COMMENTS OF THE COMPETITIVE ENTERPRISE INSTITUTE
REGARDING THE FDA'S
DRAFT REPORT OF QUANTITATIVE RISK AND BENEFIT ASSESSMENT OF CONSUMPTION OF COMMERCIAL FISH, FOCUSING ON FETAL NEURODEVELOPMENT EFFECTS (MEASURED BY VERBAL DEVELOPMENT IN CHILDREN) AND ON CORONARY HEART DISEASE AND STROKE IN THE GENERAL POPULATION
AND
DRAFT SUMMARY OF PUBLISHED RESEARCH ON THE BENEFICIAL EFFECTS OF FISH CONSUMPTION AND OMEGA-3 FATTY ACIDS FOR CERTAIN NEURODEVELOPMENTAL AND CARDIOVASCULAR ENDPOINTS

Docket No. FDA-2009-N-0018
74 Fed. Reg. 3615 (January 21, 2009)

The Competitive Enterprise Institute respectfully submits these comments on the agency's *Draft Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish* (Draft Risk and Benefit Assessment) and *Draft Summary of Published Research on the Beneficial Effects of Fish Consumption and Omega-3 Fatty Acids* (Draft Summary of Published Research). These documents represent the agency's first response to a 2006 report from the National Academies of Science's Institute of Medicine (IOM), which noted that scientific research has identified various health benefits of seafood consumption and called for a better way "to characterize the risks combined with the benefits" derived from eating commercial fish species.[1]

The Competitive Enterprise Institute (CEI) is a 501(c)(3) non-profit public interest group dedicated to promoting rational risk regulation and consumer choice. CEI has a long history of research and advocacy regarding the regulation of health and safety risks, with a particular emphasis on food and drug safety. We have frequently observed that attempts to limit exposure to certain risks unintentionally increases exposure to other, potentially more hazardous risks. Consequently, we applaud the FDA's decision to carefully study the growing body of scientific literature examining the net health impact of fish consumption and to consider the beneficial effects of fish consumption and Omega-3 fatty acids along with the hazards associated with exposure to methylmercury.

The overwhelming weight of this scientific evidence suggests that consumption of most commercial fish species provides substantial net health benefits. In addition to being a good source of dietary protein, seafood is a uniquely beneficial source of essential dietary nutrients such as Omega-3 fatty acids that contribute to cardiac health

[1] Institute of Medicine, Committee on Nutrient Relationships in Seafood: Selections to Balance Benefits and Risks, *Seafood Choices: Balancing Benefits and Risk* (Washington, D.C.: National Academy Press, 2006) p. 6.

and fetal development.[2] Accordingly, the *Dietary Guidelines for Americans* jointly issued by the U.S. Department of Health and Human Services and U.S. Department of Agriculture in 2005 recommend consuming two eight-ounce servings of fish each week for optimal health.[3] Similarly, the American Heart Association recommends eating fish (particularly fatty fish) at least two times a week because "[f]ish is a good source of protein and doesn't have the high saturated fat that fatty meat products do."[4] And the American College of Obstetricians and Gynecologists has long encouraged pregnant women to consume two to three servings of fish each week to ensure healthy babies.[5]

In addition, most commercial fish species contain relatively small amounts of methylmercury. The four fish species containing the highest levels of methylmercury (an average greater than 1.0 part per million) in the commercial fish supply constitute less than one percent of U.S. fish consumption.[6] Thus, even if current dietary levels of mercury exposure in certain fish species were to pose some small risk, the benefits obtained by consuming fish vastly outweigh the risk associated with exposure to mercury. According to Walter Willett, professor of nutrition at the Harvard University School of Public Health, the benefits of eating seafood "are likely to be at least 100-fold greater than the estimates of harm, which may not exist at all."[7]

