Setting National Ambient Air Quality Standards: Role of Science and Judgment

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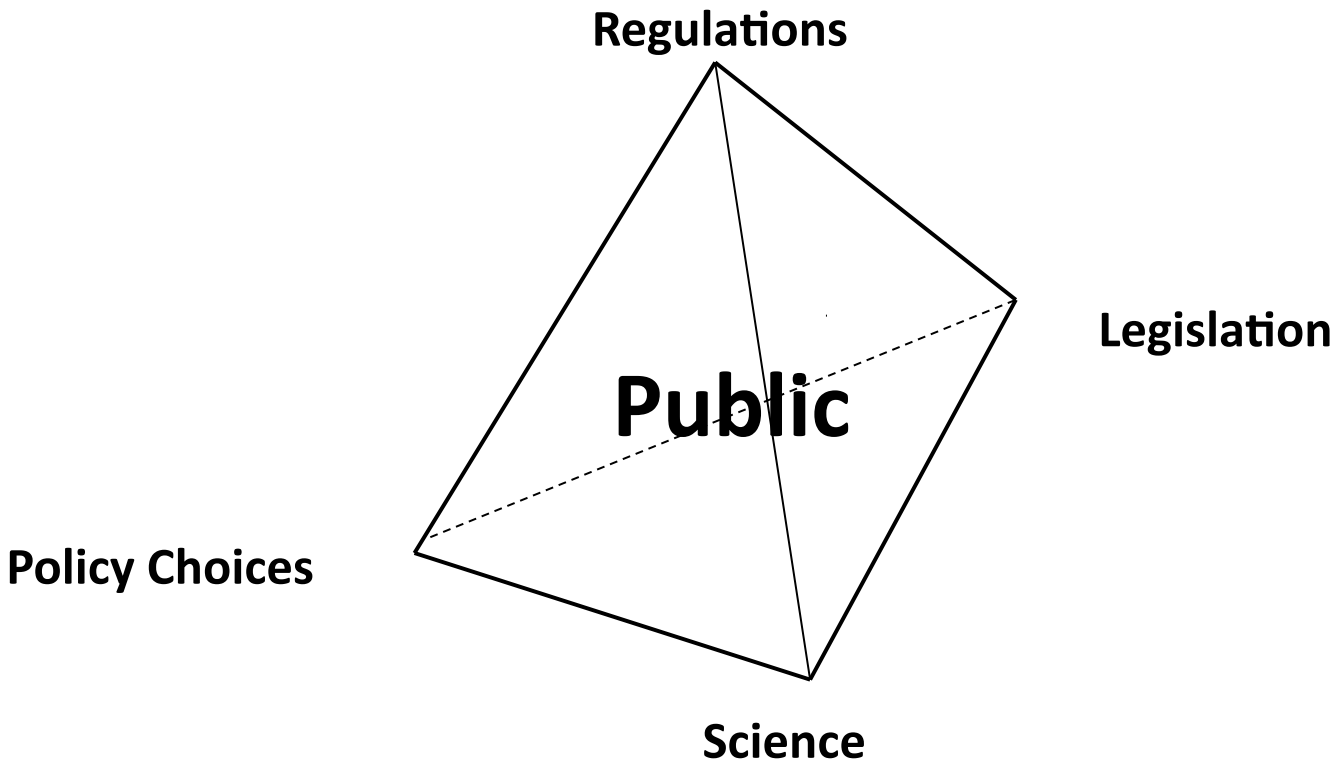
Roger O. McClellan's Declaration of Interest

- **Learned from my grandparents – good jobs and working hard and smart are important and other than hard work deal with everything in moderation**
- **Early experience with potential toxicants was with radiation, radionuclides and essential nutrients**
- **Everything is potentially hazardous, the "dose makes the poison," quantitation is important**
- **Involvement with Ozone began in late 1960s, intensified with passage of Clean Air Acts amendments of 1970**
- **Served on original EPA Science Advisory Board and Chaired Ad Hoc Committee to advise on initial Criteria Document on Airborne Lead (Pre-CASAC), very early learned setting of NAAQS involves more than science**
- **Served on umpteen CASAC Panels, Chaired CASAC (1988-1992)**
- **Worked with individuals from academe, government and industry (some folks are smart and a delight to work with; others you hope you never see again, no sector has a corner on smarts or xxxxx**
- **Been compensated by academe, government and private sector and a lot of time by no one. The views I express are my own!**
- **Conflicts of interest are in the eye of the beholder**

Central Theme:

- **Policy and regulations should be informed by Science.**
- **Science alone is not sufficient basis for policy and regulatory decisions**
- **Judgment is required.**



Scientists need to clearly communicate scientific information divorced from their own personal desired policy outcome.

