

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

**VERTEX PHARMACEUTICALS
INCORPORATED,**

Plaintiff,

v.

**UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, *et al.*,**

Defendants.

Civil Action No. 24-2046 (JEB)

MEMORANDUM OPINION

Vertex Pharmaceuticals Incorporated has developed an innovative gene-editing therapy to treat — and potentially cure — two serious blood disorders: sickle-cell disease and transfusion-dependent beta-thalassemia. Patients who receive the therapy (called CASGEVY) must first undergo chemotherapy, which can have severe adverse effects on their fertility. Worried that those effects will deter many patients from opting for treatment with CASGEVY, Vertex proposed a program that would provide eligible CASGEVY patients with up to \$70,000 for fertility-support services. The company then sought an advisory opinion from the Department of Health and Human Services about the lawfulness of that program and, after a lengthy back-and-forth, was eventually informed that its proposal would run afoul of the Anti-Kickback Statute and the Beneficiary Inducement Statute. Vertex then initiated this suit against HHS, its Office of Inspector General, and their top officials, challenging the agency’s interpretation of the relevant statutes as contrary to law. The parties have now filed Cross-Motions for Summary Judgment. Although Vertex does admirable work in pressing its view of nuanced statutes, the Court

ultimately concludes that HHS’s interpretation was lawful and thus grants its Motion and denies Plaintiff’s.

I. Background

A. Legal Background

Many elderly, disabled, and low-income Americans receive health insurance via Medicare or Medicaid. Through both programs, the Government reimburses healthcare providers for delivering medical care to qualifying individuals. See New LifeCare Hosps. of N.C., LLC v. Becerra, 7 F.4th 1215, 1219 (D.C. Cir. 2021). In 1972, in response to concerns that pecuniary motives were improperly driving healthcare decisions, Congress enacted the Medicare and Medicaid Fraud and Abuse Statute — popularly known as the Anti-Kickback Statute. See Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). The law seeks to prevent providers from offering and patients from selecting, in exchange for financial rewards and on the Government’s dime, healthcare services that are unnecessary, overly expensive, or otherwise medically inappropriate. To do so, it deems guilty of a felony anyone who

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.

42 U.S.C. § 1320a-7b(b)(2).

The initial 1972 version of the statute did not use word “remuneration” — instead applying solely to “kickback[s],” “bribe[s],” and “rebate[s]” — and it imposed only misdemeanor penalties. See 86 Stat. at 1419. Congress expanded the scope of the statute in 1977, however, to encompass “any remuneration”; criminalize not only its offering and payment,

but also its solicitation and receipt; and provide felony penalties for violations. See Pub. L. No. 95-142, § 4, 91 Stat. 1175, 1180 (1977). The Anti-Kickback Statute’s general prohibition is tempered by numerous exceptions. See 42 U.S.C. § 1320a-7b(b)(3). Congress has immunized from the statute’s reach, for example, “a bona fide mental health or behavioral health improvement or maintenance program.” Id. § 1320a-7b(b)(3)(L). In addition to those statutory exceptions, HHS can establish by regulation new safe harbors from the Anti-Kickback Statute’s general prohibition. Id. § 1320a-7d(a).

Decades later, Congress enacted the similar Beneficiary Inducement Statute, which targets patients’ choice of a particular provider as opposed to a particular product. See Pub. L. No. 104-191, § 231(h)(5), 110 Stat. 2012, 2014 (1996). That act imposes civil penalties on any person who

offers to or transfers remuneration to any individual eligible for benefits [under a federal or state healthcare program] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole in part, under [a federal or state healthcare program].

42 U.S.C. § 1320a-7a(a)(5). Like the Anti-Kickback Statute, the Beneficiary Inducement Statute contains several carveouts, including what is referred to as the Promotes Access to Care Exception. That exception establishes that the statute does not proscribe “any . . . remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs.” Id. § 1320a-7a(i)(6)(F).

Because of the harsh penalties at stake, Congress has created a mechanism through which parties can request advisory opinions from HHS resolving whether certain activities would violate either statute. See id. § 1320a-7d(b). The agency has delegated that advisory-opinion function to its Office of Inspector General. See 42 C.F.R. pt. 1008. Such advisory opinions are

binding on both HHS and the party requesting the opinion. See 42 U.S.C. § 1320a-7d(b)(4). HHS is obligated by statute to promulgate regulations that set out the procedures for requesting and issuing an advisory opinion, id., § 1320a-7d(b)(5)(A), and that require the agency to issue such “advisory opinion by not later than 60 days after the request is received.” Id. § 1320a-7d(b)(5)(B)(i).

B. Factual and Procedural Background

Sickle-cell disease is an inherited blood disorder affecting approximately 100,000 Americans. See ECF No. 25 (Joint Appendix) at ECF p. 3 (Vertex Request) at 5 [ECF p. 7]. Gene mutations cause red blood cells — normally disc shaped and flexible — to become “rigid, sickle-shaped, and sticky.” Id. at 6 [ECF p. 8]. Those sickle-shaped cells block the flow of blood and oxygen throughout the body, causing chronic (often intense) pain, along with other physical and psychological difficulties. Id. at 6–7, 8–10 [ECF pp. 8–9, 10–12]. The disease is also associated with premature mortality: patients with the disease have a median age of death of 43 years. Id. at 8 [ECF p. 10]. Approximately 50% to 60% of people with sickle-cell disease are enrolled in Medicaid. See Joint Appendix at ECF p. 417 (Vertex Feb. 2024 Request for Opinion), Exh. A at ECF p. 420. Although several treatments can manage the disease’s symptoms, see Vertex Request at 21–25 [ECF pp. 23–27], only one curative therapy exists: hematopoietic-stem-cell transplantation. Id. at 26 [ECF p. 28]. Fewer than 25% of people have an appropriate genetic donor for the standard stem-cell transplant procedure, however, and patients must be healthy enough to tolerate an intensive chemotherapy regimen. See Joint Appendix at ECF p. 475 (Stem Cell Transplant Study) at 1.

Transfusion-dependent beta-thalassemia (TDT), which affects approximately 2,000 Americans, is another hereditary blood disorder. See Vertex Request at 14 (ECF p. 16). It is

caused by anomalies in the synthesis of hemoglobin that reduce red-blood-cell production and lead to anemia. Id. Approximately 45% of TDT patients who are insured are covered by Medicare, Medicaid, or the Department of Veterans Affairs. Id. at 15 [ECF p.17]. Like with sickle-cell disease, hematopoietic-stem-cell transplantation is the only established curative therapy for TDT. Id. at 30 [ECF p. 32]. Given the aforementioned challenges with that procedure, however, the current standard of care requires blood transfusions administered every two to five weeks for the duration of the patient’s life. Id. at 28 [ECF p. 30]. Individuals with TDT need those regular blood transfusions to survive. Id. at 14 [ECF p. 16]. Still, patients often develop complications as a result of such frequent transfusions, and the median age of death for a person with TDT is 37 years. Id. at 14–15 [ECF pp. 16–17].

Plaintiff Vertex is a biotechnology company “that develops and manufactures innovative medicines to treat patients with serious diseases.” ECF No. 12 (Am. Compl.), ¶ 3. One such treatment is a one-time therapy that is a functional cure for sickle-cell disease and TDT. That therapy, CASGEVY, uses genome-editing technology to modify patients’ stem cells in a way that induces them to produce fetal hemoglobin. See Vertex Request at 16–17 [ECF pp. 18–19]. That hemoglobin production “reduce[s] manifestation of their disease.” Id. at 16 [ECF p. 18]. Based on efficacy studies, CASGEVY promises to be a highly effective treatment for both sickle-cell disease and TDT. Id. at 19 [ECF p. 21]. CASGEVY patients, however, must undergo an arduous multistep process to prepare for the treatment. Id. at 17–18 [ECF pp. 19–20]. Part of that process is a chemotherapy regimen that suppresses the patient’s bone-marrow activity, which allows the edited stem cells to be grafted into the bone marrow. Id. at 18 [ECF p. 20]. That chemotherapy is “associated with numerous serious side effects,” including adverse consequences for patients’ fertility. Id. It is no surprise “that many [sickle-cell disease] patients

may delay or reject gene therapy due to the risk and fear of infertility.” Joint Appendix at ECF p. 214 (Vertex Oct. 2023 Provision of Information) at 7 [ECF p. 220]. Fertility treatments, however, are “typically not covered by insurance, especially by federal health care programs.” Vertex Request at 46 [ECF p. 48].

