No. 22-339

In the Supreme Court of the United States

PFIZER INC., PETITIONER

v.

DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

The Anti-Kickback Statute (AKS), 42 U.S.C. 1320a-7b(b), makes it unlawful to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) * * * to any person to induce such person * * * to purchase * * * any good * * * for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. 1320a-7b(b)(2)(B). Petitioner sought an advisory opinion about the potential application of the AKS to a program petitioner wishes to implement in connection with one of its patented cardiovascular drugs. Because of the drug's $225,000 list price, Medicare beneficiaries would ordinarily be required to bear cost-sharing requirements of roughly $13,000 per year for treatment with the drug. In order to eliminate the disincentive to use of the drug created by that high out-of-pocket cost, petitioner proposed to pay nearly all of the cost-sharing amounts owed by qualifying Medicare beneficiaries, while the Medicare program would pay its own share of the cost. The question presented is as follows:

Whether the Department of Health and Human Services correctly determined that petitioner's proposed program would violate the AKS if petitioner implemented the program with the requisite intent.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-25a) is reported at 42 F.4th 67. The opinion of the district court (Pet. App. 26a-64a) is not published in the Federal Supplement but is available at 2021 WL 4523676.

JURISDICTION

The judgment of the court of appeals was entered on July 25, 2022. The petition for a writ of certiorari was filed on October 7, 2022. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

A. Statutory And Regulatory Background

1. The Anti-Kickback Statute (AKS), 42 U.S.C. 1320a-7b(b), makes it unlawful to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly

or covertly, in cash or in kind to any person to induce such person * * * to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. 1320a-7b(b)(2)(B).

The Department of Health and Human Services (HHS) may exclude from participation in federal health care programs "[a]ny individual or entity that [it] determines has committed an act" in violation of (among other provisions) the AKS. 42 U.S.C. 1320a-7(b)(7). HHS may also impose civil monetary penalties on AKS violators. 42 U.S.C. 1320a-7a(a)(7). In addition, for purposes of the False Claims Act (FCA), 31 U.S.C. 3729 *et seq.*, "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim." 42 U.S.C. 1320a-7b(g); see *United States ex rel. Wilkins* v. *United Health Grp., Inc.*, 659 F.3d 295, 314 (3d Cir. 2011), abrogated on other grounds by *Universal Health Servs., Inc.* v. *United States ex rel. Escobar*, 579 U.S. 176 (2016). Persons who violate the AKS are also subject to criminal penalties. 42 U.S.C. 1320a-7b(b).

Congress has authorized HHS to "issue written advisory opinions" on various subjects related to the AKS, including "[w]hether any activity or proposed activity constitutes grounds for the imposition of a sanction under" the statute. 42 U.S.C. 1320a-7d(b)(1) and (2)(B). HHS has delegated that authority to its Office of the Inspector General (HHS-OIG). See 42 C.F.R. Pt. 1008. Advisory opinions are "binding as to" HHS "and the party or parties requesting the opinion," 42 U.S.C. 1320a-7d(b)(4)(A), but HHS-OIG's determination that proposed conduct could violate the AKS does not

require HHS or any other agency to pursue an enforcement action.

2. This case concerns HHS-OIG determinations regarding the potential applicability of the AKS to subsidies of cost-sharing obligations under Medicare Part D, 42 U.S.C. 1395w–101 *et seq*. Part D provides outpatient prescription-drug benefits to Medicare enrollees through private health plans.

a. Like most health-insurance plans, Part D plans incorporate deductibles and other cost-sharing requirements. Pet. App. 6a. For the standard Part D benefit, a plan enrollee is responsible for 100% of drug costs up to an annual deductible, and for 25% of any additional costs until her out-of-pocket expenditures have reached a specified threshold. *Ibid.* An enrollee pays five percent of any drug costs beyond that threshold. *Ibid.* The government provides subsidies for Part D plans to reduce or eliminate the cost-sharing obligations of Part D enrollees whose income falls below 150% of the federal poverty line and whose resources fall below certain thresholds. See 42 C.F.R. 423.773, 423.782.

In estimating the costs of the Part D program when it was first proposed, the Congressional Budget Office (CBO) explained that the Part D drug benefit would "make Medicare enrollees * * * less sensitive to drug prices" and thus could cause drug prices to rise for all Americans. CBO, *A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit* 15 (July 2004), https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/07-21-medicare.pdf. But "CBO estimated that the cost-sharing requirements" of Part D "would limit the extent of that price effect" by causing Medicare enrollees to bear some exposure to higher costs. *Ibid.*

b. In 2005, shortly before the Part D benefit took effect, HHS-OIG issued a Special Advisory Bulletin on Patient Assistance Programs for Part D enrollees. 70 Fed. Reg. 70,623 (Nov. 22, 2005).

