No. 08-889

In The
Supreme Court of the United States

Tri-Union Seafoods, L.L.C,
d/b/a Chicken of the Sea,
Petitioner,

v.

Deborah Fellner,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Third Circuit correctly held that Deborah Fellner's state-law claims based on failure to warn of the risks of mercury in tuna are not preempted by the Food and Drug Administration's issuance of an advisory to pregnant women, nursing women, women who might become pregnant, and young children about mercury in seafood; by its decision not to require mercury warnings as a condition of placing health claims related to omega-3 fatty acids on seafood; and by its sending of an informal letter to a party in another case stating the view that the particular state law at issue in that case was preempted.

2. Whether the presumption against preemption—reaffirmed by the Court twice already this Term in conflict preemption cases—continues to apply in such cases.

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INTRODUCTION

The Food and Drug Administration ("FDA") has "promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect." Pet. App. 35a. Nonetheless, Petitioner Tri-Union Seafoods urges this Court to review the Third Circuit's decision that Deborah Fellner's state-law claims based on failure to warn of the risks posed by mercury in seafood are not preempted by the FDA's "regulatory actions." Pet. 15. As *Wyeth v. Levine*, __ U.S.__, No. 06-1249 (March 4, 2009), makes clear, however, the court of appeals correctly held that the FDA's few informal actions on mercury in seafood do not constitute federal law capable of preempting state law under this Court's Supremacy Clause jurisprudence. Moreover, the decision below does not conflict with *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (2004), just because both cases involve agency letters. As for Tri-Union's second question presented, the Court has reaffirmed the presumption against preemption twice already this Term and has rejected the argument that it does not apply to conflict preemption cases. The petition for a writ of certiorari should be denied.

STATEMENT OF THE CASE

A. Factual Background

1. Methylmercury is a highly toxic form of mercury that builds up in fish and other seafood. Despite the dangers of methylmercury in seafood, the FDA has issued no regulations pertaining to it: It has not placed a regulatory limit on the acceptable amount of mercury in

seafood; it has not promulgated labeling regulations pertaining to mercury in seafood; and it has not issued regulations either requiring or forbidding warnings about mercury in seafood.

What the FDA has done is provide some consumers with advice about mercury through a brochure and its website. In particular, the FDA has made advice available to women who might become pregnant, women who are pregnant, nursing mothers, and young children in an advisory entitled "What You Need to Know About Mercury in Fish and Shellfish" (the "Consumer Advisory"), available at http://www.cfsan.fda.gov/~dms/admehg3.html. The Consumer Advisory states that fish and shellfish are an important part of a healthy diet, but that they contain traces of mercury and "some fish and shellfish contain higher levels of mercury that may harm an unborn baby or young child's developing nervous system." *Id.* It counsels the women and children at whom it is aimed to avoid shark, swordfish, king mackerel, and tilefish; to eat no more than 12 ounces a week of other fish (including canned light tuna) and no more than 6 ounces a week of albacore tuna; and to check local advisories about freshly caught fish. *Id.* Neither the Consumer Advisory nor the backgrounder that accompanied it mentions food labels or warnings or sets limits on mercury levels in canned tuna.

The FDA has also issued non-binding guidance to its enforcement division setting forth a level of mercury—called an "action level"—above which the seafood may be considered adulterated. *See* http://www.fda.gov/ora/compliance_ref/cpg/cpgfod/cpg540-600.html (providing "criteria for recommending legal action").

2. In September 2004, the FDA addressed a different issue related to seafood: whether food producers could make claims about the health benefits of eating foods containing omega-3 fatty acids. The FDA issued a letter stating that it would not take enforcement action against manufacturers of foods that claimed that "supportive but not conclusive research" shows that eating certain omega-3 fatty acids may reduce the risk of heart disease. At the same time, the FDA rejected a request by Martek Biosciences Corporation that it require any such claims on seafood to be accompanied by a label statement about the harmful effects of mercury. *See* Letter from William K. Hubbard, FDA, to Martin J. Hahn, Hogan & Hartson, Responding to Health Claim Petition dated November 3, 2003 (Martek Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease (the "Martek Petition Response"), available at http://www.cfsan.fda.gov/~dms/ds-ltr37.html. In other words, the FDA decided that it would not consider seafood bearing an omega-3 fatty acid health claim to be misbranded just because the claim was not accompanied by a mercury warning. *See id.* ("FDA has decided that it would be preferable not to use a label statement about mercury . . . as a condition for the agency's enforcement discretion for the omega-3 fatty acid qualified health claims."); *compare* Pet. at 8, 19 (quoting only first part of sentence).