In June 2023, see id. at 1 [ECF p. 3], Vertex requested an advisory opinion from HHS regarding a program it proposed “to facilitate appropriate access to [CASGEVY] and to foster the safety and well-being of patients to be treated with [CASGEVY] both before and after treatment.” Id. at 30 [ECF p. 32]. That program, which it called the Fertility Support Program, would “provide financial support, up to a maximum of \$70,000, for medically necessary fertility support for eligible male and female patients prescribed [CASGEVY] and whose insurance does not cover fertility.” Id. at 34 [ECF p. 36]. Vertex explained that the Program would “remove barriers to treatment and facilitate adherence to independent treatment decisions by making it possible for patients to . . . take steps to potentially preserve their fertility.” Id. at 40 [ECF p. 42].

Thirteen days later, HHS — via its Office of the Inspector General — formally accepted Vertex’s request for an advisory opinion and requested additional information it deemed necessary “to render an informed opinion.” Joint Appendix at ECF p. 212 (HHS Acceptance) at 1–2 [ECF pp. 212–13]. The agency told Vertex that, pursuant to internal regulations, “the time for preparing your advisory opinion will be tolled from the date of this letter until we receive the requested information.” Id. at 2 [ECF p. 213]. Vertex provided the requested information several months later, in October. See Vertex Oct. 2023 Provision of Information at 1 [ECF p. 214].

At the end of November, HHS verbally informed Plaintiff that it believed the Fertility Program would violate the Anti-Kickback and Beneficiary Inducement Statutes and that Vertex's request would thus result in an unfavorable advisory opinion. See Joint Appendix at ECF p. 241 (Vertex Dec. 2023 Request for Opinion) at 1; ECF No. 19 (Vertex Mot.) at 6. After Vertex requested a written opinion, see Vertex Dec. 2023 Request for Opinion, the agency again asked for additional information about the Program and stated that “the time period for the issuance of the advisory opinion[] will be tolled until we receive the requested information.” Joint Appendix at ECF p. 248 (HHS Dec. 2023 Email) at 2 [ECF p. 249]. Around the same time, the Food and Drug Administration approved CASGEVY as a treatment for sickle-cell disease. See Joint Appendix at ECF p. 359 (Vertex Dec. 2023 Request for Reconsideration) at 1, 5–6 [ECF pp. 359, 363–64]; Vertex Mot. at 7. Citing that approval, Vertex requested that HHS reconsider its position on the Program's lawfulness. See Vertex Dec. 2023 Request for Reconsideration at 2 [ECF p. 360].

In January 2024, HHS orally informed Vertex that it still would not issue a favorable opinion regarding the Fertility Program, and Vertex requested in response that the agency “move forward expeditiously with finalizing and publishing the advisory opinion.” Vertex Feb. 2024 Request for Opinion at 1 [ECF p. 417]. After Vertex followed up three more times in March, April, and June 2024 about the status of the written opinion, see Joint Appendix at ECF p. 441 (Vertex June 2024 Request for Opinion), HHS eventually informed Plaintiff at the end of June that it had completed the advisory opinion and was “awaiting final clearance from [the Department of Justice.” Joint Appendix at ECF p. 450 (June 2024 Email Thread) at 1. Vertex initiated this litigation in mid-July, requesting — among other things — that this Court compel

HHS to issue a written advisory opinion. See ECF No. 1 (Compl.), ¶¶ 173–79. HHS delivered its final opinion three days later. See Joint Appendix at ECF p. 455 (Advisory Opinion).

As promised, HHS concluded in its advisory opinion that the Fertility Program would constitute “prohibited remuneration under” both the Anti-Kickback Statute and the Beneficiary Inducement Statute if the requisite intent were present. Id. at 2 [ECF p. 456]. Specifically, the agency determined that the Program would be “designed to remove a financial barrier so that eligible patients would purchase [CASGEVY]” and that it could induce healthcare providers to recommend CASGEVY over “competitor drugs or other clinically appropriate treatments.” Id. at 7 [ECF p. 461]. As a result, the Program would violate the Anti-Kickback Statute. HHS similarly decided that the Program was “valuable remuneration” that was likely to influence patients to select certain medical centers and physicians over other options and thus would violate the Beneficiary Inducement Statute. Id. at 8 [ECF p. 462]. Because of the novelty of gene therapies and the lack of information about them, the agency concluded that it could not determine that the Program would be sufficiently low risk to offer prospective immunity under the Anti-Kickback Statute or that it would fall under the Beneficiary Inducement Statute’s Promotes Access to Care Exception. Id. at 6, 8 [ECF pp. 460, 462]. The upshot of the advisory opinion is that Vertex cannot offer the Program to patients insured by government healthcare programs, including Medicare and Medicaid, for fear of inviting an enforcement action. It can, however, continue to offer the Program to commercially insured patients because their medical care is not eligible for federal reimbursement. See Vertex Mot. at 5–6.

Following the release of HHS’s advisory opinion, Vertex filed an Amended Complaint claiming that the Fertility Program does not violate the Anti-Kickback Statute or the Beneficiary Inducement Statute and that the agency’s advisory-opinion regulations are contrary to law for

allowing untimely decisions. See Am. Compl., ¶¶ 139–70. Vertex seeks a declaratory judgment saying so. Id., ¶¶ 166–68. Both parties have now filed Motions for Summary Judgment. See Vertex Mot; ECF No. 21-1 (HHS Mot.).

II. Legal Standard

Although styled as Cross-Motions for Summary Judgment, the submissions in this case seek the Court’s review of an administrative decision. The summary-judgment standard set forth in Federal Rule of Civil Procedure 56 does not apply to Administrative Procedure Act claims because of the limited role of a court in reviewing the administrative record. See Sierra Club v. Mainella, 459 F. Supp. 2d 76, 89–90 (D.D.C. 2006). “[W]hen a party seeks review of agency action under the APA, . . . the district judge sits as an appellate tribunal.” Rempfer v. Sharfstein, 583 F.3d 860, 865 (D.C. Cir. 2009) (quotation marks and citation omitted). The APA “sets forth the full extent of judicial authority to review executive agency action for procedural correctness.” FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009). It requires courts to “hold unlawful and set aside agency action, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). It also obligates courts to “exercise their independent judgment in deciding whether an agency has acted within its statutory authority.” Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412 (2024).

III. Analysis

Vertex primarily takes issue with HHS’s conclusions that its Program would violate both the Beneficiary Inducement Statute and the Anti-Kickback Statute. Because the Court’s discussion of the former will inform how it reads the latter, it considers (and rejects) Plaintiff’s arguments regarding those laws in that order. After doing so, the Court discusses Vertex’s

contention that HHS’s regulations violate the statute’s mandatory timeline for issuing advisory opinions and concludes that it lacks standing on that claim.

A. Beneficiary Inducement Statute

The Beneficiary Inducement Statute forbids “offer[ing] to or transfer[ring] remuneration to any individual eligible for benefits under [a federal or state healthcare program] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [a federal or state healthcare program].” 42 U.S.C. § 1320a-7a(a)(5). HHS concluded that the Fertility Program would run afoul of that statute because the fertility-treatment funds constitute “valuable remuneration” that would likely influence patients to seek out particular treatment centers and physicians. See Advisory Opinion at 8 [ECF p. 462].

Vertex does not appear to disagree with that conclusion. See Vertex Mot. at 30–31. It instead hangs its hat on its belief that its Fertility Program should fall under the Beneficiary Inducement Statute’s exception for “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs.” Id. at 32–38 (quoting 42 U.S.C. § 1320a-7a(i)(6)(F)). HHS has determined by regulation that the Promotes Access to Care Exception applies to:

Items or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—

- (i) Being unlikely to interfere with, or skew, clinical decision making;
- (ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
- (iii) Not raising patient safety or quality-of-care concerns[.]

42 C.F.R. § 1003.110(6). The agency concluded that the Program does not satisfy that exception because it “lack[s] data that would allow [it] to determine that providing the [Fertility Program] to eligible patients improves the ability of patients to access [CASGEVY].” Advisory Opinion at 8 [ECF p. 462].

Vertex does not substantively challenge HHS’s statement that there was a dearth of evidence for applying the exception, see Vertex Mot. at 32–38; ECF No. 22 (Vertex Reply) at 32, and it would face an uphill climb if it attempted to do so. Courts give “an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise,” City of Waukesha v. EPA, 320 F.3d 228, 248 (D.C. Cir. 2003) (quotation marks omitted), and are, moreover, “particularly deferential in matters implicating predictive judgments.” Alon Refin. Krotz Springs, Inc. v. EPA, 936 F.3d 628, 663 (D.C. Cir. 2019) (quotation marks omitted). The Department is therefore entitled to significant deference on its determination that it lacked sufficient information to find that the Program would improve access to care while posing a low risk of harm to patients.

