National Research Council of the National Academy of Science

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Assessing Toxicological Risks to Human Subjects Used in Controlled Exposure Studies of Environmental Pollutants

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Open meeting presentation by John Dale Dunn MD JD, with the handout below provided to Committee Members and Staff and the public attendees.

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Thank you for your attention.

I am a 45 year physician, emergency physician since 1974, inactive attorney admitted to the Texas and Louisiana Bars. I have special interests in medical ethics/medicolegal issues and also environmental human effects science and policy making.

Lying for Justice or the Noble Lie

There is a fundamental problem with lying when governments and people are committed to an ideology, cause or belief. Lying for Justice is part and parcel of what Joseph Schumpeter, famous economist, said on the matter—but he was probably repeating an observation that goes back at least to Plato—the noble lie is often the product of what, at least to the liar, is a means to a good end or result.

Schumpeter said that the first casualty of idealism is the truth. Does it matter that people lie for a cause and ignore the evidence? Well sure it does, since honesty is the cement of civilized human relationships, and the truth is what we seek in education, scientific inquiry, and our relations with others.

I would suggest to the committee that there is a lot of lying that happens for various reasons, usually somewhat selfish reasons. Today I will talk about lying and deceit in matters of environmental science and in particular the use of epidemiology, and how that resulted in a serious conundrum for the United States Environmental Protection Agency, a more than 10 year project involving human exposures to small particle air pollution that the US EPA has declared publically and repeatedly to be toxic, lethal and even alleged it to be carcinogenic, that should

make the human experiments forbidden under domestic and international law, custom and medical/scientific ethics. Instead at 10 domestic and 6 foreign medical schools the US EPA says experiments have been performed, approved by Institutional Review Boards that should prevent such activity.

Eric Hoffer is the best analyst of mass movements who put pen to paper, and he said that all great causes become businesses then rackets. Environmentalism is in the racket stage. Milloy, Young and I are here to expose a lie, the lie that air pollution is a terrible killer. We are here by the great good fortune of a big US EPA mistake—they wanted to buff up their weak claims derived from junk epidemiology and decided to do some human exposure experiments.

I assert that ambient small particle air pollution is benign and isn't killing anybody. In 45 years of medical practice I am still waiting for a death from small particle exposure. Unreliable epidemiology makes for the scare about air pollution, but it is an empty vessel. Epidemiology is not junk science, it's just limited to be less than proof of causation because it is so uncontrolled, but epidemiology can become deceitful if done without recognizing the limits of the methods and the uncertainties. I see this US EPA air pollution research project—that has been funded by billions, from mostly government sources as a gigantic deceit, built on uncontrolled observational studies and projecting non proof small associations to create big claim of deaths in particular. I hope to make this presentation worth your while and I will do my best to imitate Richard Feynman and talk evidence.

In the beginning were the EPA and the Clean Air Act

The US EPA, armed with the Clean Air Act that should have been titled the Safe Air Act, made policy about small particle air pollution, and had to use epidemiology to make the case, since toxicology experiments with animals didn't prove up a case for toxicity of air pollutants. The fall back method was population studies.

Small particles are 2.5 microns or smaller in diameter, and could be particles of dust, talcum powder, smoke from a fire, emissions from an engine, allergenic pollen from natural vegetation, or weaponized anthrax. The US EPA never bothers to tell the public or politicians that small particles vary in composition geographically because their research doesn't bother to distinguish; they just keep pounding the table that small particles are a result of evil industry, business, and human activities. They fail to even mention that dust is a component, and exists in places where humans don't live or work. No matter, the campaign against human activity allows for a little cheating. Lying for Justice. Human activity produces some of the small particle load in the air and that can be regulated, and agencies regulate.

The second component of the lie was studying populations in uncontrolled settings assuming that regional air monitors measured human exposures—nonsense for sure, since people spend the majority of their time indoors. Then the population researchers compounded the fraud by studying death rates against short arbitrary lag times for air pollution, looking for positive correlations but having nothing at all to do with plausible mechanisms for how pollution might kill.

