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

REPLY BRIEF FOR APPELLANT DEBORAH FELLNER

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES, LAWS, RULES, AND RESTATEMENTS

INTRODUCTION

"In all pre-emption cases, and particularly in those in which Congress has 'legislated . . . in a field which the States have traditionally occupied' . . . we 'start with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'" *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). With regard to methlymercury in seafood, the FDA has simply provided advice to some women and children about the upper limits of the amount of fish they should eat and given guidance to its enforcement section about when to initiate action against seafood manufacturers. These minimal actions do not constitute the sort of federal scheme that preempts state law.

Nonetheless, Tri-Union contends that Ms. Fellner's claims are preempted by the FDA's "regulatory approach for dealing with the issue of methylmercury in seafood." Tri-Union Br. 1. It repeats again and again that the FDA has "rejected" the use of methylmercury warnings, contends that it therefore cannot comply with both federal and state law, and asserts that the Court should "defer" to the FDA's decision to forgo warnings. However, the FDA's advisories and backgrounder, which constituted the agency's "approach" to methylmercury during the period when Ms. Fellner was injured, do not mention methylmercury warnings, let alone

expressly reject them. And although the FDA has not *required* seafood manufacturers to place warnings on their products, it has not *forbidden* them to do so, so Tri-Union can comply with both state and federal law.

Moreover, even if the FDA had rejected methylmercury warning requirements for tuna, that would not mean that states could not require such warnings or that state-law damages actions would be preempted. The cases Tri-Union cites for its claim that the FDA's rejection of warnings is dispositive are neither applicable to the regulatory scheme for food nor applicable to the facts of this case. States are permitted to impose safety requirements different from, and greater than, those imposed by the federal government, as long as there is no actual conflict between state and federal law. As explained in detail in Ms. Fellner's opening brief, no such conflict exists here.

Finally, Tri-Union's assertion that the statements on preemption in the FDA letter deserve deference—that, indeed, they are dispositive of the case—must fail. The letter does not relate to claims for damages, and even if it did, the FDA lacks authority to determine whether its actions preempt such claims. And the letter is, after all, just a letter, lacking both the force of law necessary for substantial deference and the persuasiveness necessary to deserve any weight.

In short, the FDA's few informal measures on methylmercury do not

preempt Ms. Fellner's state-law damages claims. The district court's decision should be reversed and the case remanded for a trial on the merits.

ARGUMENT

A. Tri-Union Can Comply with Both New Jersey and Federal Law.

Contrary to Tri-Union's repeated assertions, *see* Tri-Union Br. 12, 20, 21, 30, complying with both federal law and a state-law methylmercury warning requirement would not be impossible. Even if Ms. Fellner sought to require Tri-union to place methylmercury warnings on tuna—which she does not, since her claims are solely for damages, App. A-33—Tri-Union could easily comply with "the FDA's mandates and/or regulations while also complying with any New Jersey law requiring warnings," Tri-Union Br. 20, because the FDA has not regulated tuna manufacturers' activities with regard to methylmercury or methylmercury warnings. Simply put, there are no FDA mandates or regulations that are binding on Tri-Union with regard to methylmercury warnings.

Tri-Union claims that it cannot comply with both federal and state law because "the FDA has determined that warnings are not necessary and has rejected their use." Tri Union Br. 21. However, although the FDA has not *itself* required methylmercury warnings to be placed on tuna, and although it rejected the Martek petition's suggestion that food containing an omega-3 fatty acid qualified health

claim be deemed misbranded if it did not also contain a methylmercury warning, App. A-178, the agency has nowhere *forbidden* tuna manufacturers to place methylmercury warnings on seafood, or forbidden states to require such warnings. Placing methylmercury warnings on tuna would therefore not put Tri-Union out of compliance with any federal law.

Tri-Union also claims that it cannot comply with both federal and state law because any methylmercury warning would be misleading and, therefore, would render its tuna products misbranded under the FDCA. Tri-Union Br. 33-37. No one questions, however, that tuna contains mercury or that mercury is toxic, and it is unimaginable that the FDA would come after Tri-Union for voluntarily placing truthful information on its labels.

