

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 23, 2026

Decided September 4, 2026

No. 25-5133

VERTEX PHARMACEUTICALS INCORPORATED,
APPELLANT

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN
SERVICES, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:24-cv-02046)

Douglas H. Hallward-Driemeier argued the cause for appellant. With him on the briefs was *Andrew J. O'Connor*.

Daniel Winik, Attorney, U.S. Department of Justice, argued the cause for appellee. With him on the brief were *Brett A. Shumate*, Assistant Attorney General, and *Michael S. Raab* and *Charles W. Scarborough*, Attorneys.

Michael S. Labson and *Deborah Malamud* were on the brief for amicus curiae Sick Cell Reproductive Health Education Directive in support of appellant.

John S. MacGregor was on the brief for amicus curiae Dravet Syndrome Foundation in support of appellant.

James C. Stansel, John T. Delacourt, and Kwaku A. Akowuah were on the brief for amici curiae Pharmaceutical Research and Manufacturers of America & Biotechnology Innovation Organization.

Before: RAO and WALKER, *Circuit Judges*, and RANDOLPH, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* RAO.

RAO, *Circuit Judge*: Vertex Pharmaceuticals developed a gene therapy that treats two hereditary blood disorders but may have adverse effects on fertility. To address the risk that fertility concerns might deter individuals from taking the therapy, Vertex designed a program that would offer patients up to \$70,000 to support fertility services. Vertex requested an advisory opinion from the Department of Health and Human Services to ensure its program complied with federal law. After a long delay, HHS issued an unfavorable advisory opinion, concluding that Vertex's program would violate both the Anti-Kickback Statute and the Beneficiary Inducement Statute. Vertex sued, claiming the advisory opinion was unlawful and unreasonable. Vertex also challenged HHS's regulations regarding the timing for issuing advisory opinions. The district court granted summary judgment for HHS across the board.

HHS correctly determined that Vertex's program would run afoul of the Anti-Kickback Statute. We affirm summary judgment as to that part of the advisory opinion, but otherwise reverse. HHS failed to adequately explain why the program would violate the Beneficiary Inducement Statute, and the timing regulations unlawfully evade a statutory deadline for issuing advisory opinions.

I.

A.

This case turns on two statutes that protect the integrity of federal healthcare programs: the Anti-Kickback Statute (“AKS”) and the Beneficiary Inducement Statute (“BIS”).

Medicare and Medicaid provide federal funds to cover healthcare costs for certain eligible groups. Concerned about the possibility that individuals would offer payments to influence medical decisionmaking and inflate federal reimbursements, Congress enacted the AKS. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, Title II, § 242(b), 86 Stat. 1329, 1419. Congress has amended the AKS multiple times, for instance to broaden the scope of illicit payments and to add a scienter requirement to ensure the statute penalizes only conduct that is both knowing and willful. As revised and relevant here, the AKS criminalizes “knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) ... to any person to induce such person ... to purchase” a federally reimbursable medical product or service. 42 U.S.C. § 1320a-7b(b)(2)(B).

AKS violations are felonies punishable by up to a \$100,000 fine and 10 years of imprisonment. *Id.* § 1320a-7b(b)(2). The AKS contains safe harbors that except certain activities from criminal liability, and the HHS Secretary has authority to create additional safe harbors. *Id.* §§ 1320-7b(b)(3), 1320a-7d(a)(1)(B).

The BIS imposes civil penalties for influencing a beneficiary’s choice of provider for services or goods paid for by Medicare or Medicaid. Specifically, the BIS prohibits “offer[ing]” or “transfer[ring]” to a beneficiary “remuneration” that a person “knows or should know is likely to influence” a

beneficiary's choice of "provider, practitioner, or supplier." *Id.* § 1320a-7a(a)(5). The BIS contains several unique exceptions, in addition to the AKS's safe harbors, which generally extend to violations of the BIS. *Id.* § 1320a-7a(i)(6). Relevant here is an exception for remuneration that "promotes access to care and poses a low risk of harm to patients and Federal health care programs." *Id.* § 1320a-7a(i)(6)(F) ("Promotes Access to Care Exception").

Parties may seek an advisory opinion from the HHS Secretary regarding whether a proposed activity would violate either the AKS or the BIS. *Id.* § 1320a-7d(b)(1)–(2). The advisory opinion may determine whether a proposed action violates the AKS or the BIS, whether a statutory exception applies, and whether HHS will exercise discretion to not pursue violations because there is a low risk of fraud or abuse. An advisory opinion is "binding as to the Secretary and the party ... requesting the opinion." *Id.* § 1320a-7d(b)(4)(A).

