UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Richmond Division

PATIENT SERVICES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Civil Action No. 3:18-cv-0016 (MHL)**
	)	
UNITED STATES OF AMERICA, *et al.*,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION FOR LEAVE TO TAKE DISCOVERY

Plaintiff Patient Services, Inc. ("PSI") asserts that certain provisions of an advisory opinion issued by the Department of Health and Human Services' ("HHS") Office of Inspector General ("OIG") violate its "constitutionally protected right to communicate with pharmaceutical manufacturer donors." Compl. for Declaratory J. & Injunctive Relief ("Compl.") ¶ 3, ECF No. 1. In particular, PSI contends that three provisions of the advisory opinion – which reflect factual certifications to which PSI, acting through counsel, voluntarily agreed to conform its conduct – restrict its ability to engage in lawful, truthful and non-misleading speech that is protected under the First Amendment. In order to analyze PSI's First Amendment claims, the Court will need to consider whether PSI knowingly and voluntarily waived its right to engage in the speech that it alleges is protected by the First Amendment, and whether the interests promoted by enforcement of the speech-related provisions of OIG's advisory opinion outweigh any public policy harms that would result from enforcement. Because the administrative record underlying OIG's decision-making in this case is insufficient to allow the Court to answer these questions, which relate not to OIG's actions but to PSI's decision-making and the harms it has suffered as a result of the advisory

opinion, a brief period of discovery is necessary to enable the Court to resolve this case and ensure that it has jurisdiction, as set forth below.

BACKGROUND

I. The OIG Advisory Opinion Process

OIG is an independent and objective oversight unit created to carry out the mission of preventing fraud and abuse and promoting economy, efficiency, and effectiveness of HHS programs and operations. *See* 5 U.S.C. App. 3 § 2 (Inspector General Act of 1978). One of its functions is to issue, in consultation with the Department of Justice ("DOJ"), written advisory opinions regarding the interpretation and application of certain statutory provisions designed to deter fraud and abuse in the referral of federal healthcare program beneficiaries (such as Medicare and Medicaid recipients) to particular medical goods and services. *See* 42 U.S.C. § 1320a-7d(b).

Congress provided for the advisory opinion process because the Social Security Act's penalty provisions are, on their face, "quite broad," creating a risk of imposing liability for "relatively innocuous commercial arrangements." Interim Final Rule, HHS, OIG, *Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG*, 62 Fed. Reg. 7350 (Feb. 19, 1997). Two provisions of the Social Security Act are of particular relevance here. First, the "Anti-Kickback Statute" ("AKS") makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward the referral or generation of business reimbursable by any Federal health care program, including Medicare and Medicaid. 42 U.S.C. § 1320a-7b. Second, the Social Security Act provides for the imposition of civil monetary penalties against any person that "offers to or transfers remuneration" to a Medicare beneficiary that the benefactor "knows or should know is likely to influence [the beneficiary] to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [, *e.g.*, Medicare]."

Id. § 1320a-7a(a)(5) (known as the "beneficiary inducements civil monetary penalty (CMP)"). These provisions are designed to prevent, with respect to individuals who receive federal healthcare program benefits, the distortion of the healthcare system that occurs when federally reimbursed patients are directed to providers for reasons other than legitimate reasons such as quality or cost.

Accordingly, Congress authorized the creation of "safe harbors," *see* 42 U.S.C. § 1320a-7d(a); 42 C.F.R. § 1001.952 – which prospectively sanction certain "generalized, hypothetical arrangements," *see* 62 Fed. Reg. at 7351 – as well as the advisory opinion process. In contrast to the safe harbors, an advisory opinion provides a means of "relating the anti-kickback statute to the particular facts of a specific arrangement," giving prospective cover where the arrangement "contains limitations, requirements or controls that give adequate assurance that Federal health care programs [cannot] be abused." *Id*. These advisory opinions address such topics as what constitutes prohibited "remuneration" under the AKS and civil monetary penalty provisions discussed above, and whether an existing or proposed business arrangement or activity constitutes grounds for administrative sanctions or civil penalties under those provisions, 42 U.S.C. § 1320a-7d(b)(2).

