

No. _____

In the Supreme Court of the United States

VERTEX PHARMACEUTICALS INCORPORATED,
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 DISTRICT OF COLUMBIA CIRCUIT*

PETITION FOR A WRIT OF CERTIORARI

ANDREW J. O'CONNOR
SANDRA H. MASSELINK
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199
(617) 951-7000

DOUGLAS H. HALLWARD-DRIEMEIER
Counsel of Record
BRENDAN M. KEARNEY
ROPES & GRAY LLP
2099 Pennsylvania Ave., N.W.
Washington, DC 20006
(202) 508-4600
Douglas.Hallward-Driemeier
@ropesgray.com

QUESTION PRESENTED

As in *Skilling*, *McDonnell*, *Kelly*, and *Snyder*, the government presses an overbroad reading of an anti-corruption statute. Here, the purported crime is merely helping patients access medically necessary treatment without suffering permanent infertility.

The Anti-Kickback Statute (AKS) makes it a felony to willfully “solicit[] or receive[] any remuneration (including any kickback, bribe, or rebate) * * * in return for purchasing” federally insured goods or services or to “offer[] or pay[] any remuneration * * * to induce” such a purchase. In *Hansen*, this Court held that “induce” in a criminal statute presumptively carries its criminal-law meaning of “criminal solicitation.” Applying *Hansen*, the Ninth Circuit held that the term “remuneration * * * to induce” reaches only “wrongful” influence, consistent with the Fifth and Seventh Circuits. Here, the D.C. Circuit joined the Second and Fourth Circuits to read “induce” to mean mere “influence,” the standard in the AKS’s civil analog, but did not import the civil statute’s exception for promoting access to healthcare. Despite the resulting absurdity, the court of appeals held that petitioners could face *criminal* liability under the AKS for conduct that Congress shielded from even *civil* penalties.

The question presented is: Whether “remuneration (including any kickback, bribe, or rebate) * * * to induce” in the criminal AKS means the same as “remuneration * * * to influence” in its civil analog, but without any exception for programs that promote “access to care,” criminalizing conduct Congress expressly protected from civil liability.

PARTIES TO THE PROCEEDINGS BELOW AND RULE 29.6 STATEMENT

Petitioner Vertex Pharmaceuticals Incorporated (VRTX) was the plaintiff in the district court and the appellant in the D.C. Circuit.

Respondents, who were the defendants in the district court and appellees in the D.C. Circuit, are: United States Department of Health and Human Services (HHS); Robert F. Kennedy, Jr., Secretary, HHS; HHS Office of Inspector General (OIG); and T. March Bell, Inspector General, OIG.

In accordance with Supreme Court Rule 29.6, petitioner discloses that Vertex is a publicly traded biotechnology company incorporated in the Commonwealth of Massachusetts. No parent company, subsidiary, or affiliate of Vertex, nor any other company having outstanding securities in the hands of the public, owns 10% or more of Vertex's stock.

RELATED CASES

- *Vertex Pharms. Inc. v. HHS*, No. 25-5133, U.S. Court of Appeals for the District of Columbia Circuit. Judgment entered September 4, 2026.
- *Vertex Pharms. Inc. v. HHS*, No. 24-cv-2046, U.S. District Court for the District of Columbia. Judgment entered March 31, 2025.

TABLE OF CONTENTS

	Page
Opinions below	1
Jurisdiction	1
Statutory provisions involved	2
Introduction.....	3
Statement of the case.....	7
A. Statutory background	7
B. Factual background	9
C. Proceedings below	11
Reasons for granting the petition	15
I. The courts of appeal are split on the meaning of “induce” in—and the application of <i>Hansen</i> to— federal anti-kickback statutes	16
A. The correct side of the circuit split gives “induce” its specialized criminal-law meaning	17
B. The D.C., Second, and Fourth Circuits incorrectly equate “induce” with “influence”	20
C. The conflict regarding this important question is deep, clearly defined, and outcome-determinative	22
II. The court of appeals’ construction is wrong because multiple canons of statutory construction reinforce the <i>Hansen</i> presumption	23
A. The court of appeals ignored <i>Hansen</i> ’s criminal-law presumption and attempted to distinguish it on unpersuasive grounds ...	23

Table of Content—Continued	Page
B. The AKS’s text, structure, and history confirm that Congress intended to prohibit corruption, not mere influence	27
1. The language surrounding “induce” reinforces petitioner’s interpretation under several canons of construction.....	27
2. Other statutory clues confirm a narrow, specialized criminal-law interpretation of “induce”	29
3. The court of appeals failed to follow this Court’s decisions narrowing the scope of criminal statutes in light of over-criminalization, due process, and lenity concerns	31
C. The court of appeals’ construction of the AKS produces an absurd result by criminalizing conduct exempted from civil liability under the CMPL.....	33
III. The Court should take this opportunity to rein in an overbroad construction of the AKS, so that other beneficial programs are not deterred	35
Conclusion.....	38
Appendix A — Court of appeals opinion (September 4, 2026).....	1a
Appendix B — District court opinion (March 31, 2025).....	28a
Appendix C — OIG advisory opinion (July 18, 2024).....	75a
Appendix D — Statutory provisions	93a

VI

TABLE OF AUTHORITIES

	Page
Cases:	
<i>Barton v. Barr</i> , 590 U.S. 222 (2020)	26
<i>Circuit City Stores, Inc. v. Adams</i> , 532 U.S. 105 (2001).....	29
<i>Fischer v. United States</i> , 603 U.S. 480 (2024)	29
<i>George v. McDonough</i> , 596 U.S. 740 (2022)	28
<i>Hanlester Network v. Shalala</i> , 51 F.3d 1390 (9th Cir. 1995)	18
<i>Hughey v. United States</i> , 495 U.S. 411 (1990)	28
<i>Kelly v. United States</i> , 590 U.S. 391 (2020)	31
<i>Leocal v. Ashcroft</i> , 543 U.S. 1 (2004)	33
<i>McDonnell v. United States</i> , 579 U.S. 550 (2016) ...	31
<i>Mission Prod. Holdings, Inc. v. Tempnology, LLC</i> , 587 U.S. 370 (2019).....	26
<i>Pfizer, Inc. v. U.S. Dep’t of Health & Hum. Servs.</i> , 42 F.4th 67 (2d Cir. 2022), cert. denied, 143 S. Ct. 626 (2023)	16, 21, 22
<i>Pharmaceutical Coal. for Patient Access v. United States</i> , 126 F.4th 947 (4th Cir. 2025)	16, 21, 22, 32, 37
<i>Samantar v. Yousuf</i> , 560 U.S. 305 (2010)	29
<i>Skilling v. United States</i> , 561 U.S. 358 (2010) ...	28, 31
<i>Snyder v. United States</i> , 603 U.S. 1 (2024)	31
<i>United States v. Hansen</i> , 599 U.S. 762 (2023).....	3-5, 7, 13-18, 20, 21, 23-27, 29, 30, 35
<i>United States v. Marchetti</i> , 96 F.4th 818 (5th Cir. 2024)	16, 18, 19, 21, 22

VII

Cases—Continued:	Page(s)
<i>United States v. Miles</i> , 360 F.3d 472 (5th Cir. 2004)	19
<i>United States v. Ninsawat</i> , 2025 WL 1217385 (6th Cir. Apr. 28, 2025)	24
<i>United States v. Schena</i> , 142 F.4th 1217 (9th Cir. 2025)	16-18, 20
<i>United States v. Sorensen</i> , 134 F.4th 493 (7th Cir. 2025)	16, 19, 20, 23, 25
<i>United States v. Sun-Diamond Growers of Cal.</i> , 526 U.S. 398 (1999)	29
<i>United States v. Williams</i> , 553 U.S. 285 (2008)	29
<i>United States v. Zacher</i> , 586 F.2d 912 (2d Cir. 1978)	7, 28
<i>United States ex rel. Hart v. McKesson Corp.</i> , 96 F.4th 145 (2d Cir. 2024), cert. denied, 145 S. Ct. 163 (2024)	29
<i>United States ex rel. Martin v. Hathaway</i> , 63 F.4th 1043 (6th Cir. 2023), cert. denied, 144 S. Ct. 224 (2023)	8, 30, 33
<i>United States ex rel. Ruggiero v. Ultragenyx Pharm. Inc.</i> , No. 21-cv-11176-ADB (D. Mass. July 19, 2021)	37
<i>United States ex rel. Witkin v. Medtronic, Inc.</i> , 2024 WL 1892405 (D. Mass. Mar. 31, 2024)	12
<i>Van Buren v. United States</i> , 593 U.S. 374 (2021) ...	32
Statutes and regulations:	
Anti-Kickback Statute, 42 U.S.C. 1320a-7b	8
42 U.S.C. 1320a-7b(b)	7

