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.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF OF *AMICUS CURIAE* TRIALCARD INC. IN SUPPORT OF PETITIONER

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae TrialCard Inc. is a biopharmaceutical-services organization that aims to make medications more accessible and affordable. To that end, TrialCard administers coupon programs that connect patients with manufacturer discounts.

As the leading administrator of prescription coupons, TrialCard seeks to ensure that patients are aware of and can access drugmakers' patient-assistance programs. When patients visit pharmacies to fill their prescriptions, TrialCard facilitates the distribution of patient-assistance offers. Patients then use these coupons to cover the copays that many private health-insurance plans require. This helps patients to afford the medications that their doctors have selected as the best therapy. To date, TrialCard has served nearly 36 million patients, administering over $22 billion in branded-drug savings from more than 400 life-science companies.

TrialCard has a substantial interest in this case because it would like to serve not only patients with private insurance but also patients enrolled in federal healthcare programs. Specifically, TrialCard would like to assist charities in offering need-based coupons or copay cards for drugs that a patient's medical provider has already prescribed as the best treatment option for the patient. But TrialCard and the charities it

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[1] Counsel of record for all parties received timely notice of *amicus*'s intent to file this brief and have consented to its filing. No counsel for any party authored this brief in whole or in part, and no person or entity aside from *amicus* and its counsel funded its preparation or submission. Counsel for *amicus*'s law firm is filing a brief on behalf of separate *amici* that have a different perspective on the issue presented by the petition.

would like to serve cannot proceed because respondents view these charitable activities as a criminal offense. Under respondents' longstanding policy, TrialCard may not offer federal-healthcare patients any manufacturer-sponsored coupons or cards. That policy misinterprets federal law and harms patients.

SUMMARY OF ARGUMENT

This Court should grant review to address a legal issue of urgent public-health importance concerning the rules governing Medicare: whether it is lawful to provide assistance to patients when they otherwise cannot afford life-saving treatments. The decision below affirmed the ruling by respondents, which refused to provide Pfizer protection under the Advisory Opinion process from possible criminal prosecution under the federal Anti-kickback Statute ("AKS"). The Second Circuit's decision thus affirms a determination by the Department of Health and Human Services Office of Inspector General that effectively bars drugmakers from helping Medicare patients to pay out-of-pocket costs in connection with their prescription drugs under Medicare. That opinion is based upon a misguided and patently incorrect interpretation of the AKS. Further, respondents have now cited the Second Circuit's decision in preventing a charitable organization from providing assistance to needy federal-healthcare patients with cancer.

As the petition correctly explains, the Second Circuit's decision was wrong, and this case is an ideal vehicle for deciding the appropriate meaning of the AKS. *Amicus* writes separately to underscore just how important the question presented is to patients across the country who depend on Medicare and other federal programs for life-saving treatments and to explain

how the decision below flouts the AKS's ordinary meaning.

I. Review of the petition is warranted because the question presented is critically important. When Medicare's restrictive benefits leave patients with out-of-pocket costs they cannot afford, they often fail to fill their prescriptions or abandon treatments prematurely. This situation has dire real-world consequences. In fact, a 1% increase in a patient's out-of-pocket costs is associated with a 3% increase in mortality rates. *See infra* at 6. Payment-assistance programs offer a much-needed solution. By helping Medicare patients meet their out-of-pocket costs under Medicare, programs like Pfizer's and those that charitable organizations wish to implement would ensure access to innovative, life-saving drugs for needy patients. Congress did not outlaw such aid, and the Second Circuit erred in ruling that respondents properly interpreted the AKS in a manner that forecloses efforts by manufacturers or charitable organizations to assist Medicare patients. The question presented is critically important to federal-healthcare patients, medical providers, the healthcare industry, and the public at large, and, as a result, the Court should grant the petition to address it.

