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Dear Commissioner Hamburg and Administrator Jackson:

We are writing to urge you to update and expand the 2004 EPA/FDA joint consumer advisory[1] and to improve your respective agencies' risk communication efforts on methylmercury and fish consumption. Research since the advisory was developed has enhanced our understanding of the benefits and risks of fish consumption, and we believe advice that is more detailed and nuanced than what the current advisory offers is now required.

The 2004 advisory is nominally based on the Reference Dose (RfD), developed by the EPA in 1999.[2] Studies published since the RfD was promulgated have addressed uncertainties that permeated earlier research on the effects of prenatal exposure to methylmercury on cognitive development. Beneficial fish nutrients and methylmercury each can affect prenatal brain development, with antagonistic effects that may mask each other. But recent studies with improved statistical methods have done a better job of controlling for confounding, and have yielded several important new insights:

- When the results from the prospective epidemiological study in the Faeroe Islands were reanalyzed to take into account imprecision in the mercury exposure assessment and the beneficial effects of maternal fish consumption during pregnancy on children's cognitive development, the adverse effects of methylmercury were determined to be about twice as large as had originally been reported.[3]
- When the team conducting the prospective epidemiological study in the Seychelles Islands sought to measure beneficial effects of prenatal fish consumption on cognitive development, they were unable to detect statistically significant benefits. But by separating beneficial and adverse effects, they for the first time reported methylmercury damage to the developing nervous system in their study cohort. The investigators concluded that adverse effects had probably been masked by beneficial effects (and vice-versa) in prior analyses.[4]

- An ongoing epidemiological study in Boston has measured cognitive development at the ages of six months[5] and three years[6] in children born to women whose fish consumption and mercury exposure during gestation were determined. High fish consumption was associated with higher scores on cognitive tests, while elevated mercury exposure was associated with lower scores. The positive and negative effects were of about the same magnitude, from 2 to 6 points on a 100-point scale for various measures used.[7] Women enrolled in the Boston study eat typical American diets, averaging about one fish meal per week, and their mercury exposure quite closely fits the national profile from the 1999-2004 NHANES sample.
- An epidemiological study in New York City has associated beneficial effects on cognitive development with maternal fish consumption during pregnancy, and found adverse effects of elevated methylmercury exposure, in children examined at 12, 24, 36 and 48 months.[8] As in the Boston study, the New York women had fish consumption and mercury exposure levels typical of US women as a whole. The geometric mean blood mercury level in the New York cohort was 0.91 µg/L, compared to 0.92 µg/L for the 1999-2002 NHANES sample.[9]
- Although prenatal exposure (including the mother's exposure before she is pregnant) remains the top public-health concern, other subpopulations are known to have elevated mercury exposure. Surveys in Wisconsin[10] have found middle-aged and older men to be the most highly exposed group; 30 percent of older men had elevated hair mercury, compared to just 12 percent of women of childbearing age.

These and other recent studies strongly suggest several conclusions: Maternal fish consumption during pregnancy can significantly benefit prenatal cognitive development, while exposure to methylmercury during gestation can significantly damage prenatal cognitive development. Both beneficial and adverse effects have now been associated with ordinary American levels of fish consumption. In particular, adverse effects have been observed at dose levels near or below the RfD for methylmercury, and no evident threshold for these effects has been identified within the range of typical US exposures. And, while they are still the central focus of public health concern, women of childbearing age are not the only population that needs guidance about minimizing methylmercury exposure from fish consumption.

The association of both clear benefits and risks of harm with ordinary fish consumption requires messages that address both elements in a balanced way. While some nutritionists encourage all Americans, including women of childbearing age, to eat more fish, such advice must be coupled with the caution to choose low-mercury fish. (For example, many states now offer advice to "Eat fish, be smart, choose wisely," or variations on that theme.)

