IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

PHARMACEUTICAL COALITION FOR PATIENT ACCESS,	)	
Plaintiff,	)	
v.	)	Civil Action No. 3:22-cv-714 (RCY)
UNITED STATES OF AMERICA,	)	
DEPARTMENT OF HEALTH AND HUMAN SERVICES,	)	
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GENERAL,	)	
CHRISTI A. GRIMM,[1] *in her official capacity as Inspector General of the United States Department of Health and Human Services*,	)	
and	)	
XAVIER BECERRA, *in his official capacity as United States Secretary of the Department of Health and Human Services,*	)	
Defendants.	)	

MEMORANDUM OPINION

This is a lawsuit challenging an action by a federal agency. Plaintiff Pharmaceutical Coalition for Patient Access ("PCPA") commenced this litigation to appeal a negative advisory opinion issued by the U.S. Department of Health and Human Services, Office of the Inspector

[1] When this suit began, Michael H. Horowitz was the Inspector General of the United States Department of Health and Human Services. When Christi A. Grimm took over the role, she was automatically substituted as the proper defendant. *See* Fed. R. Civ. P. 25(d).

General ("HHS OIG" or "the Agency"), which dooms a Medicare Part D patient assistance program that PCPA wished to implement.

This case is currently before the Court on the parties' cross-motions for summary judgment.[2] The matters have been fully briefed, and the Court dispenses with oral argument because the materials before it adequately present the facts and legal contentions, and argument would not aid the decisional process. E.D. Va. Loc. Civ. R. 7(J). For the reasons stated below, the Court finds that PCPA cannot show that the Agency erred, let alone that the Agency acted arbitrarily, capriciously, or not in accordance with law. The Court thus affirms the opinion below and will grant Defendants' motion in full and deny PCPA's cross-motion.

I. STANDARD OF REVIEW

Under the Administrative Procedure Act ("APA"), a reviewing court must "hold unlawful and set aside" agency actions—including advisory opinions—if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The same goes for agency actions "contrary to constitutional right[s.]" *Id.* § 706(2)(B).

"In an APA suit challenging agency action, review is limited to the administrative record and 'resolution . . . does not require fact finding on behalf of [the] court.'" *Hyatt v. U.S. Pat. & Trademark Off.*, 146 F. Supp. 3d 771, 780 (E.D. Va. 2015) (alterations in original) (quoting *Nw. Motorcycle Ass'n v. U.S. Dep't of Agric.*, 18 F.3d 1468, 1472 (9th Cir. 1994)); *see* 5 U.S.C. § 706; *Camp v. Pitts*, 411 U.S. 138, 142 (1973) ("focal point" for judicial review is "the administrative record already in existence, not some new record made initially in the reviewing court"). "Accordingly, the ordinary summary judgment standard under [Federal Rule of Civil Procedure 56(c)] does not apply" because "the presence or absence of a genuine dispute of

[2] Defendants' motion includes a request to dismiss one of PCPA's claims for lack of subject matter jurisdiction, and the motion is properly styled as such. *See generally* Def.'s Mot. Dismiss for Lack of Subject Matter Jurisdiction and for Summ. J., ECF No. 34.

material fact is not in issue, as the facts are all set forth in the administrative record." *Hyatt*, 146 F. Supp. 3d at 780. Therefore, "when a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001).

II. BACKGROUND

A. Factual Background

The following factual narrative, drawn from the administrative record before HHS OIG, represents the undisputed facts for the purpose of resolving the cross-motions for summary judgment:

1. Oncology Care and Medicare Part D

There is no question that many patients with cancer suffer significant financial burdens associated with their care. Administrative Record ("AR") 4–8, ECF No. 42 (PCPA Advisory Op. Request); *accord* AR 86 (OIG Advisory Op. No.[3] 22-19). For example, PCPA certified that some innovative oncology medicines can run a patient up to (and beyond) $10,000 for a monthly supply at retail. AR 5 (PCPA Advisory Op. Request); *accord* AR 94 (Advisory Op. No. 22-19) ("'[F]rom 2008 to 2021, launch prices for new drugs increased exponentially by 20% per year . . . . [I]n 2020-2021, 47% of new drugs were initially priced above $150000 per year' and . . . '[t]he highest prices were among . . . oncology drugs[.]'" (quoting Benjamin N. Rome et al., *Trends in Prescription Drug Launch Prices, 2008-2021*, JAMA NETWORK (June 7, 2022), https://jamanetwork.com/ journals/jama/fullarticle/2792986 [https://perma.cc/RK73-QEJF])). This is where Medicare comes into play.

[3] Hereinafter, all OIG Advisory Opinions will be referred to simply as "Advisory Op. No. __."

Medicare has four parts, the relevant part here being Medicare Part D. Medicare Part D covers outpatient prescription drugs (including cancer drugs), but beneficiaries remain responsible for certain specified deductibles and co-pays.[4] Part D beneficiaries are responsible for 100% of an initial deductible, which in 2022 was $480. After satisfying that deductible, beneficiaries enter various coverage phases, where they are responsible for a 25% co-insurance payment until they reach the "catastrophic coverage" threshold. Upon reaching the "catastrophic" threshold, which in 2022 was $7,050 (including the prior deductible and co-insurance payments), beneficiaries continue to pay 5% of the cost for brand-name medications. There is no upper limit on the 5% contribution. Given these figures, it is little surprise that both PCPA and the Agency acknowledge that "some patients, including some Federal health care program beneficiaries, are unable or unwilling to access medically necessary oncology drugs due to the[se] significant out-of-pocket costs incurred under the current Medicare Part D cost-sharing structure." AR 94 (Advisory Op. No. 22-19)); *see, e.g.*, AR 4–8 (PCPA Advisory Op. Request).

From the government's perspective, as explained by HHS OIG, this cost-sharing structure has a purpose: the structure "expos[es] beneficiaries to the economic effects of drug prices set by manufacturers," thereby acting as a "market safeguard" to protect against over-inflated drug prices. AR 102–03 (Advisory Op. No. 22-19) (citing Cong. Budget Off., *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit* 15 (July 2004), https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/07-21-medicare.pdf [https://perma.cc/YGH9-JQUH]). By retaining some beneficiary sensitivity to branded drug prices, drug manufacturers would have to keep beneficiaries' financial limitations in mind and thus, in theory, could not excessively raise their prices. *See id.*

[4] For the monetary figures the Court discusses in this paragraph, *see* AR 305, tbl. V-6 (Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (Jan. 15, 2021)).

To illustrate the payment structure outlined above using PCPA's $10,000-per-month cancer drug hypothetical,[5] under Medicare Part D, the patient would owe approximately $2,800 in deductibles and co-insurance payments for that medication for the first month. *See* AR 5–6 (PCPA Advisory Op. Request); *accord* AR 89 (Advisory Op. 22-19). Every following month, the patient would be in the "catastrophic" phase of the benefit design and owe a 5% co-insurance payment for the remainder of the year for that prescription, equaling $500 per month. *See* AR 6 (PCPA Advisory Op. Request). In such a case, the total annual cost for the patient for this single prescription would exceed $8,000.[6] *See id.* PCPA pointed to one study indicating that 41% percent of cancer patients abandoned medication if their out-of-pocket costs were between just $500.01 and $2,000. *See id.* at 6 n.11 (citing Jalpa A. Doshi et al., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, 36 J. OF CLINICAL ONCOLOGY 476 (2018)).

2. PCPA's Proposed Coalition-Model Patient Assistance Program

To address these concerns, PCPA proposed a coalition-model patient assistance program to serve financially needy Medicare Part D patients diagnosed with cancer. *Id.* at 1. Through the program, PCPA would provide subsidies as co-pay assistance to Part D enrollees so long as the enrollee had: (1) a cancer diagnosis; (2) a household income between 150% and 350% of the federal poverty line; (3) already been prescribed a Part D oncology drug produced by a participating manufacturer; and (4) their Part D plan initially approve the coverage of the Part D

[5] This example applies to enrollees who do not qualify for Medicare Part D's low-income subsidy—that is, enrollees who do not fall below 150% of the federal poverty level. Enrollees who qualify for and enroll in the low-income subsidy program pay zero or nominal cost sharing, *see* 42 C.F.R. § 423.773; *see also id.* § 423.782, and, most important for present purposes, do not qualify for PCPA's proposed program (as explained *infra*).

[6] According to a 2019 study cited by HHS OIG, the mean annual out-of-pocket costs for Part D oncology drugs was $5,285. *See* AR 95 (Advisory Op. No. 22-19) (citing Thomas J. Hwang et al., *Assessment of Out-of-Pocket Costs With Rebate Pass-Through for Brand-Name Cancer Drugs Under Medicare Part D*, JAMA ONCOLOGY (Jan. 2022), https://jamanetwork.com/journals/jamaoncology/fullarticle/2786074 [https://perma.cc/D2ED-A75M]).

drug. *Id.* at 11–12, 15; AR 46 (PCPA Add'l Info. Resps.). Enrollees qualified for PCPA's program would pay $35 per month for branded drugs (or $10 per month for generic products) plus either 25% or 10% of the otherwise applicable co-insurance obligation (that percentage dependent on the particular enrollee's financial need); PCPA would cover the rest of the enrollee's cost. *See* AR 12 (PCPA Advisory Op. Request). So, if the $10,000-per-month oncology drug described previously were branded and produced by a participating manufacturer, under PCPA's program (and depending on the enrollee's financial need), PCPA would cover approximately somewhere between $6,380 and $7,280 of the enrollee's annual co-pay for that drug. The government, through Medicare, would foot the rest of the over-$111,000 bill for the year.

On the manufacturer side, participation in PCPA's arrangement would be open to any manufacturer of branded or generic oncology products reimbursed by Medicare Part D. *Id.* at 15. Each participating manufacturer would pay PCPA for the costs associated with the cost-sharing subsidies PCPA pays for that participating manufacturer's own products. *Id.* at 14. In essence, the participating manufacturers would subsidize the Part D enrollees' cost-sharing amounts for their own products, with PCPA as the middleman. But again, the manufacturers would do so only for their own drugs, not for the drugs of any other participating manufacturer. *Id.*

In addition to the co-pay subsidies, PCPA would also operate programs to support "Addition Medical Needs" of cancer patients, which would include financial assistance with health insurance premiums for qualifying patients and other initiatives to address health disparities. *Id.* at 13. The participating manufacturers' respective costs for the "Additional Medical Needs" program would be in part based on the manufacturers' market share of Part D oncology drug sales. *Id.* at 14. Participating manufacturers would also help cover PCPA's

operating costs, with their financial obligations for that being calculated the same way as for the additional needs. *Id.*

3. The Anti-Kickback Statute

The statute at the heart of this dispute is the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b. Congress first enacted the AKS in 1972 to combat fraud and abuse in connection with Medicare and Medicaid. The AKS prohibits, in relevant part, "knowingly and willfully offer[ing] or pay[ing] any remuneration" to "induce" an individual to purchase a federally reimbursable healthcare product. *Id.* § 1320a-7b(b)(2)(B). Liability under the AKS includes both civil and criminal penalties, including the possibility of an entity's complete exclusion from federal healthcare programs—and thus exclusion from federal reimbursement for its products. *See id.* § 1320a-7(b)(7). At least in part because the AKS sanctions can be so severe, Congress established a process through which parties may seek written advisory opinions from HHS OIG as to whether a proposed course of action would violate the AKS. *Id.* § 1320a-7d(b). Advisory opinions are "binding as to" HHS "and the party or parties requesting the opinion," unless set aside by a reviewing court. *Id.* § 1320a-7d(b)(4).

