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 SUPPORT OF ITS MOTION TO DISMISS

IGNACIA S. MORENO
Assistant Attorney General
Environment & Natural Resources Division
U.S. Department of Justice

CYNTHIA J. MORRIS
ELIZABETH DAWSON
Environmental Defense Section
P.O. Box 7611
Washington, D.C. 20044
(202) 616-7554 (Morris)
(202) 514-8293 (Dawson)

Washington, D.C. 20044-0663

NEIL H. MacBRIDE
United States Attorney
Eastern District of Virginia
U.S. Department of Justice

Bernard G. Kim
Assistant United States Attorney
Justin W. Williams U.S. Attorney's Building
2100 Jamieson Avenue

Alexandria, Virginia 22314
(703) 299-3911 (direct)
(703) 299-3983 (fax)
bernard.kim@usdoj.gov

OF COUNSEL:

JOHN HANNON
STEVEN SILVERMAN
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

FEDERAL STATUTES

FEDERAL REGISTER

LEGISLATIVE MATERIALS

INTRODUCTION

On September 21, 2012, Plaintiff American Tradition Institute Environmental Law Center ("ATI/ELC")[1] filed a complaint for declaratory and injunctive relief against Defendants United States Environmental Protection Agency and Lisa P. Jackson, Administrator ("EPA"), alleging improprieties with respect to EPA's research regarding fine particulate matter ("PM2.5"). Dkt. No. 1 ("Complaint"). Plaintiff moved for a temporary restraining order to prevent EPA from conducting any currently ongoing studies, Dkt. No. 7, which EPA opposed, Dkt. No. 14. This Court denied the motion at a hearing on October 9, 2012, Dkt. No. 17, finding no "clear showing of a likelihood of success on the merits," due to questions regarding this Court's subject matter jurisdiction and Plaintiff's standing, Transcript of Proceedings, October 9, 2012, Dkt. No. 19 ("Transcript") at 57:9–17, 58:12–15, 19–20.

Pursuant to Federal Rule of Civil Procedure 12, EPA now moves to dismiss Plaintiff's Complaint for lack of jurisdiction. This Court does not have subject matter jurisdiction over Plaintiff's Complaint because Plaintiff has not identified a final agency action subject to judicial review and because ATI/ELC does not have standing to assert the claims alleged in the Complaint.[2] Plaintiff has thus failed to state a claim upon which relief can be granted and this Court should dismiss the Complaint.

---

[1] The plaintiff, as captioned, is the "American Tradition Institute Environmental Law Center," which appears to be an entity distinct from the "American Tradition Institute," also referenced in the Complaint, Complaint ¶ 1. To avoid confusion, we refer to the captioned plaintiff as "ATI/ELC" and references to "Plaintiff" refer to ATI/ELC.

[2] In addition to these jurisdictional defects, there is some question as to whether venue is proper in the Eastern District of Virginia. See 28 U.S.C. § 1391(b). EPA does not reside in the District, nor did any of EPA's activities giving rise to Plaintiff's claim occur there. Moreover, it is not clear whether Plaintiff is a Virginia entity. However, the United States is not moving to dismiss
(continued on the next page . . .)

STANDARD OF REVIEW

On a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1), the court must determine whether the complaint sets forth allegations sufficient to establish the court's jurisdiction over the subject matter of the claims for relief. The burden of establishing subject matter jurisdiction rests with the plaintiff. Piney Run Pres. Ass'n v. Carroll County Comm'rs, 523 F.3d 453, 459 (4th Cir. 2008). Where subject matter jurisdiction does not exist, "the court cannot proceed at all in any cause." Steel Co. v. Citizens for a Better Env't, 523 U.S. 83, 94 (1998) (internal quotation marks and citation omitted).

Jurisdiction under the Administrative Procedure Act ("APA")[3] and standing both fall under the rubric of subject matter jurisdiction. 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)[4]; Bender v. Williamsport Area Sch. Dist., 475 U.S. 534, 541 (1986) (standing defect

---

the Complaint for improper venue because the issues of standing and the absence of final agency action subject to review are dispositive issues that would deprive any district court of subject matter jurisdiction.

[3] As discussed further below, while Plaintiff has asserted jurisdiction under the APA, if the Court were to find a final agency action to exist in this case, review would be in accordance with the judicial review provisions of the Clean Air Act. 42 U.S.C. § 7607(b).

[4] In the Fourth Circuit, whether final agency action is a jurisdictional prerequisite is not entirely settled. In Long Term Care Partners, the court assumed without deciding that the Supreme Court's holding in Arbaugh v. Y & H Corp., 546 U.S. 500 (2006) rendered final agency action inquiries under the APA nonjurisdictional, contradicting the reasoning of Flue-Cured Tobacco. 516 F.3d at 231–33. Nevertheless, the Eastern District of Virginia has since stated that final agency action is a jurisdictional question. Wollman v. Geren, 603 F. Supp. 2d 879, 883 (E.D. Va. 2009). The District of Columbia Circuit, however, has ruled that final agency action under the APA is a cause of action, not a jurisdictional prerequisite. Trudeau v. FTC, 456 F.3d 178, 340-42 (D.C. Cir. 2006). Regardless, since no final agency action exists here, should this Court determine that it is not a jurisdictional question, this Court could equally dismiss for failure to state a claim pursuant to F. R. Civ. P. 12(b)(6).

is defect in court's subject matter jurisdiction); Allen v. Wright, 468 U.S. 737, 751 (1984) (standing "embraces several judicially self-imposed limits on the exercise of federal jurisdiction"). In the Fourth Circuit, "analysis of whether a case presents 'final agency action' [under the APA] 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).

STATUTORY AND REGULATORY BACKGROUND

I. THE ADMINISTRATIVE PROCEDURE ACT

The APA provides persons "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute," a right of judicial review. 5 U.S.C. § 702. The APA defines "agency action" as "the whole or a 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). Review of "agency action" is only available if "made reviewable by statute" or if it constitutes a "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. §§ 702, 704; see Norton v. S. Utah Wilderness Alliance, 542 U.S. 55, 61-62 (2004). Among other remedies, reviewing courts may "compel agency action unlawfully withheld or unreasonably delayed" or "set aside agency action . . . found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706.

