UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIVIL ACTION NO.: 06-CV-688 (DMC) (MF)

DEBORAH FELLNER, Individually and on Behalf of Those Similarly Situated,	)
Plaintiff,	)
v.	)
TRI-UNION SEAFOODS, L.L.C., d/b/a CHICKEN OF THE SEA,	)
Defendant.	)

DEFENDANT'S REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S COMPLAINT

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INTRODUCTION

Defendant Tri-Union Seafoods, L.L.C., d/b/a Chicken of the Sea ("defendant" or "Tri-Union") respectfully submits this Reply brief in further support of its motion to dismiss plaintiff Deborah Fellner's ("plaintiff") individual claims.

Plaintiff argues, among other things, that purported warning label requirements contained in the New Jersey Products Liability Act ("NJPLA") and the New Jersey Consumer Fraud Act ("NJCFA") are not preempted by the Food and Drug Administration's ("FDA") regulatory approach which was outlined in the 2005 FDA Preemption Letter (attached as *Exhibit C* to Defendant's Motion for Judicial Notice). Plaintiff's opposition also contains several misleading arguments buttressed by misquoted exhibits and factually inaccurate statements.

In short, plaintiff's arguments have no merit. First, because there exists an actual conflict between the FDA's carefully considered and researched regulatory approach, and the warning requirements alleged to arise under the NJPLA and the NJCFA, and because compliance with both state and federal law would be impossible, New Jersey state law must be preempted. Second, contrary to plaintiff's contention, the 2005 FDA Preemption letter is entitled to substantial deference from the court. Indeed, because the FDA is authorized by the Food Drug and Cosmetic Act ("FDCA") to administer the Act and promulgate regulations on food labeling, and because of the substantial technical expertise that the FDA has in the area of food labeling, the FDA is "uniquely qualified" to interpret its own regulations and powers when the Act is silent as to preemption. Moreover, plaintiff's reliance on *Feldman v. Lederle Labs*, 125 N.J. 117 (1991) and *McNellis v. Pfizer*, No. 05-1286-JBS, 2005 WL 3752269 (D.N.J. Dec. 29, 2005) is misplaced. Both cases are distinguishable from the instant matter in several respects and based on those substantial differences, *Feldman* and *McNellis* are not instructive with respect to the

preemption issue at the heart of this motion. Lastly, plaintiff's common law fraud claim against defendant should be dismissed because plaintiff did not oppose defendant's argument that such claim is subsumed by the NJPLA.

In sum, because the FDA's regulatory approach preempts the NJPLA and NJCFA with respect to the issue of warnings on food labels and, in particular, the question of whether defendant was required to place a methylmercury warning label on tuna cans, and for the reasons set forth in defendants initial moving papers, defendant's motion to dismiss the plaintiff's Complaint must be granted.

POINT I

THE NEW JERSEY PRODUCT LIABILITY ACT AND THE NEW JERSEY CONSUMER FRAUD ACT ARE PREEMPTED BY THE FDA'S REGULATORY APPROACH BECAUSE COMPLIANCE WITH BOTH STATE AND FEDERAL LAW WOULD BE IMPOSSIBLE AND CONSTITUTES AN ACTUAL CONFLICT.

In plaintiff's opposition to defendant's motion to dismiss her individual claims, she argues, without legal basis, that federal law does not preempt failure to warn claims under the New Jersey state law because no actual conflict exists between state and federal law. Assuming *arguendo* that defendant placed a warning about methylmercury on the label of its tuna products, any such warning would both conflict with the explicit regulatory approach of the FDA, which specifically rejected the use of warnings and would be deemed "misleading" in violation of section 403 of the FDCA.

A. Any Warning Requirements Arising Under New Jersey State Law Would Create An Actual Conflict With The FDA's Regulatory Approach For Dealing With Methylmercury In Fish.

As an initial matter, contrary to plaintiff's argument, the warning requirements contained in the NJPLA and the NJCFA are directly in conflict with the FDA's regulatory approach. Pursuant to its authority under the FDCA, the FDA has consistently opposed the use of warnings

to accomplish its objectives under the FDCA. This policy dates back to well before the 2005 FDA Preemption Letter. As early as May 1995, the FDA prepared "FDA Consumer Article," as part of the FDA's Methylmercury Advisory, entitled "Is Mercury in Fish a Safety Concern?" *See* [Schoen Reply Cert., Exhibit "1"]. Therein, the FDA specifically stated:

> FDA seafood specialists say that **eating a variety of types of fish, the normal pattern of consumption, does not put any one in danger of mercury poisoning. It is when people eat fad diets – frequently eating only one type of food or a particular species of fish – that they put themselves at risk.** (Emphasis added).

