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October 18, 2012

Arthur A. Elkins, Jr.
Inspector General
U.S. Environmental Protection Agency
Office of Inspector General
1200 Pennsylvania Avenue, N.W. (2410T)
Washington, DC 20460

Dear Mr. Elkins:

I write today to request that the Office of Inspector General (OIG) review recent human research studies involving concentrated airborne particles conducted by the U.S. Environmental Protection Agency (EPA) and the University of North Carolina – Chapel Hill (UNC).

Specifically, I request that the OIG consider and determine whether EPA, as part of its research, followed applicable laws, regulations, policies, procedures, and guidance when it exposed human subjects to concentrated airborne particles or diesel exhaust emissions.[1] The review should extend to the role and policies of EPA's standing Human Studies Review Board, as well as EPA's Institutional Review Board (IRB), which oversees EPA's human research studies. In this case, IRB responsibilities were handled by the UNC School of Medicine Committee on the Protection of the Rights of Human Subjects. While a more specific set of questions is included at the end of this letter, this evaluation should determine whether EPA, in conducting the XCON, KINGCON, OMEGACON and related studies exposing 41 human subjects to concentrated air particles from 2010 to 2011:

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 UNC 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.

Background

[1] Diesel PM emissions are to be primarily addressed as they relate to cardiovascular and respiratory effects.

Despite frequent warnings regarding the dangers of fine particulate matter ($PM_{2.5}$), including ultrafine particles, and diesel engine exhaust, EPA conducted a series of tests that exposed humans to these emissions at the Office of Research and Development's Human Studies Facility.

According to EPA's fact sheet accompanying its recent proposal to lower $PM_{2.5}$ standards:

> An extensive body of scientific evidence shows that exposure to particle pollution causes premature death and is linked to a variety of significant health problems, such as increased hospital admissions and emergency department visits for cardiovascular and respiratory problems, including non-fatal heart attacks. PM also is linked to the development of chronic respiratory disease.
>
> People most at risk from fine and coarse particle pollution exposure include people with heart or lung disease (including asthma), older adults, children, and people of lower socioeconomic status. Research indicates that pregnant women, newborns, and people with certain health conditions, such as obesity or diabetes, also may be more susceptible to PM-related effects.[2]

Additionally, numerous EPA sources have concluded there is *no threshold* for human health effects or premature mortality resulting from exposure to $PM_{2.5}$. For example, recent EPA cost-benefit analysis for a variety of Clean Air Act regulations have assumed that more than 300,000 people die annually from $PM_{2.5}$ and that premature mortality takes place at concentrations going down to the lowest measurable level.[3] Further, EPA's June 2012 Regulatory Impact Analysis for the proposed new $PM_{2.5}$ National Ambient Air Quality Standards stated that, "there is no evidence of a population-level threshold in $PM_{2.5}$-related health effects in the epidemiology literature."[4]

Similarly, the Chairman of EPA's Clean Air Scientific Advisory Council (CASAC) stated in a 2011 *New England Journal of Medicine* article that for particulate matter pollution, "no

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[2] The National Ambient Air Quality Standards, "Overview of EPA's Proposal to Revise the Air Quality Standards for Particle Pollution (Particulate Matter)," available at: http://www.epa.gov/pm/2012/fsoverview.pdf.

[3] Anne Smith, Testimony before the House Science, Space, and Technology Committee, Subcommittee on Energy and Environment, October 4, 2011, available at: http://www.gpo.gov/fdsys/pkg/CHRG-112hhrg70587/pdf/CHRG-112hhrg70587.pdf; and Michael Honeycutt, Testimony before the House Science, Space, and Technology Committee, Subcommittee on Energy and Environment, June 6, 2012, available at: http://science.house.gov/letter/dr-honeycutts-powerpoint-and-qfrs.

[4] Regulatory Impact Analysis for the Proposed Revisions to the National Ambient Air Quality Standards for Particulate Matter, available at: http://www.epa.gov/ttnecas1/regdata/RIAs/PMRIACombinedFile_Bookmarked.pdf; EPA staff conducting these tests should have been aware of these statements, as the now-Director of the division overseeing the Human Studies Facility, Wayne Cascio, was a member of the Clean Air Scientific Advisory Committee that reviewed the state of the science. See: http://yosemite.epa.gov/sab/sabpeople.nsf/WebCommitteesSubcommittees/CASAC%20Particulate%20Matter%20Review%20Panel.

thresholds have been identified below which there is no risk at all."[5] EPA's Assistant Administrator for the Office of Air and Radiation has reiterated these conclusions in communications with Congress.[6]

Since 2004, EPA has conducted the following three series of studies exposing humans to $PM_{2.5}$ or diesel exhaust, which contains $PM_{2.5}$:

- The XCON study exposed "adults with metabolic syndrome (including the elderly) to high levels of toxic $PM_{2.5}$."
- The OMEGACON study exposed "older adults to high levels of diesel exhaust (which contains $PM_{2.5}$ and other 'toxic' substances)."
- The KINGCON study exposed "older adults suffering from moderate asthma to $PM_{2.5}$."[7]