II. Review is also warranted because the decision below cannot be squared with the statutory text. To begin with, payment assistance is not illegal "remuneration." In holding otherwise, the Second Circuit overlooked the plain language selected by Congress, as well as clear contextual signals confirming that Congress used "remuneration" to cover only illicit, corrupt payments. Nor do payment-assistance programs "induce" patients to buy their prescriptions. As ordinarily used, the word "induce" requires more than merely addressing a financial barrier in the path of an already-

motivated actor. Moreover, context underscores the mismatch between the conduct prohibited by the AKS and that at issue under Pfizer's program (or programs that respondents have now banned in reliance on the decision below). In all events, the Second Circuit's approach leads to absurd results, and the rule of lenity resolves any remaining doubt about the statute's scope in favor of Pfizer and charitable organizations interested in helping needy patients.

ARGUMENT

I. THE COURT SHOULD GRANT REVIEW BECAUSE THE QUESTION PRESENTED IS CRITICALLY IMPORTANT.

Prescription-drug access under Medicare and other federal programs is a pressing public-health issue. All too often, out-of-pocket costs prevent patients with limited means from receiving essential medical treatment—especially patients who rely on Medicare. Many Medicare patients are retired, with low or fixed incomes, which makes it difficult for them to afford the out-of-pocket costs associated with innovative therapies under Medicare. While insurers recognize the value of these medicines, they often deliberately set out-of-pocket costs that put treatment out of reach.[2] The agents that Medicare uses to deliver Medicare coverage are no different.

For example, cutting-edge cancer therapies can cost $10,000 or more per month. Under Medicare's prescription-drug program, a treatment like that would cost a patient more than $2,000 out of pocket in the

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[2] *See* Liz Szabo, *As Drug Costs Soar, People Delay Or Skip Cancer Treatments*, NPR (Mar. 15, 2017), www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments.

first month alone. Small wonder that 61% of cancer patients and survivors find it either very difficult or somewhat difficult to afford treatment.[3] In fact, research shows that half of all patients with cancer will abandon therapy if their out-of-pocket costs exceed $2,000.[4]

For many patients on Medicare and other federal programs—especially retirees with low or fixed incomes—these costs put life-saving medicine beyond their financial reach. When needy Medicare patients must pay even modest out-of-pocket costs, they are significantly less likely to start treatment after receiving a new diagnosis. And even when they do begin treatment, they are less likely to refill their prescriptions on time and more likely to abandon treatment altogether.[5] Researchers see these patterns across the board—even in patients with cancer and other serious conditions.[6]

The consequences of these decisions can be catastrophic. For example, higher out-of-pocket costs are

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[3] *See* Am. Cancer Soc'y, *Survivor Views: Affordability, Prescription Drugs, & Pain* (2021), https://www.fightcancer.org/policy-resources/survivor-views-affordability-prescription-drugs-pain.

[4] *Id.*

[5] *See* Jalpa A. Doshi et al., *Addressing Out-Of-Pocket Specialty Drug Costs In Medicare Part D: The Good, The Bad, The Ugly, And The Ignored*, Health Affairs (July 25, 2018), www.healthaffairs.org/do/10.1377/hblog20180724.734269/full/.

[6] *See* Jorge L. De Avila et al., *Prevalence and Persistence of Cost-Related Medication Nonadherence Among Medicare Beneficiaries at High Risk of Hospitalization*, JAMA Network (Mar. 3, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2776944.

linked to higher mortality.[7] Indeed, one study found that for every 1% increase in a patient's copay, there is a 3% increase in mortality tied to delaying, limiting, or stopping drug therapy.[8] Another study shows that cancer patients who skip their prescriptions are more likely to end up in the hospital—both placing their health at risk and taxing the healthcare system.[9] The public interest and public-health considerations strongly favor encouraging the use of physician-prescribed treatments.

Payment-assistance programs like Pfizer's, or those that charities wish to provide, offer a solution. By helping Medicare patients with their out-of-pocket costs, such programs make treatment affordable, ensuring that patients can access the medicines their doctors prescribe. Yet, the Second Circuit incorrectly concluded that such efforts qualify as illegal "remuneration" that induces conduct in violation of the AKS. That decision is wrong on the law, and it has devasting real-world consequences for the patients in dire need of medicine to treat their illnesses. The Court should grant review and address this question of great importance to patients, providers, and the healthcare industry.

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[7] Amitabh Chandra et al., *The Health Costs of Cost-Sharing* 5–6, Nat'l Bureau of Econ. Rsch. (Feb. 2021), https://www.nber.org/system/files/working_papers/w28439/w28439.pdf.

