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DEBORAH FELLNER, Plaintiff, vs. TRI-UNION SEAFOODS, L.L.C., dba CHICKEN OF THE SEA, Defendant.	:	**UNITED STATES DISTRICT COURT** **DISTRICT OF NEW JERSEY** Civil Action 2:06-cv-00688-DMC-MF CERTIFICATION OF BARRY R. EICHEN, ESQ., IN SUPPORT OF PLAINTIFF'S OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

I, **BARRY R. EICHEN**, of full age, certify and say:

1. I am a member in good standing of the bars of the State of New Jersey and the United States District Court for the District of New Jersey. I am a partner of the law firm of Eichen Levinson & Crutchlow, LLP, 40 Ethel Road, Edison, New Jersey, 08817, counsel for Plaintiff in this matter.

2. I make this affidavit in support of the Plaintiff's Opposition to the Defendant's Motion to Dismiss under Fed. R. Civ. P. 12(b)(6).

3. True and correct copies of the Exhibits described in Plaintiff's Brief ("Exhibits A and B"), are attached hereto

I certify under penalty of perjury that the foregoing is true and correct.

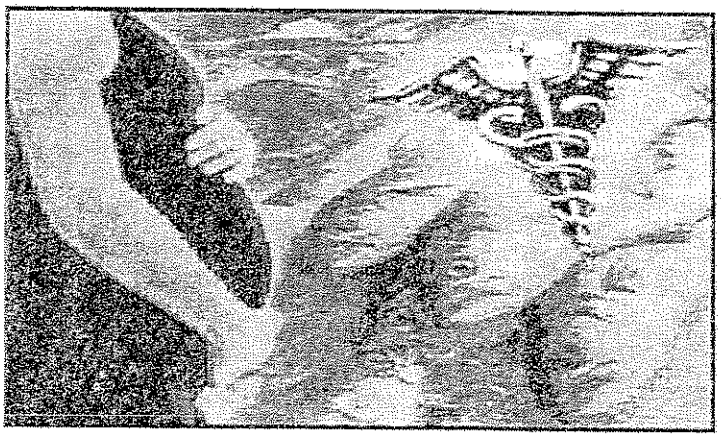
Respectfully Submitted,
EICHEN LEVINSON & CRUTCHLOW, LLP
Attorneys for the Plaintiff

Dated: September 21, 2009

By: _____
Barry R. Eichen

Exhibit A

Can The Tuna:



FDA's Failure to Protect Children From Exposure to Mercury in Albacore "White" Canned Tuna

Mercury Policy Project
A Project of the Tides Center

new england zero Mercury Campaign

June 19, 2003

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Research, review or comment on this report does not imply endorsement.

The New England Zero Mercury Campaign is: Clean Water Action and Clean Water Fund, Environmental Health Strategy Center, Heath Care Without Harm, Mercury Policy Project, National Wildlife Federation, Natural Resources Council of Maine, Sierra Club RI Chapter, Toxics Action Center.

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NOTE: This educational report does not constitute legal, health or technical advice. Institutions and individuals facing questions or concerns should, of course, consult legal, health and technical experts to determine appropriate measures.

Executive Summary

Americans consume more than one billion pounds of canned tuna every year, yet most people are unaware of the neurotoxic risks from exposure to methylmercury contained in canned tuna. For the two most sensitive populations—pregnant women and young children—canned tuna is consumed at alarming rates; it is the most frequently consumed fish among women of childbearing age, while children eat more than twice as much tuna as any other fish. But for more than a decade the U.S. Food & Drug Administration (FDA) has ignored substantial evidence that its mercury content and frequent consumption make canned tuna—and especially "white" albacore tuna—a public health risk to sensitive populations.

Recent independent sampling of canned tuna taken from supermarket shelves in the U.S., and commissioned by the Mercury Policy Project for mercury testing, found that over six-percent of white albacore tuna samples contain mercury at or above the FDA's Action Level of 1 part-per-million (ppm). Tests results also found that amounts of mercury in "white" albacore canned tuna had average levels over four-times higher than "light" tuna.

Based on our analysis, pregnant women who routinely consume albacore tuna with mercury levels above 0.5 ppm mercury—the average amount of mercury in our tests—are exposed to levels that greatly exceed the U.S. Environmental Protection Agency's (EPA's) reference dose (RfD). A second round of canned tuna mercury sampling (soon to be released) by the Environmental and Occupational Health Sciences Institute in Piscataway, New Jersey found similar results. These test results reinforce what the FDA has known for at least a decade, and what its own Food Safety Committee stated nearly a year ago: due to its mercury levels and frequent consumption, canned tuna poses a risk to the developing fetus through maternal consumption of fish, and infants and young children are at a higher risk as a result of greater intake per body weight and susceptibility to methylmercury toxicity.

Methylmercury—the organic form mercury assumes in fish—crosses the placental barrier during pregnancy and is linked to neurological damage in babies. The latest U.S. Centers for Disease Control and Prevention (CDC) data indicates that eight percent of women of childbearing age are at risk of giving birth to babies with learning disabilities and other developmental defects caused by in utero mercury exposure, translating to approximately 300,000 babies born at risk of mercury poisoning in the U.S. each year.

FDA officials acknowledge that none of the existing population studies of methylmercury have clearly shown the level at which the developing fetus can tolerate exposure. Yet, the Agency has for years failed to act responsibly to address this public health crisis even though they readily admit that 30-50 percent of all women across the U.S. remain largely unaware of exposure risks from methylmercury. Under apparent pressure from the U.S. tuna industry, FDA has stopped testing mercury levels in canned tuna, relies on canned tuna mercury data from over a decade ago and 20 year old industry consumption estimates and risk assessments, and has ignored the latest findings on methylmercury from the National Academy of Sciences (NAS).

The current FDA mercury standard uses as its endpoint overt neurological symptoms in adults, and does not take into account sensitive subpopulations, notably the developing fetus and young

children. Nor does it account for the enormous quantities of canned tuna fish that Americans consume. As one EPA scientist noted publicly last fall at a United Nations conference on global mercury, "[t]he reason for breaking out canned tuna separately [from other fish] is because people eat so much more of it than other kinds of fish, so that the actual exposure of canned tuna is probably the largest, on average, exposure of people to mercury." FDA's allowable daily intake, the amount of methylmercury that can be consumed daily over the lifespan without producing appreciable harm, is weaker by a factor of 4 (0.1 ug/kd/day for EPA, and 0.4 ug/kg/day for FDA) compared to guidance recommended by the EPA and supported by NAS and the European Union.

In July 2002, the FDA's Food Safety Committee recommended a series of sweeping policy changes which included harmonizing the FDA's action level with EPA's more stringent RfD, warning specific sensitive populations to limit consumption of canned tuna, conducting mercury testing for canned tuna and other fish, and determining what the exposure risks are for sensitive populations—particularly for young children. According to Dr. Michael Shannon with Children's Hospital in Boston and one of the Food Safety Committee members, "[t]he burning question is whether it is safe for kids to be eating tuna fish sandwiches for lunch every day." Inexplicably, in the year since the Committee made its recommendations, the FDA has not officially responded to this question or implemented any of the Committee's eight recommendations.

In fact, the U.S. government continues to promote unsafe methylmercury exposure through its Women, Infants and Children's (WIC) program, a program that serves more than 7 million low-income people who get WIC benefits each month. Because poultry and meat are not included on the list of potential items that may be purchased using WIC benefits, canned tuna is one of the primary animal protein sources purchased through the WIC program.

There are also concerns that FDA is not taking precautions to protect public health, but is instead protecting the $1 billion per year US tuna industry. Canned tuna is consumed in 90 percent of U.S. households, and accounts for 25-35 percent of all fish consumption in the country. The tuna industry has publicly stated that it believes any mention of canned tuna in the FDA fish consumer advisory for sensitive populations would result in a 24 percent decline in sales. In recent years, concerns about FDA's science on mercury and the relationship between the Agency and industry have drawn the attention of Capitol Hill, resulting in several studies and recent congressional inquiries over the past decade or so. Yet based on FDA's track record of not adequately responding to earlier concerns raised by NAS in their mercury reports of 1991 and 2000, and General Accounting Office reports from 1991 and 2001, it appears unlikely that these latest congressional inquiries will be sufficiently addressed.

In the face of FDA inaction, states and others are attempting to fill the void by embracing approaches that are more restrictive than the FDA's action level. Eleven states have issued advisories warning women and children to limit canned tuna consumption, and several states warn that the "white" canned tuna contains higher mercury levels than "light" tuna. Also, new warning signs are being posted at national grocery store chains in California for sensitive populations cautioning limits on consumption of fresh or frozen tuna and stating that "Chunk or chunk light tuna has less mercury than solid white or chunk white tuna." Nationally, some grocery chains are also beginning to post similar messages.

Recommendations

I. Women who are pregnant or considering pregnancy and nursing mothers should avoid consumption of "white" albacore canned tuna to protect developing fetuses and babies from methylmercury exposure. As a precautionary measure, parents should steer infants and young children away from consuming "white" albacore tuna as well.

II. To ensure sensitive subpopulations are protected in the long term, the Food & Drug Administration should adopt the following recommendations:

1. Adopt EPA's more protective reference dose for human exposure to methylmercury.
2. Set a regulatory limit that would take seafood with high mercury levels off the market.
3. Resume its methylmercury monitoring program for canned tuna and predatory seafood.
4. Issue more targeted seafood consumption advice in an effective manner.
5. Mandate mercury fish warnings in markets and restaurants.
6. Prohibit the WIC program from promoting consumption of "white" albacore tuna.
7. Specifically warn women and children to limit consumption of canned tuna.

III. The World Health Organization should adopt the more protective EPA's reference dose for human exposure to methylmercury.

IV. All anthropogenic mercury uses and releases should be reduced or eliminated, exports curtailed, and surplus quantities of mercury placed indefinitely in secure, long-term, monitored above ground storage to reduce mercury levels in the environment and in fish over time.

