Topic: Secret Science Reform Act of 2014

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Committee on Science, Space and Technology, U.S. House of Representatives

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My name is John D. Graham. I am Dean of the School of Public and Environmental Affairs (SPEA) at Indiana University (IU), one of the largest public affairs schools in the United States and one of the few that combines programs in environmental science with programs in public administration. I cannot resist reporting that, in the most recent rankings published by U.S. News and World Report, IU-SPEA was ranked #2 out of 266 programs with an accredited Master's Degree in Public Affairs (MPA). In this survey, for the first time in history, IU-SPEA was ranked ahead of Harvard's Kennedy School of Government and is the highest ranked MPA program at a public university in the United States.

Prior to serving at IU, I served as Dean of the Pardee RAND Graduate School at the RAND Corporation in Santa Monica (2006-8), Administrator of the Office of Information and Regulatory Affairs (OIRA) at the U.S. Office of Management and Budget (OMB), and Professor of Policy and Decision Sciences at the Harvard School of Public Health, where I founded and led the Harvard Center for Risk Analysis (1985-2001).

With regard to my educational background, I earned a BA in politics and economics at Wake Forest University (1978), an MA in public affairs at Duke University (1980), and a Ph.D. in urban and public affairs at Carnegie-Mellon University (1983). Before joining the Harvard faculty in 1985, I completed a post-doctoral fellowship in environmental science and public policy at the Harvard School of Public Health.

I am pleased that the Committee is giving priority to the topics of transparency, reproducibility, and quality in the science at the U.S. Environmental Protection Agency (EPA). This topic has been a strong interest of mine for decades. In 1988 I co-authored In Search of Safety: Chemicals and Cancer Risk (Harvard University

Press), which examined the scientific and political aspects of the federal government's regulation of two industrial chemicals: formaldehyde and benzene. In particular, we reviewed the relevant risk assessments at EPA, the Occupational Safety and Health Administration (OSHA), and the Consumer Product Safety Commission (CPSC). In 1991 I edited Harnessing Science for Environmental Regulation (Praeger Press), which explored alternative institutional models for strengthening the quality of science at EPA, including the constructive contributions of EPA's Science Advisory Board. In the late 1990s, I also worked with teams of environmental scientists from multiple countries to develop norms in the quest for greater transparency and reproducibility in environmental science studies that support regulatory decision making. Most recently, I organized an international team of scientists and practitioners to examine the scientific and policy aspects of regulating persistent, bioaccumulative and toxic chemicals http://www.indiana.edu/~spea/faculty/pdf/scientific_policy_analysis_of_persistent_bioaccumulative_and_toxic_chemicals_PBT_.pdf.

STATEMENT OF THE PROBLEM

No scientific organization can produce data, analytic results, and interpretations that are completely free of bias or error or misleading interpretation. Organizations, whether they be universities, think tanks, government laboratories or regulatory bodies are imperfect. They are imperfect in part because they are staffed by human beings, and people are imperfect. Consequently, mechanisms have been developed to enhance the quality of science produced by organizations. Those mechanisms range from strategies to enhance the scientific training of the personnel who perform the work to procedures of internal and external peer review to ensure that scientific products meet applicable information-quality objectives.

The quest for greater quality in the scientific products at EPA is particularly challenging for several reasons.

First, EPA's standards of quality generally need to be quite high, since the reports that are issued have an important impact on regulation, public health, environmental quality, affected businesses and workers, and the economy as a whole. An analytic mistake in an EPA report can cause numerous people to become sick or lose their lives due to inappropriately high levels of environmental pollution. If erroneous information about the hazards of an industrial chemical or pesticide is disseminated, the affected company can lose an entire product line and

people can lose their jobs. Entire sectors of the U.S. economy (e.g., energy, manufacturing, and agriculture) are strongly impacted by EPA regulation, and thus it is crucial that EPA's scientific determinations achieve a high level of quality.

Second, the scientific culture at EPA is fragile and still at an early stage of development. In my experience working with EPA, I have found that the political, legal and engineering cultures are fairly strong but the cultures of science and economics are highly variable across the agency's programs. The uneven role of science at EPA should not be surprising because EPA is seen as a mission-oriented agency more than as a science agency, and first-rate scientists who are interested in public service employment might be more inclined to launch a career at the National Institutes of Health or the National Science Foundation or the National Research Council/National Academy of Sciences than a career as a scientist at EPA. For years EPA has been taking constructive steps to enhance the scientific culture of the agency and there are numerous outstanding scientists working at the agency. Nonetheless, the effort to build a culture of sound science at EPA is a work in progress.

