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United States Senate

WASHINGTON, D.C. 20510

October 7, 1999

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

Dear Secretary Shalala:

We are writing this letter to ascertain what actions the Food and Drug Administration (FDA) has taken to protect American consumers from the risk posed by mercury-contaminated foods. Pregnant women, women who may become pregnant, unborn children, and young children are especially at risk because methyl mercury stored in a woman's body can pass through the placental barrier and cause adverse developmental effects and other negative health outcomes. These groups deserve to be fully protected.

The 1997 Mercury Study Report to Congress estimated that at least 1.6 million Americans are potentially at risk from food contaminated by mercury pollution that enters the environment principally as the result of human activities. At present count, 40 states have issued advisories warning the public to restrict or cease consumption of freshwater fish based on high mercury levels, and several states, including Florida and Texas, have issued advisories for mercury-contaminated ocean fish. Some states, including Vermont, Minnesota, Michigan and New Jersey, have also implemented a two-tiered guidance system that includes more stringent warnings for women of child-bearing age and pregnant women about consuming canned tuna and other mercury-contaminated ocean fish.

The FDA has established an "action level" of 1.0 parts per million (ppm) methyl mercury for fish in interstate commerce. This level differs substantially from the 0.1 ppm methyl mercury "reference dose" that is used by the Environmental Protection Agency. Both of these levels are currently under review by a committee under the direction of the National Academy of Sciences (NAS) with a report from NAS slated for completion by July 2000. However, the NAS review of methyl mercury levels does not relieve FDA of its ongoing responsibility to protect all Americans from contaminated food in interstate commerce, including fish contaminated with methyl mercury. The pendency of the NAS review should not impede gaining a more complete understanding of FDA's action level and its monitoring and consumer information programs for tuna, swordfish, shark and other ocean fish that exhibit levels of methyl mercury in excess of the 1.0 ppm action level.

No 99-6575

Please provide us with a detailed response to the following questions:

1. Action Level.

a. As we understand it, the original action level established by FDA for mercury in 1969 was 0.5 ppm, or twice as stringent as the current standard. On what scientific or other basis was the current action level of 1.0 ppm established? That is, was it set at a level that would be protective of the health of sensitive populations (e.g. women of child-bearing age, pregnant women and their fetuses, and young children) with a margin of safety? Or, was it set at a level that is only protective of adult humans?

b. Does the action level incorporate or otherwise reflect economic considerations? Specifically, is the action level as a matter of law or practice set at a less protective level than if it were based solely on protection of human health and, if so, is that less protective level selected due to economic, cost or other non-health-related considerations? What was the role, if any, of the fishing industry in setting the 1 ppm level?

c. Does the current action level reflect trends in per capita consumption of fish, especially in women of childbearing age, pregnant women and young children since that level was established in 1979? Does information collected by FDA on consumption suggest that there has been an increase in mercury exposure to the American public, and especially to Native Americans, subsistence fishers and sensitive populations? If so, has FDA found that there has been a corresponding increase in mercury body burden for these sub-populations? Please discuss why, given an increase in mercury exposure, FDA would or would not expect a corresponding increase in human health risk for these sub-populations.

d. Has the FDA developed guidance for all Americans on how often and how much certain kinds of contaminated fish can be safely consumed? If so, do these publications explicitly state who the action level was (or was not) established to protect? Further, explain how FDA's guidance takes into account variations within the general population and sub-populations, including differences in weight, consumption patterns, and the ability to eliminate mercury from the body.

2. Monitoring

a. Certain foods are known to contain high levels of mercury. These often include larger predatory fish such as tuna, shark, swordfish, seabass, halibut, Spanish mackerel, king mackerel and marlin. Does FDA itself monitor these and other fish for mercury levels, whether sold fresh, frozen or canned, and does it also work in conjunction with other federal and state agencies to do so? If so, which agencies does FDA work cooperatively with and to what extent?

b. For each of the past ten years (1988 through 1998), describe FDA's monitoring program for chemical contaminants (specifically mercury) in fish. More specifically, provide detailed information on the following: the number of areas monitored for mercury in fish; the location of these areas; the testing frequency for fish in these areas; the species, age, size and sex of the fish tested; the method of testing (including quality assurance and quality control/chain of custody issues); and the type of sample used in testing (i.e. fillet, steak or whole fish). Also, for the same time period, provide information, including data, on both the number and the percentage of samples for each species which tested over FDA's action level. Were fish caught from that area withdrawn from sale to market(s)? How much of these fish caught were withdrawn (as percent of total yearly catch and weight for that species)? Has the FDA banned sale of fish from specific waters and how does FDA insure that fish caught from these waters are not sold in domestic markets? What is done with fish banned from sale by FDA?

c. Does FDA's monitoring program include all domestically sold fish (including imported canned, fresh, frozen and dried fish)? If so, please describe these monitoring efforts. What measures does FDA take to insure the safety from chemical contaminants (specifically mercury) of fish processed outside the United States that is sold domestically? If domestic catch or imported fish from foreign producers are not included in monitoring programs, what assurances do American consumers have that these fish are safe to eat?

d. Has there been a discernible trend in the body burdens of mercury in fish or in human consumers? If body burden trend data are available, please provide detailed information by population subgroup, including Native Americans, subsistence fishers and other vulnerable sub-populations such as pregnant women, women of childbearing age, infants and young children.

3. General Information

a. Information on the nutritional value and contents of most packaged foods is disclosed on the labels of those foods. Increasingly, many fresh meats also contain comparable information, including food safety warnings to cook meat and poultry thoroughly where there is a risk of food borne illness. In contrast, fresh seafood is not accompanied by similar information despite consumption of uncooked seafood being associated with a risk of food-borne illness (for example, raw shellfish) and the fact that there are fish consumption advisories for mercury in most of our country. Instead, the FDA utilizes other information in its risk communication efforts. Please provide samples of leaflets and other forms of consumer publications regarding consumption of mercury-contaminated fish and explain how FDA reaches out to culturally distinct sub-populations. For each leaflet or publication, please state how many copies were printed and when, as well as how they were disseminated, to whom and in what quantities. Please provide specific examples of FDA's efforts to convey this information to sensitive populations, for example, by providing literature to pediatricians, obstetricians, and gynecologists. If such efforts to disseminate information have not occurred, please explain why not.

We look forward to receiving your responses to these questions by no later than November 5. Please contact us if you have any questions about this request. Your staff may direct questions to Susanne Fleek or Rick Duffy of Senator Leahy's office at 224-4242.

Sincerely,

PATRICK LEAHY
United States Senator

THOMAS HARKIN
United States Senator

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