Also of importance, the FDA advised that, "**[c]onsumption advice is unnecessary for the top 10 seafood species, making up about 80 percent of the seafood market – canned tuna, shrimp.**" *See id.* (emphasis added).

Thereafter, early in 2001, the FDA issued an Advisory on Methylmercury in Fish, which advises pregnant women, women of childbearing age, nursing mothers and young children against consuming shark, swordfish, king mackerel, and tilefish, but further advised this subpopulation that "seafood can be an important part of a balanced diet for pregnant women and those of childbearing age who may become pregnant. **FDA advises these women to select a variety of other kinds of fish – including shellfish, canned fish,** smaller ocean fish or farm-raised fish ... and that these women can safely eat 12 ounces per week of cooked fish." *See* [Schoen Reply Cert., Exhibit "2"].

Then, on September 8, 2004, the FDA Associate Commissioner William Hubbard, prepared a letter outlining the FDA's position against the use of a warning regarding the existence of methylmercury in fish in response to the "Martek Petition," dated November 3, 2003. *See* [Schoen Reply Cert., Exhibit "3"]. In the petition, Martek Biosciences Corporation ("Martek") sought to require warning labels for shark, swordfish, king mackerel and tilefish that

included the FDA's "advisory statement suggesting a limited weekly intake for a vulnerable population of pregnant women, women of childbearing age, nursing mothers, and young children." In response, the FDA expressly rejected a warning as suggested by Martek. *See id.* Consequently, the FDA expressly rejected warnings on fish products regarding the existence of methylmercury.

After the *Martek* issue was resolved, in response to an action commenced by the California Attorney General, the FDA concluded in an August 12, 2005 letter that state laws requiring warnings on tuna products are preempted by federal law. *See* 2005 FDA Preemption Letter. Therein, the FDA articulated specific reasons why requiring the tuna companies to comply with Proposition 65 directly conflicted with federal law, and noted that only under exceptional circumstances does the FDA require manufacturers to provide warnings on their labels. *Id.* Specifically, buoyed by its years of research and analysis of methylmercury in tuna, the FDA stated that using advisories rather than explicit warnings remains the preferred method for advising the public. *Id.* The FDA believes that state laws warnings for methylmercury on tuna products frustrate this long-standing, "carefully considered agency approach." *Id.*

Accordingly, the FDA concluded that it would be impossible to comply with both state law warning requirements, such as purported by plaintiff to exist under the New Jersey Products Liability Act, and the FDA's carefully considered regulatory approach. Therefore, as a result of the actual conflict between the state and federal law, New Jersey state law is preempted. In turn, Plaintiff's claims under New Jersey state law must be dismissed.

B. Preemption Of State Law Is Appropriate Because Any Proposed Warnings About Methylmercury In Tuna Are Misleading Pursuant To Section 403 Of The FDCA And Therefore Compliance With Both New Jersey State Law And The FDCA Would Be Impossible.

In the 2005 FDA Preemption Letter, the FDA also stated that the Proposition 65 warnings[1] were misleading and thus, in violation of Section 403(a)(1) of the FDCA because they omitted material facts, such as providing 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. The FDA concluded that these facts were necessary to place the information in its proper context. *Id.* Likewise, defendant respectfully submits that any warning requirements arising under New Jersey law would similarly be misleading and would therefore create a direct conflict between state law and the FDCA. Under these circumstances, preemption of state law is appropriate.