Introduction

For more than a decade the U.S. Food & Drug Administration (FDA) has ignored evidence collected by its own scientists that albacore, or "white" canned tuna, has mercury concentrations two to three times higher than "light" canned tuna,[1] and failed to warn the public properly about the higher mercury levels in "white" tuna. Recent independent tests commissioned by the Mercury Policy Project show that on average "white" canned tuna has mercury levels over four times higher than "light" tuna. Yet the FDA itself acknowledges that 30-50 percent of women remain unaware of the risks associated with consumption of canned tuna and other fish.[2]

Mercury is a potent neurotoxicant that is most dangerous for developing fetuses, infants, and young children. Methylmercury—the organic form mercury assumes after entering the environment—crosses the placental barrier during pregnancy and is linked to neurological damage in infants. For pregnant women, consuming albacore tuna on a regular basis could result in methylmercury intakes above the EPA's reference dose and pose risks of developmental deficits to young children.[3]

Canned tuna accounts for 25-35 percent of all seafood consumption in the U.S.,[4] and is a staple in 9 out of every 10 households in the country.[5] Americans consume one billion pounds of canned tuna every year,[6] with albacore "white" tuna comprising 29% of the market share.[7] Children eat more than twice as much tuna as any other fish, and canned tuna is the most frequently consumed fish among women of childbearing age.[8] In addition, the Federal Government promotes methylmercury exposure by subsidizing the purchase of canned tuna through its Women, Infants and Children's (WIC) program—a program that serves more than 7 million low-income people who get WIC benefits each month.[9]

In the case of mercury, seafood species matters. Virtually all fish contain some level of mercury in their tissue, but the concentration of mercury varies significantly in proportion to the type and size of a fish. Mercury bioaccumulates after entering the environment, meaning that its concentration increases as it ascends the food chain. Large fish accumulate mercury from the small fish that they eat, and end up with higher mercury levels than the smaller fish. Larger fish also tend to be older, so their mercury levels reflect more prolonged exposure to mercury. Albacore tuna is a bigger fish than the skipjack that comprises the more popular "light" tuna. An average albacore is between 20-45 pounds, although some larger fish can weigh as much as 85 pounds.[10] By comparison, the "light" tuna such as the skipjack averages between 6 and 12 pounds.[11]

2003 Independent Canned Tuna Sample Results for Mercury

A recent sampling of canned tuna, commissioned by the Mercury Policy Project, indicates that 3 of the 48 samples, or over six-percent of white-albacore tuna contained mercury at or above the FDA's "action level" of 1 part per million (ppm). The results showed that "white" canned tuna has mercury levels over four times higher than "light" tuna. Random samples primarily of the three major brands of canned tuna—Starkist, Bumblebee, and Chicken of the Sea—were purchased from Safeway, Whole Foods, Trader Joe's, Shaw's, and other grocery stores and sent for testing in late March 2003 to the Landmark Laboratory in Benton Harbor, Michigan.

Canned Tuna Mercury Test Results[12]

White (Albacore) Tuna

Sample Number	Mercury Levels (ppm)
1	0.54
2	0.47
3	0.34
4	0.39
5	0.29
6	0.32
7	0.34
8	0.31
9	0.23
10	0.55
11	0.56
12	0.62
13	0.51
14	0.40
15	0.30
16	1.10
17	0.46
18	1.00
19	0.97
20	0.39
21	0.32
22	0.48
23	0.56
24	0.48

Continued	
25	0.45
26	0.73
27	0.48
28	0.41
29	0.85
30	0.43
31	0.47
32	0.36
33	0.48
34	0.52
35	0.26
36	0.39
37	1.00
38	0.57
51	0.56
52	0.42
53	0.59
54	0.65
55	0.44
56	0.47
57	0.47
58	0.34
59	0.41
60	0.63

Average amount of mercury in white (albacore) tuna: 0.506 ppm

Light Tuna

Sample Number	Mercury Level (ppm)
39	0.058
40	0.065
41	0.13
42	0.11
43	0.15
44	0.067

Continued	
45	0.17
46	0.047
47	0.12
48	0.18
49	0.18
50	0.14

Average amount of mercury in light tuna: 0.118 ppm

After these initial test results were completed, ten replicate samples from the first batch were then tested in early April 2003 at the National Food Laboratory in Dublin, California—the same lab used by the U.S. tuna industry. These results confirmed the initial tests with a variation between the two tests of less than 10 percent.[13]

Canned Tuna Mercury Test Results-Replicates[14]

White (Albacore) Tuna

Sample number	Mercury Levels (ppm)
11	0.50
12	0.52
13	0.43
14	0.37
15	0.28
16	1.02
17	0.39
18	0.97
19	0.85
20	0.35

Average amount of mercury in replicate samples: 0.568 ppm

These test results confirm what the FDA has known for more than a decade: regardless of the brand, "white" albacore tuna has substantially higher levels of mercury than "light" tuna. A 1992 FDA study of canned tuna found average mercury levels in albacore to be twice as high as concentrations in "light" canned tuna, with mercury levels in the "light" tuna averaging 0.11 ppm, the "chunk white" tuna measuring 0.31 ppm and the "solid white" to be 0.26 ppm.[15]

According to the FDA[16] and repeatedly echoed by the US Tuna Foundation, the combined average mercury concentration of "light" and "white" canned tuna weighted by the market abundance of each kind is equal to a mercury concentration of 0.17 ppm. While these data are from over a decade ago,[17] the tuna industry and FDA use this average to justify consumption and calculate safety advisories, not publicly acknowledging in their consumer information that the "white" has at least twice the amount of mercury as the "light" canned tuna. The average mercury levels cited by FDA and the tuna industry may be accurate for the "light" varieties, but, according to our more recent testing, may not accurately reflect mercury levels in "white" albacore varieties currently sold in supermarket shelves across the U.S.

Furthermore, the FDA's approach of averaging the mercury concentration in all types of tuna together to obtain a weighted average concentration, and using this value to estimate mercury exposure from tuna consumption is misleading because it assumes that consumers "sample" and consume canned tuna at random from the market shelves. This approach ignores the fact that many, perhaps most, individuals will tend to consistently buy only one type of tuna. Thus, those who consistently buy "white" canned tuna will have a mercury exposure much greater than that suggested by FDA's averaging approach.

Our test results show that "white" canned tuna has mercury levels over four times higher than "light" tuna (0.118 ppm). The average mercury content in 48 "white" canned tuna samples was 0.51 ppm, with the upper 10th percentile having mercury levels at 0.91 ppm. Also, an additional sampling of a larger data set of canned tuna by the Environmental and Occupational Health Sciences Institute in Piscataway, New Jersey confirmed similar results in which "white" canned tuna had significantly higher levels of mercury than "light" tuna.[18]

Based upon our analysis, eating just one 6 oz can (170 grams) of "white" tuna with a mercury concentration of 0.5 ppm could give a women of child bearing age a dose of about 1.4 ug/kg/week, or twice EPA's reference dose (RfD), and at 4 ounces, she would have already exceeded the EPA's RfD by 35%. If a woman of childbearing age with a typical weight of 132 lbs (60 kg) eats 12 ounces of canned tuna per week—the limit advised by FDA—she will be exposed to 0.4 ug/kg/day of mercury, or 4 times the EPA's reference dose of 0.1 ug/kg/day. A 44 pound child eating 6 ounces of canned tuna per week with a mercury concentration of 0.5 ppm would be exposed to 4.3 ug/kg/week, or over six times EPA's RfD. A 22 pound toddler would have an intake over four times the EPA limit by eating only 2 ounces per week and a young child (at 88 pounds) would exceed the EPA's RfD three-fold by consuming weekly only one 6 ounce can of tuna with a 0.5 ppm mercury concentration.

How Is the Public Warned About Canned Tuna?

The FDA has primary authority for regulating commercial seafood in the marketplace, while EPA provides guidelines for recreational fish. FDA's allowable daily intake, the amount of methylmercury that can be consumed daily over the lifespan without producing appreciable harm, is weaker by a factor of four (0.1 ug/kd/day for EPA, and 0.4 ug/kg/day for FDA) compared to guidance recommended by the EPA and supported by National Academy of Sciences[19] (NAS) and the European Union.[20]

In 2001, EPA issued a national consumer advisory on recreationally caught freshwater fish. EPA's advisory warns women who are pregnant or may become pregnant, and nursing mothers to limit their fish consumption to just 6 to 8 ounces per week—as opposed to the FDA's recommendation of 12 ounces per week for a variety of fish (except shark, swordfish, king mackerel, and tilefish, which FDA advised sensitive populations not to consume at all). EPA also advises young children to limit consumption of fish to 2 to 3 ounces per week. Meanwhile, FDA's advisory states, "[t]here is no harm in eating more than 12 ounces of fish in one week as long as you don't do it on a regular basis."[21] FDA's justification for allowing greater consumption is that seafood has lower mercury levels, on average, than freshwater fish.[22] However, as evidenced by our testing of mercury in "white" canned tuna, it appears that this may not be the case.

Despite recent scientific advances in understanding of how even low concentrations of methylmercury exposure poses a risk to the developing fetus, the FDA has not conducted any thorough and comprehensive testing of mercury levels in canned tuna since 1992,[23] and stopped its seafood methylmercury monitoring program in 1998.[24] Regarding seafood testing for methylmercury, FDA scientist Dr. Michael Bolger has stated publicly that "[i]t would be a waste of valuable resources" to continue monitoring fish for mercury.[25] Moreover, in the past three years the FDA has failed to implement the findings of the NAS after the Academy endorsed EPA's more stringent reference dose for

methylmercury. In addition, the FDA has ignored its own findings from focus group studies, and even ignored recommendations requested last year from its own Food Safety Committee—a panel of experts assembled by the FDA to review the Agency's advisory for methylmercury in seafood.[26]

A History of FDA Inaction on Methylmercury in Fish

In July 2002, FDA's Food Safety Committee recommended that FDA provide justification for continuing to use its action level rather than employing EPA's more stringent reference dose.[27] An action level identifies the level of contamination above which FDA may bring informal enforcement action and remove fish from the market. It is not the same as a regulatory limit that is legally binding on the agency, the industry, and establishments where fish are sold. Each time FDA brings a case to remove seafood from the market on the basis of an action level, it has to prove that the seafood poses a threat to public health. Yet this happens only infrequently and seafood exceeding the FDA's action level is sold everyday in markets and restaurants across the U.S.

