

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND**

**KNOWLEDGE ECOLOGY
INTERNATIONAL,**

Plaintiff,

v.

**NATIONAL INSTITUTES of
HEALTH, et al.,**

Defendants.

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Civil No. **PJM 18-1130**

MEMORANDUM OPINION

Knowledge Ecology International (KEI), a nonprofit organization that advocates for greater public access to affordable medicine and related intellectual property concerns, has sued the National Institutes of Health (NIH), the National Cancer Institute (NCI), and senior officials of both organizations, alleging violations of the Federal Property and Administrative Services Act, 40 U.S.C. §§ 101 *et seq.*, and the Administrative Procedure Act, 5 U.S.C. §§ 701-706. KEI takes issue with NIH’s decision to grant a particular exclusive license to a private pharmaceutical company, despite objections that KEI filed after the notice of the proposed license was published in the Federal Register. KEI also appeals NIH’s refusal to allow it to administratively appeal the decision.

Defendants have filed a Motion to Dismiss, (ECF No. 5), arguing that KEI lacks standing to pursue its claims. The Court heard oral arguments on the Motion on October 15, 2018. The parties thereafter filed supplemental briefing on the propriety of NIH’s denying KEI the right to appeal. The Court has considered the initial briefs of the parties, their oral argument, and their

supplemental briefs. For the reasons that follow, Defendants' Motion to Dismiss (ECF No. 5) is **GRANTED.**

I. FACTUAL AND PROCEDURAL BACKGROUND

KEI, an organization based in Washington, D.C., conducts research, writes, and advocates on behalf of patients, taxpayers, and consumers. Its work focuses principally on assessing and, where it deems appropriate, opposing proposed exclusive licenses of federally-invented medical technologies to private organizations. KEI representatives frequently testify before governmental bodies with respect to these issues as well as drug pricing issues, especially where questions of intellectual property and public health intersect. KEI has been recognized by the MacArthur Foundation for its work, having won the MacArthur Award for Creative and Effective Institutions in 2006, and has been accredited as a non-state actor of the World Health Organization. It has a Board of Directors, a Board of Advisers, and a staff that it claims are directly affected by drug-pricing issues generally and, specifically, by the high price of cancer drugs. KEI maintains multiple email lists through which it communicates with patients, taxpayers, consumers, academics, and other interested persons. It lacks, however, a formal membership structure.

In the present case, KEI challenges the propriety of an exclusive license of a federally-owned and federally-funded cancer treatment technology that NIH, through NCI, proposes to grant to Kite Pharma, Inc., a wholly-owned subsidiary of Gilead Sciences, Inc., a multi-billion dollar company. The treatment to which the license in question extends is a type of immunotherapy related to chimeric antigen receptor therapies, or CAR T treatments.¹ CAR T treatments are considered among the newest and most promising therapies for cancer. There are currently two

¹ Chimeric Antigen Receptor Therapies (hereinafter CAR T treatments) refer to treatments in which immune system cells from a patient's body are changed in a laboratory so they will attack cancer cells. Compl. ¶ 37.

CAR T cancer treatments on the market. Both treatments allegedly cost consumers hundreds of thousands of dollars for just one round of therapy, while the costs to the manufacturers are allegedly as low as \$15,000 per treatment. KEI points out that exorbitant prices for such treatments as these stem, at least in part, from rights granted to patent holders, who are then able to exclude competition via patents and related exclusive rights. KEI argues that high drug prices tend to decrease when patent terms expire and the field is open to competition. High prices of treatments create severe hardships for patients who benefit or would like to benefit from such therapies.

KEI alleges that NIH took a final action reviewable under the Administrative Procedure Act when it proceeded to grant the exclusive license to Kite Pharma without complying with 40 U.S.C. § 559, which requires the agency to seek and obtain the advice of the Attorney General, before “dispos[ing] of property to a private interest,” as to whether that disposal “would tend to create or maintain a situation inconsistent with antitrust law.” 40 U.S.C. § 559(b)(1). KEI also objects to NIH’s decision to deny it the right to administratively appeal NIH’s rejection of its comments with respect to the license.