But after those two method flaws were introduced it got even worse, because the US EPA researchers were forced to live with small associations that don't mean anything and could be called harvesting noise. So we had and have optimistic, politically motivated LYING for JUSTICE, silly small associations projected to large numbers of acute, called premature, deaths so that politically the US EPA became invincible, making fraudulent claims of thousands of deaths by small particles produced by evil fossil fuels and industrial, human activities. LYING for JUSTICE. The noble lie to justify action against industry and business and fossil fuel use--bring on the regulations.

Some of the members of the committee might remember the outcry against the US EPA air regulations proposed by Administrator and fanatic environmentalist Carol Browner in the mid-90s. The opposition to accepting the Pope and Dockery research claims used by Browner to justify an aggressive regulatory regime, was widespread and included the US EPA Clean Air Scientific Advisory Committee, divisions and departments within the Clinton administration, but Browner not only rejected the opposition, she doubled down and put the regs on fast track. Her example has been followed by the US EPA since—be confident, be aggressive.

Since the fateful period of the mid 90s when science was thrown out the window, millions, billions of dollars have been spent supporting research in toxicology and epidemiology to identify and quantify the harm caused by small particle air pollution, in preference to other pollutants, because the initial efforts on other criteria pollutants were not so promising for producing regulatory interventions. Only ozone was used as another pollutant, and there are plenty of scientific problems with US EPA ozone claims, but that's not important for this presentation.

The regulatory opportunities for the US EPA were not as attractive for carbon monoxide, the ozone precursors, and volatile chemicals. Small particles are ubiquitous, and will never go away because they are produced by natural processes, the regulation of small particles was the focus of the US EPA, the gift to the regulators and scaremongers that keeps on giving.

If one might consider the small particles claim of acute death effects, Steve Milloy asks the cogent question—if hookah and cigarette smokers inhale thousands of micrograms of small particles and don't drop dead, how can ambient small particles levels less than 50 micrograms in the ambient air kill people within days? Even very high ambient levels for coal miners, people living in Chinese cities don't kill. With that in mind how do US EPA officials claim hundreds of thousands of small particle deaths annually?

US EPA officials, for example the physician Chair of the US EPA Clean Air Scientific Advisory Committee (CASAC), Jon Samet MD MPH, declare there is no safe level of air pollution:

http://www.nejm.org/doi/full/10.1056/NEJMp1103332

Dr. Samet says:

> As the air standards, acronym NAAQS, have been reset at lower and

> lower concentrations, the gaps between acceptable concentrations and irreducible background levels have narrowed, raising the question of how much lower the limits can be pushed. 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.

It is ironic that Jon Samet succeeded Leon Gordis MD MPH DrPH as Chair of Epidemiology at Johns Hopkins Bloomberg School of Public Health. Samet has always been a slave to small associations epidemiology, something Gordis condemned energetically. Gordis, the grand man of epidemiology, wrote, with 2 co-authors, the Chapter on Epidemiology in the three editions of the *Reference Manual on Scientific Evidence,* a comprehensive guide for judges, lawyers and scientists on the issue of admissibility of scientific testimony and evidence.

In the Epidemiology Chapter for the 3rd edition, published by National Academies Press (Docket 60 i), Green, Freedman and Gordis discuss in depth how epidemiology can be used as evidence of causation, general and specific, and they emphasize that the critical factor in epi studies is strength of the association, and robust associations that overcome the problem of confounders in uncontrolled studies.

Ref Manual says at page 602:

> The higher the relative risk, the stronger the association and the lower the chance that the effect is spurious. Although lower relative risks can reflect causality, the epidemiologist will scrutinize such associations more closely because there is a greater chance that they are the result of uncontrolled confounding or biases.

