The Environmental Protection Agency's Particulate Matter Rules: One Physician's Crusade against Cargo Cult Science

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The U.S. Environmental Protection Agency has an annual budget of almost $10 billion, and influence and power far beyond that, with U.S. industry and society always subject to EPA orders, regulations, guidelines, fines, and edicts on environmental compliance.

My effort to expose EPA's bad science and policy making began in the early 1990s, and has culminated in the past 2 years in EPA's admissions, in declarations under penalty of perjury, that inadequate and unreliable science underlies EPA regulatory regimes under the Clean Air Act (CAA).

In the infamous Tuskegee syphilis experiment, innocent black Americans suffered the depredations of advanced syphilis as federal public health agents denied them treatment. Now EPA-sponsored studies deliberately expose human subjects to pollutants that the EPA claims to be toxic, lethal, and carcinogenic. The Tuskegee experiment was unnecessary—the effects of advanced syphilis had been known for centuries. The EPA claims it already knows how dangerous fine-particulate air pollution is, but the agency is funding human exposure experiments with what EPA-published air quality standards say are toxic levels of fine-particulate air pollution.

Environmental Law Course

I was a small-town emergency physician and inactive attorney when the dean of sciences at the local Howard Payne University asked me to teach environmental law for the new undergraduate major in environmental science. I obtained the federal and state statute books and put the course on the curriculum to include adult education for community people interested in compliance issues, as well as the environmental science students.

My study of the economics and politics of environmental regulation led to the conclusion that it involved a form of cargo cult science (fake science that looks like science), as described by Nobel Prize winner Richard Feynman,[1] that develops when government money is lavishly given to people in the academy to support a political agenda built on a false threat of public harm. EPA's cargo cult science was in the area of epidemiology (population studies) and toxicology (study of poisons and harmful substances). It allowed EPA to beat the panic drum and scare people about killer environmental poisons that were not harming anyone in the ambient environment. This coincided with the growth of the radical environmentalist movement, which I would describe as a cult built on pantheism and a commitment to statist control of society.

One of my guest lecturers, an engineer responsible for compliance for Phillips 66 and an alumnus of Howard Payne, said that EPA would eventually take as much as five percent out of the gross domestic product. His predictions didn't seem so exaggerated when, in the mid-1990s, ozone air standards proposed by EPA Administrator Carol Browner under President Clinton were estimated by economists to cost the economy more than $100 billion. Browner pushed ahead in spite of objections and opposition by EPA's in-house Clean Air Scientific Advisory Committee, and all the Democrat administration-controlled executive agency divisions and offices.

Many aspects of junk science in the public health sector promoted by agencies like EPA are explained by biostatistician and lawyer Steve Milloy in his books *Science Without Sense* (Cato, 1995), *Silencing Science* (with Michael Gough, Cato, 1998), and *Junk Science Judo* (Cato, 2001). Other valuable books on bad science are by Peter Huber: *Galileo's Revenge* (Basic Books, 1991); *Phantom Risk: Scientific Inference and the Law* (MIT Press, 1993); and the most extraordinary study of junk science I have read, *Judging Science: Scientific Knowledge and the Federal Courts* (with Kenneth Foster, MIT Press 1997). The last focuses on the question of science as evidence and how rules of evidence should be used to determine admissibility of scientific testimony and evidence in court proceedings.

"Clean" Air vs. Safe Air: Justifying Regulatory Overreach

The cottage industry of air pollution research is committed to the proposition that air pollution panic is justifiable if it allows regulatory reach by the EPA that would satisfy an aesthetic demand for "clean" air. In my opinion, the research community is distorting the intent of the Clean Air Act (CAA), which should have been named the Safe Air Act since it is impossible to make the air "clean" of pollutants (such as dust, for example). The statutory language of the CAA required the EPA to identify harmful air pollution and mitigate the effects, not make the air "clean."

