

August 25, 2022

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Re: Review of EPA's 2021 Draft Formaldehyde Assessment
Public Comment on Provisional Committee Appointment

Dear Dr. Guyton,

In accord with the August 5, 2025 NASEM notice, I am submitting an August 25, 2022 Public Comment on the Provisional Committee Appointment (<https://www.nationalacademies.org/our-work/review-of-epas-2022-draft-formaldehyde-assessment#sectionCommittee>) for the **Review of EPA's 2022 Draft Formaldehyde Assessment** (<https://www.nationalacademies.org/our-work/review-of-epas-2022-draft-formaldehyde-assessment>). I request that NASEM disqualify Committee Chair Jonathan M. Samet and Committee Member Elizabeth (Lianne) Sheppard because of the extensive evidence that they cannot objectively assess the health effects of Environmental Tobacco Smoke (ETS) and Fine Particulate Matter (PM2.5) and because they violate the Federal Advisory Committee Act Criteria that govern the appointment of members to this committee.

As evidence, I have attached selected pages from my October 10, 2007 Epidemiologic Perspectives & Innovations article, which can be found at these weblinks: <http://www.epi-perspectives.com/content/4/1/11> , <https://pubmed.ncbi.nlm.nih.gov/17927827/> , and https://www.heartland.org/_template-assets/documents/publications/23215.pdf . Also, I have attached my October 18, 2021 Declaration (<http://scientificintegrityinstitute.org/JEEDecEPA101821.pdf>) in Support of the October 28, 2021 Young & Cox v. EPA Lawsuit opposing the current EPA CASAC & SAB (<https://junkscience.com/2021/10/former-casac-chair-added-as-plaintiff-in-young-v-epa/>) or (<http://scientificintegrityinstitute.org/YoungCoxEPA102821.pdf>). A critical CARB weblink in my Declaration (<https://cal-span.org/unipage/?site=cal-span&owner=CARB&date=2010-02-26>) has been replaced with a new weblink (https://cal-span.org/meeting/carb_20100226/).

Additional details can be provided to supplement the evidence in the attached 18 pages. Please confirm that you have received my Public Comment and confirm that it will be fully evaluated.

Thank you very much for your assistance in this important matter.

Sincerely yours,

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Analytic Perspective

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Defending legitimate epidemiologic research: combating Lysenko pseudoscience

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Abstract

This analysis presents a detailed defense of my epidemiologic research in the May 17, 2003 *British Medical Journal* that found no significant relationship between environmental tobacco smoke (ETS) and tobacco-related mortality. In order to defend the honesty and scientific integrity of my research, I have identified and addressed in a detailed manner several unethical and erroneous attacks on this research. Specifically, I have demonstrated that this research is not "fatally flawed," that I have not made "inappropriate use" of the underlying database, and that my findings agree with other United States results on this relationship. My research suggests, contrary to popular claims, that there is not a causal relationship between ETS and mortality in the U.S. responsible for 50,000 excess annual deaths, but rather there is a weak and inconsistent relationship. The popular claims tend to damage the credibility of epidemiology.

In addition, I address the omission of my research from the 2006 Surgeon General's Report on Involuntary Smoking and the inclusion of it in a massive U.S. Department of Justice racketeering lawsuit. I refute erroneous statements made by powerful U.S. epidemiologists and activists about me and my research and I defend the funding used to conduct this research. Finally, I compare many aspects of ETS epidemiology in the U.S. with pseudoscience in the Soviet Union during the period of Trofim Denisovich Lysenko. Overall, this paper is intended to defend legitimate research against illegitimate criticism by those who have attempted to suppress and discredit it because it does not support their ideological and political agendas. Hopefully, this defense will help other scientists defend their legitimate research and combat "Lysenko pseudoscience."

Background

This analysis presents a detailed response to the extensive attacks that have been made on my epidemiologic research in the May 17, 2003 *British Medical Journal*, "Environmental tobacco smoke and tobacco related mortality in a prospective study of Californians during 1960-98" [1]. I seek to defend the honesty and scientific integrity of my research and I directly respond to my most powerful critics, who have attempted to suppress and discredit findings that do not support their ideological and political

agendas. To put a historical perspective on the tactics that have been used against me, I conclude by making an analogy with the pseudoscientific practices of Trofim Denisovich Lysenko [2]. Hopefully, my defense will encourage and/or help other honest scientists to defend their research against unwarranted and illegitimate criticism.

This analysis deals with several important elements of the attacks, with a primary focus on the epidemiologic issues involved. Additional elements of the attack are mentioned

briefly in this analysis and are presented in detail on my Scientific Integrity Institute website, under 'Research Defense' [3]. Being attacked for publishing unpopular scientific findings is not unique to me or my research. However, the nature and scope of the attacks to which I have been subjected is quite unusual and needs to be documented and addressed.

Being able to distinguish between real and implied scientific misconduct is important to the integrity of science in general and to the integrity of individual scientists in particular. Falsely accusing an honest scientist of scientific misconduct is just as wrong as scientific misconduct itself. Implying that an honest scientist has committed scientific misconduct because he has published unpopular findings or has used an unpopular funding source is wrong and falls under the category of "scientific McCarthyism" [4].

Analysis

Background on BMJ Paper

I begin with a presentation of the background necessary to understand the issues involved with the May 17, 2003 *British Medical Journal* (BMJ) paper that I wrote with Dr. Geoffrey C. Kabat [1]. This account primarily involves me and thus is written in the first person, but it also refers to Kabat where appropriate and not otherwise noted. Our paper found no relationship between environmental tobacco smoke (ETS) and tobacco-related mortality in a prospective study of Californians during 1960–1998, with some associations slightly below the null and some slightly above the null, but none statistically different from the null. It concluded, "The association between exposure to environmental tobacco smoke and coronary heart disease and lung cancer may be considerably weaker than generally believed." It is the largest (in terms of statistical power), most detailed (in terms of results presented), and most transparent (in terms of information about its conduct) epidemiologic paper on ETS and mortality ever published in a major medical journal.

The study is based on the California (CA) portion of the original 25-state Cancer Prevention Study (CPS I) [1]. CA CPS I was begun by the American Cancer Society (ACS) in 1959 and has been conducted at UCLA by me since 1991. Kabat and I are both well qualified epidemiologists who have had long and successful careers dating back to the 1970s, as can be confirmed by examining our epidemiologic publications on PubMed. Our paper was deemed to be scientifically sound and worthy of publication after being peer reviewed by two distinguished epidemiologists, a BMJ statistician, and a BMJ editorial committee. The details of the entire peer review process and the names of all the individuals involved in the review process are available online as the "Prepublication history" [5]. The paper was subjected to the same review process and selec-

tion criteria as other papers submitted to the *BMJ*, which publishes less than 10% of the total submissions it receives [6].

