

PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 24-1230

PHARMACEUTICAL COALITION FOR PATIENT ACCESS,

Plaintiff – Appellant,

v.

UNITED STATES OF AMERICA; DEPARTMENT OF HEALTH AND HUMAN SERVICES; OFFICE OF THE INSPECTOR GENERAL, U.S. Department of Health and Human Services; CHRISTI A. GRIMM, In Her Official Capacity as Inspector General of the United States Department of Health and Human Service; XAVIER BECERRA, In his official capacity as United States Secretary of the Department of Health and Human Services,

Defendants – Appellees.

Appeal from the United States District Court for the Eastern District of Virginia, at Richmond. Roderick Charles Young, District Judge. (3:22-cv-00714-RCY)

Argued: October 30, 2024

Decided: January 23, 2025

Before DIAZ, Chief Judge, KING, Circuit Judge, and Louise W. FLANAGAN, United States District Judge for the Eastern District of North Carolina, sitting by designation.

Affirmed by published opinion. Judge Flanagan wrote the opinion, in which Chief Judge Diaz and Judge King joined.

ARGUED: Paul J. Zidlicky, SIDLEY AUSTIN, LLP, Washington, D.C., for Appellant. Daniel Lee Winik, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellees. **ON BRIEF:** William A. Sarraille, PHARMACEUTICAL COALITION

FOR PATIENT ACCESS, Washington, D.C.; Madeleine Joseph, SIDLEY AUSTIN LLP, Washington, D.C., for Appellant. Brian M. Boynton, Principal Deputy Assistant Attorney General, Michael S. Raab, Charles W. Scarborough, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Jessica D. Aber, United States Attorney, OFFICE OF THE UNITED STATES ATTORNEY, Richmond, Virginia, for Appellees.

FLANAGAN, District Judge:

In this appeal, Pharmaceutical Coalition for Patient Access (the “Coalition”), a charitable organization involving a group of drug manufacturers, challenges an unfavorable advisory opinion issued by the Office of the Inspector General for the United States Department of Health and Human Services (the “Inspector General”), and the district court’s decision below declining to disturb that opinion. We find no error in the district court’s rulings and so affirm.

I.

Interaction between the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and the Coalition’s proposed patient assistance program to Medicare beneficiaries is at the heart of the dispute. We begin with a brief overview of Medicare, the Coalition’s program, and the Anti-Kickback Statute as pertinent to this case.

Medicare has four parts. Relevant here is Part D, which generally covers outpatient prescription drugs in conjunction with beneficiary co-pays. A Part D beneficiary is responsible for an initial deductible, and then enters various coverage thresholds, where the beneficiary is responsible for a 25% co-pay until reaching a “catastrophic coverage” threshold. At that point, the beneficiary is responsible only for a 5% co-pay, but with no dollar figure cap.¹

¹ Subsequent changes in the law altered some of these numbers, but these figures governed during the events of this case, and the subsequent changes make no difference to the legal issues now before the court. *See* J.A. 159.

As a result, some Part D beneficiaries are unable to access medically necessary oncology drugs due to significant out-of-pocket costs. J.A. 165. According to the advisory opinion, this structure exposes beneficiaries to the economic effects of drug pricing, thereby discouraging drug manufacturers from setting excessive prices. *See* J.A. 173–74.

The Coalition conceived of a patient assistance program to help Part D beneficiaries afford oncology drugs. The program would subsidize a Part D beneficiary’s co-pays if he or she had 1) a cancer diagnosis; 2) a household income between 150% and 350% of the federal poverty line; 3) a prescription for a Part D oncology drug produced by a participating manufacturer; and 4) initial approval for coverage for the drug through his or her Part D plan. J.A. 96, 125. Participation in the program would be open to any manufacturer of branded or generic oncology drugs reimbursed by Part D, and each participating manufacturer would pay the Coalition for costs associated with the subsidies the Coalition pays for that manufacturer’s own products (hereinafter the “funding manufacturers”). *See* J.A. 95, 169–70, 172. In addition to these co-pay subsidies, the Coalition would offer support for a cancer patient’s “additional medical needs,” and for various initiatives to support cancer screening and research. J.A. 94.

The Anti-Kickback Statute prohibits, as pertinent here, “knowingly and willfully offer[ing] or pay[ing] any remuneration” to “induce” an individual to purchase a federally reimbursable healthcare product. 42 U.S.C. § 1320a-7b(b)(2).

The relevant part of the statute is as follows:

(2) 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 –

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) 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.

Id.

Given the statute's criminal penalties, Congress also permitted parties to seek advisory opinions from the Inspector General on whether a proposed program would violate the statute. *Id.* § 1320a-7d(b). Advisory opinions bind the Department of Health and Human Services and the requesting party. *Id.* § 1320a-7d(b)(4)(A).

In this case, the Coalition requested such an opinion January 25, 2022. The Inspector General informed the Coalition that it had reached an unfavorable decision July 8, 2022, which would issue in the form of an advisory opinion if the Coalition did not voluntarily withdraw its request. The Coalition declined. Thereafter, the advisory opinion issued, which determined that the Coalition's proposed program would fall within the statute's proscriptions if the required mens rea were present, on grounds that the Coalition would pay remuneration in the form of subsidies to induce Part D beneficiaries to purchase funding manufacturers' drugs. According to the advisory opinion, the program was "highly suspect" as an attempt to "sidestep" the Anti-Kickback Statute and Medicare Part D, and would constitute grounds for sanctions if carried out. J.A. 174, 177.

