UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2021

(Argued: May 25, 2022 Decided: July 25, 2022)

Docket No. 21-2764-cv

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PFIZER, INC.,
*Plaintiff-Appellant*,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL, CHRISTI A. GRIMM, in her official capacity as Principal Deputy Inspector General of and Senior Official in the United States Department of Health and Human Services Office of Inspector General,
*Defendants-Appellees*.

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Before: POOLER, SACK, and NATHAN, *Circuit Judges*.

Plaintiff-appellant Pfizer, Inc. brought this action in the United States District Court for the Southern District of New York under the Administrative Procedure Act, 5 U.S.C. § 706(2), challenging an advisory opinion issued by the United States Department of Health and Human Services Office of Inspector General ("HHS OIG"). Pfizer produces and sells a drug called tafamidis that treats a rare, progressive heart condition known as transthyretin amyloid cardiomyopathy. To make the expensive treatment more affordable, Pfizer proposed a Direct Copay Assistance Program, through which Pfizer would directly cover the cost of a patient's co-pay for tafamidis. HHS OIG issued an advisory opinion stating that the Direct Copay Assistance Program would violate the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B). The district court (Mary K. Vyskocil, *J.*) granted summary judgment to defendants, rejecting Pfizer's argument that liability under the Anti-Kickback Statute requires

an element of "corrupt" intent. We agree with the district court that the agency's interpretation of the Anti-Kickback Statute is not contrary to law. We therefore

AFFIRM the judgment of the district court.

DOUGLAS HALLWARD-DRIEMEIER, Ropes & Gray LLP, Washington, DC (Samantha Barrett Badlam, Ropes & Gray LLP, Washington, DC; Joan McPhee, Ropes & Gray LLP, New York, NY; Ilana H. Eisenstein, DLA Piper LLP, Philadelphia, PA, *on the brief*), *for Plaintiff-Appellant*;

REBECCA S. TINIO (Benjamin H. Torrance, *on the brief*), *for Damian Williams, United States Attorney for the Southern District of New York, New York, NY, for Defendants-Appellees.*

SACK, *Circuit Judge*:

Pfizer, Inc. produces and sells a drug called tafamidis, which treats a rare, progressive heart condition known as transthyretin amyloid cardiomyopathy ("ATTR-CM"). Tafamidis is considered a breakthrough treatment – it is currently the only drug approved by the United States Food and Drug Administration ("FDA") to treat ATTR-CM. It also carries an extremely high price tag: $225,000 per year.

Because ATTR-CM disproportionately affects older Americans, most ATTR-CM patients are covered by Medicare. Under Medicare's pricing formula,

patients who use tafamidis are responsible for a co-pay of about $13,000 per year. Concerned that many patients cannot afford this price, Pfizer proposed a program, called the Direct Copay Assistance Program (the "Direct Program"), which would directly cover a patient's co-pay if the patient met specified eligibility criteria. Pfizer sought an advisory opinion from the United States Department of Health and Human Services Office of Inspector General ("HHS OIG") to ensure that its proposal did not run afoul of federal laws.

HHS OIG ultimately issued an unfavorable advisory opinion, concluding that the Direct Program would violate the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(2)(B), if implemented with the intent specified in the statute. Pfizer then brought this action in the United States District Court for the Southern District of New York under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), challenging the agency's interpretation of the AKS as contrary to law. Following cross-motions for summary judgment, the district court (Mary K. Vyskocil, *Judge*) granted summary judgment to the government on the APA claim. *Pfizer, Inc. v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021). The court rejected Pfizer's narrower reading of the AKS, which would require an element of "corrupt" intent to

impose liability. The district court concluded that the agency's interpretation was not contrary to law. For the reasons set forth below, we AFFIRM the judgment of the district court.

## BACKGROUND

### *Factual Background*

The following facts, which are substantially undisputed by the parties, are drawn from Pfizer's complaint and the administrative record before HHS OIG.

#### *A. Pfizer's Drug*

ATTR-CM is a rare cardiac condition characterized by deposits of amyloid protein in the heart muscle, "causing the heart to stiffen and thereby limiting its ability to pump blood to the body." Compl. ¶ 3, at A.12. ATTR-CM patients "experience a progressive decline in function, beginning with fatigue and shortness of breath and ending with potential heart failure, inability to perform even the most basic daily activities, and eventually death." *Id.* Without treatment, patients have a median life expectancy of two to three-and-a-half years after diagnosis. An estimated 100,000 to 150,000 Americans, most of whom are elderly, suffer from the condition.

