EPA Disregards Science and the Law in Proposing to Retain NAAQS for Particulate Matter That Do Not Protect Public Health

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Outline

- Clean Air Act mandate for National Ambient Air Quality Standards (NAAQS)
- How Standards Were/Should be Reviewed
- How the Particulate Matter (PM) NAAQS Was Reviewed
- Advice of Dismissed PM Review Panel
- Proposed Rule and Its Flaws
- Next Steps

Statutory Mandate for National Ambient Air Quality Standards

- Section 108 of Clean Air Act
  - Identify and list certain air pollutants
  - Issue **air quality criteria** for those pollutants.
  - In Administrator's "judgment, cause or contribute to air pollution which **may reasonably be anticipated to endanger public health or welfare**;"
  - "the presence of which in the ambient air results from numerous or diverse mobile or stationary sources;"
  - "**accurately reflect the latest scientific knowledge**"

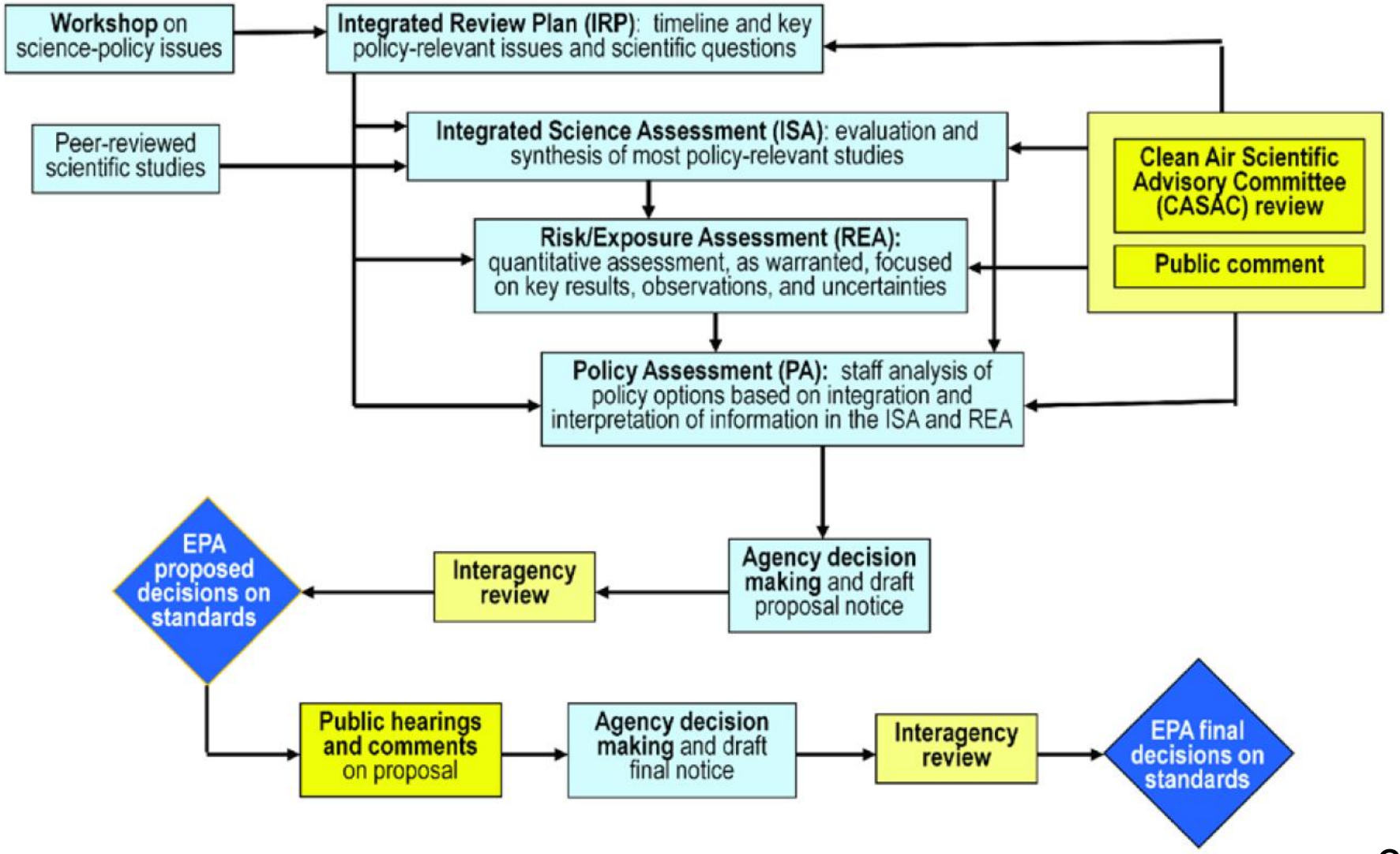
National Ambient Air Quality Standards: "Primary Standard"