These are the facts:

On December 20, 2017, NIH posted a notice in the Federal Register pertaining to its proposed granting of a worldwide exclusive license to Kite Pharma of patents for a CAR T technology for cancer treatment. Compl. ¶ 47. The notice included details about the specific patents and relevant cancers, *see id.* ¶¶ 48-49, and opened a period for public comment, which encompassed the Christmas holidays and the New Year, to close on January 4, 2018.² *Id.* at ¶ 50. On January 4, 2018, KEI submitted written comments objecting to the exclusivity of the license

² It is hard to overlook the severely restricted time frame allowed for comments to be filed. The Court does not intend to approve that sort of crunch time, which may be relevant in future proceedings of this sort, but the issue is moot in this case.

and requesting the inclusion of what it deemed to be public interest safeguards in any license that might be issued. Given what it termed the early stage of clinical trials and relevant patent proceedings, KEI advised that the proposed exclusive license was premature, indicating that it would therefore be unwise for NIH to create a monopoly on this government-funded and invented technology. Finally, KEI recommended the inclusion of certain contractual protections in any license that it believed would protect U.S. residents against excessive prices and barriers to access. *Id.* at ¶¶ 51-53.

On January 25, 2018, Defendant Dr. David Lambertson sent an email to KEI, acknowledging receipt of its comments, but rejecting KEI's substantive objections and suggestions, indicating that "NCI intends to proceed with the negotiation of the proposed exclusive license." Compl. ¶ 54.

On February 13, 2018, KEI sent an email to both Dr. Lambertson and NIH, inquiring whether NIH, under 40 U.S.C. § 559, had requested and obtained advice from the Attorney General in regard to NIH's compliance with antitrust laws prior to transferring a patent and related rights to a private interest. *Id.* ¶ 55. On February 15, NIH replied to KEI, saying, "[t]he statute you reference is directed to the disposal (assignment) of government property. It has little relevance to our patent licensing activities, which are principally governed by the Bayh-Dole Act and its regulations." ECF No. 5-2 at 27. KEI contends that this reply constituted an admission that Defendants have violated 40 U.S.C. § 559 and the black letter obligations of the FPASA—specifically, that Defendants did not seek or obtain the antitrust advice of the Attorney General regarding the disposal of government property, i.e., the license of the CAR T technology to a private party (Kite). *Id.* ¶¶ 64-65.

On February 14, 2018, KEI sent an email to Dr. Lambertson and co-Defendant Dr. Francis Collins, Director of NIH, notifying them of KEI's intent to file an administrative appeal of the decision and requesting that NIH provide guidance with respect to its appeal procedures, which were not available on the NIH website, KEI noting in its email that the link to what appeared to be NIH's appeal procedures was "broken." Compl. ¶ 56. But on February 26, Dr. Lambertson, prior to receiving or viewing the KEI inquiry regarding an appeal, responded to KEI's February 14 email. In his response, Dr. Lambertson made no mention of KEI's request for information as to NIH's appeal procedures, stating simply that NIH had "determined that there is no likelihood that KEI will be damaged by the agency action. Accordingly, we will not entertain an appeal of our decision." *Id.* ¶ 58.

There appears to be no express basis for KEI to further pursue the matter administratively, and no other possible remedy other than the present filing in this Court. Compl. ¶ 59.

Nevertheless, the position of the NIH Defendants is that KEI lacks standing to bring this suit; hence, their Motion to Dismiss.

