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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
(NEWARK VICINAGE)

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

DEBORAH FELLNER, Individually and on Behalf of Those Similarly Situated,	
Plaintiffs,	
v.	**RETURN DATE: APRIL 10, 2006**
TRI-UNION SEAFOODS, L.L.C., d/b/a CHICKEN OF THE SEA,	
Defendant.	

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

The Plaintiff, Deborah Fellner ("Plaintiff"), filed a Class Action Complaint ("Complaint"), individually and on behalf of those purportedly similarly situated against the sole Defendant, Tri-Union Seafoods, L.L.C., d/b/a Chicken of the Sea ("Defendant"), a manufacturer and distributor of canned tuna, for violation of the New Jersey Products Liability Act, violation of the New Jersey Consumer Fraud Act, and common law fraud. Pursuant to Fed. R. Civ. P. 12(b)(6), the Defendant moves to dismiss the Complaint as it fails to allege facts sufficient to state a cause of action against the Defendant.

INTRODUCTION

Plaintiff's Complaint against Defendant alleges violations of the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1, et seq., (Counts I and II), and the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq., (Count III) and common law fraud (Count IV) for canning and

distributing tuna which purportedly contained methylmercury and failing to disclose to the public that consumption of tuna containing methylmercury could result in mercury poisoning by using a warning label.

In short, the claims set forth in the Complaint are deficient in several respects and should be dismissed, with prejudice, in their entirety, for the following reasons: (1) the United States Food and Drug Administration (hereinafter "FDA") pre-empts state law in the areas of establishing the maximum allowable concentration of methylmercury in fish and of advising/warning consumers about the presence of methylmercury in tuna and its potential effects upon consumption; (2) Defendant is not liable under New Jersey law for injuries incurred by Plaintiff for abnormal consumption of its product (tuna); (3) New Jersey law does not impose a duty upon Defendant to warn potential plaintiffs about a product that only may be dangerous if over-consumed; and (4) Plaintiff's claim for common-law fraud is subsumed by the New Jersey Products Liability Act thereby rendering Count IV moot.

As an initial matter, Plaintiff's Complaint should be dismissed because the United States Food and Drug Administration (hereinafter "FDA") pre-empts state law in the areas of: (1) establishing the maximum allowable concentration of methylmercury in fish; and (2) advising/warning consumers about the presence of methylmercury in tuna and its potential effects upon consumption.

Indeed, the Federal Food, Drug, and Cosmetic Act provides the FDA with broad authority to regulate food labeling. Plaintiff seeks relief under New Jersey state law, alleging violations by the Defendant for: (1) distributing canned tuna which contains methylmercury; and (2) failing to label, or otherwise warn, that canned tuna contains methylmercury and that consumption of methylmercury can allegedly lead to mercury poisoning. However, mandating

warnings or bans or establishing a maximum concentration of methylmercury in tuna, pursuant to New Jersey state law or any other state law, directly conflicts with the FDA's authority and is pre-empted by the FDA's regulatory scheme.

In response to decades of research conducted by the FDA on methylmercury in tuna: (1) the FDA adopted a regulatory approach of issuing advisories on methylmercury and tuna to a select population group – pregnant women, women who might become pregnant, nursing mothers and young children; (2) the FDA rejected an advisory to the general population; (3) the FDA expressly rejected direct warnings on canned tuna; and (4) the FDA has maintained the maximum allowable concentration of mercury in fish at 1 parts per million (ppm) since it first set this limit in 1979 (modified to 1 ppm of methylmercury in 1984). Despite the fact that the FDA has specifically addressed and rejected the idea of placing direct warnings on canned tuna and has permitted tuna companies to sell and distribute tuna which may contain no more than a maximum allowable concentration of methylmercury, Plaintiff seeks relief under New Jersey state law. Here, New Jersey state law directly conflicts with the FDA's direct mandates, and is preempted by the FDA's authority under the Federal Food, Drug and Cosmetic Act. Consequently, Plaintiff's suit should be dismissed.

