

Focus Pocus

The FDA withholds information from pregnant women on mercury-contaminated fish, citing “focus groups” as justification



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Contents

Executive Summary 1

FDA takes the industry line 5

1. FDA fails to set mercury regulation at level that protects public health 7

2. FDA fails to justify their unprotective action level and advisory 7

3. Focus group transcripts show that, contrary to what FDA says, some pregnant women eat significant amounts of tuna 9

4. Contrary to FDA’s claims, focus group participants wanted even more detailed information about mercury in seafood 11

5. FDA and the tuna industry reject all peer reviewed science that shows low level mercury toxicity 11

6. FDA fails to test and enforce 12

7. FDA has failed to educate the public about the hazards of mercury 14

Recommendations 17

References 19

Focus Pocus

Executive Summary

Mercury is toxic to the developing fetal brain and is a poison of growing concern to health authorities nationwide. When the U.S. Food and Drug Administration's latest health advisory for mercury in seafood was issued in January 2001, the Agency came under immediate fire from independent scientists and public health activists for failing to adopt the recommendations of a National Academy of Sciences study on mercury (NAS 2000), and for not providing pregnant women with complete information on what fish to avoid during pregnancy - particularly tuna.

Speaking to the press in May 2001, Dr. Robert Goyer, chairman of the NAS committee on mercury toxicity, criticized the Agency's health advisory for mercury, saying "The F.D.A. should be providing people with the best information and let them be the judge. The F.D.A. has stopped short of what it should have done."

Newly-available, internal FDA documents obtained by the Environmental Working Group (EWG) reveal that FDA, under pressure from the seafood industry, is deliberately withholding critical information from pregnant women on mercury-contaminated tuna and other fish, and using "focus group"¹ sessions as a justification.

In May of 2001, FDA's Director of the Division of Risk Assessment, Michael Bolger, told the press that the Agency had conducted focus groups and concluded that if women were given a more comprehensive list of fish that should be avoided or eaten only in moderation during pregnancy, they would simply not eat fish at all. To investigate this claim, EWG obtained and analyzed 1,036 pages of focus group transcripts under the Freedom of Information Act.

We found that the word-for-word account of focus group discussions flatly contradicts Bolger's assertion. We also found compelling evidence that the Agency is failing to protect the public from mercury-contaminated seafood. Internal FDA focus group transcripts considered together with publicly available FDA documents, show that the Agency is failing to regulate mercury levels in seafood, has shut down its mercury monitoring program, has not issued an enforceable limit for mercury in fish, and has not implemented the mercury education program that it promised.

1. "Focus groups" are small groups selected from a broader population and interviewed through facilitator-led discussions, for opinions and emotional responses about a particular subject. Focus groups are a common market research tool. Results are qualitative and are not statistically significant.

Internal FDA documents obtained by the Environmental Working Group (EWG) reveal that FDA, under pressure from the seafood industry, is deliberately withholding critical information from pregnant women on mercury-contaminated tuna and other fish, and using "focus group"¹ sessions as a justification.

A senior FDA scientist admits to a Boston focus group that supposedly safe seafood could put a fetus at risk for neurological damage: “... the action levels that we have in place for fish are not protective enough for this - the fetuses...”

Stunning admissions by FDA official in focus group transcripts

FDA’s own focus group transcripts directly refute Dr. Bolger’s claim that women would stop eating seafood if given detailed information on mercury levels. In fact, when presented with draft health advisories, an overwhelming majority of the participants said that they would keep eating fish but avoid those with high mercury levels (30 of 37 individual comments) - exactly the behavior that the FDA was aiming for (Tables 1 and 2).

But beyond what FDA officials were told by consumers are several stunning admissions FDA officials made to participants during those same sessions. EWG’s detailed review of 1,036 pages of word-for-word transcriptions of 11 FDA-sponsored focus groups in Denver, Boston, and Calverton, Maryland conducted in October and November 2000, reveals:

1. FDA is withholding from pregnant women information on their need to limit consumption of tuna in order to protect their babies. The Agency’s January 2001 advisory contains no mention of tuna, yet in the documents obtained by EWG, a senior FDA scientist reveals that:

“... the dilemma that we have is that to lower the action levels, so they’re protective of fetuses, it would actually put the availability of certain kinds of fish in question. We would lose some fish.” Then he is asked: *“Like King Mackerel [sic], shark, and swordfish?”* He replies, *“Well, those in particular, **but also tuna.**”* (emphasis added, Macro International, Inc. 2000i - Boston, November 8, 8 pm, pg 65²).

2. Seafood that is technically “safe” according to FDA’s mercury action level is actually endangering public health. A senior FDA scientist admits to a Boston focus group that supposedly safe seafood could put a fetus at risk for neurological damage: *“... the action levels that we have in place for fish are not protective enough for this - the fetuses...”* (Macro International, Inc. 2000i - Boston, Nov 8, 8 pm, pg 65).

FDA scientists acknowledge the health risks during the focus groups. At one point during the focus groups, a woman whose child has Attention Deficit Hyperactivity Disorder pressed an FDA scientist: *“I mean, now you find a lot of Attention Deficit Disorder and they’re really not saying where it is coming from... But maybe it could be coming from eating too much fish - you know - I mean, is that a possibility?”* The scientist replies, *“Yes, that’s why we’re - yes, that is a possibility. That is why we’re interested in this.”* *“So my daughter is on medication, now, because I ate fish...”*, she asks. FDA’s scientist responds, *“- now that we have this research, that now is a possibility.”* (Macro International, Inc. 2000i - Boston, Nov 8, 8 pm, pp 70-71)

2. All references to focus group documents (e.g., Macro International, Inc. 2000i) are appended with the location, date, and time of the focus group discussion and the relevant page number of the focus group transcript document.

Table 1. Contrary to what FDA told the public, when given advice on mercury in fish, most people said they would keep eating seafood, avoiding the high mercury fish.