- Section 109: "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an **adequate margin of safety**, are **requisite to protect the public health**."
  - Interpretation has been reviewed in numerous court cases
  - Intended to address uncertainties
  - Reasonable degree of protection
  - Does not require zero risk
  - Should address highly exposed or susceptible ("at-risk") populations

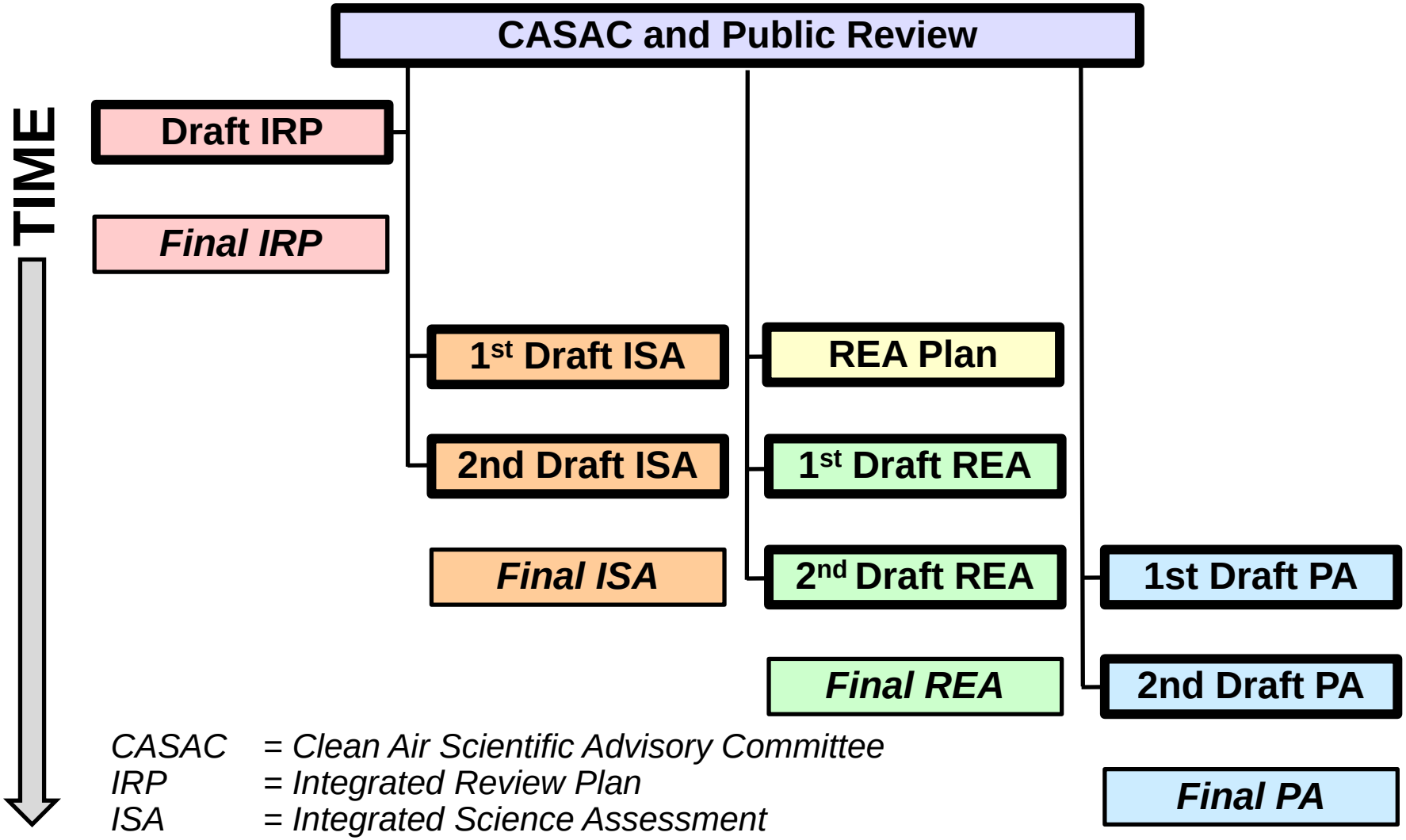
Statutory Mandate for EPA Clean Air Scientific Advisory Committee (CASAC)

- Section 109(d)(2) requires that an independent scientific review committee
  - "shall complete a **review of the criteria** . . .
  - "and the national primary and secondary ambient air quality standards . . .
  - "and shall **recommend to the Administrator** any **new** . . . standards and **revisions** of existing criteria and standards as may be appropriate . . . ."
- Clean Air Scientific Advisory Committee – charter filed with Congress every 2 years.