In the interest of transparency and full disclosure, the paper included the following detailed statements about the funding history of the study and the competing interests of the authors: "Funding: The American Cancer Society initiated CPS I in 1959, conducted follow up until 1972, and has maintained the original database. Extended follow up until 1997 was conducted at the University of California at Los Angeles with initial support from the Tobacco-Related Disease Research Program, a University of California research organisation funded by the Proposition 99 cigarette surtax. After continuing support from the Tobacco-Related Disease Research Program was denied, follow up through 1999 and data analysis were conducted at University of California at Los Angeles with support from the Center for Indoor Air Research, a 1988–99 research organisation that received funding primarily from US tobacco companies. Competing interests: In recent years JEE has received funds originating from the tobacco industry for his tobacco related epidemiological research because it has been impossible for him to obtain equivalent funds from other sources. GCK never received funds originating from the tobacco industry until last year, when he conducted an epidemiological review for a law firm which has several tobacco companies as clients. He has served as a consultant to the University of California at Los Angeles for this paper. JEE and GCK have no other competing interests. They are both lifelong non-smokers whose primary interest is an accurate determination of the health effects of tobacco." [1].

Initial Attacks on BMJ paper

Even though our paper satisfied (and in many ways exceeded) the accepted standards of epidemiologic analysis and writing, it was immediately attacked by people who did not like the results we reported. Beginning in the days before May 17, 2003, our *BMJ* paper was subjected to a large-scale *ad hominem* attack. Since our honesty or scientific integrity had never previously been questioned, such an attack seemed to us to be quite implausible and indeed incredible. Based on what I have learned since May 2003, I describe the key elements of this attack in order to expose the tactics that have been used in an attempt to discredit and silence legitimate epidemiologic research. Additional details are presented on my Scientific Integrity Institute website [3]. The attack has been largely due to the fact that we published politically incorrect null findings from a long-term study primarily funded by the ACS, but completed with a research award to UCLA from the Center for Indoor Air Research (CIAR), a now-defunct tobacco-industry funded research organization.

evident when his 2-page 2005 meta-analysis [72] is compared with our 12-page 2006 meta-analysis [39].

Jonathan M. Samet, M.D., and the 2006 Surgeon General's Report

False and misleading statements about my research were also made by Jonathan M. Samet, M.D., M.S., who has played a prominent role in reviews of the epidemiologic evidence on ETS for over 20 years. First, Samet made a statement that neither he nor anyone else has substantiated in the May 16, 2003 Los Angeles Times, when he described my *BMJ* paper as "one very flawed study" that "just doesn't contribute" [22]. Then, he co-signed serious accusations about my research that appeared in a May 30, 2003 *BMJ* rapid response [20] and an August 30, 2003 *BMJ* letter [73]. These two items stated "Enstrom and Kabat's conclusions are not supported by the weak evidence that they offer, and although the accompanying editorial alluded to 'debate' and 'controversy', we judge the issue to be resolved scientifically, even though the 'debate' is cynically continued by the tobacco industry." To understand the outlandish nature of these accusations, recall that we used a large and highly respected dataset and accepted epidemiologic methods; we reported study details in the paper itself, in the "Prepublication History", and in our subsequent letters; we have supported our conclusions to a greater extent than can be found for any other study of ETS and mortality; our methods have never been substantively challenged; and our results are consistent with the entire body of U.S. evidence [39].

These statements from Samet might have been somewhat plausible if he had any evidence that there were errors in my 2003 paper or that I was "pro-tobacco" based on my research before 2003. But neither he nor other critics have made a plausible case for fundamental errors in my paper, and I have never been "pro-tobacco." Samet has been aware of my epidemiologic research since we both participated in the August 23–25, 1978 National Cancer Institute Workshop on "Populations at Low Risk of Cancer" held in Snowbird, Utah. The proceedings of the workshop, including the list of participants, were published in *JNCI* in November 1980 [74]. I gave three talks at this Workshop and two of them described the reduced cancer death rates among nonsmokers, one dealing with Mormons [75] and another dealing with a representative sample of U.S. nonsmokers [76]. Indeed, I have investigated the healthy lifestyles of Mormons and other nonsmokers during my entire epidemiologic career [77,78].

Further evidence of Samet's willingness to dismiss scientific evidence when it does not support his agenda appears in the June 27, 2006 release and publication of the 727-page Surgeon General's Report on "*The Health Consequences of Involuntary Exposure to Tobacco Smoke*" [79].

Samet was the Senior Scientific Editor of this report and the most influential epidemiologist involved with the report [80]. In addition, Glantz was a Contributing Editor and Thun was a Reviewer on this report. Although Samet, Thun, and Glantz were fully aware of the importance of my *BMJ* paper, as evidenced by their extensive efforts to discredit it, the paper was simply omitted from the Surgeon General's Report without comment. A search for "enstrom j" of the entire PDF version of the report [79], reveals that the only mention of the *BMJ* paper is in the Appendix on page 673, where it is listed as one of the papers not included in the report. Another search reveals that the *BMJ* paper was omitted without explanation from the database for the Report [81]. This database was prepared by Johns Hopkins University and the Centers for Disease Control and Prevention's Office on Smoking and Health. It includes "approximately 900 key articles regarding involuntary smoking and disease outcomes" and supposedly "reflects the most recent findings in the scientific literature."

In order to illustrate the selective and unscientific nature of this omission, I examined the references used in Chapters 1–10 of the Surgeon General's Report and the references in the Appendix that were not used. Of 38 total references from 2003, 33 were used in Chapters 1–10 and only 5 references, including the *BMJ* paper, were not used. Of 71 references from 2004, 53 were used and 18 were not used; of 39 references from 2005, 26 were used and 13 were not used; of 22 references from 2006, 7 were used and 15 were not used. In summary, the report used 119 references from 2003–2006, but omitted without comment the 2003 *BMJ* paper. The *BMJ* paper was the only U.S. study relating ETS to lung cancer and coronary heart disease that was omitted. Because of this omission, the Surgeon General's Report does not accurately reflect all the peer-reviewed epidemiologic evidence on the relation of ETS to lung cancer and coronary heart disease mortality in the U.S.

Chapter 7, page 423, reports: "This chapter considers the full body of evidence on secondhand smoke exposure and lung cancer published through 2002, the ending date for the systematic review of the epidemiologic studies." Based on comparing never smokers ever married to a smoker with never smokers never married to a smoker, a worldwide relative risk (RR) of 1.21 (1.13–1.30) was reported on page 435. However, there is no reason for an ending date of 2002, given that other sections of the report cite results published during 2003–2006 (by my count 119 such publications are cited). It appears that the ending date of 2002 was intentionally selected in order to exclude my 2003 *BMJ* results. Consequently, the above worldwide RR is misleading because it does not reflect that fact that my results substantially weaken the U.S. evidence [1,29].

My own meta-analysis of all U.S. spousal smoking studies, yields a U.S. RR of 1.10 (1.00–1.21), which barely constitutes a relationship.

Chapter 7 contains this inaccurate statement on page 435: "There were no significant differences in the RR estimates by geographic area; the point estimate was 1.15 (95 percent CI, 1.04–1.26) for studies conducted in the United States and Canada, 1.16 (95 percent CI, 1.03–1.30) for studies conducted in Europe, and 1.43 (95 percent CI, 1.24–1.66) for studies conducted in Asia." Obviously, the RR = 1.43 for studies in Asia is statistically greater than the RR = 1.15 for studies in U.S. and Canada and the RR = 1.16 for studies in Europe. Indeed, there is substantial variation around the world and all these results cannot be accurately represented by a single RR of 1.21. This geographic variation should have been properly acknowledged in the Report.