Focus group participant	Context of remark or type of person who made the remark	What the participant said	Reference
Name not given	Pregnant woman	"I'll stay away from... the three, but I'm not going to quit eating fish."	2 (pg 56)
Name not given	Pregnant woman	"My advice would be not to eat the mackerel, the shark, and the swordfish... limit your intake of the tuna and then, you know, eat the rest of the fish in moderation."	2 (pg 59)
Name not given	Pregnant woman	"I will probably stay within..."	2 (pg 41)
Name not given	Pregnant woman	"...that to me would be why I would want to know which ones have a low level so that I could just eliminate them from my diet and not eat a big enough portion to be adequate to one of the others."	2 (pg 47)
Name not given	Pregnant woman	"I would tell my friend; my doctors said don't eat swordfish, shark and mackerel... I wouldn't go into the low levels; I would just state the facts."	2 (pg 57)
Name not given	Pregnant woman	"...everything in moderation would be safe, but it's nice to know that if king mackerel was your favorite fish that's one thing you should eliminate..."	2 (pg 58)
Phyllis	Pregnant woman	"You want to eat it... in moderation, and I would suggest once a month, maybe twice a month, but to also find out which foods or which fish are low moderate versus the no mercury."	2 (pg 61)
Name not given	Pregnant woman	"I'm not going to eat these [high mercury fish], but I know I can eat these as long as I eat them in moderation."	2 (pg 89)
Tim	Father of a teenager. Pretending to be a pregnant woman.	"It just tells you what fish to avoid. I would avoid those." [high mercury fish]	1 (pg 23)
Elizabeth	Mother of a teenager. Pretending to be a pregnant woman.	"I think I'd be inclined to stay away from the types of fish that there are cautions with and eat other types."	1 (pg 25)
Elizabeth	Mother of a teenager. Pretending to be a pregnant woman.	"I, for some reason, would feel a little bit comfortable doing some canned tuna."	1 (pg 25)
Name not given	Pretending to be a pregnant woman.	Would you eat tuna steak? "No, I wouldn't!" but would continue to eat tuna sandwiches.	1 (pg 26)
Katherine	Single woman. Pretending to be a pregnant woman.	"So I would probably, you know, stick within the guidelines that they discussed."	1 (pg 28)
Phyllis	Mother of a teenager. Pretending to be a pregnant woman.	"Well, if I went to a restaurant and they featured the tuna [steaks] and it sounded really good and it's okay three times a month, I'll go for it."	1 (pg 28)
Name not given	Pretending to be a pregnant woman.	"I suppose, if I read this and I were a pregnant woman, I could definitely avoid this... fish with a high level of mercury"	1 (pg 52)
Rosa	Mother - 2 grown kids, 2 preteen girls	"When you start thinking about what kinds of fish and make a selection, that's it... From the low ones."	3 (pp 30-31)
Ed	Grandfather	"Well, we haven't read anything yet that it is a negative thing to do unless you are pregnant. So, based on what we've read so far, I don't think I would change anything at this point."	3 (pg 31)
Name not given		"I would try to do too [stay away from high Hg fish]. Just in case something happened. Who knows in the future? I prefer to avoid."	3 (pg 31)
Cecelia	Mother of a 2-year-old	"If I'm not pregnant and I think it would make my life easy since I don't like fish. I'd just take vitamins." [question specific to high-mercury fish]	3 (pg 32)
Rosa	Mother - 2 grown kids, 2 preteen girls	"...because if you cook something and somebody comes to eat in your house or a guest or relative and they are healthy woman, thinking to about getting pregnant or maybe pregnant already. I don't want to cook anything troubles." [no high Hg fish in her house]	3 (pg 32)
Howard	Father with 2 grown sons	"I like king mackerel and tuna. I'm going to eat it."	3 (pg 33)
Craig	Father with 2 teenagers	"I've been in traffic here and there, played the dodge car show, see, and I guess my time was up five years ago, maybe twenty years ago, you never know. But, to make a long story short, I'll eat anything."	3 (pg 33)
Howard	Father with 2 grown sons. Pretending to be a pregnant woman	"I'd probably abstain from it." [high mercury fish]	3 (pg 33)
Craig	Father with 2 teenagers. Pretending to be a pregnant woman	"Yeah. I'd abstain. I can always eat later. I will." [high mercury fish]	3 (pg 34)
Judy	Grandmother. Advice she would give her daughter.	"If you're going to get pregnant within the next year, avoid these kinds of fish. ...first the king mackerel, the shark and the swordfish, and eat very moderate amounts of tuna."	3 (pg 35)
Ed	Grandfather	"I'd warn my daughters-in-law, but I haven't read yet that it says it's going to be harmful to me or harmful to my wife, who is beyond childbearing age. So, I don't think I'd change anything."	3 (pg 36)
Duane	Single man	"All the fish that have high mercury in it, and I don't eat anyway, so I think I'm going to be pretty safe on that."	3 (pg 36)
Name not given		"So, I would remember mackerel, shark, and swordfish and say no, and be moderate with the tuna fish steaks and all the rest is okay."	3 (pg 43)
Name not given		"I'd remember those three, but I also picked out ones on the lower list that I know I like. I'm like, next time out; it's okay to order salmon. I know for sure that's safe."	3 (pg 43-44)
Stacey	Mother of two: 3-year-old and 7-month-old. Pretending to be a pregnant woman.	"I almost want like a scientific, how it affects the baby's nervous system so that I can... rationalize in my mind that once a month is okay. Because otherwise... I'm going to say, it's not even worth the risk of having it one time." [high mercury fish]	3 (pg 56)

Source: Environmental Working Group. Compiled from FDA focus group transcripts.

References: 1 - Macro International, Inc. 2000 – Boston, Nov 8, 8pm; 2 - Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm; 3 - Macro International, Inc. 2000k – Calverton, Nov 14, 8 pm.

Table 2. Only 7 individual remarks in all 267 pages of final focus group transcripts support FDA’s claims.

