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

Hearing on Examining the Scientific and Operational Integrity of EPA's IRIS Program

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Thank you for the opportunity to address the Subcommittees on Environment and Oversight at today's hearing on EPA's IRIS Program. I am Dr. Thomas Burke, Professor at the Johns Hopkins University Bloomberg School of Public Health. I am also Director of Johns Hopkins Risk Science and Public Policy Institute.

First, as a former Houstonian and graduate of the University of Texas School of Public Health, I want to express my deep sympathy for all those impacted by Hurricane Harvey. Please know that I, and the public health community at Johns Hopkins and throughout the country, stand ready to assist in any way we can. This hearing is particularly timely, as Texas and Louisiana work to protect public health, restore safe drinking water, and evaluate the risks from contaminated floodwaters and chemical releases.

I speak today as an individual, informed by a career devoted to public health and protecting our environment. Before joining the faculty at Johns Hopkins I worked as both an environmental and health official for the State of New Jersey, serving three governors, both republicans and democrats. I have served as a member of the National Academy of Sciences Board on Environmental Science and Toxicology, and a Member of the EPA Science Advisory Board and Board of Scientific Counselors. I also served as Chair of the National Academy of Sciences Committee on Improving Risk Analysis Approaches Used by the U.S. EPA. Perhaps most relevant to today's topic, from January 2015 to January 2017 I served as the EPA Science Advisor and Deputy Assistant Administrator for the Office of Research and Development.

The capacity to evaluate the hazards of toxic chemicals is essential to protecting our public health. It is essential for clean air and safe drinking water, for responding to emergencies, and protecting our communities from harmful exposures. It is equally essential for business, industry, and agriculture to provide safe products, protect workers, and preserve the safety of our food supply.

### **The IRIS Program**

The EPA IRIS Program is a cornerstone of our national capacity to protect public health. IRIS, within the National Center for Environmental Assessment (NCEA), is charged with the daunting task of synthesizing enormous amounts of scientific information to identify the potential for a chemical to cause adverse health effects. The program was started in 1985 to provide a consistent scientific source of toxicity data for the many program offices throughout the Agency and the broader regional and state environmental protection efforts.

IRIS is not a regulatory program, but the assessments provide essential scientific guidance for Agency decisions. There is an important distinction between the IRIS assessment process and the ultimate risk management decision. They provide insights on the magnitude of risks---but they do not tell us what level of risk is “acceptable”. Nor do they tell us how to manage or reduce risks. Ultimately, regulatory options are the responsibility of the program offices and the Administrator.

## **Challenges to IRIS**

The demand for information about the safety of chemicals is constantly growing. Although the actual number is often debated, there are thousands of chemicals in commerce and in our environment. One of our greatest environmental challenges is the lack of basic information on the toxicity and health effects of these chemicals. The 2016 bipartisan passage of the Frank R. Lautenberg Chemical Safety for the 21<sup>st</sup> Century Act represents a step forward, but the key to success will be the scientific capacity of EPA. IRIS is essential to that capacity.

The IRIS process includes weighing the scientific evidence that a chemical may cause adverse impacts such as developmental and reproductive effects or cancer. IRIS assessments can also be the starting point for many of the agency's most difficult and far-reaching regulatory decisions about chemical pollutants. Not surprisingly, they are also controversial.

Unfortunately, there are inherent uncertainties in toxicology and epidemiology studies that present difficult challenges to IRIS assessments. For example, does finding of cancer in laboratory test animals mean that exposure will cause cancer in humans? If epidemiology studies give conflicting results for an adverse health effect, which study do you choose to characterize the hazard? These vexing questions are examples of the challenges faced by IRIS scientists charged with evaluating and presenting the evidence. Rigorous stakeholder and peer review is built in to the IRIS process and is an essential to

producing credible results, addressing uncertainties, and explaining the scientific basis for conclusions.

The IRIS program is challenging both from a management and science perspective. Over the past few years there has been a tremendous commitment to improvement. This progress is reflected in reviews by the National Academies of Science (NAS), the Government Accountability Office (GAO), and the EPA Science Advisory Board (SAB). The 2011 NAS review of the IRIS Draft Formaldehyde Assessment presented a roadmap to improve the process by increasing transparency and improving the systematic review and of evidence. (1) The follow up NAS report in 2014 credited the program for making steady progress in addressing the recommendations for improvement. The GAO also made recommendations for improvements and has recently noted the progress of the IRIS program. (2) Most recently, the EPA SAB expressed their strong support for the program in a letter to EPA Administrator Pruitt. The Board recognized the progress in responding to NAS recommendations, and noted significant “impactful changes” that “constitute a virtual reinvention of IRIS”.

### **Conclusion**

EPA is a science-based agency. Ultimately the success and credibility of EPA decisions depends upon the quality and integrity of the science behind them. The core mission of EPA is to protect public health. IRIS has a unique and essential role in supporting that mission, and the public health efforts of our states and tribes.

I would like to close on a more personal note. During my time at the agency I came to know the great people of EPA ORD and IRIS. They are dedicated and talented public servants and world-class scientists. Their work goes far beyond the tedium IRIS document preparation. They are there to take on the toughest environmental challenges we face. From the dusts of the World Trade Center and the faucets of Flint; to the toxic waters of Katrina and Harvey; they are there, working selflessly to protect our Nation's environment and public health. Our health depends on them.

Thank you for this opportunity to speak with you today.

#### References

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