No. 07-1238

IN THE UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

DEBORAH FELLNER,

Plaintiff-Appellant,

v.

TRI-UNION SEAFOODS, LLC,

Defendant-Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT
COURT FOR THE DISTRICT OF NEW JERSEY

BRIEF FOR APPELLANT DEBORAH FELLNER

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STATEMENT OF SUBJECT MATTER AND APPELLATE JURISDICTION

This appeal is from a decision of the district court granting Defendant Tri-Union Seafood's ("Tri-Union") motion to dismiss. The district court had jurisdiction under 28 U.S.C. § 1332 based on diversity of citizenship. *See* Notice of Removal. Its judgment was entered on January 8, 2007. *See* App. A-2. Plaintiff Deborah Fellner filed her timely notice of appeal on January 23, 2007. *See* App. A-1. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUE

Whether the Food and Drug Administration's ("FDA") issuance of an advisory, backgrounder, and action level relating to methylmercury in seafood preempts Plaintiff's state-law damages claims.

This issue was raised in Defendant's motion to dismiss dated March 9, 2006, which was opposed by Ms. Fellner in a memorandum dated April 4, 2006. The district court ruled on this issue in a memorandum and order filed on January 8, 2007. (App. A-2, A-3-A-17).

STATEMENT OF THE CASE

This appeal involves an action 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*., based on Tri-Union's canning of tuna products that were not reasonably safe, its failure to adequately warn the public that its tuna products contained methylmercury and other harmful compounds that can result in mercury poisoning, and its misrepresentation of the safety of its tuna products. On Defendant's motion to dismiss, the district court held that Plaintiff's claims are preempted by the FDA's "approach" to the presence of mercury in seafood.

Part A below describes the FDA's statutory authority with regard to food labeling and the interaction of federal and state food labeling requirements. Part B sets forth the agency's "approach" to methylmercury in seafood. Part C describes a letter, found "persuasive" by the district court, that the FDA sent to the Attorney General of California, in which the FDA stated its belief that a California warning law was preempted by federal law. Finally, Part D describes the facts concerning Ms. Fellner's case and briefly summarizes the proceedings below.

A. The FDCA and Its Interaction with State Law

Under the Food, Drug, and Cosmetics Act ("FDCA"), the FDA has authority to regulate in the area of food safety. *See* 21 U.S.C. § 371. The FDA can set food definitions and standards of quality, *id*. § 341, establish tolerance levels for poisonous or deleterious substances in food, *id.* § 346, and initiate enforcement proceedings against manufacturers of adulterated or misbranded

food. *Id*. § 332 (injunctions), § 333 (criminal penalties), § 334 (seizure), § 342 (defining "adulterated"), § 343 (defining "misbranded"). Among the ways a food can be deemed misbranded is if its labeling is "false or misleading in any particular," *id.* § 343(a)(1), or if its label does not contain required nutrition information (such as serving size, number of servings per container, total number of calories, and total number of calories derived from fat). *Id.* § 343(q). In a few instances, the FDA has promulgated regulations requiring particular warnings on labels of particular foods to alert consumers to potential health risks. *See, e.g.*, 21 C.F.R. § 101.17(d) (requiring label of food advertised for weight loss that contains more than 50% of its calories from protein to contain warning that very low calorie protein diets can lead to serious illness or death).

The FDCA contains express preemption provisions preempting various types of state labeling requirements that are not identical to federal requirements, such as requirements about the definition of a food, labeling imitation foods, and the prominence of nutrition information on food labels. 21 U.S.C. § 343-1. These express preemption provisions do not preempt warnings about the harmful effects of a food. The Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353, 2364 (1990), specified that these express preemption provisions should "not be construed to apply to any requirement respecting a

statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food," and that the express preemption provisions and savings clause do not "affect preemption" of a state requirement arising under other provisions of the FDCA or final agency action. *Id*.

B. The FDA's Approach to Methylmercury in Seafood

Methylmercury is a highly toxic form of mercury that builds up in fish and other seafood. Mercury can harm multiple organs, including the brain and heart. Fish and shellfish are the primary source of methylmercury exposure in people. App. A-99-100, A-115, A-126-A127, A-140.

Despite the dangers of methylmercury in seafood, the FDA has issued no regulations pertaining to methylmercury. It has not placed a regulatory limit on the acceptable amount of mercury in seafood. It has not promulgated any labeling regulations pertaining to methylmercury in seafood. And it has not issued regulations requiring (or forbidding) warnings about methylmercury in seafood.

What the FDA has done is provide some consumers with advice about methlymercury in seafood through a brochure and on its website. In particular, together with the Environmental Protection Agency ("EPA"), 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." App. A-35-A-37. The 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." App. A-35. It suggests that the people at whom the advisory is aimed stay away from shark, swordfish, king mackerel, and tilefish; not eat more than 12 ounces a week of other fish (including canned light tuna) or more than 6 ounces a week of albacore tuna; and check local advisories about freshly caught fish. App. A-35-A-36. The FDA and EPA also issued a "backgrounder" for the advisory. App. A-38-A-40. The backgrounder summarizes the advisory's recommendations and message, explains how it is different from previous advisories, and provides general dietary advice and information on methylmercury. Neither the advisory nor the backgrounder mentions food labels or warnings, provides limits for how much mercury can be in seafood, or says anything about the FDA's intent to preempt state law of any kind.

In addition, the FDA has 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 adultered. FDA Compliance Policy Guide § 540.600 (providing "criteria for recommending legal action"). App. A-49.

C. The FDA's Letter to the California Attorney General

In June 2004, the State of California sued Tri-Union and other tuna fish companies under the Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health and Safety Code § 25249.6 ("Proposition 65"), for their failure to warn that the tuna products they sold contained chemicals known to cause cancer and reproductive harm. App. A-50-A-55. Proposition 65 requires reasonable warnings before a person doing business can "knowingly and intentionally expose any individual" to such a chemical. Cal. Health & Safety Code § 25249.6.

During discovery in that case, defendants turned over an unsigned letter and memorandum, dated August 12, 2004, from an attorney at Covington & Burling to the Chief Counsel of the FDA. App. A-75-A-98. The letter urged the FDA to send a letter to California officials detailing the FDA's intent to preempt Proposition 65 warnings on tuna. The memorandum explained that:

> It is unlikely that, standing alone, the Consumer Advisory would be deemed to preempt Proposition 65 warnings on tuna. The advisory is designed to inform consumers. It does not on its face mandate, prohibit or authorize any particular labeling for canned tuna, nor does it purport to interpret any statute or regulation. Further, it does not cite the FDA's power to regulate food labeling or an FDA/EPA conclusion or rationale against state labeling requirements. . . . Accordingly, the Advisory of its own force does not preempt Proposition 65, because it lacks the force of law and does not set forth FDA's labeling authority,

> preemptive conclusion or complete rationale against mercury-warning labeling for fish.

