**Risk and Justice:**
**Comments on the Office of Management and Budget's**
**Proposed Risk Assessment Bulletin**

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The comments below focus on issues of risk and justice raised by the Office of Management and Budget's (OMB's) Proposed Risk Assessment Bulletin ("Bulletin"). These comments thus do not comprise an exhaustive account of the issues raised by the Bulletin. For a more comprehensive account, please see the comments filed by the Center for Progressive Reform.

## I. "Central Estimates" in the Face of Variability in Exposure

The Bulletin in several instances directs agencies to focus their assessment and characterization of risk on a "central estimate," that is, "the mean or average of the distribution; or a number which contains multiple estimates of risk based on different assumptions, weighted by their plausibility; or any estimate judged to be most representative of the distribution" (Bulletin, at 16). Although the Bulletin is less than clear in this regard, it appears to require that agencies "highlight," present or include a "central estimate" as a response both to uncertainty about and to variability in the parameters to a risk assessment. For example, the Bulletin requires that "every quantitative risk assessment should provide a range of plausible risk estimates, when there is scientific uncertainty or variability" (Section II: Applicability; Bulletin, at 9); that each quantitative characterization of risk "include a range of plausible risk estimates, including central estimates. . . . The central risk estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk" (Section IV: General Risk Assessment and Reporting Standards; Bulletin at 16); that "[i]f highly exposed or sensitive subpopulations are highlighted, the assessment should also highlight the general population to portray the range of variability" (Section V: Special Standards for Influential Risk Assessments; Bulletin, at 19); and states that "[c]entral or expected estimates of risk play an especially critical role in decision analysis and cost-benefit analysis" (Section V: Special Standards for Influential Risk Assessment;, Bulletin, at 19).

### A. Uncertainty and Variability Require Different Responses

It is important to maintain a distinction between uncertainty and variability when discussing the inputs to an assessment of risk. The responses to uncertainty and variability may have the same effect operationally on an estimate of risk (i.e., they are both accounted for mathematically as part of a risk assessment equation), but the justifications for the responses are entirely different.[1] Briefly, responses to uncertainty address the fact that we do not know the true value for an input (e.g., cancer potency) to

the risk assessment equation. A response may be more or less "conservative," representing a choice *among errors*. A conservative approach chooses one error: erring on the side of caution. A non-conservative approach chooses the opposite error. Responses to variability, on the other hand, address the fact that we know that there is a range of true values for an input (e.g., fish consumption rate) to the risk assessment equation. The true values are not in question; they simply vary. A response to variability, then, is not a choice among errors. Rather, it is a choice among known values – and in the case of interindividual variability regarding exposure, it is a choice to set regulatory standards to address one individual's circumstances of exposure or another's, that is, a choice of *who merits protection*.

B. "Central Estimates" and Variability in Exposure

In responding to variability in exposure, as noted above, the risk assessor chooses inputs to the risk assessment equation from among values representing various individuals' circumstances of exposure. The risk assessor may choose a mean (or average or "central estimate"), a 90$^{th}$ percentile value, a maximum value, or some other value for each parameter that comprises an exposure pathway. This choice may be of little import where variability is not large within the population of concern – where everyone who is likely to be exposed breathes the same quantity and quality air, or eats the same amount and kinds of fish. Where variability is not large, no one in a population is exposed to environmental contaminants (or other hazards) at levels that differ much from the bulk of the population (represented by a mean, an average or a "central estimate"). In this situation, a choice to set regulatory standards to protect the "average" individual will *also* protect all other individuals, because no one's circumstances of exposure place her very far from the mean. However, in the health, safety and environmental context, this condition is often not met. Rather, as will be discussed below, anecdotal and quantitative data continue to document the fact that certain individuals and subpopulations are exposed to environmental contaminants (and other hazards) at much greater levels than the mean or average of the general population. These individuals reside adjacent to contaminated lands; they play in the school yard near multiple sources of air pollution; they eat fish caught in waters that harbor methylmercury. These individuals would be severely underprotected by a choice of central estimates or average values as inputs to an assessment of risk.

