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

SUPPLEMENTAL BRIEF FOR THE PETITIONERS

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INTRODUCTION

The question presented is not whether traditional state-law causes of action that seek to vindicate independent, distinctive state-law interests are preempted. It is whether private litigation that seeks only to enforce state laws that duplicate federal standards are preempted, when Congress has broadly proscribed private enforcement of the federal standards themselves. The United States never explains why private litigation, which Congress considered to be a direct obstacle to the accomplishment of the Federal Food, Drug, and Cosmetic Act's ("FDCA") purposes when undertaken in federal court, suddenly harmonizes with those statutory purposes when undertaken under identical state law in state courts. The United States reaches its mistaken position not by focusing on the practical impact of private class-action litigation – as implied preemption should – but by focusing on the wrong source of preemption, and by understating the incompatibility of private litigation with the FDCA's federally centralized enforcement scheme.

I. THIS CASE CONCERNS IMPLIED PREEMPTION UNDER FDCA SECTION 337, NOT EXPRESS PREEMPTION UNDER SECTION 343-1.

The United States' recommendation against certiorari rests centrally on its analysis of the "preemptive intent" of FDCA section 343-1, concluding that section 343-1 "does not prevent States from

providing private actions to enforce state requirements that mirror FDCA requirements." (Brief for the United States ("U.S. Br."), pp. 8, 10.) But the question presented by the Petition for Writ of Certiorari ("Petition") is *not* whether section 343-1 of the Nutrition Labeling and Education Act of 1990 ("NLEA") preempts Respondents' claims, but rather whether section 337, enacted more than 50 years earlier, preempts them. It is section 337 – the FDCA's mandate of exclusive government enforcement – that conflicts with private claims seeking to enforce FDCA requirements via state law – not section 343-1.

For that reason, this Court's interpretation of express preemption provisions similar to section 343-1 in *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) (U.S. Br., p. 10), has little relevance here. Those decisions, which addressed only whether the challenged state law claims fell within the scope of express preemption provisions akin to section 343-1, never considered section 337 or conflict preemption. (Reply to Brief in Opposition ("Reply"), pp. 8-10.) Although the United States suggests that *Lohr* and *Riegel* "implicitly recogniz[e] that the FDCA does not contain any generally applicable provision preempting [private] suits" (U.S. Br., p. 15), 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).[1]

Moreover, the fact that Respondents' state law claims are identical to "FDCA requirements," as section 343-1 requires, does not, as the United States suggests, immunize those claims from "a conflict with the FDCA or its enforcement scheme." (U.S. Br., p. 17.) This Court has repeatedly 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, as here, "'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)).

Wyeth v. Levine, No. 06-1249 (argued Nov. 3, 2008), which also concerns "obstacle" conflict preemption principles in the FDCA context, may shed significant light on the question presented here. Like *Wyeth*, this "is a paradigmatic case of state law frustrating the objectives and purposes of a federal regulatory regime," Petition for Writ of Certiorari, *Wyeth v.*

[1] In any event, Petitioners have never argued that there is a "generally applicable provision" preempting all private suits. The only suits preempted by section 337 are those that seek to enforce federally prescribed standards.

Levine, 2007 WL 776723, at *25 (Mar. 12, 2007). If the Court does not grant the Petition, Petitioners urge this Court to hold the Petition pending that decision.

II. THE UNITED STATES' CHARACTERIZATION OF CONGRESS' INTENDED ENFORCEMENT SCHEME IS MISGUIDED.

A. Section 337 *Must* Preclude Both Private Federal And Identical State-Law Actions.

In its brief, the United States never explains the question at the heart of this case: why Congress would expressly prohibit private actions and even unsupervised state government actions to enforce the FDCA, but allow unregulable private actions to enforce state laws *identical* to the FDCA. Permitting private litigants to enforce state laws that admittedly "mirror" FDCA requirements (U.S. Br., p. 13) cannot be squared with Congress' intent that such requirements be enforced by government entities alone and that control over such litigation be federally centralized.