Nevertheless, Tri-Union contends that a methylmercury warning would be misleading because it would not contain the scientific basis for the harm, the amount of tuna required to cause the harm, or the countervailing benefits of the tuna. But the FDA's own warnings, when it requires them, do not contain such detailed information. *See, e.g.*, 21 C.F.R. § 101.17(d)(1) (requiring foods advertised as diet products that contain more than 50% of their calories from protein to warn that "[v]ery low calorie protein diets (below 400 Calories per day) may cause serious illness or death," without discussing the scientific

underpinnings of the statement, the countervailing benefits of the diet product, or the importance of maintaining a healthy body weight). And the FDA often approves health claims characterizing the relationship between a substance in food and a health-related condition without specifying the amount of the substance required for the relationship. *See, e.g., id.* § 101.76 (permitting health claim on label stating "[l]ow fat diets rich in fiber-containing grain products, fruits, and vegetables may reduce the risk of some types of cancer, a disease associated with many factors" without including a definition of "low fat" or "rich").

In any event, although Tri-Union claims that *any* methylmercury warning would be misleading, warnings could be written that address both the benefits and risks of eating tuna. Notably, although Tri-Union states—without citing any authority—that it is "critical[]" that Ms. Fellner did not suggest warning language in her complaint or her response to its motion to dismiss, Tri-Union Br. 35, Tri-Union ignores the language Ms. Fellner used as an example in her opening brief (at 33): "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." While Ms. Fellner is not seeking specific warning language, such language illustrates that a warning could address Tri-Union's purported concerns for public health.

Finally, Tri-Union contends that a methylmercury warning would be misleading "because the FDA has rejected the need for any warnings on tuna labels about the existence of methylmercury in tuna to the general public." Tri-Union Br. 35. That the FDA does not itself a require a warning, however, does not automatically make that warning misleading. The FDA rarely requires warnings on foods, but not all food products containing warnings are misbranded under the FDCA.

B. The FDA Letter's Statements on Preemption Are Not Entitled to Deference and Do Not Support Preemption of Ms. Fellner's Claims.

Given that there is no substantive federal law on methylmercury warnings, Tri-Union devotes a large part of its brief to arguing that the FDA's letter to the California Attorney General deserves substantial deference and supports preemption of Ms. Fellner's claims. Neither contention is true.

To begin with, the FDA letter did not "conclude[] that it would be impossible to comply with *any* state law warning requirements, such as those purported by Appellant to exist under the New Jersey Products Liability Act, and the FDA's carefully considered regulatory approach." Tri-Union Br. 7 (emphasis added). The letter pertained specifically to California's Proposition 65's safe-harbor warnings, and nowhere discussed whether the FDA thought methylmercury

warnings using different language would be preempted, let alone whether it believed state-law damages claims would be preempted. App. A-42-47. However, preemption of state-law damages claims does not necessarily follow from preemption of positive state-law requirements. *See, e.g., Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984); *Feldman v. Lederle Labs.*, 592 A.2d 1176, 1186-92 (N.J. 1991). The FDA's statement that it believed Proposition 65's safe-harbor warnings were preempted does not demonstrate its belief that Ms. Fellner's damages claims are preempted as well.[1]

Even if it did address state damages actions such as Ms. Fellner's, however, the FDA letter's statements on preemption still would not be deserving of substantial deference. *Chevron* deference is only accorded to agency interpretations "when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that

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[1]Tri-Union asserts that Ms. Fellner's explanations of why the FDA's approach to methylmercury does not preempt state-law damages actions are "inapplicable" to this case. Tri-Union Br. 43. However, damages are the sole relief Ms. Fellner seeks. App. A-33. Tri-Union's entire brief focuses on why it should not be required to place methylmercury warnings on its products, but a judgment in Ms. Fellner's favor would not, in fact, require Tri-Union to do so.

authority." *United States v. Mead Corp*., 533 U.S. 218, 226-27 (2001). As explained in Ms. Fellner's opening brief (at 36-41), Congress's delegation to the FDA of the authority to promulgate food labeling rules did not include a delegation of authority to determine the preemptive effect of those rules on state damages actions, and the FDA's informal letter to the California Attorney General did not even purport to carry the force of law.