The Coalition sued in the United States District Court for the Eastern District of Virginia on November 9, 2022, arguing that the advisory opinion violated the Administrative Procedure Act (“APA”), 5 U.S.C. § 706(2). Appellees moved for summary judgment on all the Coalition’s claims but one, and to dismiss for lack of subject matter jurisdiction over the Coalition’s last claim. The Coalition filed a cross-motion for summary judgment. The district court granted appellees’ motion, denied the Coalition’s motion, and dismissed the Coalition’s claims January 17, 2024. J.A. 645–46. This appeal followed.

II.

This court reviews a grant of summary judgment on an APA claim de novo. *Casa de Maryland v. Dep’t of Homeland Sec.*, 924 F.3d 684, 695 (4th Cir. 2019). This court reviews the grant of a motion to dismiss for lack of subject matter jurisdiction de novo. *Berkley v. Mountain Valley Pipeline, LLC*, 896 F.3d 624, 629 (4th Cir. 2018).²

III.

A.

The Coalition presents four broad arguments on appeal. First, it argues that the word “induce” in the Anti-Kickback Statute has a criminal law meaning of which its program does not fall afoul. Second, it contends that “remuneration,” as used in the statute, must corrupt medical decision-making, which its program does not. Third, it asserts that its proposed program does not involve any prohibited quid pro quo. Finally, it argues that

² The district court had jurisdiction under 28 U.S.C. § 1331. We have jurisdiction under 28 U.S.C. § 1291.

the district court erred in dismissing for lack of jurisdiction its claim that it was treated differently from similarly situated entities which have received favorable advisory opinions.

Statutory interpretation begins with the text of the statute. *Groff v. Dejoy*, 600 U.S. 447, 468 (2023); *Othi v. Holder*, 734 F.3d 259, 265 (4th Cir. 2013). To determine a statute’s plain meaning, this court looks not only to the statute’s language, but also to the context in which that language appears, and the broader context of the statute as a whole. *King v. Burwell*, 576 U.S. 473, 486 (2015); *Country Vintner of N.C., LLC v. E. & J. Gallo Winery, Inc.*, 718 F.3d 249, 258 (4th Cir. 2013). This court generally gives undefined terms their ordinary or natural meanings. *HollyFrontier Cheyenne Refining, LLC v. Renewable Fuels Ass’n*, 594 U.S. 382, 388 (2021). If statutory language is ambiguous, this court may turn to other sources of meaning such as canons of construction or background principles of law to determine meaning. *Bond v. United States*, 572 U.S. 844, 859–60 (2014); *Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 461–62 (2002).

B.

We turn first to the Coalition’s arguments on the word “induce.” We agree with the district court that that word should be construed under its ordinary meaning, not its specialized criminal law meaning.

The Coalition’s arguments revolve around *United States v. Hansen*, 599 U.S. 762 (2023), so we begin there. *Hansen* assessed a constitutional overbreadth challenge to 8 U.S.C. § 1324(a)(1)(A)(iv), which criminalizes “encourag[ing] or induc[ing]” unlawful immigration. *Hansen*, 599 U.S. at 766. The Supreme Court concluded that “induce,” as

used in that statute, has a “specialized, criminal-law” meaning which incorporated “common-law liability for solicitation and facilitation,” or in other words, “the intentional encouragement of an unlawful act” and “the provision of assistance to a wrongdoer with the intent to further an offense’s commission,” respectively. *Id.* at 771, 774. In contrast, the ordinary meaning of “induce” is “to lead on; to influence; to prevail on; to move by persuasion or influence.” *Id.* at 774 (citing *Induce, Webster’s New International Dictionary* (2d ed. 1953)).

The Court also cautioned lower courts against “stack[ing] the deck” in favor of a statutory term’s ordinary meaning, and emphasized that when a term has several plausible meanings, context differentiates among them. *Id.* at 775. The parties therefore clash on whether the Anti-Kickback Statute uses “induce” in its specialized or ordinary meaning, as evidenced by its statutory context.

The Coalition places much weight on *Hansen*’s discussion of the history of the word “induce” in criminal statutes, and the principle that when Congress uses a legal term of art in a statute, it presumably adopts the ideas attached to the term. *Id.* at 774. It argues that, just as in *Hansen*, Congress used “induce” as a term of art, thereby importing its common law roots in criminal solicitation and facilitation.

We disagree. Although the *Hansen* Court cautioned against “stack[ing] the deck” towards ordinary meaning, the Coalition attempts to stack the deck in the opposite direction, overriding numerous flags in the statutory history, which *Hansen* recognized as a key method through which to determine whether a statutory term has its ordinary or specialized meaning. *Id.* at 775.

First, the Coalition points out that, in *Hansen*, the Court bolstered its conclusion by observing that the immigration statute at issue prohibited inducing a separate violation of law, such that inducing the unlawful immigration necessarily constituted criminal solicitation and facilitation. *Id.* It therefore argues that the same principle applies here because no violation of the Anti-Kickback Statute can occur without a corresponding criminal violation by the recipient of the inducement. The Coalition is correct that the statute also prohibits “knowingly and willfully solicit[ing] or receiv[ing] any remuneration” in return for referring an individual to a person for the furnishing of any item or service for which payment may be made under a federal healthcare program. 42 U.S.C. § 1320a-7b(b)(1). At first glance, it would therefore appear that anytime a party offered remuneration, the offeree would necessarily violate the provision forbidding solicitation or receipt of such remuneration. But this reasoning does not stand up to scrutiny, and *Hansen*’s logic does not apply here in the manner the Coalition suggests.