VIII

Statutes and regulations—Continued:	Page(s)
42 U.S.C. 1320a-7b(b)(1)	2, 3, 13, 20, 25, 27, 31
42 U.S.C. 1320a-7b(b)(2)	2, 4, 9, 14, 27, 31
42 U.S.C. 1320a-7b(b)(3)(A)	7
42 U.S.C. 1320a-7b(b)(3)(B).....	26
42 U.S.C. 1320a-7b(g).....	9, 29, 36
Civil Monetary Penalties Law, 42 U.S.C.	
1320a-7a	8
42 U.S.C. 1320a-7a(a)	9
42 U.S.C. 1320a-7a(a)(5).....	3, 9
42 U.S.C. 1320a-7a(a)(7).....	9, 29
42 U.S.C. 1320a-7a(i)(6)(B)	29
42 U.S.C. 1320a-7a(i)(6)(F)	3, 9, 34
Eliminating Kickbacks in Recovery Act, 18 U.S.C.	
220	9
18 U.S.C. 220(a)(2)	9
18 U.S.C. 220(a)(2)(A).....	17, 30
18 U.S.C. 220(a)(2)(B).....	30
5 U.S.C. 702	13
5 U.S.C. 706	13
8 U.S.C. 1324(a)(1)(C)	25
18 U.S.C. 666	31
18 U.S.C. 2251(a).....	25
42 U.S.C. 1320a-7(b)(7)	36
42 U.S.C. 1320a-7d(b).....	8
42 U.S.C. 1395nn(b) (1976)	7
42 U.S.C. 1396h(b) (1976).....	7

IX

Statutes and regulations—Continued: Page(s)

42 C.F.R. 1001.952(e)	26
Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972).....	7, 28
Pub. L. No. 95-142, § 4(a), 91 Stat. 1175-1183 (1977).....	7, 8
Pub. L. No. 96-499, § 917, 94 Stat. 2625, 2625 (1980).....	8
Pub. L. No. 100-93, § 14, 101 Stat. 680, 697 (1987).....	8
Pub. L. No. 111-148, § 6402(F), 124 Stat. 119, 759 (2010)	8

Miscellaneous:

Black’s Law Dictionary:

(Rev. 4th ed. 1968)	24, 27
(12th ed. 2024)	27

H.R. Rep. No. 85, 100th Cong., 1st Sess. (1987)	8, 26
--	-------

Press Release, Pharmaceutical Company Ultragenyx Agrees to Pay \$6 Million for Allegedly Paying Kickbacks to Induce Claims for its Drug Crysvita (Dec. 21, 2023).....	37
--	----

Publication of OIG Special Advisory Bulletin on Pa- tient Assistance Programs for Medicare Part D En- rollees, 70 Fed. Reg. 70,623 (Nov. 22, 2005).....	37
---	----

In the Supreme Court of the United States

No. _____

VERTEX PHARMACEUTICALS INCORPORATED,
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 DISTRICT OF COLUMBIA CIRCUIT*

PETITION FOR A WRIT OF CERTIORARI

Petitioner Vertex Pharmaceuticals Incorporated respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-27a) is not yet reported, but is available at 2026 WL 2617588. The district court's opinion (App., *infra*, 28a-74a) is reported at 774 F. Supp. 3d 211.

JURISDICTION

The judgment of the court of appeals was entered on September 4, 2026. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The AKS makes it a felony and provides substantial penalties for anyone:

Who[] knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind * * * in return for purchasing, leasing, ordering, or arranging for or recommending 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)(1).

The AKS also makes it a felony and provides substantial penalties for anyone:

Who[] knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person * * * 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).

The Civil Monetary Penalties Law (CMPL) establishes civil penalties in relevant part for:

Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that * * * offers to or transfers remuneration to any individual eligible

for benefits under subchapter XVIII of this chapter, or under a State health care program (as defined in section 1320a-7(h) of this title) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under subchapter XVIII, or a State health care program (as so defined).

42 U.S.C. 1320a-7a(a)(5).

The CMPL creates a safe harbor for certain patient-assistance programs by defining “remuneration” to exclude any program that:

promotes access to care and poses a low risk of harm to patients and Federal health care programs.

42 U.S.C. 1320a-7a(i)(6)(F).

INTRODUCTION

This case concerns a 3-3 circuit split regarding the meaning of “induce” in federal criminal anti-kickback statutes. One side of the split faithfully applies this Court’s ruling in *United States v. Hansen*, 599 U.S. 762, 774-775 (2023). The other does not, thereby criminalizing conduct that Congress expressly safe-harbored from even *civil* liability.

The AKS makes it a felony to willfully “solicit[] or receive[] any remuneration (including any kickback, bribe, or rebate) * * * *in return for* purchasing * * * or * * * recommending” federally insured items or services. 42 U.S.C. 1320a-7b(b)(1) (emphasis added). The very next provision criminalizes the opposite side of such corrupt transactions, making it a felony to offer or

pay “any remuneration (including any kickback, bribe, or rebate) * * * *to induce*” such a purchase or recommendation. 42 U.S.C. 1320a-7b(b)(2) (emphasis added).

This Court recognized in *Hansen* that “induce” in a criminal statute presumptively carries a specialized meaning akin to criminal solicitation—not mere influence. 599 U.S. at 774-775. The D.C. Circuit, following the Second and Fourth Circuits, nevertheless held that “induce” in the AKS carries its “ordinary,” non-criminal-law meaning of “influence.” That conflicts with the Fifth and Seventh Circuits’ constructions of the AKS and the Ninth Circuit’s application of *Hansen* to identical language in an analogous anti-kickback statute. The court of appeals’ overbroad interpretation requires the Court’s intervention, just as in other recent anti-corruption cases, to ensure the AKS does not criminalize innocent conduct contrary to the statute’s text and Congress’s intent.

Vertex developed CASGEVY, a one-time, potentially curative gene therapy for sickle cell disease and transfusion-dependent beta-thalassemia (TDT). Before receiving this breakthrough therapy, patients must undergo myeloablative conditioning, a type of chemotherapy that can cause permanent infertility. Due to that risk, many patients—most of whom are young—delay or forgo CASGEVY to preserve their ability to have children, because fertility-preservation services are expensive and rarely covered by insurance. But delaying therapy can mean patients are no longer healthy enough to receive CASGEVY, sentencing them to a median life expectancy of 43 years and, often, burdening the federal government with many millions of dollars in lifetime healthcare expenses. Vertex therefore proposed the Fertility Support Program (the Program), which

provides up to \$70,000 for medically necessary fertility services to income-limited patients prescribed CASGEVY for an FDA-approved use, enabling them to receive treatment and still have biological children.

To confirm the Program’s legality, Vertex sought an OIG advisory opinion. OIG concluded that the Program would violate the AKS because fertility support, by ameliorating a significant risk with pre-treatment, would influence patients’ decisions to pursue treatment with CASGEVY. OIG also opined that the Program would violate the AKS by providing hospitals and physicians opportunities to earn treatment fees. OIG reasoned that the *criminal* AKS’s “to induce” language should be construed as “likely to influence”—the standard in the AKS’s *civil* counterpart, the CMPL. OIG refused, however, to apply the CMPL’s “promotes access to care” safe harbor to the AKS, or even to recognize that petitioner’s Program came within the CMPL exception, even though the Centers for Medicare & Medicaid Services (CMS) expressly recognized that fertility preservation services are necessary to promote patients’ access to cell and gene therapies like CASGEVY.

The district court adopted OIG’s construction of “to induce,” and the D.C. Circuit upheld that construction, deepening an existing circuit split. The Fifth, Seventh, and Ninth Circuits recognize that “induce” in criminal anti-kickback statutes means improper influence akin to criminal solicitation—consistent with *Hansen*—but the D.C., Second, and Fourth Circuits interpret it to reach mere influence. Under the mere-influence interpretation, any financial assistance that helps a patient overcome an obstacle to obtaining appropriately prescribed, federally reimbursed healthcare satisfies the statute’s

actus reus; under the other circuits' rule, a program that does not corrupt medical decision-making would not.

