IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

KNOWLEDGE ECOLOGY INTERNATIONAL, Plaintiff, v. NATIONAL INSTITUTES OF HEALTH, *et al.*, Defendants.	Case No. 8:18-cv-01130-PJM

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS

Defendants, National Institutes of Health ("NIH"), National Cancer Institute ("NCI"), Francis S. Collins ("Collins"), and David Lambertson ("Lambertson," and together with NIH, NCI, and Collins, the "Defendants"), by and through their counsel, Robert K. Hur, United States Attorney for the District of Maryland, and Alan C. Lazerow, Assistant United States Attorney for that district, respectfully submits this *Memorandum in Support of Motion to Dismiss*.

I. INTRODUCTION

By the *Complaint for Declaratory, Injunctive, and Other Relief*, *see* ECF No. 1 (the "Complaint"), Knowledge Ecology International ("KEI" or the "Plaintiff"), a public-interest organization, challenges NIH's grant of an exclusive license for technology relating to certain cancer treatments to a large pharmaceutical company. The Court need not address the merits of Plaintiff's contentions, because Plaintiff lacks standing to bring this suit.

First, because Plaintiff does not allege what injuries KEI will suffer because of Defendants' alleged conduct, Plaintiff lacks what the caselaw has coined "organizational standing." And because Plaintiff does not allege that the patients, taxpayers, and consumers Plaintiff purports to represent control KEI's functions, elect or serve on KEI's leadership, or finance KEI's activities,

Plaintiff lacks "associational standing" to sue on behalf of its purported constituents. For these reasons, and as explained more fully below, the Court should dismiss the Complaint for lack of subject-matter jurisdiction, under Rule 12(b)(1) of the Federal Rules of Civil Procedure (the "Rules").

II. FACTS

A. THE PROPOSED LICENSE

Through its technology transfer program, NIH makes patents and other intellectual property owned by the United States available to public and private companies, through the granting of exclusive and non-exclusive licenses to use that technology. Declaration of Dale D. Berkley, Ph.D., J.D. (the "Berkley Declaration")[1] ¶ 2. Licenses granted through the technology transfer program, in almost all cases, require the licensees to pay royalties to the United States. *Id.* ¶ 3. Royalties obtained through licensing provide a return to NIH that supports further research and provide compensation to government employee inventors. *Id.*

On December 20, 2017, NIH posted a notice of intent (the "Notice of Intent") in the Federal Register regarding the proposed grant of an exclusive license to Kite Pharma, Inc. ("Kite") for CAR T technology for the treatment of cancer (the "Proposed License"). *See* 82 Fed. Reg. 60406, 60407 (Dec. 20, 2017); Complaint ¶ 47. The Notice of Intent provided that "the public may file comments or objections," relating to the Proposed License, and that "the prospective exclusive license may be granted unless, within fifteen (15) days from the date of this published notice, [NCI] receives written evidence and argument that establishes that the grant of the license would

[1] A copy of the Berkley Declaration is attached as **Exhibit A**.

not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404." 82 Fed. Reg. 60406, 60407.

B. PLAINTIFF OPPOSES THE LICENSE

On January 4, 2018, James Love – apparently affiliated with KEI – wrote to Collins and Lambertson to "express [KEI's] opposition to the [P]roposed [License]." Berkley Declaration ¶ 6.[2] Mr. Love attached a five-page document outlining KEI's opposition to the Proposed License. *Id.* On January 25, 2018, Lambertson responded to Mr. Love by email and attached a response, explaining that "[w]hile your comments have been given full consideration, they do not persuade us that the [Proposed License] would be inconsistent with the regulations and, furthermore, advance public health." *Id.* ¶ 7.[3]

On February 14, 2018, Andrew Goldman – also with KEI, and counsel of record for KEI – emailed Collins and Lambertson asking about KEI's appeal rights, asking Collins and Lambertson to "let [KEI] know what formal procedures the NIH requires for these appeals …." *Id.* ¶ 8.[4] On February 26, 2018, Lambertson responded to Mr. Goldman, noting that under 37 C.F.R. § 404.1(a)(3), an appeal can be taken by only "a person who can demonstrate to the satisfaction of the agency that such person may be damaged by the action," that NIH "determined

[2] A copy of the January 4, 2018 email from Mr. Love to Collins and Lambertson, with an attachment, is attached as **Exhibit 1** to the Berkley Declaration.