II. THE CLEAN AIR ACT

When enacting the Clean Air Act ("CAA"), in addition to declaring the overarching purpose "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare . . . ," 42 U.S.C. § 7401(b)(1), Congress also declared as a purpose "to initiate and accelerate a national research and development program to achieve the prevention

and control of air pollution," id. § 7401(b)(2). To achieve the former purpose, Congress required EPA to set National Ambient Air Quality Standards ("NAAQS") for "criteria" pollutants it determines may endanger public health or welfare. Id. §§ 7408(a)(1), 7409. Areas that meet the NAAQS are designated as in "attainment." Id. § 7407(d)(1)(A)(ii). To achieve the latter purpose, Congress required 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." Id. § 7403(a), (a)(1) (emphasis added). Congress specifically added the emphasized phrase in the 1990 amendments to the Clean Air Act, clarifying that EPA's research mandate is to include the effects of air pollution on human health and welfare. See Pub. L. No. 101-549, § 901(a)(1) (1990). Congress also provided direction in the 1990 amendments regarding how EPA should "identify and assess the risks to human health from both routine and accidental exposures to individual air pollutants and combinations thereof." 42 U.S.C. § 7403(d)(2); Pub. L. No. 101-549, § 901(b) (1990). Legislative history confirms Congress' approval of human exposure studies as part of EPA's essential air pollution research. See, e.g., 136 Cong. Rec. 4609 (1990) (statement of Sen. Kennedy) ("The EPA's health research primarily involves in-house clinical studies—that is, research on voluntary human subjects in EPA laboratories."); 136 Cong. Rec. 11,922 (1990) (statement of Rep. Roe) ("[W]ithout a sound scientific foundation, even our most well-intentioned efforts to improve air quality are doomed to failure. The time has come to recognize that air pollution research is just as important in fighting air pollution as regulations."). With the exception of specifically identifying ozone and wood smoke as pollutants of concern, the research provisions provide broad discretion to EPA with

respect to which air pollutants to investigate. 42 U.S.C. § 7403(c)(3), (d)(1).

To implement this statutory research mandate, EPA conducts controlled human exposure testing to evaluate important 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 participants conducted or supported by those federal departments or agencies. See Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,003 (June 18, 1991). EPA has codified the Common Rule in its regulations at 40 C.F.R. Part 26. EPA's regulations require, among other elements, informed consent of study participants, 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). These elements are assured through the approval of proposed research by an institutional review board ("IRB") qualified to "ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice." Id. § 26.107(a).

The CAA provides a right of review of "final action[s]" EPA takes under that statute. 42 U.S.C. § 7607(b)(1) (providing review of "any other final action of the Administrator under this chapter . . . which is locally or regionally applicable . . . in the United States Court of Appeals for the appropriate circuit" or "in the United States Court of Appeals for the District of Columbia if such action is based on a determination of nationwide scope or effect"). Judicial review of such "final action" is exclusively under that provision, and not under the judicial review provisions of the APA, because review under the CAA constitutes "other adequate remedy in court"

precluding APA review. 5 U.S.C. § 704; see also Harrison v. PPG Indus., Inc., 446 U.S. 578, 589 (1980) ("[W]e agree with the petitioners that the phrase, 'any other final action,' in the absence of legislative history to the contrary, must be construed to mean exactly what it says, namely, *any other* final action" (emphasis in original)). Nevertheless, the test for what is "final action" for the purposes of review under the CAA mirrors the test for "final agency action" under the APA. See Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 478 (2001).

FACTUAL BACKGROUND[5]

ATI/ELC's Complaint challenges the legality of EPA's controlled human exposure studies relating to $PM_{2.5}$. See, e.g., Complaint ¶¶ 99, 102, 105, 108, 111. These studies, carried out by EPA's National Health and Environmental Research Laboratory, implement EPA's statutory mandate to protect human health and the environment by providing information necessary to expand EPA's understanding of the effects of particulate air pollution on human health. Human exposure studies are conducted only if there is evidence that any effects to the study participants will be mild, transient, and reversible, and 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. Declaration of Robert Devlin, Dkt. No. 14-1 ("Devlin Decl."), ¶ 11 (p. 16–17 of 135).

EPA conducts two types of controlled human exposure studies involving $PM_{2.5}$. The first type exposes study participants to concentrated $PM_{2.5}$ from the ambient air in Chapel Hill,

[5] This factual background is provided only as context for this motion. For a more detailed rendition of the facts, see our Memorandum in Opposition to Plaintiff's Motion for Temporary Restraining Order (Dkt. No. 14) and supporting declarations and exhibits.

North Carolina (concentrated air particle study, or "CAPS"). The second type exposes study participants to diluted diesel exhaust particles ("DEP"). Any risks to study participants are minimal. In the CAPS studies, study participants are exposed to concentrations of $PM_{2.5}$ within expected exposure levels in their normal day-to-day life. The dose of $PM_{2.5}$ in these CAPS studies averaged 120 ug/m3 (micrograms per cubic meter of air) over two hours. Declaration of Dr. James Samet, Dkt. No. 14-1 ("Samet Decl."), ¶ 18 (p. 69 of 135). Over a 24-hour period this is the equivalent of experiencing a concentration of 10 ug/m3, well within the National Ambient Air Quality Standard ("NAAQS") 24-hour $PM_{2.5}$ level of 35 ug/m3.[6] This is also less exposure than is experienced in a single hour in many areas attaining the $PM_{2.5}$ NAAQS.[7]

In the DEP studies, study participants are exposed for two hours to DEP which has been diluted at a ratio of 1 part DEP to 1000 parts clean air to reach a DEP concentration of 100-300 ug/m3. See Declaration of David Diaz Sanchez ("Diaz Sanchez Decl.") ¶ 5, Ex. 3 at 8 (TRUCKIN IRB Application).[8] In a risk assessment submitted to the North Carolina IRB as part

---

[6] In the ongoing, incomplete CAPTAIN CAPS study, the average dose of $PM_{2.5}$ received by subjects over two hours is 238.25 ug/m3. This concentration is equivalent to experiencing a concentration of 19.85 ug/m3 over a 24-hour period, again well within the 35 ug/m3 level of the 24-hour $PM_{2.5}$ NAAQS, Samet Decl. Ex. 3 (p. 115 of 135), and less than hourly exposures experienced in $PM_{2.5}$ attainment areas.

[7] Between 2009 and 2011, there were over 600 instances of hourly ambient air concentrations of 120 ug/m3 or greater in counties in Alaska, Arizona, California, Florida, Hawaii, Idaho, Louisiana, Maryland, Minnesota, Missouri, Montana, Nebraska, New Hampshire, North Carolina (Wake County, which is virtually adjacent to Orange County, the location of Chapel Hill), North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Washington, and Wyoming, all of which are attaining the annual and the 24-hour $PM_{2.5}$ NAAQS. See generally United States Environmental Protection Agency, Technology Transfer Network Air Quality System, http://epa.gov/ttn/airs/airsaqs (last visited Nov. 16, 2012).

