Testimony before the U.S. House of Representatives

Committee on Science, Space, and Technology

Hearing:

The Environmental Protection Agency's

Process for Evaluating and Using Science During Its Regulatory Decision Making Activities

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Chairman Smith, Ranking Member Johnson, and Members of the Committee, thank you for the opportunity to testify today concerning the Environmental Protection Agency's use of science for regulatory decision-making. My testimony in informed by 30 years of experience with environmental science and economics that began in earnest during my doctoral research at Harvard University.

I. Background

After completing my dissertation, in 1988 I joined the Office of Information and Regulatory Affairs at the Office of Management and Budget as a staff economist. I served five years under the administrations of Presidents Reagan and George H.W. Bush and five years under the administration of President Clinton. My job was to review Regulatory Impact Analyses prepared by Federal agencies in support of regulations expected to have annual costs exceeding $100 million. Many of the RIAs I reviewed concerned regulations with estimated costs of many billions of dollars. I reviewed RIAs from several agencies including the Food and Drug Administration, the U.S. Departments of Agriculture, Commerce, Interior and Labor, but mostly the Environmental Protection Agency. Because of my dissertation work on the potential use of deposit-refund systems for managing hazardous waste, within EPA I focused on major rules developed by the Office of Solid Waste and Emergency Response and the Office of Water.

The principles I followed during my reviews were the same under all three administrations: provide OMB officials and White House staff the most objective estimates possible of benefits, costs and other effects. My job was strictly analytical. Both Executive Order 12291, signed by President Reagan, and Executive Order 12866, signed by President Clinton, clearly stated a preference that the net social benefits of federal regulation be maximized. But this objective is infeasible if decision-makers lack unbiased estimates of benefits and costs.

I left OMB in 1998, and after a stint as a visiting professor, in 2001 I opened a private consulting practice. My testimony today is not on behalf of any client, past or present.

II. Fundamental Characteristics of EPA Risk Assessment

A. EPA risk assessments are, by design, not objective

I learned during my doctoral research that EPA risk assessments did not objectively characterize risk. Rather, they were described as "conservative."[1] This term is misleading because it does not make clear what it is being "conserved." EPA risk assessments are neither "conservative" nor liberal," but they are intended to approximate something close to the worst case. I have reviewed some risk assessments in which risk estimates were either practically or theoretically impossible.

You need not take my word for it. In 2004, the EPA Science Advisor published a report on its risk assessment practices. At the time, EPA faced a chorus of criticism alleging that the Agency grossly exaggerated risks. EPA defended its practices by stating as follows:

> EPA risk assessments tend towards protecting public and environmental health by preferring an approach that does not underestimate risk in the face of uncertainty and variability. In other words, EPA seeks to adequately protect public and environmental health by *ensuring that risk is not likely to be underestimated*.[2]

In plain English, this means that whenever there is scientific uncertainty, EPA errs on the side of *overstating* human health risk. Further, when characterizing health risk in a population, EPA looks for individuals who faces the highest potential risk and uses those persons to describe the population.

These are not sensible practices. If we were characterizing the risk to Americans posed by peanuts, we would not say that the risk of death from anaphylactic shock from peanut ingestion is 50%, even though it is conceivable that there is someone for whom this is true. Similarly, if we were concerned about obesity in the United States, we would not say that Americans weigh 1,036 pounds – the reputed weight of the heaviest person in the United

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[1] Another descriptor EPA uses for its risk assessments is "protective," but that term also begs the question what is being protected. Precautionary efforts to protect the public from risk in one area necessarily exposes them to risk in another.

[2] U.S. Environmental Protection Agency Office of the Science Advisor (2004), p. 11 (emphasis in original).

States.[3] When thinking about the health risk posed by PM2.5, we do not assume that *everyone* is elderly, infirm, or suffers from chronic obstructive pulmonary disease.