App. A-82.

The memorandum also noted that "the language of the Supreme Court's decisions . . . suggests that only a so-called 'legislative rule,' that is, 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." App. A-80. Nonetheless, the industry memorandum stated that a court might give deference to a letter from the FDA to California officials asserting its intention to preempt Proposition 65 mercury warnings on tuna. The memorandum detailed points it thought the FDA should make in such a letter. App. A-83.

Parroting many of the arguments and even some of the exact language in the industry memorandum, on August 12, 2005, the FDA Commissioner sent Bill Lockyer, then Attorney General of California, the requested letter contending that Proposition 65's "safe harbor" warnings— "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"—are preempted by federal law. App. A-42-A-48. The FDA described the history of its advisory and backgrounder and noted that it

had rejected the suggestion that food producers should be required to warn about methylmercury when they made claims about the health effects of omega-3 fatty acids. App. A-43-A-45. The letter asserted that the FDA had deliberately implemented a "nuanced approach, relying primarily on disclosure of ingredient information and nutrition information . . . and, only under exceptional circumstances, requiring manufacturers to provide warnings on their labels," that it "remain[ed] convinced that the issuance of an advisory remains the preferred route for advising the public," and that the "Proposition 65 warnings frustrate this carefully considered agency approach, causing federal law to preempt California's warnings." App. A-46. In addition, the letter contended that the Proposition 65 warnings would be misleading under section 403 of the Act because they "omit facts which are necessary to place the information in its proper context," and that, therefore, tuna products with the warnings would be considered misbranded under federal law. *Id*. According to the letter, "[t]una manufacturers would not be able to comply both with Proposition 65 and the Act and, hence, the Proposition 65 warnings are conflict preempted under federal law." *Id*.[1]

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[1]On May 11, 2006, the Superior Court of California, San Francisco County, held that the Proposition 65 warnings were preempted. *See People ex rel. Lockyer v. Tri-Union Seafoods, LLC*, 2006 WL 1544384 (Cal. Sup. Ct. 2006). That decision is currently on appeal. *See* Cal. App. 1st Dist., Case No. A116792.

D. Statement of the Facts and Proceedings Below

Defendant Tri-Union cans and distributes Chicken-of-the-Sea brand tuna. Plaintiff Deborah Fellner contracted severe mercury poisoning after making Defendant's tuna products a primary part of her diet. App. A-30. On January 16, 2006, she filed this action against Tri-Union in the Superior Court of New Jersey under the New Jersey Products Liability Act, the New Jersey Consumer Fraud Act, and common-law fraud for canning and distributing tuna products that were not reasonably fit, suitable, and safe; failing to disclose that its tuna products contained methylmercury and other harmful compounds that could result in mercury poisoning; and making material representations or omissions regarding the safety of the tuna products it canned or distributed. App. A-23-A34. Tri-Union removed the case to the District Court for the District of New Jersey.[2]

Tri-Union moved for judicial notice of the advisory, backgrounder, FDA letter, and action level, and moved to dismiss the complaint. On January 8, 2007, the district court granted both motions. App. A-2. First, the court took judicial notice of the four records. It then discussed "the facts regarding mercury in the environment," accepting as true facts within the judicially-noticed documents,

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[2]The complaint was brought as a class action, but, on May 12, 2006, the parties stipulated to the dismissal of the class action allegations. App. A-254.

even though those facts are disputed by Plaintiff. App. A-5-A-6.

With regard to the motion to dismiss, the court stated that "[i]n this case, there is a pervasive federal regulatory scheme implemented by and through the FDA." App. A-8. Although the FDA advisory neither discusses how much mercury is permitted in seafood nor mentions warning labels at all, the district court found that "[t]he Advisory specifically regulates the levels of methylmercury allowed in canned tuna and specifically rejected the notion that warning labels should be included on cans of tuna." App. A-9. Thus, according to the district court, because the advisory and backgrounder were released before the California complaint was filed, "[c]learly, the FDA had already taken the position against blanket warning labels before the California suit which prompted the FDA letter," App. A-12, and the FDA letter "only crystallizes the already transparent intent of the FDA to preempt state law." App. A-14. The court found that "the FDA's Advisory and Backgrounder are entitled to deference and that the FDA level is persuasive," and that "applying the carefully structured and implemented regulatory scheme of the FDA to Plaintiff's allegations . . . shows that it would impossible for Defendant to comply with the FDA and New Jersey law." App. A-15.

RELATED CASES AND PROCEEDINGS

This case has not previously been before this Court. Plaintiff is not aware of any related cases or proceedings.

STANDARD OF REVIEW

A district court's order granting a motion to dismiss is reviewed *de novo*. *Santiago v. GMAC Mortgage Group, Inc.*, 417 F.3d 384, 386 (3d Cir. 2005). When considering a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), a court must accept as true all well-pleaded allegations and view them in the light most favorable to the plaintiff. *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974). A court must also accept as true any and all reasonable inferences derived from those facts. *Unger v. Nat'l Residents Matching Program*, 928 F.2d 1392, 1400 (3d Cir. 1991). Moreover, it is not necessary for the plaintiff to plead evidence or the facts that serve as the basis for the claim. *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 446 (3d Cir. 1977). The question before the court is not whether the plaintiff will ultimately prevail; rather, a complaint may not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957).

SUMMARY OF ARGUMENT

This Court has considered cases in which Congress has expressly preempted state-law requirements and the question is whether the particular claims at issue fall within the scope of the express preemption provisions. *See, e.g., Mortellite v. Novartis Crop Protection, Inc.*, 460 F.3d 483 (3d Cir. 2006). This isn't one of those cases. This Court has also considered preemption cases in which the relevant agency has promulgated extensive regulations on the topic at hand. *See, e.g., C.E.R. 1988, Inc. v. Aetna Cas. and Sur. Co.*, 386 F.3d 263 (3d Cir. 2004). This isn't one of those cases either.

Instead, in this case, an agency, the FDA, has taken a few informal actions, providing non-binding advice about methylmercury in seafood to a narrow segment of the public and to its own enforcement division. Tri-Union now claims that those informal actions impliedly preempt all state-law damages claims related to the product brought by any member of the public. But state law is not preempted whenever a government agency publishes a brochure on a topic. Preemption exists only when there is a "clear and manifest" intent by Congress to preempt state-law, *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 485 (1996) (citations omitted), and no such intent is present here: Federal regulation pertaining to methylmercury in seafood cannot be deemed to leave no room for state law, and

there is no conflict between federal law and Plaintiff's claims.