Science: The body of knowledge that has been accumulated by human kind from repeated, confirmed observations and the testing of hypotheses with well-designed experiments that can be replicated, findings reproduced, and conclusions validated.

Policy Choices: Decisions required or allowed by statute that are made using judgment informed by science and other considerations.

Risk versus Risk

"In the United States and some other industrial democracies, where people and their governments tend to be risk averse, legislatures, courts, and administrative entities usually *create a presumption favoring more safety rather than less*. The definitions of risk in law are often vague ("reasonable certainty of no harm" or "adequate margin of safety") and are likely to encourage an unrealistic belief that risks can be minimized or even eliminated altogether.

Donald Kennedy, Editor-in-Chief, Science 309: 2137 (30 September 2005)

ILLUSTRATION: PAT N. LEWIS

Clean Air Act

Multi-faceted

- Regulates sources
  - Stationary Sources
  - Mobile Sources and Fuels
- Provides for Standards
  - Criteria Pollutants
  - Hazardous Air Pollutants
  - Air Toxics

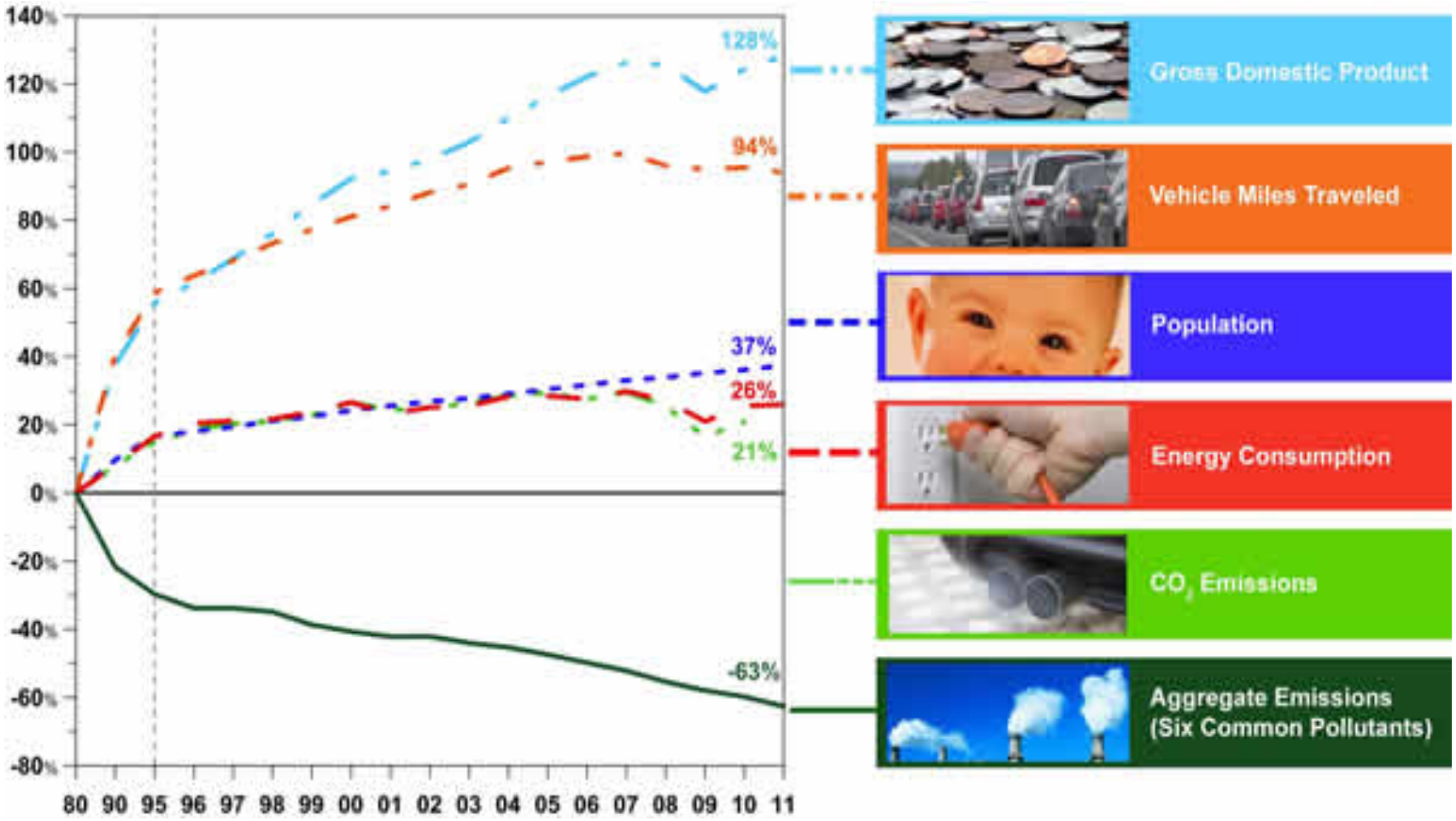
Multiple Parties

- EPA
- State, Local and Tribal Entities
- Public
- Industries

Extraordinarily successful as evaluated by:

- reduced emissions
- improved air quality
- health risks attributable to air pollution reduced

Comparison of Growth and Emissions, 1980-2011



How low is low enough?

Setting National Ambient Air Quality Standards

- **Hazard**: Scientific agreement that when exposures to particulate matter and ozone are sufficiently high, adverse health effects are observed in people.

- **Risk**: Scientific question is what are the adverse health effects at low levels of exposure to particulate matter and ozone.