Through nearly two decades of research and testing, Pfizer developed a treatment for ATTR-CM called tafamidis, which it sells under the brand names Vyndaqel and Vyndamax. Tafamidis is not a cure, but it slows the decline in quality of life, reduces hospitalization rates, and typically helps patients live longer. In May 2019, the FDA approved tafamidis for the treatment of ATTR-CM, making it the first, and currently the only, FDA-approved pharmacological treatment for the disease. Other treatments exist, but they are "off-label," i.e., not approved by the FDA to treat ATTR-CM. Some patients may also have non-pharmacological options, such as an organ transplant.

Pfizer charges $225,000 for a one-year course of tafamidis. According to Pfizer, the price of the drug reflects its "strong efficacy and safety profile, its slowing of the decline in functional status and quality of life, and the relatively small population of patients with ATTR-CM." Compl. ¶ 5, at A.13. The FDA designated tafamidis as an "orphan drug," which is a special classification that offers financial incentives, including potential market exclusivity, for the development of treatments for rare disease. Pfizer asserts that such drugs have nonetheless become increasingly expensive for pharmaceutical companies to develop. *Id.* ¶ 32, at A.21. Pfizer also contends that the "off-label" options for

treating ATTR-CM are more expensive than tafamidis, as is a heart or liver transplant. *Id.* ¶ 5, at A.13; A.79-80. HHS, on the other hand, cites a 2020 study concluding that tafamidis is "the most expensive cardiovascular drug ever launched in the United States."[1]

*B. The Direct Copay Assistance Program*

Because ATTR-CM disproportionately affects older persons, most ATTR-CM patients are beneficiaries of Medicare.[2] Almost all Medicare plans provide coverage for tafamidis, but under Medicare Part D – which covers outpatient prescription drugs – beneficiaries remain responsible for certain specified deductibles and co-pays. As relevant to this case, Part D beneficiaries are responsible for 100% of an initial deductible, which in 2020 was $435. After satisfying that deductible, beneficiaries enter various coverage phases, where they are responsible for a 25% coinsurance payment until they reach the

[1] OIG Advisory Op. No. 20-05, 12 (Dep't of Health & Human Servs. Sept. 18, 2020), at A.219 (citing Dhruv S. Kazi et al., *Cost-Effectiveness of Tafamidis Therapy for Transthyretin Amyloid Cardiomyopathy*, 141 CIRCULATION RES. 1214 (2020), https:// ahajournals.org/doi/epub/10.1161/CIRCULATIONAHA.119.045093).

[2] *See Who is eligible for Medicare?*, U.S. Dep't of Health & Human Servs., https://hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicare/index.html ("Generally, Medicare is available for people age 65 or older, younger people with disabilities[,] and people with End Stage Renal Disease (permanent kidney failure requiring dialysis or transplant).").

"catastrophic coverage" threshold. Upon reaching "catastrophic coverage," which in 2020 was $2,652 out-of-pocket (including the prior deductible and coinsurance payments), beneficiaries continue to pay 5% of the cost for brand-name medications. There is no upper limit on that 5% contribution.

From the government's perspective, as explained by HHS OIG, this cost-sharing structure "expos[es] [Medicare] beneficiaries to the economic effects of drug pricing" and thereby acts as "a market safeguard that Congress included [in Medicare Part D] to protect against inflated drug prices." OIG Advisory Op. No. 20-05, 17-18 (Dep't of Health & Human Servs. Sept. 18, 2020), at A.224-25. The government provides a subsidy to assist lower-income Medicare beneficiaries, but only if they fall below 150% of the federal poverty level, or an annual income of $19,140. Survey data suggests that, in 2016, approximately 29% of Part D participants qualified for this subsidy.[3]

Under the payment structure outlined above, Medicare beneficiaries who use tafamidis are responsible for a co-pay of approximately $13,000 per year. Pfizer's concern is that many "middle-income" Medicare patients, who do not

[3] Compl. ¶ 49 n.8, at A.27 (citing Jack Hoadley et al., *Medicare Part D in 2016 and Trends over Time*, Kaiser Family Foundation (Sept. 16, 2016), https://www.kff.org/report-section/medicare-part-d-in-2016-and-trends-over-time-section-4-the-low-income-subsidy-program).