The letter the FDA sent to the Attorney General of California during litigation in California does not warrant preemption. That letter considered only the particular warnings required under California law and nowhere stated that the FDA would consider all warning requirements, no matter how phrased, to be preempted, let alone that the FDA believed its actions preempted damages claims. Accordingly, it is irrelevant to this case. In any event, given its lack of formality, the FDA letter is not worthy of substantial deference, and, given its context and content, it lacks the power to persuade. The FDA letter, therefore, is not entitled to any weight.

Finally, even assuming that Ms. Fellner's failure-to-warn claims are preempted, the district court at the very least erred in holding that her design-defect claims, which are completely unrelated to warnings, are preempted as well. It further erred in deciding contested issues of fact at the motion to dismiss stage.

ARGUMENT

Supremacy Clause cases "typically involve analysis of the scope of pre-emptive intent underlying statutory provisions that impose federal regulation." *Puerto Rico Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 499-500 (1988). Courts focus on statutory text and legislative history because

"the purpose of Congress is the ultimate touchstone in every pre-emption case," *Medtronic,* 518 U.S. at 485 (internal quotations marks and citation omitted), and congressional intent cannot be ascertained "in a vacuum, unrelated to the giving of meaning to an enacted statutory text." *Puerto Rico Dep't of Consumer Affairs*, 485 U.S. at 501. In other words, a finding of preemption requires relevant federal law, and preemption cases focus on whether a preemptive inference can be drawn from that law.

No such federal law exists here. Below, the district court did not hold that a particular statute preempted Ms. Fellner's claims, nor that they were preempted by particular regulations. Indeed, the court cited no federal statutes or regulations at all. Instead, it concluded that Ms. Fellner's claims were preempted by the FDA's "approach" to methylmercury in seafood. But "[t]here is no federal preemption *in vacuo*," *id*. at 503, and the FDA's "approach" to methylmercury in seafood does not come close to qualifying as the type of federal scheme upon which preemption may be based.

For that reason alone, there is no preemption of Ms. Fellner's claims. Even assuming, however, that an ordinary preemption analysis should be conducted here, the district court's decision cannot stand. To begin with, there is a strong presumption against preemption: When Congress has legislated in a field

traditionally occupied by the states, a court must start with the assumption that the historic police powers of the states are not to be superceded.

Further, federal law preempts state law under only three circumstances, *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990), none of which is present in this case. First, Congress can expressly preempt state law. Second, state law is subject to field preemption "if it regulates conduct in a field that Congress intended the Federal Government to occupy exclusively." *Id* at 79. Finally, "state law is preempted to the extent it actually conflicts with federal law." *Id*. Actual conflict can exist "where is impossible for a private party to comply with both state and federal requirements" or where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Id*. (internal quotation marks and citations omitted).

Here, Tri-Union has not claimed (nor could it) that Congress expressly preempted Ms. Fellner's claims, and there is no comprehensive regulatory scheme indicating that Congress intended exclusively to occupy the field. Moreover, the FDA has placed no requirements on Tri-Union with respect to methylmercury warnings, so it can easily comply with both federal and state law, and permitting Ms. Fellner's state-law claims to continue would not serve as an obstacle to any congressional purpose or objective. Accordingly, Ms. Fellner's state-law damages

claims are not preempted.

I. A Presumption Against Preemption Applies in this Case.

The federal preemption doctrine has its origin in the Supremacy Clause, article VI, clause 2 of the Constitution of the United States, which states:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, and any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The Supremacy Clause provides the constitutional authority for the proposition that conflicts between federal and state law are resolved in favor of federal law. *See McCulloch v. Maryland*, 4 Wheat. 316, 427, 4 L. Ed. 579 (1819); *Cipollone v. Liggett Group, Inc.* 505 U.S. 504, 516 (1992).

However, in light of the constitutional imperative of federalism embodied, among other places, in the Tenth Amendment, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana,* 451 U.S. 725, 746 (1981); *see Cipollone*, 505 U.S. at 516. A party seeking preemption of state law thus bears a heavy burden, for "[p]reemption of state law by federal statute or regulation is not favored 'in the absence of persuasive reasons—either that the nature of the

regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained.'" *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.* 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142 (1963)). This strong presumption against preemption may be overcome only by "clear and manifest" congressional intent to the contrary. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985) (citations omitted); *Green v. Fund Asset Mgmt., L.P.*, 245 F.3d 214, 224 (3d Cir. 2001) (quoting *Medtronic,* 518 U.S. at 485).

The presumption against preemption applies with particular force where, as here, state prerogatives over the health and safety of its citizens are at issue. *See Medtronic,* 518 U.S. at 485; *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230-31 (1947). The presumption is "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation" because "the regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County,* 471 U.S. at 716, 719.

Moreover, where the federal regulatory scheme does not itself provide a damages remedy, the Supreme Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See English*, 496 U.S. at 87-90; *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *see also Bates v. Dow*

Agrosciences, LLC, 544 U.S. 431, 449 (2005). This interpretive principle is important here because Tri-Union's argument for preemption, if accepted by the Court, would leave Ms. Fellner and injured consumers like her without any redress.

The foregoing anti-preemption precepts are not mere precedential idiosyncrasies. Rather, they are deeply embedded in the "federal-state balance" that is fundamental to the constitutional plan. *Hillsborough County*, 471 U.S. at 717; *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (citation omitted). The Supreme Court's Supremacy Clause jurisprudence is "an acknowledgment that the States retain substantial sovereign powers under our constitutional scheme, powers with which Congress does not readily interfere." *Gregory v. Ashcroft*, 501 U.S. 452, 461 (1991). Accordingly, even if it were ambiguous whether the FDA's approach to methylmercury in seafood preempts Ms. Fellner's claims—which it is not—the ambiguity would have to be resolved in Ms. Fellner's favor.

II. The Advisory, Backgrounder, and Action Level Do Not Preempt Ms. Fellner's Claims.

The district court's opinion does not make clear whether the court held that Ms. Fellner's claims are preempted under field preemption or conflict preemption. The district court began its application of preemption principles by stating that

"[i]n this case, there is a pervasive federal scheme," App. A-8, which sounds like field preemption, but it then found it would be "impossible for Defendant to comply with the FDA and New Jersey law," App. A-15, which sounds like conflict preemption. Similarly, if the district court based its decision on conflict preemption, it is unclear which type of conflict preemption it found decisive. Thus, this brief will address both field preemption and both types of conflict preemption, none of which preempts Ms. Fellner's claims.

