UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

VERTEX PHARMACEUTICALS INC.,

Plaintiff,

v.

XAVIER BECERRA, *et al.*,

Defendants.

No. 1:24-CV-02046-JEB

DEFENDANTS' REPLY IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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Vertex cannot explain away the fact that its offer to give patients $70,000 in free fertility services in exchange for purchasing its Product plainly would fall within the AKS's prohibition on offering "any remuneration … to induce" the purchase of services covered by a federal healthcare program. Instead, Vertex falls back on policy arguments by repeatedly portraying its Program as "beneficial" and designed "merely [to] facilitate[] patients' ability" to obtain necessary treatment. Pl.'s Reply Mem. of Law in Supp. of Mot. for Summ. J. & Opp'n to Defs.' Cross-Mot. for Sum. J. ("Pl.'s Reply") at 1, ECF No. 22. But that self-serving depiction elides the fact that Vertex designed its Program with the specific purpose of persuading patients who may otherwise be "deter[red] … from pursuing treatment" by the side effect of its Product, *id.* at 29, and that Vertex itself stands to reap millions of dollars in revenue for each federal healthcare beneficiary whom it successfully encourages to purchase its gene-editing therapy. More importantly, the statute Congress wrote prohibits offering or paying "any remuneration … directly or indirectly, overtly or covertly, in cash or in kind," if made with the relevant purpose and scienter, and contains no exception for remuneration with arguable social merit. On the contrary, Congress crafted various exceptions to the statute, and granted HHS authority to create others, to protect socially meritorious activities that otherwise would fall within the statute's scope. Vertex's attempts to twist the statute's meaning through analogies to inapt, unrelated statutory provisions and dismissal of inconvenient parts of the statutory text—including the exceptions Congress *did* codify—are unpersuasive. OIG correctly found that Vertex's payments on behalf of its gene-therapy customers would violate the AKS if undertaken with the requisite scienter.

I. THE AKS's PROHIBITION ON "ANY REMUNERATION" IS NOT LIMITED TO CORRUPT TRANSACTIONS

A. OIG's interpretation is supported by on-point caselaw

OIG demonstrated in its opening brief that the plain text of the AKS, the history of its codification, and caselaw applying it all demonstrate the flaws in Vertex's contention that the AKS prohibits only corrupt payments. Defs.' Combined Mem. In Supp. of Mot. for Summ. J. & Opp'n to

Pl.'s Mot. for Summ. J. ("Defs.' Mot.") at 12-19, ECF No. 21-1. In response, Vertex doubles down on its misportrayal of precedent by claiming to rely on "the Supreme Court's recent explication of one of the AKS's key terms," Pl.'s Reply at 1. *See also id.* at 3 (alleging that "OIG's construction of the AKS is contrary to Supreme Court precedent" (casing fixed)). In truth, however, the Supreme Court never has held that the AKS prohibits only corrupt transactions—nor has it determined that the AKS uses "induce" in its specialized, criminal-law meaning to prohibit only criminal solicitation. Rather, the precedent on which Vertex hinges its argument, *United States v. Hansen*, 599 U.S. 762 (2023), analyzed an entirely unrelated portion of the criminal code and lends no support to Vertex's interpretation of the AKS. Vertex essentially asks this Court to disregard plain meaning and elevate alleged public policy goals in an attempt to intuit a congressional intent that is at odds with the statute's plain text. *See* Pl.'s Reply at 3 (arguing the AKS does not prohibit "socially desirable activities"). The Court must reject these entreaties and uphold OIG's determination.[1]

Recall that *Hansen* analyzed whether a statute that prohibits "encourag[ing] or induc[ing] an alien to come to, enter, or reside in the United States, knowing or in reckless disregard of the fact that such coming to, entry, or residence is or will be in violation of [the] law," criminalized immigration advocacy. *Hansen*, 599 U.S. at 766, 771. The Court answered that question in the negative, concluding that the provision incorporated the criminal-law meanings of the terms "encourage" and "induce." But although the Court observed that the use of "a criminal-law term … in a criminal-law statute … is a good clue that it takes its criminal-law meaning," *id.* at 775, the Court did not base its interpretation on that "clue" alone. Rather, the Court emphasized that the provision in question prohibited "'encouraging' and 'inducing' *a violation of law*," which is likewise "the focus of criminal solicitation and

[1] Vertex's charge that OIG's interpretation "would reach all conduct that merely 'influences' a patient to obtain essential healthcare," Pl.'s Reply at 3, is incorrect. The AKS prohibits only the offering or paying of *any remuneration* with the purpose of inducing the purchase of federally insured healthcare (with the requisite scienter) and does not reach, *e.g.*, speech advocating that a patient accept treatment.

facilitation." *Id.* And more generally, the Court explained the importance of context in choosing among "plausible definitions" of statutory terms, including "when the choice is between ordinary and specialized meanings." *Id.* The Court also relied on the canon of constitutional avoidance, explaining that "even if the" narrower construction of the provision at issue "were not the best one," it was "at least fairly possible," such that it should be adopted to avoid the need to resolve whether the broader construction would violate the First Amendment. *Id.* at 781 (quotation marks omitted).

