IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

THE AMERICAN TRADITION INSTITUTE
ENVIRONMENTAL LAW CENTER
0033 Brook Ford Rd.
Burke, VA 22015

Plaintiffs,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and
LISA P. JACKSON, ADMINISTRATOR
1200 Pennsylvania Ave., N.W.
Washington, DC 20460,

Defendants.

Civil Action No. _____

VERIFIED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

I. Nature of the Action

1. On behalf of its members, the American Tradition Institute (ATI), by and through counsel, brings this action pursuant to 28 U.S.C. § 2201and the Administrative Procedure Act ("APA"), 5 U.S.C. Part I, Chapter 7, *et seq*, seeking declaratory and injunctive relief against the United States Environmental Protection Agency (EPA or the Agency). Pursuant to 5 U.S.C. § 702, ATI also files against EPA Administrator Lisa P. Jackson.

2. Plaintiffs ask the Court to find EPA failed to comply with laws controlling human experimentation and to order the Agency to fully comply. Specifically, through a companion filing Plaintiffs will seek a Temporary Restraining Order and through this filing seeks a Preliminary Injunction to immediately halt EPA's human experimentation which intentionally

exposes human subjects, including some "more susceptible to the effects of air pollutants" to "fine particles" such as those "produced by car and coal-fired power plants", that EPA and its Administrator have described as "lethal" and for which EPA has concluded there is no exposure level "below which there is no risk at all." Second, Plaintiffs seek declaratory relief finding EPA has failed to adequately inform project participants that the pollution they will inhale imposes a risk to their health and that there is no benefit whatever to the participants of the study, as well as other violations of controlling laws, regulations and policies as described below. Third, Plaintiffs seek injunctive relief barring any human experimentation by EPA absent an independent determination that the Agency is in full compliance with human experimentation laws, regulations and policies. Fourth, Plaintiffs seek injunctive relief requiring EPA to withdraw and destroy or excise any publications in any form that are based, even in part, on results of illegal human experimentation. Lastly, Plaintiffs seek a stay in implementation of any rules authorized under the Clean Air Act to control fine particulate matter until such time as the Agency can review the regulatory basis it used in their promulgation, amend its support documents and otherwise reevaluate the risks from fine particulate matter to ensure EPA does not rely in any fashion upon illegal human experimentation.

II. Parties

A. Plaintiffs

3. The American Tradition Institute is a 501(c) (3) organization dedicated to the advancement of rational, free-market solutions to America's land, energy, and environmental challenges. It has members throughout the nation, including in Virginia. The Institute and its Law Center were formed to find and challenge at law governmental actions that violate the core principles of good science, honest government and the rights of citizens and man. *See*, Schnare

Decl. at ¶9.

4. The American Tradition Institute has no central offices. Like many national public interest policy and law institutes, its staff works from locations throughout the nation. The hub of its environmental law activities are in Burke, Virginia. The mailing address of the Environmental Law Center is 9033 Brook Ford Road, Burke, Virginia 22015. ATI and its Environmental Law Center litigates matters on behalf of its members where those members could otherwise assert their own rights, as in this case. *Id* at ¶ 10.

5. Landon Huffman is a member of the American Tradition Institute who supports and shares the ATI's purposes. *See* Huffman Decl. at ¶ 7.

6. In November 2006 and May 2007 Mr. Huffman participated in human experimentation conducted by the U.S. Environmental Protection Agency (EPA) of the kind at issue in this matter. *Id* at ¶ 2.

7. He received a consent form that did not explain that he would be exposed to something that the EPA claims to be lethal. Nor was he ever informed that human experimentation was only supposed to be done in a manner that would potentially and directly benefit those subjected to human experimentation. *Id* at ¶ 3.

8. He was lead to believe that the benefit of the experiment would be to help people with asthma, something from which he suffers. He was not informed that the pollution EPA was forcing into his lungs could actually cause him to have an asthma attack. Nor was he ever given anything from EPA that would possibly relieve his asthma. *Id* at ¶ 4.

9. Since learning that the EPA considers the gases to which he was exposed were lethal, he has been distraught and experienced emotional distress, such as a fear of becoming ill or dying. His health is of utmost importance to him and he is disturbed by the fact that because

of his participation in EPA's human experimentation, his health is in greater jeopardy than when he voluntarily agreed to participate in those studies. As a result of those studies, he is distressed that he may not be able to provide for his wife and family in the short-term as well as long-term. *Id* at ¶ 5.

10. He is also distressed that others may suffer the way he does if they participate in ongoing studies. He believes no one should be falsely and unknowingly exposed to a lethal gas and only by stopping this human experimentation will he be relieved of his continuing concern that others not suffer what he now does. *Id* at ¶ 6.

11. Steven J. Milloy is a member of the American Tradition Institute who supports and shares the ATI's purposes. *See* Milloy Decl. at ¶ 7.

12. One of the great horrors Mr. Milloy and his family suffer is the memory of the incarceration of Mr. Milloy's uncle, Zoran Galkanovic, at the Mauthausen concentration camp. Upon threat of death, Mr. Galkanovic was forced to rise each morning and identify those individuals at the concentration camp too ill to work, knowing they would subsequently be executed. *Id* at ¶ 2.