[8] Amitabh Chandra, *Health Consequences of Patient Cost-Sharing* 17, L. & Econ. Symp. (Apr. 28, 2021), https://laweconomicssymposium.com/wp-content/uploads/2021/05/les_webinar_health-consequences-of-patient-cost-sharing.pdf.

[9] *See* R.L. Cutler et al., *Economic Impact of Medication Non-Adherence by Disease Groups: A Systematic Review* 1, BMJ Open (Jan. 21, 2018), https://bmjopen.bmj.com/content/bmjopen/8/1/e016982.full.pdf.

II. THE ANTI-KICKBACK STATUTE DOES NOT PROHIBIT PAYMENT-ASSISTANCE PROGRAMS.

The federal Anti-kickback Statute makes it a felony to "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate)" to "induce" a purchase "for which payment may be made … under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). The decision below misread that language and overextended the scope of subsection (b)(2) to cover conduct that Congress did not intend to criminalize.

A. Payment-assistance programs are not illegal "remuneration."

As the petition explains (Pet. 9), Pfizer seeks to help Medicare patients afford their out-of-pocket costs associated with purchasing prescription drugs. The proposed aid would go directly to eligible patients—after those patients had sought treatment, been diagnosed, and received a prescription. That sort of payment assistance is not illegal "remuneration," and the Second Circuit was wrong to hold otherwise.

1. "Remuneration" means illicit payment that is corrupt.

a. "As always, we begin with the text." *Sw. Airlines Co.* v. *Saxon*, 142 S. Ct. 1783, 1789 (2022). Subsection (b)(2) covers "any *remuneration* (including any kickback, bribe, or rebate)" paid to "induce" a purchase. 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). Congress did not define "remuneration," so this Court asks "what that term's 'ordinary, contemporary, common meaning' was when Congress enacted [the statute]." *Food Mktg. Inst.* v. *Argus Leader Media*, 139 S. Ct. 2356, 2362 (2019) (quoting *Perrin* v. *United States*, 444 U.S. 37, 42 (1979)). Then (as now), "remuneration" meant "pay" or "compensation." *Funk & Wagnalls*

New Comprehensive International Dictionary of the English Language 1066 (1978). Indeed, contemporary dictionaries have noted that "remuneration" meant a "quid pro quo," *Black's Law Dictionary* 1459 (4th ed. 1968), or "reward," *Random House Dictionary of the English Language* 1214 (1973).

Because "many words in English" are "chameleon[s] drawing color from [their] surroundings," *Johnson* v. *Ga. Pac. Corp.*, 19 F.3d 1184, 1188 (7th Cir. 1994) (Easterbrook, J.), it is particularly important here to examine the several linguistic signals that confirm that Congress employed "remuneration" in a narrower sense—covering only illicit payments that corrupt the medical decision-making process.

b. The statute's heading strongly supports that result. See *Almendarez-Torres* v. *United States*, 523 U.S. 224, 234 (1998) (headings are "tools available for the resolution of doubt about the meaning of a statute" (citation and quotation marks omitted)). Subsection (b) is captioned "Illegal remunerations." 42 U.S.C. § 1320a-7b(b). That language "conveys no suggestion that the section prohibits … any and all" payments or compensation. *Yates* v. *United States*, 574 U.S. 528, 539 (2015) (plurality). Instead, the adjective "[i]llegal" shows that the statute identifies a subset of "remunerations" that Congress sought to criminalize.

c. The neighboring parenthetical confirms this limitation. Subsection (b)(2) lists three examples of the kinds of remuneration that Congress sought to outlaw: kickbacks, bribes, and rebates. 42 U.S.C. § 1320a-7b(b)(2). While these examples are "illustrative, not exhaustive," *Christopher* v. *SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012), they give "more precise content" to "remuneration"—showing the specific sense in which Congress used that term. *United States* v. *Williams*, 553 U.S. 285, 294 (2008); see also

Gustafson v. *Alloyd Co.*, 513 U.S. 561, 575 (1995) (the Court "avoid[s] ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." (quotation marks omitted)).

