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 1:12-cv-01066-AJT-TCB

EMERGENCY MOTION AND MEMORANDUM IN SUPPORT FOR A TEMPORARY RESTRAINING ORDER

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I. INTRODUCTION AND SUMMARY OF ARGUMENT

Pursuant to Fed. R. Civ. P. 65, Plaintiff American Tradition Institute (ATI), moves the Court for an immediate Temporary Restraining Order ("TRO") enjoining Defendants U.S. Environmental Protection Agency (EPA) and EPA Administrator Lisa P. Jackson, and their agents, assigns and employees: (i) from continuing the CAPTAIN study and any other EPA human experimentation which intentionally exposes human subjects to fine particulate matter ($PM_{2.5}$); and, (ii) from.

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." Additional EPA policies further 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 illegally exposed human subjects to $PM_{2.5}$, a pollutant EPA states is lethal and can cause death within hours of exposure, all 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 their statutory duties to ensure ethical research using human subjects.

Each of the foregoing actions threatens to result in irreparable harm to Plaintiff's interest, to the prospective and current subjects of the $PM_{2.5}$ human experimentation and to the interests

of the citizens, generally. As 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.[1] The irreparable harm will include, among other things, subjecting humans to toxic or lethal levels of small particles with no promise of any direct benefit to those subjects. According to expert medical ethicist John Dale Dunn, MD, JD, this type of irreparable harm is "an egregious violation of ethical norms" and runs counter to both Federal rules and "any acceptable ethical and moral norms" for human experimentation. *See* Dunn Decl. (ECF No. 1-4.)

The requested TRO is necessary to avoid these irreparable public health, ethical and moral harms. As Dr. Dunn explains, "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." *Id*. Only immediate injunctive relief will protect those human subjects scheduled or being recruited to participate in these $PM_{2.5}$ studies.

II. STATEMENT OF FACTS

Plaintiffs have filed a Verified Complaint for Declaratory and Injunctive Relief (Complaint), setting out in 96 paragraphs the facts documenting the responsibilities under law EPA has failed to meet. For purposes of this Motion, Plaintiffs stress the following facts. EPA says $PM_{2.5}$ can be lethal within hours of exposure. 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. EPA believes there is no safe level of $PM_{2.5}$. EPA states that everyone is at risk of death and sickness from $PM_{2.5}$, although some populations are "more susceptible," including those suffering from mutations of the gene GSTM1, glutathione-S-transferase. The CAPTAIN study specifically seeks the participation of subjects suffering from

[1] *Environmental Defense Fund v. EPA*, 510 F.2d 1292, 1299 (D.C. Cir. 1975).

mutations of the gene GSTM1, glutathione-S-transferase, meaning EPA is exposing subjects most at risk from the carcinogen $PM_{2.5}$ exposure. EPA is currently recruiting subjects to participate in the CAPTAIN study. The CAPTAIN study consent form fails to inform prospective subjects that they are at increased risk of death within hours after exposure to $PM_{2.5}$ and will be subjected to levels 135 times greater than the average (mean) $PM_{2.5}$ emissions exposure in the United States which EPA estimates will increase the risk of their immediate death by 10 percent.

With regard to applicable law, EPA is not permitted to engage in human experimentation absent full compliance with 45 C.F.R. Part 46, 40 C.F.R. Part 26 and EPA Order 1000.17 Change A1. These rules apply "to all research involving human subjects conducted, supported or otherwise subject to [federal] regulation**."** 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. 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 those benefits cannot include a generalized benefit to society from the knowledge gained.[2] 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." 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." 42 U.S.C. § 3515b, 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. EPA Order 1000.17 Change A1, § 3(g)

[2] *Id.* "The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility."

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. 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.

Through the CAPTAIN study, EPA has violated each of these regulations and policies, thus causing and threatening to cause irreparable harm to the prospective subjects. Because these experiments cause severe emotional distress to ATI members each day the CAPTAIN study continues, absent a cessation of the study, members of the Plaintiffs suffer irreparable harm – days of suffering that can never be reclaimed.