In 2009, the FDA published a draft quantitative risk/benefit analysis of fish consumption and the methylmercury exposure associated with it.[11] That draft was extensively criticized for pervasive bias, data selection and data omission errors, and other scientific flaws.[12] Although FDA has said it is revising the draft, the EPA has objected to FDA's process, stating a strong preference for a

multi-agency approach.[13] While its exact status is unclear, some have urged the Commissioner to finalize the document, and promulgate it as a basis for policy.[14]

We disagree. If such an analytical effort is to be pursued at all, it should be by a joint interagency task force, one that includes expertise FDA does not possess and did not bring to bear on its draft analysis. However, given uncertainties in evidence for both benefits and risks in this case, efforts to quantify and compare the two will inevitably require arbitrary assumptions that must seriously limit the validity of the results. Although such an analysis might identify critical data gaps and research needs, we do not believe a quantitative risk-benefit analysis on this topic can currently provide a valid scientific basis for policy. We therefore urge FDA formally to withdraw its effort to quantify these effects. An open concession that current science cannot produce a credible quantitative risk-benefit comparison on this topic, and that FDA is therefore abandoning the effort, should help restore badly diminished public confidence in the agency's commitment to rely on sound scientific data and methods.

Instead, EPA and FDA should proceed to update and expand their current joint advisory on fish consumption and methylmercury exposure, relying on qualitative concepts and common sense. The following principles should guide improved advice:

(1) There is no need to choose between benefits and risks or to trade one off against the other. Consumers can enjoy nutritional benefits of fish consumption and minimize methylmercury exposure, by choosing lower-mercury fish.

(2) Mercury cannot be regulated out of the seafood supply—at least, not in the short term. The most practical option is for consumers to manage their own exposure. To support that approach, consumers need better information than they are generally now getting.

(3) Because popular seafood choices vary by more than 100-fold in average mercury content,[15] which fish a person chooses to eat is the primary determinant of his or her methylmercury exposure. Consumers therefore need more specific information about the relative mercury content of the full range of seafood choices.[16]

(4) Although women of childbearing age should remain a primary focus of advice, a number of reports have been published of clinical methylmercury poisoning in adults who ate high-mercury fish frequently.[17] As a matter of common sense, consumers of both genders and all ages who eat fish often (twice a week or more) should be advised about mercury exposure risks, and guided to choose lower-mercury seafood varieties.

The current EPA/FDA joint advisory on fish consumption and methylmercury is deficient in the following ways:

- It urges women of childbearing age to consume no more than 12 ounces of fish and shellfish per week, needlessly limiting potential nutritional benefits.

- It assumes that no one eats more than 12 ounces of seafood a week, ignoring several percent of the population who currently do exceed that intake level[18] and offering no advice for high-end consumers, despite the obvious likelihood that such high-end consumers bear the greatest risk of excessive methylmercury exposure.
- It lists only five high-mercury fish varieties as choices for women to avoid or limit intake of, and names just five "lower-mercury" choices, offering no advice about the rest of the seafood market except to "eat a variety of other fish." That "other fish" category includes 41 seafood items that range from 0.010 to 0.554 ppm mercury, and which of those the items one chooses to eat can profoundly affect a consumer's methylmercury exposure.
- It recommends canned light tuna as a "lower-mercury" choice, although canned light tuna has an above average methylmercury level and is the largest single source of mercury exposure in the US diet.[19] FDA has acknowledged that it included canned light tuna in the "lower-mercury" category to avoid harming the market for this staple item.[20]
- It is addressed only to women of childbearing age and parents of young children, ignoring other population subsets' needs for guidance to manage methylmercury exposure.

We believe the nutritional and environmental health communities should come together behind a unified message: "Eat fish, and choose wisely to minimize methylmercury exposure." Several states already agree on that advice. To follow such advice, however, consumers need better information about the mercury content of all widely available seafood choices, not just the handful listed in the current joint advisory. We believe the attached chart[21] offers a prototype of more complete information needed to support sound consumer choices.