In addition, to the federal preemption bar to this action, the Complaint should also be dismissed because: (1) a seller is not liable for a consumer's abnormal consumption of a product; and (2) Defendant is not subject to any duty to warn of a product that only may be dangerous if over-consumed. Here, Plaintiff alleges in her Complaint that she "almost exclusively" consumed canned tuna for a five year period (1999-2004). Case law and common sense dictate that there is no duty to warn a consumer of the dangers of over-consumption. By way of comparison, the United States Supreme Court has taken notice that a person could be harmed by ingesting too

much of a traditionally harmless product or substance like table salt, or even water. *Flemming v. Florida Citrus Exchange*, 358 U.S. 153, 163 , 79 S. Ct. 160 (1958). Accordingly, the Defendant owed no duty to warn against the dangers of over-consumption and cannot be liable to Plaintiff for injuries that she incurred by abnormally consuming canned tuna "almost exclusively" for five years and therefore, Plaintiff's individual claims in the Complaint should be dismissed.

Next, Count IV, which alleges common law fraud, should be dismissed because the New Jersey Products Liability Act subsumes a claim for common law fraud, so no separate claim for common law fraud can comply. Lastly, the Complaint's strict liability and breach of warranty claims must be dismissed as the alleged "harmful compound," methylmercury occurs naturally in tuna and does not result from an additive or from an error in the manufacturing process.

In sum, because (1) the FDA's regulatory scheme pre-empts New Jersey state law in the areas of establishing the maximum allowable concentration of methylmercury in fish and in advising/warning consumers about the presence of methylmercury in tuna and its potential effects upon consumption; (2) there is no liability on the part of a seller for injuries incurred by a plaintiff as a result of their abnormal consumption of the seller's product; (3) Defendant has no duty under New Jersey law to warn of a product that only may be dangerous if over-consumed; and (4) Plaintiff's claim for common-law fraud is subsumed by the New Jersey Products Liability Act thereby rendering Count IV moot, this Court should grant Defendant's motion to dismiss Plaintiff's individual claims pursuant to Fed R. Civ. P 12(b)(6).

STATEMENT OF FACTS

I. THE COMPLAINT

On January 16, 2006 (Summons erroneously dated January 19, 2004), Plaintiff filed a Class Action Complaint and individual claims alleging violations of the New Jersey Products

Liability Act, N.J.S.A. 2A:58C-1, et seq., and the New Jersey Consumer Fraud Act, N.J.S.A. 56:8-1, et seq., and common law fraud for canning and distributing tuna which allegedly contained methylmercury and failing to disclose that consumption of tuna containing methylmercury could allegedly result in mercury poisoning. *See* [Schoen Cert., Exhibit "A" (Complaint, ¶ 1)]. Plaintiff states that her diet consisted "almost exclusively" of canned tuna for five years between 1999 and 2004. *Id.* at ¶ 7.

I. BACKGROUND OF METHYLMERCURY IN FISH

The nature of this action necessitates consideration of the universally understood and well-documented facts regarding (1) mercury in the environment, (2) methylmercury in fish, (3) the United States Food and Drug Administration's ("FDA") approach to the issue of methylmercury in fish, and (4) the indeterminable number of variables relevant to evaluating whether any given person will experience, or has experienced, adverse health effects due to ingesting methylmercury through consumption of fish products, as well as (5) the extent to which such symptoms are due to factors other than ingestion of fish or methylmercury. [1]

It is well-known that mercury is present in nearly all fish.[2] Mercury is a naturally occurring element in the environment and is also released into the air through industrial pollution. Mercury that falls from the air often accumulates in streams and oceans. Bacteria in the water causes chemical changes that transform mercury into methylmercury. Fish absorb the

[1] *See* Defendant's Motion Requesting Judicial Notice in Support of Its Motion to Dismiss Plaintiff's Complaint and Motion to Dismiss Plaintiff's Class Action Allegations ("Motion for Judicial Notice"). *See also See Hollis-Arrington v. PHH Mortgage Corp.*, No. 05-2556FLW, 2005 WL 3077853, * (D. N.J. Nov. 15, 2005), *Benak v. Alliance Capital Mgmt. L.P.*, 349 F. Supp. 2d 882, 889 n. 8 (D. N.J. 2004), and *Sonntag v. Papparozzi*, 256 F. Supp. 2d 320, 324 (D. N.J. 2003) (finding it appropriate to take judicial notice of publicly available documents in deciding upon a motion to dismiss and/or documents or facts integral to resolving a motion to dismiss).