Agencies have long evinced a special concern for those among us who are most vulnerable to environmental contaminants (and other hazards). They seek, for example, to set standards for mercury that are protective of children, or to set standards for ozone that are protective of asthmatics. Indeed, in several instances, this particular concern has been incorporated into agencies' statutory directives. With respect to exposure, agencies have captured this concern by gauging protection to the level of the individual who is most exposed to the relevant contaminant or hazard. Although the Bulletin does not appear to require risk assessors to cease to estimate risk to the most exposed individual, it nonetheless looks to undermine this long-standing focus. In addition to the language quoted above directing agencies to "highlight" central estimates, the Bulletin takes pains to "discourage[e]" agencies from presenting numerical assessments that portray the high-

end estimates of risk (Bulletin, at 17) – which would include numerical assessments of risk to those most exposed. Although the Bulletin talks of offering ranges for risk, including central estimates, it does not conceal its antipathy for estimates that represent those most exposed. The Bulletin discusses central estimates, *inter alia*, in Section V.4 *Standard for Characterizing Uncertainty*. Yet it seems to be speaking not only to uncertainty when it proclaims: "Central or expected estimates of risk play an especially critical role in decision analysis and cost-benefit analysis." Here and elsewhere, the Bulletin seems to anticipate a process that highlights central estimates for inputs (whether these inputs are uncertain, variable or both) to the risk assessment equation and that ultimately produces a central estimate for the output of the risk assessment exercise. In fact, OMB seeks to have it both ways – calling for "ranges," "plausible ranges," and "population risks" when a focus on the maximally exposed individual would lead to a single estimate of risk that is large, but calling for a single estimate (and, specifically, the "central estimate" or "expected risk") when it comes time to feed the result into a cost-benefit analysis or to portray the result to the public.

This focus on central estimates in the face of variability in exposure is troubling from both an environmental justice and a public health perspective. A particularly problematic example involves the fish consumption pathway – the single greatest means of human exposure to methylmercury, PCBs, and a host of other contaminants. Variability for this parameter is great and the distribution is skewed, with some individuals (e.g., members of the various fishing tribes, members of various Asian-American and Pacific Islander groups) consuming fish at large rates and some individuals consuming no fish at all.[2] As a consequence, the mean or average for the entire U.S. population (which is how the Bulletin defines "central estimate") will often be "zero" or close to it – that is, the effect of so many individuals with zero values is to cancel out the relatively fewer number of individuals with large positive values.[3] If all one cared about were averages in the abstract, this might be interesting information but, of course, there are human lives at stake here. Several points are important. First, the choice of a mean or average value has the effect of "averaging away" individual characteristics that are very far away from those shared by the bulk of the population. This practice might be likened to taking the mean of a population that includes men and women to determine the "central estimate" for prostate cancers, or examining the general population's (most of whom are adults) hand-to-mouth contact with soils to determine children's likely exposure to lead. It makes no sense as a matter of public health to set standards for water quality or air emissions so that they gauge the level of protection to those who are not exposed, i.e., those who don't eat fish.

Second, the fact that recent data have demonstrated that those likely to comprise the most exposed are American Indians and Alaska Natives, people of color, and low-income individuals raises environmental justice issues – and, in some instances, legal concerns. For example, studies of the fishing tribes of the Puget Sound and of the Columbia River Basin in the Pacific Northwest have quantified fish consumption for these peoples at rates as high as several hundred times the rate of the average American.[4] Studies of the various Ojibwe and other fishing tribes of the Great Lakes have similarly documented

fish consumption practices that differ markedly from the general population and place members of these tribes among the most exposed.[5]

