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

AMERICAN TRADITION INSTITUTE ENVIRONMENTAL LAW CENTER, Plaintiff, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., Defendants.	)	Civil Action No. 1:12-cv-1066-AJT-TCB

UNITED STATES' MEMORANDUM IN OPPOSITION TO PLAINTIFF'S MOTION FOR TEMPORARY RESTRAINING ORDER

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INTRODUCTION

In its Complaint, American Tradition Institute Environmental Law Center ("ATI") challenges the legality of the Environmental Protection Agency ("EPA")'s controlled human exposure studies relating to fine particulate matter, or $PM_{2.5}$. In its Motion for Temporary Restraining Order ("Motion"), ATI seeks to halt the continuation of the CAPTAIN study and any other EPA-conducted study involving controlled human exposure to fine particulate matter.[1] The CAPTAIN study is investigating the effects of exposure to concentrated air particles ("CAPS"), in particular, $PM_{2.5}$, on healthy individuals between 50 and 75 years of age who have a genetic trait related to protection from oxidants. Declaration of Dr. James Samet ("Samet Decl.") ¶¶ 8–9. At this time the CAPTAIN study is the only ongoing controlled human exposure study EPA is conducting that involves $PM_{2.5}$. Therefore, this Opposition focuses on the facts surrounding CAPTAIN.

ATI's Motion must be denied because ATI has established no likelihood of success on the merits of the Complaint, it will suffer no irreparable harm in the absence of the injunctive relief requested, the balance of equities strongly favors continuation of the CAPTAIN study, and the public interest will not be served by delaying the CAPTAIN study.

STANDARD OF REVIEW

Because a "preliminary injunction is an extraordinary and drastic remedy," Mazurek v. Armstrong, 520 U.S. 968, 972 (1997) (per curiam), whose "purpose . . . is merely to preserve the

[1] Under the guise of protecting human health by halting EPA's research, Plaintiffs seek as their ultimate relief to stay the implementation of any rules promulgated under the CAA to control PM2.5 -- the very regulations that protect human health and welfare. Complaint ¶ 116.

relative positions of the parties until a trial on the merits can be held," Univ. of Texas v. Camenisch, 451 U.S. 390, 395 (1981), the party seeking such an injunction must make a "clear showing" that temporary equitable relief is necessary. Mazurek, 520 U.S. at 972; see Doran v. Salem Inn, Inc., 422 U.S. 922, 931 (1975) ("stringent" showing required).

The standard for granting injunctive relief was set forth by the Supreme Court in Winter v. Natural Resource Defense Council, Inc., 555 U.S. 7 (2008) and embraced by the Fourth Circuit in Real Truth About Obama, Inc. v. Federal Election Comm'n, 575 F.3d 342, 346 (4th Cir. 2009) (vacated on other grounds, in Citizens United v. Federal Election Commission, 558 U.S. 310 (2010), standard reaffirmed in Real Truth About Obama, Inc. v. Federal Election Com'n, 607 F.3d 355 (4th Cir. 2010)). A plaintiff must establish: (1) that it is likely to succeed on the merits; (2) that it is likely to suffer irreparable harm in the absence of injunctive relief; (3) that the balance of equities tips in its favor and (4) that an injunction is in the public interest. Winter, 555 U.S. at 20 (citations omitted); Real Truth About Obama, 575 F.3d at 346.

The Fourth Circuit has abandoned the "balance of hardship" test of Blackwelder Furniture Co. of Statesville v. Seilig Manufacturing Co., Inc., 550 F.2d 189 (4th Cir. 1977), which is relied upon by Plaintiff. Motion at 6. Blackwelder held that "the likelihood of success requirement [need] be considered, if at all, only *after* a balancing of hardships is conducted, and then only under the relaxed standard of showing that 'grave or serious *questions* are presented' for litigation." Real Truth About Obama, 575 F.3d at 346, quoting Blackwelder, 550 F.2d at 195-96 (emphasis in original). The Winter standard is much stricter. Plaintiffs must now establish each element independently and, regardless of the balance of hardships, it is no longer sufficient to demonstrate a "grave or serious question" regarding the merits. A plaintiff must

now make a "clear showing that it will likely succeed on the merits." Real Truth About Obama, 575 F.3d at 346, citing Winter, 555 U.S. at 22.

In assessing whether Plaintiff has established a likelihood of success on the merits, this Court must determine whether it has jurisdiction to consider the claims asserted in the Complaint.[2] Because the claims are asserted under the Administrative Procedure Act ("APA"), 5 U.S.C. § 551, et. seq. Plaintiff must identify a final agency action that is subject to judicial review. Bennett v. Spear 520 U.S. 154 (1997). If this Court finds that there is a final agency action subject to judicial review, it must apply the applicable standard of review for administrative action, and EPA's action must be upheld unless it is found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The court may not substitute its judgment for that of the agency, but must instead affirm the agency's action so long as the agency has considered the relevant factors and articulated a "'rational connection between the facts found and the choice made.'" Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983) (citation omitted).

In the case of a facial challenge to a final agency action, it is not enough to show that the agency action may be invalid in some cases. See INS v. Nat'l Ctr. for Immigrants' Rights, Inc., 502 U.S. 183, 188 (1991). Rather, Plaintiff has the burden of establishing that "no set of

[2] In addition to determining jurisdiction, the court must also determine whether venue is proper in this Court. Venue would rest more appropriately in the District of Columbia, where EPA resides, or in North Carolina, where the challenged activity is taking place. 28 U.S.C. § 1391(b). The Court must also determine whether Plaintiff has standing to assert the claims. If this Court concludes that this is an improper venue or that Plaintiff lacks standing, then Plaintiff cannot succeed on the merits and the motion must be denied. The United States is not briefing those issues in opposition to the Motion for Temporary Restraining Order, but reserves the right to raise and fully brief these issues in a subsequent motion.

circumstances exists under which the agency action would be valid." Reno v. Flores, 507 U.S. 292, 301 (1993) (citation omitted); accord Sherley v. Sebelius, 644 F.3d 388, 397 (D.C. Cir. 2011).

STATUTORY AND REGULATORY BACKGROUND

The Clean Air Act ("CAA") requires EPA to "establish a national research and development program for the prevention and control of air pollution" including "experiments, demonstrations . . . and studies relating to the causes, effects (including health and welfare effects), extent, prevention, and control of air pollution." 42 U.S.C. §§ 7403(a), 7403(a)(1).[3] To implement this statutory mandate, EPA conducts controlled human exposure testing to evaluate important and legitimate research objectives.