OIG has promulgated regulations at 42 C.F.R. Part 1008 to govern the advisory opinion process. These regulations allow "[a]ny individual or entity" to submit to the OIG a request for an advisory opinion regarding the application of specific facts, relating to an existing or proposed arrangement, to certain specified topics, including, as noted above, whether any activity or proposed activity constitutes grounds for sanctions under the AKS or other fraud and abuse civil sanction provisions. 42 C.F.R. §§ 1008.5, 1008.11, 1008.15. A request must include a "complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested," including a signed certification, under penalty of perjury,

that the information provided is correct. *Id*. §§ 1008.36; 1008.38. Upon receipt of a request, OIG has broad discretion to request "whatever additional information or documents it deems necessary;" to conduct, along with DOJ, "whatever independent investigation" it believes appropriate; and, where appropriate, to "consult with the requesting party to the extent the OIG deems necessary." *Id*. § 1008.39. OIG's written advisory opinions set forth "the OIG's opinion regarding the subject matter of the request based on the facts provided to the OIG." *Id*. § 1008.43.

II. Patient Assistance Programs

As alleged in the Complaint, PSI is a charitable organization that offers "patient assistance programs" ("PAPs"), which provide financial assistance, primarily in the form of insurance premium and copayment assistance, to indigent patients. Compl. ¶ 13; *see* Notice, HHS, OIG, *Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70,623 (Nov. 22, 2005) ("2005 PAP Bulletin"). In part because many PAPs have been supported by donations from (and even sponsored by) pharmaceutical manufacturers, *id*., arrangements between PAPs and their donors to provide payment assistance to Medicare enrollees present a heightened risk of "fraud, waste, and abuse with respect to Medicare and other Federal health care programs." Notice, HHS, OIG, *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31,120 (May 30, 2014) ("2014 PAP Bulletin"). Critically, as it relates to oversight of PAPs, the AKS prohibits a pharmaceutical manufacturer from directly subsidizing a Medicare beneficiary's purchase of the manufacturer's medications or services. Accordingly, in its guidance to the industry, OIG has emphasized that PAPs, even those like PSI that are not directly sponsored by a pharmaceutical manufacturer, "must not function as a conduit for payments by the pharmaceutical manufacturer to patients" or "impermissibly influence beneficiaries' drug choices." 2005 PAP Bulletin, 70 Fed. Reg. at 70,627.

OIG's 2014 PAP Bulletin, which was issued following years of experience with the manner

in which PAPs operated to provide cost-sharing assistance for prescription drugs to federal beneficiaries, highlighted two particular "remunerative aspects" of PAP arrangements deserving scrutiny under the AKS. 2014 PAP Bulletin, 79 Fed. Reg. at 31,121. The first is a donor's contribution to a PAP – if the donation is made "to induce the PAP to recommend or arrange for the purchase of the donor's federally reimbursable items, the statute could be violated." *Id*. And the second is a PAP's financial assistance award to a federal beneficiary – if done to "influence the patient to purchase (or to induce the patient's physician to prescribe) certain items, the statute could be violated." *Id*. In addition, PAP arrangements risk violation of the beneficiary inducements CMP where they allow for a pharmaceutical manufacturer to provide, through a PAP, subsidies "likely to influence a Medicare or State health care program beneficiary's selection of a particular provider, practitioner, or supplier, such as by making eligibility dependent on the patient's use of certain prescribing physicians or certain pharmacies to dispense the drugs." *Id*. Based on these risks, OIG issued its "amplifie[d]" industry-wide guidance in 2014 to promote the independence of charitable PAPs from their donors, recognizing that some existing favorable advisory opinions would need to be modified to ensure consistency with the guidance. *Id*. at 31,123.

