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EPA's Illegal Use of Children in Diesel Exhaust Experiments

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JunkScience.com has confirmed through the Freedom of Information Act that the U.S. Environmental Protection Agency paid the University of Southern California (USC) and the University of California, Los Angeles (UCLA) to conduct experiments testing whether exposure to diesel exhaust harms children. These experiments are illegal under the Nuremberg Code, California state law and federal regulations concerning the protection of human subjects in medical research.

Background

Based on documents received by means of FOIA during 2012, JunkScience.com reported that the EPA had for many years conducted illegal scientific experiments in which human study subjects were intentionally exposed to air pollutants the EPA considered lethal at any dose or exposure. These experiments were deemed illegal for two basic reasons: (1) Federal regulations prohibit EPA researchers from placing human study subjects at risk of death; and (2) EPA failed to disclose to the study subjects that their participation in the experiments entailed a risk of death. The EPA Office of Inspector General validated these findings in a March 2014 report.

While all of the foregoing experiments involved adult humans subjects, it came to the attention of JunkScience.com in late 2012 that the EPA-funded researchers at USC may have also experimented on children. Not only do California state law and federal regulations prohibit endangering children in non-therapeutic scientific experiments, but as minors, children cannot provide the legally-required consent to participate in such experiments.

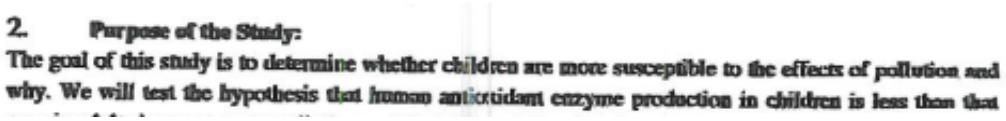
JunkScience.com's effort to investigate this matter was not only rebuffed by the USC researchers but the EPA also endeavored to cover-up the child experiments in February 2013. After multiple FOIA requests, the EPA finally released some documents to JunkScience.com in December 2014.

What the Documents Show

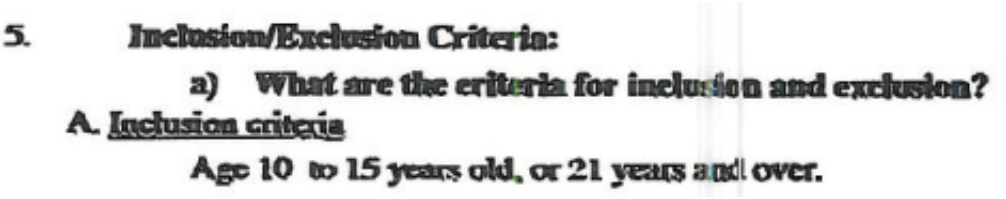
1. The children were treated as guinea pigs in a non-therapeutic experiment

The experiments on children were part of a larger research project that ran from November 1, 2003 through October 31, 2010. A basic purpose of this project was "to investigate the role of… locally emitted fresh vehicle exhaust in airway inflammation and in asthma occurrence in childhood" and then to "translate the… research findings into public health action and policy…" [p.1].

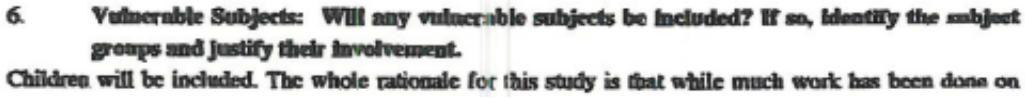
The children-as-guinea-pigs nature of the experiment is captured in this description from the application for approval submitted by the researchers to the UCLA Institutional Review Board (IRB).