The court of appeals' decision creates an absurdity that illustrates why its side of the circuit split is incorrect. Unlike the AKS, the CMPL prohibits remuneration "likely to influence" medical decisions but expressly excludes remuneration that promotes access to care and poses a low risk of abuse. Yet under the court of appeals' construction, the same access-promoting assistance that Congress shielded from civil liability is a felony under the criminal AKS. Not only does that construction ignore Congress's deliberate use of different words ("induce" vs. "influence"); it renders the CMPL's "access to care" exception a nullity.

This case offers an exceptional—and urgently needed—opportunity to clarify the AKS's scope and resolve a circuit split that is already chilling a broad range of lawful, beneficial, patient-supporting activities. It presents a pure question of statutory interpretation on an undisputed administrative record, arising from a challenge to a final advisory opinion.

Meaningful judicial review is otherwise often out of reach. AKS enforcement actions involving patient-assistance programs rarely proceed through appeal because the consequences of litigation are overwhelming: defendants face up to ten years' imprisonment, substantial criminal fines, treble damages and penalties under the False Claims Act (FCA), and potential exclusion from federal healthcare programs. Nor is the advisory-opinion process a realistic alternative. It is lengthy and costly—and, after the decision below, may be effectively futile. Defendants often have little choice but to abandon beneficial patient programs or settle with the

government rather than litigate for years to obtain judicial review.

If Vertex’s Program—designed to mitigate a documented side effect associated with pre-treatment for a potentially curative therapy—does not pass muster, arguably no meaningful patient-assistance program will. The Court should grant certiorari to resolve the circuit split, confirm *Hansen’s* presumption, and hold that the AKS reaches only corrupting remuneration and wrongful influence, not every activity that influences or assists patients to obtain necessary medical care.

STATEMENT OF THE CASE

A. Statutory Background

AKS. Congress enacted the AKS in 1972 to protect Medicare and Medicaid from waste, fraud, and abuse. Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). The original statute prohibited soliciting, receiving, or offering a “kickback” or “bribe,” as well as a particular type of “rebate”—a “rebate of any fee or charge for referring” a patient for federally funded services (*i.e.*, a kind of kickback). *Ibid.*; 42 U.S.C. 1395nn(b), 1396h(b) (1976). Those three terms “each involve[d] a corrupt payment” that violated the duty to use federal funds for their intended purposes. *United States v. Zacher*, 586 F.2d 912, 916 (2d Cir. 1978).

In 1977, Congress amended the statute, making violations felonies and specifying that it prohibited “any remuneration (including any kickback, bribe, or rebate)” solicited or received “in return for,” or offered or provided “to induce,” the purchase or recommendation of federally reimbursed goods or services. Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1179-1183 (1977) (now codified at 42 U.S.C. 1320a-7b(b), (b)(3)(A)). At the same time,

Congress clarified that the AKS does not prohibit bona fide rebates in the ordinary sense by excepting “discount(s) or other reduction(s) in price” that are “properly disclosed and appropriately reflected in the costs claimed or charges made.” *Ibid.* The amendment expanded the possible forms of payment—cash or in kind, direct or indirect—without eliminating the corrupt character signaled by the parenthetical examples.

Congress later required that violations be made “knowingly and willfully,” Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980), and in 1987 directed HHS to create regulatory safe harbors (in addition to the statutory exceptions) “to ensure that published interpretations of the law are not impeding legitimate and beneficial activities.” H.R. Rep. No. 85, 100th Cong., 1st Sess. 27 (1987); see Pub. L. No. 100-93, § 14, 101 Stat. 680, 697 (1987). Recognizing that the statute’s severe penalties could still deter lawful and beneficial arrangements, Congress also created an advisory-opinion process—42 U.S.C. 1320a-7d(b)—requiring HHS to issue written opinions within 60 days after receiving requests. In 2010, Congress made AKS violations a basis for FCA liability and clarified that a person need not have actual knowledge of the AKS to violate it. Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, 759 (2010).

CMPL. The CMPL, adopted in 1996, has been recognized as the AKS’s civil “cousin.” *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1049 (6th Cir. 2023), cert. denied, 144 S. Ct. 224 (2023). They appear next to one another in the U.S. Code, cross-reference each other multiple times, and both address paying or soliciting “remuneration” in connection with the provision of federally funded healthcare. See 42 U.S.C. 1320a-7a (citing the AKS nine times, *e.g.*, 1320a-7a(a)(7)); 42 U.S.C.

1320a-7b (citing the CMPL three times, *e.g.*, 1320a-7b(g)). But while the AKS criminalizes “remuneration (*including any kickback, bribe, or rebate*) * * * to induce” purchasing decisions, the CMPL imposes civil penalties more broadly for “remuneration * * * *likely to influence*” those decisions. Compare 42 U.S.C. 1320a-7b(b)(2) (emphases added), with 42 U.S.C. 1320a-7a(a)(5) (emphasis added). The CMPL, however, expressly excludes beneficiaries from its scope (Section 1320a-7a(a)) and provides an express safe harbor for remuneration that “promotes access to care and poses a low risk of harm to patients and Federal health care programs.” 42 U.S.C. 1320a-7a(i)(6)(F).

EKRA. In 2018, Congress enacted the Eliminating Kickbacks in Recovery Act (EKRA), 18 U.S.C. 220, to address kickbacks connected to recovery-home, clinical-treatment, and laboratory services, including services reimbursed by private insurance. Congress borrowed verbatim from the AKS (not from the civil CMPL) to provide that EKRA criminalizes “any remuneration (including any kickback, bribe, or rebate)” “in return for” or “to induce” a referral. 18 U.S.C. 220(a)(2).

B. Factual Background

Sickle cell disease is a genetic disorder affecting approximately 100,000 Americans. App., *infra*, 31a. Rigid, sickle-shaped blood cells block blood flow and oxygen, causing vaso-occlusive crises, severe pain, organ damage, hospitalization, and premature death. *Ibid.* Sickle cell patients have a median survival of approximately 43 years, and more than half rely on federal healthcare coverage. *Ibid.*

TDT is a hereditary blood disorder affecting approximately 2,000 Americans. App., *infra*, 32a. TDT reduces

the body's production of healthy blood cells, requiring regular transfusions to prevent severe anemia and other debilitating complications. *Ibid.* TDT patients have a median survival of approximately 37 years, and a substantial share have federal healthcare coverage. *Ibid.*

Vertex developed CASGEVY to address the underlying causes of both diseases through CRISPR gene editing. App., *infra*, 33a. CASGEVY is administered once, after a lengthy pre-treatment process, and is potentially curative, offering patients a chance to escape chronic crises, transfusions, and the progressive damage caused by their diseases. *Ibid.*

CASGEVY requires myeloablative conditioning—chemotherapy that prepares the patient's bone marrow so the edited cells can engraft. App., *infra*, 33a. That chemotherapy can cause serious side effects, including infertility. *Ibid.* The risk of infertility is a leading reason patients delay or forgo treatment for these life-threatening diseases. *Ibid.* Tragically, delay itself can make a patient too sick to safely undergo treatment. *Ibid.* Fertility-preservation services are rarely covered by commercial insurance or federal healthcare programs and can cost tens of thousands of dollars. *Ibid.*

Vertex therefore designed the Program to provide up to \$70,000 for medically necessary fertility services. App., *infra*, 34a. Eligible patients must be U.S. or U.S.-territory residents, have annual household income at or below 670% of the Federal Poverty Level, be prescribed CASGEVY for an FDA-approved use, and lack insurance coverage for fertility care. *Id.* at 81a. Covered services can include counseling, fertility medication, collection and storage of oocytes or sperm, medical tests,

intrauterine insemination, and in-vitro fertilization. *Id.* at 80a.

The Program does not reward physicians for prescribing CASGEVY or direct patients to particular fertility providers. It is available to eligible patients regardless of treatment center, is offered only after CASGEVY has been prescribed, and is not promoted to physicians as a reason to prescribe the therapy. Vertex already offers the Program to eligible commercially insured patients but cannot extend it to government-insured patients without risking enforcement. App., *infra*, 5a.