[8] This declaration is submitted solely for the purpose of providing the Court with additional factual information, and is not necessary to support the arguments that form the bases of this

(continued on the next page . . .)

of the approval application, EPA scientists estimated conservatively that the risk of lung cancer from exposure to 100 ug/m3 DEP for two hours is less than 1 in a billion,[9] a risk so small as to possibly be non-existent. Diaz Sanchez Decl. ¶ 2, Ex. 1 at 5. In a second assessment submitted to the IRB as part of the approval application, EPA scientists estimated that the risk from the most potent carcinogenic component of DEP, at the concentrations experienced in the study, would be the equivalent of smoking 5/1000th of a cigarette one single time, likewise a minimal risk. Diaz Sanchez Decl. ¶ 3, Ex. 2 at 1.

The North Carolina IRB has reviewed both the CAPS and the DEP studies multiple times, and has found them to be consistent with the Common Rule. E.g., Samet Decl. ¶ 17 (p. 68 of 135); Diaz Sanchez Decl. ¶ 7, Ex. 5. The last such approval was given October 8, 2012. Diaz Sanchez Decl. ¶ 9, Ex. 7. In addition to the required IRB approval, EPA's own internal review and approval process (a review above and beyond the review required by the Common Rule) reviewed and approved all of these studies as being consistent with the Common Rule. E.g., Samet Decl. Ex. 5 (p. 120 of 135); Diaz Sanchez Decl. ¶ 8, Ex. 6.

All participants in EPA's controlled human exposure studies are fully informed of any risks associated with the exposure. EPA obtains the informed consent of its participants, both through an oral explanation and a written form. Samet Decl. ¶¶ 20–30; Diaz Sanchez Decl. ¶ 6, Ex. 4 at 7. Before the exposure in the CAPS studies, participants receive a medical exam. Samet Decl. ¶¶ 24, 27. During the exposure, participants are continuously monitored by

---

Motion to Dismiss.

[9] The estimate is conservative because it assumed that carcinogenic components of DEP (polyaromatic hydrocarbons, or PAH) are ten times more concentrated, and hence ten times more potent, than they are in fact. Diaz Sanchez Decl. ¶ 2, Ex. 1 at 3, 5.

electrocardiography (ECG) and pulse oximetry (measuring the amount of oxygen in the blood), and their blood pressure is monitored periodically. Any rapid change in symptoms or other cause for concern to the participant or researcher would result in cessation of the exposure. Following the exposure, the participant's ECG is also monitored for 20 hours, and the participant has a follow-up appointment with a nurse the next day. Samet Decl. ¶¶ 14–16. Participants in the DEP studies are likewise closely monitored by nurses and physicians before, during, and after exposure. Diaz Sanchez Decl. ¶ 6, Ex. 4 at 3, 5, 6, 8. Participants may terminate their participation in the study at any time for any reason. Samet Decl. ¶ 29; Diaz Sanchez Decl. ¶ 6, Ex. 4 at 12.

ARGUMENT

I. THIS COURT LACKS JURISDICTION OVER PLAINTIFF'S CLAIM.

This Court lacks subject matter jurisdiction because Plaintiff has not identified any agency action within the meaning of the APA, much less an agency action that is made reviewable by statute or that is final agency action subject to review under the APA. If there was a final action subject to judicial review, review would be proper only in a Court of Appeals under the judicial review provisions of the CAA because, as explained below, the CAA provides a an exclusive right of review of EPA's "final action[s]" in the Courts of Appeals. 42 U.S.C. § 7607(b)(1). Therefore, APA review is unavailable even if this Court determines a final action has occurred.

A. Plaintiff Has Alleged No "Agency Action" Within the Meaning of the APA.

The APA "does not provide judicial review for everything done by an administrative

agency."[10] 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)). While Plaintiff alleges that EPA is improperly conducting its controlled human exposure research with respect to $PM_{2.5}$, it has failed to allege that EPA's research constitutes an "agency action" within the meaning of the APA, i.e., a rule, an order, a license, a sanction, a form of relief, or a failure to act. 5 U.S.C. § 551(13). Based on this failure alone the Court should dismiss Plaintiff's claim. The research challenged by Plaintiff essentially constitutes the collection of data—there is no agency action, as defined by the APA, associated with it. While EPA may at some point rely upon the results of such health effects research to support an agency rulemaking, the rule EPA promulgates would be the final agency action subject to judicial review, not the research conducted prior to the rulemaking. The challenged research process itself is thus not "agency action" that would give rise to judicial review under the APA.

B. The Action Plaintiff Challenges Is Not Made Reviewable by Statute.

Even if Plaintiff identified some action of EPA in the course of its research that constituted "agency action" under the APA, neither the statute nor the regulations governing controlled human exposure research studies provide a right to judicial review of EPA's research, as the APA requires. 5 U.S.C. § 704. The Common Rule regulations were promulgated pursuant to 5 U.S.C. § 301 (providing heads of Executive departments the authority to promulgate regulations) and 42 U.S.C. § 300v-1(b) (Community Mental Health Centers

[10] Contrary to Plaintiff's assertion, the APA is not "there when there is no other means for reviewing agency action" as a last resort to air a grievance related to anything an agency does. Transcript at 50:8–9.

Extension Act of 1978). See 56 Fed. Reg. 28,003, 28,022 (June 18, 1991). These statutes provide no right of judicial review. Nor do the regulations Plaintiff alleges EPA is violating create rights for private entities to challenge any research involving human participants. The enforcement provisions contained within the relevant regulations only allow EPA to take certain actions; they do not allow private litigants to enforce the regulations. 40 C.F.R. § 26.123(a) (providing the authority to terminate or suspend agency support for a project where an institution "has materially failed to comply with the terms" of EPA's research policy); id. §§ 26.1501–07 (providing procedures for administrative actions for noncompliance by an IRB or an institution, and reserving the right to institute other appropriate judicial or regulatory action). Plaintiff identifies no provision of the regulations it has invoked that would allow it, as a private party, to challenge a particular study. Indeed, at the hearing on Plaintiff's motion for a temporary restraining order, counsel for Plaintiff conceded that "[t]here's no judicial review opportunity within [the informed consent] rule or within that law or within those regulations."[11] Transcript at