We first disagree that the Anti-Kickback Statute necessarily prohibits the inducement of a separate violation of law. Merely referring an individual for a covered item or service is not criminal. That act becomes criminal only if done in return for remuneration. *Id.* If, for example, a party offered remuneration to a physician to furnish a federally reimbursable healthcare service with the requisite mens rea, and the physician refused the remuneration but furnished the service anyway under her independent professional judgment, the offering party, but not the physician, would have violated the statute. *See id.* (prohibiting only “solicit[ing] or receiv[ing]” remuneration).

The Coalition argues that in this example, the offering party still would have solicited, even if not facilitated, an Anti-Kickback Statute violation. However, this scenario would not involve even solicitation, in the criminal sense, of a violation of that statute. The Anti-Kickback Statute forbids seeking or receiving remuneration in return for furnishing covered health services, not the provision of such services in itself. So, the physician just discussed would not have violated the statute because she neither sought nor accepted any remuneration, meaning no violation of § 1320a-7b(b)(1) occurred. Put simply, a party can violate the Anti-Kickback Statute by offering remuneration without a corresponding violation by the offeree, if the latter did not seek or accept the remuneration, because furnishing covered healthcare goods is not inherently criminal. Accordingly, even with the Coalition’s caveat, the example just given would not align with *Hansen* because the offering party violated the Anti-Kickback Statute without soliciting or facilitating any independent criminal conduct, counselling against application of that case’s reasoning here.

In addition, “inducing” in the Anti-Kickback Statute is not a criminal act, but rather the motive or purpose that must exist for another act, offering or paying remuneration, to become criminal. The statute prohibits remuneration to induce a person to take certain other acts, such as purchasing a federally reimbursable healthcare good. *Id.* § 1320a-7b(b)(2). In contrast, the statute in *Hansen* prohibited inducing certain conduct in and of itself, when that other conduct was defined as necessarily criminal. *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 [action] *is or will be in violation of law*” (emphasis added)).

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.

As the Department of Health and Human Services observes, many of the other criminal statutes the *Hansen* Court cited in its discussion also limited prohibited inducement to commit another act to conduct expressly designated as criminal. *See, e.g.*, 18 U.S.C. § 2 (criminalizing inducing “an offense against the United States”); *id.* § 373(a) (criminalizing inducing a certain category of “felon[ies] . . . in violation of the laws of the United States”); *id.* § 2422(a) (criminalizing inducing prostitution “for which any person can be charged with a criminal offense”). Other examples abound. *See, e.g., id.* § 201(b)(1)(C) (criminalizing bribery to induce a public official “to do or omit to do any act in violation of the lawful duty of such official”); *id.* § 2314 (criminalizing inducing a person to travel in interstate or foreign commerce as part of a fraud offense).

In contrast, the Anti-Kickback Statute is more aligned with provisions that prohibit inducement of conduct that is not itself inherently criminal. For example, 18 U.S.C. § 706 proscribes wearing Red Cross emblems or insignia for the fraudulent purpose of inducing the belief that the wearer is a member thereof. Inaccurately believing another person is a member of the Red Cross is not criminal conduct, and so this statute would make no sense under a criminal law meaning of “induce,” because solicitation and facilitation liability necessarily depend on the existence of a crime at least contemplated by another. *See Hansen*, 599 U.S. at 771. One therefore could not criminally solicit a mistaken belief about membership in the Red Cross. The same logic applies to the Anti-Kickback Statute,

because purchasing a federally reimbursable healthcare product is not inherently criminal. We therefore agree that the text of the Anti-Kickback Statute counsels against reading “induce” to refer only to conduct that “leads or tempts to the commission of a crime.” *Hansen*, 599 U.S. at 776.

To summarize this point, the Anti-Kickback Statute does not criminalize the pure act of inducement, nor the underlying conduct, healthcare purchases or referrals, a defendant seeks to influence. Instead, it prohibits inducement accompanied by a specific motive, which does not necessarily lead to an independent crime. In contrast, the statute in *Hansen* prohibited the act of inducement in itself, when done knowing that an independent violation of law necessarily would result. *See id.* at 777 (“in violation of law”). Inducement in the *Hansen* statute is necessarily linked to other criminal conduct, but the same is not true here. This difference is only the first distinction in statutory context that persuades us that “induce” bears its ordinary meaning here.

We next observe that the canon of constitutional avoidance performed significant work in *Hansen*. When performing statutory interpretation with possible constitutional implications, “it is a cardinal principle that this Court will first ascertain whether a construction of the statute is fairly possible by which the [constitutional] question may be avoided.” *Jennings v. Rodriguez*, 583 U.S. 281, 296 (2018). Accordingly, *Hansen* presented a First Amendment overbreadth challenge, and the Court emphasized that it adopted its reading of the immigration inducement statute at least in part to avoid First Amendment concerns. *See id.* at 781. In contrast, the Coalition raises no constitutional

issues with the Anti-Kickback Statute, and so a factor that influenced the *Hansen* Court to adopt a specialized reading of “induce” in that statute is absent here.