The justifications typically offered for using central estimates for exposure, moreover, are inapposite in this context. That is, the argument might be made that a composite of maxima – such as may be the result of selecting maximum values for every parameter that varies in a risk assessment equation – represents a "worst-case" scenario that is unlikely to describe any one individual's actual exposure circumstances. No individual, this argument goes, is likely to reside in the same location, to catch the same species from the same waters, to consume the fish at rates reflected by a 95$^{th}$ percentile or maximum value, and to do so for her entire life: the average American moves his place of residence every few years; the average American eats modest quantities of fish obtained from a variety of sources. However, these assumptions do not hold true for the fishing tribes of the Pacific Northwest, the Great Lakes, and elsewhere. Members of these tribes *do* in fact live in the same place, fish the same lakes and rivers, and consume large quantities of the same species for their whole lives.[6] Their resulting exposure to environmental contaminants is therefore depicted by a composite of maxima. To choose, instead, mean or central estimates for some or all of the inputs to a risk assessment is to *misstate* – noteably, to understate – the actual risk to these individuals.

C. Variability, Identifiability and "Expected Risk"

The Bulletin in several places refers to "expected risk," and once suggests that this term is to be used in the same sense as "central estimate." Although the Bulletin does not make clear precisely what OMB means by the term "expected risk," one recent discussion warrants comment. A few members of the National Academy of Sciences team that produced *Science and Judgment in Risk Assessment* made the following argument, which, it should be noted, did not command consensus. They suggested, in effect, that large variability might be ignored in risk assessments:

> [S]ome argue that people should be indifferent between a situation wherein their risk is determined to be precisely $10^{-5}$ or one wherein they have a 1% chance of being highly susceptible (with risk = $10^{-3}$) and a 99% chance of being immune, with no way to know which applies to whom. In both cases, the expected value of individual risk is $10^{-5}$, and it can be argued that the distribution of risks is the same, in that without the prospect of identifiability no one actually faces a risk of $10^{-3}$, but just an equal chance of facing such a risk.[7]

Professor Matthew Adler similarly asserts that "[f]or most hazards, even those where the regulator is very confident (ex ante) that one or more deaths will result from the hazard if left unregulated, the regulator will not know (ex ante) the identities of the persons who will die."[8] The precondition for this argument, however, is unlikely to exist in the context of health and environmental risk assessments, at least for exposure (and, increasingly, even for susceptibility). That is, even crude or anecdotal information allows individuals (or agency risk assessors) to identify which individuals or groups are likely to be among the most exposed for many parameters that comprise the exposure portion of

the equation. And, quantitative data are continuing to be gathered and publicized, so that not only those exposed, but agency risk assessors are aware of these identities. These data document, e.g., that fishing tribes eat more fish, fish at the same spots their entire lives, consume the species most contaminated with mercury, etc. The fact of identifiability, then, has real implications for distributive justice here (and implications for some of Adler's and others' prescriptions).[9] We don't all have an equal chance of facing a large risk from methylmercury- or dioxin-contaminated fish; some of us face it and some of us don't.

## II. Population Versus Individual Risk

The Bulletin seeks to move agencies away from a focus on risk to individuals (which gauges regulatory responses by the level of risk to exposed individuals) and toward a focus on population risk (which gauges regulatory responses by the number of people exposed). The Bulletin directs that "[w]hen estimates of individual risk are developed, estimates of population risk should also be developed. Estimates of population risk are necessary to compare the overall costs and benefits of regulatory alternatives." (Section IV: General Risk Assessment and Reporting Standards; Bulletin, at 16). In many instances, the Bulletin's directive will have the effect of diluting or obscuring the risk to highly exposed individuals, particularly if only population risk numbers are fed into cost-benefit analyses.

Although the Bulletin does not appear to require that estimates of individual risk be jettisoned entirely, it lays the groundwork for utilitarian arguments that regulation ought not be undertaken where only relatively few individuals are highly exposed. This shift undermines protection for highly exposed subpopulations – small groups whose exposure circumstances are not shared by the majority or dominant population. Given recent data identifying *who* comprises these subpopulations, this shift works specifically to the disadvantage, e.g., of children, members of the various fishing tribes, and members of low-income communities living adjacent to contaminated sites. As such, it is flatly discriminatory.

