Disemboweling is not the Same as Streamlining:

Administrator Wheeler's Attack on EPA's IRIS Program

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"EPA's IRIS Program: Reviewing its Progress and Roadblocks Ahead"

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Chairwoman Sherrill, Chairwoman Fletcher, Committee Members

I am Bernard Goldstein MD, Professor Emeritus and Dean Emeritus of the University of Pittsburgh Graduate School of Public Health. In my testimony today I plan to focus on why IRIS was developed and on the specific issue of formaldehyde. I also will briefly put the IRIS issue in the context of other issues related to science at EPA

I began my involvement in environmental protection in 1966-68 as a Commissioned Officer in the US Public Health Service Division of Air Pollution, an organization that in 1970 was moved by President Nixon into the newly formed EPA.

My relevant background includes in 1983-85 serving as President Reagan's appointee as EPA Assistant Administrator for Research and Development, confirmed by the US Senate. I served under EPA Administrators William Ruckelshaus and Lee Thomas. I had previously been appointed under Administrator Anne Gorsuch to be head of the Clean Air Scientific Advisory Committee. I am also an elected member of the National Academy of Medicine and of the American Society for Clinical Investigation, and am Past President and Fellow of the Society for Risk Analysis. In relation to formaldehyde leukemogenesis, I began my medical career as a specialist in hematology, have performed research on leukemogenesis and have taken care of patients with leukemia. I have been board certified in both Hematology and in Toxicology. I have also served as a voting expert member of working groups on two occasions when the leukemogenesis of formaldehyde was considered by the World Health Organization's International Agency for Research on Cancer (IARC).

Through the years I have worked closely with industry. Examples include service on the Board of the Chemical Industry Institute for Toxicology and of the International Life Science Institute (ILSI), including ILSI's Risk Science Institute; receipt of research funding or donations to our programs in New Jersey from the American Petroleum Institute and a variety of chemical and petrochemical companies; and service on industry-based committees or on other committees which have active industry representatives. In my consultant work in toxic tort cases, depending upon the facts of the case I have about equally been an expert defending an industry as I have been an expert on the plaintiff's side suing industry.

My relationship with industry has not always been smooth. For example, our research funding from the American Petroleum Institute on benzene was not continued after we concluded that benzene was a cause of human leukemia; funding was also cut to our center in New Jersey because of our findings on the gasoline additive MTBE; and I resigned from ILSI because of actions that I disagreed with. However, I maintain great respect for the scientific and technical skills of the US chemical and petrochemical industry in general, and the ability of some individual companies to appropriately couple scientific advances with protection of the public, and to consider issues such as sustainability.

What I plan to tell you today is based on more than half a century of highly active involvement in issues related to the scientific basis for environmental protection. I have seen many ups and downs in American industry's willingness to subsume their interests in immediate profits to the goal of appropriate use of science in environmental decision making – which in the long term is in their best interests. There is no question that today we are at the lowest point ever since the formation of EPA. There can no longer be any doubt that EPA's leadership, at the behest of large portions of the American chemical, petrochemical and fossil fuel industries, is out to destroy EPA's carefully developed consensus processes to insure that science contributes its appropriate share to providing the most effective and

most efficient regulation of the American environment permitted under our laws. While I previously held out hope that EPA leadership would not be captured by its rhetoric, its current actions related to CASAC and to IRIS go well beyond my worst fears.

Why IRIS was developed

I arrived at EPA in 1983 soon after the NAS Red Book had laid out the principles that led to standardization of risk assessment. EPA was already doing risk assessments, as was FDA and other federal agencies. In fact, many of the principles on which risk assessment is built came originally from EPA, particularly its Carcinogen Assessment Group, and from FDA. But the silo structure that characterized EPA then, and still persists, made risk assessment at EPA in 1983 a shambles. As examples, each silo had different default assumptions that were used in extrapolating from animals to humans, or from high doses to low doses. This led to unacceptable differences in the risk assessments for the same chemical depending upon which part of the agency was regulating it. (Note that some differences are appropriate, e.g., based on different toxicokinetics due to different routes of exposure). We spent much effort, with the help of the external scientific community and the National Academies of Science, to address the appropriate default assumptions to be used – a process that needs to continue as newer toxicological and epidemiological methods are developed.

A related issue greatly concerned Administrator Ruckelshaus. For risk assessment to be useful, it needed to be sufficiently standardized and transparent so that, as in his words, it would not be like beating a spy to get whatever answer you wanted.

