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REGULATORY STUDIES PROGRAM ¹

Public Interest Comment on

FDA's Report of Quantitative Risk and Benefit Assessment of Commercial Fish Consumption

Docket Number FDA-2009-N-0018-138.1

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The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of the impact of regulation on society. As part of its mission, RSP conducts careful and independent analyses employing contemporary economic scholarship to assess rulemaking proposals from the perspective of the public interest. Thus, this comment does not represent the views of any particular affected party or special interest group but is designed to comment on FDA's recent release of risk analyses.

In a recent release, FDA has made available two draft documents, the *Report of Quantitative Risk and Benefit Assessment of Commercial Fish Consumption, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children and on Coronary Heart Disease and Stroke in the General Population)* and *Summary of*

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Published Research on the Beneficial Effects of Fish Consumption and Omega-3 Fatty Acids for Certain Neurodevelopmental and Cardiovascular Endpoints. FDA has had a risk communication bulletin out on methyl mercury in fish for over a decade, with the most recent advisory coming as a joint product between FDA and EPA.² These two analyses appear to be intended to inform potential changes to that bulletin and are the most complete studies of the effects of methyl mercury (MeHg) to date by FDA despite the modest announced goal of adding “to the growing body of scientific literature investigating the likelihood, magnitude, and direction of health impacts linked to consumption of commercial fish.”³

FDA is to be commended for this important step that advances its approach to consumer communication and, more generally, risk analysis to the next level. Risk analysis consists of risk assessment, risk communication, and risk management. For any problem associated with communications to consumers about their purchase behavior, it is imperative that all three aspects of risk analysis are directed toward the actual decisions that consumers make, i.e., whether or not to purchase a product. They do not decide whether to purchase a component or an attribute of a product: these are only factors in the more holistic purchase decision.

This should not be a new discovery. Senators George McGovern and Bob Dole held nutritional hearings in the 1970s that came to the same conclusion: To get nutrient changes, they concluded that recommendations should be about increasing or decreasing certain types of foods.⁴ FDA should apply this model across all food-risk

² FDA and EPA, *What You Need to Know about Mercury in Fish and Shellfish*, <http://www.epa.gov/fishadvisories/advice/>.

³ U.S. Food and Drug Administration, *Draft Risk and Benefit Assessment Report: Report of Quantitative Risk and Benefit Assessment of Consumption of Commercial Fish, Focusing on Fetal Neurodevelopmental Effects (Measured by Verbal Development in Children) and on Coronary Heart Disease and Stroke in the General Population*, January 15, 2009, <http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm088794.htm>.

⁴ Select Committee on Nutrition and Human Needs, *Dietary Goals for the United States*, (Washington, DC: GPO, February 1977), http://zerodisease.com/archive/Dietary_Goals_For_The_United_States.pdf.

communications to consumers whether the subject is nutrition or safety.⁵ For food safety, this means communicating the risks and benefits of the food as a whole and steering away from, for example, specific information about potential chemical or pathogenic contamination (e.g., *Listeria monocytogenes* in various products, salmonella in shell eggs, mycotoxins, or methyl mercury).

FDA has wisely recognized that seafood, as do all foods, contains both nutritional benefits and food-safety risks. Being able to compare risks and benefits has implications for risk assessment as well as risk communication. Importantly, FDA has moved beyond a safety analysis toward estimating the actual risks associated with methyl mercury. Safety analyses, as opposed to risk assessments, attempt to make a conservative determination of a “safe” level of exposure. Safety assessments are done by scientists (not managers), and they are essentially qualitative judgments, even if derived in a quantitative fashion, of an intake level where there is a low (or hypothetical zero) probability of harm, usually to a highly exposed or highly sensitive subgroup. Examples of safety assessments include FDA’s Acceptable Daily Intake (ADI) and EPA’s Reference Dose (RfD),⁶ which are appropriate as screening tools to determine whether a compound presents sufficient risk to warrant further investigation. For other types of decisions or where a screen indicates that there is enough risk to take potential action, the decision to take action on a hazard should depend on multiple factors to ensure that the decision accounts for risks, benefits, and costs. But in its comment on FDA’s methyl-mercury analyses, EPA stated, “It is well known that 5–10% of the population (depending on the specific region) of women of childbearing age exceeds a health benchmark, the EPA’s MeHg reference dose (RfD).”⁷ Calling an RfD a “health benchmark” does not change the fact that this safety assessment does not say anything about risk above or below the RfD, including countervailing risks such as the presence of

⁵ One attempt to convey holistic nutrition information on all food macronutrients and ingredients is the “Smart Choice” symbol that will be introduced this summer. See <http://www.smartchoicesprogram.com/>.