Hansen's analysis cannot, as Vertex urges, simply be grafted onto the AKS. 599 U.S. at 771. That is most obviously true because it would render the relevant provision of the AKS essentially inoperative. Unlike the statute at issue in *Hansen*, the conduct that the AKS forbids remuneration "to induce"—the purchase or provision of a good or service covered by a federal healthcare program—is virtually always lawful, so offering or paying remuneration "to induce" it will virtually never be unlawful under Vertex's interpretation. Courts should strain to avoid "interpretations of a statute that would 'rende[r] the law in a great measure nugatory,'" *Garland v. Cargill*, 144 S. Ct. 1613, 1626 (2024). And here, that disfavored outcome can be easily avoided by simply giving "induce" its ordinary meaning—"'[t]o lead on; to influence; to prevail on; to move by persuasion or influence,'" *Hansen*, 599 U.S. at 774—rather than the specialized meaning that *Hansen* gave it in a very different statutory context. In other words, because the underlying act (purchasing healthcare) is not criminal, the AKS cannot logically be limited to corrupt payments that would constitute criminal solicitation. It is the offer or payment of "*any* remuneration" which transforms an otherwise-lawful transaction into a forbidden one—a distinction that stands in stark contrast to the statute in *Hansen*, which criminalized encouraging or inducing an individual *to commit a crime*, *i.e.*, unlawful entry into the United States.[2]

[2] Vertex urges the Court to dismiss directly on-point caselaw applying the AKS and rejecting the narrow interpretation pressed here by Vertex, simply because it pre-dates *Hansen*'s analysis of an entirely unrelated statute. *E.g.*, Pl.'s Reply at 6 (criticizing OIG's reliance on *Pfizer, Inc. v. U.S. Dep't of Health & Hum. Servs.*, 42 F.4th 67 (2d Cir. 2022), *cert. denied*, 143 S. Ct. 626 (2023)). But since *Hansen*

Vertex responds that the AKS criminalizes both sides of the transaction, by imposing liability on the *recipient* of prohibited remuneration. Pl.'s Reply at 8. The AKS's prohibition on accepting remuneration in exchange for purchasing federally reimbursable healthcare, 42 U.S.C. § 1320a-7b(b)(1), simply reflects Congress's choice to hold accountable both parties in a covered transaction. It does not, as Vertex insists, transform the fundamental nature of the transaction into a necessarily corrupt one, nor does it indicate any limitation to payments constituting criminal solicitation. Once again, the nature of the transaction itself—the thing induced—is not inherently criminal, unless it is undertaken with the requisite scienter and in exchange for the offer or payment of remuneration.

Vertex next attempts to shoehorn the *Hansen* statute into the AKS's mold by arguing that, in *Hansen*, "the prohibited inducement took the form of persuasive speech," which, according to Vertex, mirrors the AKS's prohibition because, in both statutes, "it is the inducement that is prohibited." Pl.'s Reply at 7. This argument is directly refuted by key language in the Court's opinion, which expressly refused to interpret inducement to sweep in persuasive speech. *Hansen*, 599 U.S. at 782-83 ("the provision encompasses a great deal of nonexpressive conduct—which does not implicate the First Amendment at all," and, "[t]o the extent [the statute] reaches *any* speech, it stretches no further than speech integral to unlawful conduct"). Contrary to Vertex's portrayal, the *Hansen* statute "reaches no further than the purposeful solicitation and facilitation of specific acts known to violate federal law," *id.* at 781, meaning "encourag[ing] or induc[ing]" certain conduct *was* the illegal act, *id.* at 766. Any comparison to the AKS collapses because here it is not the inducement itself which is criminalized, but the *offering or paying of remuneration* with the purpose and motive of inducing an individual to

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did not interpret the AKS, nor did it articulate a blanket rule applicable to each use of the word "induce" in the criminal code, there is no basis to conclude that *Pfizer* would have been decided differently had it been issued post-*Hansen*. Moreover, as noted in OIG's opening brief, each court to consider whether *Hansen*'s interpretation of "induce" applies to the AKS has rejected the argument advanced by Vertex here. *See* Defs.' Mot. at 14 (citing decisions declining to apply *Hansen* to the AKS).

purchase certain healthcare. The two schemes bear no resemblance. *See* Defs.' Mot. at 15-16.

Vertex next strains to counter examples provided by OIG of other criminal statutes in which Congress plainly intended "induce" to carry its ordinary meaning—statutes that, like the AKS, use the word "induce" in describing the purpose with which it is unlawful to commit another act, rather than in criminalizing "inducement" as the actual unlawful act. Pl's. Reply at 9 (discussing Defs.' Mot. at 16-17). But Vertex's response misses the point. Consider 18 U.S.C. § 441, which forbids "giv[ing] or perform[ing] … any consideration whatever to induce any other person not to bid for" a "contract for furnishing supplies to the Postal Service." The word "induce" in that statute must carry its ordinary rather than its criminal-law meaning, because the act of not bidding for a Postal Service contract is perfectly lawful; if the word "induce" carried its criminal-law meaning then the statute would be inoperative. Vertex responds that "[n]ot bidding … would become" a crime if it were part of "a bid-rigging conspiracy" in which the non-bidder was a knowing participant. But there is no reason to think Congress meant for the statute to be limited in that fashion, as opposed to criminalizing all payments meant to induce someone not to bid. It is likewise implausible that Congress used the specialized criminal-law meaning of "induce" when criminalizing wearing "the sign of the Red Cross … for the fraudulent purpose of inducing the belief" that the wearer is a member of the organization, 18 U.S.C. § 706. Vertex has no answer to the absurdity that would result if each appearance of "induce" in the criminal code were limited to the specialized meaning.

