EPA's Human Experiments With Particulate Matter: Proof of Government Science Corruption

12th International Conference on Climate Change
March 23, 2017
By Steve Milloy
Publisher, JunkScience.com
Senior Fellow, Energy & Environment Legal Institute

Dedicated to

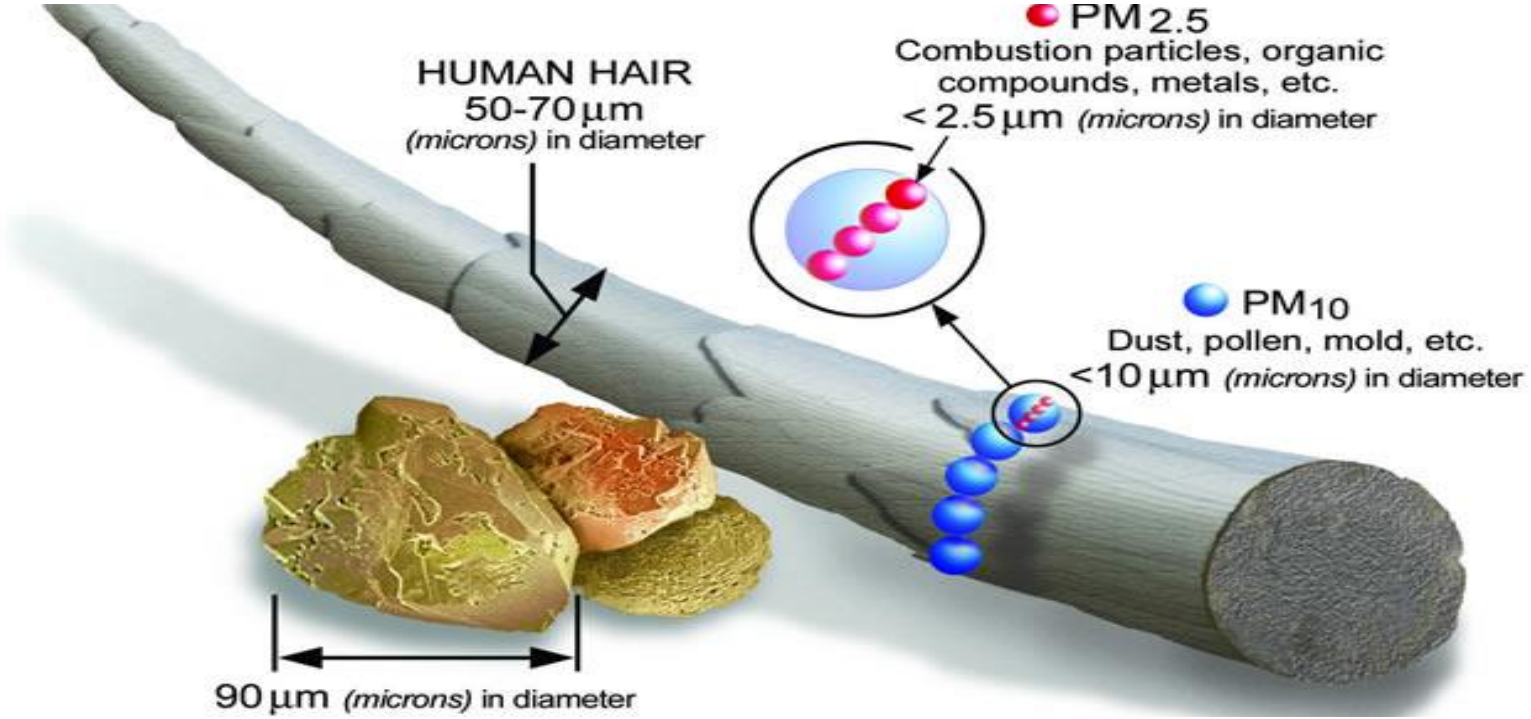
Haiyan ‘Nicole’ Wan

1977-1996

EPA's Human Experiments

- Substances experimented with:
  - **Particulate matter (PM, $PM_{2.5}$)**
  - **Diesel exhaust (95% $PM_{2.5}$)**
  - Ozone (smog)
  - Combinations of above
  - Chlorine gas and other substances

Imagining PM



Sources of PM – Natural

Sources of PM - Manmade

PM Lethality:

Any Exposure Can Kill, Within Hours

- From EPA's 2009 $PM_{2.5}$ Assessment:

Summary of $PM_{2.5}$ Risk Estimates

The risk estimates for all-cause mortality for all ages ranged from 0.29% Dominici et al. (2007, 097361) to 1.21% Franklin et al. (2007, 091257) per 10 µg/m^3 increase in $PM_{2.5}$ (Figure 6-26). An examination of cause-specific risk estimates found that $PM_{2.5}$ risk estimates for cardiovascular deaths are similar to those for all-cause deaths (0.30-1.03%), while the effect estimates for respiratory deaths were consistently larger (1.01-2.2%), albeit with larger confidence intervals, than those for all-cause or cardiovascular deaths using the same lag/averaging indices. Figure 6-27 summarizes the $PM_{2.5}$ risk estimates for all U.S.- and Canadian-based studies by cause-specific mortality.

An examination of lag structure observed results similar to those reported for PM_{10} with most studies reporting either single day lags or two-day avg lags with the strongest effects observed on lag 1 or lag 0-1. In addition, seasonal patterns of $PM_{2.5}$ risk estimates were found to be similar to those reported for PM_{10}, with the warmer season showing the strongest association. An evaluation of regional associations found that in most cases the eastern U.S. had the highest $PM_{2.5}$ mortality risk estimates, but this was dependent on the geographic designations made in the study. When grouping cities by climatic regions, similar $PM_{2.5}$ mortality risk estimates were observed across the country except in the Mediterranean region, which included CA, OR, and WA.

PM Lethality (cont'd):

No Safe Exposure

- Former EPA CASAC Chair Jonathan Samet in *New England J. Med.* (July 11, 2011).

> For ozone and particulate-matter pollution, because no thresholds have been identified below which there is no risk at all, the EPA is using scenarios of risk and exposure to gauge the effects of setting the standards at various concentrations and giving consideration to the burden of avoidable disease. In promulgating the

PM Lethality (cont'd):

Death from Any Exposure

- Letter from then-EPA air chief Gina McCarthy to House Energy Committee (Feb. 3, 2012)

EPA's approach for estimating benefits from reducing fine particle pollution is science-driven. Studies demonstrate an association between premature mortality and fine particle pollution at the lowest levels measured in the relevant studies, levels that are significantly below the NAAQS for fine particles. These studies have not observed a level at which premature mortality effects do not occur. The best scientific evidence, confirmed by independent, Congressionally-mandated expert panels, is that there is no threshold level of fine particle pollution below which health risk reductions are not achieved by reduced exposure. Thus, based on specific advice from scientific peer-review, we project benefits from reducing fine particle pollution below the level of the NAAQS and below the lowest levels measured in the studies.

PM Lethality (cont'd):
Death Within Hours of Exposure

- From EPA 2004 Integrated Scientific Assessment for $PM_{2.5}$:

9.2.2.7 Summary and Conclusions

Epidemiological evidence can help to inform judgments about causality. The present discussion evaluated the epidemiologic evidence in relation to the first five criteria listed in the beginning of Section 9.2, including key considerations with regard to criteria such as the strength (magnitude, precision) and robustness of reported associations. Information related to last of the six criteria (coherence and biological plausibility of the evidence) is discussed in the following section.

Overall, there is strong epidemiological evidence linking (a) short-term (hours, days) exposures to $PM_{2.5}$ with cardiovascular and respiratory mortality and morbidity, and (b) long-term (years, decades) $PM_{2.5}$ exposure with cardiovascular and lung cancer mortality and respiratory morbidity. The associations between $PM_{2.5}$ and these various health endpoints are positive and often statistically significant. There are fewer studies available for $PM_{10-2.5}$ and the

PM Lethality (cont'd):

Just Death. No Sickness.

