PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 07-1238

DEBORAH FELLNER, individually and
on behalf of those similarly situated

v.

TRI-UNION SEAFOODS, L.L.C.
d/b/a CHICKEN OF THE SEA

Deborah Fellner,
Appellant

On Appeal From the United States District Court
For the District of New Jersey
(D.C. Civil Action No. 06-cv-00688)
District Judge: Hon. Dennis M. Cavanaugh

Argued February 12, 2008

BEFORE: SLOVITER, SMITH and STAPLETON,
Circuit Judges

(Opinion Filed: August 19, 2008)

Kenneth A. Schoen
Scott H. Goldstein
Bonner, Kiernan, Trebach & Crociata
299 Cherry Hill Road, Suite 300
Parsippany, NJ 07054

John A. Kiernan (Argued)
Bonner, Kiernan, Trebach & Crociata
One Liberty Square, 6th Floor
Boston, MA 02109
Attorneys for Appellee

William O. Crutchlow
Khalid Elhassan
Eichen, Levinson & Crutchlow
40 Ethel Road
Edison, NJ 08817

Adina H. Rosenbaum (Argued)
Brian Wolfman
Public Citizen Litigation Group
1600 20th Street, NW
Washington, DC 20009
Attorneys for Appellant

OPINION OF THE COURT

STAPLETON, Circuit Judge:

Plaintiff Deborah Fellner filed this lawsuit against defendant Tri-Union Seafoods, LLC ("Tri-Union") in the Superior Court of New Jersey seeking damages for harm she allegedly sustained as a result of her consumption of methylmercury and other harmful compounds contained in Tri-Union's tuna fish products. The case was removed to federal court, and Tri-Union filed a motion to dismiss for failure to state a claim asserting that Fellner's lawsuit is preempted by regulatory actions of the United States Food and Drug Administration ("FDA"). The District Court granted the motion, ruling that Fellner's claims are preempted by the FDA's "regulatory approach" to the risks posed by mercury compounds in tuna fish. Because we conclude that the FDA has taken no regulatory action which preempts Fellner's lawsuit, we will reverse and remand for further proceedings.

I. Facts and Procedural Background

Fellner alleges that Tri-Union produces, cans and distributes Chicken-of-the-Sea brand tuna fish and that, from 1999 to 2004, her diet consisted almost exclusively of Tri-Union's tuna products. She further avers that those products contained methylmercury and other harmful compounds that can

result in mercury poisoning and that "[d]ue to the negligence and statutory violations of the Defendant . . . Fellner contracted severe mercury poisoning and suffered extreme physical and emotional injuries." App. at 30a, ¶ 28. She seeks recovery under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, *et seq*. ("NJPLA"), based on Tri-Union's failure to warn of the risks incurred in consuming its products.[1]

The factual landscape of this case is colored by recent litigation in California. On June 21, 2004, then-Attorney General of California, Bill Lockyer, filed a lawsuit against Tri-Union and other defendants under California's "Proposition 65," CAL. HEALTH & SAFETY CODE § 25249.6, seeking an injunction and civil penalties for defendants' failure to warn consumers that their tuna products contain dangerous mercury compounds. While that suit was pending, the Commissioner of the FDA sent a letter to Mr. Lockyer expressing the opinion that the FDA's prior regulatory actions preempt the State's

[1]While the complaint refers to a design defect, we find it unclear whether the alleged design defect is the failure to warn or is a claim based on excessive mercury concentrations which is distinct from the failure to warn. The District Court apparently reached the former conclusion; it dismissed the failure-to-warn claim without addressing whether the complaint asserts a separate design-defect claim and whether any such claim is preempted. Due to this posture, and because our disposition of this appeal will result in remand to the District Court, we decline to address the design defect claim, if one there be, and instead will allow the parties to raise these issues before the District Court if they so choose.

lawsuit. In the Commissioner's view, the defendants would be unable to comply both with that approach and state law and the existence of the lawsuit would "frustrate the [FDA's] carefully considered federal approach" to the issue of mercury in fish. *See People v. Tri-Union Seafoods*, 2006 WL 1544377 (Cal. Super. Ct. May 12, 2006) (taking judicial notice of the letter). In May 2006, following a bench trial, the Superior Court of California found the Attorney General's lawsuit preempted by federal law. *People v. Tri-Union Seafoods*, 2006 WL 1544384 (Cal. Super. Ct. May 11, 2006), *appeal docketed*, No. A116792 (Cal. Ct. App. 1st Dist. Feb. 20, 2007).

Tri-Union removed Fellner's lawsuit to the United States District Court for the District of New Jersey and filed a motion to dismiss for failure to state a claim accompanied by motions requesting that the Court take judicial notice of four documents: (1) a consumer advisory published by the FDA in 2004 regarding the risks of mercury in fish ("the Advisory"); (2) a "backgrounder" for the FDA's 2004 Advisory, which provides further information about those risks ("the backgrounder"); (3) Section 504.0600 of the FDA's Compliance Policy Guide, a guideline recommending that the FDA initiate enforcement action if the concentration of mercury in fish exceeds "1 ppm" ("the Compliance Guide"); and (4) the above-described letter sent by the Commissioner of the FDA to the Attorney General of California ("the Commissioner's letter").

The District Court took judicial notice of the four documents submitted by defendant and granted defendant's motion to dismiss. *Fellner v. Tri-Union Seafoods*, 2007 WL 87633 (D.N.J. 2007). It found that the FDA had implemented

a "pervasive regulatory scheme" pertaining to the risks of methylmercury in fish consisting of the FDA's Advisory, backgrounder, Compliance Guide, and the Commissioner's letter. It concluded that the FDA had deliberately declined to require warnings in favor of a more "nuanced" and "balanced" approach consisting of targeted advisories, and that the state law duties relied upon by Fellner in her lawsuit would upset that approach. As a result, the Court dismissed the complaint, holding that the FDA's regulatory scheme regarding mercury in fish preempts Fellner's state law claims. She timely appealed.

