TESTIMONY OF

GEORGE GRAY, PhD
ASSISTANT ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT
U.S. ENVIRONMENTAL PROTECTION AGENCY
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Good morning, Madam Chair and Members of the Committee. My name is Dr. George Gray, and I am the Assistant Administrator for Research and Development (ORD) at the Environmental Protection Agency (EPA). I also serve as the Agency's Science Advisor. Thank you for this opportunity to appear before the Committee to discuss science, science policy, and decision making at EPA, and our ongoing efforts to strengthen the scientific integrity of all decisions made by the Agency.

EPA conducts research that provides scientific and technical information to support our mission to protect public health and the environment. Our scientists conduct research independent of political influence, publish results in peer-reviewed journals, present findings at scientific and technical conferences, and speak openly with the public about their work.

We are committed to using the best available science and the most defensible science-policy choices to achieve our strategic goals and fulfill our mission. Science informs, and provides a foundation for, EPA's regulatory decisions. At the same time, it is important to recognize that what often appear to be purely scientific questions or assessments generally involve both "science" and "science-policy" considerations. For example, developing risk values requires many decisions, choices, and assumptions that are generally guided by Agency science policy.

While it is important to integrate our scientists' research and development products with the Agency's regulatory needs, it is also vital that the research itself is independent, objective, transparent, and of the highest quality. During the past several years, EPA has taken a number of steps to maintain a program of sound scientific research to inform Agency decisions without allowing regulatory objectives to guide or distort scientific findings or analyses. These steps have included open, transparent, and peer-reviewed research planning; competitively awarded extramural research grants; independent and external peer review of our science publications, assessments, and documents; and rigorous evaluations of EPA's research laboratories and centers.

EPA's science program is at the leading edge in many areas of science and technology. With our focus on high-quality, relevant support for the Agency's activities and decisions, we are well-positioned to address the challenges of the 21st century. We constantly look for ways to build on our strengths so that EPA's decisions and actions continue to be informed by the best available science and the most defensible science-policy choices.

EPA's Scientific Staff

As the Assistant Administrator of EPA's Office of Research and Development (ORD), the Agency's key scientific body, I cannot emphasize enough what a privilege it is to work with so many world-class scientists. A substantial percentage of publications by our scientists and grantees achieved "highly cited" and "high-impact" status in our most-recent analysis using Thomson Scientific's *Essential Science Indicator*s. Overall, over 20 percent of our publications are "highly cited" and over 30 percent are published in "high-impact" journals.

Our scientists are also active participants in many scientific organizations, including the American Public Health Association, Association for Practical and Professional Ethics, Geological Society of America, American Geophysical Union, Ecological Society of America, Air and Waste Management Association, Society for Risk Analysis, International Society of

Exposure Analysis, Society of Toxicology, and more. Many of our scientists hold leadership positions in, and have received prestigious awards from, major scientific organizations such as the Intergovernmental Forum on Chemical Safety, International Commission on Radiological Protection, and Society of Toxicology, as well as major research universities.

Considering the scientific and technical talent in our organization, and our experts' clear commitment to public service, it is my aspiration to have ORD be the premier environmental-science organization in the federal government. We have demonstrated positive momentum toward this goal with many achievements, such as:

- Award-winning tools and strategies to protect public health developed by our National Homeland Security Research Center;
- Cutting-edge models to test chemical effects and interactions developed by our National Center for Computational Toxicology;
- Ground-breaking reports on the effects of climate change to inform national and international dialogues developed by our Global Change Research Program; and
- Grants awarded to scientists across the nation to research environmental challenges and develop innovative solutions through our National Center for Environmental Research.

Science Planning and Science Management at EPA

EPA's first priority is "doing the right science." A number of sources, both internal and external to the Agency, provide information and guidance on how EPA can prioritize its research. EPA's Strategic Plan serves as the first organizing principle for EPA's research agenda. Next, EPA's Program and Regional Offices communicate their science needs based on their unique policy and regulatory responsibilities. EPA's Office of the Science Advisor also provides critical input. The Agency must incorporate into its research planning Congressional mandates, the priorities of the Administration and other agencies, as well as advice from external advisory committees. Other research stakeholders, including non-governmental

organizations and industry, may voice their priorities. EPA management and directors of ORD research take input from these various sources into account when setting the research agenda.