Sections 403(a)(1) and 201(n) of the FDCA imbue the FDA with authority to require warnings on food and take action against misbranded food. In addition, the FDA is empowered to promulgate labeling rules to achieve the purposes of the FDCA, whether expressed or implicit. *Am. Frozen Food Inst. v. Matthews*, 413 F.Supp. 548 (D.D.C. 1976) *aff'd* 555 F.2d 1059 (D.C. Cir. 1977). Section 403(a)(1) provides that a food shall be deemed to be misbranded if its labeling is false or misleading in any particular way. Section 201(n) explains that in determining whether a food is misbranded because its labeling is misleading, the FDA will consider, among other things, whether the labeling fails to reveal facts that are material with respect to consequences which may result from the use of the article of food. The FDA's regulations similarly provide, in relevant part, that the labeling of a food shall be deemed to be misleading if it fails to reveal facts that are material in light of other representations made or suggested in the labeling, or material to the consequences that may result from the use of the article under the customary or usual conditions of use of the article. 21 C.F.R. § 2.1(a).

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[1] The Proposition 65 warnings purported to convey that methylmercury is known to cause cancer and reproductive harm. *See* 2005 FDA Preemption Letter.

Based on this information, the FDA opined that the Proposition 65 warnings were misleading under section 403 of the FDCA and would cause tuna products with such warnings to be misbranded pursuant to the statutory definition and in violation of federal law. *See* 2005 FDA Preemption Letter. Accordingly, the FDA determined that there was no way that tuna manufacturers could comply with both Proposition 65 and the FDCA, and that Proposition 65 conflicted with federal law. *Id.*

For the same reasons, requiring defendant to comply with the warning requirements purported by plaintiff to exist under the NJPLA and the NJCFA would directly conflict with federal law. First, although no specific warning language has been suggested by plaintiff or mandated by the State of New Jersey, virtually any warning that does 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 would be misleading in violation of section 403 of the FDCA.

Second, such warnings would also be misleading because they would not balance out the negative methylmercury information with positive information about the numerous healthy attributes of canned tuna. Even worse, the unbalanced warnings could serve to scare consumers away from a healthy product where there is no clear evidence of a hazard. The overexposure of consumers to warnings could result in consumers ignoring all such statements and hence create a far greater public health problem. *See* 2005 FDA Preemption Letter, at 6. Critically, as no specific language has been proposed in this case, the likelihood is that the warnings would be far more encompassing and prohibitive than were the Proposition 65 warnings which merely addressed pregnant women and children.[2]

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[2] The California Attorney General withdrew the People's request for warnings on tuna products for the general population.

Moreover, the conflict between the FDA's "benefits emphasis" policy and compliance with warning requirements alleged to exist under the New Jersey state law mirrors the conflict which the California Supreme Court found supported a finding of implied preemption in *Dowhal v. Smithkline Beecham Consumer Healthcare*:

> [I]n most cases FDA warnings and Proposition 65 warnings would serve the same purpose – informing the consumer of the risks involved in use of the product – and differences in wording would not call for federal preemption. Here, however, the FDA warning serves a nuanced goal – to inform pregnant women of the risks of [smoking cessation] products, but in a way that will not lead some women, overly concerned about those risks, to continue smoking. This creates a conflict with the state's more single-minded goal of informing the consumer of the risks. That policy justifies federal preemption here. 32 Cal. 4th 910, 929, 934-35 (2004).

Even an attempt to balance the negative methylmercury warnings to the general population with the positive information contained in an FDA Consumer Advisory would not remedy the above-described misbranding problem and would create substantial confusion and potential health injury.

Accordingly, contrary to plaintiff's argument, requiring defendant to add a mercury warning to its canned tuna products pursuant to the NJPLA and/or the NJCFA creates an actual direct conflict with federal law. On that basis, plaintiff's complaint should be dismissed.

POINT II

THE 2005 FDA PREEMPTION LETTER IS ENTITLED TO SUBSTANTIAL DEFERENCE FROM THIS COURT BECAUSE THE FDA IS AUTHORIZED BY THE FOOD DRUG AND COSMETIC ACT TO PROMULGATE REGULATIONS ON LABELING AND IS "UNIQUELY QUALIFIED" TO INTERPRET ITS OWN POWERS WHEN THE STATUTE IS SILENT AS TO PREEMPTION.

A. The FDA's Interpretation Of Its Labeling Regulations And Powers Under The FDCA Are Entitled To Substantial Deference From This Court.

Plaintiff erroneously argues that the 2005 FDA Preemption Letter, which sets forth the FDA's opinion on the preemptive effect of its regulations, is entitled to no deference from the

Court. To the contrary, the FDA's findings and legal opinion that its regulatory approach preempts state law are entitled to substantial deference because the FDA is "uniquely qualified" to interpret its own regulations and powers under the FDCA.