To be sure, HHS’s explanation of that point was brief. See Advisory Opinion at 8 [ECF p. 462]. The agency could have better articulated the open questions that remained and the nature of the data it needed. But its decision need not be “a model of analytic precision to survive a challenge.” Dickson v. Sec’y of Def., 68 F.3d 1396, 1404 (D.C. Cir. 1995). Rather, “[a] reviewing court will ‘uphold a decision of less than ideal clarity if the agency’s path may reasonably be discerned.’” Id. (quoting Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 286 (1974)). Here, the Department’s conclusion about data came shortly after a full, evenhanded discussion of CASGEVY’s promises and perils. HHS noted, for example, that “cell and gene therapies consist of an evolving field that holds significant promise

for improving the health of patients, including Federal health care program enrollees.” Advisory Opinion at 6 [ECF p. 460]. Acknowledging the “transform[ative]” potential of such therapies, the agency stated that the number “that are available in the marketplace is rapidly increasing” and that stakeholders were still “adapting to the proliferation of these innovative therapies (*e.g.*, paying for and providing these treatments).” Id. HHS went on to explain that the “novel[ty]” of the treatments meant that “much is yet unknown about them and optimal arrangements for ensuring appropriate access to them.” Id. That “uncertainty,” it explained, “makes it difficult to assess the risk of the” Fertility Program. Id. The Department finally stated that, as gene therapies “become available to patients and the marketplace for them evolves, [it] expect[s] additional data to become available regarding the ability of Federal health care program enrollees to access these important treatments, as well as data regarding costs, benefits, risks, and outcomes of treatments.” Id. It is clear, then, that HHS’s conclusion regarding the Promotes Access to Care Exemption was informed by its earlier findings regarding the lack of available information about using and accessing novel gene therapies. Its determination thus was both reasonable and reasonably explained.

In drawing its conclusion, the agency did not depart from its precedents, as Vertex asserts. The company invokes several instances in which HHS approved what Plaintiff believes to be comparable programs, none of which the Court finds to be persuasive analogues. Vertex cites a program in which a pharmaceutical company provided patients with smartphones to collect and transmit biomedical information, see Vertex Mot. at 33, and another in which a company furnished travel, lodging, and meals to help patients visit certain medical facilities. See id. at 35. Those examples are inapposite. Neither involved novel treatments for which HHS’s primary concern was a lack of data. The type of compensation provided in those programs, moreover,

directly enabled patients to access the treatment itself and therefore differs from the Fertility Program's monetary reimbursement, which principally aims to make the treatment more attractive by offsetting a potential negative side effect.

Vertex next points to the Cell and Gene Therapy Access Model, a pilot program operated by the Centers for Medicare & Medicaid Services, a separate branch of HHS from the Office of Inspector General, the entity that issues advisory opinions. See Vertex Mot. at 37–39. The Access Model “seeks to test” over eleven years whether “addressing a range of barriers to equitable access to cell and gene therapies,” including fertility-related obstacles, “will improve access and health outcomes for people with Medicaid.” Joint Appendix at ECF p. 443 (Cell and Gene Therapy Access Model Overview Factsheet) at 1–2 (ECF pp. 443–44). To do so, CMS requires participating drug manufacturers to, among other things, “cover certain fertility preservation services” because “the care journey for [sickle-cell-disease cell and gene therapy] typically results in infertility,” and “[I]ack of access to fertility preservation services presents a significant access barrier to individuals considering [cell and gene therapy].” Id. at 2 [ECF p. 444]. According to Plaintiff, the existence of the Access Model is tantamount not merely to a declaration by CMS that funding fertility treatment will increase access to care, but a proclamation that is binding on the rest of HHS. See Vertex Mot. at 37–38.

Vertex misunderstands both the nature of the Access Model and its relevance to the issue at hand. First, the Access Model is a limited, experimental program that explores — not endorses — the effect of eliminating certain obstacles to patients' ability to access innovative gene therapies. Indeed, the Model's very existence suggests that HHS remains unsure about the relationship between access to fertility-preservation services and access to care. See Advisory Opinion at 6 [ECF p. 460] (“[W]e expect additional data related to the provision of fertility

services by a pharmaceutical manufacturer at no cost to Medicaid enrollees who receive gene therapy treatments from the Cell and Gene Therapy Access Model . . .”).

Second, the Court doubts that CMS’s Access Model and any statements it made in the course of promoting that Model could bind CMS’s own future actions, much less OIG’s advisory opinions. There is “conflicting” caselaw about to what extent unofficial pronouncements like interpretive rules and policy statements are binding on the agency, but in general “the ‘binding’ quality of a particular rule or statement will depend on whether the agency intended to establish a ‘substantive’ rule, one which is not merely interpretative but which creates or modifies rights that can be enforced against the agency.” Nat’l Latino Media Coal. v. FCC, 816 F.2d 785, 788 n.2 (D.C. Cir. 1987). For Vertex’s purposes, the Access Model fails each of these preconditions. CMS never published a rule or statement announcing the supposedly positive consequences of fertility coverage on patients’ access to care, and it certainly did not evince an intent for its descriptions of the Access Model to establish substantive rules or enforceable rights. The CMS Access Model thus holds little significance here.

In sum, the Court concludes that HHS reasonably determined that Vertex’s Fertility Program would not fall under the Promotes Access to Care Exception and therefore that it would violate the Beneficiary Inducement Statute.

B. Anti-Kickback Statute

With the Beneficiary Inducement Statute out of the way, the parties dispute whether the Program violates the Anti-Kickback Statute, a statutory-interpretation morass that turns largely on the meaning of the words “induce” and “remuneration.” Vertex insists that those terms carry specialized criminal connotations, while Defendants urge the Court to use their ordinary

meanings. In an exegesis that is admittedly involved, the Court takes each word in turn before addressing Vertex’s additional arguments regarding how to interpret the statute.

1. “*Induce*”

The Anti-Kickback Statute does not define the term “induce.” As a result, HHS urges the Court to give “induce” its common meaning: “entice or persuade another person to take a certain course of action.” HHS Mot. at 13 (cleaned up) (quoting Induce, Black’s Law Dictionary (11th ed. 2019)); accord Induce, Black’s Law Dictionary (4th ed. 1968) (“bring on or about, to affect, cause, to influence to an act or course of conduct, lead by persuasion or reasoning, incite by motives, prevail on”). For its part, Vertex does not dispute that the Government’s definition of “induce” is the ordinary one. It instead insists that, in the context of the Anti-Kickback Statute, the word “induce” should “carr[y] a specialized criminal-law meaning that restricts the reach of the statute to corrupt *quid-pro-quo* transactions.” Vertex Mot. at 13.

As the Supreme Court has noted, “A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.” Perrin v. United States, 444 U.S. 37, 42 (1979); accord Mac’s Shell Serv., Inc. v. Shell Oil Prods. Co. LLC, 559 U.S. 175, 182–83 (2010). “[W]e do not assume that a . . . word is used as a term of art.” Johnson v. United States, 559 U.S. 133, 139 (2010). The Court therefore presumes that “induce” should be understood in this context to mean what it does in most other contexts.

Vertex pins its hopes chiefly on United States v. Hansen, 599 U.S. 762 (2023). See Mot. at 13–16. There, the Supreme Court reviewed a provision making it unlawful to “encourag[e] or induc[e] 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.”

Hansen, 599 U.S. at 770 (alterations in original) (quoting 8 U.S.C. § 1324(a)(1)(A)(iv)).

Cautioning against “stack[ing] the deck in favor of ordinary meaning,” id. at 775, the Court held that the statute “uses ‘encourages or induces’ in its specialized, criminal-law sense.” Id. at 774.

The Court noted that its decision was “not much of a contest” and concluded based on the statutory context and legislative history that “induce” should take “its criminal-law meaning” — “that is, as incorporating common-law liability for solicitation and facilitation.” Id. at 774–75.

The Hansen Court defined solicitation as “the intentional encouragement of an unlawful act” and facilitation as “the provision of assistance to a wrongdoer with the intent to further an offense’s commission.” Id. at 771.

The parties’ dispute over “induce” largely boils down to a disagreement about whether Hansen’s conclusion regarding the term should apply to criminal statutes generally or only to those akin to the statute at issue there. At first glance, the Hansen holding appears to be, as Plaintiff insists, an appropriate match for today’s conundrum. The Supreme Court at times couched its interpretation of the statute in wide-ranging language. For example, it noted that “when a criminal-law term is used in a criminal-law statute, that — in and of itself — is a good clue that it takes its criminal-law meaning.” Id. at 775. In that way, the Court explained, “induce” was similar to “attempt,” which “we would not understand . . . in its ordinary sense of ‘try’” when considering “a criminal prohibition”; “[w]e would instead understand it to mean taking ‘a substantial step’ toward the completion of a crime with the requisite *mens rea*.” Id. at 774–75. The Court also chided the lower court for neglecting to “give[] specialized meaning a fair shake.” Id. at 775.