Kickback. In 1972, as today, "kickback" meant "a percentage of income given to a person in a position of power or influence as payment for having made the income possible: usually considered improper or immoral." *Random House Dictionary of the English Language* 785 (1973); see also *Longman Dictionary of Contemporary English* 605 (1978) ("money for services (usu[ally] unlawful) that have helped you to make money"). As these definitions show, the word ordinarily meant an illicit or corrupt payment.

Bribe. Similarly, a "bribe" is "a price, reward, gift, or favor bestowed or promised with a view to pervert the judgment or corrupt the conduct esp[ecially] of a person in a position of trust." *Webster's Third New International Dictionary* 275 (1976); see also *American Heritage Dictionary* 164 (1975) ("Anything … offered or given to someone in a position of trust to induce him to act dishonestly."). Like "kickback," the word "bribe" conveys an illicit payment, offered to sway a decisionmaker corruptly.[10]

Rebate. In context, "rebate" likewise carries a similar meaning. A "rebate" can be a "deduction from an amount to be paid or a return of part of an amount given in payment." *American Heritage Dictionary* 1088 (1975). But it can also be an illicit transaction. Compare *Black's Law Dictionary* 1139 (5th ed. 1979)

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[10] Importantly, this definition emphasizes that the corrupt nature of a bribe is linked to "inducing" a "dishonest" or "corrupt" act, mirroring the statute's use of "to induce" as a mechanism to limit the illegal "remuneration" described in the statute.

(cross-referencing the definition of "kickback") with *Webster's Third New International Dictionary* 1241 (1976) (defining "kickback" as "secret rebate"). Here, Congress's choice to place "rebate" alongside "bribe" and "kickback" strongly points to the latter reading. See *Yates*, 574 U.S. at 543 ("immediately surrounding" words may "cabin the contextual meaning of [a] term").

A neighboring provision supports that reading—clarifying that the statute prohibits only undisclosed rebates. Subsection (b)(3) states that the AKS "shall not apply" to any "reduction in price" that is "properly disclosed and appropriately reflected in the costs claimed or charges made." 42 U.S.C. § 1320-7b(b)(3). It follows that rebates count as "[i]llegal remuneration" only when they are not "properly disclosed" and "appropriately reflected." *Id.* And that makes sense. The AKS prohibits secret rebates alongside kickbacks and bribes because, when not "disclosed" and "reflected," rebates can, in fact, corrupt.

Statutory history further confirms that Congress used "rebate" in its illicit, secret-rebate sense. See, *e.g.*, *Scheidler* v. *Nat'l Org. for Women, Inc.*, 547 U.S. 9, 18 (2006) (consulting earlier versions of a statute); *Almendarez-Torres*, 523 U.S. at 265 (Scalia, J., dissenting) ("[S]tatutory history is a legitimate tool of construction."). An earlier version of subsection (b)(2) outlawed "kickback[s]," "bribe[s]," and "rebate[s] of any fee or charge for referring any such individual" for services. Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). In other words: a "rebate" was an illicit payment that diverted federal funds from a provider to a third party, in exchange for a referral—corrupting the basis upon which treatment or a treatment provider was selected for a patient.

Although Congress later streamlined the AKS to bar "any kickback, bribe, or rebate," that change did not

transform the meaning of "rebate." See *Fourco Glass Co.* v. *Transmirra Prods. Corp.*, 353 U.S. 222, 227 (1957) ("[I]t will not be inferred that Congress, in revising and consolidating the laws, intended to change their effect, unless such intention is clearly expressed."); *Posadas* v. *Nat'l City Bank of N.Y.*, 296 U.S. 497, 503 (1936) ("[R]epeals by implication are not favored."). The legislative history confirms this. In the House Report accompanying the streamlined bill, Congress referred to "kickbacks or bribes, *including rebates* or a portion of fees or charges for patient referrals." H.R. Rep. No. 95-393, pt. 2, at 52 (1977) (emphasis added). That linguistic evidence shows that Congress used "rebate" in its illicit sense—as a shorthand for the same conduct described in the earlier version of the statute.

