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Epidemiological Basis for $PM_{2.5}$ Primary NAAQS

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Epidemiological Studies' Averages Do Not "Translate" into Necessary NAAQS Level (Reason 1)

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- The studies use "composite monitor" $PM_{2.5}$ levels, *i.e.*, the average $PM_{2.5}$ across all of a city's monitors
  - See, *e.g.*, Fed Reg at p. 38932.
- The NAAQS must be achieved by the "maximum" or worst case monitor in each city
- For a city with more than 1 monitor, composite $PM_{2.5}$ level < maximum monitor $PM_{2.5}$
  - Multiple monitors are most commonly found in cities with relatively high $PM_{2.5}$ levels

Actual Monitoring Data Show Composite Levels Are below NAAQS, Even in Non-Attaining Areas

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Average Maximum and Composite Annual $PM_{2.5}$ for CBSAs with 2006-2008 Design Values Exceeding and Just Below Current Annual NAAQS of 15 µg/m³

Design Value Range Selected	Number of CBSAs in Design Value Range	Average of Maximum Monitor Annual Mean (µg/m³)	Average of Composite Monitor Annual Mean (µg/m³)
Greater than 15.0 µg/m³	33	17.2	14.3
Between 14.5 and 15.0 µg/m³	11	14.8	13.6

"CBSA" = Community-Based Statistical Area

Source: Table 1, Anne Smith, Comments on $PM_{2.5}$ NAAQS Proposed Rule, submitted with UARG Comments, Aug 31, 2012.

EPA's Risk Analysis Also Demonstrates that Composite $PM_{2.5}$ Levels Will Be Below the NAAQS Limit

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Risk Assessment Location [1]	Rollback Method	Design Value		Recent Air Quality (2007)	Maximum Monitor-Specific Avg. of 2005, 2006, 2007 Annual Avgs. (Max. M-S) and 2007 Annual Average at Composite Monitor (2007CM) (in µg/m³)											
					15/35 [2]		14/35		13/35		12/35		13/30		12/25	
		Annual	24-Hr	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM
Atlanta, GA	Proportional	16.2	35.0	15.3	15.0	14.2	14.0	13.3	13.0	12.3	12.0	11.4	13.0	12.3	11.8	11.2
	Hybrid [3]				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				---	---	---	---	---	---	---	---	---	---	14	11.76
Baltimore, MD	Proportional	15.6	37.0	13.9	14.8	13.1	14.0	12.5	13.0	11.6	12.0	10.7	12.7	11.3	10.7	9.5
	Hybrid				14.3	13.0	14.0	12.7	13.0	11.8	12.0	10.9	12.3	11.2	10.3	9.4
	Locally focused				15.2	13.6	---	---	---	---	---	---	13.1	12.0	11.0	10.0
Birmingham, AL	Proportional	18.7	44.0	15.7	15.0	12.7	14.0	11.8	13.0	11.0	12.0	10.2	13.0	11.0	11.1	9.4
	Hybrid				15.0	14.2	14.0	13.2	13.0	12.3	12.0	11.4	13.0	12.3	11.3	10.7
	Locally focused				---	---	---	---	---	---	---	---	---	---	12.3	11.4
Dallas, TX	Proportional	12.8	26.0	11.4	12.8	11.4	12.8	11.4	12.8	11.4	12.0	10.7	12.8	11.4	12.0	10.7
	Hybrid				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				---	---	---	---	---	---	---	---	---	---	---	---
Detroit, MI	Proportional	17.2	43.0	13.9	14.1	11.4	14.0	11.4	13.0	10.6	12.0	9.8	12.2	9.9	10.2	8.3
	Hybrid				13.2	11.7	13.2	11.7	13.0	11.5	12.0	10.6	11.4	10.1	9.6	8.5
	Locally focused				14.1	12.6	---	---	---	---	---	---	12.2	11.0	10.2	9.2
Fresno, CA	Proportional	17.4	63.0	17.4	9.9	9.9	9.9	9.9	9.9	9.9	9.9	9.9	8.6	8.6	7.3	7.3
	Hybrid				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				10.1	10.3	10.1	10.3	10.1	10.3	10.1	10.3	8.8	8.9	7.4	7.5
Houston, TX	Proportional	15.8	31.0	13.2	15.0	12.5	14.0	11.7	13.0	10.9	12.0	10.1	13.0	10.9	12.0	10.1
	Hybrid				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				---	---	---	---	---	---	---	---	---	---	---	---
Los Angeles,	Proportional	19.6	55.0	14.6	12.7	9.5	12.7	9.5	12.7	9.5	12.0	9.0	10.9	8.2	9.2	7.0

Source: Table 3-4, EPA, Quantitative Health Risk Assessment, p. 3-25.