B. Relevant Procedural History

1. HHS OIG Advisory Opinion

On January 25, 2022, PCPA submitted a request to HHS OIG for an advisory opinion on the legality of its proposed program. *See generally* AR 1–41 (PCPA Advisory Op. Request). On around July 8, 2022, HHS OIG informed PCPA that it had reached an unfavorable opinion and would issue and advisory opinion to that effect if PCPA did not voluntarily withdraw the request. Am. Compl. ¶ 142, ECF No. 17. PCPA did not withdraw its request, and the Agency issued its advisory opinion on September 30, 2022. *Id.* ¶¶ 142, 146.

In the advisory opinion, HHS OIG explained that PCPA's proposed program "would fit squarely within" the AKS's prohibitions if the requisite intent were present: PCPA proposes to "pay[] remuneration (i.e., cost-sharing subsidies) to Medicare Part D enrollees so that such enrollees would 'purchase . . . any item for which payment may be made in whole or in part under a Federal health care program . . .' so long as the item is a Part D oncology drug manufactured by a Funding Manufacturer." AR 97–99 (Advisory Op. No. 22-19). The Agency viewed the participating manufacturers' payments to PCPA as "calculated to induce Part D enrollees to purchase their Part D oncology drugs." *Id.* at 97; *see also id.* at 101 ("[E]ach Funding Manufacturer—via Requestor—would offer remuneration (the cost-sharing subsidies) to a qualifying Part D enrollee that would be contingent on the purchase of that particular Funding Manufacturer's oncology products (i.e., no Funding Manufacturer would subsidize any other manufacturer's products).").

The Agency also recognized that PCPA attempted to structure its proposal on a 2005 Special Advisory Bulletin (one predating the launching of the Part D program). *See id.* at 100. *See generally* discussion *infra* Part III.C (discussing in greater depth the 2005 Special Advisory Bulletin). But, the Agency explained, the advisory opinion was the Agency's "first opportunity to evaluate an arrangement involving a coalition of manufacturers subsidizing cost sharing for their own drugs . . . in the context of an implemented Part D program." *See* AR 100 (Advisory Op. No. 22-19). And in conducting a legal analysis on PCPA's proposal's own merits, the Agency concluded that it would (mens rea pending) run afoul of the AKS and that nothing from the "premature," "brief discussion" about potential coalition models in 2005 Special Advisory Bulletin mandated otherwise. *See id.*

Additionally, in the opinion, the Agency concluded "that the cost-sharing subsidies under [PCPA's] Proposed Arrangement would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute," and are indeed "highly suspect . . . as a way to sidestep the cost-sharing structure that Congress included in the standard Part D benefit." *Id.* at 101, 103–04. The Agency noted that the proposal would "lay bare the dangers of allowing manufacturers to dictate the terms of this market safeguard" and thus "present significant risk" of increased drug prices.[7] *Id.* at 103. "[T]he Medicare program and taxpayers," the Agency explained, "would bear the financial brunt of those unchecked drug prices." *Id.* For those reasons, among others, HHS OIG found that PCPA's proposed program "would constitute grounds for the imposition of sanctions" (i.e., civil penalties and exclusion from the program) under the AKS. *Id.* at 106.

2. Federal Court Action

On November 9, 2022, PCPA filed this action challenging HHS OIG's advisory opinion on its program as violative of the APA, 5 U.S.C. § 706(2). PCPA filed its Amended Complaint on January 5, 2023. On March 7, 2023, the parties filed their cross-motions, *see* ECF Nos. 34, 36, and their respective supporting memoranda, *see* Pl.'s Mem. Supp., ECF No. 37; Def.'s Mem. Supp., ECF No. 35. In their motion, Defendants seek dismissal of one of PCPA's two dissimilar treatment claims, *see, e.g.*, Def.'s Mem. Supp. 16–18; discussion *infra* Part III.B.1, and judgment

[7] Throughout the years, HHS OIG has consistently warned of the pricing risks associated with co-pay assistance programs involving drug manufacturers. In 2005 (in the above-mentioned Special Advisory Bulletin), the Agency explained that

> cost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions.

70 Fed. Reg. 70626 (Nov. 22, 2005). The Agency reiterated this concern in 2014, explaining that "the ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support." 79 Fed. Reg. 31122 (May 30, 2014).

on all of PCPA's other claims. The parties filed their responses on April 3, 2023, *see* Pl.'s Resp., ECF No. 39; Def.'s Resp., ECF No. 38, and their replies on April 24, 2023, *see* Pl.'s Reply, ECF No. 41; Def.'s Reply ECF No. 40. On July 14, 2023, with leave of the Court, PCPA filed two notices of supplemental authorities. *See* ECF Nos. 47, 48. Defendants filed a response on July 26, 2023, *see* ECF No. 51, and PCPA filed a reply to the response two days later, *see* ECF No. 54. On December 21, 2023, the Court accepted the filing of a letter from PCPA alerting the Court "to significant timing constraints on the implementation of the program at issue in this litigation" and seeking resolution of the instant cross-motions by January 31, 2024. *See* Dec. 18, 2023 Letter, ECF No. 59; Mot. Leave File Letter, ECF No. 57. The Government filed its response to that letter on December 26, 2023. *See* ECF No. 60. This opinion follows.

III. DISCUSSION

The question presented here is whether HHS OIG's unfavorable advisory opinion was arbitrary and capricious or contrary to law. *See* 5 U.S.C. § 706(2). PCPA says it is. PCPA gives four alternative reasons for why it believes it is entitled to relief in this case: (1) the opinion is contrary to law because HHS OIG's interpretation of the AKS runs "contrary to the plain language of the AKS;" (2) the opinion is arbitrary and capricious because it treats PCPA's proposal in an unjustifiably dissimilar fashion to similarly-situated parties; (3) a 2005 Special Advisory Bulletin renders the negative opinion arbitrary and capricious; and (4) the negative opinion infringes upon PCPA's First Amendment free speech rights. *E.g.*, Am. Compl. ¶¶ 161, 191, 196, 206, 212–13, ECF No. 17; Pl.'s Mem. Supp. 16, 25–27, 29–30, ECF No. 37. On each score, the Court disagrees.

A. Plain Language of the AKS

The Court first addresses whether HHS OIG's interpretation of the AKS was contrary to law. The Court "begin[s] with the text" of the AKS. *Facebook, Inc. v. Duguid*, 592 U.S. 395,

402 (2021); *see Williams v. Carvajal*, 63 F.4th 279, 285 (4th Cir. 2023) ("As always, an issue of statutory interpretation begins with the text."). The AKS provides, in pertinent part:

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2)(B).

PCPA argues that the AKS's plain language requires both a quid pro quo and a showing of corruption. PCPA bases its argument on (1) the phrase "any remuneration . . . to induce;" (2) the "(including any kickback, bribe, or rebate)" parenthetical; and (3) the canon against absurdity. Because, says PCPA, HHS OIG failed to apply these alleged requirements, the advisory opinion must be in error.

The Court disagrees with PCPA and holds that HHS OIG's interpretation of the AKS was not contrary to law.[8]

1. <u>"[A]ny remuneration . . . to induce"</u>

a. Quid Pro Quo

First, PCPA contends that the phrase "any remuneration . . . to induce" necessarily connotes a quid pro quo. *See, e.g.*, Pl.'s Mem. Supp. 17–19. The Court concludes that it need not decide whether this language constitutes a quid pro quo requirement because HHS OIG's reasoning for why PCPA's proposed arrangement would run afoul of the AKS clearly shows that PCPA's program would involve a quid pro quo, in that the program "would involve paying

[8] Because the Court finds no ambiguity in the AKS on this question and instead finds that the "traditional tools of statutory construction" all show that HHS OIG's reading is plainly correct, the Court "give[s] effect to the unambiguously expressed intent of Congress" and does not rely on *Chevron* deference in deciding this matter. *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842–43, 843 n.9 (1984).

remuneration (i.e., cost-sharing subsidies) to Medicare Part D enrollees," paid by the participating manufacturers, "so that such enrollees would purchase" the manufacturers' federally reimbursable products. *See* AR 99 (Advisory Op. No. 22-19) (internal quotation marks omitted). And as the Agency repeatedly emphasized, each participating manufacturer involved in the program would provide subsidies (i.e., pay remuneration) *only* for its *own products*. *See, e.g.*, *id.* at 101 ("[E]ach Funding Manufacturer—via Requestor—would offer remuneration (the cost-sharing subsidies) to a qualifying Part D enrollee that would be contingent on the purchase of that particular Funding Manufacturer's oncology products (i.e., no Funding Manufacturer would subsidize any other manufacturer's products)."). This falls squarely within the definition of "quid pro quo": "something for something." *Pfizer, Inc. v. United States Dep't of Health & Hum. Servs.*, 42 F.4th 67, 75 (2d Cir. 2022), *cert. denied* 143 S. Ct. 626 (2023); *see also* BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "quid pro quo" as "[a]n action or thing that is exchanged for another action or thing of more or less equal value; a substitute"). Each participating manufacturer would furnish subsidies (quid) for (pro) the purchase of its drugs (quo).

PCPA insists that something cannot be a quid pro quo if, as is the case with the proposal at issue here, the offeror gives the offeree many different options.[9] *See* Pl.'s Mem. Supp. 18–19 (arguing that the instant proposal "does not involve a quid pro quo" because "[n]o specific purchase of any particular drug is made in exchange for the assistance"); Pl.'s Reply 5, ECF No. 41 (arguing that something can only be a quid pro quo if it is "for a particular good or service" and this proposal "is expected to involve at least 50 oncology products" (internal quotation

[9] In PCPA's program, a qualified Medicare Part D enrollee would be able to choose from any participating manufacturers' drug selection, and each manufacturer would offer all its oncology drugs. *See, e.g.*, AR 21–22 (PCPA Advisory Op. Request); AR 99 (Advisory Op. No. 22-19).

marks omitted)). But PCPA's assertion is inaccurate.[10] Paying money for a meal at a restaurant is undoubtedly a literal quid pro quo—a "this for that." *See Pfizer*, 42 F.4th at 74 (using this example). But restaurants have menus, replete with numerous options from which the customer may choose to sate their appetite. Likewise, something can be a quid pro quo even when, again, as here, multiple offerors extend multiple options to an offeree. *Contra* Pl.'s Mem. Supp. 19 (protesting that "where broad-based assistance is offered through a coalition, any nexus between the remuneration and the product selected is severed" and thus there can be no quid pro quo (alteration and internal quotation marks omitted)). Many restaurants all offering their services in the same food court does not make a customer's lunch purchase from one any less a "this for that."[11]

As a final roll of the dice on the quid pro quo point, PCPA argues that HHS OIG cannot argue (and this Court cannot find) that the proposal constitutes a quid pro quo because HHS OIG "never considered the quid pro quo requirement," and "[t]hat phrase never appears in the Opinion—anywhere." Pl.'s Resp. 8–9, ECF No. 39. It is, of course, black-letter administrative law that a "reviewing court . . . must judge the propriety of [agency] action solely by the grounds invoked by the agency." *SEC v. Chenery Corp.*, 332 U.S. 194, 196 (1947). However, "[e]ven when an agency explains its decision with 'less than ideal clarity,' a reviewing court will not

[10] PCPA also incorrectly asserts that, via a brief opposing the certiorari petition in the Second Circuit's *Pfizer* case, "the Solicitor General has specifically conceded that an AKS violation can only occur where a quid pro quo for 'particular' good or service [sic] is present." Pl.'s Reply 5; *see* Pl.'s Mem. Supp. 18 ("The government . . . represented to the Court that its position was that an AKS violation could only occur when the arrangement at issue was in exchange for a specific, 'particular' item or service." (quoting Br. Resp'ts Opp. 18, *Pfizer Inc. v. Dep't of Health & Hum. Servs.*, 143 S. Ct. 626 (2023) (No. 22-339), http://www.supremecourt.gov/DocketPDF/22/22339/249960/20221214150742697_Pfizer%20Opp%20-%2022-339.pdf)). The language quoted by PCPA refers to payments for the purchase of "any particular goods or services," in the plural. Br. Resp'ts Opp. 18, *Pfizer*, 143 S. Ct. 626.