In sum, each noun in question ("kickback," "bribe," and "rebate") refers most naturally to an illicit payment, offered to corrupt. And that, in turn, clarifies what is meant by the term "remuneration" as used in subsection (b)(2). Far from outlawing all payments, the word "remuneration" covers *illicit* payments—like kickbacks, bribes, and secret rebates—that corrupt the medical decision-making process. See *United States* v. *Taylor*, 142 S. Ct. 2015, 2023 (2022) ("a law's terms are best understood by 'the company they keep'" (cleaned up)).

Any other reading of the term "remuneration" would render parts of the AKS superfluous. To begin with, if the word "remuneration" covered *all* payments—illicit *and* above-board—Congress would have no reason to single out kickbacks, bribes, and rebates in a parenthetical. See *Mackey* v. *Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 837 (1988) ("We are hesitant to adopt an interpretation of a congressional enactment which renders superfluous another portion of

that same law."); A. Scalia & B. Garner, *Reading Law* 174 (2012) (no provision "should needlessly be given an interpretation that causes it to duplicate another"). As explained below, see *infra* at 21, this makes all the more sense here, since the AKS is a criminal statute.

Likewise, if "remuneration" covered anything that has the capacity to "influence" or "persuade" a purchase, then it would just mean "anything of value," without any limitation. But if something has "value," it must necessarily have at least some ability to "influence" or "persuade." In that case, the statutory terms "remuneration" and "to induce" would have no separate meaning. The phrase "to induce," central as it is to the statutory language, would become entirely "superfluous." *Mackey*, 486 U.S. at 837.

* * *

Under the most appropriate reading, the word "remuneration" does not cover a payment-assistance program that Pfizer or a charitable organization might offer. For starters, there is nothing "improper or immoral" about donative aid that helps patients afford their prescriptions. Cf. Kickback, *Random House Dictionary of the English Language* 785 (1973). Instead, Pfizer proposes to send aid directly to patients—after an independent medical practitioner has reached an independent medical decision. As a result, no ordinary English speaker would say that the payment assistance "pervert[s]" medical judgment, Bribe, *Webster's Third New International Dictionary* 275 (1976), or causes anyone to "act dishonestly," Bribe, *American Heritage Dictionary* 164 (1975). Far from it. After the medical provider has made a diagnosis and signed the prescription, payment-assistance programs give

Medicare- and other federally-insured patients the help they need to afford often life-saving medication.[11]

2. The Second Circuit misread "remuneration."

The decision below offered several reasons for reaching the opposite conclusion. Each falls flat.

According to the Second Circuit, the associated-words canon—*noscitur a sociis*—does not apply here because "remuneration" is "not ambiguous" and "therefore must be read according to its plain meaning." Pet. App. 18a. But that confuses *textual* with *substantive* canons. Substantive canons come into play "only when, after the application of ordinary textual analysis," the statute admits of "more than one construction" and a court needs a tie-breaker. *Clark* v. *Martinez*, 543 U.S. 371, 385 (2005). Textual canons like *noscitur a sociis* are different. Since "the rules that govern language often inform how ordinary people understand the rules that govern them," courts properly consult textual canons from the start when determining ordinary meaning. *Niz-Chavez* v. *Garland*, 141 S. Ct. 1474, 1485 (2021).

Nor does the word "any" change matters. In the Second Circuit's view, "the modifier 'any' further broadens the scope" of "remuneration." Pet. App. 16a. But controlling precedent says otherwise. "Any" may sometimes be "[e]xpansive," but it is not "transformative." *Freeman* v. *Quicken Loans, Inc.*, 566 U.S. 624, 635 (2012). "It can broaden to the maximum, but never change in the least, the clear meaning of the phrase selected by Congress …." *Id.* Put another way, the

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[11] If a federal program or its agents—often large insurance companies—found a product or service medically unnecessary, they could always prevent its use or pay the provider less for it.

word "any" does not change the specified type of corrupt payments that count as illegal "remuneration" in the first place.