2. Purpose of the Study:
The goal of this study is to determine whether children are more susceptible to the effects of pollution and why. We will test the hypothesis that human antioxidant enzyme production in children is less than that

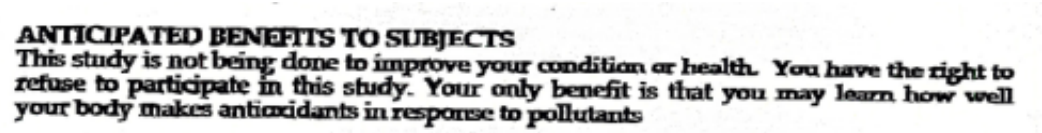
The experiment involved exposing the children to four different doses of diesel exhaust particles, ranging from 0 to 300 micrograms. The children were exposed to the diesel exhaust particles by nasal spray. A total of 20 children were experimented on in this way.[pp. 7-8]. As revealed in the IRB application, the age range of the children was 10 to 15 years of age.


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.

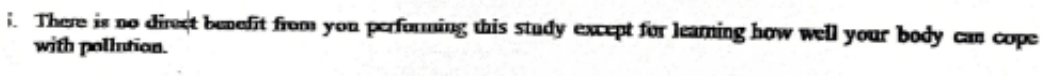
These children were considered by the researchers to be more "vulnerable" than adults to the effects of the diesel exhaust particles.


6. Vulnerable Subjects: Will any vulnerable subjects be included? If so, identify the subject groups and justify their involvement.
Children will be included. The whole rationale for this study is that while much work has been done on

As disclosed in the consent form, this experiment provided no health benefits to the children.


ANTICIPATED BENEFITS TO SUBJECTS
This study is not being done to improve your condition or health. You have the right to refuse to participate in this study. Your only benefit is that you may learn how well your body makes antioxidants in response to pollutants

The absence of health benefit was reiterated in the assent form to be signed by the children.


i. There is no direct benefit from you performing this study except for learning how well your body can cope with pollution.

2. The experiments were dangerous and potentially lethal, according to federal and state scientific assessments.

The children were intentionally exposed to diesel exhaust particles. The researchers described this exposure in the IRB application as being of "minimal risk."

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

The level of exposure was described as being equivalent to two days worth of exposure to Los Angeles air.

Diesel exhaust particle challenge. **A small amount of fluid (about 5 drops) containing diesel exhaust particles in an amount up to that equivalent to about 2 days exposure to Los Angeles air is simply sprayed into the nose.**

The researchers dismissed the health risks of diesel exhaust as limited to lung cancer from high lifetime-long exposures — none of which would occur during the proposed experiments.

Diesel exposure

Diesel is considered a toxic air contaminant in California, and a "likely" carcinogen by the U.S. EPA. However, it is clear that its potential effects on cancer come only upon high level life-time exposures and not acute exposures. Indeed, the US EPA itself has given approval for its own scientists to do human diesel exposures. It should be stressed that the concentrations used here mimic real world exposure levels. It is very important to realise that the cancer risk associated with diesel is solely for lung cancer. In this case following nasal challenge, the amount that will reach the lung is extremely small; most is cleared by the nasal cilia in 48 hours or else swallowed and naturally excreted. In rare cases, subjects may experience an unpleasant taste like soot. Some itching may occur.

But in 1998 — six years before the experiments — the California Air Resources Board (CARB) released an assessment of diesel exhaust concluding that diesel exhaust can cause cancer and that there is no safe exposure to diesel exhaust, as follows:

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

The CARB also identified short-term health effects from diesel exhaust, as follows:

12. A number of adverse short-term health effects have been associated with exposures to diesel exhaust. Occupational exposures to diesel exhaust particles have been associated with significant cross-shift decreases in lung function. Increased cough, labored breathing, chest tightness, and wheezing have been associated with exposure to diesel exhaust in bus garage workers. A significant increase in airway resistance and increases in eye and nasal irritation were observed in human volunteers following one-hour chamber exposure to diesel exhaust. In acute or subchronic animal studies, exposure to diesel exhaust particles induced inflammatory airway changes, lung function changes, and increased the animals' susceptibility to infection.