13. German physicians conducted large-scale human experimentation at the Mauthausen concentration camp. "German doctors subjected Mauthausen prisoners to pseudoscientific medical experiments, including testing levels of testosterone, experimenting with delousing chemicals, medicines for tuberculosis, and nutrition experiments. Camp physician Hermann Richter surgically removed significant organs--e.g., stomach, liver, or kidneys--from living prisoners solely in order to determine how long a prisoner could survive without the organ in question. Eduard Krebsbach, the executive camp doctor between autumn 1941 and autumn 194 3, killed an undetermined number of prisoners by injecting phenol directly into their hearts."

See, U.S. Holocaust Memorial Museum, "Mauthausen Killing Operations," Holocaust Encyclopedia, http://www.ushmm.org/wlc/en/article.php?Moduleid=l0007729 (accessed September 11, 2012. "It was behind the gray stone walls of Mauthausen, in his native Austria, that Dr. [Aribert] Heim committed the atrocities against hundreds of Jews and others that earned him the nickname Dr. Death and his status as the most wanted Nazi war criminal still believed by the Simon Wiesenthal Center to be at large. Dr. Heim was accused of performing operations on prisoners without anesthesia; removing organs from healthy inmates, then leaving them to die on the operating table; injecting poison, including gasoline, into the hearts of others; and taking the skull of at least one victim as a souvenir. *See*, New York Times, "Uncovering Lost Path of the Most Wanted Nazi," February 4, 2009. *Id* at ¶3.

14. Because of the inhumanity forced on Mr. Galkanovic, Mr. Milloy has accepted as a family responsibility the fight against any government who subjects its citizens to inhumane treatment. *Id* at ¶ 4. He is deeply aggrieved by the kind of human experimentation being conducted by the U.S. EPA and will not be relieved until it stops. *Id* at ¶ 5.

15. After learning of how the U.S. Environmental Protection Agency (EPA) was risking the lives and health of human study subjects and was failing to honestly represent the nature of the human experimentation that is the subject of the instant matter, Mr. Milloy was appalled by this inhumanity. *Id* at ¶ 4.

16. Mr. Milloy has dedicated a majority of his current work effort to expose and stop the EPA's improper, unethical and illegal human experimentation. Mr. Milloy is deeply aggrieved by the kind of human experimentation being conducted by the U.S. Environmental Protection Agency and will not be relieved until it stops. *Id* at ¶ 4.

17. Mr. Milloy owns and maintains two websites dedicated to exposing government

excess and dishonest science. Since 1996, JunkScience.com (http://www.junkscience.com) has been dedicated to exposing the abuse of science by special interests, including the EPA. Since September 2012, EPAHumanTesting.com (http://www.epahumantesting.com) has focused on exposing EPA's unlawful and immoral failure to protect human study subjects. These efforts reflect Mr. Milloy's dedication to ensuring honest, ethical government, especially in cases where the government engages in science and human experimentation. *Id* at ¶ 6.

18. David Schnare is a member of the American Tradition Institute who supports and shares the ATI's purposes. *See* Schnare Decl. at ¶ 9.

19. Dr. Schnare's parents selected his name, David, to honor the last male relative to die before his birth. That man's name was David Steiner, a Jew who died in Buchenwald concentration camp on May 3, 1945, 21 days after the camp was liberated. Tattooed on his body was the number 59059. *See*, http://www.buchenwald.de/totenbuch/. *Id* at ¶ 2.

20. German physicians conducted large-scale human experimentation at Buchenwald. Some 729 inmates were used as test subjects, of whom 154 died. This human experimentation included determining the dose of a poison necessary to cause death. *See*, Spitz, Vivien, *Doctors from hell: the horrific account of Nazi experiments on humans*, Sentient Publications, Boulder, CO ISBN 1-59181-032-9 (2005).

21. Dr. Schnare more than abhors current governmental experimentation on humans for the purposes of determining the effect of poisons. It is not only that such activity dishonors those who should have been the last to have suffered in such a manner, it sickens and angers him. It causes him to stand up for those who could not and cannot. Dr. Schnare does not hold the name David as a whim or merely as a naming tradition. He views his name as an honor to one who did not survive the horrors of a government utterly without ethics. He believes he can do no

less than rise in opposition to any government who would experiment on subjects without their well-informed willingness, and where they have they do not have the opportunity to personally benefit from such an experiment. Schnare Decl. at ¶ 4.

22. Dr. Schnare was employed by the U.S. Environmental Protection Agency (EPA) for 33 years, first as a scientist and policy analyst, finally as an enforcement attorney. In the last years with the Agency, he realized that EPA had abandoned much of the even-handed, science-based approach to protection of human health and the environment which marked its early years and left the Agency, in part, because senior appointees and employees had rejected the core values held by honest scientists and civil servants. When he learned of the human experimentation at issue in this case, he realized a duty to challenge EPA's misanthropic activities, if for no other reason than to preserve his own legacy of having worked assiduously on behalf of public health. *Id* at ¶ 5.