II. Jurisdiction and Standard of Review

We have jurisdiction pursuant to 28 U.S.C. § 1291. We exercise plenary review of the District Court's order granting defendant's motion to dismiss. *Santiago v. GMAC Mortgage Group*, 417 F.3d 384, 386 (3d Cir. 2005). When reviewing a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6), we accept as true all well-pled factual allegations in the complaint and all reasonable inferences that can be drawn from them, and we affirm the order of dismissal only if the pleading does not plausibly suggest an entitlement to relief. *Wilkerson v. New Media Tech. Charter Sch.*, 522 F.3d 315, 321-22 (3d Cir. 2008).

III. Discussion

The sole question presented in this appeal is whether Fellner's state claim for damages is preempted by federal law. Tri-Union offers three distinct theories of preemption: (1) that the FDA has adopted a "pervasive regulatory approach" –

embodied in the FDA's Advisory, backgrounder and internal enforcement guideline – with which Fellner's state lawsuit actually conflicts; (2) that the FDA has "reject[ed] the use of warning labels" in favor of a more "nuanced" approach – that is, that the FDA has reached a decision that warnings should not be regulated, a decision which preempts the state from entertaining a claim based on a duty to warn theory; and (3) that the FDA would have rejected any warning as "misbranding," a determination which preempts Fellner's failure-to-warn claim.

A. The Doctrine of Federal Preemption

The doctrine of federal preemption is rooted in the Supremacy Clause of the United States Constitution, U.S. Const. art. VI, cl. 2, which invalidates state laws that "interfere with, or are contrary to, federal law." *Hillsborough County v. Automated Med. Labs.*, 471 U.S. 707, 712 (1985) (quoting *Gibbons v. Ogden*, 22 U.S. 1 (9 Wheat. 1, 211), (1824)). As we recently explained,

> [t]he Supreme Court has identified three major situations where there is preemption . . . (1) "express" preemption, applicable when Congress expressly states its intent to preempt state law; (2) "field" preemption, applicable when "Congress' intent to pre-empt all state law in a particular area may be inferred [because] the scheme of federal regulation is sufficiently comprehensive" or "the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject;" and (3)

> "conflict" preemption, applicable when "state law is nullified to the extent that it actually conflicts with federal law," even though Congress has not displaced all state law in a given area.

Colacicco v. Apotex Inc., 521 F.3d 253, 261 (3d Cir. 2008) (quoting *Hillsborough County*, 471 U.S. at 713). *See also English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990) (summarizing the three types of preemption). Tri-Union has not argued, nor could it, that Fellner's lawsuit is expressly preempted by the Food, Drug and Cosmetics Act ("FDCA") or by federal regulation.[2] Similarly, we do not interpret Tri-Union's brief as asserting a field preemption claim, and any such claim would be unavailing.[3] If preemption exists in this

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[2]The Act includes an express preemption provision, 21 U.S.C. § 343-1, but Tri-Union does not urge that it governs this case. The inclusion of express preemption provisions does not preclude the operation of ordinary implied preemption principles. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000).

[3]Courts rarely find field preemption, especially in areas traditionally regulated by the states, unless the structure of a regulatory program leaves little doubt that Congress intended federal law to be exclusive in a particular field. *See, e.g.*, *Hillsborough County*, 471 U.S. at 717 ("merely because the federal provisions [are] sufficiently comprehensive to meet the need identified by Congress [does] not mean that States and localities [are] barred from identifying additional needs or imposing further requirements in the field . . . . We are even

case it must be conflict preemption.

As the Supreme Court frequently reiterates, in all cases "preemption fundamentally is a question of congressional intent." *English*, 496 U.S. at 78-79. *See also Medtronic v. Lohr*, 518 U.S. 470, 485 (1996) ("'[t]he purpose of Congress is the ultimate touchstone' in every preemption case") (citation omitted). However, "state laws can be preempted by federal regulations as well as by federal statutes." *Hillsborough County*, 471 U.S. at 713. Where Congress has delegated the authority to regulate a particular field to an administrative agency, the agency's regulations issued pursuant to that authority have no less preemptive effect than federal statutes, assuming those regulations are a valid exercise of the agency's delegated authority. *Fidelity Fed. Savings and Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153-54 (1982).

Although federal administrative law as well as Congressional enactments are the supreme law of the land, we must reiterate, lest the analysis become unmoored, that it is federal *law* which preempts contrary state law; nothing short of federal law can have that effect. The Supreme Court's longstanding interpretation of the Supremacy Clause, and indeed the Supremacy Clause itself, mandate this principle:

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more reluctant to infer preemption from the comprehensiveness of regulations than from the comprehensiveness of statutes . . ."). In this case, the "regulatory scheme" identified by Tri-Union and the Commissioner's letter fall far short of the sort of comprehensive federal program ordinarily addressed in field preemption cases.

> Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any states to the Contrary notwithstanding." Art. VI, cl.2. Thus, since our decision in *M'culloch v. Maryland*, it has been settled that state law that conflicts with federal law is "without effect."

Cipollone, 505 U.S. at 516 (emphasis added). *See also Colacicco*, 521 F.3d at 261 ("[e]arly in our constitutional history, the Supreme Court interpreted this language to invalidate state laws that 'interfere with, or are contrary to,' federal law, the genesis of the preemption doctrine") (emphasis added; citation omitted).

As we have noted, there is no doubt that federal regulations as well as statutes can establish federal law having preemptive force. *New York v. Fed. Commc'n Comm'n*, 486 U.S. 57, 63 (1988) ("The phrase 'Laws of the United States' [in the Supremacy Clause] encompasses both federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization"). Although there is some authority for the proposition that the only regulatory process which can produce "federal law" for purposes of the Supremacy Clause is formal, notice and comment rulemaking, *Good v. Altria Group*, 501 F.3d 29, 51-52 (1st Cir. 2007), *cert. granted*, 128 S. Ct. 1119 (2008) (collecting cases), we have joined those courts which hold that, in appropriate circumstances, federal agency action taken pursuant to statutorily granted authority short of formal, notice and

comment rulemaking may also have preemptive effect over state law. *Colacicco*, 521 F.3d at 271 (citations omitted).