- **Policy issue** is *how low is low enough?* This is a judgment, informed by science that can only be made by the EPA Administrator.

- **Legislative Language**: Set primary NAAQS using the "latest scientific knowledge" at levels that in the judgment of the Administrator are "requisite to protect public health" while "allowing an adequate margin of safety"

National Ambient Air Quality Standards (NAAQS)

Pollutant [final rule cite]		Primary/ Secondary	Averaging Time	Level	Form
Carbon Monoxide [76 FR 54294, Aug 31, 2011]		primary	8-hour	9 ppm	Not to be exceeded more than once per year
			1-hour	35 ppm	
Lead [73 FR 66964, Nov 12, 2008]		primary and secondary	Rolling 3 month average	0.15 $\mu g/m^3$ (1)	Not to be exceeded
Nitrogen Dioxide [75 FR 6474, Feb 9, 2010] [61 FR 52852, Oct 8, 1996]		primary	1-hour	100 ppb	98th percentile of 1-hour daily maximum concentrations, averaged over 3 years
		primary and secondary	Annual	53 ppb (2)	Annual Mean
Ozone [73 FR 16436, Mar 27, 2008]		primary and secondary	8-hour	0.075 ppm (3)	Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years
Particle Pollution Dec 14, 2012	$PM_{2.5}$	primary	Annual	12 $\mu g/m^3$	annual mean, averaged over 3 years
		secondary	Annual	15 $\mu g/m^3$	annual mean, averaged over 3 years
		primary and secondary	24-hour	35 $\mu g/m^3$	98th percentile, averaged over 3 years
	PM_{10}	primary and secondary	24-hour	150 $\mu g/m^3$	Not to be exceeded more than once per year on average over 3 years
Sulfur Dioxide [75 FR 35520, Jun 22, 2010] [38 FR 25678, Sept 14, 1973]		primary	1-hour	75 ppb (4)	99th percentile of 1-hour daily maximum concentrations, averaged over 3 years
		secondary	3-hour	0.5 ppm	Not to be exceeded more than once per year