3. In June 2004, the State of California sued Tri-Union and other tuna companies under the state's Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health and Safety Code § 25249.6 (commonly referred to as "Proposition 65"), for selling canned tuna without a warning that the products contained mercury. During

discovery in that case, the defendants produced an unsigned letter and memorandum dated August 12, 2004, to the FDA Chief Counsel, from an attorney at Covington & Burling, which represented the canned tuna industry in the litigation. *See* Court of Appeals App. A-75 - A-98. The letter urged the FDA to send a letter to California officials stating that the FDA intended to preempt Proposition 65 warnings on tuna. The memorandum explained that "the language of the Supreme Court's decisions . . . suggests that only . . . a binding rule of law promulgated pursuant to the agency's delegated rule-making authority from Congress, qualifies as a 'Law of the United States' for purposes of preemption under the Supremacy Clause." *Id.* A-80. Nonetheless, the memorandum stated that a court might give deference to a letter from the FDA asserting the intent to preempt Proposition 65 mercury warnings. The memorandum detailed points that the FDA should make in such a letter.

Parroting many of the arguments and some of the exact language in the Covington & Burling memorandum, on August 12, 2005, the FDA Commissioner sent the California Attorney General the requested letter expressing the "belie[f]" that the specific warnings at issue in that case were preempted by federal law. *See* Letter from Lester M. Crawford, Commissioner of Food and Drugs, to Bill Lockyer, Attorney General of the State of California, RE: a suit filed on June 21, 2004 in San Francisco Superior Court, *The People of the State of California v. Tri-Union Seafoods, LLC, et al.* (the "Commissioner's Letter"), available at http://www.cfsan.fda.gov/~dms/fl-ltr65.html. The Commissioner's Letter asserted that the FDA "implemented its regulatory

authority with a nuanced approach," and that the "Proposition 65 warnings frustrate this carefully considered agency approach, causing federal law to preempt California's warnings." *Id.* The letter also contended that the FDA believed that the Proposition 65 warnings would be misleading because they "omit facts which are necessary to place the information in its proper context," and that, therefore, tuna products with the Proposition 65 warnings would be misbranded under federal law. *Id.*

B. Proceedings Below

Deborah Fellner developed severe mercury poisoning after making Tri-Union Seafood's tuna a primary part of her diet between 1999 and 2004. On January 16, 2006, she filed this action for damages under the New Jersey Products Liability Act, N.J.S.A. 2A:58-C et seq., and the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1 et seq. Tri-Union moved for judicial notice of the Consumer Advisory, backgrounder, Commissioner's Letter, and action level, and to dismiss on the ground that Ms. Fellner's claims are preempted by the FDA's actions. On January 8, 2007, the district court granted both motions. Pet. App. 38a.

The Third Circuit reversed. The court began by explaining that regulations, as well as statutes, can preempt state law and that, under its case law, agency action may be preemptive even if it is not taken through notice-and-comment rulemaking. *Id.* 9a. However, the court stated, that "does not mean . . . that federal law capable of preempting state law is created every time someone acting on behalf of an agency makes a statement

or takes an action within the agency's jurisdiction." *Id.* 11a-12a. Noting that the Supremacy Clause provides that state law will be preempted only by federal "law," the court held that preemptive effect should not be afforded to informal measures "lacking the 'fairness and deliberation' which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law." *Id.* 12a (quoting *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)). With regard to the Commissioner's Letter, the court stated that it had found no case in which a letter that was not the product of an agency proceeding and did not purport to impose new legal obligations on anyone was held to be federal law capable of preemption. *Id.* 13a. It also pointed out that "mere deliberate agency inaction" does not alone preempt, and that it could find "no support for the proposition that an agency's informal explanation for its decision not to regulate can alone imbue such a decision with preemptive force." *Id.* 16a.