A. Field Preemption Is Inapplicable Here.

Federal law can preempt state law under a field preemption theory when a "scheme of federal regulation" is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *English*, 496 U.S. at 79 (citation omitted). There is no such federal scheme here. To begin with, even comprehensive federal regulations do not necessarily preempt state law. *English*, 496 U.S. at 87. As the Supreme Court has explained, "[t]o infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulation will be exclusive. Such a rule, of course, would be inconsistent with the federal-state balance embodied in our Supremacy Clause jurisprudence." *Hillsborough County*, 471 U.S. at 717. Moreover, even where Congress has

entirely preempted a field with regard to state positive law, it has not necessarily preempted that field with regard to state-law damages claims. *See Silkwood*, 464 U.S. at 249-56 (holding punitive damages not preempted even though agency had exclusive regulatory authority over the field); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988).

Here, there is no reason to believe that Congress intended to occupy the entire field of food label warnings in general or methylmercury warnings in particular. Neither the defendant's briefs below, the FDA letter, nor the district court opinion refer to a single statute or regulation that regulates the permissible level of methylmercury in seafood or governs methylmercury warnings on food labels. Rather, they rely on the general requirement that foods not be adulterated or misbranded. And the advisory and backgrounder that supposedly constitute the FDA's "carefully structured and implemented regulatory scheme," App. A-15, do not purport to interpret any statute or regulation, do not place any regulatory requirements on manufacturers, and do not mention labels at all. They just offer advice to a relatively small segment of the population, suggesting that pregnant women, women who might become pregnant, nursing women, and young children include fish in their diet, avoid certain fish, and not eat more than a certain amount

of other fish.

Furthermore, "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted" under field preemption principles. *Cipollone*, 505 U.S. at 517; *see also Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 613 (1991) (express preemption provision would be "pure surplusage if Congress had intended to occupy the entire field"). Accordingly, the FDCA provisions expressly preempting certain types of state labeling requirements, 21 U.S.C. § 343-1, and expressly *not* preempting warnings about the safety of food, 104 Stat. at 2364, indicate that Congress did not intend to displace such warning requirements. Field preemption simply does not apply under these circumstances.

B. Defendant Can Comply with Both Federal and State Law.

1. Federal law also preempts state law when it is "impossible" to comply with both laws. *English*, 496 U.S. at 79; *see Lindsey v. Caterpillar, Inc*., 480 F.3d 202, 205 (3d Cir. 2007) ("Actual conflict arises when it is impossible to comply with both the federal and state laws . . . ."). Thus, for example, federal law would preempt state law if federal law "forbade the picking and marketing of any avocado testing more than 7% oil," while state law "excluded from the State any avocado measuring less than 8% oil content." *Florida Lime & Avocado Growers*,

373 U.S. at 143. Or, to use facts closer to this case, federal law would preempt state regulations if the state regulations required warnings about methylmercury while federal law forbade those same warnings.

Notwithstanding the district court's conclusion that "it would be impossible for Defendant to comply with the FDA and New Jersey law," App. A-15, no such conflict exists here. The FDA's advisory and backgrounder do not conflict with state law because the advisory and backgrounder place *absolutely no obligations* on seafood product manufacturers. They do not require seafood product manufacturers to place warnings on their products, forbid them from placing warnings on their products, or limit the warnings they can place on their products. They neither permit, nor forbid, nor even address canning or distributing seafood products containing either more or less than certain amounts of methylmercury. Indeed, the advisory and backgrounder do not require or forbid seafood product manufacturers from doing *anything at all*. The advisory and backgrounder are not even directed to seafood product manufacturers. They are directed to a subset of the consuming public, yet they do not place obligations even on those consumers. By its very name, the *advisory* contains only *advice*, not requirements. And the action level, too, is just a non-binding guideline. In short, Tri-Union can easily comply with both state and federal law regarding methylmercury in seafood

because the advisory, backgrounder, and action level create *no federal law* binding Tri-Union. *Cf. Freightliner Corp. v. Myrick,* 514 U.S. 280, 289 (1995) ("[I]t is not impossible for petitioners to comply with both federal and state law because there is simply no federal standard for a private party to comply with.").

2. The FDA letter sent to the California Attorney General at the industry's request claimed the existence of a conflict between federal law and the methylmercury warnings at issue in the California case by asserting that those warnings would be misleading under section 403 of the FDCA, 21 U.S.C. § 343, and that tuna labels with those warnings would therefore be misbranded. App. A-46. In other words, the FDA letter claimed that if a tuna manufacturer, for its own reasons, *voluntarily* placed methylmercury warnings like the Proposition 65 safe-harbor warnings on its cans of tuna, the FDA would initiate enforcement proceedings against that manufacturer for having misbranded food. According to the FDA letter, the warnings would be misleading because they convey factual information "without any scientific basis as to the possible harm caused by the particular foods in question, or as to the amounts of such foods that would be required to cause this harm." *Id*.

The FDA letter's statements about the Proposition 65 warnings are inapplicable to this case. Ms. Fellner is not seeking to have warnings placed on

tuna labels; she is seeking damages for injuries caused by Defendant's tuna. As the Supreme Court has explained, it is "perfectly rational for Congress not to pre-empt common-law claims" when preempting state regulatory law, because common-law claims "perform an important remedial role in compensating accident victims." *Sprietsma*, 537 U.S. at 64; *see also Cipollone,* 505 U.S. at 518 ("[T]here is no general, inherent conflict between federal pre-emption of state warning requirements and the continued vitality of state common-law damages actions."); *cf. Goodyear Atomic Corp.*, 486 U.S. at 185-86; *Silkwood*, 464 U.S. at 256. Thus, even if the FDA were correct that California's regulation of labels was preempted by federal law, that question would not dictate the outcome in this case. Because Tri-Union could pay damages to Ms. Fellner without altering its labels and thus without implicating the FDA's concern about misbranding, there is no conflict between Ms. Fellner's state-law damages claims and federal law.