HHS-OIG observed that pharmaceutical manufacturers and independent charitable organizations had previously created Patient Assistance Programs to "offer cash subsidies, free or reduced price drugs, or both," generally to benefit "patients of limited means who do not have insurance coverage for drugs." 70 Fed. Reg. at 70,623-70,624. HHS-OIG noted that, although Part D would provide drug coverage to many previously uninsured patients, manufacturers had "expressed interest in continuing to assist Medicare Part D enrollees of limited means who do not qualify for the low-income subsidy." *Id.* at 70,624.

HHS-OIG stated that a manufacturer's creation of a Patient Assistance Program to "subsidize Part D cost-sharing amounts" for the manufacturer's own drugs "would implicate the [AKS] and pose a substantial risk of program and patient fraud and abuse," "because the manufacturer would be giving something of value (*i.e.*, the subsidy) to beneficiaries to use its product." 70 Fed. Reg. at 70,624-70,625. HHS-OIG explained that such subsidies would "present all of the usual risks of fraud and abuse associated with kickbacks," such as "steering beneficiaries to particular drugs" and "reducing beneficiaries['] incentives to locate and use less expensive, equally effective drugs." *Id.* at 70,625; see *id.* at 70,625-70,626 (discussing risks in greater detail). HHS-OIG noted that such subsidies could also "increas[e] costs to Medicare," including by "eliminating a market safeguard against inflated prices" and by causing some enrollees' drug spending to exceed the threshold beyond

which the government pays 95% of an individual's costs. *Id.* at 70,625-70,626.

Nine years later, HHS-OIG issued a new bulletin primarily addressing Patient Assistance Programs established through independent charities. 79 Fed. Reg. 31,120 (May 30, 2014). In explaining the need for guardrails on such programs, HHS-OIG reiterated that, if pharmaceutical manufacturers could "subsidize copayments for their own products," they would have an incentive "to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support." *Id.* at 31,122.

B. Facts And Procedural History

1. In 2019, petitioner Pfizer Inc. asked HHS-OIG to issue an advisory opinion concerning a proposed subsidy program under which petitioner would provide cost-sharing assistance to certain patients who use tafamidis, a drug for which petitioner had recently obtained approval from the Food and Drug Administration (FDA). C.A. App. 811-842.

At the time of petitioner's request, tafamidis was the only drug approved for the treatment of transthyretin amyloid cardiomyopathy (ATTR-CM), a serious cardiovascular disease. C.A. App. 811.[1] Petitioner established a list price for the drug of $225,000 for each year of treatment. Pet. App. 69a. According to one study, that makes tafamidis "the most expensive cardiovascular drug ever launched in the United States." *Id.* at 82a (quoting Dhruv S. Kazi et al., *Cost-Effectiveness of Tafamidis Therapy for Transthyretin Amyloid*

[1] In requesting an advisory opinion, petitioner indicated that the FDA might approve a competitor's proposed treatment as early as 2021. See Pet. App. 97a-98a.

Cardiomyopathy, 141 Circulation 1214 (Apr. 14, 2020) (Kazi Study)); see *id.* at 5a. The study estimated that treating all eligible patients with tafamidis would increase annual health care spending in the United States by more than $32 billion and increase total spending on all prescription drugs in the United States by more than nine percent. Kazi Study 1215. Most patients for whom tafamidis might be prescribed are Medicare beneficiaries. Pet. App. 68a.

Petitioner has estimated that, under the standard Part D cost-sharing requirements described above, p. 3, *supra*, the $225,000 list price it established for tafamidis will result in an annual out-of-pocket cost of roughly $13,000 for Part D enrollees who use the drug, unless they qualify for the low-income subsidy. C.A. App. 812.[2] Recognizing that "these out-of-pocket costs operate as a financial impediment for a substantial portion of the Medicare population, preventing them from purchasing" its drug, petitioner proposed a program targeted to Part D enrollees who meet certain financial criteria and are prescribed tafamidis. *Id.* at 211; see *id.* at 212-213. Under the program, petitioner would cover nearly all of those enrollees' out-of-pocket costs for tafamidis. *Id.* at 212-213. Meanwhile, the Part D program (and taxpayers) would bear the brunt of the drug's cost, with petitioner benefiting from each purchase.