We know not to assume the worst when we make routine decisions in almost every avenue of life. For some reason, however, we do not practice common sense in environmental health policy. And it is EPA policy not to use common sense. Quoting again from the 2004 report of the EPA Science Advisor (p. 13):

> [S]ince EPA is a health and environmental protective agency, EPA's policy is that risk assessments should not knowingly underestimate or grossly overestimate risks. This policy position prompts risk assessments to take a more "protective" stance given the underlying uncertainty with the risk estimates generated.

In plain English, this means EPA will strive for the highest estimate of risk that does not bring upon the Agency unbearable ridicule. You simply cannot rely on EPA risk assessment to give you an unvarnished perspective. When given an EPA risk assessment, all you know is risk can't be any worse.

These practices undermine responsible regulatory decision-making at least three ways.

First, they needlessly and irresponsibly scare the public about the hazards of life. Exaggerating risk is an excellent tactic for gaining the most attention from Congress, the White House, the press and the public, and for increasing one's budget and delegated legislative authority to regulate.

Second, they undermine the responsible estimation of benefits from regulation. If I'm given a worst-case risk assessment, I cannot use it to estimate public health benefits. I need, at a minimum, a *central tendency* estimate, like an average or median. Ideally I would have much more information than this, but I can use a central tendency estimate risk estimate to approximate health benefits to the population. I can't do anything useful or informative with a "conservative" or "protective" risk estimate.

Third, it usurps the authority of the EPA Administrator, who is charged by Congress with making oftentimes hard choices. When EPA staff give the Administrator an exaggerated risk estimate, the Administrator cannot make a fully informed decision. He faces extraordinary pressure to ratify the policy preferences the staff have hidden away. If the Administrator learns that EPA staff are sandbagging him and looks elsewhere for more objective information, he will be accused of "ignoring science." Indeed, EPA staff produce so-called "conservative" risk

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[3] My source for this is Wikipedia, which though often inaccurate is accurate enough for present purposes.

assessments to tie the Administrator's hands. This enables Agency staff to make critical policy decisions secretly through the back door.