23. The University of North Carolina (UNC) awarded Dr. Schnare a Doctor of Philosophy in Environmental Management and its School of Public Health awarded him a Master of Science in Public Health. During his graduate matriculation at UNC, he served on the Dean's Cabinet, the advisory and decision-making body assisting the Dean of the School of Public Health. Among the many subjects addressed during his tenure on the Cabinet, the Dean and Faculty took special interest in ensuring the faculty fully complied with all requirements mandated by the Institutional Review Board (IRB) and federal and state statutes and rules dealing with human experimentation. *Id* at ¶ 6.

24. After learning of how EPA failed to honestly represent the nature of the human experimentation that is the subject of the instant matter, he was appalled that the UNC Biomedical IRB review process failed to conduct the kind of independent review necessary to

ensure the representations by EPA were not only true but complete and fully reflected EPA's knowledge about the poisons with which they intended to force into the lungs of unsuspecting and inadequately informed human subjects. As an alumnus of the University, he is deeply upset at this failure and it adds to his great angst and the emotional harm he suffers from the on-going illegal human experimentation. *Id* at ¶ 7.

25. The relief sought in the instant matter will significantly ameliorate his suffering and will help return honor to the memory of David Steiner and all those who died at the hands of the "Doctors from hell." *Id* at ¶ 8.

B. Defendants

26. Defendant United States Environmental Protection Agency is the federal agency responsible for conducting experiments on humans that involved exposing those persons to toxic substances the Agency believes will cause death and which the Agency therefore regulates under the auspices of the Clean Air Act, 42 U.S. C. Chapter 85.

27. Defendant Lisa P. Jackson is the Administrator of the United States Environmental Protection Agency and, as such, is charged with the supervision and management of all decisions and actions of the agency, including those that authorized human experimentation. She is sued in her official capacity only.

28. Wayne Cascio, Martha Sue Carraway, Andrew J. Ghio, Jon R. Sobus, Joachim D. Pleil and Michael C. Madden are self-identified by as EPA employees subject to oversight and management control by Defendant Lisa P. Jackson and are the EPA employees who personally ordered human subjects be placed into a gas chamber and exposed to a lethal gas.[1] They are also

[1] *See*, Ghio, A. *et al*, Swiss Med Wkly. 2012;142:w13597 "Controlled human exposures to diesel exhaust" (*citing their organizational association as* "National Health and Environmental Effects Research Laboratory and National Exposure Research Laboratory, US Environmental Protection Agency, Chapel Hill, North Carolina, USA." *See*, http://www.smw.ch/content/smw-2012-13597/ (*accessed* 9/12/2012).

identified as EPA employees as documented by the EPA staff locator. *See*, http://www.epa.gov/aboutepa/ (*accessed* 9/12/2012). Messrs. Ghio, Sobus, Pleil and Madden may be the individuals personally responsible for the repugnant experiments at issue in this case, but are not defendants. They, and others of their ilk, are the employees Plaintiffs pray Administrator Jackson will direct to stop the alleged inhumanity, upon court order.

III. Jurisdiction and Venue

29. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. § 703 because Plaintiffs' claims arise under the laws of the United States.

30. The declaratory and injunctive relief requested is authorized by 28 U.S.C. §§ 2201 and 2202.

31. Venue is appropriate in this judicial district pursuant to 28 U.S.C. § 1391 (e)(1)(C) because this matter does not involve real property, the locus of Plaintiff ATI's Environmental Law Center is in Burke, Virginia and a member of Plaintiff ATI resides in Burke, Virginia.

IV. Facts

A. The EPA Says $PM_{2.5}$ Can be Lethal Within Hours of Exposure

32. EPA describes $PM_{2.5}$, also known as "fine particulate matter" as follows:

> "Particulate matter," also known as particle pollution or PM, is a complex mixture of extremely small particles and liquid droplets. Particle pollution is made up of a number of components, including acids (such as nitrates and sulfates), organic chemicals, metals, and soil or dust particles.
>
> The size of particles is directly linked to their potential for causing health problems. EPA is concerned about particles that are 10 micrometers in diameter or smaller because those are the particles that generally pass through the throat and nose and enter the lungs. Once inhaled, these particles can affect the heart and lungs and cause serious health effects. EPA groups particle pollution into two categories:
>
> - "Inhalable coarse particles," such as those found near roadways and dusty

industries, are larger than 2.5 micrometers and smaller than 10 micrometers in diameter.