In January 2024, the month after FDA first approved CASGEVY, CMS announced that sickle cell disease would be the first focus of CMS’s Innovation Center’s Cell and Gene Therapy Access Model (Access Model). The Access Model *requires* sickle cell disease gene therapy manufacturers to “‘cover certain fertility preservation services,’ because ‘the care journey for [sickle-cell-disease cell and gene therapy] typically results in infertility.’” App., *infra*, 42a (citation omitted; brackets in original). CMS explained that “[l]ack of access to fertility preservation services presents a significant access barrier to individuals considering [cell and gene therapies].” *Ibid.* (citation omitted; brackets in original). Despite CMS’s recognition that fertility preservation addresses an “access barrier,” the Access Model applies only to states who opt to participate and does not cover all necessary fertility services, underscoring continuing patient need for the Program. *Ibid.*

C. Proceedings Below

OIG Advisory Opinion. On June 13, 2023, Vertex requested an advisory opinion from OIG regarding the

Program. Only after Vertex’s repeated requests and the filing of a lawsuit did OIG issue Advisory Opinion No. 24-06 over a year later. App., *infra*, 75a-92a.

OIG concluded that the Program would violate the AKS by providing (i) remuneration to patients likely to influence their decisions to pursue CASGEVY, and (ii) an opportunity for hospitals and treating physicians to earn fees related to CASGEVY treatment. App., *infra*, 86a-87a. Invoking the CMPL’s “likely to influence” formulation, OIG opined that because the Program would address “the patient’s inability to pay the costs associated with fertility services,” which is “a reason a patient would not receive [the] treatment,” the Program “likely would influence the patient’s purchasing decision” and would therefore “implicate” the AKS. *Id.* at 86a-88a. Even though payments under the Program would be paid to fertility specialists, not to CASGEVY-prescribing hematologists, OIG also opined that, by increasing the number of patients who would receive CASGEVY, the Program constituted remuneration to “treating physicians in the form of the opportunity to earn fees related to treatment with the Product.” *Id.* at 87a.¹

OIG also concluded that the Program implicated the CMPL but declined to opine whether it met the CMPL’s promotes-access-to-care exception, stating that OIG lacked the data to determine whether fertility support improved CASGEVY access. App., *infra*, 89a. OIG did

¹ The Department of Justice chose not to defend this rationale before the court of appeals, see Gov’t C.A. Br. 23 n.2, but it has been asserted before other courts, which have adopted this rationale, see *United States ex rel. Witkin v. Medtronic, Inc.*, 2024 WL 1892405, at *18 (D. Mass. Mar. 31, 2024) (upholding AKS-based FCA theory that assisting doctors to interpret testing results created an “opportunity to bill,” constituting remuneration).

not address the intra-agency conflict between that conclusion and CMS’s contemporaneous Access Model determination.

District Court. Petitioner sought an order vacating OIG’s determination regarding the proposed Program as contrary to law under the Administrative Procedure Act, 5 U.S.C. 702, 706, and challenged the regulations governing the timing for issuing advisory opinions. The district court granted the government’s motion for summary judgment on March 31, 2025. App., *infra*, 74a. It rejected Vertex’s argument that *Hansen* requires giving “induce” its specialized criminal-law meaning and that textual and structural features reinforce that presumption; upheld OIG’s refusal to opine on the CMPL exception; and concluded that Vertex lacked standing to challenge the advisory-opinion timing regulations. *Id.* at 47a-69a.

Court of Appeals. The court of appeals affirmed the district court’s construction of the criminal AKS, applying the “ordinary,” *non-criminal* meaning of “induce”—to “influence”—rather than the narrower, criminal-law meaning recognized in *Hansen*. App., *infra*, 8a-13a. Instead of applying *Hansen*’s presumption that “induce” carries its criminal-law meaning in criminal statutes, it did the opposite: it assumed courts should “start” with a word’s “ordinary meaning” since the specialized meaning applies only “sometimes.” *Id.* at 9a.

The court also attempted to distinguish *Hansen* by asserting that the AKS does not prohibit inducement of “clearly unlawful activity” (since selecting medical services is “generally lawful”). App., *infra*, 10a. But the court failed to discuss, or even acknowledge, 1320a-7b(b)(1)’s prohibition on soliciting or receiving

remuneration “in return for” purchasing federally reimbursed items or services—the very crime that is being induced by a violation of 1320a-7b(b)(2). *Id.* at 8a-13a. Nor did it acknowledge *Hansen’s* explanation that the presumption that “induce” takes its criminal-law meaning was “even stronger” when the induced conduct was a crime—not that the induced conduct *needed* to be criminal for the presumption to apply. *United States v. Hansen*, 599 U.S. 762, 775 (2023).

The court also rejected Vertex’s argument that the AKS’s “induce” must be given a distinct meaning from the CMPL’s “influence,” reasoning that the statutes were enacted at different times—ignoring that they cross-reference each other, sit in neighboring sections of Title 42, and are parallel in structure and purpose. App., *infra*, 12a-13a; see pp. 8-9, *supra*. It also reasoned that the AKS’s safe harbors support the ordinary meaning, because the criminal-law meaning would purportedly make the safe harbors “superfluous.” App., *infra*, 11a. Nowhere, however, did the court of appeals address the Ninth Circuit’s contrary analysis of EKRA’s identical criminal-law language and parallel safe harbors—nor did it address the exception for certain benign activities in the statute at issue in *Hansen*.

Under the court of appeals’ decision, conduct Congress protected from civil liability under the CMPL’s promotes-access-to-care exception will always fall within the *actus reus* of the criminal AKS, thus making the CMPL’s exception superfluous. The court acknowledged that its interpretation of “induce” as applying to the conduct safe harbored under the CMPL creates a “perceived absurdity,” but regarded construing “induce” consistent with *Hansen* to be “rewrit[ing]” the

statute, rather than sound interpretation. App., *infra*, 14a.

The court of appeals nevertheless reversed on the CMPL, holding OIG’s refusal to opine on the access-to-care exception was arbitrary and capricious, and on the advisory-opinion timing regulations, finding them contrary to law. The court of appeals noted petitioner’s “significant evidence” that its Program satisfies the promotes-access-to-care exception because the Program increases patients’ access to CASGEVY by addressing a “significant access barrier”—infertility—for many patients who might otherwise choose CASGEVY, while also “impos[ing] controls” to minimize fraud by providing access to the Program only *after* patients are prescribed CASGEVY. App., *infra*, 20a-21a. The court did not explain what good the CMPL’s safe harbor would do petitioner or patients, since the Program would remain a crime under the court’s reading of the AKS.

REASONS FOR GRANTING THE PETITION

This Court should grant certiorari to resolve a circuit split concerning whether “induce” in federal criminal anti-kickback statutes carries its criminal-law meaning akin to criminal solicitation or its ordinary meaning of “influence.” *Hansen* establishes that a criminal-law term (such as “induce”) in a criminal-law statute presumptively carries its criminal-law meaning; in the AKS, that conclusion is confirmed by the statute’s text, history, and structure. Nevertheless, three circuits’ contrary interpretation imports the CMPL’s broader *civil* standard of “influence” into the AKS, while refusing to carry over the CMPL’s express protection for access-promoting conduct, threatening to chill *all* patient-assistance activity. This Court should grant the petition to

resolve this pure legal question, thereby restoring a coherent boundary between criminally corrupt exchanges and lawful efforts to help patients obtain necessary healthcare.

I. THE COURTS OF APPEAL ARE SPLIT ON THE MEANING OF “INDUCE” IN—AND THE APPLICATION OF *HANSEN* TO—FEDERAL ANTI-KICKBACK STATUTES

Circuit courts are divided as to whether “induce” in the AKS carries its specialized criminal-law meaning of wrongful solicitation or the non-criminal, “ordinary” meaning of “influence.” On one side, the Second, Fourth, and now D.C. Circuits have held that “induce” means simply to “influence” a person, such that virtually anything of value a manufacturer does to increase access to its product (even if wholly beneficial) satisfies the statute’s prohibition. App., *infra*, 9a-10a; *Pfizer, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 42 F.4th 67, 75 (2d Cir. 2022), cert. denied, 143 S. Ct. 626 (2023); *Pharmaceutical Coal. for Patient Access v. United States (PCPA)*, 126 F.4th 947, 953-958 (4th Cir. 2025). On the other side, the Fifth, Seventh, and Ninth Circuits have concluded that “induce” as used in the AKS and EKRA requires a showing of improper, undue, or wrongful influence before triggering the criminal prohibition. *United States v. Marchetti*, 96 F.4th 818, 826-827 (5th Cir. 2024) (AKS); *United States v. Sorensen*, 134 F.4th 493, 500-503 (7th Cir. 2025) (AKS); *United States v. Schena*, 142 F.4th 1217, 1224-1225 (9th Cir. 2025) (EKRA). Left unresolved, this conflict means that identical conduct—*e.g.*, Vertex’s Program—would be a felony in some circuits, but permissible in others.