otherwise qualify for co-pay assistance options, will be unable to afford that price. Compl. ¶ 7, at A.13-14. Even if the company cut the price of tafamidis in half, Pfizer contends, the Medicare co-pay would be approximately $8,000, which remains a significant financial barrier for many patients. *Id.* ¶ 53, at A.28. Pfizer pointed to one study indicating that 49% of cancer patients failed to refill their prescriptions when the out-of-pocket costs exceeded $2,000.[4]

To address this concern, Pfizer proposed the Direct Copay Assistance Program. Through this program, Pfizer would cover almost the entirety of a Medicare beneficiary's co-pay for tafamidis so long as: (1) the patient was prescribed tafamidis to treat ATTR-CM, (2) the patient is a U.S. resident, and (3) the patient meets program criteria for financial need, which are tailored to address the burden that "middle-income" patients face in acquiring tafamidis. Patients who are eligible for the Direct Program would be responsible for only $35 per month, with Pfizer covering the remainder of the approximately $13,000 annual co-pay. The federal government, through Medicare, would pick up the rest of the $225,000 tab.

[4] Compl. ¶ 51 n.10, at A.27 (citing Jalpa A. Doshi et al., *Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, 36 J. OF CLINICAL ONCOLOGY 476 (2018)).

Pfizer emphasized, both in its submissions to HHS and in its complaint in the district court, that it would not use the Direct Program to solicit new patients for tafamidis – a patient would only become eligible for the Direct Program after a physician prescribes the treatment. Compl. ¶ 63, at A.30; A.81. Pfizer also stated that the Direct Program provides no financial incentive to physicians to favor a tafamidis prescription. Compl. ¶ 65, at A.31; A.84.

*C. The Anti-Kickback Statute*

The statutory scheme at issue is the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. Congress first enacted the AKS in 1972 to combat fraud and abuse in connection with Medicare and Medicaid. The AKS prohibits, in relevant part, "knowingly and willfully offer[ing] or pay[ing] any remuneration" to "induce" an individual to purchase a federally reimbursable healthcare product. *Id.* § 1320a-7b(b)(2)(B). Liability under the AKS includes both civil and criminal penalties, including the possibility of a pharmaceutical company's complete exclusion from federal reimbursement for its drugs. *See id.* § 1320a-7(b)(7). At least in part because the sanctions under the AKS are severe, Congress created a process by which parties may seek advisory opinions from HHS OIG as to whether a proposed course of action would violate the AKS. *Id.* § 1320a-7d(b).

Advisory opinions are binding on both the government and the requesting parties, unless set aside by a reviewing court. *Id.* § 1320a-7d(b)(4).

***Procedural History***

*A. HHS OIG Advisory Opinion*

On June 27, 2019, Pfizer submitted a request to HHS OIG for an advisory opinion on the legality of the Direct Program. On December 9, 2019, HHS OIG informed Pfizer that it had reached an unfavorable opinion and would issue an advisory opinion to that effect if Pfizer did not voluntarily withdraw the request. In response, Pfizer sought further consultation with the agency to explain "why there was little risk of fraud or abuse" with the Direct Program, and how the program would be limited to patients who "had been prescribed tafamidis by their physician[] and were only unable to access their medication due to financial need." Compl. ¶¶ 106-07, at A.43. Nevertheless, on May 26, 2020, HHS OIG informed Pfizer that its position remained unchanged. Pfizer did not withdraw its request, and the agency issued its advisory opinion on September 18, 2020.

In the advisory opinion, HHS OIG explained that the Direct Program "plainly would" involve prohibited conduct under the AKS: Pfizer proposes to "provide remuneration in the form of a valuable Subsidy Card to eligible

Medicare beneficiaries," which would in turn "induce that beneficiary to purchase [tafamidis] by removing the financial impediment" of the cost-sharing obligation. OIG Advisory Op. No. 20-05, 14-16, at A.221-23. The agency concluded that the Direct Program "would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute," and is indeed "highly suspect . . . because one purpose of the [Direct Program]—perhaps the primary purpose—would be to induce Medicare beneficiaries to purchase [Pfizer's] federally reimbursable Medications." *Id.* at 16, at A.223. The agency "[did] not express any opinion as to the appropriateness of [tafamidis's] list price," but noted that the Direct Program "would effectively abrogate statutory cost-sharing requirements under the Medicare Part D program," and consequently "drive up costs to the Medicare program."[5] *Id.* at 17-18, at A.224-25.