FDA's action level is currently 1 ppm for methylmercury, but when it was first developed it was 0.5 ppm—twice as stringent as it is now. The current U.S. action level was first issued as an administrative guideline for fish in 1969 in response to a mass mercury poisoning incident in Minamata, Japan. At the time, the Agency set the permissible level of mercury at 0.5 ppm and found many canned tuna samples exceeded that level. According to an October 1972 National Geographic article, when FDA scientists found levels of mercury in canned tuna above 0.5 ppm, the Agency "ordered the withdrawal of 12.5 million cans of tuna..."[28]

In 1974, FDA converted "the permissible level" standard of 0.5 ppm to an action level, recognizing that chronic exposure to fish and shellfish containing methylmercury posed a greater danger to women of childbearing age than to the general population. But in later actions FDA ignored the critical public health consideration that there are sensitive sub-populations within the general population. In 1979, following litigation by the fishing industry challenging its mercury action level, FDA weakened the standard to its current action level of 1 ppm (from its original action level of 0.5 ppm), effectively ignoring the 1974 finding that methylmercury might harm fetuses, and eliminating additional protection for pregnant women and children. This decision followed the National Marine Fisheries Service's conclusion that "[t]he higher level would provide a significant economic benefit to those industries most seriously affected by regulatory actions under the 0.5 ppm guideline."[29]

It is not surprising then that when the NAS issued its seafood safety reports in 1991, it roundly criticized the methodology used by FDA for establishing its methylmercury action level, and warned that it did not adequately protect pregnant women and their children. The NAS criticized FDA for basing its standard on the lowest blood level of mercury reported to produce adverse health effects—the LOAEL—rather than its typical approach of using the no observable adverse effect level—NOAEL. Additionally, the NAS pointed out that FDA's standard failed to account for two critical variables: well-documented differences among individual rates of mercury elimination, and the fetal response to mercury exposure. The NAS concluded, "[a]lthough the 10-fold safety factor as applied appears to offer a reasonable degree of protection for adult effects, projections of the fetal dose-response data suggest the possibility of appreciable risk from methylmercury exposure even at levels to which many people are exposed via their diet."[30] Yet FDA never responded to the 1991 NAS study, nor has it responded to a second NAS study in

2000 that endorsed EPA's more stringent mercury standard as "scientifically justifiable for the protection of public health."[31] Now more than 20 years old, FDA's current action level is based on outdated data that sets the standard at least four times too high.[32]

In addition to the other recommendations discussed earlier, FDA's Food Safety Committee also urged that FDA make several sweeping changes to its methylmercury policies and programs. These included advising FDA to warn specific sensitive populations to limit consumption of canned tuna, conduct mercury testing for canned tuna and other fish, and determine what the exposure risks are for sensitive populations, particularly for young children.[33] Inexplicably, in the year since the Committee made its recommendations, FDA has not publicly implemented any of these measures.

State Health Agencies Fill the Federal Void Created by FDA

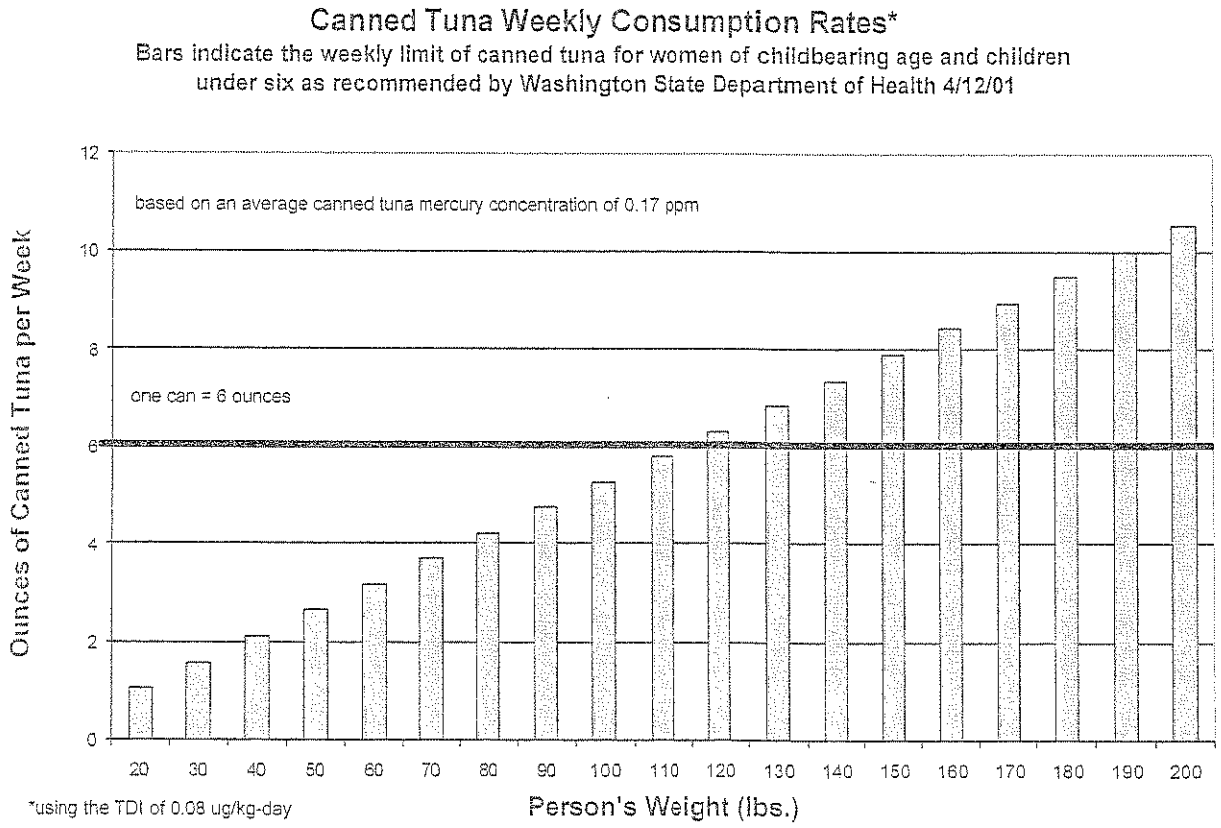
State health agencies have started filling the void left by FDA by issuing advisories for canned tuna that are much more restrictive than FDA's action level.[34] Eleven states now voluntarily warn pregnant women and children to limit canned tuna consumption. These states are Michigan, Minnesota, New Jersey, Vermont, Connecticut, Maine, Massachusetts, New Hampshire, Washington, Wisconsin, and most recently California.[35] Some states also advise sensitive populations to eat less white canned tuna than the light, based on a 1992 FDA study which found mercury levels higher in the "white" tuna.[36]

State Canned Tuna Mercury Advisories

State	Date	Advisory-Provided no other fish consumed at same time
Michigan	1997	Pregnant women limit to 7 oz. of tuna/week
Minnesota	1997	Pregnant women limit to 7 oz. of tuna/ week
New Jersey	1997	Pregnant women limit to 8 oz. of tuna/week
Vermont	1999	Pregnant women limit to 7 oz. of tuna/week
Maine	2000	Women of child-bearing age and children under 8, limit to 1 can of "white" or 2 cans of "light" tuna/week
Massachusetts	2001	No more than 12 oz. of tuna/week. Very small children, including toddlers, should eat less
New Hampshire	2001	Pregnant women, women who may get pregnant & nursing women limit to 1 can of "white" or 2 cans of "light"/week; children limit to ½ can "white" or 1 can "light"/week
Washington	2001	Women of child-bearing age limit to less than 6 oz. per week
Wisconsin	2001	Women of child-bearing age and children under 15 limit to 1 can per week
California	2002	Women who are pregnant or might become pregnant, nursing mothers and children under 6 limit consumption to 12 oz. per week

In addition, interim warnings posted at major grocery store chains in California—developed by the state Attorney General in consultation with the Department of Health Services—state that "Chunk or chunk light tuna has less mercury than solid white or chunk white tuna."[37] Most recently, the national natural food grocery chain Wild Oats Market, Inc. committed to posting these warnings at its 101 stores located in 25 states,[38] and Whole Foods Market, Inc. now provides similar information on its website.[39]

Further, the Washington State Health Department website[40] provides canned tuna mercury consumption recommendations for women and children by personal body weight assuming the FDA's 1992 sampling average of mercury levels in canned tuna at 0.17 ppm.



Of course, if the average levels of mercury were over 0.5 ppm, as in our recent independent testing, the recommended allowable consumption amounts for these sensitive populations would be far, far less. For instance, a 22 pound toddler would exceed the EPA reference does 4 times over by eating only 2 ounces of canned tuna per week that had mercury concentrations over 0.5 ppm. Even a 176 pound man reaches the EPA reference dose by eating only 4 ounces of canned tuna per week that contains mercury concentrations over 0.5 ppm.

FDA Protecting the Tuna Industry, Rather than the Public

Rather than taking precautions to protect public health, it appears that FDA is instead intent on protecting the $1.1 billion per year tuna industry. During the drafting of its fish consumption advisory in 2000, FDA met privately on three separate occasions—September 25, November 6, and November 22—with industry leaders from Chicken of the Sea, StarKist, Bumble Bee, the U.S. Tuna Foundation (the national organization representing canned tuna processors and the fishing boats that supply them), and the National Food Processors Association (NFPA)—the trade association representing the $460 billion food processing industry.[41] Following these meetings, FDA dropped both fresh and canned tuna from its fish consumption advisory for sensitive populations issued January 11, 2001—even though prior to that FDA scientists had included canned tuna advisories in its focus groups and explained, as noted in its own transcripts, why canned tuna was a methylmercury exposure concern for sensitive populations.[42]

In its written submittals to FDA, the U.S. tuna industry projects that canned tuna consumption would significantly decline if it were to be mentioned in FDA's advisory.[43] A December 2000 letter to the FDA from the U.S. Tuna Foundation warned that purchases of canned tuna could decline by 24 percent if canned tuna were mentioned specifically in an advisory.[44] Shortly after FDA dropped canned tuna from its advisory, the NFPA announced that it had "scored a decisive victory when FDA released a revised consumer advisory earlier in the year that did not mention canned tuna and did not lower the tolerance level."[45]

However, the decision to omit fresh and canned tuna from its consumption advisory runs contrary to mission statements of the FDA and other health agencies to protect the public from contaminated food. It also runs contrary to the conviction held by other government agencies, scientists, and health officials, that canned tuna consumption poses a threat to public health, due to mercury levels and frequent consumption.