NAAQS Review Process
(since 2006 (until 2018), with revisions)



Generic "Full" National Ambient Air Quality Standard (NAAQS) Science Review from Document Perspective



CASAC = *Clean Air Scientific Advisory Committee*
IRP = *Integrated Review Plan*
ISA = *Integrated Science Assessment*
REA = *Risk and Exposure Assessment*
PA = *Policy Assessment*

Expertise Needed

- Atmospheric sciences, air quality
  - » Modeling
  - » Measurement
- Exposure Assessment
  - » Modeling
  - » Measurement
- Epidemiology
- Toxicology
- Controlled Human Studies
- Risk Assessment
- Areas of medical specialization
- Others
- Typically need 2-4 experts in key areas to have diversity of perspectives

History of CASAC Review Panels

Review	Primary or Secondary	Years	CASAC Members	Consultants	Total
CO Review	P	1999 to 2000	7	5	12
CO Review	P	1991 to 1992	6	5	11
CO Review Panel	P	2008 to 2010	3	13	16
Lead Review Committee	P,S	1986 to 1990	7	12	19
Lead Review Panel	P,S	2006 to 2008	7	17	24
Lead Review Panel	P,S	2011 to 2013	2	18	20
NOx and Sox Secondary Review Panel	S	2008 to 2011	4	12	16
NOx and Sox Secondary Review Panel	S	2013 to present	1	21	22
Oxides of Nitrogen Review Panel	P	2007 to 2009	7	17	24
Oxides of Nitrogen Review Panel	P	2013 to 2017	4	13	17
Ozone Review Committee	P,S	1987 to 1992	7	12	19
Ozone Review Panel	P,S	1995 to 1996	6	10	16
Ozone Review Panel	P,S	2005 to 2008	7	18	25
Ozone Review Panel	P,S	2010 to 2014	7	13	20
PM Review Panel	P,S	1994 to 1996	6	15	21
PM Review Panel	P,S	2001 to 2006	7	15	22
PM Review Panel	P,S	2008 to 2010	7	15	22
PM Review Panel	P,S	2016 to 2018	6	20	26
Sulfur Oxides Panel	P	2007 to 2010	7	17	24
Sulfur Oxides Panel	P	2013 to 2018	6	16	22

12 Ad Hoc Changes to the Review Process Since 2017

1. Appoint CASAC members based on geographic location, not scientific expertise.

2. Appoint CASAC members based on governmental affiliation, not scientific expertise.

3. Ban nongovernmental recipients of EPA scientific research grants.

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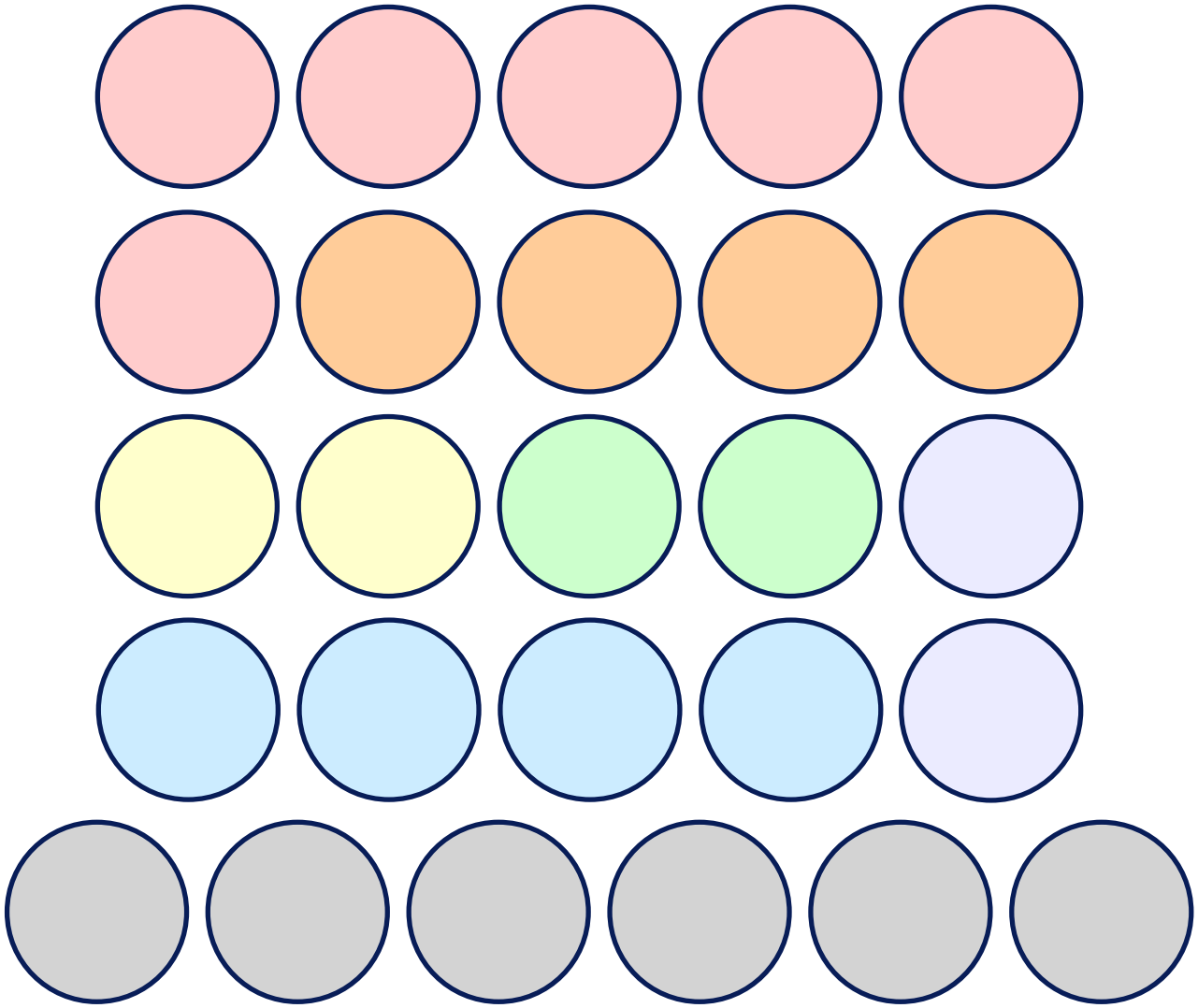
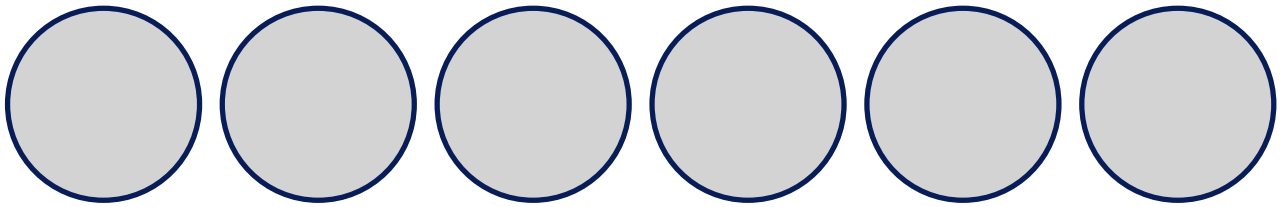
2015 EPA CASAC Particulate Matter Review Panel (20) to Augment CASAC (6 active members)



