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Supplementary Materials for

Don't abandon evidence and process on air pollution policy

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This PDF file includes:

Supplementary Text

This PDF file includes: Further readings in support of passages from the main text (*italicized*).

Section 1: *“These review panels provide pollutant-specific, evidence-based advice needed for EPA to set air pollution standards. Even in the face of enormous political and financial pressures to roll back pollution controls, this process has worked remarkably well across both Republican and Democratic administrations and has been upheld in the courts, where several legal challenges to its use in past pollutant reviews have been defeated.”*

14. J. M. Samet, The Clean Air Act and health—A clearer view from 2011. *N. Engl. J. Med.* **365**, 198–201 (2011). [doi:10.1056/NEJMp1103332](https://doi.org/10.1056/NEJMp1103332) [Medline](#)
15. J. M. Samet, T. A. Burke, B. D. Goldstein, The Trump Administration and the Environment - Heed the Science. *N. Engl. J. Med.* **376**, 1182–1188 (2017). [doi:10.1056/NEJMms1615242](https://doi.org/10.1056/NEJMms1615242) [Medline](#)
16. US EPA. Particulate Matter (PM) Standards - Documents from Review Completed in 2012 – Litigation. (2012) https://www3.epa.gov/ttn/naaqs/standards/pm/s_pm_2007_lit.html

Section 2: *“This approach is rooted in the scientific community’s decades-long effort to evaluate the relationship between cause and effect, beginning with work by Sir Bradford Hill in 1965 and a 1964 report from the US Surgeon General, and then with approaches later developed by leading scientific bodies such as the National Academy of Medicine and International Agency for Research on Cancer.”*

17. A. B. Hill, The environment and disease: Association or causation? *Proc. R. Soc. Med.* **58**, 295–300 (1965). [Medline](#)
18. U.S. Department of Health, Education, and Welfare. Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service, 1964.
19. The National Academies of Sciences, Engineering, and Medicine, *Using 21st Century Science to Improve Risk-Related Evaluations* (National Academies Press, 2017). <http://www.toxicologia.org.ar/wp-content/uploads/2017/02/Risk-Book-2017.pdf>
20. The National Academies of Sciences, Engineering, and Medicine, Scientific Evidence for Causation in the Population 7, 150 (2008) <https://www.nap.edu/read/11908/chapter/10>

Section 3: *“Under this framework, to justify regulatory action, air pollution epidemiological studies must demonstrate manipulative causation, that is, there must be a direct evidence that the implementation of a regulatory action and/or a reduction in pollutant exposure leads to a health benefit. As an attempt to be more precise from a statistical viewpoint, the position argues that one way to demonstrate manipulative causation is to apply causality tests to observational data, such as the one implemented by the Causal Analytics Toolkit (CAT), proposed by Dr. Cox himself, and/or other approaches (Granger causality, information relations in Directed Acyclic Graph models, and Bayesian networks).”*

21. L. A. T. Cox Jr., Modernizing the Bradford Hill criteria for assessing causal relationships in observational data. *Crit. Rev. Toxicol.* **48**, 682–712 (2018). [doi:10.1080/10408444.2018.1518404](https://doi.org/10.1080/10408444.2018.1518404) [Medline](#)
22. L. A. T. Cox Jr., Do causal concentration-response functions exist? A critical review of associational and causal relations between fine particulate matter and mortality. *Crit. Rev. Toxicol.* **47**, 609–637 (2017). [doi:10.1080/10408444.2017.1311838](https://doi.org/10.1080/10408444.2017.1311838) [Medline](#)
23. Cox Associates Consulting (2019), Causal Analytics Toolkit. <http://cox-associates.com/>

Section 4: “The great majority of epidemiological studies are designed to estimate how changing an exposure leads to a change in health outcomes while adjusting for confounders, that is, keeping fixed all the other variables that may affect outcomes (such as weather, income, copollutants, etc.). Many of the peer-reviewed epidemiological studies included in the EPA’s science assessments rely on careful selection of the study design (e.g., time series, prospective cohorts, quasi-experiments), and these studies adjust for confounding bias to infer causality. Many of these studies use regression methods and include the confounders as covariates. Other studies use methods for causal inference and rely on matching, that is, they compare communities or individuals that have different exposures but are matched with respect to the value of the confounders (e.g., individuals with the same education level but different air pollution exposure)”