The statutory provisions governing advisory opinions instruct the Secretary to promulgate regulations establishing procedures for the issuance of advisory opinions. Importantly, one subsection outlines the "Specific contents" for those regulations, which include that "the Secretary shall be required to issue to a party requesting an advisory opinion by not later than 60 days after the request is received." *Id.* § 1320a-7d(b)(5)(B)(i). HHS's regulations provide that it will issue an advisory opinion "within 60 days after the request for an advisory opinion has been formally accepted." 42 C.F.R. § 1008.43(c)(1). Furthermore, the regulations toll the 60-day period under certain circumstances, including from when HHS requests additional information until the time the requested information is submitted. *Id.* § 1008.43(c)(3)(ii).

B.

Vertex Pharmaceuticals is a biotechnology company that developed Casgevy, a novel treatment for sickle cell disease and transfusion-dependent beta-thalassemia, two hereditary blood disorders that afflict thousands of Americans. As part of Casgevy's treatment course, patients must undergo intensive chemotherapy, which can have significant negative effects on fertility. Because older patients are often unable to tolerate the chemotherapy regimen, patients ideally take Casgevy when they are young, with their childbearing years ahead of them. And because of the side effects of chemotherapy, patients may require fertility treatments that can cost tens of thousands of dollars.

Recognizing that fertility concerns and the costs of associated treatment might deter some patients from choosing Casgevy, Vertex created the Fertility Support Program. The Program provides up to \$70,000 to Casgevy patients for fertility services. Vertex opened the Program to privately insured patients, but did not include patients with federally provided healthcare, fearing the Program might violate the AKS and the BIS by offering a valuable service to incentivize patients to take Casgevy and choose certain healthcare providers.

On June 13, 2023, Vertex requested an advisory opinion from HHS about the lawfulness of extending the Program to federally insured patients. Vertex argued the Program did not violate the AKS and the BIS. In the alternative, Vertex argued that under the AKS, the Program posed a low risk of fraud or abuse and so HHS should exercise its discretion to withhold enforcement. And under the BIS, Vertex maintained the Program would satisfy the Promotes Access to Care Exception

because fertility concerns are a barrier to treatment that the Program would address.

A prolonged back-and-forth between HHS and Vertex followed. On June 26, HHS formally accepted Vertex's request and then asked for additional information about the Program. HHS tolled the 60-day deadline until Vertex provided the requested information on October 10. At a teleconference in November, HHS informed Vertex that it was unable to issue a favorable advisory opinion. The next month, Vertex requested that HHS publish its written decision within the period required by its regulations, but HHS did not do so. Over the following months, Vertex repeatedly requested that HHS finalize and publish the advisory opinion.

On July 15, 2024, Vertex sued in district court to compel issuance of the advisory opinion.¹ Vertex also alleged that the timing procedures in the advisory opinion regulations were contrary to law.

Three days later, more than one year after Vertex first requested an advisory opinion, and nine months after Vertex provided additional information to the agency, HHS issued the advisory opinion. HHS concluded that the Program provides prohibited remuneration within the meaning of the AKS and the BIS. HHS explained that "[i]f a reason a patient would not receive treatment with [Casgevy] is the patient's inability to pay the costs associated with fertility services," the Program would "address that inability to pay for these costs and likely would influence" the decision to purchase Casgevy. J.A. 590.

¹ Vertex sued HHS, the HHS Secretary, HHS's Office of Inspector General, and the HHS Inspector General. The Secretary has delegated his advisory opinion authority to the Office of Inspector General. *See* 42 C.F.R. § 1008.1.

Providing such remuneration to patients thus would violate the AKS if undertaken with the requisite scienter. *Id.* at 590, 592. Similarly, HHS concluded the Program falls under the BIS because the Program is likely to “influence” patients to choose physicians and centers Vertex has approved to provide Casgevy. *Id.* at 586, 591. HHS also “decline[d] to offer prospective immunity” from prosecution under the AKS because the agency lacked sufficient information to evaluate the risk of fraud and abuse created by the Program. *Id.* at 590. Finally, HHS concluded the Program did not qualify for the Promotes Access to Care Exception because it “lack[ed] data” on whether the Program improved patient access to Casgevy. *Id.* at 591.

After receiving the advisory opinion, Vertex amended its complaint to seek vacatur of the opinion under the Administrative Procedure Act (“APA”). Vertex argued that HHS’s interpretation of the AKS and the BIS was contrary to law and that it was arbitrary and capricious to not explain why Vertex’s proffered evidence was insufficient to decide whether the Program fits within the Promotes Access to Care Exception.

The district court granted summary judgment for HHS across the board. *Vertex Pharms. Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 774 F. Supp. 3d 211 (D.D.C. 2025). The court concluded that the terms “induce” and “remuneration” in the AKS reflect their ordinary meaning, and the Program would therefore violate the AKS by offering “recompense” in the form of payment for fertility services to “influence” patients to choose Casgevy. *Id.* at 222–31, 234–35. On the Promotes Access to Care Exception, the district court acknowledged that HHS failed to articulate what additional data it needed but nonetheless deferred to the agency’s reasoning. Finally, the district court found Vertex’s challenge to the advisory opinion regulations nonjusticiable because Vertex had “no ongoing

injuries” from those regulations after its advisory opinion had been issued. *Id.* at 235–37.