EPA's Risk Analysis Also Demonstrates that Composite $PM_{2.5}$ Levels Will Be Below the NAAQS Limit

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Risk Assessment Location [1]	Rollback Method	Design Value		Recent Air Quality (2007)	Maximum Monitor-Specific Avg. of 2005, 2006, 2007 Annual Avgs. (Max. M-S) and 2007 Annual Average at Composite Monitor (2007CM) (in µg/m³)											
					15/35 [2]		14/35		13/35		12/35		13/30		12/25	
		Annual	24-Hr	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM	Max. M-S	2007 CM
CA	Hybrid				13.3	10.5	13.3	10.5	13.0	10.3	12.0	9.5	11.5	9.1	9.6	7.7
	Locally focused				13.9	12.1	13.9	12.1	13.9	12.1	---	---	12.0	10.6	10.1	9.1
New York, NY	Proportional	15.9	42.0	13.8	13.3	11.6	13.3	11.6	13.0	11.3	12.0	10.4	11.5	10.0	9.7	8.4
	Hybrid				13.6	11.8	13.6	11.8	13.0	11.3	12.0	10.4	11.7	10.2	9.8	8.5
	Locally focused				14.3	13.3	14.3	13.3	---	---	---	---	12.3	11.6	10.3	9.8
Philadelphia, PA	Proportional	15.0	38.0	13.4	13.9	12.3	13.9	12.3	13.0	11.6	12.0	10.7	11.9	10.7	10.0	9.0
	Hybrid				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				15.5	13.0	15.5	13.0	---	---	---	---	14.1	11.3	11.8	9.5
Phoenix, AZ	Proportional	12.6	32.0	9.9	12.6	9.9	12.6	9.9	12.6	9.9	12.0	9.4	11.8	9.3	9.9	7.8
	Hybrid				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				---	---	---	---	---	---	---	---	12.2	9.7	10.2	9.0
Pittsburgh, PA [5]	Proportional	19.8	60.0	14.9	13.3	11.6	13.3	11.6	12.8	11.2	11.8	10.5	11.5	10.0	9.7	8.4
	Hybrid				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				15.6	13.2	15.6	13.2	15.3	11.8	15.3	11.2	15.6	11.4	13.9	9.6
Salt Lake City, UT	Proportional	11.6	55.0	11.4	7.7	7.5	7.7	7.5	7.7	7.5	7.7	7.5	6.7	6.6	5.7	5.6
	Hybrid				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				10.8	9.7	10.8	9.7	10.8	9.7	10.8	9.7	10.8	8.8	9.1	7.7
St. Louis, MO	Proportional	16.5	39.0	14.3	14.9	12.9	14.0	12.1	13.0	11.3	12.0	10.4	12.8	11.1	10.8	9.3
	Hybrid				15.0	13.5	14.0	12.6	13.0	11.7	12.0	10.8	13.0	11.7	11.0	9.9
	Locally focused				16.5	14.1	---	---	---	---	---	---	14.2	12.4	11.9	10.4
Tacoma, WA	Proportional	10.2	43.0	9.7	8.4	8.0	8.4	8.0	8.4	8.0	8.4	8.0	7.4	7.0	6.3	6.0
	Hybrid				---	---	---	---	---	---	---	---	---	---	---	---
	Locally focused				8.5	8.0	8.5	8.0	8.5	8.0	8.5	8.0	7.4	7.0	6.3	6.0

Source: Table 3-4 continued, EPA, Quantitative Health Risk Assessment, p 3-26.

Epidemiological Studies' Averages Do Not "Translate" into Necessary NAAQS Level (Reason 2)

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- The $PM_{2.5}$ averages cited in the Proposed Rule are inappropriately low for the chronic risk studies
- Chronic mortality risk accumulates over decades and should be attributed to $PM_{2.5}$ levels prior to deaths
  - E.g., Krewski et al. (2009) is said to find elevated risks in cities with average $PM_{2.5}$ = 14 μg/m^3, but:
    - Deaths in that study occurred during 1982-2000
    - Although $PM_{2.5}$ averaged 14 μg/m^3 in 1999-2000, the same cities' $PM_{2.5}$ averaged 21 μg/m^3 in 1979-1983
    - Therefore, it is not valid to say differences in risk found by that study can be attributed to $PM_{2.5}$ that averaged 14 μg/m^3
- No elevated risk has been found for deaths observed over a period in which $PM_{2.5}$ averaged 14 μg/m^3

Associations Remain as $PM_{2.5}$ Declines, But that Does Not Imply Elevated Risk is Caused by the Lower $PM_{2.5}$ Levels