- During a September 22, 2011 hearing of the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee, Administrator Jackson testified:
  - ***"Particulate matter causes premature death. It doesn't make you sick. It's directly causal to dying sooner than you should."***

PM Lethality (cont'd):
1 Out of 5 Deaths Caused by PM

- From September 22, 2011 House hearing (transcript):
  - *REP. MARKEY: How would you compare it to the fight against cancer, reducing particulate matter?*
  - *MS. JACKSON: Yeah, I was briefed not long ago. If we could reduce particulate matter to healthy levels it would have the same impact as finding a cure for cancer in our country.*
  - *REP. MARKEY: Could you say that sentence one more time?*
  - *MS. JACKSON: Yes, sir**. If we could reduce particulate matter to levels that are healthy we would have an identical impact to finding a cure for cancer**.*
- Annual US cancer mortality
  - ~570,000
  - ~ 20+% of all US deaths annually

PM Lethality (cont'd):

Air in LA, NY & EPA Experiments May Kill

- Declaration of EPA clinical studies coordinator:

14. I provide participants with information about fine particles ($PM_{2.5}$). I say that $PM_{2.5}$ are particles so small that they are able past through your airways and go deep into your lungs, these

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Case 1:12-cv-01066-AJT-TCB Document 14-1 Filed 10/04/12 Page 10 of 135 PageID# 320

particles are so small that your usual lining and cilia of your airways are not able to prevent these particles from passing into your lungs. Therefore, if you are a person that for example lives in a large city like Los Angeles or New York, and it's been a very hot day, and you can see the haze in the air, and you happen to be someone that works outside, and if you have an underlying unknown health condition, or, you may be older in age; the chances are that you could end up in the emergency room later on that night, wondering what's wrong, possibly having cardiac changes that could lead to a heart attack; there is the possibility you may die from this.

PM Lethality (cont'd):

Deadly Within Hours, No Safe Exposure

American Heart Association Scientific Statement: Evidence Growing of Air Pollution's Link to Heart Disease, Death

May 10, 2010, 18:45 ET from American Heart Association

"Particulate matter appears to directly increase risk by triggering events in susceptible individuals within hours to days of an increased level of exposure, even among those who otherwise may have been healthy for years," said Robert D. Brook, M.D., lead author of the statement, which was written after review of epidemiological, molecular and toxicological studies published during the past six years.

"These studies also indicate that there is no 'safe' level of PM2.5 exposure," he said.

PM Lethality (Cont'd):

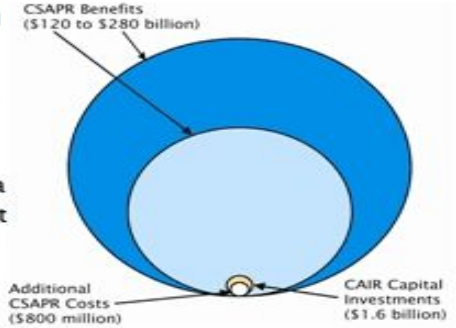
EPA-Funded Researcher Renounces PM Experiments

- After Brook's EPA-funded human experiments with PM were reported in the *Detroit News* (July 23, 2013):
  - ***"I'm not going to do (these tests) because I don't believe in exposing people. I've shown PM2.5 is bad for you."***

EPA Regulates on the Basis that PM Kills

The benefits of the Cross-State Air Pollution Rule far outweigh the costs of the rule.

The final rule yields $120 to $280 billion in annual health and environmental benefits in 2014, including the value of avoiding 13,000 to 34,000 premature deaths. This far outweighs the estimated annual costs of CSAPR. The $800 million in annual projected costs of this rule in 2014, along with the roughly $1.6 billion per year in capital investments already under way as a result of CAIR, are improving air quality for over 240 million Americans. This rule will not disrupt a reliable flow of affordable electricity for American consumers and businesses. Health benefits will be achieved at a very low cost, and while the effect on prices for specific regions or states may vary, they are well within the range of normal electricity price fluctuations. Any such costs will be greatly outweighed by the benefits.



PM Is Most Toxic Substance?

As Lethal As A Bullet to the Brain?

- EPA says any exposure to PM can kill in as little as hours – no safe exposure.
- Even radiation and chemical carcinogens regulated on the basis of the linear no-threshold model (LNT) ‘only’ have cancer as the health endpoint.
- No known poison kills on an ‘any exposure’ basis.

No Disclosure of the Nature of PM's Lethality to IRBs

- **EPA staff researchers and EPA-funded university researchers did NOT provide any of this toxicity information or equivalent to any Institutional Review Board (IRB).**
  - At most, occasional, vague, soft-pedaled and/or glancing mention of PM's correlation with 'mortality'
  - IRBs only given impression of 'minimal risk.'

(i) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

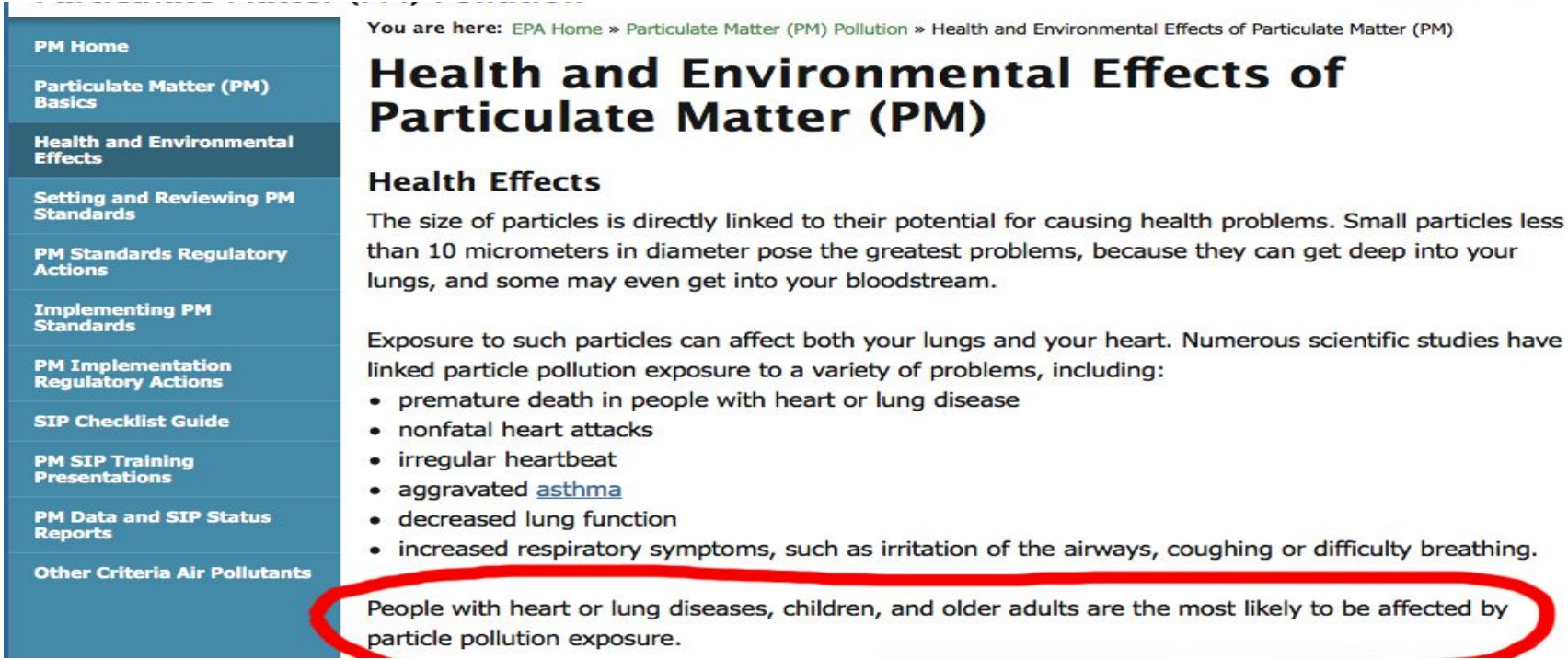
EPA's Human Experiments

Exhaust from Idling Diesel Truck…

EPA Human Experiments (cont'd):

… Pumped Into Chamber Containing Study Subject

Who Does EPA Say Are Most Vulnerable to The Effect of PM?



