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<https://www.acepidemiology.org/2019-annual-meeting>

ACE Luncheon Roundtable
Misuse of Epidemiology Regarding PM2.5 and Roundup
September 9, 2019

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Consistent with the theme of the ACE Annual Meeting, this Roundtable will discuss two substances where real-world epidemiologic evidence has been manipulated and used for designations and policies that are unjustified based upon traditional epidemiologic standards. The two substances are the air pollutant fine particulate matter (PM2.5) and the herbicide glyphosate (Roundup). These two substances are particularly relevant to California because they currently provide the unjustified bases for multibillion-dollar PM2.5 regulations and multibillion-dollar Roundup lawsuits.

Thirty-year abuse of air pollution epidemiology has been used to turn a weak positive relationship between PM2.5 and total mortality (RR ~ 1.1) into the primary public health justification for costly EPA PM2.5 regulations. This weak relationship has recently been shown to be null (RR = 1.0) in a meta-analysis of eight US cohort studies. The problems with this relationship are described in my July 20, 2009 Doctors for Disaster Preparedness Talk "The PM2.5 Deaths Controversy: Combating Pseudoscientists" (<https://youtu.be/8j3a4MBUU40>). Also, a 205-page April 11, 2019 EPA Clean Air Scientific Advisory Committee Review has heavily criticized the Draft 2018 EPA PM2.5 Integrated Science Assessment (<https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsARsLastMonthCASAC/932d1df8c2a9043f852581000048170d!OpenDocument&TableRow=2.3#2>).

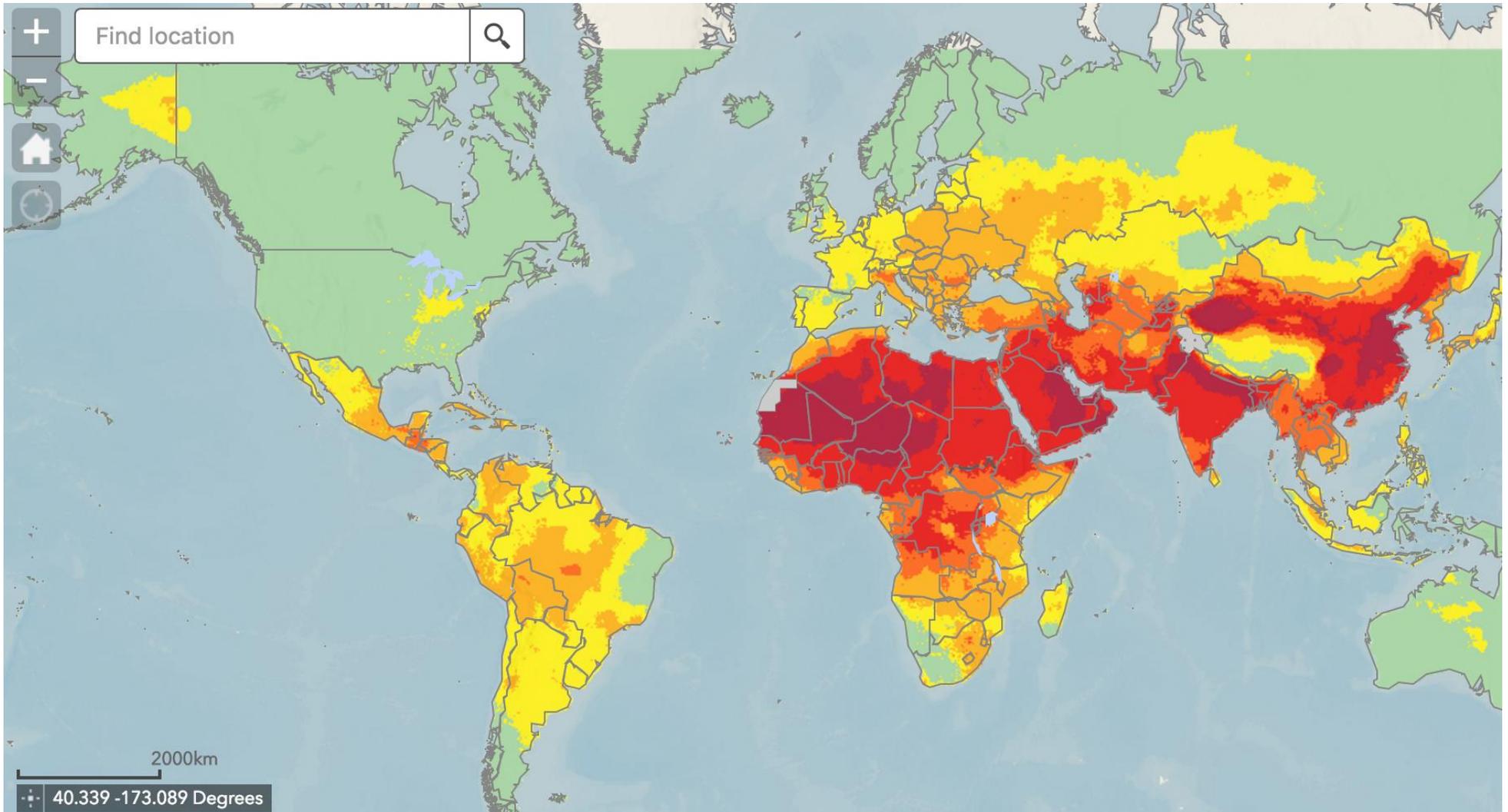
In 2015, IARC became the first agency to classify glyphosate (Roundup) as “probably carcinogenic to humans.” This contested IARC assessment ignored the extensive null epidemiologic evidence in favor of one controversial animal study that suggested a relationship. The ‘cancer’ classification of glyphosate has generated lawsuits in California that have resulted in three recent jury awards of \$289 million, \$80 million, and \$2 billion to plaintiffs who claim their cancer is due to exposure to Roundup. These awards are being appealed, but there are now about 15,000 pending lawsuits that will likely bankrupt the manufacturer of Roundup. Severe criticism of this glyphosate misclassification is given in published articles and a forthcoming article “Who’s Afraid of Roundup?” by courageous epidemiologist Geoffrey Kabat (<https://www.geoffreykabat.com/articles>) and perceptive science writer Paul Driessen (<https://townhall.com/columnists/pauldriessen/2019/02/03/keep-fraudulent-science-out-of-our-courtrooms-n2540723>).