Third, the headquarters office for EPA, where many of the key regulatory decisions are made, is located in Washington, DC but many of the agency's top scientists are located elsewhere (Research Triangle Park, North Carolina; Cincinnati, Ohio; and Ann Arbor, Michigan, for example). From the sheer perspective of physical location, many scientists at EPA are more at the periphery than at the center of the Agency's decision making.

Fourth, the field of environmental science is full of uncertainties and the literature is constantly exploding with new scientific results and alternative interpretations of previous results. Keeping abreast of this field is quite challenging, as environmental science has to be one of the most dynamic fields within the physical and life sciences. Staying up to date is particular challenging because of the multiple disciplines that contribute information, everything from environmental epidemiology and toxicology to nanotechnology and atmospheric chemistry.

Finally, the credibility of one of the Agency's most important scientific tools, risk assessment, is constantly under attack. Industry says the agency's risk assessments rely too much on conservative, default assumptions. Environmental groups say the agency's risk assessments are preoccupied with cancer and are downplaying the importance of persistence, bioaccumulation, and endocrine disruption in setting priorities for chemical risk assessment and regulation.

A series of reports from the National Research Council/National Academy of Sciences over the last fifteen years has documented persistent shortcomings in the quality, transparency and reproducibility of the agency's scientific determinations. Those reports have addressed specific substances such as fine particulate matter, dioxin, TCE, formaldehyde, to name just a few. A more recent report, Science and Decisions: Advancing Risk Assessment (NRC, 2009), addresses the way science and risk assessments are used in support of decision making at the agency.

TWO CASE STUDIES FROM MY OMB EXPERIENCE

During my tenure as OIRA administrator, I was periodically drawn into issues where EPA science issues consumed my time in ways that I could not have predicted. Here are two examples where shortcomings in EPA science caused significant diversion of energy inside the Executive Office of the President.

Example #1: perchlorate contamination

In the 2002-3 period, my boss at OMB, Mitch Daniels, called me into his office and asked me what I was doing about "perchlorate". I confessed that I did not know what he was talking about; indeed I thought he was referring to the solvent perchloroethylene that is widely used in dry cleaners. He was not. He was talking about a substance (primarily ammonium perchlorate) that is used as an oxidizer in solid rocket fuels and propellants for munitions. When rockets and other munitions are tested at US military sites, it is not uncommon for residual perchlorate to end up in the soil and in nearby surface water.

EPA was concerned about the perchlorate contamination. On the other hand, at that time, our troops in Afghanistan and Iraq were stretched to the limit, even though defense spending was growing rapidly. OMB could not duck a key resource-allocation issue: Would it be wise to spend billions of dollars cleaning up small concentrations of the perchlorate at military installations or to dredge the Colorado River in a quest to clean up sediments that contained perchlorate? I agreed to look into the issue.

I went back to my office and requested, along with the White House Office of Science Technology, an EPA briefing on perchlorate. EPA's response was straightforward. In 1985 perchlorate contamination had been detected in drinking water wells near California Superfund sites but it was not until 1997 that EPA

detected a national contamination issue. Apparently, more than 11 million people in the United States have perchlorate in their drinking water above the agency's minimum reporting level of 4 parts per billion (4 micrograms per liter). The reporting level is not a safety threshold but simply the lowest level that is required to be reported to the agency in its data system. No national drinking water standard for perchlorate had been set, the type of EPA standard that would be designed to protect public health. EPA had issued in 2002 a draft risk characterization for perchlorate that implied that a drinking water standard of 1 part per billion would be necessary to protect public health with an appropriate margin of safety. This figure is a factor of 30 more stringent than the interim guidance on perchlorate that EPA had issued in 1998 during the Clinton administration. EPA was working through comments on the new draft risk characterization and had already received scientific advice from a committee of the EPA's Science Advisory Board.

In a second meeting at OSTP, I learned that a bitter dispute about the safe level of exposure to perchlorate was being waged by scientists at EPA, the National Aeronautics and Space Administration (NASA), the Department of Defense (DOD) and the Department of Energy (DOE). EPA was relying on a standard analysis of animal data and protective uncertainty factors to make its determination; NASA, DOD and DOE were arguing that available human data could support a much more permissive safety determination, though their analytic approach would be different than the one EPA normally uses. The issue was important because the most sensitive group for exposure to perchlorate were the fetuses of pregnant women who might have hypothyroidism or iodide deficiency.