Upon closer inspection, however, the Hansen statute reveals itself to be an unsuitable analog to the Anti-Kickback Statute. The Court there made clear that its holding was grounded

in the specific language and circumstances of that statute, which differ meaningfully and in several ways from those of the Anti-Kickback Statute.

To begin with, the Hansen statute is a bare prohibition on “encourag[ing] or induc[ing] an alien to come to, enter, or reside in the United States”; aside from a *mens rea* requirement, it contains no caveats or other limitations on its scope. See 8 U.S.C. § 1324(a)(1)(A)(iv). The Anti-Kickback Statute, on the other hand, is peppered with congressionally enacted safe harbors for broad swaths of conduct, with room for HHS to establish even more. See 42 U.S.C. § 1320a-7b(b)(3)(A)–(L); id. § 1320a-7d(a).

“It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.” TRW Inc. v. Andrews, 534 U.S. 19, 31 (2001) (quotation marks omitted). That principle, also known as the canon against surplusage, guides the Court’s understanding of the Anti-Kickback Statute’s use of the word “induce.” If Plaintiff were correct that the statute prohibits only “corrupt *quid-pro-quo* transactions,” Vertex Mot. at 13, its twelve exceptions would be mere surplusage. See 42 U.S.C. § 1320a-7b(b)(3)(A)–(L). Those exceptions, painstakingly spelled out by Congress, would do nothing to curb the statute’s reach that is not already accomplished by a specialized meaning of “induce.”

Take, for example, § 1320a-7b(b)(3)(B), which exempts from the statute’s ambit “any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.” That provision makes clear that if an employer (*e.g.*, a hospital) makes a payment (*e.g.*, a salary) to its bona-fide employee (*e.g.*, a doctor) to “induce” the doctor to provide federally reimbursable medical services, neither the employer nor the doctor runs afoul of the Anti-Kickback Statute. Such run-

of-the-mill income payments are plainly not “corrupt *quid-pro-quo* transactions,” Vertex Mot. at 13, and therefore would already be perfectly legal under Vertex’s understanding of the statute. Were that the case, it would be odd — indeed, wholly unnecessary — for Congress to have expressly exempted those innocent transactions from liability under the statute. The same is true for the other exceptions, each of which concerns an ordinary economic interaction that would not need to be explicitly protected if the word “induce” were limited on its own terms to unlawful conduct.

That is not even to mention § 1320a-7d(a), which gives HHS virtually unlimited discretion to create “safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1320a-7b(b)” as well as to modify existing safe harbors. See 42 U.S.C. § 1320a-7d(a)(1)(A)(i)–(ii). The statute provides only that the agency “may consider” the extent to which a particular safe harbor “may result” in, for example, “[a]n increase or decrease in access to health care services,” “[a]n increase or decrease in the quality of health care services,” and “[a]ny other factors [HHS] deems appropriate.” Id. § 1320a-7d(a)(2). If Vertex is correct that the statute applies only to already unlawful transactions, § 1320a-7d(a) grants HHS unbounded license to exempt forms of “criminal solicitation,” Vertex Mot. at 16, from criminal liability. The Court finds it difficult to imagine that HHS actually possesses the ability to inoculate certain types of corrupt solicitation and facilitation against criminal penalties, much less that Congress intended to bestow that staggering power in the same breath that it outlawed corrupt transactions in federal healthcare programs in the first place. In the interest of giving effect to all of the Anti-Kickback Statute’s provisions, the Court believes that the Government’s reading is the better one.

True, “[t]he canon against surplusage is not an absolute rule.” Marx v. Gen. Revenue Corp., 568 U.S. 371, 385 (2013); see Cook Inlet Tribal Council, Inc. v. Dotomain, 10 F.4th 892, 896 (D.C. Cir. 2021) (interpreting another statute in “a belt-and-suspenders manner”). But there are strong indications that the canon should apply here. First, the Court is not presented with competing interpretations that would both produce surplusage. See Marx, 568 U.S. at 385 (“[T]he canon against surplusage ‘assists only where a competing interpretation gives effect to every clause and word of a statute.’”) (quoting Microsoft Corp. v. i4i Ltd. P’ship, 564 U.S. 91, 106 (2011)). Rather, Vertex’s proposed understanding of the statute creates superfluity, rendering needless the enumerated exemptions, while the Government’s does not. The Anti-Kickback Statute, moreover, does not address the kind of substantive issue — such as attorney fees and costs, see Marx, 568 U.S. at 385–86, or burdens of persuasion and standards of proof, see Microsoft, 564 U.S. at 106–07 — where redundancies are known to be commonplace. While Plaintiff insists that Congress must have included superfluous exceptions in an attempt to “make crystal clear” that certain activities would not be criminalized, the only reason it provides to explain why the legislature would have included so many redundancies is that the Anti-Kickback Statute “is a criminal law that carries serious penalties.” Vertex Reply at 10–11. Vertex, however, ignores that courts regularly apply the canon of surplusage to serious criminal laws without fear of loosening statutory belts and suspenders. See, e.g., Fischer v. United States, 603 U.S. 480, 493–96 (2024); Pulsifer v. United States, 601 U.S. 124, 143 (2024); Yates v. United States, 574 U.S. 528, 543 (2015). Last, “the canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme,” Marx, 568 U.S. at 386 (considering two different statutes), as is the case here.

Vertex responds by invoking Mission Product Holdings, Inc. v. Tempnology, LLC, 587 U.S. 370 (2019), which it contends “rejected . . . that, under the rule against superfluities, a general rule had to be read in a manner that would normally encompass an enumerated list of exceptions.” Vertex Reply at 10. The Supreme Court chose not to apply the canon against surplusage in that case because the enumerated exceptions “emerged at a different time, over a span of half a century,” and “each responded to a discrete problem,” often “correcting a judicial ruling.” Mission Prod. Holdings, 587 U.S. at 383. The exceptions in the Anti-Kickback Statute similarly arose over decades — although Plaintiff does not claim that they were likewise enacted to respond to and correct individual events. See Vertex Reply at 10 n.3. But the Mission Product Holdings Court declined to rely on the canon against surplusage largely because it would have led to an incoherent understanding of the statute “to say essentially its opposite.” 587 U.S. at 383. Given those unique circumstances, this Court understands Mission Product Holdings to counsel only gently against applying the canon against surplusage and in circumstances not present here. Because significant force militates in favor of the canon’s application in this case, the Court is comfortable relying on it.

This Court’s reading of the Anti-Kickback Statute is bolstered by other aspects of Hansen that made the broad meaning of “induce” particularly dubious there. The Supreme Court was asked to decide whether the statute “punishes so much protected speech” that it is facially unconstitutional under the First Amendment. See 599 U.S. at 769. The Court determined the meaning of “induce,” then, only as a first step toward its ultimate constitutional holding: it had to “determine what [the statute] covers” in order to “judge whether [it] is overbroad.” Id. at 770. Given that First Amendment framing, it is unsurprising that the Justices were loath to give “induce” its more expansive ordinary meaning. As the Court explained, the everyday meaning

of “induce” would have “turned an ordinary solicitation and facilitation offense into a novel and boundless restriction on speech.” Id. at 777. The Court doubted that Congress meant to impose that “sweeping — and constitutionally dubious” — restriction. Id. at 778. Indeed, the Court made a point to “emphasi[ze]” that the canon of constitutional avoidance “counsel[ed]” it to adopt the narrow, specialized reading of “induce.” Id. at 781. Noting that its task was “to seek harmony” between the statute and the Constitution, “not to manufacture conflict,” Hansen acknowledged that its statutory holding was motivated in part by a desire to avoid the constitutional issues that would attend reading the statute to criminalize a virtually unlimited range of conduct. See id. All the more reason, then, to understand the Supreme Court’s holding there as tailored — and thus limited — to the unique circumstances of that statute and challenge at issue.

The Anti-Kickback Statute, moreover, differs from the Hansen statute in several other important ways. For one, the two statutes criminalize different types of actions. The Hansen statute proscribes the inducement itself, while the Anti-Kickback Statute criminalizes the offering or payment of remuneration with the goal of inducement. Compare 8 U.S.C. § 1324(a)(1)(A)(iv) (“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”), with 42 U.S.C. § 1320a-7b(b)(2) (“knowingly and willfully offers or pays any remuneration . . . to induce such person [to take certain actions]”). In the Anti-Kickback Statute, inducement is relevant only because it provides the improper motive that a person who runs afoul of the statute possesses. In other words, a person does not violate the Anti-Kickback Statute by inducing another individual to perform certain actions; he violates it

only if he offers or pays remuneration to that individual with the goal of such inducement. By contrast, a person violates the Hansen statute purely through inducing a violation of law.

