

June 16, 2016

Mr. Ray Wassel
National Academy of Sciences
500 Fifth St., N.W.
Washington, D.C. 20001

Re: Comment on “Assessing Toxicologic Risks to Human Subjects Used in Controlled Exposure Studies of Environmental Pollutants” (DELS-BEST-14-05)

I am submitting these comments to the public docket for the above-caption project. I request that they be distributed to Committee members as soon as possible. I apologize for their apparent tardiness, but I only learned about the Committee’s work this week due the absence of public notice of the Committee’s formation and meetings. I am concerned that absent informed public input, the Committee’s work will suffer and ultimately possibly serve as an inadvertent whitewash of egregious if not illegal conduct by the U.S. Environmental Protection Agency (EPA).

Background

The committee for this project owes its existence to my original investigative report and subsequent letter to the EPA inspector general (IG) of May 14, 2012 concerning the potential illegality of EPA’s experiments on humans with fine particulate matter (PM_{2.5}).¹ My letter resulted in Congress requesting that the EPA inspector general investigate the EPA’s human experimentation program. This, in turn, led to the March 31, 2014 report by the IG.²

Although the EPA IG report validated all the points of concern raised in my May 2012 letter, the IG failed entirely to evaluate the EPA’s human testing program in the appropriate context, which is:

If PM_{2.5} is as lethal as the EPA claims, then EPA’s human testing program is entirely illegal as it violates every rule established since the Nuremberg Code for the protection of human subjects in scientific experiments.

The EPA’s human experiments with PM_{2.5} may be viewed as legal only if short-term exposure to acute very high levels of PM_{2.5} is essentially harmless — i.e., involve only “minimal risk” to the study subjects. In

¹ See <http://junkscience.com/wp-content/uploads/2012/05/epa-oig-final-051412.pdf>.

² See <https://www.epa.gov/sites/production/files/2015-09/documents/20140331-14-p-0154.pdf>.

this case, the EPA has mischaracterized and misrepresented to the public and Congress, and in its justifications for multiple major regulations that short-term ambient-level exposure to PM_{2.5} can be lethal.

These are the only two possible explanations for EPA's PM_{2.5} human testing program. There is no third possibility.

Alleged Toxicity of PM_{2.5}

Since at least 2004, the EPA has essentially characterized PM_{2.5} as the most toxic substance known to man. The EPA has repeatedly claimed that:³

- No inhalation of PM_{2.5} is safe.
- Any inhalation of PM_{2.5} can cause death.
- Death from inhaling PM_{2.5} can occur as soon as hours or days following inhalation.

These claims, of course, defy well-established principles of toxicology and all relevant data including independently conducted and EPA-sponsored air quality epidemiology, existing occupational and tobacco epidemiology, and animal toxicology. Nonetheless, the EPA relies on these claims to both alarm the public and to justify major regulations.

The EPA also makes claims about PM_{2.5} causing death over periods of years and decades and about PM_{2.5} causing cancer. But for ease of discussion, these comments will be limited to the EPA's claims about the potential acute or short-term effects of inhaling PM_{2.5}.

It is important to note that while I do not personally believe that PM_{2.5} presents any sort of mortality risk to anyone, the EPA claims that that PM_{2.5} is a dire threat to public health responsible for more than one-in-five U.S. deaths annually.⁴ As such, it is important to approach the issue of the PM_{2.5} human experiments from the supposed mindset of the EPA. So for the following discussion, we will accept for the sake of argument EPA's assertions about the mortality risks posed by inhaling PM_{2.5}.

³ See <https://epahumantesting.com/the-most-toxic-substance-on-earth/>.

⁴ *Ibid.*

The EPA's exposed human subjects to extraordinarily levels of PM_{2.5} not observed in the U.S.