III. PSI's Modified Advisory Opinion And This Lawsuit

OIG originally issued PSI an advisory opinion on April 4, 2002, covering PSI's proposed arrangement to subsidize the medical care costs of "financially needy Medicare beneficiaries." *See* Compl. ¶¶ 75-77 and Ex. A at 1. Following publication of the 2014 PAP Bulletin, however, OIG informed PSI (as it did other PAPs with advisory opinions that were inconsistent with the 2014 PAP Bulletin) that, in light of the concerns reflected in that guidance document, OIG would require certain changes for PSI to retain its favorable advisory opinion. Index to Administrative

Record ("AR") (listing pp. 92-96) (attached as Exhibit 1).[1] This set off a lengthy negotiation process between OIG and PSI, which lasted for more than two years, over the facts that PSI would need to certify as true in order to retain its favorable advisory opinion. *See* Index to AR (listing pp. 92-653). PSI was represented by sophisticated counsel throughout these negotiations. *See id*. (including email correspondence between OIG and PSI's attorneys). Finally, on February 1, 2017, PSI's counsel sent OIG an executed list of the certifications with which PSI would agree to conform its conduct in accordance with the modification of its 2002 Advisory Opinion. Index to AR (listing pp. 645-53). These certifications were reflected in the modified advisory opinion OIG issued PSI on March 3, 2017 (the "Modified Advisory Opinion"). *See* Ex. B. to Compl. Based on PSI's certification of various facts designed to respond to OIG's concerns identified in the 2014 PAP Bulletin, as well as to ensure compliance with OIG's "long-standing guidance respecting independence from donors," OIG issued the Modified Advisory Opinion binding itself not to seek – on the basis of the facts certified – civil penalties or administrative sanctions under the AKS or beneficiary inducements CMP. *Id*.

On January 8, 2018, PSI filed the instant lawsuit, alleging that three of the provisions of the Modified Advisory Opinion, each reflecting certifications that PSI affirmatively made to OIG, violate PSI's right to free speech under the First Amendment. Specifically, PSI challenges: (1) its certification not to "solicit suggestions from donors regarding the identification or delineation of disease funds" (the "Solicitation Provision"), Compl. ¶ 89, (2) its certification that no "donor or affiliate of any donor" "directly or indirectly influences or will influence the identification or

[1] Defendants have cited to and attached the Index to the Administrative Record for certain propositions, rather than attaching the pages from the Record themselves, because they may contain PSI's confidential business information. Defendants can, of course, file the referenced pages or the full Administrative Record (if necessary, under seal) at the Court's request.

delineation of any of [PSI's] disease funds" (the "Influence Provision"), *id*. ¶ 90, and (3) its certification not to "establish or modify funds for specific diseases at the request or suggestion of donors or prospective donors (or affiliates of donors or prospective donors) that manufacture drugs or devices for the treatment of such diseases or that otherwise have a financial interest in the establishment [or] modification of such funds" (the "Modification Provision"). *Id*. ¶ 91. PSI alleges that the certifications encompassed in the Modified Advisory Opinion restrict "lawful, truthful and non-misleading speech" between PSI and its donors and prospective donors, *id*. ¶¶ 106-07, and it identifies a dozen categories of allegedly restricted speech, *id*. ¶ 129. According to PSI, these "restrictions" "cut off" its "best source of information regarding diseases and their treatment," "crippl[ing]" its efforts to "establish new disease funds" that will "receive enough donations to help any patients." *Id*. ¶ 119. PSI asserts that that it has already "experienced material reductions in donor support" as a result of the Modified Advisory Opinion, and "estimates a 17% reduction in donations for its patient funds in 2018." *Id*. ¶ 118.

