No. 22-339

In the Supreme Court of the United States

PFIZER INC., PETITIONER

v.

UNITED STATES 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

REPLY BRIEF OF PETITIONER

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Respondents improperly expand the AKS's reach by construing the statute's terms in isolation, divorced from their context, while assigning no meaning to the statute's key parenthetical phrase and ignoring clear structural features that confine this criminal provision to illegal payments akin to a "kickback, bribe, or rebate" designed to corrupt medical decision-making for federally insured patients.

Contrary to the administrative decision under review, Congress did not criminalize merely "influencing" a patient to fill already prescribed essential medication. Rather, as the government is arguing in another merits case before this Court, the statutory phrase "to induce" in criminal statutes like the AKS has a well-established meaning that connotes "criminal solicitation and aiding-and-abetting." Pet. at 13, *United States* v. *Hansen*, cert.

granted, No. 22-179 (Dec. 9, 2022) (citation omitted). Respondents also ignore that the AKS criminalizes *both sides* of a prohibited transaction. Such reciprocal liability only makes sense if the statute bars inducement of the recipient's *improper* conduct. It is unimaginable that Congress intended to impose felony liability on a terminally ill patient who accepts assistance to afford medication her doctor prescribed to slow her disease's progress.

The government's reading of the AKS has morphed dramatically in recent years, and further evolved throughout this litigation. OIG's 2005 guidance described the AKS as a tool to combat fraud and abuse. More recently, however, OIG treats it as a policy-driven cost-control statute imposing a virtual *per se* prohibition on any financial assistance allowing patients to access their federal insurance benefits, limited only by prosecutorial discretion.

Recognizing, as the district court did, that OIG's newer reading would criminalize even desirable acts of charity, respondents have tried to walk back that construction on appeal, offering various a-textual limitations in briefs and at oral argument—including an undefined "bad purpose" (short of corruption), "persuasion" (short of corrupt inducement), and now, for the first time in their opposition, that the remuneration must seek to induce purchases of "particular" goods or services, Br. in Opp. 18. Respondents offer no reason to prefer these ambiguous, a-textual limits to the ones Congress gave in the examples of "kickback, bribe, or rebate."

This case is an ideal vehicle to resolve a question of exceptional national importance, which potentially touches every senior citizen in the United States and

those who care for them. The AKS is presently being employed by respondents in criminal prosecutions and administrative proceedings to block programs that would provide critical medical care.

Pfizer initiated this proceeding more than three years ago—longer than the life expectancy of a patient diagnosed with ATTR-CM if not treated—to clarify that the AKS does not prohibit it from providing financial assistance to allow federally insured patients to access the sole FDA-approved treatment for that progressive, fatal disease. The AKS can and should be applied to deter programs designed to skew medical decision-making for patients. It should not be applied to ration access to essential federal insurance benefits. The Court should grant the Petition and reverse the judgment below.

I. Respondents Contort A Statute Proscribing Corruption Of Federally Reimbursed Healthcare Into A Cost-Control Provision

A. Respondents' expansive interpretation of the AKS depends on a misreading of the statute's key term "induce" in a manner that contradicts the government's own reading of the same word in another case pending before this Court and ignores the textual and contextual clues in the AKS, including its repeated reference to "kickback, bribe, or rebate," which demonstrate the statute's focus on fraud, abuse, and corruption of federal healthcare programs.

1. Respondents' interpretation contradicts the government's own position in its *Hansen* petition, which asserts that, when Congress used the term "induce" in the context of a criminal statute, it "carried forward the established criminal-law meanings of th[at] term[],"

"targeting" "*criminal solicitation and aiding-and-abetting*." Pet. at 13-14, *Hansen*, *supra* (No. 22-179) (emphasis added). In *Hansen*, the government chastises the Ninth Circuit for "blindly relying on lay-dictionary definitions to reach an overly broad interpretation of the law" and for "disregard[ing] important contextual and historical evidence demonstrating the statute's more limited reach." *Id.* at 18 (quotations omitted). But the government does just that here, favoring dictionary definitions over "ordinary criminal-law meaning" to urge that "induce" reaches any conduct that would merely "influence" a "course of action." *Id.* at 12 (citing *American Heritage Dictionary of the English Language* 896 (5th ed. 2016)). At the same time, the government acknowledges that "to induce *a crime* is to entice or persuade another person *to commit it*." *Id.* at 12 n.3 (cleaned up, emphasis added). That well-established meaning of inducement has no reasonable application to a patient diagnosed with a fatal condition who accepts financial assistance to access the only FDA-approved therapy for it.