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Health and Environmental Effects of Particulate Matter (PM)

Health Effects

The size of particles is directly linked to their potential for causing health problems. Small particles less than 10 micrometers in diameter pose the greatest problems, because they can get deep into your lungs, and some may even get into your bloodstream.

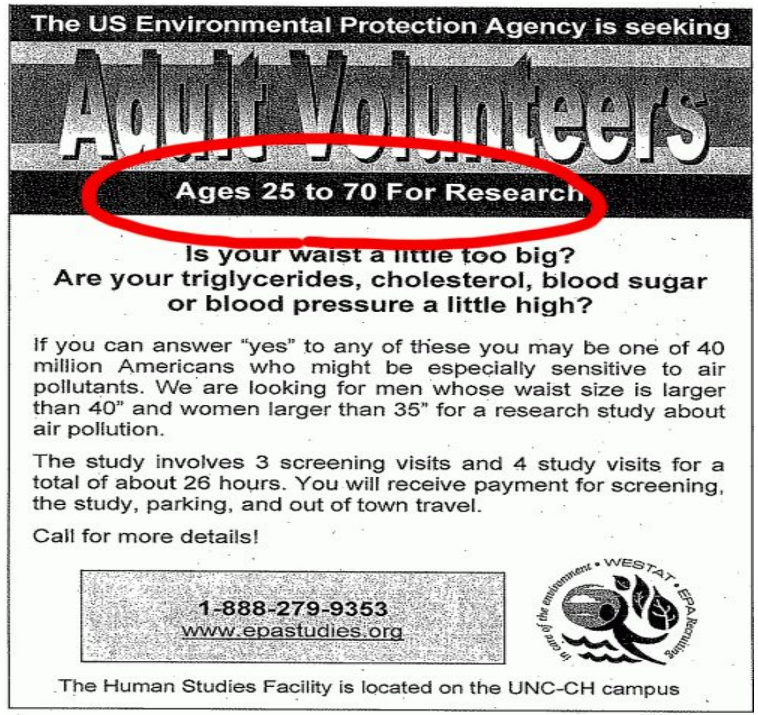
Exposure to such particles can affect both your lungs and your heart. Numerous scientific studies have linked particle pollution exposure to a variety of problems, including:

- premature death in people with heart or lung disease
- nonfatal heart attacks
- irregular heartbeat
- aggravated asthma
- decreased lung function
- increased respiratory symptoms, such as irritation of the airways, coughing or difficulty breathing.

People with heart or lung diseases, children, and older adults are the most likely to be affected by particle pollution exposure.

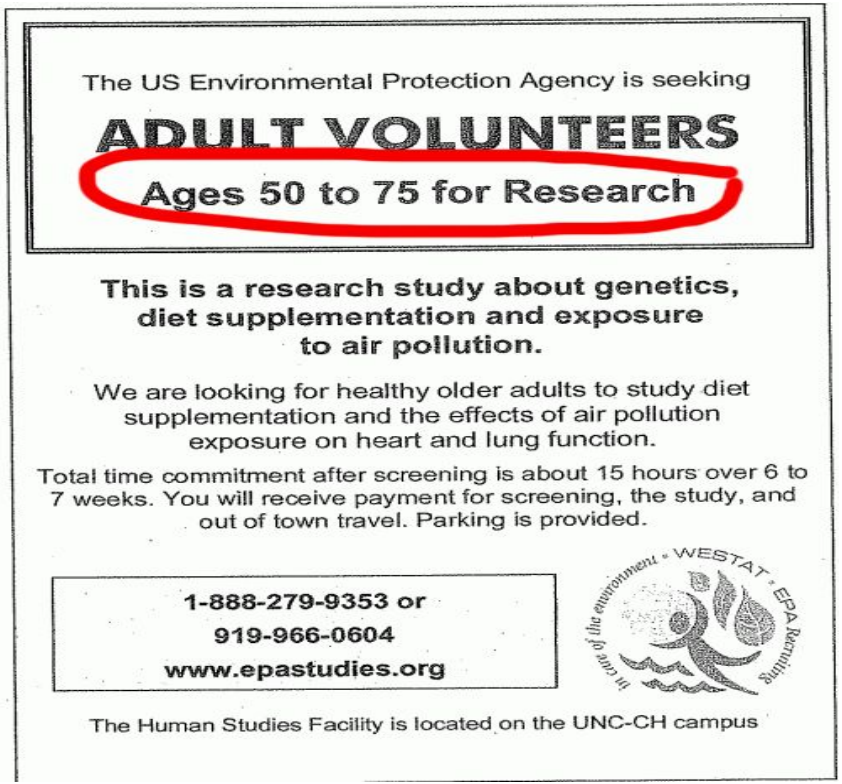
Who Are EPA's Human Subjects?

The Elderly



Who Are EPA's Subjects? (cont'd):

Even More Elderly



The US Environmental Protection Agency is seeking

ADULT VOLUNTEERS

Ages 50 to 75 for Research

This is a research study about genetics, diet supplementation and exposure to air pollution.

We are looking for healthy older adults to study diet supplementation and the effects of air pollution exposure on heart and lung function.

Total time commitment after screening is about 15 hours over 6 to 7 weeks. You will receive payment for screening, the study, and out of town travel. Parking is provided.

1-888-279-9353 or
919-966-0604
www.epastudies.org

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The Human Studies Facility is located on the UNC-CH campus

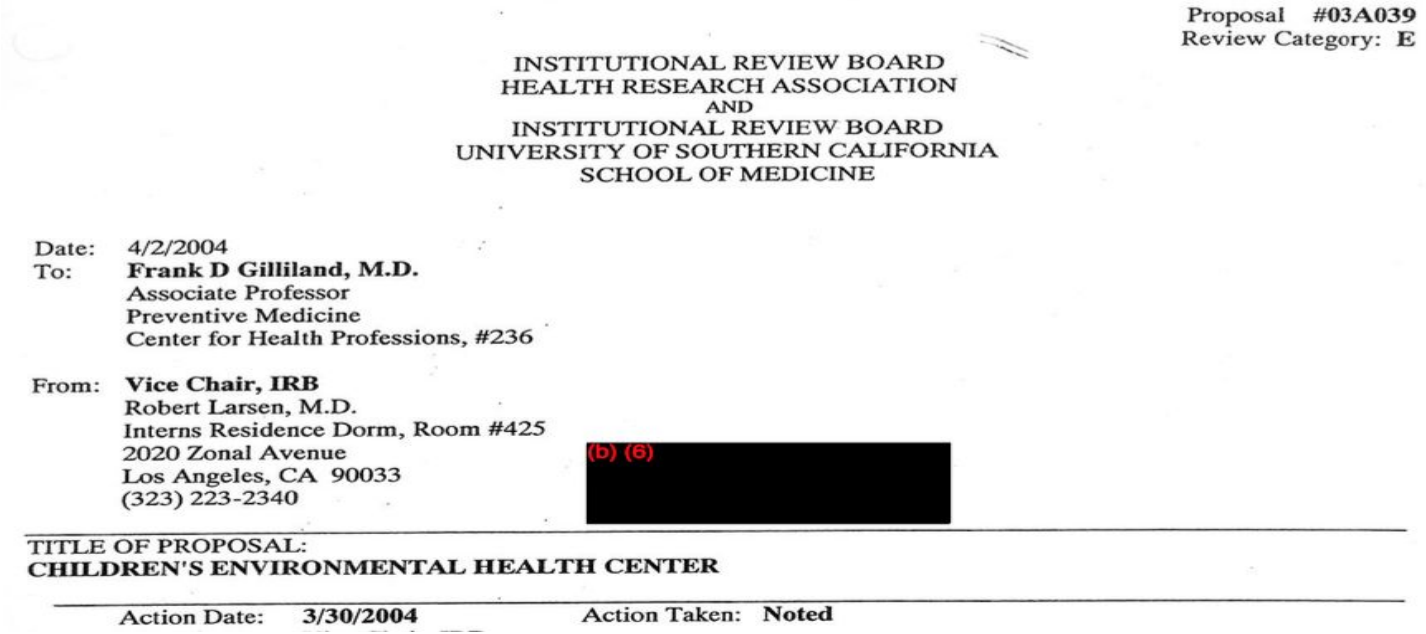
Who Are EPA's Subjects? (cont'd):