It is clear, for example, that federal agency orders resulting from quasi-judicial agency proceedings may constitute "federal law" under the Supremacy Clause: "[i]t is well established that when developing law on a subject, an agency usually has a choice between the method of rulemaking and that of adjudication," *General Motors Corp. v. Abrams*, 897 F.2d 34, 39 (2d Cir. 1990) (citation omitted); both agencies' quasi-legislative as well as their quasi-judicial powers "have the binding force of 'federal law.'" *Id*. (citation omitted). *See also Chicago and Nw. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 314-15, 321-28 (1981) (Interstate Commerce Commission order following quasi-judicial proceeding governing abandonment of rail lines preempted state law). Moreover, in addition to orders from formal adjudicatory proceedings, we have recently given preemptive effect to a federal agency order in a similar situation where a comprehensive federal regulatory scheme authorized a process for the agency to apply a federal standard to concrete circumstances, and it had utilized that process in a manner establishing a federal duty or policy. In *Colacicco*, the plaintiffs' alleged claims for failure to warn that a family of drugs used to treat anxiety and depression caused an increased risk of suicidality. The FDCA conferred jurisdiction upon the FDA to regulate drug labeling. Regulations authorized by the FDCA predicated the marketing of drugs on FDA approval of the drugs' labeling both at the time the drugs were initially marketed and on an ongoing basis thereafter. Defendants' labels had received FDA approval both before and after the suicides at

issue. The plaintiffs pointed out, however, that the regulations required that the labeling be revised by the manufacturer unilaterally "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.57(c) (2003). Plaintiffs argued that this meant the defendants could have complied with both the federal regulations and the state duty to warn, and thus no conflict existed. We rejected this argument because, although the regulations allowed a manufacturer to amend warnings unilaterally, all such amendments remained contingent on the manufacturer ultimately receiving FDA approval, and the FDA in a number of different agency proceedings had previously considered the scientific evidence relied upon by plaintiffs and had exercised its prerogative under the regulations to reject suicidality warnings based on that evidence. The FDA had "clearly and publicly stated its position [regarding the propriety of the warning in the pertinent circumstances] prior to the prescriptions and deaths at issue. . . ." *Colacicco*, 521 F.3d at 271. Although defendants had not been shown to be participants in those proceedings, we concluded that a conflict existed because, much like agency quasi-judicial proceedings, *see Security and Exchange Commission v. Chenery Corp.*, 332 U.S. 194, 201-03 (1947), the FDA's actions in those proceedings established a policy against the sought-after warnings applicable not only to the immediate participants but also to others in like circumstances, such as the defendants. Thus, defendants could not have complied with the requirements of both federal and state law.

This does not mean, however, that federal law capable of preempting state law is created every time someone acting on

behalf of an agency makes a statement or takes an action within the agency's jurisdiction. As the Supreme Court has explained, "[i]t is fair to assume generally that Congress contemplates administrative action with the effect of law when it provides for a relatively formal administrative procedure tending to foster the fairness and deliberation that should underlie a pronouncement of such force." *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001) (addressing which types of agency actions should be afforded *Chevron* deference). We believe that similar considerations are pertinent here. We decline to afford preemptive effect to less formal measures lacking the "fairness and deliberation" which would suggest that Congress intended the agency's action to be a binding and exclusive application of federal law. Courts with good reason are wary of affording preemptive force to actions taken under more informal circumstances. *See, e.g.*, *Good*, 501 F.3d at 51-52; *Wabash Valley Power Assn. v. Rural Elec. Admin.*, 903 F.2d 445, 453-54 (7th Cir. 1990); *General Motors Corp.*, 897 F.2d at 39. Regularity of procedure – whether it be the rulemaking and adjudicatory procedures of the APA or others which Congress may provide for a particular purpose – not only ensures that state law will be preempted only by federal "law," as the Supremacy Clause provides, but also imposes a degree of accountability on decisions which will have the profound effect of displacing state laws, and affords some protection to the states that will have their laws displaced and to citizens who may hold rights or expectations under those laws.

Tri-Union points to the Commissioner's letter as both establishing federal law capable of preemption and as evidencing the agency's interpretation of previously established

law, an interpretation to which we should defer. We evaluate below the deference to which we believe that letter is entitled as an interpretation of pre-existing federal law. With respect to Tri-Union's claim that it established federal law, we note that we have found no case in which a letter that was not the product of some form of agency proceeding and did not purport to impose new legal obligations on anyone was held to create federal law capable of preemption. *See Wabash Valley*, 903 F.2d at 453-54 (declining to give preemptive effect to an agency letter where the prescribed procedures were not followed); *Thomas v. New York*, 802 F.2d 1443 (D.C. Cir. 1986) (same).[4]

Finally, the Supreme Court occasionally has confronted a claim that a federal agency's decision not to regulate should be granted preemptive effect because it constitutes a federal determination that the issue shall be *un*regulated – here, the decision not to require (or otherwise regulate) mercury warnings. As the Court explained, "a federal decision to forego regulation in a given area may imply an authoritative federal determination that the area is best left *un*regulated, and in that

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[4]Contrary to Tri-Union's suggestion, we do not read *Geier* as indicating otherwise. Although *Geier* declined to require a "specific, formal agency statement identifying a conflict in order to conclude that [] a conflict in fact exists," *Geier*, 529 U.S. at 884, it did require that state law actually conflict with a federal law. The Court ruled that a state lawsuit was preempted because it actually conflicted with a Department of Transportation ("DOT") regulation (FMVSS 208), *id*. at 874, and the Court merely "place[d] some weight upon the DOT's [informal] interpretation of FMVSS 208's objectives . . .," *id*. at 883, to help it determine whether the two in fact conflicted.

event would have as much preemptive force as a decision to regulate." *Ark. Elec. Co-op v. Ark. Pub. Serv.*, 461 U.S. 375, 384 (1983) (emphasis in original).