And "including" does not expand the meaning of "any remuneration" beyond the category of corrupt remuneration either. Contra Pet. App. 17a. To be sure, the word "including" allows that subsection (b)(2) might cover transactions other than those listed in the parenthetical. For example, an undisclosed "discount" made at the time of purchase is as corrupt as an undisclosed "rebate" made after the purchase. Subsection (b)(2) would thus bar such a discount because it falls within the category of "remuneration" that the parenthetical describes. But none of that undermines the point that the parenthetical defines a category of "remuneration" that is prohibited—and distinguishes it from "remuneration" that is not.

B. Payment-assistance programs do not illegally "induce" a purchase.

Pfizer's program also falls outside the statute because it does not "induce" anyone to do anything. 42 U.S.C. § 1320a-7b(b)(2). The decision below also fundamentally misconstrued subsection (b)(2) by ignoring ordinary meaning and statutory context.

1. "Induce" requires more than removing a financial obstacle from the path of a motivated actor.

Text and statutory context agree. As ordinarily used, the word "induce" does not apply when financial assistance gives an already motivated actor the financial wherewithal to achieve ends already chosen. And context confirms this. In the criminal law (and even in ordinary usage), "induce" connotes solicitation or entrapment. Neither sense of the word describes the financial assistance provided by Pfizer's program.

a. We once again start with the ordinary meaning of "induce." "Without a statutory definition, we turn to the phrase's plain meaning at the time of enactment." *Tanzin* v. *Tanvir*, 141 S. Ct. 486, 491 (2020). To "induce" meant then, as it does now, to "lead or move by persuasion or action." *Random House Dictionary of the English Language* 726 (1973). Contemporary dictionaries describe the manner of that persuasion as "prevail[ing] on" or "incit[ing] by motives." *Black's Law Dictionary* 697 (5th ed. 1979); accord *Funk & Wagnalls New Comprehensive International Dictionary of the English Language* 645 (1978) ("prevail on"). Another dictionary adds that "induce may indicate overcoming indifference, hesitation, or opposition." *Webster's Third New International Dictionary* 1154 (1976). Hence, yet another dictionary provides the example, "I was induced to come against my will." *Longman Dictionary of Contemporary English* 570 (1978).

All of this shows that "inducement" requires more than removing a financial obstacle from the path of an already-motivated actor. Consider food assistance, by contrast. In the 1970s, a court might have said that "food stamps[s] … '*permit* low-income households to purchase a nutritionally adequate diet.'" *Smith* v. *United States*, 392 F. Supp. 1116, 1117 (W.D. La. 1975) (emphasis added) (citation omitted). But no ordinary English speaker would have said that the food-stamp program *induced* families to buy food. Or take federal grants. The Department of Health, Education, and Welfare issued grants in the 1970s "to *assist* in the establishment of regional cooperative arrangements among medical institutions." *Nat'l Ass'n of Reg'l Med. Programs, Inc.* v. *Mathews*, 551 F.2d 340, 341 (D.C. Cir. 1976) (emphasis added). Yet, no hospital administrator would have said that the agency *induced* her

doctors to "research and train[] in the fields of heart disease, cancer, stroke, and kidney disease." *Id.*

The same is true of payment assistance. Programs like Pfizer's or a charitable organization's offer donative aid to patients already motivated to purchase life-saving drugs—medicines that doctors have independently selected as the best treatment. That aid removes a financial obstacle created by inadequate benefit plans, but it does not "prevail on" patients. See Induce, *Black's Law Dictionary* 697 (5th ed. 1979). Nor is it natural to say that payment assistance leads patients to act "against [their] will." See Induce, *Longman Dictionary of Contemporary English* 570 (1978). Instead—like the examples just mentioned—payment assistance from Pfizer or a charitable organization would *permit* or *assist* motivated patients to take action that they already want to take: buying prescriptions that a federal program specifically covers. Offering them the wherewithal to do so is far outside the ordinary meaning of "induce."

b. Context reinforces that conclusion. The AKS is a criminal statute, and in the criminal law, "induce" is a term of art associated with solicitation or entrapment. Those contextual connotations highlight the mismatch between the statutory text and a payment-assistance program offered by Pfizer or a charitable organization. See *George* v. *McDonough*, 142 S. Ct. 1953, 1963 (2022) ("'[W]hen Congress employs a term of art,' that usage itself suffices to 'adopt the cluster of ideas that were attached to each borrowed word' in the absence of indication to the contrary." (alteration omitted) (quoting *FAA* v. *Cooper*, 566 U.S. 284, 292 (2012))).