One of the most prominent EPA-sponsored researchers in air pollution is Jonathan Samet, M.D., chair of epidemiology at Johns Hopkins Bloomberg School of Public Health and chair of the EPA Clean Air Scientific Advisory Committee (CASAC). In a 2000 paper in *New England Journal of Medicine*,[2] he claimed that fine particles were causing deaths. This claim was based on an inadequately small association of fine particulates and deaths in a study of 20 cities. Small associations are not proof of causation and could easily be a random effect or result from data mining and dredging.

By the year 2000 EPA had used its junk science to stack up a well-funded and sponsored pile of papers using the same bad methodology and claims as the Samet paper, going all the way back to the Pope[3] and Dockery[4] foundational air pollution studies that created the EPA air pollution research and regulation crusade of the 1990s.

Samet and his fellow air pollution researchers, who had become advocates, would mine the data to find a small association and then announce a threat and crisis. In his 2000 paper,[2] however, Samet made an admission that I thought very important: he could not find a toxic effect from the other EPA criteria air pollutants, carbon monoxide, sulfur oxides, ozone, or ozone precursors such

as nitrogen oxides and volatile organics. Today, however, Samet campaigns against ozone as if he had never written that paper.

After a two-part science and legal critique that I wrote on Samet's 2000 *New England Journal of Medicine* 20-city study of effects of air pollution at the website of the American Council on Science and Health,[5,6] James Enstrom, Ph.D., research professor at the University of California at Los Angeles, contacted me and asked for assistance with his efforts to stop California government efforts to create more air pollution regulations that would harm business and industry. I submitted public comments opposing proposed EPA particulate and ozone regulations in 2006[7] and 2007,[8] with no effect on EPA policy or attitude. EPA continued to make absurd claims that this or that air pollution regulation would save lives.

During that same period, I benefited from the statistics expertise of S. Stanley Young, Ph.D., of the National Institute for Statistical Science in Research Triangle Park, North Carolina.

U.S. EPA Board of Scientific Counselors

In 2007 Enstrom, Young, and I decided to approach EPA's Board of Scientific Counselors (BOSC), an outside independent scientific advisory group that was supposed to monitor and critique EPA science and policy making to encourage research compliance with basic scientific rules. BOSC was composed of members of high professional standing who were in private or state activities, and not EPA employees.

We articulated our positions, based on our areas of concern for BOSC subcommittee meetings in late 2007, and then the executive committee in early 2008. Our pleas and arguments were:

1) Irresponsible and false epidemiology and toxicology by EPA researchers claimed an effect that clearly fell well below any threshold needed to show a toxic effect in observational epidemiological population studies. Evidence for claimed air pollution death effects was inadequate to prove any causation and was asserted without a plausible toxicological mechanism.
2) Studies with multiple inquiries exaggerate the chance of false positives. The EPA was misusing the concept of statistical significance by failing to adjust for the multiple inquiries.
3) The EPA and its sponsored researchers and reviewers ignored studies that disproved their theories and suffered from tunnel vision and confirmation bias. Moreover they persecuted researchers like Enstrom who found results that didn't support the EPA agenda.[9]

I traveled to Maryland to present my concerns in person to the BOSC subcommittee of the Human Health Risk Assessment Committee, and Enstrom and Young presented by telephone. After waiting through hours of presentations by insider EPA officials and researchers before the scheduled public comment period, each of us was allowed only three minutes. Considering the inhospitable reception we received, it was not surprising we were the only outside commenters. Many lectures of an hour or more had been followed by laudatory comments from other EPA employees and officials present. I also noted that the roster of committee members was clearly made up of people who had previously, or would in the future, want to be grantees of EPA largesse. It was definitely a home game, with home umpires.

I reviewed the Board of Counselors minutes for the previous five years and found there were no public comments at Board of Counselors meetings in those years. Even highly placed people in private industry, who were severely affected by its regulations, had no taste for criticizing EPA or its sponsored researchers. Favoritism and influence peddling are constant factors in governmental programs. Enstrom, Young, and I decided that appeals to the supposedly independent BOSC were worthless. Nonetheless, we made presentations to another subcommittee and then the BOSC executive committee.