[11] And insofar as PCPA contends it makes any difference in the AKS analysis that the program, as designed, would facilitate the quid pro quo through PCPA as a middleman, *see* Pl.'s Mem. Supp. 18–19 (appearing to frame the program as PCPA covering drug options and offering therapies, as opposed to offers and payments coming from the manufacturers themselves), PCPA is incorrect. That is because the AKS plainly prohibits payments made either "directly or indirectly." 42 U.S.C. § 1320a-7b(b)(2)(B).

upset the decision on that account 'if the agency's path may reasonably be discerned.'" *Alaska Dep't of Env't Conservation v. E.P.A.*, 540 U.S. 461, 497 (2004) (quoting *Bowman Transp., Inc. v. Arkansas—Best Freight System, Inc.*, 419 U.S. 281, 286 (1974)).

Here, the Agency's path is readily discernable. Per PCPA, the AKS's (alleged) quid pro quo requirement comes from "to induce" following "any remuneration." *See* Pl.'s Mem. Supp. 16 (arguing that HHS OIG "failed to apply the 'to induce' language and the *quid pro quo* requirement"); *id.* at 17 ("[I]f [the quid pro quo] requirement were not recognized, the 'to induce' language specifically chosen by Congress would become mere surplusage.").[12] And PCPA admits (though it does its best to bury the admission in a dense footnote) that HHS OIG's relevant explanation in the advisory opinion—where the Agency lays out precisely why it concluded that the proposed "cost-sharing subsidies . . . would fit squarely within the [AKS's] plain language prohibiting the offer of *remuneration to induce* the purchase" of the manufacturers' federally reimbursable health products, AR 97 (Advisory Op. 22-19) (emphasis added)—was an analysis of "to induce." *See* Pl.'s Resp. 8 n.12 (confessing, in the quid pro quo section of its brief, that HHS OIG's decision addressed "the argument that the 'to induce' requirement is met"). Guided by PCPA's own framing of the issue, it is clear that HHS OIG's path to arguing to this Court that this proposal constitutes a quid pro quo is based on its decision and reasoning below. Thus, the argument is proper, and the Court finds that it carries the day on this issue.

b. Corrupt Intent

Second, PCPA advances an additional, but distinct, "induce" argument. PCPA asserts that the word "induce," by itself, implies corrupt intent that must be read into "any

[12] Only in its later filings does PCPA attempt to reframe "to induce" as a "separate issue" from the quid pro quo issue. Pl.'s Resp. 8 n.12, ECF No. 39. The Court will not allow PCPA to slyly backtrack from its original characterization of its own interpretive argument.

remuneration." *See, e.g.*, Pl.'s Mem. Supp. 22–23. Thus, PCPA goes on, the AKS must prohibit only corrupt payments. *See, e.g.*, *id.* at 19. The Court is not persuaded.

In making this argument, PCPA does not rely on the ordinary meaning[13] of "induce." The ordinary meaning of "induce" is to "entic[e] or persuad[e] another person to take a certain course of action." *Inducement*, BLACK'S LAW DICTIONARY (11th ed. 2019); *see also Induce*, AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (5th ed. 2022) (defining "induce" as "[t]o lead or move, as to a course of action, by influence or persuasion," or "[t]o bring about or stimulate the occurrence of; cause," as in "a drug used to induce labor"); *Induce*, MERRIAM-WEBSTER (accessed Dec. 20, 2023), https://www.merriam-webster.com/dictionary/induce [https://perma.cc/9TKC-U4L2] (defining "induce" as "to move by persuasion or influence" or "to call forth or bring about by influence or stimulation," as in "[t]he advertisement is meant to induce people to eat more fruit"). The ordinary meaning of the word is thus "neutral with regard to intent—one can persuade another to take an action with good or bad motives." *Pfizer*, 42 F.4th at 75.

PCPA is thus backed into arguing that the Court should not apply the ordinary meaning of "induce." Instead, PCPA contends that the Court is bound to apply the narrow, specialized, criminal-law term of art meaning of "induce," which "goes hand-in-hand with soliciting an inherently criminal act." Pl.'s Mem. Supp. 22. For this proposition, PCPA points to the Supreme Court's recent decision in *United States v. Hansen*, 599 U.S. 762 (2023). *See* Pl.'s

[13] The Court applies the ordinary meaning of statutory terms absent an indication that Congress intended otherwise. *See, e.g.*, *Smith v. United States*, 508 U.S. 223, 228 (1993) ("When a word is not defined by statute, we normally construe it in accord with its ordinary or natural meaning."); *United States v. Abdelshafi*, 592 F.3d 602, 607 (4th Cir. 2010) ("[I]n interpreting the plain language of a statute, we give the terms their ordinary, contemporary, common meaning, absent an indication Congress intended the statute's language to bear some different import." (internal quotation marks omitted)); *United States v. Snider*, 502 F.2d 645, 651 (4th Cir. 1974) ("It is a familiar rule of statutory construction that Congress is presumed to have used words according to their ordinary meaning, unless a different signification is clearly indicated.").

Second Not. Supp'l Auth., ECF No. 48. *Hansen* held that the phrase "encourages or induces" in 8 U.S.C. § 1324(a)(1)(A)(iv)[14] was used "in its specialized, criminal-law sense" and thus incorporated "common-law liability for solicitation and facilitation." 599 U.S. at 774. PCPA also points to 18 U.S.C. § 373(a),[15] which prohibits "[s]olicitation to commit a crime of violence" and applies to anyone who "solicits, commands, induces, or otherwise endeavors to persuade such other person to engage in such conduct." Pl.'s Mem. Supp. 22–23. Neither authority persuades the Court that Congress intended to use a specialized meaning of "induce" in the AKS.

PCPA essentially argues that *Hansen* lays out a categorical rule that "Congress'[s] use of the term 'induce' in the context of a criminal prohibition is a 'term[] of art,' with a more narrow, specialized meaning, namely, 'an intent to bring about a particular unlawful act.'" Pl.'s Second Not. Supp'l Auth. 3–4 (quoting *Hansen*, 599 U.S. at 771); *see also* Pl.'s Reply to Def.'s Resp. to Nots. Supp'l Auth., ECF No. 51. But *Hansen* did not purport to hold that "induce" is always read as a term of art whenever it is used in a criminal statute. Though the Court offered some *dicta* which opined that a term with a criminal-law meaning appearing in a criminal statute "is a good clue" that a term "takes its criminal-law meaning," *Hansen*'s holding was ultimately based on the particular statutory text and context before it. 599 U.S. at 775; *see also id.* (citing *Corning Glass Works v. Brennan*, 417 U.S. 188, 202 (1974)) ("When words have several plausible definitions, context differentiates among them. That is just as true when the choice is between

[14] "Any person who . . . encourages or induces an alien to come to, enter, or reside in the United States, knowing or in reckless disregard of the fact that such coming to, entry, or residence is or will be in violation of law . . . shall be punished . . . ." 8 U.S.C. § 1324(a)(1)(A)(iv).

[15] Whoever, with intent that another person engage in conduct constituting a felony that has as an element the use, attempted use, or threatened use of physical force against property or against the person of another in violation of the laws of the United States, and under circumstances strongly corroborative of that intent, solicits, commands, induces, or otherwise endeavors to persuade such other person to engage in such conduct, shall be [punished] . . . .

18 U.S.C. § 373(a).

ordinary and specialized meanings."). What convinced the *Hansen* majority was the fact that "clause (iv) prohibits 'encouraging' and 'inducing' *a violation of law*," which mirrors the focus of the common-law criminal offenses of solicitation and facilitation. *Id.* (emphasis in original); *see also id.* at 771 (facilitation and solicitation "are longstanding criminal theories targeting those who support the crimes of a principal wrongdoer"). *Hansen* announced no categorical rule about either "induce" or "encourage" in criminal statutes or elsewhere: rather, "the context of these words—the water in which they swim—indicate[d] that Congress used them as terms of art" in 8 U.S.C. § 1324(a)(1)(A)(iv). *Id.*; *cf. United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 754 (2023) (Supreme Court's prior interpretation of statutory terms "was ultimately tied to the [other statute]'s particular text," and to read the prior case "as establishing categorical rules for those terms would accordingly 'abandon the care [courts] have traditionally taken to construe . . . words in their particular statutory context'" (quoting *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich, L.P.A.*, 559 U.S. 573, 585 (2010))).

Because the AKS's particular text and context governs in discerning whether Congress wished to supplant the ordinary meaning "induce" with its specialized meaning in the AKS, neither 18 U.S.C. § 373(a) nor 8 U.S.C. § 1324(a)(1)(A)(iv) control the present analysis. Section 373(a) applies only to "solicit[ing], command[ing], induc[ing], or otherwise endeavor[ing] to persuade" another person to commit a crime, because the statutory language specifically limits its reach to criminal conduct. 18 U.S.C. § 373(a) ("conduct constituting a felony that has an element the use . . . of physical force . . . *in violation of the laws* of the United States" (emphasis added)). The specific context and language there requires the term "induce" to specifically relate to an inducement to commit an independent crime. *See id.* Likewise, the prohibited

"ecourag[ing] or induc[ing]" in 8 U.S.C. § 1324(a)(1)(A)(iv) is tied to a separate "violation of law." *See* 8 U.S.C. § 1324(a)(1)(A)(iv); *Hansen*, 599 U.S. at 775.

Unlike 8 U.S.C. § 1324(a)(1)(A)(iv) and 18 U.S.C. § 373(a), the AKS does not outlaw inducing something that is, on its own, a violation of another law. The AKS, in certain circumstances, makes it illegal to pay or offer to pay remuneration "to induce" a person "to refer an individual . . . for the furnishing . . . of" or "to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering" items or services paid for by a federal health program. 42 U.S.C. § 1320a-7b(b)(2). *Compare id.*, *with* 8 U.S.C. § 1324(a)(1)(A)(iv) (person who "encourages or induces [conduct that] is or will be *in violation of law* . . . shall be punished" (emphasis added)), *and* 18 U.S.C. § 373(a) (person who, "with intent that another person engage in conduct constituting a felony . . . *in violation of the laws* of the United States . . . solicits, commands, induces, or otherwise endeavors to persuade such other person to engage in such conduct, shall be imprisoned . . ." (emphasis added)). The AKS does not specifically require that the things to be induced be independently unlawful—as is the case with criminal solicitation.