Both of these facts distinguish this case from *Hillsborough County v. Automated Medical Laboratories*, 471 U.S. 707 (1985), the case cited by Tri-Union for its claim that the FDA's position on preemption is "dispositive." Tri-Union Br. 17. There, the operator of a blood plasma center sued Hillsborough County, arguing that county ordinances and regulations governing blood plasma centers were preempted by FDA regulations on the same topic. The Supreme Court found that the FDA's statement that its regulations on blood plasma centers did not preempt state and local authorities from regulating the same subject matter was dispositive on the question of implicit intent to preempt, unless inconsistent with clearly expressed congressional intent or unless subsequent developments showed a change in the agency's position. 471 U.S. at 714-15. In *Hillsborough County*, the FDA's preemption statement went to a matter within the scope of the authority delegated to it by Congress—regulation of blood plasma centers. That

is, the FDA's authority to regulate blood plasma centers carried with it authority to address the preemptive effect of its regulation on state and local regulation of that same area.

Likewise, in *Medtronic*, 518 U.S. 470, another case quoted by Tri-Union for the proposition that the Court should defer to the agency's view on preemption, Congress had "explicitly delegated to FDA the authority to exempt state regulations from the pre-emptive effect of the [Medical Device Amendments]—an authority that necessarily requires the FDA to assess the pre-emptive effect that the Act and its own regulations will have on state laws." *Id*. at 496. Here, on the other hand, if the FDA's statements about preemption applied to state damages claims, they would go to a matter outside the scope of the authority delegated to the FDA. The authority to regulate food labels may carry with it the authority to determine the preemptive effect of federal food labeling regulations on state food labeling regulations, but it does not carry with it authority to determine the preemptive effect of federal regulation on damages actions meant to compensate injured individuals.

Just as importantly, the statement to which the Court in *Hillsborough County* gave deference accompanied the regulation's publication in the Federal Register. 471 U.S. at 714. Similarly, in *Medtronic*, the views accorded weight

were contained in agency regulations. 518 U.S. at 495. Here, in contrast, the FDA's views on preemption were stated in an unpublished, informal letter. A-42-47. "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); *see also Packard v. Pittsburgh Transp. Co.*, 418 F.3d 246, 252 (3d Cir. 2005); *Madison v. Res. for Human Dev., Inc.,* 233 F.3d 175, 186 (3d Cir. 2000). The FDA letter does not carry the force of law and is not entitled to substantial deference.

Although Tri-Union cites many Supreme Court and Third Circuit cases in its discussion of deference, none of them supports giving *Chevron* deference to a document as informal as the FDA letter. *Barnhart v. Thomas*, 540 U.S. 20, 24-26 (2003), *NVE, Inc. v. Department of Health & Human Services*, 436 F.3d 182, 196 (3d Cir. 2006), and *Southwestern Pennsylvania Growth Alliance v. Browner*, 121 F.3d 106, 116-17 (3d Cir. 1997), all involved rules promulgated through formal rulemaking procedures. *Robert Wood Johnson Hospital v. Thompson*, 297 F.3d 273, 281 (3d Cir. 2002), involved arguments "rooted in regulations and administrative practice," although, in dicta, the Court then noted that, given the complex and highly technical nature of Medicare, the agency's interpretation