[11] Later on during the hearing, Plaintiff cited 42 U.S.C. § 3515b, which prohibits specific agencies from spending funds for research involving human participants without their informed consent. Plaintiff erroneously alleged that it "covers EPA." Transcript at 52:11–24. As the Court noted, Plaintiff did not assert jurisdiction under that statute in its Complaint. Id. at 53:4–8. In fact, any future attempt to assert such jurisdiction would likely be unavailing, because by its terms, the statute only applies to the Departments of Labor, Health and Human Services, and Education, and "Related Agencies"—not EPA. 42 U.S.C. § 3515b. While that provision does not define "Related Agencies," Title IV of the appropriations bill containing this provision, entitled "Related Agencies," includes such entities as the Corporation for Public Broadcasting, the Federal Mediation and Conciliation Service, the National Council on Disability, and the United States Institute of Peace, but not the Environmental Protection Agency. Pub. L. No. 102-394, 106 Stat. 1792 (1992). While this statute has been invoked in a few cases, those cases involved challenges to the Department of Health and Human Services's decisions in administering benefits programs. See, e.g., Newton-Nations v. Betlach, 660 F.3d 370, 374, 376 (9th Cir. 2011). Tellingly, EPA did not invoke this statute when promulgating its Common Rule regulations. Furthermore, because Congress did not specifically mention EPA in this statute or include it the "Related Agencies" category, Congress did not "unequivocally express[]" a waiver

(continued on the next page . . .)

5:4–6. While the regulations Plaintiff invokes would have been subject to judicial review when promulgated, the time for that challenge has passed. See 42 U.S.C. § 7607(b) (providing sixty days from date of action to file a challenge).

Furthermore, at least one court has determined that similar regulations did not provide a private right of action. Wright v. Fred Hutchinson Cancer Research Ctr., 269 F. Supp. 2d 1286, 1289–1290 (W.D. Wash. 2002). In Wright, plaintiffs representing deceased research participants alleged violations of 45 C.F.R. Part 46 (provisions analogous to those governing EPA found at 40 C.F.R. Part 26). The court noted that "agency regulations cannot give rise to a private cause of action where the authorizing statute does not confer such a right." 269 F. Supp. 2d at 1289. The court also determined that the regulations did not create a private right of action because the regulations are "not focused on the individual benefitted" and because the regulations contain their own regulatory enforcement provisions which do not provide a private cause of action. Id. Similarly here, nothing in the Clean Air Act or EPA's Common Rule regulations indicate that Congress intended to provide a right of review of EPA's research to the participants in such research, much less an organization that does not represent any current participants.

C. Plaintiff Has Not Identified Any Final Agency Action Subject to Judicial Review.

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."[12] The "final agency

---

of sovereign immunity with respect to EPA. United States v. Nordic Vill., 503 U.S. 30, 33 (1992) (internal quotation marks and citations omitted). Waivers of sovereign immunity "must be construed strictly in favor of the sovereign." Id. at 34 (internal quotation marks and citations omitted). This Court should thus not infer such a waiver here.

[12] Plaintiff has not established that there is no other adequate remedy in court for participants in a
(continued on the next page . . .)

action" requirement is a threshold question that determines the availability of judicial review of the merits of a claim. See Flue-Cured Tobacco, 313 F.3d at 857. 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).

The Supreme Court has explained that two conditions must be satisfied for agency action to be "final." "First, the action must mark the 'consummation' of the agency's decisionmaking process" and "must not be of a merely tentative or interlocutory nature." Bennett v. Spear, 520 U.S. 154, 177-78 (1997) (quotation omitted). Second, the agency action "must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" Id. at 178 (quotation omitted). As discussed above, there is no final agency action here because the collection of scientific data is not agency action. EPA is merely undertaking studies which may later inform its rulemakings. Even if the approval to undertake a particular study after internal review were considered the consummation of EPA's decisionmaking process,[13] 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

---

study who allege that they have suffered injury as a result of participating in EPA's research. See, e.g., Samet Decl. Ex. 6 at 8 (describing potential remedies in the event of injury).

[13] There is no consummation of a decisionmaking process here in the way such processes are typically understood, i.e., as part of a rulemaking, which would be final agency action. Even if there were such a consummation, the action would still not be "final" for review under the APA, due to the lack of legal consequences. See Nat'l Ass'n of Homebuilders v. Norton, 298 F. Supp. 2d 68, 78–79 (D.D.C. 2003) (finding the U.S. Fish and Wildlife Service's formulation of survey protocols relating to an endangered species to be the consummation of a decisionmaking process, yet the action was nonetheless not a "final agency action" because no legal rights or duties flowed from that determination).

report concerning the health hazards of secondhand tobacco smoke. 313 F.3d 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. Similarly here, the studies do not create binding authority over Plaintiff. While EPA's studies may one day be used to inform its rulemakings, which may be final agency actions subject to judicial review, the studies themselves are not. In sum, Plaintiff has not identified any final agency action reviewable under the APA, and this Court should dismiss its Complaint.

Although Plaintiff failed to identify in its Complaint any action that would give rise to review under the APA, during the hearing for its motion for a temporary restraining order counsel for Plaintiff suggested two agency actions that may be subject to judicial review: (1) the "contract" Plaintiff asserts was created by the consent form signed by participants, and (2) the decision to undertake studies regarding $PM_{2.5}$ with human participants. See Transcript at 15:20–22, 50:19–25. Because they were not identified in Plaintiff's Complaint, they cannot form the basis of this Court's jurisdiction. But even if the Court were to consider those two allegations as well-pled, neither qualifies as "final agency action" within the meaning of the APA, as discussed below.

1. The Consent Form Signed by Participants Is Not Final Agency Action.

Plainitff attempted to argue that the consent form that participants sign constitutes a "contract" that is a final agency action under the APA. However, Plaintiff offered no legal

foundation to support that claim and, indeed, none exists. The APA only extends to agency actions as defined within the statute, i.e. "the whole or a 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). Tellingly, the statute does not include "contract" in its definition of "agency action." See id. § 551(13). Moreover, while the consent form informs participants about their rights, it does not "create" the rights—indeed, the rights already exist, whether or not the participants are aware of them or sign a document reflecting that they were informed of them. See, e.g., 40 C.F.R. § 26.116 (describing general requirements for informed consent). There is no consummation of a decisionmaking process from which rights or obligations flow. Instead, the consent form EPA provides to participants in its studies is a part of the fulfillment of EPA's requirements of informed consent under the Common Rule. Participants sign the form to indicate they have read it and understand all aspects of their participation. It does not form a binding "contract" with EPA.[14]

2. EPA's Decision to Study $PM_{2.5}$ with Human Participants Is Not Final Agency Action.

Counsel for Plaintiff also suggested at the hearing on its motion for a temporary restraining order that EPA's decision to undertake studies regarding $PM_{2.5}$ constituted a final agency action. Again, Plaintiff could not support that assertion, because there is no legal basis for it. First, to the extent Plaintiff refers to some initial, general decision to conduct studies regarding $PM_{2.5}$, Plaintiff does not identify any such decision. EPA has been conducting

[14] Even if it did, this Court would still lack subject matter jurisdiction over Plaintiff's claim because jurisdiction over a claim for breach of such a contract would rest with the Court of Federal Claims, not this Court, 28 U.S.C. § 1491(a)(1), and any dispute related to the contract would be reviewed under contract law.

controlled human exposure testing of PM2.5 since the late 1990s. See generally Devlin Decl. ¶ 8. Any claims concerning the initial decision to study PM2.5 are thus now far beyond the statute of limitations. See 42 U.S.C. § 7607(b) (providing sixty days from date of action to file a challenge). Second, whether Plaintiff refers to a decision to research PM2.5 generally or EPA's decision to conduct a specific study, neither constitutes final agency action.