24. M. Makar, J. Antonelli, Q. Di, D. Cutler, J. Schwartz, F. Dominici, Estimating the Causal Effect of Low Levels of Fine Particulate Matter on Hospitalization. *Epidemiology* **28**, 627–634 (2017). [doi:10.1097/EDE.0000000000000690](https://doi.org/10.1097/EDE.0000000000000690) [Medline](#)
25. C. M. Zigler, F. Dominici, Y. Wang, Estimating causal effects of air quality regulations using principal stratification for spatially correlated multivariate intermediate outcomes. *Biostatistics* **13**, 289–302 (2012). [doi:10.1093/biostatistics/kxr052](https://doi.org/10.1093/biostatistics/kxr052) [Medline](#)
26. Y. Wang, I. Kloog, B. A. Coull, A. Kosheleva, A. Zanobetti, J. D. Schwartz, Estimating Causal Effects of Long-Term PM_{2.5} Exposure on Mortality in New Jersey. *Environ. Health Perspect.* **124**, 1182–1188 (2016). [doi:10.1289/ehp.1409671](https://doi.org/10.1289/ehp.1409671) [Medline](#)
27. J. Schwartz, K. Fong, A. Zanobetti, A National Multicity Analysis of the Causal Effect of Local Pollution, NO₂, and PM_{2.5} on Mortality. *Environ. Health Perspect.* **126**, 87004 (2018). [doi:10.1289/EHP2732](https://doi.org/10.1289/EHP2732) [Medline](#)

Section 5: “There is a vast literature on methods for casual inference applied to air pollution studies, including the role of causality in data-driven science to inform air pollution regulatory actions.”

28. G. W. Imbens, D. B. Rubin, Causal Inference for Statistics, Social, and Biomedical Sciences (Cambridge University Press, May 2015).
29. C. M. Zigler, C. Kim, C. Choirat, *et al.*, Causal Inference Methods for Estimating Long-Term Health Effects of Air Quality Regulations. HEI Research Report 187 (Health Effects Institute, Boston, MA, 2016).

30. Y. Wang, I. Kloog, B. A. Coull, A. Kosheleva, A. Zanobetti, J. D. Schwartz, Estimating Causal Effects of Long-Term PM_{2.5} Exposure on Mortality in New Jersey. *Environ. Health Perspect.* **124**, 1182–1188 (2016). [doi:10.1289/ehp.1409671](https://doi.org/10.1289/ehp.1409671) [Medline](#)
31. J. Schwartz, E. Austin, M.-A. Bind, A. Zanobetti, P. Koutrakis, Estimating Causal Associations of Fine Particles With Daily Deaths in Boston. *Am. J. Epidemiol.* **182**, 644–650 (2015). [doi:10.1093/aje/kwv101](https://doi.org/10.1093/aje/kwv101) [Medline](#)
32. K. L. Moore, R. Neugebauer, M. J. van der Laan, I. B. Tager, Causal inference in epidemiological studies with strong confounding. *Stat. Med.* **31**, 1380–1404 (2012). [doi:10.1002/sim.4469](https://doi.org/10.1002/sim.4469) [Medline](#)
33. J. M. Robins, P. Zhang, R. Ayyagari, R. Logan, E. T. Tchetgen, L. Li, T. Lumley, A. van der Vaart; HEI Health Review Committee, New statistical approaches to semiparametric regression with application to air pollution research. *Res. Rep. Health Eff. Inst.* (175): 3–129 (2013). [Medline](#)
34. L. A. Cox Jr., D. A. Popken, Has reducing fine particulate matter and ozone caused reduced mortality rates in the United States? *Ann. Epidemiol.* **25**, 162–173 (2015). [doi:10.1016/j.annepidem.2014.11.006](https://doi.org/10.1016/j.annepidem.2014.11.006) [Medline](#)

Section 6: *“The Health Effects Institute (HEI), a highly regarded independent research institute funded primarily by the EPA and the motor vehicle industry, appointed an independent panel of scientists to reanalyze the results of the landmark American Cancer Society and Harvard Six-Cities Studies that demonstrated the link between long-term particulate exposure and premature death.”*