OSTP and OMB decided, after multiple meetings with the agencies, that it was best to refer the issue to an appropriate committee of health scientists at the National Research Council of the National Academy of Sciences. The relevant agencies reluctantly agreed, recognizing that the NRC/NAS review would take additional time. All of the agencies contributed funds to make the NAS report possible, not knowing what NRC/NAS would conclude.

To make a long story short, the NRC/NAS committee, after hearing the views of all the agencies and reviewing the scientific literature, concluded in 2005 that the EPA analysis of animal data was inappropriate and the human data on exposures to perchlorate should be utilized to determine a safe level of exposure. The committee went further and produced an analysis suggesting that EPA's draft figure of 1 part per billion was a factor of 24 too low, meaning that public health would not be at risk, even at much higher concentrations of perchlorate in drinking

water. (See National Research Council. Health Implications of Perchlorate Ingestion. National Academy Press, 2005.) I have not followed this issue closely since I left the federal government in 2006 but my understanding is that EPA has still not proposed a national drinking water standard for perchlorate, though they have plans to do so (see http://water.epa.gov/drink/contaminants/unregulated/perchlorate/cfm).

Example #2: fine particle pollution

According to EPA and OMB reports, one of the most beneficial suite of regulations issued by the federal government is a set of air quality rules aimed at reducing human exposure to fine particulate matter (sometimes called soot). Particles vary not only in size but in chemical composition. Carbon-containing particles are emitted directly by diesel engines while sulfate and nitrate particles may be formed in the atmosphere after the gases sulfur dioxide and nitrogen dioxide are emitted from electric power plants or other sources. From my faculty colleagues at the Harvard School of Public Health, I was already aware of two curious features of EPA's scientific position on particles.

First, EPA was assuming that all particles are equally toxic, regardless of their chemical composition. (By way of contrast, scientists at the European Commission in Brussels were producing benefit estimates in 2005 suggesting that sulfates are much less toxic than other forms of particles). Second, EPA was not reporting much uncertainty in its estimates of the benefits of reducing human exposures to fine particle matter. Thus, when EPA forecasted that (say) 1,000 lives might be saved from a particular regulation, it was not clear whether the truth could fall between 900 and 1100 or whether the truth could be anywhere from 0 to 10,000. I devoted three years of effort with my staff at OMB, nudging EPA in the direction of addressing these two curious features of their scientific position on the health benefits of reducing particle pollution.

I made more progress on the second issue than the first issue, in part because in 2002 the National Research Council/National Academy of Sciences released a report recommending that EPA do a better job of quantifying the degree of uncertainty in the agency's estimates of public health benefit from reduced exposure to particles. (See National Research Council. Estimating the Public Health Benefits of Proposed Air Pollution Regulations. National Academy Press, 2002.) By 2005 EPA was reporting quantitative uncertainty estimates that addressed some of the fundamental uncertainty about the pollution-mortality relationship.

My takeaway message from EPA's uncertainty work was not that EPA's lifesaving estimates were biased on the high side but that the truth could easily be a factor of 3 lower or higher than the agency's primary estimates. When all of the uncertainties in EPA's benefit analysis for particles are considered, I became convinced that decision makers should recognize that uncertainties were quite large indeed.

In the 2001-2006 period, one of the key barriers to doing comprehensive uncertainty analysis of particle-benefit estimates was that the original health data from the underlying epidemiology studies (e.g., the Harvard Six-Cities Study and the American Cancer Society cohort) were not being made publicly available to researchers through EPA's web site. I checked briefly on EPA's web site prior to preparing this testimony and – 10 years later – EPA has still not made the underlying data publicly available on their web site. To their credit, EPA did – in the 2000-2003 period subject the key particle-oriented health studies to a peer review, replication, and re-analysis by an independent team of scientists at the Health Effects Institute. Although the HEI replication did not discover any major errors, HEI did find some instability in coefficients depending on which pollutants are included in the statistical models (e.g., some of the results for sulphur dioxide and sulfates were unexpected). If the underlying data from the key health studies were made publicly available for all researchers to analyze (rather than just a select few appointed by HEI), I think it is quite possible that many new insights would be gleaned and some of the conventional wisdoms we now accept as fact would be dislodged or refined.