I also recommend the assertions of the GRADE International Group (Docket 62 a) that assesses methods to improve reliability of epidemiology and writes in the 9th paper in a series on integrity of evidence in the *Journal of Clinical Epidemiology* the following (see Docket 62 b):

> Modeling studies addressing the degree of associations
> between causal factors and confounders, and between
> Table 1. Factors that may increase the quality of evidence
> ! Large magnitude of effect (direct evidence, relative risk [RR]52e
> 5 or RR50.5e0.2 with no plausible confounders); very large with
> RRO5 or RR!0.2 and no serious problems with risk of bias or
> precision (sufficiently narrow confidence intervals); more likely to
> rate up if effect rapid and out of keeping with prior trajectory;
> usually supported by indirect evidence.
> ! Dose-response gradient.
> ! All plausible residual confounders or biases would reduce a demonstrated
> effect, or suggest a spurious effect when results show no
> effect.
> 2 G.H. Guyatt et al. / Journal of Clinical Epidemiology - (2011) -
> confounders and outcomes, needed to induce different effect

> sizes of confounding support the decision to rate up for a large magnitude of effect. This modeling suggests that confounding (from nonrandom allocation) alone is unlikely to explain associations with a relative risk (RR) greater than 2 (or less than 0.5), and very unlikely to explain associations with an RR greater than 5 (or less than 0.2) [2].
> These conclusions are supported by some empirical work. A Cochrane methods review of 35 comparisons (from 15 studies) of randomized vs. nonrandomized trials of the same intervention found 22 comparisons in which the nonrandomized trials had larger estimates of effect, 8 with similar results, and 4 in which nonrandomized trials found smaller effects [3]. The difference between randomized and nonrandomized trials ranged from a 76% smaller (1/4) to a 400% larger (4/1) effect. Although further research is warranted, both modeling and empirical work suggest the size of bias from confounding is unpredictable in direction but bounded in size. Hence, the GRADE group has previously suggested guidelines for rating quality of evidence up by one category (typically from low to moderate) for associations greater than 2, and up by two categories for associations greater than 5 [4]. Other simulations have suggested that a threshold RR of 10 may be more appropriate for rating up by two levels [5,6].

My associates and colleagues who share my concerns about scientific integrity and reliable methods in epidemiology in air pollution research have made the point about small associations not being reliable proof of causation many times. Dr. Young, speaker today, Dr. James Enstrom, epidemiologist (UCLA), and I presented to subcommittees and the executive committee of the US EPA Board of Scientific Counselors in 2007 and 2008 on the subject. Many have made submissions to the US EPA and its affiliated state environmental agencies about small association epidemiology, to no avail.

This public comments opportunity provided by this committee, today, is the first time in my 20 plus year career of challenging the epidemiology of small associations sponsored by the US EPA, that wasn't limited to 3 minutes or a place to send a written comment. I always submitted detailed written documents that were summarily ignored. I therefore applaud you all for listening, and the discussion on Epidemiological issues now must turn to the reason we are here—why, if the US EPA asserts to Congress and the Public that small particles are lethal, toxic and carcinogenic, could the US EPA sponsor human exposure experiments with millions of dollars in grants to 10 domestic medical schools. ?

This committee must ask and answer the questions:

1. Why did the US EPA sponsor air pollutant human exposure experiments; and
2. Under what circumstances can human subjects be used in experiments on toxicity of air pollutants?

Why human experiments?

As Robert Devlin, senior EPA Research Scientist in the EPA North Carolina School of Medicine Human Experiments project said in his Declaration under Oath before the Eastern Virginia Federal District Court that the human experiments were done because epidemiology is inadequate to prove toxicity or lethality.

Robert Devlin Declaration (Docket 59 a) at paragraph 7:

> 7. Epidemiological observations are the primary tool in the discovery of risks to public health such as that presented by ambient PM2.5. However, epidemiological studies do not generally provide direct evidence of causation. They indicate the existence or lack of a statistical relationship between ambient levels of PM2.5 and adverse health outcomes. Large population studies cannot assess the biological mechanisms (called biological plausibility) that could
> explain how inhaling ambient air pollution particles can cause illness or death in susceptible individuals. This sometimes leaves open the question of whether the observed association in the epidemiological study is causal or whether PM2.5 is merely a marker for some other unknown substance.
> 8. Controlled human exposure studies conducted by EPA scientists and EPA funded scientists at multiple universities in the United States fill an information gap that cannot be filled by large population studies

Human exposure experiments with subjects exposed to air pollutants certainly might seem to be a gold standard, but there is a problem—if the US EPA epidemiology based claims asserted that small particles are toxic, lethal and carcinogenic, no human should ever be intentionally exposed such an allegedly toxic and deadly air pollutant.