II. LEGAL STANDARD

A party may move for dismissal of a lawsuit against it pursuant to Federal Rule of Civil Procedure 12(b)(1) where the Court lacks subject matter jurisdiction over the claims alleged in the complaint. Fed. R. Civ. P. 12(b)(1). "Article III gives federal courts jurisdiction only over 'cases and controversies,' U.S. Const. art. III, § 2, cl. 1, and the doctrine of standing identifies disputes appropriate for judicial resolution." *Miller v. Brown*, 462 F.3d 312, 316 (4th Cir. 2006) (citing *Valley Forge Christian Coll. v. Ams. United for Separation of Church and State, Inc.*, 454 U.S. 464, 471–76 (1982)). The plaintiff, as the party asserting jurisdiction, bears the burden of

proving that the district court has subject matter jurisdiction. *See Richmond, Fredericksburg & Potomac R.R. Co. v. United States*, 945 F.2d 765, 768 (4th Cir. 1991).

Accordingly, to establish “the irreducible constitutional minimum of standing” at the pleading stage, KEI must “clearly . . . allege facts demonstrating” that it “(1) [has] suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). An “injury-in-fact” is “‘an invasion of a legally protected interest’ that is ‘concrete and particularized’ and ‘actual or imminent, not conjectural or hypothetical.’” *Id.* at 1548 (quoting *Lujan*, 504 U.S. at 560). The injury must be “legally and judicially cognizable,” and the dispute must be one that “is traditionally thought to be capable of resolution through the judicial process.” *Raines v. Byrd*, 521 U.S. 811, 819 (1997) (quoting *Flast v. Cohen*, 392 U.S. 83, 97 (1968)).

When the alleged injury is the failure of an administrative agency to honor a party’s right to appear before that agency, the party is still obliged to establish standing to sue to redress that injury in an Article III court. “*Lujan* [*v. Defenders of Wildlife*, 504 U.S. 555 (1992)] and the cases that have followed it reason that the right to participate in the proceedings of an agency does not give one the right to seek redress for the deprivation of that right in federal court...” *Bensman v. U.S. Forest Service*, 408 F.3d 945, 953 (7th Cir. 2005). In light of *Lujan*, “Plaintiffs must show a separate concrete interest in order to assert a procedural injury...” *Sierra Club v. U.S. Def. Energy Support Ctr.*, No. 1:11-cv-00041, 2011 WL 3321296, at *4 (E.D. Va. July 29, 2011). Indeed, “an allegation of procedural injury may suffice for purposes of standing,” *id.*, “so long as” the “government’s failure to follow statutorily prescribed procedures... impairs a separate concrete interest of the plaintiff.” *Pye v. United States*, 269 F.3d 459, 467 (4th Cir. 2001).

An organization, as opposed to an individual, can establish standing under two theories: either (a) organizational standing, which is to say standing in its own right, or (b) associational standing based on the fact that at least some of the individual 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).

In determining whether a party has organizational standing, the court “conduct[s] the same inquiry as in the case of an individual.” *Havens Realty Corp. v. Coleman*, 445 U.S. 363, 378 (1982). Thus, organizational standing confers standing on an organization that can establish the traditional elements of Article III standing that any individual would need to meet: injury-in-fact, causation, and redressability. Generally, the injury to the organization must be something more than an affront to the organization’s mission; “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-cd-00607, 1993 WL 561879, at *3 (M.D.N.C. Nov. 19, 1993). “[A]n injury to organizational purpose, without more, does not provide a basis for standing.” *S. Walk at Broadlands Homeowner’s Ass’n, Inc. v. OpenBand at Broadlands, LLC*, 713 F.3d 175, 183 (4th Cir. 2013).

It is true that the diversion of resources away from an organization’s primary mission in order to address an allegedly improper action may suffice to establish standing if pled with enough specificity. And while significant and very specific time and money diversion can meet this standard, less specific claims may also suffice so long as they establish generally what the organization had to forego. *See, e.g., North Carolina State Conference of NAACP v. North Carolina State Board of Elections*, 283 F. Supp. 3d 393, 402 (M.D.N.C. 2017) (Plaintiff organization had standing where it alleged it “ha[d] been forced to divert its valuable and limited

resources away from its core mission and planned voter-mobilization, voter-protection, and voter-education activities... in order to investigate, respond to, mitigate, and address the concerns of its members resulting from defendants' unlawful en masse voter challenge and purging practices"). In that sense, an organization can have standing when an injury to its ability to advance its institutional purposes is paired with a consequent drain on organizational resources. *See S. Walk at Broadlands*, 713 F.3d at 183. "An 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).