B. Vertex cannot add exceptions to Congress's carefully calibrated scheme

OIG demonstrated in its opening brief that Vertex's interpretation of the AKS cannot be correct because Congress delineated twelve exceptions to the AKS's criminal penalties yet most, if not all, of those exceptions would be meaningless if the AKS reached only corrupt transactions. *See* Defs.' Mot. at 18-19. For instance, there would be no need to explicitly exempt from liability remuneration paid "by an employer to an employee" in "a bona fide employment relationship" for providing medical

care in the course of employment, 42 U.S.C. § 1320a-7b(b)(3)(B), if—as Vertex insists—the AKS prohibited only criminal facilitation and similarly corrupt practices. There would similarly be no need for Congress to carve out from liability a public health center's waiver of copayments by indigent patients. *Id.* § 1320a-7b(b)(3)(D). In response, Vertex boldly claims that Congress's carefully crafted exclusions from liability "confirm that the statute" does not "prohibit … desirable[] transactions," Pl.'s Reply at 9 (casing fixed). And because Vertex's fertility payments are, in its view, "desirable," they, too, must be permissible under the statute.

Vertex essentially asks this Court to canvass the dozen exceptions Congress *did* write, *see* 42 U.S.C. § 1320a-7b(b)(3)(A)-(L), observe that each of those statutory exceptions reflect "desirable" transactions, Pl.'s Reply 9, deem Vertex's proposal equally "innocent," *id.* at 11, and on that basis declare it lawful. That is not how statutory interpretation works. Vertex cites no doctrine, and undersigned counsel is aware of none, that would permit this Court to create a new exception for "legitimate and beneficial activities," *id.*, by analogy by determining that valuable remuneration to treat a side effect of a federally reimbursable medical treatment is equally good public policy to the exceptions Congress *did* create. On the contrary, the fact that the legislature needed to carve out from liability a number of transactions that plainly would *not* involve corruption demonstrates Vertex's fallacy. The statutory exceptions would be plainly superfluous if the AKS reached only criminal solicitation. And the error of Vertex's argument is particularly clear because Congress expressly envisioned the potential need to create additional exceptions to protect socially desirable activities—and expressly vested that authority in HHS, rather than in a federal court. 42 C.F.R. § 1001.952(ii).[3]

[3] Vertex's reliance on *Mission Product Holdings, Inc. v. Tempnology, LLC*, 587 U.S. 370, 383-84 (2019), is misplaced. The Court there did not, as Vertex suggests, hold that "Congress often enumerates exceptions simply to clarify limits to a general rule," Pl.'s Reply at 10. Nor did the Court otherwise undermine the rule against superfluities. Instead, it rejected an interpretation that would have "offer[ed] no account of how to read [the statute] … to say essentially its opposite," 587 U.S. at 383—*i.e.*, a nonsensical statutory interpretation.

C. The Beneficiary Inducement Statute is a distinct statute with a different scope, not a "civil counterpart" to the AKS

As explained in OIG's opening brief, the Beneficiary Inducement Statute is not a mere civil counterpart to the AKS. Defs.' Mot. at 26. Indeed, although Vertex doggedly refers to the latter as "the criminal AKS," *e.g.*, Pl.'s Mot. at 11, 16, 17, 22; Pl.'s Reply at 12, 13, 19, Congress expressly provides for civil monetary penalties for "commit[ing] an act described in [the AKS]" in the same section as the Beneficiary Inducement Statute. 42 U.S.C. § 1320a-7a(a)(7). In fact, conduct that violates both the AKS and Beneficiary Inducement Statute could be subject to civil monetary penalties for each such violation under the separate provisions under 42 U.S.C. § 1320a-7a(a). The Beneficiary Inducement Statute is an entirely separate statute that Congress adopted nearly two decades after the AKS, in unrelated legislation (the Health Insurance Portability and Accountability Act of 1996), and which imposes liability on distinct conduct. *See* Defs.' Mot. at 26. Yet Vertex persists that Congress's choice of the verb "influence" in the much-later-enacted Beneficiary Inducement Statute, rather than the AKS's "induce," signals that the AKS was intended to apply narrowly to only corrupt transactions resembling criminal solicitation.

Vertex is grasping at straws. *Babb v. Wilkie*, 589 U.S. 399, 410 (2020), did not, as it claims, "hold[] that differing language within neighboring statutory provisions that otherwise address the same subject matter provides valuable insight when interpreting the statutory text." Pl.'s Reply 11–12. Rather, *Babb* observed that the private- and public-sector provisions *of the same statute*, the Age Discrimination in Employment Act, impose differing liability standards despite being enacted several years apart. Nothing in the brief discussion Vertex cites supports its request that the Court interpret the much-earlier enacted AKS through comparison to language adopted decades later by a different Congress in unrelated legislation (regardless whether "the two statutes are codified in adjacent sections of the U.S. Code," Pl.'s Reply at 12). The Beneficiary Inducement Statute plainly was enacted to sweep in distinct conduct—specifically, remuneration that influences a Medicare or State healthcare program

beneficiary's choice of provider or supplier, 42 U.S.C. § 1320a-7a; it cannot have been enacted, as Vertex suggests, merely to serve as the civil counterpart to the AKS.