"would not be without force" even if presented for the first time in a legal brief. Finally, in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), *Sprietsma*, 537 U.S. at 68, and *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), federal agency amicus briefs were not given *Chevron* deference, even though they were more formal than the FDA letter in this case. In *Geier*, the Court gave the amicus brief only "some weight," in light of the agency's expertise and consistency, after having already concluded that the plaintiff's claim would frustrate congressional objectives. 529 U.S. at 883. In *Sprietsma*, the Court noted that the reasoning in *Geier* provided "strong support" for the argument against preemption, given that the agency had filed an amicus brief against preemption. 527 U.S. at 68. And in *Buckman*, which Tri-Union cites for the proposition that "[i]n recent years, each time the Supreme Court has confronted the question of whether the FDCA preempts state law, it has deferred to the FDA's preemption position," the majority opinion neither discussed deference nor mentioned the agency's amicus brief. In short, Tri-Union cites no precedent for affording substantial deference to a letter.[2]

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[2]The Supreme Court does not, in fact, always defer to or even agree with the government's preemption position. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 448-52 (2005) (rejecting interpretation of express preemption provision set forth in government amicus brief).

Furthermore, as explained in Ms. Fellner's opening brief (at 41-43), the FDA letter lacks the power to persuade necessary to receive any weight under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). Tri-Union emphasizes the importance of consistency, Tri-Union Br. 27, and claims that the FDA has made its intent to preempt state methylmercury warning requirements "crystal clear" "throughout the past decade." Tri-Union Br. 12. But until the FDA letter in 2005, the FDA had never claimed that its "approach" to methylmercury in seafood preempted state-law warning requirements. The advisories that Tri-Union contends made the FDA's preemptive intent so clear over the past ten years do not mention warnings on labels, let alone whether state-law warning requirements or damages claims are preempted; they just contain advice to certain consumers about the maximum amount of fish they should eat. App. A-35-37, A-155-58.

The FDA did not express the view that any state warning requirement was preempted until it was prompted to do so in a letter by an industry lawyer who recognized that it was "unlikely that, standing alone, the Consumer Advisory would be deemed to preempt Proposition 65 warnings on tuna." App. A-82. The circumstances that prompted the FDA letter call into question the amount of serious consideration it received, and the views that it expressed are not persuasive on the merits: As discussed in detail in Ms. Fellner's opening brief (at 23-35),

placing methylmercury warnings on tuna would neither render the labels misleading nor frustrate the federal approach to educating consumers about methylmercury. Given the FDA letter's lack of persuasiveness, this Court should not place any weight on it.

C. The Absence of an FDA Warning Requirement for Tuna Does Not Preempt Ms. Fellner's Claims.

As Tri-Union recognizes, "it is essential that an agency declare, at a high degree of specificity, its intention that its inaction preempt state law before we may assume such a desire and give it legal effect." Tri-Union Br. 31 (quoting *Baltimore & Ohio R.R. Co. v. Oberly*, 837 F.2d 108, 115 (3d Cir. 1988)). Tri-Union claims that the FDA has stated its intent that its inaction with respect to methylmercury warnings preempt state law with the requisite level of clarity and specificity. However, because the only place that the FDA has discussed preemption of a state methylmercury warning requirement is in the FDA letter, Tri-Union's assertion (at 31-32) that the FDA clearly stated its intention to preempt state warning requirements by not requiring warnings is once again a call for the Court to defer to the preemption position in the FDA letter. The FDA letter, however, makes no clear statement about the FDA's intent to preempt state-law damages actions or warnings other than Proposition 65's, and, in any event, is

not deserving of any weight.

Similarly, Tri-Union repeatedly emphasizes that the FDA has "rejected" placing methylmercury warnings on tuna. *See* Tri-Union Br. 1, 4, 5, 11, 20, 21, 27, 29, 30, 32, 35, 37, 40, 41, 42, 43, 44. According to Tri-Union, it "is unquestioned that the FDA's regulatory approach over the past decade consistently rejected the use of warning labels in favor of the use of advisories." Tri-Union Br. 27. As noted above, however, the advisories and backgrounder, which made up the FDA's regulatory approach during the years in which Ms. Fellner was injured by Tri-Union's products, do not mention warning labels. In other words, the advisories and backgrounder do not "reject" methylmercury warnings; they just do not, themselves, require them. The notion that the FDA considered methylmercury warnings and consciously decided not to require them comes from the FDA letter, which, as discussed above, does not carry the force of law and deserves no weight.[3]