Of course, in many contexts, population risk (i.e., the number exposed) *is* already taken into account in regulatory decisions (e.g., in determining Superfund cleanup priorities under CERCLA). However, while the number exposed might be relevant in some regulatory contexts (e.g., priority setting) it is not in others (e.g., risk estimates). In the latter context, the Bulletin seems only to call for estimates of population risk to dilute the impact of large risks to individuals.

It is also important to note that the Bulletin's directive in this regard flies in the face of some statutory mandates. For example, Clean Air Act section 112(f)(2)(a), which governs the assessment of residual risk from hazardous air pollutants, specifically requires consideration of risk to the "individual."[10]

## III. Uniformity, Objectivity, and Science

### A. Objectivity, Reproducibility, and Accuracy

The Bulletin's call for standard statistical methods, peer review, reproducibility and access to data all may work to the disadvantage of data regarding and/or gathered by some affected groups, especially tribes. Tribes are often at the forefront of efforts to assess the effects of environmental contamination on the health of their members and the natural resources on which they depend. For example, the fishing peoples of the Pacific Northwest and the Great Lakes continue to work to understand and address the effects of methylmercury and other contaminants on fish and shellfish. This commitment is perhaps unsurprising, given the centrality of fish to the physical, spiritual, cultural, economic, social, and political health of these fishing peoples. Indeed, the expertise that tribes bring to bear on these problems is likely to be unmatched by those whose way of life is less closely intertwined with the fish and the ecosystems that support them. Tribal environmental professionals are often able to draw on knowledge born of generations of residency in place or familiarity with a particular resource, and to meld this with current research methods to produce results that are highly accurate. For a variety of reasons, however, the most accurate studies of and by these groups may nonetheless depart from standard practice in one or more of the respects addressed by the Bulletin. It is standard statistical practice, for example, to throw out "outlier" values in consumption studies, on the assumption that some error accounts for the large discrepancy between the outlier and mean values. A recent fish consumption study conducted of and by the Suquamish Tribe, however, enhanced accuracy by retaining those "outlier" values that the investigator had reason to believe (because of personal knowledge of the subjects – another problem for standard scientific notions of "objectivity"[11]) were in fact true values (i.e., here, that the subjects in fact consumed the large quantities of fish indicated).[12] Note, too, that the Suquamish fish consumption study could not have been conducted – without sacrificing accuracy – by someone unfamiliar with the tribe's history, culture, and contemporary ways. In a similar vein, requirements of access to data may be at odds with cultural constraints prohibiting tribal members entrusted with certain information from sharing it with non-tribal members.[13]

In addition, the Bulletin makes clear that one of its goals is "uniformity" in risk assessment. However, tribes and those who work closely with them have pointed out that standard risk assessment methods do not capture fully the impacts of environmental contamination from the perspective of tribes and their members. Barbara Harper and Stuart Harris, for example, have worked to develop alternative methods of assessing risk when tribes and the natural resources on which they depend are affected.[14] If the Bulletin were to prohibit agencies from conducting their inquiries in ways more appropriate to tribes in these instances, it would contribute not only to inaccuracy but also to injustice, as tribes' particular cultural and political circumstances are unaccounted for and, ultimately, undermined.

B. "Scientific" Comments

The Bulletin's requirement that all "significant" public comments be addressed and its statement that "[s]cientific comments shall be presumed to be significant" is likely biased against community-based knowledge, traditional and/or tribal science, and other sources of non-credentialed but valid information. Although it is unclear precisely how OMB means to define the term "scientific," there is reason to be concerned that it intends to include regulated industry-funded "research" groups (e.g., the Electric Power Research Institute), but to exclude others. Moreover, the Bulletin places a thumb on the scale favoring inaction, by placing the burden of proof on agencies seeking to regulate when it directs agencies to respond to and explain why they decline to adopt these "significant" comments. Furthermore, to the extent that agencies' regulatory decisions affect treaty-protected and other tribal resources, the federal trust responsibility holds them to the highest fiduciary standards. Among other things, this responsibility would seem to obligate agencies to view as especially "significant" the comments of tribes.

