



DEPARTMENT OF HEALTH & HUMAN SERVICES

(80)

Food and Drug Administration  
Rockville MD 20857

JAN 31 2001

The Honorable Patty Murray  
United States Senate  
Washington, D.C. 20510-4704

Dear Senator Murray:

Thank you for your letter of September 18, 2000, addressed to Donna E. Shalala, former Secretary of Health and Human Services and your letter of November 30, 2000, to Jane E. Henney, M.D., former Commissioner of Food and Drugs, co-signed by several colleagues, regarding the National Academy of Sciences (NAS) report, *Toxicological Effects of Methylmercury* and the Food and Drug Administration's (FDA) reassessment of its consumer guidance and action level for methylmercury in seafood. I apologize for the delay in responding to your letters.

FDA shares your concerns about human exposures to mercury and its compounds and believes that the NAS report represents a significant and important contribution regarding the health effects of methylmercury. FDA is carefully reviewing this report, as well as other information that continues to emerge from around the world regarding this important environmental issue.

FDA issued a new fish consumption advisory on methylmercury on January 12, 2001, (copy enclosed). As part of the decision-making process, FDA met with interested parties (consumers, industry, health care providers, etc.) to obtain various perspectives on this important issue. A copy of the questions asked of these groups also is enclosed. FDA also tested different types of messages with consumer focus groups to determine whether these types of messages are clearly understood and how they would be acted upon by consumers. These message tests helped determine the best ways of reaching the public with this important information.

This fiscal year FDA will develop an overall public health strategy for methylmercury in commercial seafood, including a review of the action level. In addition, FDA will need to reconsider the results of any additional studies on methylmercury in fish. This includes the results of the evaluation of the Seychelles Islands cohort study at seven

Page 2 - The Honorable Patty Murray

years, which is expected to be available in the spring of 2001. This information will allow, for the first time, a side-by-side comparison between the Faroe Islands study, which reported results of evaluation of the children at seven years, and the Seychelles Islands study involving children evaluated at the same age using the same battery of neurologic tests. While methylmercury surveillance data has remained relatively stable for most species, FDA will consider additional steps as part of its overall strategy on methylmercury.

In closing, let me reiterate FDA's commitment to protecting the public's health and the environment regarding mercury. Please be assured that FDA will carefully evaluate the NAS report and all other relevant information and take appropriate actions based on that evaluation.

Thank you again for conveying your concerns about this important health issue. A similar letter has been sent to your colleagues who co-signed your letter.

Sincerely,



Melinda K. Plaisier  
Associate Commissioner  
for Legislation

2 Enclosures



## CONSUMER ADVISORY

Center for Food Safety and Applied Nutrition, U.S. Food and Drug Administration

January 2001

### AN IMPORTANT MESSAGE FOR PREGNANT WOMEN AND WOMEN OF CHILDBEARING AGE WHO MAY BECOME PREGNANT ABOUT THE RISKS OF MERCURY IN FISH

Seafood can be an important part of a balanced diet for pregnant women. It is a good source of high quality protein and other nutrients and is low in fat.

However, some fish contain high levels of a form of mercury called methylmercury that can harm an unborn child's developing nervous system if eaten regularly. By being informed about methylmercury and knowing the kinds of fish that are safe to eat, you can prevent any harm to your unborn child and still enjoy the health benefits of eating seafood.

#### HOW DOES MERCURY GET INTO FISH?

Mercury occurs naturally in the environment and it can also be released into the air through industrial pollution. Mercury falls from the air and can get into surface water, accumulating in streams and oceans. Bacteria in the water cause chemical changes that transform mercury into methylmercury that can be toxic. Fish absorb methylmercury from water as they feed on aquatic organisms.

#### HOW CAN I AVOID LEVELS OF MERCURY THAT COULD HARM MY UNBORN CHILD?

Nearly all fish contain trace amounts of methylmercury, which are not harmful to humans. However, long-lived, larger fish that feed on other fish accumulate the highest levels of methylmercury and pose the greatest risk to people who eat them regularly. You can protect your unborn child by not eating these large fish that can contain high levels of methylmercury:

Shark  
Swordfish  
King mackerel  
Tilefish

While it is true that the primary danger from methylmercury in fish is to the developing nervous system of the unborn child, it is prudent for nursing mothers and young children not to eat these fish as well.

**Food and Drug Administration's (FDA) Questions to  
Interested Parties on Methylmercury**

1. Given the National Academy of Sciences (NAS) report and the emissions standards set by the Environmental Protection Agency, should FDA revise its advisory to consumers (and in particular to vulnerable populations such as pregnant women and women who may become pregnant)? If so, what should the new advisory say?
2. Given the potential nutritional contribution of fish and seafood to a healthful diet, should a consumer advisory be crafted so that it conveys the benefit/risk balance of methylmercury-containing fish? If so, what should be the content of such a message?
3. With additional Seychelles study data expected to be released next spring, what impact, if any, should such new data have on the timing and content of any FDA advisory?
4. What other factors, if any, should impact a decision on whether and how to revise the current consumer guidance?
5. What methods of communication should FDA use to best convey such a consumer advisory?
6. How could FDA measure its success in reaching the consumer audience, including vulnerable populations?

PATTY MURRAY  
WASHINGTON

COMMITTEES  
APPROPRIATIONS  
SUDAPT  
HEALTH, EDUCATION, LABOR  
AND PENSIONS  
VETERANS' AFFAIRS

# United States Senate

WASHINGTON, DC 20510-4704

September 18, 2000

The Honorable Donna Shalala  
Secretary  
Dept. of Health and Human Services  
615 Hubert H. Humphrey Bldg.  
200 Independence Ave. SW  
Washington, D.C. 20201

Dear Secretary Shalala:

I understand that the Food and Drug Administration (FDA) is currently re-assessing its defect action level and consumer guidance for methylmercury in fish. This is an important undertaking that could profoundly affect consumers and producers of seafood. I am writing, therefore, to urge the FDA to ensure that a comprehensive and thorough evaluation of the scientific data is completed during this review.