"Doing the science right" by promoting effective management and implementation of ORD's research strategies is an equally important responsibility and serves to strengthen scientific integrity. It is vital that EPA strive for the highest quality and credibility in its activities and decision-making processes if the American public is to have confidence in our decisions. To this end, EPA scientists, managers, and union representatives jointly developed the EPA *Principles of Scientific Integrity* under the auspices of the National Partnership Council. To ensure that management and staff understood the importance of scientific integrity at all levels of the organization, the release of this document was followed with online training. The Principles include the following:

- *Honesty* - EPA employees are responsible and accountable in all aspects of their science.
- *Accuracy* - Employees represent their work, and the work of others, fairly and accurately.
- *Recognition* - The intellectual contributions of others are recognized and acknowledged.
- *Freedom from conflicts* - All science is conducted in an atmosphere free of conflicts of interest.
- *Knowledge of statutory authorities* - Know and understand the statutes and regulations that guide EPA's work.
- *Responsibility* - Breaches of these principles must be promptly reported when discovered.
- *Open-mindedness* - Differing views and opinions on scientific and technical matters are a welcome part of the scientific process.

To monitor performance, ORD requests feedback from EPA Program and Regional Offices on the timeliness and quality of its research. ORD research programs also undergo formal performance evaluations by the Office of Management and Budget by way of OMB's

Performance Assessment Rating Tool (PART). Additionally, the Board of Scientific Counselors, Science Advisory Board, National Academies of Science, and other advisory panels provide program evaluations that facilitate continuous improvement and ensure ORD is advancing the state of the science in key areas. Members of EPA's advisory boards are non-EPA scientists, engineers, and economists, and other social scientists who are recognized experts in their fields. They come from academia, industry, government, research institutes, and non-governmental organizations throughout the United States. EPA chooses them for their demonstrated ability to examine and analyze environmental issues with objectivity and for their interpersonal, oral and written communication, and consensus-building skills.

In sum, ORD's research is guided by strategic directions and stakeholder input, adjusted according to annual budget decisions, evaluated to ensure effective and efficient management, and ultimately applied to inform environmental decision-making.

The Science to Decision-Making Continuum at EPA

Similar to other federal agencies that are required to produce both scientific assessments and make regulatory decisions, EPA views the relationships between science, science-policy, and decision-making as a continuum—from science and science-policy to official Agency decision-making.

To start, EPA science is conducted by individuals and teams working in our laboratories or in the field. All of their work is reviewed by subject-matter experts in accordance with EPA's highly regarded peer-review process and information-quality guidelines. Once an EPA scientific product meets scientific standards of quality and credibility, scientists are encouraged to publish and otherwise communicate their findings. Note that these independent, scientific findings do not necessarily represent official Agency policy positions, as national policies must also take other factors into account.

Science policy is an integral part of the continuum. Because the scientific method encourages critical thinking and professional disagreement, it does not commonly lend itself to a "bright line" that decision-makers can use as a reliable reference point. A range of reasonable and scientifically defensible options or decisions are usually available, and there is rarely a single "best answer" for use in decision-making. Scientific assessments also entail varying degrees of uncertainty and many decisions, choices, and assumptions must be made based on science-policy considerations.

To meet our statutory requirements, we often cannot wait for independent scientific findings to converge on a solution—this would cause long delays in environmental decision-making. Therefore, we rely on science-policy considerations, which often entail synthesizing and assessing a range of scientific opinions and data points. This process also involves filling in knowledge gaps in the body of technical information, and where necessary, using weight-of-evidence approaches to make scientific inferences or assumptions. The scientific models that inform most national policies require this kind of give and take. This work draws on expert insights from multiple scientific disciplines, and it is further strengthened by Agency, interagency, and public review.

Decision-making is further along the continuum. Science, however, is but one aspect of EPA's regulatory decisions. Other important considerations need to be factored into EPA's decisions without compromising scientific integrity, the Agency's mission, or statutory mandates. These considerations include technological feasibility, implementation costs, local autonomy versus federal control, justice, and equity. The impacts or limitations of these non-science factors, as well as the current state of the science, will influence how scientific considerations are brought to bear on environmental decisions facing the Agency.

Administrator Johnson and his leadership team give serious weight to science and science-policy choices in developing options for national policy. Nevertheless, the science to decision-making continuum does not end with regulation and rules. Every Agency decision

feeds back into science and science-policy considerations as we monitor the effectiveness of our national policies and use updated information about changes in the quality of human health and the environment to adjust our policies over time.

Peer Review

An important and practical way to ensure the integrity of scientific programs and products is through independent and external peer review—i.e., the evaluation of programs and products by outside experts. EPA has a very strong peer-review program to ensure that only high-quality science is released and/or used by the Agency. Hundreds of Agency products undergo peer review each year, and nearly 90 percent are reviewed by independent experts who are not affiliated with the Agency.

EPA's Science Policy Council maintains our Peer Review Handbook—a "how-to" manual that is used by staff across the Agency. In addition, external stakeholders often refer to the Handbook as a model of good peer-review practices, which include: peer review by experts who are independent of the Agency and have no conflicts of interest; public review and comment as appropriate; and maintenance of transparent, public records of scientific products at key stages of development. Our updated Peer Review Policy (2006) and 3rd edition of the Peer Review Handbook (2006) benefit from insights gained by implementing the program over the last decade. The 2006 Handbook clarifies ethical standards, improving understanding and compliance on the part of staff and management.