as of October 2011

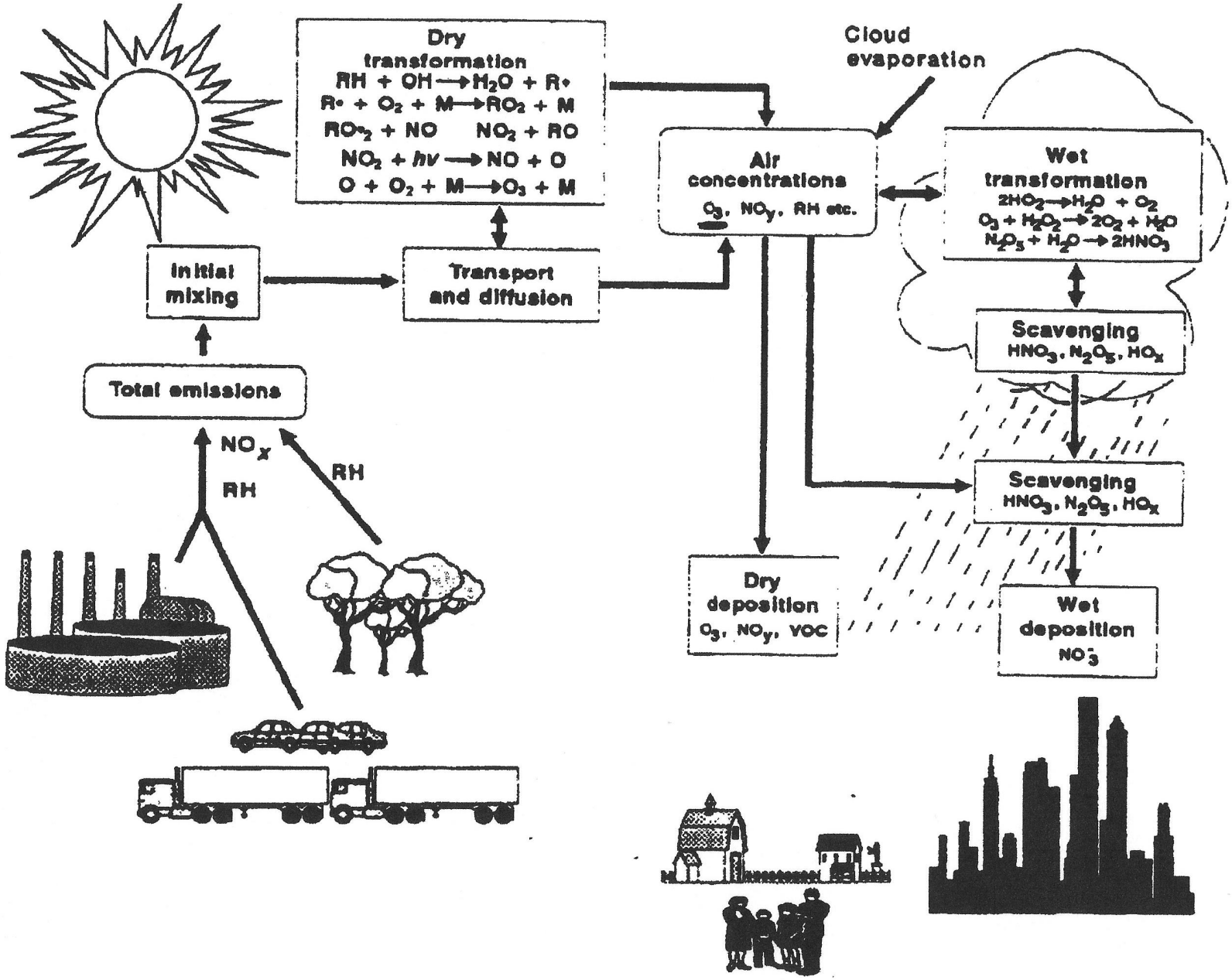
Table of Historical Ozone NAAQS

History of the National Ambient Air Quality Standards for Ozone During the Period 1971-2008

Final Rule/Decision	Primary/ Secondary	Indicator (1)	Averaging Time	Level (2)	Form
1971 36 FR 8186 Apr 30, 1971	Primary and Secondary	Total photochemical oxidants	1-hour	0.08 ppm	Not to be exceeded more than one hour per year
1979 44 FR 8202 Feb 8, 1979	Primary and Secondary	O_3	1-hour	0.12 ppm	Attainment is defined when the expected number of days per calendar year, with maximum hourly average concentration greater than 0.12 ppm, is equal to or less than 1
1993 58 FR 13008 Mar 9, 1993	EPA decided that revisions to the standards were not warranted at the time				
1997 62 FR 38856 Jul 18, 1997	Primary and Secondary	O_3	8-hour	0.08 ppm	Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years
2008 73 FR 16483 Mar 27, 2008	Primary and Secondary	O_3	8-hour	0.075 ppm	Annual fourth-highest daily maximum 8-hr concentration, averaged over 3 years

(1) O_3 = ozone

(2) Units of measure are in parts per million (ppm).