Vertex timely appealed. We review de novo the district court’s grant of summary judgment. *Sault Ste. Marie Tribe of Chippewa Indians v. Haaland*, 25 F.4th 12, 17 (D.C. Cir. 2022).

II.

We first address Vertex’s argument that HHS erred in determining the Program would violate the AKS.² The AKS prohibits “knowingly and willfully offer[ing] or pay[ing] 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” a federally reimbursable medical product or service.³ 42 U.S.C. § 1320a-7b(b)(2)(B).

² Following its usual practice, HHS did not formally consider the AKS’s scienter requirement in issuing the advisory opinion. *See* 42 U.S.C. § 1320a-7b(b)(2) (prohibiting “knowing[] and willful[]” conduct). For simplicity, we speak of HHS as having concluded the Program would violate the AKS.

³ In full, the provision at issue makes it a felony to:

knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

At issue here is whether the Program provides “remuneration ... to induce” a person to purchase Casgevy. Vertex does not dispute that the AKS bars the Program if the statute uses “remuneration” and “induce” in line with their ordinary meanings. But Vertex argues that both terms should be read narrowly, such that the AKS prohibits only quid-pro-quo transactions that corrupt medical decisionmaking.

We conclude the AKS employs the ordinary meaning of these terms, and therefore HHS correctly found the Program would violate the AKS by providing “remuneration” in the form of financial support for fertility treatment to “induce” persons to purchase Casgevy.

A.

We start with “induce,” the more contested term. The meaning of “induce” depends on whether the AKS uses the term in its ordinary or specialized criminal law meaning. Statutes are typically interpreted according to their ordinary meaning at the time of enactment, but they sometimes contain “terms of art in which are accumulated the legal tradition and meaning of centuries of practice.” *United States v. Hansen*, 143 S. Ct. 1932, 1942 (2023) (cleaned up).

In ordinary parlance, “induce” broadly means to influence or prevail on a person. *See Induce*, The Oxford English Dictionary (2d ed. 1989) (“To lead (a person), by persuasion or

(B) 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).

some influence or motive that acts upon the will *to* ... some action, condition, belief, etc.; to lead on, move, influence, prevail upon (any one) *to do* something.”); *Induce*, Black’s Law Dictionary (5th ed. 1979) (similar). By contrast, Congress sometimes employs “induce” in a “specialized, criminal-law sense” that “incorporat[es] common-law liability for solicitation and facilitation.” *Hansen*, 143 S. Ct. at 1942. Criminal solicitation requires that a person intentionally encourage another to commit a crime. 2 Wayne R. LaFare, *Substantive Criminal Law* § 11.1 (3d ed. 2018); Model Penal Code § 5.02(1) (A.L.I. 1985). Criminal facilitation, commonly known as aiding and abetting, is the “provision of assistance to a wrongdoer with the intent to further an offense’s commission.” *Hansen*, 143 S. Ct. at 1940. In this specialized sense, “induce” means to encourage a person to commit a crime or to assist that person in doing so.

We look to statutory context to determine whether the AKS uses “induce” to mean “influence” or instead to reflect criminal solicitation and facilitation. *See id.* at 1942–44. The scope of the AKS’s prohibition indicates the statute uses the ordinary meaning of “induce.” The AKS does not directly prohibit the inducement of clearly unlawful activity. It limits the ways in which one person can induce another to select medical services, but the selection of medical services by a recipient of Medicare and Medicaid is generally lawful, and the particular choice of services is not itself a crime. *See* 42 U.S.C. § 1320a-7b(b)(2).

By contrast, the statute at issue in *Hansen* criminalized “encourag[ing] or induc[ing]” illegal immigration. 143 S. Ct. at 1938 (quoting 8 U.S.C. § 1324(a)(1)(A)(iv)). Under that statute, the act being induced was itself a crime, and the Supreme Court thus interpreted “induce” in the criminal law sense. *See id.* at 1940–45. But any presumption that Congress

carried over the old soil of common law solicitation or facilitation is weakened in the AKS, in which the prohibition on inducement is not directed at an unlawful act.

Furthermore, looking to the broader context of the statute, the AKS’s extensive list of safe harbors supports construing “induce” in line with its ordinary meaning. “It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *West Virginia v. EPA*, 142 S. Ct. 2587, 2607 (2022) (cleaned up). When interpreting statutes, “every word and every provision is to be given effect” and constructions that result in provisions of “no consequence” are generally to be avoided. Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 174 (2012); *see also TRW Inc. v. Andrews*, 534 U.S. 19, 29 (2001) (rejecting an interpretation that would “render [a statutory] exception entirely superfluous in all but the most unusual circumstances”).