EPA CASAC Particulate Matter Review Panel Was Dismissed by EPA Administrator Wheeler on 10/10/18



THERE ARE NO EPIDEMIOLOGISTS ON CASAC

12 Ad Hoc Changes to the Review Process Since 2017

4. Replace all seven members of the chartered Clean Air Scientific Advisory Committee

5. Disband the CASAC Particulate Matter Review Panel, which had 20 additional experts

6. Refuse to form a CASAC Ozone Review Panel (the last one had 15 additional experts)

12 Ad Hoc Changes to the Review Process Since 2017

7. Form an ad hoc "pool" of 12 consultants, who cannot deliberate with CASAC

8. Compress the review time frame and reduce opportunities for public review and comment

9. Refuse to provide second external review drafts of complex documents

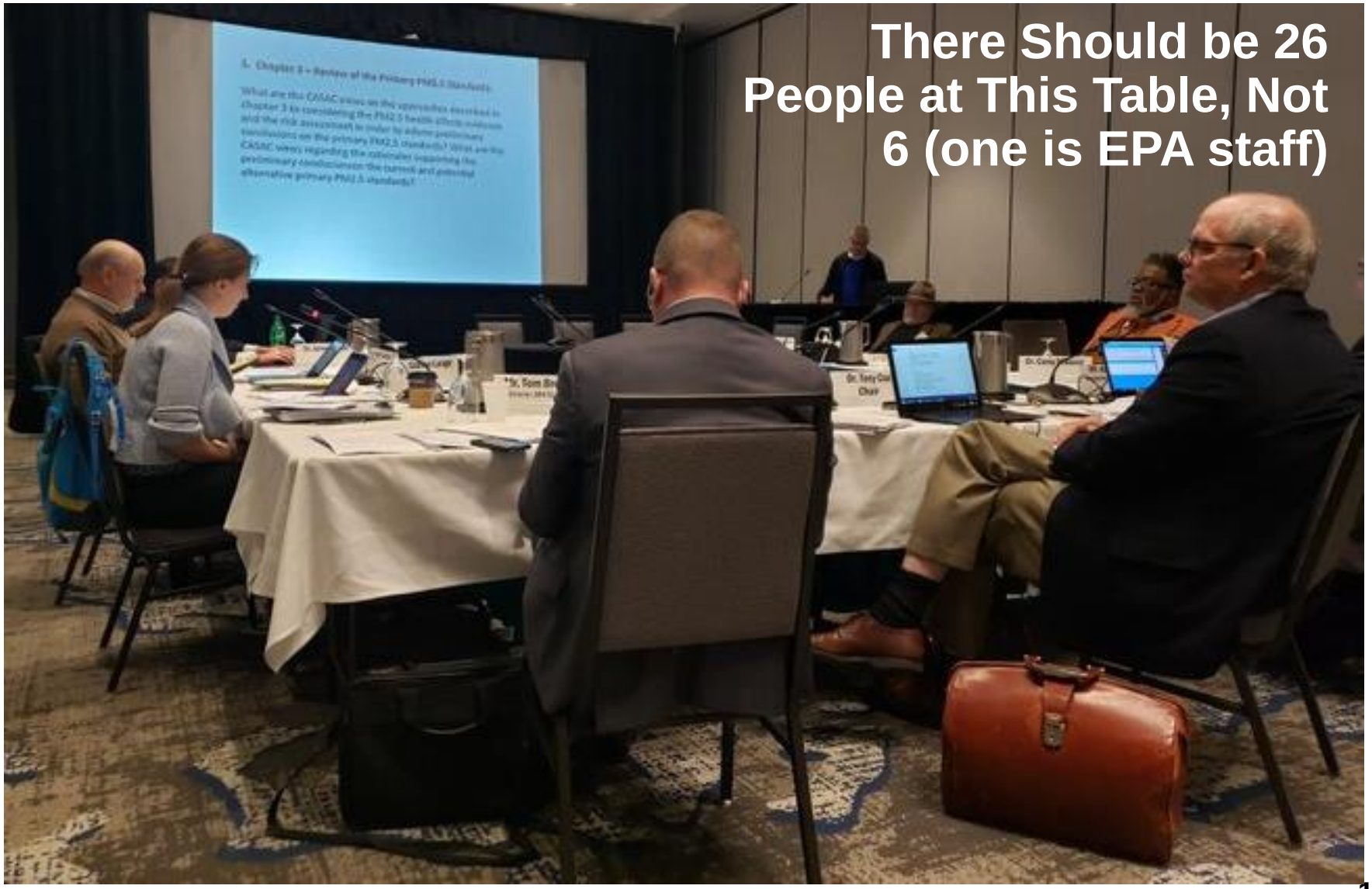
12 Ad Hoc Changes to the Review Process Since 2017

10. Eliminate the planning document for risk and exposure assessments

11. Eliminate separate external review drafts of risk and exposure assessments

12. Commingle development, review, and advice on science and policy documents

Meeting of the Clean Air Scientific Advisory Committee on October 24-25, 2019



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Independent Particulate Matter Review Panel

- Formerly the CASAC PM Review Panel
- Disbanded October 10, 2018
- Met October 10, 2019 to October 11, 2019 in Crystal City, VA
- Follow-up Teleconference October 18, 2019 to finalize report

Independent Particulate Matter Review Panel

- **Dr. H. Christopher Frey**, Chair, North Carolina State University
- **Dr. Peter Adams**, Carnegie Mellon University
- **Dr. John L. Adgate**, Colorado School of Public Health
- **Mr. George Allen**, NESCAUM
- **Dr. John Balmes**, University of California at San Francisco
- **Dr. Kevin Boyle**, Virginia Tech
- **Dr. Judith Chow**, Desert Research Institute
- **Dr. Douglas W. Dockery**, Harvard T.H. Chan School of Public Health
- **Mr. Dirk Felton**, NY State Dept. of Environmental Conservation