ARGUMENT

I. Discovery Is Needed For The Court To Have An Adequate Record On Which To Decide This Case.

It is true that courts often decide APA claims solely on the basis of the administrative record. But "often" is not always. There are exceptions – and for good reason: In some cases, the administrative record simply does not provide the Court with all of the information it needs to answer the questions presented. This is one of those cases. PSI's complaint requires the Court to decide whether PSI knowingly and voluntarily waived its First Amendment rights, and whether the interests promoted by enforcement of the speech-related provisions of the Modified Advisory Opinion outweigh any public policy harms resulting from their enforcement. The administrative record alone does not answer these questions. Nor would it be expected to. It is a record of

OIG's decision-making process, not PSI's. And any alleged harms resulting from enforcement would necessarily post-date the issuance of the Modified Advisory Opinion. *See, e.g., Stand Up for California! v. U.S. Dep't of Interior*, 71 F. Supp. 3d 109, 117 (D.D.C. 2014) (noting that the "administrative record includes all materials that were 'before the agency at the time the decision was made'" (citation omitted)). Thus, as the administrative record lacks the necessary information, a short period of limited discovery is appropriate.

When a plaintiff brings claims under the APA, as PSI has, Compl. ¶¶ 126, 138, judicial review is generally limited to the administrative record, *Fort Sumter Tours, Inc. v. Babbitt*, 66 F.3d 1324, 1335 (4th Cir. 1995), which is a record of the agency's decision-making process, *see Occidental Petroleum Corp. v. S.E.C.*, 873 F.2d 325, 344 (D.C. Cir. 1989). But there are exceptions to the administrative-record exclusivity norm, *i.e.*, instances when courts permit discovery. *Fort Sumter Tours*, 66 F.3d at 1336. Varying formulations of these exceptions exist. *Compare Pub. Power Council v. Johnson*, 674 F.2d 791, 794 (9th Cir. 1982) (cited in *Fort Sumter Tours*) *with IMS, P.C. v. Alvarez*, 129 F.3d 618, 624 (D.C. Cir. 1997). "Underlying all of these exceptions[,]" however, "is the assessment that resort to extra-record information is necessary to enable judicial review to become effective." *Nat'l Mining Ass'n v. Jackson*, 856 F. Supp. 2d 150, 157 (D.D.C. 2012) (quotations and brackets omitted). In other words, "[c]onsideration of extra-record information is appropriate when simply reviewing the administrative record is not enough to resolve the case." *Pacific Shores Subdivision Cal. Water. Dist. v. U.S. Army Corps of Engineers*, 448 F. Supp. 2d 1, 6 (D.D.C. 2006).

The animating principle underlying these exceptions applies in this case, because "the administrative record is so deficient as to preclude effective review." *Hill Dermaceuticals v. FDA*, 709 F.3d 44, 47 (D.C. Cir. 2013). It is not deficient because of any failure by OIG to compile a proper record. Rather, as noted above and demonstrated below, it is deficient because

of the nature of the questions presented by PSI's complaint – questions about (1) PSI's decision-making (rather than OIG's), and (2) matters occurring after the issuance of the Modified Advisory Opinion. Defendants now turn to these questions.

II. The Current Record Is Insufficient To Resolve PSI's Claims Under The Governing First Amendment Standard.

Recall, PSI contends that the Modified Advisory Opinion, through the Solicitation, Influence, and Modification Provisions, Compl. ¶¶ 89-91, "restricts lawful, truthful and non-misleading communications between PSI and its donors, prospective donors and their affiliates" regarding a dozen categories of speech, *id.* ¶¶ 129. In other words, PSI alleges that the Modified Advisory Opinion violates the First Amendment. First Amendment case law, of course, does not lack for standards of review. So, the question becomes: What standard applies?

The Court should apply the standard articulated by the Fourth Circuit in *Lake James Cmty. Volunteer Fire Dep't, Inc. v. Burke Cty., N.C.*, 149 F.3d 277, 280 (4th Cir. 1998) because this case, like *Lake James*, involves a negotiated waiver of First Amendment rights. In *Lake James*, the Fourth Circuit held that a fire department's "agreement to consent to citizens' petitions and not to challenge them in court [wa]s [an] enforceable" waiver of its First Amendment rights. *Id.* Notably, the court applied this standard notwithstanding the fire department's argument that it had been put to the choice between agreeing to a contract that included what it perceived to be unconstitutional provisions and going without the contract and the benefits it provided. *See id*. at 281 (finding that choosing between executing a contract and going without one might be a "difficult choice," but that making a difficult choice "does not render the execution of the contract involuntary"). Because the case ultimately involved a negotiated waiver of constitutional rights, the court applied the test, described below, to determine the enforceability of that waiver.

