The Center For Consumer Freedom®

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Docket No. FDA-2009-N-0018

Comments on the Food and Drug Administration draft report "Report of Quantitative Risk & Benefit Assessment of Commercial Fish Consumption, Focusing on Fetal Neurodevelopmental Effects and on Coronary Heart Disease & Stroke in the General Population"

Submitted by the Center for Consumer Freedom

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

To the FDA:

These comments address the potential impact of the FDA draft risk and benefit assessment report on seafood consumption and public health.

Research conducted by some of the world's leading epidemiologists has clarified that the current FDA/EPA seafood advisory has been sending consumers the wrong message. Though modest in its conclusions, the current FDA draft report is a crucial first step toward re-evaluating that advisory's net impact on Americans' health.

Most notable is the report's assessment of the health *benefits* of seafood consumption along with the risks associated with natural trace levels of methylmercury. This balanced approach to risk assessment is sorely overdue. In light of the growing body of research documenting positive cardiac, cardiovascular, cognitive, and other health benefits of eating significant amounts of fish, the report's departure from a risk-only assessment model is its most important feature.

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Consuming any food or beverage is an exercise in balancing benefits and risks. Recent investigations into the health advantages of consuming fish illustrate what should be obvious: Consumers are not ingesting methylmercury in a vacuum. Omega-3 fatty acids, selenium, and other nutrients and vitamins are consistently present in fish when trace levels of methylmercury are ingested. It is critical for the FDA to examine the total health effects of eating seafood so that it can communicate them to consumers most effectively and accurately.

Evidence is mounting that the current advisory's risk-only model of nutrition assessment is discouraging seafood consumption. The result, as National Institutes of Health researcher Dr. Joseph Hibbeln put it in 2007, is that the advisory "causes the harm that it was intended to prevent."[1]

The misinterpretation of the advisory by pregnant women is of particular concern. In the case of tuna—one of the most omega-3-rich fish—pregnant women who follow the advisory are unable to deliver sufficient omega-3 nutrients to the unborn child. According to one particularly robust study, the amount of canned tuna consumption required for a child *in utero* to avoid negative effects on brain development, and reap the cognitive advantages of omega-3 intake, is more than two cans per week.[2] This is explicitly greater than what the advisory permits.

Advocacy groups have claimed that data is lacking to support the fish-consumption impact of the current advisory. This is not true. The Center for Consumer Freedom has made data available to the public confirming Dr. Hibbeln's assessment. Using consumer-panel purchasing data from ACNielsen's "Homescan" program, we found last year that seafood consumption in general declined dramatically in households earning $30,000 or less between 2000 and 2006. The purchase of canned tuna in these underprivileged households—their *only* affordable source of omega-3s—dropped substantially. Over four million low-income households completely stopped buying canned tuna in that six-year period.[3]

Factoring in U.S. Census data and peer-reviewed studies about the role of omega-3s in cognitive development, we have calculated that 260,000 babies were born into those financially disadvantaged households during that time period. Because their mothers completely avoided eating fish during their pregnancies, those children were born at a significantly higher risk of developing abnormally low IQs.

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[1] Salynn Boyles, "Study Questions Fish for Pregnant Moms: FDA Advice on Fish Consumption By Pregnant Women May Do More Harm Than Good To Babies," *CBS News,* February 15, 2007 http://www.cbsnews.com/stories/2007/02/15/health/webmd/main2484126.shtml

[2] JR Hibbeln, "Maternal seafood consumption in pregnancy and neurodevelopmental outcomes in childhood: an observational cohort study," *The Lancet* 369.9561 (2007): 578-85.

[3] Center for Consumer Freedom, "Tuna Meltdown: How Green Groups and the Federal Government Put America's Poorest Children at Risk," (2009) http://www.mercuryfacts.org/downloads/TunaMeltdown.pdf

It's striking to contrast this finding with the claims of advocacy groups who insist that an epidemic of mercury toxicity demands government response. Thus far, the entire medical literature contains *zero* documented cases of methylmercury poisoning connected to the consumption of commercial fish in the United States.[4] Yet it's easy to project the impact upon more than a quarter-million poor children of an overreaching and widely misinterpreted government seafood advisory.

By incorporating seafood's beneficial nutrition profile into its health assessment of commercial seafood consumption, the FDA draft report has the potential to gradually steer public policy back toward consumers' best interests. However, it could have gone further in putting the risks associated with traces of methylmercury in seafood in better perspective.

We offer these brief criticisms of the FDA report for your consideration:

(1) The draft analysis of risks and benefits of seafood consumption should have recommended that the 2004 FDA/EPA advisory be revised or withdrawn. Consumers—even those in populations targeted by the advisory—acquire significant health benefits by eating fish. They simply cannot ingest the traces of methylmercury in fish without also gaining health advantages. Unfortunately, seafood consumption data suggest that the advisory has led them to believe otherwise.

    This fundamental weakness also introduces a bias into the risk assessment, because FDA and EPA seafood advisories have greatly exaggerated the likelihood of mercury toxicity related to commercially available fish.

(2) The FDA analysis missed an important opportunity to address the fact that advocacy group "education" campaigns influencing seafood consumption habits are often scientifically deficient. Many of these groups rely on the false presumption that seafood advice will only affect targeted populations, and few of them put government guidelines in the proper context of their included ten-fold safety factors. They also tend to ignore or distort research about the health benefits of fish consumption.