The Coalition also contends that Congressional use of the word “influence,” rather than “induce” in the related Beneficiary Inducement Statute, 42 U.S.C. § 1320a-7a(a)(5), which imposes merely civil penalties, reflects a choice to subject “induces” in the Anti-Kickback Statute to its criminal meaning. However, this form of negative inference by implication weakens when two relevant statutory provisions are not considered or enacted together. *See Gomez-Perez v. Potter*, 553 U.S. 474, 486 (2008) (rejecting statutory construction that relied upon similar inference because the two pertinent provisions were not considered or enacted together). Here, the Anti-Kickback Statute and the Beneficiary Inducement Statute were not considered or enacted “even close in time.” *Pfizer, Inc. v. U.S. Dep’t of Health & Human Servs.*, 42 F.4th 67, 78 (2d Cir. 2022) (rebuffing exactly this argument). This contention therefore has little force. *See Potter*, 553 U.S. at 486–88 (rejecting similar argument for this reason).

Next, the Coalition’s reading would render superfluous a large swath of the Anti-Kickback Statute. The Supreme Court, and this court, have routinely emphasized that statutes should be interpreted in ways that avoid superfluity, including specifically of statutory exceptions. *E.g., Ysleta Del Sur Pueblo v. Texas*, 596 U.S. 685, 698–99 (2022); *Ark. Best Corp. v. C.I.R.*, 485 U.S. 212, 218 (1988) (applying principle to statutory exceptions); *Foxglenn Investors Ltd. P’Ship v. Cisneros*, 35 F.3d 947, 950 (4th Cir. 1994) (similar).

The Anti-Kickback Statute includes no fewer than 12 carve-outs excepting certain conduct from its proscriptions. *See* 42 U.S.C. § 1320a-7b(3). Many of these provisions do substantial work. For example, one excepts payments made as part of a bona fide employment relationship in the provision of covered items or services. *Id.* §1320a-7b(3)(B). Without this exception, the statute would likely cover much of the practice of medicine, because medical practices pay their doctors to provide or perform federally reimbursable healthcare goods and services. Under the Coalition’s reading, this exception would serve no purpose, because medical practices generally do not pay their doctors to solicit or facilitate violations of the criminal law.

Or consider another exception protecting a pharmacy’s waiver of a co-pay if the waiver is not advertised, does not routinely occur, and the pharmacy determines the patient is in financial need. *See id.* §§ 1320a-7b(3)(G), 1320a-7a(i)(6)(A). Absent this exception, the pharmacy would provide remuneration, the waiver, to influence a patient to purchase a federally reimbursable healthcare good, thereby violating the statute. Under the Coalition’s reading, in contrast, this exception does no work because waiving a co-pay does not solicit or facilitate criminal conduct.

A third provision excepts ordinary healthcare supply transactions from the statute provided certain conditions are met. *Id.* § 1320a-7b(3)(C). Under the Coalition’s interpretation, this exception would, again, be pointless, because ordinary contracting for the purchase of healthcare supplies is not criminal. In contrast, each exception performs a function under the reading advanced by the Department of Health and Human Services, as the medical practice, pharmacy, or supplier would in each instance influence the purchase

of a federally reimbursable healthcare good or service through something of value. The exceptions are thus necessary to protect these activities because Congress used the ordinary meaning of induce in the Anti-Kickback Statute.

The Coalition counters that these exceptions were redundant legislation, intended merely to confirm an existing understanding that these activities do not fall within the statute. Indeed, the Supreme Court has recognized that “sometimes in a congressional effort to be doubly sure, sometimes because of congressional inadvertence or lack of foresight, or sometimes simply because of the shortcomings of human communication,” statutory redundancies may exist. *Barton v. Barr*, 590 U.S. 222, 239 (2020). However, cases applying this logic often involve clashing interpretations that *both* involve superfluity, or a position that creates only minor redundancy. *See Barr*, 590 U.S. at 239 (rejecting interpretation that would rewrite a statute to avoid moderate redundancy, and recognizing that both sides’ positions created redundancies); *Rimini Street, Inc. v. Oracle USA, Inc.*, 586 U.S. 334, 345–46 (2019) (clashing redundancies); *Wis. Cent. Ltd. v. United States*, 585 U.S. 274, 281–82 (2019) (provision would perform at least some function under either side’s reading). The Coalition’s position, if adopted, creates far deeper redundancy issues than the cases just cited. It would make pointless a core feature of the Anti-Kickback Statute. This consequence is far afield from the minor redundancies created in these cases. Moreover, even setting aside these issues, the Coalition provides no evidence or legal argument about pre-enactment enforcement practices that could suggest the exceptions set forth above were recognized prior to their codification through statutory enactment.

Because the Coalition’s reading of “induce” would create vast superfluity in the statute, and its argument that the statutory exemptions merely reconfirmed pre-existing understandings is unpersuasive, the canon against superfluity helps convince us that that word bears its ordinary meaning here. *See, e.g., Ysleta Del Sur Pueblo*, 596 U.S. at 698–99 (rejecting statutory interpretation that created substantial redundancy).

Finally, the Coalition resorts to policy arguments, asserting that a contrary reading of “induce” would criminalize societally beneficial conduct. The Supreme Court has consistently pronounced that courts should not use extratextual considerations to circumvent the meaning of an unambiguous statute. *E.g., McGirt v. Oklahoma*, 591 U.S. 894, 915–16 (2020). In light of the above, we conclude that the meaning of the word “induce” in the Anti-Kickback Statute is not sufficiently ambiguous to justify consultation of any such considerations, in contrast to the cases the Coalition cites. In each, the statute was ambiguous or other considerations were at play, such as the Court’s suspicion of mens rea-less criminal statutes. *See Ruan v. United States*, 597 U.S. 450, 458–60 (2022) (noting ambiguity of mens rea provision and restating limitations on strict liability criminal offenses); *McDonnell v. United States*, 579 U.S. 550, 574–75 (2016) (government’s interpretation of criminal statute “raise[d] significant constitutional concerns”); *Skilling v. United States*, 561 U.S. 358, 408–09 (2010) (similar).