⁶ The *Business Dictionary* defines RfD as the “concentration of a chemical at which adverse effect(s) on human health are known to occur” and ADI as the “maximum amount of a substance . . . to which an individual can be exposed to (through contact or intake), on a daily basis over his or her life span . . . without causing any harmful effects.

⁷ EPA, Comment to FDA’s Docket 2009-N-0018.0138.1, April 17, 2009, 5.

omega-3 fatty acids. If seafood consumption is reduced because of the methyl-mercury advisory, then there will also be a reduction in beneficial omega-3 fatty acids (a countervailing risk).

When there are such trade-offs, it is also important to avoid conservative assumptions in risk assessments so as to be able to weigh all factors on the same scale. Conservative assumptions lead to an overestimate of risk, usually by an indeterminate level, so that it then becomes impossible to compare target risks with other risks, benefits, or costs.

A final major problem with safety analyses is that they can allow agencies to hide behind the science. Safety analyses are the results of scientific modeling, but that does not necessarily translate to a transparent and well-reasoned risk-management decision. As Cary Coglianese and Gary Marchant point out, “Science describes; it does not prescribe.”⁸ Thus, having a safety analysis does not relieve risk managers from using all relevant information to make a decision, just as consumers must do.⁹ This is particularly true when a compound contains a hazard for which there does not appear to be a threshold, as may be the case with methyl mercury. EPA, in its comment, suggests that no threshold exists for MeHg as listed in EPA’s IRIS assessment. But when a standard must be set, the standard “must, at least implicitly, (be set) based on some criteria other than the science, since the science indicates that health effects likely occur at levels below the standard selected by the regulators.”¹⁰ Again, this should not be a new finding. As cited by the Coglianese and Marchant paper, “Senator Muskie, the primary sponsor of the amendments (to the Clean Air Act in 1978), observed that for nearly all criteria pollutants, ‘there is no threshold health effect which can be used to say that above this threshold there is danger to health and below it there is not.’”¹¹ The House likewise acknowledged in 1977 “that the ‘safe threshold’ concept underlying Section 109 (Clean

⁸ Cary Coglianese and Gary Marchant, “Shifting Sands: The Limits of Science in Setting Risk Standards,” *University of Pennsylvania Law Review* 152, no. 4 (April 2004), 1,274.

⁹ Richard A. Williams and Kimberly M. Thompson, “Integrated Analysis: Combining Risk and Economic Assessments While Preserving the Separation of Powers,” *Risk Analysis* 24, no. 6.

¹⁰ Coglianese and Marchant, “Shifting Sands,” 1,286.

¹¹ *Ibid.*

Air Act) was ‘at best’ a *necessary myth* [italics added for emphasis] since ‘no safe threshold can be established.’”¹² Conglianese and Marchant go on to say, “When EPA or any other agency invokes science to justify its regulatory decisions, it fails to provide the public with a transparent and principled justification for its regulatory decisions.”¹³ Thus, by moving away from safety assessments for seafood risk, FDA has moved a step forward in risk-management transparency and toward providing consumers with information that helps them weigh risks and benefits in the same way that consumers make these decisions.