Moreover, even if the FDA had explicitly decided, in issuing the advisories, not to require methylmercury warnings on tuna, that would not be determinative of

[3]The agency's response to the Martek petition also discussed FDA's reasons for not requiring warnings, but only in the context of rejecting the suggestion that methylmercury warnings should be required "as a condition for the agency's enforcement discretion for the omega-3 fatty acid qualified health claims." A-178.

whether states could require such warnings or whether state damages actions could go forward. Tri-Union contends that deference should be given to the FDA's "views on appropriate labeling," its "regulatory approach," and its "unequivocal[] determin[ation] that warning labels about methylmercury in tuna to the general public are unnecessary." Tri-Union Br. 23-24. If this case were an Administrative Procedure Act challenge to an FDA regulation providing that the FDA would not impose methlmercury warnings on tuna, such deference might be warranted. But this is not an APA case. This case is about whether federal law preempts Ms. Fellner's claims for damages under state law. Under our system of federalism, absent an express preemption provision or actual conflict, states are allowed to come to conclusions that differ from the federal government's about what safety regulations are necessary. As the Supreme Court has explained, state law claims ordinarily are not preempted "solely because they impose liability over and above that authorized by federal law." *English v. Gen. Elec. Co.*, 496 U.S. 72, 89 (1990) (quoting *California v. ARC America Corp*., 490 U.S. 93, 105 (1989)). Thus, so long as there is no actual conflict between the federal and state laws, whether the FDA considers methylmercury warnings on tuna necessary or not is not pertinent to the case.

Finally, as explained in detail in Ms. Fellner's opening brief (at 31-35), a

state methylmercury warning requirement would not interfere with any of the reasons the FDA stated in its letter for not requiring methylmercury warnings (and, again, Ms. Fellner does not seek such a requirement, just monetary damages). The FDA could continue to issue its advisory to ensure that the target audience received the proper message, and Tri-Union has not demonstrated that requiring a methylmercury warning on tuna would decrease the amount of fish eaten below the unspecified amount the FDA thinks is optimal. *See Hillsborough*, 471 U.S. at 720-21. Moreover, warnings could be crafted that explain fish's benefits while still warning about the dangers of methylmercury. Because there is no conflict between Ms. Fellner's claim and the FDA's "regulatory approach," Ms. Fellner's claims should be permitted to go forward.

D. *Colacicco* and *Perry* Are Inapposite.

Citing two district court cases from Pennsylvania, *Perry v. Novartis Pharmaceutical Corp.*, 456 F. Supp. 2d 678, 685-86 (E.D. Pa. 2006), and *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 527 (E.D. Pa. 2006), Tri-Union claims that where the FDA has made a "conclusive determination" about the link between "the drug (or food product) at issue and some adverse health consequence," state law cannot impose warnings beyond those imposed by the

FDA. Tri-Union Br. 28. *Perry* and *Colacicco* are inapposite to this case.[4]

Perry and *Colacicco* involved preemption under the FDA's scheme for approving drug labels, which requires drug manufacturers, before marketing drugs, to submit an application to the FDA that includes a proposed label. 21 U.S.C. § 355. Once a drug and its label are approved, a drug manufacturer generally must seek approval from the FDA before changing the label, 21 C.F.R. § 314.70(b), although it can add or strengthen a warning without prior approval so long as it files a supplemental application with the FDA. *Id.* § 314.70(c)(6)(iii)(A). In *Perry*, the district court considered whether a drug manufacturer could be held liable for failure to warn in light of this detailed approval process and decided that preemption was limited to cases where the FDA had made a "conclusive determination, positive or negative, as to the existence of a link between the drug at issue and some adverse health consequence" suffered by the plaintiff. 456 F. Supp. 2d at 686. Because, at the time of the plaintiff's injury, the FDA had made no finding regarding a link between the drug and the health risk, the court held that the plaintiff's claims were *not* preempted. *Id*. at 687. In *Colacicco*, on the other hand, where the FDA had repeatedly rejected the

[4]Tri-Union also quotes *Bates*, 544 U.S. at 453-54. That quote, however, discusses the interpretation of an express preemption provision in the Federal Insecticide, Fungicide, and Rodenticide Act that no one claims is applicable here.

claim of a link between the drug and the health risk in the years before plaintiff's injury, the court held that the plaintiff's claims were preempted.