[3] A copy of the January 25, 2018 email from Lambertson to Mr. Love, with an attachment, is attached as **Exhibit 2** to the Berkley Declaration.

[4] A copy of the February 14, 2018 email from Mr. Goldman to Collins and Lambertson is attached as **Exhibit 3** to the Berkley Declaration.

that there is no likelihood that KEI will be damaged by the agency action," and that NIH "will not entertain an appeal of our decision." *Id.* ¶ 9.[5]

Undeterred, also on February 26, 2018, Mr. Goldman responded to Collins and Lambertson, attaching KEI's appeal of NIH's response to KEI's opposition to the Proposed License. *Id.* ¶ 10.[6] In the attached appeal, KEI represented that it is "a public interest organization" that "represents taxpayers and patients, including cancer patients, who are stakeholders in the outcome of the NIH decision," and also stated that KEI "represents persons who will be damaged by the decision to proceed with [the Proposed License] …." *Id.*

C. THE COMPLAINT

On April 19, 2018, Plaintiff filed the Complaint. Count I of the Complaint asserts a violation of the Federal Property and Administrative Services Act and 5 U.S.C. 706(2)(A), alleging that NIH's failure "to seek and obtain the antitrust advice of the Attorney General prior to the disposal of federal property to private interests" "is a violation of 40 U.S.C. § 559 and applicable regulations, and constitutes agency action that is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law under 5 U.S.C. § 706(2)(A), or that is illegal agency action under 5 U.S.C. § 706(1)." Complaint ¶¶ 61, 65. Count II of the Complaint asserts a violation of 37 C.F.R. § 404.11 and 5 U.S.C. 706(2)(A), alleging that "Defendants have refused to entertain the rightful appeal of KEI without explanation," and that such denial "constitutes a violation of 37 C.F.R. § 404.11, as well as an agency action that is arbitrary, capricious, an abuse

[5] A copy of the February 26, 2018 email from Lambertson to Mr. Goldman is attached as **Exhibit 4** to the Berkley Declaration.

[6] A copy of the February 26, 2018 email from Mr. Goldman to Collins and Lambertson, with attachments, is attached as **Exhibit 5** to the Berkley Declaration.

of discretion, or otherwise not in accordance with the law under 5 U.S.C. § 706(2)(A), or that is illegal agency action under 5 U.S.C. § 706(1)." Complaint ¶¶ 69, 70.

In addition to seeking a declaration of the violations above, by the Complaint, Plaintiff seeks to "[i]nvalidate the exclusive license of the NCI CAR technology to Kite," and asks the Court to "enter appropriate preliminary and permanent injunctive relief to ensure that Defendants comply with FPASA and specifically to ensure that Defendants and their agents take no further actions toward proceeding with the challenged license until they have complied with FPASA and granted KEI the right of appeal." Complaint at p. 17.

D. PLAINTIFF'S ALLEGATIONS BEARING ON STANDING

As explained below, Plaintiff bears the burden of establishing that it has standing to bring this lawsuit. Thus, a review of Plaintiff's allegations in the Complaint bearing on standing is appropriate. *See Henley v. Cleveland Bd. of Educ.*, No. 1:10-cv-00431, 2010 WL 796835, at *2 (N.D. Ohio Mar. 3, 2010) ("When a court considers whether a plaintiff has standing to pursue preliminary relief, standing is determined by analyzing the material allegations in the complaint …."); *see also BayFirst Solutions, LLC v. United States*, 104 Fed. Cl. 493, 501 (Fed. Cl. 2012) ("Standing, this court has typically held, is predicated on an initial review of the complaint and the allegations therein.").