Photochemical air pollution from emission to deposition

Critical Science Issues

- Role of co-pollutants
- Role of socioeconomic covariates
- Nature of ambient concentration-excess risk relationship for health endpoints
- What changes ae adverse
- Spatial and geographic variations in ambient concentrations and health endpoints are dramatic
- Temporal changes including pollutants and other risk factors such as smoking and SES

Use of linear concentration-excess risk and large baseline risks drive calculated excess risk

Supreme Court Justice Breyer
(Whitman v. American Trucking Association)

- **Administrator is not to consider economic cost of implementation in setting NAAQS**

- **Administrator's judgment must be made in a "comparative health" context when "deciding what risks are acceptable in the world in which we live."**

- **Administrator is not required to "eliminate" every health risk….at any economic cost…. to the point of hurtling industry over the brink of ruin." The Clean Air Act gives the Administrator "sufficient flexibility to avoid setting [NAAQS] ruinous to industry."**

- **Industry is the economic driver of a healthy Society. Thus, I feel comfortable substituting Society for Industry in Breyer's guidance.**

Who makes the judgment of "acceptable risk" in setting the level and form of NAAQS?

- Central issue – *How low is low enough?*
- Heated debate over role of EPA Administrator vs. Clean Air Scientific Advisory Committee

Indicator	Old Standard	CASAC	Administrator
$PM_{2.5}$ – 24 hour	65 $\mu g/m^3$	25-35 $\mu g/m^3$	35 $\mu g/m^3$ (2006)
Annual	15 $\mu g/m^3$	13-14 $\mu g/m^3$	15 $\mu g/m^3$ (2006)*
Ozone – 8 hour	84 ppb	60-70 ppb	75 ppb (2008)