A. The Correct Side of the Circuit Split Gives “Induce” Its Specialized Criminal-Law Meaning

In *Hansen*, this Court rejected the argument that “encourages or induces” in a criminal statute carries the broad dictionary meaning of mere influence. 599 U.S. at 773-775. Instead, the phrase conveys criminal solicitation and facilitation because “encourage” and “induce” have established legal meanings in the criminal context, and Congress “presumably” adopts the legal tradition attached to terms of art. *Id.* at 774. The Court emphasized that the appearance of a criminal-law term in a criminal-law statute is “in and of itself” a “good clue” that the term carries its criminal-law meaning. *Id.* at 775.

Ninth Circuit. In *Schena*, the Ninth Circuit faithfully applied *Hansen*’s reasoning to EKRA, a criminal anti-kickback statute employing language identical to the AKS (“any remuneration (including any kickback, bribe, or rebate) * * * to induce”). 18 U.S.C. 220(a)(2)(A). Holding that “induce” connotes “not mere causation, but wrongful causation,” *Schena* concluded that “it makes sense to read EKRA as incorporating the ‘well-established legal meaning[]’ of ‘induce,’ because ‘when Congress borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word.’” 142 F.4th at 1224 (quoting *Hansen*, 599 U.S. at 774) (brackets in original).

Applying that standard, the Ninth Circuit held that “a percentage-based marketing arrangement, without more,” does not violate EKRA because “[a]ll marketing

efforts are intended to influence the recipient.” *Schena*, 142 F.4th at 1225. *Schena* required a showing of “undue influence”—a standard it derived from *Hansen* and a pre-*Hansen* AKS case, *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995), which held that “mere encouragement would not violate the [AKS]” and that “induce” “connotes an intent to exercise influence over the reason or judgment of another in an effort to cause the referral of program-related business.” *Schena*, 142 F.4th at 1224 (quoting *Hanlester*, 51 F.3d at 1398).

Schena’s reasoning applies in full to the AKS, as EKRA and the AKS are “analogous” provisions with virtually identical language enacted for the same purpose. 142 F.4th at 1223. Indeed, *Schena* relied on AKS precedent—from the Fifth, Seventh, and Ninth Circuits—to interpret EKRA, explaining that in an AKS prosecution, the government “must prove that the defendant ‘intended improperly [to] influence[]’ those who make healthcare decisions on behalf of patients.” *Id.* at 1225 (quoting *Marchetti*, 96 F.4th at 827) (brackets in original).²

Fifth Circuit. In *Marchetti*, the Fifth Circuit held that the government failed to prove certain AKS violations because there was no evidence that the defendant “intended ‘improperly [to] influence[]’ those who make healthcare decisions on behalf of patients.” 96 F.4th at 826-827 (quoting *United States v. Miles*, 360 F.3d 472,

² This Court has granted certiorari in similar situations in which the conflict concerns different constructions of the same language across statutes. See, e.g., Petition for a Writ of Certiorari at 6-7, *Smith v. City of Jackson*, No. 03-1160 (Feb. 11, 2004) (noting conflicting construction of identical language in the Age Discrimination in Employment Act and Title VII).

481 (2004) (brackets in original)). As the court recognized, “not every sort of influence is improper.” *Id.* at 827. *Marchetti* reaffirmed the Fifth Circuit’s previous ruling in *Miles* where the court agreed with the defendant that the AKS “was designed to ensure that a doctor’s independent judgment regarding patient care is not compromised,” which is not implicated if the purported remuneration could not “unduly influence the doctor’s decisions.” *Miles*, 360 F.3d at 480-481 (distinguishing Seventh Circuit AKS decision in which the “decisionmaker * * * was shown to have been improperly influenced by the payments he received”). The Fifth Circuit’s improper-influence rule respects the statute’s criminal character by construing the AKS *not* to criminalize every payment that may influence increased healthcare usage.

Seventh Circuit. The Seventh Circuit likewise applied the improper-influence requirement in *Sorensen*, holding that payments to marketers did not impermissibly “induce” referrals. 134 F.4th at 500-503. The Seventh Circuit held that where “physicians always had ultimate control over their patients’ healthcare choices and applied independent judgment in exercising that control,” the AKS was not violated—even though the marketers’ business model was to influence physicians’ prescribing decisions—because the AKS proscribes payments made to “induce *an unlawful* referral.” *Id.* at 502 (quoting *Marchetti*, 96 F.4th at 831) (emphasis added). Applying the same framework as the Fifth Circuit, the court concluded that the defendant’s payments were made “in exchange for ordinary and legal services—advertising, manufacturing, and shipping products—not for referrals.” *Id.* at 504. Those payments did not “induce” physicians to prescribe treatment “in return for”

remuneration—the counterpart crime for recipients set forth in Section 1320a-7b(b)(1). Critically, *Sorensen* recognizes the practical problem with respondents’ interpretation: because legitimate marketing and patient-support efforts inherently intend to influence someone, influence alone cannot constitute the corrupt activity Congress criminalized.

Together, these three circuits properly recognize that the AKS and EKRA’s prohibition on remuneration “to induce” requires something beyond ordinary influence. The government must prove that the defendant employed improper, undue, or wrongful influence over a healthcare decisionmaker—a requirement rooted in the “longstanding history” of “induce” as a criminal-law term of art. *Hansen*, 599 U.S. at 778; *Schena*, 142 F.4th at 1224. Thus, a payment intended to purchase a referral, steer a patient away from independent medical judgment, or reward a provider for selecting a product remains within the statute’s scope; removing a barrier to care without corrupting the medical decision-making process does not.

B. The D.C., Second, and Fourth Circuits Incorrectly Equate “Induce” With “Influence”

D.C. Circuit. The D.C. Circuit held that “induce” means merely to influence, despite *Hansen*’s presumption of a criminal-law meaning when that term appears in a criminal statute. As discussed more fully below, see pp. 23-26, *infra*, the D.C. Circuit acknowledged *Hansen* but inverted its presumption, concluding that words in criminal statutes are “typically” interpreted according to their ordinary meaning, and only “sometimes” carry their criminal-law meaning. App., *infra*, 9a-10a.

Fourth Circuit. In *PCPA*, a case involving a charitable organization’s program to help low-income patients “afford oncology drugs” by subsidizing their co-pays and additional medical needs, the Fourth Circuit reached the same inverted result. *PCPA*, 126 F.4th at 951-956. Relying on similar reasoning, the Fourth Circuit treated “induce” as ordinary influence, rejected the specialized criminal-law meaning, and barred the charitable program, even though the program was designed (consistent with OIG guidance) to cover *all* potential treatments precisely to avoid corrupting providers or patients’ choices among alternatives. *Ibid.* Like the court of appeals here, the Fourth Circuit attempted to distinguish *Hansen* on the ground that the conduct “induce[d]” in the AKS is not criminal. *Id.* at 955-956. But, like the D.C. Circuit, the Fourth did not mention the fact that paragraph (1) of the same AKS provision *does* criminalize purchasing or recommending “in return for” remuneration, as *Marchetti* recognized, 96 F.4th at 831.

Second Circuit. In a case involving a program to help low-income patients afford co-pays for the only FDA-approved drug to treat a rare progressive heart disease, the Second Circuit in *Pfizer* also construed “induce” as “influence or persuasion,” asserting that the word is “neutral with regard to intent—one can persuade another to take an action with good or bad motives.” 42 F.4th at 71-76. Although *Pfizer* predated *Hansen*, the D.C. and Fourth Circuits relied on it to conclude that the AKS bars programs that would increase patients’ access to drugs that treat their disease, even without distorting medical decision-making.