III. STANDARDS FOR GRANTING TEMPORARY RESTRAINING ORDER

The standards for a temporary restraining order are the same as those for a preliminary injunction. *Rum Creek Coal Sales, Inc. v. Caperton*, 926 F.2d 353 (4th Cir. 1991); *Railway Labor Executives' Ass'n v. Wheeling Acquisition Corp.*, 736 F. Supp. 1397 (E.D. Va. 1990). The standard for issuance of a preliminary injunction is the balance-of-hardship test stated in *Blackwelder Furniture Co. v. Seilig Mfg. Co.*, 550 F.2d 189 (4th Cir. 1977). Under this test a district court must consider (1) the likelihood of irreparable harm to a plaintiff without an injunction, (2) the likelihood of harm to the defendant with an injunction, (3) the plaintiff's likelihood of success on the merits, and (4) the public interest. *S.C. Dep't of Wildlife & Marine Res. v. Marsh*, 866 F.2d 97, 99 (4th Cir. S.C. 1989).

IV. STANDARD OF REVIEW

Where a statute does not provide for a private right of action, the APA provides for judicial review of challenges to final agency actions under 5 U.S.C. § 702 (2006). *See Ohio*

Valley Envtl. Coalition v. Aracoma Coal Co., 556 F.3d 177, 192 (4th Cir. W. Va. 2009). As a general rule, agency action, findings, and conclusions will be set aside when they are "found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2) (2000); *Citizens To Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 413-14, 91 S. Ct. 814, 28 L. Ed. 2d 136 (1971); *Ohio Valley Envtl. Coalition v. Aracoma Coal Co.*, 556 F.3d at 192. The arbitrary and capricious standard focuses on the rationality of the agency's decision process rather than on the rationality of the actual decision. In this regard, the Fourth Circuit examines whether the agency followed the law:

> this scrutiny of the record is meant primarily "to educate the court" so that it can "understand enough about the problem confronting the agency to comprehend the meaning of the evidence relied upon and the evidence discarded; the questions addressed by the agency and those bypassed; the choices open to the agency and those made." *Ethyl Corp., 541 F.2d at 36*.

Id. at 192 -193 (*emphasis added*).

V. ARGUMENT

A. Plaintiffs are likely to Prevail on the Merits

i. EPA Unlawfully Failed to Inform Subjects of the Risks posed by $PM_{2.5}$

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." *And see, Bonds v. Leavitt*, 629 F.3d 369, 374 (4th Cir. Md. 2011) ("no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or of the subject's legally authorized representative"); 45 C.F.R. § 46.122 (2010) ("Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirement of this policy have been satisfied.")). The elements of the required legally effective informed consent include:

> (2) A description of any reasonably foreseeable risks or discomforts to the subject;
>
> (3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
>
> (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

45 C.F.R § 46.116(a).

In the three studies for which we have been able to obtain the consent forms, not one described the risk of cancer or the toxic effects of typical engine exhausts such as nitrogen oxides, sulfur dioxide, carbon monoxide and heavy metals. *See*, Exhibit 1 pp. 8-10. ; Exhibit 2 pp. 9-13 ; *and*, Exhibit 3 pp. 4-5, ECF Nos. 1-5, 1-6 and 1-7, respectively. In the KINGCON and OMEGACON consent forms there is no discussion of the risk of death. Exhibit 2 pp. 9-13, ECF No. 1-6 and Exhibit 1 pp. 8-10, ECF No. 1-5, respectively.

As described in the Complaint, EPA believes PM2.5 causes cancer and can cause death within hours of exposure. The failure of EPA to include this information on its consent forms violates the 45 C.F.R § 46.116(a)(2) by filing to describe "any reasonably foreseeable risks."

ii. EPA Unlawfully imposed greater than Minimized Risks

EPA may not impose risks to human subjects that are greater than minimal risks.