The CARB Toxic Air Machine Project of 2007-2008

The battle was over at EPA, since it was a fixed game, but at the same time there was a battle going on in California led by Enstrom, which heated up in 2008 because of a new set of diesel engine rules focused on fine-particulate air pollution. These regulations were proposed and supported by research sponsored by EPA and the California Air Resources Board (CARB), a subdivision of the California EPA.

In 2005 Enstrom published his results of a robust and current study on the effects of fine-particulate air pollution in California. The study[10] involved 50,000 people in the years 1973-2002. It showed no premature death effect in California from fine-particulate air pollution. Moreover, California's air pollution of the 1950s and 1960s had declined for 30 years. Nonetheless, the increasing rate of asthma was misrepresented as a sign of an air pollution crisis justifying more air pollution regulations for no discernible benefit. Enstrom was also concerned that economic hardships would prove to be important causes of deprivation and decreased human life expectancy, as demonstrated in reliable population studies.[11]

In 2007, the CARB "solicitation" and review process was set up for a document entitled "Methodology for Estimating Premature Deaths Associated with Long-term Exposure to Fine Airborne Particulate Matter in California." The process included three scientific advisors and six "independent" but paid reviewers well known to, and allies of, CARB. Then CARB staff in May of 2008 released a draft report and proposed regulatory regime, claiming that air pollution caused premature deaths in California. A public comment period began, and the CARB business-as-usual process ran into vigorous critiques[12] submitted by Enstrom and other distinguished public health scientists and engineers in July 2008.

Public criticisms of the CARB draft report included:

1) Panel reviewers were reviewing their own or their close colleagues' air pollution studies.
2) CARB had discarded the Enstrom study and ignored geographic and time trend evidence available in the reviewed research that argued against their conclusions of air pollution death effects in California and the need for more regulations.
3) CARB had failed to adjust for changes in engines and emissions that also made older studies invalid.
4) Basic rules of the sciences of epidemiology and toxicology were violated in the CARB research that made claims based on small associations that were inadequate to claim a premature death effect.

My critique[10, pp 129-135] of the comments document discusses basic principles of scientific evidence that the EPA violates in its overreach. According to the Federal Judicial Center's *Reference Manual on Scientific Evidence*,[13,14] which discusses the magnitude of toxic effect required in observational studies that are used in public health toxicology research, an agent was more likely than not the cause of an individual's disease when the relative risk (RR) is 2.0, that is, a 100 percent increase in the disease or effect (e.g.

premature death) in the exposed population. For example, the research on effects of cigarette smoking showed the RR of lung cancer in cigarette smokers is 10.

An RR greater than 2.0 would permit an inference that an individual plaintiff's disease was more likely than not caused by the implicated agent. None of the cited foundational and supportive studies EPA or CARB use to justify air pollution regulatory regimes have the minimum RR of 2 needed to assert evidence in associations of causation.

While epidemiologists study population effects, toxicologists study adverse effects. In the early 1950s, Sir Austin Bradford Hill, British icon of public health research, originated nine criteria referred to by the Federal Judicial Center in the *Reference Manual* for proving toxicity. Hill's first and most important criterion was evidence of a measurable and significant toxic effect. Other criteria include that the toxic effect proposed has to be plausible, has to make temporal and dosage exposure sense, and should be evaluated to make sure some other factor is not in play.[15]

EPA has consistently disregarded the Bradford Hill criteria, in particular using small associations that fail the test of adequate evidence of effect. There is no real knowledge of actual exposure of individuals alleged to be affected or dead, and certainly no assurance that outside air quality is the exposure that is appropriate to measure, since people spend the majority of their time indoors. A final and important consideration is that EPA research shows no evidence of a current understanding of a plausible mechanism for fine-particle toxicity or lethality.

CARB staff in October 2008 issued a final report that was the same as the preliminary draft report of May 2008. CARB staff admitted that they didn't show the public scientific critiques to the expert panel or request an expert response to those criticisms of CARB research conclusions or policy proposals.