Chapter 8 contains on page 521 selective criticism about and dismissal of the analysis by LeVois and Layard of ETS and CHD deaths in the ACS CPS I and CPS II studies [40]. This paper is important because of its size and statistical power, as discussed in our 2006 meta-analysis of ETS and CHD deaths in the U.S. [39]. One basis for the dismissal is the inaccurate statement, "The investigators did not distinguish between current exposures from spousal secondhand smoke and former exposures, nor did they separately report the effect of current spousal smoking on the risk of CHD." Table 4 of the LeVois and Layard paper clearly shows results for three levels of current ETS exposure for both males and females. Furthermore, Table 2 summarizes the dose-response relationship between ETS and CHD deaths based on the results from the three largest U.S. studies [1,40,82]. There is no meaningful difference in the results for these studies and no dose-response relationship in any of them.

Furthermore, note that the meta-analysis of ETS and CHD is summarized in Figure 8.1 on page 524. Since this figure only shows studies through 2001 it obviously omits the 2003 *BMJ* study.

The *BMJ* study has a major impact on the meta-analysis, as pointed out in our 2003 *BMJ* letter [29] and our 2006 meta-analysis [39]. Note that inclusion of *BMJ* results yields a relative risk (RR) of CHD death in the U.S. of 1.05 (0.99–1.11), based on a comparison of current to never exposure to ETS. This is much less than the summary RR (exposed/unexposed) of 1.27 (1.19–1.36) contained in Figure 8.1. The Surgeon General's Report should have pointed out that the ETS and CHD relationship is much larger outside of the U.S. than it is within the U.S. We estimated that the RR outside the U.S. is approximately 1.5 [39] and the 1999 Thun meta-analysis found the RR was

1.41 (1.21–1.65) [32]. This large difference between the RRs within the U.S. and those outside of the U.S. is worthy of further discussion and investigation, in order to determine if it is a real difference or an anomaly due to methodological issues.

The Introduction of the Surgeon General's Report makes the statement that "about 50,000 excess deaths result annually from exposure to secondhand smoke (Cal/EPA 2005). Estimated annual excess deaths for the total U.S. population are about 3,400 (a range of 3,423 to 8,866) from lung cancer, 46,000 (a range of 22,700 to 69,600) from cardiac-related illnesses, and 430 from SIDS." [79]. Given the fact that the two largest epidemiologic studies on ETS and tobacco-related mortality [1,40] have been omitted from the Surgeon General's Report and the fact that these two U.S. studies suggest a substantially weaker ETS and mortality relationship in the US, the above estimate of excess deaths appears to be an intentional exaggeration of what the entire body of scientific evidence shows. A complete evaluation of all the peer-reviewed U.S. epidemiologic evidence suggests that ETS exposure is associated with a much smaller number of lung cancer and CHD deaths in U.S. never smokers. Furthermore, there is not a "causal" relationship by traditional epidemiologic standards.

An August 23, 2006 "research news and perspective" report in *JAMA* questioned various aspects of the Surgeon General's Report, particularly findings regarding the acute effects of small amounts of ETS exposure and the claim by the Surgeon General that "There is no safe level of exposure to secondhand smoke" [83]. This *JAMA* report is particularly noteworthy because it quotes two experts who have extensive experience regarding the ETS issue. Michael Siegel, MD, MPH, a professor of social and behavioral sciences at Boston University School of Public Health and a prominent tobacco control researcher, told *JAMA* "We're really risking our credibility [as public health professionals or officials] by putting out rather absurd claims that you can be exposed briefly to secondhand smoke and you are going to come down with heart disease or cancer. People are going to look at that and say that's ridiculous." Siegel's own paper expanding on this point is published alongside the present article [84]. Furthermore, since March 2005, Siegel has posted many detailed and insightful analyses regarding ETS and tobacco control on his personal website, "The Rest of the Story: Tobacco News Analysis and Commentary" [85]. Each post includes "Comments" from readers who provide additional insights. For instance, on June 28, 2006, he posted "Surgeon General's Communications Misrepresent Findings of Report; Tobacco Control Practitioners Appear Unable to Accurately Portray the Science" [86].

John C. Bailar III, MD, PhD, a prominent epidemiologist and biostatistician, who is Professor Emeritus at the University of Chicago, told *JAMA* "It doesn't make sense for the cardiovascular risk of secondhand smoke to be as high as one third of the risk from direct smoking. . . . That's a far bigger ratio than risk for lung cancer and it's hard for me to believe that it's real" [83]. These comments are similar to those in his March 25, 1999 *NEJM* editorial on ETS and coronary heart disease, in which he stated "I regretfully conclude that we still do not know, with accuracy, how much or even whether exposure to environmental tobacco smoke increases the risk of coronary heart disease" [87]. On June 7, 2006, just 20 days before the release of the Surgeon General's Report, the Select Committee on Economic Affairs of the House of Lords in London issued an important report on the management of risk, which suggests that passive smoking in England may be a relatively minor health risk [88]. The committee obtained testimony from Professor Sir Richard Peto of the University of Oxford on February 14, 2006 [89]. Sir Richard's testimony clearly states the substantial doubt that he has about the quantitative health risks of passive smoking [90,91]. The very fact that two major reports published in the same month, June 2006, come to substantially different conclusions about the health risks of ETS indicates that these risks are still uncertain and difficult to measure accurately.

Further evidence of the uncertainty regarding the health risks of ETS is contained in the June 28, 2007 *Nature* news article on ETS. Various claims made by Glantz about the acute and chronic health effects of ETS are questioned by Peto, Bailar, and Siegel, who restated their concerns that the dangers of ETS have been exaggerated [92]. For instance, Peto stated "Passive smoking must kill some people, but the big question is how many." This statement clearly underscores the existing uncertainty and directly contradicts the June 27, 2006 statement by U.S. Surgeon General Richard H. Carmona that "The debate is over" regarding the health effects of secondhand smoke [93].

Jonathan M. Samet, M.D., and United States of America v. Philip Morris USA, et al

One particularly pernicious aspect of the attack described above is the fact that my *BMJ* paper is now part of the largest (\$280 billion) Racketeer Influenced and Corrupt Organizations Act (RICO) lawsuit ever filed, United States of America v. Philip Morris USA, et al. [Civil Action No. 99-CV-02496(GK)] [94,95]. My research and I are described in a defamatory way on pages 821–830 within the section "Defendants Used Their Jointly Controlled Organizations to Promote Their Agenda Through Symposia, Publications and a Roster of Long-time Paid Scientists" of the 2543-page pretrial "UNITED STATES' FINAL PROPOSED FINDINGS OF FACT (July 2004)" prepared

by the U.S. Department of Justice (USDOJ) [96]. The trial took place in front of U.S. District Court Judge Gladys Kessler from September 2004 through June 2005 [94]. Additionally, my research and I are described in a defamatory way in several places in the 2454-page post-trial document "UNITED STATES' FINAL PROPOSED FINDINGS OF FACT (Incorporating Errata of August 16, 2005)" prepared by the USDOJ [97]. Specifically, my *BMJ* paper is listed on page vii of the Table of Contents under the category "Cooking the Books: The Manufacture of False Science to Support the Industry Position on ETS." On page 493 it is included among "examples of scientific fraud" and on page 589 it is described as "at best a contamination of the scientific literature and at worst a scientific fraud." It is discussed in detail on pages 609–615, where there are numerous false statements and distortions, such as, "the Enstrom/Kabat study is yet another self-serving, unreliable, and scientifically questionable product of the industry's unabated effort to attack the scientific consensus on passive smoking." Although no actual evidence was presented of errors in my study or of scientific misconduct on my part, the lawsuit makes it appear that I have engaged in scientific fraud.