Focus group participant	Context of remark or type of person who made the remark	What the participant said	Reference
Monica	Pregnant woman	"...if you can eat enough of the low to make it medium or high. I probably won't eat any type of seafood for the rest of my pregnancy...and I will be an advocate out there telling all pregnant women, stay away from fish."	2 (pg 40)
Name not given	Pregnant woman	"Right. That's why I said: I just wouldn't eat any fish at all, period. You never know how much of the low that you eat could be high."	2 (pp 47-8)
Shawna	Pregnant woman	"I'm going to stay away from fish."	2 (pg 42)
Shawna	Pregnant woman	"I would respond by not buying any more fish sticks and substituting fish sticks for something else on the menu."	2 (pg 49)
Trevor	Father with 3 kids ages 5, 12, and 13. Pretending to be a pregnant woman.	"I would not eat fish for the first trimester."	1 (pg 24)
Name not given	Pretending to be a pregnant woman.	"I might find other ways to get the nutrients, without even risking the fish."	1 (pg 29)
Name not given	Pretending to be a pregnant woman.	"I would simply say, okay, avoid fish. I wouldn't eat it at all if I were pregnant."	3 (pg 56)

Source: Environmental Working Group. Compiled from FDA focus group transcripts.

References: 1 - Macro International, Inc. 2000 – Boston, Nov 8, 8pm; 2 - Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm; 3 - Macro International, Inc. 2000k – Calverton, Nov 14, 8 pm.

3. FDA initially mentioned tuna in its draft mercury advisory but then dropped it after three meetings with the seafood industry.

The Agency’s draft focus group materials contained warnings for pregnant women such as: *“Tuna steaks can be eaten three times a month... You can eat one and a half six-ounce cans of tuna every week with no problems.”* (see, for example, Macro International, Inc. 2000j - Calverton, Nov 14, 6 pm, pp 32). At the Calverton session, an FDA senior scientist reiterates the potential hazards tuna poses to pregnant women and extends the warning to toddlers and even adult males:

“The advice for pregnant women is once a month or less for things like king mackerel, tuna steaks, whatever.” (Macro International, Inc. 2000k - Calverton, Nov 14 2000, 8 pm, pp 45-46)

“It is prudent, particularly for pregnant women to avoid these high mercury fish and moderate their tuna fish consumption...” (Macro International, Inc. 2000j - Calverton, November 14, 6 pm, pg 72).

“I have a fifteen month old and he loves tuna. I would want to know, should I be limiting the amount of tuna that I give him?” asks a focus group member. FDA’s scientist replies, *“It would be, you know, prudent to cut back if he’s eating more than a can and a half a week.”* She asks for clarification: *“So, it’s the same can and a half for a fifteen month old as it is for him, you know, for an adult male?”* He replies *“That is our - yes. It would be the same. It depends on how much you’re doing.”* (Macro International Inc. 2000k - Calverton, Nov 14, 8 pm, pp 48-49).

While crafting language for the advisory, FDA met privately three times - September 25, November 6, and November 22, 2000 – with Chicken of the Sea, StarKist, Bumble Bee, U.S. Tuna Foundation, and National Food Processors Association (FDA 2000a, 2000b, 2000c). The Agency’s final advisory, issued January 12, 2001, was stripped of any reference to tuna (FDA 2001a).

While crafting language for the advisory, FDA met privately three times - September 25, November 6, and November 22, 2000 – with Chicken of the Sea, StarKist, Bumble Bee, U.S. Tuna Foundation, and National Food Processors Association. The Agency’s final advisory, issued January 12, 2001, was stripped of any reference to tuna.

4. FDA official admits that the agency will rely on the seafood industry, not doctors, to educate women about the hazards of mercury in fish. A senior FDA scientist reveals to one of the focus groups that *“The industry is probably going to be one of the major ways that this information gets put out.”* (Macro International, Inc. 2000i – Boston, Nov 8, 8 pm, pg 97) The seafood industry, however, has yet to warn women of the potential dangers of mercury. In fact, the industry used a recent study on the benefits of fish consumption (specifically, of Omega 3 fatty acids) to promote tuna consumption for pregnant women in a recent press release: *“...this new study adds to the long list of startling health benefits scientists believe Omega-3s fatty acids provide to pregnant women and small children. The most convenient, economical source of Omega-3s for moms and kids is, quite simply, canned tuna!”* (U.S. Tuna Foundation, 2001). This press release provides a clear indication that the tuna industry has no plan to protect its customers from the dangers of mercury by steering them toward safer fish.

FDA takes the industry line

Internal FDA focus group transcripts considered together with publicly available FDA documents point to a complete collapse of the government's efforts to protect the public from mercury. The Agency is failing to regulate mercury levels in seafood, has shut down its mercury monitoring program, has not issued an enforceable limit for mercury in fish, and has not implemented the mercury education program that it promised.

Instead, the Agency has adopted a series of policies that mirror the positions of the seafood industry, contradict the recommendations of the National Academy of Sciences, ignore significant new findings from the Centers for Disease Control that confirm elevated levels of mercury in the blood of the human population, and reject the positions of the participants in their focus group sessions. One is hard pressed to find a single important policy decision related to mercury in seafood where the Agency has not adopted the industry line (Table 3). For example:

- ***Only the tuna industry and the FDA reject all existing peer reviewed epidemiological and animal studies that show mercury is toxic at very low doses, and instead use a single study as justification for not adopting more protective standards.***

The National Academy of Sciences advised: "because there is a large body of evidence showing adverse neurodevelopmental effects, including well-designed epidemiological studies, the committee concludes that an RfD should not be derived from a study...that did not observe any association with [mercury]." (NAS 2000) The U.S. EPA agrees with the NAS and has developed a mercury safety standard about an order of magnitude more stringent than FDA's unenforceable action level (EPA 2000).

- ***Only the tuna industry and the FDA argue that there is no need to protect pregnant women from mercury in seafood because women do not eat much fish*** (Table 3). The U.S. EPA safety standard protects all women regardless of how much fish they eat (EPA 2000). The NAS estimated that 60,000 pregnant women a year eat enough fish to put their babies at risk (NAS 2000). Blood monitoring results from the Centers for Disease Control and Prevention show that 10 percent of American women of childbearing age eat sufficient fish to have mercury in their bodies at levels that put a fetus at increased risk for adverse neurological effects (CDC 2001). And pregnant

One is hard pressed to find a single important policy decision related to mercury in seafood where the Agency has not adopted the industry line.

Table 3. FDA's rationale for an unprotective mercury advisory mirrors the positions of the seafood industry.

