeal in a May 16, 2008 opinion reversed the trial court's judgment of dismissal based on those other grounds.

But even setting aside the fact that the FDCA lies at the heart of Respondents' complaint, the "state law requirements" that Respondents seek to enforce are – by their own admission – "*identical* to FDCA provisions." (Opp., p. 10; *see also* JA 169-172 (Complaint).)[2] Whatever label they place on their claims, the fact remains that Respondents seek to remedy a violation of FDCA requirements and, in order to succeed, will necessarily have to prove that Petitioners violated the FDCA. Indeed, Respondents' whole basis for claiming a right to private enforcement is FDCA section 343-1, which requires that the state laws enacted by state governments be *identical* to federal law. 21 U.S.C. § 343-1.

Respondents' private action to enforce state laws identical to the FDCA would be just as devastating to Congress' carefully planned government enforcement scheme as a private action to enforce the FDCA itself, which even Respondents do not claim exists. Congress always anticipated that the government would control the enforcement of FDCA standards, and with

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[2] Quizzically, Respondents insist that the question before this Court is whether they "may sue under state law based on state labeling requirements" – not, as Petitioners put it, whether they may bring "state law claims to enforce FDCA requirements." (Opp., pp. 9-11.) But because the state laws on which Respondents rely indisputably duplicate federal requirements wholesale (Opp., p. 3), the "state labeling requirements" at issue in this case are identical to FDCA standards. Thus, Respondents' "question presented" argument is nothing more than a shell game.

that framework in mind afforded the FDA a panoply of enforcement options, 21 U.S.C. §§ 332-334, including restitution and disgorgement, *United States v. Universal Management Servs., Inc.,* 191 F.3d 750, 760-62 (6th Cir. 1999); *United States v. Lane Labs-USA, Inc.,* 324 F. Supp. 2d 547, 575-79 (D.N.J. 2004). Allowing a private state law action to remedy all violations of FDCA requirements would rob the FDA of the authority to decide among those options, as well as the discretion *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. Permitting private class actions to redress conduct in violation of the FDCA would also jeopardize the "major advantages" of government enforcement, "including expertise, ability to solicit comment from appropriate sources, direct representation of the public interest, and a unitary enforcement policy." *Bailey v. Johnson,* 48 F.3d 965, 968 (6th Cir. 1995). It would wrest enforcement from the hands of experienced government entities capable of coordinating their enforcement efforts, resulting in inconsistent lawsuits, inconsistent judgments, and inconsistent enforcement.

For those very reasons, lower courts have consistently dismissed 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," *Healthpoint, Ltd. v. Ethex Corp.,* 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001), as

attempts to circumvent the FDCA's express prohibition against private enforcement actions. Petition for a Writ of Certiorari ("Petition"), pp. 15-16 (citing cases). While Respondents confusingly maintain that those cases "'invariably deal with a party seeking to enforce (sometimes through the use of state law) the FDCA,'" and that their claims "do not require referring to, or applying the FDCA" (Opp., pp. 21-22 (quoting Pet. App. 31)), ultimately *all* claims to enforce state laws identical to the FDCA necessitate establishing a violation of federal standards – a responsibility that Congress entrusted to the government, *see, e.g., Heckler v. Chaney,* 470 U.S. 821, 835 (1985) (recognizing that the FDCA's "enforcement provisions . . . commit complete discretion to the [FDA] to decide how and when they should be exercised"); *United States v. Sullivan,* 332 U.S. 689, 694 (1948) (discussing the wide prosecutorial discretion that the FDCA affords the FDA).

Congress' deliberate objective, in sum, was to prohibit *all* private enforcement actions, which – whether based on federal or identical state law – compromise the "major advantages" of exclusive government enforcement. *Bailey v. Johnson,* 48 F.3d at 968. Because the preclusion of private actions to enforce federal standards was Congress' "clear and manifest purpose," any presumption against preemption was overcome when Congress enacted the FDCA in 1938 and barred private enforcement of the

FDCA.[3] *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996) (presumption against preemption does not apply where preemption was Congress' "clear and manifest purpose").