The ordinary meaning of “induce” gives effect to the safe harbors in the AKS. If the AKS prohibits remuneration offered to influence the purchase of federally reimbursable healthcare products and services, then the list of safe harbors identifies many ordinary transactions that are excluded from the AKS prohibition. *See* 42 U.S.C. § 1320a-7b(b)(3); *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 155 (2d Cir. 2024) (“To cabin the statute’s broad reach, Congress defined twelve exceptions to the AKS’s criminal penalties.”). For example, one safe harbor permits the payment of ordinary compensation from a hospital to its doctors. 42 U.S.C. § 1320a-7b(b)(3)(B). Another safe harbor allows the waiver of coinsurance by a healthcare center for a patient who qualifies for subsidized services. *Id.* § 1320a-7b(b)(3)(D). Yet another permits pharmacies to waive co-pays if certain conditions are met,

including that the pharmacy “determin[es] in good faith that the individual is in financial need.” *Id.* §§ 1320a-7b(b)(3)(G), 1320a-7a(i)(6)(A). The safe harbors include many commonplace transactions that influence healthcare decisions and therefore accord with an understanding of “induce” that means simply to influence another person.

If we adopted Vertex’s specialized understanding of “induce” as akin to criminal solicitation, there would be no need to include the safe harbors for prosaic actions like hospitals paying their doctors or for waivers of co-pays. Because criminal inducement would never reach such conduct, the specialized meaning of “induce” would render many of the safe harbors wholly superfluous.

Drawing meaning from superfluity of course depends on context. Some repetition or overlap in a statute may reflect Congress’s effort to legislate in a “hyper-vigilant way” that can “remove any doubt as to things not particularly doubtful in the first instance.” *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1074 (2018) (cleaned up). In the AKS, however, the list of safe harbors is extensive and detailed, so accepting a criminal solicitation reading of “induce” would “create vast superfluity in the statute.” *Pharm. Coal. for Patient Access v. United States*, 126 F.4th 947, 958 (4th Cir. 2025). Such superfluity weighs heavily against Vertex’s preferred construction. By giving the safe harbors work to do, the ordinary meaning of “induce” provides a coherent way of understanding the prohibition and safe harbors together. The statute’s structure confirms that “induce” reaches a wide range of conduct, including actions that may be beneficial or have a low risk of fraud and abuse.

Vertex also maintains that interpreting the AKS’s use of “induce” in line with criminal solicitation coheres with the

BIS’s civil prohibition against offering remuneration “likely to influence” a beneficiary’s selection of providers, practitioners, or suppliers. 42 U.S.C. § 1320a-7a(a)(5). Vertex argues these different terms must carry different meanings, and therefore “induce” in the criminal AKS must mean something narrower than “influence” in the civil BIS. Although courts will often look across the U.S. Code when interpreting a particular statutory provision, there are limits to that approach. The BIS was enacted roughly two decades after the AKS. That a different Congress later used the term “influence” in the BIS does not necessarily mean that “induce” in the AKS refers only to conduct analogous to criminal solicitation.⁴ *See Pfizer, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 42 F.4th 67, 78 (2d Cir. 2022) (declining to draw any AKS inference from the BIS because of the long gap between enactments); *Pharm. Coal. for Patient Access*, 126 F.4th at 956–57 (same).

If anything, context likely weighs against drawing any distinction between “induce” and “influence” in the two statutes. When Congress enacted the BIS, it prohibited remuneration “likely to influence” the selection of providers under the title, “Prohibition Against Offering *Inducements* to Individuals Enrolled Under Programs or Plans.” Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, Title II, § 231(h), 110 Stat. 1936, 2014 (emphasis added). The statute expressly referred to acts that influence as inducements.

Vertex also maintains that we must read “induce” narrowly in the AKS because the statute does not contain the same safe harbors as the BIS, and it is absurd that Congress did

⁴ On the facts of this case we have no occasion to determine whether “induce” in the AKS, while meaning generally to influence or prevail on, has an identical meaning to “influence” in the BIS.

not extend all of the BIS's safe harbors to the AKS. Perhaps extending the BIS's safe harbors to the AKS would be good policy; perhaps not. But courts cannot rewrite statutes based on perceived absurdity and policy preferences. *Englehardt v. Blanche*, --- F.4th ---, 2026 WL 2234240, at *8 (D.C. Cir. Aug. 4, 2026). In any event, because the BIS and the AKS prohibit different conduct, Congress's policy choice to not extend a BIS safe harbor to the AKS provides little, if any, contextual evidence about the meaning of the AKS.

Applying the traditional tools of statutory construction, the term "induce" in the AKS is best read in line with its ordinary meaning—to influence or prevail on a person.

B.

We next consider the meaning of "remuneration." The AKS prohibits "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. § 1320a-7b(b)(2). As with "induce," the parties disagree about whether "remuneration" includes a wide range of payments or only corrupt payments and transactions.