The court next discussed two rules of interpretation: the presumption against preemption and deference. The Court stated that the presumption applied here because "it is hard to imagine a field more squarely within the realm of traditional state regulation than a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product." *Id.* 19a-20a. With regard to deference, the court explained that an agency's informal views on a legal issue are entitled to deference in accordance with their power to persuade. *Id.* 22a. It concluded that "the circumstances of this letter suggest that it merits a particularly low level of deference," *id.* 23a, noting that the letter was not shown to be the product of an agency proceeding, bore a "striking

resemblance" to the Covington & Burling memo, and had apparently been "formulated without the benefit of exposure to conflicting views or critiques," *id.* 24a; that the views in it were not expressed at the time of the purportedly preemptive actions or before Ms. Fellner's claims arose; that the views were "certainly not self-evident from the nature" of the purportedly preemptive actions and were ultimately expressed "only later, through a most informal of methods—a letter offering a legal theory for the litigation in California," *id.*; and that the reasoning of the letter was not persuasive. *Id.*

The court then turned to Tri-Union's specific conflict preemption theories. *Id.* 24a-35a. First, the court rejected Tri-Union's argument that Ms. Fellner's lawsuit conflicts with a federal regulatory scheme. The court explained that the FDA had not taken any action pertaining to mercury or mercury warnings that could be considered an exclusive application of federal law. Moreover, the court stated that even if the FDA's actions were of a type that could preempt state law, Tri-Union had identified no conflict between those actions and Ms. Fellner's claims. *Id.* 26a.

In particular, the court noted that the FDA had not acted to regulate, reiterating that "the letter itself does not establish a federal policy against warnings capable of preempting state law." *Id.* 29a. With regard to the Martek Petition Response, the court pointed out that it had not been asked to take judicial notice of the response and that it was therefore not clear that it could consider the response in the context of a motion to dismiss. It nonetheless addressed the response, explaining that it discussed mercury only briefly and in a different context, and that the FDA "merely explained that it would decline

to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited." *Id.*

The Third Circuit next addressed Tri-Union's argument that Ms. Fellner's claims conflict with a federal decision not to regulate. The court reiterated that state law is not preempted by a mere decision by an agency not to act, and that it had found "no authority for the proposition that the FDA could institute a regime affirmatively proscribing all warning obligations via mere informal expressions of policy such as those found in the Commissioner's letter." *Id.* 30a. "[C]ourts have declined to permit agencies to promulgate express preemption decisions by informal letter." *Id.* 31a.

Finally, the court explained that Tri-Union's argument that the FDA would have deemed any tuna containing mercury warnings to be misbranded suffered "from the same shortcomings as its prior theories": Tri-Union had identified no regulatory actions through which the FDA established that a product containing mercury warnings was misbranded under federal law, *id.* 34a, and, in any event, had failed to identify an actual conflict between Ms. Fellner's claims and any FDA concerns. *Id.* 35a.

Having found "no federal law with which the alleged state duty to warn conflicts," the court reversed the district court's decision. *Id.* 36a. Tri-Union's petition for rehearing *en banc* was denied. *Id.* 55a-56a.

REASONS FOR DENYING THE WRIT

I. The Decision Below Is Consistent With *Dowhal* and This Court's Precedent.

1. Tri-Union claims that the decision below conflicts with *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910 (2004), because the California Supreme Court held that the letter at issue in that case "adopt[ed] a federal policy that preempted conflicting state law," while the Third Circuit held that the letter at issue here did not. Pet. 19. Not all letters are the same, however, and the letter at issue in *Dowhal* is not comparable to the letter in this case.[1]

The letter in *Dowhal* was the FDA's response to a citizen petition asking the FDA to require over-the-counter nicotine-replacement therapy (NRT) drug products to bear warnings similar to a warning it had approved for one NRT product. The FDA rejected the proposed warning, but set forth specific language for a revised warning. The California Supreme Court found that it was "apparent from the tenor of the letter that it imposes a duty on the defendants," *Dowhal*, 32 Cal. 4th at 927, and concluded that the letter was a "ruling" that "required" defendants to use the specific warning language and "prohibit[ed] defendants from giving consumers any warning other than the one approved by the FDA." *Id.* at 927-29.