Tuna industry says...	FDA says publicly...	Focus group transcripts, independent scientists, EPA and CDC say...
<p>Given detailed information, women would just stop eating fish. "Focus group studies have demonstrated that women of childbearing age will stop consuming fish when shown an advisory." (U.S. Tuna Foundation, 2001, pg 17)</p>	<p>"When given... detailed information, members of the focus groups said they would stop eating fish altogether." - Dr. Michael Bolger, FDA's Director of the Division of Risk Assessment (Burros 2001)</p>	<p>Women say otherwise "...my inclination would be to go with things that aren't going to cause any risk of harm – but still eat fish." – focus group participant reflecting 80% of the relevant comments (Macro International, Inc. 2000i, pg 25)</p>
<p>Women really do not eat much fish, even tuna. "Expressed in ounces per week, the 95th percentile of consumption is less than 5 oz/week." - Tuna Industry Consultant (ENVIRON International Corporation 2000)</p>	<p>"Information provided by the National Food Processors Association and FDA's own assessment indicated that... consumption is not as great as anecdotal observations would indicate." (FDA 2001b)</p>	<p>Some pregnant women eat a lot of tuna "One of the things that I could eat was a can of tuna, and I think two tablespoons of mayonnaise, was my lunch every day for I think – well, while I was – five days a week. Okay, so every day, five days a week for lunch for ... seven weeks of my pregnancy. You know, so for seven weeks I'm eating more than they recommend." - FDA focus group participant (Macro International, Inc. 2000j, pg 34)</p>
<p>FDA's action level and advisory are perfectly protective. "Based on the facts, an Advisory is not warranted." (U.S. Tuna Foundation, 2000, pg 24)</p>	<p>"We feel we've evaluated the science in an appropriate way and our advisory is right on target." - Dr. Michael Bolger, FDA's Director of the Division of Risk Assessment (Burros 2001)</p>	<p>The chairman of the National Academies of Sciences committee on mercury toxicity, and FDA scientist speaking to focus group participants "The FDA has stopped short of what it should have done." - Dr. Robert Goyer, Chairman of NAS on methylmercury toxicity (Burros 2001) "... the action levels that we have in place for fish are not protective enough for this – the fetuses." - Senior FDA scientist speaking to Boston focus group (Macro International, Inc. 2000i, pg 65)</p>
<p>Canned tuna is perfectly safe to eat. "This new study adds to the long list of startling health benefits scientists believe Omega-3s fatty acids provide to pregnant women and small children. The most convenient, economical source of Omega-3s for moms and kids is, quite simply, canned tuna!" (U.S. Tuna Foundation, 2001)</p>	<p>"Specific advice for canned tuna [is] not necessary and should be subsumed within the advice dealing with fish consumption in general." (FDA 2001b)</p>	<p>FDA scientist speaking behind closed doors says "It is prudent, particularly for pregnant women to avoid these high mercury fish and moderate their tuna fish consumption." - FDA senior scientist (Macro International, Inc. 2000j, pg 72) "... the dilemma that we have is that to lower the action levels, so they're protective of fetuses, it would actually put the availability of certain kinds of fish in question. We would lose some fish. Then he is asked: "Like King Mackerel [sic], shark, and swordfish?" He replies, "Well, those in particular, but also tuna." - FDA Senior scientist (Macro International, Inc. 2000i, pg 65)</p>

women in FDA's focus groups describe how they increased their canned tuna consumption dramatically during pregnancy to satisfy their protein needs or other dietary concerns.

- **Only the tuna industry and the FDA say that women will stop eating fish when given detailed information on fish to avoid during pregnancy** (Table 3). When presented with draft health advisories, participants in FDA's own focus groups said that they would keep eating fish but avoid those with high mercury levels (Tables 1 and 2).

1. FDA fails to set mercury regulation at level that protects public health

Seafood that is technically "safe" according to FDA's mercury action level is actually endangering public health. In a focus group session held in Boston, a senior FDA scientist that supposedly safe seafood could put a fetus at risk for neurological damage: "... the action levels that we have in place for fish are not protective enough for this – the fetuses..." (Macro International, Inc. 2000i – Boston, Nov 8, 8 pm, pg 65).

In the same focus group, a woman whose child has Attention Deficit Hyperactivity Disorder pressed an FDA scientist: "I mean, now you find a lot of Attention Deficit Disorder and they're really not saying where it is coming from... But maybe it could be coming from eating too much fish – you know – I mean, is that a possibility?" The scientist replies, "Yes, that's why we're – yes, that is a possibility. That is why we're interested in this." "So my daughter is on medication, now, because I ate fish..." FDA's scientist responds, "– now that we have this research, that now is a possibility." (Macro International, Inc. 2000i – Boston, Nov 8, 8 pm, pp 70-71)

In spite of these admissions, FDA has no plans to strengthen their action level for mercury in seafood, and has based their advisory to pregnant women on this same action level (one part per million of mercury in fish) that they admit does not protect the fetus.

2. FDA fails to justify their unprotective action level and advisory

Transcripts undercut FDA claims that consumer reactions justify withholding information

FDA's Dr. Michael Bolger claimed in a national news story (Burros 2001) that the FDA-sponsored focus groups proved "it was difficult to communicate to people the concept that there are safe fish, unsafe fish and some fish that should be eaten infrequently. When given such detailed information, members of the focus groups said they would stop eating fish altogether." Even though this is one of FDA's primary reasons for providing such a severely limited advisory to pregnant women, the focus group transcripts do not support this assertion.

"So my daughter is on medication, now, because I ate fish..."
FDA's scientist responds, "– now that we have this research, that now is a possibility."

Eighty percent of comments relating to seafood consumption (30 of 37 comments) indicated that after hearing FDA’s proposed advisory, people would continue to eat seafood or would avoid just the high mercury fish

In the 267 pages of transcripts from the final three focus groups, which were the only groups that were presented information in a form similar to FDA’s final advisory, 80 percent of comments relating to seafood consumption (30 of 37 comments) indicated that after hearing FDA’s proposed advisory, people would continue to eat seafood or would avoid just the high mercury fish (Table 1). Only seven individual comments support FDA’s claim to the press. These seven individual comments came from, at most, three women in a focus group of pregnant women (Shawna, Monica, and an unidentified participant who echoed Monica’s statement and may have been Monica speaking again). The remaining four comments came from, at most, three people pretending to be pregnant, one of them a man named Trevor (Table 2).