Further, even if Deborah Fellner's failure-to-warn claims motivated Tri-Union to place methylmercury warnings on its tuna products, those warnings still would not render Tri-Union's tuna products misbranded. The FDA's letter pertained specifically to Proposition 65's safe-harbor warnings for carcinogens and reproductive toxicants 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." App. A-42. It was these particular warnings—and no others—that the FDA found would "omit facts which are necessary to place the information in its proper context." App. A-46. Ms. Fellner, however, has not claimed that Tri-Union should have used the Proposition 65 safe-harbor language, or any other specific wording, in its warning about mercury poisoning, or that it should have omitted other facts when warning consumers about the dangers of methylmercury. Thus, a finding of preemption here would require the Court to hold that *every* warning, no matter how phrased and no matter what other information was included, would be misleading and cause the tuna to be misbranded. *Cf. Pearson v. Shalala*, 164 F.3d 650, 658 (D.C. Cir. 1999) (noting that FDA's concerns about deceptiveness of health claims could be accommodated by adding disclaimers rather than by prohibiting the claim altogether).

Moreover, even a simple warning stating that tuna contains methylmercury, which can cause mercury poisoning, would not be misleading. Notably, the FDA does not disagree that tuna products contain methylmercury, *see* App. A-35 (advisory stating that "nearly all fish and shellfish contain traces of mercury"), or that methylmercury can have harmful effects. *Id.* (advisory discussing how

women and young children can "reduce[] their exposure to the harmful effects of mercury"); App. A-43 (FDA letter claiming FDA knows best how to handle "the public health concerns related to methylmercury in fish"). Rather, the FDA letter claims that the warnings would be misleading because they do not "place the information in its proper context." App. A-46. However, the FDA's warnings on other types of foods neither state the scientific basis for those warnings nor put the warnings in context by stating the benefits of eating the food. For example, the FDA's required warning for unpasteurized juices—"This product has not been pasteurized and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems," 21 C.F.R. § 101.17(g)—neither mentions the benefits of drinking juice nor explains the scientific basis for how bacteria causes serious illness. Whether a label is misleading depends on how it would be perceived by consumers, and consumers do not expect detailed scientific explanations on food labels or assume that foods with warnings lack benefits. In short, there is no evidence that consumers would be misled in any way by a warning about methylmercury in tuna.

Finally, the determination that food is misbranded is not the FDA's to make. If the FDA wants to pursue an enforcement action for alleged misbranding, the agency must file suit against the manufacturer in a federal district court. 21 U.S.C.

§ 332, § 333, § 334. Because the filing of an enforcement action does not guarantee that the FDA will prevail, no conflict would exist until the FDA had won the action. And as the Supreme Court has explained, "[t]he existence of a hypothetical or potential conflict is insufficient to warrant the preemption of the state [law]." *Rice v. Norman Williams Co.,*458 U.S. 654, 659 (1982); *see also English*, 496 U.S. at 89 ("The 'teaching of this Court's decisions . . . enjoin[s] seeking out conflicts between state and federal regulation where none clearly exists.'") (*quoting Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 446 (1960)). The FDA letter's speculation that warnings about methylmercury would cause tuna products to be misbranded does not warrant preemption of Ms. Fellner's state-law damages claims.

C. Ms. Fellner's Claims Do Not Stand as an Obstacle to Federal Purposes and Objectives.

Federal law also preempts state law when the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Sprietsma,* 537 U.S. at 64 (citation omitted). Despite the district court's references to the FDA's "deliberately nuanced" and "carefully balanced approach," App. A-15, that the FDA has not required warnings on tuna, but instead has just made available some advice to a small subset of consumers, does

not warrant preemption under this theory either.

In *Sprietsma*, the Supreme Court considered whether the Coast Guard's decision not to require propeller guards on motor boats impliedly preempted a state-law damages action alleging that the manufacturer's motor boat was unreasonably dangerous because the motor was not protected by a propeller guard. Rejecting the manufacturer's preemption argument, the Court explained that it was "quite wrong" to view that decision as the "functional equivalent" of a prohibition against state regulation of the subject matter. *Id*. Rather, that decision was "fully consistent with an intent to preserve state regulatory authority." *Id.*; *see also Freightliner Corp.,* 514 U.S. at 289 (where agency had no standard either requiring or prohibiting antilock brakes, state common-law claim regarding antilock brakes not preempted); *Puerto Rico Dep't of Consumer Affairs*, 485 U.S. at 501-04 (absent explicit statement of intent, federal inaction has no preemptive effect); *Baltimore and Ohio R.R. Co. v. Oberly*, 837 F.2d 108, 115 (3d. Cir. 1988) (requiring agency to declare its preemptive intent "at a high level of specificity" before inaction can preempt state law).

Here, no statements contemporaneous with the agency's activities on methylmercury evidence any intent on the part of the FDA to prohibit state law damages claims relating to the toxin. The advisory and backgrounder are just the

FDA's effort to inform certain vulnerable consumers about methylmercury in seafood; they do not pertain to whether or not manufacturers have *their* own obligations to warn consumers about the dangers of methylmercury, let alone do they indicate that they are intended to supplant all state-law claims. In other words, the FDA's approach to mercury in seafood is just what the FDA has decided it *itself* is going to do on the issue.[3] The advisory, backgrounder, and action level do not speak to what *states* can do to warn consumers about the

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[3]Similarly, despite Tri-Union's contention in its papers below that "the FDA expressly rejected warnings on fish products regarding the existence of mercury," Def. Reply at 4, in its response to a petition regarding omega-3 fatty acid qualified health claims, that response does not speak to what *states*' policies can or cannot be regarding warning consumers about methlymercury. A little background is in order. Food companies cannot make health claims—claims characterizing the relationship between a nutrient in food and a disease or health-related condition—without first receiving FDA approval. If a company makes such a claim without FDA approval, the food is misbranded. 21 U.S.C. § 343(r)(1), (3). The FDA has approved a qualified health claim stating that "supportive but not conclusive research" shows that eating certain omega-3 fatty acids may reduce the risk of heart disease. In doing so, it rejected requiring the qualified health claim to be accompanied by a warning about the harmful effect of methylmercury. App. A-176-A-178. In other words, the FDA did not reject *allowing* methylmercury warnings on fish; it rejected *requiring* methylmercury warnings on fish *as a condition* of the agency's enforcement of the qualified health claim. That the agency rejected the notion that putting the qualified health claim on foods without a mercury warning would render the food misbranded does not demonstrate, as Tri-Union claimed below, that the FDA took a "position against the use of a warning regarding the existence of methylmercury in fish," Def. Reply at 3, let alone that it took a position against allowing state-law damages claims to go forward.

dangers of mercury in seafood.