- "Fine particles," such as those found in smoke and haze, are 2.5 micrometers in diameter and smaller. These particles can be directly emitted from sources such as forest fires, or they can form when gases emitted from power plants, industries and automobiles react in the air.[2]

33. In the Agency's most recent scientific assessment of $PM_{2.5}$, the EPA concluded that $PM_{2.5}$ can kill people shortly after exposure.[3] EPA states that the risk of death from $PM_{2.5}$ exposure is proportional to the level of $PM_{2.5}$ exposure and that death can occur within hours (described as with a lag from exposure of 0-1 days) and that each increase in $PM_{2.5}$ of 10 *ug*/m^3 increases the rate of death by about 1.21 percent.[4]

34. EPA states "there is strong epidemiological evidence linking (a) short-term (hours, days) exposure to $PM_{2.5}$ with cardiovascular and respiratory mortality and morbidity."[5]

B. EPA Believes there is No Safe Level of $PM_{2.5}$

35. EPA's 2004 and 2009 scientific assessment expressly found that there is no safe level of $PM_{2.5}$.[6]

36. In July, 2011, the Chairman of EPA's Clean Air Scientific Advisory Council stated that for particulate matter "no thresholds have been identified below which there is no risk at all.[7]

37. In a February 3, 2012 letter from EPA Assistant Administrator Gina McCarthy to the Honorable Fred Upton, Chairman of the House Committee on Energy and Commerce, Ms. McCarthy stated "The best scientific evidence, confirmed by independent, Congressionally-

[2] USEPA "Particulate Matter (PM)," *see*, http://epa.gov/airquality/particlepollution/ (*accessed*, 9/12/2012).
[3] USEPA "Integrated Science Assessment for Particulate Matter" EPA/600/R-09/139F (Dec. 2009) p. 172 *et seq*. *See*, http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=494948 (*accessed* 9/12/2012).
[4] *Id*. at 6-179.
[5] USEPA "Air Quality Criteria for Particulate Matter" EPA/600/P-99/002Bf (October 2004) Sec. 9.2.2.7 at p. 9-46.
[6] *Id* and *op cit* Integrated Science Assessment for Particulate Matter" EPA/600/R-09/139F.
[7] Samet, J.M., New England Journal of Medicine 2011; 365:198-201, July 21, 2011.

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."[8]

38. EPA alleges that $PM_{2.5}$ has a "causal relationship" with cancer and in particular lung cancer morality,[9] and that $PM_{2.5}$ is a genotoxic carcinogen,[10] which means that there is no exposure level below which it can be considered safe.[11]

39. EPA states that everyone is at risk of death and sickness from $PM_{2.5}$, although some populations are "more susceptible," [12] including those suffering from mutations of the gene GSTM1, glutathione-S-transferase.[13]

40. In September 2011, EPA Administrator Lisa Jackson testified to Congress that of all deaths occurring in the United States, 1 in 4 "is attributable to $PM_{2.5.}$"[14]

41. EPA has used the $PM_{2.5}$ mortality relationship to justify the vast majority of the benefits of its Mercury Air Toxics Standard, issued in December 2011. Of the total benefits that EPA estimates the Mercury rule will prevent, virtually all reflect EPA's allegation that $PM_{2.5}$ kills people.[15]

C. EPA Has Exposed Human Subjects to Lethal Levels of $PM_{2.5}$

[8] *See*, http://epahumantesting.files.wordpress.com/2012/08/2-3-12-epa-letter-to-upton-re-pm-benefits.pdf (*accessed* 9/20/2012).
[9] *Op. cite* USEPA "Integrated Science Assessment for Particulate Matter" EPA/600/R-09/139F at p. 7-68. *See*, http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=216546 (*accessed* 9/20/2012).
[10] *Id*. at p. 68.
[11] USEPA, "Guidelines for Carcinogen Risk Assessment" EPA/630/P-03/001B (March 2005) p. 3-21, *see* http://books.google.com/books?id=bGrTqDumhgkC&printsec=frontcover&dq=inauthor:%22United+States.+Environmental+Protection+Agency.+Risk+Assessment+Forum%22&source=bl&ots=B7bHt5U2OB&sig=P-c1kXwrsez-htWBrnHWpxrsglw&hl=en&sa=X&ei=TCJbULTkLIeB0AGy7IHgBA&ved=0CDwQ6AEwAg#v=onepage&q&f=false (*accessed* 9/20/2012).
[12] *Id*. at Chapter 8 page 8-15.
[13] USEPA Clinical Studies in Environmental Health, *see*, https://www.epastudies.org/Public/EPAStudies/SelectedStudies.aspx (CAPTAIN study).
[14] Lisa Jackson, EPA Administrator, Testimony before the House Oversight and Investigations Subcommittee, Sept 22, 2011, Hearing on Regulatory Reform Series #7, preliminary transcript at line 2027, *see* http://democrats.energycommerce.house.gov/sites/default/files/image_uploads/092211%20OI%20%20Regulatory%20Reform%207%20-%20EPA%27s%20Regulatory%20Planning%2C%20Analysis%2C%20and%20Major%20Action.pdf (*accessed*, 9/12/2012).
[15] USEPA (2011) Final Mercury rule, *see*, http://www.epa.gov/mats/pdfs/20111216MATSfinal.pdf.

42. During a September 22, 2011 hearing of the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee, Administrator Jackson said: "Particulate matter causes premature death. It doesn't make you sick. It's directly causal to dying sooner than you should." [16]

43. EPA scientists Ghio, Sobus, Pleil and Madden exposed human subjects to $PM_{2.5}$ from diesel truck exhausts to levels 32 times the mean exposure in Durham, North Carolina[17], 90 times the average environmental exposure of the general population levels and 135 times the mean diesel truck emissions exposure in the United States, increasing the risk of their immediate death by 10 percent.[18]

44. Starting in 2004 in a study entitled "XCON", EPA exposed adults with metabolic syndrome (including the elderly) to high levels of toxic $PM_{2.5}$.