D. Offering patients $70,000 in free fertility services in exchange for purchasing federally reimbursable healthcare is not "analogous" to driving a voter to a polling location

Vertex's next argument is baseless: It claims to identify "conflicts" between OIG's interpretation here and DOJ's explication of an entirely unrelated statute prohibiting vote-buying. *See* Pl.'s Reply at 13-14 (casing fixed). Specifically, because DOJ's prosecutorial guidance specifies that offering rides to the polls to facilitate voting by "individuals who have already made up their minds to vote," *id.* at 14 (quotation omitted), is permissible under a law criminalizing "pay[ing] … for voting," 52 U.S.C. § 10307(c), Vertex claims that so, too, is its offer of tens of thousands of dollars in fertility services to mitigate a side effect of its Product. The flaws in this reasoning are self-evident. Most glaringly, Vertex is not offering $70,000 to *any* sickle cell patient who undergoes myeloablative conditioning to prepare for treatment, regardless whether that patient elects to purchase Vertex's Product, or its competitor's similar gene-therapy product, *or* a bone- and blood-marrow transplant. Vertex is only offering payments on behalf of patients who select *its own* Product. Vertex's offer might be analogous to the voting scenario it posits only if, say, a campaign offered rides to the polls *only* for voters who attested an intent to vote for its own candidate. Moreover, Vertex's insistence that its offer constitutes "wholly beneficial conduct" on behalf of patients "who have already made up their minds" to buy its ($2 million) Product is both self-serving and ignores reality. *Id.* As explained repeatedly in OIG's opening brief, patients are now presented with several treatment options for sickle cell disease and transfusion-dependent beta-thalassemia, and Vertex's valuable offer obviously has the potential to sway patient and clinical decisionmaking.

There is no conflict between OIG's interpretation and DOJ's prosecutorial guidance permitting offers of transportation to facilitate voting.

E. The AKS's inclusion of a "kickback, bribe, or rebate" is neither superfluous nor does it limit the reach of "*any* remuneration"

Vertex's argument regarding the AKS's parenthetical, which confirms that the statute prohibits offering "*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) (emphases added), is largely repetitive of its opening brief, *see generally* Pl.'s Reply at 15-18. Vertex fails to rebut OIG's showing that when Congress expanded the statute's reach in 1977 to cover any "remuneration," it plainly retained the references to kickbacks, bribes, and rebates—which had been prohibited since the statute's 1972 enactment—to avoid any unwarranted inference that it meant to remove such payments from the ambit of the statute by deleting the express references to them. *See generally* Defs.' Mot. at 19-23. Reading the statute as written—to include kickbacks, bribes, and rebates, but not to restrict the statute to such transactions—certainly does not mean those terms "serve[] no purpose and [are] superfluous." *Contra* Pl.'s Reply at 15. Rather, they serve a purpose that Vertex itself characterizes as "'common'": Congress was seeking "to be 'doubly sure,'" *id.* at 10, that everyone would still understand the AKS as forbidding kickbacks, bribes, and rebates, notwithstanding the revision that made "remuneration" its primary focus.

Cases relied upon by Vertex do not aid its campaign. *See* Pl.'s Reply at 16. The Tenth Circuit in *United States v. McClatchey* upheld a jury instruction that charged the government with proving, in relevant part, that hospital executives "offer[red] or pa[id] remuneration with the intent *to gain influence* over the reason or judgment of a person making referral decisions" and that "intent to gain such influence must, *at least in part*, have been the reason the remuneration was offered or paid." 217 F.3d 823, 834 (2000) (first emphasis added). The court did not find—as Vertex suggests—that Congress included the parenthetical examples to limit the AKS to corrupt transactions. Instead, the Tenth Circuit held that Congress intended to impose liability where "one purpose" behind an offer of remuneration was "to gain influence over the reason or judgment of a person," even if legitimate services also were rendered, rather than only in situations where there is no legitimate purpose behind

a payment. *Id.* at 834-35. *McClatchey* is thus affirmatively unhelpful to Vertex. The same is true of *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985) (relied upon in Pl.'s Reply at 16). The court there explained that, "[b]y including such items as kickbacks and bribes, the statute expands 'remuneration' to cover situations where no service is performed," and, just because "a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist." 760 F.2d at 71. Vertex's contention that "the statute reaches only transactions that corrupt physicians' or patients' decisionmaking and thus solicit or facilitate an unlawful act on the part of the recipient in return for the payment," Pl.'s Reply at 17, is directly at odds with the construction given in either *McClatchey* or *Greber*. In fact, neither decision even mentions any form of the word "corrupt" (or "solicitation" or "facilitation") or otherwise supports such a limitation.

F. Vertex provides no other, persuasive reason to disregard the AKS's text

Finally, Vertex reiterates its hail-Mary trio of arguments: That the AKS is ambiguous and thus must be narrowly construed under the rule of lenity; that criminalizing the payment of tens of thousands of dollars in fertility services to patients who elect to buy its Product violates due process[4] because its proposal is "socially desirable"; and that doing so leads to an absurd result. Pl.'s Reply at 19-20. These arguments were addressed in OIG's opening brief, Defs.' Mot. at 27-28, and need not be repeated here, except to say that Vertex's hypothetical "that anything a generous family member does to help their sick loved one access a federally reimbursed treatment is potentially a crime," Pl.'s Reply at 19, is refuted by the statute's limitation to only knowing and willful violations, as well as the fact that § 1320a-7b(b)(2) prohibits only remuneration that is meant "to induce" the purchase or provision of particular federally reimbursable items or services. A family member will generally have

[4] Vertex contends that "the government ignores altogether" Vertex's due-process argument in its opening brief, but that argument is fully addressed in Defendant's motion at page 27.

no interest in the particular items or services that the patients choose, *see Pfizer*, 42 F.4th at 79.