The AKS employs "remuneration" in its ordinary sense, as including valuable compensation, such as payments, goods, or services. The ordinary meaning of "remuneration" is "[r]eward, recompense, repayment; payment, pay." *Remuneration*, The Oxford English Dictionary (2d ed. 1989); see *Remuneration*, Black's Law Dictionary (5th ed. 1979) (similar). Relatedly, the BIS's definition of "remuneration" includes "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6). We have suggested that "remuneration" in the AKS tracks this definition and encompasses "anything of value, including payments or

services below fair market value.” *United States ex rel. Winnon v. Lozano*, 146 F.4th 1197, 1204 (D.C. Cir. 2025).

Importantly, Congress used broad language to capture the scope of covered remuneration, extending AKS liability to “any remuneration (including any kickback, bribe, or rebate).” 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). The repeated use of “any,” which has an “expansive meaning,” makes clear the prohibition encompasses all forms of remuneration. *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219 (2008) (cleaned up). Similarly, Congress set off the parenthetical that follows “remuneration” with “including,” which indicates the types of remuneration are illustrative, rather than exhaustive. Remuneration in the AKS captures valuable compensation, including but not limited to “any kickback, bribe, or rebate.”

Vertex does not contest that remuneration generally captures payments or services below market value. Rather, Vertex argues the adjacent parenthetical—“(including any kickback, bribe, or rebate)” —means that remuneration should be narrowly read to apply only to corrupt transactions that improperly skew medical decisionmaking. *See* 42 U.S.C. § 1320a-7b(b)(2). Under the interpretive principle of *noscitur a sociis*, a word is known by the company it keeps. When faced with a list sharing a common quality, courts may sensibly interpret the list in light of that common quality. But the actions listed in the parenthetical following “remuneration” are not all inherently corrupt. While “kickback” and “bribe” certainly have corrupt connotations, “rebate” does not. *See Rebate*, The Oxford English Dictionary (2d ed. 1989) (“A deduction from a sum of money to be paid, a discount; also, a repayment, drawback.”); *Rebate*, Black’s Law Dictionary (5th ed. 1979) (“Discount; deduction or refund of money in consideration of prompt payment.”). Looking to the text of the AKS, we decline to limit “remuneration” to only corrupt transactions when the

neighboring and illustrative list extends beyond corrupt conduct.⁵

Next, Vertex relies on the rule of lenity and constitutional avoidance to support a construction of the AKS that is limited to criminal solicitation or facilitation. Vertex contends that interpreting the AKS in line with the ordinary meaning of both “remuneration” and “induce” would sweep in a wide range of innocuous conduct and raise due process concerns. These arguments are unavailing because “neither lenity nor avoidance has any role to play where,” as here, “text, context, and structure decide the case.” *Bondi v. VanDerStok*, 145 S. Ct. 857, 876 (2025) (cleaned up).

More fundamentally, there is no constitutional problem to avoid. The “mere fact that close cases can be envisioned” does not “render[] a statute vague” in violation of due process. *United States v. Williams*, 553 U.S. 285, 305–06 (2008). And “[r]esolution of the pros and cons of whether a statute should sweep broadly or narrowly is for Congress.” *United States v. Rodgers*, 466 U.S. 475, 484 (1984). Although “remuneration” to “induce” the purchase of medical treatment is broad, it is not unbounded. Furthermore, the AKS’s scienter requirement

⁵ Resisting this conclusion, Vertex argues that, when initially enacted, the AKS used “rebate” to refer only to corrupt rebates functioning as kickbacks and that Congress maintained this understanding of “rebate” with later amendments to the statute. 86 Stat. at 1419, § 242(b). This statutory history, however, weighs against Vertex’s preferred construction. When Congress amended the AKS in 1977, it extended the statute’s prohibition to cover “any remuneration (including any ... rebate).” Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 4, 91 Stat. 1175, 1179–80 (1977). In these amendments, Congress chose the broader term “remuneration” and specified that it extended beyond corrupt rebates.

“alleviates vagueness concerns.”⁶ *McFadden v. United States*, 576 U.S. 186, 197 (2015) (cleaned up).

“Remuneration” in the AKS carries its ordinary meaning: valuable compensation, such as payments, goods, or services. We join the Second and Fourth Circuits in concluding that “remuneration” extends beyond corrupt transactions. *See Pfizer*, 42 F.4th at 76–77; *Pharm. Coal. for Patient Access*, 126 F.4th at 958–61.

* * *

Applying this interpretation, we hold that HHS correctly concluded that the Fertility Support Program would run afoul of the AKS because it provides remuneration to induce the purchase of Casgevy by patients who would otherwise decline it due to fertility concerns.⁷ To reach this conclusion, we need not determine the degree of influence required to constitute inducement under the AKS. Providing up to \$70,000 in financial support for fertility services constitutes “remuneration” to patients who are prescribed Casgevy. And that remuneration is intended to induce patients to choose Casgevy. Indeed, the entire point of the Program is to

⁶ We note that the other circuits to consider the question have similarly rejected vagueness challenges to the AKS. *See, e.g., United States v. Starks*, 157 F.3d 833, 839–40 (11th Cir. 1998); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1397–98 (9th Cir. 1995); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 32–33 (1st Cir. 1989).