However, the Supreme Court has since cautioned that this statement in *Arkansas Electric Co-op* "was obviously not meant in an unqualified sense; otherwise, deliberate federal inaction could always imply preemption, which cannot be. There is no federal preemption *in vacuo*, without a constitutional text or a federal statute to assert it." *P.R. Dep't of Consumer Affairs v. Isla Petroleum Corp.*, 485 U.S. 495, 503 (1988). The Court further explained,

> [w]e are presented with the decidedly untypical claim that federal pre-emption exists despite not only the absence of a statutory provision specifically announcing it, but the absence of any extant federal regulatory program with which the state regulation might conflict and which might therefore be thought to imply pre-emption."

Id. at 500. The Court rejected the claim, concluding that "unenacted approvals, beliefs, and desires are not laws. Without a text that can, in light of those statements, plausibly be interpreted as *prescribing* federal pre-emption it is impossible to find that a free market was mandated by federal law." *Id*. at 501 (emphasis in original).

The Court again confronted, and rejected, a similar claim just a few years ago. Although the Court acknowledged that the agency had the authority to enact a regime free of any regulation

concerning the risk at issue, it declined to infer such a regime from a mere decision not to regulate, absent an "'authoritative' message of a federal policy against [regulation]." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67 (2002). The Court explained,

> [i]t is quite wrong to view [the Coast Guard's decision not to adopt a regulation] as the functional equivalent of a regulation prohibiting all States and their political subdivisions from adopting such a regulation . . . . Of course, if a state common-law claim directly conflicted with a federal regulation promulgated under the Act, or if it were impossible to comply with any such regulation without incurring liability under state common law, pre-emption would occur. This, however, is not such a case.

Sprietsma, 537 U.S. at 65 (emphasis added).[5]

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[5]*Sprietsma* discussed the agency's informal, contemporaneous explanation for its decision not to regulate and also emphasized that the agency had taken an anti-preemption position in briefings for the Court. *Sprietsma*, 537 U.S. at 67-68. We do not interpret *Sprietsma* to have implied that, had the agency adopted a pro-preemption stance in an informal statement or briefings for the Court, those views alone would have imbued the agency's decision not to regulate with preemptive force. *Geier* directs that courts should consider any views expressed by the agency regarding the purposes and objectives of its actions claimed to preempt state law, and therefore it was only natural for *Sprietsma* to note the agency's

Isla Petroleum and *Sprietsma* make clear that mere deliberate agency inaction – an agency decision *not* to regulate an issue – will not alone preempt state law. Furthermore, we find no support for the proposition that an agency's informal explanation for its decision not to regulate can alone imbue such a decision with preemptive force; in all cases concerning alleged "federal determination[s] that [an] area is best left *un*regulated," *Ark. Elec. Co-op*, 461 U.S. at 384, the Supreme Court and Courts of Appeals have inquired whether some extant law or regulation evinced an "authoritative message of federal policy" that an issue is to remain free of state regulation (or any regulation at all); "unenacted approvals, beliefs, and desires" will not suffice.[6]

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agreement. Furthermore, *Sprietsma* emphasized a "stark contrast" with *Geier*: unlike the case before it, in *Geier* it was not mere inaction or a "decision not to regulate" combined with informal agency views that preempted state law but rather a federal regulation (FMVSS 208) that promulgated the "affirmative policy judgment" – the "authoritative message of a federal policy" – with which the state lawsuit was found to conflict. *Id*. at 68 (internal quotation marks and citation omitted).

[6]We find only two situations in which courts have given preemptive effect to decisions not to regulate. First, the Supreme Court has found deliberate federal *in*action to preempt state law (so-called "negative preemption") through what is essentially a field preemption analysis: "[w]here a comprehensive federal scheme intentionally leaves a portion of

the regulated field without controls, *then* the preemptive inference can be drawn – not from federal inaction alone, but from inaction joined with action." *Isla Petroleum Corp.*, 485 U.S. at 503 (emphasis in original). In such cases, courts have concluded from the comprehensiveness of a statutory scheme and their interpretation of the purposes and objectives of the statute that Congress intended federal jurisdiction to be exclusive or the field to be free of any regulation whatsoever. *See, e.g.*, *Ark. Elec. Co-op*, 461 U.S. at 384 (citing field preemption case for the proposition that a federal decision to forego regulation may imply an "authoritative federal determination that the area is best left *un*regulated;" finding no such determination); *Transcontinental Gas Pipe Line v. State Oil and Gas Bd.*, 474 U.S. 409, 422, 425 (1986) (finding this brand of field preemption); *Bldg. & Constr. Trades Council v. Associated Builders & Contractors*, 507 U.S. 218, 224-27 (1993) (discussing two lines of such field preemption cases under the NLRA). *Cf. Ray v. Atlantic Richfield Co.*, 435 U.S. 151, 178 (1978) (agency's decision *not* to adopt a particular regulation contributed to a finding of conflict preemption where the agency took the subsequent step of adopting an alternate federal standard governing the issue with which, the Court found, the state rule would be inconsistent).

Second, other such cases appear to be simply express preemption cases – Congress and federal agencies possessing the appropriate authority certainly may announce by law or regulation a federal policy that an issue is to remain unregulated. *See, e.g.*, *Ark. Elec. Co-op*, 461 U.S. at 388-89 (stating that the federal agency could have announced a policy "that the area is best left *un*regulated" in a "rule [] valid under the [Act]" but had

B. Presumption Against Preemption and Deference to the Agency

The parties dispute the applicability of two familiar rules of interpretation. Fellner asserts that we should apply a presumption against preemption. Tri-Union asserts that Fellner's reliance on the presumption against preemption is misplaced, and that in fact we should afford deference to the agency's views on preemption.