In December 2008, Enstrom and three other prominent California air pollution experts directly contacted CARB board members to urge rejection of the 2008 report. The four also wrote a public letter to CARB to recommend that CARB reassess the report and delay any decision on air pollution and diesel regulations.[16]

Enstrom and Young checked the credentials of Hien Tran, lead author of the CARB Report on Fine Particles and Premature Death in California, and found that he had a fake Ph.D., purchased for $1,000 from a drop box, Thornhill University.[17] Enstrom and others also pursued another scandal—that CARB executive Mary Nichols knew of the Tran fraud and had not reported it to the CARB Board before Dec 12, 2008, when it voted to approve the Truck and Bus Regulation. Enstrom's research into the enabling legislation for CARB also found that most members of the Scientific Review Panel on Toxic Air Contaminants had served in their positions longer than the specified term of 3 years without following the nomination and appointment process of members required by the 1983 enabling statute. Pacific Legal Foundation filed a lawsuit in June 2009 to force compliance with the nomination and appointment process, resulting in the removal of five of the nine members.

A taxpayers' protest was held with speeches and demonstrations at the State Capitol on Aug 28, 2009, reinforced by the sound of a 220-truck convoy sponsored by the California Dump Truck Owners Association (now the California Construction Trucking Association). The convoy circled the Capitol building and, on cue, sounded truck horns for one minute. The convoy and the Capitol steps rally on California agency overreach were not covered by the press, but the legislators were there.

Business leaders and industry sectors that use diesel engines raised their voices. Dr. Bill Wattenberg, an engineer and influential talk show host from San Francisco's KGO, railed against CARB. Bloggers and other radio hosts joined in. Bryan Bloom, Lee Brown, and Betty Plowman and other trucking industry people were eloquent in public meetings. Jay McKeenan for the California Independent Oil Marketers Association, representatives of the logging industry organizations, Bill Davis with the Southern California Contractors Association, and Shelly Sullivan of the California Manufacturers and Technology Association, all pressed for a CARB suspension of the new diesel rules and a sensible agency retreat from its aggressive stance. Skip Brown, construction executive, was a steady and important participant as a speaker and writer.

California Assemblyman Roger Niello (R-5th Assembly District) presented a bipartisan letter with 52 signers demanding that CARB suspend the new diesel rules. Senator Robert Dutton (R-31st Senate District) and Assemblyman Dan Logue (R-3rd Assembly District) introduced bills to slow down CARB implementation plans on greenhouse gas and global warming regulations. Gov. Arnold Schwarzenegger weighed in to advocate a suspension of any new fine particulate/diesel regulations until the California economy could recover.

As a result of this 2-year campaign, CARB attempted to repair its damaged reputation for reliable research with a full-day scientific discussion and "cage match" debate on Feb 26, 2010 at the California EPA hearing room in Sacramento.

CARB designated three experts from the original scientific review panel: Daniel Krewski, Ph.D., Michael Jerrett, Ph.D., and Arden Pope, Ph.D., well-credentialed and also longtime friends and beneficiaries of CARB and EPA grants, members of the insider air pollution club with senior status. CARB paid for them to appear just as they had paid for previous research and review work.

Krewski has headed a large group that did a national study.[18] A close look at the results showed that they found no air pollution "associations" that would support a claim of human health effects in California, but they ignored their own results, which would argue against their basic premise. During the symposium, Jerrett admitted that he couldn't find an air pollution health effect in California, but a year later he manipulated the data to show a minor association in one of his models[19] created by a trick in methodology and geographic gerrymandering that he called "conurbation."[20] As noted above, the Pope and Dockery group[3,4] have been prolific and always predictably produced studies with very weak associations that they claim support their position that air pollution kills.

For the opposing public critics, James Enstrom, Ph.D., Fred Lipfert, Ph.D., Robert Phalen, Ph.D., Roger McClellan, D.V.M., Suresh Moolgavkar, M.D., Ph.D, and Tom Hesterberg, Ph.D., M.B.A., appeared. These well-qualified researchers urged no more regulations and no more exaggeration of the science on air pollution health effects.