The FDA is entrusted to protect the safety of seafood in the United States and has broad authority to accomplish its charge through the administration of the FDCA and the Fair Packaging and Labeling Act ("FPLA").[3] The FDA's approach to implementing the FDCA pursuant to Congress's purpose is to balance the health benefits of a product with any potential health and safety issues posed by consumption. The FDA's comprehensive policy of promoting a healthy diet includes the consumption of fish, while taking measured steps to educate the subpopulation of the public regarding the existence of possible risks such as methylmercury.

When a statute's language is plain, the sole function for the courts is to enforce it according to its terms. *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000). As in the instant case, where the FDCA does not directly state whether the Act preempts state law on the issue of labeling food products, a federal agency's own views on whether state law conflicts with federal requirements it administers are to be accorded substantial deference. *Sprietsma v. Mercury Marine*, 537 U.S. 51, 67-68 (2002). *See also Robert Wood Johnson Univ. Hospital v. Thompson*, 297 F.3d 273, 284 (3rd Cir. 2002) (citing *Thomas Jefferson University v. Shalala*, 512 U.S. 504, 512 (1994)).

The FDA's views on appropriate labeling merit particular respect. *See Henley v. FDA*, 77 F.3d 616, 620 (2d Cir. 1996) (FDA's determination of what labeling best reflects current scientific information regarding the risks and benefits of an FDA-regulated product "involves a high degree of expert scientific analysis"). A court "must generally be at its most deferential"

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[3] The FDA's general statutory power to require food warnings is grounded in the misbranding provisions of the FDCA. *See* 21 U.S.C. §§ 343(a)(1) and 321(n); *see generally* 21 U.S.C. § 371(a) (Secretary of H.H.S. has "[t]he authority to promulgate regulations for the efficient enforcement of" the FDCA.).

when reviewing determinations within an agency's area of special expertise. *Southwestern Pennsylvania Growth Alliance v. Browner,* 121 F.3d 106, 117 (3rd Cir. 1997). This FDA expertise extends both to the warnings that should be given and those that should not. *Brooks v. Howmedica, Inc.* 273 F.3d 785, 796 (8th Cir. 2001).

Accordingly, because of the FDA's expertise in food labeling and its considerable investigation, research and knowledge about the necessity of warning labels for methylmercury in tuna, the FDA's findings and opinion set forth in the 2005 FDA Preemption Letter, where it expressly rejected the need for warning labels about methylmercury in tuna to the general public, should be afforded a high level of deference from this Court.

B. Assuming Arguendo That The 2005 FDA Preemption Letter Is Deemed An Informal Document, It Is Still Entitled To Substantial Deference From The Court.

Informal agency actions taken pursuant to congressionally granted authority can preempt state law. *See Geier v. American Honda Motor Co.* 529 U.S. 861, 884-885 (2000) ("[T]he Court has never before required a specific, formal agency statement identifying conflict in order to conclude that such a conflict in fact exists."); *Dowhal v. Smithkline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 929 (2004) (finding preemptive intent in an FDA letter establishing its policy regarding FDA approved nicotine warnings); *Bank of Am v. City of San Francisco*, 309 F.3d 551, 563-564 (9th Cir. 2002) (conflict preemption found based on interpretation of national bank powers set forth in "amicus brief" and "two interpretative letters").

Indeed, *Geier's* rationale for according deference specifically to a federal agency's interpretation of the preemptive effect of its own regulations is equally applicable to the FDA's reasoning in the 2005 FDA Preemption Letter:

- Congress has delegated to the FDA the authority to implement the FDCA;

- The subject matter is technical and the relevant history and background are complex and extensive;
- The FDA is likely to have a thorough understanding of its own regulations and its objective, and is uniquely qualified to comprehend the likely impact of state requirements; and
- The FDA has explained the failings of food labeling over time and has consistently adhered to the advisory approach in addressing the matter of mercury in fish.