What some focus group participants did say was that they would stay away from moderately-contaminated tuna and would choose to eat low-mercury fish instead. *“Gee, I don’t think I’m going to eat tuna,”* said a pregnant woman in a Denver focus group after hearing that pregnant women should limit their consumption of canned tuna. (Macro International Inc. 2000g - Denver, Oct 17, 6 pm, pg 75). A woman in a Boston focus group describes how she will avoid fish with any consumption warning attached to them: *“...my inclination would be to go with things that aren’t going to cause any risk of harm – but still eat fish.”* (Macro International, Inc. 2000i – Boston, Nov 8, 8 pm, pg 25)

And contrary to what FDA’s Bolger told the public, between the first and the 11th focus group, FDA came a long way toward finding ways to communicate the hazards of mercury in seafood without turning people off to seafood. One pregnant woman in a Calverton focus group summed up the information like this: *“My advice would be not to eat the mackerel, the shark and the swordfish. But, I would also put in a note; you should limit your intake of the tuna and then, you know, eat the rest of the fish in moderation. Don’t consume large quantities of fish. Don’t assume that you can.”* (Macro International, Inc. 2000j – Calverton, November 14, 6 pm, pg 59). That is the message FDA was supposed to be trying to convey: that some – not all – fish are unacceptably high in mercury.

Further undercutting Bolger’s claim are the reactions from male consumers in the focus groups. Most were completely comfortable with continuing to eat seafood after hearing it contains mercury. A grandfather from Calverton correctly points out that FDA’s message to pregnant women was not intended for men: *“Well, we haven’t read anything yet that it is a negative thing to do unless you are pregnant. So, based on what we’ve read so far, I don’t think I would change anything at this point.”* (Macro International, Inc. 2000k – Calverton, Nov 14, 8 pm, pg 31). A Calverton father of two teenage sons is unimpressed with the level of risk mercury poses to him: *“I’ve been in traffic here and there, played the dodge car show, see, and I guess my time was up five years ago, maybe twenty years ago, you never know. But, to make a long story short, I’ll eat anything.”* (Macro International, Inc. 2000k – Calverton, Nov 14, 8 pm, pg 33).

Of the approximately 100 people included in all 11 focus groups, only a handful voiced the opinion that they would stop eating seafood after hearing that it contains mercury. And some of those participants' remarks are difficult to interpret. For example, during one focus group, a participant is asked how she would respond to hearing that canned tuna consumption should be limited to four three-ounce servings a week. She replies, "*I would never buy it again. I would cut back if I ate a lot. I would cut back on it quite a bit. I'd have it occasionally.*" (verbatim, Macro International, Inc. 2000g – Denver, October 17, 6 pm, pg 32).

In some cases, as focus group participants were led through information over the course of their session, their perceptions evolved. In a Calverton, Maryland focus group the moderator introduced the issue of mercury in fish by reading an excerpt from the National Academy of Sciences study that speaks to the risks. One participant's response: "*once I read this article right here, then I'm going to stop eating fish. . . . Because it's – like it says small amounts. You don't know how many amounts, what quantity or what. So, I will stop eating fish, and I will call me a lawyer.*" (Macro International, Inc. 2000a – Calverton, October 11, 6 pm, pg 43) But later, after learning that farm-raised catfish and trout are considered safe, a participant considers backtracking on her original position:

"It seems like it's tempting, it's really, really tempting. It does. But – I mean, I don't want to sit up here – Once I set my mind to something, then I pretty much stick to it. But, you know, if it's saying that it's no mercury concern for these species, for farm-raised catfish or trout, to be honest and realistically speaking, it's a small possibility that I might have like a little teenie piece of the freshwater catfish or trout, just a little, teenie piece." (Macro International, Inc. 2000a – Calverton, October 11, 6 pm, pp 96-97)

A participant named Trevor in a Boston focus group said that if he were a pregnant woman, "*I would not eat fish for the first trimester.*" (Macro International, Inc. 2000i – Boston, Nov 8, 8 pm, pg 24). To be conservative, we counted this as one of the people who would avoid fish entirely.

3. Focus group transcripts show that, contrary to what FDA says, some pregnant women eat significant amounts of tuna

The defense FDA offers in dropping tuna from its advisory is that fish is a small portion of the diet, and therefore the risk is not significant. Specifically, FDA cites a tuna trade association study purporting to show that "*canned tuna... consumption is not as great as anecdotal observations would indicate... For this reason, the agency concluded that specific advice for canned tuna was not necessary and should be subsumed within the advice dealing with fish consumption in general.*" (FDA 2001b).

Two problems with this logic jump out immediately. First, the amount of tuna women eat should have no impact on whether they receive sound advice about safe consumption levels. And if, in fact, women don't eat

The focus groups strongly contradict the industry's contention that fish consumption, particularly for pregnant women, is overestimated.

much tuna, then advising them on safe consumption levels should raise few issues about the advisory's economic impact on the seafood industry.

On top of that, the focus groups strongly contradict the industry's contention that fish consumption, particularly for pregnant women, is overestimated.

One woman in a Calverton focus group describes the canned tuna diet prescribed to her by her doctor: *"But see, when I had my first son I had gestational diabetes and I was put on a very strict diet. One of the things that I could eat was a can of tuna, and I think two tablespoons of mayonnaise, was my lunch every day for I think – well, while I was – five days a week. Okay, so every day, five days a week for lunch for...seven weeks of my pregnancy. You know, so for seven weeks I'm eating more than they recommend."* She reveals to the group that her baby was born prematurely and died of SIDS shortly after birth, a condition that has not been linked to mercury exposure. (Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm, pp 34-35,37).

Another pregnant woman recalls that her canned tuna consumption the previous summer probably exceeded FDA's safe level: *"...I ate during the summer a lot more tuna because I would just throw it on some lettuce and call it a salad. It was light. It was quick for work. It was done. So, now that I think about that, I did eat probably more than a can and a half in one week during the summer."* (Macro International, Inc. 2000j – Calverton, November 14, 6 pm, pg 41).