45. Starting in 2007 in a study entitled "OMEGACON", EPA exposed older adults to high levels of disel exhaust (which contains $PM_{2.5}$ and other "toxic" substances) and then "treated" them with omega-3 fatty acids to see if whatever harm caused by $PM_{2.5}$ was mitigated. In 2008, the diesel exhaust was replaced by plain $PM_{2.5}$.

46. Starting in 2008 in a study entitled "KINGCON", EPA exposed older adults suffering from moderate asthma to $PM_{2.5}$.

D. EPA Intends to Gas additional Humans with $PM_{2.5}$

47. EPA is seeking human subjects suffering from mutations of the gene GSTM1,

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[16] Lisa Jackson, EPA Administrator, Testimony before the House Oversight and Investigations Subcommittee, Sept 22, 2011, Hearing on Regulatory Reform Series #7, preliminary transcript at line 2027, *see* http://democrats.energycommerce.house.gov/sites/default/files/image_uploads/092211%20OI%20%20Regulatory%20Reform%207%20-%20EPA%27s%20Regulatory%20Planning%2C%20Analysis%2C%20and%20Major%20Action.pdf (*accessed*, 9/12/2012).

[17] According to EPA, the mean ambient $PM_{2.5}$ level in Durham, North Carolina, in 2011 was 9.2 $ug/m^{3.}$ USEPA "Air Quality Statistics Report" for Durham, N.C.; *see*, http://www.epa.gov/airdata/ad_rep_con.html (*accessed* 9/19/2012).

[18] *See*, Ghio, A. *et al*, Swiss Med Wkly. 2012;142:w13597, *op. cit.*

glutathione-S-transferase, and thus "more susceptible to the effects of air pollutants," for the express purpose of exposing them to excessive levels of $PM_{2.5}$ in a study they have titled "CAPTAIN".[19]

E. The Law only allows Limited Experimentation on Humans

48. The U.S. Court of Appeals for the D.C. Circuit has explained, "the ethical problems of conducting cancer experiments on human beings are too obvious to require discussion.[20] The facts of this filing suggest otherwise.

49. In 1932, the U.S. Public Health Service and the Tuskegee Institute recruited about 600 poor, African-American farmers for the purpose of studying the natural progression of syphilis in men. The men volunteered under the impression that they were to receive free medical care for life. They were not informed that they had syphilis and their syphilis was never treated, even though by 1947 penicillin had become the standard treatment. The facts of this experiment became public in July 1972 whereupon the study was immediately terminated, but not before many of the men had died and had communicated syphilis to their wives and children[21]

50. The Tuskegee syphilis experiment and other U.S. governmental sponsored human research horrors prompted Congress to pass the National Research Act of 1974 which created a commission to develop principles for the protection of human subjects in scientific experimentation.

51. Four years later, the commission produced: the "Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the

[19] USEPA, "Clinical Studies in Environmental Health" *and see*, Exhibit 13. https://www.epastudies.org/Public/EPAStudies/SelectedStudies.aspx (*accessed* 9/20/2012).
[20] *Environmental Defense Fund v. EPA*, 510 F.2d 1292, 1299 (D.C. Cir. 1975).
[21] *See*, Centers for Disease Control, "The Tuskegee Timeline", *see*, http://www.cdc.gov/tuskegee/timeline.htm (*accessed* 9/20/2012).

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research."[22]

52. In 1991, the Belmont Report was incorporated into federal regulations at 45 CFR Part 46, also known as "the Common Rule."

53. EPA adopted the Common Rule into its regulations at 40 C.F.R. Part 26.

54. In conjunction with its rules, EPA issued an order, "EPA Order 1000.17" as its means to implement the Belmont Report. Amended in 1999 and 2011, the order is now entitled "EPA Order 1000.17 Change A1."[23]

55. Statements below associated with failure of EPA to properly implement its own order reflect the 1999 version of the order as that was the order in effect in the timeframe of EPA's violations, and other references to the order in this subsection also reference the 1999 version for the same reason.

56. 42 U.S.C. § 3515b states that no "funds appropriated by this Act or subsequent Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Acts shall be used to pay for any research program or project or any program, project, or course which is of an experimental nature, or any other activity involving human participants, which is determined by the Secretary or a court of competent jurisdiction to present a danger to the physical, mental, or emotional well-being of a participant or subject of such program, project, or course, without the written, informed consent of each participant or subject."

57. Federal rules found at 45 C.F.R. Part 46 and 40 C.F.R. Part 26 apply "to all research involving human subjects conducted, supported or otherwise subject to [federal] regulation."

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[22] DHEW Publication No. (OS) 78-0012. *See* http://epahumantesting.files.wordpress.com/2012/08/ohrp_belmont_report.pdf (*accessed* 9/20/2012).
[23] *See*, http://www.epa.gov/phre/pdf/epa-order-1000_17-a1.pdf (*accessed* 9/20/2012).