I made little progress at OMB trying to nudge the agency toward a more plausible position on the relative toxicity of different types of particles. The agency holds to a default position that all fine particles are equally toxic, and does not do any quantitative uncertainty analysis of this assumption. In fairness to the Agency, they have been supporting more than a decade of research at the Health Effects Institute (Cambridge, MA) on the relative effects of different particles but I am not aware that any of this HEI-sponsored research has yet had any quantitative impact on EPA estimates of the benefits of fine particle control.

I trust that these two case studies, from the trenches of my OMB experience, illustrate some of the challenges in bringing more rigor and humility to the scientific determinations of EPA.

OMB EFFORTS ON DATA ACCESS AND REPRODUCIBILITY

In October 1999 OMB issued Circular A-110 on data access that was intended to spur agencies to make available the original data from federally-funded studies. OMB actually softened what was intended by the underlying legislation (the "Shelby Amendment") because OMB applied the data access requirement only to new studies, not to those that were initiated before the legislation and before OMB's circular were finalized. As a result, OMB's data access policies are not having much impact on public access to the key health data that support EPA's air quality regulations.

When I served at OMB from 2001 to 2006, I led a government-wide effort to establish information-quality (IQ) guidelines pursuant to new information-quality legislation that was passed by Congress before the Bush administration began. We established IQ guidelines at OMB and then I supervised a process whereby each agency, including EPA, established their own IQ guidelines. A central theme of these IQ guidelines was transparency and reproducibility of original data and results from analytic models. The key operational feature of the agency guidelines was an opportunity for the public to petition an agency and accomplish a correction of agency information that does not meet the agency's information-quality guidelines. Unfortunately, the impact of those guidelines has been weakened because federal courts have ruled that the agency's IQ guidelines are not legally binding. Outside parties (e.g., businesses, labor unions and environmental groups) do not have access to the courts to seek relief in situations where a petition is handled arbitrarily by an agency, and thus the agencies know that the law has little teeth.

COMMENTS ON THE "SECRET SCIENCE REFORM ACT OF 2014"

The legislation you have asked me to comment upon is commendably short, and it is a proposed amendment to Section (b) of the Environmental Research, Development, and Demonstration Authorization Act of 1978. In summary, EPA is not permitted to issue regulations (or other "covered actions") unless (A) all scientific and technical information relied upon is specifically identified; (B) such information is publicly available in a manner that is sufficient for independent analysis and substantial reproduction of research results.

I fully support point A, as it is an elementary principle of transparency. A third party (or even another federal agency or OMB) cannot possibly evaluate the merits of a covered action if they do not know what specific scientific and technical information was relied upon by EPA.

I also support point B, which I believe is the heart of the legislation, as it requires both public access to the scientific and technical information, and access in a form that facilitates independent analysis and reproduction of research results. With regard to agency compliance, what I envision is simply a link on EPA's web site – one for each covered action -- that contains one or more files of original scientific and technical information (including original data and analytic models and guidance about how to access and utilize the files) that are sufficiently detailed that a third party could process the information and thereby substantially reproduce the results that the agency is relying upon. The word "substantially" is preferred to a word such as "completely" because a reproduction within a certain number of significant figures is certainly adequate in the vast majority of cases. Or there may be cases where the agency results – or the results of a third party -- contain a harmless numerical error that is judged to satisfy the standard of substantial reproduction but would not satisfy the standard of complete reproduction.

From a practical point of view, agency compliance with the public access provision is most straightforward for studies that the agency funds in the future. The agency will simply require the grantee to include with their final report files of data and guidance that satisfy the provisions of this legislation. The National Science Foundation already has a procedure for grantees to submit original information to NSF at the end of a grant period, and EPA could look at the NSF procedure as a possible model. NIH may also have some useful guidance of this sort. For a previously-funded EPA study (i.e., prior to enactment of this legislation), compliance should be addressed only at the point that EPA staff determine that they intend to use such a study in support of a covered action. At that point, agency staff should reach out to the relevant author(s) and seek submission of the underlying information. There may be situations where the authors no longer have possession of the underlying information (e.g., in the case of older studies) or do not have the time or money to prepare the research results in the form that EPA requests. In such cases, EPA may need to establish a consulting or contractual arrangement to obtain the underlying information or may decide instead to rely on a different source of scientific and technical information for the covered action.