Because the statute here is not ambiguous, we decline to base our decision on policy concerns. “Achieving a better policy outcome . . . is a task for Congress, not the courts.” *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 13–14 (2000).

Applying the above reasoning to this case, we agree with the Department of Health and Human Services and with the district court that the Coalition’s program would involve inducement in the ordinary sense, as it would offer subsidies to support the purchase of federally reimbursable healthcare goods and services, thereby plainly influencing patients towards such purchases. *Hansen*, 599 U.S. at 774.

C.

Next, the Coalition contends that its proposed program would not violate the Anti-Kickback Statute because it would not offer illegal remuneration that corrupts the medical decision-making process. We disagree.

The Anti-Kickback Statute prohibits offering “any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind[.]” to induce a person to refer another for the furnishing of any federally reimbursable healthcare good or service, or to induce purchasing or ordering any such good or service. 42 U.S.C. § 1320a-7b(b)(2). The parties clash over the meaning of the word “remuneration,” largely through the dueling use of interpretative canons. We conclude that the Department of Health and Human Services has the better of this argument.

The Coalition contends that “remuneration” is limited to remuneration that corrupts the medical decision-making process, not its ordinary meaning of any kind of reward or compensation as understood both now and at the time of enactment. *Wis. Cent. Ltd.*, 585 U.S. at 278; *Remuneration*, *Black’s Law Dictionary* (4th ed. 1968). We disagree.

First, the Coalition argues that the sub-heading for this portion of the statute, “illegal remunerations,” proves its point. However, such headings are valid tools of interpretation

only if part of the text Congress actually enacted. *See Adoptive Couple v. Baby Girl*, 570 U.S. 637, 648 n.5 (2013). The phrase “illegal remunerations” here does not appear in the text Congress enacted, but arose instead as a codifier’s addition. *See Social Security Amendments of 1972*, Pub. L. No. 92-603, § 242, 86 Stat. 1329, 1419 (1972); *Medicare-Medicaid Anti-Fraud and Abuse Amendments*, Pub. L. No. 95-142, 91 Stat. 1175, 1180 (1977). This first argument therefore carries no force.

The Coalition’s interpretation of “remuneration” as limited to corrupt transactions is therefore glaringly absent from the text of the statute. The Coalition instead attempts to enlist the interpretative canon of *noscitur a sociis* to link corrupt connotations from surrounding words to “remuneration.”

Noscitur a sociis, a rule of construction that a word receives more precise content by the words with which it associates, helps courts determine the meaning of ambiguous statutory terms. *United States v. Williams*, 553 U.S. 285, 294 (2008). The Coalition argues that the textual association of “remuneration” with “kickbacks, bribes, and rebates” demonstrates that the former term shares the corrupt meaning inherent to each member of the latter group.

The parties agree that kickbacks and bribes are generally corrupt, *see* Resp. Br. at 33, and so spar primarily on “rebates.” This term has no inherent corrupt meaning, either now or at the time of enactment. *See Rebate*, *Black’s Law Dictionary* (4th ed. 1968); *Rebate*, *Black’s Law Dictionary* (12th ed. 2024); *see also, e.g.*, 26 U.S.C. § 6211(b)(2) (defining tax “rebate” without any criminal connotations). The Coalition resists this conclusion with two other dictionaries. The first is a version of *Black’s* which included an

ambiguous cross-reference to both the corrupt “kickback” and the innocuous “refund.” *Rebate*, *Black’s Law Dictionary* (5th ed. 1979). We draw little value from this nebulous notation. The second defines “kickback” as a “*secret* rebate.” *Kickback*, *Webster’s Third New International Dictionary* (1976) (emphasis added). The addition of the adjective “secret” therefore implies that rebates are usually not related to kickbacks, and so not corrupt. Neither of the Coalition’s dictionaries helps it.

The Coalition also points to *United States v. Zacher*, 586 F.2d 912 (2d Cir. 1978) for the proposition that “rebate” is necessarily a corrupt payment. That case indeed includes language supporting its position. *Id.* at 916 (“each [term] involve[s] a corrupt payment”). However, the Second Circuit recently clarified that given the issues presented on appeal in *Zacher*, its decision there did not turn on “whether *any* payment prohibited by the [Anti-Kickback Statute] must involve dishonesty,” but rather whether the particular payments qualified as bribes. *Pfizer, Inc.*, 42 F.4th at 75 (emphasis in original). We follow the Second Circuit in declining to rely upon dicta from *Zacher* to resolve this appeal. *See id.*

The Coalition also employs the canon of *ejusdem generis*, which provides that when “general words follow specific words in a statutory enumeration, the general words are usually construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words.” *Yates v. United States*, 574 U.S. 528, 545 (2015) (plurality op.). Specifically, it argues that, as with its *noscitur a sociis* point, we should read “remuneration” to encompass only corrupt payments such as kickbacks, bribes and, in its

view, rebates. As just discussed, however, we do not think that “rebates” bears the corrupt connotation the Coalition suggests.