C. The Conflict Regarding this Important Question Is Deep, Clearly Defined, and Outcome-Determinative

Three circuits have ruled that “induce” means mere influence, while three others required improper or undue influence that distorts medical decision-making. These incompatible rules mean that a healthcare arrangement may be lawful in one circuit and criminal in another.

The conflict is dispositive for many patient-assistance programs. OIG concluded that the Program would violate the AKS (and the court of appeals affirmed) simply because it would address “[a] patient’s inability to pay the costs associated with fertility services” that were an obstacle to the patient following their physician’s prescription. App., *infra*, 86a. OIG and three circuit courts would reach the same conclusion even if the drug in question were the *only* FDA-approved treatment to cure a life-threatening condition (*Pfizer*) or the assistance were designed to ensure *all* potential treatments were covered (*PCPA*), so that the program could not distort the patient’s or physician’s choice. The Fifth, Seventh, and Ninth Circuits standard, by contrast, would lead to a different result altogether, because those circuits require a showing that the defendant “intended ‘improperly [to] influence[]’ those who make healthcare decisions on behalf of patients.” *Marchetti*, 96 F.4th at 827 (citation omitted; brackets in original).

Notably, the court of appeals observed that petitioner’s Program inherently “poses a low risk of harm to federal healthcare beneficiaries and programs” through strict access controls designed to avoid any corrupt or improper influence over any physician’s or patient’s

medical judgment. App., *infra*, 20a-21a. Where “physicians always had ultimate control over their patients’ healthcare choices and applied independent judgment,” *Sorensen*, 134 F.4th at 502, patient-assistance programs addressing a medical side effect—like chemotherapy-induced infertility that CMS itself acknowledged “presents a significant access barrier,” App., *infra*, 20a—would fall short of the kind of improper influence the Fifth, Seventh, and Ninth Circuits require, but would remain a felony in other circuits.

II. THE COURT OF APPEALS’ CONSTRUCTION IS WRONG BECAUSE MULTIPLE CANONS OF STATUTORY CONSTRUCTION REINFORCE THE *HANSEN* PRESUMPTION

The court of appeals acknowledged that applying the civil CMPL’s “influence” standard (without its safe harbor) to the criminal AKS resulted in a “perceived absurdity” by criminalizing conduct excepted from civil liability in a neighboring provision of the U.S. Code. App., *infra*, 14a. That absurdity can be avoided simply by applying *Hansen*’s presumption and giving “induce” its established criminal-law meaning, under which it is unnecessary to import the access-to-care exemption, because such programs would not come within the AKS’s scope in the first place. Other canons of construction support the same result.

A. The Court of Appeals Ignored *Hansen*’s Criminal-Law Presumption and Attempted to Distinguish It on Unpersuasive Grounds

The court of appeals did not, as *Hansen* instructs, assume that “when Congress ‘borrows terms of art in which are accumulated the legal tradition and meaning of centuries of practice, it *presumably knows and adopts*

the cluster of ideas that were attached to each borrowed word.’ ” 599 U.S. at 774 (emphasis added; citation omitted). Black’s Law Dictionary has long defined “inducement” to mean “that which leads or tempts to the commission of crime.” 599 U.S. at 776 (quoting Black’s Law Dictionary 617 (1891)). That remained the criminal-law definition when “inducement” was added to the AKS. See Black’s Law Dictionary 915 (Rev. 4th ed. 1968). Because the AKS uses “induce” in a criminal statute, the court of appeals should have regarded that as a “good clue” that “induce” carries its specialized meaning—akin to criminal solicitation or facilitation—rather than mere influence.

Yet the court of appeals ignored *Hansen* and applied the opposite presumption, starting with the principle that “[s]tatutes are *typically interpreted* according to their ordinary meaning,” and only “sometimes” carry a more specialized meaning. App., *infra*, 9a (emphasis added). It asserted that “any presumption that Congress carried over the old soil of * * * solicitation or facilitation is weakened in the AKS, in which the prohibition on inducement is not directed at an unlawful act.” *Id.* at 11a.

Here, the court of appeals mischaracterized both *Hansen* and the AKS. *Hansen* did not hold that, for “induce” to carry a specialized meaning, the conduct induced must be independently unlawful. *Hansen* held that using a criminal-law term in a criminal-law statute “in and of itself” is a “good clue” that the term carries its criminal-law meaning. 599 U.S. at 775. The unlawfulness of the induced conduct in *Hansen* merely made the presumption “even stronger,” *ibid.*; it was not essential, as other courts have recognized, see, e.g., *United States v. Ninsawat*, 2025 WL 1217385, at *6 (6th Cir. Apr. 28,

2025) (applying *Hansen* to 18 U.S.C. 2251(a), where enticed conduct is not unlawful).

The court of appeals also ignored that the conduct induced under AKS subsection (b)(2) *is* made unlawful under subsection (b)(1). The AKS *does* criminalize making purchases or recommendations reimbursable by federal health programs if the purchase or recommendation is “in return for” remuneration (*i.e.*, is “induced” by the remuneration). 42 U.S.C. 1320a-7b(b)(1). Indeed, the Fifth and Seventh Circuits recognized that the two provisions work together; “to violate the statute [in (b)(2)], ‘the payments have to be made in order to induce an *unlawful* referral [or purchase],’” *i.e.*, a referral or purchase that would be made “in return for” the payment in violation of (b)(1). *United States v. Sorensen*, 134 F.4th 493, 502 (7th Cir. 2025) (quoting *United States v. Marchetti*, 96 F.4th 818, 831 (5th Cir. 2024)) (emphasis added).

The court of appeals’ attempt to distinguish *Hansen* on the ground that the AKS’s safe harbors would be rendered superfluous if “induce” took its specialized meaning likewise fails. See App., *infra*, 11a. The *Hansen* statute *also* contained an exception for conduct that would not normally constitute criminal solicitation (religious organizations’ efforts to recruit U.S.-based ministers and missionaries, see 8 U.S.C. 1324(a)(1)(C)). And, in any event, contrary to the court of appeals’ suggestion, several AKS safe harbors protect conduct that could, at least in certain circumstances, implicate the AKS under its narrower, criminal-law construction. For example, the employee safe harbor protects payments to employees hired to promote products, even though the payments could distort employees’ recommendation (if, for example, they genuinely felt a competitor’s product was

superior), 42 U.S.C. 1320a-7b(b)(3)(B), and the “sale of practice” safe harbor protects payments to a physician owner referring her entire patient population to a purchasing physician, even if she might otherwise have referred at least some patients to other practitioners, 42 C.F.R. 1001.952(e).

Even if some AKS exceptions were arguably superfluous under a construction consistent with *Hansen*, it is hardly uncommon for Congress to adopt exceptions to make “doubly sure” that beneficial conduct is not deterred. *Barton v. Barr*, 590 U.S. 222, 239 (2020). Indeed, in *Mission Product Holdings, Inc. v. Tempnology, LLC*, this Court rejected a similar argument, cautioning against placing too much weight on the supposed superfluity of statutory exceptions that accumulated over time in response to “discrete problem[s].” 587 U.S. 370, 383-384 (2019). Like the exceptions in *Tempnology*, the AKS’s safe harbors were not enacted as a comprehensive scheme; they were added over the years to clarify that the AKS does not prohibit certain “legitimate and beneficial activities,” even at the expense of allowing conduct that might possibly corrupt decision-making in particular cases. H.R. Rep. No. 85, 100th Cong., 1st Sess. 27 (1987).

By failing to adequately engage with *Hansen*’s presumption—let alone rebut it—the court of appeals fell into the interpretive error *Hansen* warned against: it “stacked the deck in favor of ordinary meaning” when it should have “given specialized meaning a fair shake.” 599 U.S. at 775.

B. The AKS’s Text, Structure, and History Confirm that Congress Intended to Prohibit Corruption, Not Mere Influence

Contrary to the court of appeals’ construction, the AKS’s text, context, and history confirm that “remuneration (including any kickback, bribe, or rebate) * * * to induce” carries inducement’s specialized criminal-law meaning and describes a corrupt payment, rather than any item of value that may influence a healthcare decision.