See Geier, 529 U.S. at 883 (describing why weight should be given to the Department of Transportation's interpretation of a safety standard). *See also Dowhal*, 32 Cal. 4th at 929 (concluding that FDA's letter responding to a citizen's petition established a federal policy prohibiting defendants from giving consumers any warning other than the one approved by FDA in that letter, and that the use of a Proposition 65 warning could conflict with that policy).[4]

Accordingly, the FDA's purportedly informal findings and legal opinion that its regulatory approach preempts state law are entitled to substantial deference, and this Court should find that any New Jersey law requiring mercury warnings on canned tuna is preempted.

POINT III

PLAINTIFF'S RELIANCE ON THE *FELDMAN* AND *MCNELLIS* CASES IN OPPOSITION TO PLAINTIFF'S MOTION TO DISMISS IS MISPLACED.

Plaintiff relies on *Feldman v. Lederle Labs* and *McNellis v. Pfizer* to support her argument that the NJPLA and the NJCFA are not preempted by federal law. However, the holdings in *Feldman* and *McNellis* are readily distinguishable and inapplicable to the case at bar.

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[4] *See also Auer v. Robbins*, 519 U.S. 452, 462 (1997) (stating that the fact that the Secretary of Labor's interpretation of regulations were set forth in the form of a legal brief did not "make it unworthy of deference;" specifically, "[t]he Secretary's position is in no sense a 'post hoc rationalization' advanced by an agency seeking to defend past agency action against attack" and "there is simply no reason to suspect that the interpretation does not reflect the agency's fair and considered judgment on the matter in question"); *McCarthy v. Option One Mortgage Corp.*, 362 F.3d 1008, 1014 (7th Cir. 2004) (although Office of Thrift Supervision opinion letter had no legal force, the Court considered the OTS's interpretation of its own regulation as persuasive authority and the state law was held preempted), *modified on other grounds* 2004 WL 1005605 (7th Cir. May 7, 2004).

A. The *Feldman* Case Is Distinguishable From The Instant Case And Is Inapposite.

In *Feldman*, the New Jersey Supreme Court found that federal law did not preempt state law because it was "satisfied that federal law did not clearly require Lederle [the drug manufacturer] to obtain prior approval from the FDA before warning of a known or knowable danger." *Feldman v. Lederle Labs*, 125 N.J. at 147. Indeed, testimony at the *Feldman* trial revealed that there was only an industry understanding that the FDA regulations required prior approval. *Id.* at 148.

Here, as distinguishable from *Feldman*, the FDA has explicitly stated that 1) state laws requiring disparate or elaborate warnings conflict with the FDA's regulatory approach of advising consumers of the risks and benefits of eating fish and shellfish, and 2) compliance with both the FDCA and state law is impossible and thus state law is preempted under federal law. *See* 2005 FDA Preemption Letter.

Moreover, there are significant factual distinctions between *Feldman* and this case. Specifically, the product at issue in *Feldman* was Declomycin, which was similar to and posed the same dangers as three other drugs for which the FDA required warnings. 125 N.J. 126. Rather than include a warning similar to that required for the other drugs, the drug manufacturer [Lederle] waited for the FDA to approve such a warning on its specific product despite Lederle's independent knowledge that Declomycin was unsafe as distributed because it posed the same dangers as the other products. *Id.* at 126-27.

The instant case differs because there is clear evidence of a conflict between complying with warning requirements purported by plaintiff to exist under the New Jersey state law and

complying with the FDA's explicit prohibition of warnings about methylmercury on tuna cans.[5] Unlike in *Feldman*, defendant is not simply waiting for approval from the FDA of a warning that it knows is necessary and expects imminently. On the contrary, the FDA has expressly rejected the use of warning labels on canned tuna, preferring to use a nuanced regulatory approach of issuing advisories on methylmercury in tuna to a select population group – pregnant women, women who might become pregnant, nursing mothers and young children while rejecting the need for even an advisory to the general population. In short, based on the FDA's exhaustive research and investigation into the effect of the methylmercury found in tuna on humans, the FDA has determined that canned tuna is essentially safe for consumption by the general population. *See* 2005 FDA Preemption Letter.

As the FDA's long-standing regulatory approach rejecting the use of warning labels about the existence of methylmercury in tuna is far more explicit than the unclear requirement in *Feldman*, and here, unlike *Feldman*, the FDA was not examining whether a warning might be necessary, but rather, had already rejected the need for a warning about methylmercury in tuna, it would be impossible for defendant to comply with the FDA's mandates and/or regulations and comply with any New Jersey state law which may require warnings.