II. VERTEX'S OFFER OF $70,000 IN FREE FERTILITY SERVICES IN EXCHANGE FOR PURCHASE OF ITS PRODUCT WOULD VIOLATE THE AKS, IF UNDERTAKEN WITH THE REQUISITE SCIENTER

As shown above, Vertex's constrained interpretation of the AKS finds no support in the statute's text, legislative history, or caselaw applying it. Despite all this evidence of legislative intent, Vertex contends that it is OIG that "fails to answer Vertex's showing that the proposed Program … does not constitute criminal solicitation or a *quid pro quo* under the AKS." Pl.'s Reply at 20. No such showing is required, of course. The AKS prohibits *any* remuneration to induce purchases of federally reimbursable healthcare, if the offer, payment, solicitation, or receipt is undertaken knowingly and willfully, and Vertex's offer to pay for tens of thousands of dollars in valuable fertility treatments for patients that elect to purchase its treatment (but not those of its competitors or other available treatments) would plainly fall within the statute's ambit. Vertex's insistence that its program would not constitute criminal solicitation, *id.* at 21-24, simply misses the point.

Vertex's arguments to the contrary are a distraction. It charges OIG with failing to "grapple with the clinical trial data demonstrating" that its Product is effective and can "improve the quality of life of many … patients." Pl.'s Reply at 21. But that is not in dispute. There is no exception to AKS liability for effective and beneficial pharmaceutical products. In a similar vein, Vertex once again argues that its Product is cheaper than its competitor's gene therapy and lacks the safety warning carried by the other product. That also is not in dispute, but equally irrelevant: Vertex's assertion that its Product is superior does not mean that there are no patients for whom its competitor's therapy would be the more clinically appropriate choice or no reasons why a physician might recommend its competitor's therapy for a particular patient. Both treatments are FDA approved as effective therapies for the relevant conditions. And the administrative record certainly does not establish that Vertex's Product is clearly superior for all patients, and even were that the case, that would not negate the

potential for Vertex's valuable offer of remuneration to distort patient and clinical decisionmaking, *especially* when the current standard of care is a blood- and bone-marrow transplant, not gene therapy. AR 2891; 3116-26.

Vertex also claims that the Court must reject purported "*post-hoc* arguments the government now advances," Pl.'s Reply at 22, but there is nothing *post-hoc* about the argument to which Vertex refers. In its opening motion, Vertex argued that its offer of remuneration "will not improperly … skew medical decisionmaking because it does not offer any independent benefit to patients," Pl.'s Mot. at 25. In response, OIG pointed out that the offer of $70,000 in free fertility services would *obviously* constitute an "independent benefit" even if offered in an unrelated context, such as through an employer health plan, and is likewise an "independent benefit" here for patients who select Vertex's treatment. Just as obvious is the potential for patient decisionmaking to be skewed if patients are presented with three treatment options: Vertex's Product, which comes with an offer of $70,000 in fertility treatments, or either its competitor's gene-editing therapy or a blood- and bone-marrow transplant, both of which require conditioning (and may cause infertility) but do not come with such a generous offer. This argument merely applies logic to fact to counter a claim made by Vertex in its motion for summary judgment; it is not a forbidden *post-hoc* rationalization.[5]

Vertex also continues to insist that, if OIG's interpretation is affirmed, "the AKS would similarly be violated if … Vertex addressed the side effect of infertility by developing" an improved treatment because "such an alternative would constitute a valuable benefit to patients and would likely

[5] Vertex reiterates its odd claim that OIG found that "patients would undergo the arduous months-long treatment regimen required for CASGEVY, *see* AR 18-19, solely to obtain fertility preservation services." Pl.'s Reply at 22. But AR 18-19 contains Vertex's initial request to OIG, not any language by OIG purporting to opine that patients would undergo gene editing just to get fertility treatment, so it is unclear to what Vertex refers. Regardless, OIG already explained, Defs.' Mot. at 34, that "OIG did not find that patients would somehow be prescribed, and undergo, unnecessary gene editing in an illicit attempt to gain fertility services."

'influence' them to undergo treatment." Pl.'s Reply at 24-25. Vertex continues to ignore the statutory requirement that *remuneration be paid*, *see* Defs.' Mot. at 28. Improving a pharmaceutical product to eliminate a side effect plainly would not qualify as offering or paying remuneration—in contrast to the present scheme, through which Vertex proposes tens of thousands of dollars in remuneration be paid.