EPA conducts its controlled human exposure studies in accordance with the requirements of the "Common Rule." The Common Rule is a set of regulations promulgated by EPA, along with fourteen other federal departments and agencies, to govern the ethical and scientific conduct of research with human subjects conducted or supported by those federal departments or agencies. *See* Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28003 (June 18, 1991). EPA has codified the Common Rule in its regulations at 40 C.F.R. Part 26.

STATEMENT OF FACTS

EPA, along with 14 other federal departments and agencies as well as numerous research institutions both domestic and foreign (including the University of Michigan, University of Washington, University of Rochester, the University of Southern California, and Rutgers), conduct or support research involving human participants. Controlled human exposures studies

[3] It is this statutory authority that governs EPA's research, not descriptions of such research in budgetary line-items, as ATI erroneously suggests. Motion at 11.

have been conducted for decades on important air pollutants such as ozone, particulate matter (PM) [4], nitrogen dioxide (NO_2), sulfur dioxide (SO_2), and carbon monoxide (CO). Devlin Decl ¶¶ 8,9,10. The National Research Council of the National Academy of Science has recognized that controlled human exposure studies provide an opportunity to gain valuable scientific insights in the health effects of particulate matter. Devlin Decl. ¶ 8. Most of the controlled human exposure studies involving exposure to PM are in fact conducted by research institutions other than EPA. Declaration of Wayne Cascio ("Cascio Decl.") ¶ 11. This research has provided valuable information to help characterize and control risks to public health. See id. Exh. 1.

These studies help to determine whether the mathematical associations between ambient (outdoor) levels of air pollutants and health effects seen in large-scale epidemiological studies are biologically plausible (or are not). They help to determine the mechanisms by which air pollutants cause adverse effects, whether certain people are more or less susceptible to exposure to air pollutants, and (for $PM_{2.5}$) whether certain chemical types are responsible (or not) for adverse effects. Controlled human exposures studies have been conducted for decades on important air pollutants such as ozone, particulate matter, nitrogen dioxide (NO_2), sulfur dioxide (SO_2), and carbon monoxide (CO). Devlin Decl. ¶¶ 8–10.

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[4] The term "particulate matter" (PM) covers a broad class of discrete, but chemically and physically diverse, particles in the ambient air. There are two generally different modes of PM – fine and coarse. Fine particles derive from combustion by-products or from gases (such as sulfur oxides and nitrogen oxides) that react and transform in the atmosphere after being emitted. $PM_{2.5}$ is roughly synonymous with fine PM, and generally includes all particulate matter with an aerodynamic diameter of 2.5 micrometers or less. 40 C.F.R. § 50.13(a). Principal sources of $PM_{2.5}$ are fossil fuel combustion, including motor vehicle and power plant emissions, natural and anthropogenic biomass burning, as well as other industrial processes such as smelting. Declaration of Robert Devlin ("Devlin Decl.") ¶ 4.

This controlled exposure research provides information that cannot be obtained from large-scale epidemiological studies. Epidemiological studies, the primary tool in the discovery of risks to public health presented by ambient $PM_{2.5}$, typically use data from large populations of people with varying susceptibility to $PM_{2.5}$. They evaluate the relationship between changes in ambient levels of $PM_{2.5}$ and changes in health effects. However epidemiological studies do not generally provide direct evidence of causation; instead they indicate the existence or absence of a statistical relationship. Large population studies cannot assess the biological mechanisms that could explain how inhaling ambient air pollution particles can cause illness or death in susceptible individuals. Devlin Decl. ¶¶ 6,7,8.

For $PM_{2.5}$, the epidemiological studies indicate that when very large numbers of people are exposed, as occurs in major population centers, the overall risk to the public is large enough to present a serious public health problem in the form of increased mortality and morbidity. The studies also indicate that the risk of serious health effects from exposure to typical levels of $PM_{2.5}$ is largely focused on people with preexisting illnesses, such as people with cardiovascular diseases or respiratory illnesses. See 77 Fed. Reg. 38890, 38906-911 (June 29, 2012). It is this serious risk to the overall public health that leads EPA to describe PM as a serious public health problem. Devlin Decl. ¶¶ 12–14. Controlled human exposure studies are used to help answer the questions these epidemiological studies do not answer: Why does $PM_{2.5}$ have this effect? What are the biological mechanisms that lead to this result? Answers to these questions assist in finding causes and treatments for PM-related health effects, and inform EPA's judgment in carrying out its statutory responsibility to establish national ambient air quality standards (NAAQS), which protect the public. 42 U.S.C. § 7409(b)(1).

EPA's National Health and Environmental Research Laboratory (NHEERL), which conducts CAPTAIN and other controlled human exposure studies, only conducts a human exposure study if there is prior data from one or more of the following types of research: testing in laboratory animals, observational research involving only naturally-occurring human exposures, or human studies involving a closely related air pollutant, and only if the biological effects to study participants will be mild, temporary, and reversible. Devlin Decl. ¶ 11. EPA's regulations implementing the Common Rule require, among other elements, informed consent of study participants, approval of the proposed research by a special review body, minimization of risk to study participants, and a reasonable relationship between risks (if any), benefits, and the importance of the knowledge that may reasonably be expected to result. 40 C.F.R. § 26.111(a). In addition to the required approval by an Institutional Review Board ("IRB"), EPA has a rigorous internal approval process that further ensures the integrity of the proposed research. See Samet Decl. Section II.

The CAPTAIN study seeks to obtain information regarding the effects of exposure to $PM_{2.5}$ on 50-75 year-old healthy individuals who have a genetic trait that precludes them from making a specific protein involved in protection from oxidants (GSTM1).[5] This genetic trait is present in approximately 40% of the population. Samet Decl. ¶ 5.

Under the CAPTAIN study protocol, study volunteers are exposed to concentrated $PM_{2.5}$ from the ambient air in Chapel Hill, North Carolina. Samet Decl. ¶ 26. Hence, this type of study is often referred to as a Concentrated Air Particle Study, or "CAPS." The level of

[5] While this trait results in a different biological response to $PM_{2.5}$, there is no evidence that it increases the risk of an adverse cardiovascular effect. Prior studies involving exposure of people with this trait to concentrated $PM_{2.5}$ demonstrate no adverse effects. Samet Decl. ¶ 9.

exposure experienced thus far by the 6 volunteers who have participated in CAPTAIN is well within expected exposure levels in their normal day-to-day life. The average dose of PM received by these subjects is equivalent to experiencing a concentration of 19.85 ug/m3 (micrograms per cubic meter of air) over a 24 hour period. Samet Decl. ¶ 11. This is well below the level of the 24-hour average National Ambient Air Quality Standard for $PM_{2.5}$ of 35 ug/m3 (micrograms per cubic meter of air). 40 C.F.R. § 50.13(c).[6]

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

Given the expected levels of exposure in the study, the generally low annual and 24-hour levels experienced on a day-to-day basis in Chapel Hill, the good health of the participants and their absence of evidence of cardiovascular or respiratory disease, the expert judgment of the EPA was that the risk to an individual participant in the CAPTAIN study is very small. Samet Decl. ¶ 12. The IRB and the internal EPA review process reached the same conclusions. Samet

[6] The NAAQS for $PM_{2.5}$ includes both an annual average standard and a 24-hour average standard. The 24-hour standard is for the 98^{th} percentile of days, meaning that approximately 7 or 8 days a year could be above 35 ug/m3. The air quality in Chapel Hill, NC, the location of the CAPTAIN study, is well within levels that attain the annual and 24-hour NAAQS for $PM_{2.5}$. Devlin Decl. ¶ 16, n.2.