- **Dr. Terry Gordon**, New York University School of Medicine
- **Dr. Jack Harkema**, Michigan State University
- **Dr. Joel Kaufman**, University of Washington
- **Dr. Patrick Kinney**, Boston University School of Public Health
- **Dr. Michael T. Kleinman**, University of California at Irvine
- **Dr. Rob McConnell**, University of Southern California
- **Mr. Richard Poirot**, Independent Consultant
- **Dr. Lianne Sheppard**, University of Washington
- **Dr. Jeremy Sarnat**, Rollins School of Public Health, Emory University
- **Dr. Barbara Turpin**, University of North Carolina at Chapel Hill
- **Dr. Ronald Wyzga**, Retired, Electric Power Research Institute

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Independent Particulate Matter Review Panel

- Followed the same process and procedures as we did formerly as the CASAC PM Review Panel
- Developed a letter to the EPA Administrator and Consensus Responses to EPA Charge Questions on the Draft Policy Assessment
- Submitted our report to CASAC, the docket, and the Administrator
- **ucsusa.org/pmpanel**

Acknowledgment of EPA Staff

- The Panel finds that the EPA staff in the Office of Air Quality Planning and Standards have undertaken a good faith effort to produce a first draft of the PA.
- This draft was produced under extenuating, unprecedented, and inappropriate constraints.
- **The Panel commends the staff for this effort.**

Causality: Annual and 24-Hour Exposures to $PM_{2.5}$ and Premature Death

- **Consistent epidemiological evidence** from multiple multi-city studies, **augmented with** evidence from **single-city studies**, at policy-relevant **ambient concentrations** in areas with design values at and **below the levels of the current standards.**
- **Supported** by research from **experimental models** in animals and humans and by **accountability studies**
- **Causal, biologically plausible** relationship between ambient concentration levels well below the current $PM_{2.5}$ standards and adverse health effects, including premature death