Plaintiff alleges that it "is an award-winning nonprofit organization that works extensively on issues pertaining to access to affordable medicines and related intellectual concerns." Complaint ¶ 5. Plaintiff "conducts research, writing and advocacy in the public interest on behalf of patients, taxpayers, and consumers, including on the licensing of federally-funded and/or federally-owned medical technologies, and comments frequently on proposed exclusive licenses …." *Id.* Plaintiff "maintains multiple email lists on … public health issues for patients, taxpayers,

and consumers, academics, and other interested persons …." *Id.* Plaintiff maintains an "'IP-Health' listserv of approximately 2400 subscribers." *Id.*

Plaintiff alleges that the relief it seeks "would redress actual, concrete injuries to Plaintiff and the patients, taxpayers and consumers Plaintiff represents …." *Id.* ¶ 14. In Plaintiff's view, Defendants' actions are "an affront to patients, payments, and consumers … who will be damaged by the higher prices stemming from [the Proposed License] …." *Id.* ¶ 72; *see id.* ¶ 1 (mentioning "Defendants' waste of taxpayer funds that will result in the denial of affordable cancer treatments for patients").

III. APPLICABLE LEGAL STANDARD: MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION

As explained below, Defendant maintains that Plaintiff lacks standing to bring this suit. Dismissal under Rule 12(b)(1) is appropriate under such circumstances. *See Zaycer v. Sturm Foods, Inc.*, 896 F. Supp. 2d 399, 403 (D. Md. 2012) ("Under Rule 12(b)(1), if a party lacks standing the court automatically lacks subject matter jurisdiction."); *McInnes v. Lord Baltimore Employee Retirement Income Account Plan*, 823 F. Supp. 2d 360, 362 (D. Md. 2011) ("Because standing is an element of subject matter jurisdiction, a defendant's motion to dismiss for lack of standing should be treated under Rule 12(b)(1).").

As this Court has explained:

> A challenge to standing may take two forms: a facial challenge, asserting that the allegations pleaded in the complaint are insufficient to establish standing, or a factual challenge asserting that the jurisdictional allegations of the complaint are not true, or that other facts, outside the four corners of the complaint preclude the exercise of subject matter jurisdiction.

Franklin v. Jackson, No. 8:14-cv-00497, 2015 WL 1186599, at *8 (D. Md. Mar. 3, 2015) (internal quotation marks and modifications omitted). Defendants contend that the allegations in the

Complaint cannot establish Plaintiff's standing. "When analyzing a facial challenge, the court determines whether the allegations in the Complaint, taken as true, are sufficient to establish standing under the plausibility standard of Rule 12(b)(6) and *Iqbal/Twombly*." *Allah-Mensah v. Law Office of Patrick M. Connelly, P.C.*, No. 8:16-cv-01053, 2016 WL 6803775, at *2 (D. Md. Nov. 17, 2016).

A motion to dismiss based on lack of subject-matter jurisdiction, under Rule 12(b)(1), raises whether the court has the competence or authority to hear and decide a particular case. *See Davis v. Thompson*, 367 F. Supp. 2d 792, 299 (D. Md. 2005). As a result, the court "generally may not rule on the merits of a case without first determining that it has the jurisdiction over the category of claim in suit (subject-matter jurisdiction)." *Sinochem Int'l Co. Ltd. v. Malaysia Int'l Shipping Corp.*, 549 U.S. 422, 430-31 (2007) (citing *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 93-102 (1998)). The plaintiff bears the burden of proving that subject-matter jurisdiction exists, including proving that it has standing to sue. *See McInnes*, 823 F. Supp. 2d at 362 ("The plaintiff in a federal action bears the burden of demonstrating that he possesses standing to pursue his claims in federal court.").

The requirement that a plaintiff establish subject-matter jurisdiction "as a threshold matter 'spring[s] from the nature and limits of the judicial power of the United States' and is 'inflexible and without exception.'" *Steel Co.*, 523 U.S. at 95 (some internal quotation marks omitted). For that reason, "[t]he objection that a federal court lacks subject-matter jurisdiction … may be raised by a party, or by a court on its own initiative, at any stage in the litigation, even after trial and the entry of judgment." *Arbaugh v. Y & H Corp.*, 546 U.S. 500, 506 (2006) (citing Rule 12(h)(3)).