    The draft report is insufficiently candid about the weakness of anecdotal evidence and amateur experiments upon which these groups often rely. The FDA should caution the public that advice from advocacy group "experts" may not be reliable.

[4] Will Dunham, "Eat fish while pregnant, U.S. experts recommend," Reuters, October 4, 2007 http://uk.reuters.com/article/outsourcingNews/idUKLAU47849420071004

The popularity of amateur fish "testing" experiments based on the 2004 advisory, to name one example, has perpetuated the myth that one too many servings of sushi or other fish can cause mercury toxicity. In reality, of course, consumers would need to consume a very large amount of fish, consistently and over a long period of time, in order to incur any such risk. And Americans simply are not eating that much seafood.

(3) Because it builds on existing federal advisories, the report frames its analysis around the misleading distinction of so-called "low mercury" and "high mercury" fish. As the available consumer purchasing data indicates, many Americans have misinterpreted these designations to mean that so-called "high mercury" fish are uniformly too dangerous to eat. In fact, the tiny levels of methylmercury in *all* commercially available fish pose few (if any) health risks unless consumed in unrealistically large amounts.

Hypothetical health risks for Chilean sea bass (often considered a "high mercury" fish), for example, would begin at a weekly intake of more than 2 pounds for a 135 pound woman; and months, if not years, of steady consumption at this level would also be required.[5]

(4) Our own detailed analysis of omega-3 levels in different fish and shellfish indicates that typical U.S. consumption of *all* commercial varieties of fish offers significantly more health benefits than (even minimal) risks. We endorse this approach of communicating the nutritional value of eating fish as part of a revised risk evaluation.

By eating a single three-ounce serving of canned light tuna, for instance, a 135-pound woman acquires the proven health benefits[6] of:

Long-chain omega-3 fatty acids: 0.11g (21.9% of recommended daily intake)
Protein: 24.9g (49.5%)
Vitamin B12: 1.8mcg (31.2%)
Potassium: 177mg (5.1%)
Selenium: 64.5mcg (117.6%)
Iron: 1.17mg (6.6%)

That same 135-pound woman would need to consume *eight pounds* of canned tuna every week for a prolonged period of time to incur any hypothetical health risk from methylmercury.[7]

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[5] Calculation based on the "Benchmark Dose Lower Limit" (BDML) incorporated in the Environmental Protection Agency's Reference Dose and before the arbitrary 10-fold safety cushion.

[6] U.S. Department of Agriculture nutrient database search for "Fish, tuna, white, canned in water, drained solids
Fish, tuna, light, canned in oil, drained solids," http://www.nal.usda.gov/fnic/foodcomp/search/

(5) We have reviewed several recent studies which strongly suggest that the consumption of omega-3-rich fish such as tuna and salmon during pregnancy is crucial to the developing fetal brain.

While the draft report incorporates the same research, it does not go far enough in emphasizing that these nutritional benefits—such as improved heart health, lower risk of cardiovascular disease, and fetal cognitive development—far outweigh the incredibly slim (and historically constant) risks associated with methylmercury exposure.

(6) It is also increasingly clear from ACNielsen purchase data that the current seafood consumption advisory is commonly misinterpreted by Americans *outside* its population targets. A 2006 Institute of Medicine report warned of a "spillover effect" seen when Americans wrongly follow fish advisories not intended for them.[8]

By every reliable measure, Americans do not eat enough fish. In 2005, when asked under oath in a California courtroom if there is a "scientific consensus" that "people in America would be better off eating more fish," former U.S. Secretary of Health and Human Services Dr. Louis Sullivan testified: "Very definitely, yes."[9]

Based on careful analysis of the draft report, we recommend that FDA take the following actions:

- Consider the draft risk/benefit assessment as the first step toward a more prudent and scientifically sound public policy. Abandon any plans to continue the use of a "risk only" model of assessment as a basis for policy decisions.

- Revise or withdraw the outdated 2004 seafood advisory, in order to reflect scientific consensus about the health benefits of seafood consumption and put the comparatively minuscule risks of getting mercury poisoning from seafood into more realistic perspective.

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[7] Calculation based on the BDML incorporated in Environmental Protection Agency's Reference Dose, before the arbitrary 10-fold safety cushion.

[8] Institute of Medicine, "Seafood Choices: Balancing Benefits and Risks," (2006) http://www.iom.edu/CMS/3788/23788/37679.aspx

[9] *People v. Tri-Union Seafoods* (Cal. Super. Ct. CGC-01-402975). 14 Tr. 1720:19-21-1721:4-7. San Francisco Superior Court Judge Robert Dondero also recounted Dr. Louis Sullivan's testimony in his opinion (page 4 at http://www.consumerfreedom.com/downloads/reference/docs/060512_mercury_decision.pdf).

- During the interim, while action is being considered, develop an “add-on” to the current advisory to communicate the health advantages of omega-3 fatty acids in fish; recommend that this add-on be posted wherever the current advisory is displayed to consumers.

- Expand efforts to promote the nutritional benefits of fish consumption to shoppers in poverty-level U.S. households.

Thank you for considering these comments.

Respectfully submitted,

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The Center for Consumer Freedom is a 501(c)(3) nonprofit organization.