Ethical Aspects of Fine Particulate Matter Epidemiology

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Fine Particulate Matter ($PM_{2.5}$)

$PM_{2.5}$ is defined by particle size (≤2.5 μm in diameter) and not by chemical composition, as in the case of a gaseous air pollutant like ozone. $PM_{2.5}$ is generated mainly by combustion processes. The major sources of $PM_{2.5}$ are forest fires, agricultural dust, industrial combustion, and diesel engines and these sources vary across the US

$PM_{2.5}$ epidemiology has been used to establish the following two controversial regulations that have had multi-billion dollar economic impacts in the United States and California:

1) 1997 US Environmental Protection Agency Annual National Ambient Air Quality Standard (NAAQS) for $PM_{2.5}$ at 15 $\mu g/m^3$
2) 2008 & 2010 California Air Resources Board Truck and Bus Regulation of Diesel Vehicles in California

"Premature Deaths" Attributed to $PM_{2.5}$

An increased relative risk [RR > 1.00], based on increase in total (all cause) mortality risk for 10 $\mu g/m^3$ increase in $PM_{2.5}$ level, is interpreted by US EPA and CARB as evidence that $PM_{2.5}$ "causes" "premature deaths"

Because EPA assigns a lifetime monetary value of about $7-9 million to each "death," the health benefits of preventing these "deaths" exceed the compliance costs of the EPA and CARB regulations that are designed to reduce $PM_{2.5}$ levels and $PM_{2.5}$-related "premature deaths"

Without $PM_{2.5}$-related "premature deaths" the EPA and CARB regulations are not justified on a cost-benefit basis

Major Reasons for Lack of Proof that $PM_{2.5}$ "Causes" "Premature Deaths"

1) Small Variable Effect: the relative risk of death due to $PM_{2.5}$ is small (RR ~ 1.10), varies by time and place, and there is no consistent dose-response relationship

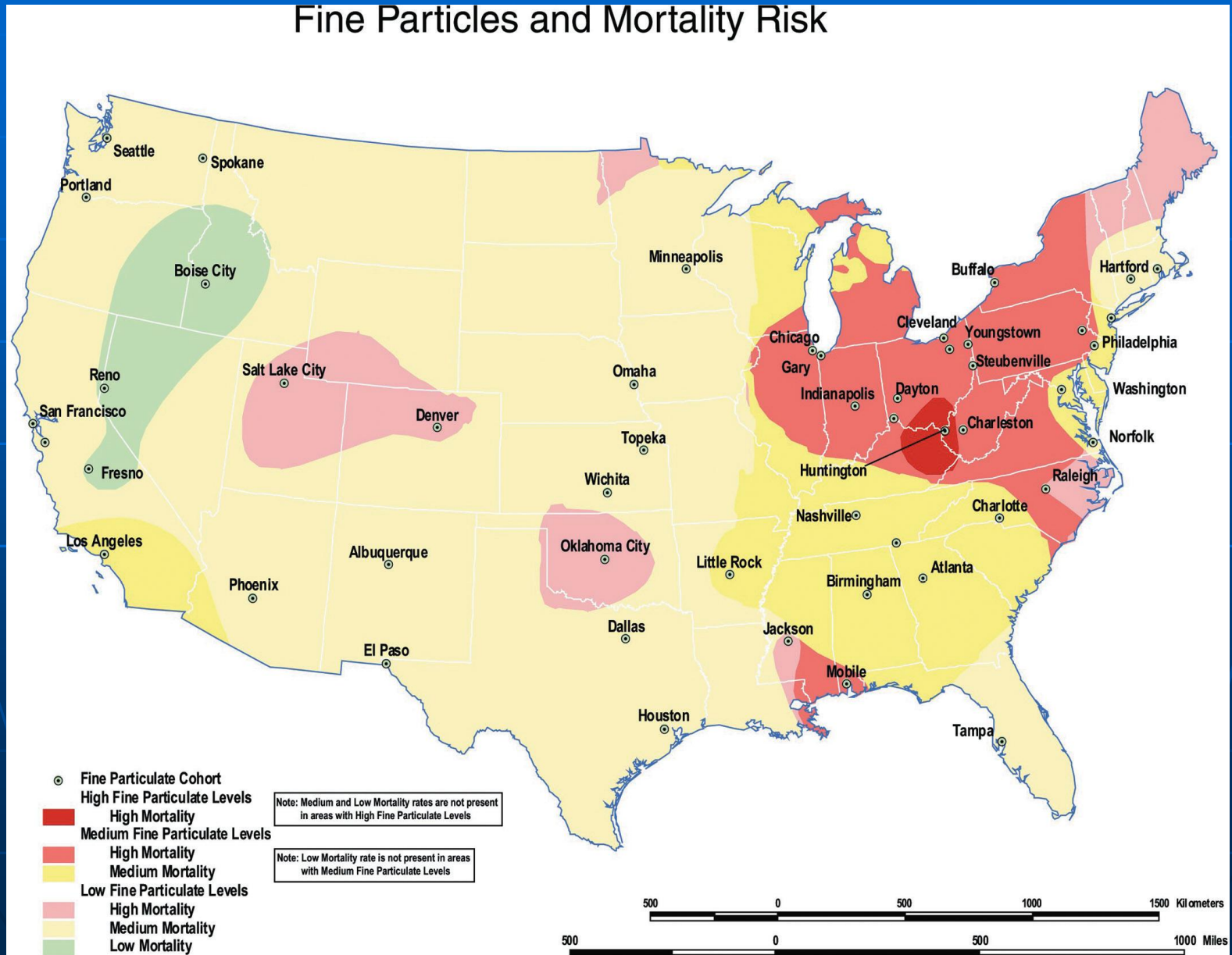
2) Confounding Variables: confounders, including other pollutants, often reduce $PM_{2.5}$ effect to zero (RR ~ 1.00)