1. *The language surrounding “induce” reinforces petitioner’s interpretation under several canons of construction*

The “water in which [induce] swims” confirms its meaning. *Hansen*, 599 U.S. at 775. Black’s Law Dictionary defines “remuneration” as “compensation, esp. for a service that someone has performed,” Black’s Law Dictionary (12th ed. 2024), *i.e.*, something paid *in exchange for* the conduct the payor seeks to influence. See Black’s Law Dictionary 1460 (Rev. 4th ed. 1968) (noting that the term implies “*quid pro quo*”). That meaning is supported by the AKS’s primary prohibition of “remuneration (including any kickback, bribe, or rebate) * * * *in return for*” a purchase or referral, 1320a-7b(b)(1) (emphasis added)—the very crime 1320a-7b(b)(2) prohibits inducing.

The parenthetical “(including any kickback, bribe, or rebate)” likewise confirms the statute’s focus on corrupt payments. “Kickback” and “bribe” are established terms connoting improper or corrupt conduct, and “rebate,” is a term of art that refers to the corrupt referral-related payments prohibited by the pre-amendment statute, which penalized a “rebate of any fee or charge

for referring” a patient. Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). Those terms prohibit corruptly skewing medical decision-making—not mere influence. See *Skilling v. United States*, 561 U.S. 358, 412-413 (2010) (explaining that a “kickback” is a thing of value provided “for the purpose of improperly obtaining or rewarding favorable treatment,” and bribery requires corruption under federal law); *United States v. Zacher*, 586 F.2d 912, 916 (2d Cir. 1978) (the terms “kickback[], bribe[], and rebate[]” in the original AKS “each involve[d] a corrupt payment or receipt of payment”).

The court of appeals, however, applied the dictionary definition of “rebate” and ruled that the actions listed in the parenthetical following “remuneration” are “not all inherently corrupt.” App., *infra*, 16a. That conclusion conflicts with the Second Circuit’s ruling that the terms “kickback, bribe, and rebate” under the original AKS “each involve[d] a corrupt payment or receipt of payment,” and that this interpretation “makes logical the grouping together of the three practices in one prohibition.” *Zacher*, 586 F.2d at 916 n.9. When Congress retained the term “rebate” in the amended AKS, it understood its prior usage, which shared the corrupt character of the transactions covered by the AKS. See *George v. McDonough*, 596 U.S. 740, 746 (2022).

Traditional canons of statutory construction confirm that the exemplary parenthetical should inform the meaning of “remuneration * * * to induce.” Under *ejusdem generis*, where specific words accompany a general word in describing a particular subject, the general word is construed to embrace only objects similar in nature to those objects enumerated by the specific words. See *Hughey v. United States*, 495 U.S. 411, 419 (1990) (“[A] general statutory term should be understood in

light of the specific terms that surround it.”). And under *noscitur a sociis*, “a word is ‘given more precise content by the neighboring words with which it is associated.’” *Fischer v. United States*, 603 U.S. 480, 487 (2024) (quoting *United States v. Williams*, 553 U.S. 285, 294 (2008)); see *Samantar v. Yousuf*, 560 U.S. 305, 317 (2010).

The trio of “kickback, bribe, or rebate” must therefore indicate that “remuneration” shares the common characteristic of the examples: corruption. If the words in the parenthetical do not serve that purpose, they would be superfluous. See *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 114 (2001).

2. *Other statutory clues confirm a narrow, specialized criminal-law interpretation of “induce”*

As this Court observed in *Hansen*, the best “clue” that “induce” takes its criminal-law meaning is that it appears in a criminal statute. But the court of appeals misinterpreted several other clues that also favor the narrower construction.

First, the textual differences between the AKS and the CMPL, which the court of appeals failed to afford any weight, App., *infra*, 14a, support petitioner’s reading. When Congress uses different words in related or parallel provisions, courts respect that choice and give different effect to each provision. See *United States v. Sun-Diamond Growers of Cal.*, 526 U.S. 398, 404-405 (1999) (differentiating “gratuity” from “bribe”). Many other courts have recognized that the AKS and CMPL are neighboring provisions, cross-reference one another, and relate to payments involving federally reimbursed healthcare, and that any construction of one should be informed by the other. See 42 U.S.C. 1320a-7a(a)(7), 1320a-7a(i)(6)(B), 1320a-7b(g); see also *United States ex*

rel. Hart v. McKesson Corp., 96 F.4th 145, 157 (2d Cir. 2024) (interpreting the AKS by comparing its language with the CMPL, its “civil counterpart”), cert. denied, 145 S. Ct. 163 (2024); *United States ex rel. Martin v. Hathaway*, 63 F.4th 1043, 1049 (6th Cir. 2023) (construing the AKS in light of its “cousin,” the CMPL), cert. denied, 144 S. Ct. 224 (2023). By using the broader “likely to influence” in the CMPL (and omitting the AKS’s exemplary parenthetical), Congress indicated its intent that the CMPL cover at least some conduct outside the ambit of the criminal AKS. At the same time, however, Congress also circumscribed the CMPL’s broader scope in important ways, such as by reaching only influence to choose a “particular” provider, excluding beneficiaries, and, as discussed further below, see pp. 33-35, *infra*, excluding programs that promote access to care. By importing into the AKS only the CMPL’s “likely to influence” standard, without the ways in which Congress limited that standard in the CMPL, the court of appeals failed to attribute significance to Congress’s conscious choice to use different language in related statutes.

Congress’s enactment of EKRA—decades after passing the AKS and CMPL—further confirms its conscious choice between “influence” and “induce.” In crafting a new criminal statute targeting healthcare-related kickbacks, Congress deliberately used the AKS’s formulation (“remuneration (including any kickback, bribe, or rebate) * * * to induce”), not the CMPL’s broader “likely to influence.” 18 U.S.C. 220(a)(2)(A)-(B). Had Congress wished instead to prohibit mere influence in EKRA, it knew how to do so from the CMPL.

The fact that the CMPL broadly exempts beneficiaries from civil liability, but the AKS does not, should also have led the court of appeals to follow *Hansen’s*

instruction. In subsections 1320a-7b(b)(1) and (b)(2), the AKS criminalizes both sides of the corrupt transaction (or attempts on either side). By reading out of the AKS any element of corruption, the court of appeals' construction would potentially subject to criminal liability patients who merely accept remuneration allowing them to access life-saving healthcare their physicians have prescribed for them without any distortion.

3. *The court of appeals failed to follow this Court's decisions narrowing the scope of criminal statutes in light of over-criminalization, due process, and lenity concerns*

Recently, the Court has intervened on several occasions to curtail the overbroad reading of anti-corruption statutes advanced by the Department of Justice and adopted by lower courts. See *Snyder v. United States*, 603 U.S. 1, 5 (2024) (construing 18 U.S.C. 666 to reach only bribes, not gratuities, to avoid sweeping in potentially ordinary gifts and tokens of appreciation); *Kelly v. United States*, 590 U.S. 391, 398 (2020) (construing federal wire fraud and program fraud statutes as limited to where obtaining money or property is the object of the fraud, to prevent those statutes from becoming general-purpose prohibitions on dishonest local government); *McDonnell v. United States*, 579 U.S. 550, 572-577 (2016) (declining to construe a bribery theory of liability to reach commonplace acts of constituent service); *Skilling*, 561 U.S. at 408 (limiting the honest-services fraud statute to established forms of corruption—bribes or kickbacks—to prevent “proscrib[ing] a wider range of offensive conduct” than Congress intended). In so doing, the Court has rejected government assurances that overbreadth concerns are ameliorated through prosecutorial discretion. *Snyder*, 603 U.S. at 17.

Yet, under the court of appeals’ interpretation of the AKS, anything of value that might “influence” the purchase or recommendation of a federally reimbursable healthcare product or service is a crime—even where there is no corruption, no improper influence on medical decision-making, and no harm to the federal fisc. App., *infra*, 13a. Stripped of any corruption requirement, the AKS criminalizes a considerable swath of socially desirable behavior, making potential felons out of doctors, pharmaceutical manufacturers, charitable organizations, hospitals, and even patients. Such “breathtaking” scope “underscores the implausibility of the [g]overnment’s interpretation.” *Van Buren v. United States*, 593 U.S. 374, 393-94 (2021).