Other courts have disagreed with the approach taken by the Eastern District of Pennsylvania in *Perry* and *Colacicco*. *See In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 276-77 (E.D.N.Y. 2007) (explaining that there would be no actual conflict between failure-to-warn claims and federal law, even if the FDA had previously rejected a warning as scientifically unsubstantiated, because "[j]ury verdicts do not impose mandatory labeling requirements on drug manufacturers; rather, they impose damages . . . in particular cases"); *McNellis v. Pfizer, Inc.*, 2006 WL 2819046 (D.N.J. Sep. 29, 2006) (holding no preemption where FDA had repeatedly rejected the need for warnings because drug manufacturers can add or strengthen warnings without FDA approval).[5]

Whether or not *Perry* and *Colacicco* were correctly decided, they are not relevant to whether Ms. Fellner's claims are preempted. The FDA exerts far less control over food labels than over drug labels. Food manufacturers do not need to seek FDA approval of their labels, obtain approval to change their labels, or alert the FDA when they place new warnings on their products. And whereas *Perry*

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[5]Both *Colacicco* and *McNellis* are currently pending before this Court. *See* Nos. 06-3107 and 06-5148.

and *Colacicco* address the situation where a manufacturer has proposed a labeling change and the "FDA has made a specific determination regarding [the] proposed warning," *Perry*, 456 F.Supp.2d at 685, Tri-Union never proposed a methylmercury warning to the FDA, and the agency's regulations on food do not contemplate that it would. Given the differences in the regulation of drug labels and food labels, and that *Perry* and *Colacicco* involved the preemptive effect of the particular regulations governing pharmaceutical drug approval and labeling, those cases are inapplicable to food products.

In any event, at the time of Ms. Fellner's injuries, the FDA had not made a "conclusive determination" of a lack of a connection between tuna and methylmercury poisoning. To the contrary, it had acknowledged and warned some consumers about the dangers of methylmercury in tuna. And it had not made any explicit determination about whether or not warning labels were necessary. App. A-35-37, A-155-58; *see Perry*, 456 F. Supp. 2d at 685. As noted, the advisory and backgrounder did not mention warning labels at all, let alone explicitly reject them. "Because federal law was effectively silent on whether such a warning was warranted, state law was not barred from requiring it." *Id*. at 687.

E. The Presumption Against Preemption and Congressional Actions Weigh Against Preemption.

Although Tri-Union expresses uncertainty about whether the presumption against preemption has "continuing validity," Tri-Union Br. 30, the Supreme Court has recently reaffirmed that "[b]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly pre-empt state-law causes of action." *Bates*, 544 U.S. at 449 (quoting *Medtronic*, 518 U.S. at 485). "In areas of traditional state regulation, we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'" *Id*. (citations omitted).

Here, if anything, Congress has expressed intent *not* to preempt state warning requirements. When it passed the nutrition labeling requirements in the Nutrition Labeling and Education Act (NLEA), Pub. L. No. 101-535, 104 Stat. 2353 (1990), Congress amended the FDCA to contain multiple express preemption provisions, preempting, for example, state requirements for food labeling that differ from federal requirements with regard to standards of identity, misleading containers, prominence of information on labels, labeling of artificial flavoring, and labeling of imitation food. 21 U.S.C. § 343-1. Congress made clear, however, that it did not intend these provisions to preempt state warning

requirements, stating that the express preemption provisions "shall 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." NLEA § 6(c)(2), 104 Stat. at 2364. Congress added that the express preemption provisions do not affect preemption, express or implied, that may arise under the Constitution, other laws, final agency actions, or provisions of the FDCA not amended by Section 6(a) of the NLEA. *Id*. § 6(c)(3). Section 6(a) states that it is amending chapter four of the FDCA, the chapter on food, by adding the express preemption provisions. *Id*. § 6(a).