The decision to undertake research is not a rule, a license, a sanction, an order, a form of relief, or a failure to act, and is thus not an "agency action" under the APA. Furthermore, EPA's initiation of studies relating to PM2.5 did not mark the consummation of a decisionmaking process from which rights or obligations flow, as required for APA review of final agency action under Bennett. Rather, EPA's PM2.5 research is part of the information gathering Congress directed EPA to undertake in order to form a base of knowledge concerning air pollution. See Chemical Mfrs. Ass'n v. EPA, 26 F. Supp. 2d 180, 183 n.2 (D.D.C. 1998) ("[T]he relevant question is not whether the action concludes *a* decisionmaking process -- such as what a policy published in the Federal Register is to contain -- but whether the action concludes *the* decisionmaking process -- that is, a broader process that impacts individual parties and their rights and obligations." (emphasis in original)). The decision to study PM2.5 thus lacks the basic indicia of a final agency action to garner review under the APA.

Moreover, while EPA must follow the Common Rule when undertaking its research, the internal approval of a study, standing alone, does not change any regulations with respect to PM2.5, EPA's obligations in conducting its research, or ATI/ELC's legal rights or obligations. See DRG Funding Corp. v. Sec'y of Housing & Urban Dev., 76 F.3d 1212, 1214 (D.C. Cir. 1996) (agency action not final where it "does not itself adversely affect [the plaintiff] but only

affects [its] rights adversely on the contingency of future administrative action" (citation omitted)). Indeed, Plaintiff has not demonstrated that EPA's undertaking research has any effect whatsoever on ATI/ELC's operations as an organization. See Franklin v. Massachusetts, 505 U.S. 788, 797 (1992) ("The core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties."); see also Wollman, 603 F. Supp. 2d at 884–85 (describing the question as "'whether the action had a direct impact on the day-to-day business of the plaintiff'" (quoting Trinity Indus., Inc. v. Herman, 173 F.3d 527, 532 (4th Cir. 1999)). EPA's decision to undertake research in general or any individual study in particular is thus neither an "agency action" nor "final" for the purpose of review under the APA.

D. EPA's Decision to Study PM2.5 with Human Participants Is a Decision Committed to Agency Discretion by Law.

Even if some element of EPA's program of controlled human exposures studies involving $PM_{2.5}$ could be considered a final agency action, Plaintiff's claim still must be dismissed because EPA's decision regarding what studies it chooses to conduct is committed to agency discretion by law and, therefore, is not subject to review under the APA. See 5 U.S.C. § 701(a)(2). The APA bars judicial review of discretionary agency action where the statute "is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." Heckler v. Chaney, 470 U.S. 821, 830 (1985).

Here, Congress directed EPA to study the causes and effects of air pollution. 42 U.S.C. § 7403. Nothing in the CAA provides a "meaningful standard" to evaluate what air pollution EPA chooses to study or how. To the contrary, the CAA gives EPA broad discretion in the subject matter of its research program. The only CAA provision applying to EPA's research is CAA

Section 103, 42 U.S.C. § 7403, where Congress broadly mandated that EPA study the health effects of air pollution. But no CAA provision tells EPA what air pollutants to study, with the exception of ozone and wood smoke. 42 U.S.C. § 7403(c)(3), (d)(1). Nor does it provide any standard or direction for how EPA must decide what to study or not, when to conduct studies, what kinds of studies to conduct, how to set and when to shift research priorities. The specific methods for EPA's research are likewise not specified, i.e., whether EPA involves human participants in its research; although, as mentioned above, the involvement of human participants was known to Congress when debating the CAA. Congress prescribed certain timelines for the prioritization of environmental health assessments of hazardous air pollutants, id. § 7403(d)(2)(B)-(C), but did not address any of the issues involved in developing and implementing a research program for any other air pollutant.

Deciding what research program to pursue and how to pursue it "involves a complicated balancing of a number of factors which are peculiarly within [the Agency's] expertise." Heckler, 470 U.S. at 831. EPA must determine whether its resources are best spent in the study of certain types of pollutants, whether such studies will be fruitful, and whether such studies best fit with the Agency's statutory mandates. Because "no judicially manageable standards are available for judging how and when [EPA] should exercise its discretion" in deciding what research to undertake, EPA's decision to study the health effects of $PM_{2.5}$ using controlled human exposure studies was a decision committed to EPA's discretion and immune from review under the APA. Id. at 830.

In sum, because Plaintiff has failed to identify an agency action, an agency action for which a statute provides review, a final agency action, or an action which provides a meaningful

standard for this Court to review, this Court should dismiss the Complaint.

E. If This Court Determines That a Final Agency Action Exists, This Court Lacks Jurisdiction Because Exclusive Jurisdiction Would Rest in the Courts of Appeals Under the Clean Air Act.

Even if this Court determines that any part of EPA's research constitutes a final agency action, such action would not be reviewable under the APA because there is "other adequate remedy in a court" that divests this Court of jurisdiction under the APA. 5 U.S.C. § 704. Since EPA is conducting its research pursuant to its duties under the CAA, review of any action deemed "final" by this Court must comport with that statutory framework. 42 U.S.C. § 7607(b)(1). Thus, depending on where the action originated and whether it is locally or nationally applicable, review of such action would exclusively rest in the appropriate Court of Appeals under the CAA's provisions for judicial review. Id.; see also Harrison, 446 U.S. at 588. Accordingly, if this Court determines that there is a "final agency action" subject to judicial review, this Court would lack subject matter jurisdiction to review that action, and Plaintiff's Complaint must be dismissed.