CARB identified presumably serious immunological responses to diesel exhaust, as follows:

14. Studies have shown that diesel exhaust particles can induce immunological reactions and localized inflammatory responses in humans, as well as acting as an adjuvant for pollen allergy. Intranasal challenge with diesel exhaust particles in human volunteers resulted in increased nasal IgE antibody production and a significant increase in mRNA for pro-inflammatory cytokines. Co-exposure to diesel exhaust particles and ragweed pollen resulted in a nasal IgE response greater than that following pollen or diesel exhaust particles alone. Effects of intratracheal, intranasal, and inhalation exposures of laboratory animals are supportive of the findings in humans. These effects include eosinophilic infiltration into bronchi and bronchioles, elevated IgE response, increased mucus secretion and respiratory resistance, and airway constriction.

The CARB also noted that the EPA set the regulatory allowable level for inhalation of diesel exhaust at 5 micrograms per cubic meter.

15. Based on the animal studies, the U.S. EPA determined a chronic inhalation Reference Concentration value of 5 $\mu g/m^3$ for noncancer effects of diesel exhaust. This estimate takes into consideration persons who may be more sensitive than others to the effects of diesel exhaust. The report supports the recommendation of 5 $\mu g/m^3$ as the California Reference Exposure Level (REL) (Table 1). It should be noted that this REL may need to be lowered further as more data emerge on potential adverse noncancer effects from diesel exhaust.

But the children in the experiment were exposed to diesel exhaust dose via nasal spray as high as 300 micrograms — 60 times higher than the EPA's allowable exposure standard.

The CARB also concluded that diesel exhaust is genotoxic, mutagenic, and cause "chromosomal aberrations" and "unscheduled DNA synthesis."

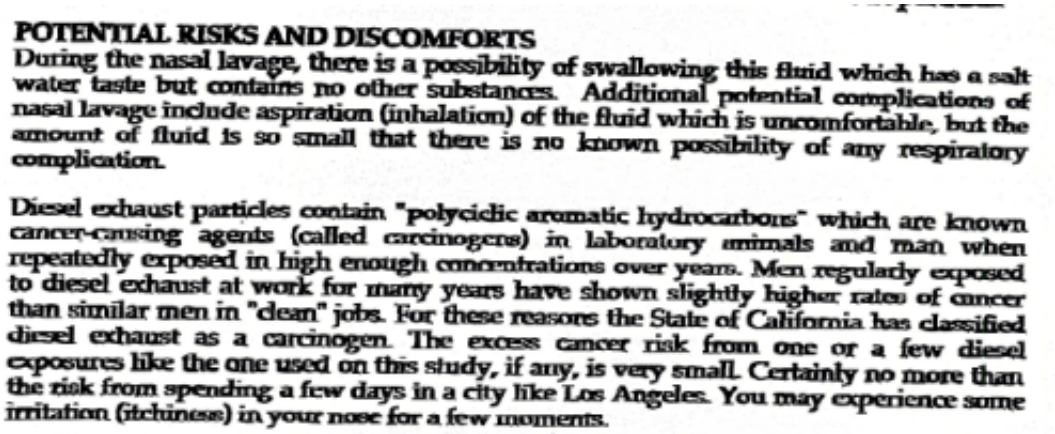
16. Diesel exhaust contains genotoxic compounds in both the vapor phase and the particle phase. Diesel exhaust particles or extracts of diesel exhaust particles are mutagenic in bacteria and in mammalian cell systems, and can induce chromosomal aberrations, aneuploidy, and sister chromatid exchange in rodents and in human cells *in vitro*. Diesel exhaust particles induced unscheduled DNA synthesis *in vitro* in mammalian cells. DNA adducts have been isolated from calf thymus DNA *in vitro* following treatment with diesel exhaust particle extracts. DNA adducts have been shown to increase following inhalation exposure of rodents and monkeys to whole diesel exhaust. Elevated levels of DNA adducts have been associated with occupational exposure to diesel exhaust. Results of inhalation bioassays in the rat, and with lesser certainty in mice, have demonstrated the carcinogenicity of diesel exhaust in test animals, although the mechanisms by which diesel exhaust induces lung tumors in animals remains uncertain.