Resisting that distinction, Vertex contends that both statutes prohibit inducement and that “[t]he only difference is the form and object of the inducement.” Vertex Reply at 7. According to Plaintiff, the prohibited inducement in Hansen “took the form of persuasive speech,” while inducement here takes the form of remuneration. See id. Vertex is mistaken. The Hansen statute prohibits all forms of inducement; a person would presumably violate the law by inducing a nonresident to enter the United States via a wide range of speech and conduct, such as issuing threats, withholding resources in the home country, leading by example, and — of course — offering or providing remuneration. Indeed, as the Supreme Court explained there, “To the extent that [the statute] reaches any speech, it stretches no further than speech integral to unlawful conduct.” 599 U.S. at 783. The Hansen statute, then, criminalized inducement broadly, not just persuasive speech. Vertex cannot rewrite the DNA of that statute to serve its own purposes. By contrast, the Anti-Kickback Statute prohibits inducement only in the form of remuneration. A person could induce the purchase of healthcare services through persuasive speech alone and remain in compliance with the statute. The word “induce,” then, plays an entirely different role in the Anti-Kickback Statute than it does in the Hansen statute. And when inducement itself is the criminal activity, it stands to reason that “induce” would take its criminal-law meaning. It would be bizarre, however, to apply the specialized, criminal-law meaning of induce to statutes that use inducement only to describe the motive with which it is unlawful to perform some other action. See HHS Mot. at 16 (providing examples).

Take, for example, 18 U.S.C. § 706, which makes it a crime for a person to “wear[] or display[] the sign of the Red Cross . . . for the fraudulent purpose of inducing the belief that he is

a member of or an agent for the American National Red Cross.” It is perplexing to imagine how the specialized meaning of “induce” Plaintiff urges — *i.e.*, the word “inducing” in a criminal statute always means the “intentional encouragement of an unlawful act,” Hansen, 599 U.S. at 771 — could operate in the context of 18 U.S.C. § 706. Plaintiff insists that, when a statute criminalizes certain conduct performed with the purpose of inducing a particular action, a prerequisite for liability is that the induced action is unlawful. For the Red Cross statute, the “unlawful act” would be “belie[ving]” that the person wearing the Red Cross insignia “is a member of or an agent for the American National Red Cross.” 18 U.S.C. § 706. It is of course not unlawful to think that another person is a member of the Red Cross. If Vertex is to be believed, then, no unlawful act would ever be induced, so no criminal liability would ever attach to the act of fraudulently wearing the sign of the Red Cross. Title 18 U.S.C. § 706 would be rendered completely inoperative — an outcome that would defy reason. Because the Anti-Kickback Statute is structured identically to 18 U.S.C. § 706 — each forbids conduct (offering or paying remuneration; wearing or displaying the sign of the Red Cross) with the motivation of inducing an action (purchasing healthcare services; believing another person is a member of the Red Cross) — the same logic applies.

Next, the Hansen statute prohibits the inducement of an independent criminal act: a violation of the immigration laws. See 8 U.S.C. § 1324(a)(1)(A)(iv) (“encourages or induces an alien to come to, enter, or reside in the United States knowing . . . that such coming to, entry, or residence is or will be in violation of law”) (emphasis added). The Supreme Court itself noted that it was more confident in its conclusion that “induce” took its criminal-law meaning because of the statute’s “focus” on inducing “a violation of law.” Hansen, 599 U.S. at 775. The Anti-Kickback Statute, on the other hand, is concerned with the inducement of conduct that is not

inherently criminal: purchasing federally reimbursable healthcare services. Because the Anti-Kickback Statute does not “necessarily link[]” inducement “to other criminal conduct,” this Court doubts that Congress meant to limit its scope to criminal solicitation and facilitation. See Pharm. Coal. for Patient Access v. United States (PCPA), 126 F.4th 947, 956 (4th Cir. 2025) (making same distinction). As the Fourth Circuit explained when considering the same issue, “By limiting the inducing offense to encompass only encouraging other criminal conduct, the Hansen statute, by its very language, left no room for inducement of any non-criminal acts.” Id. at 955. That court noted that many of the criminal statutes cited by Hansen — and many statutes forbidding inducement — outlaw the inducement of independent violations of law. Id. (collecting statutes). In those contexts, it is perfectly sensible to give “induce” a narrow meaning rooted in the criminal nature of the induced conduct. But when no independent violation of law is induced, that justification does not apply.

In short, aside from containing the word “induce,” the Hansen statute and the Anti-Kickback Statute are far from mirror images of each other. Rather, they employ different structures to criminalize wholly different categories of conduct. Given those incompatibilities, the Court is unwilling to simply transplant the Supreme Court’s holding in Hansen into the Anti-Kickback Statute.

The D.C. Circuit decisions cited by Vertex likewise shed little light on the dispute at hand. One opinion concerned a statute that “makes it a felony to ‘own[], manage[], or operate[]’ an interactive computer service — for example, a website, chat room, or search engine — ‘with the intent to promote or facilitate the prostitution of another person.’” Woodhull Freedom Found. v. United States, 72 F.4th 1286, 1292 (D.C. Cir. 2023) (alterations in original) (quoting 18 U.S.C. § 2421A(a)). There, the Circuit held in the context of a First Amendment challenge

that the statute used the term “promoting prostitution” in its specialized, criminal-law sense: “aid[ing] and abet[ting] prostitution.” *Id.* at 1300 (citing Hansen, 599 U.S. at 771). Like in Hansen, the Woodhull statute involved an independent violation of law (*i.e.*, prostitution) and was subject to First Amendment overbreadth and vagueness challenges. And like in Hansen, those characteristics indicate that its lessons are of limited relevance here. As for the other case Plaintiff cites, the Circuit indeed noted that “inducement generally requires a showing that the government agent actually solicited or suggested the criminal conduct.” United States v. Williamson, 903 F.3d 124, 132 (D.C. Cir. 2018) (emphasis added) (quotation marks omitted). It made that statement, however, when discussing the entrapment defense, not a criminal statute, and it caveated its assertion with an acknowledgment that “[a] range of government conduct could qualify as inducement . . . , including persuasion, fraudulent representations, threats, coercive tactics, harassment, promises of reward, or pleas based on need, sympathy or friendship.” *Id.* (quotation marks omitted). The Court thus finds little utility in those cases.

Vertex also invokes a DOJ guidance document concerning a statute that makes it unlawful to “knowingly or willfully . . . pay[] or offer[] to pay or accept[] payment either for registration to vote or for voting.” Vertex Reply at 13 (alterations in original) (quoting 52 U.S.C. § 10307(c)). Plaintiff cites a portion of the guidance explaining that giving voters “a ride to the polls or time off from work” does not constitute a “payment” that violates the statute. *Id.* at 14 (quoting Richard C. Pilger, Federal Prosecution of Election Offenses, Dep’t of Just. 44 (8th ed. Dec. 2017), <https://perma.cc/LD5T-EM7K>). Even assuming DOJ’s guidance regarding one statute could bind HHS’s interpretation of a wholly different law, Justice limited its instruction to items that “are given to make [voting] easier” to “individuals who have already made up their minds to vote.” *Id.* It is unsurprising that DOJ does not consider such interactions to be

payments that induce individuals to vote. That conclusion matters little when considering whether a transaction would persuade an individual to purchase certain healthcare services. DOJ's internal policy regarding a separate statute that does not even use the word "induce" does not shift the calculus here.

In sum, the Court concludes that the ordinary meaning of "induce" — "influence to an act or course of conduct, lead by persuasion or reasoning, incite by motives, prevail on," Induce, Black's Law Dictionary (4th ed. 1968) — controls.

2. "*Remuneration*"

Vertex does not stop at "induce"; it also relies on the word "remuneration." Recall, the statute criminalizes "offer[ing] or pay[ing] 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 take certain actions. See 42 U.S.C. § 1320a-7b(b)(2). "Remuneration" ordinarily means "[r]eward; recompense; salary." Remuneration, Black's Law Dictionary (4th ed. 1968); accord Pfizer, Inc. v. HHS, 42 F.4th 67, 75 (2d Cir. 2022) ("payment; compensation, especially for a service that someone has performed") (cleaned up) (quoting Remuneration, Black's Law Dictionary (11th ed. 2019)). Plaintiff, however, believes that "remuneration" within the Anti-Kickback Statute refers only to "transactions that corrupt physicians' and patients' decision making and thus solicit or facilitate an unlawful act on the part of the recipient." Vertex Mot. at 18.

