Spoken Comments by Corwin Zigler* at the U.S. Environmental Protection Agency Chartered Clean Air Scientific Advisory Committee (CASAC) Public Meeting on Particulate Matter

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I am an associate professor of statistics and data sciences at the University of Texas at Austin and Dell Medical School, where I recently moved after several years on the faculty at the Harvard TH Chan School of Public Health. I am a biostatistician specializing in the development and application of causal inference methodology, and a large portion of my work has focused specifically on air pollution epidemiology and accountability studies. I led a research grant from the Health Effects Institute on accountability for air quality regulations and I have published papers on causal inference methods in the context of air pollution studies in top statistics and epidemiology journals.

Renewed focus on "causality" within the ISA has apparently brought some confusion about what causal inference methods are and how they can be useful for informing policy. Specifically, recent discussion, including by members of CASAC, appears to promote what I believe to be a **false dichotomy** that a particular study or quantitative result is *either* a causal result or otherwise not useful for policy. This seems to imply that studies using a specific type of causal inference methods should always be considered more credible than studies using more traditional statistical approaches, which is simply not true. Classifying studies as either "causal" or "associational" on the basis of the statistical analysis method is not only a gross oversimplification of the challenges to inferring causality from observational data, it would also unnecessarily discount many of the highest quality and most informative research in the field.

The type of causality regulators seek – knowledge of the expected change in public health that would be caused by a change in exposure – can and should be generated from synthesizing a wide variety of study designs and analytic approaches, not just those nominally described as "causal." What causal inference methods provide, when deployed responsibly, is a framework for making **transparent and explicit** assumptions about what must hold in order for estimated associations to be interpreted as evidence of causality. Such assumptions are **always** required to infer causality from observed data, regardless of the specific statistical analysis approach or model used for estimation. The validity of a particular study should be judged in light of these assumptions, which are themselves inextricably linked to fundamental features of the study such as its design and the structure of underlying data. These issues are more central than many of the specific issues about finer grade details of statistical model specification raised today. Methods that are touted as "causal" but do a poor job of making such assumptions explicit can be *less* reliable than careful and rigorous studies using more traditional analysis approaches. For example, a carefully conducted regression analysis of detailed, high quality data that makes plausible assumptions about issues such as confounding could very well provide more reliable causal inferences than an analysis using purportedly "causal analysis techniques" that is anchored to poor quality data and obfuscates key underlying assumptions.

While there are relatively few applications of rigorous causal inference methods in air pollution research, I wish to point out that the most reliable causal methods are grown from a rich tradition - starting decades ago in fields such as statistics, epidemiology, econometrics, and computer science - and continuing to mature in fields such as political science, education, sociology, and medicine. In comparison, the methodological contributions of statistical causal inference for observational studies may seem relatively new to environmental science and even newer to toxicology. Statistical causal methods research published in these literatures should be considered considerably less vetted than that coming from disciplines with a long tradition of deploying causal methods in population-based studies such as statistics, epidemiology, economics, political science, and medicine.

Finally, I wish to address the draft ISA's use of causal language. For the purposes of communicating policy recommendations, I find the ISA's usage of causal language appropriate, as it will be generally interpreted as the type of causality policy makers seek: evidence of the expected changes in public health that might result from changes in ambient pollution. More detailed refinements of causal terminology such as those offered by CASAC members to distinguish manipulative causation from counterfactual causation from predictive causation (and others)- are unnecessary for these purposes, and for reasons similar to those stated previously, should not be used as a strict guide to classify studies or conclusions in terms of how they contribute to the policy questions at hand.

In summary:

- The current “weight of evidence” determinations of causality in the ISA are useful for judging the causal consequences of an anticipated change in PM concentrations.
- Individual studies contributing to these determinations should be interrogated and weighed according to their design, data structure, statistical analysis, and plausibility of underlying assumptions, not simply based on whether the methods used are nominally described as “causal.”
- A variety of study designs and analysis approaches have the potential to produce reliable causal inferences, and no single method should be viewed as “automatically” capturing causal relationships.
- To the extent that formal causal inference methods are available in air pollution studies, their usefulness should be viewed in light of a mature literature in fields that focus on population-based observational studies.