In addition to its CARB-determined toxicity, there is the EPA-determined short-term lethality of diesel exhaust. About 95% of diesel exhaust is classified as fine particulate matter, also known as $PM_{2.5}$. Around the time of the experiments in question, the EPA issued a scientific assessment in which the EPA determined that any exposure to $PM_{2.5}$ could kill within hours of inhalation. A more complete discussion of the EPA-determined lethality of $PM_{2.5}$ may be found at EPAHumanTesting.com.

2. The researchers failed to provide the children and their parents legally required informed consent.

Keeping in mind the above-described and CARB/EPA-determined health effects from diesel exhaust and that federal regulations and state laws require that physicians and scientists obtain informed consent from human study subjects, below is the risk disclosure the researchers provided the children.

From the consent form, signed by the parents:



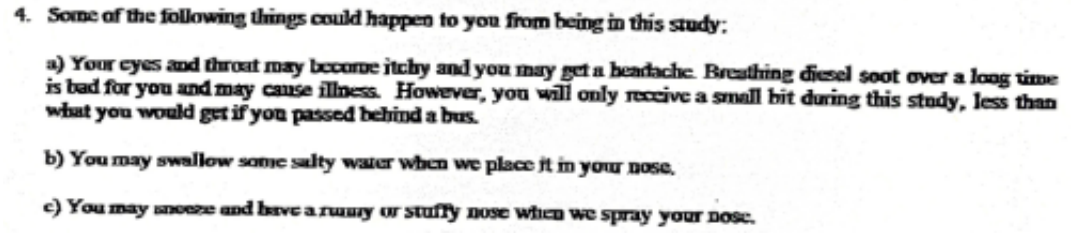
POTENTIAL RISKS AND DISCOMFORTS
During the nasal lavage, there is a possibility of swallowing this fluid which has a salt water taste but contains no other substances. Additional potential complications of nasal lavage include aspiration (inhalation) of the fluid which is uncomfortable, but the amount of fluid is so small that there is no known possibility of any respiratory complication.

Diesel exhaust particles contain "polycidic aromatic hydrocarbons" which are known cancer-causing agents (called carcinogens) in laboratory animals and man when repeatedly exposed in high enough concentrations over years. Men regularly exposed to diesel exhaust at work for many years have shown slightly higher rates of cancer than similar men in "clean" jobs. For these reasons the State of California has classified diesel exhaust as a carcinogen. The excess cancer risk from one or a few diesel exposures like the one used on this study, if any, is very small. Certainly no more than the risk from spending a few days in a city like Los Angeles. You may experience some irritation (itchiness) in your nose for a few moments.

Note that the consent form:

- Fails to disclose the EPA-determined short-term risk of death from inhalation to diesel exhaust.
- Fails to disclose that there is no safe exposure to diesel exhaust, even though the form cites the CARB conclusion about diesel exhaust being a carcinogen;
- Fails to disclose the CARB-determined short-term health effects from exposure to diesel exhaust;
- Fails to disclose the CARB-determined immunological effects of diesel exhaust;
- Fails to disclose that the children would be exposed to diesel exhaust at a level 60 times higher than EPA allows; and
- Fails to disclose that CARB determined diesel exhaust is genotoxic, mutagenic, and causes "chromosomal aberrations" and "unscheduled DNA synthesis."

Below is the description of the risks in the assent form signed by the children (who were not legally competent and so this had no legal meaning).



4. Some of the following things could happen to you from being in this study:

a) Your eyes and throat may become itchy and you may get a headache. Breathing diesel soot over a long time is bad for you and may cause illness. However, you will only receive a small bit during this study, less than what you would get if you passed behind a bus.

b) You may swallow some salty water when we place it in your nose.

c) You may sneeze and have a runny or stuffy nose when we spray your nose.