The convenience of canned tuna make it a preferred food for busy pregnant women.

Also, according to FDA's focus group research, the convenience of canned tuna can make it a preferred food for busy pregnant women: *"...for me it was what was most convenient. What was most convenient was taking a can of tuna fish, my two things of mayonnaise and my half an apple to work every day for lunch. That was what was convenient for me. ..."* (Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm, pg 37.) And the price of canned tuna makes it a preferred food for others: *"I just bought a whole bunch of it because it was on sale, too. They were like 39, 49 cents – you know – use your Safeway or Giant bonus card,"* a sentiment that another woman in the group sums up as *"It is real cheap."* (Macro International, Inc. 2000a – Calverton, October 11, 6 pm, pg 75).

A pregnant woman in an Calverton focus group describes how she ate tuna to lose weight before pregnancy: *"I was doing it before I got pregnant because I was planning to get pregnant. As part of doing the Adkins Diet, you can have stuff like that with fish or your chicken, as much of that as you want to consume. So, I ate a lot of that bag of salad, can of tuna, hard-boiled egg, that was my lunch, or salmon or whatever..."* (Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm, pp 52).

Further undercutting FDA's faulty rationale is a major study from the Centers for Disease Control and Prevention showing that ten percent of women of childbearing age (about 7,000,000 women) have mercury in their

bodies at levels that may put a fetus at risk for adverse nervous system effects (CDC 2001 and NAS 2000). FDA's low consumption estimates are irrelevant in the face of these direct measurements showing that 7,000,000 women have higher mercury exposure than FDA thought.

4. Contrary to FDA's claims, focus group participants wanted even more detailed information about mercury in seafood

A consistent theme throughout the focus groups was that participants wanted more information so that they could make informed decisions for themselves.

For example, when the moderator asks one group, *"And what do they need to say in terms of telling you about the risks but, also, on the other hand, not over-scaring you?"* a participant replies, *"They need to tell you the truth. They can tell you – you know, if it is not good for you, then don't eat it. You know, they just need to tell you exactly what the study said – what the truth is. Then you can make up your own mind."* Another participant adds, *"And you need the facts to know whether or not you want to go ahead with this. There are no facts in this,"* or, as one woman in the Calverton group said about FDA's reluctance to give complete information: *"Why don't they tell us?"* (Macro International, Inc. 2000i – Boston, Nov 8, 8 pm, pp 46-47 and Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm, pp 37-8.)

Despite this strong consumer feedback from FDA-sponsored research, the Agency severely limited its advisory, eliminating any reference to tuna and a number of additional fish that the Agency's own data show have even higher levels of mercury than does tuna, including sea bass, orange roughy, halibut, red snapper, grouper, and mahi mahi (FDA 2001c).

5. FDA and the tuna industry reject all peer reviewed science that shows low level mercury toxicity

Timing of meetings with lobbyists suggest industry won deletion of health warning

Additional public documents show that FDA, by leaving their lax mercury consumer advisory in place, has followed the advice of the tuna trade association over the recommendations of the National Academy of Sciences. Specifically, the U.S. Tuna Foundation urged FDA to consider data from a study that the NAS recommended against using in deriving health standards for mercury.

The use of data from this single study (the "Seychelle Islands study") results in the most lax safety standard possible. FDA met privately with the Seychelle Island scientists as they crafted their new advisory to pregnant women, but met with none of the scientists involved in the other, more sensitive studies (FDA 2001d).

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FDA chose to take the advice of the tuna industry over the National Academy of Sciences.

In a November 6, 2000 U.S. Tuna Foundation meeting with FDA, industry advised the Agency to use the Seychelle Islands data and leave a lax safety standard in place, and then warned of legal implications if FDA strengthened the mercury action level: *“Canned tuna and other fishery products have been sold in the U.S. for more than a century. In recent years, FDA has repeatedly confirmed the safety of these products. Any change in this policy will be seen as an admission that earlier statements were inaccurate and will put in doubt the safety of these products. This would encourage spurious lawsuits to be filed against seafood producers by individuals who will now believe that the seafood product they thought was safe carried the risk of neurodevelopmental deficits.”* (U.S. Tuna Industry, 2000)

In sharp contrast to the tuna industry’s recommendations, the National Academy of Sciences recommends: *“...because there is a large body of scientific evidence showing adverse neurodevelopmental effects, including well-designed epidemiological studies, the committee concludes that [safety standards] should not be derived from a study, such as the Seychelles study, that did not observe any associations with [mercury]”* (NAS 2000). In particular, the Academy cites the two major studies of children (in the Faroe Islands and New Zealand) that found evidence of adverse neurological effects at very low levels of maternal mercury exposure.

FDA chose to take the advice of the tuna industry over the National Academy of Sciences. On May 9, 2001 the NAS mercury committee chairman commented to The New York Times: *“I had thought the F.D.A. would pay more attention to our report.”* (Burros 2001)

Despite FDA’s admissions that mercury poses a real risk to the fetus, the Agency abandoned its mercury testing program in 1998.

6. FDA fails to test and enforce

FDA does not monitor seafood or enforce mercury safety standards, but it admits to participants that mercury poses a real risk to a fetus

Despite FDA’s admissions that mercury poses a real risk to the fetus, the Agency abandoned its mercury testing program in 1998 (GAO 2001). When a focus group participant pressed FDA’s scientist on the issue of testing: *“Is the FDA considering inspecting fish the way the Department of Agriculture inspects meat?”* FDA’s scientist replies, *“We don’t do that. That’s not the way we regulate things. What we tend to do is set standards, and that it is illegal not to adhere to the standards. So, if we identify a fish that exceeds the standard, that’s violative and we can take action against it.”* *“But is it periodically checked, across the board?”* he is asked. *“But we don’t do proactive testing,”* he replies. (Macro International, Inc. 2000i – Boston, November 8, 8 pm, pg 61)

Later in the focus group session, FDA’s senior scientists points out that, while *“It’s true that there is no proactive inspection system for fish, [t]he actual context for this information is that we do have these standards for mercury levels that can be in fish. They’ve been set, you know, 20 years ago.”* (Macro International, Inc. 2000i – Boston, Nov 8, 8 pm, pg 64)

These standards are non-enforceable action levels that, by FDA's own admission in these focus groups, are upheld by the Agency through a program that involves no testing.