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[2] Petitioner's estimate does not account for changes to the Part D cost-sharing requirements that Congress adopted as part of the Inflation Reduction Act of 2022. See Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11201, 136 Stat. 1877-1879. Once those changes take effect in 2024, Medicare beneficiaries will no longer be responsible for cost-sharing in the catastrophic phase, and starting in 2025, a Medicare beneficiary's out-of-pocket drug spending will be capped at $2000 (subject to annual inflation-based adjustments).

2. In September 2020, HHS-OIG issued an advisory opinion concluding that petitioner's proposed program would be "highly suspect under" the AKS. Pet. App. 89a; see *id.* at 65a-108a. The opinion stated that the program would provide "remuneration to an individual to induce that individual to purchase an item or service for which payment may be made under a Federal health care program." *Id.* at 85a. The opinion explained that, without the subsidy from petitioner, a Medicare enrollee might "be unwilling or unable to purchase" petitioner's drug "due to his or her cost-sharing obligations," but that the subsidy "would induce that beneficiary to purchase the" drug "by removing the financial impediment, and the Medicare program would bear the costs." *Id.* at 87a. The subsidy thus "would operate as a *quid pro quo*—[petitioner] would offer remuneration * * * to the beneficiary in return for the beneficiary purchasing" petitioner's drug. *Id.* at 85a. The opinion noted that such remuneration "presents many of the traditional risks of fraud and abuse that the [AKS] is designed to prevent, including increased costs to Federal health care programs." *Id.* at 88a; see *id.* at 89a-95a (elaborating on those costs). HHS-OIG also explained that the proposed subsidy could affect physicians' prescribing decisions, since doctors may consider a patient's projected out-of-pocket costs "when determining the preferred treatment option for a patient." *Id.* at 96a; see *id.* at 99a-101a.

HHS-OIG determined that petitioner's proposed subsidy program "would generate prohibited remuneration under the [AKS] if the requisite intent to induce * * * purchases of[] items and services reimbursable by a Federal health care program were present." Pet. App. 106a. HHS-OIG explained that it could not "reach

a definitive conclusion regarding the existence of an [AKS] violation," however, because any such conclusion would require consideration of the "intent" of the "arrangement as implemented." *Ibid.*; see *id.* at 86a n.33, 87a n.37.

3. Petitioner brought this suit under the Administrative Procedure Act, 5 U.S.C. 701 *et seq.*, to challenge HHS-OIG's determination. The district court granted summary judgment in the government's favor. Pet. App. 26a-64a.

The district court explained that petitioner "does not contend that [its proposed program] would not 'induce' purchases of tafamidis that otherwise might not occur. Instead, its primary argument is that, even if [petitioner's] intent were to induce purchases, that intent would be insufficient to constitute a violation of the AKS" because payments can violate the AKS only if they are made "with a 'corrupt' intent." Pet. App. 51a-52a.

The district court rejected that argument, agreeing with the "unanimous view" of the Third, Fifth, Seventh, Ninth, and Tenth Circuits "that 'corrupt intent' is not necessary for liability under the AKS." Pet. App. 56a (quoting *United States* v. *Borrasi*, 639 F.3d 774, 782 (7th Cir. 2011), and citing *United States* v. *Greber*, 760 F.2d 68, 71 (3d Cir.), cert. denied, 474 U.S. 988 (1985); *United States* v. *Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); *United States* v. *Kats*, 871 F.2d 105, 108 (9th Cir. 1989) (per curiam); and *United States* v. *McClatchey*, 217 F.3d 823, 835 (10th Cir.), cert. denied, 531 U.S. 1015 (2000)). The court held that, "[b]ecause the stated intent of the payments [petitioner] proposes here [is] to increase the number of Medicare beneficiaries who

purchase the drug," petitioner was not entitled to "judgment in its favor on the APA claim." *Id.* at 61a.

4. The court of appeals affirmed. Pet. App. 1a-25a.

Like the district court, the court of appeals rejected petitioner's contention that its subsidy program would not violate the AKS unless "administered with a 'corrupt' intent"—that is, "as a quid pro quo that 'improperly or corruptly' skews the patient's decision-making." Pet. App. 11a. For multiple reasons, the court of appeals held that the AKS does not require an "element of 'corrupt' intent," and it perceived "no ambiguity in the AKS on this question." *Id.* at 11a n.6, 13a.