58. 45 C.F.R. § 46.102 (i) and 40 C.F.R. § 26.102 (i) defines "Minimal risk" as "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."

59. 45 C.F.R. § 46.111 and 40 C.F.R. § 26.111 (a) (1) prohibits risks to human subjects that are greater than minimal risks.

60. 45 C.F.R. § 46.111 and 40 C.F.R. § 26.111 (a) (2) prohibits EPA imposing risks that are not reasonable in relation to anticipated benefits, and in evaluating risks and benefits, limits EPA to considering only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research); and prohibits consideration of possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) when weighing risks and benefits.

61. 45 C.F.R. § 46.116 and 40 C.F.R. § 26.116 prohibits human experimentation "unless the investigator has obtained the legally effective informed consent of the subject."

62. 45 C.F.R. § 46.116 and 40 C.F.R. § 26.116 (a)(2) requires the informed consent to provide "a description of any reasonably foreseeable risks or discomforts to the subject."

63. 45 C.F.R. § 46.120 and 40 C.F.R. § 26.120 requires Agency department head approval for any human experimentation.

64. 45 C.F.R. § 46.122 and 40 C.F.R. § 26.122 specifically prohibits expenditure of Federal funds for research involving human subjects unless the requirements of 45 C.F.R. Part 46 and 40 C.F.R. Part 26 rules have been satisfied.

65. 45 C.F.R. § 46.123 and 40 C.F.R. § 26.123 provides authority for an agency head

to require agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the agency head finds an institution has materially failed to comply with the terms of 45 C.F.R. Part 46 and 40 C.F.R. Part 26 rules.

66. 40 C.F.R. § 26.1503 authorizes the EPA Administrator to disqualify an IRB or the parent institution from participating in EPA studies involving human subjects.

67. 40 C.F.R. § 26.1506 authorizes EPA to recommend an institution or investigator be declared ineligible to participate in EPA-supported research (debarment) if that institution or investigator repeatedly has not complied with or has committed an egregious violation of the applicable regulations in subparts A through L of Part 26 rules.

68. 40 C.F.R. § 26.1703 prohibits EPA from relying on data from any research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child.

69. EPA Order 1000.17 Change A1, § 3(g) defines "risk of substantial injury" as a significant probability that the research may lead to a substantial impairment of normal activities or long-lasting or irreversible damage to the health of a human subject.

70. EPA Order 1000.17 Change A1, § 4(d) requires EPA to presume that studies involving risk of substantial injury to a human subject from the conduct of a study and that studies testing for irreversible health effects in humans will not be approved.

71. EPA Order 1000.17 Change A1, § 4(b) requires that all human observational exposure studies conducted or supported by EPA will adhere to the principles set forth in Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES)

72. SEAOES § 2.4.2 recognizes that "[u]nlike some biomedical research that involves the study of interventions or procedures that hold out the prospect of direct diagnostic,

therapeutic, or preventative benefit for the study participants, observational human exposure studies often do not have a similar prospect of direct benefit to the participant."

73. SEAOES § 2.4.2 states that a study would not meet the regulatory criteria for minimal risk if the research introduced risks over and above those minimal risks experienced by normal subjects living in safe healthy environments.

F. EPA did not Properly Inform its Human Subjects

74. In the 2010 OMEGACON study, EPA exposed human subjects with asthma to lethal $PM_{2.5}$ without informing them that $PM_{2.5}$ could cause death within a one day from the exposures they would suffer. *See*, Exhibit No. 1, p. 7.

75. In the 2010 OMEGACON study, EPA exposed human subjects with asthma to lethal $PM_{2.5}$ despite admitting the subjects "will not benefit directly from being in this research study." *Id*.

76. The Principal Investigator in the OMEGACON study was Haiyan Tong. *Id*.

77. In the 2009 KINGCON study, EPA exposed older subjects with asthma to lethal $PM_{2.5}$ without informing them that $PM_{2.5}$ could cause death within a one day from the exposures they would suffer. *See* Exhibit No. 2, p. 8-12.

78. In the 2009 KINGCON study, EPA exposed human subjects with asthma to lethal $PM_{2.5}$ despite admitting the subjects "will not benefit personally from being in this research study." *See* Exhibit No. 2, p. 8.

79. The Principle Investigator in the KINGCON study was Martha Sue Carraway.

80. In the 2010 XCON study, EPA exposed human subjects with metabolic syndrome to lethal $PM_{2.5}$ without informing them that $PM_{2.5}$ could cause death within a one day from the exposures they would suffer. *See*, Exhibit No. 3, p. 3.

81. On information and belief, in the 2010 XCON study EPA exposed human subjects with metabolic syndrome to lethal $PM_{2.5}$ despite admitting the subjects "will not benefit directly from being in this research study." *Id*. (Plaintiff's counsel believe that this is presented on missing page "4 of 9" of Exhibit 3, a page not supplied by EPA in its FOIA response to Plaintiffs).

82. The Principle Investigators in the XCON study were Robert Devlin, Candice Bailey and Martha Sue Carraway. *Id*. at p. 1.