Since the agency often relies on scientific and technical information that the agency has not funded (e.g., university-funded research in the peer-reviewed literature, technical submissions by scientists from industry and environmental groups, information submitted by other federal agencies, and so forth), compliance with this legislation may be facilitated by an EPA rule or guidance that explains how public access to such information will be accomplished. In the course of

preparing covered actions, agency personnel will often need to reach out to the authors of scientific and technical information and request that the underlying information that the Agency intends to rely upon be submitted to the Agency in a particular form. This type of information request and exchange is common throughout the scientific community on a day-to-day basis. In fact, many authors of scientific papers are now posting on their web sites supplementary information that supports a paper that has been published in a peer-reviewed journal. The supplementary information may include original data and descriptions of analytic models and computer code. In some cases, identifiers are removed to protect the confidentiality of human subjects. There may be some segments of the scientific community that perceive new data-access requirements to be onerous (particularly as they relate to older studies) but the vast majority of the environmental scientific community should not have difficulty satisfying the public access provision in the draft legislation. The last sentence does not mean that the Committee will not hear complaints from scientific societies about this legislation. I predict that you will hear complaints about how practical issues will be worked out but it is important to remember that the scientific community is not accustomed to being told by the government how to assemble and disclose their work products, particularly products that were published years ago. Working out the kinks in this process will take some time and consensus building.

I have already alerted Committee staff that the Institute of Medicine (Washington, DC) will soon by holding a public workshop (March 19, 2014) to address how "data sharing" should be accomplished in the field of environmental health, especially when data from human subjects are at issue. The summary of the charge to the workshop indicates that "Environmental health experts agree that the question is not "if" research data should be shared but "how."" I encourage Committee staff to attend the workshop (Workshop on Principles and Best Practices for Sharing Data from Environmental Health Research, Institute of Medicine, March 19, 2014, 8:30 AM, http://www.iom.edu/activities/environment/environmentalHealthRT/2014-Mar-19.aspx).

With regard to the "covered actions," it is extremely reassuring that this language goes beyond "regulations" to include technical documents used to support federal regulations (e.g., regulatory impact analyses) and scientific and technical documents issued by EPA that are known to influence subsequent regulations by EPA, the states and international bodies. In my experience, some of the most significant actions taken by EPA are scientific determinations rather than

regulations per se and they are often issued as guidance (e.g., IRIS determinations about chemicals are normally considered guidance).

With regard to (2) the clarification and exclusion regarding disclosures that are prohibited by law, I assume this covers confidential business information, some types of security-related information (e.g., how a chemical is used by the Defense Department in a particular weapon system) and possibly some privacy laws. I am not aware of any other kinds of disclosures that would be prohibited by law.

SUPPORT FROM ORGANIZATIONS

In conclusion, I would like to cite support for data access and reproducibility that was previously stated by authoritative organizations.

1. Administrative Conference of the United States (excerpts below)
http://acus.gov/sites/default/files/documents/Science%20Recommendation%20APPROVED-FINAL_1.pdf

"Disclosing Underlying Studies and Data. To the extent practicable and permitted by law and applicable policies, each agency should identify and make publicly available (on the agency website or some other widely available forum) references to the scientific literature, underlying data, models, and research results that it considered. In so doing, the agency should list all information upon which it relied in reaching its conclusions, as well as any information material to the scientific analysis that it considered but upon which it ultimately did not rely. Consistent with the limitations in the Information Quality Act (IQA) guidelines issued by the Office of Management and Budget and its own IQA guidelines, each agency should ensure that members of the public have access to the information necessary to reproduce or assess the agency's technical or scientific conclusions."

"Data Disclosure. To the extent practicable and in compliance with applicable legal restrictions, privileges, protections, and authorities, agencies should seek to provide disclosure of data underlying scientific research, including both privately and federally funded research being considered by the agencies. Where practicable, such information should be disclosed in machine-readable format. Where such data are not subject to legal or other protections, and the data's owners nonetheless will not provide such access, agencies should note that fact and explain why they used the results if they chose to do so. Agencies should review their confidential business information policies to ensure that they include appropriate mechanisms to prevent over-claiming."

2. The submission guidelines for the prestigious journal Science.

"As a condition of publication, authors must agree to make available all data necessary to understand and assess the conclusion of the manuscript to any reader of *Science*."

Thank you in advance for the invitation to testify. Please do not hesitate to contact me if I can answer any questions or if I can supply any additional information.