First, the court of appeals held that the statutory phrase "'any remuneration . . . to induce'" does not "necessarily connote[] a quid pro quo[] * * * 'designed to corrupt the recipient's behavior.'" Pet. App. 13a (citation omitted). The court observed that, to the extent the word "induce" suggests a quid pro quo, that requirement is satisfied here for the reason HHS-OIG had identified: Petitioner's program would give Medicare enrollees a subsidy in exchange for using petitioner's drug. *Ibid.* The court explained that not "every quid pro quo is inherently corrupt," and it found "no support" for petitioner's argument "that the word 'induce' * * * implies a corrupting influence or ill motive." *Id.* at 14a.

Second, the court of appeals held that "the parenthetical following 'any remuneration'—'(including any kickback, bribe, or rebate)'—[does not] limit[] the statute to corrupt payments." Pet. App. 17a. Rather, the "including" language of the AKS merely identifies kickbacks, bribes, and rebates as "non-exhaustive examples" of payments encompassed by the operative statutory term, which is "any remuneration." *Id.* at 18a.

Third, the court of appeals rejected petitioner's argument "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.'" Pet. App. 19a (citation omitted). The court explained that "a 'bad purpose' is not synonymous with a corrupt intent," but instead means simply "'a voluntary, intentional violation of a known legal duty.'" *Ibid.* (quoting *United States* v. *Bishop*, 412 U.S. 346, 360 (1973)). The court determined that, while the "willful" element thus means that "the AKS does not apply to those who are unaware that [their] payments are prohibited by law and accidentally violate the statute," that element does not require proof of any additional "corrupt intent." *Ibid.*

Finally, the court of appeals rejected petitioner's various non-textual arguments. Pet. 20a-25a. It held that the word "induce" in the AKS need not be read "more narrowly than the term 'influence'" in a different provision known as the Beneficiary Inducement Statute (BIS), 42 U.S.C. 1320a-7a(a)(5), because "[t]he AKS is not simply a narrower version or criminal counterpart of the BIS." Pet. App. 21a. The court was likewise "unpersuaded" by petitioner's suggestion "that the agency's reading of the AKS 'would produce an absurd and unjust result'" by preventing family members from assisting Part D enrollees with their medical bills. *Id.* at 24a (citation omitted). The court found it "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." *Ibid.* And the court perceived no basis to conclude that the agency's interpretation would obviate the advisory-opinion process. *Id.* at 24a-25a.

ARGUMENT

Petitioner contends (Pet. 12-30) that the payment of "remuneration * * * to induce" the purchase of Medicare-covered items or services, 42 U.S.C. 1320a-7b(b)(2), does not violate the AKS unless the payor acts with the intent to corrupt medical decision-making. The court of appeals correctly rejected that argument, which lacks any sound basis in the statutory text and which appears never to have been adopted by any court. This Court's review is not warranted.

1. The AKS makes it unlawful to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) * * * to any person to induce such person * * * to purchase * * * any good * * * for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. 1320a-7b(b)(2)(B). The apparent purpose of the proposed subsidy program at issue here is to provide "remuneration to an individual to induce that individual to purchase an item or service for which payment may be made under" Medicare Part D. Pet. App. 85a. HHS-OIG stated that it could not reach a "definitive conclusion regarding" petitioner's intent to induce such purchases unless and until the subsidy program is actually implemented. *Id.* at 86a n.33, 87a n.37, 106a. But the agency correctly concluded that the proposed subsidy program "would generate prohibited remuneration under the [AKS] if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present." *Id.* at 106a.

That conclusion reflects a straightforward understanding of the AKS terms "any remuneration" and "to induce." 42 U.S.C. 1320a-7b(b)(2). Where, as here,

"Congress does not furnish a definition of its own," courts "generally seek to afford a statutory term 'its ordinary or natural meaning.'" *HollyFrontier Cheyenne Ref., LLC* v. *Renewable Fuels Ass'n*, 141 S. Ct. 2172, 2176 (2021). "[T]he plain meaning of 'remuneration' is * * * '[p]ayment'" or "'compensation, esp[ecially] for a service that someone has performed,' and the modifier 'any' further broadens the scope of the phrase." Pet. App. 16a (quoting *Black's Law Dictionary* 1550 (11th ed. 2019) (*Black's*)) (brackets in original). The subsidies that petitioner proposed to offer for the purchase of tafamidis constitute "remuneration" within that ordinary meaning. Those subsidies are "'[p]ayment[s]'" to patients, *ibid.*, worth thousands of dollars annually, to offset the financial burdens of using the drug.