Decl. Exhs. 4, 5. This is fully consistent with EPA's view that the risks to society as a whole are much larger and more serious when large populations of people, including those with preexisting illnesses, are exposed to high ambient levels of PM. Devlin Decl. ¶ 14.

Nevertheless, studies involving human exposure entail some risk, even if it is small. Because exposure to $PM_{2.5}$ is not free of risk, EPA carefully screens the people who apply for the CAPTAIN study to assure that they are healthy and not the type of susceptible individual who could be at greater risk from short-term exposure to $PM_{2.5}$.[7] EPA thoroughly informs participants of the risks associated with their participation. EPA does so both with a written consent form and during extensive oral interviews with each potential study participant. See, e.g., Samet Decl. ¶ 26. Researchers inform potential participants that they will be exposed to fine particulate matter, how that will occur, and what tests will be performed to gauge their biological reactions. They are also made aware that there is a possibility of airway irritation, cough, shortness of breath, wheezing, and other potential temporary irritations. They are told that everyone is exposed to PM in daily life and that exposure has been associated with increased illness and death. Samet Decl. ¶¶ 20–30; Declaration of Haiyan Tong ("Tong Decl.") ¶¶ 5–11; Declaration of Martin Case ("Case Decl.") ¶¶ 5–15. Researchers also explain to participants the rationale for the CAPTAIN study, and it is made clear that the benefit of the study is not to the individual participant, but rather to society as a whole. Each participant receives monetary compensation and a medical examination. Participants are given ample opportunity to ask

[7] People with a history of angina, cardiac arrhythmias, ischemic myocardial infarction, or coronary bypass surgery are excluded. Also excluded are people using pacemakers, suffering from uncontrolled hypertension, or with a history of bleeding diathesis. Likewise, people with illnesses such as diabetes and cancer may not participate. Samet Decl. ¶ 8.

questions about all of this during the interview process, and they can end their participation in the study at any time. Samet Decl. ¶¶ 20–22, 27–29**.**

During the exposure, participants are continuously monitored by electrocardiography (ECG) and pulse oximetry (measuring the amount of oxygen in the blood). Blood pressure is also monitored at intervals throughout the exposure. If at any time a rapid change in symptoms or other cause for concern to the participant or researcher were to occur, the exposure would cease. The participant's ECG is also monitored for 20 hours following the exposure, and there is a follow-up appointment with a nurse the next day. Samet Decl. ¶¶ 14–16.

EPA takes its responsibility for the safety of participants very seriously. EPA has conducted 297 controlled human exposures to PM with only one clinically significant event, in which the study participant experienced no harm or injury.[8] These studies are an integral part of EPA's effort to understand the effects of particulate air pollution on human health, and support its statutory mandate to protect human health and the environment.

ARGUMENT

Plaintiff is not entitled to the injunctive relief requested because it cannot establish a likelihood of success on the merits. As explained below, Plaintiff has no likelihood of success on the merits because (1) the court lacks jurisdiction over the Complaint because Plaintiff has not

[8] In one case a research volunteer was exposed to concentrated ambient particulate matter and during the exposure the normal heart rhythm converted to atrial fibrillation. The subject was not aware of the change in the rhythm, and was completely free of any symptoms. However, because atrial fibrillation persisting for more than 24 hours can be associated with an increased risk for stroke, she was transferred to the University of North Carolina Hospital for monitoring, assessment of the rhythm, and further evaluation and medical management. Even though the rhythm returned to normal prior to transfer, and persisted for much shorter than 24 hours, it was judged prudent to transfer her for further monitoring as a precautionary matter. At no time was the research volunteer's health in danger. Samet Decl. ¶ 19.

identified any final agency action subject to judicial review under the APA; and (2) even if Plaintiff could identify a final agency action subject to judicial review, Plaintiff's claims are demonstrably false, as EPA's human testing is conducted safely and in full compliance with all applicable requirements. Because Plaintiffs cannot establish a likelihood of success on the merits, the Court need not consider the remaining elements for injunctive relief.

To the extent the Court examines the remaining elements required for the grant of injunctive relief, Plaintiff's request must fail because Plaintiff has identified no irreparable harm. Plaintiff's request must also fail because an injunction is not in the public interest. The public interest is served by the significant societal benefits provided by these studies and no legitimate interest would be served by unnecessarily delaying the studies.

These elements of Plaintiff's claim for injunctive relief are discussed more fully below.

I. PLAINTIFF CANNOT ESTABLISH A LIKELIHOOD OF SUCCESS ON THE MERITS.

ATI is not likely to succeed on the merits of its claim because ATI has identified no agency action which is subject to judicial review under the APA. For that reason alone, this Court should deny the relief requested. However, should the Court decide to consider the merits of the claim, ATI cannot prevail because EPA is conducting its research in full compliance with all regulatory requirements.

A. This Court Lacks Subject Matter Jurisdiction over Plaintiff's Claim.[9]

[9] It also appears that Plaintiff lacks standing. While this is also a defect in subject matter jurisdiction, Bender v. Williamsport Area School Dist., 475 U.S. 534, 541 (1986) (standing defect is defect in court's subject matter jurisdiction); Allen v. Wright, 468 U.S. 737, 750 (1984) (standing is a jurisdictional argument for which courts have courts have independent obligation to ensure compliance), we are limiting our argument here to final agency action because, in the
(continued on the next page . . .)