Moreover, as the FDA stated in its letter, the agency rarely requires warning on labels, "relying primarily on disclosure of ingredient information and nutrition information." App. A-43, A-46; *see also* App. A-13 (district court opinion stating "it is not uncommon for the FDA to specifically choose the issuance of an advisory rather than an official warning"). Yet it cannot be that the FDA's decision only rarely to enter the field of warning requirements preempts *all* state warning requirements and common-law claims pertaining to *all* issues and *all* foods, completely foreclosing consumers' ability to challenge inadequate warnings on food labels. *See Silkwood* 464 U.S. at 251 ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct."). Nor can it be true, as a general principle, that whenever an agency publishes a brochure on a topic it has, through that brochure, impliedly preempted all state-law claims related to the topic.

The argument that Ms. Fellner's claims would frustrate the federal approach of issuing an advisory but not requiring a warning boils down to a notion that when a state takes an approach to a problem that differs from the federal approach, that state approach, simply because it is different, frustrates the federal government's approach. Were that the case, all state regulations that were not

identical to federal regulations would be preempted. That is not the law. It is well-settled that states can apply standards and regulations that differ from the federal government's, so long as there is no actual conflict. *See Hillsborough County*, 471 U.S. at 717 ("[M]erely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were barred from identifying additional needs or imposing further requirements in the field."); *Feldman v. Lederle Labs.*, 125 N.J. 117, 136 (1990) ("Ordinarily, state causes of action are not pre-empted solely because they impose liability over and above that authorized by federal law.") (quoting *English*, 496 U.S. at 89 (citations omitted)); *cf. Green*, 245 F.3d at 227 (rejecting notion that procedural differences between federal and state law demonstrate Congress's intent to preempt state law as being "actually contrary to the Supreme Court's preemption jurisprudence"). In short, the fact that the FDA published an advisory about methylmercury, but does not require warnings, does not demonstrate the "clear and manifest purpose of Congress" to preempt "a field which the States have traditionally occupied." *Medtronic,* 518 U.S. at 485 (citations omitted).

In addition, permitting Ms. Fellner's state-law damages claims to go forward would not interfere with any of the three reasons the FDA gave in its

California letter for choosing to educate the public through a consumer advisory rather than through warnings on labels: that consumer advisories are communicated to the target audience directly, rather than the whole population; that it believes that consumer advisories are more effective than label statements at relaying complex messages; and that a label statement that reaches the public at large can have the unintended negative health consequence of causing those outside the targeted audience to eat less fish or refrain from eating fish altogether. App. A-43.

The FDA's first two arguments are reasons in favor of a consumer advisory but, because they are not mutually exclusive, are not reasons to preclude label warnings, much less damage awards in cases such as this one. That is, the FDA could continue publishing its consumer advisory, thereby ensuring (assuming that it distributed the advisory in an effective manner) that its target audience received the message the agency hoped to relay, even if state law were to require a methylmercury warning on seafood products or call for an award of damages.

With regard to the third argument, Ms. Fellner's suit seeks damages, not a change in warning requirements, and Tri-Union's payment of damages to Ms. Fellner would not cause those outside the FDA's target audience to reduce their fish consumption. Further, even if a damages award motivated Tri-Union to place

a methylmercury warning on its tuna products, warning statements could be crafted that, like the advisory itself, inform consumers of both seafood's benefits and risks. For example, a warning label could state: "Fish and shellfish are an important part of a healthy diet. However, nearly all fish contain traces of mercury that may, in large quantities, cause mercury poisoning." Such a statement would further the FDA's goals of encouraging seafood consumption while warning about its risks. *Cf. Bates*, 544 U.S. at 454 (although federal pesticide statute expressly preempts labeling requirements in addition to or different from those required by statute, "[t]o survive pre-emption, the state-law requirement need not be phrased in the *identical* language as its corresponding [federal] requirement").

In any event, any concern that requiring warnings on tuna would serve as an obstacle to encouraging people to include fish in their diet is "too speculative to support pre-emption." *Hillsborough County*, 471 U.S. at 720. In *Hillsborough County*, the Supreme Court rejected the argument that county ordinances that imposed more stringent requirements than federal regulations on plasma centers and donors were preempted because they presented an obstacle to the federal goal of ensuring an adequate blood supply. The Court noted that the district court had rejected the evidence that the plasma vendor population would decrease, and explained that, even if the regulations did reduce the supply of plasma, that

reduction would not necessarily frustrate federal objectives because "neither Congress nor the FDA . . . has struck a particular balance between safety and quantity," the federal regulations "merely establish minimum safety standards," and, absent an indication of what constituted an adequate plasma supply, it had no "reason to believe that any reduction in the quantity of plasma donated would make that supply 'inadequate.'" *Id*. at 720-21. Similarly, here, there is no evidence that placing methylmercury warnings on tuna would cause consumers to reduce their tuna consumption, and, even if it did, the FDA has not struck a "particular balance between safety and quantity" of seafood consumption. Aside from stating that fish is an important part of a healthy diet and should be included particularly in the diets of certain women and young children, the FDA has said nothing about the *minimum* amount of fish people should eat. *See* App. A-35 (advisory suggesting that certain consumers can eat "up to" 12 ounces a week of fish). Accordingly, there is no evidence that methylmercury warnings on seafood would reduce consumption of seafood to a level the FDA considers unacceptable.

Finally, but fundamentally, the FDA's mission is neither to encourage nor discourage the eating of particular foods. The FDA's "mission" is to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner" and

to "protect the public health by ensuring that human . . . foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393. That is, the FDA's role is to ensure that the food supply is safe and that manufacturers provide consumers with adequate information with which to make decisions about what to eat. Accordingly, whether or not a methylmercury warning would discourage a consumer from eating tuna products, such a warning would not interfere with any objective within the scope of the FDA's statutory authority.

III. This Court Should Not Defer to the FDA Letter.

As explained above, the advisory, backgrounder, and action level do not, on their own, preempt state-law damages claims. Thus, the only way Ms. Fellner's claims would be preempted is if the statements in the FDA letter about preemption applied to state-law damages claims and if the letter were dispositive. Neither is the case.

A. The FDA Letter Does Not Address State-Law Damages Claims.

The FDA letter does not suggest that federal law preempts Ms. Fellner's state-law damages claims. Indeed, the letter does not discuss damages claims at all; it only addresses Proposition 65's safe-harbor warning requirements. That an agency believes that state regulatory authority is preempted does not mean that it believes that damages claims are preempted as well. *Cf. Silkwood*, 464 U.S. at 256

(even though Congress "was well aware of the [agency's] exclusive authority to regulate safety matter" it "assumed that state-law remedies, in whatever form they might take, were available to those injured"); *Sprietsma*, 537 U.S. at 64; *Goodyear Atomic Corp.,* 486 U.S. at 185-86; *Cipollone*, 505 U.S. at 518; *Feldman*, 125 N.J. at 150. And, as explained above (at 24-25), even if the FDA thought that failure-to-warn claims had some regulatory effect, the letter is specific to Proposition 65's safe-harbor warnings. The letter does not suggest that every possible warning about methylmercury would either make tuna products misbranded or frustrate the agency's approach to warning about methylmercury in seafood. Given that the FDA letter addressed only specific warning requirements that are not at issue here, it is irrelevant to this case.