The webcast is seven hours long.[21] The net effect was that the public commenters exposed the nature of the CARB malfeasance on human health effects science, and demonstrated that the CARB research project was a setup that involved conflicts of interest and a failure to objectively evaluate competing data and evidence on the question of California air quality and its effect on health.

No regulatory relief came from the debate and the proof of CARB malfeasance, and CARB proceeded with the originally planned air pollution regulations.

Washington Politics

The Space Science and Technology Committee of the House of Representatives contacted me in 2010, and I provided information from the CARB wars and the previous challenges of EPA air pollution research claims and policy making. Congress had hearings in the fall of 2010 and through 2011 on EPA air pollution research and regulations. In 2011 and 2012, the House Energy and Commerce Committee also had activities and an interest, and in February 2012 former chairman Rep. Joe Barton (R-Texas) gave a speech outlining the perfidy of the EPA on many aspects of science and policy, as well as legal aspects of EPA misconduct.

Barton condemned:

- EPA's refusal to assess risk and benefit on regulations;
- EPA's burdensome and nonsensical power plant regulations;
- EPA's failure to cooperate with congressional oversight;
- Persistent and flagrant conflicts of interest among EPA researchers and advisers who receive tens of millions of dollars in research grants from the agency while serving as reviewers of EPA research;[22]
- EPA researchers' refusal to comply with basic rules of public health research in toxicology and epidemiology;
- Inappropriate reliance on the precautionary principle;
- Circumvention of congressional oversight; and
- Grant-giving to non-governmental advocacy groups that then enter into collusive lawsuits and aggressive regulatory requests that promote the agency's agenda and expand its regulatory and political power.

As Barton pointed out, "I believe that the American public and taxpayers should not be paying for an agency that manipulates data and funds researchers in the form of exterior grants, who in turn serve on the internal committees within the EPA to create policy and work in an oversight capacity. This is an incredible conflict of interest to the American public."[23]

Rep. Barton's dressing-down of EPA and its administrator was a first step in the right direction. But now Rep. Barton and his colleagues need to follow through by implementing real solutions that will stop EPA's regulatory excesses.

EPA and the Admissibility of Scientific Evidence

EPA research on human health effects of 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). The Daubert majority opinion, written by Justice Harry Blackmun, discarded the old rule of "generally accepted" for scientific testimony and evidence, from the 1923 case of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923) and adopted new, more rigorous tests for admissibility of science testimony and evidence, under Federal Rules of Evidence (1975), particularly Rule of Evidence 702 on Testimony by Experts. The rule provides that if scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue (Rule 104 test), a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

In his written opinion, Justice Blackmun provided an erudite discussion on the philosophy of science, with a strong dose of the theories of a respected philosopher of science, Karl Popper.

Justice Blackmun's major points were as follows:

1) Trial judges were the gatekeepers to assure that reliable science was admitted as evidence.
2) Scientific testimony and other scientific evidence had to be consistent with everyday good scientific practice.
3) The science would be assessed generally as follows:
   a. The general acceptance rule of Frye did not survive the new Federal Rules of Evidence.
   b. Knowledge is more than subjective belief or unsupported speculation; it must be supported by evidence and proven methods.
   c. An expert witness is permitted wide latitude under the federal rules of evidence to offer opinions, including those that are not based on firsthand knowledge or observation.
   d. Under Federal Rule of Evidence 104, a federal trial judge must determine the threshold question of whether the evidence is relevant and material to the case and will assist the trier of fact.

Justice Blackmun continued that if the threshold test of Rule 104 is satisfied (3d above), then the judge, in applying the rules of *Daubert*, must assess the admissibility of the scientific evidence and testimony on the basis of four tests under Federal Rule of Evidence 702 on Testimony of Experts:

1) Whether the theory or technique can be and has been tested;
2) Whether the theory or technique has been subjected to peer review and publication (this test is not dispositive, only additive);
3) Whether the technique or method has a known or potential rate of error; and
4) Acceptance of the theory or technique within a relevant scientific community of scholars.