Unfortunately, there is evidence that increasingly stern warnings about the effects of methylmercury exposure have led some consumers to reduce the amount of fish in their diets. Data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey indicate that nearly 95 percent of U.S. women of childbearing age eat less than 12 ounces of fish per week.[8] And a study examining fish consumption trends before and after the FDA's 2001 mercury advisory found that, following the advisory, pregnant women in particular reduced their consumption of fish

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[2] Dariush Mozaffarian and Eric B. Rimm, "Fish Intake, Contaminants, and Human Health: Evaluating the Risks and the Benefits," *Journal of the American Medical Association*, Vol. 296, No. 15 (2006) pp. 1885-99; Hiroyasu Iso, Kathryn M. Rexrose, Meir J. Stampfer, JoAnn E. Manson, Graham A. Colditz, Frank E. Speizer, Charles H. Hennekens, and Walter C. Willett, "Intake of Fish and Omega-3 Fatty Acids and Risk of Stroke in Women," *Journal of the American Medical Association*, Vol. 285, No. 3 (2001) pp. 304-12; Penny Kris-Etherton, W.S. Harris, and Lawrence J. Appel, "Summary of the Scientific Conference on Dietary Fatty Acids and Cardiovascular Health, Nutrition Committee of the American Heart Association," *Circulation*, Vol. 103, No. 7 (2001) pp. 1034–39.

[3] Dietary Guidelines Advisory Committee, *Nutrition and Your Health: Dietary Guidelines for Americans* (Washington, D.C.: U.S. Department of Health and Human Services and U.S. Department of Agriculture, 2005).

[4] American Heart Association, "Fish and Omega-3 Fatty Acids: AHA Recommendation," AHA website (accessed April 17, 2009), available at http://www.americanheart.org/presenter.jhtml?identifier=4632.

[5] Statement of Dr. Charles Lockwood, Chairman of the American College of Obstetricians and Gynecologists' Panel on Obstetric Practice, before an FDA Food Advisory Committee meeting on methylmercury, July 23-24, 2002.

[6] Center for Food Safety and Applied Nutrition, Draft *Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopment Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population* (Rockville, Md.: U.S. Food and Drug Administration, January 15, 2009) p. 13.

[7] Sally Squires, "Good Fish, Bad Fish: Sorting Seafood's Benefits from Risks Can Leave Consumers Floundering," *Washington Post*, August 8, 2006, F1, 5.

[8] Center for Food Safety and Applied Nutrition, Draft *Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish*, p. 85.

by approximately 1.4 servings per month due to fears about mercury exposure.[9] Because the consumption of the Omega-3 fatty acids DHA and EPA appears to be critical to the diets of pregnant women and nursing babies to ensure optimal vision, behavioral, and cognitive development,[10] there is reason to believe that developing fetuses and nursing babies are put at much greater risk by the reduction in their mothers' fish consumption than they are by the presence of methylmercury in commercial seafood.

Of course, FDA is not the only source of information about methylmercury in fish. The most dire warnings about fish consumption have come from environmental and consumer activist organizations pursuing regulatory policies that mandate reduced mercury emissions from power plants.[11] However, the focus on methylmercury risks in the FDA's and the Environmental Protection Agency's mercury advisories can provide a misleading picture of the net health impacts of fish consumption. The end result of these warnings is that consumers are unnecessarily frightened away from eating fish, and they may therefore be put at greater health risk than they would be with more complete information. As the Draft Risk and Benefit Assessment notes, "[a] risk/benefit approach can provide a holistic view of the overall consequences of any risk management strategy."[12] Such a holistic view is important to the promotion of overall public health.