Most of the contested findings on these substances have come from non-epidemiologists who have ignored the traditional epidemiologic standards for establishing a causal relationship and who refuse to cooperate with efforts to confirm that their ‘positive’ findings are transparent and reproducible. ACE Members and Fellows should be aware of this misuse of epidemiology and should combat it.

World Health Organization Map

2015 Annual Mean Ambient PM_{2.5} (µg/m³)

<http://www.who.int/airpollution/en/>



REVIEW & OUTLOOK

A Scientific Roundup

Perhaps you've read that science should rule when determining environmental standards. So why aren't progressives cheering an Environmental Protection Agency order declaring that the chemical glyphosate doesn't cause cancer?

In an extraordinary intervention, the EPA recently said it will no longer approve prod-

uct labels that claim glyphosate is carcinogenic to humans. Glyphosate is the active ingredient in Roundup, the popular weed killer. The herbicide has been on the U.S. market since 1974, and the scientific consensus is that it isn't carcinogenic in humans.

The letter is a rebuke to California, which in 2015 said it would add glyphosate to its official list of carcinogens under the state's 1986 Safe Drinking Water and Toxic Enforcement Act, known as Proposition 65. California cited the World Health Organization's International Agency for Research on Cancer's finding that glyphosate "probably" causes cancer.

This is the U.N. outfit that has warned against cancer from pickled vegetables, caffeine and working the night shift. California's move has inspired a flood of lawsuits against Roundup-maker Monsanto, including a \$2 billion jury judgment (reduced to \$86 million by a judge) in May for a California couple claiming glyphosate caused their cancer.

EPA's letter is an attempt to restore science to the glyphosate debate and counter California's rogue regulation. The letter cites EPA's extensive review of the scientific literature on glyphosate, as well as the concurring judgments of regulators in Canada, Australia, the European

Union, Germany, New Zealand and Japan.

The agency also cites its labeling authority under the Federal Insecticide, Fungicide, and Rodenticide Act, which should pre-empt state law. The EPA letter says it "considers the Proposition 65 warning language based on the chemical glyphosate to constitute a false and misleading

The EPA intervenes against California's rogue cancer regulation.

statement."

