COMMENTS ON EPA'S INTEGRATED SCIENCE ASSESSMENT FOR PARTICULATE MATTER

(EXTERNAL REVIEW DRAFT-OCTOBER 2018)

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March 28, 2019

I will briefly demonstrate the increase in scientific information that is being reviewed by a dramatically smaller external group, and will point out that by definition one person cannot be a consensus.

I am a former chair of CASAC (1981-3) under EPA Administrator Anne Gorsuch. But I want to first focus on one of the two CASAC subcommittees I had previously served on beginning in 1980 – the Subcommittee on the Health Effects of Sulfur Oxides and Particulates. Subsequently this subcommittee had to be split into two as the amount of research necessary to review for both pollutants exceeded the abilities of a single subcommittee.

This increase in research continues. My MPH student, Varun Patel, did a quick review of the number of references in the 2009 and 2018 Integrated Scientific Assessment documents, selecting those chapters more directly related to health effects. In 2006 there were two chapters (Integrated Health Effects of Short Term Exposure, and Integrated Health Effects of Long Term Exposure) with a total of 965 references. In 2018 this had mushroomed to seven different chapters (Respiratory Effects; Cardiovascular Effects; Metabolic Effects; Nervous System Effects; Reproductive and Developmental Effects; Cancer; and Mortality) with a total of 1648 references. Note that not all of these references are epidemiological and we have not removed duplicates. But the inevitable conclusion is that there continues to be significant increases in particulates health research on which the consensus decision of the CASAC committee needs to be based.

The fact that there are seven chapters considering different health effect areas, and only seven members of CASAC, is coincidental – but it directly illustrates the devastating impact of the

abrupt dismissal of the particulates subcommittee. No seven humans could by themselves cover these areas – even if their expertise had been chosen to match the subjects of these chapters. Most blatant, as has been repetitively pointed out, including by members of CASAC, is the absence of epidemiological expertise on CASAC. It is particularly scary to me as I believe I qualify as much or more as an epidemiologist than anyone presently on CASAC, having done a six month sabbatical in an epidemiology unit specifically to learn about the field, published in epidemiological journals, and managed units with strong epidemiological components. But I know that I am far from sufficiently knowledgable to take on the particulates epidemiology literature by myself.

Dr Cox.s use of Bayesian models for statistical inference in relation to environmental causality is not new. I first became aware of Bayesian approaches to interpreting environmental science from Dr Bernard Altshuler in the 1970s. Dr Altshuler was a senior statistician at NYU's Institute of Environmental Medicine, perhaps the prime program in this field. His work included statistical models related to life shortening by cigarette smoke (see review at https://ehp.niehs.nih.gov/cms/attachment/2c4fa564-41ca-42fb-8fbb-e24731a2dd7b/ehp.8981107.pdf). He also got his hands dirty participating in research on particulates (see his NYTimes obituary at https://www.nytimes.com/1997/10/12/nyregion/bernard-altshuler-78-expert-on-effects-of-pollutants-on-lungs.html). I have since frequently heard debates about the use of Bayesian methodology as an alternate to more standard causal inference approaches at various scientific meetings, including a recent meeting of a National Academies committee. But such Bayesian-based approaches have generally not supplanted the more standard methodology incorporated

in the weight of evidence classically used by scientists in environmental health consensus determinations.

To continue to protect public health, it is important that the advice given by CASAC is based on scientific consensus rather than on the confrontational processes more appropriate for law or politics. By and large consensus on environmental health issues depends upon replication that occurs through different scientists using different methodology in different populations coming up with roughly the same answer. In environmental health we rarely have the luxury of being able to perform the gold standard for epidemiology, that of a double blind randomized clinical trial. An RCT lessens the possibility of a hidden confounder. On the face of it, the approach taken by Dr Cox appears to fit into what the legal scholar Thomas O. McGarity has called corpuscularization (On the Prospect of "Daubertizing" Judicial Review of Risk Assessment, 66 L. & Contemp. Prob. 155, 2003). This is an approach used in toxic torts in which each side tries to throw out all of the scientific papers cited by the experts of the other side by showing that none of the individual papers are perfect. While if I were accused of a crime, I would very much want my lawyer to be confrontational, this is not how we approach environmental health science.

Let me also point out that Dr Cox's work in this area related to environmental health has generally been published in journals that usually do not accept letters critiquing the journal article, with a rebuttal from the original authors. Publishing in such journals, while not necessarily inappropriate, limits the opportunity for public debate which is particularly pertinent to the present situation. I also note that one of the journals, the *International Journal of Public Health and Environmental Research* in which Dr Cox and his colleagues lay out their Bayesian approach, has been controversially subject to allegations of lack of scientific rigor

(https://www.universityaffairs.ca/features/feature-article/beware-academics-getting-reeled-scam-journals/, The publisher has denied these charges. See https://www.universityaffairs.ca/letter-let-us-set-record-straight/)

In teaching graduate students about statistical approaches, I have often used an adage I heard many years ago during my own education. It goes as follows:

> Boy Scouts always walk single file. I know this because I saw a Boy Scout once.

More seriously, positions taken on human health issues, and most certainly about environmental health, focus on developing a consensus. I personally have had a lot of respect for Dr Cox and serve on the editorial board of the Society for Risk Analysis journal *Risk Analysis* which he heads. But by definition one individual cannot be a consensus.

I would welcome hearing an academic debate about causal inference in which Dr Cox was a participant. But the current situation is one in which if I were a member of CASAC I would emphatically state my intention to resign unless the particulates subcommittee as formerly constituted would be restored, and an open and transparent discussion were held. Further, I would insist that this discussion include the experts in the field, defined broadly, and that it be done in a deliberative fashion. I am perhaps biased as a member of the National Academy of Medicine who has chaired a dozen or so academy committees, but I strongly urge that the issues raised by Dr Cox about causal inference be brought to the NAS.

In summary, I would resign before allowing myself to be part of a process in which a CASAC recommendation could well be made that does not uphold the legal standard to protect public health required by the Clean Air Act, makes it seem as if I claim far more expertise than I have a right to do, and runs the strong risk of forfeiting the respect of my peers in the scientific community