It is therefore appropriate that the FDA should undertake a thorough analysis of the net health effects of consuming commercial fish species, and that it should endeavor to provide information about methylmercury risks that are put in an appropriate overall context. Only by doing so can the agency provide sufficient information to guide consumers in their dietary choices. As the IOM's 2006 report notes, it is important that consumers understand that there may be greater risks of reducing fish consumption, or of eating no fish at all, than of consuming seafood that contains methylmercury at the levels currently found in most commercial fish species.[13]

Peer reviewers and the FDA itself make note of various limitations in the published literature and in the agency's study methodology, both of which are reflected in shortcomings of the Draft Risk and Benefit Assessment and Draft Summary of Published Research. Importantly, the Draft Risk and Benefit Assessment does not distinguish among various fish species that may have greater or lesser amounts of both methylmercury and beneficial nutrients, for a species-by-species net health analysis. Due

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[9] Emily Oken, Ken. P Kleinman, Wendy E. Berland, Steven R. Simon, Janet W. Rich-Edwards, and Matthew W. Gillman, "Decline in Fish Consumption Among Pregnant Women After a National Mercury Advisory," *Obstetrics & Gynecology*, Vol. 102, No. 2 (2003) pp. 346-351.

[10] JL Daniels, MP Longnecker, AS Rowland, and J Golding, "Fish Intake During Pregnancy and Early Cognitive Development of Offspring," *Epidemiology*, Vol. 15, No. 4 (2004) pp. 394-402.

[11] *See, for example*, Michael Shore, *Out of Control and Close to Home: Mercury Pollution from Power Plants* (New York: Environmental Defense Fund, 2003); Environmental Working Group, "FDA's Midnight Mischief Heightens Mercury Risk to Pregnant Women, Infants," EWG website (December 12, 2008) available at http://www.ewg.org/book/ export/html/27431. *See also* Sandy Szwarc, *Fishy Advice: The Politics of Methylmercury in Fish and Mercury Emissions* (Washington, D.C.: Competitive Enterprise Institute, 2004).

[12] Center for Food Safety and Applied Nutrition, Draft *Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish*, p. 5.

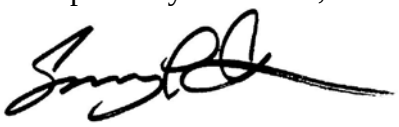
[13] Institute of Medicine, *Seafood Choices: Balancing Benefits and Risk*, p. 6.

to insufficient availability of published research on the topic, the draft assessment also does not examine all relevant neurodevelopmental or cardiovascular health endpoints. Nor does it estimate the likely net health impacts of various sub-populations who may consume higher than average amounts of certain fish species that may contain especially high amounts of methylmercury. It would be appropriate for the agency to conduct additional analyses when feasible in order to rectify these shortcomings. Still, some critics have inappropriately criticized the mere attempt to measure net health impacts of fish consumption, which they characterize as an effort to "mislead consumers about mercury in fish."[14]

The goal of warning consumers about the presence of methylmercury in fish appeals to the common sense notions that providing information about potential risks and "erring on the side of caution" must necessarily be beneficial. However, it is not uncommon for well-meaning public policies aimed at improving public health to have unintended effects that do more harm than good. That can ultimately lead consumers, not in the direction of greater safety, but toward greater danger. Far too often, public health interventions are based on the false premise that no harm can ever come from avoiding exposure to harmful substances. But, public health policy should never be based on a premise that systematically and intentionally fails to consider both sides of the risk equation. Thus, the assumption that it is better for FDA and other agencies to inform consumers only about the hazards associated with methylmercury exposure in commercial fish than to provide balanced and scientifically-validated information about the net health effects of seafood consumption is misguided and would likely put consumers at heightened risk.

The FDA's Draft Risk and Benefit Assessment and Draft Summary of Published Research reflect an effort by the agency to quantify the net health impact of consuming commercial fish species. By aggregating the results of a large body of peer reviewed published research, the documents provide additional scientific information about the likelihood and magnitude of both beneficial and negative health effects of seafood consumption. They therefore represent important contributions to the public health literature, and they should be considered more fully in future public policy development.

Respectfully submitted,



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April 21, 2009

[14] *See*, Environmental Working Group, "FDA's Midnight Mischief Heightens Mercury Risk to Pregnant Women, Infants."