Even More Elderly

Gericon

The purpose of this study is to evaluate pulmonary and cardiac effects of exposure to air pollution particles in older adults ages 60 to 80. Time commitment includes one 24 hour screening period plus two 6-hour test days with follow-up. Exposures are separated by several weeks. Volunteers will breathe concentrated Chapel Hill air during one exposure visit and clean air during the other. Tests include cardiac monitoring, blood draws, lung function tests, and brachial artery imaging.

Who Are EPA's Subjects? (cont'd):
Children



Proposal #03A039
Review Category: E

INSTITUTIONAL REVIEW BOARD
HEALTH RESEARCH ASSOCIATION
AND
INSTITUTIONAL REVIEW BOARD
UNIVERSITY OF SOUTHERN CALIFORNIA
SCHOOL OF MEDICINE

Date: 4/2/2004
To: **Frank D Gilliland, M.D.**
Associate Professor
Preventive Medicine
Center for Health Professions, #236

From: **Vice Chair, IRB**
Robert Larsen, M.D.
Interns Residence Dorm, Room #425
2020 Zonal Avenue
Los Angeles, CA 90033
(323) 223-2340

(b) (6) [redacted]

TITLE OF PROPOSAL:
CHILDREN'S ENVIRONMENTAL HEALTH CENTER

Action Date: **3/30/2004** Action Taken: **Noted**

Who Are EPA's Subjects? (cont'd)

- Diesel exhaust particles sprayed up noses of children.

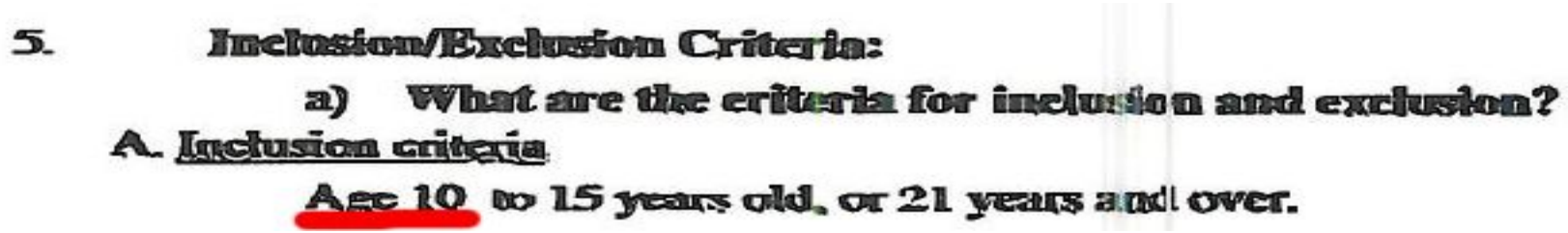
PROCEDURES
If you volunteer to participate in this study, you will be asked to do the following:

1) Nasal Challenge
The nasal challenge, involves placing several small mists of fluid into the nasal cavity. Each challenge will consist of between one and five small samples (0.1cc, or about three drops) of fluid applied to the nasal cavity through a sprayer and will contain soot from a diesel truck (diesel exhaust particles).

The diesel exhaust particles will be administered in small mists of fluid containing different amounts of particles. The highest amount of particles you may be given is equal to two day's average urban exposure in Los Angeles. This is less than you would receive from passing behind a diesel bus as it starts its engine. There have been no reported adverse reactions to this procedure, other than the possible uncomfortable feeling of fluid being sprayed into your nose.

Who Are EPA's Subjects? (cont'd)

- How old were the children?



5. **Inclusion/Exclusion Criteria:**

a) **What are the criteria for inclusion and exclusion?**

A. **Inclusion criteria**

Age 10 to 15 years old, or 21 years and over.

Who Are EPA's Subjects? (cont'd)

- EPA-funded researchers described risk to Institutional Review Board as 'minimal.'

pollutant: diesel exhaust particles (DEP) in combination with nasal lavage. These procedures involve minimal risk. We will then measure the amount of antioxidants produced upon

Who Are EPA's Subjects? (cont'd)

- State of California determined in 1998 that **diesel exhaust causes cancer** and that there is no safe exposure.

20. Based on available scientific information, a level of diesel exhaust exposure below which no carcinogenic effects are anticipated has not been identified.

Who Are EPA's Subjects? (cont'd)

- EPA commenced the process to ban experimenting on children in 2003 and finalized the ban in 2006.

Human Testing; Advance Notice of Proposed Rulemaking

A Proposed Rule by the Environmental Protection Agency on 05/07/2003

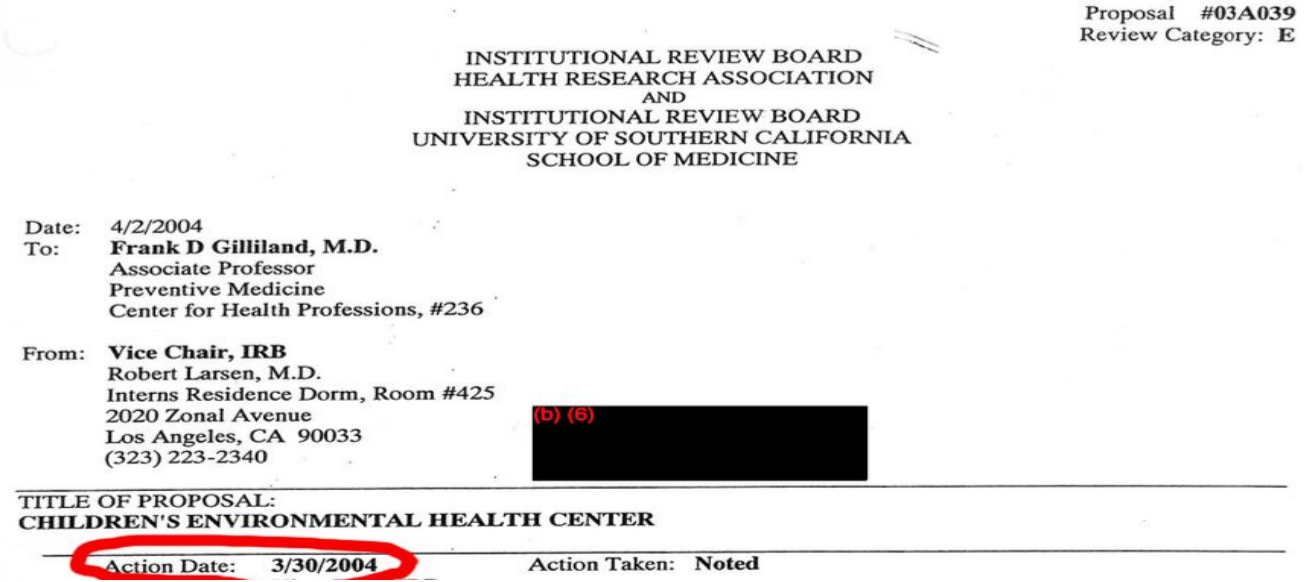
§26.203 Prohibition of research conducted or supported by EPA involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or child.