The EPA letter should also be evidence in current litigation brought by farm groups against California. In 2018 a federal judge issued a preliminary injunction against California, finding the farm plaintiffs would likely prevail in their claims that the state's cancer-label requirement violates their First Amendment rights.

California's Office of Environmental Health Hazard Assessment responded to the EPA letter by calling it "disrespectful of the scientific process," but the opposite is true. California is the regulatory outlier attempting to impose its standards despite the precedent that federal law sets national standards on health and safety when Congress's language is clear.

The EPA might also make a difference in thousands of lawsuits against glyphosate manufacturers. Many of the suits claim Monsanto and others failed to warn consumers about cancer risks, and defendants can now point out that they are barred by federal regulators from issuing such warnings.

California state judges overseeing current glyphosate lawsuits have largely excluded EPA's conclusions as evidence in court. But anyone who cares about science and the law should welcome the EPA's intervention.



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September 6, 2019

Mary Nichols
Chairman
California Air Resources Board
1001 I Street
Sacramento, CA 95814

Dear Chairman Nichols:

On July 25, 2019, CARB, on behalf of the State of California, announced a “groundbreaking framework agreement” with four automakers—Ford, Volkswagen, Honda, and BMW—to apply certain new greenhouse gas (GHG) emissions standards and related terms to the light-duty cars and trucks the four automakers manufacture for sale in the United States. These automakers have agreed to build vehicles to meet new specified emissions standards beginning with model year 2022 and not to “challenge California’s GHG and ZEV [zero-emission vehicle] programs.” In exchange, California has announced its intention to treat the four automakers’ compliance with the emissions standards and other terms set forth in the “framework” as satisfying CARB’s regulatory program for GHG emissions and ZEVs. Notably, one of the terms of the “framework” addresses credits for model year 2020 vehicles, which appears to have imminent, if not already effective, impacts on cars in commerce today. The State in its announcement of this deal styled it as “an alternative path forward for clean vehicle standards nationwide.”

The purpose of this letter is to put California on notice that this framework agreement appears to be inconsistent with Federal law. Congress has squarely vested the authority to set fuel economy standards for new motor vehicles, and nationwide standards for GHG vehicle emissions, with the Federal government, not with California or any other State. Section 209 of the Clean Air Act prohibits California and other States from adopting or attempting to enforce their own emissions standards. And the Energy Policy and Conservation Act (EPCA) expressly preempts States from setting fuel economy standards for motor vehicles or taking any other action “related to” the regulation of fuel economy. Given the direct, scientific link between tailpipe GHG emissions and fuel economy, any effort by California to adopt or apply the standards and related commitments agreed to in the framework clearly implicates EPCA’s preemption provision. Moreover, the State cannot take any action that does not comply with the requirements of Section 209 of the Clean Air Act.

Under EPCA and the Clean Air Act, it is DOT and EPA that have controlling authority to establish fuel economy and nationwide GHG emissions standards for new motor vehicles in the United

States, and the standards and commitments laid out in the framework agreement have not been issued pursuant to Federal law. Accordingly, CARB's actions in furtherance of the framework appear to be unlawful and invalid. We recognize California's disagreements with the Federal government's policy proposals in this area, but those policy disagreements cannot justify CARB's pursuit of a regulatory approach that would violate Federal law.

Given the importance Congress placed on the authority of DOT and EPA for motor vehicle fuel economy and nationwide vehicle emissions standards under Federal law, we urge you to act immediately to disassociate CARB from the commitments made by the four automakers. Those commitments may result in legal consequences given the limits placed in Federal law on California's authority.

Sincerely,



Steven G. Bradbury
General Counsel
U.S. Department of Transportation



Matthew Z. Leopold
General Counsel
U.S. Environmental Protection Agency

Cc:

Gavin Newsom, Governor of the State of California
Xavier Becerra, Attorney General for the State of California
James Hackett, President and CEO, Ford Motor Company
Shinji Aoyama, President and CEO, American Honda Motor Company
Scott Keogh, President and CEO, Volkswagen Group of America
Bernhard Kuhnt, President and CEO, BMW of North America