[5] In 2005, HHS OIG published guidance that elaborated on the risks of co-pay assistance programs from drug manufacturers: "[C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions." 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005). The agency reiterated this concern in 2014, explaining that "the ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support." 79 Fed. Reg. 31,120, 31,122 (May 30, 2014).

*B. Federal Court Action*

Meanwhile, on June 26, 2020, Pfizer filed this action in the United States District Court for the Southern District of New York challenging, in relevant part, HHS OIG's advisory opinion on the Direct Program as contrary to law under the Administrative Procedure Act, 5 U.S.C. § 706(2). The parties filed cross-motions for summary judgment, and the government filed for dismissal of certain claims that are not on appeal.

On September 30, 2021, the district court granted summary judgment to the government on the APA claim. *Pfizer, Inc. v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021). Pfizer's primary argument is that the Direct Program must be administered with a "corrupt" intent in order to violate the AKS, and Pfizer defines "corrupt" intent as a quid pro quo that "improperly or corruptly" skews the patient's decision-making. *See* Appellant's Br. 10, 20. The district court disagreed, finding nothing in the text of the AKS that is "amenable to a reading that there be corruption involved." *Id.* at *11. Rather, the district court reasoned, the plain meaning of the terms "remuneration" and "induce" describe a payment that persuades another to take a certain course of action. *Id.* at *11-13. The district court concluded:

"Because the stated intent of the payments Pfizer proposes here [is] to increase the number of Medicare beneficiaries who purchase the drug, the Court is unable to . . . issue judgment in [Pfizer's] favor on the APA claim, since the AKS prohibits all remuneration that induces purchases of drugs like tafamidis . . . ." *Id.* at *15.

Pfizer appeals.

## DISCUSSION

I. Standard of Review

"On appeal from a grant of summary judgment in a challenge to agency action under the APA, we review the administrative record and the district court's decision *de novo*."[6] *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 77 (2d Cir. 2006) (internal quotation marks omitted). Under the APA, agency actions –

[6] Where the plaintiff challenges an agency's interpretation of a statute that Congress has designated for administration by that agency, this Court also applies the analytical framework described in *Chevron U.S.A., Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837 (1984), to determine if the agency's interpretation is owed any deference. *Chevron* first requires that we determine whether the statute "is silent or ambiguous with respect to the specific issue." *Id.* at 843. Neither the district court nor Pfizer raises the issue of *Chevron* deference, presumably because they find no ambiguity in the AKS on this question. Because we find no ambiguity and agree with the district court's interpretation of the statute, we too do not rely on *Chevron* deference in reaching our conclusion.

including advisory opinions – must be set aside if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

II. APA Claim

*A. Textual Arguments*

When interpreting a statute, "[w]e begin with the text." *Facebook, Inc. v. Duguid*, 141 S. Ct. 1163, 1169 (2021); *see also Katz v. Focus Forward, LLC*, 22 F.4th 368, 372 (2d Cir. 2022) ("If the statutory language is unambiguous, we construe the statute according to the plain meaning of its words." (internal quotation marks omitted)).

The AKS provides, in relevant part:

> (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—
>
> . . . .
>
> (B) to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2)(B). Pfizer argues that three phrases in the statute's text suggest an element of "corrupt" intent: (1) "any remuneration . . . to induce," (2) "(including any kickback, bribe, or rebate)," and (3) "willfully." We disagree.

*a. "[A]ny remuneration . . . to induce"*

Pfizer first contends that the phrase "any remuneration . . . to induce" necessarily connotes a quid pro quo, and that quid pro quos are "designed to corrupt the recipient's behavior." Appellant's Br. 26. The district court disagreed that a quid pro quo is required for AKS liability, reasoning that "the plain meaning of the word 'inducement' implies a 'one-way' transaction, where the requestor simply gets someone to take an action." *Pfizer*, 2021 WL 4523676, at *13. For the purposes of this appeal, we do not need to decide whether the AKS contains a quid pro quo element. HHS OIG expressly stated in the advisory opinion that the Direct Program would "operate as a *quid pro quo*," in that Pfizer "would offer remuneration . . . to the beneficiary in return for the beneficiary purchasing [tafamidis]." OIG Advisory Op. No. 20-05, 14, at A.221. "Quid pro quo" translates literally to "something for something." *See* BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "quid pro quo" as "[a]n action or thing that is exchanged for another action or thing of more or less equal value; a

substitute"). We have no doubt that at least some kind of quid pro quo, direct or indirect, exists here. *See* Appellees' Br. 25 n.5 ("[W]hether there was a quid pro quo in this case—in the sense of an exchange of one thing for another—is not at issue.").