The EPA's 24-hour standard for PM_{2.5} is 35 micrograms per cubic meter of air (μm^3). The EPA's annual standard is on the order of 11 μm^3 . The EPA claims that there is no safe exposure to PM_{2.5}. Yet the PM_{2.5} study subjects were intentionally exposed to levels of PM_{2.5} up to 600 μm^3 for periods of two hours. Some human subjects were inadvertently exposed to as much as 750 μm^3 — i.e., over 20 times higher than the agency's 24-hour standard. These exposures are, of course, infinitely higher than the level of PM_{2.5} exposure that the agency deems to be safe (i.e., zero μm^3). Nowhere in the U.S., do people breathe such high levels of PM_{2.5} from ambient air over such a short period of time.

The EPA's human guinea pigs are precisely the sorts of people that EPA claims are most vulnerable to the alleged health effects of PM_{2.5}

The EPA claims that the elderly and health-compromised people are most vulnerable to PM_{2.5}. Yet the EPA has experimented on the elderly⁵ (up to age 80), asthmatics, elderly asthmatics⁶, diabetics⁷, people with heart disease⁸, people with metabolic syndrome, and even children as young as 10-years old.⁹

The EPA's PM_{2.5} Experiments Are Inherently Illegal

If you accept the EPA's characterization of PM_{2.5} as a highly lethal substance, then experimenting with PM_{2.5} on humans is inherently illegal.

Federal law and regulations (called "The Common Rule") allow human subjects, under certain circumstances, to agree to risk their lives or serious injury in therapeutic experiments — i.e., those that are designed to save their lives or treat serious diseases and conditions. Clearly, the EPA's PM_{2.5} human experiments do not fall into the category of therapeutic experiments.

The Common Rule also allows federal agencies and their researchers to conduct human experiments for non-therapeutic purposes. But clear limitations are placed on non-therapeutic experiments. The most important of these limitations is that human subjects may not be exposed to more than "minimal risk," which is defined

⁵ See <https://epahumantesting.com/analysis-of-the-epa-documents-part-5/>.

⁶ See <https://epahumantesting.com/analysis-of-the-epa-documents-part-7/>.

⁷ See <http://junkscience.com/2012/12/epa-funded-university-of-rochester-researchers-test-deadly-air-pollutant-on-diabetics/>.

⁸ See e.g., <https://epahumantesting.com/discovery-of-epa-wrongdoing/>.

⁹ See <http://junkscience.com/2015/01/epas-illegal-use-of-children-in-diesel-exhaust-experiments/>.

essentially as no greater a risk than that normally or typically encountered in daily life.

As discussed above, the EPA believes that any exposure to PM_{2.5} may cause near-immediate death. In litigation over one of its human experiments, an EPA staff member claimed that he orally informed human subjects participating in the “CAPTAIN” study before experimentation that,

There is the possibility you may die from this [experiment].

Clearly the EPA-claimed possibility of near-immediate death is not “minimal risk.”

The EPA violated federal and state law by failing to provide informed consent to study subjects.

Informed consent is a legal prerequisite to human experimentation. The Common Rule states:¹⁰

No investigator may involve a human being as a subject in research covered by this subpart unless the investigator has obtained the legally effective informed consent of the subject. An investigator must seek such consent only under circumstances that provide the prospective subject sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject must be in language understandable to the subject. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Despite that the EPA has believed since 2004 that PM_{2.5} can cause near-immediate death, it never disclosed that belief of that to any study subject. Below is an example of how EPA described the risks to study subjects in a 2009 PM_{2.5} experiment:¹¹

PM Exposure: *During the exposure to the concentrated air pollution particles, you may experience some minor degree of airway irritation, cough, shortness of breath or wheezing. These symptoms typically disappear 2 to 4 hours after exposure, but may last longer for particularly sensitive people.*

In this example, there is absolutely no mention of the possibility of death. As study subjects were not informed of the possibility of near-immediate death, proper and legal consent was not obtained in violation of the Common Rule and state laws against medical battery.

¹⁰ See 40 CFR 26.1116

¹¹ See <https://epahumantesting.com/analysis-of-the-epa-documents-part-6/>.

In some of the disclosure forms, the EPA mentions that studies have linked diesel exhaust (which is 95% comprised of PM_{2.5}) with death as follows:¹²

Exposure to the air pollution particle concentration used in this study for short periods of time has never been found to cause permanent health effects. However, some studies suggest that older people, particularly those with underlying cardiovascular diseases are at increased risk for getting sick and even dying during episodes of high air pollution.