In closing, it bears emphasis that where Indian tribes and their members, other communities of color, and low-income communities are among those affected by agency risk assessments, OMB is not free to ignore relevant normative and legal commitments.[15] Specifically, the Bulletin's directives cannot undermine agencies' obligations under Executive Order 12,989, which requires agencies to address environmental injustice in minority and low-income communities. Nor, in the case of Indian tribes, can the Bulletin's directives undermine agencies' duties under the various treaties between the tribes and the United States, under the federal trust responsibility, and under executive commitments to consultation with tribal governments.

Respectfully submitted,

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[1] This argument is discussed at length in Catherine A. O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 STANFORD ENVIRONMENTAL LAW JOURNAL 3 (2000) [hereinafter O'Neill, *Variable Justice*].

[2] *See* NATIONAL ENVIRONMENTAL JUSTICE ADVISORY COUNCIL, FISH CONSUMPTION AND ENVIRONMENTAL JUSTICE (2002), *available at* www.epa.gov/compliance/resources/publications/ej/fish_consump_report_1102.pdf.

[3] O'Neill, *Variable Justice*, *supra* note 1, at 78-81.

[4] *See, e.g.*, THE SUQUAMISH TRIBE, FISH CONSUMPTION SURVEY OF THE SUQUAMISH TRIBE OF THE PORT MADISON INDIAN RESERVATION, PUGET SOUND REGION (2000); KELLY A. TOY, ET AL., A FISH CONSUMPTION SURVEY OF THE TULALIP AND SQUAXIN ISLAND TRIBES OF THE PUGET SOUND REGION (1996); COLUMBIA RIVER INTER-TRIBAL FISH COMMISSION, TECHNICAL REPORT 94-3, A FISH CONSUMPTION SURVEY OF THE UMATILLA, NEZ PERCE, YAKAMA, AND WARM SPRINGS TRIBES OF THE COLUMBIA RIVER BASIN (1994).

[5] *See, e.g.*, GREAT LAKES INDIAN FISH AND WILDLIFE COMMISSION, 1993 SURVEY OF TRIBAL SPEARERS (1993).

[6] *See, e.g.*, O'Neill, *Variable Justice*, *supra* note 1, at 83-85 and accompanying notes.

[7] NATIONAL RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 213-16 (1994).

[8] Matthew D. Adler, *Against "Individual Risk": A Sympathetic Critique of Risk Assessment*, 153 UNIVERSITY OF PENNSYLVANIA LAW REVIEW 1121, 1199 (2005).

[9] *See* O'Neill, *Variable Justice*, *supra* note 1.

[10] 42 U.S.C. § 7412(f)(2)(a).

[11] *See* Catherine A. O'Neill, *Restoration Affecting Native Resources: The Place of Native Ecological Science*, 42 ARIZONA LAW REVIEW 343 (2000) [hereinafter O'Neill, *Native Ecological Science*].

[12] *See* THE SUQUAMISH TRIBE, *supra* note 4; NEJAC, *supra* note 2.

[13] *See* O'Neill, *Native Ecological Science*, *supra* note 11.

[14] See, e.g., Stuart Harris and Barbara Harper, A Native American Exposure Scenario, 17 RISK ANALYSIS 789 (1997); Stuart Harris and Barbara Harper, Using Eco-Cultural Dependency Webs in Risk Assessment and Characterization of Risks to Tribal Health and Cultures, ENVIRON. SCI. AND POLLUT. RES. (Special Issue 2) 91 (2000); Stuart Harris and Barbara Harper, 2001, Lifestyles, Diets, and Native American Exposure Factors to Possible Lead Exposures and Toxicity, 86 ENVIRONMENTAL RESEARCH 140 (2001).

[15] I elaborate these points at greater length in O'Neill, *Variable Justice*, *supra* note 1; and Catherine A. O'Neill, *Mercury, Risk, and Justice*, 34 ENVIRONMENTAL LAW REPORTER 11070, 11112-15 (2004).