In support of this interpretation, Vertex points to the heading of 42 U.S.C. § 1320a-7b(b), which reads "Illegal remunerations," to argue that the Anti-Kickback Statute prohibits only "illegal," not "innocuous or even beneficial remuneration." Vertex Mot. at 21. Plaintiff's effort to rely on that heading is understandably half-hearted. While section headings can sometimes be

instructive, see Dubin v. United States, 599 U.S. 110, 120–21 (2023), they “are not binding, may not be used to create an ambiguity, and do not control an act’s meaning by injecting a legislative intent or purpose not otherwise expressed in the law’s body.” iTech U.S., Inc. v. Renaud, 5 F.4th 59, 65 (D.C. Cir. 2021) (quotation marks omitted). Besides, even if the section heading were edifying, it expresses little beyond the uncontroversial fact that the provision denotes which remunerations are illegal.

In addition to the section heading, Vertex relies chiefly on the *ejusdem generis* and *noscitur a sociis* canons, which together counsel that general words should be understood in light of the more specific terms surrounding them. See Fischer, 603 U.S. at 487. Specifically, Plaintiff argues that the meaning of the word “remuneration” should be limited by the listed examples of “kickback, bribe, or rebate,” which it believes all share an element of corruption. See Vertex Mot. at 18–22.

The Court first takes issue with Vertex’s premise. “Kickback” and “bribe” do generally carry corrupt connotations — although that implication is not a given. See Kickback, Black’s Law Dictionary (5th ed. 1979) (“Payment back of the purchase price to buyer . . . by seller to induce purchase or to influence improperly future purchases or leases”); Bribe, Black’s Law Dictionary (4th ed. 1968) (“Anything of value; any gift, advantage, or emolument; any price, reward or favor. Any money, goods, right in action, property, thing of value, or any preferment, advantage, privilege or emolument, or any promise or undertaking to give any, asked, given, or accepted, with a corrupt intent to induce or influence action, vote, or opinion of person”) (citation omitted). The word “rebate,” however, does not contain the same undercurrent of dishonesty. See Rebate, Black’s Law Dictionary (4th ed. 1968) (“Discount . . . A deduction or drawback from a stipulated payment, charge, or rate”). That is true notwithstanding Vertex’s

attempt to argue that an Anti-Kickback Statute rebate must involve corruption, for which it cites only a footnote in an out-of-circuit case that was decided before the relevant amendment to the law. See Vertex Mot. at 18–19 (citing United States v. Zacher, 586 F.2d 912, 916 n.9 (2d Cir. 1978)); Pfizer, 42 F.4th at 75 (“[I]n Zacher we interpreted the original 1972 version of the [Anti-Kickback Statute], which prohibited only kickbacks, bribes, or rebates. Congress did not expand the statute to cover ‘any remuneration’ until the statute was amended in 1977. Zacher’s reading of the 1972 statute thus gives us little guidance on resolving the current appeal.”) (citation omitted).

Even accepting *arguendo* that kickbacks, bribes, and rebates are all necessarily corrupt transactions, however, Vertex’s argument fails to clear several additional obstacles. It is, for one thing, unclear that the *ejusdem generis* canon applies when the general word precedes rather than follows the list of specific terms. See HHS Mot. at 22 (noting this point); Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 202–05 (2012) (explaining that “the *ejusdem generis* canon is properly limited to its traditional application: a series of specifics followed by a general,” providing reasons, and citing historical examples). Although Vertex attempts to bolster its point with this Court’s decision in Chestnut Hill Benevolent Ass’n v. Burwell, 142 F. Supp. 3d 91 (D.D.C. 2015), its reliance on that case is misplaced. See Vertex Reply at 18. There, the Court did apply the *ejusdem* canon to a regulation in which the specific words followed the general one, but it nevertheless described the enumeration of the terms as an “illustrative,” “nonexclusive list . . . [of] exemplars.” Chestnut Hill Benevolent Ass’n, 142 F. Supp. 3d at 104.

To the extent that the canon does have force here, the Anti-Kickback Statute makes clear that kickbacks, bribes, and rebates are merely examples of remuneration. The first clue is the

statute’s use of the word “including.” See 42 U.S.C. § 1320a-7b(b)(2) (“including any kickback, bribe, or rebate”) (emphasis added). “[T]he word ‘includes’ is usually a term of enlargement, and not of limitation.” Burgess v. United States, 553 U.S. 124, 131 n.3 (2008) (alteration in original); accord Fabi Constr. Co., Inc. v. Sec’y of Lab., 508 F.3d 1077, 1086 (D.C. Cir. 2007) (“It is hornbook law that the use of the word ‘including’ indicates that the specified list . . . that follows is illustrative, not exclusive.”) (omission in original) (quotation marks omitted). The Court is therefore reluctant to read a list introduced with the word “including” to limit rather than expand the meaning of “remuneration.”

Next, the provision uses the word “any” — which “has an expansive meaning that usually indicates” an “indiscriminate[.]” category “of whatever kind,” Del. Dep’t of Nat. Res. & Env’t Control v. EPA, 895 F.3d 90, 97 (D.C. Cir. 2018) (quotation marks omitted) — not once, but twice. See 42 U.S.C. § 1320a-7b(b)(2)(A) (“any remuneration (including any kickback, bribe, or rebate)”) (emphases added). On top of that, the statute’s “use of parentheses emphasizes the fact that that which is within is meant simply to be illustrative, hence redundant — a circumstance underscored by the lack of any suggestion that Congress intended the illustrative list to be complete.” Chickasaw Nation v. United States, 534 U.S. 84, 89 (2001). And if that were not enough, Congress took pains to make clear that it intended to prohibit a broad scope of transactions by emphasizing that remuneration is barred whether it is “direct[.] or indirect[.], overt[.] or covert[.], in cash or in kind.” 42 U.S.C. § 1320a-7b(b)(2). The word “remuneration” is therefore best read to refer to a wide range of payments, not only corrupt ones, and the parenthetical is best understood as a nonexhaustive list of examples.

Vertex rejoins that, if the “kickback, bribe, or rebate” parenthetical does not limit the meaning of remuneration, it constitutes an unacceptably redundant locution. But the

remuneration parenthetical, unlike the exemptions from liability that would be rendered superfluous under Vertex's interpretation of the Anti-Kickback Statute, has good reason to exist even if "remuneration" is read to cover many types of transactions.

The statutory history demonstrates that the enacting Congress viewed kickbacks, bribes, and rebates as the prototypical types of payments forbidden by the Anti-Kickback Statute. The original 1972 version of the statute criminalized the solicitation, offering, or receipt of "any . . . kickback or bribe" or "rebate." 86 Stat. at 1419. In 1977, Congress changed that provision to the version that remains in force today: "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." 91 Stat. at 1180. Those additions reflect a clear congressional effort to expand the Anti-Kickback Statute's reach beyond only kickbacks, bribes, and rebates. See *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) ("The phrase 'any remuneration' was intended to broaden the reach of the law which previously referred only to kickbacks, bribes, and rebates."). As the Government notes, it would have been reasonable for Congress to retain the statute's mentions of kickbacks, bribes, and rebates "to foreclose any unwarranted inference that it meant to remove such payments from the statute's ambit by deleting reference to them." HHS Mot. at 21. Indeed, unlike when a list of specific terms is followed by a general word, "[f]ollowing the general term with specifics can serve the function of making doubly sure that the broad (and intended-to-be-broad) general term is taken to include the specifics," particularly when the specifics are introduced "with a term such as including." Scalia & Garner, *supra*, at 204.

The Court is thus satisfied that the Government's interpretation of the statute does not render wholly superfluous the "kickback, bribe, or rebate" parenthetical. Even if it did, the Court would still find that to be the better reading. To read remuneration to be only criminal in nature,

as Vertex urges, would nullify the statute’s reticulated scheme of exceptions, while the Government’s position would at most make a short list of illustrative transactions redundant. “The sacrifice is easy — a few words saves the whole.” United States v. Akinyoyenu, 199 F. Supp. 3d 106, 117 (D.D.C. 2016); accord Pulsifer, 601 U.S. at 143 (“When a statutory construction . . . renders an entire subparagraph meaningless, this Court has noted, the canon against surplusage applies with special force.”) (cleaned up); Mowrer v. U.S. Dep’t of Transp., 14 F.4th 723, 732 (D.C. Cir. 2021) (“[O]ne short, unavoidably redundant catchall phrase is a far cry from . . . the pointless incorporation . . . of one . . . requirement after another.”).

The Court, in sum, concludes that the best understanding of the term “remuneration” is again the ordinary one: any “[r]eward; recompense; [or] salary.” Remuneration, Black’s Law Dictionary (4th ed. 1968).