The EPA and its researchers would say—well air pollution is ubiquitous, so maybe we could refine the consideration to prohibiting exposures in excess of "safe" levels. BUT *US EPA says there is no safe level.* Moreover, the experiments routinely used exposures greater than the "safe" levels established, admittedly arbitrarily, by the US EPA.

Assuming the US EPA is truthful and sincere in publications and public claims, including testimony before congress, about the toxicity and lethality of small particles, there is no excuse for the exposures.

The properly informed experimental subject, even one exposed to a "safe" and not the high levels commonly used in the experiments would still have to be told candidly that the US EPA, sponsor of the research, asserts that ambient air pollution kills, acutely and chronically, harms and causes disease, even cancer, at any level, so where is the window for human experimentation?

Dr. Martin Case US EPA researcher at UNC human experiments lab explained how he obtained a form of quasi informed and incomplete consent for the experiments in his declaration (I would call it an admission) under oath (Docket 58 h):

> 7. . . . I state very clearly that "their participation in this study and any
> study here at EPA is strictly and completely volunteer, and

that they may stop their participation at anytime for any reason without any coercion

whatsoever.,

8. . . . I will explain to them that they will be receiving clean air on one day of the study, concentrated particles from the air outside the test building on the second day of the study, and the third day is a follow-up day. I will state in lay terms how they will be exposed to the particles for 2 hours, and explain what this is similar to (comparable to) as compared to going about their everyday activities based on where they live.

> 11. . . . I inform that EPA will reimburse them up to $5,000.00 if is it determined by our on-call duty doctor that we have injured them in any way or caused illness by participating in this study. I always assure them that by signing this consent they are not signing away their right to sue if they feel they have been injured or wrongfully damaged by lack of reasonable care or neglect on our part.
>
> 13. . . . I show the subject that they are always on camera, that they can just speak up to be heard, and that I am always just several feet away at the console watching them. As I am performing the training, I physically show them the controlled testing chambers and point out all of these features and safe guards that we have in place. In addition, I informed them of our emergency medical equipment, our overhead paging capability, immediate emergency response by our nurses, and that a dedicated on-call physician is always in the facility at all times when any study is taking place. I state again, "any questions."

I would point out for the committee that there is no evidence in Dr. Case's declaration or in any of the consent forms obtained by FOIA requests that indicates the subjects were informed that the US EPA considered small particles lethal, toxic and carcinogenic at any level as had been asserted in publications by the US EPA and US EPA official testimony before congress.

Effect of an inadequate and incomplete, not candid "Consent "

There is obviously a scam involved—and it is important for the committee to consider—What if the subjects looked to the US EPA publications and found out that they were being exposed to what the EPA thought was so toxic, lethal and carcinogenic? I have already made my case for the fact that the US EPA does not have reliable proof of the claims of deaths or toxicity, so actual harm is unlikely, but what about mental distress and fear, a concern about cancer, risk of death created? If not told about the US EPA positions, is there any way subjects are provided proper information for an informed consent? Would any reasonable person consider Dr. Case's consent process to be candid and honest? Would the subject be

concerned about this toxicity, death and cancer thing? Maybe? We know that none of the signed consent forms used in the EPA sponsored human experiments indicated that the EPA official position was that small particles are toxic, lethal, and carcinogenic at any level. That is not consistent with the obligation of experimenters to give an informed consent from subjects after a full and candid discussion of risks and methods to be used.

Do "Controlled" Human Exposure Experiments Immunize the researchers and the US EPA?

The EPA sponsored human experiments involving "controlled" exposures, a word repeatedly used by the EPA in its submissions and adopted, apparently, by the committee. I assert that illegal and unethical human exposure experiments are controlled and such experiments have been "controlled" in the past, by controlling monsters who caused great harm to innocents and, in some cases were convicted and executed.

Human experiments designed and paid for by the US EPA are intended to elicit harmful effects. Otherwise what they be used for—the US EPA is not interested in proving small particles are benign—this whole project makes humans guinea pigs to improve the research portfolio of the US EPA in its war on fossil fuels and industry.