Examples of Key Scientific Findings

- The epidemiological evidence is robust across diverse study designs in different populations and locations using a variety of statistical approaches.
- New epidemiologic studies consider large populations and report effects below the current annual standard, either by restricting the cohort analyzed to individuals living in areas with lower ambient exposures, or because average cohort exposures are well below the annual standard.
- The populations in these studies are more than an order-of-magnitude larger than studies available for previous reviews, because of scientific developments in quantification of spatial variability in ambient concentrations using new modeling tools.
- We found no evidence for an ambient concentration threshold for health effects at the lowest observed levels either for annual or 24-hour exposure time periods

Key Studies in the Current Review

Di Q, Dai L, Wang Y, Zanobetti A, Choirat C, Schwartz JD, & Dominici F, Association of short-term exposure to air pollution with mortality in older adults. Journal of the American Medical Association, 318(24), 2446-2456 (2017).

Di Q, Wang Y, Zanobetti A, Wang Y, Koutrakis P, Choirat C, Dominici F and Schwartz, JD (2017). Air pollution and mortality in the Medicare population. New Engl J Med 376(26): 2513-2522.

Ito K, Ross Z, Zhou J, Nádas A, Lippmann M, Thurston GD. National Particle Component Toxicity (NPACT) initiative: Study 3. Time-series analysis of mortality, hospitalizations, and ambient PM2.5 and its components. Boston, MA, Health Effects Institute: 95-125 (2013).

Pinault, L, Tjepkema, M, Crouse, DL, Weichenthal, S, van Donkelaar, A, Martin, RV, Brauer, M, Chen, H and Burnett, RT (2016). "Risk estimates of mortality attributed to low concentrations of ambient fine particulate matter in the Canadian community health survey cohort." Environmental Health: A Global Access Science Source 15(1): 18

Pope CA, Turner MC, Burnett R, Jerrett M, Gapstur SM, Diver WR, Krewski, D and Brook, RD (2015). Relationships between fine particulate air pollution, cardiometabolic disorders and cardiovascular mortality. Circul Res 116(1): 108-U258

Shi L, Zanobetti A, Kloog I, Coull BA, Koutrakis P, Melly SJ and Schwartz JD (2016). "Low-concentration $PM_{2.5}$ and mortality: estimating acute and chronic effects in a population-based study." Environmental Health Perspectives 124(1): 46-52.

Thurston GD, Ahn J, Cromar KR, Shao Y, Reynolds HR, Jerrett M, Lim CC, Shanley R, Park Y and Hayes RB. Ambient particulate matter air pollution exposure and mortality in the NIH-AARP Diet and Health Cohort. Environ Health Perspect 124(4): 484-490 (2016).

Weichenthal S, Lavigne E, Evans GJ, Godri Pollitt KJ and Burnett RT, "$PM_{2.5}$ and emergency room visits for respiratory illness: effect modification by oxidative potential." American Journal of Respiratory and Critical Care Medicine 194(5): 577-586 (2016).

Weichenthal S, Lavigne E, Evans G, Pollitt K and Burnett RT, "Ambient $PM_{2.5}$ and risk of emergency room visits for myocardial infarction: Impact of regional PM2.5 oxidative potential: A case-crossover study." Environmental Health 15:46 (2016).