We therefore request that EPA and FDA update and expand their joint consumer advisory on fish consumption and methylmercury exposure, to include the following changes and improvements:

- Better integrate messages on benefits and risks.
- Emphasize that the more fish one eats, the greater the likely nutritional benefit, and the greater the need to be aware of mercury content and choose lower-mercury items.
- Sort all popular fish and shellfish varieties (such as the 51 market categories developed by FDA) by mercury content, as in the attached chart.
- Expand monitoring of mercury levels in commercially-caught fish and shellfish, to provide a better basis for that sorting.
- Separately, sort the same fish and shellfish market categories by omega-3 unsaturated fatty acid content.
- Explicitly address advice to people who eat fish often (twice a week or more), whether or not they are women of childbearing age.

- Because some people eat both commercially caught fish and sport-caught fish, integrate advice about mercury exposure from both types in a single advisory.

- Stop recommending canned light tuna as a low-mercury choice. Let the fact of canned light tuna's above-average mercury level (as reflected in the attached chart and in FDA's own analyses) speak for itself.

In addition to updating, improving and expanding the joint advisory, we also urge your agencies to substantially increase your efforts to promote public awareness and understanding of this advice, which several surveys have shown are disappointingly low. In this regard, federal support for and coordination of state and private-sector initiatives to provide point-of-sale information on the mercury content of different seafood choices is urgently needed.

Please do not hesitate to contact us if you, or your staff, have questions or need additional information.

Sincerely,[22]

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Guide to mercury levels in different varieties of fish and shellfish

LOW-MERCURY FISH AND SHELLFISH

VERY LOW	BELOW AVERAGE
Shrimp	Pollock
Sardines	Atlantic Mackerel
Tilapia	Anchovies, Herring & Shad
Oysters & Mussels	Flounder, Sole & Plaice
Clams	Crabs
Scallops	Pike
Salmon	Butterfish
Crayfish	Catfish
Freshwater Trout	Squid
Ocean Perch & Mullet	Atlantic Croaker
	Whitefish

MODERATE-MERCURY FISH AND SHELLFISH

ABOVE AVERAGE	MODERATELY HIGH
Pacific Mackerel (Chub)	Carp & Buffalofish
Smelt	Halibut
Atlantic Tilefish	Sea Trout
Cod	Sablefish
Canned Light Tuna	Lingcod & Scorpionfish
Spiny Lobster	Sea Bass
Snapper, Porgy, Sheepshead	Pacific Croaker
Skate	American Lobster
Freshwater Perch	Freshwater Bass
Haddock, Hake, Monkfish	Bluefish

HIGH-MERCURY FISH

HIGH	VERY HIGH
Canned Albacore Tuna	King Mackerel
Spanish Mackerel	Swordfish
Fresh/Frozen Tuna	Shark
Grouper	Gulf Tilefish
Marlin	Tuna Sushi/Bluefin Tuna
Orange Roughy	