This Court lacks subject matter jurisdiction because ATI has failed to identify a final agency action that is subject to judicial review under the APA. Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA, 313 F.3d 852, 857 (4th Cir. 2002) (lack of final agency action is a lack of subject matter jurisdiction). The APA "does not provide judicial review for everything done by an administrative agency." Invention Submission Corp. v. Rogan, 357 F.3d 452, 459 (4th Cir. 2004) (quoting Hearst Radio, Inc. v. FCC, 167 F.2d 225, 227 (D.C. Cir. 1948) (ruling that an advertising campaign undertaken by an agency was not reviewable under the APA)). The party asserting jurisdiction under the APA has the burden to demonstrate such jurisdiction. Wollman v. Geren, 603 F. Supp. 2d 879, 883 (E.D. Va. 2009). For a litigant to bring suit under the APA, it must identify either an "agency action" "made reviewable by statute" or a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. §§ 702, 704. The APA defines "agency action" as "the whole or part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act." 5 U.S.C. § 551(13).

Plaintiff has identified no agency action—much less an agency action made reviewable by statute or a final agency action otherwise without remedy—that is reviewable under the APA. Plaintiff alleges that EPA is improperly conducting research using human participants. However, Plaintiff does not allege that these studies constitute a rule, an order, a license, a sanction, a form of relief, or a failure to act. The studies challenged by Plaintiff essentially constitute the collection of data — there is no agency action, as defined by the APA, associated

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Fourth Circuit, "analysis of whether a case presents 'final agency action' should precede a standing inquiry." Long Term Care Partners, LLC v. United States, 516 F.3d 225, 231 (4th Cir. 2008) (citing Flue-Cured Tobacco, 313 F.3d at 857). However, we reserve the right to challenge standing in a later motion if the Court should find that there is a final agency action subject to judicial review.

with them. While the studies may at some point be relied upon for support of an agency rulemaking, Plaintiff has identified no such rule or other agency action. Until the challenged data is used pursuant to EPA's rulemaking authority, there is no final agency action that is subject to judicial review.

Even if this Court were to find that EPA's decision to conduct controlled human exposure studies constituted an "agency action" within the meaning of the APA, neither the statute nor the regulations governing the research provide a right to judicial review of EPA's decision to undertake such studies, as 5 U.S.C. § 704 requires. The regulations were promulgated pursuant to 5 U.S.C. § 301, 7 U.S.C. § 136w(a)(1), 21 U.S.C. § 346a(e)(1)(C), Pub. L. No. 109-54 § 201, or 42 U.S.C. § 300v-1(b). See, e.g., 40 C.F.R. § 26.101. These statutes provide no right of judicial review. The regulations ATI alleges EPA is violating do not create rights for private entities to challenge any research involving human subjects. The only enforcement provisions contained within the relevant regulations exist at 40 C.F.R. § 26.123 and §§ 26.1501–07; they do not allow for private litigants to enforce the regulations. ATI identifies no provision of the regulations it cites that would allow it as a private party to challenge a particular study. While the challenged regulations would have been subject to judicial review when promulgated, the time for that challenge has long passed.

Without a statute providing a right of review, Plaintiff must show that there is a "final agency action for which there is no other adequate remedy in a court."[10] To be "final," an

[10] ATI has not established that there is no adequate remedy in court for participants in a study who allege that they have suffered injury as a result of participating in EPA's research. In fact, the Consent form for the CAPTAIN study provides that participants may have a claim under the Federal Tort Claims Act. Samet Decl. Exh. 6 at 8.

agency action must mark the "consummation of the agency's decisionmaking process," and it must be an action that determines rights or obligations or from which legal consequences flow. Bennett, 520 U.S. at 156 (citations omitted). There is no consummation of a decisionmaking process here—EPA is merely undertaking studies which may later inform final agency actions, e.g., rulemakings. In National Association of Homebuilders v. Norton the court found that the U.S. Fish and Wildlife Service's formulation of survey protocols relating to an endangered species marked the consummation of its decisionmaking process (notably, not the *implementation* of the protocol, but the adoption of the final protocol itself), yet the action was nonetheless not a "final agency action" because no legal rights or duties flowed from that determination.[11] 298 F. Supp. 2d 68, 78–79 (D.D.C. 2003). Similarly here, even if the Court were to find that the decision to undertake a particular study represented the consummation of EPA's decisionmaking process, no legal rights or duties flow from the decision.

Agency action which carries no "direct and appreciable legal consequences" is not reviewable under the APA. Flue-Cured Tobacco, 313 F.3d at 859 (citing Bennett, 520 U.S. at 178). In Flue-Cured Tobacco, plaintiffs challenged EPA's publication of a report concerning the health hazards of secondhand tobacco smoke. Id. at 854. In finding that there was no final agency action, the Fourth Circuit pointed out that the report had no "legally binding authority" on the plaintiffs. Id. at 859. Significantly, the court found that "even when agency action significantly impacts the choices available to the final decisionmaker, this distinction does not transform the challenged action into reviewable agency action under the APA." Id. at 860.

[11] This is not a case similar to Batterton v. Marshall, where the court found a scientific methodology to be a "rule" because a statute made it the "critical factor in an otherwise inflexible" formula for allocating funds. 648 F.2d 694, 705 (D.C. Cir. 1980).

Similarly here, EPA's studies may one day be used to inform its rulemakings, which are final agency actions reviewable under the APA. The studies themselves, however, are not. In sum, Plaintiff has not identified any final agency action reviewable under the APA. Because this Court therefore does not have jurisdiction to consider the merits of the claim asserted, ATI has no likelihood of success on the merits of its APA claim.

B. EPA's Research Complies with EPA's Regulations and the Common Rule.

Should the Court find jurisdiction and proceed to consider the merits, ATI is not likely to succeed on its claim that EPA's $PM_{2.5}$ studies do not conform to the Common Rule.[12] EPA's regulations implementing the Common Rule provide a detailed structure governing controlled human exposure research, with multiple levels of oversight, and EPA is fully compliant with these regulations. Furthermore, with respect to the present Motion, ATI has presented no evidence to support its factual assertions regarding the CAPTAIN study. As established in the Declarations submitted herewith, those factual assertions are demonstrably false, and EPA's CAPTAIN study is in full compliance with the Common Rule and EPA's regulations.

1. The participants in EPA studies were, and continue to be, fully informed of the risks posed by $PM_{2.5}$.

EPA's regulations implementing the Common Rule require that all human participants of research studies provide their informed consent. 40 C.F.R. § 26.116. The informed consent regulations require that participants be informed of "any reasonably foreseeable risks or discomforts *to the subject*" that may result from participation in the study, 40 C.F.R. §

[12] Although Plaintiff challenges several prior studies conducted by EPA as violating the Common Rule, the Motion for Temporary Restraining Order is limited to the CAPTAIN study, as that is the only study currently ongoing.

26.116(a)(2) (emphasis added). The regulations do not require a description of the more generalized risks to the public at large posed by the subject matter of the study. Indeed, as explained above with respect to $PM_{2.5}$, the risks to a healthy individual from a time-limited, though concentrated, exposure are wholly distinct from the larger societal risks, which include especially vulnerable populations.