***2012, Annual $PM_{2.5}$ NAAQS reduced to 12 $\mu g/m^3$**

The Clean Air Act reserves that judgment exclusively to the Administrator

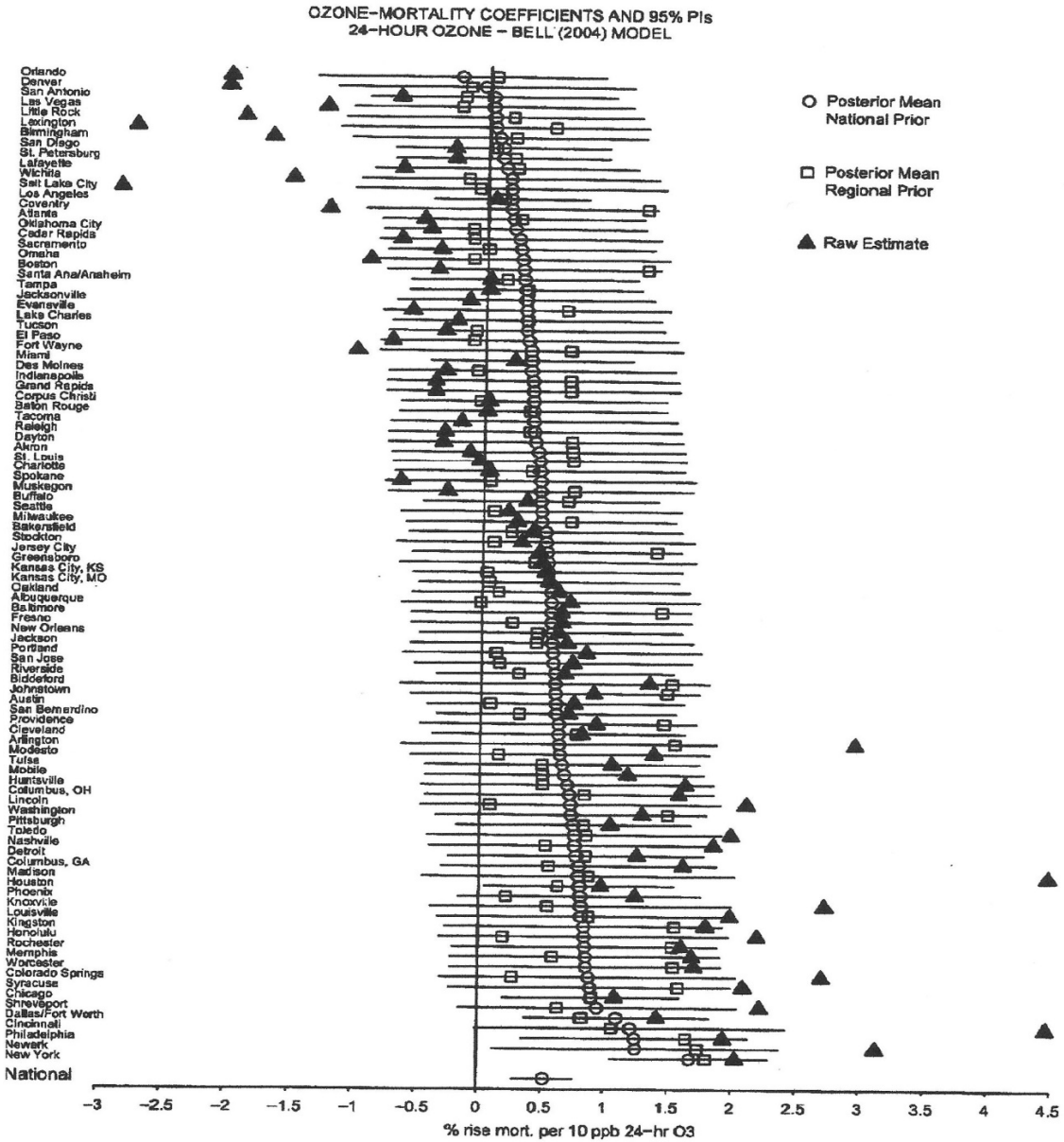


Figure 2. Ninety-five percent posterior intervals for the ozone-mortality coefficients, all-year data, by the hierarchical Bayesian method as in Figure 2 of Bell et al. (2004). The Bayesian posterior estimates under the "national prior" (circles) are shown alongside those for the "regional prior" (squares) and the raw maximum likelihood estimates (triangles) (Figure 1 of Smith et al., 2009).

Should background levels matter in setting NAAQS?

GEOS-CHEM Global Chemical Transport Model

	Fiores et al. (2002)	Wang et al. (2009)
Dimensions		
Spatial (grid cell)	138 x 173 miles	69 x 69 miles
Temporal	24-hour average over summer months	Maximum 8-hour
Concentration (O_3)	15-35 ppb	Up to 60 ppb*

*"We thus find that eliminating US anthropogenic emissions would maintain surface ozone concentrations in the US below 60 ppb at all times."

Is the public & scientific community concerned with the most significant hazards/risks?

Mortality rate ratio = $\frac{\text{Lowest Quartile}}{\text{Highest Quartile}}$ of socioeconomic status .

	All Cause	Heart Disease	Stroke	Diabetes	COPD
Men	2.02	1.88	2.25	2.19	3.59
Women	1.29	1.84	1.53	1.85	2.09

	Lung Cancer	Breast Cancer	Colorectal Cancer	External Causes
Men	2.15	-	1.21	2.67
Women	1.31	0.76	0.91	1.41

Steenland et al. (2004)

Common Sense Policy Judgments by EPA Administrator should consider:

- Complex nature of ozone formation and degradation
- Relative importance of biogenic VOCs, anthropogenic VOCs, anthropogenic NO_x, topography, meteorology and sunlight vary spatially and temporally
- Receptor population demographics vary widely
- Remember in the big picture ambient Ozone concentrations have minor impact on human and environmental health
- Care must be taken in selecting a one size fits all National Ambient Air Quality Standard

Future

- The latest scientific knowledge must be integrated and synthesized to inform Administrator's policy judgments on setting the level and statistical form of the NAAQS

- Clearly articulated policy guidance is needed for deciding *how low is low enough* to minimize controversy

- Policy judgments are going to get tougher to make as Standards go lower and lower. The potential exists for policy makers to argue "the Science made me do it"

- Although costs cannot be considered in setting NAAQS, common sense says the incremental costs of making further reductions will go higher and higher

- Research needs to shift from single risk factors to multiple risk factors to provide information that will guide allocation of resources to maximize health benefits of interventions

My recommendation to the EPA Administrator is:

- **Do not be confused by the conflicting music from the "different scientific bands"**
- **Demand that the scientific community and interested parties (including State Governments and Industry) provide contextual information for the NAAQS decision**
- **How will a decision on setting the NAAQS at varying levels impact the health and economic well being of multiple communities**
- **Where does Ozone stack up as a risk factor on the priority list of concerns for different communities**
- **In my opinion, the Administrator needs to take a common sense view and reaffirm the 2008 NAAQS before erecting a new "ozone standard" at a lower concentration using the same statistical form**

SOUND DECISIONS ARE ALL ABOUT CONTEXT!