The circumstances here also strongly suggest that the proposed remuneration would be offered "to induce" the purchase of goods for which payment would be made through Medicare Part D. 42 U.S.C. 1320a-7b(b)(2). "The plain meaning of 'induce' is to 'entic[e] or persuad[e] another person to take a certain course of action.'" Pet. App. 14a (quoting *Black's* 926) (brackets in original); see *American Heritage Dictionary of the English Language* 896 (5th ed. 2016) (cited at Pet. App. 14a) (to "induce" means "[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" an outcome).[3] The

[3] The government's petition for a writ of certiorari in *United States* v. *Hansen*, cert. granted, No. 22-179 (Dec. 9, 2022), likewise explains that "[t]o induce a crime is to 'entic[e] or persuad[e] another person' to commit it.'" Pet. at 13, *Hansen*, *supra* (No. 22-179) (quoting *Black's* 926). Contrary to petitioner's suggestion (see Pet. 15 & n.3), the government's argument in that petition does not support petitioner's reading of the AKS.

subsidies that petitioner proposed would entice, influence, or persuade patients to purchase tafamidis in a context in which payment for the drug would be made under Medicare Part D. 42 U.S.C. 1320a-7b(b)(2). Indeed, the stated purpose of the proposed subsidies is to enable use of tafamidis by Part D enrollees who otherwise would have been unable or unwilling to use it because of its high list price and correspondingly high out-of-pocket cost. See Pet. App. 87a ("[Petitioner] identified inability to pay these cost-sharing obligations as an impediment to a significant portion of Medicare beneficiaries purchasing [tafamidis]. [Petitioner] designed the Subsidy Program to address this impediment.").

2. Petitioner contends (Pet. 15) that payments to induce purchases of Medicare-covered drugs are permissible unless the government can prove that the payor "seek[s] to corrupt the medical decision-making process." See Pet. 12-30. That argument is incorrect.

a. The "standard principles of statutory construction" that petitioner invokes, Pet. 21 (capitalization and emphasis omitted), do not support petitioner's proposed corruption element.

Petitioner argues (Pet. 21) that, under the *ejusdem generis* and *noscitur a sociis* canons, Congress's enumeration of "kickback[s], bribe[s], and rebate[s]" as three types of "remuneration" means that a payment cannot constitute prohibited "remuneration" unless it "share[s] the common characteristic of the offered examples"—in petitioner's view, "corruption." As the court of appeals correctly explained, neither of those canons supports petitioner's position here. Pet. App. 18a.

Ejusdem generis applies "[w]here general words follow specific words in a statutory enumeration." *Circuit City Stores, Inc.* v. *Adams*, 532 U.S. 105, 114 (2001)

(citation omitted; brackets in original).[4] Here, however, the word "remuneration" precedes the parenthetical "(including any kickback, bribe, or rebate)." 42 U.S.C. 1320a-7b(b)(2). That structure makes clear that the AKS uses "remuneration" as an umbrella term that "includ[es]," but is not limited to, the three "non-exhaustive examples" listed within the parentheses. Pet. App. 18a.

Petitioner's reliance on the *noscitur a sociis* canon is likewise misplaced. That canon can help to identify which of several meanings Congress intended an ambiguous word to carry in a given context—establishing, for example, that Shakespeare was referring to a spear rather than a type of fish when he listed "pike" alongside "sword," "knife," and "gun." Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 195 (2012) (*Reading Law*). Here, however, the listed examples do not suggest the artificially narrow meaning of "remuneration" that petitioner advances. While "kickback" and "bribe" may connote corrupting influence, "rebate" does not. 42 U.S.C. 1320a-7b(b)(2). Rather, the most obvious shared feature of the three terms is that all three describe payments commonly made to induce the recipients to engage in particular conduct or transactions.

While petitioner contends (Pet. 20-21) that the Second Circuit gave "rebate[s]" a narrower construction in a 1978 decision, that case addressed bribes, not rebates. See *United States* v. *Zacher*, 586 F.2d 912, 914 (1978). The Second Circuit's passing reference to "rebates" was mere dictum. See *ibid.* And apart from describing *Zacher* as a "leading case," Pet. 20, petitioner offers no

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[4] Petitioner cites (Pet. 22) *Samantar* v. *Yousuf*, 560 U.S. 305, 317 (2010), as an exception to that rule, but the Court in *Samantar* invoked *noscitur a sociis* rather than *ejusdem generis*.

reason to think that Congress or other courts have treated that dictum as authoritative or understood it to narrow the statute's plain meaning. See Pet. App. 15a (explaining that the court in *Zacher* construed an earlier version of the AKS, and that the prior decision "gives us little guidance on resolving the current appeal").