Based on an examination of FDA's focus group transcripts, some[46] believe that FDA's decision was intended to allay industry's concern that its inclusion in the advisory would lead people to curtail purchases of canned tuna.[47] To justify this move, FDA spokespeople asserted that even the biggest consumers of canned tuna ate only seven ounces per week,[48] in other words not enough to warrant taking action to minimize tuna consumption in any part of the population.[49] These numbers, which suggest that the usual consumption of canned tuna by women averages less than seven grams per day, are based on a study commissioned by the US Tuna Foundation.[50] Moreover, the tuna industry regularly tests mercury levels in canned tuna but does not make this research publicly available.[51] Yet according to a spokesperson from the tuna industry, "extensive research" found that four percent of the tuna tested reached or exceeded the FDA's action level of 1 ppm.[52]

Congressional Inquiry

Concerns about the FDA's questionable relationship with the tuna industry and human exposure risks to methylmercury have sparked congressional involvement and inquiries. In March and July of 2002, Representative Frank Pallone (D-NJ) wrote to FDA and then Inspector General of the Department of Health & Human Services, Janet Rehnquist, questioning "the undue influence from the seafood industry."[53] Representative Pallone concluded: "[d]ocuments brought to my attention suggest that top

FDA officials spent taxpayer money on public opinion focus group tests to learn how to best communicate to female consumers the hazards of eating mercury contaminated tuna fish, then dropped the warning after it met with seafood industry lobbyists."[54]

In a March 2002 letter to then Inspector General Rehnquist, Representative Pallone requested that the Inspector General investigate reports that FDA scientist Michael Bolger misrepresented the results of focus group research on how to communicate mercury risks to women. Pallone also voiced concerns that the focus group process was unfair and lacking impartiality. Pallone writes: "[i]ssues of improper conduct and undue influence by industry loom unanswered here, and your action is needed to clear up these important questions...I ask that you take precautionary measures to ensure any undue industry influence ceases while you are reviewing this matter..."

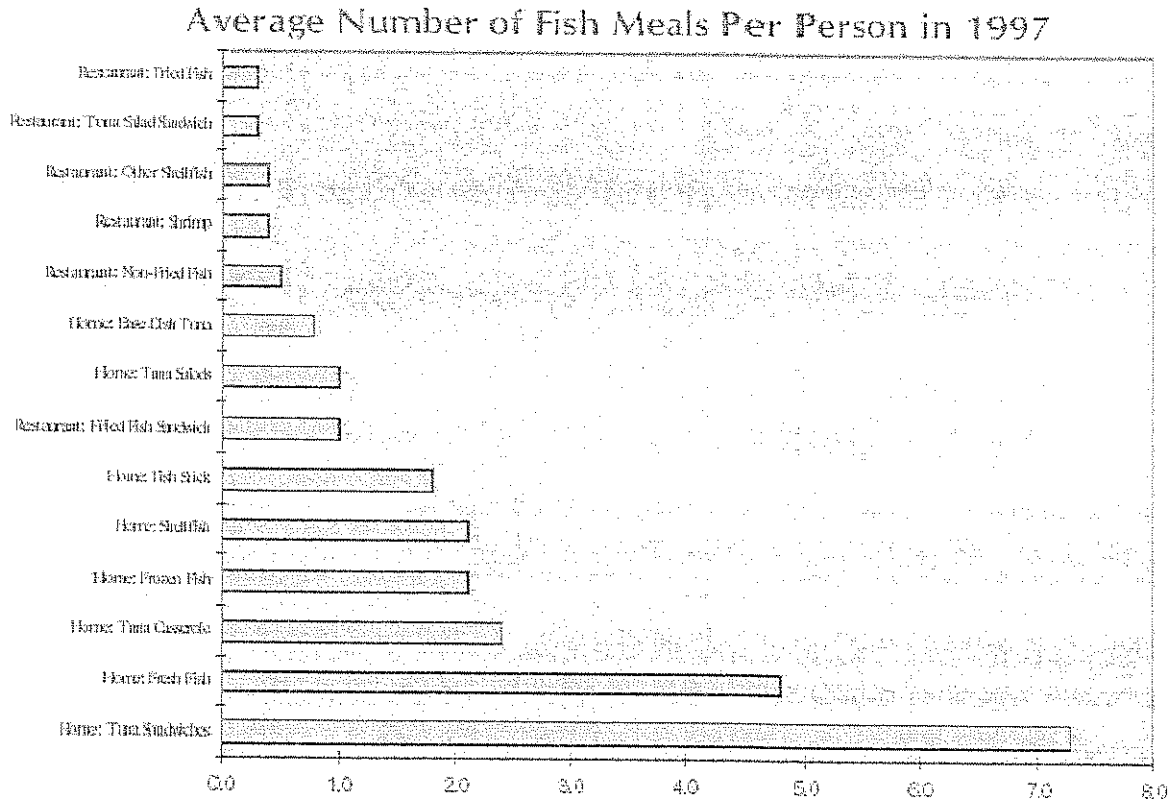
Similarly, citing specific concern with the agency's failure to adopt recommendations made by the 2000 NAS Committee on Methylmercury, Democratic Senators Patrick Leahy (VT), Edward Kennedy (MA), Hillary Rodham Clinton (NY), John Edwards (NC), and Tom Harkin (IA) wrote to then-acting FDA Deputy Commissioner Bernard Schwetz on February 25, 2002, stating: "We are concerned that the FDA has not adopted the NAS recommendation and the EPA standard. Nor has the agency included all species with high methylmercury levels in its public health advisories, leaving pregnant women, women of childbearing age, and other seafood consumers vulnerable to the risks described in the NAS report."[55]

Meanwhile, a January 2001 report by the U.S. General Accounting Office (GAO) criticized FDA for its handling of mercury in commercial seafood.[56] According to the GAO, FDA does not provide guidance to the fishing industry to identify and prevent fish contaminated with mercury from reaching consumers, even though the Agency's own testing found that over half of the swordfish met or exceeded its action level of 1 ppm.

The GAO report also noted that for over 10 years FDA has been evaluating the hazards of mercury in fish, but has never completed its study. "In the meantime," the GAO report states, "FDA advises industry and inspectors not to identify methylmercury as a hazard reasonably likely to occur." However, in prior draft FDA Fish & Fisheries Guides, methylmercury was "identified as a potential hazard in certain seafood species consumed by humans, including swordfish and tuna."[57] Yet now FDA omits "a serious hazard because methylmercury, a highly toxic substance, is not identified or covered in FDA's seafood guide as a hazard reasonably likely to occur," according to the GAO report.[58]

Americans are Not "Average" Fish Consumers:
FDA's Action Level vs. EPA's Reference Dose for Warning the Public About Mercury

Americans eat canned tuna meals more frequently than all other fish meals combined.[59] The average fish consumer eats between one and three fish meals per week, including canned tuna. But according to a report from the State of New Jersey, a significant percentage of the population eats five or more fish meals per week.[60] More to the point, while some people don't eat any fish, others are eating well more than the average, with some people reportedly eating ten fish meals per week.[61] As an example of the average annual number of fish meals per person, and the large percentage specifically related to consumption of canned tuna, see the graph below, from an annual report on the U.S. seafood industry.[62]



Sources: 1998 Annual Report on the United States Seafood Industry

According to an EPA scientist speaking at a United Nations mercury meeting last fall, "[t]he reason for breaking out canned tuna separately is because people eat so much more of it than other kinds of fish so that the actual exposure of canned tuna is probably the largest, on average, exposure of people to mercury. In fact, even at the average exposure of 0.2 [parts per million] or there about, you can easily exceed he (EPA's) reference dose at non-pathological levels."[63]

In April 2003, FDA's newly appointed chief medical officer in the science office, Dr. David Acheson, announced what appeared to be a reversal of the Agency's refusal to accept the NAS recommendation to adopt EPA's more stringent safe level for mercury in the human body. Speaking to Mobile Register reporter Ben Raines, Acheson said: "The FDA is now basing its advisory on the EPA's reference dose."[64] While he stopped short of announcing that FDA was firmally endorsing EPA's safe level, a recent paper co-authored by EPA, FDA, CDC, and NOAA published in the Journal of the American Medical Association[65], appeared to set the stage for an inter-agency harmonization of intake levels for methylmercury—something which consumer advocates have long pushed for.

A few days later, on April 9, 2003, Acheson indicated that the Agency will decide what advice to provide about canned tuna by the end of 2003.[66] Already the tuna industry has begun a public campaign urging consumers to ignore concerns about the link between seafood consumption and neurodevelopmental disorders. As recently as May 15, 2003, the US Tuna Foundation issued a press release endorsing the view that "canned tuna, which contains only trace amounts of mercury, poses no health risks...Canned

tuna is one of the safest, healthiest foods on the market today."[67] This in spite of FDA acknowledgement that none of the studies of methylmercury have clearly shown the level at which newborns can tolerate exposure.

If FDA adopts EPA's reference dose, the agency will almost certainly have to revise its advice to women and children for canned tuna consumption. This would mean reducing the per weekly consumption of canned tuna significantly, from two six ounce cans to one can of tuna for women and considerably less for children, and even less for infants. The current FDA standard uses as its endpoint frank neurologic effects in adults resulting from the mercury poisoning epidemic in Iraq in the 1970s, [68] so it does not take into account sensitive subpopulations, notably pregnant women, young children, and low income communities relying on canned fish as a cheap source of protein.[69]

In its July 2002 meeting, the Food Advisory Committee advised FDA to justify more accurately how the agency can continue to use a 1 ppm action level[70] that, according to many, fails to adequately address methylmercury exposure risks to the developing fetus and to young children. The FDA's advisories are based on consumption of a mixture of fish corresponding to the average mercury concentration among the all market fish. Yet realistically, people eating seafood do not consume average amounts of a particular fish. People who eat canned tuna, tuna steaks, swordfish, shark, king mackerel, and other high risk fish generally eat these fish over and over again. According to Dr. Michael Shannon with Children's Hospital in Boston and one of the Food Safety Committee members, "[t]he burning question is whether it is safe for kids to be eating tuna fish sandwiches for lunch every day."[71]

By contrast, EPA used a group of tests of pysho-neurologic performance including language, attention, and memory administered to Faroese children as the basis for its RfD. EPA's reference dose is designed to account for the acceptable daily dose of a substance even for sensitive subgroups, in this case the developing fetus and young children. EPA's current reference dose for methylmercury is 0.1 ug/kilogram/body weight/day. According to a statement made by EPA scientist Dr. Kate Mahaffey, this amounts to approximately "5 to 7 micrograms per day [of mercury] for someone who weighs between 100-150 pounds."[72] Based on this calculation, EPA's RfD guides states to warn women and children to limit fish consumption to 6 to 8 ounces per week, as opposed to the FDA's recommendation of 12 ounces per week. For a 44 pound child, the EPA guidance utilized by certain states translates to only 3 ounces of light tuna or 1.5 ounces of white tuna weekly—one tuna sandwich a week—based on the 1992 FDA average of mercury in canned tuna of 0.17 ppm.[73] Again, the amount of tuna consumed under EPA's RfD would be far less when the mercury levels exceed 0.5 ppm, as in the case of our recent tuna testing.