B. Congress Did Not Alter Its Prohibition Against Private Enforcement Actions When It Amended The FDCA In 1990.

Without any statutory analysis, Respondents insist in their Opposition that FDCA section 343-1, part of the 1990 amendments to the FDCA, "permits states to adopt labeling requirements that are identical to federal requirements and to provide private

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[3] Respondents rely on *Silkwood v. Kerr-McGee Corp.,* 464 U.S. 238 (1984) (Opp., p. 12), which addressed whether a state law award was preempted by the Atomic Energy Act, but in that case there was "no indication that Congress even seriously considered precluding the use of [state] remedies when it enacted the Atomic Energy Act in 1954 or when it amended it in 1959." *Id.* at 251. To the contrary, the Act's legislative history signaled that "Congress assumed that such remedies would be available." *Id.* In contrast with the Atomic Energy Act at issue in *Silkwood,* here "we have clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 352 (2001) (citing 21 U.S.C. § 337).

Moreover, while the Atomic Energy Act discussed in *Silkwood* failed to provide any federal remedy to persons injured by nuclear accidents, *Silkwood,* 464 U.S. at 251, the FDCA gives the FDA the authority to obtain restitution and disgorgement on behalf of persons injured by FDCA violations, *Universal Management Servs., Inc.,* 191 F.3d at 760-62; *Lane Labs-USA, Inc.,* 324 F. Supp. 2d at 575-79.

remedies for violation of those requirements." (Opp., p. 17.)

While section 343-1 undoubtedly permits states to adopt labeling requirements identical to federal standards, there is no evidence that Congress intended to "provide private remedies for violation of those requirements" – and Respondents cite none. As explained in the Petition, when Congress amended the FDCA in 1990, it knew that section 337 had been consistently interpreted to preclude private actions brought under both federal and state law. It easily *could have declared, while permitting states to enact* laws identical to certain FDCA provisions, that it was also opening the door to private state law claims to enforce those federal standards. Instead, Congress in 1990 was silent with respect to private actions, carving out only a narrow, detailed exception to exclusive federal enforcement for state governments. 21 U.S.C. § 337(b). Certainly, Congress would have given some signal before effecting a monumental change to its decades-old regime of government enforcement.[4]

Respondents have no response to those statutory arguments, nor could they. Instead, they rely on three

[4] Further devastating Respondents' theory is the 1990 amendments' legislative history, which indicates that Congress intended for the state laws enacted pursuant to section 343-1 to be enforced only by "governmental entities." (Pet. App. 74 (H.R. Rep. No. 101-538, 2d Sess., p. 8 (1990).) Respondents present no contrary history in their Opposition.

of this Court's decisions, *Medtronic, Inc. v. Lohr,* 518 U.S. 470 (1996), *Bates v. Dow Agrosciences LLC,* 544 U.S. 431 (2005), and *Riegel v. Medtronic, Inc.,* 128 S. Ct. 999 (2008), none of which has any relevance here. All three cases addressed only whether the challenged state law claims fell within the scope of the express preemption provisions at issue there, never addressing the possibility of conflict preemption under section 337.

In *Medtronic* and *Riegel,* this Court analyzed the express preemption provision found in the FDCA's Medical Device Amendments, section 360k, which preempts state laws "different from, or in addition to" federal requirements. 21 U.S.C. § 360k. This Court, however, never considered section 337. *Buckman Co. v. Plaintiffs' Legal Committee,* 531 U.S. 341, 352 (2001) ("*Medtronic* did not squarely address the question of implied pre-emption."); *Riegel,* 128 S. Ct. at 1011 (stating that "§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," without considering section 337). Although Respondents question in their Opposition "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" (Opp., p. 17), it is axiomatic that cases are not authority for propositions never considered by the Court, *see, e.g., Waters v. Churchill,* 511 U.S. 661, 678 (1994) ("These cases cannot be read as foreclosing an argument that they never dealt with.").