In short, upon considering the preemption of labeling requirements, Congress specifically decided *not* to preempt state warning requirements, giving rise to an inference that it intended such requirements to be permitted. *Cf. Gary v. Air Group, Inc.*, 397 F.3d 183, 190 n.7 (3d Cir. 2005) ("In general, the existence of an express preemption provision supports the inference that there is no implied preemption.") (citing *Freightliner Corp. v. Myrick,* 514 U.S. 280, 289 (1995), and *Horn v. Thoratec Corp.,* 376 F.3d 163, 166 (3d Cir. 2004)). This inference is not overriden by the FDA's issuance of an advisory, backgrounder, and action level on methylmercury—none of which mentions, let alone purports to preempt, state warning requirements.

F. Ms. Fellner's Design Defect Claims Are Not Preempted.

For all the reasons explained above and in Ms. Fellner's opening brief, none of her claims is preempted. At the very least, however, her design defect claims—the claims that do not rely on Tri-Union's failure to warn—are not preempted.[6]

Tri-Union asserts that all of Ms. Fellner's claims are failure-to-warn claims. It contends that "a review of paragraphs 7-12 and 26-27 of the Complaint reveals that her sole theory of liability" is failure to warn. Tri-Union Br. 39. However,

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[6]Tri-Union claims that Ms. Fellner waived various arguments in her brief—including those related to her design-defect claims—because she did not make those specific arguments before the district court. Tri-Union Br. 38-39. Although Tri-Union is correct that issues not raised in the district court cannot be made for the first time on appeal, *see, e.g., Newark Morning Ledger Co. v. United States*, 539 F.2d 929, 932 (3d Cir. 1976), Ms. Fellner is not bringing up new issues. She is arguing, as she did below, that her claims are not preempted by the FDA's "approach" to methylmercury in tuna. "Once a . . . claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they made below." *Yee v. Escondido*, 503 U.S. 519, 534 (1993); *see also Bankers Life & Cas. Co. v. Crenshaw*, 486 U.S. 71, 78 n.2 (1988). The specific points to which Tri-Union objects constitute additional reasons why Ms. Fellner's claims, as she argued below, are not preempted. Accordingly, those points have not been waived.

Tri-Union also claims that Ms. Fellner has "waived all arguments as to the judicially-noticed documents" by not opposing its motion for judicial notice. Tri-Union Br. 44-46. Ms. Fellner did not oppose the motion, however, because she does not oppose judicial notice of the *existence* of those documents. She does, however, oppose treating as true facts in those documents that are "subject to reasonable dispute." Fed. R. Evid. 201.

paragraph 1 of Ms. Fellner's complaint explains, for example, that "[i]ncluded in the unlawful acts and practices committed by the Defendants are the following: . . . Canning and distributing Tuna Products that were not reasonably fit, suitable, and safe." App. A-23-24. Paragraph 9 states that "Defendant, acting negligently, directly manufactured, processed, tested, canned, marketed and sold its Tuna Products." App. A-25. And paragraphs 10 and 27 assert "all claims and causes of action pertaining to the design, manufacture, sale and distribution of the defective Tuna Products which were not reasonably fit, suitable or safe for their intended purposes as they were defectively designed, manufactured and/or failed to contain adequate warnings and/or instructions." App. A-25-26, A-29. Thus, Ms. Fellner's complaint makes claims that are not based on Tri-Union's failure to warn.