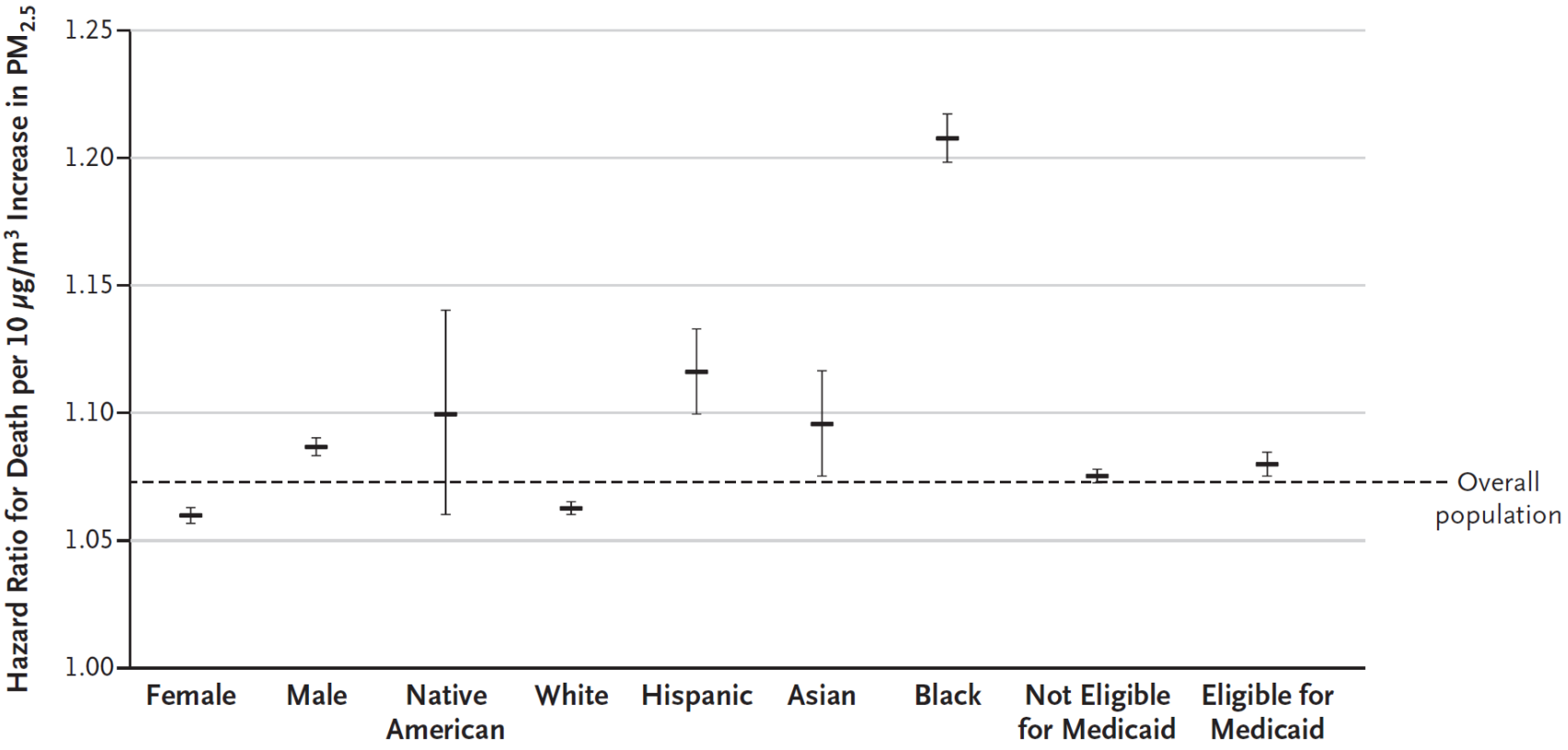
Zanobetti A, Dominici F, Wang Y, Schwartz JD. A national case-crossover analysis of the short-term effect of PM2.5 on hospitalizations and mortality in subjects with diabetes and neurological disorders. Environ Health 13(1): 38 (2014).

Major Findings: Fine Particle Standards

- The current primary fine particle ($PM_{2.5}$) annual and 24-hour standards are **not protective of public health**.
- Retain current indicators, averaging times, and forms.
- The **annual** standard should **be 10 μg/m³ to 8 μg/m³** (versus 12 μg/m³ now).
- The **24-hour** standard should be **30 μg/m³ to 25 μg/m³** (versus 35 μg/m³ now).

At Risk Groups

- Di et al. (2017a) chronic Medicare study shows that the relative risk for African Americans is three times higher than that of the entire population (hazard ratio of 1.21 per 10 μg/m^3 increase in $PM_{2.5}$).



Advice from the Cherry-Picked Rigged CASAC

- Associations between $PM_{2.5}$ exposures and mortality or serious morbidity effects "can reasonably be explained in light of **uncontrolled confounding** and other **potential sources of error and bias**''
- "recent epidemiologic studies reporting positive associations at lower estimated exposure concentrations **mainly confirm what was anticipated or already assumed in setting the 2012 NAAQS**"
- "**do not provide new information** calling into question the existing standard"
- Other members: new evidence "does reasonably call into question the adequacy of the 2012 annual $PM_{2.5}$ [standard]"

Cox, LA. (2019a). Letter from Louis Anthony Cox, Jr., Chair, Clean Air Scientific Advisory Committee, to Administrator Andrew R. Wheeler. Re: CASAC Review of the EPA's *Policy Assessment for the Review of the National Ambient Air Quality Standards for Particulate Matter (External Review Draft—September 2019).* December 16, 2019. EPA–CASAC–20–001. U.S. EPA HQ, Washington DC. Office of the Administrator, Science Advisory Board. Available at: *https://yosemite.epa.gov/sab/sabproduct.nsf/264cb1227d55e02c85257402007446a4/E2F6C71737201612852584D20069DFB1/$File/EPA-CASAC-20-001.pdf.*

THERE ARE NO EPIDEMIOLOGISTS ON CASAC

"Sound Science"

- Tony Cox presentation to NACAA, 5/18/20
- Tony Cox statements during CASAC meetings, e.g., 10/24/20
- My comments to CASAC on 10/24/20:
  - "this CASAC does not understand the statutory mandate of the Clean Air Act for the decision context. **The decision context** is not for Tony Cox to define. … It's **given to you by Congress**."
  - "Dr. Cox has used the phrase **"sound science."** That is often an **ideological statement to require a higher burden of proof than is required by the statute**. Based on his remarks, that's exactly where he's going with this. That's why I emphasize that you need to understand the law."
  - "**you don't have the needed expertise** and the domain knowledge at this table"
  - "**This panel is making judgments**. **You are not conditioned to make these judgments**. A key predicate of expert judgment formation is conditioning based on the full body of evidence. **You don't even have the right disciplines represented at the table**."