35. Health Effects Institute. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality (2000). <https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air>

Section 7: *“Three separate letters, penned by 15 members of the dismissed particulate matter review panel, 17 former members of the previous ozone review panel, and 7 previous CASAC members express the concern about the process and scientific substance of the particulate and ozone reviews led by Cox. Separately, 206 air pollution and public health experts have called on the EPA to reconvene the disbanded particulate matter review panel.”*

36. C. Frey et al., Letter to US EPA (2018)
[https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/\\$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/086D8B853E0B63AE8525835F004DC679/$File/PMRP+Letter+to+CASAC+181210+Final+181210.pdf)
37. C. Frey et al., Letter to US EPA (2018)
[https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/\\$File/Ozone+Letter+181126+Submitted-rev2.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/0AC9E8672B0CA54985258351005BE54F/$File/Ozone+Letter+181126+Submitted-rev2.pdf)

38. J. M. Samet et al., Letter to US EPA (2018)
[https://yosemite.epa.gov/sab/sabproduct.nsf/02F0FC7F714CAAF08525836000638F9C/\\$File/CASAC_ISA_PM_Comment-samet.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/02F0FC7F714CAAF08525836000638F9C/$File/CASAC_ISA_PM_Comment-samet.pdf)
39. C. Fincher et al., Letter to US EPA (2018)
[https://yosemite.epa.gov/sab/sabproduct.nsf/1B13EFE9060E4BB68525835B0055E411/\\$File/12.10.18+Expert+Sign-on+letter+to+CASAC+and+EPA+Acting+Administrator+Wheeler+.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/1B13EFE9060E4BB68525835B0055E411/$File/12.10.18+Expert+Sign-on+letter+to+CASAC+and+EPA+Acting+Administrator+Wheeler+.pdf)

Section 8: *“The rule would restrict the studies that the EPA can use in regulatory decisions by declaring that “the dose response data and models” that underlie regulations must be transparent and accessible to the public. Such restrictions would severely hamstring the EPA’s ability to protect people from ambient air pollution. While some studies do rely on Medicare claims data and therefore would be able to comply with such a requirement, the sweeping proposal raises concerns about study subject privacy regarding medical records, intellectual property, and reproducibility, among other challenges.”*

40. Fed. Reg. **83**, 18768 (2018)
41. W. Wagner, E. Fisher, P. Pascual, Whose science? A new era in regulatory “science wars”. *Science* **362**, 636–639 (2018). [doi:10.1126/science.aau3205](https://doi.org/10.1126/science.aau3205) [Medline](#)
42. A. A. Rosenberg, L. M. Branscomb, V. Eady, P. C. Frumhoff, G. T. Goldman, M. Halpern, K. Kimmell, Y. Kothari, L. D. Kramer, N. F. Lane, J. J. McCarthy, P. Phartiyal, K. Rest, R. Sims, C. Wexler, Science and regulation. Congress’s attacks on science-based rules. *Science* **348**, 964–966 (2015). [doi:10.1126/science.aab2939](https://doi.org/10.1126/science.aab2939) [Medline](#)
43. S. Cosier, Clever use of public data could sidestep new rule. *Science* **360**, 473 (2018). [doi:10.1126/science.360.6388.473](https://doi.org/10.1126/science.360.6388.473) [Medline](#)
44. J. Schwartz, “Transparency” as Mask? The EPA’s Proposed Rule on Scientific Data. *N. Engl. J. Med.* **379**, 1496–1497 (2018). [doi:10.1056/NEJMp1807751](https://doi.org/10.1056/NEJMp1807751) [Medline](#)
45. G. T. Goldman. Scientific American. Scott Pruitt Will Restrict the EPA’s Use of Legitimate Science. 20 March 2018. <https://blogs.scientificamerican.com/observations/scott-pruitt-will-restrict-the-epas-use-of-legitimate-science/>

Section 9: *“More than 23 million Americans live in areas that exceed the current particulate matter standard and more than a third of the nation’s population lives in areas that exceed the current ozone standard.”*

46. US EPA. Summary Nonattainment Area Population Exposure Report (31 December 2018).
<https://www3.epa.gov/airquality/greenbook/popexp.html>