Just so here. PSI agreed to the three provisions about which it now complains, *i.e.*, to the

extent these provisions affect PSI's rights, it is because PSI waived those rights. PSI, through a document signed by its then-CEO Dana Kuhn, made certain certifications in connection with the modification to its advisory opinion. *See* Index to AR (listing pp. 651, 653). PSI certified the following, as reflected in its Modified Advisory Opinion: (1) that it "does not, and will not, solicit suggestions from donors regarding the identification or delineation of disease funds"; (2) "[n]o donor or affiliate of any donor . . . directly or indirectly influences or will influence the identification or delineation of any of [PSI's] disease funds"; and (3) PSI "will not establish or modify funds for specific diseases at the request or suggestion of donors or prospective donors (or affiliates of donors or prospective donors) that . . . have a financial interest in the establishment or modification of such funds." Ex. B. to Compl. at 5-6. Moreover, these waivers were negotiated. *See* Index to AR (listing pp. 92-653). Indeed, the negotiations were conducted by the Agency and counsel for PSI, and they stretched for more than two-and-a-half years, from May 2014 through January 2017.[2] *See id*.

Under *Lake James*, a negotiated waiver of First Amendment rights is valid if it (1) is a "knowing waiver," that is (2) "voluntarily given," (3) and which does "not undermine the relevant public interest." 149 F.3d at 280. Discovery is needed to supply the Court with facts relevant to the *Lake James* criteria. Judicially noticeable facts and facts included in the administrative record – namely, the size and sophistication of PSI, *see* PSI 2017 Annual Report, at 17, https://www.patientservicesinc.org/wp-content/uploads/2018/07/PSI-Annual-

[2] The Modified Advisory Opinion is not technically a contract, but the record confirms that, in this case, it was the product of a negotiation between the parties, and the *Lake James* decision, while drawing on "common-law contract principle[s]," did not suggest that its analysis would apply only in the context of a traditional contractual agreement. *See* 149 F.3d at 280. Indeed, it cited a broad range of "voluntary agreements with the government," and the overarching principle – that a negotiated waiver of constitutional rights should be enforced so long as it is knowing and voluntary and its enforcement would not undermine the public interest – is directly applicable in this case.

Report_2017_Final-070518.pdf (stating that PSI distributes over $100 million), the fact that it was assisted by counsel, and the fact that negotiations stretched on for years – indicate that any waiver of First Amendment rights was both knowing and voluntary. But discovery would help confirm these facts. *See, e.g.*, *United States v. Easterling*, 602 Fed. App'x 919, 920 (4th Cir. 2016) (noting that knowing and intelligent waiver of a criminal defendant's appellate rights looks to the "totality of the circumstances"); *United States v. Frostman*, 221 F. Supp. 3d 718, 728 (E.D. Va. 2016) (waiver of constitutional rights must be made "with sufficient awareness of the relevant circumstances and likely consequences").

The third element of the *Lakes James* test requires the Court to assess whether upholding the waiver would "undermine the relevant public interest." *Lake James*, 149 F.3d at 280. This requires the Court to determine if the "interest promoted by its enforcement is outweighed by the public policy harms resulting from enforcement." *Id.; see also Overbey v. Mayor & City Council of Baltimore*, Civil Action No. MJG-17-1793, 2017 WL 5885657, at *6 (D. Md. Nov. 29, 2017) ("Regarding public interest, the 'contract will be enforced unless the interest promoted by its enforcement is outweighed by the public policy harms resulting from enforcement.'") (parenthetical quoting *Lake James*). The interest promoted by enforcement of the challenged provisions is set out in regulations and the administrative record: It is an interest in eliminating fraud and abuse in a field – the operation of PAPs, like PSI – that is rife with opportunity for misconduct. As discussed above, arrangements between PAPs and their pharmaceutical manufacturer donors to provide payment assistance to Medicare recipients present unique risks of fraud and abuse, *supra* pp. 4-5, including that the PAP will work with its donors to channel patients to the donor's products and services in lieu of cheaper options at the government's expense (and in violation of the AKS and beneficiary inducements CMP). *See* 2014 PAP Bulletin, 79 Fed. Reg. at 31,120-123; AR at 64-68 (Barron's Article regarding PAP known as Chronic Disease Fund,