3. *Beneficiary Inducement Statute*

In addition to its contentions based on the statutory language, Vertex argues that the Anti-Kickback Statute should be read with reference to the Beneficiary Inducement Statute. The Court finds those arguments unpersuasive.

Despite the similarities between the two statutes, they were enacted at different times by different Congresses. The Anti-Kickback Statute was enacted in 1972 and reworked in 1977, and the Beneficiary Inducement Statute was not enacted until 1996. The Supreme Court has declined to use one provision to interpret another when they “were not considered or enacted together.” Gomez-Perez v. Potter, 553 U.S. 474, 486 (2008) (discussing statutes enacted seven years apart). The Beneficiary Inducement Statute, then, provides little guidance for interpreting the Anti-Kickback Statute. See Pfizer, 42 F.4th at 78 (drawing same conclusion). The Court, unlike Vertex, accordingly finds little significance in the fact that the Anti-Kickback Statute uses

the word “induce,” while the Beneficiary Inducement Statement uses “influence.” It is far from clear that the two Congresses, decades apart, made a conscious decision to use “distinct language” or denote a “narrower scope” in the Anti-Kickback Statute, see Vertex Mot. at 16 — not least because the heading for that section of the enacted version of the Beneficiary Inducement Statute is titled “Prohibition Against Offering Inducements to Individuals Enrolled Under Programs or Plans.” 110 Stat. at 2014 (emphasis added).

In fact, many of Vertex’s arguments are premised on the notion that the Beneficiary Inducement Statute is simply the “civil penalty counterpart” of the Anti-Kickback Statute. See Vertex Reply at 3–4. As a result, Plaintiff contends, the criminal activity outlawed by the Anti-Kickback Statute must comprise a subset of the civil conduct forbidden by the Beneficiary Inducement Statute. Because Plaintiff maintains that the Fertility Program does not violate the latter, it insists that the Program thereby cannot violate the former.

As previously explained, the Court disagrees that the Fertility Program falls under the Promotes Access to Care Exception and therefore concludes that it does violate the Beneficiary Inducement Statute. Even absent such a violation, the Program’s status under that statute does not necessarily affect its footing with regard to the Anti-Kickback Statute. The two laws are motivated by different concerns and consequently prohibit different activities. The Anti-Kickback Statute guards against improperly induced purchases, while the Beneficiary Inducement Statute focuses on a beneficiary’s choice of provider. See Pfizer, 42 F.4th at 78 (making same distinction). One can imagine why Congress might have drawn this distinction: there may be good reasons to criminalize inducing a patient’s choice of a particular treatment but only civilly punish inducing a patient’s choice of a hospital. Certain conduct could, as a result, violate the former but not the latter — if, for example, a manufacturer intended to induce a

patient's purchase of a drug but did not attempt to influence the patient's choice of provider from whom to obtain the drug — which HHS has concluded in the past and which a court upheld. See id. Indeed, the Beneficiary Inducement Statute is not the sole path for entities to incur civil penalties for offering behavior-changing remuneration; individuals are independently subject to civil damages for violating the Anti-Kickback Statute. See 42 U.S.C. § 1320a-7a(a)(7). Vertex is wrong to suggest, then, that its liability *vel non* under one statute inevitably has implications for the other.

The Court likewise sees no reason to — *pace* Vertex, see Vertex Mot. at 30–32 — transport the Beneficiary Inducement Statute's Promotes Access to Care Exception to the Anti-Kickback Statute. Congress knows how to write exceptions into the Anti-Kickback Statute, see 42 U.S.C. § 1320a-7b(b)(3)(A)–(L), and evidently has opted not to include the Promotes Access to Care Exception in that law. The Court will not do so itself.

4. *Other Canons of Interpretation*

Needing to stanch the bleeding, Vertex resorts to several extratextual rationales to contend that the Anti-Kickback Statute should be read to cover only corrupt transactions. In arguing for its preferred interpretation, Plaintiff often relies on policy considerations — going so far as to state that blocking the Fertility Program is an “absurd” result that cannot be tolerated. See Vertex Mot. at 22–23. Because CASGEVY has the potential to help ill patients who until now have had nowhere to turn, Vertex's argument goes, HHS cannot block its attempt to make the treatment more widely available. The Court, recognizing the importance of mitigating the harmful side effects brought on by potentially life-saving treatments, does not doubt that CASGEVY is an innovative and important treatment that could increase many patients' access to medical care. Indeed, the Government itself “recognize[d] that cell and gene therapies consist of

an evolving field that holds significant promise for improving the health of patients, including Federal health care program enrollees.” Advisory Opinion at 6 [ECF p. 460]. It acknowledged that “cell and gene therapies, like [CASGEVY], can transform the lives of individuals living with” sickle-cell disease and TDT. *Id.*

At the same time, the Anti-Kickback Statute addresses complicated and high-stakes issues of healthcare, fraud, and medical decisionmaking. Congress determined how those questions are best answered and left HHS to fill in any gaps. The Court does not have the authority — and would not be equipped — to construe the statute’s words based on its own assessment of which medical treatments are sufficiently valuable to justify influencing patients’ and providers’ healthcare decisions. As Defendants have explained, gene-editing therapies are “novel” treatments, and “much is yet unknown about them and optimal arrangements for ensuring appropriate access to them.” Advisory Opinion at 6 [ECF p. 460]. It is not implausible that Vertex’s Fertility Program could change doctors’ and patients’ decisionmaking in undesirable ways that should, for now, be avoided. Today’s outcome, then, certainly does not “def[y] rationality by rendering a statute nonsensical or superfluous,” nor is it “so contrary to perceived social values that Congress could not have intended it.” *United States v. Cook*, 594 F.3d 883, 891 (D.C. Cir. 2010) (cleaned up); *accord* Scalia & Garner, *supra*, at 237 (explaining absurdity canon is limited to dispositions “that no reasonable person could intend. . . . where the absurdity and injustice of applying the provision to the case would be so monstrous, that all mankind would, without hesitation, unite in rejecting the application” of canon) (quotation marks omitted). The Court thus sees no reason to doubt its holding on policy grounds.

Vertex also points to the lenity canon and due-process principles, which it argues require the Court to construe the Anti-Kickback Statute “narrowly to avoid improperly criminalizing

innocent behavior.” Vertex Mot. at 23–26. For starters, there is reason to doubt that lenity and due-process concerns should play much of a role here: the purpose of the lenity canon is to provide individuals with “fair warning concerning conduct rendered illegal,” Liparota v. United States, 471 U.S. 419, 427 (1985), and “adequate notice lies at the heart of due process.” Gray Panthers v. Schweiker, 652 F.2d 146, 168 (D.C. Cir. 1980). Vertex has not been subject to any enforcement actions; this case instead arises out of the advisory-opinion mechanism that Congress created for potential violators to learn whether their activities would run afoul of the law. There is therefore no reason to fear that Vertex will be subject to enforcement without receiving adequate notice.

In any case, the lenity canon is a last resort that should be employed only when all other interpretive methods have been exhausted. See Moskal v. United States, 498 U.S. 103, 107–08 (1990). Given the accumulation of evidence in favor of Defendants’ diagnosis, the Court will not turn to alternative medicines.

* * *

In sum, the Court agrees with Defendants that the Anti-Kickback Statute forbids all forms of remuneration done with the purpose of inducing the purchase of federally reimbursable healthcare services, regardless of whether the remuneration or induced conduct is independently unlawful.

5. *Violation of Statute*

With the meaning of the statute established, the Court can now turn to the final task at hand: whether HHS reasonably determined that Vertex’s Program would violate the law. Plaintiff does not meaningfully dispute that, under the Government’s interpretation, the Program

would run afoul of the Anti-Kickback Statute if implemented with the necessary *mens rea*. Rightly so.

The Program would provide patients with \$70,000 for fertility services: recompense for the potentially negative effects of CASGEVY on fertility or, in other words, remuneration. Medical providers could also prescribe CASGEVY in order to earn remuneration in the form of fees related to the treatment. See Advisory Opinion at 7 [ECF p. 461]. Plaintiff protests that, if the Program falls under Defendants’ interpretation of “remuneration,” so too would an alternative treatment regimen that does not have adverse effects on patients’ fertility. See Vertex Mot. at 27–28; Vertex Reply at 24–25. That is not correct. Unlike a payment of up to \$70,000 for fertility services, such an enhancement in the product could not conceivably be considered a “reward” or “recompense” to patients or providers; rather, it would simply be a different and improved treatment.