Our peer-review program fits within the context of a larger, Agency-wide quality system. EPA's quality system is the means by which we manage our scientific information in a systematic, organized manner and it provides a framework for planning, implementing, and assessing EPA's scientific work. Our peer-review policies also incorporate the provisions of the Office of Management and Budget's (OMB) Final Information Quality Bulletin for Peer Review. This Bulletin contains provisions for conducting peer review at all federal agencies in order to

enhance transparency and accountability and applies to “influential scientific information” and “highly influential scientific assessments.” OMB’s Information Quality (IQ) Guidelines, together with our own IQ guidelines, are important elements in our quality system.

EPA’s Principles of Transparency further support the Agency’s scientific quality by providing explicit information about our research-planning process, as well as the process for developing science and science-policy assessments that are used for regulatory decision-making. The Principles were written so that any reader would understand all the steps, logic, key assumptions, limitations, and decisions in the assessment process, and also comprehend the supporting rationale that led to the outcome. EPA’s 2000 *Risk Characterization Handbook* provides a number of transparency goals that we try to consider during the risk-characterization process. Specifically, the *Handbook* states that transparency achieves full disclosure in terms of:

- The assessment approach employed;
- The use of assumptions and their impact on the assessment;
- The use of extrapolations and their impact on the assessment;
- The use of models *vs*. measurements and their impact on the assessment;
- Plausible alternatives and the choices made among those alternatives;
- The impacts of one choice *vs*. another on the assessment;
- Significant data gaps and their implications for the assessment;
- The scientific conclusions identified separately from default assumptions and policy calls;
- The major risk conclusions and the assessor’s confidence and uncertainties in them; and
- The relative strength of each risk assessment component and its impact on the overall assessment (e.g., the case for the agent posing a hazard is strong, but the overall assessment of risk is weak because the case for exposure is weak).

Along with adherence to the Principles of Transparency, individual scientific studies and scientific assessments follow a rigorous peer-review process. The peer review of assessments, which often synthesize multiple scientific studies, may include a number of steps: internal peer consultation, EPA review, interagency review, and external review. For example, to enhance the quality and transparency of assessments in EPA's Integrated Risk Information System (IRIS), each report undergoes peer review as follows:

- Internal Peer Consultation: Internal (EPA) peer reviewers are selected to provide detailed scientific feedback on the draft assessment.
- EPA Review: The draft assessment is reviewed by a standing group of senior health scientists representing EPA's Offices and Regions and by selected senior health scientists with scientific expertise relevant to the substance under review.
- Interagency Review: The revised draft assessment is distributed through the Office of Management and Budget for review by scientists in other federal agencies.
- External Peer Review: EPA obtains external peer review, typically via a panel meeting that is open to the public. At this time, the draft assessment is posted on the internet for public comment. EPA may submit more challenging assessments to high-level advisory panels, such as the EPA Science Advisory Board or National Academies of Science.

Peer review is also conducted at a higher level of planning and management. The Science Advisory Board, among other bodies, reviews EPA's research program. Science Advisory Board reviews provide critical cross-Agency perspectives as we establish research priorities. EPA also ensures systematic, external peer review of its ORD research programs by the Board of Scientific Counselors and others. Each ORD research program undergoes a detailed review approximately every four years, with a mid-cycle review after two years.

Additionally, all grants awarded by ORD's Science to Achieve Results (STAR) program are selected through a rigorous peer-review process, whereby panels of independent researchers review all the proposals for their scientific quality. The STAR program's commitment to scientific quality earned accolades from the National Academies' National

Research Council in a 2003 report, “The Measure of STAR.” Dr. Harold Mooney, the chair of the committee that wrote the report, concluded, "The STAR program has established and maintained a high degree of scientific excellence. It has provided EPA with independent analysis and perspective that has improved the agency's scientific foundation. By attracting young researchers, this program has also expanded the nation's environmental science infrastructure."

Conclusion

EPA has a proud history of producing science that has informed decisions to protect the environment and human health. Our scientists and engineers are among the finest and most productive in the Federal government, and they share a deep commitment to public service. Our personal and organizational commitment to scientific integrity is further strengthened by EPA’s Principles of Scientific Integrity, Principals of Transparency, our peer-review guidelines, independent advisory committees that oversee our work, and other elements of the EPA information-quality system. From the lab bench to the Administrator’s desk, we follow a science-to-decision-making continuum in common with other federal agencies that rely on both science and science-policy considerations in decision-making. However, science rarely provides a “bright line” that directly translates into a decision. Making decisions in a timely manner requires that science be taken into consideration with other legal, technical, and economic concerns.

Thank you, Chairwoman Boxer and members of the Committee for this opportunity to describe EPA’s critical scientific work. I look forward to answering any questions you may have.