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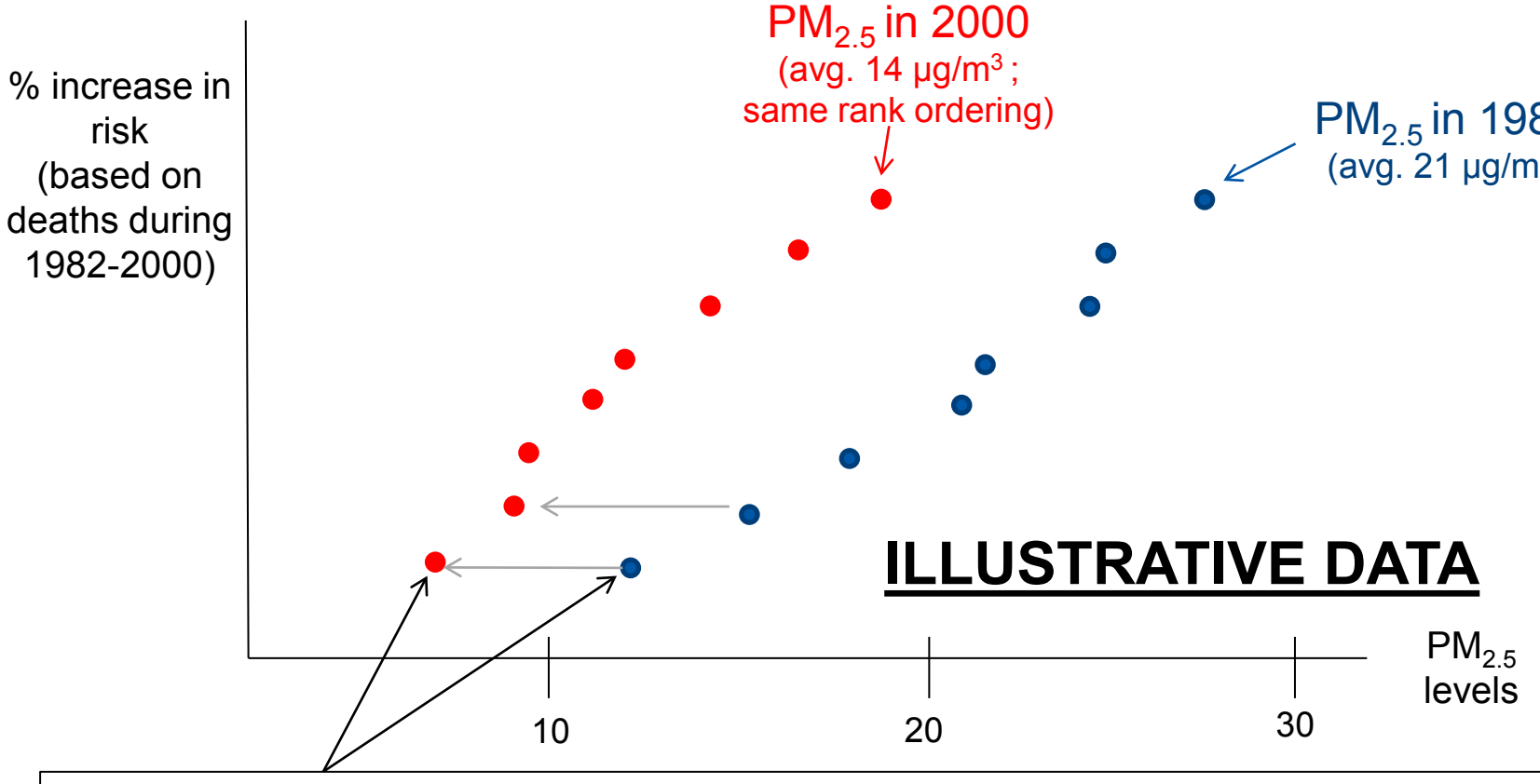
…But Slopes Estimated Using Lower Recent $PM_{2.5}$ Data Are Higher, Which Falsely Implies a Higher Relative Risk per Unit $PM_{2.5}$ Exposure



"The rank ordering of cities by relative pollution levels remained nearly the same" for each city in ACS data when comparing their 1979-1983 $PM_{2.5}$ levels to their 1999-2000 $PM_{2.5}$ levels (Pope et al., 2002, p. 1136)

Increased Estimates of Relative Risk Using Lower Recent $PM_{2.5}$ Levels Is Consistent with What is Actually Reported

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REAL ESTIMATES IN LITERATURE

	Using 1979-83 $PM_{2.5}$ levels (avg = 21 µg/m^3)	Using 1999-2000 $PM_{2.5}$ levels (avg = 14 µg/m^3)
Pope et al., 2002	Relative risk = 4% per 10 µg/m^3	Relative risk = 6% per 10 µg/m^3
Krewski et al., 2009	Relative risk = 4% per 10 µg/m^3	Relative risk = 6% per 10 µg/m^3

Same deaths are being explained in estimates from both columns

New Epidemiological Studies Suggest $PM_{2.5}$ Associations May Not Be Causal

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- Greven et al., *J. of Am. Statistical Assn.*, 2011 and Janes et al., *Epidemiology*, 2007 find that the overall relative risk found in other chronic epi studies is a result of:
  - Strong positive relative risk associated with temporal downward trend in $PM_{2.5}$ shared across all cities
  - Zero relative risk associated with any city-specific deviations from the shared temporal trend
- This evidence suggests that the overall $PM_{2.5}$ association is not causal because:
  - If $PM_{2.5}$ changes cause changes in mortality risk, those changes in risk should be apparent whether the $PM_{2.5}$ changes are occurring in other cities or not.
- These papers make use of richer, recent data sets not available until recently:
  - Continuous $PM_{2.5}$ monitoring data since 1999
  - Huge cohort (18 million - Medicare enrollees)