which has since been renamed Good Days) (attached as Exhibit 2), AR at 79-83 (New York Times Article regarding the same) (attached as Exhibit 3). No discovery on this point is needed (or appropriate).

The administrative record, however, does not reflect the harms, if any, resulting from "enforcement" of the challenged provisions of the Modified Advisory Opinion. Nor could it, as they occurred, if at all, after the issuance of the Modified Advisory Opinion. PSI, in its complaint, alleges that the Solicitation, Influence, and Modification provisions (to which it agreed) have resulted in a number of harms, including that it can no longer engage in certain categories of "lawful, truthful and non-misleading communications" with its donors, and that it has lost donations. *See, e.g.*, Compl. ¶¶ 118, 120. But Defendants (and the Court) should not be required to just take PSI's word for it on these important points. *Cf. Williams v. Griffin*, 952 F.2d 820, 823 (4th Cir. 1991) (once a case proceeds to the summary judgment stage, a party cannot "merely rely on matters pleaded in the complaint"). Defendants should be allowed to explore, for example, whether the speech that PSI previously engaged in, but is now forsaking, constituted "lawful, truthful, and non-misleading communications," or whether it was something else. Defendants should also be allowed to probe whether the challenged (agreed-to) provisions have cost PSI donations, or whether any decrease in PSI's donations was due to other causes. Finally, Defendants should be allowed to take discovery relevant to the Court's jurisdiction over this suit. In short, the Court should allow Defendants to test PSI's allegations and gather evidence regarding both (1) the harms, if any, caused by the challenged provisions and (2) the Court's jurisdiction. *See Livingstone v. N. Belle Vernon Borough*, 91 F.3d 515, 533 n.28 (3d Cir. 1996) (noting, in a related context, that while "the ultimate question of whether enforcement of a release-dismissal agreement is in the public interest is a question of law for the court, there may be factual issues intertwined with the legal issues").

Thus, as explained above, limited discovery is needed because the administrative record does not contain all of the information that the Court needs to resolve the issues presented in this case.

CONCLUSION

For the foregoing reasons, the Court should grant Defendants' motion for leave to take discovery.

Dated: July 18, 2018

Respectfully submitted,

G. ZACHARY TERWILLIGER
United States Attorney

CHAD READLER
Acting Assistant Attorney General
Civil Division

CHRISTOPHER R. HALL
Assistant Director
Federal Programs Branch

JUSTIN M. SANDBERG
Senior Trial Counsel
U.S. Department of Justice
Civil Division, Federal Programs Branch
20 Mass. Ave. NW, Rm. 7302
Washington, D.C. 20530
(202) 514-5838 (phone)
justin.sandberg@usdoj.gov

/s/ R. Charlie Merritt
R. Charlie Merritt
Virginia No. 89400

Special Assistant U.S. Attorney
Office of the United States Attorney

Trial Attorney

U.S. Department of Justice
Civil Division, Federal Programs Branch

919 East Main Street, Suite 1900
Richmond, Virginia 23219
(202) 616-8098 (phone)
(804) 819-7417 (fax)
robert.c.merritt@usdoj.gov

CERTIFICATE OF SERVICE

I hereby certify that on July 18, 2018, I electronically filed the foregoing via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

/s/ R. Charlie Merritt
R. Charlie Merritt
Virginia No. 89400

Special Assistant U.S. Attorney
Office of the United States Attorney

Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch

919 East Main Street, Suite 1900
Richmond, Virginia 23219
(202) 616-8098 (phone)
(804) 819-7417 (fax)
robert.c.merritt@usdoj.gov