Professor Michael Fenner of Creighton Law School wrote a helpful, in-depth review of the *Daubert* opinion.[24] In *Judging Science*,[25] Kenneth Foster and Peter Huber (MIT Press 1995) also review and analyze *Daubert*, providing much background analysis on the problems of junk science and fallacious science and also on the methods that produce reliable evidence and avoid scientific negligence and misconduct.

The Federal Rules of Evidence provide a means to challenge EPA-sponsored research, claims, conduct, actions, and policy-making. The burden of the challenge to an action, or ruling or fine or penalty, is to prove that the agency was arbitrary and capricious in its analysis of the pertinent science and research on human health effects and detriment. A common-sense understanding of those words entails actions taken without good justification or rationale. The courts have been inclined to be excessively deferential and allow agency hegemony, even refusing to hear arguments on the arbitrary and capricious standard for agency acceptance of scientific research assertions.

Jurisprudence allows for judicial deference to agency discretion in matters of ambiguous statutory provisions, described by Justice Antonin Scalia in *Whitman v. American Trucking Association*.[26] What the erudite Justice Scalia fails to constrain is the inordinate and inappropriate expansion of the deference allowed EPA in reference to interpretation of ambiguous statutory language to include arbitrary and capricious agency acceptance of what would be arguably inadmissible scientific testimony and evidence.

Judges are, however, and always have been, the ones to decide what's admissible as evidence. Agency discretion under

the jurisprudence of the *Chevron* decision[27] should not allow unreliable scientific evidence into the record under the rules of Daubert, whether it's a hearing or a trial. The evidence must be admissible for purposes of proving that the agency is or is not being arbitrary or capricious, which makes the decision on evidentiary admissibility and reliability separate from whatever idea the court might have about agency authority and discretion.

Unreliable scientific evidence is inadmissible and therefore cannot be used to justify agency actions. The admissibility rulings on evidence trump some arcane idea about agency discretion that is all tied up in the jurisprudence on congressional delegation. There is no law that Congress has passed that permits agencies to use and promote junk science.

In the excessive support of congressional delegation to agencies under the statutes, and the general deference for agency discretion under *Chevron*, Scalia allows EPA research to cheat and avoid a challenge under the "arbitrary and capricious" standard. Justice Scalia just plain ignores the commonly and legally understood meaning of "arbitrary and capricious." Proposing inadmissible scientific evidence and testimony on critical research assertions that are foundations for policy and regulatory action would certainly cross the threshold of "arbitrary and capricious" under the Administrative Procedure Act.

The Role of the Administrative Procedure Act (APA)

The Administrative Procedure Act (APA) allows a successful challenge of agency conduct when that action is arbitrary (without good reason) and capricious (on a whim and without a good reason). Violating scientific rules, like the ones that are clearly outlined in the *Reference Manual on Scientific Evidence*[11,12] to educate judges on science, would certainly raise the question of irrationality that is the fundamental issue for claiming that an agency has acted in an arbitrary and capricious manner.

The courts have, however, been very lenient with the EPA on the violations of scientific rules and provided many opportunities for agencies to violate the rules of science, so legislative actions may be necessary to force better science and policymaking at EPA. The alternative is to find a judge with integrity and an appellate court that doesn't undermine a judgment of inadmissibility, or will entertain and find valid an appeal to reverse an improper judgment on *Daubert* admissibility.

Legislative Remedies

In the political sphere, Congress can modify standards of administrative and judicial review to demand good science and a better standard for agency conduct, with more reasonable rules on challenges to EPA actions. This is similar to the rules for challenges to actions by the Occupational Safety and Health Administration, which carry a preponderance-of-evidence burden.

The pertinent legislative act is the Congressional Review Act (CRA), found at 5 U.S.C. 801, which allows Congress to jump in when the agencies are involved in misconduct. CRA was enacted as section 251 of the Contract with America Advancement Act of 1996, also known as the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA). The law allows Congress to review, by means of an expedited legislative process, new federal regulations and, by passage of a joint resolution, to overrule a regulation.