II. PLAINTIFF LACKS BOTH CONSTITUTIONAL AND PRUDENTIAL STANDING

This Court should also dismiss Plaintiff's claim for lack of standing because ATI/ELC – the captioned plaintiff in this case - has not pled sufficient facts to establish that it has standing to challenge EPA's research of $PM_{2.5}$.[15]

A. Plaintiff Lacks Constitutional Standing.

To satisfy the "case or controversy" requirement of Article III of the Constitution,

[15] As noted, the Complaint refers to both ATI and ATI/ELC somewhat interchangeably, although they are separate and distinct entities. We are challenging the standing of the named Plaintiff, ATI/ELC. However, we also explain that ATI would lack standing for the same reasons.

ATI/ELC must demonstrate that: (1) it or one of its members has suffered an "injury in fact" that is actual and imminent, not conjectural or hypothetical; (2) the injury complained of is caused by or fairly traceable to the challenged action of EPA; and (3) it is likely that a favorable decision would redress the injury. See Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992); Bishop v. Bartlett, 575 F.3d 419, 423 (4th Cir. 2009). The burden is on ATI/ELC to demonstrate affirmatively and clearly that it possesses sufficient standing to seek the requested relief. See FW/PBS, Inc. v. City of Dallas, 493 U.S. 215, 231 (1990); Bishop, 575 F.3d at 424. ATI/ELC has failed to demonstrate that it has satisfied this standard either to bring the claims on its own behalf, or as an organization on behalf of its members.

1. Plaintiff Cannot Establish Representational Standing to Bring Its Claim on Behalf of Its Members.

To establish "representational" standing, Plaintiff must show that "(1) its own members would have standing to sue in their own right; (2) the interests the organization seeks to protect are germane to the organization's purpose; and (3) neither the claim nor the relief sought requires the participation of individual members in the lawsuit."[16] Md. Highways Contractors Ass'n, Inc. v. Maryland, 933 F.2d 1246, 1251 (4th Cir. 1991) (citing Hunt v. Wash. State Apple Adver. Comm'n, 432 U.S. 333, 343 (1977) (remaining citations omitted)).

a. None of ATI/ELC's Members Have Standing to Bring This Claim.

ATI/ELC has identified only one member whose interests it seeks to protect: Dr. David

[16] Only the first two prongs are at issue here; since the Complaint seeks only declaratory and injunctive relief, whether the individual members' participation would be required is not in dispute. Lansdowne on the Potomac Homeowners Ass'n, Inc. v. Openband at Lansdowne LLC, et al., No. 11-872, 2012 WL 2462301, at *7 (E.D. Va. June 27, 2012).

Schnare.[17] Declaration of David W. Schnare, Dkt. No. 1-1 ("Schnare Decl.") ¶ 9. His declarations alone are insufficient to support standing as an individual; thus, ATI/ELC lacks standing. Dr. Schnare has not shown an "injury-in-fact"—an "invasion of a legally protected interest which is (a) concrete and particularized" and (b) "actual or imminent, not conjectural or hypothetical." Lujan, 504 U.S. at 560 (internal quotations and citations omitted). "Abstract injury is not enough;" the injury must be "real and immediate." City of Los Angeles v. Lyons, 461 U.S. 95, 101-102 (1983) (internal quotations and citation omitted). Dr. Schnare alleges purely emotional injury. See Declaration of David W. Schnare, Dkt. No. 1-1 ("Schnare Decl."), ¶ 7; Supplemental Declaration of David W. Schnare, Dkt. No. 6 ("Schnare Supp. Decl."), ¶¶ 10, 14. "[G]eneral emotional harm, no matter how deeply felt, cannot suffice for injury-in-fact for standing purposes." Humane Soc'y of U.S. v. Babbitt, 46 F.3d 93, 98 (D.C. Cir. 1995) (internal quotations omitted). Emotional harm can only satisfy the actual injury requirement of standing if the harm is to a "legally protected" or "judicially cognizable" interest. Al-Aulaqi v. Obama, 727 F. Supp. 2d 1, 25 (D.D.C. 2010) (citations omitted). Neither the CAA nor the Common Rule exists to protect non-participants from emotional harm. See generally id. (holding that wrongful death statute provided no "legally protected interest in preserving [a father's] relationship with his adult son"). Nor is a third party's freedom from emotional injury a legally-protected right such that the courts could enforce it. See Smith v. Frye, 488 F.3d 263, 273–74 (4th Cir. 2007) (upholding ruling that plaintiff lacked standing because civil rights claim for emotional distress

[17] Dr. Schnare and Mr. Milloy are both representing ATI/ELC in this lawsuit as attorneys. They both also submitted declarations as members of the American Tradition Institute. Without passing on the propriety of Dr. Schnare and Mr. Milloy's submittal of declarations, Defendants note the tension this raises under Virginia Rule of Professional Conduct 3.7, which counsels against lawyers acting as both advocate and witness in an adversarial proceeding.

flowing from the mistreatment of his mother was "insufficient as an Article III injury in fact").

Dr. Schnare's supplemental declaration (submitted after the Complaint was filed) also asserts that this emotional distress has caused some discrete changes in behavior, such as avoiding the University of North Carolina campus and the Federal Triangle Metro stop. Schnare Supp. Decl. ¶¶ 10, 14. Dr. Schnare does not, however, identify a particular instance where he felt too distressed to visit either of the places, nor that he has planned or would plan a visit at any time in the foreseeable future, as would be necessary to demonstrate an imminent injury. Lujan, 504 U.S. at 564 ("'some day' intentions – without any description of concrete plans . . . do not support a finding of the 'actual or imminent' injury that our cases require" (citation omitted)). In any event, even if Dr. Schnare were again to supplement his declaration to make such assertions, the actions of EPA are so far removed from directly impacting the rights of Dr. Schnare as to render the assertions of emotional harm implausible and, in any case, insufficient.[18] In sum, because the only identified member of ATI/ELC does not have standing on his own to assert ATI/ELC's APA claims, ATI/ELC lacks standing to assert such claims on his behalf.

b. None of ATI's Members Have Standing to Bring This Claim.

The other Declarants, Mr. Milloy and Mr. Huffman, allege that they are "member[s] of the American Tradition Institute," not ATI/ELC. Declaration of Steven J. Milloy (Dkt. No. 1-3)

[18] In its Motion for a Temporary Restraining Order Plaintiff sought to support its argument that emotional injury can be cognizable by citing the dissenting opinion in Kennedy v. Secretary of the Army, No. 99-15214, 1999 WL 710317, at *4 (9th Cir. Sept. 10, 1999). There, however, the challenged government action actually affected the plaintiff, not a third party. Id. at *4. The case the Kennedy dissent cites also is readily distinguishable because the challenged action affected the plaintiff in a concrete way. See Chalk v. U.S. Dist. Court C.D. Cal., 840 F.2d 701, 709 (9th Cir. 1988) (finding emotional injury when plaintiff was transferred to different employment). ATI/ELC cites no case supporting a finding that cognizable emotional injury can flow from actions wholly involving other people for the purposes of standing.