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not done so); *Wabash Valley Power Ass'n*, 903 F.2d at 453-54 (discussing *Ark. Elec. Co-op*); *Gracia v. Volvo Europa Truck*, 112 F.3d 291, 296-97 (7th Cir. 1997), *cert. denied*, 522 U.S. 1050 (1998) (explaining that, in contrast to cases where an agency simply declined to regulate an issue, "here there is a specific federal standard . . . [which] determined that this type of vehicle should be exempt from the affixing requirement . . ."); *Lynnbrook Farms v. Smithkline Beecham Corp.*, 79 F.3d 620, 625 (7th Cir. 1996), *cert. denied*, 519 U.S. 867 (1996) (agency "declaration" of preemption issued in a formal rule); *Evans v. Bd. of County Comm'rs*, 994 F.2d 755, 758-60 (10th Cir. 1993) (agency issued a "limited preemption policy" via a "Memorandum Opinion and Order" following notice and comment); *Ray*, 435 U.S. 171-72 (stating that the federal agency could promulgate "rules" announcing that it desired *no* regulation of an issue but had not done so); *Baltimore & Ohio R.R. v. Oberly*, 837 F.2d 108, 115-16 and n. 3 (3d Cir. 1988) (citing *Ray*, 435 U.S. at 172-73 & n. 23, and other cases for the same proposition).

1. Presumption Against Preemption

The Supreme Court historically has applied a presumption against the preemption of state laws:

> because 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. 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 were not superseded by the Federal Act unless that was the clear and manifest purpose of Congress."

Medtronic v. Lohr, 518 U.S. 470, 485 (1996) (citations omitted). *See also Hillsborough County v. Automated Med. Labs.*, 471 U.S. 707, 715 (1985) ("[w]here . . . the field that Congress is said to have pre-empted has been traditionally occupied by the States 'we start with the [presumption];'") (citation omitted); *Bates*, 544 U.S. at 449 (similar).

Recent Supreme Court jurisprudence suggests that the presumption remains applicable when preemption claims concern areas of the law "which the States have traditionally occupied," but that it may not be applicable "where the interests at stake are 'uniquely federal' in nature." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001) (declining to apply the presumption because "[p]olicing fraud against

federal agencies is hardly 'a field which the States have traditionally occupied' . . . . To the contrary, the relationship between a federal agency and the entity it regulates is inherently federal in character") (citations omitted). *See also United States v. Locke*, 529 U.S. 89, 108 (2000) (presumption applies "in field[s] which the states have traditionally occupied," but declining to apply it because "national and international maritime commerce" is not such a field) (citations omitted).

In the present case, it is hard to imagine a field more squarely within the realm of traditional state regulation than a state tort-like action seeking damages for an alleged failure to warn consumers of dangers arising from the use of a product. *See, e.g., Bates*, 544 U.S. at 449 ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption"). Furthermore, state tort law and other similar state remedial actions are often deemed complementary to federal regulatory regimes, and this appears to be such a case. Federal regulatory programs frequently do not include a compensatory apparatus, and the Supreme Court has recognized that state tort law can also play an important information-gathering role not easily replicated by federal agencies.[7] When a litigant asserts that a

[7]*See, e.g., Sprietsma*, 537 U.S. at 64 ("It would have been perfectly rational for Congress not to pre-empt common-law claims, which – unlike most administrative and legislative regulations – necessarily perform an important remedial role in compensating accident victims."); *Bates*, 544 U.S. at 449, 451 ("[p]rivate remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the

private right of action, as opposed to a state statute or regulation, is preempted, we are cognizant that preemption may leave individuals with rights but no private remedy, where traditionally there has been one. Although Congress certainly can afford, and in some instances has afforded, federal regulators exclusive jurisdiction over a particular subject matter, and federal regulations will preempt state laws that actually do conflict with them, we do not lightly infer such a result where state compensatory regimes have traditionally played an important role.

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functioning of FIFRA . . . . FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings . . . tort suits can serve as a catalyst in this process;" concluding that "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly"); *Medtronic*, 518 U.S. at 487 (plurality opinion) ("because there is no explicit private cause of action [in the federal Act] . . . [a finding of preemption would mean] Congress would have barred most, if not all, relief for persons injured by defective medical devices. Medtronic's construction of § 360k would therefore have the perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation"); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

Although we are aware that the Supreme Court has applied the presumption in few conflict preemption cases of late, and arguments have been raised that the conflict preemption analysis subsumes or supplants the presumption, *see Colacicco*, 521 F.3d at 265, we will continue to apply the traditional presumption until the Supreme Court provides guidance to the contrary. *Id*. *See also Hillsborough County*, 471 U.S. at 715 (applying the presumption to implied preemption claims). However, even where the presumption applies it will be overcome where a Congressional purpose to preempt or the existence of a conflict is "clear and manifest." *Id*.

2. Deference to Federal Agency Views

Tri-Union argues that "the FDA's findings and opinion set forth in the FDA Preemption Letter as well as its regulatory approach (the FDA Advisory and Backgrounder) should be afforded a high level of deference and/or persuasion." Appellee's Br. at 24.

As we recently explained, "[w]e would ordinarily be leery of an agency's view of what is essentially a legal issue," *Colacicco*, 521 F.3d at 274, but in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), the Supreme Court "place[d] some weight," on the agency's informal views of the purposes and objectives of the regulation at issue and the agency's view that the state lawsuit would "stand as an obstacle" to those objectives. *Id*. at 883. We concluded that "such a position is subject to a level of deference approximating that set forth in *Skidmore v. Swift & Co.*, 323 U.S. 134 [] (1944)." *Colacicco*,

521 F.3d at 275. As with *Skidmore* deference, the agency's informal views are entitled to "a respect proportional to [their] 'power to persuade' . . . . [Such informal interpretations] claim the merit of its writer's thoroughness, logic and expertness, [their] fit with prior interpretations, and any other sources of weight." *Mead Corp.*, 533 U.S. at 235 (citation omitted). However, *Geier* does not suggest that courts abdicate their duty to examine whether federal and state law actually conflict – *Geier* did not rely exclusively on the agency's views, explaining that it found the conflict "clear enough" even absent those views. *Geier*, 529 U.S. at 886.

The District Court concluded that "the FDA's Advisory and Backgrounder are entitled to deference and [] the FDA Letter is persuasive." *Fellner v. Tri-Union Seafoods*, 2007 WL 87633, *7 (D.N.J. 2007). *Geier* and cases applying it have afforded some weight to an agency's informal interpretation of the purposes and objectives of its regulations which are claimed to preempt state law. However, the FDA's Advisory and backgrounder are not agency interpretations of regulations claimed to preempt state law but rather are the very agency actions which are claimed to preempt state law. We fail to understand how a court could defer to those documents; they offer no interpretation to which we can defer.