⁷ Because this holding is sufficient to resolve Vertex’s AKS challenge, we do not reach HHS’s separate conclusion that the Program provides prohibited remuneration to doctors and medical centers by providing “the opportunity to earn fees related to treatment with [Casgevy],” which might induce them to recommend Casgevy over other treatments. J.A. 590.

encourage patients to choose Casgevy, as opposed to other treatments, by promising to pay for fertility services that may be necessary to address the treatment's side effects. Because the AKS sweeps in actions that go beyond corrupt transactions, HHS correctly concluded the Program would violate the AKS.⁸

III.

Vertex next challenges HHS's determination that the Program would subject Vertex to BIS sanctions. After reasoning that the Program would implicate the BIS's civil prohibition, HHS concluded that the Program would not qualify for the Promotes Access to Care Exception because HHS lacked data to make this determination. HHS's conclusion that the Program violated the BIS was arbitrary and capricious because it failed to reasonably explain why the Promotes Access to Care Exception does not apply.

The APA requires agencies to engage in reasoned decisionmaking. *See* 5 U.S.C. § 706. When issuing an advisory opinion, HHS must "articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "The agency's statement must be one of 'reasoning'; it must not be just a 'conclusion.'" *Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010). "Conclusory explanations for matters involving a central factual dispute where there is considerable evidence in conflict do not suffice." *Genuine Parts Co. v. EPA*,

⁸ Vertex properly does not seek judicial review of HHS's decision that it lacked sufficient data about the risk of fraud and abuse to provide a favorable advisory opinion granting prospective immunity from enforcement of the AKS. HHS may of course take a different view on remand, particularly as it must reconsider whether the Promotes Access to Care Exception applies for civil liability under the BIS. *See infra* at 21.

890 F.3d 304, 312 (D.C. Cir. 2018) (cleaned up); *see also Erwin v. FAA*, 23 F.4th 999, 1007 (D.C. Cir. 2022) (requiring agency to give “*explicit* consideration” to a party’s arguments and evidence).

The statutory provisions governing advisory opinions state that HHS “shall” issue an advisory opinion as to whether a “proposed activity constitutes grounds for the imposition of a sanction under” the BIS. 42 U.S.C. § 1320a-7d(b)(2)(E). Sanctions under the BIS are available only when an activity falls under the statutory prohibition and fails to qualify for a statutory exception. HHS must therefore consider the BIS’s exceptions when an individual requests an advisory opinion as to whether a proposed program may lead to BIS sanctions. The Promotes Access to Care Exception, which covers activities that “promote[] access to care and pose[] a low risk of harm to patients and Federal health care programs,” is one such exception. *Id.* § 1320a-7a(i)(6)(F). The Exception extends to items or services that (1) “improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid,” and (2) “pose a low risk of harm to Medicare and Medicaid beneficiaries and ... programs.” 42 C.F.R. § 1003.110.

Vertex requested an advisory opinion from HHS regarding whether the Program presents grounds for sanctions under the BIS. As part of its request and in response to requests for further information, Vertex provided significant evidence that the Program satisfies the Promotes Access to Care Exception. To begin with, Vertex demonstrated that the Program improves the ability of patients to access Casgevy and thus treat their blood disorders. For instance, Vertex submitted studies showing the risk of infertility from chemotherapy is a significant reason why sickle cell disease patients forgo potentially lifesaving treatment. The company also cited evidence indicating that many patients lack the financial means

to secure fertility treatment and would not choose Casgevy due to fertility concerns. Finally, Vertex pointed to CMS guidance that recognizes the “[l]ack of access to fertility preservation services presents a significant access barrier” to individuals considering gene therapy treatments, such as Casgevy. J.A. 559.

Vertex further put forth evidence that the Program poses a low risk of harm to federal healthcare beneficiaries and programs. For example, Vertex imposed controls such as making the Program available to patients only after they are prescribed Casgevy. Moreover, Vertex pointed to the high cost of care for sickle cell disease patients and suggested that increasing access to gene therapies could alleviate this burden on federal healthcare programs by treating additional patients.

In response to all of Vertex’s arguments and evidence, HHS simply stated the Promotes Access to Care Exception was not applicable because HHS “lack[s] data that would allow [it] to determine that providing the [Program] to eligible patients improves the ability of patients to access [Casgevy].” *Id.* at 591. Despite months of delay, this was the full extent of its explanation. HHS did not explain what data it lacked, nor why it could not readily obtain that data, nor why Vertex’s detailed evidence was insufficient to show that the Program would improve patient access to Casgevy. Advising that the Program violated the BIS without providing a meaningful explanation for why it did not satisfy the Promotes Access to Care Exception was inconsistent with HHS’s statutory obligation and unreasonable.