G. EPA did not Properly Inform the Institutional Review Board

83. In four separate IRB applications, EPA failed to fully describe the risk of immediate death from an acute exposure to $PM_{2.5}$, a risk of substantial injury, an irreversible health effect and a reasonably foreseeable risk. Exhibit 5 p. 3 & Exhibit 7 p. 1; Exhibit 9 p. 2 and Exhibit 12 p. 2.

84. In four separate IRB applications, EPA failed to propose a legally effective informed consent for the reasons given in the previous subsection, included here by reference.

H. The Institutional Review Board Failed in its Duties

85. EPA uses the Medical Institutional Review Board of the University of North Carolina (Chapel Hill) for purposes of research EPA conducts at the Human Studies Facility on the UNC-Chapel Hill campus Exhibit 10 p. 1; *and see*, https://www.epastudies.org/Public/EPAStudies/QuestionsAndAnswers.aspx#q8.

86. The IRB failed to deny four EPA human experimentation applications despite EPA indicated "acute" exposures (meaning high levels for short durations) to $PM_{2.5}$ are associated with "mortality." Exhibit 4 p. 7; Exhibit 6 p. 7; Exhibit 8; Exhibit 10 p. 7 and Exhibit 11 p. 7.

87. The IRB failed to deny four EPA human experimentation applications despite EPA stating there was no benefit to the subjects, but were multiple short and long-term risks of morbidity and mortality.

88. The IRB failed to deny four EPA human experimentation applications despite the fact that EPA failed to propose a legally effective informed consent.

I. EPA's $PM_{2.5}$ Research Conduct is a Shocking Violation of Acceptable Ethical and Moral Norms

89. John Dale Dunn, MD, JD, is an expert in medical ethics who has written and lectured on professional ethics, medical/legal affairs, patient safety and risk management, and health care quality and practice guidelines and provided consultation on professional peer review matters for more than 25 years. Dunn Decl.

90. For the past 10 years he has been actively involved in analyzing the human health effects research of the EPA. His work has resulted in writing and lecturing on human health epidemiology and toxicology issues. He is a Policy Advisor to the American Council on Science and Health that is intensely involved in analyzing and evaluating public health research and policy making. *Id*.

91. He has examined the facts presented in the preceding paragraphs. *Id*.

92. He was shocked and outraged to read Ghio, A. *et al*, Swiss Med Wkly. 2012;142:w13597 "Controlled human exposures to diesel exhaust", which described an obese woman with hypertension and pre-experiment evidence of cardiac irritability, was put in a chamber and exposed to small particles at levels far above what the EPA had published as safe. *Id*.

93. It is Dr. Dunn's expert opinion this EPA study was an egregious violation of

ethical norms—to expose a human subject to what was considered a toxic and lethal level of small particles. *Id*.

94. Dr. Dunn has concluded that Consent forms used in these studies showed that not only was the research in violation of any acceptable ethical and moral norms, but the volunteers who were the subjects were not warned of the EPA position that small particles were lethal. *Id*.

95. Dr. Dunn's response to the facts given above is, in his own words, "I am outraged and saddened to know that highly trained and expert physicians would be involved in scandalously unethical and immoral professional research, subjecting humans to toxic or lethal levels of small particles." *Id*.

96. After reviewing the facts and underlying documents supporting the facts listed above, Dr. Dunn has concluded: "There can be no further tolerance of this misconduct. As a licensed physician I cannot imagine the conduct that has been going on in North Carolina. It must be stopped. One patient, one subject is too many to expose. If the EPA wants to withdraw its claims of toxicity and lethality of small particles, then that must be done in an appropriate scientific manner, and can't be done on the fly to excuse these immoral experiments that harken back to historical scandals that were the product of immoral decision made by misguided and unethical physicians and government officials." *Id*.

V. Summary

97. Federal rules and EPA policies control the conduct of human experimentation by EPA, its employees and the Institutional Review Boards EPA uses to ensure EPA employees and grantees meet all ethical research requirements. In experiments conducted by EPA employees and approved by an EPA contractor serving as an Institutional Review Board, EPA has unethically, immorally, repeatedly and ultimately illegally exposed human subjects to $PM_{2.5}$, a

pollutant EPA states is lethal and can cause death within hours of exposure without informing the human subjects of this fact. EPA failed to properly complete its IRB application and failed to properly inform human subjects of the risks they would face if participating in the proposed studies. The Institutional Review Board failed to take account of the lack of personal benefit to the human subjects when weighing the risks, including the risk of death, associated with the proposed research and thus improperly approved the proposals. Both EPA and the IRB failed to meet its statutory duties to ensure ethical research using human subjects.

VI. Claims For Relief

A. First Claim for Relief

98. Plaintiffs incorporate by reference paragraphs 1 – 96 above.

99. EPA's ongoing CAPTAIN study imposes a risk of immediate death from an acute exposure to $PM_{2.5}$, and other risks that individually and together are more than minimal and impose risks of a substantial injury, an irreversible health effect and reasonably foreseeable risks, and in doing so the CAPTAIN study violates 45 C.F.R. § 46.111 and 40 C.F.R. § 26.111 (a) (1) which prohibit risks to human subjects that are greater than minimal risks.