> (a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied:
>
> > (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and ***which do not unnecessarily expose subjects to risk***

45 C.F.R. § 46.111 and 40 C.F.R. § 26.111 (a) (1).

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

45 C.F.R. § 46.102(i) (*emphasis added*).

EPA's induced exposures to cancer-causing pollutants and to an undefined and unknown mixture of toxic substances in their gas chamber were and are not a risk ordinarily encountered in the daily life of the test subjects. The EPA exposures were much larger than normal life for these subjects. EPA exposed human subjects[3] to $PM_{2.5}$ from diesel truck exhausts to levels 32 times the mean exposure in Durham, North Carolina[4], 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. [5]

Particularly odious and imposing risks profoundly greater than "minimalized risks" are EPA's past and current efforts to find subjects already at risk and place them at still greater risk, when alternatives to this approach exist.[6] Notably, many other studies exist that examine the health impacts on individuals living in areas with elevated $PM_{2.5}$ levels, including studies of susceptible sub-populations.[7] EPA could minimize risks by using "body monitors" that record

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[3] *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).

[4] 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).

[5] USEPA "Integrated Science Assessment for Particulate Matter" EPA/600/R-09/139F (Dec. 2009) p. 179 *et seq*. *See*, http://ofmpub.epa.gov/eims/eimscomm.getfile?p_download_id=494948 (*accessed* 9/12/2012).

[6] These studies, including the current CAPTAIN project, have recruited subjects with pre-existing conditions that make them more susceptible to harm from $PM_{2.5}$. The XCON studies exposed adults with metabolic syndrome exacerbated by $PM_{2.5}$. The KINGCON study exposed older adults suffering from moderate asthma to $PM_{2.5}$. In the CAPTAIN study, EPA is seeking human subjects suffering from mutations of the gene GSTM1, glutathione-S-transferase, people clinically "more susceptible to the effects of air pollutants," for the express purpose of exposing them to excessive levels of $PM_{2.5}$.

[7] *See*, *e.g.*, Bell ML, Ebisu K, Peng RD, Samet JM, and Domenici F. 2009. Hospital

the $PM_{2.5}$ to which an individual is exposed, selecting subjects who normally work in high $PM_{2.5}$ environments, and examine these subjects health status using the same medical monitoring techniques used in the gas chamber studies, as some of the studies cited in footnote 7 have done. By failing to use these techniques, or otherwise failing to rely exclusively on such existing studies, EPA has failed in its duty to minimize risks.

iii. EPA Unlawfully imposed risks that were unreasonable in relation to the anticipated benefits to subjects

45 C.F.R. § 46.111 and 40 C.F.R. § 26.111 (a) (2) prohibit EPA from imposing risks that are not reasonable in relation to anticipated benefits and those benefits cannot include a generalized benefit to EPA's regulatory activities.[8]

Plaintiffs ask the Court to take special note of the purposes of EPA's research program, which is to support "policy and regulatory development" at its Human Studies Facility which is

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Admissions and Chemical Composition of Fine Particle Air Pollution. Am J Respir Crit Care Med 179:1115-1120; Franklin M, Koutrakis P, Schwartz J. 2008. The Role of Particle Composition on the Association Between PM2.5 and Mortality. Epidemiology 19:680-689; Ito K, Mathes R, Ross Z, Nadas A, Thurston G, and Matte T. 2011. Fine Particulate Matter Constituents Associated with Cardiovascular Hospitalizations and Mortality in New York City. Environ Health Perspect 119:467-473; Janssen, N. A. H., Schwartz, J., Zanobetti, Z., and Suh, H. H. 2002. Air conditioning and source-specific particles as modifiers of the effect of PM10 on hospital admissions for heart and lung disease. Environ. Health Perspect. 110:43–49; Lall R, Ito K, and Thurston GD. 2011. Distributed Lag Analyses of Daily Hospital Admissions and Source-Apportioned Fine Particle Air Pollution. Environ Health Perspect 119:455-460; Lipfert FW, Baty JD, Wyzga RE, Miller JP. 2006. PM2.5 constituents and related air quality variables as predictors of survival in a cohort of U.S. military veterans. Inhal Toxicol 18:645–657; Metzger KB, Tolbert PE, Klein M, Peel JL, Flanders WD, Todd K, Mulholland JA, Ryan PB, Frumkin H. 2004. Ambient air pollution and cardiovascular emergency department visits. Epidemiology 15:46–56; Ostro B, Lipsett M, Reynolds P, Goldberg D, Hertz A, Garcia C, Henderson KD, and Bernstein L. 2010. Long-Term Exposure to Constituents of Fine Particulate Air Pollution and Mortality: Results from the California Teachers Study. Environ. Health Perspect. 118:3633-369.