The FDA (indirectly) has offered its interpretation of the purposes and objectives of the regulatory measures at issue in this case in the Commissioner's letter. We agree with the District Court that *Geier* directs us to consider the views expressed in that letter and, as we have explained, those views are entitled to consideration proportional to their ability to persuade: "The weight [accorded to an administrative]

judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all of those factors which give it power to persuade, if lacking power to control." *Mead Corp.*, 533 U.S. at 228 (quoting *Skidmore*, 323 U.S. at 140) (bracketed text in original). Here, however, we do not find the letter persuasive. The circumstances of this letter suggest that it merits a particularly low level of deference. The views the FDA there offers, and the significance it there attributes to its prior administrative actions, have not been shown to be the product of any agency proceeding,[8] were not expressed at the time those actions were taken nor even at the time that Fellner's damages allegedly arose, and are certainly

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[8]The District Court granted the motion to dismiss relying solely on the four documents of which it took judicial notice. Accordingly, our record does not provide a full context for the Commissioner's letter. We can only say that the letter does not itself purport to be the product of an agency proceeding, and the record here does not show it to be. The record in the California litigation does reveal that the Commissioner's letter follows, and bears a striking resemblance to, a letter and memorandum that counsel at a private law firm – counsel who, according to his public law firm biography, represents the canned tuna industry in the California litigation – sent to the agency's chief counsel urging the FDA to "issue[] an appropriately worded letter" asserting preemption over the litigation in California and offering suggestions for the content of such a letter. The agency had never before expressed such views. Those views apparently were formulated without the benefit of exposure to conflicting views or critiques.

not self-evident from the nature of the actions themselves. The FDA expressed those views only later, through a most informal of methods – a letter offering a legal theory for the litigation in California. Most importantly, we simply do not find the letter's reasoning persuasive, for the reasons we set forth below.

C. Tri-Union's Three Theories of Conflict Preemption

As we have explained, this is a conflict preemption case. Therefore, Fellner's state law claims will be impliedly preempted if they are "in actual conflict with federal law." *Sprietsma*, 537 U.S. at 64. The Supreme Court has identified two varieties of "conflict" preemption: (1) where "it is impossible for a private party to comply with both state and federal requirements," and (2) where "state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English*, 496 U.S. at 79 (internal quotation marks and citations omitted).

We begin our analysis by taking note of the authority that Congress has bestowed on the FDA and the extent to which it has exercised that authority in a relevant manner. The FDCA grants the FDA authority to regulate the field of food safety. 21 U.S.C. § 371. The FDA has the authority, *inter alia*, to promulgate food definitions and standards of food quality, *id*. at § 341, and to set tolerance levels for poisonous substances in food. *Id*. at § 346. The FDA is also delegated enforcement authority, including the authority to take various steps to enforce the Act's ban on "adulterated" or "misbranded" food. *Id*. at §§ 331-336, 342-343. The FDA has, however, promulgated no pertinent regulations under this authority.

Nevertheless, it has employed various other means to address the risk of mercury in fish, including issuing a consumer advisory and related "backgrounder" regarding those risks, and including in its internal Compliance Guide a provision recommending that the agency initiate enforcement action if mercury concentrations in fish exceed a specified level. Tri-Union offers three theories of conflict preemption based on these actions.

1. Theory 1: Conflict with a Federal Regulatory Scheme

Tri-Union first argues that the FDA has adopted a "pervasive regulatory approach" with which Fellner's lawsuit actually conflicts. Appellee's Br. at 13, 18-20. This argument suffers from two infirmities. First, as we have explained, state law is preempted only by federal law. The FDA has promulgated no pertinent legal standard pertaining either to the risks posed by mercury in fish or to warnings for that risk, and it has not otherwise acted on the issue in a manner that could be deemed an exclusive application of federal law. Second, even accepting *arguendo* the FDA's "regulatory scheme" were of a type that could preempt state law, Tri-Union has identified no actual conflict between Fellner's claims and the pertinent FDA actions.

We cannot agree with the District Court that the FDA's Advisory and backgrounder "specifically regulate[]" the levels of methylmercury in tuna and "specifically rejected the notion that warning labels should be included on cans of tuna." *Fellner*, 2007 WL 87633 at *4. That Advisory, titled "What You Need to Know About Mercury in Fish and Shellfish," and

the related backgrounder, offer "[a]dvice" for "women who might become pregnant[,] women who are pregnant[,] nursing mothers[, and] young children," App. at 35a, and provide "3 recommendations for selecting and eating fish" that such people are advised to follow. *Id*. We are unable to conclude that the Advisory and backgrounder "specifically regulate[]" anything – they simply give non-binding advice to a class of consumers and do not promulgate a federal legal standard with which Fellner's state law claims could potentially conflict.

Fellner's lawsuit does not conflict with the "advice" in those documents – the concerns expressed therein are entirely consistent with, and arguably complementary to, a duty state law may impose on manufacturers to warn consumers of the risks posed by tuna consumption. *See Bates*, 544 U.S. at 449-51. The mere fact that the FDA chose to warn only certain "at risk" consumers, rather than all consumers, does not create a conflict. Nothing in these documents indicates that consumers other than those "at risk" individuals are *not* at risk of harm from mercury in fish or that they should *not* be warned. The Advisory does recommend continued fish consumption within certain parameters, but that recommendation is clearly not inconsistent with a warning against excess consumption.

Tri-Union also points to the FDA's internal enforcement guideline suggesting mercury levels which might prompt FDA enforcement action, and the District Court similarly referenced an FDA "tolerance level" of "1 ppm." *Fellner*, 2007 WL 87633 at *2. *See* FDA Compliance Policy Guide, Section 540.600.[9]

[9]Under the heading "Regulatory Action Guidance," this section offers "criteria for recommending legal action to

Based on this guideline, Tri-Union argues that "[t]he FDA has determined that there is no hazard associated with methylmercury concentrations of less than 1 ppm." Appellee's Br. at 37. We find no such determination. Although the FDA has authority to promulgate standards for food quality and tolerance levels for poisonous foods, 21 U.S.C. §§ 341, 346, it has not done so. The internal guideline for allocation of agency resources "recommend[ed]" in the Compliance Policy Guide will not alone preempt state law.