IV. ARGUMENT: THE COURT SHOULD DISMISS THE COMPLAINT, AS PLAINTIFF LACKS STANDING

"An organization may establish standing under two theories: either (a) standing in its own right, or organizational standing, or (b) representational, also known as 'associational,' standing based on the fact that members it represents have been harmed." *Equal Rights Ctr. v. Camden Prop. Trust*, No. 8:07-cv-02357, 2008 WL 8922896, at *5 (D. Md. Sept. 22, 2008). Because Plaintiff asserts that it "brings this action on its own behalf and on behalf of the adversely affected patients and taxpayers that the organization represents," Complaint ¶ 5, this case implicates both organizational and associational standing. As explained below, Plaintiff lacks both.

A. BECAUSE PLAINTIFF DOES NOT ALLEGE THAT IT HAS OR WILL SUFFER HARM FROM THE PROPOSED LICENSE, PLAINTIFF LACKS ORGANIZATIONAL STANDING

"An organizational plaintiff suing on its own behalf, like an individual, must satisfy the familiar elements of injury-in-fact, causation, and redressability to establish Article III standing."[7] *Retail Indus. Leaders Ass'n v. Fielder*, 475 F.3d 180, 186 (4th Cir. 2007); *see Havens Realty Corp. v. Coleman*, 455 U.S. 363, 378 (1982) ("In determining whether [an organizational plaintiff] has standing … , we conduct the same inquiry as in the case of an individual.").

Plaintiff purports to "bring this action on its own behalf," and asserts that "[t]he requested relief would redress actual, concrete injuries to Plaintiff …." Complaint ¶¶ 5, 14. But the Complaint is silent about what "actual" or "concrete" injuries KEI will suffer because of Defendants' alleged conduct. To be sure, Plaintiff complains of "the denial of affordable cancer

[7] If a plaintiff has Article III standing, it must also show that it has prudential standing to sue. Here, because Plaintiff lacks Article III standing, the Court need not address prudential standing. *See, e.g.*, *Greenberg v. Bush*, 150 F. Supp. 2d 447, 455 (E.D.N.Y. 2001) ("Because Plaintiffs have not satisfied the threshold Article III standing requirements, the court need not analyze prudential standing considerations.").

treatment *for patients*," Complaint ¶ 1 (emphasis added), the "mismanage[ment of] *taxpayer* funds," *id.* ¶ 4 (emphasis added), while referencing the "adversely affected *patients and taxpayers*," *id.* ¶ 5 (emphasis added), and the asserted "affront to *patients, taxpayers, and consumers* …." *Id.* ¶ 72 (emphasis added). But these asserted harms purport to inure to the detriment of cancer patients, taxpayers,[8] and consumers – not to KEI. And although Defendants' asserted conduct may, in some way, implicate KEI's institutional goals and purposes, "institutional goals and purposes cannot sustain federal standing absent some other injury." *Amalgamated Clothing and Textile Workers Union, AFL-CIO, CLC v. BRLR, Inc.*, No. 2:91-cv-00607, 1993 WL 561879, at *3 (M.D.N.C. Nov. 19, 1993); *see Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 40 (1976) ("[A]n organization's abstract concern with a subject that could be affected by an adjudication does not substitute for the concrete injury required by Art. III …."). Plaintiff thus does not sufficiently allege an injury-in-fact, a causal link between Defendants' alleged conduct and any injury, and redressability, and Plaintiff lacks organizational standing.[9]

B. BECAUSE PLAINTIFF DOES NOT ALLEGE THAT THE PATIENTS, TAXPAYERS, AND CONSUMERS IT PURPORTS TO "REPRESENT" CONTROL KEI'S FUNCTIONS, ELECT OR SERVE ON KEI'S LEADERSHIP, OR FINANCE KEI'S ACTIVITIES, PLAINTIFF LACKS ASSOCIATIONAL STANDING

"Since they allege no injury to themsel[f] as [an] organization[] … [Plaintiff] can establish standing only as representatives of those of their members who have been injured in fact, and thus

[8] Such taxpayers themselves would lack standing. *See, e.g., Cobb v. U.S. Dep't of Educ. Office for Civil Rights*, No. 05-2439, 2006 WL 1662965, at *7 (D. Minn. June 15, 2006) ("There is a well-established rule barring federal taxpayer standing.").

[9] Although KEI may incur litigation and other expenses in bringing this suit, "[a]n organization cannot, of course, manufacture the injury necessary to maintain a suit from its expenditure of resources on that very suit." *Spann v. Colonial Village, Inc.*, 899 F.2d 24, 27 (D.C. Cir. 1990).

could have brought suit in their own right." *Simon*, 426 U.S. at 40. Stated differently, because Plaintiff lacks organizational standing, the analysis turns on whether Plaintiff has sufficiently pled facts to support associational standing.