Vertex's *quid pro quo* response also is easily dispatched. It first argues that the Court should refuse to consider OIG's argument on this point "because it impermissibly raises a *post-hoc* justification, as the Advisory Opinion did not analyze whether the Program would involve a *quid pro quo*." Pl.'s Reply at 25. Vertex misunderstands the meaning of *post-hoc*. It is *Vertex* that argued throughout its motion for summary judgment that the AKS reaches only *quid pro quo* transactions and that its Program does not involve such an exchange, *e.g.*, Pl.'s Mot. at 13, 19, 21, 26, 29, and there is nothing "*post-hoc*" about an agency responding to an argument first raised by the plaintiff in litigation. *See* Defs.' Mot. at 23 (countering arguments raised by Vertex at 21, 26, 29 of its opening brief).

More substantively, Vertex's *quid pro quo* argument relies on the assertion that the AKS reaches only corrupt acts and thus repeats the same flawed reasoning addressed above. *See* Pl.'s Reply at 25 (criticizing the *Pfizer* court, which rejected the same argument advanced by Vertex, for "incorrectly declin[ing] to limit the AKS to *corrupt quid-pro-quo* transactions akin to criminal solicitation and the trio of corrupt examples"). Vertex's assertion that its offer of $70,000 in fertility services in exchange for buying its Product is not a *quid pro quo* because it "is available … only *after* a patient has already been prescribed" the gene therapy, *id.* at 26, is disingenuous. Vertex implies that a patient will have made her treatment decision before learning of Vertex's generous offer, but that plainly is not true (as informed consent would require a doctor to disclose risks of treatment and potential mitigation options), and in any event, it is belied by Vertex's repeated admission that its Program was designed

expressly to overcome patients' resistance to accepting treatment.[6] *See, e.g.*, *id.* at 29 ("The risk of infertility deters many patients … from pursuing treatment.").

Finally, Vertex obfuscates by pointing out that a "patient is not undergoing the arduous months-long process for treatment … in order to get fertility preservation," Pl.'s Reply at 26. Of course not, but that is beside the point. The point is that Vertex's offer of fertility treatment in exchange for purchasing its Product, and only its Product, is meant to induce patients to choose that Product when they otherwise might not. That is a quintessential *quid pro quo*.

III. THE COURT *CANNOT* INCORPORATE INTO THE AKS AN EXCEPTION THAT CONGRESS EXCLUDED FROM THE STATUTE

Vertex reiterates its criticism of both OIG and the Second Circuit in *Pfizer* for using the word "influence" when analyzing "inducement," Pl.'s Reply at 27 (citing 42 F.4th at 75), yet Vertex is, once again, ignoring that it is the American Heritage Dictionary of the English Language that defines "induce" as "[t]o lead or move, as to a course of action, by influence or persuasion," or "[t]o bring about or stimulate the occurrence of; cause" as in "a drug [] to induce labor." *Induce*, Ahdictionary.com, https://www.ahdictionary.com/word/search.html?q=induce. It is thus unsurprising that OIG would use the term "influence" in discussing whether a particular fact pattern constitutes inducement.[7]

Vertex's quibble over syntax has a purpose, however: It presses this Court to graft onto the AKS the Promotes Access to Care Exception that appears nowhere within its text, but instead only in the separate Beneficiary Inducement Statute. Pl.'s Reply at 27. Far from "leav[ing] essentially

[6] In a similar vein, Vertex insists that "the Program ensures that patients cannot simply select the Product in return for participation in the Program" because it "require[es] that patients are diagnosed with [the relevant conditions] and then [are] prescribed the Product." Pl.'s Reply at 26. This is equally illogical. Just because a patient *receives* fertility services and the Product after an appropriate diagnosis and prescription does not mean that patients won't be steered to *Vertex's* therapy, as opposed to other clinically appropriate treatments, because of Vertex's offer of valuable benefits in exchange for patients' purchase.

[7] Caselaw relied upon by Vertex *also* defined "inducement" in the AKS to include "influence" over another person. *United States v. McClatchey*, 217 F.3d 823, 834-35 (2000).

unanswered Vertex's argument" on this score, as Vertex claims, *id.*, OIG thoroughly explained in its opening brief why the Court cannot rewrite the AKS, as Vertex requests, to except conduct that Congress did not see fit to exclude, *see* Defs.' Mot. at 29-30. Vertex's reliance on *George v. McDonough*, 596 U.S. 740, 746 (2022), is particularly misplaced, since Congress did not "employ[] a term of art obviously transplanted from another legal source," *contra* Pl.'s Reply at 27, and it instead is Vertex that seeks to transplant legislation. The Beneficiary Inducement Statute—which *does* contain the exception Vertex invokes—was codified decades after the AKS, and Congress's choice to include the exception only in the former, not the latter, must be respected.

In addition to arguing that the Promotes Access to Care exception should be transplanted into the AKS, in its motion for summary judgment Vertex further urged the Court to analyze the exception—a fact-bound analysis that includes, *inter alia*, whether a scheme "pose[s] a low risk of harm," 42 C.F.R. § 1003.110—and to determine, in the first instance, that Vertex's Program qualifies for the exception. Pl.'s Mot. at 32-27 (arguing application of multi-factor test). In response to Vertex's argument, OIG demonstrated why the record before the Court does not demonstrate that Vertex's proposal satisfies the Beneficiary Inducement Statute's exception. *See* Defs.' Mot. at 30-34. Vertex now contends that the Court should disregard OIG's response to this argument, first raised by Vertex, as "a series of *post-hoc* rationalizations," Pl.'s Reply at 28, but, once again, Vertex misapplies the doctrine. The rule against *post-hoc* explanations restricts the offering of new *rationales* to support an agency decision—it does not hamstring an agency from explaining why a plaintiff's arguments fail on their own terms. *See SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943). "It does no violence to *Chenery* … principles for an agency to advance a legal argument in support of its … decision." *Am.'s Cmty. Bankers v. FDIC*, 200 F.3d 822, 836 (D.C. Cir. 2000). OIG's responses to Vertex's invocation of the Promotes Access to Care exception are properly before the Court.