The Department of Health and Human Services also suggests that *ejusdem generis* simply cannot apply here, because the general word in the Anti-Kickback Statute precedes the specific, while *Yates* instructs us to apply the canon “when general words *follow* specific words[.]” *Id.* (emphasis added). This court has applied *ejusdem generis* in the opposite sequence, albeit before *Yates*. See *Adams v. Dole*, 927 F.2d 771, 776–77 (4th Cir. 1991). However, there is no need to assess whether *Yates* limited *ejusdem generis* to the “specific then general” sequence, or merely recounted the most common circumstances of its application, because even with this point in its favor, the Coalition’s arguments on “remuneration” do not prevail.³ *Ejusdem generis* does not apply “woodenly,” and sometimes Congress elects to include specific examples to remove doubt about a statute’s scope, even if the examples should fall within a general term anyway. See *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 226–27 (2008). Here, Congress similarly may have wished to make clear to courts that the insertion of “remuneration” into the Anti-Kickback Statute was augmentation, not substitution, and so retained the specific examples. See *id.*

Importantly, the Coalition’s interpretation of “remuneration” also runs afoul of key words in the statute: “any” and “including.” *Zacher*, upon which the Coalition relies,

³ We nonetheless observe that post-*Yates* applications of *ejusdem generis* from the Supreme Court and this court have involved the “specific then general” sequence. See *Lagos v. United States*, 584 U.S. 577, 582 (2018); *Ford v. Sandhills Med. Found.*, 97 F.4th 252, 259 (4th Cir. 2024); *Wikimedia Found. v. NSA/Cent. Sec. Serv.*, 14 F.4th 276, 296–97 (4th Cir. 2021).

construed the original 1972 statute, which lacked this feature. Pub. L. No. 92-603, 86 Stat. 1329, 1419 (1972). Congress saw fit later to enlarge the scope of the Anti-Kickback Statute’s prohibitions by adding those key words. The statute now prohibits “any remuneration (*including* any kickback, bribe, or rebate)[.]” 42 U.S.C. § 1320a-7b(b)(2) (emphases added). Both “any” and “including” are terms of enlargement, which clarify that given examples are merely illustrative. *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012); *Dep’t of Hous. & Urb. Dev. v. Rucker*, 535 U.S. 125, 131 (2002). Congress’s choice of these two words demonstrates that the three named transactions are only examples, and do not confine the word “remuneration” as the Coalition suggests. The three examples’ appearance in a parenthetical reinforces this conclusion, because “[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).

The Coalition resists this conclusion by pointing to *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043 (6th Cir. 2023). There, the Sixth Circuit stated that “any” functions merely to extend the statute to remuneration “of any type (cash, services, goods)[.]” *Id.* at 1051. We must respectfully disagree with the Sixth Circuit. The Anti-Kickback Statute includes other language that more clearly performs this function: “directly or indirectly, overtly or covertly, *in cash or in kind*[.]” 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). The Coalition’s reading of the words “any” and “including” would render this specific language redundant, counselling against that conclusion. *Ysleta Del Sur Pueblo*, 596 U.S. at 698–99. We therefore see no reason to depart from interpreting

“any” and “including” under their ordinary statutory functions of enlargement. *Christopher*, 535 U.S. at 131.

The Coalition makes several other arguments on “remuneration,” none of which succeeds.

First, it argues that the 1977 amendments added “any” and “including” to address a particular loophole under which defendants could avoid liability by performing some minimal medical service. *See United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985) (discussing this history). But whatever its purpose, Congress elected to use very sweeping language to accomplish that aim. The plain meaning of the language Congress enacted supports the reading advanced by the Department of Health and Human Services, not the Coalition, and when “the statutory language is clear, as it is in this case, our inquiry must end.” *Mort Ranta v. Gorman*, 721 F.3d 241, 253 (4th Cir. 2013).

Second, the Coalition invokes the canon against absurdity, which permits courts to look beyond the plain language of a statute when “literal application” of the language creates an “absurd” outcome “that is so gross as to shock the general moral or common sense,” or produces an outcome “demonstrably at odds with clearly expressed Congressional intent.” *In re Sunterra Corp.*, 361 F.3d 257, 265 (4th Cir. 2004). This canon should be applied only in “exceptionally rare” instances. *Id.* The Coalition does not come close to meeting the stringent standard for application of this canon.

Finally, the Coalition invokes the same policy concerns as in its arguments on “induce.” These concerns are neither a proper basis for our decision on their own terms, nor so “shock[ing]” as to justify application of the canon against absurdity. *Sunterra Corp.*,

361 F.3d at 265; *see also United States v. Dauray*, 215 F.3d 257, 264 (2d Cir. 2000) (applying canon against absurdity, but only to consider legislative history, when each side’s interpretation created gaping and illogical holes in core conduct covered by statute).

We therefore determine that “remuneration” here has its ordinary meaning of payment or compensation, not a specialized meaning of a corrupt payment that distorts the medical decision-making process. The Coalition’s program would offer remuneration under that word’s ordinary meaning. The subsidies it proposes are valuable payments. *E.g., Wis. Cent. Ltd.*, 585 U.S. at 278; J.A. 125. We find no error in the district court’s resolution of this issue.

D.

Third, the Coalition argues that its program would not constitute a forbidden quid pro quo. We again disagree.