Notwithstanding any other provision of this part, under no circumstances shall EPA conduct or support research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

[71 FR 36175, June 23, 2006]

Who Are EPA's Subjects? (cont'd)

- EPA-funded USC experiments on children occurred during 2004-2005



Proposal #03A039
Review Category: E

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Action Date: **3/30/2004** Action Taken: **Noted**

EPA fails to explain deletion of kids diesel experiment on from data base

- As reported on JunkScience.com (April 25, 2013):

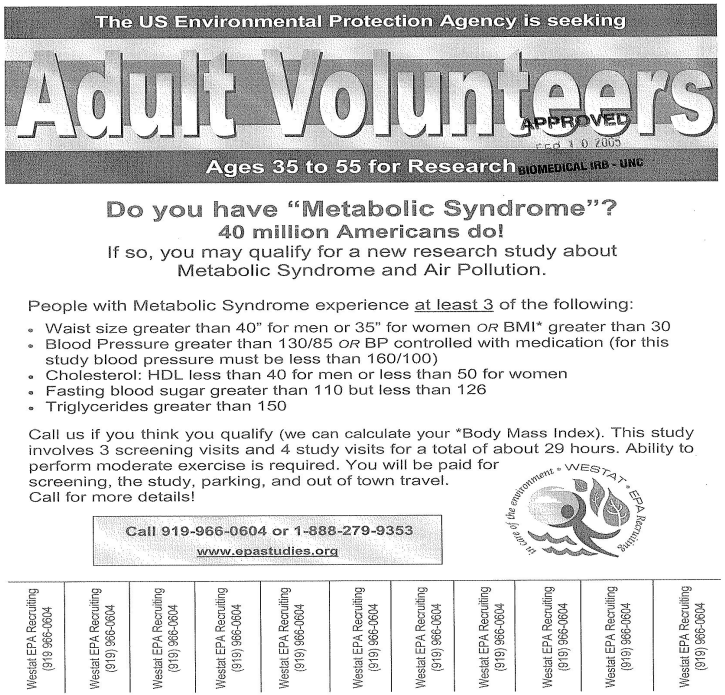
In February we FOIA-ed EPA for an explanation of why/how a report describing an illegal experiment exposing children to diesel exhaust was deleted from its data base. EPA responded to our request today.

You can read the EPA's response (collection of e-mails between technical staff) for yourself, but the bottom line appears to be:

- **JunkScience did not imagine the deletion.** The deletion did in fact occur;
- **The deletion was unusual.** It was the first deletion of its kind in the EPA databases's 13 years of existence; and
- **The miscreant remains undiscovered.** Although the mechanics of the deletion are understood, no one knows what caused it to occur.
- **Cover-up?** An EPA higher-up stated, "this situation is very disconcerting in that [EPA Research Triangle Park staff] as of yet has no idea what caused the problem to occur in the first place."

Who Are EPA's Subjects? (cont'd):

Unhealthy People –Metabolic Syndrome



The US Environmental Protection Agency is seeking

Adult Volunteers

APPROVED
FEB 10 2005
BIOMEDICAL IRB - UNC

Ages 35 to 55 for Research

Do you have "Metabolic Syndrome"?

40 million Americans do!

If so, you may qualify for a new research study about Metabolic Syndrome and Air Pollution.

People with Metabolic Syndrome experience at least 3 of the following:

- Waist size greater than 40" for men or 35" for women *OR* BMI* greater than 30
- Blood Pressure greater than 130/85 *OR* BP controlled with medication (for this study blood pressure must be less than 160/100)
- Cholesterol: HDL less than 40 for men or less than 50 for women
- Fasting blood sugar greater than 110 but less than 126
- Triglycerides greater than 150

Call us if you think you qualify (we can calculate your *Body Mass Index). This study involves 3 screening visits and 4 study visits for a total of about 29 hours. Ability to perform moderate exercise is required. You will be paid for screening, the study, parking, and out of town travel. Call for more details!

Call 919-966-0604 or 1-888-279-9353
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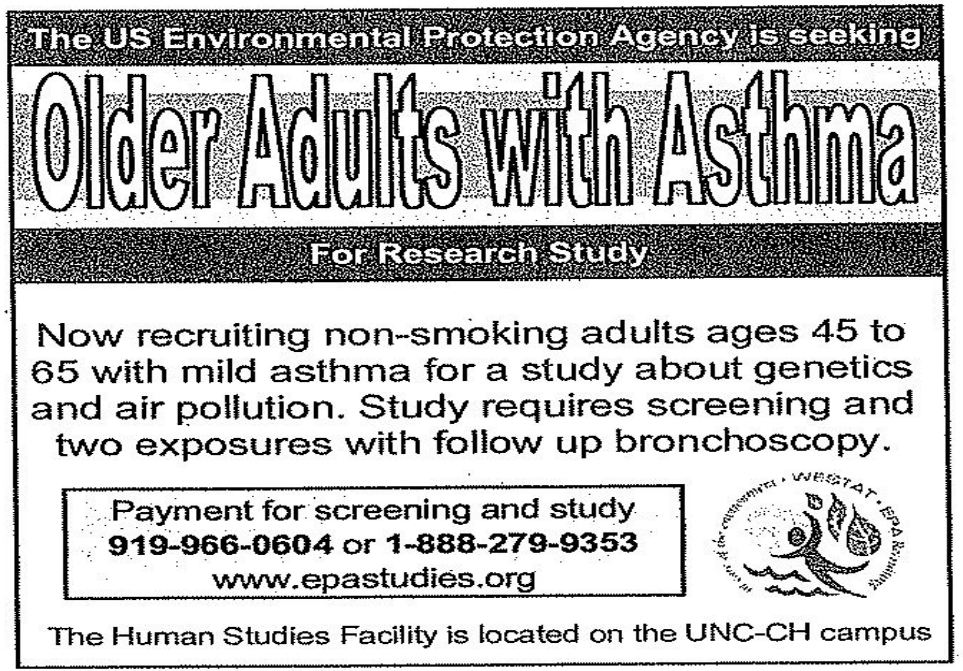
Who Are EPA's Subjects? (cont'd):

Unhealthy - Older Asthmatics



Who Are EPA's Subjects? (cont'd):

Unhealthy People - Diabetics

2. Inhalation of carbon UFP in diabetics

We have completed our study of the effects of inhalation of ultrafine carbon particles in subjects with diabetes. Diabetics have vascular endothelial dysfunction which may increase their risk for adverse cardiovascular effects from airborne particles. Type 2 diabetics, age 30-60, without clinical cardiovascular disease and not on "statin" medications, were exposed to filtered air or 50 µg/m3 carbon UFP (count median diameter ~30 nm, GSD 1.8) by mouthpiece for two hours, in a randomized double-blind cross-over study. Exposures were separated by at least two weeks. Nineteen subjects completed the study.

Who Are EPA's Subjects? (cont'd):

Unhealthy People: Heart Attack Waiting to Happen

Case report: Supraventricular Arrhythmia Following Exposure to Concentrated Ambient Air Pollution Particles

Andrew J. Ghio, Maryann Bassett, Tracey Montilla, Eugene H. Chung, Wayne E. Cascio, Martha Sue Carraway

http://dx.doi.org/10.1289/ehp.1103877

Online 6 September 2011

Who Are EPA's Subjects? (cont'd):

Unhealthy People: Heart Attack Waiting to Happen

Abstract

CONTEXT: Exposure to air pollution can result in the onset of arrhythmias.