The United States' only answer is that Respondents' claims arise from "an independent state-law duty" (U.S. Br., p. 14 n.2) – not, as in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), "solely from the violation of FDCA requirements," *id.* at 352. Respondents' claims, however, are not based on "independent" state laws, but rather on FDA

regulations and identical California law. (JA 169-72.) The only injury alleged is the failure to comply with federal standards duplicated in state law, and Respondents seek only to punish departure from those standards. Just as in *Buckman*, Respondents are not "relying on traditional state tort law which had predated the federal enactments in question. On the contrary, the existence of these federal enactments is a critical element in their case." *Buckman*, 531 U.S. at 353.

There is, in sum, no distinct or independent state interest that Respondents' complaint seeks to vindicate beyond enforcing compliance with their vision of federal law. While Respondents certainly could bring any claims they might have that – as in *Lohr* – relied on "traditional state tort law which had *predated* the federal enactments in question," *Buckman*, 531 U.S. at 353 (emphasis added), they cannot avoid the impact of section 337 by bringing claims based on state laws that *postdate* and mirror the federal enactments in question.

Moreover, whereas in *Lohr*, as the United States recognizes, plaintiffs sought "a *traditional* damages remedy" (U.S. Br., pp. 10-11 (citing *Lohr*, 518 U.S. at 495) (emphasis added)), here Respondents seek *punitive* damages for violation of federal requirements that Congress intended to be remedied only by seizure, injunction, and civil and criminal penalties. 21 U.S.C. §§ 332-334. Thus, in the absence of *any* independent state interest, the lower court's decision allows an extreme remedy – one that Congress itself

omitted from its enforcement arsenal – for violation of laws *identical* to the FDCA. Under the lower court's decision, massive punitive damages actions could be brought by private class counsel not charged with representing the public interest, even after the FDA had already determined that a warning letter, injunction, or even non-enforcement is appropriate. The resulting multi-million dollar judgments would inevitably lead to over-deterred production and over-protective, non-uniform labeling – the exact consequences Congress sought to avoid by prohibiting private enforcement.

B. Section 343-1 Did Not Alter Congress' Explicit Mandate Of Exclusive Government Enforcement.

The United States adopts the lower court's theory that Congress in 1990 *silently* changed the law to allow private enforcement of state laws identical to the FDCA – when for the prior 50 years it had unequivocally prohibited private enforcement of the FDCA itself. That position inexplicably assumes that in the NLEA, Congress spoke only about state government enforcement, 21 U.S.C. § 337(b), which it went to great lengths to regulate, but actually intended to allow unregulable private enforcement as well, without ever mentioning the subject.

The United States' argument rests on a series of errors. First, it insists that the two pre-NLEA decisions cited in the Petition barring state-law claims to

enforce FDCA requirements "did not cite Section 337 in support of their preemption holdings." (U.S. Br., pp. 15-16.) Not so. *National Women's Health Network, Inc. v. A.H. Robins Co.*, 545 F. Supp. 1177 (D. Mass. 1982), analyzes the language, context, and history of section 337 in detail, and concludes that "[a] private right of action is equally inconsistent with the federal regulatory scheme, whether the right is based in federal or state law." *Id.* at 1179, 1181. *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass.), *aff'd*, 802 F.2d 440 (1st Cir. 1986), quotes *National Women's Health*'s discussion of the "federal regulatory scheme," and – although it does not refer to section 337 by name – quite clearly discusses the provision's preemptive effect: "Massachusetts cannot confer on private persons the power to enforce a federal statute whose enforcement Congress left to federal administrative agencies." *Id.* Thus, contrary to what the United States argues, there *was* uniform case-law interpreting section 337 to preclude state-law FDCA enforcement claims before the NLEA was adopted.[2]

Next, the United States contends that "Petitioners concede that Section 343-1 authorizes States to

[2] While the United States notes that Congress "presumably was aware that the vast majority of States permitted private parties to enforce state laws prohibiting deceptive business practices" (U.S. Br., p. 10), there is *no* pre-1990 authority – and the United States cites none – permitting private parties to enforce state laws *identical* to the FDCA.

sue to enforce [ ] state requirements and that *Section 337 does not preempt or otherwise limit those suits*." (U.S. Br., p. 16 (citing Pet. 20) (emphasis added).) Nothing in the Petition – or any of Petitioners' other briefs – makes such a "concession."