Two additional contextual features of the AKS further weaken PCPA's attempted analogy between it and criminal solicitation. First, the pertinent provision of the AKS uses only the term "induce," but the other statutes to which PCPA directs the Court's attention use "induce" along with other words that harken to criminal solicitation. *Compare* 42 U.S.C. § 1320a-7b(b)(2) ("induce"), *with* 8 U.S.C. § 1324(a)(1)(A)(iv) ("encourages[16] or induces"), *and* 18 U.S.C. § 373(a) ("solicits, commands, induces, or otherwise endeavors to persuade"). Second, the AKS's mens rea requirement does not track that of criminal solicitation. Criminal

[16] Though typically innocent, "encourage" did significant work to support the analogy to solicitation and facilitation in *Hansen*. *See Hansen*, 599 U.S. at 771–73. Indeed, *Hansen*'s holding was "that clause (iv) uses 'encourages or induces' in its specialized, criminal-law sense," referring to the pair of words in the collective singular. 599 U.S. at 774.

solicitation traditionally is a specific intent crime. *See, e.g.*, *Hansen*, 599 U.S. at 771, 778, 781; *Intent: Specific Intent*, Black's Law Dictionary (11th ed. 2019) ("At common law, the specific-intent crimes were . . . solicitation[.]"); *see also* 8 U.S.C. § 1324(a)(1)(A)(iv); 18 U.S.C. § 373(a). But PCPA itself acknowledges that "'a person need not have actual knowledge of [the AKS] or specific intent to commit a violation' to be guilty of a felony" under the AKS. Pl.'s Mem. Supp. 25 (quoting 42 U.S.C. § 1320a-7b(h)).

At the end of the day, PCPA provides the Court with little more than the fact that the AKS is a criminal statute and carries criminal penalties to argue that it is like the statute in *Hansen* and thus that the specialized meaning of "induce" ought to apply here. *See* Pl.'s Reply to Def.'s Resp. to Nots. Supp'l Auth. 2. PCPA argues that "like the statute in *Hansen*, the AKS is directed at efforts to 'induce' a corrupt or unlawful result." *Id.* at 3. But neither "corrupt" nor "unlawful" are valid parallels between the two statutes. The word "corrupt" does not appear anywhere in *Hansen*. *See generally* 599 U.S. at 766–85. So even if PCPA were right that the AKS covers only "corrupt" payments, PCPA provides no valid support for its contention that "[b]oth" the AKS *and* the statute in *Hansen* "punish conduct that results in corruption." Pl.'s Reply to Def.'s Resp. to Nots. Supp'l Auth. 3.

And PCPA's argument that "the AKS statute punishes a violation of law" and thus is like the statute in *Hansen* misses the point. Of course the AKS punishes a violation of law—but that violation is itself created by the AKS. The point is that the statute interpreted in *Hansen* punishes only encouraging or inducing someone to do an *independently* unlawful thing. *See* 8 U.S.C. § 1324(a)(1)(A)(iv), *construed in Hansen*, 599 U.S. at 775; *accord* 18 U.S.C. § 373(a), *cited in Hansen*, 599 U.S. at 772. And for that reason, the statute tracked the longstanding crimes of solicitation and facilitation. That is why the specialized meanings of "encourage" and

"induce" applied. *See Hansen*, 599 U.S. at 775 ("[C]lause (iv) prohibits 'encouraging' and 'inducing' *a violation of law*. That is the focus of criminal solicitation and facilitation too." (emphasis in original) (internal citation omitted)); *see also id.* at 771 (providing background on solicitation and facilitation). PCPA's argument is that—through a convoluted textual interpretation—the AKS prohibits only "corrupt" remunerations, i.e., "kickbacks," "bribes," and "secret rebates." Pl.'s Mem. Supp. 23. PCPA never argues that the AKS punishes only kickbacks, bribes, and secret rebates that induce something that is unlawful independent of the AKS, and the Court finds no basis for that in the AKS's text. Thus, the analogy to solicitation does not work here, as it did in *Hansen*.

"[T]he water in which ['induce'] swim[s]" in the AKS does not indicate to this Court that Congress intended to attach a specialized meaning to "induce." *See Hansen*, 599 U.S. at 775. To conclude that *Hansen* requires the Court to apply the specialized meaning of "induce" in this instance would be to read *Hansen* as holding that the term "induce" must always be read as a term of art whenever it is used in a criminal statute. Contrary to PCPA's intimations, *Hansen* does no such thing. The Court "has given specialized meaning a fair shake," *id.*, but failing to find the Congressional, contextual signals relied upon in *Hansen* here, the Court concludes that the AKS contemplates simply the ordinary meaning of "induce."[17]

For these reasons, the Court concludes that HHS OIG did not apply an incorrect reading of "any remuneration . . . to induce" in the advisory opinion.

[17] The *Hansen* Court also relied upon the canon of constitutional avoidance to apply the specialized meaning of "encourages or induces" to avoid a collision between § 1324(a)(1)(A)(iv) and the First Amendment. *Hansen*, 599 U.S. at 781 ("[E]ven if the [specialized] reading of ['encourages or induces'] were not the best one, the interpretation is at least fairly possible—so the canon of constitutional avoidance would still counsel us to adopt it." (internal quotation marks omitted)). PCPA urges that this consideration is relevant here, too, and counsels this Court to adopt a narrow definition of "induce" in the AKS. Pl.'s Second Not. Supp'l Auth 4–5; *see also* Pl.'s Mem. Supp. 30 n.74; Pl.'s Resp. 29 n.28. But for reasons the Court explains *infra*, the AKS does not create any First Amendment problems, and thus there is nothing to avoid. *See* discussion *infra* Part III.D; *cf.* discussion *infra* n.31.

2. "([I]ncluding any kickback, bribe, or rebate)"

PCPA next argues that the parenthetical immediately following "any remuneration"—"(including any kickback, bribe, or rebate)"—limits the AKS's scope to only any "corrupt" remuneration. But PCPA's proposed reading is belied by the plain text and history of the statutory language.

The Court's starting point is the extremely broad, plainly corruption-free phrase "any remuneration." 42 U.S.C. § 1320a-7b(b)(2). This phrase clearly has no corrupt connotation. The plain meaning of "remuneration" does not, on its own, imply corruption. *Remuneration*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("1. Payment; compensation, esp. for a service that someone has performed. 2. The act of paying or compensating."). And "any" means, well, "any."

Undeterred, PCPA seeks to limit the broad "any remuneration" as the starting point in the analysis. PCPA argues that because the AKS refers to "[i]llegal remunerations" in the operative subsection heading, *see* 42 U.S.C. § 1320a-7b(b), and "prohibited remuneration" in a different section, *see id.* § 1320a-7d(b)(2), that "necessarily mean[s] that some renumeration is impermissible and some is not" under the AKS. Pl.'s Mem. Supp. 19. PCPA is correct as a general matter, but PCPA is incorrect to take the further step to equate "illegal" and "prohibited" with "corrupt." Rather, the "illegal" and "prohibited" language PCPA cites merely serves to confirm what is obvious from the AKS's text: that it does not outlaw all possible remunerations, but rather only *knowing and willful* offers or payments of any remuneration *to induce* someone to purchase *federally reimbursable healthcare products* (that do not fall under a statutory exception or regulatory safe harbor). 42 U.S.C. § 1320a-7b(b)(2)(B). Only "any" of those "remuneration[s]" are made "illegal" by the AKS, *id.* § 1320a-7b(b), and thus are "prohibited

remuneration[s] *within the meaning of section 1320a-7b(b)*," *id.* § 1320a-7d(b)(2) (emphasis added). The plain meaning of "any remuneration" in the AKS thus clearly extends beyond corrupt payments, and the burden lies with PCPA to demonstrate why that broad phrase is, in fact, constricted.

PCPA argues that "any remuneration" must be construed as covering only corrupt transactions when read with the words "kickback, bribe, or rebate." *See* Pl.'s Mem. Supp. 20. But even accepting PCPA's argument that all three of those parenthesized terms connote corruption, the Court could not accept its contention that "(including any kickback, bribe, or rebate)" curtails the breadth of "any remuneration." The parenthetical begins with "including," and it is well-established that the word "includes" in a statute "is usually a term of enlargement, and not of limitation." *Burgess v. United States*, 553 U.S. 124, 131 n.3 (2008) (internal quotation marks omitted); *see also In re Grewe*, 4 F.3d 299, 305 n.5 (4th Cir. 1993) (describing "the general rule of statutory construction that [a] parenthetical beginning with 'including' enlarges the scope of [a statute] rather than limits it"). And beyond the use of "including," the fact that "(. . . kickback, bribe, or rebate)" is in a parenthetical actually undercuts PCPA's position. The Supreme Court has made clear that "[t]he use of parentheses emphasizes the fact that that which is within is meant simply to be illustrative." *Chickasaw Nation v. United States*, 534 U.S. 84, 85 (2001). This Court cannot "rel[y] on th[is] parenthetical to drive the interpretation of the whole provision, thereby allowing the statutory tail to wag the dog. A parenthetical is, after all, a parenthetical, and it cannot be used to overcome the operative terms of the statute." *Cabell Huntington Hosp., Inc. v. Shalala*, 101 F.3d 984, 990 (4th Cir. 1996), *quoted in Chickasaw Nation*, 534 U.S. at 94–95.

PCPA argues that the Supreme Court's recent decision in *Dubin v. United States*, 599 U.S. 110 (2023), applying the canon of *noscitur a sociis* in reading the federal aggravated identity theft statute, 18 U.S.C. § 1028A(a)(1), supports PCPA's position that "any remuneration" should be read in light of "(. . . kickback, bribe, or rebate)." *See* Pl.'s First Not. Supp'l Auth., ECF No. 47. But PCPA misses the mark. The *noscitur a sociis* canon stands for the proposition that "an ambiguous term may be given more precise content by the neighboring words with which it is associated." *United States v. Stevens*, 559 U.S. 460, 474 (2010) (internal quotation marks omitted); *see, e.g.*, *United States v. Davis*, 872 F. Supp. 1475, 1480 (E.D. Va. 1995) ("*[N]oscitur a sociis* . . . hold[s] that the meaning of an ambiguous term may be determined by reference to other terms accompanying it in the statute."), *aff'd*, 98 F.3d 141 (4th Cir. 1996); 2A N. Singer, *Sutherland Statutory Construction* § 47:16 (7th ed. 2023 update) (*noscitur a sociis* "does not apply absent ambiguity"). PCPA has never argued, and the Court does not find, that "any remuneration" is ambiguous in this context. The *noscitur a sociis* canon is thus inapplicable.

Moreover, PCPA's *Dubin* argument is wrong on *Dubin*'s terms. *Dubin* interpreted the word "uses" in § 1028A(a)(1) by reference to the surrounding words "transfers" and "possesses" in that statute. *See Dubin*, 599 U.S. at 124. This makes sense because, in that statute, "uses" is part of a list with "transfers" and "possesses." *See* 18 U.S.C. § 1028A(a)(1) (applying to a defendant who "knowingly transfers, possesses, or uses, without lawful authority . . ."). But in the AKS, "remuneration" is not part of a list with "kickback, bribe, or rebate"—those three terms are a separate, illustrative list. *See* 42 U.S.C. § 1320a-7b(b)(2). PCPA's *Dubin*-based *noscitur a sociis* argument is a good one to argue that, for example, "rebate" should be read with "kickback" and "bribe." *Cf. Pfizer Inc. v. United States Dep't of Health & Hum. Servs.*, No.