Another legislative effort to bring the pressure to bear on the federal agency and their sponsored researchers is the Data Quality Act, which requires agency-sponsored research to hold to good scientific principles or be subject to review and possible modification or recision.

Even without legislation, responsible, competent, and serious legislators can find reasons to question EPA conduct, and lawyers can frame evidentiary challenges so that the courts and administrative hearings will be required to make clear rulings on admissibility of scientific evidence with an accompanying rationale for appellate review.

A bad evidentiary ruling is a reversible error; a good ruling will nurture good science in the courtroom. No lawyer but a pettifogger would admit to arguing for bad science that violates the public trust.

At present EPA, following Samet,[28] asserts the theory of "no threshold" for a toxic effect of air pollution, allowing EPA to pursue any pollutant to the last molecule. This impossible goal allows for unlimited expansion of EPA power. Chemical toxicology still is based on thresholds. "No threshold" chemical air pollutant toxicology turns the Clean Air Act (42 USC 7401. 1963, amended 1970, 1990) on its head and nullifies and abandons the strategy Congress intended.

Human Experimentation Scandal

As previously described in this journal,[29] EPA has been sponsoring research in which human subjects are exposed to air pollutants at levels far exceeding those EPA declares to be toxic or lethal. It is illegal, unethical, and immoral to expose experimental subjects to harmful or lethal toxins.[30] The *Reference Manual on Scientific Evidence*, 3rd ed. (2011), [12, p 555] declares that exposing human subjects to toxic substances is "proscribed" by law, and cites case law. The editor of *Environmental Health Perspectives (EHP)* refused a request by Steve Milloy of *JunkScience.com* to withdraw a paper based on one such study and conduct an investigation.[31]

According to information obtained by Milloy from a Freedom of Information Act (FOIA) request, a University of North Carolina research study exposed 42 people to what EPA says are harmful or lethal levels of fine particles, with some receiving 10 times EPA's declared safe level of 35 micrograms per cubic meter of air. The EPA human experiments described were conducted from January 2010 to June 2011, and ended three months before then-EPA Director Lisa Jackson's congressional testimony, during which she still asserted dramatic claims of the lethality of small particulates less than 2.5 microns in diameter ($PM_{2.5}$), claiming thousands of deaths and hundreds of billions of dollars in economic consequences from the deaths and disabilities caused by fine particles.

There have been no publications of toxic effects as declared by the authors of the paper, other than the one case report of a cardiac arrhythmia described earlier;[29] the researchers failed to report that none of the other subjects had any adverse effects,

despite the obligation of researchers to report results both for and against their hypothesis.

Did EPA risk the deaths of 42 subjects? Or are EPA officials lying in their testimony about the dangers of small-particle air pollution and deliberately misleading Congress and the public?

After filing complaints with EPA officials and the editor of *EHP*, Milloy and I filed complaints with the North Carolina Board of Medicine and the University of North Carolina (UNC) School of Medicine. The North Carolina medical board found no violation of the Medical Practice Act by the physicians, and no action was taken by the UNC School of Medicine.

A lawsuit was filed in Federal District Court in Arlington, Va., to ask for injunctive relief or a remedy that would stop the human experiments. The Court said it didn't have the authority or jurisdiction to stop the human experiments, but declarations under penalty of perjury obtained from officials of the EPA research team at UNC Chapel Hill School of Medicine were revealing.