ATI asserts in its motion that EPA is violating the consent requirements of the Common Rule with respect to the CAPTAIN study. Motion at 5–6. However, ATI relies entirely on consent forms that do not relate to that study.[13] ATI Complaint Exhs. 1 (ECF 1-5), 2, (ECF 1-6) and 3 (ECF 1-7). Furthermore, ATI Complaint Exhibits 9–12 (ECF 1-13–1-16) are labeled as the "CAPTAIN IRB Application," but are not the application for the CAPTAIN study and make no reference to the CAPTAIN study that even suggests it is related. The actual CAPTAIN IRB application and consent form are submitted as Exhibits 1 and 6 to the Declaration of Dr. Samet, respectively. While the utter lack of evidence presented regarding the CAPTAIN study alone should cause the Court to disregard ATI's claim, EPA can unequivocally demonstrate that the CAPTAIN study is proceeding in accordance with its regulations. EPA obtained approval to conduct the CAPTAIN study from the IRB, Samet Decl. Exh. 4, and obtained valid informed consent from each participant.

[13] In addition to the fact that the consent forms relied upon by ATI are not relevant to its Motion seeking to enjoin the CAPTAIN study, its assertion that those consent forms do not describe the risk of "cancer or the toxic effects of typical engine exhausts such as nitrogen oxides, sulfur dioxide, carbon monoxide, and heavy metals" is irrelevant. None of the studies to which those consent forms apply involve exposure of participants to "engine exhausts," but rather to concentrated particulate matter from the ambient air in Chapel Hill. ATI Complaint Exhs. 1 (ECF 1-5) at 6, 2 (ECF 1-6) at 5, 3 (ECF 1-7) at 1. The CAPTAIN study similarly only involves concentrated particles from the ambient air in Chapel Hill, Samet Decl. Exh. 6 at 5, so this reference is completely unrelated to the subject of the Motion.

40 C.F.R. § 26.116 sets out the requirements for informed consent for participants involved in human research studies. Basic requirements relevant here are that investigators provide an explanation of the purposes of the research, a description of any reasonably foreseeable risks or discomforts to a study participant, and a description of any benefits to the subject or to others reasonably to be expected from the research. 40 C.F.R. § 26.116(a)(1)-(3). EPA's procedures for CAPTAIN (and its other studies) more than satisfy these requirements.

CAPTAIN study prospective participants are given a written consent form and, in addition, participate in an oral interview with a researcher. This oral interview is important because "[p]articipants often find discussions with research staff more useful than written consent forms." EPA Nat'l Exposure Research Lab., Office of Research and Dev., Scientific and Ethical Approaches for Observational Exposure Studies, EPA 600/R-08/062 at 53 (May 2008), available at http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf (last visited October 2, 2012). Researchers inform participants about what they will be exposed to -- ambient air from Chapel Hill in which $PM_{2.5}$ is concentrated for a period of two hours -- and what they may feel during the exposure. Samet Decl. ¶ 26. Specifically, the consent form states:

> During the exposure to the concentrated air pollution particles, you may experience some minor degree of airway irritation, cough, and shortness of breath or wheezing. These symptoms typically disappear 2 to 4 hours after exposure, but may last longer for particularly sensitive people…Air pollution particles may induce an inflammatory reaction that can last for 24 hours after exposure and may increase the chance of you catching a cold.

Samet Decl. Exh. 6 at 7-8. Participants are informed that "the amount of particles [they] will [be] exposed to is less than what [they] would likely encounter over 24 hours on a smoggy day in an urban area." Id. at 5. The consent form also explains the potential risks and discomforts which may result from performing breathing tests, having blood drawn, and experiencing heart

monitoring, blood pressure monitoring, and brachial artery ultrasound. Id. at 7. Participants are also told how the study will be conducted, and what biological monitoring will be done before, during and after the test. Samet Decl. ¶¶ 23–26.

Although the regulations do not require an explanation of the larger societal risks associated with $PM_{2.5}$, participants are told that everyone is exposed to PM continuously in daily life and that such exposure has been associated with increased illness and death. Samet Decl. ¶ 26; Tong Decl. ¶ 6; Case Decl. ¶ 4. Researchers also explain to participants the rationale for the study. Specifically, the informed consent form states that "[t]he purpose of this research study is to determine if a component of ambient air pollution to which we are all exposed, particulate matter (PM), elevates the risks of cardiac changes and to investigate the role of a common genetic polymorphism (GSTM1) in these effects." Samet Decl. Exh. 6 at 1. The consent form further explains:

> Results from this study may increase the understanding of how gaseous and particulate air pollutants (which cause the haze seen in some polluted cities) may adversely affect the functioning of the human cardiovascular (heart and blood vessels) and respiratory (lung) systems. This understanding may be especially important for patients with cardiopulmonary diseases.

Id.

The consent form makes clear that the benefit of the study is not to the individual participant, but rather to society as a whole. Participants are given ample opportunity to ask questions about all of this during the interview process, and they can end their participation at any time. Samet Decl. ¶¶ 27–29. This process fully and fairly satisfies the requirements for informed consent in 40 C.F.R. § 26.116. ATI has not and cannot demonstrate that EPA's informed consent procedures are deficient.

2. Any risks to CAPTAIN study participants are minimal.

The participants in the CAPTAIN study are not exposed to more than minimal risk.[14] "Minimal risk" is defined 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." 40 C.F.R. § 26.102(i). As explained above, CAPTAIN study participants are exposed to $PM_{2.5}$ (air particles) drawn from the air surrounding the test building in Chapel Hill, North Carolina. On a mass dose basis, particle concentrations "will not exceed an exposure an individual receives over a 24 hour period while visiting a typical urban center in America on a smoggy day." Samet Decl. Exh. 1 at 13, 16. Under the study protocol, the concentration of inhaled particle mass to which participants are exposed cannot exceed 600 ug/m3 for more than a few minutes during a two hour period. Id. at 13. Exposure will be terminated within 6 minutes if concentrations exceed 600 ug/m3. Id. In fact, study participants are exposed to far lower concentrations than authorized by the study protocol, which calls for dilution of air entering the study chamber when the concentration of particles is measured at 500 ug/m3 in any two minute average. Samet Decl.