2. The broader statutory context confirms that Congress intended the AKS to prohibit payments that corrupt medical decision-making. Since its adoption in 1972, the AKS has focused on punishing a "kickback or bribe" or a particular kind of "rebate"—diverting a portion of a Medicare charge to a third party "for referring" the patient for the service. 42 U.S.C. 1395nn(b) (1976). When Congress amended the AKS in 1977, it added the phrase "any remuneration" to clarify that the AKS reaches any *form* of compensation ("in cash or in kind," "direct[] or indirect[]"), but retained multiple references to "kickback, bribe, or rebate." 42 U.S.C. 1320a-7(b). The retention of these terms clearly indicates Congress's intent to incorporate their inherent element of

corruption. See *Skilling* v. *United States*, 561 U.S. 358, 412-413 & n.45 (2010) (noting established statutory meanings for "bribe" and "kickback" that involve improper or corrupt conduct); *United States* v. *Zacher*, 586 F.2d 912, 916 (2d Cir. 1978) (noting that "rebate," as used in the original AKS, also "involve[s] a corrupt payment" that diverts federal funds); *George* v. *McDonough*, 142 S. Ct. 1953, 1959 (2022) ("Where Congress employs a term of art 'obviously transplanted from another legal source,' it 'brings the old soil with it.' ") (cleaned up). The same amendment expanded the statute to encompass not only the provider who "furnish[ed]" the good or service, but also potentially patients if they participate in the corrupt bargain. See 42 U.S.C. 1320a-7b(b)(1) (punishing "[w]hoever" "solicits or receives any remuneration (including any kickback, bribe, or rebate) * * * in return for purchasing" a federally reimbursed good or service).

Nothing in this amended provision suggests Congress intended to *criminalize* a sick patient's acceptance of copay assistance to afford critical medical care. Had Congress intended such a surprising result, surely it would have stated that intent in clear terms.

3. Respondents brush aside the usual tools of statutory construction, including *ejusdem generis*, *noscitur a sociis*, the rule against surplusage, and the rule of lenity, Br. in Opp. 13-18, on the basis that the canons are not "wooden[]" or "absolute," *id.* at 15-16, but these are a straw arguments. Pfizer cites these rules in precisely the manner respondents acknowledge is appropriate—"to identify which of several meanings Congress intended." *Id.* at 14. Here the question is whether the phrase "remuneration * * * to induce" in the AKS encompasses even socially desirable "influence," such as

easing a financial barrier to critical healthcare, as OIG assumed in the Advisory Opinion under review, Pet. App. 87a & n.36, or the more limited sense that the government advocates in *Hansen*, akin to criminal solicitation or aiding and abetting. The statute's repeated reference to the original AKS's "kickback, bribe, or rebate" and criminalization of both sides of the transaction confirms the narrower meaning. 42 U.S.C. 1320a-7b(b)(1), (2). Contrary to respondents' assertions, this is *precisely* the circumstance in which these canons are most useful—they constrain the government's otherwise "unbounded reading" of a criminal statute, and "avoid * * * giving unintended breadth to the Acts of Congress," such as by "ensur[ing] that a general word will not render specific words meaningless." *Yates* v. *United States*, 574 U.S. 528, 543, 546 (2015) (plurality opinion) (citations omitted).

Respondents also refuse to consider the relevance of Congress's choice in the civil BIS to use "influence," rather than "induce," and to omit the reference to "kickback, bribe, or rebate." Br. in Opp. 19-20. Where, as here, two statutes have similar subject matter, appear sequentially in the U.S. Code, and cross-reference each other, it is wrong to ignore the different words Congress chose. See, *e.g.*, 42 U.S.C. 1320a-7b(b)(3)(G); *McGirt* v. *Oklahoma*, 140 S. Ct. 2452, 2479 (2020) (using the fact that 18 U.S.C. 1152 "applie[d] to a broader range of crimes" to inform its understanding of 18 U.S.C. 1153(a)).