When criminal statutes refer to "inducement," that term goes hand-in-hand with soliciting an inherently criminal act. For instance, the federal law prohibiting

"[s]olicitation to commit a crime of violence" applies to anyone who "solicits, commands, *induces*, or otherwise endeavors to persuade [another] person to engage in such conduct." 18 U.S.C. § 373(a) (emphasis added). Likewise, the federal accomplice-liability statute says that "[w]hoever commits an offense against the United States or aids, abets, counsels, commands, *induces*, or procures its commission, is punishable as a principal." *Id.* §2(a) (emphasis added). Read against that backdrop, the word "induce" in subsection (b)(2) of the AKS covers an orthopedic surgeon who bribes a physical therapist to send Medicare patients his way.

In addition, this Court's cases illustrate a second connotation—entrapment. In *Jacobson* v. *United States*, for example, the Court explained that government agents "may not originate a criminal design, implant in an innocent person's mind the disposition to commit a criminal act, and then *induce* commission of the crime." 503 U.S. 540, 548 (1992) (emphasis added). And *Sorrells* v. *United States* used the word similarly, describing a person who is "by … *inducement* lured into the commission of a criminal act." 287 U.S. 435, 445 (1932) (emphasis added). So read, "induce" describes a person who bribes a reluctant medical provider to prescribe more equipment or more prescription drugs than the circumstances warrant.

But neither sense of the word fits Pfizer's payment-assistance program or similar efforts by a charitable organization. To qualify for assistance under the Pfizer program, patients must have (i) sought treatment, (ii) been diagnosed, and (iii) received a prescription. It would be strange to say that payment assistance solicits or lures those patients to take the final step and (iv) purchase the life-saving medicine that has been prescribed for them.

2. The Second Circuit misread "induce."

The decision below considered none of these linguistic and contextual elements at the core of the statute. Rather, the Second Circuit devoted three sentences to what it perceived as the ordinary meaning of "induce"—quoting two dictionaries and then declaring the case closed because "induce" is "neutral with regard to intent." Pet. App. 14a–15a. But "dictionary definitions" are "not dispositive." *Yates*, 574 U.S. at 538. And in relying solely on them, the court avoided the crucial question: whether ordinary English speakers would say that payment assistance "induces" patients to fill life-sustaining prescriptions. As explained above, the answer is no. Although payment assistance might *permit* or *assist* patients to buy medicine, it does not "induce" them to do so. And the context here resolves any doubt, confirming that "induce" carries connotations that do not apply to Pfizer's program.

C. The Second Circuit's contrary reading of the AKS yields absurd results and raises fair-notice concerns.

The decision below distorts the ordinary meaning of "remuneration" and "induce," leading to absurd applications that the text cannot bear. No limiting principle avoids these results. As a result, the Second Circuit's reading raises fair-notice concerns that—at a minimum—trigger the rule of lenity.

1. As explained above, text, structure, and history show that the AKS does not prohibit payment-assistance programs like Pfizer's or a charity's. But if any doubt remained, the canon against absurdity confirms that the ordinary meaning of "remuneration" and "induce" must prevail. When this Court interprets statutes, it seeks a "'sensible construction' that avoids attributing to the legislature either 'an unjust or an

absurd conclusion.'" *United States* v. *Granderson*, 511 U.S. 39, 56 (1994) (quoting *In re Chapman*, 166 U.S. 661, 667 (1897)). That rule is "an implementation of (rather than … an exception to) the ordinary meaning rule." W. Eskridge, *Interpreting Law* 72 (2016); see also *Bostock* v. *Clayton Cnty.*, 140 S. Ct. 1731, 1827 n.4 (2020) (Kavanaugh, J., dissenting) (absurdity canon "reflects the law's focus on ordinary meaning rather than literal meaning," telling courts "to avoid construing a statute in a way that would lead to absurd consequences").