Tri-Union next claims that it should not be held liable for the defectiveness of its products. According to Tri-Union, its sale of tuna with methylmercury in it "is not a valid basis to impose liability" and "the allegations in the Complaint do not support a claim for a defective 'design.'" Tri-Union Br. 40-41. Although it may not be intuitive to discuss the "design" of tuna, Ms. Fellner's argument is that the fish sold by Tri-Union was defective because it was not reasonably fit to eat. "The elements of a *prima facie* case of strict liability for design defects are proof that (1) the product design was defective; (2) the defect existed when the product

was distributed by and under the control of defendant; and (3) the defect caused injury to a reasonably foreseeable user." *Michalko v. Cooke Color & Chem. Corp.*, 451 A.2d 179, 183 (N.J. 1982); *see also Jurado v. Western Gear Works,* 619 A.2d 1312, 1317 (N.J. 1993). "Whether a product is defective depends on whether it 'is not reasonably fit, suitable and safe for its intended or reasonably foreseeable purposes.'" *McGarvey v. G.I. Joe Septic Serv., Inc.*, 679 A.2d 733, 740 (N.J. Super. App. Div. 1996) (*quoting Jurado*, 619 A.2d at 1317). Tri-Union may believe that Ms. Fellner cannot meet her burden of proof, or that it has a defense to liability, but those issues cannot be decided at this stage in the case.

Finally, Tri-Union asserts that the design defect claims are also preempted because if Ms. Fellner recovered under a design defect theory it would "frustrate the FDA's regulatory approach which promotes fish consumption" and "effectively punish it for selling a product which the FDA has deemed safe." Tri-Union Br. 40-41. That the FDA does not outlaw a product, however, does not mean that the product's manufacturer is immune from all product liability claims. And that the FDA thinks there are benefits to fish consumption does not mean that compensating people who are injured by methymlercury in tuna frustrates any legitimate agency objective. *See Silkwood*, 464 U.S. at 257 (finding that award of damages for radiation injuries did not frustrate congressional objective of

promoting nuclear power). In short, Ms. Fellner's design defect claims do not conflict with federal law and therefore are not preempted.

G. Tri-Union Does Not Automatically Win on the Merits of Ms. Fellner's State-Law Claims.

Tri-Union asserts that because Ms. Fellner's complaint does not allege that Tri-Union's tuna contains more than 1 ppm of methylmercury, the FDA's action level, "there is no reason to warn based on the instant case."[7] Tri-Union Br. 38. But the standards for determining whether a company is liable under New Jersey law are not necessarily identical to the FDA's standard for determining whether the product should be removed from interstate commerce. That the FDA may not consider a product adulterated does not mean that its manufacturer cannot be held liable for failure to warn. Similarly, that the FDA has not instructed Tri-Union to stop selling its products and has "rejected" the use of methylmercury warnings does not mean that "Tri-Union cannot be liable for any state law damage claims." Tri-Union Br. 42. The FDA's decision not to forbid a company from selling a

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[7]Contrary to Tri-Union's contentions, the FDA has established neither a "tolerance level" for methylmercury in seafood, see Tri-Union Br. 3, nor a "maximum concentration of methylmercury for a can of tuna to be considered fit for consumption." Tri-Union Br. 20. Rather, it has established an "action level"—non-binding enforcement guidance about when a food may be considered adulterated. App. A-49. Tolerance levels, which set a level above which the food *is* considered adulterated, are established through regulation; action levels are not. 21 C.F.R. § 109.4.

product or to require warnings to be placed on it does not automatically resolve all state-law claims in the product manufacturer's favor. Liability under New Jersey law is not dependent on the FDA's actions, and companies can be liable under state law even if the FDA permits the product to be sold and does not require a product to have warnings on it. *Cf.* Restatement (Third) of Torts, Product Liability, § 4(b); *Feldman v. Lederle Labs.*, 592 A.2d at 1197 (concluding that FDA's determination that a warning on an approved prescription drug was not justified did not "create a conclusive presumption that the labeling contained an adequate warning").

CONCLUSION

For the foregoing reasons, the Court should reverse the district court's decision and remand the case.

Respectfully submitted,

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July 30, 2007

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July 30, 2007

CERTIFICATE OF SERVICE

I hereby certify that on July 30, 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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