CASE PRESENTATION: We present a case of a 58 year old woman who volunteered to participate in a controlled exposure to concentrated ambient particles (CAPs). Twenty minutes into the exposure, telemetry revealed new onset of atrial fibrillation. The exposure was discontinued and she reverted to normal sinus rhythm approximately two hours later. No abnormality was evident on the volunteer's laboratory examination or echocardiography which could explain an increased risk for supraventricular arrhythmia.

Who Are EPA's Subjects? (cont'd):

Unhealthy People: Heart Attack Waiting to Happen

On the day of exposure to CAPs, the volunteer had no symptoms. There was a history of osteoarthritis and hypertension treated with an angiotensin-converting enzyme inhibitor and a diuretic (lisinopril 10 mg and hydrochlorothiazide 12.5 mg). Previous surgeries included a hernia repair, a cholecystectomy, and a total left knee arthroplasty. The family history was significant for her father dying at 57 years of age with a myocardial infarction. The volunteer was a lifetime non-smoker. On physical examination, she was 173 cm tall and weighed 104.4 kg (the body mass index was 34.9 and her waist was 45 inches). Her pulse was regular at 66 per minute and her blood pressure was 144/61. The baseline electrocardiogram showed normal sinus

4

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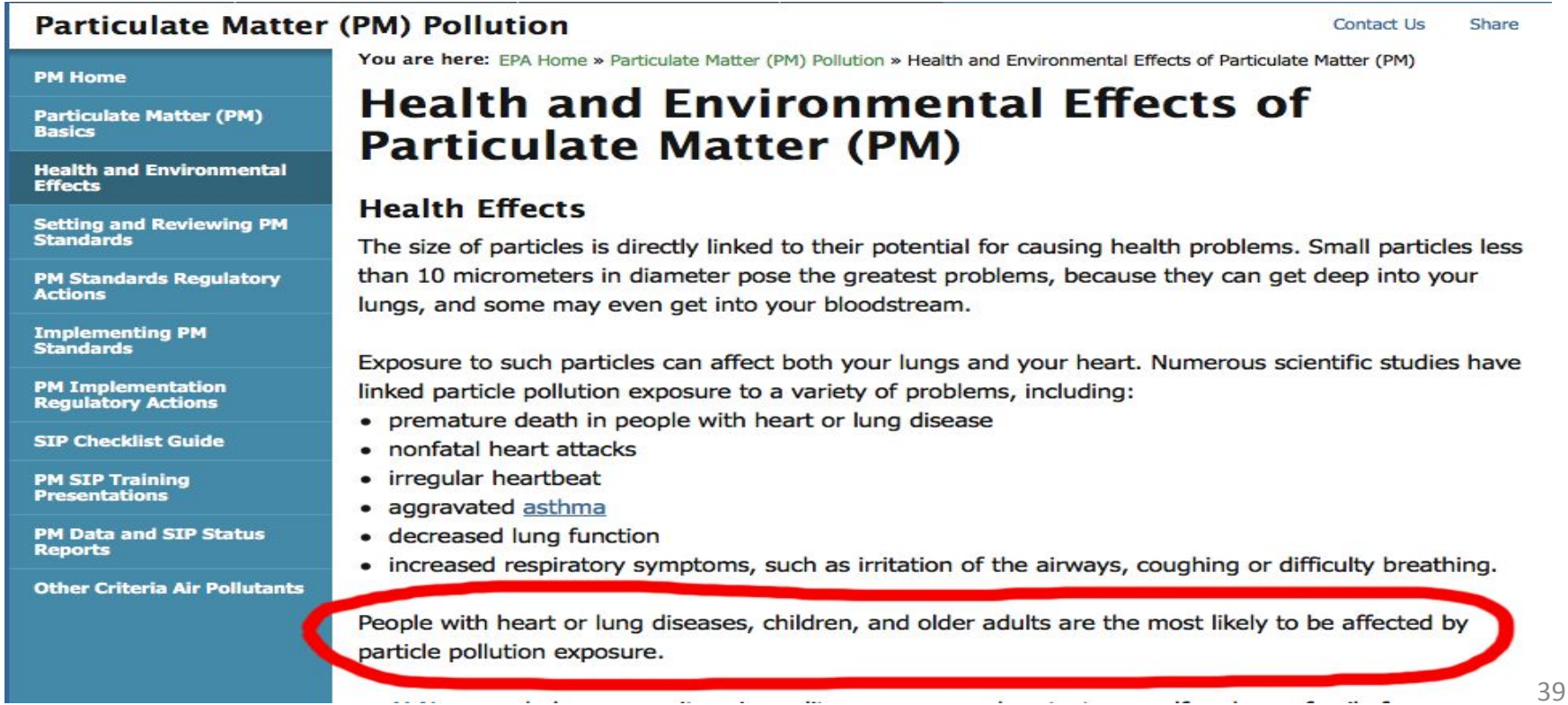
rhythm (Figure 1A). A holter monitor was placed and this demonstrated evidence of increased supraventricular ectopy with 157 ± 34 premature atrial contractions per hour during the 3 hours immediately preceding the exposure to CAPs.

Twenty three minutes into the exposure to CAPs (with a filter weight revealing 112 $\mu g/m^3$ and the particle number being 563912/cc), the telemetry monitor revealed that the subject

Who Does EPA Say Are Most Vulnerable to Effects of PM?



Particulate Matter (PM) Pollution

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Health and Environmental Effects of Particulate Matter (PM)

Health Effects

The size of particles is directly linked to their potential for causing health problems. Small particles less than 10 micrometers in diameter pose the greatest problems, because they can get deep into your lungs, and some may even get into your bloodstream.

Exposure to such particles can affect both your lungs and your heart. Numerous scientific studies have linked particle pollution exposure to a variety of problems, including:

- premature death in people with heart or lung disease
- nonfatal heart attacks
- irregular heartbeat
- aggravated asthma
- decreased lung function
- increased respiratory symptoms, such as irritation of the airways, coughing or difficulty breathing.

People with heart or lung diseases, children, and older adults are the most likely to be affected by particle pollution exposure.

How Much PM Did EPA Expose Study Subjects to?

- Recall: There is **no safe exposure** to PM, according to EPA.
- Average U.S. outdoor air has ~ **10 micrograms per cubic meter** of $PM_{2.5,}$ according to EPA.
  - 'Minimal risk' level for Common Rule purposes
- EPA acute exposure standard to $PM_{2.5}$ is **35 micrograms per cubic meter**.
  - Exceeding standard violates the law

How Much PM Did EPA Expose Study Subjects to?

- 58 year-old woman spotlighted in the Case Report

> Twenty three minutes into the exposure to CAPs (with a filter weight revealing 112 $\mu g/m^3$ and the particle number being 563912/cc), the telemetry monitor revealed that the subject had non-sustained atrial fibrillation that quickly organized into atrial flutter. She was

- 112 micrograms/m^3 is:
  - 3.2 times greater than EPA acute PM standard
  - 11 times greater than 'minimal risk'

How Much PM Did EPA Expose Study Subjects to?

- Diesel exhaust experiments

Procedures (methods): In the pilot study, subjects will have 3 sequential exposures to the diesel exhausts at concentrations approximately 100 $\mu g/m^3$, 200 $\mu g/m^3$, and 300 $\mu g/m^3$ for 2 hours with a about 2 weeks of interval between exposures. In the main study, GSTM1 positive and GSTM1

- 300 micrograms/m^3 is:
  - 8.5 times greater than EPA acute PM standard
  - 30 times greater than 'minimal risk'

How Much PM Did EPA Expose Study Subjects to?