However, we do not think it is the case, as Pfizer suggests, that every quid pro quo is inherently corrupt. There are, of course, many such transactions made without corrupt intent. A commercial contract, for example, is literally a quid pro quo – a "this for that." Arguing that "quid pro quo" necessarily implies corruption, Pfizer points to a case in the bribery context where we explained that "[t]he 'corrupt' intent necessary to a bribery conviction is in the nature of a quid pro quo requirement." *United States v. Alfisi*, 308 F.3d 144, 149 (2d Cir. 2002). But the question in *Alfisi* was how "bribery" should be defined for the purposes of criminal liability under 18 U.S.C. § 201(b)(1)(A). We concluded that to be a bribe, which is by definition corrupt, a payment must involve a quid pro quo element. *Id.* So be it – but that does not mean the inverse is true, i.e., that all quid pro quo transactions are necessarily corrupt. Otherwise, any number of commonplace transactions – paying money for a meal, for example – would, according to Pfizer's theory, be made with corrupt intent.

Pfizer further argues that the word "induce," even on its own, implies a corrupting influence or ill motive, but we find no support for this proposition. The plain meaning of "induce" is to "entic[e] or persuad[e] another person to take a certain course of action." BLACK'S LAW DICTIONARY (11th ed. 2019); *see also* AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (5th ed. 2022) (defining "induce" as "[t]o lead or move, as to a course of action, by influence or persuasion," or "[t]o bring about or stimulate the occurrence of; cause," as in "a drug used to induce labor"). The word is thus neutral with regard to intent – one can persuade another to take an action with good or bad motives.

Pfizer relies heavily on two cases to argue that the word "induce" implies corruption. Neither supports its position.

In *United States v. Zacher*, 586 F.2d 912 (2d Cir. 1978), this Court considered a case in which a nursing home administrator accepted supplemental payments from families of Medicaid patients equal to the difference between the Medicaid reimbursement rate and the private pay the nursing home ordinarily charged. We concluded that the defendant was not liable for accepting bribes under the AKS because the payments merely "influenc[e]d [the defendant] to admit the patient," rather than "induc[ing] him to act dishonestly." *Id.* at 916. We further

noted that "[k]ickbacks, rebates and bribes," as prohibited under the AKS, "each involve a corrupt payment." *Id.* But the appeal in *Zacher* "turn[ed] on the question of whether the payments received by [the defendant] *can be considered bribes* within the meaning of th[e] [AKS]," not whether *any* payment prohibited by the AKS must involve dishonesty. *Id.* at 914 (emphasis added). Moreover, in *Zacher* we interpreted the original 1972 version of the AKS, which prohibited only kickbacks, bribes, or rebates. Congress did not expand the statute to cover "any remuneration" until the statute was amended in 1977. *See* Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1180 (1977). *Zacher*'s reading of the 1972 statute thus gives us little guidance on resolving the current appeal.

Pfizer argues that the 1977 amendment is immaterial to our consideration of *Zacher*, because it did not alter the statute's original focus on corrupt payments. But the plain meaning of "remuneration" is clearly broader than a kickback, bribe, or rebate: "Remuneration" means "[p]ayment; compensation, esp[ecially] for a service that someone has performed," and the modifier "any"

further broadens the scope of the phrase. BLACK'S LAW DICTIONARY (11th ed. 2019).[7]

Pfizer's second case, *United States v. Krikheli*, 461 F. App'x 7 (2d Cir. 2012), was an unpublished summary order affirming the jury instructions for an AKS charge. The district court instructed the jury that "[t]o induce a person means to attempt to gain influence over the reason or judgment of that person," and the government needed to prove "that the remuneration was offered or paid as a quid pro quo in return for the referring of the patient." *Id.* at 11. A panel of this Court concluded that those instructions "accurately described the law." *Id.* Even treating this non-precedential case as though it were authoritative, nothing in *Krikheli*'s instructions required an element of corruption to find an inducement. As discussed above, a quid pro quo transaction is not necessarily corrupt. And "to gain influence over the reason or judgment" of a person is simply the