I am concerned about the individuals EPA asked to participate in these studies, which included unhealthy and elderly adults who, in some cases, were explicitly selected to participate *because* they suffered from moderate asthma and metabolic syndrome. My concerns appear to be justified by the experiences of two study subjects who participated in EPA experiments between January 5, 2010 and June 9, 2011 when 41 human study subjects were exposed to $PM_{2.5}$ levels ranging from 41.54 micrograms per cubic meter to 750.83 micrograms per cubic meter for periods of up to 2 hours.[8]

On October 7, 2010, a 58-year old subject with a history of heart and health problems was removed from the experiment chamber and transported to a hospital "due to the onset of new atrial (or supraventricular) fibrillation."[9] She had been exposed to $PM_{2.5}$ levels of 111.68 micrograms per cubic meter for about 49 minutes. On February 10, 2011, another subject was removed from the chamber because of an elevated heart rate after being exposed to $PM_{2.5}$ levels of 66.26 micrograms per cubic meter for about 23 minutes.[10] These levels exceed the EPA outdoor air quality standards for $PM_{2.5}$ of 35 micrograms per cubic meter on a 24-hour basis, and 15 micrograms per cubic meter on an annual average basis.[11]

Issues and Questions

According to EPA, $PM_{2.5}$ exposure causes "premature death and is linked to a variety of significant health problems, such as increased hospital admissions and emergency department

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[5] Jonathan M. Samet, M.D., "The Clean Air Act and Health – A Clearer View From 2011," The New England Journal of Medicine, July 21, 2011, available at: http://www.nejm.org/doi/full/10.1056/NEJMp1103332.
[6] Letter to Members of the House Energy and Commerce Committee, from Gina McCarthy, Assistant Administrator for the Office of Air and Radiation, February 3, 2012.
[7] According to documents received by the Committee from EPA and provided to your staff in August of this year.
[8] Letter to Arthur Elkins, Inspector General, EPA, from Steve Milloy, Publisher, JunkScience.com, May 14, 2012, available at: http://epahumantesting.files.wordpress.com/2012/08/epa-oig-final-051412-optimized.pdf.
[9] Ibid.
[10] Ibid.
[11] National Ambient Air Quality Standards, available at: http://www.epa.gov/air/criteria.html.

visits for cardiovascular and respiratory problems, including non-fatal heart attacks."[12] In light of EPA's characterization of health and mortality concerns associated with these pollutants and its execution of experiments that appear inconsistent with these findings, I question the appropriateness of testing humans with high concentrations of pollutants that EPA considers dangerous at any level. The following questions specifically reflect my concerns:

1) Did EPA conduct experiments that exposed humans to levels of $PM_{2.5}$ that exceeded standards set by the agency?
    a) Can EPA conduct experiments that expose humans to *any* levels of $PM_{2.5}$?

2) Did EPA sufficiently alert the IRB to the levels of diesel exhaust emissions[13] or concentrated airborne particles that human subjects were exposed to?
    a) Conversely, did the IRB understand to what levels of diesel exhaust emissions or concentrated airborne particles the human subjects would be exposed?

3) Did EPA and the IRB adequately inform human study subjects before exposing them to diesel exhaust emissions[14] or concentrated airborne particles?

4) Did the EPA Human Subjects Research Review Official, also known as the Review Official, review and approve this project after the IRB review and approval process?

5) Did EPA and the IRB adequately address any adverse events that occurred, including notifying the Human Studies Review Board or the Review Official?
    a) Did EPA or the IRB revise consent forms as needed and provide appropriate clinical follow-up?
    b) Should consent forms have been amended after the October 7, 2010 and February 10, 2011 incidents?

6) Were EPA's actions consistent with the Common Rule, 40CFR26, and EPA Order 1000.17 regarding "Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research?"[15]

7) According to EPA, the Human Studies Facility "is primarily intended for research to support EPA standards and regulations."[16] Considering the great disparity between

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[12] See footnote 2.
[13] See footnote 1.
[14] See footnote 1.
[15] "Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research," available at: http://www.epa.gov/phre/pdf/epa-order-1000_17-a1.pdf.
[16] "EPA's Human Studies Facility at Chapel Hill," available at: nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=910000GN.txt.

current regulatory concentrations and the test exposures discussed above, of what value is this data?

8) Do EPA's and the IRB's regulations, policies, procedures, and guidance provide sufficient protection to human subjects in these types of experiments, or do they need to be updated?

9) Do applicable laws, regulations, policies, procedures, and guidance protect human research subjects from experiments that may result in premature mortality?

I ask that this work be completed by April 2013, and that your office contact me if this deadline cannot be met. Should you have any questions, please contact Raj Bharwani with the Investigations and Oversight Subcommittee staff at (202) 225-6371.

Sincerely,

Rep. Paul Broun, M.D.
Chairman
Subcommittee on Investigations
and Oversight