Even if "rebate" had the constricted meaning that petitioner attributes to it, moreover, the *noscitur a sociis* canon does not apply "woodenly" whenever "Congress includes a specific example along with a general phrase." *Ali* v. *Federal Bureau of Prisons*, 552 U.S. 214, 227 (2008). In *Ali*, for example, the plaintiff argued that the Federal Tort Claims Act's reference to "any officer of customs or excise *or any other law enforcement officer*," 28 U.S.C. 2680(c) (emphasis added), was limited "to law enforcement officers enforcing customs or excise laws." *Ali*, 552 U.S. at 216. The Court rejected that argument, concluding that "Congress' use of 'any' to modify 'other law enforcement officer' is most naturally read to mean law enforcement officers of whatever kind." *Id.* at 220.

The same is true of the AKS's reference to "any remuneration." 42 U.S.C. 1320a-7b(b)(2). To be sure, the statute's reference to remuneration paid "to induce" the recipient to engage in specified types of transactions, *ibid.*, significantly limits the class of payments to which the statute applies. See pp. 12-13, *supra*; Pet. App. 86a n.35 (HHS-OIG explains that "the term 'to induce'" specifies the "intent" required to trigger the AKS) (citation omitted). But far from supporting petitioner's argument, Congress's specification of the intent that will trigger the statute further discountenances reading in a "corrupt intent" requirement that has no grounding in

the text. And where intent to induce is shown, there is no sound basis for adopting an artificially narrow reading of the term "remuneration."

Petitioner additionally suggests (Pet. 22) that the court of appeals "violated the rule against surplusage" in accepting HHS-OIG's interpretation of the statute. But the words "kickback, bribe, or rebate" are not surplusage under HHS-OIG's interpretation. They make explicit that those types of payments qualify as "remuneration," without limiting what other types may also qualify. Indeed, petitioner acknowledges that "remuneration" "may not be limited to conduct that precisely meets" the definition of a "'kickback, bribe, or rebate.'" Pet. 21 (citation omitted). In any event, to the extent the statute would have a similar meaning if it referred only to "remuneration," that is no basis to give the word a cramped reading. "The canon against surplusage is not an absolute rule," *Marx* v. *General Revenue Corp.*, 568 U.S. 371, 385 (2013), because "[s]ometimes drafters *do* repeat themselves and *do* include words that add nothing of substance," *Reading Law* 176.

Petitioner's argument is also inconsistent with the AKS's history. When Congress enacted that statute, it did not prohibit the offering or payment of "any remuneration * * * to induce" the purchase or recommendation of federally covered items or services. 42 U.S.C. 1320a-7b(b). Rather, the original prohibition applied only to a "kickback or bribe in connection with the furnishing of such items or services," or a "rebate of any fee or charge for" a referral for "such items or services." Social Security Amendments of 1972, Pub. L. No. 92-603, Tit. II, § 242(b) and (c), 86 Stat. 1419-1420. Five years later, Congress amended the statute to refer to "any remuneration (including any kickback, bribe, or

rebate)." Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 4(a), 91 Stat. 1180. That amendment plainly "was intended to broaden the reach of the law." *Hanlester Network* v. *Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995), superseded by statute on other grounds as stated in *United States* v. *Shvets*, 631 Fed. Appx. 91, 96 (3d Cir. 2015), cert. denied, 578 U.S. 911 (2016). And the statute's evolution helps to explain why the current AKS includes "kickback, bribe, or rebate" as examples of the operative term "remuneration." 42 U.S.C. 1320a-7b(b)(2).

b. Petitioner separately contends that the Court should adopt a "narrowing construction[]" to prevent the AKS from encompassing conduct that petitioner deems "[r]outine, [e]ven [d]esirable." Pet. 14, 18 (emphasis omitted); see Pet. 14-20. That argument fails for two reasons.

First, for the reasons just discussed, petitioner's proposed "narrowing construction" cannot be reconciled with the statutory text. "This Court has explained many times over many years that, when the meaning of [a] statute's terms is plain," the Court's interpretive task "is at an end." *Bostock* v. *Clayton Cnty.*, 140 S. Ct. 1731, 1749 (2020). "[E]xtratextual considerations" cannot "overcome" a statute's plain terms; they can serve only to "'clear up,'" not to "'create,'" statutory ambiguity. *McGirt* v. *Oklahoma*, 140 S. Ct. 2452, 2469 (2020) (citation omitted).