B. Plaintiff's Reliance on *McNellis v. Pfizer* is Likewise Misplaced.

Plaintiff contends that the defendant in *McNellis* made similar arguments to Tri-Union, and that such arguments were rejected by the Court. Yet, plaintiff's argument fails to note that in the *McNellis* Court **did not** reject the defendant's preemption argument. Moreover, plaintiff's analysis and reliance on *McNellis* in opposition to defendant's preemption argument is without proper support.

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[5] In fact, the 2005 FDA Preemption Letter codified the FDA's long-standing regulatory approach of explicitly rejecting warnings about methylmercury on tuna cans dating back to the earliest allegations levied against the tuna industry in the California Proposition 65 litigation in May of 1997.

The central issue in *McNellis* was whether Pfizer failed to adequately warn of the risk of suicide associated with antidepressants such as Zoloft despite the presence of the warning label which the FDA had authorized to be given verbatim. *See generally*, 2005 WL 3752269. In *McNellis*, the Court found that its inquiry in the case was limited to whether plaintiff's state law claim that Pfizer should have included an enhanced warning on Zoloft "would conflict with the federal requirements imposed." *Id.* at 10.

Like the instant case, the *McNellis* Court found that a limiting regulation facing Pfizer was that the warning must not be false or misleading, "[a]s that would lead ultimately to the FDA's rejection of Pfizer's labeling...." *Id.* Based on the evidence before it, the *McNellis* Court found it lacked sufficient evidence to determine whether the warning violated the FDCA and needed to determine whether Pfizer had knowledge of a heightened risk of suicide, which should have resulted in enhanced labeling beyond the FDA-approved warning. The Court concluded that plaintiff's state law claims **may be preempted** by federal law unless Pfizer had such knowledge. *Id.* at 11.

Plaintiff's analysis of *McNellis* is misleading and factually erroneous. First, plaintiff failed to mention that the Court did not rule on the vital question of whether state law was preempted by the FDA regulations at issue in the case. *See generally*, 2005 WL 3752269. Significantly, the Court left open the possibility that state law could be preempted by federal law under the circumstances set forth above. *Id.* at 10-11. Second, the issue in *McNellis* was whether an existing warning should have been strengthened, and that question hinged on whether Pfizer knew of a heightened risk of suicide which would have required enhanced labeling. *Id.* at 11.

Here, as opposed to *McNellis*, the FDA has fully investigated and analyzed the issue of methylmercury in tuna and, as discussed above, has explicitly determined that the state law

warning requirement conflicts with federal law and has specifically rejected the need for warning on tuna can labels for the general population as well as for pregnant women, nursing mothers and young children. *See* 2005 FDA Preemption Letter.

Moreover, the FDA directly advised the defendant and other members of the tuna industry that any warnings on tuna cans that do not also include the scientific basis for the possible harm caused by the particular food in question, or the amounts of food that would cause this harm, would violate section 403 of the FDCA. Because compliance with any state law requiring warnings would cause defendant to violate federal law, such requirements under the NJPLA and/or the NJCFA should be preempted as in direct conflict with federal labeling law.

Accordingly, because the facts of *McNellis* are distinguishable from the facts in this matter in several material respects, and because the *McNellis* Court did not decide the issue of whether state law was preempted by the FDA regulations, plaintiff's reliance on it in opposition to Tri-Union's motion to dismiss is misplaced.

POINT IV

PLAINTIFF'S OPPOSITION IS REPLETE WITH IRRELEVANCIES, FACTUAL INACCURACIES AND MISLEADING STATEMENTS, FURTHER UNDERCUTTING PLAINTIFF'S ARGUMENTS PERTAINING TO PREEMPTION.

Plaintiff's opposition attempts to undercut defendant's motion to dismiss by proffering numerous arguments which, if taken at face value, may appear to support plaintiff's opposition to defendants' motion. However, scrupulous examination of plaintiff's arguments reveals that they are factually inaccurate, misleading and irrelevant.