1:20-cv-4920, 2021 WL 4523676, at *12 (S.D.N.Y. Sept. 30, 2021) (concluding that the plain meaning of "rebate" does not connote corruption even though the plain meanings of "kickback" and "bribe" do), *aff'd sub nom.* 42 F.4th 67 (2d Cir. 2022). But because of Congress's use of parentheses and the term "including," PCPA's success on such a hypothetical does not alter the Court's reading of "any remuneration." This also makes *Dubin* otherwise inapposite, because § 1028A(a)(1) does not use "including" and has no words in parentheses. Put differently, *Dubin* does not displace the longstanding, applicable interpretive guideposts outlined in *Burgess*, *Chickasaw Nation*, and the accompanying Fourth Circuit precedents that the Court relies on here. For these reasons, "the listed examples of 'kickback, bribe, or rebate' in the AKS do not limit the meaning of 'any remuneration'; they are merely non-exhaustive examples."[18] *Pfizer*, 42 F.4th at 76.

Finding no support in the text of the AKS for its narrow interpretation of "any remuneration," PCPA attempts a history-based argument. The AKS, as originally drafted in 1972, outlawed "kickback[s] or bribe[s] in connection with the furnishing of . . . items or services," or "rebate[s] of any fee or charge for" a referral for "items or services." Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). But in 1977, Congress amended the law to extend to "any remuneration (including any kickback, bribe, or rebate)[.]" Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1180 (1977). PCPA argues that this amendment did not extend the AKS's focus

[18] And because "(. . . kickback, bribe, or rebate)" is nothing more than an illustrative, clarifying list of examples, the Court rejects PCPA's argument that reading "any remuneration" in accord with its plain text is impermissible as rendering "(including any kickback, bribe, or rebate)" superfluous. *Cf.* Pl.'s First Not. Supp'l Auth. 3 (citing *Dubin*, 599 U.S. 110); Pl.'s Mem. Supp. 22. The antisuperfluity canon does not "woodenly apply" to invalidate any interpretation of a statute that treats clearly illustrative or clarifying language as such. *See Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 226–27 (2008) ("[T]he rule against superfluities lends petitioner sparse support . . . . Congress may have simply intended to remove any doubt . . . . In any event, we do not woodenly apply limiting principles every time Congress includes a specific example along with a general phrase."); *accord City of Providence v. Barr*, 954 F.3d 23, 46 (1st Cir. 2020) ("The canon against surplusage is not a straitjacket. It should not, therefore, be employed inflexibly to rule out every interpretation of a statute that treats certain language as illustrative or clarifying."). To the contrary, the Supreme Court has made clear that "[t]he canon against surplusage is not an absolute rule[.]" *Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 385 (2013).

beyond corrupt kickbacks, bribes, and rebates. *See* Pl.'s Resp. 10–13; Pl.'s Reply 8–10; *see also* Pl.'s Mem. Supp. 6, 20–21. But the federal courts of appeals who have considered the issue agree that "[t]he phrase 'any remuneration' was intended to broaden the reach of the law." *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995); *accord Pfizer*, 42 F.4th at 75, 75 n.7 ("[T]he original 1972 version of the AKS . . . prohibited only kickbacks, bribes, or rebates. Congress did not expand the statute to cover 'any remuneration' until the statute was amended in 1977. . . . Pfizer argues that the 1977 amendment is immaterial . . . because it did not alter the statute's original focus on corrupt payments. But the plain meaning of 'remuneration' is clearly broader than a kickback, bribe, or rebate: 'Remuneration' means '[p]ayment; compensation, esp[ecially] for a service that someone has performed,' and the modifier 'any' further broadens the scope of the phrase. . . . Congress[] broaden[ed] . . . the AKS through the 1977 amendment."); *see also United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) ("By adding 'remuneration' to the statute in the 1977 amendment, Congress sought to make it clear that even if the transaction was not considered to be a 'kickback' for which no service had been rendered, payment nevertheless violated the Act. . . . [A] more expansive reading is consistent with the impetus for the 1977 amendments[.]"). This Court must give effect to Congress's intent, as reflected in the text.

In sum, the "(including any kickback, bribe, or rebate)" parenthetical is no basis to deviate from the plain, intentionally broad meaning of "any remuneration." The Court thus finds that HHS OIG properly interpreted the AKS in this respect.

3. Canon Against Absurdity

Lastly, PCPA argues that "[t]he canon against absurdity confirms that PCPA's plain language reading of the AKS'[s] *quid pro quo* and corruption requirements must apply." Pl.'s

Mem. Supp. 24. Again, the Court is unpersuaded.

Though really a vehicle to evade the plain meaning of a statutory text, the canon against absurdity has been described as "an implementation of (rather than . . . an exception to) the ordinary meaning rule." W. Eskridge, INTERPRETING LAW 72 (2016). *But see Hillman v. I.R.S.*, 263 F.3d 338, 342 (4th Cir. 2001) (describing the absurdity canon as an "extremely narrow exception[] to the Plain Meaning Rule"); John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387, 2395 (2003) (describing absurdity doctrine as "operat[ing] as an exception" to the "'plain meaning' presumption"). The canon against absurdity provides that statutes "are to be given a sensible construction"—interpretations that would lead to absurd consequences "should be avoided whenever a reasonable application can be given consistent with the legislative purpose." *United States v. Rippetoe*, 178 F.2d 735, 737 (4th Cir. 1949). Absurdity exists "when literal application of the statutory language at issue results in an outcome that can truly be characterized as absurd, i.e., that is so gross as to shock the general moral or common sense." *In re Sunterra Corp.*, 361 F.3d 257, 265 (4th Cir. 2004). The instances in which the canon against absurdity applies "are, and should be, exceptionally rare." *Id.* (quoting *Hillman*, 263 F.3d at 342).

PCPA maintains that this Court should find that the AKS applies only to corrupt quid pro quos because finding to the contrary would result in absurd overcriminalization. *See, e.g.*, Pl.'s Mem. Supp. 24–25. PCPA raises some hypothetical parties who it claims are at risk of criminal liability under HHS OIG's interpretation, such as a generous son who helps to cover the cost of his elderly mother's medical treatment. *Id.* at 24. But a concerned son would presumably help pay for any needed medical treatment or product whatever the treatment and source of payment for the rest of the cost—i.e., regardless of whether that treatment or product was federally

reimbursable. Contrast that to PCPA's proposed program, which is specifically designed to induce Medicare beneficiaries to select only from certain federally reimbursable products offered by the participating manufacturers, and each participating manufacturer would only pay cost-sharing subsidies for its own products. The concerned son does not have the same financial interest that the pharmaceutical companies have in whether the federal government reimburses the company for the drug—again, the son just wants to help his mom. So, it does not strike the Court as overly likely that PCPA's hypothetical, do-gooder family member would provide financial assistance to their loved one with the purpose of inducing them to buy specifically a *federally reimbursable* health product to bring them within the provisional scope of the AKS in the first instance, let alone that they would act with the requisite "purpose to commit a wrongful act" in so doing.[19] *United States v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498 (D.S.C. 2016) (citing *United States v. McClatchey*, 217 F.3d 823, 829 (10th Cir. 2000)) ("To *prove* a violation of the AKS, the Government will need to show that Defendants acted with a purpose to commit a wrongful act." (emphasis in original)); *see also Pfizer*, 42 F.4th at 79 ("[I]t is difficult to imagine the circumstances under which a family member's financial support would carry the specific purpose of inducing the purchase of a federally reimbursable drug."). The Court is thus unpersuaded that HHS OIG's reading of the AKS (that is, its reading of the AKS's plain text) leads to a practical result that "is so gross as to shock the general moral or common sense." *See In re Sunterra Corp.*, 361 F.3d at 265.

[19] PCPA insists that under the Agency's reading of the AKS, "all that is required is that a person knows he or she is giving something of value that will help a patient obtain a federal service." Pl.'s Reply at 14. That is wrong. It is required that a person knows he or she is giving something of value *to induce* a patient to obtain a federally reimbursable service (not just to help them financially), and it is further required that said person *know that their conduct is unlawful* (not necessarily that they know that their conduct violates the AKS specifically, but rather that they just know that their conduct violates *some* law). *See United States ex rel. Hart v. McKesson Corp.*, 602 F. Supp. 3d 575, 592–95 (S.D.N.Y. 2022) (unpacking the AKS's mens rea requirement).

The AKS is broad. But that is Congress's call. *Cf. Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 576 (1982) ("The remedy for any dissatisfaction with the results in particular cases lies with Congress and not with this Court."). PCPA has not persuaded the Court that this is one of those "exceptionally rare" instances where the absurdity canon must apply and override the plain text of the statute at hand. *See In re Sunterra Corp.*, 361 F.3d at 265. Accordingly, the Court cannot agree with PCPA that HHS OIG's adherence to the AKS's plain text was contrary to law.

B. Dissimilar Treatment

Next, PCPA alleges that the negative opinion is arbitrary and capricious because HHS OIG has treated PCPA in a dissimilar fashion to other similarly situated parties. PCPA lodges two "safe harbor"-based arguments. First, PCPA says that the instant negative opinion is inconsistent with past opinions where HHS OIG issued favorable opinions by choosing to not impose sanctions on arrangements the Agency found could violate the AKS (something the Agency has called "particularized" or "case specific" safe harbors, *see* 63 Fed. Reg. 38313 (July 16, 1998)). *See* Pl.'s Mem. Supp. 25–26. Second, and alternatively, PCPA argues that the negative opinion is inconsistent with HHS OIG's adoption of safe harbors that are codified at 42 C.F.R. § 1001.952(k). *See* Pl.'s Mem. Supp. 26–27. The Court finds that both arguments fail right off the block, before even reaching the merits.

1. Reviewability of HHS OIG's Exercise of Sanction Authority

HHS OIG argues that the Court lacks the authority to hear PCPA's first dissimilar treatment claim because the aspect of the negative opinion PCPA seeks to challenge as arbitrarily and capriciously dissimilar—the Agency's imposition of administrative sanctions—is unreviewable as a matter of law. *See* Def.'s Mem. Supp. 14–18. HHS OIG thus argues that the

Court must dismiss this claim for lack of subject matter jurisdiction. *See id.* The Court agrees and accordingly will dismiss this claim.

To refine the precise reviewability question here, a bit more background is needed on the prior favorable opinions and the present negative opinion PCPA challenges. In all of the past opinions to which PCPA cites, HHS OIG concluded that the proposed schemes could run afoul of the AKS if the requisite mens rea were present. *See* AR 3835, 3839, 3842, 3845, 3849, 3853, 3859, 3862–63 (Advisory Ops. Nos. 07-18, 06-10, 06-13, 07-06, 07-11, 07-18, 10-07, 11-05). HHS OIG concluded the exact same in the advisory opinion in this case. *See* AR 106 (Advisory Op. 22-19). So, that legal determination is not the dissimilar treatment of which PCPA complains. Where the past opinions and the opinion in this case diverge—and thus the crux of PCPA's argument here—was whether HHS OIG would impose administrative sanctions in connection with the proposals. In the prior decisions, HHS OIG concluded it "would not," AR 3835, 3839, 3842, 3845, 3849, 3853, 3859, 3862–63, whereas in this case, the Agency concluded that it "would," AR 106 (Advisory Op. 22-19). Thus, this dissimilar treatment claim turns on HHS OIG's decision to impose sanctions, and the instant question is thus whether that decision is reviewable.