Burden of Proof

- The Clean Air Act does not require the burden of proof as assumed by CASAC and imposed by the Administrator
  - Does not require 100% true positives
  - What about false negatives?
- In fact, the CAA requires that EPA regulate based on “anticipated” effects
- Uncertainty is not an excuse to do nothing

Administrator Acknowledgment

"the requirement to provide an adequate margin of safety was intended to address uncertainties associated with inconclusive scientific and technical information and to provide a reasonable degree of protection against hazards that research has not yet identified"

ENVIRONMENTAL PROTECTION AGENCY
40 CFR Part 50
[EPA–HQ–OAR–2015–0072; FRL–10008–31–OAR]
RIN 2060–AS50
Review of the National Ambient Air Quality Standards for Particulate Matter
Proposed action
85 FR 24094

Yet, Administrator's "Rationale"…

- "He concludes that such associations alone, **without supporting experimental evidence at similar $PM_{2.5}$ concentrations**, leave important questions unanswered"
- "lack of studies reporting public health improvements attributable to reductions in ambient $PM_{2.5}$ in locations meeting the current standards"
- "important limitations in the evidence remain"
- "considerable uncertainty"
- "The Administrator proposes to retain the current suite of primary $PM_{2.5}$ standards, without revision, in this review"

Omitted

- The Administrator's Proposed Decision on the Current Primary $PM_{2.5}$ Standards omits:
  - Any mention of at-risk populations
  - Any mention of environmental justice
  - Explanation of why uncertainty means raising the burden of proof rather than anticipating adverse effects
  - Provisional assessment of new evidence since the Integrated Science Assessment

EPA Typically Does a Provisional Assessment of Literature More Recent than that in the ISA

ORIGINAL RESEARCH

American Heart Association.

Associations Between Long-Term Fine Particulate Matter Exposure and Mortality in Heart Failure Patients

Cavin K. Ward-Caviness, PhD; Anne M. Weaver, PhD; Matthew Buranosky, BS; Emily R. Pfaff, MS; Lucas M. Neas, PhD; Robert B. Devlin, PhD; Joel Schwartz, PhD; Qian Di, PhD; Wayne E. Cascio, MD; David Diaz-Sanchez, MD

Background—Environmental health risks for individuals with heart failure (HF) have been inadequately studied, as these individuals are not well represented in traditional cohort studies. To address this we studied associations between long-term air pollution exposure and mortality in HF patients.

Methods and Results—The study population was a hospital-based cohort of individuals diagnosed with HF between July 1, 2004 and December 31, 2016 compiled using electronic health records. Individuals were followed from 1 year after initial diagnosis until death or the end of the observation period (December 31, 2016). We used Cox proportional hazards models to evaluate the association of annual average fine particulate matter ($PM_{2.5}$) exposure at the time of initial HF diagnosis with all-cause mortality, adjusted for age, race, sex, distance to the nearest air pollution monitor, and socioeconomic status indicators. Among 23 302 HF patients, a 1 $\mu g/m^3$ increase in annual average $PM_{2.5}$ was associated with an elevated risk of all-cause mortality (hazard ratio 1.13; 95% CI, 1.10–1.15). As compared with people with exposures below the current national $PM_{2.5}$ exposure standard (12 $\mu g/m^3$), those with elevated exposures experienced 0.84 (95% CI, 0.73–0.95) years of life lost over a 5-year period, an observation that persisted even for those residing in areas with $PM_{2.5}$ concentrations below current standards.

Conclusions—Residential exposure to elevated concentrations of $PM_{2.5}$ is a significant mortality risk factor for HF patients. Elevated $PM_{2.5}$ exposures result in substantial years of life lost even at concentrations below current national standards. (***J Am Heart Assoc.*** **2020;9:e012517. DOI: 10.1161/JAHA.119.012517.)**

Later This Year

- Final Rule
- EPA Will Be Sued

Acknowledgments

- Members of the Independent Particulate Matter Review Panel.
- Union of Concerned Scientists hosted the October 2019 meetings of the Panel. Special thank you to Dr. Gretchen Goldman.
- Mr. Chris Zarba acted in the role of a designated officer for the panel.
- Mr. John Bachmann and Mr. Steven Silverman provided technical and legal clarifications, respectively.

- This presentation has not been reviewed or approved by anyone. The author is solely responsible for its content.

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Report of the Independent Particulate Matter Review Panel is at:

ucsusa.org/pmpanel