Here, there is "no ambiguity in the AKS on th[e] question" presented. Pet. App. 11a n.6. No rule of statutory construction could justify reading into the statute the additional element that petitioner proposes, under which the government must prove not only that remuneration has been paid "to induce [a] person * * * to

purchase * * * any good * * * for which payment may be made" under the Medicare program, 42 U.S.C. 1320a-7b(b)(2)(B), but also that the payment is "intend[ed] to corrupt the recipient's medical decision-making," Pet. I. See pp. 11-17, *supra*.[5]

Second, HHS-OIG's interpretation of the AKS does not "criminalize a broad swath of everyday, socially desirable conduct," as petitioner contends. Pet. 20. Petitioner asserts (Pet. 17) that, if a particular patient could not afford copayments for tafamidis, and "a generous family member" chipped in "to help the patient pursue the treatment, that act of charity would satisfy the *actus reus* of the AKS" under HHS-OIG's interpretation. The court of appeals correctly rejected that contention. Pet. App. 24a.

The AKS is violated only by the offering or payment of remuneration "to induce" the purchase of "any good * * * for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. 1320a-7b(b)(2)(B). A "concerned family member" is unlikely to offer financial assistance to induce the purchase of any particular goods or services; "she just wants to ensure that her relative receives medical treatment" appropriate for her condition, whatever that treatment might be. Pet. App. 24a. Petitioner's proposed subsidy, by contrast, could "only be used to pay for Medicare cost-sharing obligations specific to"

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[5] For the same reason, petitioner's reliance on the rule of lenity (Pet. 27-28) is misplaced. "That rule applies only when a criminal statute contains a 'grievous ambiguity or uncertainty,' and 'only if, after seizing everything from which aid can be derived,' the Court 'can make no more than a guess as to what Congress intended.'" *Ocasio* v. *United States*, 578 U.S. 282, 295 n.8 (2016).

tafamidis. *Id.* at 86a. And even if the family member's gift were viewed as an effort "to induce" the purchase of tafamidis, the family member would not likely make the gift with the requisite "knowing[] and willful[]" scienter—*i.e.*, "with the intent to violate a known legal duty." *Id.* at 23a; see, *e.g.*, *Cheek* v. *United States*, 498 U.S. 192, 200 (1991) (discussing decisions construing "the term 'willfully' as connoting 'a voluntary, intentional violation of a known legal duty'") (citation omitted).

c. Petitioner also argues (Pet. 23-25) that the AKS should be read narrowly because of its interplay with the BIS and the FCA. Those arguments lack merit.

The BIS imposes civil liability on a person who "offers to or transfers remuneration to any individual eligible for benefits under" a federal or state health care program if the person "knows or should know" that the "remuneration * * * is likely to influence" the recipient "to order or receive from a particular provider, practitioner, or supplier any item or service" covered by the health care program. 42 U.S.C. 1320a-7a(a)(5). Petitioner contends (Pet. 24) that "Congress intended the AKS to have a narrower reach than" the BIS. But as petitioner further explains, the BIS is facially narrower than the AKS in key respects, including that it covers only "a subset of transactions covered by the AKS" and "expressly 'exclud[es] a beneficiary' from its scope." *Ibid.* (citation omitted; brackets in original). Indeed, HHS-OIG concluded that the subsidy program at issue here "would implicate the AKS but *not* the BIS." Pet. App. 21a; see *id.* at 101a-105a. The court of appeals correctly found "no reason to interpret the AKS by reference to the text of the BIS," especially since "the BIS and AKS were not enacted through the same bill, or

even close in time." *Id.* at 21a-22a; see *Gomez-Perez* v. *Potter*, 553 U.S. 474, 486 (2008) ("'[N]egative implications raised by disparate provisions are strongest' in those instances in which the relevant statutory provisions were 'considered simultaneously when the language raising the implication was inserted.'") (citation omitted; brackets in original).

Petitioner's reliance (Pet. 25) on a 2010 amendment addressing the connection between the AKS and the FCA is likewise misplaced. That amendment specified that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. 1320a-7b(g); see Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f)(1), 124 Stat. 759. Petitioner contends (Pet. 25) that the 2010 amendment "makes sense" only if the AKS is limited to circumstances where "a medical decision [has been] corrupted by an AKS violation," because only then has the government been "deprive[d] * * * of the benefit of its bargain." But as HHS-OIG explained, payments like the ones petitioner proposed here can interfere with the intended operation of federal health care programs, such as "through elimination of beneficiary sensitivity towards * * * price," "beneficiary steering," and "anti-competitive effects." Pet. App. 88a-89a; see pp. 4-5, *supra* (discussing HHS-OIG's 2005 and 2014 bulletins). If a pharmaceutical manufacturer knowingly uses direct payments to Medicare beneficiaries to negate the market-based safeguards designed to protect the Medicare program from overspending, its conduct raises the concerns that underlie the FCA.