The Committee website used the word "controlled" liberally because it implies care and concern about safety, but that is just not true here, the experiments are intended to find some harm—to produce some harm, and we all know that the worst human experiments in history involve "control" and a lot of it. Obtaining
consent for a harmful exposure cannot be finessed.

I noted that it appears another argument by the US EPA is that the human experiments are like Phase I drug trials, but that is deceitful.

Phase I drug discovery protocols proceed in steps:

1. Use a motivating example to propose a theory.

2. Test the theory in animals for efficacy and safety.

3. Test in humans.

If at any step in this process, the compound is deemed not safe or not efficacious, the theory is discarded. The Phase one protocols are intended to avoid harm to subjects, not create harm.

If one would attempt another excuse and say that a short term high level exposure in a chamber would be cumulatively equivalent to a day's or a week's ambient exposure that ignores what the committee knows is the reality of toxicity—dose makes the poison—and an acute dose exposure would predictably be a greater risk concern than a lower dose exposure over a period of time. The simple example of acetaminophen or any drug or chemical toxicity you could name, like iron or lithium, should explain how the committee can reject that gambit. Short term acute exposures are not the same as long term chronic exposures because of basic human protective and metabolic, excretion processes.

The exceptions repeatedly mentioned in codes for a sorely needed objective and/or an experiment that the researchers are willing to do on themselves is not applicable because there was no need—the deceit of the epidemiology had provided the US EPA with the arguments to promote its agenda of regulation, so human experiments were politically unnecessary and still unethical and illegal.

Historical Codes, Agreements and Laws on Experimental Ethics

Pertinent ethical commentaries and excerpts from codes and laws follow for emphasis. The original language and texts are found at Docket a-f and Mr. Milloy provides in depth discussion of the Common Rule and EPA rule 1000.17, so I will not repeat. I also will not read the documents below—they all say a subject should not be exposed to harm and a properly informed consent including candid exposition of risks and benefits should be obtained when a human is subject to treatment and particularly to experimental exposure.

Hippocratic Oath (I have it propped a few feet away)

> I will Follow that method of treatment which, according to my ability and judgment , I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to anyone if asked, nor suggest any such counsel, . . .

Berlin Code of 1900 Docket 58 a

> Berlin Code of Ethics (1900) guaranteed that "all medical interventions for other than diagnostic, healing, and immunization purposes, regardless of other legal or moral authorization are excluded under all circumstances if (1) the human subject is a minor or not competent due to other reasons; (2) the human subject has not given his unambiguous consent; (3) the consent is not preceded by a proper explanation of the possible negative consequences of the intervention."

German Code of 1931 (Circular of the Reich Minister of the Interior) Docket 58 b

> The freedom to be granted to the physician accordingly shall be weighed against his special duty to remain aware at all times of his major responsibility for the life and health of any person on whom he undertakes innovative therapy or performs an experiment.
> 3. For the purposes of these Guidelines, "innovative therapy" means interventions and treatment methods that involve humans and serve a therapeutic purpose, in other words that are carried out in a particular, individual case in order to diagnose, treat, or prevent a disease or suffering or to eliminate a physical defect, although their effects and consequences cannot be sufficiently evaluated on the basis of existing experience.
>
> 4. Any innovative therapy must be justified and performed in accordance with the principles of medical ethics and the rules of medical practice and theory.

In all cases, the question of whether any adverse effects which may occur are proportionate to the anticipated benefits shall be examined and assessed. Innovative therapy may be carried out only it if has been tested in advance in animal trials (where these are possible).

5. Innovative therapy may be carried out only after the subject or his legal representative has unambiguously consented to the procedure in the light of relevant information provided in advance. Where consent is refused, innovative therapy may be initiated only if it constitutes an urgent procedure to preserve life or prevent serious damage to health and prior consent could not be obtained under the circumstances.

Nuremberg Code (summary of Code) 1947 Docket 58c

1. Voluntary Consent is essential
2. The results must be for the greater good of society
3. Should be based on previous animal experimentation
4. Should be conducted by avoiding physical/mental suffering and injury
5. No experiments should be conducted if it is believed to cause death/disability
6. Risks should never exceed the benefits
7. Adequate facilities should be used to protect subjects
8. Conducted only by qualified scientists
9. Subject should always be at liberty to stop at any time
10. Scientist in charge must be prepared to terminate the experiment when injury, disability, or death is likely to occur

World Medical Association Helsinki Accords Docket 58 e

17. Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.