B. Tellingly, the government's own historical understanding of the AKS is consistent with Pfizer's. OIG's 2005 Guidance recognized that the AKS focuses on *corrupt* inducements arising from "fraud and abuse,"

"beneficiary steering," "disincentive[s]" to use lower-cost treatments or generics, and "lock[ing] in[]" patients to the detriment of "his or her best medical interests." 70 Fed. Reg. 70,623, 70,625-70,626 (Nov. 22, 2005). Similarly, the government argued in court for years that a claim for federal reimbursement resulting from an AKS violation was *per se* "false" under the FCA precisely because an AKS violation necessarily meant that medical judgment had been corrupted. See Pet. 25. And just a few months ago, an article published by the Department of Justice described AKS violations as "illegal remunerations [that] corrupt the process by which Medicare beneficiaries choose health-care providers, often leading to the over-use of these providers' products and services at the expense of the Medicare Trust." Ellen Bowden McIntyre & Jake M. Shields, *Illegal Payment of Kickbacks and Other Unlawful Remuneration to Medicare Beneficiaries: Routine Copayment Waivers, Cost-Sharing Assistance Charities, and Free Items and Services*, 70 J. Fed. L. & Practice 37, 49 (2022).

OIG has pivoted in its more recent guidance, however, to wielding the AKS as a policy-driven, cost-containment tool, on the unproven speculation that allowing middle-income Medicare patients to benefit from patient support programs "may encourage manufacturers to increase prices." 79 Fed. Reg. 31,120, 31,122 (May 30, 2014). In the Advisory Opinion here, OIG similarly focused on patients' increased ability to afford tafamidis (already prescribed by their physicians), as the primary reason for rejecting Pfizer's proposed copay assistance program, notwithstanding that the only alternative medication is not FDA-approved *and* "more expensive than tafamidis." Pet. App. at 5a; see *id* at 86a n.35, 89a

(rejecting proposal because it "could improperly increase overall costs to the Medicare program"). And OIG rejected a charity to assist cancer patients on these same grounds. U.S. Dep't of Health and Human Servs., OIG Advisory Op. No. 22-19 at 4, 20 (Sept. 30, 2022). Respondents cite no amendment to the AKS warranting this expansion of criminal liability, but instead rely on OIG's 2014 change to its "guidance." Br. in Opp. 2-4. OIG cannot, of course, expand criminal liability through revising its own "guidance."

C. In any event, respondents' focus on cost is misplaced. To be clear, this case is *not* about whether the government will pay its share of this costly medication—respondents acknowledge that Medicare will cover its share of this breakthrough therapy for ATTR-CM, as long as the patient is wealthy enough to cover the copay or poor enough to qualify for a government subsidy. Moreover, CMS, which administers the Part D program, expressly acknowledges that copays need not be paid by the patient herself. Payments made "by another person, such as a family member, on behalf of the individual" count against the patient's out-of-pocket obligation, 42 U.S.C. 1395w-102(b)(4)(C)(ii), including payments from "a manufacturer patient assistance program," 70 Fed. Reg. 4,194, 4,239-4,240 (Jan. 28, 2005).

Congress could have categorically prohibited manufacturers (or other third parties) from assisting Part D beneficiaries with their copay, but it did not. It is not for OIG, through reinterpretation of the AKS, to erect a ban that Congress did not impose.

II. RESPONDENTS' READING CRIMINALIZES DESIRABLE ACTS OF CHARITY, AND THEIR ATTEMPTS TO DISCLAIM THOSE RESULTS FAIL

Respondents' efforts to limit the AKS's overreach on their construction, but *without* acknowledging the textual limitations that Congress intended, are unavailing and create more problems than they solve. Most critically, respondents attempt to avoid the consequences of their reading by stating that "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." Br. in Opp. 19 (cleaned up). But that construction of "willfully" is contrary to the text of the AKS, which Congress amended in 2010 to provide that "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation." 42 U.S.C. 1320a-7b(h). And, in any event, that caveat still leaves family members of sick patients, who are the most likely to be well-informed on coverage issues, exposed to potential liability for acts of generosity.

Sensing that its "willfully" argument does not do the work it hoped, the government offers another a-textual limitation—for the first time in its opposition— suggesting that a "concerned family member is unlikely to offer financial assistance to induce the purchase of any *particular* goods or services" and instead would just "want[] to ensure that her relative receives medical treatment appropriate for her condition, whatever that treatment might be." Br. in Opp. 18 (quotations omitted and emphasis added).[1] Because tafamadis is the *only* approved

[1] This further conflates the AKS with the BIS, which *does* reference choosing a "particular" provider, 42 U.S.C. 1320a-7a(a)(5), while the AKS does not.

treatment for ATTR-CM, however, the family member *would*, almost certainly, offer the assistance so the patient can purchase this *particular* drug. Without some element of impropriety or corruption, respondents' construction cannot avoid ensnaring innocent patients and their family members. And prosecutorial discretion is no answer. See Pet. 19.