d. Petitioner is also wrong in contending (Pet. 26-27) that HHS-OIG's interpretation of the AKS would

render the advisory-opinion process superfluous. The AKS prohibits remuneration only when it is "offer[ed] or pa[id] * * * to induce" a purchase reimbursable by a federal health care program. 42 U.S.C. 1320a-7b(b)(2). As the court of appeals recognized, the HHS-OIG advisory-opinion process is "helpful for determining when a proposed program is designed to 'induce' the purchase of a federally reimbursable medical treatment." Pet. App. 25a. It also allows parties to seek a determination whether HHS-OIG will exercise its discretion to waive enforcement of administrative sanctions against a proposed program.

e. Finally, petitioner contends (Pet. 28-30) that the court of appeals misunderstood the significance of the AKS's *mens rea* requirement. That too is incorrect.

Petitioner does not appear to invoke the statute's "knowingly and willfully" language as direct support for its argument that an AKS violation requires an "inten[t] to corrupt * * * medical decision-making" (Pet. I). Rather, petitioner urges (Pet. 29-30) the Court to draw an inference from the fact that, in a prosecution under the AKS, the government need not prove that the defendant had "actual knowledge of" the statute or "specific intent" to violate it. 42 U.S.C. 1320a-7b(h). In petitioner's view (Pet. 30), Congress's adoption of a knowing-and-willful standard, rather than a specific-intent standard, shows that Congress understood the AKS to reach only conduct that is "inherently corrupt and wrongful."

Petitioner identifies no decision in which this Court, or any other court, has invoked the absence of a specific-intent requirement to narrow the plain reach of a statute in the manner petitioner proposes. Relying on such an attenuated inference would be particularly

unwarranted in the context of the AKS, since the statute's "knowingly and willfully" element requires proof that the defendant committed "'a voluntary, intentional violation of a known legal duty.'" Pet. App. 19a (citation omitted). Even without a specific-intent requirement, that heightened scienter standard ensures that "the AKS does not apply to those who are unaware that such payments are prohibited by law." *Ibid.*

3. Petitioner identifies no conflict among the courts of appeals that would warrant the Court's review. See Sup. Ct. R. 10. Indeed, petitioner identifies no other judicial decision that has even addressed an argument like the one it offers here. Cf. Pet. App. 56a (describing the "unanimous view" of the Third, Fifth, Seventh, Ninth, and Tenth Circuits "that 'corrupt intent' is not necessary for liability under the AKS"). And particularly given the interpretive guidance that HHS-OIG had issued in 2005 and 2014 (see pp. 4-5, *supra*), petitioner could not plausibly argue that the 2020 advisory opinion disrupted previous expectations regarding the AKS's application to drug manufacturers' subsidy programs.

Petitioner suggests (Pet. 31-36) that, under the court of appeals' interpretation, the AKS could be employed to prosecute "charitable family members and friends" in addition to "medical product manufacturers." But as discussed above, those possibilities are speculative and farfetched. And because arrangements like petitioner's proposed subsidy program have a clear potential to generate an ultimate pecuniary benefit to the payor, see Pet. App. 10a n.5, 90a-91a, this case would be an unsuitable vehicle to clarify the AKS's application to circumstances where that financial motivation is absent. If the scenarios that petitioner posits ever come to pass, they

can be addressed as they arise, with this Court's review available if necessary.

Finally, petitioner suggests (Pet. 35) that "[i]ssues regarding the reach of the AKS" may "evade[] review" because potential defendants are more likely to settle, or to conform their conduct to an interpretation with which they disagree, than to "fight an enforcement action through trial and appeal." But petitioner sought and obtained judicial review in this case without subjecting itself to an enforcement action. And while some of petitioner's amici point to a September 2022 advisory opinion in suggesting that review is warranted here, see Johnson & Johnson Patient Assistance Found., Inc. and Janssen Pharm., Inc. Amici Br. 14-15, that opinion is already the subject of judicial review in the United States District Court for the Eastern District of Virginia. *Pharmaceutical Coal. for Patient Access* v. *United States*, No. 22-cv-714 (E.D. Va. filed Nov. 9, 2022). If the Fourth Circuit adopts an interpretation of the AKS that conflicts with the interpretation adopted by the court below, this Court's review may be appropriate. But given the current absence of any circuit conflict, and the paucity of decisions even addressing petitioner's proposed approach to the statute, the Court's review is not warranted at this time.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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DECEMBER 2022