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 underlaying 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). 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 µg/m³ (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 µg/m³, because as of 2019 the average population-weighted PM2.5 level in the US was 7.7 µg/m³, 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 µg/m³ 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/EPATransJEE051820.pdf).

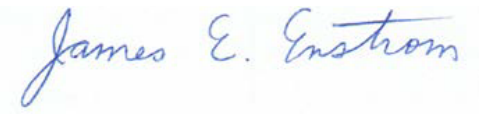
16. My September 2, 2020 Letter to the Editor in response to the August 13, 2020 NEJM Sounding Board "The Need for a Tighter Particulate-Matter Air-Quality Standard" by the Independent Particulate Matter Review Panel was rejected without peer review on September 10, 2020 by NEJM (http://www.scientificintegrityinstitute.org/NEJMJEE091020.pdf).

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