Moving past the likelihood of the children's inability to understand and appreciate the risks described, the assent form fails to mention any of the risks determined by CARB.

3. These experiments are illegal based on California state law.

Because the Nuremberg Code developed after the post-World War II trials of Nazi physicians are unenforceable in California, the state developed its own laws covering human experimentation. *See California Codes of Health and Safety Section 24170-24179.5* The purpose of the law is to "from unauthorized, needless, hazardous, or negligently performed medical experiments on human beings." [Section 24171(d)]

Each and every medical experiment performed in violation of any provision of the California law is a separate and actionable offense. [Section 24176(e)] Punishment includes fines of up to $10,000 per offense and/or imprisonment.

The experiments conducted by USC/UCLA researchers are "medical experiments" covered by the law as they involve the "penetration or damaging of tissues of a human subject." [Section 24174(a)]

Researchers must provide study subjects with a:

> *... description of any attendant discomforts and risks reasonably to be expected from the experiment.*

The researchers failed to disclose to the study subjects the health risk of diesel exhaust as determined by CARB, including that there is no safe level of exposure to diesel exhaust. [Section 24172(c)]

Based on the mandatory risk disclosures, the researchers were then required to obtain the informed consent of the study subjects. [Section 24173] As discussed previously, the disclosures were not made. So it was impossible for the study subjects to provide the required informed consent.

Despite the foregoing, the experiments themselves are illegal since informed consent from someone other than the study subject,

> *... shall only be for medical experiments related to maintaining or improving the health of the human subject or related to obtaining information about a pathological condition of the human subject.*

These experiments were not related to improving or maintaining the health of the children and, in fact, only needlessly exposed the children to new health risks. [Section 24175(e)].

4. The experiments are illegal based on federal law.

The protection of human subjects in scientific research is covered by the federal Common Rule as adopted by individual federal agencies, including the EPA, which funded the current experiments. EPA has also adopted

protections in addition to the Common Rule.

To avoid redundant discussion, the EPA version of the Common Rule and its additional protections similarly bar the treatment of human beings as guinea pigs in non-therapeutic scientific experiments and require disclosure of risks and the obtaining of informed consent. As discussed previously, all these provisions were violated by the USC/UCLA experiments.

Discussion

EPA and CARB have both determined that diesel exhaust is lethal, carcinogenic and otherwise toxic. EPA's characterization of the $PM_{2.5}$ component renders diesel exhaust essentially one of the most deadly substances known to man in that *any* exposure can kill *within* hours. While JunkScience.com disagrees with this characterization, EPA and CARB nonetheless regulate diesel exhaust and $PM_{2.5}$ on this basis. For the purposes of EPA's human experiments, if diesel exhaust is deadly when it comes from an exhaust pipe, then it is also deadly in a medical clinic and science laboratory. Regulators says there is no safe exposure to diesel exhaust and, for the purposes of discussing human experiments, we take them at their word.

Given this context, the conduct of the EPA, USC, UCLA and researchers in intentionally exposing children as young as 10 years old without informed consent to a deadly substance is quite clearly illegal, not to mention heinous and barbaric. That the EPA and USC apparently attempted to conceal these facts from the public once they were discovered underscores the criminality of the conduct. The only defense the EPA has to these charges would be admissions that its and the CARB's pronouncements on the lethality and toxicity of diesel exhaust and $PM_{2.5}$ are not true.

In essence, EPA and CARB have been caught lying to someone about something. If they have lied to the public and Congress about the toxicity of diesel exhaust and $PM_{2.5}$, then two things should happen:

- All regulatory programs relying on the false science should be reviewed and amended to reflect what the science actually shows; and
- An investigation of how this false science came to pass should be undertaken by an independent prosecutor.

If EPA and CARB have not lied about the science, then the EPA and the researchers conducted flatly illegal experiments and lied to the children and other human subjects involved in the experiments. In this case, the institutions and individuals involved should be investigated, and subject to civil and criminal liability as prescribed by law.

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