B. The FDA Lacks Authority to Override State Tort Law.

Even assuming that the FDA letter could be construed to apply to Ms. Fellner's state-law damages claims, deference to the letter would be inappropriate because the FDA does not have the authority to determine the scope of preemption of warning requirements on food labels. *Chevron* deference is premised on the assumptions that an ambiguity in the statute at issue reflects a gap within which Congress intended to delegate lawmaking discretion to an agency and that the agency's reasonable interpretation reflects a lawful exercise of that delegated

discretion. *See United States v. Mead Corp*., 533 U.S. 218, 227, 229 (2001); *Chevron, USA, Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 843 (1984). Thus, the starting point for considering whether deference is warranted is the statute that provides the basis for the agency's authority. As the Supreme Court recently explained:

> Deference in accordance with *Chevron* . . . is warranted only "when it appears that Congress delegated authority to the agency to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority."

Gonzalez v. Oregon, 126 S. Ct. 904, 915 (2006) (quoting *Mead*, 533 U.S. at 226-27). In other words, "*Chevron* deference . . . is not accorded merely because the statute is ambiguous and an administrative official is involved. To begin with, the rule must be promulgated pursuant to authority Congress has delegated to the official." *Id.* at 916 (citing *Mead*, 533 U.S. at 226-27).

With respect to food, Congress has not delegated to the FDA the authority to determine the preemptive effect of food labeling rules on state damages actions. To be sure, the FDA has authority to issue various labeling rules, *see* 21 U.S.C. § 343, but nowhere does the FDCA imply an ancillary power to patrol the border between federal substantive rulemaking authority regarding food labeling and the state's historic power to compensate its citizens through the tort system for harms

caused by undisclosed hazards of food products. Because the FDCA contains no delegation on the topic for which preemption is sought, no basis for deference exists.

The principle that no deference is owed to an agency's position on a topic outside the agency's delegated authority is illustrated by *Adams Fruit Co. v. Barrett*, 494 U.S. 638 (1990). There, a migrant worker sued under the federal private right of action established by the Migrant and Seasonal Agricultural Worker Protection Act ("AWPA"), seeking compensation for injuries he sustained while being transported in a van owned by his employer. The Supreme Court declined to give deference to the Secretary of Labor's position that the federal remedy was unavailable because state workers' compensation law provided a remedy to migrant workers on the ground that Congress had not given the agency authority to determine the preemptive scope of the AWPA's right of action. The Court held that the employer could not premise its call for deference to the Secretary on the statute's delegation to the agency of the authority to issue safety standards for employers' vehicles. To the contrary, the delegation did "not empower the Secretary to regulate the scope of the judicial power vested by the statute. Although agency determinations within the scope of delegated authority are entitled to deference, it is fundamental 'that an agency may not bootstrap itself

into an area in which it has no jurisdiction.'" 494 U.S. at 650 (citation omitted).

Just as the agency's authority to issue vehicle safety standards in *Adams Fruit* did not extend to determining the scope of civil remedies available to plaintiffs injured in vehicles, FDA's authority to issue food labeling regulations does not extend to the question of civil remedies for failure to warn. Indeed, the claim to authority here is even weaker than in *Adams Fruit*. There, Congress had at least contemplated the issue of remedies, and it had supplied a federal remedy at the same time it authorized the agency to issue vehicle safety standards. Here, Congress declined to provide a federal damages remedy in the FDCA. Having made no effort to legislate on the topic of damages remedies, Congress can hardly be said to have authorized the FDA to supersede the damages remedies traditionally provided by the states.

C. The FDA Letter Deserves No Weight in Any Event.

Even apart from the absence of congressional delegation to FDA of authority to override state common law, the FDA letter warrants no weight. First, the letter lacks the formality necessary to be accorded substantial deference. "Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference." *Christensen v. Harris*

County, 529 U.S. 576, 587 (2000). Here, the FDA letter is simply a letter, from the FDA to the California Attorney General, expressing the FDA's views on the California litigation. The letter itself does not even purport to carry the force of law. Instead, it repeatedly reiterates that it is stating the agency's *beliefs* about preemption. *See* App. A-43 ("FDA *believes* that such warnings are preempted under federal law."); App. A-46 ("[T]he agency *believes* that Proposition 65 is preempted by federal law with respect to the proposed warnings concerning mercury and mercury compounds in tuna.") (emphases added). Moreover, the agency did not go through any formal procedures to compose the letter. Typically, rules qualifying for *Chevron* deference go through notice-and-comment rulemaking, and thus the public has an opportunity to participate before the agency acts with the force of law. *See Mead*, 533 U.S. at 230-31. A letter is at the exact opposite end of the formality spectrum. To accord substantial weight to the letter "would unduly validate the results of an informal process." *Madison v. Res. for Human Dev., Inc.,* 233 F.3d 175, 186 (3d Cir. 2000); *see Packard v. Pittsburgh Transp. Co.*, 418 F.3d 246, 252 (3d Cir. 2005) (denying *Chevron* deference to "informal and cursory" interagency letter and opinion letter).

Below, the district court cited *Geier v. American Honda Motor Corp*., 529 U.S. 861 (2000), for the proposition that informal statements may warrant

deference. In *Geier*, the Supreme Court considered the preemptive effect of a 1984 Department of Transportation regulation regarding passive restraint systems. The regulation, which did not address preemption, set a five-year phase-in period for required use of passive restraints and gave automakers a choice of passive restraints to install during that period. The Court concluded that the regulation preempted a claim that Honda was negligent for choosing one of the regulatory options and not another, based on the Court's reading of the purpose and substantive requirements of the regulation itself, as expressed by the agency at the time it formulated the regulation. *See id.*, 529 U.S. at 877-81. Only after independently deciding that the plaintiff's claim would stand as an obstacle to the purposes of the regulation did the Court address the agency's amicus brief. Even then, the Court did not find that the agency's view was entitled to substantial deference. Rather, consistent with its opinion the following term in *Mead*, the Court stated that the brief was entitled to "some weight," given considerations such as the agency's expertise and the consistency of its views. *Id*. at 883.