[7] Our sister circuits have also noted Congress's broadening of the AKS through the 1977 amendment. *See, e.g.*, *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) ("The phrase 'any remuneration' was intended to broaden the reach of the [AKS] which previously referred only to kickbacks, bribes, and rebates."); *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) ("By adding 'remuneration' to the [AKS] in the 1977 amendment, Congress sought to make it clear that even if the transaction was not considered to be a 'kickback' for which no service has been rendered, payment nevertheless violated the Act.").

definition of "persuade," which is neutral in connotation. Pfizer's attempt to read a more sinister intent into the phrase "any remuneration . . . to induce" fails.

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

Pfizer next argues that the parenthetical following "any remuneration" – "(including any kickback, bribe, or rebate)" – limits the statute to corrupt payments. As an initial matter, the district court disagreed with Pfizer as to whether the term "rebate" implies corrupt intent: The court reasoned that the plain meaning of "rebate" is neutral, *Pfizer*, 2021 WL 4523676, at *12 (quoting BLACK'S LAW DICTIONARY (11th ed. 2019), which defines "rebate" as "[a] return of part of a payment, serving as a discount or reduction"), whereas Pfizer insists that the term "rebate" in the AKS refers to a particular kind of corrupt payment for Medicare and Medicaid services.

Even if Pfizer were correct on that score, the Supreme Court has made clear that the word "includes," when used in a statute, "is usually a term of enlargement, and not of limitation." *Burgess v. United States*, 553 U.S. 124, 131 n.3 (2008) (internal quotation marks omitted); *see also Google LLC v. Oracle Am., Inc.*, 141 S. Ct. 1183, 1197 (2021) (explaining that, for a statutory provision involving the fair use doctrine, the "provision's list of factors is not exhaustive" because it

uses "the words 'include' and 'including'"); *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012) ("[T]he definition [of a 'sale' in a section of the Fair Labor Standards Act of 1938] is introduced with the verb 'includes' instead of 'means.' This word choice is significant because it makes clear that the examples enumerated in the text are intended to be illustrative, not exhaustive."). Therefore, the listed examples of "kickback, bribe, or rebate" in the AKS do not limit the meaning of "any remuneration"; they are merely non-exhaustive examples.

Pfizer counters with two canons of statutory interpretation, *ejusdem generis* and *noscitur a sociis*. We do not think either is applicable. *Ejusdem generis* refers to the understanding that "[w]here general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words." *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 114-15 (2001) (internal quotation marks omitted). This canon applies only where the general phrase *follows* the specific list of items, making it a "residual" phrase. *See id.* (applying *ejusdem generis* to a statute listing "seamen, railroad employees, or any other class of workers engaged in foreign or interstate commerce"). Here, by contrast, the term

"any remuneration" comes *before* the specific list of items and cannot fairly be characterized as a "residual" phrase. Rather, as noted above, the parenthetical – "(including any kickback, bribe, or rebate)" – is better read as a list of non-exhaustive examples.

*Noscitur a sociis* refers to the rule that "an ambiguous term may be 'given more precise content by the neighboring words with which it is associated.'" *United States v. Stevens*, 559 U.S. 460, 474 (2010) (quoting *United States v. Williams*, 553 U.S. 285, 294 (2008)). "Any remuneration," however, is not ambiguous, at least in this context, and it therefore must be read according to its plain meaning.

*c. "[W]illfully"*

Pfizer's final textual argument is that the "willful" mens rea required by the AKS suggests "an element of corruption or improper influence," because a "willful" act is one taken with a "bad purpose." Appellant's Br. 34 (quoting *Bryan v. United States*, 524 U.S. 184, 191 (1998)). But a "bad purpose" is not synonymous with a corrupt intent – it is more accurately understood as "a voluntary, intentional violation of a known legal duty." *United States v. Bishop*, 412 U.S. 346, 360 (1973); *see also Cheek v. United States*, 498 U.S. 192, 200-01 (1991) (explaining that "willfully," as defined by a "bad purpose," does not require "proof of any

motive other than an intentional violation of a known legal duty" (quoting *United States v. Pomponio*, 429 U.S. 10, 12 (1976))). According to a contemporaneous House Budget Committee report, Congress added the willfulness element to the AKS to avoid punishing "an individual whose conduct, while improper, was inadvertent." H.R. Rep. 96-1167, at 59 (1980). In other words, the AKS does not apply to those who are unaware that such payments are prohibited by law and accidentally violate the statute.[8] Contrary to Pfizer's assertion, the mens rea element goes no further.