[8] *Id*. "The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility."

"primarily intended for research to support EPA standards and regulations" [9] as opposed to, for example, the National Institutes of Health whose purpose is to support "fundamental causes and mechanisms of disease."[10] EPA studies may have the collateral benefit of providing information about the mechanism of disease, but EPA is not authorized, and funds it expends are not authorized to be used to conduct studies for such a purpose. EPA and its research funding is exclusively intended to "provide the scientific and technology basis for the Environmental

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[9] Office of the President, "The Budget for Fiscal Year 2013" Environmental Protection Agency p. 1188; *see* http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/epa.pdf (*accessed* 9/26/2012) (*emphasis added*):

> This appropriation finances salary, travel, science, technology, environmental monitoring, research, and development activities including laboratory and center supplies, certain operating expenses (including activities under the Working Capital Fund), contracts, grants, intergovernmental agreements, and purchases of scientific equipment. **These activities provide the scientific and technology basis for the Environmental Protection Agency (EPA) policy and regulatory development actions.**

And see, USEPA, "EPA's Human Studies Facility" at p. 2 "The Human Studies Facility is primarily intended for research to support EPA standards and regulations." *See*, http://nepis.epa.gov/Exe/ZyNET.exe/910000GN.TXT?ZyActionD=ZyDocument&Client=EPA&Index=2000+Thru+2005&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C00thru05%5CTxt%5C00000022%5C910000GN.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL

[10] Office of the President, "The Budget for Fiscal Year 2013" Department of Health and Human Services, http://www.whitehouse.gov/sites/default/files/omb/budget/fy2013/assets/budget.pdf (*accessed* 9/26/2012)(*emphasis added*):

> "Supports Biomedical Research at NIH. Biomedical research contributes to improving the health of the American people as well as the economy. The Budget includes $31 billion for NIH to support research on-campus and at academic and independent research institutions across the country. Tomorrow's advances in health care depend on today's investments in **basic research on the fundamental causes and mechanisms of disease**, new technologies to accelerate discoveries, advancing translational sciences, and encouraging new investigators and new ideas."

Protection Agency (EPA) policy and regulatory development actions."[11]

Thus, in evaluating compliance with 45 C.F.R. § 46.111 and 40 C.F.R. § 26.111 (a) (2), while NIH is allowed to balance the risk to its human subjects with the importance of the knowledge about the causes of disease that may reasonably be expected to result from the experiment, EPA may not because the purpose of EPA's research is the long-range effects of applying the knowledge gained for public policy purposes. This is not a subtle difference. EPA is not authorized to expend funds for fundamental health research. Congress gives that authority to the Department of Health and Human Services (DHHS). EPA violates the Misappropriation Act at 31 U.S.C. § 1301(a) when it does so. Because EPA cannot have as its purpose the generation of knowledge about the causes of disease, under 45 C.F.R. § 46.111 it cannot balance that potential collateral benefit against the risks posed to the human subjects.

There is a fundamental policy reason for cabining health research in DHHS and authorizing EPA to focus its research on areas needed to support its regulatory agenda. DHHS has the institutional and historical experience to properly conduct and evaluate human experimentation. EPA does not. These experiments are testament to EPA's inability to follow the human testing common rule. With this preface in mind, Plaintiffs ask the Court to find that the risks imposed on the human subjects are "not reasonable in relation to anticipated benefits."

The Court could logically begin by examining what benefit the EPA experiments offer the subjects. In a word, EPA offers none. In these studies the consent forms specifically state: "You will not benefit directly from being in this research study" (Exhibit 1 p. 8, ECF No. 1-5.); and, "You will not benefit personally from being in this research study" (Exhibit 2 p. 9, ECF No. 1-6). Instead, EPA is collecting this information to support development of public policy. *See*

[11] *Op. cite* note 9.