But note that this disclosure did not directly inform the study subject that EPA believes and even regulates on the basis that there is no safe exposure to PM_{2.5}.

Even in the previously-mentioned “CAPTAIN” study, the allegedly provided oral warning “There is the possibility you might die from this”) is inadequate as disclosure because it was not made in writing.

Why did the EPA conduct human experiments with PM_{2.5}?

The EPA bases its claims about the lethality of PM_{2.5} on epidemiologic studies — which, incidentally, have been conducted almost exclusively by recipients of EPA grant money totaling more than approximately \$581 million to date.

But epidemiologic studies are merely statistical in nature. By themselves, they are an insufficient basis to causally link PM_{2.5} with mortality. Even the EPA has admitted this. In litigation with EPA over its human studies, the agency stated:¹³

Epidemiology studies, the primary tool in the discovery of risks to public health presented by ambient PM_{2.5}, typically use data from large populations of people with varying susceptibility to PM_{2.5}. They evaluate the relationship between changes in ambient levels of PM_{2.5} and changes in health effects. However epidemiological studies do not generally provide director evidence of causation; instead they indicate the existence or absence of a statistical relationship. Large population studies cannot assess the biological mechanisms that could explain how inhaling ambient air pollution particles can cause illness or death in susceptible individuals... Controlled human exposure studies are used to help answer the questions these epidemiological studies do not answer.

So the purpose of the EPA’s PM_{2.5} human experiments is to provide biological or medical plausibility for the statistical associations allegedly observed in the epidemiologic studies. Put another way, the EPA is intentionally trying to hurt

¹² See <https://epahumantesting.com/analysis-of-the-epa-documents-part-5/>.

¹³ See <http://junkscience.com/wp-content/uploads/2016/05/EPA-Memo-in-opp-to-TRO-1.pdf>.

people with PM_{2.5} for the purposes of validating its epidemiologic claims and PM_{2.5} regulations. This is unethical, if not illegal.

Conclusion

The EPA is misrepresenting the effects of PM_{2.5} to somebody. If PM_{2.5} is as dangerous to life as the EPA claims, then EPA failed to disclose that fact to its human guinea pigs in violation of state and federal law. If PM_{2.5} is as harmless to health as it described to its human guinea pigs, then the EPA has repeatedly misrepresented that fact to the public and Congress, and the agency has regulated PM_{2.5} on false pretenses. Although these facts and conclusions are not really disputable, the EPA nevertheless attempts to dispute them by obfuscation. Also, there is no evidence that the EPA actually has applied the results of any of its PM_{2.5} human experimentation in any of its PM_{2.5} regulations.

The problems with EPA's human experimentation program extend beyond PM_{2.5}. The agency has also conducted extensive human experimentation with acute exposures to ozone, diesel exhaust, combinations of ozone and diesel exhaust¹⁴ and even chlorine gas.¹⁵ The ozone experiments involve exposures up to 400 parts per billion (ppb) for two hours — despite the EPA's 8-hour standard of 75 ppb. The Common Rule requires that human experimentation be conducted in a scientific manner. But this is not the case with the EPA's human experiments, which are small and haphazardly conducted and, so, cannot produce generalizable (i.e., scientific) results.

I request the opportunity to respond in detail to the EPA statements made to the committee responsible for "Assessing Toxicologic Risks to Human Subjects Used in Controlled Exposure Studies of Environmental Pollutants." I also propose that the committee hold a teleconference or in-person meeting in which committee members listen debate between EPA and me on the issue. This is a reasonable request given the gravity of the review and the fact that there was no meaningful public notice of the committee's only meeting open to the public, which was held on June 1, 2015.

Sincerely,



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¹⁴ See <http://junkscience.com/2013/03/greenwire-participant-in-human-soot-tests-files-2m-claim-against-epa/>.

¹⁵ See <http://junkscience.com/2013/03/chlorine-gas-possibly-used-in-syria-but-definitely-used-on-people-by-the-epa-another-shocking-human-experiment/>.