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United States Senate

WASHINGTON, DC 20510

September 15, 2000

The Honorable Donna Shalala  
Secretary  
Department of Health and Human Services  
200 Independence Ave., SW  
Washington, DC 20201

Dear Secretary Shalala:

We understand that the Food and Drug Administration (FDA) is currently re-assessing its defect action level and consumer guidance for methyl mercury in fish. This is an important undertaking that could profoundly affect consumers and producers of seafood. We are 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 Methyl mercury" reviews the potential toxic effects associated with chronic exposure to methyl mercury. The FDA, however, should carefully review and evaluate the observations in the report as it proceeds with its re-assessment. For example, we believe your analysis will not be complete or scientifically sound unless it includes 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, we understand that it was not used by the panelists because they did not want to derive a reference dose (Rfd) for methyl mercury from a study that did not find adverse effects at the observed exposure levels (i.e. methylmercury levels 10 times the average levels found in U.S. the population). We understand that Seychelles Island researchers have

added new methods to measure the neurological development in children to their battery of tests. The new data will allow more direct comparisons between the Faroe Island Study (i.e. the study selected by NAS to recommend its Rfd) and the Seychelles Study. FDA should make 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 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 methyl mercury, including carefully weighing all available scientific data.

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

Sincerely,

John Poreaux  
Frank W. Tynan

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