As "the Supreme Court has instructed, '[courts] begin with the strong presumption that Congress intends judicial review of administrative action.'" *Inova Alexandria Hosp. v. Shalala*, 244 F.3d 342, 346 (4th Cir. 2001) (quoting *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667, 670 (1986)). With that in mind, the Court turns to the APA, which provides that agency action is unreviewable if the "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). "This exception to judicial review is a 'very narrow one,' reserved for 'those rare instances where statutes are drawn in such broad terms that in a given case there is no law to

apply.'" *Inova Alexandria Hosp.*, 244 F.3d at 346 (quoting *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971)). There is "no law to apply" if the statute provides a court "no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). "In determining whether a 'meaningful standard' for reviewing agency discretion exists, courts consider the particular language . . . of the statute in question, as well as 'the nature of the administrative action at issue.'" *Speed Mining, Inc. v. Fed. Mine Safety & Health Rev. Comm'n*, 528 F.3d 310, 317 (4th Cir. 2008) (internal citations omitted). Where there is "no law to apply," a federal court is without subject matter jurisdiction as to that issue. *See Angelex Ltd. v. United States*, 723 F.3d 500, 505–06 (4th Cir. 2013).

Applying these principles, the Court finds that HHS OIG's decision to conditionally impose sanctions against PCPA is "committed to agency discretion by law" and therefore unreviewable.

First, the "particular language" of the relevant statutory provisions provides no meaningful standard of review. *Speed Mining*, 528 F.3d at 317. The operative statute for the HHS OIG's advisory opinion process is 42 U.S.C. § 1320a-7d(b), which states that the HHS Secretary "shall issue written advisory opinions as provided in this subsection." Subsection (b)(2) fleshes out the "[m]atters subject to advisory opinions," which include "[w]hether any activity or proposed activity constitutes grounds for the imposition of a sanction under section 1320a-7, 1320a-7a, or 1320a-7b of this title." *Id.* § 1320a-7d(b)(2)(E). In all the advisory opinions forming the basis of PCPA's arbitrary-and-capricious claim, HHS OIG was deciding whether to impose administrative sanctions specifically under sections 1320a–7(b)(7) or 1320a-7a(a)(7),[20] as those sections relate to the commission of acts violative of the AKS. *Compare* AR

[20] The advisory opinions all use the corresponding section numbering provided by the Social Security Act—sections 1128(b)(7) or 1128A(a)(7) of the Act. *See, e.g.*, AR 85 (Advisory Op. 22-19).

85 (Advisory Op. 22-19); *with* AR 3835, 3839, 3842, 3845, 3849, 3853, 3859, 3862–63. So, those are the operative provisions. But neither provision supplies "law to apply."

Neither § 1320a–7(b)(7) nor § 1320a-7a(a)(7) furnishes manageable standards by which to judge HHS OIG's choice to impose sanctions. First, § 1320a–7(b)(7) (housed in a subsection titled "Permissive exclusion") provides that "[t]he Secretary may exclude . . . from participation in any Federal health care program . . . [a]ny individual or entity that the Secretary determines has committed an act" that would subject the individual or entity to criminal or civil penalties under the AKS. The word "may" confers discretion—it permits, but does not require, the Secretary to exclude an individual or entity. *See* BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "may" as "[t]o be permitted to"). Although there are obviously manageable standards to determine when the civil or criminal penalty provisions are implicated, § 1320a–7(b) provides the Secretary with no direction as to when it should exercise the discretion to exclude an individual or entity in a particular case after determining that penalties may be imposed. All the statute says is that the exclusion decision is entirely "[p]ermissive," resting in the hands of the Secretary.[21] *See* 42 U.S.C. § 1320a-7(b). In other words, "Congress did not outline (even in the broadest brushstrokes) the parameters for" the Secretary's decision to exclude individuals or entities pursuant to § 1320a–7(b)(7). *Angelex*, 723 F.3d at 507. Thus, this section imparts "no law to apply." *See id.*

Section 1320a-7a(a)(7) fares no better. The penalties provision associated with that section states that any individual or entity who pays or receives any remunerations violative of the AKS (1) "shall be subject . . . to a civil money penalty of not more than . . . $100,000 for

[21] Contrast § 1320a-7(b)(7) with the subsections within § 1320a-7(a), all of which provide instances (specifically, certain qualifying criminal convictions) which *require* the Secretary to exclude individuals or entities. 42 U.S.C. § 1320a-7(a) ("The Secretary *shall* exclude the following individuals and entities . . . ." (emphasis added)).

each such act;" and (2) "shall be subject to an assessment of . . . damages of not more than 3 times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose[.]" 42 U.S.C. § 1320a-7a(a).[22] Just like "may," above, the "subject to" language here affords enforcement discretion: an AKS violation will expose an entity to the possibility of sanctions, but the decision to impose those penalties sits within the Secretary's discretionary authority. *See Subject*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("2. Exposed, liable, or prone . . . . 3. Dependent on or exposed to (some contingency); *esp[ecially], being under discretionary authority* . . . ." (emphasis added)); *Subject to*, MERRIAM-WEBSTER (accessed Dec. 19, 2023), https://www.merriam-webster.com/dictionary/subject%20to [https://perma.cc/5FWG-M4JW] ("1. Affected by or *possibly affected* by (something) . . . 3. *Dependent on something else to happen* . . . ." (emphases added)). The statute is silent on when the Secretary should indeed *subject* (used here as a transitive verb) the individual or entity to the sanctions. So, yet again, "[t]his lack of guidelines against which to measure the Secretary's exercise of its enforcement discretion leaves this court with no manageable standard to apply" as to section 1320a-7a(a)(7). *Speed Mining*, 528 F.3d at 317 (alteration and internal quotation marks omitted).

Moreover, the "nature of the administrative action at issue" supports the conclusion that the Secretary's actions as to imposing sanctions are unreviewable. *Id.* at 318 (quoting *Drake v. F.A.A.*, 291 F.3d 59, 70 (D.C. Cir. 2002)). Again, PCPA seeks to challenge HHS OIG's affirmative exercise of enforcement discretion. *See* 42 U.S.C. § 1320a–7(b) ("may"); *id.* § 1320a-7a(a) ("subject to"). *See generally* 63 Fed. Reg. 38313 ("'[P]articularized' or 'case

[22] On top of granting the discretion to impose civil money penalties, § 1320a-7a(a) also provides that "[i]n addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs," which—as explained in this Court's § 1320a-7(b)(7) discussion—also imparts standardless discretionary authority.

specific' safe harbors refer[] simply to a determination by the OIG, in the exercise of prosecutorial discretion, not to impose sanctions for specific arrangements that may constitute technical violations of OIG authorities."). But "an 'agency's exercise of its enforcement discretion' is 'an area in which the courts have traditionally been most reluctant to interfere.'" *Speed Mining*, 528 F.3d at 318 (quoting *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538 (D.C. Cir. 1986))). That is because agency enforcement decisions can "often involve[] a complicated balancing of a number of factors which are peculiarly within [the agency's] expertise." *Heckler*, 470 U.S. at 831; *see Speed Mining*, 528 F.3d at 318. And an agency "is 'far better equipped than the courts' to balance these factors and determine its enforcement priorities." *Speed Mining*, 528 F.3d at 318 (quoting *Heckler*, 470 U.S. at 831–32). "This is true" even for "presumptively reviewable decisions to enforce"[23] such as HHS OIG's discretionary decision to advise that sanctions would be imposed against PCPA in this case. *Id.*

In sum, the Court concludes that the Secretary's administrative sanction decisions in the advisory opinion process are "committed to agency discretion by law" and, therefore, unreviewable. No "meaningful standard" in the relevant statutory provisions exists for reviewing the Secretary's exercise of the discretionary sanction enforcement authority. The Court thus must conclude that it lacks subject matter jurisdiction to entertain this claim, and it will accordingly dismiss it.

2. Issue Exhaustion of Regulatory Safe Harbor Claim

PCPA's second dissimilar treatment argument is that it is arbitrary and capricious for HHS OIG to provide safe harbor to providers that reduce or waive Part D copayments under 42 C.F.R. § 1001.952(k), but not provide the same protection to PCPA (which would reduce, but

[23] As contrasted with "presumptively *un*reviewable decisions *not* to enforce," *Speed Mining*, 528 F.3d at 318 (emphases added), which is not what PCPA seeks to challenge here.

not eliminate, copayments in its proposed program). *See* Pl.'s Mem. Supp. 26–27. The Agency contends that PCPA cannot raise this issue here because it did not do so (and thus it did not exhaust the issue) below. *See* Def.'s Mem. Supp. 20–21; Def.'s Reply 14–17, ECF No. 40. PCPA disagrees. *See* Pl.'s Resp. 22–24. The Court, however, agrees with the Agency.

"In most cases, an issue not presented to an administrative decisionmaker cannot be argued for the first time in federal court." *Probst v. Saul*, 980 F.3d 1015, 1019 (4th Cir. 2020) (quoting *Sims v. Apfel*, 530 U.S. 103, 112 (2000) (O'Connor, J., concurring in part and concurring in the judgment)). But where neither a statute nor a regulation specifically speaks to issue exhaustion in the relevant context, as here,[24] courts do not mindlessly impose an exhaustion requirement; instead, "courts decide whether to require issue exhaustion based on 'an analogy to the rule that appellate courts will not consider arguments not raised before trial courts.'" *Carr v. Saul*, 593 U.S. 83, 88 (2021) (quoting *Sims*, 530 U.S. at 108–09). "The desirability of a court imposing a requirement of issue exhaustion depends on the degree to which the analogy to normal adversarial litigation applies in a particular administrative proceeding." *Id.* (quoting *Sims*, 530 U.S. at 109). This analogical inquiry "requires careful examination of the characteristics of the particular administrative procedure provided." *Id.* (quoting *Sims*, 530 U.S. at 113 (O'Connor, J., concurring in part and concurring in the judgment)) (internal quotation marks omitted). If the agency proceedings (like judicial proceedings) are clearly adversarial, the "general rule" of requiring issue exhaustion applies. *Id.* at 89 n.3; *see United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 37 (1952); *Pleasant Valley Hosp., Inc. v. Shalala*, 32 F.3d 67, 70 (4th Cir. 1994). If, however, after analyzing the procedural particulars, "the question nonetheless remains whether the . . . proceedings at issue . . . [a]re adversarial enough to support

[24] The Agency has not cited any statute or regulation that expressly requires issue exhaustion in the HHS OIG advisory opinion process. *See generally* Def.'s Mem. Supp.; Def.'s Resp.; Def.'s Reply.

the analogy to judicial proceedings," the Supreme Court has identified "two additional considerations" that can "tip the scales" in deciding whether to require exhaustion:[25] (1) the nature of the challenge and whether it "fall[s] outside the adjudicators' areas of technical expertise;" and (2) whether requiring exhaustion would be futile because the "adjudicators . . . are powerless to grant the relief requested." *Carr*, 593 U.S. at 92–93. Ultimately, "the decision of whether to impose [an exhaustion] requirement is left to 'sound judicial discretion.'" *Probst*, 980 F.3d at 1020 (quoting *McCarthy v. Madigan*, 503 U.S. 140, 144 (1992)).

In applying these standards, the two most meaningful data points are the Supreme Court's *Carr v. Saul* and the Fourth Circuit's *Probst v. Saul*, both cases declining to require issue exhaustion of Appointments Clause challenges in Social Security Administration ("SSA") disability benefits proceedings before SSA administrative law judges ("ALJs," plural). *See Carr*, 593 U.S. at 95–96; *Probst*, 980 F.3d at 1025. On this, the parties agree. *See* Pl.'s Resp. 22–23; Def.'s Reply 14–17. Unsurprisingly, they disagree on what these cases tell us. To PCPA, *Carr* and *Probst* show that requiring issue exhaustion is inappropriate here. *See* Pl.'s Resp. 22–23. The Agency gleans the opposite, using the cases to juxtapose what it views as the HHS OIG's advisory opinion process's comparatively adversarial elements and to argue the "general rule" of requiring issue exhaustion should apply. *See* Def.'s Reply 14–17.

