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Docket No. FDA-2009-N-0018

COMMENTS ON the Food & Drug Administration Report on its
“Quantitative Risk and Benefit
Assessment of Commercial Fish Consumption,”

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

Dear Sir or Madam:

The undersigned organizations are pleased to submit these comments on the draft FDA Quantitative Risk and Benefit Assessment of Commercial Fish Consumption,” which we will refer to simply as the “Food & Drug Administration (FDA) report.”

Our overall impression is that this report is scientifically unsound and should not be the basis for any policy change by FDA with respect to the federal fish consumption advisory for mercury. Lack of adequate recent data detailing the consumption of fish with higher mercury levels and other critical data gaps have required FDA to make arbitrary, untested, and in some cases, obviously unsound and inappropriate assumptions in its model. FDA’s interpretation of many of the critical studies it cites is scientifically untenable, and the report is strongly biased in ways that undercut the credibility of the results. The analysis is therefore of very limited scientific value, except as a guide for research to collect data needed to carry out a more credible assessment.

We therefore believe the FDA report is an unsound and unacceptable basis for policy decisions. In addition, its very existence, and the enormous amount of effort it represents, suggest that policy should depend on the relative magnitude of fish nutritional benefits compared with methylmercury risk. This is an unsupportable proposition. The record clearly shows that consumers can enjoy the benefits they get by eating fish, *and* avoid the risks, by choosing low-mercury fish.

Moreover, the message that consumers should eat low-mercury fish is the essence of the joint EPA/FDA 2004 advisory on mercury in fish and seafood. FDA should be working much harder to disseminate that important and indisputably valid health message. Instead, by pouring resources into this analytical endeavor, the agency seems to suggest that it had had no basis for the 2004 advisory. The report muddies the waters by often implying that all fish

are alike in terms of risks and benefits, obscuring vital distinctions between high-mercury and low-mercury fish. It sows confusion where clear, effective communication is needed.

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

(1) The draft analysis of risks and benefits of fish and seafood consumption violates a basic principle of risk analysis, by attempting both a scientific task (risk assessment) and a value-laden risk management task (balancing risk against benefit) in the same analysis. This fundamental weakness introduces massive errors and biases into the risk assessment.

The most obvious bias involves commitment to a model that seeks to quantify the “net” effects of fish consumption, a largely meaningless construct. This decision forces many data-selections, data conversions and arbitrary assumptions, based on modeling criteria rather than sound scientific criteria such as data quality, relevance, degree of uncertainty, and the like. This bias also seems to have favored continuing with the analysis despite inadequate data that largely vitiate its results. A more subtle but equally important bias is the obvious higher priority given to, and greater interest of the authors in, documenting benefits of fish consumption, rather than assessing methylmercury risks. The “net” result is a benefits-driven model that fails to come adequately to grips with several critical risk-related issues.

(2) The FDA analysis is severely scientifically deficient. The model developed in the report is based on innumerable necessary, but often invalid, questionable and/or untested assumptions about mercury exposure, intake of beneficial nutrients, magnitude of effects, and many other critical factors. The report contains numerous scientific errors, ranging from a widespread failure to understand and correctly interpret epidemiological data, to occasional attempts to restate the findings of pivotal studies in terms more amenable to the FDA’s analytical model. More often than not, these efforts distort and misrepresent original research findings.

In our judgment, the draft report is insufficiently candid about the weaknesses in the data it relied on; the arbitrary, debatable nature of many of its key assumptions; and the strong likelihood that its interpretations of key studies differ from judgments of the same data made by experts in the research fields the data are drawn from. This lack of scientific caveats tends to understate the enormous uncertainties about and the questionable validity of the results, projecting false confidence that the analysis is reliable, when in fact its credibility is very much in doubt.

(3) The report frames its analysis around a false dichotomy: Should consumers eat fish to gain nutritional benefits, and accept the risks of mercury exposure? Or should they avoid fish to minimize mercury exposure, and lose out on the benefits? This mind-set pays too little attention to the obvious “win/win” approach, advising consumers to eat more *low-mercury* fish.