[2] *See* "What You Need to Know About Mercury in Fish and Shellfish," published by the United States Department of Health and Human Services and the United States Environmental Protection Agency ("What You Need to Know"), attached to Motion for Judicial Notice as Exhibit "A."

methylmercury as they feed in these waters. Mercury becomes part of the fish meat and cannot be removed. The levels of methylmercury build up in some types of fish and shellfish more than others, depending on what the fish eat. As a result, the levels vary among different fish and even within the same fish.[3]

Whether any given individual will experience adverse health effects as a result of ingestion of methylmercury is dependent on an indeterminable number of factors. Further, mercury poisoning is a diagnosis of exclusion, in that diagnosis is only made after ruling out numerous other potential causes of symptoms which are sometimes associated with mercury poisoning, sometimes associated with alternative causes, and oftentimes are of unknown etiology.

The United States Food and Drug Administration ("FDA"), has established tolerance levels for methylmercury in fish through nutritional guidelines.[4] Further, pursuant to the Federal Food, Drug and Cosmetic Act, the FDA is provided broad authority to control the nature and extent of warnings with respect to methylmercury in fish. The FDA has noted that "[r]esearch shows that most people's fish consumption does not cause a health concern." *See* Backgrounder, at 2. Further, the FDA has recommended "that consumers eat a balanced diet, choosing a variety of foods including fruits and vegetables, foods that are low in *trans* fat and saturated fat, as well as foods rich in high fiber grains and nutrients." *Id.* The FDA has also noted that "[f]ish and

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[3] *See* "Backgrounder for the 2004 FDA/EPA Consumer Advisory: What You Need to Know About Mercury in Fish and Shellfish," published by the United States Department of Health and Human Services and the United States Environmental Protection Agency, at 2 (hereinafter "Backgrounder"), and attached to Motion for Judicial Notice as Exhibit "B."

[4] *See* What You Need to Know; *see also* Section 540.600 of the Federal Food and Drug Administration's Compliance Policy Guide, allowing up to one part of methylmercury per million non-mercury parts of the edible portion of seafood, Agency (hereinafter "Section 540.600"), attached to Motion for Judicial Notice as Exhibit "D."

shellfish can be an important part of this diet." *See id.* at 2-3. With this backdrop in mind, the FDA has instructed against providing warnings regarding methylmercury in fish.

LEGAL ARGUMENT

I. LEGAL STANDARDS FOR GRANTING A MOTION TO DISMISS

Federal Rule of Civil Procedure 12(b)(6) provides that a court may dismiss a complaint "for failure to state a claim upon which relief can be granted." In deciding a motion to dismiss under Rule 12(b)(6), all allegations in the complaint must be taken as true and viewed in the light most favorable to the plaintiff. *Warth v. Seldin,* 422 U.S. 490, 501 (1975); *Trump Hotels & Casino Resorts, Inc., v. Mirage Resorts Inc.,* 140 F.3d 478, 483 (3d Cir. 1998). However, legal conclusions offered in the guise of factual allegations are given no presumption of truthfulness. *Chugh v. Western Inventory Services, Inc.,* 333 F. Supp. 2d 285, 289 (D. N.J. 2004) (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). While a court will accept well-pled allegations as true for the purposes of the motion, it will not accept bald assertions, unsupported conclusions, unwarranted inferences, or sweeping legal conclusions cast in the form of factual allegations. *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997).

II. PLAINTIFF'S COMPLAINT DOES NOT STATE A VALID CAUSE OF ACTION THAT DEFENDANT VIOLATED EITHER THE NEW JERSEY PRODUCTS LIABILITY ACT OR NEW JERSEY CONSUMER FRAUD ACT OR COMMITTED COMMON LAW FRAUD BY FAILING TO WARN CONSUMERS OF THE DANGERS OF METHYLMERCURY AND BY DISTRIBUTING A PURPORTEDLY UNSAFE PRODUCT, AS THESE NEW JERSEY STATE LAWS ARE PRE-EMPTED BY FEDERAL REGULATIONS PROMULGATED BY THE FDA.