Environmental Health Justice:
Women, Infants, and Children (WIC) Program

In addition to developing babies and young children, methylmercury exposure from canned tuna has a disproportionate impact on low-income communities, where canned tuna is consumed in higher quantities because of its affordability. Indeed, according to industry sources, "[c]anned tuna is also critical to lower income groups as it is often 'featured' at a deep discount or as a 'loss leader' to drive traffic in the retail store."[74]

Unfortunately, the Federal government promotes unsafe methylmercury exposure through its Women, Infants and Children's (WIC) program, which serves more than 7 million people who get WIC benefits each month.[75] Under the WIC program, lower income women are provided government checks to purchase food for themselves and their families. WIC foods include iron-fortified infant formula and infant cereal, iron-fortified adult cereal, vitamin C-rich fruit and/or vegetable juice, eggs, milk, cheese, peanut butter, dried beans or peas, tuna fish and carrots.[76] Because poultry and meat are not included on the list of potential items that may be purchased using WIC benefits, canned tuna is one of the primary animal proteins purchased through the program.

New Evidence of Harm from Methylmercury in Fish

A large body of scientific knowledge demonstrating the adverse impacts of low levels of methylmercury exposure on the developing fetus has emerged since intensive study of the human health effects of methylmercury began following the mercury crisis in Minamata, Japan nearly 50 years ago. Yet new information published over the past three years sheds new light on methylmercury exposure concerns.

Most recently, a landmark article published by top U.S. federal agency scientists appeared in the April 2003 issue of the Journal of the American Medical Association. The study, conducted together by EPA, FDA, CDC, and NOAA, analyzed new CDC findings that 8 percent of women of reproductive age in the U.S. have mercury blood levels above what EPA and NAS consider safe (5.8 microgram per liter, or 5 parts per billion). This equates to more than 300,000 children born each year in the U.S. at risk of developmental neurotoxicity from exposure to methylmercury. The study also found that women who ate three or more servings of fish within a 30-day period had four times the mercury levels of women who ate no fish during that period; and children who had eaten fish in the last 30 days before sampling had blood mercury levels twice as high as those of children who had not eaten fish during that period.[77]

Another recent study, published in Environmental Health Perspectives by Dr. Jane Hightower, found unexpectedly high levels of mercury exposure among her patients, who were not otherwise selected on the basis of either fish consumption or mercury exposure.[78] Dr. Hightower measured blood mercury levels in patients who demonstrated various mercury-related symptoms, and determined, among other findings, that a number of her patients, including children, had eaten no fish other than canned tuna and still exceeded the EPA's safety level.[79] Of the 116 patients studied, who revealed symptoms indicative of mercury exposure, 89 percent had mercury levels exceeding 5 ppb.

While some medical establishments advise patients with heart problems to eat fish because it is a low-fat source of protein and beneficial omega-three fatty acids are considered protective to the heart, recent methylmercury exposure studies raise concern that moderate levels of mercury exposure from these same fish may decrease cardio-protective effects of fish intake. An extensive exposure study in Finland in 1995 examined concentrations of mercury in hair, urine, and blood samples of men with high fish consumption who were initially free from cardiovascular disease. Results revealed a significant correlation between high levels of mercury and cardiovascular disease due to fish consumption. Mercury concentrations in hair resulting from fish consumption at levels which are found among U.S. fish consumers were associated with a 2-fold increase of risk of acute myocardial infarction and coronary heart disease, other cardiovascular diseases, and death.[80] Hair mercury data in a follow-up study showed accelerated progression of carotid atherosclerosis associated with mercury accumulation.[81] In addition, a study of

European men released in the autumn of 2002 found a significant association between mercury exposure from fish consumption and subsequent elevated risk of acute myocardial infarction.[82]

These cardiovascular concerns are also supported by findings in the Faroe Islands study suggesting that prenatal exposure to methylmercury may affect the development of cardiovascular homeostasis. Blood pressure increased significantly with increased cord blood mercury concentrations up to 10 ug/l.[83] In addition, increased methylmercury in cord blood levels reduced heart rate variability, which is an indication of a lack of ability to respond appropriately to a physiological signal. Increased blood pressure is a risk factor for cardiovascular disease.

Conclusions

The Food & Drug Administration has failed in its responsibility to protect sensitive populations, including pregnant women and children, from exposure risks to methylmercury from consumption of canned tuna, and particularly "white" canned tuna. While FDA has known for over a decade that levels of mercury in "white" tuna are at least double the levels in "light" tuna, the Agency has failed to acknowledge or address this—even though 11 states now warn sensitive populations to limit canned tuna consumption and several warn that mercury levels in white tuna are much higher than light tuna.

Further, by FDA scientist's own admission, 30-50 percent of American women remain unaware of the mercury exposure risks from fish consumption.[84] FDA officials have also acknowledged that none of the studies of methylmercury have shown the level at which newborns can tolerate exposure. Unfortunately, FDA's apparent allegiance to the fishing industry has so far resulted in a public health breakdown of critical proportions. This breakdown places more than 300,000 children each year at risk of mercury poisoning, and endangers millions of people who routinely consume larger predatory fish like albacore "white" canned tuna.

Despite promises that it would prioritize methylmercury seafood issues, FDA has ignored and skewed the findings of focus groups, committee recommendations and reports. While there has been a pattern of this occurring for more than two decades, this occurred more recently in 2000 and 2001, when the FDA ignored reports put forth both by the National Academy of Sciences and U.S. General Accounting Office respectively. Since July 2002, the FDA has continued to procrastinate on implementing the recommendations of its own Food Safety Committee that it specifically requested—even though Joseph Levitt, Director of the FDA Center for Food Safety and Applied Nutrition and top official at the time in charge of the Agency's mercury policy, publicity agreed that the Committee's findings were significant and that FDA would be "taking the advice to heart."[85]

Recommendations for Action

1) **Sensitive populations should avoid consuming "white" albacore canned tuna.** Women who are pregnant or considering pregnancy and nursing mothers should avoid consumption of "white" albacore canned tuna to protect developing fetuses and babies from methylmercury exposure. Parents should steer infants and young children away from consuming "white" albacore tuna as well.

2) **FDA should adopt the EPA's reference dose for human exposure to methylmercury.** Following the recommendation of the National Academy of Science, FDA should adopt the EPA's reference dose for human exposure to methylmercury that is more protective for those most at risk.

3) **FDA should resume testing of canned tuna and other seafood.** More comprehensive tests are critically needed to improve the FDA's baseline knowledge about concentrations of mercury in seafood and canned tuna.

4) **FDA should set a regulatory limit rather than an action level for methylmercury in fish.**[86] A regulatory limit would provide both the public and the fishing industry with a clear picture of unacceptable levels of mercury in fish and provide FDA and other agencies with a much clear direction as to removal of seafood from the marketplace.

5) **FDA should issue more targeted seafood consumption advice.** Consumption advisories should be specifically aimed at presenting the public with a range of appropriate consumption levels based on body weight, consumption patterns, and mercury levels, as well as particular fish including identifying the higher risks of eating albacore "white" canned tuna.

6) **FDA and states should mandate mercury labeling in markets and restaurants.** Point-of-purchase information is a proven and effective mechanism for influencing consumer behavior. Consumers purchasing fish in the marketplace should be made aware of how much mercury the fish contains, and what consumption levels and limits are appropriate for them.

7) **Federal and state Women, Infants, and Children (WIC) Program should not allow albacore "white" canned tuna to be included in its benefits.**

8) **The World Health Organization should adopt the EPA's reference dose for human exposure to methylmercury.**

9) **All anthropogenic mercury uses and releases should be reduced or eliminated, exports curtailed, and surplus quantities of mercury placed indefinitely in secure, long-term, monitored above ground storage to reduce mercury levels in the environment and in fish over time.**

Appendix I: Mercury Timeline

1953 Fishermen, their families and the community of Minamata, Japan experienced a mercury poisoning epidemic due to consumption of mercury contaminated seafood, resulting in severe health impacts, including brain damage and death.

1969 FDA sets an "administrative guideline" of 0.5 ppm for methylmercury in marine fish.

1971 FDA finds seafood over its administrative guideline of 0.5 ppm for mercury and recalls 12.5 million cans of canned tuna and prohibits sale of swordfish and other high mercury seafood.

1972 A mercury poisoning epidemic occurs in Iraq where wheat and barley treated with ethylmercury fungicide resulted in several thousand exposures and 459 deaths. Pregnant women who consumed mercury-contaminated bread were not affected, but their offspring experienced neurological damage.

1974 FDA converts their "administrative guideline" of 0.5 ppm for mercury to an "action level" recognizing that chronic exposure to fish and shellfish containing methylmercury posed a greater danger to women of childbearing age than to the general population.

1979 After being sued by the fishing industry, FDA raised their "action level" to 1.0 ppm, ignoring the critical public health consideration that there are sensitive sub-populations within the general population.

1990 The U.S. Congress adopts the Clean Air Act amendments which, among other things, instructs EPA to conduct a comprehensive study of the health, ecological effects of mercury, and sources of mercury, and present its findings to Congress within 3 years.

1991 The General Accounting Office released a report stating that FDA failed to examine mercury's reproductive and developmental toxicity data when it weakened its action level from 0.5 to 1.0 ppm.

1991 National Academy of Sciences releases its report "Seafood Safety," which criticizes FDA for its handling of methylmercury in commercial fish. NAS stated that the adequacy of FDA's action level to protect the developing fetus "is highly doubtful," characterizing the approach as "unusual" and criticized FDA for not adequately protecting the developing fetus.