One focus group exchange expresses the hope that commercially sold seafood is tested and safe: *"I guess you could take a tester with you and put the fish in it, see how much, oh, 14%, throw it away."* (Laughter) *"We're hoping the FDA will do that for us."* (Macro International, Inc. 2000g – Denver, Oct 17, 6 pm, pg 93) But after hearing first-hand how FDA fails to regulate seafood or test fish or warn consumers, a Boston focus group member advises the attending senior FDA scientist: *"So my reaction is don't worry about the fishing industry. Just get the information out there. People will continue to eat fish because they like it and it's good for them. And, eventually, it will sort out; which fish isn't good for pregnant women."* (Macro International, Inc. 2000i – Boston, November 8, 8 pm, pg 91)

By failing to test, FDA protects fishing industry – beyond tuna

Even by the Agency's own relaxed health criteria, the limited available monitoring data show that many types of fish might pose health risks to pregnant women. In spite of this, FDA plans no further testing and plans no interim warnings to pregnant women.

A pregnant woman from Calverton hears about the problem of mercury in seafood for the first time during her focus group session, and is immediately concerned about the fish she ate early in pregnancy: *"This is new to me, because in the beginning of my pregnancy it was still summer and we live at the beach, and my husband was fishing every night so we were having fresh fish every night for dinner. You know, for a good month during the first part of my pregnancy, you know, we've had, you know, as a side dish we'd have fish or as a main course we would have fish because there was tons of fish. I didn't know about this."* (Macro International, Inc. 2000i – Calverton, Nov 14, 6 pm, pg 16).

Before she is given FDA's proposed lists of high and low mercury fish, she notes to the group, *"This child's doomed."* Later in the session the moderator reads the list of fish that should be avoided or eaten only in moderation during pregnancy, a list that includes tuna steaks and canned tuna and other even higher mercury species. The woman exclaims, *"I am home free"* – she ate bluefish from the Bay in the early months of her pregnancy, which appears nowhere on FDA's advisory (Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm, pp 31,33).

As it turns out, however, she may have consumed up to 10 times the amount of mercury that FDA considers safe for her baby. The two samples of bluefish that have been tested by the Agency since its inception show about the same average mercury level (0.30 parts per million, or ppm) as the 191 tuna steaks in the Agency's database (0.32 ppm) (FDA 2001c). The Agency's draft advice for pregnant women was to limit tuna steak consump-

The limited available monitoring data show that many types of fish might pose health risks to pregnant women.

tion to 18 ounces per month. If this woman ate 6 ounces of bluefish for 30 days, she would have eaten 180 ounces of fish, exposing her fetus to 10 times the Agency's "safe" dose of mercury.

FDA's monitoring data shows that many other types of fish that do not appear on the Agency's advisory have levels of mercury even higher than tuna. Specifically, red snapper, marlin, orange roughy, and grouper are among the fish with average mercury levels higher than the levels in tuna steaks. Fish with mercury levels higher than what is found in canned tuna include all of those, as well as cod, mahi mahi, perch, pollock, halibut, and bluefish (FDA 2001c).

7. FDA has failed to educate the public about the hazards of mercury

FDA research finds pregnant women aren't getting the information it has already announced

FDA has failed to implement the consumer education program it promised more than a year ago.

FDA has failed to implement the consumer education program it promised more than a year ago, and has a long history of failing to educate the public about mercury in seafood. Since September 1994 FDA has had in place a consumer advisory warning of high levels of mercury in shark and swordfish, which counsels both pregnant women and the general population to limit their consumption of these fish (FDA 1994). Although this advisory had been in place for a full six years prior to FDA's focus group meetings, very few participants were familiar in any way with the notion that seafood can contain mercury, let alone which types of seafood have high levels.

At the outset of each focus group, participants were asked what they knew about sources of mercury exposure or, in a separate question, pollutants in fish. In each of two groups, a participant mentioned swordfish as a concern, and in two other groups tuna – but not swordfish – was mentioned as a concern. Environmental and consumer groups, not the FDA, have tried to alert the public to mercury in tuna.

This result, while not statistically significant, gives an indication that the few environmental and consumer groups who try to alert pregnant women about mercury in tuna, may have had as big an impact on public education as the FDA. It also indicates that public interest and consumer groups can no longer assume that FDA will succeed in educating the public about the very high mercury fish, the four fish that are now black-listed for pregnant women (shark, swordfish, king mackerel, and tilefish).

One of the two mentions of swordfish was dismissive: *"I think they took – what was it – swordfish off the market. That was a while back. They claimed that it had a lot of mercury, but... I think a lot of that is maybe a little exaggerated."* (Macro International, Inc. 2000k – Calverton, Nov 14, 8 pm, pp 8 and 9).

In another focus group the extent of knowledge about mercury in fish came from a woman who knew that *“There was a mercury contaminant some time ago.”* (Macro International, Inc. 2000c – Calverton, October 12, 6 pm, pg 12) One woman sums up the Agency’s failure to educate the public in this way: *“...this is my fifth pregnancy and I haven’t heard – never, ever, you know, in nine years heard anything about this... So, why aren’t we being informed?”* (Macro International, Inc. 2000j – Calverton, November 14, 6 pm, pg 38)

“...this is my fifth pregnancy and I haven’t heard – never, ever, you know, in nine years heard anything about this... So, why aren’t we being informed?”

Women told FDA to distribute information through doctors, but officials admitted they’ll rely on industry to publicize product hazards

Even though women in the focus groups identify their doctors as their primary source of health-related advice during pregnancy, FDA officials admit in the transcripts they will rely on the seafood industry, not women’s obstetricians, to convey the health advisories for mercury.