[14] While EPA's studies do not expose participants to more than minimal risk, ATI is wrong in stating that the Common Rule and EPA regulations prohibit such exposure. Motion at 8. In fact, the regulations expressly contemplate that some controlled human exposure studies may subject participants to more than minimal risk. "For research involving more than minimal risk" participants must receive "an explanation as to whether any compensation" or "medical treatments are available if injury occurs," along with the other requirements of informed consent. 40 C.F.R. § 26.116(a)(7). While the IRB must ensure, when reviewing a research proposal, that "[r]isks to subjects are minimized," id. § 26.111(a)(1), it is only when a study seeks expedited review that the IRB must insure that the proposed research must "involve no more than minimal risk." 40 C.F.R. § 26.110(b)(1). ATI's characterization of EPA's regulations is thus inaccurate, as are the conclusions ATI draws from this mischaracterization. In any even, the risks to participants in the CAPTAIN study are minimal.

¶ 11, Exh. 2. As a result, the $PM_{2.5}$ concentrations to which the CAPTAIN participants have been exposed are well within expected exposure levels in their normal day-to-day life. The average dose of PM received by these subjects is 238.25 ug/m3. This concentration is equivalent to experiencing a concentration of 19.85 ug/m3 over a 24 hour period, far less than the level of the 24-hour $PM_{2.5}$ NAAQS (35 ug/m3). Samet Decl. ¶, Exh. 3.[15]

Although the possibility of adverse effects can never be completely ruled out, the risk posed to participants from exposure to $PM_{2.5}$ in the CAPTAIN study "is very small." While there is a risk of a serious impact on public health when a large population (tens of millions) containing people with significant risk factors such as cardiovascular disease is exposed to elevated ambient levels of $PM_{2.5}$, the risk of a serious effect to any one person exposed to $PM_{2.5}$ concentrations for a period of two hours under the controlled conditions of the CAPTAIN study is very small, especially since EPA excludes participants from the CAPTAIN study – or any controlled human exposure study of PM2.5 -- who have significant risk factors for experiencing adverse effects to $PM_{2.5}$. Samet Decl. ¶ 12. Prospective participants in the CAPTAIN study are given a physical examination prior to being approved for participation, and are not accepted if they have a history of cardiac abnormalities or diseases or illnesses such as diabetes and cancer. Id. ¶ 8.

To further assure participant safety, participants are monitored continuously by closed-circuit camera by trained EPA personnel stationed immediately outside the exposure facility while undergoing exposure to concentrated $PM_{2.5}$, and a licensed physician is available at all

[15] The dose of PM 2.5 to participant in the other EPA PM2.5 controlled human exposure studies low, averaging 120 ug/m3 over 2 hours. Samet Decl. ¶ 18. Over a 24-hour period this is equivalent to experiencing a concentration of 10 ug/m3, again far less than the 24-hour NAAQS.

times to respond to any emergency. "Biomarkers" such as heart rate, bold oxygen, and blood pressure, are monitored either continuously or at regular intervals. In the event of "any rapid change in symptoms, tachycardia and/or arrthythmia, decline in arterial oxygen saturation, or any distress of concern to the volunteer or the console operator" exposure is terminated. Samet Decl. ¶ 14.

Study researchers carefully monitor the symptoms, if any, that participants may experience either during or immediately after exposure to concentrated $PM_{2.5}$. Possible symptoms, if any, from these two hour exposures include "chest pain, mild dyspnea [shortness of breath], headache, cough, and wheeze." Id. ¶ 15. None of the CAPTAIN study participants, nor any participant enrolled in previous concentrated $PM_{2.5}$ studies -- consisting of 297 exposures over a 15 year period -- has reported any of these symptoms. Id.[16] EPA's National Health and Environmental Research Laboratory (NHEERL), which conducts CAPTAIN and other controlled human exposure studies, only conducts a human exposure study if biological effects will be mild, temporary and reversible, and if data already exists from animal testing, observational research, or studies of a related pollutant. Devlin Decl. ¶ 11. Potential risks to study participants are considered in the review process along with an array of sensitive health indicators. Given the expected levels of exposures in the study, the generally low annual and 24-hour levels experienced on a day-to-day basis in Chapel Hill, NC, the good health of the participants, and the expert monitoring of biological functions, the risk to an individual participant is very small.

[16] In the sole clinically significant event in these 297 controlled human exposures, at no time was the research volunteer's health in danger. The research volunteer experienced no harm or injury. Samet Decl. ¶ 19.

EPA submitted all of this information to the IRB as part of the application required by the Common Rule. 40 C.F.R. § 26.111. Based on the information presented in the application, the UNC Chapel Hill School of Medicine IRB approved the CAPTAIN study. The IRB specifically found that "[t]his research involves no more than minimal risk." Samet Decl. Exh. 4.

Although not required by the Common Rule, EPA conducted a further multi-level intra-agency review, culminating in the expert finding by EPA's Human Subjects Research Review Official that the CAPTAIN study met all requirements of EPA's Common Rule regulations. Samet Decl. Exh. 5. Plaintiffs have provided no reason whatsoever for this Court to question or doubt the expert judgment of EPA investigators, the University of North Carolina IRB, and EPA's Human Subject Research Review official that the CAPTAIN study poses minimal risk to study participants, and otherwise satisfies the Common Rule.

3. The CAPTAIN study does not impose unreasonable risks in relation to the importance of the knowledge to be gained from the research.

When conducting investigations pursuant to its statutory mandate, see 42 U.S.C. § 7403(a)(1), EPA is required to take into consideration "the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and *the importance of the knowledge gained or to be gained*." 40 C.F.R. § 26.120(a) (emphasis added).[17] As discussed above, the risk to the participants in the CAPTAIN study is minimal, but the potential importance of the knowledge to be gained is not. Studies such as CAPTAIN provide

[17] ATI asserts that EPA cannot conduct studies regarding the "fundamental causes and mechanisms of disease" by contrasting budgetary line-item descriptions of EPA and the Department of Health and Human Services. Motion at 11. This attempted distinction falls flat, because the statute is clear that Congress directs EPA to study the effects of air pollution, which causes disease. See 42 U.S.C. § 7403(a)(1).

EPA with knowledge about how $PM_{2.5}$ and its components affect human physiology, and how particular genetic traits can impact this effect. Epidemiological studies simply cannot perform this function. Devlin Decl. ¶ 7. Therefore, the minimal risk to participants in the study is not unreasonable on an individual level, and is clearly justified by the importance of the knowledge that can be gained. ATI's claims, therefore, must fail.

