



JAN 31 2001

The Honorable John B. Breaux
United States Senate
Washington, D.C. 20510-1803

Dear Senator Breaux:

Thank you for your letter of September 15, 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

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 letters.

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?

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

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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 Breauy

Jesus Helms

Frank W. Tynan

[Signature]

Ron Wyder

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.

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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
Chris DeM

Just Latt
Ed Kennedy

Rick Santorum

Frank W. Tompkins

Don Nicks

Mad Cohen

E King

Patty Murray



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 31 2001

The Honorable Gordon Smith
United States Senate
Washington, D.C. 20510-3704

Dear Senator Smith:

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Melinda K. Plaisier
Associate Commissioner
for Legislation

2 Enclosures

Page 3 - The Honorable Gordon Smith

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HFW-1

HFW-12

HFS-22

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R/D: Eck 12/4/00 Edits by CFSAN

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Edit: Lcarson; 1/23/01 based on aspe comments.

Cleared: MPlaisier: 1/24/01

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CONSUMER ADVISORY

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

January 2001

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[Signature]

Ron Wyder



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 31 2001

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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

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United States Senate

WASHINGTON, DC 20510

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Secretary
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200 Independence Ave., SW
Washington, DC 20201

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John Breau

Jesus Helms

Frank W. Tynell

[Signature]

Ron Wyder

RON WYDEN
OREGON

516 Hart Senate Building
Washington, DC
20510-3703
(202) 224-5244

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www.senate.gov/~wyden/

United States Senate

WASHINGTON, DC 20510-3703

December 7, 2000

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

Committees:

Budget
Commerce, Science
& Transportation
Energy & Natural Resources
Environment & Public Works
Special Committee on Aging

Oregon State Offices:

700 NE Multnomah St
Suite 450
Portland, OR 97232
(503) 326-7525

151 West 7th Ave
Suite 435
Eugene, OR 97401
(541) 431-0229

Sac Annex Building
105 Fir St
Suite 201
La Grande, OR 97850
(541) 962-7691

U.S. Courthouse
310 West 6th St
Room 118
Medford, OR 97501
(541) 858-5122

The Jamison Building
131 NW Hawthorne Ave
Suite 107
Bend, OR 97701
(541) 330-9142

707 13th St, SE
Suite 285
Salem, OR 97301
(503) 589-4555

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U.S. Senator Ron Wyden



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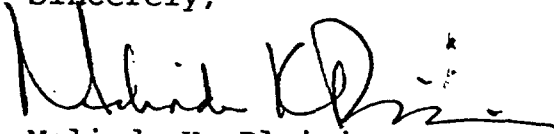
This fiscal year FDA will develop an overall public health strategy for methylmercury in commercial seafood, including a review of the action level. In addition, FDA will need to reconsider the results of any additional studies on methylmercury in fish. This includes the results of the evaluation of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

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?
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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?

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

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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 Breau

Jesus Helms

Frank W. Tynan

[Signature]

Ron Wyder



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JAN 31 2001

The Honorable Frank H. Murkowski
United States Senate
Washington, D.C. 20510-0202

Dear Senator Murkowski:

Thank you for your letters of September 15 and October 27, 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.

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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

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United States Senate

WASHINGTON, DC 20510

September 15, 2000

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

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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 Breau

Jesse Helms

Frank W. Tynan

[Signature]

Ron Wyder

FRANK H. MURKOWSKI
ALASKA
COMMITTEES:
CHAIRMAN
ENERGY AND NATURAL RESOURCES
FINANCE
VETERANS' AFFAIRS
INDIAN AFFAIRS

United States Senate

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P. O. BOX 21647
JUNEAU, AK 99802-1647
(907) 586-7408

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851 E. WESTPOINT DRIVE, SUITE 307
WASILLA, AK 99664-7142
(907) 376-7885

*** RECEIVED ***
Oct 27, 2000 16:33:20 WS# 03
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CORRESPONDENCE
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October 27, 2000

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

Dear Secretary Shalala:

Together with other members of the Senate, I wrote you on September 15 to request that the Food and Drug Administration (FDA) delay action on a reassessment of its action level and consumer guidance for methyl mercury in seafood until it has an opportunity to review additional information from the Seychelles Island epidemiological study and the NHANES IV Consumption Study.

I now understand that FDA may be going ahead with plans to revise its consumer advisory, possibly as soon as November 20. This, along with new information that has become available to me since September 15, prompts this additional letter on the topic. I believe this matter is urgent enough to require your personal intervention.

As you know, the proposed FDA action is based on the results of a study in the Faroe Islands, after a review of existing research into methyl mercury contamination by the National Academies of Science (NAS). The FDA-supported Seychelles study was also examined, but was not used to reach the NAS findings, as it did not demonstrate adverse impacts.

Dependence on the Faroe Islands study alone has raised concern among many eminent scientists. One of the most important issues is that the Faroese diet includes whale meat and blubber having high levels of PCBs and other persistent organic pollutants. These contaminants, especially PCBs, are known to cause many of the same developmental problems attributed, in this case, to methyl mercury alone. It is also noteworthy that the seafood consumption patterns noted in the Faroe Islands study bear little resemblance to consumption patterns in the United States. The influence of PCB-contaminated seafoods (whale meat and blubber) not consumed in the United States, whether consumed alone or in conjunction with more common seafoods, makes the Faroe study a questionable basis for advice to U.S. consumers.

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E-MAIL ADDRESS
EMAIL@MURKOWSKI.SENATE.GOV

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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.

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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
Chin DM

Rick Santorum

Don Nicks

Just Latt

Ed Kennedy

Frank W. Tynan

Brad Cohen

Ed King

Patty Murray
