

Environmental Protection Agency's Air Pollution Research: Unethical and Illegal?

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"First, do no harm" is a fundamental precept of medical ethics. So how do U.S. Environmental Protection Agency physicians explain their non-therapeutic experiments in which they exposed health-impaired people to high levels of concentrated diesel exhaust and other air pollutants?

A federal court may soon help clarify this dilemma.

Since at least 2004, EPA physicians have been intentionally exposing human beings to various forms of concentrated airborne particulate matter (PM), including diesel exhaust, at an EPA laboratory at the University of North Carolina School of Medicine (UNC). The diesel exhaust is generated by idling a diesel truck with its exhaust pipe located right under the air intake for the exposure chamber.

The university not only houses the EPA facility, but also provides on a contract basis the mandatory institutional review board (IRB) intended to serve as the last line of defense for human study subjects.

Although these experiments materially violate every law, regulation, and standard developed since World War II for the protection of human subjects, there are two primary violations.¹

First, these experiments should never have been approved by UNC or conducted by EPA given the allegedly lethal nature of PM as determined by EPA.

Since 1997, the agency has regulated PM on the basis that it kills people. In 2004, EPA clarified its views of PM's lethality by concluding that any inhalation of PM could result in death within hours of exposure.² The EPA reiterated this view in its 2009 scientific assessment of PM.³

In July 2011, Dr. Jon Samet, chairman of EPA's Clean Air Scientific Advisory Committee, wrote in the *New England Journal of Medicine* that there is no safe exposure to PM.⁴ This view was repeatedly echoed by EPA air chief Gina McCarthy in a February 2012 letter to House Energy and Commerce Chairman Fred Upton (R-Mich.).⁵

EPA Administrator Lisa Jackson testified before Congress in September 2011: "Particulate matter causes premature death. It doesn't make you sick. It's directly causal to dying sooner than you should." She added, "If we could reduce particulate matter to levels that are healthy we would have an identical impact to finding a cure for cancer."⁶ Cancer kills about 570,000 in the U.S. annually, according to the American Cancer Society.

In addition to the EPA-determined lethal nature of PM, EPA also says there is strong evidence that PM is carcinogenic.⁷

These characterizations of PM essentially portray it as one of the most toxic substances known to man—at least according to EPA. Though every poison has a lethal dose, any exposure to PM can kill, and kill quickly (within hours), EPA claims. Although

exposure to carcinogens like asbestos, benzene, and vinyl chloride may cause cancers decades after exposure, or after decades of exposure, these risks obviously pale in comparison to that of PM in the view of EPA.

EPA, then, is experimenting on human beings with what it views as one of the most toxic substances known to man for the simple (and illegal) purpose of evaluating what would happen, apparently in an effort to bolster its epidemiological (i.e. statistical) claims.^{8,9} Worse, many of the study subjects are health-impaired, suffering from metabolic syndrome, asthma, old age, or combinations thereof.

The idea of a government agency deliberately exposing sick people to what it portrays as an extremely toxic substance is shocking. This is, however, only part of the story.

Second, informed consent is the cornerstone of medical practice and human testing protocols. Failure to obtain informed consent, among other misconduct, resulted in the execution of 16 of 23 Nazi doctors at the Nuremberg tribunal. The so-called "Common Rule" has been adopted by American medical researchers, including EPA, as a standard for conducting human experiments, and it prohibits harmful human experiments.¹⁰

Although EPA went through the motions of having its study subjects read and sign consent forms, the forms never mentioned that any exposure to PM could result in death within hours of the experiment. Study subjects were instead told, for example, "You may experience some minor degree of airway irritation, cough or shortness of breath or wheezing. These symptoms typically disappear two to four hours after exposure, but may last longer for particularly sensitive people."¹⁰

At least hundreds, and possibly thousands of human subjects have been so experimented upon by EPA physicians or EPA-grantee physicians at universities around the country. These experiments continue even as these concerns have been pointed out to EPA in recent months.