Furthermore, even if this guideline were deemed a federal standard, Tri-Union fails to explain how Fellner's lawsuit would conflict with it. The guideline states that the FDA may recommend enforcement action if methylmercury concentrations in fish exceed "1 ppm." Much like the Advisory, the guideline appears entirely consistent with, and arguably complementary to, a state claim that Tri-Union wrongfully failed to warn consumers of the risks posed by those compounds. We are aware of no facts establishing the precise mercury concentrations in Tri-Union's tuna products. Even if Fellner had alleged a specific concentration lower than the FDA guideline – for example, if Fellner had specifically averred that Tri-Union's tuna was dangerous because it contained mercury at a concentration of 0.7 ppm – such a claim would not necessarily be in conflict with this federal "standard." On its face the guideline does not state that tuna with mercury levels

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CFSAN/Office of Compliance/Division of Enforcement: The composite analyzed in accordance with the applicable methods . . . shows: Mercury expressed as Methyl Mercury in excess of 1 ppm (edible portion only)." *Id*.

below 1 ppm poses *no* risk nor that a manufacturer has met any particular standard of care if its tuna does not exceed 1 ppm; it merely suggests that the FDA recommend enforcement action if mercury levels exceed 1 ppm.[10]

In support of its "pervasive regulatory approach" argument, Tri-Union also points to the Commissioner's letter, in which the Commissioner explains that the FDA prefers to address the risks of mercury in fish through advisories rather than warnings requirements due to the risk of overexposure to warnings and the agency's desire to promote moderate fish consumption. We presume that this is a fair concern. However, the FDA has not acted to regulate it in a manner that could

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[10]Tri-Union's brief before us emphasizes that the FDA has also conducted an educational campaign regarding mercury in fish and that the FDA discussed mercury in its response to a citizen's petition. We have not been asked to take judicial notice of these facts, and it is not clear to us that we could do so in the context of a motion to dismiss and a complaint that does not refer to them directly or indirectly. In any event, we fail to see how an educational campaign might preempt Fellner's lawsuit, and we do not read the response to the citizen's petition to speak to a relevant issue. The citizen's petition concerned not the risks of mercury in fish specifically but rather the impact of dietary supplements of "omega-3 fatty acids" on heart disease. It discusses mercury risks only briefly, in the context of mercury's impact on the health effects of omega-3 fatty acids. The FDA merely explained that it would decline to require that the omega-3 fatty acid health claim be accompanied by a mercury warning, not that all mercury warnings should be affirmatively prohibited.

preempt Fellner's claims. As we have explained, the letter itself does not establish a federal policy against warnings capable of preempting state law. As we have also explained, we do not find persuasive the letter's characterization of the FDA's prior actions on the subject as a "regulatory scheme" capable of preempting Fellner's claims.

We conclude that the FDA has regulated neither the risk of mercury in tuna nor the permissible warnings regarding that risk in a manner that conflicts with Fellner's lawsuit.

2. Theory 2: A Federal Decision Not To Regulate

Tri-Union's second theory of preemption is that the FDA has "reject[ed] the use of warning labels," Appellee's Br. at 32 – that the FDA reached a "federal decision to forego regulation" amounting to "an authoritative federal determination that the area is best left *un*regulated," a decision which preempts any state standard or duty requiring such warnings. *Id*. at 31 (quoting *Ark. Elec. Co-op.*, 461 U.S. at 384) (emphasis in original). In Tri-Union's view, just such a decision was made when the Commissioner's letter was dispatched. In that letter, the Commissioner expressed the view that, because the FDA after "studying the issue of methylmercury in fish for several years," App. at 42a, declined to require a warning and instead issued an advisory, the California lawsuit would "frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish." *Id*. Although the federal government certainly may promulgate a regulatory regime in which it decides that a particular issue is best left unregulated, as the Supreme Court has explained, "to say that [such a regime] can be created is not to say it can be

created subtly." *Isla Petroleum*, 485 U.S. at 500. A mere decision by the FDA not to adopt a federal warnings requirement certainly does not alone preclude states from imposing a duty to warn, and, as we have earlier indicated, we find no authority for the proposition that the FDA could institute a regime affirmatively proscribing all warnings obligations via mere informal expressions of policy such as those in the Commissioner's letter. *Id.* at 501, 503 ("[t]here is no federal preemption *in vacuo*, without a constitutional text or a federal statute to assert it;" "unenacted approvals, beliefs, and desires are not laws").

While the FDA may well have the authority to promulgate a regulatory scheme which would preclude any state duty to warn consumers of the risks of mercury in tuna, it simply has not done so. Tri-Union points to the Commissioner's letter, but as we have explained courts have declined to permit agencies to promulgate express preemption decisions by informal letter. In any event, we do not read the letter as purporting to declare a new preemption policy; it purports to be an explanation of what the FDA determined to do in the past. As we have indicated, however, nothing in the agency's past actions indicates that it made an "authoritative federal determination that the area is best left unregulated."

We have no reason to doubt that the FDA has studied the risks of mercury in fish, as the District Court found. However, it made no "conclusive determination" of the sort which will preempt state law – neither that mercury in fish poses no adverse health consequences, nor to prohibit some or all warnings. State law is not preempted whenever an agency has

merely "studied" or "considered" an issue; state law is preempted when federal *law* conflicts with state law. As we have explained, the cases leave no doubt that a mere decision not to regulate – in this case, a decision not to require a federal methylmercury warning – alone will not preempt state law. *See supra* note 6 and accompanying text. As we have also explained, we find no federal standard, mandate or regulatory action on the subject with which Fellner's claim conflicts nor any federal determination precluding state regulation of the issue.