Similarly, *Bates* was limited to an interpretation of the Federal Insecticide, Fungicide, and Rodenticide Act's ("FIFRA") express preemption provision, section 136v(b), concluding that the provision did not "pre-empt any state rules that are fully consistent with federal requirements." *Bates,* 544 U.S. at 452. This Court expressly refused to consider petitioners' conflict preemption argument, confining its decision to a determination of "the ordinary meaning of § 136v(b)." *Id.* at 458. In any event, because FIFRA has no provision analogous to section 337, there was no possibility in *Bates* that plaintiffs' private state law claims could conflict with FIFRA's enforcement scheme. *Id.* at 448.

In sum, neither *Medtronic, Riegel,* nor *Bates,* which were explicitly confined to the express preemption provisions before the Court, supports Respondents' theory that section 343-1 somehow immunizes private state law claims identical to federal requirements from the preemptive effect of section 337. In fact, this Court has expressly held that "Congress' inclusion of an express pre-emption clause 'does not bar the ordinary working of conflict pre-emption principles,' that find implied pre-emption '. . . where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Sprietsma v. Mercury Marine,* 537 U.S. 51, 65 (2002) (quoting *Geier v. American Honda Motor Co.,* 529 U.S. 861, 869 (2000) and *Freightliner Corp. v. Myrick,* 514 U.S. 280, 287 (1995)); *see also Buckman,* 531 U.S. at 352.

C. Respondents' Private State Law Claims To Enforce Federal Requirements *Are* At Odds With *Buckman,* Which Recognized That Private Parties Cannot Sue For Violation Of The FDCA.

Respondents' attempts to shield their claims from *Buckman's* straightforward holding that "it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with [FDCA] provisions," *Buckman,* 531 U.S. at 349 n.4, fall flat.

First, Respondents argue that their claims are not preempted under *Buckman* because they – unlike the *Buckman* plaintiffs – "rely on traditional state requirements that predate the FDCA." (Opp., p. 14.) Not so. Respondents' complaint relies on Sherman Law provisions, all of which replicate and post-date the FDCA. (JA 169.)

Second, Respondents mistakenly argue that unlike in *Buckman,* "the existence of the federal requirements regarding the labeling of foods is not an element of [their] case, let alone a critical element." (Opp., p. 15.) Federal standards that have been imported word-for-word into state law, however, are the beginning and end of Respondents' case. The notion that Respondents' claims did not arise "solely from the violation of FDCA requirements" (Opp., p. 15 (quoting *Buckman,* 531 U.S. at 352-53)) is absurd, because their claims are wholly predicated on California Health & Safety Code provisions that duplicate

federal standards exactly. Despite Respondents' efforts to confuse the issue with artful semantics, the bottom line is that the "state law requirements" on which they rely (Opp., p. 9) *are* federal standards.[5]

II. IN DEFENDING THE CALIFORNIA SUPREME COURT'S DECISION ON THE MERITS, RESPONDENTS DO NOT – AND CANNOT – DISPUTE THAT IT DECIDED AN IMPORTANT QUESTION OF FEDERAL LAW WITH FAR-REACHING CONSEQUENCES.

Respondents' Opposition is most significant not for what it says, but for what it does not say. Respondents nowhere deny that the California Supreme Court "has decided an important question of federal law that has not been, but should be, settled by this Court." Sup. Ct. R. 10(c). Nor do they deny that the California Supreme Court's decision will transfer control over FDCA enforcement from the federal and state governments to numerous class action counsel without the requisite expertise or interest in coordinating their efforts with those governments. Respondents also apparently agree that the California

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[5] In *Medtronic,* by contrast, plaintiffs' "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." *Buckman*, 531 U.S. at 352 (citing *Medtronic,* 518 U.S. at 481). While negligence claims that borrow federal standards involve additional elements of proof, here Respondents' state law claims are predicated on the same facts as an FDCA claim, and their elements are indistinguishable.

Supreme Court's decision is likely to be widely followed in other states.

Perhaps most importantly, Respondents present no reason why this Court should not call for the views of the Solicitor General before deciding whether review is appropriate. As discussed in the Petition, the FDA anticipated "work[ing] 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). It did not anticipate the impossible task of working with countless class action counsel to attempt to achieve a consistent interpretation and a uniform approach. Petitioners thus urge this Court to obtain the Solicitor General's views before condoning the decision below, which will topple a 70-year-old government enforcement regime.

CONCLUSION

The Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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