- Concentrated PM particles

The concentration of particles delivered to the chamber will vary depending on the levels of naturally occurring particles in the Chapel Hill air. Although 24 hr averages seldom exceed 15-20 ug/m3, peak values in the summer can be as high as 50-60 ug/m^3 with lower values during the rest of the year. A face mask is used to reduce the daily and seasonal variability of PM concentration. Our past experience provides a basis to expect the particle mass delivered to the mask will be up ~~range between levels of 50~~ to 600 ug/m^3. The particle burden, on a mass basis

- 600 micrograms/m^3 is:
  - 17 times greater than EPA acute PM standard
  - 60 times greater than 'minimal risk'

How Much PM Did EPA Expose Study Subjects to?

- 'Oops!' exposure

Exposure Date	SUBJECT	Entered Chamber	Exited Chamber	Filter Conc (ug/m3)	Clinical E
1/5/2010	OMC019	11:02	13:02	205.27	No clinica
1/6/2010	KCN112	9:34	11:34	153.58	No clinica
2/9/2010	OMC021	10:52	12:52	442.49	No clinica
3/9/2010	OMC023	10:45	11:08	750.83	No clinica

- 750 micrograms/m^3 is:
  - 21 times greater than EPA acute standard
  - 75 times greater than 'minimal risk'

Are EPA's PM human experiments fundamentally unethical/illegal?

- Nuremberg Code
  - 5. [An experiment] should not be conducted when there is any reason to believe that it implies a risk of death or disabling injury.
    - Principles adopted by California
    - Applied by Maryland Court to Appeals to EPA-funded experiments in *Grimes v. Kennedy Krieger Institute* (2001).
- Common Rule – as adopted by EPA
  - No more than 'minimal risk' allowed (i.e., risk of harm no more than in ordinary life)
- EPA Rule 1000.17
  - 'Presumption' against studies with risk of 'substantial injury' or 'irreversible health effects.'
- The EPA IG report never addressed whether the experiments are 'fundamentally unethical/illegal.'

Informed Consent

- Instead of the ‘fundamentally unethical/illegal’ issue, EPA IG opted to focus on informed consent deficiency.
- Informed consent required by
  - Nuremberg Code
  - Common Rule
  - State Law (applies EPA researchers who are state-licensed physicians)
    - Felony

Recall what EPA tells the public and Congress about PM

- **Any exposure** to PM can be lethal.
- Lethality can occur **within hours**.
- PM **kills hundreds of thousands** of people annually at current outdoor levels.
- **Old/sick** are especially vulnerable.

What did EPA tell study subjects?

What are the possible risks or discomforts involved with being in this study?

This study might involve the following risks and/or discomforts to you:

If you have any tendency to become uncomfortable in small closed spaces, it is possible that you may become uncomfortable during this study. You will be taken to the exposure chamber when you are first evaluated for suitability for the study to allow you an opportunity to see where you will sit and what the chamber looks like.

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

Some EPA Guineas Pigs Received This Sort of 'Disclosure'

Ultrafine particle exposure: During one of your exposure sessions you will be exposed to air containing mostly concentrated ultra-fine air pollution particles (this air may contain some larger particles as well). The risks associated with concentrated particle exposure in people with metabolic syndrome are unknown. Some studies suggest that elderly people, particularly those with underlying cardiovascular disease, are at increased risk for getting sick and even dying during episodes of high air pollution. At this time, no one understands exactly how these particles might cause people to become sick or die. While we cannot exclude the possibility that you may have an adverse reaction to breathing these particles, you will only be exposed to them for a 2 hour period, and you will not be exposed to more than 600,000 particles/cc, which is less than or equal to what you would be exposed to driving along a heavily travelled highway in a large city such as Los Angeles.

Alleged CAPTAIN Experiment Disclosure

- EPA clinical studies coordinator claimed to **orally** state to study subjects, '**you may die from this**.'
- But Common Rule would require **written** disclosure for risk of death – if such an experiment were even permissible in the first place.

Why Is EPA Experimenting With PM on Human Beings?

- EPA claims ‘thousands’ for studies support its regulation of PM (Source: EPA ‘Fact Sheet’)
  - Epidemiology
  - Animal toxicology
  - Human ‘clinical studies’ -- i.e., human experiments

EPA Admits PM Epidemiology Inadequate

- From 2012 litigation with EPA about EPA's CAPTAIN human experiment:

large-scale epidemiological studies. Epidemiological studies, the primary tool in the discovery of risks to public health presented by ambient PM2.5, typically use data from large populations of people with varying susceptibility to PM2.5. They evaluate the relationship between changes in ambient levels of PM2.5 and changes in health effects. However epidemiological studies do not generally provide direct 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. Devlin Decl. ¶¶ 6,7,8.

Animal Toxicology Not Helpful to EPA

- **No laboratory animal has ever died** from mere PM exposure, despite extremely high exposures. [Source: EPA's 2009 ISA for PM]

EPA's Last Resort: Human Guinea Pigs

- EPA explanation for human experiments from 2012 litigation over EPA's CAPTAIN study:

¶¶ 8,9,10. The National Research Council of the National Academy of Science has recognized that controlled human exposure studies provide an opportunity to gain valuable scientific insights in the health effects of particulate matter. Devlin Decl. ¶ 8. Most of the controlled human exposure studies involving exposure to PM are in fact conducted by research institutions other than EPA. Declaration of Wayne Cascio ("Cascio Decl.") ¶ 11. This research has provided valuable information to help characterize and control risks to public health. See id. Exh. 1.

These studies help to determine whether the mathematical associations between ambient (outdoor) levels of air pollutants and health effects seen in large-scale epidemiological studies are biologically plausible (or are not). They help to determine the mechanisms by which air

SO…

Is EPA doing these experiments to see…
…if incredibly high exposures to PM…
can actually kill or…
seriously harm someone…
who is supposed to be especially vulnerable…
all while claiming…
there is only ‘minimal risk’ to study subjects?

‘Fundamentally Unethical’

- Letter from EPA Human Studies Review Board to EPA Science Advisor (October 26, 2009):

a. [redacted] With regard to determining whether or not a study is fundamentally unethical, the Board’s standard is to decide if the research was intended to seriously harm participants, or if it failed to obtain informed consent, or if it was fundamentally unethical for other reasons.

EPA's Claimed Defense

- Risks only occur in the population, not study subjects.
- [illegible]

> In evaluating the risk to research volunteers, it must be recognized that the risk to an individual is very different from the overall public health risk associated with exposures of large populations of people to typical ambient air levels of $PM_{2.5}$. This is especially the case if the individual does not have the health conditions most at risk, such as a preexisting cardiovascular or respiratory illness. While small risks to individuals may evidence themselves as much larger overall public health risks when large populations are exposed to ambient levels of $PM_{2.5}$, this does not change the fact that the risk for individuals that do not exhibit these health conditions will be small. Devlin Decl. ¶ 15.

Breaking Down EPA's Claimed Defense

- EPA admits PM kills people
- EPA claims risk is large in the population, but small to individuals
  - Populations are made up of people
    - EPA says hundreds of thousands killed by PM annually
    - 'Only' 31,000 killed in auto accidents annually – don't apply EPA rationale on your way home today
  - PM can kill hours after inhalation
    - Population doesn't collectively breathe
  - EPA researcher Dr. Robert Brook – stopped doing experiments because PM not safe
- EPA claims risk small is unless you are old/sick
  - But old/sick are precisely who the study subjects are
- EPA has already determined there is no safe exposure to PM and has regulated PM on the basis of lethality since 1997
  - What is the purpose of the experiments?

The more we do to you, the less you seem to believe we are doing it.