Vertex's application of that exception remains unpersuasive, however. It first brushes aside

the fact that patients who *choose* to forego gene-editing therapy because they are dissuaded by a serious side effect are not *unable* to access treatment, within the meaning of the exception; rather, they are, as Vertex describes, "deter[red] … from pursuing treatment," Pl.'s Reply at 29, because of the intensive conditioning it requires. That is not a question of *access to care*, *i.e.*, access to the Product itself. Vertex then posits that its $70,000 offer will not interfere with or skew clinical decisionmaking because fertility services "benefit[] a patient's quality of life," Pl.'s Reply at 29. This is nonsensical. Many offers of remuneration would enhance patient quality of life, but that doesn't render them lawful. And it is a matter of simple logic that patients faced with several treatment options, all of which require conditioning that may render them infertile, may be drawn to select the treatment option that comes with the valuable offer Vertex wishes to make.[8] Vertex next repeats its off-topic assertion that the Program will not spur patients to "undergo medically unnecessary gene-editing therapy … for the sole purpose of receiving fertility" treatments, *id.* at 31, when (once again) OIG did not make any such assertion and the proper inquiry is instead whether Vertex's offer was meant to induce patients to pick its $2 million therapy over other clinically appropriate treatments. *See* Defs.' Mot. at 34. The answer to that question is self-evident. Vertex has not shown that its Program would meet the Promotes Access to Care exception—even were that exception part of the AKS scheme (which it is not).

IV. VERTEX IS PROVIDING PATIENTS WITH FERTILITY TREATMENTS THROUGH CMS's MODEL DEMONSTRATION; THAT CMS TEST PROVIDES NO BASIS ON WHICH TO PERMIT VERTEX's FAR MORE EXPANSIVE PROGRAM

[8] Vertex continues to press its claim that "physicians and patients would choose" its treatment over its competitor's "because [it] is $900,000 cheaper" and the alternate treatment "carries a boxed warning for blood cancer," Pl.'s Reply at 30. Vertex provides no reason, and none is obvious, why the indigent patients that might be eligible for its offer—or their medical providers, for that matter—would prefer the less-expensive treatment option when federally reimbursable health insurance is picking up the tab. As for the cancer warning, no evidence in the record demonstrates that Vertex's product is the most clinically appropriate treatment for all patients. Defs.' Mot. at Background § II.B. Finally, Vertex's argument continues to ignore that a bone- and blood-marrow transplant is the current standard of care.

Vertex continues to misportray CMS's Access Model. It is not, as Vertex insists, a "CMS guidance"—a term of art in the realm of agency action—opining on the necessity of fertility preservation for gene-therapy patients. As explained in OIG's motion at 35-37, the access model "tests whether a CMS-led approach to developing and administering outcomes-based agreements for cell and gene therapies improves Medicaid beneficiaries' access to innovative treatment, improves their health outcomes, and reduces health care costs and burdens to state Medicaid programs." AR 2869. As part of that broader initiative, it will allow patients to access a limited scope of fertility preservation services (not the expansive universe of services included in Vertex's Program), along with other services, including travel money, case management, and behavioral health, *no matter which eligible gene-therapy treatment they select*. *See* AR 2826-38. Just last month, both Vertex and its competitor signed negotiated contracts with CMS to participate in the Model. *See Biden-Harris Administration Takes Next Steps to Increase Access to Sickle Cell Disease Treatments*, CMS.gov (Dec. 4, 2024), *available at* https://www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-next-steps-increase-access-sickle-cell-disease-treatments. To be clear, Vertex will be able to offer its patients fertility preservation services through the Model, but on the same level playing field as its competitor. In this suit Vertex asks to go much farther than CMS determined was necessary to test in the model. Were that gambit to succeed, Vertex could actually undermine the Model CMS seeks to test, by swaying patient decisionmaking and impeding the ability for CMS to gather data on the ability of federal healthcare program enrollees to access gene-therapy treatments and data regarding the costs, benefits, risks, and outcomes of treatments.

Vertex's reliance on CMS's model as a ground for attacking OIG's opinion about the applicability of the AKS and Beneficiary Inducement Statute is seriously misplaced. CMS has *no role* in determining what conduct is permissible under those statutory schemes. OIG likewise has no obligation to consider the terms of any model test that CMS is running when it considers the

applicability of certain anti-fraud statutes, or the Promotes Access to Care exception, to a proposed course of conduct. CMS's model testing and OIG's consideration of the anti-fraud statutes are simply separate administrative processes. OIG had no obligation to "meaningfully consider," Pl.'s Reply at 32, the import of CMS's Access Model in rendering its determination that Vertex's proposed offer of $70,000 in remuneration would run afoul of the AKS (if undertaken with the requisite scienter). There is thus no "inconsistency," *id.* at 33, in the two components' decisions. That said, a regulatory safe harbor could apply to the patient assistance provided through an Access Model, protecting such assistance from potential sanctions under the AKS, 42 C.F.R. § 1001.952(ii), so Vertex is freely able to provide fertility preservation services through the Model's terms and consistent with the safe harbor without running afoul of either statute.