Absurd consequences follow from abandoning the natural reading of "remuneration" and "induce." Here, the Second Circuit concluded that all financial support counts as "remuneration" and that "induce" is akin to "facilitate." Under that interpretation, a charity that offered to help an elderly Medicare recipient with her out-of-pocket medical costs would have offered "remuneration … to induce" a purchase "for which payment may be made … under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).[12] And the same would be true of a son who tried to help his elderly mother with her Medicare copay. In both cases, the offeror would have committed a felony punishable by a ten-year prison term and a $100,000 fine—plainly an absurd reading of the AKS. See *Pub. Citizen* v. *U.S. Dep't of Justice*, 491 U.S. 440, 470–71 (1989) (Kennedy, J., concurring) (absurdity canon applies when "it is quite

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[12] This is no hypothetical: respondents recently issued an advisory opinion to that very effect. *See* U.S. Dep't of Health & Hum. Servs., OIG Advisory Opinion No. 22-19 (Sept. 30, 2022), https://oig.hhs.gov/documents/advisory-opinions/1056/AO-22-19.pdf. Citing the decision below, the opinion explains that a charity that offers payment assistance to Medicare patients with cancer "would generate remuneration that would violate the [AKS] if the requisite intent were present." *Id.* at 12.

impossible that Congress could have intended the result" and the "alleged absurdity is so clear as to be obvious to most anyone").

2. The Second Circuit provided no adequate limiting principle to avoid such absurd results.

According to the Second Circuit, the phrase "*knowingly and willfully* … pays any remuneration," 42 U.S.C. § 1320a-7b(b)(2) (emphasis added), means that the statute "does not apply to those who are unaware that such payments are prohibited by law and accidentally violate the statute." Pet. App. 19a. In other words, the charity or the generous son "must have offered the payment with the intent to violate a known legal duty." Pet. App. 23a. But that's not what the AKS says. Rather, it states that "a person need not have actual knowledge of [the Antikickback Statute] or specific intent to commit a violation" to be guilty of a felony. 42 U.S.C. § 1320a-7b(h). So a charity or a "family member who is merely trying to help a loved one" would violate the AKS under the Second Circuit's interpretation. Pet. App. 24a.

Nor does the phrase "under a Federal health care program" preclude absurd results. The Second Circuit 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." Pet. App. 24a. But—again—a person "need not have … specific intent to commit a violation," 42 U.S.C. § 1320a-7b(h), let alone specific intent that "the federal government reimburse[] the pharmaceutical company," Pet. App. 24a. Instead, a defendant need only "offer[] or pay[] any remuneration … to induce" a "purchase … for which payment *may be made* … under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). In short, the Second Circuit's limiting principles fail,

leaving charities and family members to rely on prosecutorial discretion. But see *Abuelhawa* v. *United States*, 556 U.S. 816, 823 n.3 (2009) ("[P]rosecutorial discretion is not a reason for courts to give improbable breadth to criminal statutes.").

3. At a minimum, the Second Circuit's reading raises serious fair-notice concerns—implicating the rule that "penal laws should be construed strictly." *The Adventure*, 1 F.Cas. 202, 204 (C.C. Va. 1812) (No. 93) (Marshall, C.J.).

"Respect for due process and the separation of powers suggests a court may not … construe a criminal statute to penalize conduct it does not *clearly proscribe*." *United States* v. *Davis*, 139 S. Ct. 2319, 2333 (2019) (emphasis added). Instead, when there is "ambiguity in a criminal statute," the rule of lenity "ensures fair warning" by extending the prohibition "only to conduct clearly covered." *United States* v. *Lanier*, 520 U.S. 259, 266 (1997).

That rule applies with full force here. For all the reasons given, subsection (b)(2) does not "clearly cover[]"donative aid offered to help patients afford life-saving medicine. *Id.* But if the traditional tools of statutory interpretation left any residual doubt, the rule of lenity would foreclose the reading adopted by the Second Circuit below. See *Cleveland* v. *United States*, 531 U.S. 12, 25 (2000) ("ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity"). In short: ordinary meaning, the absurdity canon, and lenity all agree—rejecting a reading so broad that it fails to warn ordinary citizens what conduct is outlawed.

CONCLUSION

For the foregoing reasons and those stated in the petition, this Court should grant the petition for a writ of certiorari.

Respectfully submitted,

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