Associational standing, on the other hand, is generally conferred upon organizational plaintiffs that sue "on behalf of [their] members when [their] members would otherwise have standing to sue in their own right." *Sierra Club v. United States Department of the Interior*, 899 F.3d 260, 283 (4th Cir. 2018). Although this generally assumes a membership-based organizational model, "an organization with no formal members can still have associational standing if it is the functional equivalent of a traditional membership organization." *Heap v. Carter*, 112 F.Supp.3d 402, 418 (E.D. Va. 2015).

III. DISCUSSION

A. *Violation of administrative procedural rules alone does not necessarily confer standing*

37 C.F.R. § 404.11, which governs appeals of decisions pertaining to the granting of federal licenses, provides that a person "who timely filed a written objection in response to the notice... and who can demonstrate to the satisfaction of the Federal agency that such a person may be damaged by the agency action" may appeal the licensing decision. NIH's appeal procedures, ultimately communicated to KEI during the pendency of this case, provide for a two-level appeal process—First, a review committee evaluates any request for reconsideration, then makes

recommendations to an NIH mid-level director, who rules on the committee recommendations and sends a final decision to the requesting party. The second level is an appeal from the mid-level director's decision to the Director of the NIH. Rohrbaugh Decl., Ex. 1 at 1. In any event, “[a]ppellants shall not be entitled to an adversary hearing” on appeal. *Id.*

Before all else, the meaning of “adversary hearing” needs analysis to the extent that it illuminates what the appeal process looks like. Does it mean that no new evidence or argument can be raised on appeal? Or does it mean that only written submissions will be entertained on appeal, without oral argument? The Court will assume that the latter interpretation of the language obtains—written submissions will be accepted, but no oral argument will be allowed. But getting to the crux of the case: who is an appropriate appellate? The party seeking to appeal must demonstrate “damage,” and that is what Defendants say KEI has not done.

KEI admits that 37 C.F.R. § 404.11 establishes some level of discretion on the part of NIH in determining whether a party has shown to the agency's satisfaction that it will be damaged by the agency action, and is therefore entitled to an appeal. ECF No. 16 at 18. But KEI argues that a decision such as was made here to preclude it from filing an appeal “without any explanation of which criteria was used to determine that KEI will not be ‘damaged by the agency action’ is a violation of procedural rules pursuant to 37 C.F.R. § 404.11.” *Id.* KEI also argues that NIH failed to follow its own two-tier procedure by refusing to consider its appeal even before it had in hand the substance of KEI's appeal. That said, even if NIH violated its own review procedures, and even if KEI suffered procedural injury in consequence, KEI still has the burden of sufficiently pleading an injury that would confirm its standing to sue in this Court.

As a further threshold observation, it is by no means clear that NIH has in fact failed to follow its own review procedures, since it determined, presumably by review committee, that KEI

was not entitled to appeal as a party that would be sufficiently damaged by the agency action. So on February 26, 2018, when NIH replied to KEI's inquiry about appeal procedures that it would not entertain KEI's appeal, the first level of appeal—consideration of whether KEI would be damaged—had already been satisfied. As such, it would not necessarily matter if NIH had not read the substance of KEI's appeal, because the pre-requisite of damage had not been established. In any case, NIH was presumably well aware of KEI's substantive position based on its initial objections in the case. *See also* ECF No. 19-1 at 2 (stating that of the fifty-one notices about proposed exclusive or partially exclusive licenses NIH has published since 2016, KEI has commented on at least thirty-four of them). Importantly, as indicated previously, NIH's appeal procedures do not entitle appellants to a hearing on their appeal(s).