But even if Petitioners *had* posited that state governments could enforce FDCA requirements in state court unimpeded by section 337(b), that still would not be "fatal" to Petitioners' preemption argument (U.S. Br., p. 16), because the issue is whether there may be *private* enforcement. In that regard, the FDA itself has underscored the importance of "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, 2457-58 (1993). Indeed, the FDA "believes that close cooperation between FDA and the States will ensure that goals of uniformity are met," and to that end has instituted a state training program to guarantee consistency. *Id.* at 2460.

Significantly, in this lengthy discussion of coordinated enforcement between federal and state governments, the FDA never hints at the possibility of private actions. And for good reason. While the FDA can oversee, train, and coordinate with state governments, it cannot possibly work with, supervise, or influence countless plaintiffs' lawyers across the country to ensure that their class actions are "as

consistent as possible with the FDA's interpretation of Federal provisions." 58 Fed. Reg. at 2458.

III. BECAUSE THE IMPACT OF THE CALIFORNIA SUPREME COURT'S DECISION WILL BE IMMEDIATE, REVIEW IS NECESSARY NOW.

The United States argues that review is not necessary now because there are no other federal appellate or state supreme court decisions addressing the preemption of private state-law claims to enforce FDCA requirements, and because the California Supreme Court's decision is interlocutory. This issue, however, cannot wait.

A. The Harmful Impact Of The Decision Is Imminent And Largely Irreparable.

If the California Supreme Court's decision stands, it will have an immediate and profound impact on what had been centralized FDA enforcement. The mere threat of massive damages actions will force businesses that the FDA regulates to undertake widely divergent, over-protective labeling measures that the FDA will have difficulty policing or altering after the fact. The FDA, after all, assuming it learns of such cases and has the resources to participate in them, cannot even appear as of right in state court – further complicating its ability to maintain uniform interpretations of the FDCA and its own regulations. Costly class actions will also significantly

deter industry dialogue with the FDA, elevate food prices that already stand at record highs, and in some instances deter production altogether because of the near impossibility of complying with the labeling demands of private litigants in all 50 states.

The United States poses a straightforward example in which a federal consent decree governing enforcement of a federal labeling requirement preempts a state-law action to enforce an identical state requirement. (U.S. Br., p. 18.) But what if the state-law action – or, more likely, a dozen state-law actions – precede the FDA lawsuit? Those state actions would be brought by various class action counsel who are not obligated to represent the public interest, have no expertise in the FDCA, and have no ability to pursue a unitary enforcement policy. Contrary to what the United States insists, those state-law actions *would* "'skew' the 'delicate balance of statutory objectives' that FDA was charged with achieving." (*Id*., p. 19 (citing *Buckman*, 531 U.S. at 348).)

It is no answer to say that litigation seeking to impose inconsistent labeling requirements can be expressly preempted. First, that point has no bearing on litigation brought before the FDA formally promulgates a standard in novel areas of application. Second, because the threat of damages is so exponentially high in the class action context, food and drug companies will be forced to settle cases even when their liability exposure is minimal. As Judge Posner observed in *In the Matter of Rhone-Poulenc Rorer Inc*., 51 F.3d 1293 (7th Cir. 1995), the "sheer

magnitude of the risk to which the class action" exposes defendants puts them under "intense pressure to settle," even where there is a "demonstrated great likelihood that the plaintiffs' claims . . . lack legal merit." *Id.* at 1297-99; *see also, e.g.*, *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1967 (2007) (explaining in class action case that "the threat of discovery expense will push cost-conscious defendants to settle even anemic cases before reaching [summary judgment] proceedings").