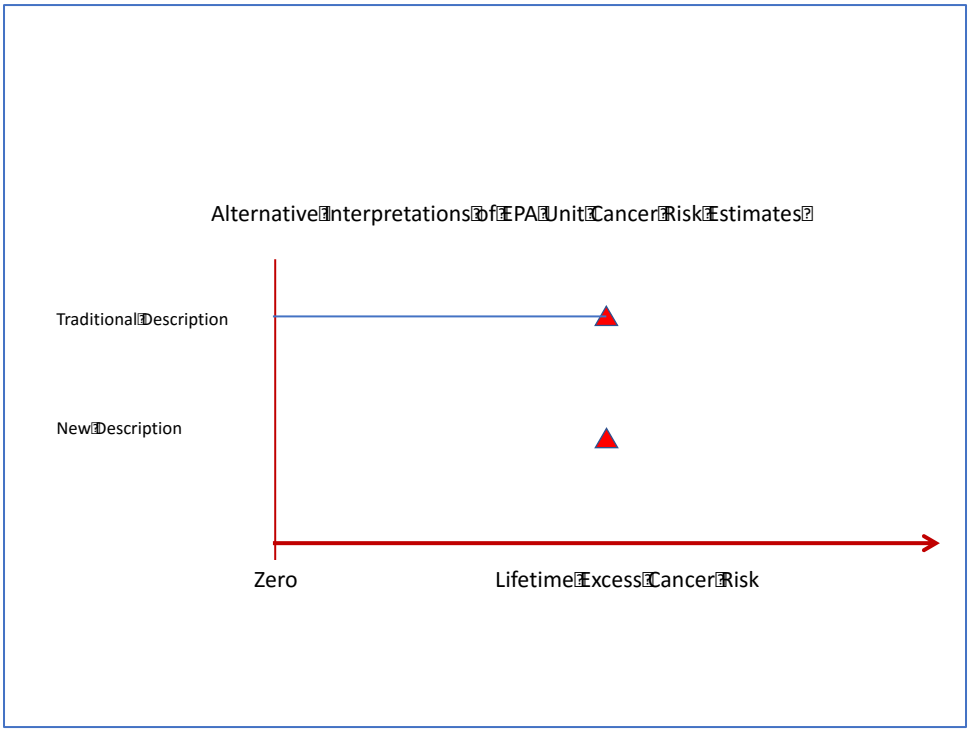
B. Nontransparency about uncertainty

Much of EPA risk assessment inevitably consists of extrapolating to humans from animals, such as rats and mice, and from very high exposure levels in a laboratory to comparatively very low exposures in the environment. These may be reasonable practices for some purposes, but often they are not reasonable at all. Rats and mice are not little people, and effects that occur when biological systems are overloaded, as they are by design in laboratory experiments, generally are not expected to occur under normal conditions.

When I began reviewing EPA cancer risk assessments in the mid-1980s, the Agency's conventional practice was to report risk estimates in a way that accounted for these key uncertainties. A common way this was done was to say, "We estimate lifetime excess cancer risk to be as high as *x*, but it could be as low as zero." And zero was understood to be the best risk estimate if, for example, extrapolating from rats or mice was biologically incorrect, or if there was a human exposure threshold below which carcinogenesis was not reasonably expected to occur. About 20 years ago, EPA abandoned the practice of qualifying its cancer risk estimates this way. Now, EPA reports them in ways that do not reveal uncertainty.

The difference between these two approaches can be seen in Figure A below. The traditional description of a cancer risk estimate told decision-makers and the public that there was substantial uncertainty, and that the true (but unknown) risk could be as low as zero. The modern description does not communicate this uncertainty.

Figure A



III. Fundamental Characteristics of EPA Safety Assessment

A lot of what the public understands to be "risk assessment" actually isn't risk assessment at all. The correct term is "safety assessment" because its purpose is to identify a "safe" level of exposure, not to estimate risk. But a safety assessment isn't science; it's a policy decision draped in scientific clothing. The reason it isn't science is science has no definition for "safety." Science is about ascertaining facts, not divining policies or making philosophical judgments.

In EPA world, the primary example of a safety assessment is the Reference Dose, often abbreviated "RfD."[4] If you are exposure below the RfD, you're said to be "safe." Except in truly extraordinary cases, you are likely to agree because the methods used to derive Reference Doses are very, very "conservative."

[4] The Reference Concentration (RfC) is an analogous tool for the inhalation pathway.

A. EPA safety assessments are, by design, controlled by undisclosed policy judgments

Nonscientific considerations are spread throughout the RfD process. To see this, let's look at EPA's definition:

> An estimate (with uncertainty spanning **perhaps** an order of magnitude) of a daily oral exposure to the human population (including **sensitive subgroups**) that is **likely** to be without an **appreciable** risk of **deleterious** effects during a lifetime. It can be derived from a **NOAEL**, **LOAEL**, or **benchmark dose**, with **uncertainty factors** generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments.[5]

I have highlighted in **bold** terms within the definition that are substantially or exclusively policy, not science. It's useful for Members to understand that EPA acknowledges that a Reference Dose is uncertain by a factor of 10. But wait. EPA says Reference Doses are uncertain by *perhaps* a factor of 10. Does that mean they might be uncertain by a factor of 100? A factor of 1,000? We don't know.

What is a "sensitive subgroup"? Is a subgroup containing a single person in the United States too small? How about 100 persons? How large must it be? One percent of the U.S. population – clearly a small fraction – means 3.25 million people. How sensitive must these people be? Twice as sensitive? Ten times as sensitive?

"Likely" means a probability greater than 50%. To what does that probability apply? According to the definition, it applies to risk of "deleterious" effects? How bad must they be to qualify? They must be "appreciably" "deleterious." Only a lawyer could tell you what it means to experience "an appreciable risk of deleterious effects." There are no scientific answers to these questions; only policy judgments. When lawyers rule, science does not.

Ambiguity in the definition of the Reference Dose goes on and on and on. It's no wonder that an EPA Administrator, trying to play it straight, does not know how to interpret this information.