ATI argues that EPA may not consider this important knowledge as a benefit, and suggests that human research may only be approved if it provides some anticipated benefit to the participant. Motion at 10-13. But the regulatory language is directly to the contrary. 40 C.F.R. § 26.111(a)(2) requires that the IRB determine that "[r]isks to the subjects are reasonable in relation to anticipated benefits, *if any*, to subjects, *and the importance of the knowledge that may reasonably be expected to result*" (emphasis added). This regulation refutes ATI's claim in two ways. First, the phrase "if any" modifies the phrase "anticipated benefits," and thus specifically contemplates that a study may not have a direct benefit to the participant. EPA consent forms clearly explain when a study has no benefit to the participant (with the exception of monetary benefit and a medical examination). Samet Decl. ¶ 27. Second, and more critically, the regulation also directs that the reasonableness of the risk be evaluated in light of "the importance of the knowledge that may reasonably be expected to result."[18] This plainly allows approval of studies that present risks even when there are no direct benefits to the participant.

ATI attempts to read this requirement out of the regulation by referencing the third sentence of 40 C.F.R. § 26.111(a)(2) which directs the IRB not to consider "possible long-range

[18] This is consistent with EPA's obligation to take into consideration "the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and *the importance of the knowledge gained or to be gained*." 40 C.F.R. § 26.120(a).

effects of applying knowledge gained in the research . . . as among those research risks that fall within the purview of its responsibility." Motion at 10. The two sentences, however, are not in conflict. The distinction being made in the first and third sentences is between the "importance of the knowledge" gained from the study, which may be considered, and a projection about the future risks from applying the knowledge that might be gained, which may not. The first sentence charges the IRB with valuing the research question being addressed; it asks the IRB to determine if that question has scientific merit. Consistent with this directive, the third sentence prevents the IRB from wandering too far afield in evaluating risk by barring speculation concerning how any knowledge gained, whatever it may be, might be applied, and what long-range effects such application might cause. Thus, ATI's claim that the third sentence cancels out the first is untenable. In sum, EPA imposes no more than minimal risk when conducting studies such as the CAPTAIN study, and this minimal level of risk is reasonable in comparison with the importance of the knowledge EPA can gain as a result.

4. Participants were not, and are not, exposed to risk of substantial injury.

As described above, participants in the CAPTAIN study are not exposed to more than minimal risk. If there is no more than minimal risk, there is certainly no risk of substantial injury.[19] There are serious public health risks from exposure of large populations of people, including those with pre-existing illnesses, to ambient levels of $PM_{2.5}$. But these are not the

[19] ATI again mischaracterizes the Common Rule and regulations as prohibiting any controlled human exposure study that involves risk of substantial injury. Motion at 13. While EPA's stated presumption is that it will not approve studies involving a risk of substantial injury, EPA Order 1000.17 A1 does not prohibit them. EPA Order 1000.17 A1 § 4(d), available at http://www.epa.gov/phre/pdf/epa-order-1000_17-a1.pdf (last visited October 2, 2012). In any event, with regard to the CAPTAIN study, no such risk exists.

same as the very small risks that individuals who do not have such conditions face when volunteering to participate in a controlled study.

While ATI asserts that "EPA believes there is no safe level of $PM_{2.5}$" (Motion at 4), that is not an accurate representation of EPA's position. Current standards for $PM_{2.5}$ are based primarily on epidemiological studies. 77 Fed. Reg. 38890, 38901 (June 29, 2012). EPA has explained setting such standards is "complicated by the recognition that no *population* threshold, below which it can be concluded *with confidence* that $PM_{2.5}$-related effects do not occur, can be discerned *from the available evidence*." Id. (emphasis added). Again, these statements are made in the context of "population" level risks, and do not reflect individual risks. If anything, this uncertainty emphasizes the need for controlled human exposure studies to increase the body of knowledge. Because the state of the science regarding $PM_{2.5}$ is not complete, it is important that EPA conduct research to better understand how $PM_{2.5}$ affects people and what particular human characteristics might impact the likelihood of an adverse reaction to it.

EPA conducts all of its studies, including CAPTAIN, in full compliance with the Common Rule and its regulations, and ATI has not shown otherwise. Accordingly, ATI has not "made a clear showing that it will likely succeed on the merits." Real Truth About Obama, 575 F.3d at 346, and its motion for emergency relief must be denied.

II. ATI HAS NOT ESTABLISHED THAT ITS MEMBERS WILL FACE IRREPARABLE INJURY ABSENT EXTRAORDINARY INJUNCTIVE RELIEF

Because a "preliminary injunction is an extraordinary and drastic remedy," the party seeking such an injunction must make a "clear showing" that temporary equitable relief is necessary. Mazurek, 520 U.S. at 972. The movant therefore carries a heavy burden not only of demonstrating that "he is likely to prevail on the merits" but also that "he will suffer irreparable

injury" without injunctive relief. Doran, 422 U.S. at 931 (emphasis added). The failure to demonstrate harm is "grounds for refusing to issue a preliminary injunction, even if the other three factors entering the calculus merit such relief." Chaplaincy of Full Gospel Churches v. England, 454 F.3d 290, 297 (D.C. Cir. 2006); accord Power Mobility Coal. v. Leavitt, 404 F. Supp. 2d 190, 204 (D.D.C. 2005), supplemented by No. 05cv2027 (RBW), 2005 WL 3312962 (D.D.C. Dec. 7, 2005).

The burden of establishing irreparable harm is "considerable" and "require[s] proof that the movant's injury is 'certain, great and actual--not theoretical--and imminent, creating a clear and present need for extraordinary equitable relief to prevent harm.'" Power Mobility Coal., 404 F. Supp. 2d at 204 (quoting Wisconsin Gas Co. v. FERC, 758 F.2d 669, 674 (D.C. Cir. 1985)); accord Hi-Tech Pharmacal Co., Inc. v. FDA, 587 F. Supp. 2d 1, 11 (D.D.C. 2008) ("the alleged injury must be certain, great, actual, and imminent"). "Bare allegations of what is likely to occur are of no value since the court must decide whether the harm will in fact occur." Wisconsin Gas Co., 758 F.2d at 674 (emphasis in original). Accordingly, "[t]he movant must provide proof . . . indicating that the harm is certain to occur in the near future . . . [and] that the alleged harm will directly result from the action which the movant seeks to enjoin." Id.