Eugene Cascio, M.D., a lead EPA physician in the research team, declared that 10 domestic medical schools and six foreign medical schools were doing human exposure experiments. They included some of the most prominent medical schools in the United States—Rutgers, Rochester, Ohio State, University of Michigan, Michigan State, University of Washington, University of California at Los Angeles, University of Southern California, and Lovelace Clinic affiliated with the University of New Mexico. The foreign medical schools included three in Europe, one in Canada, and two in the UK.[32]

Two other declarations produced by EPA officials in the lawsuit were critical to understanding EPA misconduct. Martin Case, program administrator, declared that he told the subjects they could die from the exposures, but he did not write that warning in the consents obtained.[33] Milloy has obtained the consent forms from UNC and other medical schools involved in the project for human experimentation, and none of programs warned subjects of EPA's position that fine particles were toxic, lethal, and carcinogenic, and that the subjects might suffer the consequences.[34]

Robert Devlin, Ph.D., senior research official for EPA and part of the UNC team, stated in his declaration under penalty of perjury that the EPA was sponsoring the human experimentation because the results of epidemiological studies are not reliable enough and do not establish a strong enough case for toxicity of air pollution.[35]

In paragraph 8, Devlin states:

> Controlled human exposure studies conducted by EPA scientists and EPA-funded scientists at multiple U.S. universities fill an information gap that cannot be filled by large population studies. In 1998 the Committee on Research Priorities for Airborne Particulate Matter was established by the National Research Council in response to a request from Congress. The committee was charged with producing four reports over a five-year period which describe a conceptual framework for an integrated national program of particulate-matter research, and identified the most critical research needs linked to key policy-related scientific uncertainties.

The committee states on page 36 of its report:

> Controlled human exposure studies offer the opportunity to study small numbers of human subjects under carefully controlled exposure conditions and gain valuable insights into both the relative deposition of inhaled particles and the resulting health effects. Individuals studied can range from healthy people to individuals with cardiac or respiratory diseases of varying degrees of severity. In all cases, the specific protocols defining the subjects, the exposure conditions, and the evaluation procedures must be reviewed and approved by institutional review boards providing oversight for human experimentation. The exposure atmospheres studied vary, ranging from well-defined, single-component aerosols (such as black carbon or sulfuric acid) to atmospheres produced by recently developed particle concentrators, which concentrate the particles present in ambient air. The concentrations of particles studied are limited by ethical considerations and by concern for the range of concentrations, from the experimental setting to typical ambient concentration, over which findings need to be extrapolated.
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> Controlled human exposures studies have been conducted for decades on important pollutants such as ozone, particulate matter, nitrogen dioxide (NO_2), sulfur dioxide (SO_2), VOCs [volatile organic compounds] emitted [in] new homes, and carbon monoxide (CO).

In paragraph 9 of his Declaration, Devlin states: "Controlled human exposure studies assess the biological plausibility of the associations observed in the large-population epidemiological studies."

So we have come full circle. For 20 years I have argued that EPA is involved in corrupted, invalid, unreliable epidemiology. Now, under pressure from a lawsuit for unethical conduct, it admits what we knew already, that epidemiology is being misused as a false portfolio of evidence of air pollution toxicity.

The most astounding aspect of this human experiments scandal is the refusal of state boards of medicine, institutional review boards (IRBs), deans of medical schools, and EPA officials to investigate and stop the misconduct. This is in spite of the well-known and remembered Tuskegee and horrific wartime Nazi/Japanese medical experiments on prisoners.

What we have discovered with EPA misconduct and that of the grantees at numerous medical schools is very sobering. These are not trivial violations of the ethical rules on human experimentation with which the IRBs are familiar. The rule is that one cannot perform harmful human exposure experiments—period. In only a very few circumstances where significant benefit is anticipated could subjects be exposed to harmful substances, after they are informed of the risks.

Conclusion

For 20 years or more EPA has promulgated bad epidemiology and bad toxicology that eventually evolved into research with unethical human exposure experiments. There is no easy way to excuse unethical human experiments to substantiate claims made in congressional hearings, despite lack of evidence, that air pollution or other forms of pollution are toxic and lethal.

If EPA is lying about the toxicity, the regulations fall. If it isn't, a federal agency is committing battery and unethical research that is criminal, unethical, and violates agency rules on human research. Either way, innocent experimental subjects

are victimized.

Daubert and the *Reference Manual* guidelines could be used to restore sanity and objectivity to EPA regulatory activities so that they would improve public health policy-making rather than serving a political agenda.

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