100. The Plaintiffs ask the Court to issue an order putting an immediately halt to EPA's CAPTAIN study and any other EPA human experimentation which intentionally exposes human subjects, including some "more susceptible to the effects of air pollutants," to "fine particles" such as those "produced by car and coal-fired power plants", that EPA and its Administrator have described as "lethal" and for which EPA has concluded there is no exposure level "below which there is no risk at all."

B. Second Claim for Relief

101. Plaintiffs incorporate by reference paragraphs 1 – 99 above.

102. EPA's ongoing CAPTAIN study imposes a risk of immediate death from an acute exposure to $PM_{2.5}$, and other risks that, individually and together are more than minimal and impose risks of a substantial injury, an irreversible health effect and a reasonably foreseeable risk, and in doing so the CAPTAIN study violates 45 C.F.R. § 46.111 and 40 C.F.R. § 26.111 (a) (2) which prohibits human experimentation that imposes risks that are not reasonable in relation to anticipated benefits;

103. Plaintiffs ask the Court to issue an order putting an immediately halt to EPA's CAPTAIN study and any other human experimentation which intentionally exposes human subjects, including some "more susceptible to the effects of air pollutants," to "fine particles" such as those "produced by car and coal-fired power plants", that EPA and its Administrator have described as "lethal" and for which EPA has concluded there is no exposure level "below which there is no risk at all" until such time that a competent IRB approves a new application that meets all statutory, regulatory and policy requirements.

C. Third Claim for Relief

104. Plaintiffs incorporate by reference paragraphs 1 – 102 above.

105. EPA's ongoing CAPTAIN study fails to inform study participants that the exposures to which they will be subject imposes a risk of immediate death from an acute exposure to $PM_{2.5}$, and other risks that, individually and together are more than minimal and impose risks of a substantial injury, an irreversible health effect and a reasonably foreseeable risk, and in doing so the CAPTAIN study violates 45 C.F.R. § 46.116 and 40 C.F.R. § 26.116 which prohibit human experimentation unless the investigator has obtained the legally effective informed consent of the subject.

106. Plaintiffs ask the Court to declare that EPA has not provided legally effective

informed consent to subjects participating in $PM_{2.5}$ studies

D. Fourth Claim for Relief

107. Plaintiffs incorporate by reference paragraphs 1 – 105 above.

108. EPA's ongoing CAPTAIN study expends Federal funds despite failing to fully comply with 45 C.F.R. § 46.122 and 40 C.F.R. § 26.122 which specifically prohibit expenditure of Federal funds for research involving human subjects unless the requirements of 45 C.F.R. Part 46 and 40 C.F.R. Part 26 rules have been satisfied.

109. Plaintiffs ask the Court to issue an order barring further expenditures used to conduct the CAPTAIN study.

E. Fifth Claim for Relief

110. Plaintiffs incorporate by reference paragraphs 1 – 108 above.

111. IRB approval of the CAPTAIN study demonstrates that the IRB failed to comply with 45 C.F.R. Part 46 and 40 C.F.R. Part 26 rules and demonstrates repeated noncompliance and egregious violations of subparts A through L of 40 C.F.R. Part 26 rules.

112. Pursuant to 40 C.F.R. § 26.1506 and 2 C.F.R. Part 1532, Plaintiffs ask the Court to order EPA to suspend use of the University of North Carolina Medical IRB until: (i) EPA's Inspector General completes an investigation to determine whether EPA should recommend that IRB be declared ineligible to participate in EPA-supported research (debarment); and, EPA has completed any resultant process appropriate under 2 C.F.R. Part 1532.

F. Sixth Claim for Relief

113. Plaintiffs incorporate by reference paragraphs 1 – 111 above.

114. As a matter of equitable relief, and following a policy parallel to the authority granted under 40 C.F.R. § 26.1703, Plaintiffs ask the Court to prohibit EPA from relying on data

from any research involving intentional exposure of any human subject to $PM_{2.5}$.

G. Seventh Claim for Relief

115. Plaintiffs incorporate by reference paragraphs 1 – 113 above.

116. To repair ethical lapses and as a matter of equitable relief, Plaintiffs ask the Court to stay implementation of any rules authorized under the Clean Air Act to control fine particulate matter until such time as the Agency can review the regulatory basis it used in their promulgation, amend its support documents and otherwise reevaluate the risks from fine particulate matter to ensure EPA does not rely in any fashion upon illegal human experimentation.

WHEREFORE, Plaintiffs respectfully request the declaratory and injunctive relief herein sought, and such other and further relief as the Court shall deem proper.

VERIFICATION

I David W. Schnare, declare as follows:

1. I am Director of the American Tradition Institute (ATI) Environmental Law Center.
2. I have personal knowledge of ATI and its activities, of EPA and its activities, of the University of North Carolina and its activities and of the deponents cited in this complaint and if called upon to testify I would competently testify as to the matters stated herein.
3. I verify under penalty of perjury under the laws of the United States of America that the factual statements in this *Complaint* are true and correct.

Respectfully submitted and executed this 21st day of September, 2012

AMERICAN TRADITION INSTITUTE

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