With the Fertility Program, Vertex’s motive for providing remuneration (in the form of payment for fertility services or treatment-related fees) would be “to facilitate appropriate access to [CASGEVY],” Vertex Request at 30 [ECF p. 32], and “remove barriers to treatment.” Id. at 40 [ECF p. 42]. Because Vertex seeks to “influence . . . an act or course of conduct,” Induce, Black’s Law Dictionary (4th ed. 1968) — specifically, to motivate patients to pursue treatment with CASGEVY or lead medical providers to prescribe CASGEVY over other treatment options — its motive is to induce others to purchase a service for which payment may be made under a federal healthcare program. Resisting the notion that the Program would change patients’ and physicians’ behavior, Plaintiff repeatedly insists that there are many reasons to select CASGEVY aside from the Fertility Program. See Vertex Mot. at 26–30; Vertex Reply at 21–23. The Court does not doubt that. Given the inclusive definition of “induce” the Court adopts today, it is

enough that the Program “removes the financial barrier to fertility preservation services necessary to counteract the side effect of infertility, which would otherwise prevent patients from undergoing this potentially life-altering treatment.” Vertex Reply at 24.

HHS’s conclusion that Vertex’s Program would violate the Anti-Kickback Statute if undertaken knowingly and willfully was therefore not contrary to law.

C. Timeliness

Loosing its final arrow, Vertex aims a procedural challenge at HHS’s actions. The statute requires the agency to issue its advisory opinion to the requested party “by not later than 60 days after the request is received.” 42 U.S.C. § 1320a-7d(b)(5)(B)(i). The statute also instructs the Department to “issue regulations to carry out” the advisory-opinion process, which must provide for:

- (i) the procedure to be followed by a party applying for an advisory opinion;
- (ii) the procedure to be followed by the Secretary in responding to a request for an advisory opinion; [and]
- (iii) the interval in which the Secretary shall respond

Id. § 1320a-7d(b)(5)(A). Pursuant to that requirement, HHS has established by regulation a procedure for issuing advisory opinions. As relevant here, the agency must decide whether to “[f]ormally accept the request,” “[n]otify the requestor of what additional information is needed,” or “[f]ormally decline to accept the request” “[w]ithin 10 working days of receipt of the request.” 42 C.F.R. § 1008.41(b). Once it “has formally accepted the request for an advisory opinion,” the “60-day period for issuance of an advisory opinion” begins. Id. § 1008.41(e); id. § 1008.43(c)(1). That 60-day period, however, can be extended. HHS “toll[s]” the 60-day response period when it:

- (i) Notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount until the time when the OIG receives written notice from the requestor to continue processing the request;
- (ii) Requests additional information from the requestor until the time the OIG receives the requested information;
- (iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and
- (iv) Notifies the requestor of the need for expert advice until the time the OIG receives the expert advice.

Id. § 1008.43(c)(3).

Here, Vertex requested an advisory opinion on the legality of the Fertility Program on June 13, 2023. See Vertex Request at 1 [ECF p. 3]. HHS formally accepted that request 13 days (or nine working days) later. See HHS Acceptance at 1 [ECF p. 212]. At the same time, it requested additional information and, pursuant to its regulations, tolled the response period. Id. at 1–2 [ECF pp. 212–13]. After several months of back and forth, including an additional request for information from the agency, see HHS Dec. 2023 Email at 1–2 [ECF pp. 248–49], HHS finally issued a written advisory opinion on July 18, 2024 — more than a year after Vertex’s original request. See Advisory Opinion at 1 [ECF p. 455].

Plaintiff now challenges both the 10-business-day buffer period and the tolling power as contrary to the statutory command for the agency to issue an advisory opinion within 60 days. Although Defendants dispute Vertex’s argument solely on the merits, the Court “has an independent obligation to assure that standing exists, regardless of whether it is challenged by any of the parties.” Summers v. Earth Island Inst., 555 U.S. 488, 499 (2009). A plaintiff, moreover, “must demonstrate standing for each claim he seeks to press.” DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352 (2006); see Am. Compl., ¶¶ 157–65 (setting out challenge to advisory-opinion regulations as separate count). Because Vertex lacks standing to pursue this claim, the Court declines to rule on the legality of HHS’s arguably shaky regulations.

Vertex claims that HHS has failed to adhere to a required procedure and thus seeks to enforce a procedural right: its entitlement to receive an advisory opinion within 60 days of requesting one. Assuming *arguendo* that the agency did act inconsistently with the statute, however, “[t]he mere violation of a procedural requirement . . . does not permit any and all persons to sue to enforce the requirement.” Fla. Audubon Soc’y v. Bentsen, 94 F.3d 658, 664 (D.C. Cir. 1996) (*en banc*). That is because a plaintiff must show that the procedural violation “will cause a distinct risk to a particularized interest of the plaintiff,” *id.*, a risk that must be “ongoing” when — as here — the plaintiff seeks declaratory relief. Dearth v. Holder, 641 F.3d 499, 501 (D.C. Cir. 2011); *see* Am. Compl., ¶¶ 165, 168. Whether this precept is couched as standing or as mootness is beside the point. After all, mootness is “the doctrine of standing set in a time frame: The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness).” Arizonans for Official English v. Arizona, 520 U.S. 43, 68 n.22 (1997) (quotation marks omitted).

To the extent that Vertex suffered a concrete harm purely as a result of HHS’s tardiness, rather than the substance of HHS’s determinations, that injury dissipated when the agency issued its advisory opinion. “[U]nder Article III, it is not enough for [Vertex] to allege that it was injured because [HHS] unlawfully delayed the [advisory opinion]; plaintiffs must show a ‘discrete injury flowing from’ such alleged delay.” All. for Democracy v. FEC, 335 F. Supp. 2d 39, 48 (D.D.C. 2004) (quoting Common Cause v. FEC, 108 F.3d 413, 418 (D.C. Cir. 1997)). If the Court allowed Plaintiff to establish standing to challenge the Department’s actions on the sole ground that it did not timely issue an advisory opinion, it “would be tantamount to recognizing a justiciable enforcement in the enforcement of the law. This we cannot do.” Common Cause, 108 F.3d at 418. Otherwise, the Court would risk allowing Congress to “create standing by

conferring upon all persons an abstract, self-contained, noninstrumental right to have the Executive observe the procedures required by law.” Id. (cleaned up).

That is especially true when, as here, Plaintiff has “received everything [it is] entitled to” substantively “under the” statute. All. for Democracy, 335 F. Supp. 2d at 48. Courts have often declined to grant — or even entertain requests for — relief when the agency has fulfilled its substantive obligations, even if it did so sluggishly. In the context of Freedom of Information Act requests, for example, the D.C. Circuit has explained that, “however fitful or delayed the release of information under the FOIA may be[,] . . . if we are convinced [the agencies] have, however belatedly, released all nonexempt material, we have no further judicial function to perform under the FOIA.” Tijerina v. Walter, 821 F.2d 789, 799 (D.C. Cir. 1987) (omission in original) (quoting Perry v. Block, 684 F.2d 121, 125 (D.C. Cir. 1982)). In other words, “[o]nce the records are produced[,] the substance of the controversy disappears and becomes moot.” Perry, 684 F.2d at 125 (quoting Crooker v. U.S. State Dep’t, 628 F.2d 9, 10 (D.C. Cir. 1980)). District courts in our Circuit have long followed that approach in FOIA cases. See, e.g., Ocasio v. DOJ, 70 F. Supp. 3d 469, 476–77 (D.D.C. 2014); Bangoura v. U.S. Dep’t of Army, 607 F. Supp. 2d 134, 142 n.6 (D.D.C. 2009); Sellers v. DOJ, 684 F. Supp. 2d 149, 157 (D.D.C. 2010). Similarly, in a case involving the Federal Energy Regulatory Commission, the Circuit has explained that “once the Commission has rendered a decision . . . , the issue of the timeliness of the Commission’s decision will be moot.” Potomac Elec. Power Co. v. ICC, 702 F.2d 1026, 1032 (D.C. Cir. 1983). As a result, if judicial review does not occur until after the Commission issues its decision, “there will be no effective remedy for the parties harmed by the Commission’s delay, even if that delay directly contravenes the intent of Congress.” Id.

The same principle holds true here: dilatory as HHS may have been, Vertex cannot now challenge the timeliness of its advisory opinion. Because the agency fulfilled its substantive obligations under the statute before the Court had a chance to weigh in on Plaintiff's procedural claim, it has no ongoing injuries that can be remedied or rights that must be vindicated. The Court therefore declines to address whether HHS's advisory-opinion regulations are inconsistent with the authorizing statute.

IV. Conclusion

For the foregoing reasons, the Court will grant Defendants' Motion for Summary Judgment and deny Plaintiff's Motion. A separate Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
Chief Judge

Date: March 31, 2025