22. In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be

obtained in writing, the non-written consent must be formally documented and witnessed.

27. Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

Belmont Report Docket 58d (1978)

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

2. *Beneficence.*— Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is

harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children—even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the

> principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

Common Rule Federal Law provisions are discussed by Mr. Milloy, and known to the committee. Federal law prohibits human experiments that are known to create risk of harm.

EPA Rule 1000.17 is also discussed in detail by Milloy and does not provide an excuse or back door for human experiments if the research is likely to expose subjects to harm.

California State Law, for example, adopts the Nuremberg Code, and state statutes apart from Medical Practice acts address human experiments and human experimentation and prohibit harmful experiments.

State Medical Practice Licensure Acts require licensees to act to prevent harm from medical practice by other practitioners. Physicians are always involved in US EPA human experiments and that is required by the Institutional Review Boards, so what happened here in this EPA project?

I personally am obligated by the State of Texas to act to prevent medical practice that harms the public if I come to know of it. Do the state licensed physicians on the Committee feel that same duty—I believe so, I hope so.

American and English Common Law provides for application of tort law elements of battery and infliction of mental distress, negligent or intentional torts are pertinent to the discussions, and Anglo American law proscribes conduct that would harm. Common Law jurisprudence prohibits human experiments that would harm the subject.

Medical Society and Association Ethical norms. These norms track with the pertinent ethical standards recited above, but certainly are pertinent when considering the neglect by medical boards and medical societies. Milloy and I have received NO support from medical associations, societies, medical boards or Institutional Review Boards in our efforts to expose this scandal.

The role of the Institutional and Governmental Review Boards

Milloy and I were both ignored and disregarded when we contacted editors of journals, initially, and then Agency authorities responsible for ethics and integrity, except to be told to go away. When we approached

the Michigan and North Carolina Medical Boards on the ethical lapses evident from the human experiments we received expedited rejections, in both cases in less than a month. That is remarkable, considering that Medical Boards cannot possibly complete an investigation and review the results in such a short time.

My letters to physicians in congress, which I thought would trigger their recollection that under their medical licensure they are obligated to protect the public from medical misconduct, were similarly ignored. Letters to 18 physician congressmen received no response. The text of those letters to congressmen have been submitted for committee review (Docket 59 b).

A similar lack of response came from letter I wrote to every Medical Dean of the 10 domestic medical schools (Docket 60 a) named by Dr. Cascio as grantees for US EPA sponsored human experiments in his declaration under oath (Docket 58 g).

Dr. Cascio listed the medical schools in the US in his sworn declaration and asserted that the Institutional Review Boards had determined the experiments were in compliance with the Common Rule—HOW?

11. Between 2000 and 2012 environmental research scientists in the US and abroad published 61 controlled human exposure studies in peer-reviewed scientific journals related to PM exposures. These controlled human exposure studies encompassed a variety of common air pollutants including: concentrated air particles, dilute diesel exhaust, wood smoke, and ultrafme carbon and zinc particles. Only 8, or 13% of these studies were conducted and published by the US EPA. The balance of studies, or 87% of all controlled human exposure studies to PM were approved, conducted and published by non-EPA scientists. Other institutions who have or are conducting such studies include: the University of Rochester School of Medicine and Dentistry, Rochester, NY; University of Michigan, Ann Arbor, MI; University of Washington, Seattle, WA; University of Southern California, Los Angeles, CA; Rutgers The State University and University of Medicine and Dentistry ofNew Jersey- Robert Wood Johnson Medical School,Piscataway, NJ. These studies have been

approved by Institutional Review Boards as conforming to the provisions of the Common Rule. In addition, similar studies involving controlled human exposure to PM are conducted by non-domestic institutions including the University of Toronto, Toronto, Ontario, Canada; University of Edinburgh, Edinburgh, UK, Goteborg University, Goteborg, Sweden; Umea University, Umea, Sweden; University of Copenhagen, Denmark, and the University of Southampton, Southampton, UK. Attached as Exhibit 1 to this affidavit are excerpts from EPA's 2009 Integrated Science Assessment for Particulate Matter (Devlin Declaration para.