Echoing the opinion of many women in the FDA focus groups, a pregnant woman in a Denver focus group advises FDA to use doctors as an information conduit: *“Well, if it’s only meant toward the pregnant women or women that are nursing a child, I think it should be given out during your visits with your doctor or care provider... That way you know right up front as soon as you’re pregnant what’s good and what’s not.”* (Macro International, Inc. 2000e – Denver, Oct 16, 6 pm, pg 45)

Another pregnant woman questions an FDA scientist on how the Agency will get information to pregnant women: *“Did you say, do you plan to notify OBs and pediatricians? I mean, because I am a nursing mother. . . it would be really nice if when I went in to take my baby in for its two week appointment my pediatrician says, oh, by the way – or some kind of literature. Your first OB appointment, you go in and the doctor hands you all this literature, and even in the new literature I’ve gotten I never heard anything about it. What are your stops?”* (Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm, pg 84)

An FDA official explains why the Agency does not plan to use doctors to convey to pregnant women the dangers of mercury in seafood, but they offer no evidence to justify their implication that doctor-based education initiatives would fail: *“They have a lot of things to warn you about, and there’s competition to get on their agenda. This particular threat is not high on their agenda. They quite reasonably argue that there’s lots of other things that they need to talk about in terms of more importance. So, it’s hard because you have to compete with a lot of other risks to get on their agenda.”* (Macro International, Inc. 2000j – Calverton, Nov 14, 6 pm, pg 85)

Then in an exchange that involves a participant questioning an FDA scientist on why the Agency is worrying about the effects of the health advisory on the seafood industry, the scientist reveals that *“The industry is probably going to be one of the major ways that this information gets put out.”* (Macro International, Inc. 2000i – Boston, Nov 8, 8 pm, pg 97) Feder-

ally-mandated, industry-driven consumer education has worked to some extent for alcohol and tobacco, which carry warning labels required by federal law, but it will be difficult at best for FDA to convince the seafood industry to voluntarily provide consumers with warnings about the risk their mercury-contaminated products pose to pregnant women.

Only one pregnant woman mentions that she might call “Sea King” to learn if their mercury-contaminated products cause birth defects. (Macro International, Inc. 2000g – Denver, Oct 17, 6 pm, pg 59). The seafood industry, however, has yet to warn women of the potential dangers of mercury. In fact, the industry used a recent study on the benefits of fish consumption (specifically, of Omega 3 fatty acids) to promote tuna consumption for pregnant women: “...*this new study adds to the long list of startling health benefits scientists believe Omega-3s fatty acids provide to pregnant women and small children. The most convenient, economical source of Omega-3s for moms and kids is, quite simply, canned tuna!*” (U.S. Tuna Foundation, 2001). This press release provides a clear indication that the tuna industry has no plan to protect its customers from the dangers of mercury by steering them toward safer fish.

Recommendations

FDA has a 33-year history of failed health advisories and nonenforceable mercury contamination guidelines. The Agency's monitoring programs do almost nothing to test the most commonly eaten fish for mercury. When its limited testing shows high mercury contamination, the Agency fails to protect the public. The focus group transcripts analyzed here show that FDA officials admit these failures when pressed by focus group participants but ultimately cave to the wishes of the fish industry when developing their final health advisory for mercury in seafood.

We recommend the following actions to protect pregnant women and children from dietary exposure to mercury:

1. Convene Congressional oversight hearings on FDA procedures.

EWG's review of FDA's focus group transcripts reveals that FDA is withholding critical information from the public on mercury-contaminated fish. FDA scientists admit during the focus groups that current health standards and enforcement procedures are inadequate. Despite growing scientific support for stronger health advisories, monitoring and enforcement, FDA has not responded. Independent Congressional review of the focus group transcripts will highlight the inadequate testing, monitoring, enforcement and consumer education procedures currently used at FDA.

2. Adopt the NAS recommendations for new fish advisory levels and expand the list of species to avoid during pregnancy.

Ten percent of American women enter pregnancy with elevated methylmercury levels. FDA safeguards, which are based on average exposures, do almost nothing to protect these high exposure pregnancies. If these women follow FDA's advice of 12 ounces of any fish a week, they could easily expose their fetuses to a level of methylmercury that presents a risk of adverse neurological effects. The National Academy of Sciences stated that the EPA action level is justifiable, which is eight times more stringent than the current FDA enforceable action level. NAS also recommended that a revised action level be developed that reduces the differences among agencies. The focus groups show that women can and will follow detailed health advisories about which species to avoid during preg-

nancy. Pregnant women have a right to this information, and FDA has a duty to provide it.

3. Improve monitoring of fish for methylmercury contamination.

A major flaw in FDA's system is the Agency's lack of comprehensive data on methylmercury in fish. In January 2001, FDA recommended that pregnant women avoid consumption of king mackerel based on methylmercury levels from a study published in 1979. There are many other species where the data on methylmercury contamination are similarly outdated, but where the available information indicates a potential problem. FDA must immediately expand its methylmercury monitoring program to include a host of fish where the data indicate that pregnant women and their children could receive a potentially unsafe exposure from a relatively small amount of fish. Congress should include funding in the Fiscal Year 2003 Agriculture Appropriations bill to restart the fish tissue inspection process of domestic and imported seafood.

4. Protect all babies from mercury, not just the "average" baby.

FDA needs to move beyond its antiquated and biologically implausible risk assessment methods based on average people and average fish and adopt state-of-the-art risk assessment techniques that provide a much more realistic picture of mercury exposure and risk as it is distributed throughout the population. It is not sufficient to protect the population from average exposures when it is clear that many individuals have far greater than average exposures for extended periods of time. FDA must use probabilistic risk assessment methods to assess the fetal exposure to mercury and then set standards that protect all pregnancies. The focus groups transcripts show that senior FDA scientists agree with NAS that current action levels are not protective enough for pregnant women and fetuses.

5. Monitor human exposure and health.

The U.S. lacks a comprehensive program to track disease and exposure to environmental contaminants like methylmercury. Congress should appropriate funding for the Centers for Disease Control and Prevention to build a health-tracking network and to continue biomonitoring programs in Fiscal Year 2003.

6. Reduce mercury pollution at its source.

Mercury emissions from coal-fired power plants, the largest man-made source of environmental mercury, are currently completely unregulated. Federal decision-makers should require power plants to reduce their mercury pollution by 90% and ultimately move away from polluting sources of power.

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