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[1]Tri-Union implies that the Third Circuit might have been unaware of *Dowhal*, *see* Pet. 19, but Tri-Union cited *Dowhal* multiple times in its brief below and then filed a letter further discussing the case.

In contrast, the Commissioner's Letter here was not issued through one of the FDA's formal regulatory procedures and does not place any obligations on Tri-Union or anyone else. It is an informal letter to a party in litigation stating an opinion about preemption. And the Martek Petition Response—which Tri-Union cites in an attempt to find a relevant document issued through a recognized process—similarly imposes no legal obligation on Tri-Union. Simply put, unlike the *Dowhal* letter, which the court found prohibited the warnings the plaintiff sought, the Commissioner's Letter and Martek Petition Response neither require nor prohibit anything related to warnings. The Commissioner's Letter and *Dowhal* letter are not comparable in either formality or effect, and there is thus no conflict between *Dowhal* and the decision below.

In any event, this Court's recent decision in *Wyeth v. Levine* confirms that the Third Circuit was correct in not giving the Commissioner's Letter preemptive effect. In *Wyeth*, the Court differentiated between substantive federal law, which preempts conflicting state law, and "agency proclamations of pre-emption," which are not themselves preemptive, but are given deference in accordance with their thoroughness, consistency, and persuasiveness. Slip op. at 19-20 (citing *Mead*, 533 U.S. at 234-35, *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944)). Here, the Commissioner's letter does not set forth substantive law, but rather "the agency's explanation of state law's impact on the federal scheme," *id.* at 20, and the court of appeals was correct to accord it deference only in proportion to its ability to persuade. *See* Pet. App. 23a (citing *Mead* and *Skidmore*).

2. Tri-Union also asserts that the Court should grant certiorari because the decision below is "inconsistent with this Court's precedent, which recognizes that agency actions need not rise to the level of formality that attends notice and comment procedures to carry preemptive force." Pet. 16; *see also id.* 21. Given that the Third Circuit specifically stated that "federal agency action . . . short of formal, notice and comment rulemaking may also have preemptive effect," Pet. App. 9a, this "inconsisten[cy]" is illusory.[2]

3. Finally, Tri-Union insists that the FDA has established an "authoritative policy against mercury warning labels," Pet. 21, that should be accorded preemptive effect. But Tri-Union's insistence does not make it so. The Consumer Advisory and backgrounder provide only non-binding advice on fish consumption to certain consumers; the Martek Petition Response "merely explained that [the FDA] would decline to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited," Pet. App. 29a; and the Commissioner's Letter was not the product of any agency proceeding and is a "proclamation[] of pre-emption," *Wyeth*, slip op. at 19, not substantive law.

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[2]The Third Circuit's explanation that regularity of procedure could arise from rulemaking, adjudication, or "other [procedures]," Pet. App. 12a, makes clear that the court also did not hold, as Petitioner's amicus Chamber of Commerce claims, that agency action must be the result of either notice-and-comment rulemaking or adjudication to be preemptive.

Tri-Union points to a statement in *Arkansas Electric Cooperative Corp. v. Arksansas Public Service Commission*, 461 U.S. 375, 384 (1983), that "a federal decision to forgo regulation in a given area may imply an authoritative federal determination that the area is best left *un* regulated." Pet. 21. But this Court has specifically warned against drawing "exaggerated inferences" from the *Arkansas Electric Cooperative* statement and has rejected the argument that the statement allows preemption absent federal law. *Puerto Rico Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988). "There is no federal pre-emption in vacuo, without a constitutional text or a federal statute to assert it," *id.*, and the court of appeals was correct to hold that there is no preemption here.

II. The Decision Below Would Not Allow Tri-Union to Be Held Liable for Failing to Include a Warning That Would Violate Federal Law.

Tri-Union relies on the Commissioner's Letter to argue that the decision below would allow it to be held liable for failing to include warnings that would render its products misbranded under federal law. Although Congress provided the FDA with numerous ways of enforcing the statutory prohibition on misbranded food, however, sending an informal letter setting out a legal theory is not one of them. Moreover, the determination whether food is misbranded is not the FDA's to make. As the Court explained in *Wyeth v. Levine*, "because the statute contemplates that federal juries will resolve most misbranding claims, the FDA's belief that a [product] is misbranded is not conclusive." Slip op. at 13.