At the outset, the Department of Health and Human Services concedes for the purpose of this case that an Anti-Kickback Statute violation must involve a quid pro quo. *See Resp. Br.* at 41. We accept this concession for the purposes of this case, and assume without deciding that a quid pro quo is indeed required, while reserving that question for a future case. *Pfizer, Inc.*, 42 F.4th at 74 (proceeding in same fashion). A quid pro quo is “an action or thing that is exchanged for another action or thing or more or less equal value[.]” *Quid Pro Quo*, *Black’s Law Dictionary* (12th ed. 2024).

The Coalition’s proposal as presented to the Inspector General, and as interpreted by that body, would provide subsidies only for prescriptions of the funding manufacturers’ products. “[The Coalition’s proposal] would establish a pathway for each Funding

Manufacturer to subsidize the cost-sharing amounts owed only for their own drugs, not for the drugs of any other Funding Manufacturer.” J.A. 158; *see id.* at 95.

The Coalition argues that its proposal cannot constitute a quid pro quo because it is “agnostic” about the choice of any particular drug, and because funding manufacturers would contribute millions in funding not linked even to any category of drugs. Coalition Br. at 57.

The Coalition first contends that no quid pro quo could exist here because its subsidies are not contingent on the purchase of specific, individual drugs. We are unpersuaded. This court has made clear in the analogous context of bribery that a forbidden payment need not be correlated directly to a specific official act. *See United States v. Jennings*, 160 F.3d 1006, 1014 (4th Cir. 1998). “In other words, the intended exchange in bribery can be ‘this for these’ or ‘these for these,’ not just ‘this for that.’” *Id.* “All that must be shown is that payments were made with the intent of securing a specific *type* of official action[.]” *Id.* (emphasis in original).⁴ Applying this reasoning here, the Coalition’s subsidies would constitute a quid pro quo despite the lack of a connection to individual purchases. They would still qualify as “these for these” payments, in which the forbidden payment was agnostic as to the specific act eventually performed or, in this context,

⁴ *Jennings* and this logic survived the Supreme Court’s intervening decision in *McDonnell v. United States*, 579 U.S. 550 (2016). *See United States v. McCabe*, 103 F.4th 259, 283–85 (4th Cir. 2024), *cert. denied*, ___ S. Ct. ___, 2024 WL 4486494 (mem.) (Oct. 15, 2024).

specific drug purchased. *See Jennings*, 160 F.3d at 1014. The Coalition offers no persuasive argument to the contrary.

It is helpful to consider a simplified hypothetical version of the Coalition's program. A certain disease is treatable by any of four drugs: Drugs A, B, C, and D. The manufacturers of Drugs A, B, and C convene and form a patient assistance program which would pay for medication to treat the disease. The manufacturers would subsidize purchases only of their own drugs, so that Manufacturer A would subsidize Drug A, and so on. The program would thus offer patients subsidies for any of Drugs A, B, or C, but nothing if the patient wished to use Drug D. The program would have no pecuniary interest in the choice made by the patient between Drugs A, B, or C, but would have an interest in influencing the patient's choice between *that group* of three and Drug D. A quid pro quo would still exist because the program would subsidize the patient's selection of one of the three drugs produced by the manufacturers. The existence of the program as an intermediary would merely meld multiple offers into one larger quid pro quo. The same logic applies here.

The Coalition also contends that the sheer number of participating manufacturers defeats any possible quid pro quo. It offers no persuasive argument on why a quid pro quo cannot exist with more than one offeror, and we agree instead with the district court, which rejected this argument as illogical. *See Pharm. Coal. for Patient Access v. United States*, No. 3:22-cv-714, 2024 WL 187707, at *6 (E.D. Va. Jan. 17, 2024).

The Coalition also points to a 2005 Department of Health and Human Services guidance bulletin which stated that including a large number of manufacturers in this type

of program would “sever any nexus between the subsidy and a beneficiary’s choice of drug[.]” Publication of OIG Special Advisory Bulletin on Patience Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,627 (Nov. 22, 2005). However, this same bulletin recognized that programs like the Coalition’s were “nascent,” and that any “definitive guidance on these evolving programs” would be “premature.” *Id.* This bulletin was the first foray into this field for the Department of Health and Human Services, and it expressly hedged its conclusions and declined to offer “definitive” guidance. The advisory opinion in this case recognized these caveats, and noted that the Inspector General has amassed nearly 20 years of enforcement experience since that bulletin was issued in 2005, in reaching a different conclusion on the importance of participation by multiple manufacturers. J.A. 171–72. We therefore accord little weight to this 2005 bulletin and the Coalition’s reliance thereon.

Finally, the Coalition protests that some other aspects of its program would not constitute any quid pro quo. Namely, its program would have funded other health insurance programs and other medical initiatives in addition to its drug subsidies. J.A. 160. These payments, indeed, were not linked to the purchase of any participating manufacturer’s products. *Id.* However, the Inspector General did not rule that these payments would violate the Anti-Kickback Statute, but rather concluded that the program “*as a whole*, would present more than a minimal risk of fraud and abuse under the Anti-Kickback Statute.” J.A. 176 (emphasis added). We agree with the Department of Health and Human Services that even if some other aspects of the Coalition’s program might pass

muster under the Anti-Kickback Statute on their own, their inclusion would not cure the proposed program's other infirmities.

We therefore conclude that, assuming the Anti-Kickback Statute includes a quid pro quo requirement as the Department of Health and Human Services concedes, the Coalition's program met it. It ventures to offer subsidies (quid) for a beneficiary's purchase of a covered drug, or at least one of a group of covered drugs (quo).