¶ 7; Declaration of Landon Huffman (Dkt. No. 1-2) ¶ 7.[19] Even if the Court considered ATI to be a Plaintiff, their declarations would be insufficient to support standing of ATI. Mr. Milloy asserts a general emotional injury which is insufficient for the same reasons as Dr. Schnare. The only member of ATI alleged to have actually participated in the challenged studies is Mr. Huffman, who asserts a lack of informed consent to his past participation in one of EPA's studies in 2006 and 2007. Declaration of Landon Huffman (Dkt. No. 1-2) ("Huffman Decl.") ¶¶ 3–4. Mr. Huffman's alleged harm (fear of personal injury), however, is not a "judicially cognizable" injury under the APA as alleged in the Complaint.[20] Nevertheless, even if Mr. Huffman's allegations satisfied the "injury" and "causation" prongs of standing, plaintiffs must establish standing for each form of relief sought, Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 185 (2000), and none of the relief sought would redress Mr. Huffman's injuries.[21] The relief Plaintiff seeks under the APA would not redress Mr. Huffman's

---

[19] Dr. John Dale Dunn does not state in his declaration that he is a member of ATI/ELC or ATI. Therefore, his declaration cannot be used to support standing. Moreover, if Dr. Dunn is an employee of the United States Army as he alleges, the Court should disregard his declaration unless ATI/ELC demonstrates that the Army has authorized the declaration as required by the Army's regulations. See Army Reg. 27-40 Ch. 7, § III, 7-10(a), *available at* http://www.apd.army.mil/AdminPubs/series_range_regs.asp?search=27 (click on "PDF" link corresponding to "AR 27-40") ("Present DA personnel will not provide, with or without compensation, opinion or expert testimony . . . in litigation in which the United States has an interest for a party other than the United States."). The United States reserves the right to move to strike his declaration, should its present Motion be denied.

[20] While anyone may bring a claim under the Federal Tort Claims Act, whether such claims would result in recoveries depends on the particular facts surrounding the claims. See, e.g., Goodman v. United States, 298 F.3d 1048 (9th Cir. 2002); Bibeau v. Pac. Nw. Research Found., 339 F.3d 942 (9th Cir. 2003).

[21] Indeed, neither would the relief sought redress the injuries of Dr. Schnare and Mr. Milloy, unless this Court were to find improprieties with the CAPTAIN study—the only currently-ongoing study related to PM2.5. The injunctive relief sought "cannot conceivably remedy any

(continued on the next page . . .)

injury because Mr. Huffman is not participating in any of the studies currently ongoing; thus, ATI's request to enjoin ongoing studies would be of no benefit to him. In sum, because none of the individual members presented to the Court would have standing on his own to assert the APA claims, ATI/ELC and ATI lack standing to assert such claims on their behalf.

2. **Plaintiff Cannot Establish Standing As an Organization.**

Organizations have the ability to establish standing as individuals apart from their members. Warth v. Seldin, 422 U.S. 490, 511 (1975). Like individuals, they must allege "such a personal stake in the outcome of the matter to warrant [the] invocation of federal court jurisdiction." Md. Highways Contractors Ass'n, 933 F.2d at 1250 (citing Havens Realty Corp. v. Coleman, 455 U.S. 363, 378-79 (1982)); Allen v. Wright, 468 U.S. 737, 750 (1984)). Plaintiff has not alleged that ATI/ELC or ATI have "such a personal stake in the outcome" to establish standing.

Ccourts have described the organization's required showing as follows:

> [a] concrete and demonstrable injury to the organization's activities - with [a] consequent drain on the organization's resources - constitut[ing] . . . more than simply a setback to the organization's abstract social interests . . . Indeed, [t]he organization must allege that discrete programmatic concerns are being directly and adversely affected by the challenged action.

Common Cause v. Fed. Election Comm'n, 108 F.3d 413, 417 (D.C. Cir. 1997) (quoting Nat'l Taxpayers Union, Inc. v. United States, 68 F.3d 1428, 1433 (D.C. Cir. 1995)); see also Md. Highways Contractors Ass'n, 933 F.2d at 1251 (finding a violation of an organization's "broad purposes" "insufficient to support standing"). This injury requirement "prevents the judicial process from becoming no more than a vehicle for the vindication of the value interests of

---

past wrong but is aimed at deterring" future violations. Steel Co., 523 U.S. at 108–09.

concerned bystanders." United States v. Students Challenging Regulatory Agency Procedures, 412 U.S. 669, 687 (1973). Where, as here, the claim stems "from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*," demonstrating the elements of standing are more difficult. Lujan, 504 U.S. at 562 (emphasis in original).

Even if Plaintiff alleged that EPA's actions frustrated the purpose of either ATI/ELC or ATI as an organization, which it did not, frustration of an organization's objectives "is the type of abstract concern that does not impart standing." Nat'l Taxpayers Union, 68 F.3d at 1433. Plaintiff would need to show that, beyond merely a frustration of purpose, EPA's actions interfered with the organization's ability to function. See Havens Realty Corp., 455 U.S. at 379 (impairment to housing organization's ability to provide services, as opposed to "simply a setback to the organization's abstract social interests," sufficient to show injury (citation omitted)); see also Haitian Refugee Ctr. v. Gracey, 809 F.2d 794, 818 (D.C. Cir. 1987) (no standing where organization's "ability to function . . . not at stake"). EPA's testing program has no effect on the functioning of ATI/ELC or ATI. In fact, none of ATI/ELC's stated functions relate to EPA's research with human participants except in the most tangential, distant way. See Complaint ¶ 3; see also American Tradition Institute, "Law Center," http://www.atinstitute.org/law-ctr/ (last visited Nov. 20, 2012) (describing its purpose, among other elements, as combating "governmental overreach" and securing citizens' Constitutional rights).