Notes and References

[1] EPA/FDA Advisory, http://www.epa.gov/waterscience/fish/files/MethylmercuryBrochure.pdf.
[2] US EPA Reference Dose for Methylmercury, http://www.epa.gov/ncea/pdfs/methmerc.pdf.
[3] Budtz-Jørgensen, E., Grandjean, P., Weihe, P., 2007. Separation of risks and benefits from fish consumption. Environ. Health Perspect. 115, 323-327. Also, Budtz-Jørgensen, E., Keiding, N., Grandjean, P., 2004. Effects of exposure imprecision on estimation of the benchmark dose. Risk Anal 24,1689-1696.
[4] Davidson, P.W., Strain, J.J., Myers, G.J., et al., 2008. Neurodevelopmental effects of maternal nutritional status and exposure to methylmercury from eating fish during pregnancy. Neurotoxicol. 29, 767-775.
[5] Oken, E., Wright, R.O., Kleinman, K.P., Bellinger, D., Amarasiriwardena, C.J., Hu, H., et al., 2005. Maternal fish consumption, hair mercury, and infant cognition in a U.S. cohort. Environ. Health Perspect. 113, 1376-1380.
[6] Oken, E., Radesky, J.S., Wright, R.O., Bellinger, D.C., et al., 2008. Maternal fish intake during pregnancy, blood mercury levels, and child cognition at age 3 years in a US cohort. Am. J. Epidemiol. 167, 1171-1181.
[7] Ibid.
[8] Lederman, S.A., Jones, R.L., Caldwell, K.L., et al., 2008. Relation between cord blood mercury levels and early childhood development in a World Trade Center cohort. Environ. Health Perspect. 116, 1085-1091.
[9] Ibid.
[10] Knobeloch, L., Gliori, G., and Anderson, H. 2007. Assessment of methylmercury exposure in Wisconsin. Environ. Res. **103**(2):205-10. Also, Knobeloch, L., 2005. Population-based methylmercury exposure assessment. Final report to the Wisconsin Department of Administration, Division of Energy.
[11] US Food and Drug Administration, 2009. Draft Risk and Benefit Report. Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population. Center for Food Safety and Applied Nutrition, 15 January.
[12] For example, see comments submitted to Docket FDA-2009-N-0018 by Philippe Grandjean, Kathryn Mahaffey/ Oceana, Edward Groth/Mercury Policy Project, The Environmental Working Group, and Jane Hightower, MD.
[13] US EPA, Public Comments on the FDA's draft Risk-benefit Analysis (Note 10), dated April 17, 2009.
[14] For example, on May 28, 2010, two nutrition professors sent an "open letter" to FDA Commissioner Hamburg, urging the agency to revise its advisory to promote the benefits of seafood consumption and downplay risks from methylmercury, suggesting that mercury warnings may do more harm than good. See news coverage of this public communication at http://www.seafoodsource.com/newsarticledetail.aspx?id=4294996154. A seafood industry-funded "expert group" convened under the auspices of the Healthy Mothers Healthy Babies Coalition in 2007 promoted the same policy shift (see http://www.hmhb.org/oceanfishpr.html), as did numerous seafood industry comments on the FDA's draft Risk-benefit Analysis.
[15] FDA database on mercury levels in commercial fish and shellfish, http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm115644.htm.
[16] Groth, E., 2010. Ranking the contributions of commercial fish and shellfish varieties to methylmercury exposure in the United States: Implications for risk communication. Environ. Res. 110, 226-236.
[17] Multiple cases were reported by Knobeloch, L., Steenport, D., Schrank, C., Anderson, H., 2006, Methylmercury exposure in Wisconsin: A case study series. Environ. Res. 101, 113-122. An additional case was reported by Risher, J.F., 2004, Too much of a good thing (fish): methylmercury case study. J. Environ. Health 67, 9-14, 28. Two dozen similar cases were reviewed and analyzed by Groth, E., 2008, *Over the Limit: Eating too much high mercury fish.* Mercury Policy Project http://mercurypolicy.org/wp-content/uploads/2008/12/mppoverthelimit.pdf.
[18] The FDA Risk-Benefit Analysis cited in Note 10, above, models the distribution of US fish consumption. FDA estimates that women at the 95th percentile of consumption eat an average of 345 grams of fish and shellfish per week, or about two six-ounce servings. For men, average consumption at the 95th percentile is 450 grams, about two eight-ounce servings per week. See FDA Draft RBA, Appendix B, Table AB-1.
[19] Groth 2010, see Note 15, above.
[20] Remarks by FDA's Clark Carrington at the 10 December 2003 meeting of the FDA Food Advisory Committee. Transcript, pp. 162-163 : http://www.fda.gov/ohrms/dockets/ac/03/transcripts/4010t1_.htm.
[21] Adapted from Groth 2010.
[22] Listed alphabetically. Many of those signing this letter have signed as individuals and public health scientists. Institutional affiliations are provided for purposes of identification and do not imply the endorsement of the named organizations.