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DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM OF MEETING

Date: November 8, 2000

Place: Center for Food Safety and Applied Nutrition, FDA, Washington, D.C.

Participants:*

Consumer Groups

Art Jaeger, Consumer Federation of America
Mark Silbergeld, Consumer Union
Edith Hogan, American Dietetic Association
Sarah Lister, American Public Health Association
Shawna Friedman, Congressman Allen's Office
Tim Benner, Senator Leahy's Office
Michael Bender, Mercury Policy Project (via telephone)
Diana Zuckerman, National Center for Policy Research for Women and Families
Patricia Lieberman, National Center for Policy Research for Women and Families
Caroline Smith Dewaal, Center for Science in the Public Interest
Felice Stedler, National Wildlife Fund

FDA

Joseph Levitt, Director, Center for Food Safety and Applied Nutrition (CFSAN), HFS-1
Carole Williams, Consumer Affairs Specialist, Office of Consumer Affairs, HFE-88
Kennerly Chapman, Office of Woman's Health, Office of the Commissioner, HF-8
Alan Levy, Senior Consumer Research Scientist, Consumer Studies Team, Office of Scientific Analysis and Support, HFS-727
Tamar Nordenberg, Editor/Writer, Food Safety Initiative Staff, HFS-32
Kathleen Kolar, Public Affairs Specialist, Office of Public Affairs, HFI-60
Monica Revelle, Public Affairs Specialist, Office of Public Affairs, HFI-60
Phillip Spiller, Director of Seafood, HFS-400
Marjorie Davidson, Education Lead, Food Safety Initiative Staff, HFS-32
Juanita Yates, Director, Consumer Education Staff, Office of Constituent Operations, HFS-555
Louis Carson, Acting Director, Food Safety Initiative Staff, HFS-32
P. Michael Bolger, Division of Risk Assessment, Office of Plant and Dairy Foods and Beverages, HFS-355
Michael Eck, Director, Congressional Affairs Staff 1, Office of Legislative Affairs, HFW-12
Ellis Norris, Policy Analyst, Executive Operations Staff, HFS-22

Other Government Personnel

Valerie Tully, Public Affairs/Press Office, Health and Human Services (HHS)
Roberto Pinero, General Accounting Office (GAO)
Greg Susanke, Environmental Protection Agency (EPA)

Subject: Issues Related to Methylmercury (MeHg)

Mr. Levitt opened the meeting by indicating that the National Academy of Science (NAS) issued an important report earlier this year on potential adverse effects associated with methylmercury in seafood. He explained that, in response to the findings in that report, the Center has been holding meetings with various stakeholder groups as part of its process to determine whether the Agency needs to issue a new advisory on methylmercury in seafood and, if so, what should that advisory be.

Representatives of the consumer groups expressed appreciation for the opportunity to present their views on how FDA should respond to the NAS report. Several indicated that the current action level for methylmercury in seafood (1 ppm), which was established in the late 1970s, was not designed to protect high-risk groups. They insisted that FDA should take a precautionary approach on this matter and establish an advisory that is in line with the results of the NAS report.

Several questions related to methylmercury in seafood were sent to representatives of consumer groups prior to the meeting. Presented below are summaries of the verbal responses given to some of these questions during the meeting:

1. Should FDA revise its advisory for particular vulnerable populations?

   Representatives of consumer groups indicated that there is an urgent need for FDA to establish a seafood advisory that protects those consumers who are at risk. In their view, at risk populations should include pregnant women, women who are trying to get pregnant, nursing mothers and young children. There was general agreement that these risk groups should be advised not to eat several kinds of fish, including shark, swordfish and fresh tuna, which tend to have higher methylmercury levels.

2. Should a consumer advisory be crafted so that it conveys the benefit/risk balance of methylmercury-containing fish?

   Several consumer representatives stated that the Agency should not make the argument that the potential benefits of eating seafood outweigh the risk because the potential adverse health effects associated with methylmercury can be devastating, particularly for the developing fetus. Also, some expressed a concern that, if the Agency attempted to combine risk and benefits in the same message, the safety message is likely to be too diluted to be effective.

3. What impact, if any, should new data (e.g., the Seychelles study data expected to be released next spring) have on the timing and content of any FDA advisory?

   Most consumer representatives rejected the idea that FDA should wait for the Seychelles data to develop a revised seafood advisory. Several stated that the Agency should accept the conclusion of NAS, a very reputable scientific organization, that the Faroe Island study is the best available. They strongly recommended that FDA use the data in the NAS report as the basis for revising its advisory for seafood consumption. However, one consumer representative noted that there are questions regarding the data in that study, especially the appropriateness of using those data to establish an advisory for American consumers since the type of seafood consumed (whale meat and blubber) and the pattern of consumption (high/short-term exposure) are significantly different.

4. What method of communication should FDA use to best convey a consumer advisory?

   Consumer representatives emphasized that a revised advisory message on seafood needs to be simple, clear and consistent to be effective. They stressed the importance of providing a message that not only advises against the consumption of certain seafood but also identifies safer alternatives species. In addition, consumer representatives emphasized that the seafood advisory information needs to be communicated directly to consumers and through a variety of other sources, such as health professionals (especially those who deal with pregnant women and young children) and consumer education groups. Other points made during the discussion were that the messages should be multilingual, placed on websites, and placed in popular magazines that are likely to be read by those in the at risk groups.

   Several consumer representatives indicated that an advisory to eliminate or significantly reduce the dietary intake of seafood would be in conflicts with information from other sources (e.g., the American Heart Association) that encourage consumers to increase the consumption of seafood. In view of this, they suggested that the messages needed to be tailored to minimize confusion on this issue.

5. How could FDA measure its success in reaching consumer audiences, including vulnerable populations?

   There was general agreement that an evaluation component is essential if the Agency is to determine the effectiveness of its efforts to provide consumers information they need on potential safety hazards associated with methylmercury in seafood. Several consumer representatives recommended that FDA consult with several New England states that have initiatives on methylmercury in seafood that include an evaluation component. There was also a suggestion that the Agency should consider establishing a HACCP requirement for methylmercury in fish.

Mr. Levitt expressed appreciation to the consumer representatives for the preparation and thinking that went into the information and points of view they shared and the tenor of the discussion. He summarized several points he had obtained from comments made during the meeting. These were:

1. Methylmercury in seafood is a matter of high urgency that has gone on way too long;
2. FDA could and should do something to address this health issue and you want to help;
3. By the end of November you expect to hear what the Agency plans to do to respond to your concerns regarding methylmercury in seafood.

Ellis M. Norris

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*There were probably some participants, especially those who came in after the meeting started, who did not put their names on the sign in sheet.