House Science, Space and Technology Subcommittee
on Investigations and Oversight
Review of EPA's Integrated Risk Information System (IRIS)
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TESTIMONY OF GAIL CHARNLEY PhD[1]

Good morning. I am speaking today as a toxicologist with a PhD from MIT, as a human health risk analyst, and as a toxicology consultant to private clients who has relied for many years on the information contained in the IRIS database for my work. I am speaking on the basis of my 30-year career studying the relationship between chemical exposures and human health effects, as executive director of the bipartisan Presidential/Congressional Commission on Risk Assessment and Risk Management, as a member of the National Toxicology Program's Report on Carcinogens Committee, as a former senior program officer in the National Academy of Sciences' Toxicology and Risk Program, as a member of National Academy of Sciences committees, and as a member of the National Academy of Sciences Board on Environmental Studies and Toxicology. I am not representing any organization today, however, or being paid for my testimony.

The role and purpose of IRIS are good and well-intentioned, but over the years IRIS has lost its way. IRIS started out as a good idea—a scientific advisory group that assesses chemical toxicity for the rest of EPA so as to avoid every office having to do it themselves and generating potentially conflicting toxicity values. The reach of IRIS goes far beyond EPA, however, as other federal agencies and state and local governments in the US and other countries lacking their own resources for generating chemical toxicity values have come to rely on those generated by IRIS. IRIS assessment can thus become a de facto component of regulatory decision-making without benefit of appropriate administrative process. Because the influence of IRIS is so broad, the scientific quality and integrity of its reviews are critically important.

Unfortunately, over time the IRIS process has become politicized and, as a result, it no longer has much scientific credibility outside the agency or, importantly, even within the agency. The process has strayed from science and veered towards advocacy. As you have heard from other speakers this morning, IRIS toxicity evaluations do not follow a rigorous, objective, transparent, scientific weight-of-evidence process, instead relying on cherry-picking data as needed to support policy preferences. Indeed, many of IRIS' recent conclusions appear to be based on what my colleagues and I refer to as "magical modes of action", that is, highly speculative biological explanations for toxicity.

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IRIS assessments fail to evaluate potential human cancer and noncancer effects of chemical exposures using a weight-of-evidence analysis despite the direction to do so provided by EPA's own risk assessment guidance documents and, repeatedly, by various National Academy of Sciences committees. For example, EPA's Information Quality Guidelines state that when EPA develops "influential" scientific risk assessments, it intends to use all relevant information and reach a position based on careful consideration of all such information, a process typically referred to as the "weight-of-evidence" approach.[2] EPA's Assessment Factors Handbook[3] states that a weight-of-evidence approach generally considers all relevant information in an integrative assessment and explains how the various types of evidence fit together. EPA's Risk Assessment Principles & Practices documentation asserts that risk assessment involves consideration of the weight of evidence provided by all available scientific data.[4] My point is that there is a large body of EPA documentation stating that it is EPA policy to perform balanced weight-of-evidence analysis as part of chemical risk assessment that is clearly being ignored—a glaring omission in light of EPA's own guidelines, policies, and NAS recommendations.

A weight-of-evidence analysis for any potential health effects, whether cancer or noncancer, should be more than a matter of describing a set of available studies with an array of results and then announcing one's overall subjective judgment. Because judgments made about potential risk will usually not be definitive, it is important to present the strengths and weaknesses of alternative judgments that could be made, giving the reader a picture of how strongly one or another interpretation is supported vis-à-vis alternative possible explanations. Instead, IRIS assessments preclude a weight-of-evidence analysis by selecting almost solely for studies that demonstrate a positive result and a dose-response relationship, typically excluding studies that demonstrate no effect and thereby effectively preventing a balanced consideration of available evidence supporting or refuting the biological plausibility and likelihood of effects.

A true weight-of-evidence analysis should explicitly present the criteria for inclusion and exclusion of studies so that all relevant information is included and so that biases toward inclusion of certain outcomes—such as only positive outcomes—are avoided. The goal should be to interpret possible reasons for disagreement, not to select the "best" study and rely on it even if it is contradicted by other study results. Omitting endpoints or studies that do not show a dose-response relationship in the direction EPA favors discounts valuable information, particularly information that could inform mode of action as well as dose-response.

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[2]EPA (2002) Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency. EPA/260R-02-008. Office of Environmental Information, Washington, DC

[3]EPA (2003) A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information. EPA 100/B-03/001. Science Policy Council, Washington, DC

[4]EPA (2004) Risk Assessment Principles and Practices. EPA/100/B-04/001. Office of the Science Advisor, Washington, DC

I think the solution is not to try once more to tweak or revamp the existing process but to get rid of it entirely and start over. Public health is not served by a broken, cumbersome, controversial process that lacks a rigorous scientific foundation and a transparent, replicable weight-of-evidence framework. Setting up a more effective process should follow the recommendations of a National Academy of Sciences committee convened for that purpose and should follow a weight-of-evidence procedure recommended by the Academy. Chapter 7 of the Academy's formaldehyde report provides helpful guidance to that end.[5]

Some have proposed that IRIS rely on EPA's Science Advisory Board for independent external review and oversight instead of the Academy. However, the SAB review process is not independent. EPA officials select SAB members, formulate the charge questions, provide staff support for the review process, and observe SAB deliberations and report drafting. According to the SAB web site, "The Staff Office manages EPA requests for scientific and technical advice and peer review. The Staff Office also provides policy, technical and administrative assistance to advisory committees in conducting meetings and preparing reports. The SAB Staff Office oversees the formation of advisory committees and panels . . ." and so forth. In contrast, the NAS process for selecting scientific panel members and conducting reviews assures independence and objectivity along with appropriate expertise. Truly independent peer review is the only way to give stakeholders confidence in the credibility of the outcome. Stakeholders are likely to accept the outcome of an independent Academy peer review and unlikely to accept the outcome of an EPA-administered peer review. Then there's the problem of delay. Most of the recent controversial IRIS assessments reviewed by the NAS had already been reviewed by the SAB, but ended up at the Academy anyway.

In conclusion, the IRIS process is dysfunctional and attempts to tweak it have not resulted in meaningful improvements. Developing an improved, scientifically based, transparent IRIS process would benefit greatly from National Academy of Sciences guidance. The NAS is in a unique position to provide unbiased, expert advice that, sadly, is so critically needed at this point if we are to move IRIS to a 21st century approach to assessing chemical toxicity effectively.

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[5]National Academy of Sciences/National Research Council. 2011. Review of the Environmental Protection Agency's Draft IRIS Assessment of Formaldehyde. National Academy Press. Washington, DC