The available evidence indicates that insertion of the *BMJ* paper was a collaborative effort of Glantz and Sharon Y. Eubanks (D.C. Bar No. 420147), Director of the USDOJ Tobacco Litigation Team from 1999 until December 2005, when she resigned from the USDOJ [98]. The following brief in Civil No. 99-CV-02496 (GK), "REPLY IN SUPPORT OF THE UNITED STATES' THIRD MOTION TO COMPEL PRODUCTION OF DOCUMENTS WITHHELD BY BROWN & WILLIAMSON BASED ON ASSERTIONS OF PRIVILEGE OR PROTECTION," was prepared by Eubanks and signed on December 5, 2003. This brief is posted on the same listserv that Glantz has used to post other defamatory information about me [99]. Pages 8, 9, and 14 of this brief contain a misleading and distorted presentation of my alleged "ties" with the tobacco industry going back "nearly 30 years." This presentation later appeared in the July 2004 and August 2005 Findings of Fact of the USDOJ lawsuit. This 2003 brief does not present any evidence challenging my honesty as a scientist or the validity of the findings in my *BMJ* paper. It is simply an attempt to smear my reputation with inappropriately constructed "ties" to the tobacco industry, based on the fact that I had correspondence with the tobacco industry regarding my epidemiologic research.

On August 17, 2006 District Court Judge Gladys Kessler issued a 1,653 page Final Opinion concluding that the tobacco industry had engaged in racketeering [100,101]. Eleven key pages from her decision, including pages discussing my study, were assembled by Glantz and posted on a UCSF website [102]. The Kessler decision includes a

section entitled "The 2003 Enstrom/Kabat Study" on pages 1380–1383, as well as other references to my study. The Judge repeated in her opinion a number of the misleading and inaccurate statements about my study that are contained in the 2004 and 2005 Findings of Fact. However, the Judge identified no specific errors in the study and identified no scientific misconduct by me. At no time was I ever given an opportunity to challenge or refute the statements made about me and my research in the USDOJ Findings of Fact, in the trial itself, or in the Kessler opinion. I am now in the process of clearing my name in connection with this lawsuit and this paper represents a major step in that process. Furthermore, on October 31, 2006 the U.S. Court of Appeals of the District of Columbia Circuit granted the tobacco industry's emergency motion to stay Judge Kessler's final judgment and remedial order pending appeal [103]. On May 22, 2007 the U.S. Court of Appeals issued an order setting the briefing schedule for the appeal [104].

In formulating her comments about my study, Judge Kessler relied heavily on the testimony of Samet. On page 765 of her decision she states "Dr. Jonathan Samet, a Government expert with extraordinary qualifications, is a physician and epidemiologist with extensive experience treating patients with lung cancer and COPD." On page 1232 she states: "Dr. Samet is professor and chair of the Department of Epidemiology at the Johns Hopkins Bloomberg School of Public Health. He is also a licensed physician who is board certified in pulmonary and internal medicine. Dr. Samet is a member of the National Academy of Sciences' Institute of Medicine, the Board of Scientific Counselors of the National Cancer Institute, and EPA's Clean Air Scientific Advisory Committee. He is a recipient of the Surgeon General's Medallion and has participated as an author and/or editor of nine Surgeon General's Reports, including as Consulting Scientific Editor and author for the 1986 Report. He has participated in four NCI monographs in its series on smoking and health. He chaired the 2002 review of active and passive smoking and health for the International Agency for Research on Cancer of the World Health Organization. . . . after considering Dr. Samet's superb academic credentials, his vast experience working on Surgeon General Reports and NCI monographs, his continuing practice of medicine, as well as his demeanor and responsiveness to cross-examination, the Court fully credits his testimony." On page 1234 she states: "The Court accepts and credits Dr. Samet's conclusions, based on his expertise, as well as the other factual findings herein, that exposure to secondhand smoke causes lung cancer and coronary heart disease in adults and a number of respiratory diseases in children."

It is worth repeating the allegations in the Kessler decision, first to point out that they are the same false and mis-

leading claims about the Enstrom/Kabat study by the ACS, Samet, Glantz, and others that are described above, and second to show how obviously incorrect they are. The Enstrom/Kabat study was not "CIAR-funded and managed" and was not "funded and managed by the tobacco industry through CIAR and Philip Morris." Although the study was partially funded by CIAR, it was not managed by either CIAR or Philip Morris. Indeed, CIAR assigned its entire award for the study to UCLA in 1999 just before CIAR was dissolved as a condition of the Master Settlement Agreement [105]. CIAR did not even exist when my study was being completed. The study was conducted and published without any influence from the tobacco industry. The claim that the "American Cancer Society had repeatedly warned Enstrom that using its CPS-I data in the manner he was using it would lead to unreliable results" is utterly false and the ACS has produced no documentation to support this claim. The claim "Enstrom and Kabat's conclusions are not supported by the weak evidence that they offer" made by Samet and others is utterly false because our conclusions are fully supported by the evidence in our *BMJ* paper, as stated earlier.

In addition, Samet made an inaccurate and incomplete statement in his Written Direct testimony of September 20, 2004 (page 184, lines 8–9): "When the 2002 meta-analysis carried out by IARC was redone in 2004 to include this [Enstrom and Kabat] study, the positive findings were unchanged." [106]. This statement is inaccurate because the August 30, 2003 *BMJ* letter signed by Samet correctly states: "Adding the result from Enstrom and Kabat to the IARC analysis reduces the pooled estimate to 1.23." [73]. In addition, this statement is incomplete because Samet failed to state that the Enstrom and Kabat results reduced the pooled risk ratio estimates for U.S. studies to about 1.10 for lung cancer and to about 1.05 for coronary heart disease [39]. The Enstrom/Kabat summary risk ratios are far below the widely stated summary risk ratios of about 1.25 and are not consistent with the estimate that "about 50,000 excess deaths results annually from exposure to secondhand smoke" in the US, as stated on page 8 of the Surgeon General's Report [79].

Samet made a false statement in this September 20, 2004 testimony when he claimed (page 192, lines 21–23): "Except for the analyses of CPS I and CPS II presented by LeVois and Layard in 1995, all other studies have demonstrated at least a modest increase in risk for fatal and non-fatal CHD due to secondhand smoke exposure." [106]. Our *BMJ* study showed no increase in risk for fatal CHD, other than the insignificant statistical fluctuation that was also present in the LeVois and Layard paper, and reference to our study should have been included in Samet's testimony.

Since no errors had been found in our paper, and since Kabat and I had clearly declared there was no tobacco industry influence on our results (and no one has found any evidence to the contrary), our research did not warrant inclusion in the USDOJ lawsuit. The citation of our study in the Kessler decision appears to be primarily due to the false and misleading statements about our research made by Samet. All of this casts doubt on the ability of Samet to be objective regarding the subject of ETS.

