July 8, 2011

Director Jacob J. Lew
White House Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503

Re: IRIS's Continued Importance and Efficacy

Director Lew:

We write today as Member Scholars of the Center for Progressive Reform (CPR), a network of scholars around the nation working to protect health, safety, and the environment through analysis and commentary. We want to correct several points made in the American Chemical Council's (ACC's) June 22, 2011 letter asking you to require the U.S. Environmental Protection Agency (EPA) to submit all current IRIS evaluations to the National Academy of Sciences (NAS).[1] ACC's letter is ostensibly justified by the recent NAS review of EPA's draft IRIS assessment for formaldehyde. Sensing an opening in its lengthy campaign to undermine the credibility of the work done by career IRIS staff, the ACC aggressively extrapolates from the review and argues that NAS review should be required for all IRIS assessments without any regard for the disastrous effects such a requirement would have on human health and the environment. We therefore urge OMB to recognize that EPA is continuously working to improve the IRIS system and that requiring NAS to review all assessments would grind this process to a slow walk at the expense of the health and safety of everyone in the United States.

IRIS is one of EPA's most important and effective programs for protecting health and the environment. It is the first step toward many protective regulatory actions, particularly Superfund cleanup decisions and regulations promulgated under risk-based statutes like the Clean Air Act's provisions for National Emission Standards for Hazardous Air Pollutants (NESHAPs) and the Safe Drinking Water Act. An efficient and unencumbered IRIS process is essential to good implementation of these statutes because IRIS truly is only the first step in

[1] Letter from Cal Dooley, President and CEO, American Chemistry Council, to Jacob J. Lew, Director, Office of Management and Budget (June 22, 2011).

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the regulatory process—IRIS assessments are scientific documents that regulatory staff utilize as one factor in a decisionmaking process that also considers statutory mandates, public notice-and-comment, and public policy goals.

Administrator Lisa Jackson recognized that certain aspects of the review of draft IRIS assessments drastically reduced the efficacy of the IRIS program without any apparent benefits. Accordingly, one of her first actions was to take back control of the interagency review of IRIS documents. In 2004 and 2008, Administrator Jackson's predecessors shifted control of the interagency review process to OMB. Those changes led, in large part, to the Government Accountability Office's (GAO's) January 2009 addition of the IRIS program to its "High Risk List"[2] of programs needing major improvement. In May 2009, Administrator Jackson announced a revised IRIS process that streamlined outside review and moved control over the review to a team of scientific experts within the IRIS program office. OMB and EPA can more effectively achieve their intended purposes under the current arrangement: EPA is in charge of researching and promulgating regulations to protect health and the environment while OMB reviews the draft regulations with an eye to the budget, not the scientific underpinnings. OMB's Office of Information and Regulatory Affairs (OIRA) employs just two scientists and hence is not designed to conduct scientific peer review.

ACC's request that OMB play a larger role in the scientific work of conducting IRIS assessments is a thinly veiled attempt to slow the IRIS process and thereby prevent EPA from promulgating rules that will directly benefit public health and improve the quality of life for millions of Americans. Not only will these requested delays create more work for any agency involved, including OMB, but this unnecessary review will significantly increase the costs of regulating by hundreds of thousands, if not millions, of dollars for *each* new IRIS assessment. Industry and its representative groups are therefore effectively asking the American taxpayer to pay for the privilege of delayed and ultimately less effective health and safety regulations.

Contrary to ACC's implications, perfection in an IRIS assessment will not be achieved through recurring NAS review. The science of toxicology is inherently uncertain and reasonable scientists will have different interpretations of the available data. More research will always be possible. That is why Congress empowered EPA to act with precaution to protect the public and the environment from toxic chemicals. If EPA had to obtain two rounds of NAS review for each and every IRIS assessment, as ACC requests for the next two years, the agency would fall even further behind in promulgating required rules, which would directly result in the loss of millions of dollars and human lives.

GAO's "High Risk" designation puts EPA's program for controlling chemical exposures in a group of some 30 government programs that are failing the American people and need urgent attention to improve their efficacy. As a critical linchpin for those efforts, IRIS work needs to be

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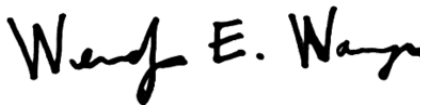
[2] GOV'T ACCOUNTABILITY OFFICE, *HIGH-RISK SERIES: An Update*, GAO-09-271 (Jan. 2009); *see also*, GAO, *Transforming EPA's Process for Assessing and Controlling Toxic Chemicals*, *at* http://www.gao.gov/highrisk/risks/safety-security/epa_and_toxic_chemicals.php (accessed July 1, 2011).

accelerated, not delayed. During this administration, the program has produced approximately nine new or updated toxicological profiles each year. At this rate, the work needed to develop profiles for statutorily-identified "hazardous air pollutants" and other chemicals that Congress and the agency have identified as needing more effective controls is already pushed back several decades into the future. Adding NAS review will only exacerbate this already protracted delay.

We therefore request that OMB recognize EPA's institutional scientific expertise by allowing EPA to fulfill its statutory duties without excessive outside review of the IRIS process.

Sincerely,



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