We disagree with the district court’s conclusion that HHS acted reasonably because its “path may reasonably be discerned.” *Vertex Pharms.*, 774 F. Supp. 3d at 221 (cleaned up). The district court pointed to statements elsewhere in the

advisory opinion emphasizing the novelty of gene therapies. That novelty, however, does not absolve HHS of its obligation to determine whether the Program fits within the statutory Exception. The district court also highlighted HHS's statement that it expects to acquire further information about gene therapies in the future. But none of these statements explain why the detailed information provided by Vertex was insufficient to determine whether the Exception should apply to the Program.

The advisory opinion was conclusory and failed to engage with Vertex's evidence that the Program satisfied the Promotes Access to Care Exception. HHS's determination that the Program would run afoul of the BIS was arbitrary and capricious, and we set it aside.

IV.

Finally, Vertex maintains that HHS regulations unlawfully extend the time for responding to advisory opinion requests. The district court held Vertex lacked standing to challenge the timing provisions after HHS issued the advisory opinion. We disagree and reach the merits, concluding that the timing provisions are contrary to law and must be set aside.

A.

When Vertex initially sued, it challenged HHS's delay in responding to its advisory opinion request and the regulations governing the timing for advisory opinions. Issuance of the advisory opinion mooted Vertex's challenge that the opinion was being unlawfully withheld, but it did not moot the challenge to the advisory opinion regulations.

It is well established that "if a plaintiff challenges both a specific agency action and the *policy* that underlies that action,

the challenge to the policy is not necessarily mooted merely because the challenge to the particular agency action is moot.” *City of Houston v. Dep’t of Hous. & Urb. Dev.*, 24 F.3d 1421, 1428 (D.C. Cir. 1994). In the context of the Freedom of Information Act (“FOIA”), for instance, we have explained that a challenge to an agency’s policies “cannot be mooted by the release of the specific documents that prompted the suit.” *Payne Enters. v. United States*, 837 F.2d 486, 491 (D.C. Cir. 1988). HHS may not evade judicial review simply by releasing an advisory opinion. Vertex’s challenge to the timing provisions is not moot.

To maintain its challenge to HHS’s timing provisions, Vertex must still demonstrate it “has standing and the claim is ripe for review.” *Crowley Gov’t Servs. v. GSA*, 143 F.4th 518, 530 (D.C. Cir. 2025). We may properly consider Vertex’s claim if the timing provisions will harm its right to obtain timely advisory opinions in the future. *See Wash. Lawyers’ Comm. for Civil Rights & Urb. Affs. v. U.S. Dep’t of Justice*, 145 F.4th 63, 67 (D.C. Cir. 2025). In considering whether a party has standing to challenge an ongoing policy, we look to whether the party is “likely to be subject again to the agency practice she seeks to challenge.” *Khine v. U.S. Dep’t of Homeland Sec.*, 943 F.3d 959, 965 (D.C. Cir. 2019).

Vertex is an innovative biotechnology company that relies on HHS advisory opinions to verify that its programs to promote patient access are lawful, within a safe harbor, or create a sufficiently low risk of fraud and abuse for HHS to withhold enforcement. Vertex has requested two advisory opinions in the past. As a repeat player whose products and programs may implicate the AKS and the BIS, Vertex has credibly represented that it plans to seek future advisory opinions. *See Newport Aeronautical Sales v. Dep’t of Air Force*, 684 F.3d 160, 164 (D.C. Cir. 2012) (concluding a

business that repeatedly requests agency records can challenge FOIA policy). Because HHS’s policy of extending the time for responding to requests is likely to harm Vertex, Vertex has standing to press its policy or practice claim.

Vertex’s claim is also ripe. Its challenge to the timing provisions raises “purely legal questions” that are “presumptively suitable for judicial review,” and HHS’s ability to extend the issuance of advisory opinions, essentially indefinitely, harms Vertex’s ability to ensure that its products and programs are lawful. *Better Gov’t Ass’n v. Dep’t of State*, 780 F.2d 86, 92–96 (D.C. Cir. 1986).

B.

On the merits, the challenged timing provisions are contrary to law.⁹ HHS has regulatory authority to specify procedures for the issuance of advisory opinions. But Congress also required “Specific contents” for the regulations, including that the agency “shall be required to issue to a party requesting an advisory opinion by not later than 60 days after [a] request is received.” 42 U.S.C. § 1320a-7d(b)(5)(B). This directive imposes a mandatory 60-day deadline for HHS to respond after receiving an advisory opinion request.¹⁰

⁹ Because the district court dismissed the claim on jurisdictional grounds, it did not reach the merits of Vertex’s challenge to the timing provisions. We review this question in the first instance because the issue is purely legal, fully briefed, and requires no further factual development. *See Aljabri v. bin Salman*, 106 F.4th 1157, 1163 n.5 (D.C. Cir. 2024).