On balance, the Court finds that applying an issue exhaustion requirement is appropriate in the context presented here. Finding key differences between the characteristics of HHS OIG's advisory opinion process at issue in this case and the characteristics of the SSA ALJ proceedings relied on in *Carr* and *Probst*, and further finding the two additional *Carr* considerations favor

[25] Though the Supreme Court in *Carr* determined that these two considerations "tip[ped] the scales decidedly against imposing an issue-exhaustion requirement" "[i]n the specific context" presented there, the Court explicitly stated that "[o]utside of th[at] context," "the scales might tip differently." *Carr*, 593 U.S. at 92, 92 n.5.

imposing an exhaustion requirement here, the Court will require issue exhaustion and find for the Agency.

a. The HHS OIG Advisory Opinion Process is Adversarial

The Court finds important differences between the instant HHS OIG proceedings and the SSA ALJ proceedings that make HHS OIG's advisory opinion process considerably much more adversarial. "The critical feature that distinguishes adversarial proceedings from inquisitorial ones is whether claimants bear the responsibility to develop issues for adjudicators' consideration." *Carr*, 593 U.S. at 89. Whereas SSA claimants have essentially no responsibility whatsoever to develop the issues, those requesting advisory opinions from HHS OIG bear the primary responsibility to make their case.

The SSA ALJ process "is not an adversarial one." *Probst*, 980 F.3d at 1022 (internal quotation marks omitted)). Claimants are not required to file a brief; quite the contrary, as the form provides claimants just three to four lines to state their claim to the ALJ. *See Carr*, 593 U.S. at 91 ("[T]he form to request an ALJ hearing provides roughly three lines for claimants to explain their disagreement with the agency's determination[.]"); *Probst*, 980 F.3d at 1023 ("[O]n the standard ALJ hearing-request form, claimants are given a meager four lines to explain why they 'disagree' with their initial benefits determination."). The *Probst* panel found this an aspect of the SSA process that "could actually 'mislead claimants to believe issue exhaustion is not required.'" *Probst*, 980 F.3d at 1023 (quoting *Sims*, 530 U.S. at 114 (O'Connor, J., concurring in part and concurring in the judgment)). Claimants are also not required to provide facts or make any case; instead, "[i]t is the ALJ's duty to investigate the facts and develop the arguments both for and against granting benefits[.]" *Carr*, 593 U.S. at 90; *see Probst*, 980 F.3d at 1022 ("By regulation, SSA ALJs bear a primary and independent responsibility to develop the facts and

issues in a non-adversarial fashion."). As a plurality of justices put it in *Sims v. Apfel* (a case dealing with the issue-exhaustion question in the context of the SSA Appeals Council[26]): "The differences between courts and agencies are nowhere more pronounced than in Social Security proceedings." *Sims*, 530 U.S. at 110 (plurality opinion). Still, though, despite the SSA process being remarkably (and perhaps uniquely) inquisitorial, the *Carr* majority did not hold that the SSA ALJ process was *dispositively* so in the analogical analysis. *See Carr*, 593 U.S. at 92–95 (proceeding to weigh the two, scale-tipping considerations, and "tak[ing] together" the non-adversarial nature of SSA proceedings and the two scale-tipping considerations to reach the ultimate holding).

Turning to the HHS OIG advisory opinion process at issue here, the Court finds it significantly more adversarial at every turn. Unlike the paltry three to four lines available in the SSA context, HHS OIG advisory opinion requests can end up looking just like judicial briefs—for instance, PCPA's request in this case was 38 pages, prepared by legal counsel. *See* AR 1–38 (PCPA Advisory Op. Request). And twenty of those pages were committed to PCPA's legal "Analysis," an in-depth discussion full of citations to cases, statutes, regulations, guidance documents, and other secondary sources. *See id.* at 18–37. This obviously looks much like what this Court sees in adversarial litigation. Ultimately, there can really be no plausible argument that PCPA lacked the opportunity to raise all the arguments it wanted to raise in its advisory opinion request.

Further strengthening the judicial analogy in this context is that fact that, unlike SSA ALJs, HHS OIG does not, "[b]y regulation, . . . bear a primary and independent responsibility to develop the facts and issues" in the advisory opinion process. *See Probst*, 980 F.3d at 1022.

[26] In the SSA adjudicative hierarchy, the Appeals Council sits a level above (and so handles appeals from) the ALJs. *See generally Carr*, 593 U.S. at 86–87.

Instead, the regulations place the burden primarily on the requestor to provide the relevant information and legal issues. *See* 42 C.F.R. § 1008.36(b). The requestor seeking an advisory opinion "must include . . . [a] *complete and specific description of all relevant information* bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the conduct[.]" *Id.* § 1008.36(b)(4) (emphasis added). And the requestor "should identify *the specific subsections* of sections [1320a–7], [1320a–7a] or [1320a–7b][27] or *the specific provision* of § 1001.952 of this chapter about which an advisory opinion is sought[.]" *Id.* § 1008.36(b)(3) (emphases added). PCPA is correct that the regulations permit HHS OIG to request additional information from the requestor and that HHS OIG has the authority to conduct an independent investigation, *id.* § 1008.39(a), (b), (d), but that does not change the fact that the regulations place the onus principally on the requestor to make its case, *see id.* § 1008.36(b), the "critical feature that distinguishes adversarial proceedings from inquisitorial ones" and strengthens the analogy to judicial proceedings, *Carr*, 593 U.S. at 89. Given all of these significant differences between the SSA and HHS OIG procedures, the Court is unpersuaded that the HHS OIG process, like the SSA process, could be reasonably understood as "affirmatively suggest[ing] that specific issues need not be raised," *Sims*, 530 U.S. at 113 (O'Connor, J., concurring in part and concurring in the judgment),[28] or "actually 'mislead[ing] [requestors] to believe issue exhaustion is not required,'" *Probst*, 980 F.3d at 1023 (quoting *Sims*, 530 U.S. at 114 (O'Connor, J., concurring in part and concurring in the judgment)).

At bottom, there can be no debate that the HHS OIG advisory process is an immensely

[27] The regulation refers to the sections as numbered in the Social Security Act—"sections 1128, 1128A or 1128B of the Act," 42 C.F.R. § 1008.36(b)(3)—which correspond to the sections of Title 42 of the United States Code substituted in the quote.

[28] Justice O'Connor's concurrence is the controlling opinion from *Sims*. *See Probst*, 980 F.3d at 1022 (citing *Marks v. United States*, 430 U.S. 188, 193–94 (1977)) ("Justice O'Connor's [*Sims*] analysis . . . controls.").

stronger analogue to adversarial judicial proceedings than the SSA ALJ process. Unlike SSA proceedings, where the ALJs are required make a claimant's case for them, in the HHS OIG context, requestors of advisory opinion bear the primary responsibility to develop the factual and legal arguments to defend their proposals. This "critical feature" leads the Court to find the HHS OIG advisory opinion process sufficiently adversarial to support the judicial analogy and trigger "general rule" barring judicial review of this unexhausted issue. *Carr*, 593 U.S. at 89, 89 n.3; *see Pleasant Valley Hosp.*, 32 F.3d at 70 ("As a general matter, it is inappropriate for courts reviewing appeals of agency decisions to consider arguments not raised before the administrative agency involved.").

b. The Additional Carr *Factors Also Support an Issue Exhaustion Requirement*

Proceeding as though "the question nonetheless remains whether" the HHS OIG advisory opinion process is "adversarial enough to support the analogy to judicial proceedings," *Carr*, 593 U.S. at 92, the Court turns to the additional considerations outlined in *Carr*: (1) the nature of the challenge and (2) futility. *See id.* at 92–96. In *Carr*, these considerations "tip[ped] the scales decidedly against" requiring exhaustion. *Id.* at 92. But this Court finds that in this case—one lying "[o]utside the context of Appointments Clause challenges"—the "scales . . . tip differently." *Id.* at 92 n.5.

In *Carr* (and in *Probst*), the petitioners sought to bring Appointments Clause challenges to the very ALJs who heard their cases. *See Carr*, 593 U.S. at 85; *Probst*, 980 F.3d at 1019. Those were "purely constitutional claims about which SSA ALJs ha[d] no special expertise[.]" *Carr*, 593 U.S. at 93. And the ALJs were "powerless to grant the relief requested," because the ALJs were not capable "of remedying any defects in their own appointments." *Id.* at 93–94.

Thus, "[b]oth considerations appl[ied] fully" in *Carr* to tip the scales against an exhaustion requirement. *Id.* at 93.

But here, "[b]oth considerations apply fully" *in favor* of an exhaustion requirement. *Id.* The particular issue PCPA seeks to raise here—whether its proposal is comparable to certain cost-sharing waivers permitted under 42 C.F.R. § 1001.952(k)—is, obviously, not a constitutional question. Instead, is "well within the expertise of" HHS OIG (it is the Agency's own regulation, after all). Def.'s Reply 16. Further, the Agency had the authority to provide precisely what PCPA sought—a favorable advisory opinion—so, HHS OIG was not "powerless to grant the relief requested." *Carr*, 593 U.S. at 93. PCPA thus cannot plausibly argue that raising this issue below would have been futile. *See id.* at 93–94; *cf.* Pl.'s Resp. 23–24.

c. Summation

Taken together, the adversarial features of the HHS OIG advisory opinion process, the familiar character (to the Agency, at least) of PCPA's instant claim, and the ready availability of the precise remedy sought, leave the Court convinced that sufficient "adversarial development" of this claim "could [have] exist[ed]" here and that this particular context sufficiently "support[s] the analogy to judicial proceedings[.]" *Carr*, 593 U.S. at 92, 95–96 (internal quotation marks omitted). Therefore, finding it a "sound" exercise of its "judicial discretion," *Probst*, 980 F.3d at 1020 (quoting *McCarthy*, 503 U.S. at 144), the Court will impose an issue-exhaustion requirement on PCPA's regulatory safe harbor dissimilar treatment claim. By not raising the claim before the Agency, *see generally* AR 1–38 (PCPA Advisory Op. Request), PCPA has forfeited the argument here. The Court thus finds for the Agency as a matter of law on this claim.

C. HHS OIG's 2005 Guidance Document

PCPA next argues that a Special Advisory Bulletin guidance issued by HHS OIG in 2005 ("2005 Guidance" or "Guidance") renders the negative advisory opinion arbitrary and capricious. *See* Pl.'s Mem. Supp. 27. On this argument, too, the Court disagrees.