3) Ecological Fallacy: $PM_{2.5}$ measurements made at selected monitoring stations are imputed to individuals

4) Variable $PM_{2.5}$: $PM_{2.5}$ is defined by specific particle size, but its composition varies greatly across the US

5) Secret Data: major $PM_{2.5}$ studies (H6CS & ACS) cannot be independently analyzed, violating Data Access Act

2000 Krewski Jerrett HEI Report Figure 21
1982-1989 CPS II $PM_{2.5}$ Mortality Risk <1.0 in CA



$PM_{2.5}$ & Total Mortality in California: RR (95% CI)

(http://scientificintegrityinstitute.org/Enstrom081512.pdf)

McDonnell 2000	AHSMOG (9 air sheds)	RR ~ 1.03 (0.95-1.12)	1976-1992
Krewski 2000 (reported in 2010)	CA CPS II (4 MSAs)	RR = 0.87 (0.81-0.94)	1982-1989
Enstrom 2005	CA CPS I	RR = 1.04 (1.01-1.07)	1973-1982
	(11 Cos & 25 Cos)	RR = 1.00 (0.98-1.02)	1983-2002
Zeger 2008	MCAPS "West" (CA,OR,WA)	RR = 0.99 (0.97-1.01)	2000-2005
Krewski 2010	CA CPS II (7 MSAs)	RR = 0.97 (0.92-1.02)	1982-2000
Jerrett 2010-11	CA CPS II (54 Cos, Nine Model Average)	RR = 1.00 (0.99-1.01)	1982-2000
Lipsett 2011	CA Teachers	RR = 1.01 (0.95-1.09)	2000-2005

Conclusions About $PM_{2.5}$ & Total Mortality in California and US

1) there is NO significant relationship between $PM_{2.5}$ and total mortality in California

2) there is substantial geographic variation nationally (West vs East) in the dose-response relationship between $PM_{2.5}$ and total mortality

3) there is no sound epidemiologic justification for setting a single national standard for $PM_{2.5}$ given the large and clear geographic variation in $PM_{2.5}$ mortality risk

US EPA Proposal to Lower National Ambient Air Quality Standard for Fine Particulate Matter

In spite of clear national geographic variation in $PM_{2.5}$ mortality risk and extensive persistent epidemiologic and statistical problems, US EPA issued proposed rule on June 29, 2012 to lower annual $PM_{2.5}$ NAAQS from 15 $\mu g/m^3$ to 12-13 $\mu g/m^3$ (http://www.epa.gov/pm/actions.html)

Lower NAAQS would impose multi-billion dollar compliance costs on impacted US industries (http://online.wsj.com/article/SB10001424052702303822204577468371370095152.html)

Ethics and Epidemiologic Decision Making for Population Benefits

Professional ethical principles are paramount in determining the best approach to using epidemiologic data to benefit population health:

1) all available epidemiologic evidence must be fairly evaluated and used in decision making
2) population attributable risk must be calculated in a manner that is consistent with all the evidence
3) relationships should be used for regulations only if they satisfy the Hill causality criteria

Conclusion: Above principles and existing epidemiologic evidence indicate US EPA has no justification for lowering the $PM_{2.5}$ NAAQS