The recently published National Academy of Science Report on the "Toxicological Effects of Methylmercury" reviews the potential toxic effects associated with chronic exposure to methylmercury. The FDA, however, should carefully review and evaluate the observations in the report as it proceeds with its re-assessment. For example, I am concerned your analysis may not be complete if it excludes data from the large epidemiological study conducted in the Seychelles Island and the NHANES IV Consumption Study, which will provide valuable consumption/exposure data.

The NAS panelists describe the Seychelles Island Study as a well-designed and carefully conducted study and they found no serious flaws in its design or conduct. In spite of the robustness of the study, I understand that it was not used by the panelists because they did not want to derive a reference dose (Rfd) for methylmercury from a study that did not find adverse effects at the observed exposure levels (i.e. methylmercury levels 10 times the average level found in the U.S. population). It is my understanding that Seychelles Island researchers have added new methods to measure neurological development in children to their battery of tests. The new data will allow more direct comparisons between the Faroese Island Study (i.e. the study selected by NAS to recommend its Rfd) and the Seychelles Study. FDA should consider making use of this new data in its assessment.

Consumers are being told that consuming a balanced diet, including protein from sources such as fish, is important to their health. Fish are a good source of high quality protein, low in fat and

200 WEST WASHINGTON  
SUITE 803  
EVERETT, WA 98201-1187  
(425) 355-8615

2018 JACKSON FEDERAL CHAMBER  
815 2nd AVENUE  
SEATTLE, WA 98104-1005  
(206) 553-2242

801 WEST MAIN  
SUITE 1213  
BROOKLINE, WA 97201-0013  
(509) 621-8615

140 FEDERAL BUILDING  
500 W. 12TH STREET  
VANCOUVER, WA 98206-3073  
(360) 878-7787

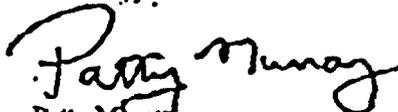
402 E. YALUMA AVENUE  
SUITE 300  
YALUMA, WA 98591-2700  
(509) 433-7482

PRINTED ON RECYCLED PAPER  
This document contains neither recommendations nor conclusions of the U.S. Government. It is the property of the U.S. Government and is loaned to your agency; it and its contents are not to be distributed outside your agency.

saturated fat and an important source of beneficial omega-3 fatty acids, which are believed to be protective against heart disease and necessary for good brain development in infants. The outcome of the FDA's review will have a major impact on the choices of fish available to consumers and the ability of the seafood industry to supply fish for the commercial marketplace. It is therefore imperative that the agency use sound scientific principles in the assessment of its action level for methylmercury, including carefully weighing all available scientific data.

I appreciate the attention you have given this issue and trust you will evaluate all the scientific data available. Please update me on the status of your review. Thank you.

Sincerely,



Patty Murray  
United States Senator

PMadk

# United States Senate

WASHINGTON, DC 20510

November 30, 2000

The Honorable Jane Henney  
Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner Henney:

We understand that the Food and Drug Administration (FDA) is considering action soon to potentially revise its consumer advisory on the topic of seafood and mercury. This is clearly a significant undertaking. It would be a major set back for public health if consumers were unnecessarily alarmed and significant segments of the population turned away from the proven benefits of fish consumption. We are writing, therefore, to urge the FDA to consider all relevant information before making any decision on changes to the existing advisory.

One of the studies sponsored by the FDA, the Seychelles Study conducted by the University of Rochester, is considered extremely valuable and relevant to the issue of seafood and mercury. Since the results of a critical phase of this study will be available to FDA within months, it would be highly appropriate to evaluate and review this information, prior to any decision regarding the release of a public advisory on fish consumption. All relevant information, particularly the benefits associated with fish consumption, should also be considered.

We understand that the motivation for revising the consumer advisory stems from issues raised in an National Academy of Science (NAS) Committee Report titled *Toxicological Effects of Methylmercury*, published in July of this year. While the Report included an estimate of the population that might be "at risk" from methylmercury exposure, we understand that there has yet to be a clear explanation of how this estimate was derived and what the term "at risk" means.

00-7427

Neither the FDA nor the Environmental Protection Agency (EPA) has been given a clear explanation for the record. There should be no consideration of an advisory to the public until these basic questions are addressed. Any decision should be based on clear and scientifically based information.

The importance of fish consumption in a healthful diet has been acknowledged not only by our own government with the recent publication of the *2000 Dietary Guidelines for Americans* and the two Food Guide Pyramids (Adults and Children) but also by the American Heart Association in its recently revised dietary guidelines. It is critical that consumers not receive conflicting messages from government agencies and credible health and medical groups.

Likely consumer response to any revisions to FDA's current fish consumption advisory must also be carefully considered. The potential impacts are not only related to public health but also to the economic viability of the seafood industry. It is therefore imperative that the Agency considers all relevant information before making any decision on changes to its existing advisory.

We would be grateful for your clarification as to how you intend to reach a scientific consensus on this important issue before the FDA takes precipitate action. We appreciate the attention you have given this issue and trust you will evaluate all the scientific data available.

Sincerely,

John Deary  
Chir DM

Rick Santorum

Don Vukobratovic

Just Latt  
Ed Henry

Frank W. Tompkins

Mad Bob

*Ed King*

---

---

---

*Patty Murray*

---

---

---