Further evidence of Samet's campaign against me appeared in the May 4, 2007 *Chronicle of Higher Education* as a two-page, 15-inch by 22-inch advertisement "Why do the University of California Regents still cash checks from tobacco racketeers?" [107]. This advertisement by "Campaign to Defend Academic Integrity" [108] is an appeal to UC Regents to implement a tobacco funding ban and it makes direct reference to me and my tobacco industry funding. Statements throughout the advertisement falsely characterize me and my research: "To make vivid how Big Tobacco co-opted world-class research institutions for its disinformation and legal defense strategies, the Court cited the misuse of American Cancer Society data by a non-faculty researcher at UCLA. . . Big Tobacco's investment in UCLA bought it the chance to argue falsely, using UCLA's name, that the science on secondhand smoke was inconclusive, to battle public health measures. Whatever the tobacco industry gains from the University, the University loses. The public loses, too." This compounding of the defamation in the court papers through paid advertising was signed by 21 prominent individuals who identify themselves as "among those who support action by the University of California Regents to refuse all future tobacco industry funding." The signatories include both Samet and Eubanks, who obviously have been directly involved in lobbying the UC Regents, a position that compromises their objectivity with regard to my inclusion in the USDOJ lawsuit. Given the obsessive focus on my tobacco industry funding, it is noteworthy that there is no indication of the funding and competing interests of those associated with this advertisement. The *Chronicle of Higher Education* website states that a "tabloid-page spread" advertisement like this one costs \$22,630 [109], a sum unlikely to have been paid by the signatories themselves.

Based on the record presented above, Eubanks has obviously dealt extensively with both Glantz and Samet regarding the issue of my *BMJ* paper and the USDOJ lawsuit. She injected herself directly into the UC tobacco industry funding ban issue with a lecture before the Regents on July 18, 2007, when she described the USDOJ lawsuit and its connection to UC [110]. She claimed that Judge Kessler was "a neutral fact finder, a federal judge, who made her findings of conspiratorial conduct objectively" based on "a full and fair record." However, she

knows that the record is not objective and that I was never given any opportunity to defend myself and my *BMJ* paper during the trial. In an eloquent defense of academic freedom at UC, the 2006–2007 UC Academic Senate Chair John B. Oakley challenged Eubank's linkage of the USDOJ lawsuit to UC and raised the issue of whether Judge Kessler's opinion would ultimately be upheld upon appeal [11188d]. A clearer understanding of this entire issue can be gained by carefully listening to the Eubanks and Oakley audio files [110,111].

Jonathan M. Samet, M.D., and Conflict of Interest

Samet has not revealed his competing interests on the subject of ETS as they relate to the *BMJ* rr [20], the *BMJ* letter [73], the IARC Report [50], the *JNCI* article [52], the Surgeon General's Report [79], his USDOJ lawsuit testimony [106], or the *Chronicle of Higher Education* advertisement [107]. Given that Samet has criticized persons who disagree with his views on ETS because of their competing interests, it is fair and reasonable to ask why he has failed to report his own substantial competing interests. A careful examination of the Surgeon General's Report reveals that it contains no conflict of interest disclosures for Senior Scientific Editor Samet or for any of the other editors or reviewers. In addition, an examination of the other items above reveals the Samet has not disclosed a financial conflict of interest which could have compromised his objectivity on ETS. This imbalance further suggests that the attacks on my research have nothing to do with a principled concern about conflicts of interest, but are purely a matter of not liking the results.

The article, "smoke out!", in the Spring 2003 issue of *Johns Hopkins Public Health*, "The Magazine of the Johns Hopkins Bloomberg School of Public Health" [112] reveals that, "After three years of preparation, Samet testified in the landmark 1998 Minnesota tobacco trial that smoking causes certain diseases like lung cancer" and that Samet was "working on the federal government's \$289 billion lawsuit that accuses tobacco companies of 50 years of deceptive marketing," which is the USDOJ lawsuit discussed above. Later, the article stated "In March, the Flight Attendant Medical Research Institute honored Samet with the '...Dr. William Cahan Distinguished Professor' Award and \$600,000 over 3 years to combat tobacco-related disease."

According to the Flight Attendant Medical Research Institute (FAMRI) website, the 'Dr. William Cahan Distinguished Professor' award to Samet during 2003–2006 was "made in recognition of the recipients' ongoing work in combating the diseases caused by exposure to second hand tobacco smoke" [113]. In addition, Samet has a prominent role in the current multi-million dollar Johns Hopkins FAMRI Center of Excellence [114]. This Center

was established in 2005 and currently has 30 FAMRI-funded research projects on "diseases and medical conditions caused from exposure to tobacco smoke," including one by Samet on "Reducing the Risks of Secondhand Tobacco Smoke Globally" [113].

FAMRI is a foundation established as a result of an October 1991 Class Action suit filed in Miami's Dade County Circuit Court in Florida, known as *Broin v. Philip Morris* [116]. This suit was filed against the tobacco industry on behalf of flight attendants who sought damages for diseases and deaths allegedly caused by their exposure to second hand tobacco smoke in airline cabins [117]. A settlement was reached in October 1997 between the plaintiffs and four tobacco companies. The Settlement Agreement included the establishment of a not-for-profit medical research foundation with funding by the tobacco industry of \$300 million. The Foundation was to have no tobacco company involvement, other than funding. The purpose of the foundation was "to sponsor scientific research with respect to the early detection and cure of diseases associated with cigarette smoking" [118]. FAMRI, as it was actually established, has a distinctly different mission, which is "to sponsor scientific and medical research for the early detection, prevention, treatment and cure of diseases and medical conditions caused from exposure to tobacco smoke." [117]. Since FAMRI's mission statement assumes that diseases like lung cancer and CHD are caused by "exposure to tobacco smoke," this funding source may have influenced Samet's decisions about which epidemiologic studies he chooses to believe and which ones he chooses to ignore, and thus should have been disclosed. As noted in an August 23, 2006 JAMA editorial, in published articles it is important "that readers are aware of the authors' financial relationships and potential conflicts of interest so that these readers can interpret the article in light of that information" [119].

Jonathan M. Samet, M.D., and the 1992 EPA Report

One might wonder how omissions, distortions, and exaggerations like those pointed out above could occur in a document as important as a Surgeon General's Report on ETS. To better understand this phenomena one must realize that Samet has dealt with the ETS issue in this manner for many years. In particular, he played a major role in the epidemiologic analysis for the December 1992 report on *Health Effects of Passive Smoking: Lung Cancer and Other Disorders: The Report of the United States Environmental Protection Agency* [120]. This EPA report classified ETS as a Group A human carcinogen, which causes about 3,000 lung cancer deaths per year in the U.S. The findings from this report were used in the *Broin v. Philip Morris* litigation described above.