In contrast to the brief in *Geier*, the FDA letter lacks the consistency, thoroughness, or persuasiveness to merit any weight. *See Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944); *Mead*, 533 U.S. at 221. The FDA did not mention preemption in its advisory, backgrounder, or any contemporaneous agency

publication. *Cf. Madison*, 233 F.3d at 187 ("In applying the *Skidmore* test, the Supreme Court has noted that agency interpretations issued contemporaneous with a statute are entitled to greater deference."). Instead, its claim of preemption was first made more than a year after the publication of the advisory, in a letter, to a party in litigation, at the request of an industry lawyer. The letter makes arguments suggested to the FDA by the industry lawyer, seriously drawing into question the level of independent analysis given to the issue by the FDA. At times, the FDA letter even apes the language used by that industry lawyer. *Compare* App. A-83 (industry letter recommending that FDA letter state that "FDA has substantial expertise in analyzing the scientific issues involved, as well as the consumer education aspects of the matter") *with* App. A-43 (FDA letter noting that FDA "has developed significant expertise in analyzing the pertinent scientific issues, together with the consumer education aspects of this matter"). The FDA did not submit the letter to a court or otherwise publish it in a formal way that would help ensure that the FDA had given it thorough consideration. *Cf. Ebbert v. DaimlerChrysler Corp.*, 319 F.3d 103, 115 (3d Cir. 2003) ("An internal agency manual is not subject to the kind of deliberateness or thoroughness that gives rise to significant deference."). In short, the context in which the FDA letter was produced severely undermines its power to persuade.

Moreover, the arguments in the letter are not persuasive on their own. As discussed in part II.B. above, a manufacturer's decision to place methylmercury warnings on its tuna products would not, in fact, cause those products to be misbranded. The FDA letter's contention that Proposition 65 warnings would render labels misleading because they would omit facts necessary to place the information in its proper context is not convincing given the nature of warnings: Even warnings required by the FDA itself do not contain full scientific analyses or list the countervailing benefits of the hazardous products, and consumers do not generally expect such information to be included in label warnings. Similarly, as discussed in part II.C, placing methylmercury warnings on tuna would not frustrate the federal approach to educating consumers about methylmercury. State warning requirements would not require the FDA to change how *it* dealt with methmercury in tuna. The agency could continue to target specific consumers through an advisory, to ensure that those consumers received important information in all its complexity. And the claim that methylmercury warnings on tuna products would reduce the consumption of tuna to a detrimental degree is too speculative to warrant preemption, especially given that the FDA has never specified a particular amount of tuna that it thinks consumers should be eating. In sum, the FDA letter is not persuasive and should be accorded no weight at all.

IV. At the Very Least, Ms. Fellner's Design-Defect Claims Are Not Preempted.

The Court should hold that none of Ms. Fellner's state-law claims is preempted by federal law. However, at the very minimum, there is absolutely no justification for holding that her design-defect claims based on Tri-Union's canning and distributing of tuna products that were unfit to eat are preempted.

In *Bates*, the Supreme Court held that an express preemption provision that preempted labeling requirements that differed from those required by federal law did not preempt design and manufacturing defect claims. As the Court explained, "[r]ules that require manufacturers to design reasonably safe products, . . . to market products free of manufacturing defects, and to honor their express warranties or other contractual commitments plainly do not . . . require[] that manufacturers label or package their products in any particular way." 544 U.S. at 444; *see also Cipollone*, 505 U.S. at 523.

Similarly, here, apart from Fellner's failure-to-warn claims, none of her claims relating to Tri-Union's canning and distributing of tuna fish that is unsafe to eat turns on warnings or the lack thereof. Accordingly, those claims would not lead to the misbranding of cans of tuna or frustrate the FDA's approach of issuing an advisory to a target population instead of placing methylmercury warnings on

labels. Likewise, the FDA's statement in its letter that federal law preempts state methylmercury warning requirements is inapplicable to those claims. Further, no federal statute or regulation requires a particular amount of methylmercury in tuna or pertains at all to the amount of methylmercury permissible in seafood. In other words, there is no basis for concluding that federal law preempts Deborah Fellner's claims pertaining to Tri-Union's design, manufacture, sale, and distribution of tuna products that were not reasonably fit, suitable, or safe to eat.

V. The District Court Erred in Deciding Contested Issues of Fact.

After granting judicial notice of the advisory, backgrounder, FDA letter, and action level, the district court discussed "the facts regarding mercury in the environment, methylmercury in fish and the FDA's approach to the issue of methylmercury in fish," App. A-5-A-6, accepting as true facts stated in the judicially-noticed records. However, the court's judicial notice of the existence and content of the four documents does not permit it to accept as true all of the facts within them. *See* Fed. R. Evid. 201 (courts can only take judicial notice of facts that are not subject to reasonable dispute); *Lum v. Bank of America*, 361 F.3d 217, 222 n.3 (3d Cir. 2004) (explaining that judicial notice of a court opinion only goes to the existence of the opinion "not for the truth of the facts asserted").

It is longstanding and settled law that when considering a motion to dismiss

under Federal Rule of Civil Procedure 12(b)(6), a court must accept as true all well-pleaded allegations and view them in the light most favorable to the plaintiff. *Scheuer*, 416 U.S. at 236. The manner in which the lower court took judicial notice of Defendant's submissions failed to view Plaintiff's allegations in the light most favorable to Plaintiff. Indeed, the lower court went beyond that and decided facts that are not only contested, but are the kind of complex scientific facts that require expert testimony in order to enable the trier of fact to make an informed decision.

Various of the facts about methylmercury accepted as true by the court, such as that mercury cannot be removed from fish meat, are ones that will be in dispute later in the lawsuit, when findings of fact are appropriate. The district court erred in deciding those facts on Defendant's motion to dismiss. On remand, they should not be accepted as true.

CONCLUSION

For the reasons stated above, the decision of the district court should be reversed and the case remanded for a trial on the merits of Ms. Fellner's claims.

Respectfully submitted,

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May 21, 2007

CERTIFICATE OF BAR MEMBERSHIP, WORD COUNT, IDENTICAL COMPLIANCE OF BRIEFS, AND VIRUS CHECK

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/s/ Adina H. Rosenbaum
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May 21, 2007

CERTIFICATE OF SERVICE

I hereby certify that on May 21, 2007, I served the foregoing brief on Defendant-Appellee by causing two copies to be sent by United States mail, first class, postage prepaid to:

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