Yet another reason for a centralized ORD-led approach to risk assessment is that risk plays a major role in assigning agency priorities. As budget follows priority ranking for regulatory activities, questions might be raised as to the rationale for inconsistencies

We recognized another very important role for IRIS, one that is often overlooked inside the Beltway. I am reasonably certain, with no data, that by far the most frequent use of IRIS is for local purposes. A recent example in my experience is responding to a gentrifying community within Pittsburgh concerned about whether emissions from some of the older industrial plants are causing adverse health effects. Pressure from community groups led local authorities to perform fenceline measurements of chromium, manganese and lead. The report of the Allegheny County Health Department describing the measured levels leans heavily on comparison with IRIS data, including direct copies of risk factor tables from IRIS. Other uses by local authorities include deciding on how to advise a community after a buried drum of chemicals is discovered in an empty lot. This is a recommendation that is best given quickly without leaving the neighbors in limbo while health concerns increase and their property values go down. The current decrease in funding of IRIS to evaluate additional chemicals is not at all responsive to local community needs. It contradicts the Trump Administration's focus on having Washington serve states and local areas, as well as contradicting Congressional direction.

IRIS is also important to another area of great emphasis by President Trump. IRIS is currently respected and accepted throughout the world, as I have observed in my work in Southeast Asia and in the EU. Having a standardized approach recognized as authoritative world-wide helps protect US trade products from being unfairly treated through other countries developing biased ad hoc approaches to risk.

Destroying the reputation of IRIS as being independent of the political process does not help the administration's goal of reducing trade barriers.

It seemed obvious then, as it is still obvious now, that there is more than ample justification for a standardized transparent approach to risk analysis useful to help moving forward decisions about regulation at the national and local levels. Further, to achieve this goal it is necessary to have a science-based organizational structure that can independently assess the scientific literature pertinent to risk, using appropriate external peer reviews. This is what we set out to do in forming IRIS under Administrators Ruckelshaus and Thomas. Administrator Wheeler's decision to move the formaldehyde issue from IRIS to the TSCA staff is a compete contradiction of the founding principles of IRIS that have sustained this organization as a world authority. This would be true even if understanding the risk of formaldehyde was not pertinent to decisions being made by other program offices under different laws.

Formaldehyde.

The formaldehyde saga has become a poster child for the intentional failure of an industry to find out whether its products are causing harm, and to do so by any means at its disposal.

I was an expert voting member of the IARC panel that reviewed formaldehyde in 2006. We voted for formaldehyde to be considered a known human carcinogen based upon causation of nasal cancer. My belief then was that that formaldehyde was unlikely to be a leukemogen, a belief that persisted until shortly before the 2010 IARC meeting which reconsidered the issue.

The reasons for my initial skeptical response to epidemiological evidence linking formaldehyde with leukemia included the observation that bone marrow damage was caused by all other known external causes of leukemia (benzene, ionizing radiation, chemotherapy). But there was then no evidence of formaldehyde producing bone marrow damage.

Just prior to the 2010 IARC meeting which reconsidered formaldehyde, a paper was published showing low blood counts and chromosome abnormalities in Chinese workers exposed to formaldehyde as compared to those working in a factory without formaldehyde (Zhang et al, 2010). The Zhang et al paper was instrumental in swinging the IARC expert vote to in essence calling formaldehyde a known cause of human leukemia. At this 2010 IARC meeting I voted with the minority for the evidence being limited. I did so because the study needed to be repeated. My reasoning on this and other formaldehyde- related issues was detailed in a published paper (Goldstein, 2011) and was directly communicated to the formaldehyde industry. Since then the original authors of the Zhang et al paper have expanded and confirmed their findings, but industry has steadfastly refused to fund such a study in a different formaldehyde-exposed group.

Rather than repeat the Zhang et al study, industry has spent much money on consultants to attack the findings. I do not completely disagree with all of the resulting science. For example, Dr Swenberg and his colleagues have produced convincing evidence that little if any inhaled formaldehyde gets into the blood of rodents. But, as I have pointed out previously, it is only in formaldehyde-exposed humans that there is evidence of chromosomal abnormalities in circulating blood – in rats virtually all the studies of such abnormalities are negative. This suggests the possibility of a species difference that, once again, could be resolved by further studies in formaldehyde-exposed humans which industry has obstinately

refused to support. Further, the issue of species differences is one that has been addressed by IRIS scientists for more than thirty years. It is in IRIS that further understanding and resolution should occur – not in a program office.