The epidemiologic methodology and conclusions of the EPA report have been severely criticized. One of the harshest critiques is the 92-page Decision issued by Federal Judge William L. Osteen on July 17, 1998, which overturned the report in the U.S. District Court [121]. For instance, in his conclusion Judge Osteen wrote: "In conducting the Assessment, EPA deemed it biologically plausible that ETS was a carcinogen. EPA's theory was premised on the similarities between MS [mainstream smoke], SS [sidestream smoke], and ETS. In other chapters, the Agency used MS and ETS dissimilarities to justify methodology. Recognizing problems, EPA attempted to confirm the theory with epidemiologic studies. After choosing a portion of the studies, EPA did not find a statistically significant association. EPA then claimed the bioplausibility theory, renominated the a priori hypothesis, justified a more lenient methodology. With a new methodology, EPA demonstrated from the 88 selected studies a very low relative risk for lung cancer based on ETS exposure. Based on its original theory and the weak evidence of association, EPA concluded the evidence showed a causal relationship between cancer and ETS. The administrative record contains glaring deficiencies. . . ."

In order to more fully understand the EPA report and its inherent flaws, one must read the complete Osteen decision [121], as well as the books *Passive Smoke: The EPA's Betrayal of Science and Policy* by Drs. Gio B. Gori and John C. Luik [122], *Ashes to Ashes: America's Hundred-Year Cigarette War, the Public Health, and the Unabashed Triumph of Philip Morris* by Richard Kluger [123], *For Your Own Good: The Anti-Smoking Crusade and the Tyranny of Public Health* by Jacob Sullum [124], and the *Brill's Content* magazine article "Warning: Secondhand Smoke May NOT Kill You" by Nicholas Varchaver [125]. Finally, one must read the January 28, 1993 *Investors' Business Daily* article "Is EPA Blowing Its Own Smoke? How Much Science Is Behind Its Tobacco Finding?" by Michael Fumento, who stimulated my own interest in the ETS issue [126].

2006 Congress of Epidemiology and Trofim Denisovich Lysenko Analogy

In order to explain the phenomenon that has made this defense of my epidemiologic research necessary, Geoffrey Kabat, Sheldon Ungar, and I presented a symposium entitled "Reassessment of the Long-term Mortality Risks of Active and Passive Smoking" at the 2nd North American Congress of Epidemiology in Seattle, Washington on June 24, 2006 [127]. We described major misrepresentations that are currently occurring with regard to the epidemiology of both active and passive smoking, as well as the silencing of science associated with this area of epidemiology. I presented the rationale for the symposium based on the fact that important epidemiologic findings have been ignored or mischaracterized in prior assessments. Then I

presented evidence that the adverse effects of active smoking on mortality are less reversible by cessation than generally believed, based on randomized controlled trials involving smoking cessation and "natural experiments" involving the CA CPS I cohort and several other cohorts [31,128,129]. Kabat presented evidence that the relationship between passive smoking and mortality is weaker than generally believed, particularly within the United States, based on our two recent ETS papers [1,39]. Ungar described the "silencing of science" phenomenon with regard to our May 17, 2003 *BMJ* paper that he documented and described in his 2005 paper [27].

In this symposium we addressed several important issues: 1) the implications of our reassessment for the relative dangers of active and passive smoking; 2) the way in which ideological and political agendas have influenced the interpretation of epidemiologic evidence; and 3) the importance of separating non-scientific agendas from objective assessment of evidence. We made the case that: 1) all epidemiologic findings must be evaluated in a fair and consistent manner in order to obtain an accurate assessment of the mortality risks of active and passive smoking; 2) epidemiologic findings must be judged on their merits and not on extraneous factors; and 3) additional epidemiologic research in this area needs to be conducted free of partisanship. Our complete presentations are available on the Scientific Integrity Institute website [130], and they include our PowerPoint slides and the audio files for our lectures.

It is quite informative to compare our Symposium with the June 23, 2006 lecture "Using Epidemiologic Evidence to Advance Health: Dealing with Critics and Criticisms" given by Samet at the same Congress of Epidemiology [131]. Samet discussed the use of epidemiologic evidence in public health policy making with regard to the environmental epidemiology issues in which he has been involved. In particular, he discussed the epidemiologic evidence on the relationship between passive smoking and lung cancer just four days before the June 27, 2006 release of the Surgeon General's Report on involuntary smoking for which he was Senior Scientific Editor [79]. He talked about the criticism of weak epidemiologic relationships, such as those described in major documents like the 2006 Surgeon General's Report. But he failed to mention that much of this criticism is due to the fact that he has attempted to turn weak and inconsistent observational epidemiologic evidence into an undisputed causal relationship. He talked about how critics raise epidemiologic issues like confounding and bias, but he failed to acknowledge his own biased presentation of the evidence, including omitting my *BMJ* paper from the report and failing to acknowledge that the U.S. evidence is weaker than the evidence outside of the U.S.

Also, it is quite telling how Samet dismissed critics of the causal relationship between passive smoking and lung cancer by classifying them as "stakeholders" linked with the "tobacco industry." He implied that it is not necessary to address the merits of their criticisms simply because they are stakeholders in decisions related to passive smoking. However, he failed to disclose his own financial interests that surely put him in the stakeholder category. He certainly never mentions that his FAMRI money originates from the tobacco industry, making it remarkably similar to my CIAR funding. Samet's lecture provides insight into his thought processes and the ways in which he manipulates evidence to fit his vision of an epidemiologic relationship with public policy implications. The transcript of a key portion of his lecture is available [132], as is the audio file [133].

We concluded our Symposium by drawing an analogy between the current situation involving ETS epidemiology in the United States and the historical situation involving agronomist Trofim Denisovich Lysenko and plant genetics in the Soviet Union during the period of 1927–1962 [2]. While it is common to invoke George Orwell or Joseph McCarthy in discussions like this, I believe the lessons from the admittedly more extreme Lysenko case are more analogous and informative. Although ETS epidemiologic evidence has never been conclusive, several major reports have been issued with definitive conclusions about a "causal relationship" between ETS and mortality. All major U.S. government and private health agencies have declared that a causal relationship exists and these organizations have created "a regime of truth that cannot be intelligibly questioned." These organizations then use any means necessary to enforce this "regime of truth." Since the publication of the influential null findings in my *BMJ* paper, which contradict the "regime of truth," I have been subjected to a massive *ad hominem* attack, my career has been threatened, and my paper has been dismissed because of its politically incorrect findings. In addition, I was inserted into a massive lawsuit by my own government in a manner that makes it appear that I have committed "scientific fraud" and have been engaged in racketeering with the tobacco industry. There also has been the attempt to force the University of California to ban the tobacco industry funding that I have used and to restrict future research in the areas of tobacco-related diseases that I have been investigating.

Lysenko used his influence and backing by the Soviet government to create a "regime of truth" and to stop others' research in order to promote scientifically invalid "vernalization" and Lamarckian plant genetics. He was also successful in attacking and destroying his critics, like Nicolai Vavilov, who espoused proper Mendelian plant genetics. Because Lysenko prevailed for such a long period of time,

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

S. STANLEY YOUNG.,

Plaintiff,

v.

UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY *et al.*,

Defendants.

No. 1:21-cv-2623

DECLARATION OF JAMES E. ENSTROM

I, James E. Enstrom, declare as follows:

1. I am a resident of Los Angeles, California and I am otherwise competent to render this declaration. My work on this declaration is pro-bono and I am not a party to this case. I am a retired Research Professor (Epidemiology) from the UCLA School of Public Health and Jonsson Comprehensive Cancer Center and I am President of the Scientific Integrity Institute in Los Angeles (<http://www.scientificintegrityinstitute.org/biography.html>). I have a PhD in elementary particle physics from Stanford University, and an MPH and postdoctoral certificate in epidemiology from UCLA. I am a Founding Fellow of the American College of Epidemiology, a member of the ACE Ethics Committee, and a Life Member of the American Physical Society. I have authored, primarily as first or sole author, about 50 peer-reviewed articles and book chapters on epidemiology, physics, and scientific integrity.