The caselaw is established that

> an association has standing to assert the rights of its members if: (1) the association's members would have standing to sue in their own right, (2) the interests the association seeks to protect are "germane to the organization's purpose," and (3) the claim asserted and the relief requested do not require the participation of individual members in the lawsuit.

Fielder, 435 F. Supp. 2d at 486 (quoting *Hunt v. Wash. State Apple Advertising Comm'n*, 432 U.S. 333, 343 (1977)). Plaintiff does not allege that it has "members"; instead it contends it maintains "multiple email lists," one of which allegedly has "approximately 2400 subscribers," and abstractly alleges that it "represents" "patients, taxpayers and consumers …." Complaint ¶ 14. Thus, Plaintiff cannot satisfy the above-referenced associational-standing factors, given that it apparently has no members.

But "an organization with no formal members can still have associational standing if it is the functional equivalent of a traditional membership organization." *Wash. Legal Found. v. Leavitt*, 477 F. Supp. 2d 202, 208 (D.D.C. 2007) (internal citations and quotation marks omitted). The caselaw has developed a "functional equivalency" test, under which an organization may have associational standing – despite a lack of membership – "if the organization (1) serves a specialized segment of the community; (2) represents individuals that have all the indicia of membership, including (i) electing the entity's leadership, (ii) serving in the entity, and (iii) financing the entity's activities, and (3) its fortunes are tied closely to those of its constituency." *Heap v. Carter*, 112 F. Supp. 3d 402, 418 (E.D. Va. 2015).

Plaintiff fails the "indicia-of-membership" test. There is nothing in the Complaint tending to show that any of the "patients, taxpayers and consumers" Plaintiff purports to "represent," *see* Complaint ¶ 14, (i) elects KEI's leadership (or even of what KEI's leadership is comprised), (ii) serves in KEI's activities and goings-on (whatever they may be), or (iii) finances KEI's budget.[10] Although there is a wide-body of caselaw applying the above-cited indicia-of-membership test – with many cases granting associational standing, with many others declining to grant associational standing – this is not a case in which a detailed analysis, analogizing and distinguishing that caselaw, is warranted. Simply put, there is nothing in the Complaint from which the Court could conclude that KEI has satisfied the indicia-of-membership test, and thus conclude that KEI has associational standing. *See, e.g.*, *Heap*, 112 F. Supp. 3d at 418-19 (holding that a non-profit organization lacked associational standing where it "provided no details about who the membership is or whether [it] can be considered a voluntary membership organization or a functional equivalent," and, as such, "[t]his makes it difficult to determine whether it is, in fact, an organization capable of asserting associational standing or whether one of its members has standing to assert the claims at issue," because the organization "has not alleged any information that would allow the Court to find that it has the kind of leadership and financial structure that is closely tied to that of its members or that its members exert any control over the direction of the organization").[11]

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[10] Plaintiff does not allege that the patients, taxpayers, and consumers it purports to "represent" pay dues of any sort.

[11] The only connection of which the Complaint speaks between KEI and those it "represents" are KEI's "multiple email lists," one of which has "approximately 2400 subscribers." *See* Complaint ¶ 5. But Plaintiff does not identify such subscribers (or allege whether Plaintiff knows their identities) or allege that they are the patients, taxpayers, and consumers Plaintiff purports to represent. In any event, merely having mailing or email lists to which people subscribe is

Absent from the Complaint are any allegations relating to certain "key factors" the cases have identified tending to bear on the indicia-of-membership test. *See Advocates for Am. Disabled Individuals LLC v. Price Co.*, No. 2:16-cv-02141, 2016 WL 5939467, at *3 (D. Ariz. Oct. 13, 2016). These include:

- **Control**. *See Heap*, 112 F. Supp. 3d at 419 (denying associational standing where plaintiff did not allege that "its members exert any control over the direction of the organization"); *Basel Action Network v. Maritime Admin.*, 370 F. Supp. 2d 57, 70 (D.D.C. 2005) (denying associational standing where there was no evidence that the purported members "have any control over the direction or organization of the [plaintiff]"); *Grp. Health Plan, Inc. v. Philip Morris, Inc.*, 86 F. Supp. 2d 912, 918 (D. Minn. 2000) ("In order to meet this 'indicia of membership' test, the constituents of an organization must exercise a certain measure of control over the organization."); *Health Research Group v. Kennedy*, 82 F.R.D. 21, 26 (D.D.C. 1979) ("Absent this element of control, there is simply no assurance that the party seeking judicial review represents that injured Party, and not merely a well-informed point of view").