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[5] U.S. Environmental Protection Agency (2017). There are also Reference Dose definitions that apply to different durations of exposure (e.g., "acute," "subchronic," "chronic") and pathways (e.g., "oral").

A. Nontransparency about uncertainty

Therefore, it's for good reason that the EPA Administrator may not know how to use a Reference Dose to inform decision-making. Let's assume for simplicity that uncertainty is exactly a factor of 10. Figure B below shows many ways the RfD might be interpreted.

Row 1 shows what EPA conventionally reports to the public.[6] It's what is called a "point estimate," meaning that no uncertainty about the estimate is communicated. Row 2 shows what the EPA staff author of the RfD probably intends; uncertainty lies *above* the RfD. But because this information is poorly communicated, and EPA Administrators have limited knowledge about the derivation process and are inclined to be worrisome when public health is involved, they may think the 10-fold uncertainty contained in the definition is *below* the RfD. Rows 4-6 show other ways this 10-fold uncertainty might be understood, and none of these interpretations is necessarily incorrect.[7]

While it is sometimes possible to use an EPA *risk* assessment to estimate the benefits of a regulation, it is impossible to use an EPA *safety* assessment for that purpose. The definition of the Reference Dose tells us nothing about how much risk is reduction is obtained by any reduction in exposure. That means we can't estimate health benefits.

Finally, I want to add that nothing I have just testified to is new. On behalf of OMB, in 1990 I wrote a chapter for the *Regulatory Program of the United States Government*. Most of that chapter, titled "Current Regulatory Issues in Risk Assessment and Risk Management,"[8] remains valid 27 years later.

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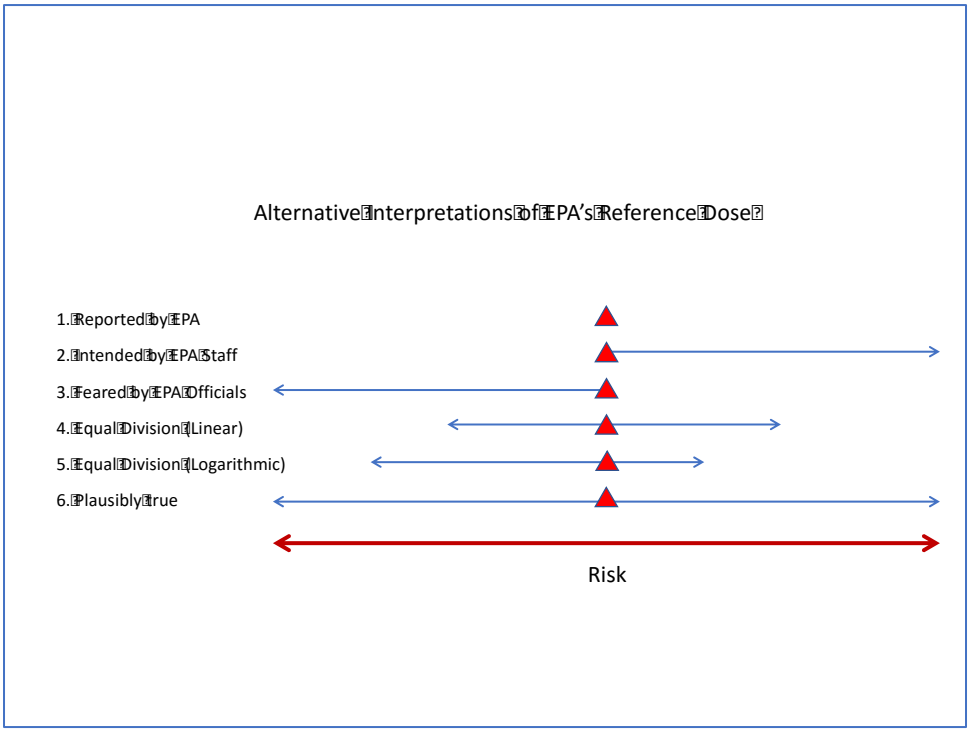
[6] U.S. Environmental Protection Agency (2016).