2. During the past 20 years I have published extensive research relevant to EPA air pollution science and regulations. I have published important articles showing that fine particulate matter (PM2.5) is not related to total mortality in the American Cancer Society (ACS) Cancer Prevention Study cohorts (CPS I and CPS II). I am the only independent scientist to

obtain and analyze original CPS cohort data and my research shows that the EPA PM2.5 NAAQS is scientifically unjustified and must undergo objective reassessment. My Scientific Integrity Institute website contains hundreds of documents that challenge the validity of EPA air pollution science and regulations (<http://www.scientificintegrityinstitute.org/documents.html>). I have received research funding from many sources, including NIH, ACS, University of California, private foundations, and industry sources, but I have never received funding from EPA. Although I have received no research funding since 2010, I have been able to conduct important epidemiologic research by using my personal assets in innovative and cost-effective ways.

3. I am over 18 years old and could testify to the facts set out herein if called upon to do so. I make this declaration based on my personal knowledge in order to address issues related to the Clean Air Scientific Advisory Committee (CASAC) and the Science Advisory Board (SAB) for the United States Environmental Protection Agency (EPA). In October 2018 I was a SAB candidate with highly relevant epidemiologic expertise (<http://www.scientificintegrityinstitute.org/EPASABJEE101618.pdf>), but I was not selected to serve on the SAB.

Clean Air Scientific Advisory Committee and Scientific Advisory Board

4. CASAC plays a very important role in EPA policy because it provides independent scientific advice to the EPA Administrator on the technical bases for EPA's National Ambient Air Quality Standards (<https://casac.epa.gov/ords/sab/f?p=105:2:5692574423233>). CASAC is required to follow the provisions of the Federal Advisory Committee Act, which include “furnishing expert advice, ideas, and diverse opinions to the Federal Government” (<https://www.gsa.gov/policy-regulations/policy/federal-advisory-committee-management/legislation-and-regulations/the-federal-advisory-committee-act>).

5. The SAB also plays an important role in EPA policy because it reviews “the quality and relevance of the scientific and technical information being used by the EPA or proposed as the basis for Agency regulations” (<https://sab.epa.gov/ords/sab/f?p=100:2:4029097575082>). EPA is supposed to choose SAB members based on “their demonstrated ability to examine and analyze environmental issues with objectivity and integrity and for their interpersonal, oral and written communication, and consensus-building skills.” In addition, SAB members are supposed to be “free from Conflicts of Interest and/or an appearance of a loss of impartiality” (<https://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument>).

6. Based on extensive evidence, many of the CASAC and SAB members appointed in 2021 have not demonstrated an ability to examine and analyze environmental issues with objectivity and integrity and are not free from conflicts of interest. I illustrate serious bias on the current CASAC and SAB by focusing on 2021 CASAC Chair and SAB Member Elizabeth A. Sheppard, 2021 SAB Chair Alison C. Cullen, and 2021 SAB Member and 2008-2012 CASAC Chair Jonathan M. Samet.

7. University of Washington Professor of Biostatistics Elizabeth A. Sheppard, PhD, is an activist scientist whose research has been unduly influenced by at least \$60,031,882 in EPA funding (<https://junkscience.com/2021/06/corrupt-epa-stacks-casac-panel-with-agency-grant-cronies-chair-is-top-agency-grant-crony/>). She was the lead scientific plaintiff in a 2018 Union of Concerned Scientists lawsuit against EPA (<https://milesobrien.com/scientists-sue-epa-pruitt-advisory-board-purge/>). She has unprofessionally exaggerated the cancer risk of glyphosate (<https://geneticliteracyproject.org/2021/02/09/the-glyphosate-debacle-how-a-misleading-study-about-the-weedkiller-roundup-and-gullible-reporters-helped-fuel-a-cancer-scare/>). She has never

addressed the serious flaw that I identified in her 2007 New England Journal of Medicine article on PM2.5 (<http://www.scientificintegrityinstitute.org/NEJM032807.pdf>). She has never cited my evidence of NO relationship between PM2.5 and mortality. Dr. Sheppard has not demonstrated the ability to analyze EPA-related issues with objectivity and integrity.

8. University of Washington Professor of Environmental Policy Alison C. Cullen, ScD, is a close colleague of CASAC Chair Sheppard. She received her doctoral degree from the Harvard TH Chan School of Public Health in 1992 and was an Assistant Professor of Environment Health during 1993-1995, when the Dockery 1993 and Pope 1995 articles were published and were then used to establish the 1997 EPA PM2.5 NAAQS. Douglas Dockery, ScD, was concurrently a Harvard TH Chan School of Public Health Professor of Environmental Health. Thus, she must be very familiar with the intense controversy surrounding PM2.5 death claims and the early and repeated demands for transparency and access to the data underlying Dockery 1993 and Pope 1995 (<http://www.scientificintegrityinstitute.org/WSJ040797.pdf>). Yet, as 2018 EPA SAB Chair, she questioned the proposed EPA Rule “Strengthening Transparency in Regulatory Science” (<https://junkscience.com/2018/05/air-pollution-mafia-attempting-to-sabotage-epa-science-transparency-rulemaking/>). Her May 12, 2018 SAB Memo did not acknowledge Enstrom 2017, which found serious flaws in Pope 1995 and which challenged the validity of the 1997 PM2.5 NAAQS, thereby demonstrating the importance of data access and transparent EPA science. I explained this issue in detail in my May 30, 2018 EPA SAB Public Comment (<http://www.scientificintegrityinstitute.org/EPASABTransJEE053018.pdf>). Dr. Cullen has not demonstrated objectivity and integrity regarding transparency in EPA science.

9. Colorado School of Public Health Dean and Professor Jonathan M. Samet, MD, MS, received his MS at Harvard TH Chan School of Public Health and has been directly

involved with PM2.5 science and policy for over 25 years. His research and decisions have been unduly influenced by at least \$28,276,921 in EPA funding. A June 13, 1996 EPA CASAC-SAB Letter by CASAC Chair George T. Wolff shows that Epidemiologist Samet recommended NO PM2.5 NAAQS, as shown on page 24 of my 31-page July 8, 2021 Review (<http://scientificintegrityinstitute.org/ESTJEEAdd070821.pdf>). Dr. Samet was well aware of the PM2.5 deaths controversy expressed by a dozen experts, including myself, in the 6.5-hour February 26, 2010 CARB Symposium “Estimating Premature Deaths from Long-term Exposure to PM2.5” (<https://cal-span.org/unipage/?site=cal-span&owner=CARB&date=2010-02-26>). I played a major role initiating this symposium because I uncovered fraud in CARB PM2.5 science (<http://www.scientificintegrityinstitute.org/Telles111609.pdf>). Additional criticism of PM2.5 death claims has been published, such as, the 2012 Texas Public Policy Foundation Report “EPA's Pretense of Science on Regulating Phantom Risks” (<http://www.scientificintegrityinstitute.org/TPPF050112.pdf>). In spite of ongoing PM2.5 controversy, 2008-2012 CASAC Chair Samet participating in the 2012 lowering of the annual PM2.5 NAAQS from 15 µg/m³ to 12 µg/m³. Dr. Samet has not demonstrated the ability to analyze EPA-related issues with objectivity and integrity.