Because the effects on industry conduct and ultimately consumers will be so sudden and severe, this Court should not wait for a case that meets the United States' desired level of conflict before granting review.[3] In fact, the only reason why a sharper conflict has not yet materialized is that it had been so clear – until now – that private actions to enforce the FDCA, whether brought under the mantle of federal or state law, are prohibited by section 337. (*See* Petition, pp. 15-16 (citing cases).) The lower court's decision upset that settled law and, if it remains, class action litigation concerning alleged violations of state statutes identical to the FDCA will explode nationwide, far exceeding the FDA's ability to

[3] While there are no federal appellate or state supreme court cases involving state-law claims to enforce the FDCA, the lower court's decision still cannot be reconciled with *Buckman*'s statement 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.

superintend enforcement and wrecking an enforcement regime that has remained intact for the last 70 years.[4]

B. This Court Should Accept Jurisdiction Because The Issue Has Been Finally Decided In State Court And Would Seriously Erode Federal Policy Absent Review.

In a final argument, the United States insists that this Court should deny the Petition because the decision below is interlocutory. (U.S. Br., p. 20.) But this Court has long reviewed state court judgments where, as here,

> the federal issue has been finally decided in the state courts with further proceedings pending in which the party seeking review here might prevail on the merits on nonfederal grounds, thus rendering unnecessary review of the federal issue by this Court, and where reversal of the state court on the federal issue would be preclusive of any further litigation on the relevant cause of action rather than merely controlling the nature and character of, or determining the admissibility of evidence in, the state court proceedings still to come.

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[4] Even the United States does not dispute that the lower court's decision is likely to be followed in other states, which have unfair competition laws – like California's – that serve as ready vehicles for the private enforcement of FDCA requirements.

Cox Broadcasting Corp. v. Cohn, 420 U.S. 469, 482-83 (1975). In those circumstances, this Court has "entertained and decided the federal issue . . . because *a refusal immediately to review the state court decision might seriously erode federal policy*." *Id.* at 483 (emphasis added); *see also, e.g.*, *Mercantile National Bank v. Langdeau*, 371 U.S. 555, 558 (1963); *Fort Wayne Books, Inc. v. Indiana*, 489 U.S. 46, 47 (1989).

As discussed, permitting private parties to enforce state laws identical to the FDCA would frustrate Congress' intent to keep enforcement in the hands of experienced government entities capable of coordinating their enforcement efforts – thus seriously eroding a 70-year-old federal policy of exclusive government enforcement.

Indeed, in *Buckman*, the Third Circuit – like the California Supreme Court here – reversed the trial court's decision granting defendant's motion to dismiss on federal preemption grounds. *Buckman*, 531 U.S. at 347 (citation omitted). Although the Third Circuit's decision was "interlocutory" and further proceedings had been ordered in the trial court, this Court exercised its certiorari jurisdiction to review the important preemption question presented. *See also Lohr*, 518 U.S. at 482-83 (accepting jurisdiction after Eleventh Circuit partly reversed district court's dismissal on federal preemption grounds and remanded for further proceedings).

Ultimately, neither the United States nor Respondents 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). If this Court refuses jurisdiction now, it could be many years before this Court has another opportunity to review this critically important federal preemption issue. During that time, countless private class actions to enforce the FDCA will be litigated, actions that will "seriously erode the federal policy" of government enforcement that Congress deliberately established more than 70 years ago. *Cox*, 420 U.S. at 483.

CONCLUSION

For all the reasons stated in this Supplemental Brief, the Petition, and the Reply, certiorari should be granted. In the alternative, the Petition should be held pending this Court's decision in *Wyeth v. Levine*, No. 06-1249.

Respectfully submitted,

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