A. The FDA's Authority Pursuant to the Federal Food, Drug, and Cosmetic Act Pre-empts New Jersey State Law.

Plaintiff's allegations against Defendant for violations of the New Jersey Product Liability Act and the New Jersey Consumer Fraud Act should be dismissed because they are pre-

empted by FDA Regulations and Advisories which specifically address and regulate the questions of whether Defendant was allowed to distribute canned tuna containing legally permitted levels of methylmercury and whether Defendant was required to warn consumers of the dangers of methylmercury, the exact issues that Plaintiff allege violates New Jersey State law.

The basis for federal preemption of state law rests within the Supremacy Clause of the Constitution. *Dewey v. R.J. Reynolds Tobacco Co.,* 121 N.J. 69, 77 (1990). The clause provides that federal law is the "supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." *U.S. Const.,* art. VI, cl. 2. State law may be preempted by valid federal statutes or regulations, and this preemption applies equally to state common law and statutory law. *Feldman v. Lederle Lab.,* 125 N.J. 117, 134 (1991), *cert. denied,* 505 U.S. 1219 (1992).

Whether a federal statute preempts state law turns on the intent of Congress when it passed the law, and that intention may be either express or implied. *Cipollone v. Liggett Group, Inc.,* 505 U.S. 504, 516 (1992). Federal law will override state law under the Supremacy Clause when (1) Congress expressly preempts state law; (2) Congressional intent to preempt may be inferred from the existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes. *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990).

"If a state common-law claim directly conflicted with a federal regulation ..., or if it were impossible to comply with any such regulation without incurring liability under state common law, [conflict] pre-emption would occur." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 65 (2002). Conflict preemption occurs either "where it is impossible for a private party to comply with both state and federal law" or where "under the circumstances of [a] particular case,

[the challenged state law] stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000) (citing *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963), and *Hines v. Davidowitz*, 312 U.S. 52, 66-67 (1941)).

In American products-liability cases, courts have recognized that, if the FDA, after review, prohibits a manufacturer from warning about a possible risk, the manufacturer cannot be found liable for failing to give that warning. *See Carlin v. Superior Court*, 920 P.2d 1347 (Cal. 1996); *Feldman*, 125 N.J. 117 (1991).

In *Housley v. Wave Energy Systems*, 343 N.J. Super. 574, 576 (App. Div. 2001), the Superior Court of New Jersey Appellate Division affirmed the Superior Court's order dismissing plaintiffs' product liability action by a group of nurses who brought suit against the manufacturers and suppliers of a product used to sterilize medical instruments holding that plaintiffs' claims were preempted under federal law. The sterilizing product was regulated by the Federal Insecticide, Fungicide & Rodenticide Act, which provided pursuant to 7 U.S.C.A. § 136(v)(b), that, "a state may not impose or effect any requirement for labeling or packaging in addition to or different from those required under this section."

Likewise, in *Canty v. Ever-Last Supply Co.*, 296 N.J. Super. 68, 73 (Law. Div. 1996), the plaintiffs filed a wrongful death and personal injury action alleging failure to warn as a violation of the New Jersey Products Liability Act after a lacquer floor sealant applied to a hardwood floor burst into flames The court dismissed plaintiffs' action and held that the plaintiffs' defective warning claims were preempted by the Federal Hazardous Substances Act ("FHSA"), stating that "plaintiffs' tort claim under the Product Liability Act is preempted

because it seeks warnings and instructions that are more elaborate or more extensive than those required under the FHSA." *Id.* at 83.

In this case, similar to the *Housely* and *Canty* cases, the FDA, has specifically and unequivocally stated that warnings regarding methylmercury in fish required by individual states are preempted under federal law, and Plaintiff improperly seeks to impose more extensive and elaborate warnings on the Defendant pursuant to New Jersey state law in an area that FDA has pervasively and comprehensively regulated.[5]

This case posits a direct conflict between the requirements of the Federal Food, Drug, and Cosmetic Act and New Jersey state law. Plaintiff seeks to impose liability on the Defendant, pursuant to the New Jersey Products Liability Act, the New Jersey Consumer Fraud Act and for common law fraud, for failure to warn about the presence of methylmercury and its potential effects and for distribution of unsafe canned tuna containing methylmercury. However, the FDA has already extensively regulated this area by establishing the maximum concentration of methylmercury for a can of tuna to be considered fit for consumption, and by expressly rejecting the notion of and/or need for warning the general population of the presence of methylmercury in tuna. *See* FDA Commissioner's Federal Preemption Letter, dated August 12, 2005.