III. Respondents Do Not Deny The Substantial National Importance Of The Question Presented Or That This Case Presents An Appropriate Vehicle For Resolving It

Respondents' opposition confirms their ambition to use the AKS as a sweeping cost-control and rationing mechanism that may broadly impact millions of federal healthcare beneficiaries and every component of the federal healthcare system: manufacturers, doctors, pharmacies, patients, and their loved ones. The issue undoubtedly is of national and pressing importance.

Respondents have advocated throughout this litigation that the AKS, enacted more than a quarter century before Part D, must be broadly construed to ensure patients who cannot afford their copay will be unable to fill prescriptions for necessary medication. See Pet. App. 91a (characterizing "exposing beneficiaries to the economic effect of drug pricing" as "one of the key pricing controls" in Part D). But respondents point to *nothing* to support this shocking assertion. Congress nowhere indicated that middle-income beneficiaries, who have paid for their health insurance through Part D, should be denied that benefit if they cannot afford to pay their coinsurance out of their own pocket. See Pt. I.C., *supra*.

Glaringly absent from respondents' opposition is the assurance they offered at oral argument before the court

of appeals that their position would *not* criminalize independent charities that help patients afford their care.[2] The government in fact has an aggressive history of enforcing the AKS against charities' patient assistance programs. See Pet. 32-34. The chilling effect of respondents' position—and their failure to reiterate that assurance here—is monumental. What charity would continue to offer assistance to Medicare enrollees given the expansive reach of the AKS as construed by respondents and the severity of the AKS's penalties? Manufacturers will be similarly deterred, not just from copay assistance programs, but from a range of beneficial arrangements that could aid in diagnosis, treatment compliance, and patient and physician education.

Petitioner's interpretation, by contrast, would resolve the potential injustice of criminalizing needy patients accessing medical care through family members' generosity or third-party charity by confining liability to parties who offer or receive compensation to corrupt the medical decision-making process, which is consistent with Congress' intent to curb fraud and abuse of federal healthcare programs.

Finally, the government does not dispute that this case is an ideal vehicle to consider this important question. This case presents a well-developed administrative record decided below as a pure question of statutory in-

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[2] Recording of Oral Arg. 16:38-17:11, *Pfizer Inc.* v. *U.S. Dep't Health & Hum. Servs.*, 42 F.4th 67 (2d Cir. 2022) (No. 21-2764) (arguing that "OIG has said that bona fide independent charities * * * that are set up really independent of pharmaceutical manufacturers" would "not have an intent to induce" even if pharmaceutical manufacturers contributed).

terpretation. Moreover, Pfizer's program does not involve corruption (such as a traditional kickback, bribe, or rebate), steering (because tafamidis is the only approved therapy), or over-utilization (because assistance is limited to those objectively diagnosed with ATTR-CM, a progressive, fatal disease) that might prevent the Court from reaching the Question Presented.[3] While respondents acknowledge that "this Court's review may be appropriate" on the issue, they urge delay until sometime in the future. Br. in Opp. 23. But many cases will never be brought, and others will never reach this Court. Moreover, Medicare enrollees cannot await a hypothetical future case: they are unable to afford their medications today and, until this Court corrects respondents' misimpression, petitioner and other healthcare participants remain unable to offer those patients assistance without exposure to serious criminal liability.[4]

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[3] Quoting the district court, respondents contend that several circuits share the "unanimous view" that " 'corrupt intent' is not necessary for liability under the AKS." Br. in Opp. 8. Those cases held only that when an improper inducement has occurred, it is not cured by another, non-corrupt, purpose. These facts involve *no* corruption.

[4] The government does not deny that its interpretation of the AKS will mean that thousands of patients suffering from ATTR-CM will not be able to afford the copay for the only approved treatment for their condition. Indeed, HHS-OIG admitted as much in its Advisory Opinion—which the district court confirmed. Pet. App. 62a ("[E]conomic hardship may result in patients with a debilitating illness foregoing treatment that otherwise might assist them.").

CONCLUSION

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted,

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