FDA has also examined the health benefits of omega-3 fatty acids. Health benefits are the subject of different kinds of claims on food products including health claims, nutrient content claims, and structure-function claims. The burden of proving that the benefits of components of food are sufficiently justified by science so that they can be advertised on food products, on labels, or in the media generally falls on the firms who wish to advertise them. Just as with risks, health benefits may also be thought of as being based on probability: a probability of a risk of hazard or a probability of a benefit occurring. Standards of evidence necessary for claiming nutrition benefits for health claims should be the same as the standards used to calculate risk hazards (expected or actual values), not ones that rely on liberal assumptions to ensure that the benefits are not overestimated. Evidence that is required to be used by firms are required to use to justify health and nutrient content claims typically requires liberal assumptions to ensure that the claim is true. But evidence to support claims and evidence to justify controlling or advising about health risks should be generated on a comparable basis as the only way that risk managers or consumers can compare risks and benefits. This is not to underestimate the difficulty of putting health and safety risks and nutrition benefits on the same scale given the necessarily different kinds of scientific protocols used to generate the evidence. It may be difficult, for example, to compare epidemiological studies of health or safety risks, which attempt to screen out all other possible sources of risk from the target risk, to nutrient benefit studies, which use clinical trials. Clinical trials do not give evidence of

¹² Ibid.

¹³ Ibid.

population risk and must be supplemented by other evidence to determine population risk. In fact, one cannot perform clinical trials on substances typically analyzed by risk assessments. Nevertheless, the goal of these studies ought to be to produce expected values, i.e., what the scientists thinks the actual risk is—not the highest possible value. In all cases, studies that find no evidence of risks or benefits should not be discarded but used to weight the evidence if they are of similar quality to those that find effects.

Further, it should be recognized when managing communication risks that there needs to be very careful deliberation to determine what information consumers will actually use. It is very difficult to reverse advice on either risks or benefits because it can be hard to dislodge previous beliefs. FDA is likely to have some difficulty convincing consumers that the risks suggested by earlier methyl-mercury communications were overstated because they were based on an incomplete risk model. Certainly, one conclusion that might be drawn from this risk/benefit analysis is that given the level of risk presented to consumers from methyl mercury in seafood, coupled with the general benefits that are derived from omega-3 fatty acids, a federal communication message about risks and benefits of eating commercial seafood, even to women of childbearing years, is not necessary. That is, FDA's analysis appears to show that this is essentially a non-problem given current exposure levels in the United States. This would support an argument for allowing this program to simply expire. Nevertheless, given the uncertainty about growth or decline of levels of methyl mercury in commercial fish, periodic monitoring seems warranted.

At a minimum however, FDA should withdraw the pamphlet entitled *What You Need to Know About Mercury in Fish and Shellfish* for two reasons.¹⁴ First, any risks to women of childbearing years (and their unborn children) are, apparently, extremely low, although there is some uncertainty. Given current U.S. consumption rates, there appears to be no harm from eating seafood, and, in fact, all consumers might be advised to increase their consumption of seafood. Second, having obstetricians focus on this relatively unimportant message detracts from real concerns such as overall diet, drug and alcohol

¹⁴<http://www.fda.gov/Food/ResourcesForYou/Consumers/ucm110591.htm>

abuse, prenatal check-ups, and other vastly more serious issues. I disagree with the suggestion from the Environmental Protection Agency that FDA engage in a Memorandum of Understanding with multiple agencies to produce a new risk analysis which will take years. EPA's advice to FDA is that it views this document as only a "valuable starting point."¹⁵ The danger to women and infants from this kind of advice being put on the same scale with other much more certain and larger risks should not be underestimated. FDA, based on its own statutory authority, should act now and withdraw this pamphlet. As EPA has noted, EPA did in fact already participate in this analysis.

In another section of its comments, EPA addresses what it perceives as the lack of the FDA modeling effort to address variability because the pattern of fish consumption for some individuals departs "from the national composite average."¹⁶ Without commenting specifically on FDA's exposure analysis, any time there is a small, identifiable at-risk population, particularly when it is due to a high level of consumption, a targeted message for such a group would be a much more appropriate strategy than a national campaign that addresses the entire population.

In conclusion, by approaching this problem with a risk/benefit analysis, FDA has taken a strong step toward better analysis that more closely mirrors consumer decisions and should consider immediately revising their risk-communication strategy.

¹⁵ EPA, Comment to FDA's Docket, 1.

¹⁶ *Ibid*, 4.