1995 EPA establishes its reference dose for human consumption of methylmercury at 0.1 micrograms per kilogram of body weight.

1996 In July, EPA completes its "Mercury Study Report to Congress" - a seven-volume, 1,700 page report that was peer-reviewed internally and externally. Rather than release the report to Congress or the public, EPA forwards it to the Science Advisory Board (SAB) for further review.

1996 In October, Senator Patrick Leahy (D-VT) leads 20 senators in a letter to the EPA Administrator calling for the immediate release of the mercury report to Congress.

1997 In February, the SAB recommends that EPA not wait for more data before moving forward with the report. SAB also finds that the EPA's report was already the best compilation to date.

1997 In May, Senator Patrick Leahy (D-VT) and Senator Jim Jeffords (R-VT) send a letter to President Clinton, urging him to instruct the EPA to release its mercury report to Congress. Senator Leahy also leads a bipartisan coalition of six senators in introducing a resolution (S. Con. Res. 28) that calls for the immediate release of the EPA mercury report and questions the reasons for the delay.

1997 In November, the Faroes Island study, "Cognitive deficit in 7-year-old children with prenatal exposure to methlymercury" is released.

1997 In December, Senators Leahy and Jeffords send a letter to EPA Administrator Browner and Secretary of Health and Human Services Donna Shalala, urging them to work together to reduce public exposure to mercury.

1997 On December 19, EPA releases its "Mercury Study Report to Congress." The report concludes that: "coal-fired power plants and municipal trash incinerators are the two largest sources of mercury emissions in the United States, mercury pollution can contaminate fish and birds and, at least 1.6 million Americans are potentially at risk from food contaminated by mercury pollution that enters the environment principally as the result of human activities."

1998 In the late spring, Representative Mollohan adds language to US House VA-HUD Appropriations bill that says EPA cannot regulate mercury until scientific studies review EPA's reference dose.

1998 In July, in a conference committee of the FY 1999 VA-HUD Appropriations bill report, Senator Leahy and Representative Mollohan compromise with language calling for EPA regulations to abide by a National Academy of Sciences study that will be completed in 2 years.

1999 In March, Senator Leahy sends a letter to HHS Secretary Shalala urging review of the Agency for Toxic Substances and Disease Registry (ATSDR) proposed "toxicity profile" of mercury. Leahy suggests that the proposed profile is a weakening of currently-available reference dose information and will cause confusion as to appropriate mercury levels. Leahy argues that ATSDR should submit data to the ongoing National Academy of Sciences study mandated in FY 1999 VA-HUD Appropriations.

1999 In April, ATSDR sets a mercury "minimal risk level" for methylmercury at 0.3 micrograms per kilogram of body weight.

1999 In October, Senators Leahy and Tom Harkin (D-Iowa) send a letter to Secretary Shalala requesting information from FDA about how the agency is protecting American consumers from the risks of mercury-contaminated food. They also ask for clarification of the basis for the FDA "action level." They set a deadline of November 5, 1999 for a response.

2000 In mid-February, FDA finally responds to the letter from Senators Leahy and Harkin. The FDA letter includes datasets that show FDA stopped monitoring domestically caught seafood for mercury contamination in 1998. This was done even though their 1997 data showed that several samples of domestically caught tuna, swordfish, and shark exceeded their own 1.0 ppm "action level."

2000 In April, Senators Leahy and Harkin release a statement expressing serious concerns over the lack of FDA monitoring of domestically caught seafood since 1998.

2000 In July, the National Academy of Sciences releases its report "Toxicological Effects of Methylmercury" to Congress. The report supports the EPA reference dose for methylmercury of 0.1 µg/kg/day. In its risk assessment section, the report defines "high consumption" levels of fish at or near 100 grams/day (approximately 3 ounces/day). This is the amount eaten by about 5% of the U.S. populations studied. Given these statistics, the NAS report estimates that, on average, 7% of women nationwide would exceed the 0.1 µg/kg/day reference dose for methylmercury. In addition, the risk may be higher in certain regions of the country.

2000 In mid-August, Senators Leahy and Harkin send a letter to Secretary Shalala to urge the FDA and ATSDR to adopt the more stringent, NAS-supported EPA reference dose.

2000 In November, FDA begins engaging in stakeholder meetings to discuss revising their methylmercury "action level" and their consumer advisory for sensitive populations.

2000 A mid-December conference report for the final FY 2001 appropriations bill of the 106th Congress includes a rider which passes to stop FDA from taking action on methylmercury in fish. The language stipulates that FDA should not develop consumer guidance on methylmercury exposure without considering "more than one relevant study," a reference to the Seychelles Islands studies.

2001 In January, Senators Leahy and Harkin send a letter to Secretary Shalala, urging the FDA to update its consumer guidance immediately to protect pregnant women, young children, and other sensitive populations. They urge FDA to update its "action level" to the stricter EPA methylmercury standard, and they note FDA's lack of response to their August 15, 2000 letter.

2001 On January 11, FDA issues a new consumer advisory for methylmercury in fish. The advisory warns pregnant women, women of childbearing age, nursing mothers, and young children to avoid swordfish, shark, king mackerel, and tilefish. It also warns them to limit other fish consumption to 12 oz. per week and to consult state and local advisories regarding freshwater fish. The new advisory does not specifically mention fresh tuna or canned tuna. FDA issues new consumer advisory but doesn't change the "action level." At a congressional briefing, FDA states that mercury is a high priority for the coming year, to include development of an overall mercury strategy.

2001 On January 11, the EPA issues a general fish consumption advisory for methylmercury in 2001, advising women who are or may become pregnant, nursing mothers and young children to limit consumption of freshwater fish to one 6-8 ounce meal per week for adults and one 2-3 ounce meal for young children, based on its RfD.

2001 On January 11, ABC's "20/20" investigative report on the health risks of methylmercury in fish airs at 10 PM. The report finds that fish with high mercury levels are readily available, and it questions the FDA's limited actions to protect consumers.

2001 On January 31, GAO releases its report "Federal Oversight of Seafood Does Not Sufficiently Protect Consumers," which criticizes FDA for its handling of methylmercury in commercial fish.

2001 In February, FDA responds, expressing its concerns about methylmercury and describing the decision-making process behind FDA's recently updated consumer advisory. The letter reiterates FDA's commitment to "develop an overall public health strategy for methylmercury in commercial seafood, including a review of the action level." The letter does not commit to any regulatory action.

2001 In March, the Centers for Disease Control and Prevention release data from the 1999 National Health and Nutrition Examination Survey, showing that 10% of women may have potentially hazardous levels of mercury. This would put far more newborns at risk than the NAS estimated in July 2000.

2002 In October, the European Commission endorses the US EPA's reference dose as the appropriate methylmercury exposure standard for Europe in a position paper.

2002 In December, the United Nations Environmental Programme released its Global Mercury Assessment report, which recognized the serious global health threats from methyl mercury:

> "Methyl mercury is adversely affecting both humans and wildlife. This compound readily passes the placental barrier and the blood-brain barrier, and is a neurotoxicant, which may in particular cause adverse effects on the developing brain. Studies have shown that methyl mercury in pregnant women's diets can have subtle, persistent adverse effects on children's development as observed at about the start of school age. Moreover, some studies suggest small increases in methyl mercury exposure may cause adverse effects on the cardiovascular system. Many people (and wildlife) are currently exposed at levels that pose risks of these, and possibly other adverse effects."[87]

2003 In February, the Food Standards Agency of the United Kingdom (FSA) advises pregnant and breastfeeding women, and women who intend to become pregnant to limit their consumption of tuna to no more than two medium-sized cans or one fresh tuna steak per week. According to the FSA, "the new safety guideline for pregnant and breastfeeding women and women intending to become pregnant is almost five times lower than that for the general population."

2003 In February, the United Nations Environmental Programme Governing Council agrees that there is sufficient evidence of significant global adverse impacts from mercury and its compounds to warrant further international action to reduce the risks to human health and the environment. It is now developing a plan to raise global awareness of the critical need to sharply reduce human exposures to mercury.

2003 In June, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) meets to consider revising the Provisional Tolerable Weekly Intake (PTWI) for methyl mercury exposure in humans.

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Exhibit B

Not Reported in F.Supp.2d, 2007 WL 1101440 (D.N.J.)
(Cite as: 2007 WL 1101440 (D.N.J.))

HOnly the Westlaw citation is currently available.NOT FOR PUBLICATION

United States District Court,
D. New Jersey.
Hadis NAFAR, on behalf of herself and all others similarly situated, Plaintiff,
v.
HOLLYWOOD TANNING SYSTEMS, INC., Defendant.
Civil Action No. 06-CV-3826 (DMC).

April 10, 2007.

Barry Benjamin Cepelewicz, Meiselman, Denlea, Packman, Carton & Eberz, PC, White Plains, NY, for Plaintiff.

Stephen M. Orlofsky, David A. Dorey, Kit Applegate, Blank, Rome, LLP, Cherry Hill, NJ, for Defendant.

OPINION

DENNIS M. CAVANAUGH, U.S. District Judge.

***1** This matter comes before the Court upon motion by Defendant Hollywood Tanning Systems, Inc. ("Defendant") for partial judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. No oral argument was heard pursuant to Fed.R.Civ.P. 78. After carefully considering the submissions of the parties and for the following reasons, Defendant's motion for partial judgment on the pleadings is **denied.**

I. *BACKGROUND*

Hadis Nafar ("Plaintiff") purchased monthly tanning memberships from Defendant in Middlesex County, New Jersey. Nafar began purchasing monthly memberships in April 2005, and continued through March 2006. Plaintiff then instituted this suit against Hollywood Tans alleging: (1) violation of the New Jersey Consumer Fraud Act, (2) fraud, (3) unjust enrichment, and (4) breach of warranty; and (5) requesting injunctive relief.