[7] Alternative interpretations of different players in the drama are described by Felter and Dourson (1998).

[8] Office of Management and Budget (1990).

Figure B



IV. Implications for Benefit-Cost Analysis

EPA uses risk assessments as inputs to its benefit-cost analyses. "Conservatism" in risk assessment is therefore propagated into the Agency's estimate of regulatory benefits.[9] So, all other things being equal, EPA will not be "knowingly underestimate" benefits. But that means they *will* overestimate benefits. Whether they "grossly" overestimate benefits depends on how "conservative" the risk assessment is, whether EPA has disclosed enough detail to permit third parties to figure it out, and whether there is a venue in which errors can be corrected Sometimes, a single "conservative" assumption is enough.[10]

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[9] This was the key point in Office of Management and Budget (1990), and it is the reason why OMB guidance on benefit-cost analysis requires agencies to estimate benefits objectively. See Office of Management and Budget (2003). OMB lacks the tools to enforce this requirement.

[10] EPA's "central estimate" of the present value of benefits from regulations promulgated under the Clean Air Act from 1990 to 2020 at $12 trillion. See U.S. Environmental Protection Agency (2011). Estimated annual benefits, $1.3 trillion, are 7% of U.S. Gross Domestic Product. Almost all benefits vanish if EPA's assumed causal relationship between low

A typical Agency benefit-cost analysis includes benefit estimates derived from these unreliable inputs. You should not be surprised if benefit estimates in these analyses are highly overstated. And you should pay no attention to OMB's Reports to Congress on the benefits and costs of federal regulation.[11] OMB does not report objective benefit or cost estimates, or their own estimates based on independent review. OMB merely summarizes what the agencies said in their published benefit-cost analyses, even if the OMB staff know that these estimates are wrong. Congress faces a similar problem with respect to reports submitted to the Comptroller General pursuant to the Congressional Review Act (5 U.S.C. § 8012(a)(1). These reports are generally unreliable, and GAO lacks the expertise and time to critically review them.

V. Implications for Congress

Consistent with the policy set forth in the 2004 EPA Staff Paper, wherever you see a nonscientific, policy term in the definition of a putative scientific concept such as a risk or safety assessment, you can be confident that EPA staff have chosen to be "conservative" – that is, they have made assumptions that do not "knowingly underestimate or grossly overestimate" the factor of interest. Risk and safety assessments are constructed using multiple "conservative" assumptions. So, while we can be quite sure that actual cancer risk is likely to be less than an EPA cancer risk estimate, and that exposures to noncarcinogens below the Reference Dose poses essentially zero risk, these risk and safety assessments are unreliable for use in benefit-cost analysis.[12]

The House recently passed H.R. 26, the "Regulations from the Executive in Need of Scrutiny Act of 2017." This is not the time or place to debate the merits of this bill. However, if the bill were enacted into law, it is certain that Members will be poorly informed about the benefits and costs of major regulations intended to reduce human health risk. Benefit estimates based on "conservative" EPA risk assessments will be exaggerated and unreliable, so Members who rely on such estimates will be misled.

PM2.5 concentrations and premature mortality is relaxed. Unsurprisingly, EPA's causality assumption is controversial. See, e.g., Cox, Popken and Ricci (2013).

[11] These Reports are mandated by the Regulatory Right-to-Know Act of 2000, Pub. L. 106-554 (title VI, Sec. 624; 114 Stat. 2763A-161) The most recent draft Report to Congress was published in draft form on December 23, 2016. See Office of Management and Budget (2016).

[12] A group of 19 experts recently published a listicle identifying 10 things non-experts should look out for in benefit-cost analysis. Number 6 on the list warns against relying on risk assessments that are not transparent or objective. See Dudley, Belzer, Blomquist, Brennan, Carrigan, Cordes, Cox, Fraas, Graham, Gray, Hammitt, Krutilla, Linquiti, Lutter, Mannix, Shapiro, Smith, Viscusi and Zerbe (2017).