My published letter describing the fallacious science in one of the industry consultant-generated papers also contains their reply. Their response claiming that I partially agreed with them is simply an obvious mis-statement of what I wrote, more befitting a legal brief than a scientific response. A more detailed response to Mundt et al by some of the authors of the original paper is at http://cebp.aacrjournals.org/content/27/1/120.long.

I make the point about the legal brief because I believe that a brief summary of what is happening to EPA's use of science is the replacement of processes that lead to obtaining the consensus of the scientific community with confrontational approaches that are more appropriate to law or to politics.

The ACC press release trumpeting Mundt et al is part of the longstanding effort, in which this Committee was previously involved, aimed at obtaining raw data so that paid industry consultants can find blemishes in studies which they can then claim to be scars (https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/New-Study-Challenges-Formaldehyde-Cancer-Findings.html.) Their claims for transparency are based on the erroneous assumption that EPA is FDA. For FDA regulatory approval of a new drug, the usual requirement is a double blind randomized study in which one half of volunteers with a disease are given a potentially valuable new medication and the other half are given placebo – and neither the patient nor the treating physician is aware of which until the code is broken. This approach cannot be used for testing a pollutant. Would you agree to be randomly chosen to be exposed to a potentially harmful pollutant? Instead, in environmental health for replication we primarily depend on evaluation and synthesis of studies in which different investigators ask the same question in different populations using different methodologies. Instead of doing so, the formaldehyde industry continues to pay consultants to find the potential confounders that are less likely to be present in an FDA double blind placebo study.

I also note that EPA leadership's insistence on full transparency is not consistent with its holding secret the draft IRIS report on formaldehyde

Why EPA particularly needs strong science-based approaches that are independently reviewed.

The founding year for EPA and for OSHA was 1970. It is almost as if the US decided to experiment in how it would organize its scientific activities in a regulatory agency. OSHA is led by an Asst. Secretary of Labor. It has a completely separate scientific component, NIOSH, which is administratively light years away from OSHA and is led by someone not subject to Senate confirmation. In contrast, EPA has the Office of Research and Development within its organizational structure. The AA/ORD is intended to be a political appointee at the same level as the Asst Administrators who head policy offices.

EPA clearly has been more successful than OSHA in developing science-based regulations, in part reflecting the close proximity of its scientific arm to program offices, and the more efficient congressional and executive branch oversight that ensures this close working relationship. But an inherent disadvantage of the EPA organizational structure is that the close proximity of ORD allows more pressure to be developed to conform to political objectives. This has led to Congress and to EPA

requiring extensive independent review processes that have evolved over decades. Mr Wheeler's abrupt dismantling of these processes, without any believable problem statement, without test runs and without the extensive consultations inside and outside EPA that have characterized the previous evolution of EPA's science-based processes, is unforgiveable. It changes what had been a relatively successful organizational structure based on the value of proximity between science and policy development into a failure. As a scientist who has been heavily involved in the evolution of this process, I find the current actions of EPA's leadership to be incredibly shortsighted – at best.

Conclusion

I begin my concluding remarks by commending EPA's professional scientific career staff leadership of the Office of Research and Development for having stayed the course in these difficult times, despite the need to compromise. I would have resigned as Asst Administrator of ORD had either Administrator Ruckelshaus or Administrator Thomas tried to make the changes now being insisted on by Administrator Wheeler. I cannot recommend that the current AA/ORD resign. There is none, nor in the third year of this administration even a rumor as to whose name might be sent to the Senate. I can understand why Administrator Wheeler does not want a Presidential appointee confirmed by the US Senate to be able to stand up for science at EPA. But he can be reassured that it is unlikely that any reputable scientist would be willing to allow him or herself to be nominated

Administrator Wheeler claims that his goal in changing the IRIS process is to streamline inefficient management practices. Certainly any complex process such as IRIS can be improved, and among many others I also have made suggestions as to how to do it. But It is poor management to choose the most challenging example to experiment with process changes, particularly with a longstanding process that has been so central to environmental progress. The choice of formaldehyde as a test for management changes in IRIS is as inappropriate as the choice of particulates to revise the CASAC process. What the changes in IRIS and in CASAC have in common is the longstanding strong support of major industry groups to counter science-based decisions, irrespective of whether this causes the wholesale disruption of EPA's interface with science. The only reasonable question is whether Mr Weaver recognizes the difference between disemboweling and streamlining. Based upon the evidence to date, I think he does. I think that his goal is to change the consensus processes of science to the confrontational processes central to law and to politics. Madame Chair, with the help of this Committee perhaps this destruction of EPA's science can be prevented.

References

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