In contrast to this demanding standard, ATI alleges only that the challenged actions "threaten[] to result in irreparable harm." Motion at 3. A mere "threatened" harm clearly falls short of the requirement in Wisconsin Gas Co. that harm will "in fact occur," and that the harm "is certain to occur in the near future." 758 F.2d at 674 (emphasis in original). Moreover, the threatened harm Plaintiff alleges is only potential harm to "prospective and current subjects of the PM 2.5 human experimentation." Motion at 3. Again, such potential harm to prospective

subjects is not a harm that will "in fact occur," or one that "is certain to occur in the near future." Id. Not only is the alleged harm not certain and imminent, but Plaintiff does even identify any of the "prospective or current subjects" of the studies and does not assert that any of them are members of ATI on whose behalf Plaintiff is seeking injunctive relief. There is simply no basis presented in the ATI Motion or in its supporting Declarations that would support a finding of irreparable harm.[20]

Perhaps in recognition of this fatal flaw in Plaintiff's motion for emergency relief, Dr. Schnare filed a Supplemental Declaration (ECF No. 6) asserting that his knowledge of the studies authorized by EPA has caused him emotional distress. Such alleged emotional distress of someone who did not even participate in any of the challenged studies does not amount to irreparable harm. The only support offered by ATI for its assertion that emotional injury can be cognizable as irreparable harm was made in a dissent to an unpublished opinion in the Ninth Circuit. Moreover, that case involved an action by a government agency that directly affected the person claiming emotional injury. Kennedy v. Sec. of Army, 191 F.3d 460, at *4 (9th Cir. 1999) (unpublished) (Reinhardt, J., dissenting). Similarly, Chalk v. U.S. District Court Central District of California, et al., cited in the Kennedy dissent, also involved a situation where the plaintiff was directly affected by the defendant's conduct (emotional injury when plaintiff was transferred to different employment). 840 F.2d 701, 709 (9th Cir. 1988). ATI cites no case finding that an irreparable emotional injury can flow from the knowledge that someone else has been subjected to an alleged harm.

[20] Not only is the alleged harm merely threatened and potential, but it is extremely unlikely to occur. As demonstrated in Argument I.B., above, there is no more than minimal risk to any of the participants in the CAPTAIN study, or any prior controlled human exposure study involving PM2.5. In the absence of any risk of injury there is no irreparable harm to the participants.

Even if generalized allegation of distress caused by the awareness of the alleged experimentation on others could be considered irreparable harm, Dr. Schnare does not declare that he has planned or would plan a visit to either of the places that cause him distress at any time in the foreseeable future. Nor is the distress alleged in the Declaration of such a magnitude that it could be considered "great," as required to constitute irreparable harm. Because the alleged harm is not "certain, great, actual, and imminent," Hi-Tech Pharmacal, 587 F. Supp. 2d at 11, it does not justify the request for emergency relief.

In any event, as demonstrated in Argument I.B., above, there is no more than minimal risk to any of the participants in the CAPTAIN study, or any prior controlled human exposure study involving $PM_{2.5}$. Given the minimal risk of injury to any of the actual participants, there can be no irreparable harm to third parties who are not directly affected. The alleged harm, if any, is not only speculative, but seemingly imaginary.

Finally, ATI's assertion that immediate injunctive relief is necessary to avoid irreparable harm is belied by its delay in seeking any relief at all. The Complaint alleges violations that occurred as early as 2004, and one of its members participated in a controlled human exposure study in 2006 and 2007. This apparent lack of urgency further undermines ATI's assertion that immediate injunctive relief is necessary here. A delay in seeking injunctive relief, though not dispositive, can "militate[] against a finding of irreparable harm." Mylan Pharms., Inc. v. Shalala, 81 F. Supp. 2d 30, 44 (D.D.C. 2000). The Court should therefore deny ATI's motion.

III. THE BALANCE OF EQUITIES WEIGHS IN FAVOR OF EPA

The balance of equities tips decidedly in favor of EPA. As indicated above, there is very little weight on the ATI side of the scales because ATI has no likelihood of success on the merits

and it has demonstrated no irreparable harm that will occur in the short term while this case is pending.[21] Accordingly, the burden on EPA to shift the balance is very modest indeed.

In contrast to the utter lack of irreparable harm demonstrated by ATI, significant administrative interests are at stake here. It is important -- not just for this case, but for all regulatory actions -- that non-final and non-binding agency activities are not subject to judicial review. To hold otherwise would encourage premature judicial challenges before the administrative process has been completed, would interfere with the administrative process, and unnecessarily waste judicial resources. The orderly functioning of legitimate government activity weighs heavily in favor of the United States and compels denial of the emergency relief requested.

Moreover, any delay in the CAPTAIN study will cause harm to EPA's legitimate research objectives. The CAPTAIN study is part of the body of research designed to provide important insights into the potential biological mechanisms or pathways for effects already observed in epidemiological studies. The CAPTAIN study also supports forthcoming clinical studies, many of which are already scheduled. These studies relate not only to $PM_{2.5}$ but to exposure to other air pollutants as well, and examine the effects (if any) on persons with the genotype studied in CAPTAIN. Delaying the progress of CAPTAIN could thus upset the scheduling of later studies as well. Harm would occur not only to EPA, but also to the past and future participants. CAPTAIN participants have already been screened for testing, have changed their diets pursuant to the study protocol, and otherwise rearranged their schedules to be available on the days of the study. Their lives will be disrupted if the study is delayed.

[21] Because this is a claim brought pursuant to the APA, it should to be resolved on cross-motions for summary judgment without discovery and trial, if not decided earlier on a motion to dismiss.

Furthermore, should the CAPTAIN study be delayed to the point where it is not feasible, financially or otherwise, to resume, past participants' participation will have been in vain. Any satisfaction they may have from knowing they contributed to this important body of research will be erased. Consequently, the equities weigh in favor of allowing EPA to continue the CAPTAIN study for the purposes authorized by the CAA in an orderly and coordinated manner, and subject to the scrutiny of the IRB.

For these reasons, the balance of the equities compels denial of the preliminary injunction.

IV. DENIAL OF THE PRELIMINARY INJUNCTION IS IN THE PUBLIC INTEREST

Absent any likelihood that ATI will succeed on the merits of its claims, and absent any irreparable harm, there is simply no public interest that would be served by an injunction here. By contrast, the studies being performed by EPA will benefit society generally by providing important information regarding the biological effects of $PM_{2.5}$ and will support further research to determine the causes of certain health effects. The entire public benefits from the advancement of science as facilitated by these studies. Therefore, the public interest is served by allowing EPA to continue its work and the public interest would not be served by enjoining this legitimate governmental activity.

CONCLUSION

For the foregoing reasons, the United States respectfully requests that the Court deny Plaintiff's motion for temporary injunction.

Respectfully submitted,

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

AMERICAN TRADITION INSTITUTE ENVIRONMENTAL LAW CENTER, Plaintiff, v. UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., Defendants.	)	Civil Action No. 1:12-cv-1066-AJT-TCB

I hereby certify that on this 4th day of October, 2012, I electronically filed the foregoing "United States' Memorandum in Opposition to Plaintiff's Motion for Temporary Restraining Order," with the Clerk of the Court using the CM/EMF system which will send notification of such filing to the following:

/s/ Bernard Kim
Assistant U.S. Attorney
Attorney for the Defendants