3. Theory 3: The FDCA's Food Misbranding Provision

Finally, Tri-Union contends that Fellner's failure-to-warn claim is preempted because that claim is premised on the theory that it should have provided a warning regarding mercury in fish, but the FDA would have deemed any such warning "misbranding," creating a conflict between the asserted state duty and federal law. Appellee's Br. at 33-37. Tri-Union argues that the FDA would deem a warning false and misleading because any such warning would not "specify the scientific basis as to the cause of the harm warned of, and/or the amounts of such food that were required to cause this harm," Appellee's Br. at 34-35, and because a warning would not "balance out the negative methylmercury information with positive information about the numerous healthy attributes of canned tuna," *id*. at 35, resulting in overexposure to warnings and scaring consumers away from a useful product. *Id*. In support of this claim, Tri-Union points to the Commissioner's letter, in which the Commissioner opined that the "Proposition 65 warnings" – the warnings requirement underpinning the California Attorney

General's lawsuit – would be false or misleading for similar reasons.

The FDCA's general misbranding provision for food provides, in pertinent part, that "[a] food shall be deemed misbranded -- (a) False or misleading label[:] If (1) its labeling is false or misleading in any particular . . . ." 21 U.S.C. § 343(a). FDA regulations further provide that "labeling of a food, drug, device, or cosmetic shall be deemed to be misleading if it fails to reveal facts that are: (1) Material in light of other representations made or suggested by statement, word, design, device, or any combination thereof . . . ." 21 C.F.R. § 1.21. The FDCA renders unlawful, *inter alia*, the misbranding of food and the distribution of misbranded food, *id*. at § 331(a)-(b), and it authorizes the FDA to enforce those prohibitions via enforcement actions in the United States District Courts for injunctions or criminal penalties. *Id*. at §§ 332, 333. The FDCA also delegates to the FDA certain additional tools to prevent misbranding. The FDA may, and indeed must, officially express its concerns with a warning or label before reporting a violation to a United States Attorney for criminal proceedings, to afford the regulated entity notice and an opportunity to present its views. *Id*. at § 335. In the case of "minor violations," the agency may issue "a suitable written notice or warning." *Id*. at § 336. The FDA is also delegated the authority affirmatively to regulate food labels and warnings.[11]

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[11]*See id*. at §§ 341, 346, 371. The FDA has, for certain other foods, exercised this authority by affirmatively requiring particular warnings, *see*, *e.g.*, 21 C.F.R. § 101.17, but it has not exercised its regulatory authority in any manner pertinent to this

Had the FDA considered the factual basis for the alleged duty to warn and exercised its misbranding authority to establish that a warning based on that data would be false or misleading under federal law – not merely that the FDA had failed to require the warning, but had exercised its authority specifically to reject it – our recent decision in *Colacicco* would govern and a state failure-to-warn lawsuit would be preempted. However, Tri-Union's misbranding theory suffers from the same shortcomings as its prior theories: it identifies no regulatory action establishing mercury warnings as misbranding under federal law, and it fails to explain how the regulatory concerns it *has* identified actually conflict with Fellner's lawsuit.

The FDA has taken no misbranding action pertaining to the risk of mercury in tuna whatsoever. In the above-listed provisions, Congress provided a broad spectrum of ways in which the FDA may act in order to enforce the statutory prohibition on misbranded food – "a suitable written notice or warning;" an administrative proceeding of the type required to precede a criminal prosecution; a federal court action seeking an injunction or criminal penalties, and affirmative regulation.[12] However, the FDA has taken no action pursuant to this authority. Instead, the FDA merely expressed an informal policy opinion in a letter, and it did so only after Fellner's injuries were allegedly suffered. We need not decide at what point a particular warning becomes established as false and

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case.

[12]Ultimately, misbranding liability may be imposed only by federal courts.

misleading for preemption purposes. Suffice it to say that the FDA must actually exercise its authority in a manner in fact establishing the state warning as false or misleading under federal law; the informal views expressed in the Commissioner's letter will not preempt Fellner's lawsuit.

Furthermore, as with its other preemption theories, Tri-Union fails to identify an actual conflict between the FDA's concerns and Fellner's claims. We perceive no actual conflict between those concerns and Fellner's lawsuit. Had Tri-Union wished to warn consumers of those risks, as Fellner alleges it should have, it is not apparent that Tri-Union would have been unable to do so in a manner that satisfied both the alleged state law duty and the FDA's concerns. For example, a warning certainly could have specified that the risks become material only with frequent tuna consumption, and that moderate fish consumption offers positive health benefits. For these reasons, we find no actual conflict between the FDA's misbranding authority and Fellner's lawsuit.

IV. Conclusion

This is a situation in which the FDA has promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect. Fellner's lawsuit does not conflict with the FDA's "regulatory scheme" for the risks posed by mercury in fish or the warnings appropriate for that risk because the FDA simply has not

regulated the matter. Fellner's duty-to-warn claim does not conflict with an FDA determination deliberately to forego warnings because the FDA took no action to preclude state warnings – at least, no binding action via ordinary regulatory procedures, and no action whatsoever until after Tri-Union allegedly wrongfully failed to warn. Finally, Fellner's lawsuit does not conflict with the FDCA's food misbranding provision or the FDA's actions thereunder because the FDA has not exercised its misbranding authority under the FDCA with respect to methylmercury warnings for fish.

The FDA has only issued a consumer advisory regarding the risks posed by mercury in fish and established a guideline regarding mercury concentrations to guide its enforcement decisions. Neither of these agency acts constitutes a federal legal standard or binding regulatory action on the subject which could give rise to a conflict, and indeed neither expresses a policy or viewpoint or approach inherently inconsistent with Fellner's lawsuit. In the final analysis, this case involves an agency effort to preempt an area of law traditionally within the states' police powers via informal letter, and to do so only after the conduct at issue in this case occurred. We understand the precedent to require more of federal agencies to institute a policy expressly precluding state regulation than a mere informal letter, and neither the Commissioner's letter nor Tri-Union's brief identifies any federal law with which Fellner's lawsuit might conflict. Although the Supremacy Clause provides that state laws will give way when they actually conflict with federal law, on this record we find no federal law with which the alleged state duty to warn conflicts.

For the foregoing reasons, we will reverse the judgment of the District Court and remand the case for further proceedings consistent with this opinion.