Probably the most effective way Congress could improve the quality of the scientific information on which regulatory decision-making depends is to require all agency science and economics to adhere to the principles set forth in OMB's Information Quality Guidelines.[13] These Guidelines have been in place for 15 years, but there is little to show for it because agencies simply do not comply. And the main reason they do not comply is no one has standing in federal court to compel them to do so. Agency performance would improve dramatically if this loophole in the law were corrected.[14]

Thank you for the opportunity to testify today. I look forward to answering any questions you might have.

VI. References

Cox T, Popken D, Ricci PF. 2013. Temperature, not fine particulate matter ($PM_{2.5}$), is causally associated with short-term acute daily mortality rates: results from one hundred United States cities. Dose-Response 11.

Dudley S, Belzer R, Blomquist G, Brennan T, Carrigan C, Cordes J, et al. 2017. Consumer's Guide to Regulatory Impact Analysis: Ten Tips for Being an Informed Policymaker. Washington DC: George Washington University Regulatory Studies Center.

Felter SP, Dourson ML. 1998. The Inexact Science of Risk Assessment (and Implications for Risk Management). Human and Ecological Risk Assessment 4:245-251.

Information Quality Act. 2000. 114 Stat. 2763A–153.

Office of Management and Budget. 1990. Current Regulatory Issues in Risk Assessment and Risk Management. In: Regulatory Program of the United States Government, April 1, 1990 -- March 31, 1991. Washington, DC: OMB, 13-26.

Office of Management and Budget. 2002. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Notice; Republication. Federal Register 67:8452-8460.

Office of Management and Budget. 2003. Circular A-4: Regulatory Analysis. Available: http://www.whitehouse.gov/omb/circulars_a004_a-4 [accessed April 6, 2011,].

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[13] Office of Management and Budget (2002).

[14] The Information Quality Act (2000), , 114 Stat. 2763A–153-154, says the government must "establish administrative mechanisms allowing affected persons to *seek and obtain* correction of information maintained and disseminated by the agency that does not comply" with OMB guidelines (emphasis added). Agencies have implemented the law so that the public may *seek* correction all it wants, but cannot *obtain* them.

Office of Management and Budget. 2016. 2016 Draft Report to Congress on the Benefits and Costs of Federal Regulations and Agency Compliance with the Unfunded Mandates Reform Act. Washington DC: OMB.

U.S. Environmental Protection Agency. 2011. The Benefits and Costs of the Clean Air Act from 1990 to 2020; Final Report – Rev. A. Washington DC: USEPA, 238.

U.S. Environmental Protection Agency. 2016. IRIS Assessments. Available: https://cfpub.epa.gov/ncea/iris2/atoz.cfm [accessed February 4, 2017].

U.S. Environmental Protection Agency. 2017. IRIS Glossary; Terms and Acronyms; 'Reference Dose'. Available: https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/termsandacronyms/search.do?search=&term=reference%20dose&matchCriteria=Contains&checkedAcronym=true&checkedTerm=true&hasDefinitions=false; Terms ands [accessed February 2, 2017].

U.S. Environmental Protection Agency Office of the Science Advisor. 2004. An Examination of EPA Risk Assessment Principles and Practices; Staff Paper, EPA/100/B-04/001.

Definition of the Reference Dose

(Substantially or wholly nonscientific, policy terms in bold)

An estimate (with uncertainty spanning **perhaps** an order of magnitude) of a daily oral exposure to the human population (including **sensitive subgroups**) that is **likely** to be without an **appreciable** risk of **deleterious** effects during a lifetime. It can be derived from a **NOAEL**, **LOAEL**, or **benchmark dose**, with **uncertainty factors** generally applied to reflect limitations of the data used. Generally used in EPA's noncancer health assessments.

Source: U.S. Environmental Protection Agency. 2017. IRIS Glossary; Terms and Acronyms; 'Reference Dose'.