Exhibit 2, ECF 1-6 at p. 3, "Research conducted by the EPA on air pollution at the Chapel Hill facility has been used to establish national air quality standards to protect public health." Because EPA does not have the authority to conduct research for the purpose of creating knowledge about the causes of disease, the Court cannot include that in the balancing. Plaintiffs suggest that EPA violated the rules under which it operates when exposing subjects to risks that were not minimized and in an unreasonable manner that offered the subjects no benefit whatever and are not otherwise properly justified.

iv. EPA Unlawfully imposed a risk of substantial injury on the human subjects

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. This Order, at § 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. Because EPA exposed human subjects to carcinogens and to pollution it believes causes premature death, through these studies EPA has imposed a risk of substantial injury.

B. The Equities and the Public Interest Favor a TRO

Not only will Plaintiffs prevail on the merits of this case, but the harm to the Plaintiffs and the harm to EPA and the public interest favor granting an injunction while the parties negotiate a sensible resolution to EPA's failure to properly inform their subjects and otherwise fail to follow human experimentation laws.

i. Plaintiffs Will Suffer Irreparable Injury

Plaintiffs come before the Court through their well-documented interest in preventing improper human experimentation and the injury in fact caused by continuation of EPA's human

experimentation.[12] Their interest is in preventing anyone from volunteering for testing without being properly informed of the risks and preventing governmental agencies from conducting human experiments where the benefits to the subjects are not greater than the risks they will suffer. Beyond the obvious irreparable injury to the next uninformed human subject, the continuation of these illegal studies causes ATI members deep emotional stress and a reduced sense of well-being and as such have caused them to change their conduct in adverse ways that prevent them from participating in professional activities that, having been missed, are opportunities lost forever. *See*, ECF Nos. 1-1 thru 1-3 and ECF No. 6.

In addition, Courts have held that these kinds of non-economic injuries constitute irreparable injury. *See, Kennedy v. Secretary of the Army,* 1999 U.S. App. LEXIS 22241, 10-11 (9th Cir. Haw. Sept. 10, 1999) (*citing to* Chalk v. United States Dist. Court Dist. Of Cal., 840 F.2d 701, 709-10 (9th Cir. 1988)).

ii. EPA will suffer no harm from an injunction

In the first instance, EPA has no authority to engage in human experimentation intended to discover the fundamental causes and mechanisms of disease; is barred from justifying human experimentation on the desire to use human experimentation to determine the long-range effects of applying any knowledge they might gain for public policy purposes such as regulatory development; is not authorized to impose substantial injury on human subjects and is not allowed to conduct human experimentation with false, incomplete and otherwise insufficient consent forms. EPA can suffer no harm if it never had the authority to engage in the practices in the first place.

Second, EPA conducts the research at issue in this matter at its Human Studies Facility.

[12] *See*, Schnare Supplemental Declaration, ECF No. 6.

Non-EPA parties may also "use these chambers to conduct research that is in the public interest," and EPA can continue to use it for other appropriate kinds of work.[13] EPA is also engaged in collecting comments on a regulatory proposal to further reduce the $PM_{2.5}$ standard and any scientists working on $PM_{2.5}$ human experimentation also qualify to support regulatory development.

Third, EPA has made no public representation that the human experimentation studies are essential to the Agency's regulatory or enforcement activities.

Fourth, even if EPA suffered some loss of income from an inability to schedule other research in its facility, purely economic injury does not constitute irreparable harm and thus cannot, as a matter of law, outweigh the threatened irreparable harm to the plaintiffs. *See, Montgomery County Ass'n of Realtors v. Realty Photo Master Corp.*, 1993 U.S. App. LEXIS 11771 (4th Cir. Md. May 20, 1993); *and*, *Minard Run Oil Co. v. United States Forest Serv.*, 670 F.3d 236, 255 (3d Cir. Pa. 2011) ("As a general matter, 'a purely economic injury, compensable in money, cannot satisfy the irreparable injury requirement, Frank's GMC Truck Ctr., Inc. v. GMC, 847 F.2d 100, 102 (3d Cir. 1988)).

iii. The Public Interest Favors an Injunction

In general, when the government is the opposing party, assessing the harm to the opposing party and weighing the public interest merge. *Minard Run Oil Co*. 670 F.3d at 256.