*B. Other Arguments*

[8] The AKS specifies that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section" in order to be held liable, 42 U.S.C. § 1320a-7b(h), but that does not override the willfulness element. In the context of certain "highly technical" statutory schemes, the Supreme Court has required "that the jury . . . find that the defendant was aware of the *specific* provision of the [law] that he was charged with violating." *Bryan*, 524 U.S. at 194 (emphasis added). Through § 1320a-7b(h), Congress simply ensured that the AKS would avoid that heightened mens rea requirement.

Assuming the heightened requirement does not apply, a person can "willfully" violate a statute as long as he knows that his conduct is illegal, even if he is not aware of the exact statutory provision that his conduct violates. *See, e.g.*, *id.* at 190 (affirming the trial court's instruction that "[a] person acts willfully if he acts intentionally and purposefully with the intent to do something the law forbids, that is, with the bad purpose to disobey or disregard the law. . . . [T]he person need not be aware of the specific law or rule that his conduct may be violating" (internal quotation marks omitted)).

Pfizer makes several additional arguments, beyond the text of the AKS, as to why the statute should be read with an element of "corrupt" intent. We find none to be persuasive.

*a. Relationship with Other Statutes*

Pfizer argues that the AKS, with its criminal penalties, should be read more narrowly than the Beneficiary Inducement Statute ("BIS"), 42 U.S.C. § 1320a-7a, a civil statute enacted in 1996 that also seeks to combat fraud against government healthcare programs. The BIS imposes liability on any person or entity who

> offers to [transfer] 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 or in part, under [a federal or state healthcare program].

42 U.S.C. § 1320a-7a(a)(5). According to Pfizer, Congress intended the BIS to be a broader, civil counterpart to the AKS, which means that we should interpret the term "induce" in the AKS more narrowly than the term "influence" in the BIS.

We find no reason to interpret the AKS by reference to the text of the BIS. The AKS is not simply a narrower version or criminal counterpart of the BIS – although the two statutes have similar subject matter, they prohibit different

activities. The AKS focuses on induced purchases of federally reimbursable goods or services, whereas the BIS prohibits improperly influencing a beneficiary's choice of the "particular provider, practitioner, or supplier" from whom they purchase such goods or services. *Id.* Accordingly, HHS OIG concluded that the Direct Program would implicate the AKS but *not* the BIS: The Direct Program might seek to induce purchases of tafamidis, but it does not attempt to influence the beneficiary's choice of provider from whom they would obtain the medication. OIG Advisory Op. No. 20-05, 24-27, at A.231-34.[9]

Furthermore, unlike the statutory provisions at issue in *United States v. Sun-Diamond Growers of California*, 526 U.S. 398 (1999), upon which Pfizer heavily relies, the BIS and AKS were not enacted through the same bill, or even close in

[9] HHS OIG explained that, "[f]or purposes of the [BIS], pharmaceutical manufacturers are not 'providers, practitioners, or suppliers' unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs." OIG Advisory Op. No. 20-05, 24, at A231 (citing OIG, Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries* (Aug. 2002), https://oig.hhs.gov/fraud/docs/alerts Andbulletins/SABGiftsandInducements.pdf). Because Pfizer is a pharmaceutical manufacturer that "does not own or operate, directly or indirectly, any pharmacies that dispense [tafamidis,] . . . [Pfizer] is not a 'provider, practitioner, or supplier' for purposes of the [BIS]." *Id.* at 24-25, at A231-32. Thus, the agency concluded, the Direct Program "would not implicate the [BIS] with respect to [Pfizer], notwithstanding the fact that this same remuneration stream would implicate the Federal anti-kickback statute." *Id.* at 25, at A.232.

time. *See id.* at 404. The Supreme Court has cautioned against finding "[n]egative implications raised by disparate provisions" when "the two relevant provisions were not considered or enacted together." *Gomez-Perez v. Potter*, 553 U.S. 474, 486 (2008); *see also Lindh v. Murphy*, 521 U.S. 320, 330 (1997) ("[N]egative implications raised by disparate provisions are strongest when the portions of a statute treated differently had already been joined together and were being considered simultaneously when the language raising the implication was inserted."). Thus, there is little utility in comparing the language of the BIS to that of the AKS.