Nor does the Complaint allege any direct adverse effect on the "discrete programmatic concerns" of either ATI/ELC or ATI. While the Complaint alleges that "the Insititute and its Law Center" have an interest in "good science, honest government and the rights of citizens and

man," Complaint ¶ 3, "a mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem, is not sufficient by itself to render the organization 'adversely affected' or 'aggrieved' within the meaning of the APA." Sierra Club v. Morton, 405 U.S. 727, 739 (1972). Palintiff's claim merely seeks "proper application of the Constitution and laws," which "no more directly and tangibly benefits [it] than it does the public at large." Lujan, 504 U.S. at 573–74. Accordingly, Plaintiff has failed to plead an organizational injury to either ATI/ELC or ATI sufficient to satisfy constitutional requirements. Id.

Nor can Plaintiff establish standing based on an alleged procedural injury (i.e., that EPA violated some procedural requirement that impacts "a separate concrete interest" of Plaintiff, see Lujan, 504 U.S. at 572), because neither ATI/ELC nor ATI has a "concrete interest" being impaired by EPA's actions. Pye v. United States, 269 F.3d 459, 467 (4th Cir. 2001). In Pye, plaintiffs alleged a procedural injury, but demonstrated that they owned property adjacent to land that would be affected by the government's decision. Id. at 468. Here, in contrast, Plaintiff has not alleged that ATI/ELC or ATI has a property interest of any kind that is affected by EPA's studying the effects of $PM_{2.5}$. Thus, neither ATI/ELC nor ATI has standing as an organization to bring its claim before this Court.

B. Plaintiff Lacks Prudential Standing.

Even if Plaintiff could establish constitutional standing, the doctrine of prudential standing would still preclude review. Prudential standing comprises three elements: (1) plaintiff may not assert only a generalized grievance; (2) plaintiff must generally assert its own rights, not those of third parties, and (3) plaintiff's grievances must fall within the zone of interests the

statute or constitutional provision protects or regulates. Bishop, 575 F.3d at 423. Neither ATI/ELC nor ATI meet the requirements to establish prudential standing.

Plaintiff's concern about the ethical implementation of studies using human participants, Complaint ¶¶ 98–116, is just the type of "generalized grievance" that cannot support standing. See United States v. Richardson, 418 U.S. 166, 179–80 (1974) (finding no unique "personal stake" in the constitutionality of the Central Intelligence Agency Act). Because ATI/ELC does not have as its purpose the protection of research participants, and because ATI/ELC is not participating in the research itself, ATI/ELC's interest in seeking to enforce EPA's compliance with the law is an "abstract, generalized interest," which fails to meet "the requirement that an injury be concrete and particularized." Bishop, 575 F.3d at 424. The same is true for ATI.

Nor can Plaintiff establish the second element of prudential standing because, as discussed above, Plaintiff does not identify any injury to the discrete programmatic concerns of either ATI/ELC or ATI. Rather, ATI/ELC purports to protect the public at large by ensuring that EPA follows its regulations and protects the participants in its studies. At the hearing on its motion for a temporary restraining order, counsel for ATI/ELC likened the organization's position to a "constructive guardian *ad litem*" for the participants in EPA's research. Transcript at 7:9–10. Such representation, which is several steps removed from the organization's own interests and purposes, does not provide ATI/ELC with standing. ATI/ELC has no member that participated in any of EPA's research, much less ongoing studies. With respect to ongoing studies, then—the studies ATI/ELC seeks to enjoin—ATI/ELC is only asserting the rights of unidentified third parties, none of whom are alleged to be members of ATI/ELC or appear to have sought representation by ATI/ELC or its attorneys.

Finally, Plaintiff fails to meet the third element of prudential standing because neither ATI/ELC nor ATI is within the zone of interests the Common Rule regulations are designed to protect.[22] As discussed above, the regulations do not provide a private cause of action. Similar regulations have already been interpreted as not providing a private cause of action because, among other reasons, they were "not focused on the individual benefitted." Wright, 269 F. Supp. 2d at 1289. Plaintiff's claim is based on an alleged violation of regulations not designed to protect ATI/ELC or ATI or provide any legal rights to them. Rather, they govern the conduct of agencies and institutions conducting research with human participants. Therefore, ATI/ELC and ATI are not within the Common Rule's zone of interests. Plaintiff has not alleged sufficient facts to establish that it has standing, constitutionally or prudentially, and this Court should therefore dismiss its Complaint for lack of subject matter jurisdiction.

CONCLUSION

For the foregoing reasons, the United States respectfully requests that the Court dismiss Plaintiff's Complaint with prejudice.

Respectfully submitted,

IGNACIA S. MORENO
Assistant Attorney General
Environment & Natural Resources Division
U.S. Department of Justice

CYNTHIA J. MORRIS
ELIZABETH B. DAWSON

[22] Unlike the elements of constitutional standing, Congress can alter the elements of prudential standing, for example, by defining the zone of interests protected by a statute. See Bennett, 520 U.S. at 163–64 (ruling that by allowing "any" person to sue to enforce the Endangered Species Act, Congress expanded the zone of interests, extending a cause of action to all people). As described above, Congress did not do so here, and thus EPA did not have the authority to do so when promulgating its regulations pursuant to congressional mandate.

Environmental Defense Section
P.O. Box 7611
Washington, D.C. 20044
(202) 616-7554 (Morris)
(202) 514-8293 (Dawson)

NEIL H. MacBRIDE
United States Attorney
Eastern District of Virginia
U.S. Department of Justice

/s/ Bernard Kim
Bernard G. Kim
Assistant United States Attorney
Justin W. Williams U.S. Attorney's Building
2100 Jamieson Avenue
Alexandria, Virginia 22314
(703) 299-3911 (direct)
(703) 299-3983 (fax)
bernard.kim@usdoj.gov

OF COUNSEL:
JOHN HANNON
STEVEN SILVERMAN
Office of General Counsel
U.S. Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

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 21th day of November, 2012, I electronically filed the foregoing "Motion to Dismiss" and "United States' Memorandum in Support of Its Motion to Dismiss," with the Clerk of the Court using the CM/EMF system which will send notification of such filing to the following:

David Walter Schnare, Esq. (VSB# 44522)
The Free Market Environmental Law Clinic
9033 Brook Ford Road
Burke, VA 22015
(571) 243-7975 (ph.)
schnare@FMELawClinic.org
Attorney for the Plaintiff

/s/ Bernard Kim

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 21th day of November, 2012, I electronically filed the foregoing "Motion to Dismiss" and "United States' Memorandum in Support of Its Motion to Dismiss," with the Clerk of the Court using the CM/EMF system which will send notification of such filing to the following:

David Walter Schnare, Esq. (VSB# 44522)
The Free Market Environmental Law Clinic
9033 Brook Ford Road
Burke, VA 22015
(571) 243-7975 (ph.)
schnare@FMELawClinic.org
Attorney for the Plaintiff

/s/ Bernard Kim