

United States Senate

WASHINGTON, DC 20510-4502

August 15, 2000

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

Dear Secretary Shalala:

In July, the National Academy of Sciences (NAS) issued a long-awaited report requested by Congress and entitled, "Toxicological Effects of Methylmercury." Among other findings, this report concludes that the most scientifically defensible reference dose (RfD) for human consumption of methylmercury is currently 0.1 micrograms per kilogram body weight per day ($\mu\text{g}/\text{kg}/\text{day}$). This is the same reference dose proposed by the Environmental Protection Agency (EPA) in 1998, the year it released its Mercury Report to Congress. In fact, the report indicates that an even lower level would be scientifically supportable.

We are writing to alert you that two of your agencies, the Food and Drug Administration (FDA) and Agency for Toxic Substance and Disease Registry (ATSDR), are now using outdated standards for human methylmercury exposure and should move quickly to consider adoption of the more stringent EPA standard. The FDA "action level," or the level at which the FDA may take legal action to remove a product from the market, is now set at 1.0 part per million methylmercury in fish tissue. When converted to units relevant to human consumption, this value is about 0.5 $\mu\text{g}/\text{kg}/\text{day}$ for methylmercury, or five times less stringent than the NAS-supported EPA level. The ATSDR minimal risk level (or MRL) of 0.3 $\mu\text{g}/\text{kg}/\text{day}$ is three times less stringent than the NAS-supported EPA level. In addition, the NAS report found that selection of studies and choice of uncertainty factors by ATSDR were scientifically-flawed.

The NAS report is the capstone of an already large body of evidence highlighting the need for FDA and ATSDR to update their methylmercury exposure standards and for FDA to resume its suspended tests for methylmercury contamination in domestically-caught fish. We are disappointed that FDA, in particular, has not considered these tasks a high public health priority. The FDA has not tested domestically-caught fish for methylmercury contamination since 1998, even after 1997 tests showed that *three of the four fish* in one sample exceeded FDA action levels. This raises serious questions about FDA's commitment to ensuring seafood safety.

Methylmercury is a dangerous neurotoxin that accumulates in human blood, brain tissue, and organs primarily through the consumption of mercury-contaminated fish. Given the

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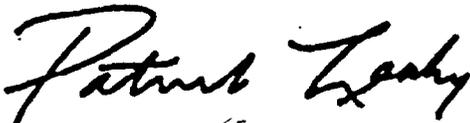
susceptibility of undeveloped neurological systems to methylmercury poisoning, the most at-risk populations in the United States include women of child-bearing age, pregnant women, and small children. According to the NAS study, five percent of U.S. populations that have been studied for methylmercury exposure eat enough fish to exceed the 0.1 $\mu\text{g}/\text{kg}/\text{day}$ EPA level -- this translates into an average of 7% of women and over 60,000 infants at risk each year. In one New Jersey study cited, 21% of women of childbearing age would exceed the EPA reference dose.

It is imperative that, as a nation, we drastically reduce mercury emissions to the atmosphere from coal-fired power plants, municipal trash incinerators, and other industries that emit over 50 tons of mercury each year -- mercury that finds its way into our nation's lakes and streams and, ultimately, fish. We have been working on legislation to do this in the Senate for over a decade and continue to do so. In the meantime, federal health agencies must protect our citizens at the most stringent, and scientifically-justified, levels. For methylmercury exposure, the National Academy of Sciences report suggests this is a level of 0.1 $\mu\text{g}/\text{kg}/\text{day}$ or less.

We hope that you will review this situation and request that (1) both the FDA and ATSDR adopt a scientifically-supported, reference dose for human methylmercury exposure that is consistent with the NAS findings and that adequately protects sensitive populations, and (2) that FDA resume domestically-caught fish monitoring immediately, using statistically-valid sampling methods. With the publication of this report from the nation's premiere scientific advisory panel, there is no longer any justification for interagency discrepancies in the protection of public health from mercury pollution, nor in inaction on the monitoring of fish eaten by our citizens.

We look forward to hearing from you as soon as possible concerning your efforts to address these issues.

Sincerely,



PATRICK J. LEAHY
United States Senator



TOM HARKIN
United States Senator