

Oral presentation for the US EPA CASAC—Policy Assessment on Small Particles 2019, meeting Dec. 3 2019.

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United States Environmental Protection Agency (EPA) research on human health effects of small particle air pollution consistently violates the rules of science and is not admissible in a federal court under the rules of *Daubert v. Merrell Dow* 509 [U.S. 579](#) (1993).

Justice Blackmun wrote in his *Daubert* opinion that:

1. Trial judges were the gatekeepers for admissibility of scientific evidence and testimony.
2. Scientific testimony and evidence had to be consistent with everyday good scientific practice.
3. The evidence would be assessed to see if it can be tested, peer reviewed, has a known rate of error and is accepted by the scientific community

The Federal Judicial Center published the *Reference Manual on Scientific Evidence in 3 editions, 1993, 2000 and 2011*. The *Manual* states in the chapter on epidemiology written by experts, that the Bradford Hill rules on proof of causation should be followed to produce reliable epidemiological proof of causation.

There are **9 Bradford Hill Rules for proof of causation:**

1. temporal relationship;
2. strength of the association;
3. dose-response relationship;
4. replication of the findings;
5. biological plausibility (coherence with existing knowledge);
6. consideration of alternative explanations;
7. cessation of exposure;
8. specificity of the association; and
9. consistency with other knowledge.

EPA small particles research fails to properly show reliable exposures, biological plausibility, and reported associations are too weak to be proof of causation. A pile of bad studies is not reliable evidence. Weight evidence arguments are fallacious.

The Human Experiments Scandal

In **September 2011** U.S. EPA administrator, Lisa Jackson testified to congress, "Particulate matter causes premature death. It's directly causal to dying sooner than you should."

"If we could reduce particulate matter to healthy levels, it would have the same impact as finding a cure for cancer in our country."

Cancer kills a half-million Americans a year – 25 percent of all deaths in the U.S. annually).

That same month *Environmental Health Perspectives*, published by the National Institutes of Health, reported a human experiment exposing a 57-year-old lady to small particle air pollution in an EPA lab at the University of North Carolina.

The [Nuremberg Code](#); the [Helsinki Accords](#); the [Belmont Report](#); and U.S. common law, statutes, and regulations, to include state laws and the Federal Code "[Common Rule](#)" and [EPA rule 1000.17](#) prohibit human experiments that might cause harm to the subjects.

Steve Milloy and David Schnare filed suit in a Virginia Federal District Court to stop the EPA sponsored human experiments. Wayne Cascio MD, EPA official, admitted in a [sworn affidavit](#) to the court that EPA funded air pollutant human experiments in 10 domestic and 6 foreign medical schools. Dr. Robert Devlin, Senior EPA research scientist admitted in his [sworn affidavit](#) that the EPA funded the human experiments because the epidemiology research wasn't proof of harm from pollutants. The lawsuit was dismissed by the court, on the excuse that Schnare, Milloy and Dunn were not experimental subjects and so they didn't have standing.

EPA hires the National Academy of Science to run cover

EPA hired the National Research Council of the National Academies to investigate the human experiments Congressional and Inspector General Inquiries. It was set up as a [whitewash](#) investigation. The closeted [investigation](#) continued for more than a year and then Milloy found out about it in June of 2016 and demanded a hearing that was held by teleconference in August. The committee membership showed that [13 out of 19](#) members of the committee were significant grantees of EPA, as much as tens of millions of dollars, cronyism and money creates bias. Evidence of NRC committee bias was on display, when in

the 2 hour presentation by Enstrom, Milloy, Young and Dunn, there was only one **question from the panel of 19 members**. The NRC committee published its [news release](#) and a [150-plus-page report](#) that exonerated the EPA for human experiments on the theory that small particles are not acutely toxic or lethal.

The CASAC must insist on good science, reliable science. The EPA has not been producing reliable human health effects science as tasked by the Clean Air Act. The CASAC must insist on good science as the basis for good policy and regulatory efforts.