First, plaintiff raises a "red herring" regarding the FDA's purportedly inadequate response to methylmercury in fish. The FDA is not a defendant in this action and the adequacy of its actions with respect to warning about methylmercury in tuna has nothing to do with the

fact that defendant followed the FDA's instructions against placing warnings on tuna cans. Simply put, irrespective of the adequacy of the FDA's actions, the fact remains that defendant is bound to follow the FDA's regulatory approach which rejects the use of warning labels on canned tuna products, and this regulatory approach preempts plaintiff's claims under New Jersey state law. Second, despite the fact that it has nothing to do with whether state law is preempted by the FDA's regulatory approach, plaintiff erroneously and inaccurately cites numerous purported facts about the levels of methylmercury currently found in fish.[6]

Moreover, plaintiff inaccurately relies on an out of date report from the lobby group "Mercury Policy Project," published in 2000, for the proposition that, "the FDA no longer even conducts a mercury monitoring program." *See* Pl.'s Opp. at 8. On the contrary, "since July 2002, the FDA has tested over 3400 cans of tuna as well as 227 fish samples, comprising 12 different species, for mercury." *See* Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish, attached as *Exhibit B* of Def.'s Mot. for Judicial Notice.[7]

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[6] By way of example, plaintiff incorrectly stated in her brief that the Environmental & Occupational Health Sciences Institute recently "conducted a study on canned tuna found in New Jersey stores," which revealed that "15% of the tuna samples contained more than the FDA's 1 p.p.m." *See* Pl.'s Opp. at 7. Upon review of the source of plaintiff's counsel's information, *Mercury in Canned Tuna: White Light and Temporal Variation*, we learned that plaintiff's statement was completely false. In actuality, the study revealed that **all of the cans of tuna** tested from a sampling of New Jersey stores contained mercury levels **less than 1 part per million** – the maximum amount of methylmercury in a can of tuna from the New Jersey stores was .992 p.p.m. *See* Pl.'s Exhibit I.

Plaintiff's brief also contains another misquote from the same study. Specifically, plaintiff stated that "women who ate three or more **tuna** servings per month had a mercury level four times higher than those who did not." Pl.'s Opp. at 7-8 (emphasis added). However, the study actually used the word "**fish**" not "**tuna**." *See* Pl.'s Ex. I, at 239. Indeed, there is a conspicuous difference between the general term "fish" which could entail numerous different species containing varying levels of methylmercury and "tuna" in the context of the quote.

[7] The FDA continues to test fish and shellfish for mercury. *Id.* Also, the FDA makes available the following: (1) "Mercury Levels in Commercial Fish and Shellfish," a table published in May 2001 and updated in February 2006, which illustrates that the FDA (i) tested canned light tune from 2002 to 2004, (ii) categorized canned light tuna as a "Fish with Lower Levels of Mercury," and (iii) reported an average mercury concentration of 0.118 p.p.m.; and (2) "Mercury Concentrations in Fish: FDA Monitoring Program (1990-2004)," a 136 page table which includes 54 pages devoted to tuna and which reflects the mercury concentration of 1350 samples of tuna between 1991 through 2004, and specifically 1090 samples of canned tuna. *See* [Schoen Reply Cert., *Exhibits 4*and *5*]. As *Exhibit*

Lastly, plaintiff's counsel speciously states that defendant's brief "seeks to belittle plaintiff" and "gratuitously characterized [plaintiff] as one seeking the "notoriety" of a "sensationalist suit." *See* Pl.'s Opp. at 6 and 24 n. 13. In no way did defendant make light of plaintiff's purported predicament. Rather, the phrase "undue notoriety of this sensationalistic suit" was used by defendant to highlight the likely detrimental impact that the publicity that will inevitably arise from this lawsuit will have on the general public's opinion about fish and will likely cause a drastic reduction in the public's fish intake, thereby unnecessarily depriving it of the positive and healthy attributes of fish. *See* Def.'s Motion to Dismiss at 28.

CONCLUSION

For the foregoing reasons, and the reasons set forth in defendant's initial brief, plaintiff's complaint should be dismissed for failure to state a claim upon which relief may be granted.

Respectfully submitted,
TRI-UNION SEAFOODS, L.L.C,
d/b/a CHICKEN OF THE SEA
By its attorney,

DATED: April 10, 2006

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5 in its entirety consists of 136 pages, which is available at http://www.cfsan.fda.gov/~frf/seamehg2.html, only the pertinent pages which reflect the tuna samples are attached.