As explained in OIG's motion, Vertex does not seriously dispute OIG's finding that insufficient data exist to show that $70,000 in fertility preservation would improve a patient's *ability to obtain* gene therapy within the meaning of the Promotes Access to Care exception. *See* Defs.' Mot. at 31-32. Instead, Vertex simply asserts that "ample evidence in the record existed to demonstrate" that the exception is met, without pointing to anything other than the mere existence of CMS's Access Model. But that Model is a *test* of a novel care-delivery mechanism, not a "determination that the provision of fertility services improves access to gene therapy," *contra* Pl.'s Reply at 32-33. For the reasons expressed herein, that Model has no bearing whatsoever on the question presented here of the proper scope of the AKS and Beneficiary Inducement Statute.[9]

Finally, Vertex contends that OIG "essentially argues that the Program … would implicate

[9] Vertex contends that OIG did not even consider the Access Model's terms, Pl.'s Reply at 32, but this is incorrect: Information on the Model is part of the administrative record considered and certified by the Agency. AR 2917. Vertex once again contends that OIG's responses in this litigation to *Vertex*'s reliance on the Access Model are *post hoc* arguments but, as shown *supra*, there is nothing *post-hoc* about OIG responding to arguments raised by Vertex in its own motion.

the [statutes] because of a supposed 'lack of data' about the effect of the Program." Pl.'s Reply at 34. Vertex is wrong. OIG determined that the Program would violate the AKS (if undertaken with the requisite scienter) and would generate prohibited remuneration under the Beneficiary Inducement Statute because Vertex wants to pay its patient-customers $70,000 in remuneration. The lack of data about an effect of the Program informed OIG's determination that the Program would not result in a sufficiently low risk of fraud and abuse under the AKS (a different question than whether the AKS applies) and whether a statutory *exception* to the definition of "remuneration" under the Beneficiary Inducement Statute applies. And OIG reasonably determined that it lacked sufficient data to conclude that the Proposed Arrangement would pose a sufficiently low risk of fraud and abuse under the AKS and that, because insufficient data exist to demonstrate that patients' *ability* to obtain care is enhanced through the Program, the Promotes Access to Care Exception is not met.

V. VERTEX's CHALLENGE TO OIG's ADVISORY OPINION REGULATIONS CONTINUES TO IGNORE KEY STATUTORY TEXT

Vertex's attack on OIG's advisory opinion regulations continues to both insert missing words and omit key language in the statute. Both of Vertex's arguments on this score are premised on the incorrect assumption that Congress established a mandatory, uninterruptible 60-day clock for OIG to issue *any* advisory opinion, regardless of the completeness (or not) of the underlying request or the complexity of the subject matter, starting on the day it receives a request. But OIG demonstrated in its motion that the statute does not clearly establish the duty Vertex claims; instead, it instructs OIG *to issue regulations* "pursuant" to which "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," 42 U.S.C. § 1320a-7d(b)(5)(B). Absent from that grant of regulatory authority is any explicit command that "a final, written advisory opinion" be issued within 60 days. There is thus no conflict between statute and regulation. OIG is not, as Vertex charges, "argu[ing] that [it] is not bound by the statutory command," Pl.'s Reply at 35; on the contrary, there is no such statutory command.

More problematic for Vertex, the statute also directs that *the Secretary* promulgate regulations setting the timeframes "in which the Secretary shall respond" to advisory opinion requests. 42 U.S.C. § 1320a-7d(b)(5)(A)(iii). In its complaint and motion for summary judgment, Vertex ignored this command; now that OIG has pointed out that error, Vertex blithely dismisses this grant of authority as an instruction for the Secretary to determine *how much faster* than 60 days it should bind itself to issue advisory opinions. *See* Pl.'s Reply at 36-37. This is unpersuasive. Vertex points to no other context in which Congress has purported to establish a swift, nondiscretionary statutory deadline but then instructed an agency to promulgate regulations deciding how much *quicker* that deadline should be. That would indeed be an anomalous statute. Instead, the only logical conclusion is that Congress instructed the Secretary to determine "the interval in which" to "respond" and did not, in fact, establish the "mandatory 60-day" duty Vertex reads into the statute, *id.* at 36.

Vertex continues to invoke cases arising under the Freedom of Information Act, Pl.'s Reply at 37-38, but OIG has explained thoroughly why those cases are inapposite (and why the statute here is readily distinguishable from the FOIA). Vertex adds nothing new to disturb that conclusion. Vertex's contention that *Allegheny Defense Project v. Federal Energy Regulatory Commission*, 964 F.3d 1 (D.C. Cir. 2020) (en banc), "is on point" merely because neither statute explicitly authorizes tolling, Pl.'s Reply at 39, is unavailing because Vertex ignores the critical distinction that the statute here *instructs* the agency to issue regulations setting the procedures and intervals for issuing advisory opinions.

CONCLUSION

For the foregoing reasons, this Court should affirm OIG's finding that Vertex's Fertility Program would, if undertaken with the requisite scienter, implicate the AKS and Beneficiary Inducement Statute. The court also should uphold OIG's advisory opinion regulations.

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Respectfully submitted,

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