Contrary to Tri-Union's argument, the decision below does not conflict with *Grocery Manufacturers of America, Inc. v. Gerace*, 755 F.2d 993 (2d. Cir. 1985). Pet. 25. There, the FDA had promulgated a regulation defining imitation food. The court held that a New York law requiring cheese products that were not imitation under the FDA regulation to be labeled "imitation" was preempted because it would cause the food to be misbranded under federal law. In other words, the state law conflicted with substantive federal law enacted through regulation. Here, in contrast, the agency action is an informal letter, not a regulation, and it does not create substantive law, but rather states an opinion about what would make a product misbranded. *See Wyeth v. Levine*, slip op. at 13, 19-20.

Moreover, even if the Commissioner's Letter did carry the force of law, it still would not preempt the claims here. The letter pertained specifically to Proposition 65's safe-harbor warning and assumed that the required warning would be some version of "WARNING: This product contains a chemical known to the State of California to cause cancer" and "WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm." It was these particular warnings—and no other—that the Commissioner said "omit facts which are necessary to place the information in its proper context." Ms. Fellner, however, has not claimed that Tri-Union should have used the Proposition 65 safe-harbor language, nor that it should have omitted other facts in warning consumers about mercury. Tri-Union jumps to the conclusion that because the Commissioner stated that the FDA would consider products with the Proposition 65 warnings to be

misbranded, it would consider any product that contained a mercury warning to be misbranded, but the Commissioner's Letter does not say that.

Finally, and most importantly, placing mercury warnings on tuna would *not* render them misbranded under the Food, Drug, and Cosmetic Act (FDCA). *See* 21 U.S.C. § 343(a)(1) (food is misbranded if its labeling is false or misleading). A mercury warning would be truthful, *see* Consumer Advisory (acknowledging that "nearly all fish" contains mercury, which can have "harmful effects"), and whether a label is misleading depends on how it would be perceived by consumers, who do not expect detailed scientific explanations on food labels or assume that foods with warnings lack benefits. Moreover, warnings could be crafted that describe both the products' benefits and the risks posed by mercury. And although Tri-Union notes that the Commissioner's Letter expresses a preference for advisories over warnings, the question here is not what the FDA prefers; it is whether tuna products with mercury warnings would be misbranded under the FDCA. They would not, and the court of appeals correctly held that Ms. Fellner's claims are not preempted.

III. This Court Has Reaffirmed the Presumption Against Preemption Twice Already This Term in Conflict Preemption Cases.

Earlier this month, in *Wyeth v. Levine*, this Court reiterated that the presumption against preemption applies "[i]n all pre-emption cases," and expressly rejected the argument that it does not apply to claims of implied conflict preemption. Slip op. at 8-9 & n.3; *see also Altria Group, Inc., v. Good*, 129 S. Ct. 538, 543 (2008)

(presumption against against preemption applies to "questions of express or implied pre-emption"). Thus, if there were any question at the time of the Third Circuit's decision about whether the presumption against preemption still applies to conflict preemption cases, that question has since been answered by this Court.

In any event, this case would not be an appropriate vehicle for considering the presumption against preemption because the presumption did not affect the outcome of the case below. Although the Third Circuit's decision includes an introductory section on the presumption, it does not mention or otherwise give any indication that it relied on the presumption in explaining why there is no conflict preemption here.[3] The court did not hold, for instance, that there might be a conflict, but the conflict was not sufficiently "clear and manifest" to overcome the presumption. *See, e.g., id.* at 543 (presumption can be overcome by "clear and manifest purpose of Congress") (citation omitted). Rather, it held that there was no conflict because FDA had not regulated mercury warnings to begin with. The court had no occasion to rely on a presumption that "the federal law should be read narrowly," Pet. 35, when there was no federal law for the court to read.

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[3]Indeed, the court of appeals relied far less on the presumption than this Court did in *California v. ARC America Corp.*, 490 U.S. 93, 101 (1989), and *Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 716 (1985), two cases that Tri-Union attempts to explain away by asserting that they "did not reply on the presumption in [their] conflict preemption" analyses. Pet. 32.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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