Furthermore, standing to appear before an administrative agency is different from standing to appear before an Article III court. Here, KEI does not claim any concrete injury suffered *as a result of* the alleged procedural injury other than what appear to be its disappointment and displeasure with NIH's ultimate decision on the proposed license. Its procedural injury at the administrative level does not, in the Court's view, by itself suffice to confer standing here, but rather collapses into a standing inquiry as to KEI's status *qua* organization or association. The Court therefore returns to the questions of whether KEI can establish either traditional organizational or associational standing.

B. KEI does not have organizational standing

KEI argues that it has expended resources on this suit, which it submits gives it organizational standing. But the only specific allegation it makes as to resource expenditures is the roughly 100 hours that KEI's in-house counsel has spent on this case. ECF No. 9 at 15-16. Time spent on this suit, however, is the very type of manufactured injury that is not recognized for

standing purposes. KEI has not alleged the diversion of any other resources with any specificity, nor has it alleged that the proposed license has made its advocacy role more difficult. Indeed, KEI's core purpose as an organization is pursuing precisely the type of advocacy it undertook here—advocating against an exclusive private license that will raise the price of cancer drugs. The Court notes again that KEI has apparently submitted comments on more than 60% of the notices NIH has published in the past two years concerning proposed partially exclusive or exclusive licenses. ECF No. 19-1 at 2. Any resources KEI spent on this specific case and the underlying events, therefore, seem very much in line with KEI's core mission rather than a diversion of resources away from it.

C. KEI does not have associational standing

Defendants argue that KEI lacks associational standing because it does not have members who independently have individual standing. In fact, say Defendants, KEI does not even have members in any traditional sense, e.g., regular dues-paying individuals. In response, KEI urges that any sort of requirement that it have traditional members is not dispositive. KEI points out that an organization that serves a specialized segment of the community may show that that constituency is the functional equivalent of a membership entity, among other indicia. *Heap*, 112 F.Supp.3d at 418; *see also Hunt v. Washington State Apple Advertising Comm'n*, 432 U.S. 333, 344-45 (1977). However, assuming the functional equivalency test applies, KEI provides no information about what specific segment of the community of interests it represents; indeed, it purports to bring this case on behalf of “adversely affected patients and taxpayers,” a group which could arguably include an unlimited number of persons throughout the country. Compl. ¶ 5. But constituents of this expansive category are not “members” of KEI in either a traditional or functionally equivalent way.

A more charitable construction of KEI's argument may be that its Boards of Directors and Advisors, many of whom are personally affected by high prices of cancer treatments, could serve as KEI's constituency. But, again, regardless of whether the functional equivalency test applies in this case, the outcome of such an analysis would still matter only if there is someone who has suffered injury-in-fact upon whose behalf KEI can sue, someone who himself or herself would have Article III standing. The only specific injury-in-fact alleged, however, is to one of KEI's Board of Directors, James Love, Director of KEI, who refers to a family member who has been diagnosed with a cancer and who may possibly benefit from the therapy covered by the license in this case. And Love himself is cited as being affected by the high price of cancer drugs and treatments in general. Respectfully, these invocations stretch the concept too far. These purported injuries-in-fact, the Court believes, are too speculative and too removed from the association itself to confer standing. The Court, therefore, finds it unnecessary to determine whether the four-part test of functional equivalency employed by the U.S. District Court for the Eastern District of Virginia in *Heap* would be adopted in Maryland. The Court finds that KEI does not satisfy the requirements of associational standing regardless.

IV. CONCLUSION

KEI is an admirable organization that undoubtedly possesses expertise in the issues going to the merits of this case. But given its structure and mission, KEI does not have either the organizational or associational standing necessary to bring suit in this Court. Accordingly, the Court **GRANTS** Defendants' Motion to Dismiss (ECF No. 5).

A separate Order will **ISSUE**.

/s/

PETER J. MESSITTE
UNITED STATES DISTRICT JUDGE

April 11, 2019