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Senate Environment and Public Works Subcommittee on Superfund, Waste Management and Regulatory Oversight

"Oversight of the Environmental Protection Agency's Implementation of Sound and Transparent Science in Regulation"

Good afternoon, Chairman Rounds, Ranking Member Booker, and distinguished members of the Committee. My name is Edward Calabrese, and I am a professor of toxicology at the University of Massachusetts, School of Public Health Sciences, Amherst, Massachusetts. I am pleased to share with you my views on the EPA Risk Assessment Transparency Proposal.

Briefly, I have been at UMass for 42 years, teaching and researching in the areas of toxicology and risk assessment. I have authored nearly 900 papers in the peer-reviewed literature, about a dozen books, served on multiple National Academy of Sciences (NAS) committees such as the Safe Drinking Water Committee and the Air Cabin Safety Committee, which recommended to the FAA to eliminate smoking on commercial aircraft, a recommendation that was quickly adopted. For the past 20 years I have been funded by the Air Force Office of Scientific Research to assess the nature of the dose response of toxic substances in the low dose zone in order to protect the health and wellbeing of Air Force

personnel. These activities have lead to a major dose-response revolution in biology, medicine, toxicology and risk assessment.

The U.S. EPA has proposed a general framework to strengthen its regulatory science procedures via enhancing transparency in multiple ways. I applaud EPA for this proposal as it is not only timely but requires scientific and administrative accountability. The proposal is broad, requiring that the Agency provide the scientific basis for proposed regulations, including underlying data. While this is an excellent start, the Agency should also commit to providing detailed explanations and public access to data that the Agency considered and decided not to use for regulation. In addition, most EPA scientific decisions are based on multiple assumptions, some of which are frequently hidden, obscured and often silent drivers of regulatory action. (e.g., the use of highly susceptible and often poorly predictive animal models). These assumptions need to be fully described, documented, and justified. This process should also include the basis for why EPA chose not to adopt the use of other/different approaches and/or assumptions. Thus, EPA's transparency proposal is excellent as far as it goes, but it needs to be expanded; it also requires explanation of what was considered and why it was rejected.

Multiple high profile controversies exist over the lack of availability of key data sets used by the EPA for regulatory decisions. While I have not been involved

in Agency disputes over such databases, I would like to note two personal examples that speak to data sharing with EPA and the scientific community and the value offered to the Agency and the public. In the 1980s I developed a database of 6,000 dose responses concerning whether carcinogens could cause cancer with but a single dose. I made many presentations on this topic across the country, including several to NAS Committees concerned with acute/short term exposures to toxic and carcinogenic agents in the aftermath of the 1984 Bhopal, India disaster. Following these presentations, EPA asked me to provide it with a copy of the single-exposure carcinogen database. These presentations and the shared database were intended to assist the NAS in guidance to EPA. Second, my group at the University of Massachusetts conducted multiple studies on soil ingestion in children and adults. EPA subsequently used these data for clean-up standards of soil/dust contamination for the benefit of children and adults. Our group created a public website with all our data available for use by the EPA and the world. These are examples to enhance improved science and transparency in regulatory activities. The EPA transparency proposal is crucial to enhance public health and should have been adopted 20 or more years ago.

With regard to risk assessment, "data transparency" should require the EPA to routinely receive and openly evaluate for accuracy any information that could significantly alter the key scientific assumptions underlying and dictating

regulatory policy and practices. This current EPA proposal does just that by stating that the EPA should no longer use the LNT (linear non-threshold) model as the default model in risk assessment. Movement away from LNT as the accepted default model is long overdue. It is compellingly supported by many peer-reviewed scientific and historical studies, and it is badly needed to advance toward a more science-based approach in the assessments of human and ecological risks.

Within this context I have researched the nature of the dose response in the low-dose zone for more than 30 years and have published about 500 articles on this topic in peer-reviewed journals. I have organized and conducted international conferences on the topic for over 25 years and created a professional journal called Dose Response, for which I am the editor in chief. I have also written chapters on dose response for some of the major toxicology textbooks. More recently in the past decade, I have exhaustively researched the historical origins and scientific foundations of the EPA's LNT model and have found it sorely wanting. LNT is important because it is the model upon which all our cancer risk assessments and key health and ecological regulations are based. What I have learned was unexpected and has turned more than 30 years of my understanding of toxicology upside down. It has revealed that what I had taught for so many years at UMass and had written about so ardently in my many articles and books was factually wrong. What I learned in this re-evaluation of LNT was that the field of

toxicology and our regulatory agencies, such as EPA, had made a serious error in their understanding of LNT and incorrectly applied it to the assessment of human and ecological risks.

During my research and publication of over a dozen peer-reviewed journal articles on the scientific origins of the LNT, I learned that the LNT dose-response model, which drives cancer risk assessment, was based on flawed science, on ideological biases by leading radiation geneticists, on scientific misconduct by an NAS Genetics Panel during the atomic radiation scares of the1950's, and on a 40-year mistaken assumption by yet another NAS Committee. I learned that these flaws, biases, misconducts and mistakes ultimately gave rise to the LNT model and were perpetuated down to the present day by subsequent Committees of the NAS and the EPA. What began for me as a routine academic exercise to affirm the scientific origins and credibility of LNT ironically ended as a remarkable repudiation of its scientific adequacy, challenging both the old guard and an EPA cancer-risk assessment process that is in need of significant revision.

My findings show that the EPA adopted the LNT for all the wrong reasons and built their flawed risk assessment edifice upon it—failing to perform the due diligence expected by Congress and the public. Secondly, extensive research findings that contradict the EPA's LNT model have now been documented in the scientific literature. With so many failed LNT predictions, EPA must not continue

to use the LNT model as its default. A crusading EPA that was young, impressionable, inexperienced and somewhat blinded adopted the flawed LNT model—believing it would save the world. Not only was it wrong scientifically, the LNT in many ways has damaged public health and the economy—the worst of both worlds. The present EPA proposal to consider non-linear models for risk assessment is a critical, positive development. Thus, I believe that EPA has made a bold and constructive proposal that is scientifically sound and should be strongly supported, approved, and implemented.