E.

The Coalition's last challenge on appeal is that the district court improperly dismissed its disparate treatment claim for lack of subject matter jurisdiction. We conclude that dismissal on this basis was proper.

Before the district court, the Coalition alleged that the advisory opinion was arbitrary and capricious because of its enforcement conclusions. Specifically, the Coalition alleged that the Inspector General pledged to forego enforcement against similar proposals, but would not disavow enforcement over its proposed program. *See* J.A. 62.

The APA prohibits judicial review of actions committed to agency discretion by law. 5 U.S.C. § 701(a)(2). This defect goes to subject matter jurisdiction. *Angelex Ltd. v. United States*, 723 F.3d 500, 505–06 (4th Cir. 2013).

Agency action is committed to the agency's discretion when no judicially manageable standards are available to assess how and when an agency should exercise its discretion such that a court would have "no law to apply." *Heckler v. Chaney*, 470 U.S. 826, 830–31 (1985). An agency's discretion not to prosecute or enforce is generally committed to the agency's "absolute discretion" and "unsuitabl[e]" for review. *Id.* at 831.

This is because 1) an agency decision not to enforce often involves complicated interest-balancing of factors within the agency’s expertise; 2) a decision *not* to enforce infringes on no liberty or property interests; and 3) this arrangement resembles the strong discretion given to prosecutors on charging decisions. *See id.* at 831–32; *see also United States v. Texas*, 599 U.S. 670, 680 (2023) (citing *Heckler* in a discussion of executive enforcement discretion); *Holbrook v. Tennessee Valley Authority*, 48 F.4th 282, 290 (4th Cir. 2022) (citing *Heckler* and the rationales just noted). The Anti-Kickback Statute itself grants prosecutorial discretion to the Inspector General as it states that it “may” exclude violators from participation in federal health programs, and that violators “shall” be subject to penalties, not that the agency *must* seek them. *See* 42 U.S.C. §§ 1320a-7(b)(7), 1320a-7b(a).

We conclude that the decision not to disavow possible enforcement here falls within the holding of *Heckler*, and that the Coalition’s arguments to the contrary are directed against the wrong target.

The Coalition invokes the general rule that agencies generally must treat like cases alike. *Kirk v. Comm’r of Soc. Sec. Admin.*, 987 F.3d 314, 321 (4th Cir. 2021). But the Coalition’s challenge is not really to the consistency of assessments on programs like the Coalition’s, but rather to how the Inspector General has elected to exercise its enforcement discretion against such programs. Every one of the advisory opinions the Coalition argues arbitrarily treated a similar proposed program differently reached the same merits conclusion on the application of the Anti-Kickback Statute as here, that the pertinent program could violate the statute if the necessary mens rea existed. *See* J.A. 539, 566, 571,

575, 578, 581, 585, 589, 595, 598–99. The Inspector General therefore treated like cases alike, *Kirk*, 987 F.3d at 321, by applying the statute in the same manner to proposals materially similar to the Coalition’s.

The Coalition characterizes these prior opinions as favorable, and the opinion here as unfavorable. But all the opinions involved here held that the proposal presented would violate the Anti-Kickback Statute if the needed mens rea existed. In that sense, they were equally unfavorable. The only difference between the advisory opinion on the Coalition’s proposal and these others is that the Inspector General reached different conclusions on whether enforcement actions might be warranted. *Compare* J.A. 539, *with* J.A. 177. The Coalition’s disparate enforcement claim is thus directed against the inconsistent exercise of discretion, not the consistent merits evaluation of these various proposals under the Anti-Kickback Statute.

The Coalition points to several provisions of the Anti-Kickback Statute governing how the Department of Health and Human Services makes merits determinations, and establishing procedural protections once sanctions actually are imposed. *See* 42 U.S.C. §§ 1320a-7d(b)(2)(A), 1320a-7(f). These sections are irrelevant here, because they constrain how the Department of Health and Human Services may assess sanctions once the prosecutorial decision to seek them is made, not its discretionary decisions on whether to pursue enforcement in the first place.

This issue also falls squarely within our decision in *Speed Mining, Inc. v. Fed. Mine Safety & Health Review Comm’n*, 528 F.3d 310 (4th Cir. 2008). In that case, we rejected as unreviewable a challenge to an agency’s decision to cite one mine-operator, but not

another. *See id.* at 317–19. This case aligns neatly with *Speed Mining*. The Coalition challenges the refusal by the Department of Health and Human Services to disavow enforcement against it, because it has declined to pursue enforcement against others in the past.

The Coalition’s only response is to double down on its argument that because the Inspector General has issued favorable opinions on similar proposals in the past, it *must* issue a favorable opinion on its program. But again, the Coalition misreads the other advisory opinions on which it relies. Each was unfavorable on the merits. More fundamentally, holding that once an agency makes an enforcement decision on a particular issue, it must reach the same conclusion in all future cases would effectively abolish enforcement discretion. *Heckler* does not countenance that result. *See Heckler*, 470 U.S. at 831; *Speed Mining*, 528 F.3d at 317–19.

The Coalition’s disparate treatment challenge is directed purely against how the Inspector General employs its enforcement discretion. It therefore must fail as unreviewable.

IV.

In sum, we conclude that the district court did not err in its rejection of the Coalition’s challenges to the advisory opinion in this case. The district court’s judgment is therefore

AFFIRMED.