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United States Senate

WASHINGTON, DC 20510

January 11, 2001

The Honorable Donna E. Shalala
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Shalala:

We understand the Food and Drug Administration is considering revising its consumer advisory regarding methylmercury contamination in commercial seafood. We strongly support a revision consistent with the conclusions of the recent National Academy of Sciences (NAS) report, one that effectively protects Americans, especially at-risk populations such as pregnant women and young children, from methylmercury exposure. As we have written to you before, this revision is needed as soon as possible to allow Americans to make well-informed diet decisions.

As you know, Congress included report language in the final omnibus budget that calls for FDA to consider "more than one relevant study" to form the basis of any FDA action. We would like to remind you that the July 2000 NAS report included the results of numerous relevant studies. These studies cover the full range of issues, from specific medical effects to dose estimation. A revised FDA advisory based on the findings of the NAS would thus include "the results of more than one relevant study." It is clear that the NAS considered a substantial body of research in preparing its report.

We understand that you have heard concerns that fully informing people about methylmercury could contradict FDA publications advising people to eat more fish. Fish is an important part of a healthy diet. However, a few large species of fish exhibit high levels of methylmercury, and consumer advisories should focus on these species. We have no doubt that FDA can make a distinction between methylmercury-contaminated fish and others in their revised consumer advisory.

Methylmercury is a dangerous neurotoxin that poses a serious health risk to people, especially pregnant women and young children, who consume contaminated fish. After innumerable delays, it is time to protect Americans from this danger. We urge you to instruct FDA to move quickly to revise and promulgate a more comprehensive consumer advisory for methylmercury in seafood and reflect the risks described in the NAS report. This advisory should include all fish species with a danger of high methylmercury levels -- in particular swordfish, shark, and large tuna.

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We also continue to urge you to reconcile the difference in the outdated FDA "action level" for methylmercury in fish tissue and the more current, stricter "reference dose" that is advocated by EPA and supported by the July 2000 NAS report. Conversion of the two numbers shows that the scientifically-supported EPA level is over four times stricter than that of FDA and we strongly believe that this level should be the federal standard to protect public health. We requested that you do this in a previous letter (sent August 15, 2000) and await a formal response.

We appreciate your attention to this important matter.

Sincerely,


PATRICK LEAHY
United States Senator


TOM HARKIN
United States Senator

cc: FDA Commissioner Jane Henney