Has anyone been harmed? At least one 58-year-old obese woman with a personal and family history of heart problems had her experiment terminated early when she developed atrial fibrillation/flutter. The case was reported,¹¹ and it was said to be "the first case report of cardiovascular disease after exposure to elevated concentrations of any air pollutant." The rhythm resolved spontaneously about 2 hours after termination of the exposure. The authors concluded: "The resolution of the arrhythmia with termination of the particle exposure further supports a causal relationship between the two." They made this strong inference even while acknowledging evidence of a high frequency of supraventricular ectopy prior to exposure, numerous preexisting risk factors, and the fact that an

electrophysiologic study 6 weeks later revealed a re-entrant circuit, which was ablated. The authors suggested a potential mechanism of “disruption of the normal cardiac autonomic control,” without acknowledging the confounding factor of a potential emotional reaction to being in a setting resembling a gas chamber and being the subject of an exposure to an inhaled air mixture in a lab.

Although EPA physicians attributed the subject’s arrhythmia to her PM exposure, they nevertheless did not modify the consent forms for subsequent human test subjects to reflect this risk.

As a result, the American Tradition Institute, a nonprofit public policy group, has filed suit in federal court against the EPA seeking an end to this illegal experimentation (*American Tradition Institute Environmental Law Center v. U.S. EPA*, Case 1:12-cv-01066-AJT-TCB, U.S. District Court for the Eastern District of Virginia—Alexandria Division).

Complaints have been filed with the North Carolina Medical Board concerning three of the North Carolina-licensed EPA physicians involved in the illegal experimentation. This investigation continues. The University of North Carolina School of Medicine has announced an internal review.

Congress has gotten involved, too. Sen. Jim Inhofe (R-Okla.) has requested that the Senate Environment and Public Works Committee, the committee responsible for overseeing EPA, schedule hearings on the scandal. Spearheaded by Rep. Paul Broun, M.D. (R-Ga.-10), the House Science Committee has requested that the EPA Office of Inspector General conduct an investigation.

The lawsuit has already produced a notable admission of sorts from an EPA employee. In his declaration,¹² EPA Clinical Studies Coordinator Martin W. Case asserted that he verbally informs human subjects in an ongoing trial that, “There is the possibility you may die from this.” In addition to the shocking nature of this “warning,” even if it were acceptable to risk the lives of human study subjects for the sake of science—and it’s not—such a warning would need to be in writing, according to federal regulations.

It’s clear that “first, do no harm” was not a high priority concern of EPA physicians involved in this shocking experimentation. EPA and UNC are now in defensive postures, and the medical community needs to hold them accountable. Given past outrages of medical science, like the Nazi experiments and the Tuskegee syphilis experiments to name just two, what will the medical, political, and legal communities do to stop this ongoing research sponsored by a United States federal agency and funded with taxpayer dollars?

Another possibility is that the EPA does not believe its own testimony to Congress, and that oppressive, costly regulations have been imposed on American industry on the basis of flawed epidemiologic studies, unwarranted extrapolations, and contrived estimates of benefits. The experiments may be designed to find a potential mechanism of harm, like the one suggested in the case report by Ghio et al.¹¹ If so, the very purpose of the experiments is to cause harm to human beings in an effort to justify false testimony.

[Editor’s Note: In a letter from the Environmental Protection Agency Office of Inspector General, dated October 22, 2012, Assistant Inspector General for Program Evaluation, Carolyn Copper, indicated the agency “plans to begin an evaluation of the Environmental Protection Agency’s (EPA’s) Research on Human Subjects...to determine whether EPA: 1) Obtained sufficient approval to expose subjects to specific levels of diesel exhaust emissions or concentrated airborne particles; 2) Obtained adequate informed consent from human study subjects before exposing them to diesel exhaust emissions or concentrated airborne particles; 3) Adequately addressed any adverse events that occurred, including notifying the University of North Carolina at Chapel Hill’s Institutional Review Board (IRB), the Human Studies Review Board, and the Human Subjects Research Review Official, revising consent forms as needed, and providing clinical follow-up in accordance with the approved protocol.” See <http://junksciencecom.files.wordpress.com/2012/11/new-assignment-memorandum-on-oig-evaluation-on-epas-research-onhuman-subjects.pdf>].

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