EPA's IRIS Program: Evaluating the Science and the Process Behind Chemical Risk Assessment

Hearing of the Subcommittee on Investigations and Oversight

House Committee on Science, Space, and Technology

Statement by the Honorable Donna F. Edwards

July 14, 2011

For fifty years the tobacco industry has fought a campaign to cast doubt on the health risks of smoking cigarettes. They invented the effort to use "science" to fight science; to harness industry-funded research for public relations campaigns; and to use friendly public officials to point to these manufactured uncertainties in opposing any effort to protect the public.

And during that entire time, public health experts have absolutely known that smoking causes cancer, and that smoking remains--in the words of the Surgeon General--"the single most important preventable cause of death in our society."

That model of industry-funded science being used to generate uncertainty and postpone even minor regulatory steps--regardless of the effects on public health--has been taken up with gusto by other industries. A similar campaign is being waged by the fossil fuel industry to cast doubt on the science of climate change. And today we are going to see some of this unfold surrounding EPA's science-based efforts to develop risk assessments of the health consequences of chemicals to which Americans are commonly exposed.

Industry tends to push for two things in the realm of science and regulation: first they demand that we must have certainty before any action can be taken, and, second, they point to studies that suggest there is uncertainty. What they don't mention quite so prominently is that they fund the production of studies designed to create doubt. That manufactured doubt is then used to justify inaction because, obviously, there is no certainty.

The country ends up in an endless science loop that makes it almost impossible to ever make a statement about the harm of anything. If an agency tries to take a position, industry argues that there is "another study" just around the bend for which the agency should wait. With enough money and willing researchers, industry can guarantee that there is always another study just around the corner no matter the evidence regarding its harm.

Of course the science that industry funds is specifically aimed at producing studies that show no harm from their products. In this world, the scientists who work for industry are not working to honestly understand a problem, but to provide answers that their clients want to use for their public relations campaigns. And make no mistake, no one pays you $325 an hour to produce science that isn't useful to their interests.

The National Academy of Sciences has not been blind to this development in America's science and regulatory landscape. In 1983, the National Academy of Sciences issued the "red book" on Risk Assessment. For almost three decades that has been the bible on how to conduct a risk assessment. The report was motivated, in part, by a desire to try to set the science of assessing risks outside the political environment that surrounded decisions about what to do about those risks--a process they labeled risk management. The Academy, perhaps naively, hoped that all the struggles over regulatory decisions would be focused on risk management.

What the Academy did not anticipate was how readily those with deep pockets would see science as fertile ground for fighting regulation. Industry learned that they can stall any movement out of the realm of risk assessment by manufacturing doubt, and the NAS red book helped institutionalize this system.

And now the Academy has again marched into a situation that they may not have fully anticipated. The NAS report on EPA's draft formaldehyde assessment contains a very useful "roadmap" for how EPA should undertake reorganizing their IRIS assessments to make them more comprehensible and transparent. To his credit, Dr. Anastas has embraced those recommendations. But the industries that

most worry about IRIS assessments have seized on the language of the NAS report to try to claim that EPA cannot be trusted to do science.

That is not the message of the NAS report nor the intention of the Academy panel.

- If the Academy panel thought EPA could not institute effective changes, they would not have suggested EPA undertake them.
- If the NAS panel did not think IRIS assessments were needed or could be produced to a high quality, they would not have advised EPA to continue to put out those assessments even as they work to incorporate changes to that process as recommended by the Academy.
- If the panel did not trust EPA's ability to make appropriate changes to the draft-formaldehyde assessment, they could have recommended that EPA return to the Academy for a second review of that assessment. They did not make such a recommendation.

Yet we will have testimony today from an industry-funded scientist that goes so far as to say that in light of the Academy study, the IRIS program should be killed.

The IRIS program was a broken program during the Bush Administration. By 2006-2007, interference by OMB and endless science challenges by industry and polluting agencies that did not want to clean-up their messes--such as those documented at Camp LeJeune--had so crippled EPA that they were able to finalize only a couple of IRIS assessments a year.

Pressure from this Subcommittee helped inspire GAO to put IRIS on their high risk watch list and inspired the new Administrator of EPA, Lisa Jackson, to put in place a new process that severely cut back on the opportunities for OMB and polluting agencies to interfere with EPA's production of IRIS assessments.

It is too soon to know whether these steps will bear fruit, but we do know this: every IRIS assessment that the Academy has reviewed in the last half-dozen years, including the formaldehyde assessment, was largely a result of that broken process whereby OMB dictated to EPA much of the content and organization of those assessments. I would suggest that if the reports lacked coherence or clear

communications perhaps it is because they were heavily interfered with by these non-EPA parties who insisted on new chapters, new sections, new issues and new articles being added.

And the cure that industry prescribes for improving IRIS reports? Why, go back to the OMB-dominated system that produced them in the first place! Mr. Dooley sent a letter making just such a suggestion to Jack Lew. They further advocate that no assessment ever be finalized without an Academy peer review of the draft assessment and then another peer review of the redrafted assessment.

Could the intent to slow roll action be any more transparent? And in the years between Academy reviews, just imagine how many new industry-funded studies might be created to throw up ever more science chaff in the path of EPA? These are not cures that will heal the IRIS program, but are designed to bleed it to death.

Instead, I suggest that we follow the National Academy's advice. Allow EPA the time to institute the kinds of changes proposed in the formaldehyde review. Dr. Anastas has already proposed an initiative tied to the Academy roadmap that appears responsive and robust. And there is a new director of the IRIS program, Dr. Cogliano, who has been recruited to do for IRIS what he did for the International Agency for Research on Cancer risk process.

We have good people in place and good advice from the Academy. Let us allow them to do their job and not get captured by the endless science doubt machine.