(4) In its comments, The Mercury Policy Project provides a detailed analysis of mercury levels in different fish and shellfish, showing the contributions of 51 different varieties of seafood to the mercury in the US supply of fish and shellfish. MPP separates the fish and seafood items into six categories, by mercury levels. We endorse that approach, which among other findings, supports the following conclusions:

- Very-low-mercury fish make up 43 percent of the total annual seafood market but contain just 9.1 percent of the total mercury. This category includes several widely consumed fish and shellfish, such as shrimp, salmon, tilapia and sardines, showing that consumers can easily find very-low-mercury varieties, if motivated to do so.
- Three categories with higher mercury levels include 20 varieties of fish and shellfish. Combined, these 20 items account for just 9 percent of the seafood market, but have 41 percent of the mercury in the US supply.
- Tuna fish (canned albacore, canned light and fresh/frozen combined) accounts for 37 percent of the total mercury. Canned light tuna and canned albacore tuna each contain about 16 percent of the total mercury in the seafood supply.
- Swordfish, tilefish, shark and king mackerel make up just 0.6 percent of the supply of fish and shellfish, but contain 6.5 percent of the total mercury—almost as much as the entire very-low-mercury category, which is 43 percent of the supply.
- Canned light tuna contains 37 percent more mercury than the weighted average for the fish supply as a whole, and is the largest single source of Americans' exposure to methylmercury. There is no rational way it can be considered a low-mercury choice.

These findings are examples of exactly the kind of information that needs to be offered to consumers, so that they can intelligently manage their mercury exposure while they enjoy a variety of fish and shellfish in their diets.

(5) MPP's comments review several recent scientific studies that strongly suggest that exposure to methylmercury can harm the developing fetal brain, even at the low doses associated with typical American fish consumption. There appears to be no threshold for this toxic effect within the range of ordinary exposure. Nutritional benefits of maternal fish consumption during pregnancy do not reduce the urgent need to help women avoid this entirely avoidable risk by advising them to choose low-mercury fish. FDA's draft report cites several of the studies but fails to grasp their significance.

(6) MPP also reviews evidence that strongly suggests that toxic effects of methylmercury occur in populations other than women of childbearing age, such as adults and children who consume much more fish than average and repeatedly eat high-mercury fish. MPP estimates that there are 275,000 Americans whose blood mercury levels are above the 99.9th percentile. Those individuals may experience subtle toxic effects, and are clearly a second population at risk from mercury in the fish they eat. Here, too, we see an urgent need to communicate effectively to such consumers the information they need to choose low-mercury fish.

Based on the points made here, we ask FDA to take the following actions:

- Consider the draft risk/benefit assessment to be an object lesson in the difficulty of doing such an assessment, with results that are not scientifically credible. Abandon any plans to use this assessment as a basis for policy decisions.
- Begin again and focus on collecting data that will support a sounder risk assessment, one that focuses on the consumption of higher-mercury fish. The first step probably should be to commission a survey to get much better data about consumption of fish and shellfish varieties with elevated (i.e., > 0.1 ppm) mercury levels.

- Promote the nutritional benefits of fish consumption *and* the importance of reducing mercury exposure by consistently and unequivocally advising consumers to choose low mercury fish.
- Expand efforts to disseminate the current EPA/FDA advisory on mercury in fish, which has not yet reached most Americans effectively.
- Develop a new, additional advisory for people who eat a great deal of fish, making clear the mercury levels in different fish and shellfish, and consumers' need to pick low-mercury varieties.
- Provide more extensive and detailed information to consumers that sorts fish into categories by mercury content, as displayed in Table 2.
- Actively support state and private-sector initiatives to place information about the mercury content of different fish on display at points of sale.
- Revise the current EPA/FDA advisory and all related information to remove canned light tuna, a fish with above-average mercury content, from the list of "low-mercury" fish and shellfish choices.
- Enforce the Action Level. The current policy of allowing fish that contain more than 1 ppm to be sold without penalty sends a message that mercury in fish is not a public health concern. Some enforcement is needed to reverse that misimpression.
- Consider making a joint request, with the EPA, for a new NAS/NRC review of recent scientific evidence on health effects of methylmercury, with emphasis on evidence that ordinary levels of exposure, associated with average fish consumption, can have significant adverse impacts on prenatal cognitive development.

Thank you for considering these comments.

Respectfully submitted,

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