Nafar alleges that Hollywood Tans fraudulently omitted the fact that *any* exposure to ultraviolet rays (UV rays) increases the risk of cancer. Plaintiff emphasizes that "excessive exposure" to UV rays is not necessary for harm to occur and that *any* exposure can suffice. Plaintiff goes on to allege that Hollywood Tans made affirmative misrepresentations through its website. Among these alleged misrepresentations are claims that exposure to UV rays may help with acne, customers will "look terrific," and UV rays may help those suffering from psoriasis, body weight issues, stress, and seasonal affective disorder. Nafar contends that Hollywood Tans distorts these "benefits" and deceptively fails to warn consumers about the dangers of indoor tanning. Defendant's website states that its tanning system "block[s] out most of the UVB rays allowing your skin to maintain natural exfoliation [which] helps high pressure tanners to stay tan longer." While Plaintiff acknowledges that Hollywood Tans' machines may block out most UVB rays, she contends that Defendant fails to inform consumers that UVA rays, also emitted by its machines, are linked to skin cancer.

Plaintiff further alleges in her Complaint that both UVA and UVB exposure destroys cell DNA, a precursor to cancer. In addition to direct DNA damage, Plaintiff asserts that ultraviolet light produces activated oxygen molecules that also damage DNA, as well as creating localized immunosuppression that blocks the body's natural anti-cancer defenses. Plaintiff emphasizes that *prior to purchasing* her memberships, Defendant did not inform her about the cancer risks or other health risks attendant with UV tanning. Plaintiff also asserts that she did not receive warnings before her sessions, and she did not sign any consents or waivers acknowledging that she was informed about the health risks of indoor tanning. Nafar disclaims any remedy for personal injuries suffered, but proceeds on her fraud-based causes of action, which provide remedies in treble damages, injunctive relief, punitive damages, attorney's fees, and costs of suit.

***2** Hollywood Tans notes that its tanning machines are regulated by the FDA and are required by FDA regulations to carry a label providing:

(1) recommended exposure positions;

(2) directions for achieving the recommended exposure positions and a warning that the use of other positions may result in overexposure;

(3) a recommended exposure schedule including duration and spacing of sequential exposures and maximum exposure times in minutes; and

(4) a statement of the time it may take before the expected results appear.

21 C.F.R. § 1040.20(d)(1)(ii)-(v).

Each machine also carries the following warning, as required by FDA regulations:

DANGER-Ultraviolet radiation. Follow instructions. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO DO SO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult physician before using sunlamp if you have a history of skin problems or believe yourself especially sensitive to sunlight. If you do not tan in the sun, you are unlikely to tan from use of this product.

21 C.F.R § 1040.20(d)(1)(i).

It is undisputed that Defendant has posted these warnings on its tanning machines in compliance with the FDA regulations.

Hollywood Tans' Motion for Partial Judgment on the Pleadings seeks judgment as to each of Plaintiff's claims that rely on a failure to warn theory, namely claims (1) violation of the New Jersey Consumer Fraud Act, (2) fraud, (3) unjust enrichment, and (5) Plaintiff's request for injunctive relief.

II. *STANDARD OF REVIEW FOR 12(C) MOTION FOR JUDGMENT ON THE PLEADINGS*

Defendant files this motion for judgment on the pleadings pursuant to Rule 12(c) of the Federal Rules of Civil Procedure. While it is generally true that a Rule 12(c) motion for judgment on the pleadings is treated similarly to a motion to dismiss under Rule 12(b)(6), there are significant differences between a Rule 12(c) motion for judgment on the pleadings and a Rule 12(b)(6) motion to dismiss for failure to state a claim.

First, a Rule 12(c) motion is brought after the close of the pleadings, while a Rule 12(b)(6) motion is brought before the close of the pleadings. *Syncsort, Inc. v. Sequential Software, Inc.*, 50 F.Supp.2d 318, 324 (D.N.J.1999). Second, "a Rule 12(b)(6) motion to dismiss is directed solely towards the procedural defects or the statement of the Plaintiff's claim for relief and does not seek to determine the substantive merits of the controversy." 5C Charles Alan Writht & Arthur R. Miller, *Federal Practice and Procedure* § 1369 (3d ed.2004).

Thus, whereas a Rule 12(b)(6) motion tests whether a plaintiff's pleading, viewed alone, states a claim, a Rule 12(c) motion moves for judgment on those claims, as pleaded. In this respect, the standard for decision the Court employs mirrors the summary judgment standard.

III. *DISCUSSION*

A. Whether Plaintiff's Consumer Fraud Claims are Subsumed by the NJPLA

***3** Hollywood Tans contends that this is a "product liability action" governed by the New Jersey Products Liability Act ("NJPLA"). N.J.S.A. § 2A:58C-1 (b)(3). Defendant interprets Plaintiff's Complaint as alleging damage to her DNA. This DNA damage increases her risk of cancer, which requires that the Defendant properly warn consumers of the risks involved. Hollywood Tans asserts that Plaintiff cannot pursue a consumer fraud theory, attorneys' fees, or other theories on a failure to warn basis because the NJPLA is the sole remedy for products liability actions.

Defendant asserts that a "failure to warn" may constitute a "product defect," which is within the realm of products liability rather than consumer fraud. *See Becker v. Baron Bros.*, 138 N.J. 145, 151-52 (1994). ("A failure to warn, or a failure to warn properly, can constitute a defect in a product sufficient to support an action in strict liability.").

New Jersey codified its products liability law in the NJPLA. N.J .S.A. § 2A:58C-1 *et seq.* The NJPLA defines a "product liability action" as "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A:58C-1(b)(3). Within the NJPLA's purview are claims based on harm caused by a failure "to contain adequate warnings or instructions...." N.J.S.A. § 2A:58C-2.

In order for the NJPLA to apply, Plaintiff must have suffered a "harm" as articulated in the statute. The harm contemplated by the NJPLA is limited to:

(a) physical damage to property, other than to the product itself;

(b) personal physical illness, injury, or death;

(c) pain and suffering, mental anguish or emotional harm; and

(d) loss of consortium or services or other loss deriving from any type of harm described in subparagraphs (a) through (c) of this paragraph.

N.J.S.A. § 2A:58C-1(b)(2).

Hollywood Tans argues that the DNA damage suffered by the Plaintiff, which could lead to cancer, constitutes "harm" under the NJPLA.

Defendant believes that Plaintiff is attempting to avoid the NJPLA by disclaiming recovery for personal injuries and couching her harm as "economic"-monetary harm suffered by the Plaintiff in the form of membership fees that she would not have paid but for Defendant's alleged fraudulent omissions. Despite this "economic" harm, Defendant emphasizes that the harm was "*caused by* a product," necessitating the NJPLA's exclusive application.

The NJPLA was enacted by the New Jersey Legislature to limit the expansion of products liability law, and is thus, "the sole method to prosecute a product liability action." *Tirrell v. Navistar Int'l, Inc.*, 248 N.J.Super. 390, 398 (App.Div.1991). The Defendant cites *Repola v. Morbark Industries, Inc.*, 934 F.2d 483 (3d Cir.1991), in which the Third Circuit dismissed a failure to warn claim based on negligence because it was subsumed by the NJPLA. Additionally, in *Brown v. Phillip Morris, Inc.*, 228 F.Supp.2d 506 (D.N.J.2002), the court dismissed the plaintiff's intentional fraud claims because the fraud claims were also subsumed by the NJPLA.

***4** If the Consumer Fraud Act ("CFA") claims cannot go forward and are subsumed by the NJPLA, Defendant will no longer face consumer fraud-based treble damages and counsel fees. Additionally, under the NJPLA:

> In any product liability action against a manufacturer or seller for harm allegedly caused by a product that was designed in a defective manner, the manufacturer or seller shall not be liable if. .(2) The characteristics of the product are known to the ordinary consumer or user, and the harm was caused by an unsafe aspect of the product that is an inherent characteristic of the product and that would be recognized by the ordinary person who uses or consumes the product with the ordinary knowledge common to the class of persons for whom the product is intended....

N.J.S.A. § 2A:58C-3(a)(2).

Also, "[i]f the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the ... [FDA], a rebuttable presumption shall arise that the warning or instruction is adequate." N.J.S.A. § 2A:58C-4. Thus, if the NJPLA applies, Hollywood Tans will be able to take advantage of both statutory defenses.

Rather than claiming personal injury damages for "harm caused by a product," Nafar seeks to recover for economic harm that she suffered from purchasing Defendant's services without being warned of the dangers associated with indoor tanning. Additionally,

Plaintiff asserts that Defendant only challenges Plaintiff's claims that are based on Hollywood Tan's failure to warn. Therefore, the Complaint has not been challenged as to claims based on affirmative misrepresentation, particularly Claim 4, breach of warranty.

Plaintiff argues that the NJPLA does not apply to this case because the economic harm Nafar suffered is not contemplated within the NJPLA's definition of "harm." In support of this proposition, Plaintiff cites to *Repola,* 934 F.2d at 492 (3d Cir.1991), where the Third Circuit explained that the NJPLA is the sole remedy for "claims falling within its purview." Therefore, the NJPLA's scope is limited by its own definitions of "product liability action" and "harm." *Id.* Although Hollywood Tans argues that Nafar suffered personal injury "harm" as contemplated by the NJPLA, Plaintiff asserts that she has not suffered any personal injury harm. Rather, she claims economic harm as a result of purchasing monthly tanning memberships that she would not have purchased but for Hollywood Tans' deceptive business practices.

In support of her claim that the NJPLA is only limited to the statute's definition of "harm," Nafar cites *Knoster v. Ford Motor Co.,* 2006 U.S.App. LEXIS 22869 (3d Cir. Sept. 6, 2006). In *Knoster,* the plaintiff brought a consumer fraud claim after a car accident, but sought damages for the car itself. The defendant argued that the NJPLA subsumed the consumer fraud claim. However, the Third Circuit held that the damage claim for the car itself was not the type of harm contemplated by the NJPLA; therefore, the consumer fraud claim was allowed to proceed.

***5** Additionally, Plaintiff argues that the NJPLA applies to suits arising from "products," while this suit is based on Hollywood Tans' deception regarding its "services." Plaintiff relies on *Universal Underwriters Ins. Group v. Public Serv. Elec. & Gas Co.,* 103 F.Supp.2d 744, 748 (D.N.J.2000), for the proposition that "when an injury does not result from a defective product, but rather from a service, the NJPLA is inapplicable."