CASAC’s 2019-2020 Recommendations Regarding Current Particulate Matter Standards

10. The prior CASAC recommended retaining current particulate matter standards in 2019-2020 based largely on the 257-page December 16, 2019 Review of the Policy Assessment for the PM2.5 NAAQS to the EPA Administrator from the 2018-2020 CASAC Chair Louis Anthony Cox, Jr.

([https://yosemite.epa.gov/sab%5Csabproduct.nsf/E2F6C71737201612852584D20069DFB1/\\$File/EPA-CASAC-20-001.pdf](https://yosemite.epa.gov/sab%5Csabproduct.nsf/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf)). My 20-page June 29, 2020 EPA Comment expressed strong

support for this Review and for retaining the current annual PM2.5 NAAQS of 12.0 $\mu\text{g}/\text{m}^3$ (<http://www.scientificintegrityinstitute.org/EPAPM25JEE062920.pdf>). My own meta-analyses show NO significant relationship between PM2.5 and total mortality in US and California cohort studies and support the evidence that the current PM2.5 NAAQS is at or below the threshold for PM2.5 deaths. Furthermore, there is NO public health benefit in lowering the annual PM2.5 national ambient air quality standard of 12 $\mu\text{g}/\text{m}^3$, because as of 2019 the average population-weighted PM2.5 level in the US was 7.7 $\mu\text{g}/\text{m}^3$, as per the 2019 State of Global Air Map (<https://www.stateofglobalair.org/data/#/air/map>). The US PM2.5 level is among lowest in the world, whereas the Chinese PM2.5 level of 48 $\mu\text{g}/\text{m}^3$ is among the highest in the world and the Chinese PM2.5 that crosses the Pacific Ocean contributes to US PM2.5, particularly in California.

EPA's Draft 2021 PM Integrated Science Assessment and Policy Assessment and NAAQS

11. I strongly object to EPA's current reconsideration of the national ambient air quality standards because there are severe flaws in the Draft September 2021 Supplement to the 2019 Particulate Matter Integrated Science Assessment (<https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=352823>) and the Draft October 2021 EPA Particulate Matter Policy Assessment (https://www.epa.gov/system/files/documents/2021-10/draft-policy-assessment-for-the-reconsideration-of-the-pm-naaqs_october-2021_0.pdf). I illustrate these flaws with a word search of the 303-page Particulate Matter Integrated Science Assessment, which reveals deliberate falsification of the existing research record on PM2.5 deaths in the US.

12. The Harvard TH Chan School of Public Health has been the leading promoter of PM2.5 deaths since the publication of Dockery 1993 and Pope 1995. Seven long-time US

proponents of PM2.5 deaths with ties to Harvard TH Chan School of Public Health (Francesca Dominici, Jaime Hart, Francine Laden, C. Arden Pope, Joel D. Schwartz, George Thurston, Annette Zanobetti) were cited 165 times in the Particulate Matter Integrated Science Assessment; eight Canadian proponents of PM2.5 deaths (Jeffrey Brook, Richard Burnett, Daniel Crouse, Michael Jerrett, Randall Martin, Lauren Pinault, Aaron van Donkelaar, Scott Weichenthal) were cited 211 times; four Chinese co-authors with Dominici (Qian Di, Liuhua Shi, Yaguang Wei, Xiao Wu) were first authors on 12 articles during 2015-2021 and were cited 102 times. Fifty authors who have published null findings or who have criticized the PM2.5 national ambient air quality standards were cited 16 times. Among these 50 authors, Dr. S. Stanley Young was cited three times and 2018-2020 CASAC Chair Tony Cox and I were NOT cited at all.

13. Most of the recent US evidence of PM2.5 deaths in the Particulate Matter Integrated Science Assessment is based on the US Medicare records for up to 69 million Americans. In spite of repeated attempts since June 2021, I have not been able to obtain any documentation that key Medicare investigators, particularly Francesca Dominici of Harvard TH Chan School of Public Health and Liuhua Shi of Emory University, have authorization to use these Medicare records for severely flawed air pollution epidemiology. My August 10, 2021 request to Medicare (<http://www.scientificintegrityinstitute.org/medicarejee081021.pdf>) and my requests to Dominici (<http://www.scientificintegrityinstitute.org/NASEMDominici091521.pdf>) and Shi (<http://scientificintegrityinstitute.org/CurranJEE083021.pdf>) have gone unanswered.

14. The Particulate Matter Integrated Science Assessment inappropriately cites extensive PM2.5 death results from activist Canadian investigators based on studies of Canadian residents. The Particulate Matter Integrated Science Assessment and Particulate Matter Policy

Assessment should focus solely on US evidence and the EPA PM2.5 national ambient air quality standards should be based solely on US evidence.

15. In addition to the above evidence of falsification of the research record, there is extensive evidence of publication bias against both null PM2.5 death findings and criticism of PM2.5 national ambient air quality standards. I illustrate this publication bias with three recent examples of my rejected criticism. My proposed March 27, 2020 SCIENCE Policy Forum in support of the EPA Transparency Rule was rejected on March 30, 2020 without any peer review, as documented in my April 17, 2020 EPA Comment in support of the EPA Transparency Rule (<http://www.scientificintegrityinstitute.org/EPATransJEE041720.pdf>). My proposed March 10, 2020 Letter to the Editor noting the failure to cite Enstrom 2017 in the February 18, 2020 JAMA Viewpoint by Fineberg and Allison was rejected on March 23 without any peer review, as documented in my May 18, 2020 EPA Comment in support of the EPA Transparency Rule (<http://www.scientificintegrityinstitute.org/EPATransJEE041720.pdf>).

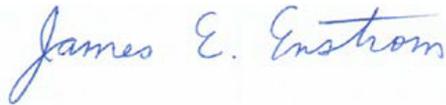
16. My September 2, 2020 Letter to the Editor in response to the August 13, 2020 NEJM Sounding Board “The Need for a Tighter Particulate-Matter Air-Quality Standard” by the Independent Particulate Matter Review Panel was rejected without peer review on September 10, 2020 by NEJM (<http://www.scientificintegrityinstitute.org/NEJMJEE091020.pdf>).

17. Current CASAC Chair Sheppard co-authored this NEJM Sounding Board (<http://scientificintegrityinstitute.org/NEJMIPMRP081320.pdf>) and her position is very clear: “We unequivocally and unanimously concluded that the current PM2.5 standards do not adequately protect public health. An annual standard between 10 µg per cubic meter and 8 µg per cubic meter would protect the general public and at-risk groups. However, even at the lower end of the range, risk is not reduced to zero.”

18. CASAC Chair Sheppard has already taken an unequivocal position in favor of tightening the PM2.5 national ambient air quality standards, without regard to the extensive contrary evidence by dozens of PM2.5 experts, such as Dr. Stanley Young, 2018-2020 CASAC Chair Cox, and myself.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on October 18, 2021, in Los Angeles.



James E. Enstrom