(Josef Mengele)

izquotes.com

Beyond PM Toxicity: Danger to Study Subjects from Experimental Protocol

- 19-year-old college student Haiyan ‘Nicole’ Wan killed during PM research (overdose of lidocaine administered for bronchoscopy).


massachusetts institute of technology

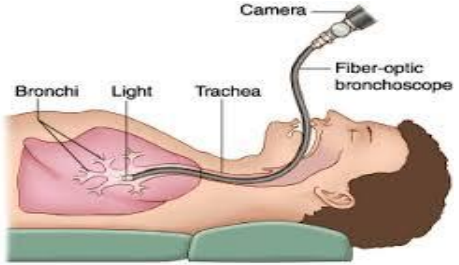
MITnews

engineering science management architecture + planning humanities, arts, and social sciences

today's news

Student dies at Rochester in MIT-based study

April 10, 1996



- Many EPA experiments involve bronchoscopy
  - UNC college student told me she had 6 or 7

Are EPA's Experiments Scientific?

- Examine spreadsheet of published human experiments in docket submitted by EPA (Summary Human Challenge Studies PM).
- Experiments not systematically designed/conducted
  - Study sizes small (as few a n=4)
  - Myriad PM tested (diesel, wood smoke, concentrated PM)
  - Various exposure levels, times
  - All results for all study subjects published?
  - Misrepresentation of study results
    - Ghio et al. (*EHP*, Sep 2011), "Case Report:…"
      - No mention of other human study subjects, i.e., contrary results
      - Disregard actual cause of reported health effect

Are EPA's Experiments Scientific? (cont'd)

UNIVERSITY OF ROCHESTER – EPA PM Center

Assessment of Ambient UFP Health Effects:
Linking Sources to Exposure and Responses in Extrapulmonary Organs

Günter Oberdörster[1]; Alison Elder[1]; Jack Finkelstein[1]; Mark Frampton[1]; Phil Hopke[2]; Annette Peters[3] Kim Prather[4]; Erich Wichmann[3,5]; Mark Utell[1]

([1]University of Rochester; [2]Clarkson University; [3]GSF, Germany
[4]UC-San Diego, [5]LMU-IBE, Germany)

Rochester PM Center Report

Grant EPA R827354
Ultrafine particles: Characterization, Health Effects and Pathophysiological Mechanisms
1999 - 2005

Are EPA's Experiments Scientific? (cont'd)

- Utility of EPA's human experiments in doubt, admit EPA funded PM researchers:

expected to produce only mild and transient responses. Furthermore, acute, transient responses seen in clinical studies cannot necessarily be used to predict health effects of chronic or repeated exposure. Endpoint assessment traditionally has included symptoms and pulmonary function, but

Are EPA's Experiments Scientific? (cont'd)

- Report from EPA's Science Advisory Board:

United States Environmental Protection Agency | Science Advisory Board (1400A) Washington DC | EPA-SAB-EC-00-017 September 2000 www.epa.gov/sab

EPA

COMMENTS ON THE USE OF DATA FROM THE TESTING OF HUMAN SUBJECTS

A REPORT BY THE SCIENCE ADVISORY BOARD AND THE FIFRA SCIENTIFIC ADVISORY PANEL

Are EPA's Experiments Scientific? (cont'd)

Bad science is always unethical; research protocols that are fundamentally flawed, such as those with sample sizes inadequate to support reasonable inferences about the matter in question, are unjustifiable.

Are EPA's Experiments Scientific? (cont'd)

- Common Rule prohibits bad science:

§26.102 Definitions.

(a) *Department or agency head* means the head of any Federal department or agency and any other officer or employee of any department or agency to whom authority has been delegated.

(b) *Institution* means any public or private entity or agency (including Federal, State, and other agencies).

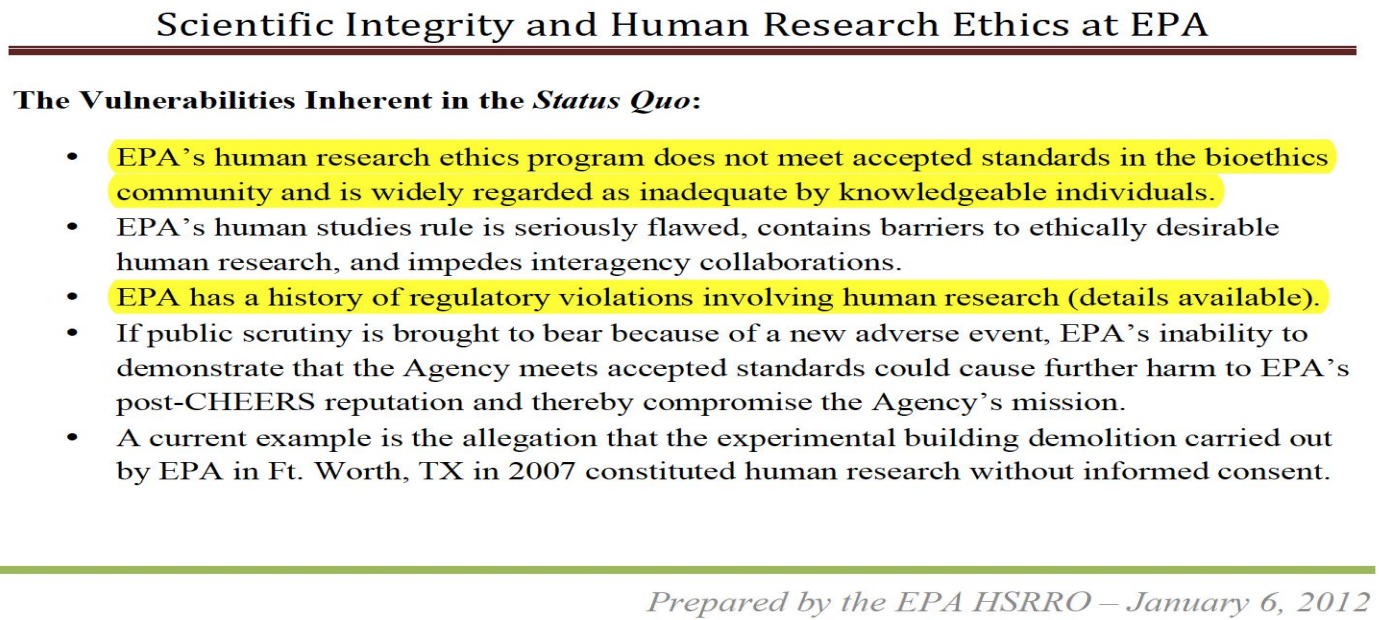
(c) *Legally authorized representative* means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

(d) *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

- EPA human experiments are
  - Not systematic
  - Not generalizable

‘History of Regulatory Violations’

- From internal EPA memo:



Scientific Integrity and Human Research Ethics at EPA

The Vulnerabilities Inherent in the *Status Quo*:

- EPA’s human research ethics program does not meet accepted standards in the bioethics community and is widely regarded as inadequate by knowledgeable individuals.
- EPA’s human studies rule is seriously flawed, contains barriers to ethically desirable human research, and impedes interagency collaborations.
- EPA has a history of regulatory violations involving human research (details available).
- If public scrutiny is brought to bear because of a new adverse event, EPA’s inability to demonstrate that the Agency meets accepted standards could cause further harm to EPA’s post-CHEERS reputation and thereby compromise the Agency’s mission.
- A current example is the allegation that the experimental building demolition carried out by EPA in Ft. Worth, TX in 2007 constituted human research without informed consent.

Prepared by the EPA HSRRO – January 6, 2012

Conclusion

- Based on EPA-determined lethality of PM, the old/sick nature of study subjects, disclosure/consent problems, and their non-scientific nature, EPA's PM human experiments are:
  - Fundamentally unethical, if not
  - Illegal.
- EPA has withheld key information from IRBs, study subjects, and the NAS Committee.

Implications of Conclusion

- If PM is as deadly as EPA claims, then its experiments violated every law/regulation established for the protection of human study subjects since the Nuremberg Code.
- The only way EPA does not have this legal culpability, is if PM is not as dangerous as EPA has told the public and Congress.
- No third option.

Thank you!

- Contact me for more information:
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  - JunkScience.com/contact
  - Twitter: @JunkScience