12. The EPA supports extramural research through the National Center for Environmental Research (NCER). NCER is currently providing research funding for human controlled exposure studies to two US academic centers; namely, the University of Michigan, Ann Arbor, Michigan, and University of Washington, Seattle,

Washington. These studies also involve research collaborators and their laboratories at Michigan State University, East Lansing, MI; Ohio State University, Columbus, OH; University California at Los Angeles, Los Angeles, CA; and the Lovelace Respiratory Research Institute, Albuquerque, NM.

The Role of the NRC

When Milloy and I heard, belatedly and almost accidentally about the formation of this committee, we realized it resulted from a luke-warm and muddled delayed report from the US EPA Inspector General in response to a letter from Dr. Broun, Chair of Oversight subcommittee of the House Space, Science and Technology committee. However, we are very pleased that the IG report made the EPA nervous enough to try to get the NRC to give them a pass.

The Behavior of the Committee is also alarming—since an easy google search would have identified Milloy and me as energetic critics of the human testing project, and qualified to complain.

It is easy to assume that the EPA hoped for a whitewash. We hope the members of the committee will see that would be an embarrassment to them personally, the NRC and the NAS.

The False Claims (fraud) Law

The False Claims Act, colloquially called the Lincoln Law, pertains to services or goods provided by Government contractors. Research is a service and if provided fraudulently or if the service provided is substandard, treble damages and other civil penalties are in play—those fines and penalties could be assessed against those who colluded to provide fraudulent services or goods, like research, so this matter creates immense potential for monetary losses for researchers and their institutions

The Federal Code of Civil and Criminal statutes has many nooks, crannies and dark places that pertain to misconduct, and an assiduous prosecutor could make a lot of fine institutions and prominent researchers very uncomfortable, armed with that Code if they were a part of the epidemiological scam/human experiments project.

The Solution

The committee could solve this dilemma very easily—declare the epidemiology research claims on air pollution made by the US EPA, the environmental community and the researchers a fraud, unreliable research evidence that does not prove small particles are toxic, lethal, carcinogenic, that there are not hundreds, thousands, millions of deaths from small particles and the claims of the US EPA are the product of deceitful scientific methods.

Then the only misconduct is scientific fraud because all along the US EPA and its researchers knew the claims of small particle toxicity and lethality were bogus. So, the only repair work required is to explain the matter to the subjects so they won't worry about their fate, redo the epidemiological studies with proper consideration of the rules of proof of causation. Cancel the Human Experiments as unnecessary and unethical until the epidemiology can be cleaned up. The epidemiological and human experimental studies on air pollutants have been an embarrassment and a collosal waste of money and resources, in addition to

exposing researchers to corrupt science in the service of political agendas.

Imagine the alarm at the US EPA and in faculty salons across the nation.

Human experiments that are a risk to harm are unethical and illegal, and should be condemned, period. IRBs across the nation need to stop and consider. IRBs, researchers and institutions should be held accountable for doing human experiments that are illegal, unethical and immoral if the researchers actually believed the public propaganda of the US EPA. If they didn't, then they were participating in an immense fraudulent research project funded by the innocent and unknowing taxpayer.

Conclusion

The committee must ask—under what circumstances could these human experiments on minors be ethical or legal? Answer—none, UNLESS the EPA and its researchers walk back their claims of hundreds, thousands, millions of people dying from exposure to ambient small particle air pollution.

How's that going to happen in this hyper political world? How can we achieve scientific integrity in such a world where money and influence push science with a political agenda? The problem of scientific integrity is a big problem caused by big science. Consider this discussion of the problem in a prominent journal:

Baker M. 2016. 1,500 scientists lift the lid on reproducibility. Survey sheds light on the 'crisis' rocking research. Nature 533, 452-454.

http://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970

Milloy, Young and I are here to ask the committee to consider the conduct, the violation of ethics, morality and the law in this human experiments project promoted by the US EPA.

We all fret about scientific integrity—but do we want to fix the problem, particularly in the context of Lying for Justice, for an environmental cause?

Respectfully submitted,
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