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[13] US EPA "EPA's Human Studies Facility" http://nepis.epa.gov/Exe/ZyNET.exe/910000GN.TXT?ZyActionD=ZyDocument&Client=EPA&Index=2000+Thru+2005&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C00thru05%5CTxt%5C00000022%5C910000GN.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=p%7Cf&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL (*accessed* 9/26/2012).

There are two public interests in this case, the ethical problems of conducting cancer experiments on human beings and the need for the information coming from the experiments for regulatory purposes.

The public interest favors an injunction. "The ethical problems of conducting cancer experiments on human beings are too obvious to require discussion."[14] Since inception of the laws following the Tuskegee syphilis experimentation, the public interest demands informed consent and that risks imposed must be less than the expected benefits of the experiment to the subjects. Where, as in this case, evidence shows these requirements have not been met, the public interest in halting the human experimentation is obvious and overwhelming.

Courts have routinely granted injunctions where environmental laws have been violated and harm to the environment is imminent, holding that the public interest is obvious. *See, e.g.*, *Sierra Club v. Lujan*, 716 F. Supp. 1289, 1293. (D. Ariz., 1989). Where harm to humans is involved, the balancing sways even more heavily toward protecting the humans.

In comparison, EPA has no authority to engage in human experimentation to support its regulatory efforts and no authority to conduct human experiments for the exclusive purpose of identifying the causes of disease. Thus, EPA can claim no public interest at state in the research. Even if it could, the plethora of other sources of similar information reduce significantly the importance of the human experimentation and certainly cannot raise that experimentation to the levels of protecting the subjects themselves.

iv. No Bond, or a Nominal Bond, is Required

The Courts have recognized that only nominal bonds or no bond are imposed in public interest cases. *See, Hoechst Diafoil Co. v. Nan Ya Plastics Corp.*, 174 F.3d 411, 421 (4th Cir.

[14] *Environmental Defense Fund v. EPA*, 510 F.2d 1292, 1299 (D.C. Cir. 1975).

S.C. 1999) ("Where the district court determines that the risk of harm is remote, or that the circumstances otherwise warrant it, the court may fix the amount of the bond accordingly. In some circumstances, a nominal bond may suffice. See, e.g., International Controls Corp. v. Vesco, 490 F.2d 1334 (2d Cir. 1974) (approving district court's fixing bond amount at zero in the absence of evidence regarding likelihood of harm)."); *and see*, *Save Our Sonoran, Inc. v. Flowers*, 408 F.3d 1113, 1126 (9th Cir. Ariz. 2005) ("we have affirmed the district court's approval of nominal bonds in public interest cases").

Public interest cases, especially like this one that seeks no damages and is brought by a non-profit public interest and charitable association, are least able to shoulder bonds. The imposition of substantial liability would frustrate the policy of Congress under the Administrative Procedures Act (APA) to challenge government action where that action is not in accord with the law. If a bond were required, Plaintiffs, a grass roots non-profit, would be challenged to proceed with this case, the goals of the APA would be frustrated and the public interest would suffer.

VI. CONCLUSION

A temporary injunction, prohibiting continuation of the CAPTAIN study and other similar studies exposing human subjects to increased risk of cancer and other adverse health effects, is appropriate given the distinct imbalance between the irreparable harm Plaintiffs and human subjects would suffer in the absence of an injunction, and the utter lack of harm to the Defendants resulting from postponing current studies. For the foregoing reasons, Plaintiff's motion for temporary restraining should be granted.

Dated this 27th day of September 2012.

Respectfully submitted,

AMERICAN TRADITION INSTITUTE

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on September 27, 2012, I will electronically file the foregoing with the Clerk of Court using the CM/ECF system, which will send a notification of electronic filing to the following:

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