Indeed, under the court of appeals’ construction, the AKS would make a felon of a generous grandparent who offers to pay the co-pay for a grandchild’s medical treatment, or, as here, for fertility preservation services in order to help them access necessary care. The grandparent’s assistance plainly “influences” the grandchild’s decision to obtain the care by removing a financial barrier, in the same way as petitioner’s Program (or PCPA’s charitable co-pay assistance) would. See *Pharm. Coal. for Patient Access v. United States (PCPA)*, 126 F.4th 947, 951-956 (4th Cir. 2025). The government argued below that the generous relative would not be liable because she would not be attempting to influence the choice of a “particular provider.” Gov’t C.A. Br. 101-102. But there is no “particular provider” limitation in the AKS; the government imported that limitation from the CMPL (where Congress included it as a limitation on the broader term “influence”). Thus, it was the government, not petitioner, who had to resort to

“rewrit[ing]” the AKS to achieve its preferred outcome. See App., *infra*, 14a.

The rule of lenity exists to avoid such overbroad constructions. See *Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004); *Martin*, 63 F.4th at 1050 (holding that “the rule of lenity favors [applying] the narrower definition” to the AKS when ambiguity exists). As *Martin* observed, any overly broad construction of “remuneration” under the AKS that “lacks a coherent end point”—as the government’s does here—is the very hallmark of a statute that should be construed narrowly under the rule of lenity. 63 F.4th at 1050-1051.

Under the correct construction, the Program—like the generous grandparent—does not improperly influence medical decision-making. Physicians prescribe CASGEVY because it offers a potential functional cure for sickle cell disease and TDT; patients choose it for the same reasons. The Program is available only *after* prescription, to all eligible patients who meet neutral criteria, and addresses the pre-treatment’s known side-effects. It removes a known barrier—the risk of infertility—to medically appropriate care. In doing so, the Program facilitates, rather than corrupts, sound medical decision-making.

C. The Court of Appeals’ Construction of the AKS Produces an Absurd Result by Criminalizing Conduct Exempted from Civil Liability Under the CMPL

The absurd consequences that flow from the court of appeals’ reading of the AKS confirm that it misreads the statute. Recognizing that the term “influence” sweeps more broadly than “induce,” Congress equipped the CMPL with important limitations, including an

exception for remuneration that “promotes access to care.” 42 U.S.C. 1320a-7a(i)(6)(F). The court of appeals, however, read “induce” in the criminal AKS as coextensive with “influence” in the CMPL, even though no comparable promotes-access-to-care exception to the AKS exists. App., *infra*, 13a. That construction leads to an absurdity Congress could not have intended: in every instance in which the CMPL’s promotes-access-to-care exception would be satisfied, thus protecting the defendant from civil liability, the entity offering the program would commit a crime under the AKS, because removing a barrier to care would “influence” a patient’s decision. In such a world, no party would ever offer such a program, though Congress plainly sought to encourage it by adopting the civil exception.

This is a case-in-point. The court of appeals acknowledged that petitioner “provided significant evidence” that the Program satisfies the CMPL’s promotes-access-to-care exception, as petitioner “demonstrated that the Program improves the ability of patients to access CASGEVY and thus treat their blood disorders,” and submitted studies showing “the risk of infertility from chemotherapy is a significant reason why sickle cell disease patients forgo potentially lifesaving treatment,” and that they “lack the financial means to secure fertility treatment.” App., *infra*, 20a. The court of appeals also recognized that petitioner “put forth evidence that the Program poses a low risk of harm to federal healthcare beneficiaries and programs,” including by “point[ing] to the high cost of care for sickle cell disease patients” and “suggest[ing] that increasing access to gene therapies could alleviate this burden on federal healthcare programs by treating additional patients.” *Id.* at 20a-21a.

The court of appeals acknowledged the “perceived absurdity” that Congress would criminalize the beneficial programs it sought to encourage through the access-to-care exception, but said it would not “rewrite” the AKS to fix the problem. App., *infra*, 14a. But petitioner is not asking to rewrite the statute. It is asking simply that the Court give “induce” its presumed criminal-law meaning. Indeed, any absurdity disappears through a faithful application of *Hansen* and a proper reading of the AKS’s text, structure, and history.

III. THE COURT SHOULD TAKE THIS OPPORTUNITY TO REIN IN AN OVERBROAD CONSTRUCTION OF THE AKS, SO THAT OTHER BENEFICIAL PROGRAMS ARE NOT DETERRED

This case presents a pure question of statutory interpretation that is dispositive of the case: does “induce” in the AKS take its specialized criminal-law meaning or does it mean mere influence? The AKS’s application to the Program has been developed in a well-defined administrative record and was decided by the courts below on summary judgment. The ancillary issues addressed below—OIG’s arbitrary and capricious refusal to opine on the application of the CMPL’s exemption and the unlawful advisory-opinion timing regulations, see p. 15, *supra*—do not inhibit review. Indeed, the court of appeals’ recognition that the Program likely meets the CMPL’s access-to-care exception crystalizes the absurdity produced by that court’s construction of the AKS.

While questions regarding the AKS’s reach arise frequently in government investigations, those cases are unlikely to provide a better vehicle for the Court to consider the statute’s proper interpretation—if they provide one at all. The AKS carries severe criminal and

collateral consequences, including up to ten years' imprisonment, exclusion from Medicare and Medicaid, and FCA liability with treble damages plus penalties. See 42 U.S.C. 1320a-7(b)(7); *id.* at 1320a-7b(g). Those consequences create overwhelming pressure to settle before a defendant is subject to a judgment and can appeal.

The Second, Fourth, and D.C. Circuits have adopted an overbroad construction of the AKS that criminalizes broad swaths of benign or even socially desirable conduct, stymying three critically needed patient-assistance programs in the process. OIG has made clear that seeking further advisory opinions on the AKS's inducement requirement would be futile. Against that backdrop, few, if any, manufacturers, hospital systems, or charities can be expected to spend millions of dollars and years of litigation to tee up the same issue again, much less risk criminal exposure in multiple circuits if they proceed with a program.

The consequences of waiting for another case to correct respondents' overbroad interpretation of the AKS will be measured in untold patient suffering. Patient-assistance programs—the factual circumstance that most clearly highlights the absurdity of OIG's construction—will not be undertaken if manufacturers believe that helping a patient overcome a barrier to necessary care exposes them to felony liability.

This is not mere speculation, nor is the loss limited to patients who would benefit from petitioner's Program. Applying OIG's overbroad construction of the AKS, the government forced a company to stop offering free testing for patients suspected of having the genetic condition that could be treated by the sponsor's drug, even though the test merely offered valuable

information about the patient's health and was not conditioned in any way on purchase of the sponsor's product. See *United States ex rel. Ruggiero v. Ultragenyx Pharm. Inc.*, No. 21-cv-11176-ADB (D. Mass. July 19, 2021), Dkt. No. 2; Press Release, Pharmaceutical Company Ultragenyx Agrees to Pay \$6 Million for Allegedly Paying Kickbacks to Induce Claims for its Drug Crysvita (Dec. 21, 2023).

Similarly, under *PCPA*, manufacturers will be dissuaded from supporting charities that help lower-income patients cover their co-pays, even if done in a manner designed to avoid distorting the doctor or patient's medical decision-making, which the government has itself acknowledged is socially beneficial. See *Pharm. Coal. for Patient Access v. United States (PCPA)*, 126 F.4th 947, 951-956 (4th Cir. 2025); Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70627 (Nov. 22, 2005) (recognizing desirability of manufacturer charity to help fund patient co-pays). While this may in the short term save federal healthcare programs money—because less well-off program beneficiaries will go without treatment, while the government pays its share for wealthier patients who can afford the co-pay—the AKS was not adopted as a strategy to ration federal healthcare dollars to benefit the wealthy over the less fortunate. That is the consequence of OIG's construction, which the court of appeals endorsed.

This Court should not allow the meaning of an important federal criminal statute to remain in dispute while beneficial medical programs disappear under the resulting uncertainty. The petition presents the right question, the right record, and an issue that is unlikely

to reach the Court again for quite some time. Certiorari is warranted.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

DOUGLAS H. HALLWARD-DRIEMEIER
ANDREW J. O'CONNOR
SANDRA H. MASSELINK
BRENDAN M. KEARNEY
ROPES & GRAY LLP

Counsel for Petitioner

OCTOBER 2026