In refutation of Defendant's case analysis, Plaintiff points out that both *Repola,* 934 F.2d 483 and *Brown,* 228 F.Supp.2d 506, are inapposite because they deal with "harm" as it *is* defined in the NJPLA. Plaintiff also claims that Defendant's reliance on *Estate of White v. R.J. Reynolds Tobacco Co.,* 109 F.Supp.2d 424, 431-32 (D.Md.2000) is misplaced. That court relied on the Restatement (Second) of Torts and the consumer expectations test in assessing a strict liability claim. Here, however, Nafar is not asserting a strict liability claim, so the consumer expectation test does not apply. If the court finds that the NJPLA applies in this case, Plaintiff seeks leave to file an amended complaint to assert claims under that statute.

Nafar alleges that Hollywood Tans misrepresented the benefits of indoor tanning and failed to disclose the harmful effects of its services. Plaintiff further alleges that she suffered a monetary loss because but for these misrepresentations and omissions, she would not have purchased Hollywood Tans' services. These allegations are enough to support a claim under the CFA.

Hollywood Tans argues that Nafar's claim is subsumed by the NJPLA. For Hollywood Tans to succeed on this defense the court would have to construe a deliberate omission of material fact as a "failure to warn." However, there are qualitative differences between a failure to warn in a products liability action and a fraudulent omission of material fact. Here, Nafar is not claiming harm for any physical injuries she may have suffered from the use of Defendant's tanning machines, as would be appropriate in a products liability action. Instead, she is claiming monetary harm because Defendant failed to inform her of the ill effects of indoor tanning, and had she been informed of those ill effects, she would not have purchased Defendant's services. If Hollywood Tans can construe economic harm resulting from the omission of a material fact as equivalent to a "failure to warn," this would render the Consumer Fraud Act inapplicable in nearly any situation where fraud is contingent on material omissions, as opposed to material misrepresentations.

B. Whether the Risks Associated with UV Exposure are of Such Common Knowledge that Plaintiff Cannot Prevail on a "Knowing Omission" Under the New Jersey Consumer Fraud Act

Defendant believes that Plaintiff's consumer fraud claim is based on a "knowing omission," specifically

that Hollywood Tans failed to warn consumers of the cancer risks associated with its tanning machines. The New Jersey CFA provides that:

***6** The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression or omission, of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice....

N.J.S.A. § 56:8-2.

However, Defendant contends that the CFA only prohibits conduct that would mislead the "average consumer." *See* *Dabush v. Mercedes-Benz USA, LLC,* 378 N.J.Super. 105, 115 (App.Div.2005) (explaining that "[t]o constitute consumer fraud ... the business practice must be 'misleading' and stand outside the norm of reasonable business practice in that it will victimize the average consumer....").

Hollywood Tans argues that it is a question of law whether its "omission" constitutes consumer fraud because it must be decided whether Hollywood Tans had a duty to disclose in the first place, and "[d]uty is a question of law." *See* *Judge v. Blackfin Yacht Corp.,* 357 N.J.Super. 418, 426 (App.Div.2003). In support of its argument, Defendant cites *Strawn v. Canuso,* 140 N.J. 43 (1995), where the New Jersey Supreme Court held that a builder-developer had a duty to disclose to prospective buyers the homes' close proximity to an abandoned hazardous waste site. The *Strawn* court emphasized that the builder-developer was liable for physical conditions "known to it and unknown and not readily observable by the buyer...." *Id.* at 65. Therefore, Hollywood Tans asserts that "knowing omission" liability under the CFA arises only if the seller knows of some material fact that is unknown or not readily observable to the buyer. *See* *Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank,* 623 N.Y.S.2d 529, 533 (N.Y.1995) (reasoning that the New York Consumer Fraud Act does not require businesses to "guarantee that each consumer has all relevant information," but businesses may be liable "where the business alone possesses material information that is relevant to the consumer and fails to provide this information."); *Beaudreau v. Larry Hill Pontiac,* 160 S.W.3d 874, 881 (Ten.Ct.App.2004) (dismissing the plaintiff's claim because "a reasonable customer should be aware that a for-profit retailer, in arranging financing for a consumer, would expect to receive some sort of remuneration for its efforts.").

Defendant first argues that whether a duty exists is a question of law. *See* *Petrillo v. Goldberg,* 139 N.J. 472, 479 (1995) (determining that "the existence of a duty is a question of law for the court."). Defendant contends that Plaintiff's interpretation of *Oswego Laborer's Local,* 623 N.Y.S.2d 529 (N.Y.1995), is improper. Plaintiff used that case to establish that the court could not rule on the parties' knowledge as a matter of law. Defendant emphasizes that the court does not have to determine the Plaintiff's subjective knowledge of the harms associated with indoor tanning. Rather, the CFA applies an objective test, and Hollywood Tans argues that the court can determine, based on the facts alleged by Plaintiff and by taking judicial notice of the articles cited by Defendant, whether the risk of cancer was of common knowledge to the average consumer.

***7** Defendant argues that Plaintiff's attempt to distinguish *Beaudreau,* 160 S.W.3d 874, is unavailing. In *Beaudreau,* the court ruled as a matter of law that there was no duty to disclose and no consumer fraud. Plaintiff claims there was an imputation of knowledge in that case which is not present in this case. The imputation was based on a Federal Reserve Ruling stating that there was no necessity to disclose the dealer reserve. Defendant asserts that Plaintiff must now concede that she has imputed knowledge of the FDA's 1985 regulation warning that tanning machines may cause cancer.

Defendant believes that Plaintiff misinterprets the knowledge requirement for CFA actions. In citing *Cipollone v. Ligget Group, Inc.,* 893 F.2d 541 (3d Cir.1990), a products liability case, Plaintiff noted that the issue whether consumers know of the dangers of cigarettes is a fact issue for the jury. However, Defendant explains that *Cipollone* was a products liability action and not a consumer fraud action. De-

fendant argues that the issue of "knowledge" in a products liability action goes to the causation requirement, a fact issue. However, in a consumer fraud action, "knowledge" goes to the question of duty, a legal determination made by the court. *See Strawn,* 140 N.J. 43.

Defendant explains that the risks associated with excessive exposure to UV light are commonly known, similar to the way in which the risks of excessive consumption of McDonalds' food is commonly known. Hollywood Tans notes that in *Pelman v. McDonald's Corp.,* 237 F.Supp.2d 512 (S.D.N.Y.2003), the court dismissed the plaintiffs' "deceptive omission" consumer fraud claims because "one necessary element of any potentially viable claim must be that McDonalds' products involve a danger that is not within the common knowledge of consumers." *Id.* at 518. Defendant also cites a number of tobacco-related cases that support its contention. *See, e.g., American Tobacco Co., Inc. v. Grinnell,* 951 S.W.2d 420, 429 (Tex.1997) ("We conclude that the general health dangers attributable to cigarettes were commonly known as a matter of law when [plaintiff] began smoking.").

In sum, Defendant argues that the dangers of excessive UV-based tanning are common knowledge, and thus, there is no duty to disclose this information under the CFA. Since there is no duty to disclose, Defendant contends that there can be no "knowing omission" liability, and Plaintiff's CFA claim should be dismissed. Defendant concludes by addressing Plaintiff's claims that there is no such thing as a "safe tan," emphasizing that there is currently a debate regarding the harms and benefits of indoor tanning, and the scientific evidence is inconclusive.

Plaintiff argues that the issue, whether the effects of "excessive" exposure is common knowledge, has no bearing on this case. First, Nafar emphasizes that *any* exposure to UV rays is harmful; exposure need not be "excessive." Second, Nafar points out that even Hollywood Tans is under the impression that the dangers of tanning are minimal and that there are an abundance of therapeutic benefits to sunless tanning. Plaintiff emphasizes that the ill effects of *any* exposure to UV rays is *not* common knowledge because even Hollywood Tans fails to recognize that *any* exposure is harmful. Because the effects of exposure to UV rays are not common knowledge, and because the average consumer would consider such information material to their decision to purchase such services, Defendant is required to provide these facts to consumers in order to avoid a fraud action.

***8** This Court cannot, at the pleading stage and before discovery, determine as a matter of law "what the average consumer knows or should know." Plaintiff notes that judgment on the pleadings is only proper where the material facts are not in dispute, and in this case, the average consumer's knowledge of the harmful effects of indoor tanning is a disputed issue.

A Rule 12(c) motion is governed by the same standard as a Rule 12(b)(6) Motion to Dismiss for Failure to State a Claim, which includes a prohibition against considering evidence beyond the pleadings. *See Mele v. Federal Reserve Bank of New York,* 359 F.3d 251, 257 (3d Cir.2004).

In *Cippolone,* 893 F.2d 54, the Third Circuit held that whether the dangerous characteristics of cigarettes are known to the average consumer is an issue of fact for the jury. Nafar goes on to contend that the "common knowledge" test should not be read into the CFA. The purpose of the CFA is to prevent fraud or deception by acts of commission or omission. *See Fenwick v. Kay American Jeep, Inc.,* 72 N.J. 372, 376-77 (1999). Plaintiff argues that reading the common knowledge test into the CFA would be in contravention of the statute, emphasizing that the CFA is remedial and should be liberally construed to protect consumers.

Under the CFA, the "omission, of any material fact with intent that others rely upon such concealment ..." is unlawful. N.J.S .A. § 56:8-2. Hollywood Tans argues that it is only required to disclose information if it has a "duty to disclose," and the recognition of a legal duty is a question of law. In doing so, Hollywood Tans conflates a "duty to disclose" with the issue of materiality.

For Plaintiff to succeed on her CFA claim, she has the burden of demonstrating that the ill effects of tanning are "material facts," facts that would be important to a consumer's decision whether or not to purchase Defendant's product. It is the materiality of those facts, the ill effects of tanning, which is at is-

sue. The ill effects of tanning would not be material if the average consumer knows about these ill effects, and this information *would be material* if the average consumer does not know about the ill effects. Determining the materiality of a misrepresentation or omission is a question of fact, not a question of law.

Because both parties dispute the very existence of any ill effects related to tanning, this is an issue to be resolved at trial. At this pleading stage, all disputed issues of material fact are resolved in favor of the non-moving party.

IV. CONCLUSION

For the reasons stated, it is the finding of this Court that Defendant's motion for partial judgment on the pleadings is **denied .** An appropriate Order accompanies this Opinion.

D.N.J.,2007.
Nafar v. Hollywood Tanning Systems, Inc.
Not Reported in F.Supp.2d, 2007 WL 1101440 (D.N.J.)

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