- **Electing and Serving on Leadership**. *See Leavitt*, 477 F. Supp. 2d at 208 (denying associational standing where plaintiff's "supporters [did not] play any role in selecting … leadership") (citing *Am. Legal Found. v. FCC*, 808 F.2d 84, 90 (D.C. Cir. 1987)); *Gettman v. DEA*, 290 F.3d 430, 435 (D.C. Cir. 2002) (denying associational standing where plaintiffs "have not shown that its readers and subscribers played any role in selecting its leadership") (internal quotation marks omitted); *Carespring Healthcare Mgmt., LLC v. Dungey*, No. 1:16-cv-01051, 2018 WL 1138428, at *9 (S.D. Ohio Mar. 2, 2018) (denying associational standing where "there is no allegation that the residents of the Plaintiff nursing homes have any say as to the leadership at the homes"); *Mental Hygiene Legal Serv. v. Cuomo*, 13 F. Supp. 3d 289, 295-96 (S.D.N.Y. 2014), *aff'd*, 609 F. App'x 693 (2d Cir. 2015) (explaining that "if an organization has an active client base and is led by an inclusive leadership, it has sufficient indicia of membership to show that it functions effectively as a membership organization for the purposes of associational standing," and holding that plaintiff lacked standing where it "concede[d] that its constituents do not elect [or] serve … the agency's activities"); *Conservative Baptist Ass'n of Am., Inc. v. Shinseki*, 42 F. Supp. 3d 125, 133 (D.D.C. 2014) ("To determine whether an individual is a member of an organization, the Court looks to whether that individual possesses the 'indicia' of membership, which include electing the leadership of the association ….").

- **Financing Group's Activities**. *See Am. Legal Found.*, 808 F.2d at 90 (denying associational standing where plaintiff's "have not shown that its readers and subscribers played any role in … financing [its] activities"); *Cuomo*, 609 F. App'x at 695 (affirming district court's denial of associational standing where plaintiff's constituents "do not finance its activities")

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insufficient to pass the indicia-of-membership test. *See, e.g., Wash. Legal Found. v. Leavitt*, 477 F. Supp. 2d, 202, 210 (D.D.C. 2007) (rejecting the contention that a person is a "member" if he or she "request[ed] to be placed on one or more of [the organization]'s mailing lists").

(internal quotation marks omitted); *Price Co.*, 2016 WL 5939467, at *3 ("Key factors include whether … the proposed constituency financed the association's activities …."); *Leavitt*, 477 F. Supp. 2d at 209 (denying associational standing where plaintiff "has not indicated that [its purported members] financially support [it]").

Plaintiff merely repeats its allegation that it "represents" patients, taxpayers, and consumers. *See* Complaint ¶¶ 5, 14, 24, 69. This falls well short of what the courts have held to be a sufficient pleading of the indicia-of-membership test. Because the Complaint lacks facts tending to show that the patients, taxpayers, and consumers Plaintiff purports to "represent" control KEI's functions, elect or serve on KEI's leadership, and finance KEI's activities, Plaintiff lacks associational standing.

V. CONCLUSION

KEI is a public-interest organization that apparently often opines on the costs of new medical technologies. That Defendant challenges its Article III standing to bring this suit "is not to say that Plaintiffs are insufficiently interested in the subject or even unqualified to debate these issues." *Philip Morris, Inc.*, 86 F. Supp. 2d at 918. But 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 [confer standing]." *Id.* (quoting *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972)). As explained above, because Plaintiff lacks both organizational and associational standing, the Court should dismiss the Complaint for lack of subject-matter jurisdiction, under Rule 12(b)(1).

Respectfully submitted,

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