To understand why this argument fails, some background on the 2005 Guidance is in order. The Agency issued the Guidance to explain the interplay between patient assistance programs ("PAPs"), Medicare Part D, and the AKS. *See* 70 Fed. Reg. 70623–24 (Nov. 22, 2005). HHS OIG stated that "pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute." *Id.* at 70624. The Agency stated it was issuing the Guidance "to identify potentially abusive PAP structures, as well as methods of providing assistance that mitigate or vitiate the potential for fraud and abuse." *Id.* But on any legal questions surrounding "Coalition Model" PAPs like PCPA's proposed one here, the 2005 Guidance disclaimed that "[i]t is premature to offer definitive guidance on these evolving programs." *Id.* at 70627. That is "because the Part D benefit ha[d] not yet begun," so the Agency conspicuously stipulated that "any assessment of fraud and abuse is necessarily speculative[.]" *Id.* at 70624. The Agency went on: "[T]his Bulletin cannot, and is not intended to, be an exhaustive discussion of relevant risks or beneficial practices." *Id.* Yet, the Guidance tentatively "observe[d] that the risk of an illegal inducement potentially may be reduced if"—

> (i) The program contains features that adequately safeguard against incentives for card holders to favor one drug product (or any one supplier, provider, practitioner, or Part D plan) over another; (ii) the program includes a large number of manufacturers, including competing manufacturers and manufacturers of both branded and generic products, sufficient to sever any nexus between the subsidy and a beneficiary's choice of drug; and (iii) each participating pharmaceutical manufacturer offers subsidies for all of its products that are covered by any Part D plan formulary.

Id. at 70627. But in the following sentence, the Guidance specified that "[o]ther safeguards may

also be needed to reduce the risk of an improper inducement" and keep a Coalition Model PAP legal under the AKS (mens rea pending). *Id.* To go along with its clearly non-exhaustive, non-committal discussion on suggested, potential practices which may reduce risk of illegality, the Guidance explicitly commanded that the ultimate "determination regarding whether a particular arrangement violates the anti-kickback statute requires a case-by-case evaluation of all of the relevant facts and circumstances, including the intent of the parties." *Id.* at 70625.

PCPA's arbitrary and capriciousness argument here rests entirely on the premise that HHS OIG "fail[ed] to follow [the] Guidance" in issuing the negative opinion. Pl.'s Mem. Supp. 27; *see also* Pl.'s Resp. 28 ("Because the Opinion does not apply the [2005] Guidance and is inconsistent with it, PCPA is entitled to the relief it seeks on that basis."). PCPA is correct that when an agency "change[s] course . . . [it] must provide a reasoned analysis indicating that prior policies and standards are being deliberately changed, not casually ignored," and that failure to do so "constitutes an inexcusable departure" that renders the challenged action arbitrary and capricious. *Ramaprakash v. F.A.A.*, 346 F.3d 1121, 1124–25 (D.C. Cir. 2003) (Roberts, J.) (internal quotation marks omitted), *cited in* Pl.'s Mem. Supp. 27. PCPA is also correct that "[w]hen an agency changes course, . . . it must be cognizant that longstanding policies may have engendered serious reliance interests," and an agency "ignor[ing] such matters" is arbitrary and capricious. *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. ----, 140 S. Ct. 1891, 1913 (2020) (Roberts, C.J.), *quoted in* Pl.'s Resp. 26. But PCPA's correctness stops there.

Given the 2005 Guidance's entirely precatory language and conspicuous retention of case-by-case discretion, HHS OIG's negative opinion in this case cannot, as PCPA insists, be understood as a change in course from the Guidance. Rather, the negative opinion was a faithful *application* of the Guidance. The Guidance made clear that it was taking no definitive stance on

the legality of any proposal. *See* 70 Fed. Reg. at 70627 ("It is premature to offer definitive guidance on these evolving programs."); *see also id.* at 70624 ("[B]ecause the Part D benefit has not yet begun, and any assessment of fraud and abuse is necessarily speculative . . . ."). Contrary to PCPA's mischaracterizations, the Guidance explicitly stated that none of the features that it mentioned (even if all present) would guarantee that a proposal comports with the AKS's requirements. *See id.* at 70627 ("[T]he risk of an illegal inducement *potentially may* be reduced if: [a program includes certain enumerated safeguards]. Other safeguards *may also be needed* to reduce the risk of an improper inducement." (emphases added)); *cf.* Pl.'s Mem. Supp. 19 (asserting that the Agency "concede[d]" in the Guidance that certain features automatically make a coalition model proposal legal under the AKS); Pl.'s Reply 17 (pointing again to this purported "concession"). Instead, the Guidance explicitly mandated that the ultimate "determination regarding whether a particular arrangement violates the anti-kickback statute requires a case-by-case evaluation of all of the relevant facts and circumstances[.]" *Id.* at 70624.

In this case, HHS OIG followed the Guidance's sole requirement to a tee. The Agency conducted the required fresh legal analysis under the AKS and concluded that PCPA's proposal "would generate prohibited remuneration if the requisite intent were present" (and thus would run afoul of the AKS if the intent were there) "[b]ased on the relevant facts" and information PCPA presented to the Agency. AR 86, 106 (Advisory Op. 22-19). *See generally id.* at 93–106. The Agency decided the advisory opinion *exactly* how the Guidance said it would.[29] There is no conflict. And because the opinion did not constitute a shift in any "longstanding polic[y]," the Court cannot say that the negative opinion harmed any of PCPA's "serious reliance interests."

[29] In addition to adhering to the Guidance's directive to analyze PCPA's proposal's conformity with the AKS based on the specific facts and context presented by the proposal, the opinion fully recognized that PCPA attempted to structure its proposal based on the Guidance and engaged with the Guidance head-on in that respect. *See* AR 100–06 (Advisory Op. 22-19).

Regents of the Univ. of Cal., 140 S. Ct. at 1913; *cf.* Pl.'s Resp. 26 n. 26. PCPA's argument thus fails.

In sum, the Court concludes that HHS OIG did not change policy or position without explanation. Accordingly, the 2005 Guidance does not render the negative advisory opinion arbitrary and capricious.

D. First Amendment Violation

As a last-ditch effort, PCPA argues that the negative opinion impermissibly infringes on PCPA's First Amendment[30] rights. PCPA never makes up its mind whether it is raising a free-standing First Amendment claim, or if it is simply claiming that the First Amendment implications render the negative opinion arbitrary and capricious. *Compare, e.g.*, Pl.'s Resp. 29 n.28 (asserting that HHS OIG's interpretation of the AKS effectuates a "substantive violation of the First Amendment" against PCPA), *and* Pl.'s Reply 18 n.18 (arguing that the negative opinion's "burden [it] place[s] on speech cannot survive strict scrutiny and thus violates the First Amendment"), *with* Pl.'s Mem. Supp. 30 ("The[] fundamental constitutional considerations underscore the arbitrary and capricious character of OIG's refusal to issue a favorable opinion."), *and* Pl.'s Resp. 28 ("[The] Opinion was arbitrary and capricious because it failed to consider the impact of its determination on PCPA's First Amendment rights."). Either way, PCPA is wrong.[31]

Though "the solicitation of charitable contributions is protected speech" under the First Amendment, *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 789 (1988), that does

[30] "Congress shall make no law . . . abridging the freedom of speech . . . ." U.S. Const. amend. I.

[31] As what appears to be a third, distinctive argument, PCPA insists that the Court should apply the canon of constitutional avoidance in interpreting "induce" in the AKS and should read in a corruption requirement. *See* Pl.'s Second Not. Supp'l Auth. 4–5; Pl.'s Mem. Supp. 30 n.74; Pl.'s Resp. 29 n.28. But for the same reasons PCPA's two primary First Amendment arguments fail, this argument does too. *Cf.* discussion *supra* n.17.

not mean that all *conduct* relating to the solicitation of money enjoys absolute constitutional protection, even when speech is involved. Quite the opposite: "it has never been deemed an abridgment of freedom of speech or press to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed." *Rumsfeld v. Forum for Acad. & Inst'l Rts., Inc.*, 547 U.S. 47, 62 (2006) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)). "Such an expansive interpretation of the constitutional guaranties of speech and press would make it practically impossible ever to enforce laws against . . . agreements and conspiracies deemed injurious to society." *Giboney*, 336 U.S. at 502; *see also Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 456 (1978) ("[T]he [Government] does not lose its power to regulate commercial activity deemed harmful to the public whenever speech is a component of that activity.").

PCPA argues that, without a favorable advisory opinion, it "cannot communicate with the public about the crisis in oncology access, the barriers to access created by Medicare, and how [PCPA's] program can address those critical issues[.]" Pl.'s Mem. Supp. 29. None of that is true. All the negative opinion does is interpret the AKS as preventing PCPA from paying or offering to pay certain remunerations to induce certain purchases. PCPA is entirely free to discuss with anyone the crisis in oncology access. PCPA can also speak freely about barriers to access created by Medicare. PCPA can talk about how its program could have addressed those issues and how it wishes the AKS did not prohibit the program. The negative opinion does no more than advise PCPA that it will be subject to liability if it engages in certain forms of transactions. The fact that those transactions might be facilitated via speech does not cause the opinion to run afoul of the First Amendment, nor can that fact render the negative opinion arbitrary and capricious on First Amendment grounds. *See United States v. Regeneron Pharms.,*

Inc., 2020 WL 7130004, at *17 (D. Mass. Dec. 4, 2020) ("[C]ommunicating with charities about their spending on specific drugs may be protected speech, but making donations to induce claims for one's own drugs based on that information is not.").[32]

The negative opinion thus does on infringe on PCPA's First Amendment rights, and the Court finds no First Amendment basis to vacate the Agency's decision.

IV. CONCLUSION

None of PCPA's theories provide a basis for the Court to grant PCPA the APA relief it seeks here. The Agency's interpretation of the AKS adheres faithfully the statute's plain text, comports with its context, and does not offend its history. And that interpretation does not shock the general moral. PCPA's two dissimilar treatment claims fail on distinct procedural grounds: the Court lacks subject matter jurisdiction over—and thus will dismiss—the first, and the Court further finds that PCPA has forfeited the second. Nothing in the 2005 Special Advisory Bulletin dictates a different result than that which the Agency reached in its negative advisory opinion. And the advisory opinion does not violate PCPA's constitutional free speech rights. The Court will thus grant Defendants' Motion to Dismiss for Lack of Subject Matter Jurisdiction and

[32] PCPA incorrectly asserts that *Regeneron* "supports [its] position." Pl.'s Reply 18 n.18. PCPA insists that the court there only found no First Amendment problem because it first applied something "consistent with a corruption requirement" by concluding that the remunerations at issue had "'impermissibly influence[d]' choice of therapy and were, therefore, 'improper.'" *Id.* (quoting *Regeneron*, 2020 WL 7130004, at *17). But PCPA's continued attempts to equate words such as "improper," "impermissible," and "prohibited" in the AKS context to "corruption" are as unavailing here as they have been throughout this Opinion. *Cf.* discussion *supra* Part III.A.2.

By finding "improper[iety]" and "impermissibl[e] influence," the *Regeneron* court did not conclude that corruption (or anything similar) is required under the AKS, nor did it find corruption. Instead, terms like "illegal" and "improper" to describe remunerations and influence (as those terms are used in the AKS and in the *Regeneron* opinion, respectively) simply serve to differentiate remunerations to induce purchases of federally reimbursable health products (which are "illegal" and thus "improper" under the AKS) from any other remunerations (which do not come within the AKS's scope). *See* discussion *supra* Part III.A.2; *see also Regeneron*, 2020 WL 7130004, at *13–14 ("In summary, the complaint alleges that defendant paid remuneration to patients, through donations to CDF, in order to induce physicians to recommend Medicare-subsidized purchases of defendant's drugs and to induce patients to purchase those drugs. The complaint thus alleges sufficient facts to support each material element of an AKS violation.").

Defendants' Motion for Summary Judgment, and the Court will deny in full PCPA's Motion for Summary Judgment.

An appropriate Order will accompany this Memorandum Opinion.

/s/ RCY
Roderick C. Young
United States District Judge

Richmond, Virginia
Date: January 17, 2024