Because the FDA's advisory specifically and unequivocally regulates the levels of methylmercury allowed in canned tuna and prohibited warning labels, by virtue of its authority under the Federal Food, Drug, and Cosmetic Act, it preempts any New Jersey state law purporting to regulate these areas.

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[5] *See* Letter from Lester M. Crawford, D.V.M., Ph.D., United States Commissioner of Food and Drugs, to Bill Lockyer, Attorney General of the State of California, dated August 12, 2005, re: a suit filed on June 21, 2004 in San Francisco Superior Court (hereinafter "FDA Commissioner's Federal Preemption Letter, dated August 12, 2005"), and attached to Motion for Judicial Notice as Exhibit "C."

B. The FDA's Regulatory Approach Has "No Less Preemptive Effect than Federal Statutes."

Federal regulations "have no less pre-emptive effect than federal statutes." *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982). The imposition of damages under state law is a form of state action subject to preemption. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 881 (2000).

A recent New Jersey wrongful death suit, *McNellis v. Pfizer, Inc.*, No. 05-1286-JBS 2005 WL 3752269, 1-3 (D.N.J., Dec. 29, 2005), involving allegations against the drug manufacturer, Pfizer, Inc., for defective design under the New Jersey Products Liability Act, failure to warn, and violations of the New Jersey Consumer Fraud Act arising out of Pfizer, Inc.'s sale of Zoloft, where Zoloft included a warning label authorized by the FDA, relied on the holdings in *Fidelity Fed. Sav.,* Geier and additional United States Supreme Court cases cited in the paragraph below.

In *Geier v. American Honda Motor Co.,* 529 U.S, at 883, the United States Supreme Court looked to the Department of Transportation's interpretation of the regulation at issue's objectives and the Department's conclusion that tort suits, like the suit against American Honda Motor Co., would stand as an obstacle to the accomplishment and execution of those objectives. The Court reasoned that "the agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements." *Id.* (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 496 (1996)). *See also Sprietsma v. Mercury Marine*, 537 U.S. at 67-68 (affording deference to the agency's position on preemption). Deference to an agency's interpretation of its own powers is appropriate when the regulatory scheme is silent as to preemption. *Barnhard v. Thomas*, 540 U.S. 20, 26 (2003). "When a statute speaks clearly to the issue at hand, courts 'must give effect to the unambiguously expressed intent of Congress,' but when the statute 'is silent or ambiguous,'

courts must defer to a reasonable construction by the agency charged with its implementation." *Id.* (quoting *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843 (1984)).

Accordingly, the FDA's regulatory approach, arising out of their broad power under the Federal Food, Drug and Cosmetic Act has "no less pre-emptive effect than federal statutes." In addition, pursuant to *Geier, Medtronic, Sprietsma, Barnhard,* and *Chevron*, the court must give deference to the FDA's interpretation of its own powers on the issue of preemption of state law. Here, in his August 12, 2005 letter to the California Attorney General, the FDA Commissioner unambiguously stated in response to proposed bans and warnings concerning methylmercury in tuna, issued by the California Attorney General, pursuant to California's Safe Drinking Water and Toxic Enforcement Act of 1986 ("Proposition 65"), that the

> **FDA believes that such warnings are preempted under federal law. They frustrate the carefully considered federal approach to advising consumers of both the benefits and possible risks of eating fish and shellfish; accordingly federal law preempts Proposition 65 warnings concerning mercury and mercury compounds in tuna. Furthermore, FDA believes that compliance with both the Federal Food, Drug and Cosmetic Act and Proposition 65 is impossible and, as a result, the latter is preempted under federal law.**

The FDA has a thorough understanding of its own regulations, the purpose of its regulations, its powers and the likely impact of individual states' attempted implementation of disparate warnings, advisories and/or bans on tuna on the FDA's carefully crafted regulatory approach which seeks to balance the potential risks of consumption by a target population and the benefits of consumption to the population at large. By virtue of the FDA's unambiguous proclamation states that it preempts state law regarding the regulation of mercury levels in tuna, the Plaintiff's Complaint should be dismissed because her claim that the New Jersey Product Liability Act requires warnings about the existence of methylmercury in tuna is preempted.