Pfizer also urges us to read a corruption element into the AKS's relationship with the False Claims Act ("FCA"), 31 U.S.C. § 3729. In 2010, Congress added a provision to the AKS that states: "[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for the purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). This provision allows the government to recover losses from claims submitted in violation of the AKS, using the procedural mechanisms established by the FCA. It does not, as Pfizer contends, mean that all AKS violations are inherently "corrupt." FCA liability can be premised on "specific representations about the

goods or services provided" which, while not expressly false, "fail[] to disclose noncompliance with material statutory, regulatory, or contractual requirements." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 190 (2016). In other words, if a company submits a claim for federal reimbursement that is based on goods or services rendered in violation of the AKS, then the claim may be "false" for the purposes of the FCA simply because it is the product of a material statutory violation.

*b. Overcriminalization*

Pfizer next contends that the agency's interpretation of the AKS "criminalizes a range of 'beneficial activities'" and leads to an "absurd and unjust result." Appellant's Br. 38 (quoting *Clinton v. City of New York*, 524 U.S. 417, 429 (1998)), 46.[10] Pfizer raises several hypothetical parties who it claims are at risk of liability under the agency's reading of the AKS, such as a generous family member who helps to cover the cost of medical treatment. Although the AKS is broad, however, it is not limitless. As discussed, a person must "knowingly and

[10] We note that much of Pfizer's overbreadth argument is made within the context of the rule of lenity, which, as Pfizer concedes, only requires a criminal statute to be construed in the defendant's favor when the statute is ambiguous. Appellant's Br. 44; *see United States v. Santos*, 553 U.S. 507, 514 (2008). As discussed above, we find no ambiguity in the contested provision of the AKS. *See supra* Section II.A.b. The rule of lenity is thus inapplicable to this case.

willfully" provide prohibited remuneration to be liable, which means she must have offered the payment with the intent to violate a known legal duty. It seems very unlikely to us that a charitable or concerned family member who is merely trying to help a loved one would meet that mens rea element.

In addition, to violate the AKS, one must intend to induce the purchase of a *federally reimbursable* healthcare product. *See* 42 U.S.C. § 1320a-7b(b)(2)(B). The Direct Program is specifically designed to induce Medicare beneficiaries to purchase Pfizer's tafamidis, a federally reimbursable drug. As such, the Direct Program falls squarely within the AKS's prohibitions. The concerned family member, on the other hand, does not have the same interest in whether the federal government reimburses the pharmaceutical company for the medication – she just wants to ensure that her relative receives medical treatment. In that sense, it is difficult to imagine the circumstances under which a family member's financial support would carry the specific purpose of inducing the purchase of a federally reimbursable drug. We are thus unpersuaded that the agency's reading of the AKS "would produce an absurd and unjust result which Congress could not have intended." *Clinton*, 524 U.S. at 429 (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 574 (1982)).

*c. Advisory Opinion Process*

Finally, Pfizer argues that the HHS OIG advisory opinion process is rendered superfluous by the district court's "far-reaching interpretation of the AKS as prohibiting any conceivable influence on a prescribing decision[, which] essentially means that the offer of anything of value is inevitably within the statute's reach." Appellant's Br. 40. If the statute has no discernible bounds, Pfizer reasons, then there is no need for an administrative process to clarify which programs are prohibited.

We think Pfizer's characterization of the district court's opinion is mistaken. The court never suggested that the AKS "prohibit[s] any conceivable influence on a prescribing decision." *Id.* Rather, the court concluded based on the plain meaning of the text that the AKS "prohibits knowingly and willfully providing remuneration which is intended to induce a purchase of [certain] medical treatments or services." *Pfizer*, 2021 WL 4523676, at *14. The advisory opinion process is thus helpful for determining when a proposed program is designed to "induce" the purchase of a federally reimbursable medical treatment, just as the agency did here. *See* A.221-23 (explaining how the Direct Program "operate[s] as a *quid pro quo*" that would induce purchases of tafamidis).

## CONCLUSION

We have considered the plaintiff's remaining arguments on appeal and conclude that they are without merit. We therefore AFFIRM the judgment of the district court.