¹⁰ HHS maintains it is ambiguous what object the verb “issue” references. But context makes clear that “issue” refers to the issuance of an advisory opinion. The sentence connects “issue” with “to a party requesting an advisory opinion,” and the statute’s header refers

Nonetheless, the advisory opinion regulations allow HHS to extend the time it has to respond to requests in two ways. First, the regulations provide that the 60-day clock does not begin to run when a request for an advisory opinion has been received. Rather, the clock starts when a request has been “formally accepted,” and HHS can take up to 10 business days after receipt to formally accept or decline a request.¹¹ 42 C.F.R. §§ 1008.41(b), 1008.43(c)(1). These rules plainly conflict with the statute’s 60-day timeline, which is tied to when “the request is received.” 42 U.S.C. § 1320a-7d(b)(5)(B)(i). The statute says nothing about delaying the acceptance of advisory opinion requests. HHS’s regulatory expansion of the 60-day review period is contrary to law.

Second, the regulations permit HHS to toll the period for responding to a request when HHS requests additional information or awaits advice from an outside expert. 42 C.F.R. § 1008.43(c)(3)(ii), (iv). HHS presses its need for flexibility. Yet the statute does not provide any flexibility as to timing. It instead requires that HHS “shall ... issue” an advisory opinion within 60 days of receipt of the request. 42 U.S.C. § 1320a-7d(b)(5)(B)(i).

to the “Issuance of advisory opinions.” *Id.* § 1320a-7d(b)(1). Neighboring provisions confirm that “issue” refers to the Secretary’s issuance of advisory opinions. *See* 42 U.S.C. § 1320a-7d(b)(1), (2), (4)(A).

¹¹ HHS’s guidance acknowledges the agency has created an additional 10-day regulatory buffer. *See* HHS Office of Inspector General, Advisory Opinions FAQs (last updated Apr. 23, 2026) (“The statute provides that advisory opinions should be issued within 60 days. In addition, the regulations establish a 10-day period for the initial review and processing of the incoming request.”).

HHS has no authority to circumvent this statutory deadline. The reasoning of our en banc decision in *Allegheny Defense Project v. FERC* is instructive. 964 F.3d 1 (D.C. Cir. 2020). We rejected FERC’s longstanding practice of using tolling to suspend clear statutory deadlines. Because FERC had 30 days to act on a petition before it was deemed to have been denied, we held that the agency’s tolling practice “delete[d] the thirty-day time limit ... from the statute.” *Id.* at 13, 15. HHS similarly has no “unwritten and unilateral power to indefinitely evade” the advisory opinion deadline established by Congress. *Id.* at 16. The challenged timing provisions are therefore contrary to law.¹²

HHS defends its timing provisions as a reasonable construction of the statute because they allow HHS to gather additional information and grapple with the complexity of advisory opinion requests. An agency’s practical need for additional time to act in a complicated area does not allow for the tolling of statutory time periods. *See id.* at 16–17. Nor can the reasonableness of a policy expand an agency’s statutory authority. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266–67 (2024).

¹² In particular, we set aside the regulatory provisions that allow HHS to toll the 60-day statutory deadline. *See* 5 U.S.C. § 706(2) (authorizing courts to “hold unlawful and set aside agency action” that is contrary to law); *id.* § 551(13) (defining “agency action” to include “the whole or a part of an agency rule”). These provisions include: 42 C.F.R. § 1008.39(a) (second sentence) (tolling the 60-day deadline after a request for information); 42 C.F.R. § 1008.43(c) (tolling the 60-day deadline); and 42 C.F.R. § 1008.41(e). HHS may otherwise administer advisory opinion requests in accordance with 42 C.F.R. § 1008.41 to the extent that such administration does not toll the 60-day time limit, which runs from the receipt of a request.

HHS also contends that its authority to set advisory opinion procedures provides flexibility to determine matters of timing. A “general grant of authority,” however, “cannot displace the clear, specific text of a statute.” *Allegheny Def. Project*, 964 F.3d at 16 (cleaned up). HHS has some discretion to set advisory opinion procedures, but Congress mandated a 60-day deadline as part of the “[s]pecific contents” of the advisory opinion regulations. 42 U.S.C. § 1320a-7d(b)(5)(B).

HHS finally argues that, unlike the statute at issue in *Allegheny Defense Project*, there is no consequence for failing to issue an advisory opinion in 60 days, and so tolling is permissible. But that absence does not mean Congress implicitly authorized HHS to regulate around the 60-day time limit.

In sum, Congress imposed a 60-day timeline for HHS to issue advisory opinions in response to a request. The agency has no authority to pause the clock and grant itself more time.

* * *

Regarding Vertex’s challenge to the advisory opinion, we hold that HHS properly concluded the Fertility Support Program would violate the AKS, but HHS’s determination that the Program would violate the BIS was arbitrary and capricious. With respect to the regulatory timing provisions, we hold that Vertex has standing and that these provisions are contrary to law. Accordingly, we affirm in part, reverse in part, and remand for further proceedings consistent with this opinion.

So ordered.